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ABSTRACTS

BREAKOUT SESSION 1

MODELING STUDIES

MO1

USING LORCASERIN FOR WEIGHT MANAGEMENT PRIOR TO BARIATRIC SURGERY: MODELING THE COST IMPLICATIONS FOR CALIFORNIA STATE MEDICAID

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OBJECTIVES: Many commercial health care plans and state Medicaid programs commonly provide coverage for bariatric surgery for patients with BMI ≥ 40 or BMI 35–39.9 with ≥ 1 obesity-related comorbidity. Coverage for anti-obesity medications, on the other hand, is less common, though some patients may benefit from anti-obesity medications and avoid bariatric surgery. This study modeled the pharmacy and medical cost implications of treating patients with lorcaserin, an FDA-approved anti-obesity medication, prior to bariatric surgery, in the California Medicaid (MediCal) population. **METHODS:** The model assumed that severely obese patients (BMI ≥ 40) whose weight was reduced to < 35 following lorcaserin treatment would avoid bariatric surgery. Model inputs included the size of the adult (age 21–64) MediCal population (6.67 million), national rate of bariatric surgery (.001%), and average cost of bariatric surgery in California (\$21K). Lorcaserin treatment and outcome variables were based on results from three Phase III clinical trials (BLOSSOM, BLOOM, BLOOM-DM) evaluating the efficacy and safety of lorcaserin for weight loss. Medication specific inputs included proportion of patients responding to lorcaserin treatment (achieving $\geq 5\%$ weight loss from baseline at week 12), expected weight loss, and medication acquisition costs (\$145/month). The model generated cost estimates over a 2-year timeline from the payer perspective. **RESULTS:** The number of patients predicted to undergo bariatric surgery was 6,140. Of these, 2,609 (42.5%) would respond to lorcaserin treatment with 459 (17.6%) obtaining a BMI < 35 at one year. Medication costs for those using lorcaserin totaled \$6.23 million. Bariatric surgery costs totaled \$119.29 million. Predicted cost savings for patients who would avoid bariatric surgery were estimated at \$2.82 million. **CONCLUSIONS:** For MediCal, using lorcaserin to treat obesity prior to bariatric surgery may lead to significant cost saving over a 2-year horizon. Real-world, long-term evidence is needed, however, to further evaluate the role of lorcaserin for weight management in patients considering bariatric surgery.

MO2

DEVELOPMENT AND VALIDATION OF AN ALGORITHM FOR IDENTIFYING PATIENTS WITH HEMOPHILIA A IN AN ADMINISTRATIVE CLAIMS DATABASE

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OBJECTIVES: Develop and validate an algorithm to identify patients with hemophilia A in an administrative claims database. **METHODS:** We first created a screening algorithm using diagnosis and treatment codes to identify potential hemophilia A patients from administrative claims data in the US HealthCore Integrated Research Database between 01/01/06 and 04/30/15. Medical records for a randomly selected subset of patients were reviewed to confirm case status. In this validation sample, we used lasso logistic regression with cross-validation to develop a predictive model using covariates in claims data to estimate the probability of being a confirmed hemophilia A case. **RESULTS:** Using the screening algorithm, we identified an initial cohort of 2,252 patients with potential hemophilia A. Of 400 medical records reviewed, 248 (62%) patients were classified as hemophilia A cases, 131 (33%) were false positives, and 21 (5%) were of indeterminate status. The lasso regression model evaluated 36 potential covariates and identified several strong predictors of hemophilia A that were not included in the screening algorithm, including: ≥ 1 inpatient, outpatient or emergency room visit for hemophilia A; diagnosis after clotting factor level tests; diagnosis made by a hematologist and ≥ 1 hemophilia A diagnosis over 3 months. A probability threshold of ≥ 0.6 resulted in a PPV of 94.7% (95%CI: 92.0–97.5), sensitivity of 94.4% (95%CI: 91.5–97.2), and specificity of 90.1% (95%CI: 85.0–95.2) in the validation sample. We applied this model to the initial cohort to identify a refined cohort of 1,507 patients. The refined cohort was more likely to be male, be under the care of a hematologist, and have fewer comorbidities. **CONCLUSIONS:** We developed and validated an algorithm to identify hemophilia A cases in an administrative claims database with high PPV, sensitivity and specificity. This

algorithm uses widely available variables that can be applied in other claims databases.

MO3

MODELLING ALZHEIMER'S DISEASE PROGRESSION USING A MULTIVARIATE MODEL FOR THE ASSOCIATED OUTCOMES OF COGNITION, BEHAVIOR AND FUNCTIONING: DATA FROM THE ICTUS STUDY

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OBJECTIVES: The ICTUS study provides longitudinal data on markers of Alzheimer's disease (AD); ADAS-cog, NPI, ADL and IADL questionnaires measuring cognitive, behavioural and functional decline, respectively. Available literature indicates that it is important that models predicting AD progression account for the joint evolution of decline. The objective of this project was to develop a model to understand AD progression using ICTUS study data. **METHODS:** AD progression was studied in the subset of European ICTUS patients (n=982/N=1375) treated with AChE inhibitors with biannual follow-up over 2 years. A multivariate linear growth model was fitted including fixed and random covariates for years since baseline for each marker, allowing the rate of change for each marker to vary for each patient. The multivariate model structure allowed quantification of the correlation between the rate of decline across markers. The model also included baseline and time-dependent covariates, including baseline age, MMSE and concurrent treatment. Exploratory modelling revealed implausible covariate estimates and unsatisfactory residual diagnostics for NPI. NPI was therefore removed as an outcome and included as a baseline covariate. **RESULTS:** The model showed a strong multivariate relationship between the rate of change in cognition and functioning. There was a strong positive correlation in the rate of decline of ADL and IADL ($\rho=0.65$) and a strong negative correlation between the rate of decline of ADAS-cog and ADL and ADAS-cog and IADL ($\rho=-0.70$ and -0.55 , respectively). ADAS-cog showed an annual increase of 4.55 [95%: 4.15, 4.94; $p < 0.001$], ADL a decrease of -0.49 [-0.54, -0.44; $p < 0.001$] and IADL a decrease of -0.87 [-0.95, -0.79; $p < 0.001$]. **CONCLUSIONS:** This study demonstrates the strength of correlation between cognition and function; providing an example of how to account for this within predictions. Whilst behaviour is also considered a conceptually important marker for AD progression; within this study it was not feasible to model all four markers simultaneously.

MO4

PREDICTORS OF DISEASE MODIFYING THERAPY INITIATION IN PATIENTS WITH MULTIPLE SCLEROSIS USING ELECTRONIC HEALTH RECORDS DATA – A MACHINE LEARNING PERSPECTIVE

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OBJECTIVES: To identify predictors of disease modifying therapy (DMT) initiation among treatment-naïve multiple sclerosis (MS) patients using machine learning and structured data from a large, geographically diverse electronic health records (EHR) database. **METHODS:** Optum-Humedica de-identified EHR dataset was used to select MS patients, ≥ 18 years with no prior DMT experience, from integrated delivery networks (1/1/2007–12/31/2013). First observed MS diagnosis was the index date, and patients had evidence of continuous clinical activity 12-months pre- and post-index. We used a proprietary machine learning platform, Reverse Engineering and Forward Simulation (REFS™), to build an ensemble of models to examine the association of patients' baseline characteristics and DMT initiation post-index. The area under the curve (AUC) statistic assessed accuracy of prediction models, and we validated prediction models in an independent dataset. **RESULTS:** Sample selection yielded 12,516 MS patients (DMT initiation=25%; mean age=49.9 years; females=76%). Predictors identified in every model of the REFS™ ensemble included year of MS diagnosis, geographic location of the patient, and prescriptions for oil-soluble vitamins. Patients diagnosed in 2012 (versus earlier years) had the largest median odds ratio (OR) in the ensemble for DMT initiation (OR, interquartile range [IQR]: 3.10, 3.09–3.12) followed by patients living in the Northeast and West (respectively, 2.59, 2.57–2.60; 2.55, 2.50–2.58). Additional predictors of DMT initiation with selection frequency $> 90\%$ included eye disorders (1.44, 1.43–1.45), stimulants (1.72, 1.69–1.73), and income (1.73, 1.70, 1.74). When validated in an independent dataset AUC was 0.71. **CONCLUSIONS:** Using REFS™ to analyze structured EHR data, we identified demographic and clinical predictors of DMT initiation with moderate to strong predictive accuracy. Further analyses should be completed using additional

granular data from unstructured fields in this data source and machine learning to refine the accuracy of our models and the predictors of DMT initiation in the MS population.

PRICING AND REIMBURSEMENT STUDIES

PR1

ONCOLOGY DRUG FUNDING IN CANADIAN PROVINCES: DOES A HIGHER ICER DELAY LISTING?

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OBJECTIVES: The Canadian Agency for Drugs and Technologies in Health (CADTH) pan-Canadian Oncology Drug Review (pCODR) provides recommendations for oncology drug's funding to Canadian provinces (except Quebec) and territories, based on clinical, cost-effectiveness, and patient input. Funding decision-making by provinces following a pCODR recommendation is not well understood. Our objective was to investigate the relationship between incremental cost-effectiveness ratio (ICER) and the time-to-listing for each Canadian province. **METHODS:** Data were extracted from the CADTH "Find a Review" database. We identified oncology drug submissions that received either a "recommend" or "recommend with (any) conditions" decision between the creation of the database (2011) and October 20, 2016. The provincial funding summary and the economic guidance document provided dates of provincial funding and the ICER, respectively. The analysis used the highest ICER proposed by the Economic Guidance Panel. We investigated the relationship between provincial time-to-list (derived from dates of recommendation and provincial listing) and the ICER through box-cox transformation and generalized linear models in SAS. **RESULTS:** A total of 57 (of 72) submissions had "recommended" or "recommended with (any) conditions" decision. Of these 57 positive decisions, 52 reported a non-dominant positive ICER, and 39 had sufficient information to derive the time-to-list in at least one province. Ontario, British Columbia, Alberta, Manitoba, Saskatchewan and Newfoundland had positive non-linear and Prince Edward Island had a positive linear (Additional 274 days [95%CI:74-474;p-value=0.012] per 100,000CAD increase in ICER) relationships between time-to-list and ICER – higher ICER leads to longer time-to-list. However, there was insufficient power to determine the strength of the ICER-time relationship. **CONCLUSIONS:** Positive pCODR recommendations are not considered similarly by provinces, and higher ICERs may lead to longer provincial funding decision-making periods. Not considering other factors (e.g., budget impact, burden of disease, patient input) in decision-making and data scarcity were limitations of this analysis.

PR2

ASSESSMENT OF TECHNOLOGY APPRAISALS OF CHRONIC PAIN DRUGS IN FIVE SELECTED EUROPEAN COUNTRIES

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OBJECTIVES: Few studies have focused on Health Technology Assessment (HTA) and reimbursement of chronic pain drugs. With a number of products in pipeline for chronic pain, difficulty in characterization and treatments, coupled with the dynamic market access landscape mean more research is necessary to understand the HTA requirements for chronic pain drugs. **METHODS:** A review was carried out in the five selected EU countries (Germany, England, France, Italy and Spain) on HTA guidelines, technology appraisals of selected chronic pain drugs together with criteria and policies for pricing and reimbursement. Selected drugs were based on countries' approved treatment pathway with focus on osteoarthritis and chronic low back pain. **RESULTS:** Despite the similarities among countries' HTA requirements, variations were observed, such as definition of standard of care as comparators. Italy and Spain comparators are limited to pharmaceutical treatments while other countries include non-pharmaceutical treatments thereby affecting HTA outcomes. Findings also showed that HTA and reimbursement requirements underestimate the clinical and economic value of chronic pain drugs. The subjectivity and complexity of chronic pain makes it difficult to demonstrate clinically relevant differences in outcomes which is not considered in the HTA of a chronic pain drug and in number of cases, the limited impact on clinical outcomes is nullified by side effects resulting in unfavourable judgments. Surprisingly, no technology appraisal was carried out in Germany on the selected drugs while the last full appraisal carried out in England was from 2000. Nevertheless, France's assessment revealed that chronic pain drug assessments have changed over the years with more attention being focused on the risk benefit ratio of the treatment. **CONCLUSIONS:** Complexity and subjectivity of chronic pain may hinder proof of superiority and innovativeness of a new treatment, hence, special consideration is required in term of outcome measures considered for the HTA requirements.

PR3

THE PRICING TRENDS OF ORAL PHARMACEUTICAL PRODUCTS ASSOCIATED WITH LOSS OF EXCLUSIVITY

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OBJECTIVES: Loss of exclusivity (LOE) of pharmaceuticals allow generic market penetration increasing patient access and decreasing the price of medications. The objective of this study is to evaluate the trend and magnitude of price change for oral medications that lost their exclusivity during the years of 2013/2014. **METHODS:** The list of medications that reached LOE in 2013/2014 was gathered from gray literature. Data on generic entry dates, manufacturers, and pricing history were collected from the FDA and AnalySource. The cost of

medications was evaluated using WAC pricing after standardizing for dosage form, strength, package size and formulation. The analysis timeframe was from 2011-2016, capturing price changes before and after LOE. The analysis was limited to oral pharmaceutical products with eight or more generic companies currently on the market. **RESULTS:** The medications included in the analysis were rabeprazole and duloxetine (LOE in 2013), and celecoxib and eszopiclone (LOE in 2014). The number of generic manufacturers present on the market are 8, 16, 10 and 11 for rabeprazole, duloxetine, celecoxib and eszopiclone, respectively. After the first year of LOE, the prices of generic rabeprazole and eszopiclone decreased by 84-93% of their branded price while the price of generic duloxetine and celecoxib decreased by 75-80% of their branded price within 2-3 years of reaching LOE. **CONCLUSIONS:** As the number of generics entering the market increases, the price difference between the brand and generic increases. This case analysis might suggest that branded products with a higher number of generic companies entering the market lead to a steep drop in pricing. Although there are many complexities that contribute to product pricing trends, it is important for payers to consider the product lifecycle and LOE time as formulary decisions are made. Future research should focus on effects of the size of molecules (small vs. large) on the LOE price change.

PR4

HOW DOES ACCESS AND REIMBURSEMENT INFLUENCE PHYSICIANS' PRESCRIBING OF TYPE 2 DIABETES THERAPIES IN THE SECOND-LINE SETTING?

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OBJECTIVES: In patients with type 2 diabetes (T2D), metformin is the standard first-line therapy. Unfortunately, many patients are unable to control their HbA1c on metformin alone, and progress to a second-line therapy. Physicians' drug selection in the second-line is typically based on patient characteristics and comorbidities. However, market access and reimbursement restrictions may limit patient access to a physician's preferred therapy, particularly for premium-priced branded therapies. By comparing physicians' actual prescribing practices with their expressed preferences, this research investigates how influential market access restrictions and pricing can be on actual clinical practice. **METHODS:** 145 U.S.-based endocrinologists and primary care physicians (PCPs) were surveyed electronically between May 2 – 9, 2016 about their actual versus preferred prescribing practices for different drug therapies in various T2D subpopulations. 29 managed care organization pharmacy and medical directors were also surveyed during this time. **RESULTS:** In the absence of payer controls, 58% of surveyed endocrinologists prefer a GLP-1 receptor agonist in their T2D patients with obesity. However, actual patient share for this class is only 18%, despite 60% of their patients being obese. Among T2D patients with renal insufficiency, 21% of endocrinologists selected the DPP-IV inhibitor linagliptin as their preferred agent – surveyed patient share is 6%. In T2D patients with heart failure, 50% of endocrinologists expressed a preference for SGLT-2 inhibitors, yet only 16% of patients receive this class in the second-line. Surveyed PCPs (12.3%) are more likely than endocrinologists (9.7%) to select access and reimbursement issues as the most influential factor on prescribing. Surveyed payers indicate that prior authorization is the primary cost-containment strategy utilized for premium-priced T2D agents. **CONCLUSIONS:** According to primary research with U.S. physicians and payers, market access and reimbursement factors significantly influence physician prescribing practices among T2D patients. Improved payer coverage and reimbursement of T2D therapies will impact prescribing and increase market uptake.

BREAKOUT SESSION 2

INFECTIOUS AND RESPIRATORY DISEASE STUDIES

IN1

RESOURCE UTILIZATION AND COSTS OF HIGH VELOCITY NASAL INSUFFLATION COMPARED TO NON-INVASIVE POSITIVE PRESSURE VENTILATION FOR RESPIRATORY FAILURE

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OBJECTIVES: High velocity nasal insufflation (HVNI), a form of high flow nasal cannula, can provide respiratory support to many patients with respiratory failure more comfortably than non-invasive positive pressure ventilation (NIPPV). Our objective was to assess clinical resource utilization and cost impact to payers and providers associated with the use of HVNI versus NIPPV in the treatment of acute-care patients presenting to the emergency department with acute respiratory failure. **METHODS:** Treatment-specific resource utilization data were collected in a randomized multi-center trial of 204 patients conducted in the United States. Patient-level reimbursement data were calculated based on Medicare fee schedules. Hospital-specific resource costs were collected from participating sites and published literature. For both strategies, unit-specific length of stay, intubation rates and duration were analyzed. Cost differences were evaluated from the Medicare payer and hospital perspectives. Differences in non-normally distributed data were assessed with the Wilcoxon ranksum (Mann Whitney U) test. **RESULTS:** HVNI was found to be associated with the same total length of stay (6.75 vs. 6.01 days, p=0.51) and the same utilization of cost-intensive ICU care (1.50 vs. 1.85 days, p=0.56), a trend towards reduced intubation rates (5.7% vs. 13.0%, 0.095), and a potentially clinically important, but not statistically

significant, reduction in ventilation hours for intubated patient (82.3 vs. 127.3 hrs., $p=0.69$). Resulting mean costs to payers (\$10,633 vs. \$11,848, $p=0.41$) and hospitals (\$12,122 vs. \$12,655) were similar. **CONCLUSIONS:** Our analysis suggests that HVNI, at outcomes clinically comparable to NIPPV, is associated with no additional cost or resource utilization. Potential decreased need for intubation and ventilation, with attendant known sequelae, need to be further evaluated and confirmed in future studies.

IN2

ACUTE INFECTION FOLLOWING TRANSFUSION AMONG ELDERLY MEDICARE BENEFICIARIES IN THE UNITED STATES, AS RECORDED BY LARGE ADMINISTRATIVE DATABASES DURING 2012-2015

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OBJECTIVES: Acute infections following transfusion (AIFT) are serious transfusion-related complications which can result in fever, chills, sepsis, septic shock, and death. The study objective was to assess AIFT occurrence and potential risk factors among inpatient elderly Medicare beneficiaries, ages 65 and older, during 2012-2015. **METHODS:** This retrospective claims-based study utilized large Medicare databases for calendar years 2012-2015. Blood transfusions were identified by ICD-9-CM procedure and revenue center codes, whereas AIFT was ascertained via diagnosis code. Our study evaluated AIFT rates (per 100,000 inpatient transfusion stays) among elderly, overall and by calendar year, age, sex, race, blood components and number of units transfused. Fisher's exact tests were performed to compare AIFT rates, and Cochran-Armitage tests were used to ascertain AIFT occurrence trends by calendar year, age, and transfusion volume. **RESULTS:** Among 7,899,680 inpatient transfusion stays for elderly beneficiaries during 2012-2015, 188 had an AIFT diagnosis recorded, an overall rate of 2.4 per 100,000 stays. AIFT rates by number of units transfused were: 1.6 for 1 unit, 2.1 for 2-4 units, 3.4 for 5-9 units, and 5.0 for > 9 units ($p<0.001$). AIFT rates by blood component groups were: 2.0 for RBCs only, 1.1 for plasma only, 8.7 for platelets only, 3.1 for RBCs and plasma, 13.6 for RBCs and platelets, and 3.2 for RBCs, plasma and platelets. AIFT rates for age categories 65-69, 70-74, 75-79, 80-84, 85 and over were 2.8, 2.7, 2.5, 2.4, and 1.6, respectively ($p=0.0173$). Females and males had AIFT rates of 1.8 and 3.1, respectively ($p<0.001$). **CONCLUSIONS:** Our large population-based study shows significantly elevated AIFT risk with greater number of units transfused and suggests higher AIFT rates for platelet transfusions. The study also suggests potential effects of advancing age and gender on AIFT occurrence, which need further investigations. Study limitations include possible underrecording or misrecording of transfusion procedures, units, and diagnosis codes.

IN3

ANALYSIS OF MOBILE HEALTH APPLICATIONS FOR CHRONIC OBSTRUCTIVE PULMONARY DISEASE MANAGEMENT USING THE MOBILE APPLICATION RATING SCALE AND GOLD GUIDELINE RECOMMENDATIONS

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OBJECTIVES: To identify and assess the quality and functionality of mobile health applications in the patient management of Chronic Obstructive Pulmonary Disease (COPD). **METHODS:** The following search terms were used to identify mobile applications in the Android "Google Play" and Apple "App Store": "COPD", "emphysema", "bronchitis", "chronic airway obstruction", and "Chronic Obstructive Pulmonary Disease". We included applications in English, free to use, patient-focused, and pertaining to the management of COPD. We excluded applications that were specific to a drug, required additional devices (e.g., portable spirometer), and were games not related to disease management. Applications were assessed independently by at least two reviewers using the Mobile Application Rating Scale (MARS) and Global Initiative for Chronic Obstructive Lung Disease (GOLD) guideline recommendations for management of COPD. **RESULTS:** Of the applications identified, 24 met inclusion criteria. Fewer than half (46%) of the applications had acceptable MARS scores (> 3.0) with mean MARS score of 2.3. COPD Navigator and CareTRx Asthma & COPD Journal applications had the highest overall MARS mean scores (3.8 and 4.1, respectively). The MARS category with the highest mean score across all applications studied was Functionality (3.3) and the lowest scoring category was Engagement (2.8). Of the applicable 11 GOLD guideline recommendations, the median number offered by applications was three. COPD education was offered most frequently (54% of applications). The least offered function was emotional support (17% of applications). The application with greatest consistency with GOLD guidelines recommendations was COPD Navigator, which met 10 recommendations. **CONCLUSIONS:** Among the health applications available through mobile platforms for patient management of COPD, less than half had acceptable MARS scores and the number of COPD guideline recommendations addressed in applications was often low. There is a need for further development of mobile applications geared toward patient management of COPD, specifically in Engagement and emotional support.

IN4

COMPLETENESS OF IMMUNIZATION INFORMATION SYSTEM VACCINE INFORMATION: A SYSTEMATIC REVIEW

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OBJECTIVES: Immunization information systems (IIS) consolidate immunization information from participating providers within defined geographic areas. State laws regarding IIS reporting requirements vary, and impact on the completeness

of IIS vaccination information is unclear. The objectives of this systematic review were to 1) compare completeness of IIS data to medical records, 2) compare completeness of IIS data to personal records, and 3) explore characteristics of IIS policy that may influence completeness. **METHODS:** Databases searched included Medline, PsychINFO, and CINAHL. Search terms used were ((immunization registry) OR (immunization information system)) AND ((accuracy) OR (complete) OR (quality)) AND ((medical record) OR (EMR) OR (personal record) OR (self report)). Grey literature and reference lists were hand-searched, extracting articles previously unidentified. Studies of registries outside the U.S. or not including a comparison data source were excluded. Studies selected included those measuring completeness through percentage of individuals up to date or receiving a particular vaccine. **RESULTS:** 255 title/abstracts were identified after removal of duplicates. 185 were determined to not be relevant and excluded. 70 full-text articles were assessed, resulting in a total of ten articles included for qualitative synthesis. The findings show that IIS data was more complete in 4 of 9 comparisons to medical records and in 3 of 6 comparisons to personal records. However, the difference was less than 10% for the majority of studies in which IIS was less complete. Among studies conducted in states with mandatory reporting, one of three found IIS data to be more complete than medical and personal records. This was also the only study taking place in a state requiring explicit consent. **CONCLUSIONS:** More research is needed to assess the completeness of IIS data compared to other sources of immunization information. Factors other than legislation may play a role in IIS data completeness and need to be considered.

MEDICARE STUDIES

ME1

TREATMENT PATTERNS AND PREDICTORS FOR OVERALL SURVIVAL IN PATIENTS WITH METASTATIC MERKEL CELL CARCINOMA IN THE UNITED STATES

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OBJECTIVES: This study analyzed real-world first-line treatment patterns and predictors of 1-year and 5-year overall survival (OS) among Medicare enrollees diagnosed with metastatic Merkel cell carcinoma (mMCC), a rare neuroendocrine carcinoma of the skin. **METHODS:** We analyzed Surveillance, Epidemiology and End Results (SEER)-Medicare data of patients aged ≥ 65 years diagnosed with stage IV MCC from 2006-11. Patients were required to have non-HMO Medicare eligibility for ≥ 12 months before and ≥ 4 months after diagnosis. Treatment received within 4 months after diagnosis was considered first-line treatment. One-year and 5-year cumulative OS were analyzed using Kaplan-Meier estimators. Predictors for 1-year and 5-year OS were analyzed using Cox regression with months of survival as a dependent variable and age at diagnosis, Charlson comorbidity score, type of first line treatment received, race, gender, and median zip-level income estimate as predictors. **RESULTS:** We identified 94 patients diagnosed with mMCC. At diagnosis, mean age was 81 years (SD=7.8), 72% (N=68) were male. Mean length of follow-up was 14.2 months (SD=11.3 months). The cumulative proportion of mMCC patients surviving was 56% at 1-year and 16% at 5-years. Eighty-three percent (N=78) of patients received first-line treatment, including surgery in 38% (N=36), radiation therapy in 39% (N=37), and chemotherapy in 46% (N=43). There were no significant differences in 1-year survival by age, sex, comorbidity, race, income, or type of treatment received at follow-up. Age ≥ 70 years ($p=0.018$) and comorbidity score ≥ 1 ($p=0.013$) were negative predictors of 5-year OS. Type of initial treatment did not predict OS at 5 years. **CONCLUSIONS:** Survival for mMCC patients is generally poor, and is adversely impacted by older age and higher comorbidity at time of diagnosis. Type of treatment received at diagnosis does not appear to impact survival, although unmeasured factors influencing selection of treatment may impact our findings.

ME2

IMPACT OF PATIENT COMORBIDITIES ON INFECTION WITHIN 90 DAYS OF PRIMARY AND REVISION JOINT REPLACEMENT

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OBJECTIVES: Primary and revision total hip and total knee arthroplasties (THA and TKA, respectively) are increasing in frequency due in part to the aging population. The impact of preoperative comorbidities and patient presentation on post-operative complications is not well understood. **METHODS:** Using MarketScan Commercial and Medicare databases (2009-2015), patients were identified by the following diagnosis (International Classification of Diseases, 9th edition (ICD-9)) or Current Procedural Terminology (CPT) codes within inpatient or outpatient settings: primary THA (P_THA: ICD-9 81.51 or CPT-4: 27130), primary TKA (P_TKA: ICD-9 81.54 or CPT-4: 27440-7), revision THA (R_THA: ICD-9 00.70-7, 81.53 or CPT 27134, 27137-38) and revision TKA (R_TKA: ICD-9 00.80-4, 81.55, CPT 27486-8). All patients had at least 365 days pre- and 90 days post-index continuous enrollment. Patients were categorized based on pre-existing diabetes (ICD 250.X), obesity (ICD 278.00, 278.01, 278.03, V85.35-45), osteoporosis (ICD 733.X) or smoking (ICD 305.X, V15.82) codes. Occurrence of 90-day infection (ICD 998.X, 686.9, 038.9, 711.05-6, 730.05-6) was queried for all patients. **RESULTS:** The 90-day infection rates were 1.9% (4,828/260,801), 1.95% (2,511/130,617), 9.5% (1,361/14,331) and 6.7% (777/11,657) for P_TKR, P_THR, R_TKR and R_THR, respectively. For primary procedures, comorbidities with the greatest effect on the odds of infection were obesity (OR: 1.814, 95%CI: 1.640-2.007 for P_THR and 1.558, 95%CI: 1.454-1.669 for P_TKR) and diabetes (OR: 1.686, 95%CI: 1.541-1.846

for P_THR and 1.344, 95%CI: 1.262-1.430 for P_TKR). Osteoporosis had a small but statistically significant effect on the odds of infection for primary procedures. For revision procedures, only diabetes (OR: 1.468, 95%CI: 1.242-1.735 for R_THR and 1.309, 95%CI: 1.162-1.474 for R_TKR) and obesity (OR: 1.324, 95%CI: 1.061-1.653 for R_THR and 1.350, 95%CI: 1.176-1.550 for R_TKR) increased the odds of infection. **CONCLUSIONS:** Diabetes and obesity are significantly associated with 90-day infection rates in patients undergoing primary or revision total hip or knee replacements.

ME3

EFFECTS OF MEDICATION ADHERENCE AMONG MEDICARE CANCER SURVIVORS

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OBJECTIVES: With the increasing availability of oral chemotherapy drugs, the use of oral chemotherapy continues to grow because it offers more advantages over intravenous chemotherapy, including convenience and less severe side effects. While adherence to oral chemotherapy plays a key role in achieving optimal cancer care, few published studies have investigated the impact of adherence to oral chemotherapy on clinical outcomes. The objective of this study was to access the effects of adherence to oral chemotherapy on the use and costs of medical services. **METHODS:** A retrospective cohort study was conducted using national representative sample obtained from Medicare Current Beneficiary Survey. Cancer patients aged over 65 who initiated oral chemotherapy during 2006 through 2010 were included in the analysis. Selected oral chemotherapy drugs were identified using pharmacy claims and self-reports. Measures of medication adherence included number of fills and proportion of days covered (PDC). Negative binomial models were used to estimate healthcare services use, and generalized linear models with gamma distribution and log-link were used for healthcare costs. **RESULTS:** Four hundred and fifty-nine elderly beneficiaries with cancer had at least one fill of oral chemotherapy drugs. For each additional fill of oral chemotherapy drugs, the likelihood of having hospitalizations and outpatient visits reduced by 7% (0.003 visits/year; p=0.006) and 3% (0.16 visits/year; p=0.03), respectively, after adjusting for socio-demographic and clinical characteristics. The adjusted costs for hospitalizations decreased by 15% (\$590/year; p=0.02), while the prescription drug costs increased by 9% (\$403/year; p<0.001). Similarly, a high level of PDC was associated with lower risk of hospitalization, reduced medical costs, and increased drug costs. **CONCLUSIONS:** Improved medication adherence to oral chemotherapy drugs was associated with better outcomes in terms of medical services use and costs. Higher costs for oral chemotherapy were more than offset by medical cost reductions, leading to a net reduction in total healthcare costs.

ME4

COST OF MALNUTRITION IN ELDERLY MEDICARE ENROLLEES WITH DIABETES

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OBJECTIVES: Diabetes is prevalent condition in elderly Medicare enrollees, and has been linked to costly comorbidities. The cost of malnutrition in this population, however, has not been quantified. Our objective is to estimate the cost of malnutrition in elderly Medicare enrollees diagnosed with diabetes. **METHODS:** We used claims data from 2000 to 2013 for a random sample of 15,000 Medicare enrollees (age ≥ 65) diagnosed with diabetes while enrolled in Medicare (96,370 subject years). Malnutrition was identified by ICD9 codes in the claims data. Cost data were reported for each subject year, and were categorized by service type (Part A, Part B and Part C) and payer (Medicare, Primary Insurance or Beneficiary). The impact of malnutrition on healthcare costs was estimated using two way random effects panel regressions. Results are reported with and without controlling for comorbidities. **RESULTS:** Nearly 16 percent of enrollees received a malnutrition diagnosis during our study period (15.9%). Enrollees who had been diagnosed with malnutrition had medical costs that were \$33,648 higher than other enrollees controlling for age and gender (p<0.01). When cardiopulmonary disease, kidney disease, cancer and depression were included in the regression, malnutrition raised total costs \$23,698 per year (p<0.01). For comparison, a diagnosis of lung cancer (the next most costly condition) raised total cost \$16,820 (p<0.01). The majority of malnutrition associated increased cost was borne by Medicare, which paid \$21,605 more per malnourished patients after controlling for age, gender and comorbidities (p<0.01). Medicare Part A had the highest increase in malnutrition associated cost (\$18,007; p<0.01) followed by Part B (\$3017, p<0.01) and Part D (\$281, p<0.01). **CONCLUSIONS:** Diabetes is a common and costly disease, which is made more costly by malnutrition. Health care providers should carefully monitor the nutritional status of patients with diabetes and integrate nutrition into patient care plans.

BREAKOUT SESSION 3

CANCER STUDIES

CN1

THE ASSOCIATION BETWEEN HOSPITAL CHARACTERISTICS AND READMISSION FOR ENDOMETRIAL CANCER PATIENTS UNDERGOING SURGERY IN THE US

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OBJECTIVES: To analyze whether patient and hospital characteristics are associated with all-cause readmissions among endometrial cancer patients undergoing surgery. **METHODS:** The 2013 Nationwide Readmission Database (NRD) was used. The NRD, managed by the Agency for Healthcare Research and Quality, includes readmissions for both insured (commercial vs. government) and uninsured patients in the

U.S., and is designed to produce readmission rates at the national level. The study population consisted of hospitalized patients undergoing surgery for non-metastatic endometrial cancer. Surgeries considered were vaginal, laparoscopic or robotic-assisted hysterectomy (minimally invasive) as well as open hysterectomy. Outcomes analyzed were 30-day, 60-day, and 90-day all-cause readmissions. For each outcome the study cohort was restricted to patients having an index hospitalization in 2013 while ensuring that the study patients also had enough time for the respective outcome. Multivariate logistic regression was performed to assess factors associated with hospital readmission rates. **RESULTS:** The 30-day, 60-day and 90-day cohorts included 23,006, 21,071 and 18,885 patients, respectively. Factors associated with hospital readmission rates were: type of surgery, patient age, comorbidity count, hospital teaching status, and hospital urban-rural designation. The following were common across the three readmission outcomes studied: 1) open surgery had approximately two times the odds of readmission compared to minimally invasive surgeries (Odds ratio or OR for 30-day outcome: 2.073, 95%CI: 1.738 -2.473); and 2) metropolitan non-teaching hospitals had approximately 26% less odds of readmission compared to metropolitan teaching hospitals (30-day OR: 0.741, 95%CI: 0.603-0.910). Furthermore, for 60-day and 90-day readmissions, small metropolitan hospitals had approximately 20% less odds of readmission compared to large metropolitan hospitals (e.g., 60-day OR: 0.789, 95%CI: 0.669-0.932). **CONCLUSIONS:** Surgical type, hospital teaching status, and hospital urban-rural designation were associated with differing all-cause readmission rates. More research is warranted to understand why and how these factors may be associated with readmission outcomes.

CN2

IMPACT OF DIFFUSE LARGE B-CELL LYMPHOMA ON VISITS TO DIFFERENT PROVIDER SPECIALTIES AMONG ELDERLY MEDICARE BENEFICIARIES: CHALLENGES FOR CARE COORDINATION

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OBJECTIVES: Newly diagnosed Diffuse Large B-Cell Lymphoma (DLBCL), a cancer with vague symptomatology, can pose significant challenges to care-coordination. We utilized a multi-level model to understand the impact of DLBCL diagnosis on visits to primary care providers (PCPs) and specialists, a key component of care-coordination, over a 3 year period of cancer diagnosis and treatment. **METHODS:** We used a retrospective longitudinal study design with SEER-Medicare linked dataset to analyze visits to PCPs and specialists by DLBCL patients (N=5,455) compared to non-cancer patients (N=19,215). Multivariable logistic regression and hurdle models were used to examine the association of DLBCL with any visit to specialists and any visit to and number of PCP visits respectively. **RESULTS:** DLBCL patients were more likely to visit PCPs (AOR [95%CI]: 1.19[1.13, 1.25]), and had greater number of visits to PCPs (beta, SE: 0.361, 0.013) than non-cancer patients. Similarly, DLBCL patients were more likely to have any visit to cardiologists (AOR [95%CI]: 1.33[1.26, 1.39]), endocrinologists (1.27 [1.08, 1.49]), and pulmonologists (1.36[1.24, 1.50]) than non-cancer patients. Among DLBCL patients, the number of PCP visits markedly increased during the treatment period compared to the baseline period (beta, SE: 0.490, 0.028) and then decreased to baseline levels (-0.464, 0.022). **CONCLUSIONS:** Visits to PCPs and specialists were much higher for DLBCL than non-cancer patients, which drastically increased during the DLBCL treatment period for chronic care. Treatment adverse effects and more frequent contact with healthcare system may have increased the visits to PCPs and specialists. Interventions to improve care-coordination may need to target the DLBCL treatment period, when care-coordination is most vulnerable.

CN3

PERFORMANCE OF CHARLSON VERSUS ELIXHAUSER COMORBIDITY SCORE IN PREDICTING SURVIVAL IN BREAST, PROSTATE, LUNG, AND COLORECTAL CANCER

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OBJECTIVES: The National Cancer Institute (NCI)'s refined Charlson comorbidity score (developed specifically for cancer) and the Agency for Healthcare Research and Quality's Elixhauser comorbidity scores are two popular methods to control confounding due to comorbidities in observational studies. The relative performance of these scores in cancer studies is unknown. The objective was to compare the performance of the Elixhauser and the Charlson comorbidity score in predicting survival in four cancers (breast, colorectal, prostate and lung). **METHODS:** This cohort study used the Texas Cancer Registry linked Medicare claims data from 2005-2011. Four cancer-specific cohorts were created: breast (n=19,082), colorectal (n=16,963), prostate (n=23,044) and lung (n=26,047) cancer. Baseline one year diagnosis claims were used to define Charlson and Elixhauser comorbidity score. Consistent with Charlson and NCI methodology, the outcome was 2-year non-cancer mortality; cancer mortality was treated as a competing risk. Competing risk models were created to determine the performance of Charlson and Elixhauser comorbidity score in predicting 2-year survival while controlling for age, gender and stage of cancer. Models were compared using Akaike information criterion (AIC), Bayesian information criterion (BIC) and c-statistics (c). **RESULTS:** The 2-year non-cancer mortality was 5.7% (breast), 11.5% (colorectal), 4.1% (prostate) and 14.5% (lung). Elixhauser (breast: AIC=9084, BIC=9101, c=0.776; colorectal: AIC=17977, BIC=18002, c=0.681) performed slightly better than Charlson (breast: AIC=9112, BIC=9129, c=0.769; colorectal: AIC=17992, BIC=18016, c=0.679) for breast and colorectal cancer. Whereas, Charlson (prostate: AIC=8379, BIC=8391, c=0.780, lung: AIC=34915, BIC=34943, c=0.581) had slightly better performance than Elixhauser (prostate: AIC=8387, BIC=8400, c=0.779; lung: AIC=34927, BIC=34955, c=0.577) for prostate and lung cancer. **CONCLUSIONS:** Performance of both scores were

comparable, with the slightly better performance of Elixhauser for breast and colorectal, and Charlson for prostate and lung. Evidence from this study can be used for selecting appropriate comorbidity score for cancer-specific observational study.

CN4

PROGRESSION-FREE SURVIVAL WITH ENDOCRINE-BASED THERAPIES FOLLOWING PROGRESSION ON AN NON-STEROIDAL AROMATASE INHIBITOR AMONG POSTMENOPAUSAL WOMEN WITH HORMONE RECEPTOR POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 NEGATIVE ADVANCED BREAST CANCER: A NETWORK META-ANALYSIS

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OBJECTIVES: This study aimed to quantify the comparative efficacy of currently available and emerging endocrine-based therapies (ETs) for postmenopausal women with HR+/HER2- ABC after NSAI progression. **METHODS:** Randomized clinical trials (RCTs) of ETs in first or later line for HR+/HER2- ABC were identified via a systematic literature review using Medline, EMBASE, Cochrane Library and key conference proceedings from 2013-2016 as search databases. RCTs with the following criteria were considered: 1) focused on women with HR+/HER2- ABC, 2) included patients who previously received ETs or chemotherapy as first-line therapy, 3) included ET as monotherapy or in combination with targeted therapy as study interventions, 4) reported PFS outcome, and 5) were published in 2007 or later (when HER2 testing became standardized). Regimens were compared using pairwise hazard ratios (HRs) and 95% credible intervals (CrIs) of PFS obtained from a Bayesian MTC model. Treatments of different approved dosage strength were pooled into the same arm. In addition, anastrozole and exemestane were pooled as aromatase inhibitors [AIs] due to clinical similarities. **RESULTS:** A total of 4 trials and 6 regimens (palbociclib+fulvestrant, everolimus+fulvestrant, everolimus+AI, fulvestrant+AI, fulvestrant, and AI) were eligible. Palbociclib+fulvestrant and everolimus+AI had 50% and 55% reduced hazard of progression or death vs AI (95% CrI upper bound ≤ 1), respectively. Palbociclib+fulvestrant, everolimus+AI and everolimus+fulvestrant had 54%, 58% and 40% reduced hazard of progression or death vs. fulvestrant (95% CrI upper bound ≤ 1), while palbociclib+fulvestrant and everolimus+AI had 52% and 55% reduced hazard of progression or death vs. fulvestrant+AI (95% CrI upper bound ≤ 1), respectively. No other significant differences in PFS between treatments were found. **CONCLUSIONS:** These results indicate that, compared to those who received fulvestrant alone, postmenopausal women with HR+/HER2- ABC who have previously failed an NSAI and received palbociclib+fulvestrant, everolimus+AI or everolimus+fulvestrant had longer PFS.

COST OF ILLNESS AND RESOURCE UTILIZATION STUDIES

CS1

TRENDS IN READMISSION RATES AND HOSPITAL CHARGES FOR PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE IN FLORIDA FROM 2009 TO 2014

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OBJECTIVES: To examine trends in hospital readmission rates and charges associated with chronic obstructive pulmonary disease (COPD) in Florida and to identify patient-level risk factors associated with 30-day readmissions. **METHODS:** A retrospective analysis of adult COPD patients (18 or older) was conducted using Healthcare Cost and Utilization Project (HCUP) Florida State Inpatient Database (SID) 2009-2014. The 30-day readmission rate was calculated by dividing the number of hospitalizations with at least one subsequent hospital stay within 30 days of an index hospitalization by the total number of index hospitalizations for COPD. Weighted least squares regression was used to perform tests of trend. Multivariable logistic regression was employed to identify patient characteristics associated with readmission. **RESULTS:** Overall, 269,790 patients were identified as having COPD. The unadjusted rate for COPD-related 30-day readmissions in Florida did not change between 2009 and 2014 (8.16% to 7.95%, $P=0.375$). However, readmission rates for patients aged 64-84 years decreased significantly (8.07% to 7.21%, $P=0.023$), whereas readmission rates for patients aged 44-63 years increased significantly (9.34% to 10.50%, $P=0.037$). Average total charge for 30-day COPD-related readmissions was significantly higher in 2014 (\$35,383) compared to that in 2009 (\$31,758) after adjusting for inflation rates ($P=0.027$). Factors associated with increased COPD-related readmission rates included male (Odds Ratio [OR]=1.133; 95% confidence interval [CI]=1.098-1.169), older age:44 <= age < 64 (OR=2.045; 95%CI=1.790-2.336) and 64 <= age <= 84 (OR=1.658; 95%CI=1.446-1.901), Medicaid beneficiaries (OR=1.401; 95%CI=1.325-1.482), lower income (OR=1.187; 95%CI=1.130-1.246), longer length of stay in hospital (OR=1.004; 95%CI=1.001-1.007), alcohol abuse (OR=1.086; 95% CI=1.019-1.158) and a higher burden of medical comorbidities including obesity (OR=1.085; 95%CI=1.032-1.140), osteoporosis (OR=1.150; 95%CI=1.080-1.224), acquired immune deficiency syndrome (OR= 1.196; 95%CI=1.002-1.427) and ischaemic heart disease (OR=1.037; 95%CI=1.001-1.075). **CONCLUSIONS:** Despite national efforts to reduce the burden of COPD, the overall COPD readmission rate has not changed in Florida. Instead, financial burdens on the COPD readmission consistently increased.

CS2

THE DIRECT AND INDIRECT ECONOMIC BURDEN OF HYPOTHYROIDISM IN THE UNITED STATES: A RETROSPECTIVE CLAIMS DATABASE STUDY

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OBJECTIVES: To examine the direct (resource utilization and associated medical cost) and indirect (productivity costs) economic burden associated with hypothyroidism in the United States. **METHODS:** Using the Truven Health MarketScan[®] databases, patients who received 2 or more diagnoses of hypothyroidism in the calendar years 2012, 2013 or 2014 were identified (N=834,713) and examined for 1 year post initial diagnosis of hypothyroidism (index date). Healthy controls were matched 1:1 to the hypothyroidism cohort based upon patient characteristics (age, sex, region, and insurance type) and availability of productivity data (absenteeism, short-term disability [STD], long-term disability [LTD], and worker's compensation [WC]). Multivariable analyses compared resource utilization, annual medical costs, and productivity costs between hypothyroidism and controls. **RESULTS:** Hypothyroidism was associated with a significantly higher probability of hospitalization (8.79% v 5.05%; OR 1.53, 95% CI 1.52-1.55) or ER visit (21.71% v 14.99%; OR 1.74, 95% CI 1.72-1.76) and a longer hospital length of stay (1.00 v 0.42 days) compared to controls (all $P < 0.0001$). This additional utilization is consistent with the finding of incremental annual total medical costs of \$6,928 per patient associated with hypothyroidism. Specifically, patients with hypothyroidism (N=799,466), compared to healthy controls (N=799,466) had significantly higher total medical costs (\$15,737 v \$8,809), as well as significantly higher inpatient (\$3,027 v \$1,495), outpatient (\$6,456 v \$3,973), emergency room (ER) (\$733 v \$423), drug (\$5,637 v \$3,273), and laboratory costs (\$104 v \$50) (all $P < 0.0001$). For the subset of patients with available productivity data, patients with hypothyroidism, compared to controls, had significantly higher costs associated with absenteeism (\$5,946 v \$5,775), STD (\$414 v \$300), LTD (\$36 v \$19) (all $P < 0.0001$) but significantly lower WC costs (\$49 v \$55; $P < 0.0001$). **CONCLUSIONS:** Findings of this large study demonstrate the substantial direct and indirect economic burden associated with hypothyroidism.

CS3

HEALTH RESOURCE UTILIZATION AND COST IN PATIENTS WITH CLINICAL ATHEROSCLEROTIC CARDIOVASCULAR DISEASE AND PRIOR STATIN USE

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OBJECTIVES: Patients with clinical atherosclerotic cardiovascular disease (ASCVD) require aggressive treatment and risk factor modification to lower risk of cardiovascular events. The objective of this study was to determine 1 year health resource utilization (HRU) and cost in these patients. **METHODS:** This was a retrospective study of adult (18+) commercial and Medicare Advantage (MA) enrollees in the Optum[®] Research Database. Patients indexed on their first diagnosis code of clinical ASCVD, defined by 2013 American College of Cardiology/American Heart Association criteria, from 1/1/2011 to 3/31/2014. Patients were continuously enrolled 1 year pre- and post-index, or until death, filled a statin during baseline, and had ≥ 1 LDL-C result ≤ 90 days before index. All-cause and ASCVD-related HRU and cost were calculated during follow-up and reported separately for the total sample, commercial, and MA populations. **RESULTS:** The study included 31,831 patients; mean age 64 years, 44% female, 50% commercially insured, and mean baseline LDL-C 95 mg/dL. The proportion of patients with an ASCVD-related visit was higher in MA patients versus commercially insured; ambulatory (54.8% vs 49.7%), emergency (6.6% vs 4.6%), and inpatient (10.3% vs 6.7%). More than half of all ambulatory and inpatient visits (52.6% and 51.2%), and 17.7% of emergency department visits, were ASCVD-related. Patients with MA had over 50% more ASCVD-related inpatient visits than commercially insured patients, and almost 50% more ASCVD-related ED visits. Mean total annual costs for the entire sample was \$15,942. ASCVD related costs were 29.3% of total costs, 54.6% of inpatient cost, 19.3% of ambulatory cost, and 18.1% of pharmacy cost. In general, costs for commercially insured patients were higher than costs for patients with MA. **CONCLUSIONS:** ASCVD-related costs contribute a large proportion of the economic burden in patients with ASCVD. Improving clinical care might help manage costs.

CS4

ASSOCIATION OF TUMOR LOCATION AND ECONOMIC OUTCOMES IN THORACIC LOBECTOMIES: RESULTS FROM A NATIONAL HOSPITAL BILLING DATASET

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OBJECTIVES: Identification of factors affecting economic outcomes in patients undergoing thoracic lobectomies for cancer may assist with procedural risk adjustment. This study assesses whether lobe anatomy affects outcomes such as Operating Room Time (ORT), Length of Stay (LOS), and total hospital costs (COSTS). **METHODS:** The study used the Premier Perspective[®] Database, which contains billing data from over 600 U.S. hospitals. Elective lobectomies with a primary diagnosis of upper, middle, or lower lobe lung cancer from 2012 to 2014 were identified. Resource utilization parameters of ORT (mins), LOS (days) and COSTS (2014 US-Dollars) were computed from billing data. Generalized estimating equations accounting for hospital-level clustering and controlling for patient, procedure, and hospital factors were used to evaluate the association of tumor lobe anatomy and resource utilization. **RESULTS:** A total of 8,750 thoracic lobectomies for lung cancer were identified: upper lobe (n=5,284), middle lobe (n=512), and lower lobe (n=2,954). A slightly higher fraction of surgical approaches were traditional thoracotomy (54.2%; n=4,746) compared to Video Assisted Thoracoscopic Surgery (VATS) (45.8%; n=4,004). Mean ORT was 249.0 mins (SD=232.7), with mean LOS of 7.0 days (SD=5.3) and COSTS of \$25,710 (SD=\$18,862). Results of the multivariable analysis showed that the adjusted mean LOS (95% CI) was significantly higher for upper lobe [7.0(6.8-7.2)] compared to middle [5.8(5.4-6.3)] or lower lobe [6.6(6.4-6.8)]. Similar results for higher economic burden for upper lobe was observed in adjusted COSTS [Upper lobe: \$26,177(\$25,132-\$27,266); Middle lobe: \$23,109(\$21,683-\$24,629); Lower lobe: \$24,557(\$23,450-\$25,717)]. Mean ORT was also higher for upper lobe [254.1(242.2-266.6)] compared to lower lobe [235.2(226.4-244.3)] but no differences were observed compared to middle lobe [243.5(217.0-273.2)]. Results were consistent when the data was sub-analyzed by approach. **CONCLUSIONS:** This analysis shows that

tumor lobe anatomy in lobectomies is significantly associated with in-hospital economic outcomes, with upper lobe tumors having increased LOS, ORT and COSTS compared to lobectomies of the lower or middle lobe.

BREAKOUT SESSION 4

PERSONALIZED MEDICINE STUDIES

PM1

COST-EFFECTIVENESS ANALYSIS OF HLA-B*5801 GENETIC TESTING PRIOR TO INITIATION OF ALLOPURINOL THERAPY TO PREVENT ALLOPURINOL-INDUCED STEVENS-JOHNSON SYNDROME/TOXIC EPIDERMAL NECROLYSIS IN MALAYSIAN POPULATION

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OBJECTIVES: Studies found strong association between allopurinol-induced Stevens-Johnson Syndrome (SJS)/ Toxic Epidermal Necrolysis (TEN) and HLA-B*5801 allele. HLA-B*5801 screening-guided therapy may mitigate the risk of allopurinol induced SJS/TEN. This study aims to evaluate the cost-effectiveness of HLA-B*5801 screening prior to allopurinol therapy initiation compared with current practice of no screening for Malaysian patients with chronic gout whom hypouricemic agent is indicated. **METHODS:** This cost-effectiveness analysis adopted societal perspective with a lifetime horizon. A decision tree model coupled with Markov models was developed to estimate the costs and outcomes, represented by quality-adjusted life years (QALYs) gained, of three treatment strategies: (a) current practice (allopurinol initiation without HLA-B*5801 screening); (b) HLA-B*5801 screening prior to allopurinol initiation; and (c) alternative treatment (probenecid) without HLA-B*5801 screening. The model was populated with data from literature review, meta-analysis, and published government documents. Cost values were adjusted to the year 2015, with costs and health outcomes discounted at 3% per annum. A series of sensitivity analysis including probabilistic sensitivity analysis were constructed to determine the robustness of the findings. **RESULTS:** Both HLA-B*5801 screening and probenecid prescribing were dominated by current practice. Compared to current practice, HLA-B*5801 screening resulted in 0.226 QALYs loss at an additional cost of USD281, while probenecid prescribing resulted in 1.744 QALYs loss at an additional cost of USD1,875. One SJS/TEN case would be avoided for every 552 patients screened. At the cost-effectiveness threshold of USD8,982 per QALY, the probability of current practice being the best choice is 98%, in contrast with 2% and 0% in HLA-B*5801 screening and probenecid prescribing respectively. This is due to low incidence of allopurinol-induced SJS/TEN in Malaysia and lower efficacy of probenecid compared with allopurinol in gout control. **CONCLUSIONS:** This analysis demonstrated that HLA-B*5801 genetic testing before allopurinol initiation is unlikely to be a cost-effective intervention in Malaysia.

PM2

DEVELOPING A TAXONOMY OF NON-HEALTH VALUE FOR GENOMIC-BASED DIAGNOSTIC TESTS

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OBJECTIVES: Genomic-based diagnostic tests provide information with the potential to improve health and non-health outcomes for patients and families with rare inherited conditions. To date, no practical solutions to using cost-effectiveness analysis exist that take account of non-health benefits and recognise the existence of opportunity cost. This study aimed to identify all relevant non-health outcomes to define a taxonomy of value potentially deriving from genomic-based diagnostic tests. **METHODS:** Meta-ethnography was used to synthesize published qualitative evidence in an interpretive manner. Systematic bibliographic searches identified studies using electronic search strategies and terms relevant to genomic testing combined with synonyms for qualitative research in four databases (MEDLINE, Embase, PsycInfo and HAPI) from time of inception to April 2016. Two researchers identified studies for inclusion using pre-defined criteria. Data analysis and synthesis, using meta-ethnography, aimed to consolidate themes and concepts in existing qualitative studies to create a taxonomy of value grounded in empirical evidence. **RESULTS:** Thirty-seven studies were included and analysed in two stages concerned with: (i) multiple genetic conditions (12 studies); single inherited conditions (25 studies). Three types of value were identified and defined: (i) value of informed decision-making (ability of genomic-based diagnostic information to facilitate important health and life decisions); (ii) value of benefit to others (recognition of impact of information on others); (iii) value of knowing (value per se from genomic information). **CONCLUSIONS:** This study developed a taxonomy of value for genomic-based diagnostic tests. This is a necessary first step to move towards understanding how to take account of health and non-health effects in cost-effectiveness analyses and also consider opportunity cost within a constrained healthcare budget. A potential next step is to use stated preference methods to quantify how people trade between health and non-health outcomes to capture the value of genomic-based diagnostic tests.

PM3

THE OPTIMAL TREATMENT REGIME TO DELAY THE ONSET OF MUCOID PSEUDOMONAS AERUGINOSA PULMONARY INFECTION ON PEDIATRIC CYSTIC FIBROSIS PATIENTS

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BACKGROUND: *Pseudomonas aeruginosa* is the most common and significant life-threatening pathogen for CF patients. The transition from non-mucoid to mucoid PaPi indicates disease progression, after which the lung function deterioration would be exacerbated. To treat continuous deterioration of lung function, CF patients need to use lung maintenance therapies chronically for an average of 20 years. However, majority of evidence identifies only short-term follow-up. Moreover, no guideline suggests when a treatment change is needed, nor the order of prescribing those treatments. **OBJECTIVES:** To investigate the comparative effectiveness of different treatment regimens to delay the acquisition of mucoid PaPi. **METHODS:** Using the Cystic Fibrosis Foundation Patient Registry, this retrospective cohort was applied to emulate an RCT under a causal inference framework. Pediatric patients (n=4970) who were diagnosed with non-mucoid PaPi before mucoid PaPi during 2006-2011 were included. A rational treatment change score was created using machine-learning method including patients' demographic characteristics, clinical signals and treatment histories. According to different thresholds of the score, which steered the decision of treatment change, 25 regimens were built. Each patient was hypothetically randomized to follow all regimens independently. A fixed parameterization of the dynamic logistic marginal structural model with the constant-time hazard was applied to investigate the effectiveness of different regimens. **RESULTS:** Using the effect of patients whose treatment changes followed a specific regime as the reference, patients whose treatment changes did not follow any regime caused 17% greater hazard of mucoid PaPi during 6-year follow-up. Compared with the reference regime, the hazard ratio ranged from 0.98 to 1.07 for other regimens. **CONCLUSIONS:** In this study, changing treatments irrationally, not followed any clinical signals, caused the worst outcome. The differences of effect were trivial among regimens. To achieve better outcomes, physicians should follow a regime, logically the optimal one, in changing lung maintenance therapy.

PM4

A TEST AND VALIDATION OF GENETIC ALGORITHMS AND CROSS-VALIDATION IN VARIABLE SELECTION AND MODEL BUILDING

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OBJECTIVES: When developing statistical models to predict health care costs, resource utilization or clinical outcomes, obtaining a reliable set of predictors that most impact the outcome can be challenging. The objective of this analysis is to test and validate genetic algorithms (GA) for variable selection with integrated cross-validation (CV) for a prediction regression model. This proposed method was compared to forward selection (FS). **METHODS:** A simulation study was performed to test and validate the integrated GA and CV (GA-CV) algorithms with repeated random selection of 50 test sets. To overcome variability from different random folds, 20 different random selections were performed. The optimal set of variables was identified based on the proportion of times each variable was included in the models that minimized the mean squared error of the predictions. Number of events was modeled from Poisson distributions in this exercise, and included a treatment variable (yes vs. no), 3 integer covariates, and 3 continuous covariates. The covariates were either: 1) unrelated to the outcome, 2) moderately associated with the outcome, or 3) highly associated with the outcome. **RESULTS:** The GA-CV algorithm selected the covariates associated with the outcomes in 96% of the simulations, and did not select the covariates unrelated to the outcomes in 57% of the simulations, compared to 83% and 55% of the simulations for FS algorithms. **CONCLUSIONS:** The GA-CV algorithm successfully identified covariates associated with outcomes while avoiding covariates not associated with outcomes in a simulation study, performing better than FS for identifying impactful variables, and equivalently to FS for identifying non-impactful variables. The integrated GA-CV algorithm should be considered when building models of count data and should be studied for its effectiveness when modeling other outcomes.

TREATMENT PATTERNS STUDIES

TP1

PREDICTORS OF PROGRESSION TO ADVANCED THERAPY AMONG RHEUMATOID ARTHRITIS PATIENTS WITH INADEQUATE RESPONSE ON CDMARDS

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OBJECTIVES: The 2015 American College of Rheumatology guidelines recommend advanced therapy (biologic disease-modifying antirheumatic drugs [DMARDs] or Janus kinase inhibitors) for patients with rheumatoid arthritis (RA) who have inadequate response (IR) to conventional DMARDs. Given limited existing evidence, we investigated real-world cDMARD-IR rates and factors associated with progression to advanced therapy. **METHODS:** Administrative claims from the HealthCore Integrated Research Database were used to select adult patients with ≥ 1 claim for cDMARDs between 01/01/2007 and 11/30/2014 (first drug claim = index date), ≥ 12 months of enrollment before (baseline) and after index, ≥ 1 claim for RA diagnosis and no fills for any DMARD over baseline, and no claims at any time for other conditions where advanced therapy is indicated. A previously-published algorithm was applied to identify cDMARD-IR status. First fill for advanced therapy over 12 months post-index was set as progression date. Patient demographic/clinical characteristics and utilization metrics were assessed over baseline and up to the progression date. Factors associated with progression were determined by logistic regression. **RESULTS:** Out of 11,274 cDMARD initiators, 9,426 (84%) were cDMARD-IR, of whom 2,046 (22%) progressed to advanced therapy. Most patients progressed to etanercept (49%), followed by adalimumab (23%) and infliximab (17%). Median (range) time-to-progression was 126 days (62-219). The top 5 factors associated with progression were index claim for methotrexate (OR 3.05, 95% CI 2.63-3.53),

post-index cDMARD adherence (3.02; 2.39-3.81), any outpatient IV medication use (2.84; 2.49-3.24), laboratory tests (1.76; 1.43-2.15), and glucocorticoid use (1.57; 1.38-1.79). Age (0.97; 0.96-0.98) and baseline Quan-Charlson comorbidity score (0.91; 0.86-0.97) were negatively associated with progression. **CONCLUSIONS:** A majority of patients (84%) in this real-world population were cDMARD-IR, but only 22% of them progressed to advanced therapy over 12 months, indicating barriers to such treatments. Factors associated with progression may help in identifying patients at higher need for intensive treatment.

TP2

FIRST-LINE TREATMENT PATTERNS AMONG YOUNGER VERSUS OLDER PATIENTS NEWLY DIAGNOSED WITH MULTIPLE MYELOMA IN THE US

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OBJECTIVES: To describe first-line treatment (1LT) patterns among patients with newly diagnosed multiple myeloma (NDMM), stratified by age group. **METHODS:** Patients with NDMM who did not receive stem cell transplant were identified from the MarketScan Commercial and Medicare claims databases (1/1/2009-9/30/2015). Patients had continuous medical/prescription coverage 12 months before (baseline) and ≥12 months after the index date of MM treatment initiation. Demographics and clinical characteristics were evaluated during baseline and 1LT patterns were compared among patients aged <65 and ≥65 years. Duration of 1LT and time to second-line treatment (2LT) were analyzed using Kaplan-Meier (KM) curves. **RESULTS:** Among the overall population with NDMM (n=3,238), 1,315 were <65 years old (mean=56.7 years), and 1,923 were ≥65 years old (mean=76.6 years). The average time from MM diagnosis until 1LT initiation was similar between age groups [2.8 vs. 3.0 months, p=0.52]. Proportions treated with triplet-, doublet-, and mono-therapy regimens in 1LT were 45.3%, 36.9%, and 10.5%, respectively, among younger patients versus 31.8%, 53.4%, and 10.9%, among older patients (p<0.001). Among younger patients, 22.7% were treated with immunomodulatory drug (IMiD)-based, 29.7% with proteasome inhibitor (PI)-based, and 38.8% with IMiD+PI combination regimens; among older patients, proportions were 32.1%, 35.1%, and 21.9%, respectively. Based on KM analysis, among younger patients median duration of 1LT was 8.8 months and time to 2LT was 32.3 months; among older patients, median duration of 1LT was 10.1 months and time to 2LT was 36.2 months. MM severity was not adjusted for due to limitations of the database. **CONCLUSIONS:** Treatment initiation occurred almost 3 months after initial MM diagnosis. Older patients were less likely to receive triplet or IMiD+PI regimens compared to younger patients. Average 1LT duration was 9-10 months. Future studies should investigate the influence of patient and physician preferences on time to treatment initiation and the implications on outcomes.

TP3

BREAST CONSERVING SURGERY OR MASTECTOMY: A TREND ANALYSIS USING NATIONWIDE INPATIENT SAMPLE

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OBJECTIVES: Breast cancer is the most common type of cancer found in women. Most breast cancer patients receive either breast conserving surgery (BCS) or mastectomy as a surgical treatment. Considering the high prevalence of breast cancer, it is important to understand the utilization of surgery and the determining factors for the surgery selection. This study aims to examine the trend and patterns of two major surgical procedures among women with breast cancer from 1998 to 2011. **METHODS:** Healthcare Cost and Utilization Project (HCUP), National Inpatient Sample (NIS) data was used to obtain a yearly proportion of surgeries in breast cancer women by surgery type, age, region, race, primary payer, and severity. BCS and mastectomy procedures were identified using ICD-9 procedure codes; severity was estimated by whether or not axillary lymph node dissection was conducted. Discharge weight was applied to extrapolate a national estimate. Surgery selection was modeled as a function of time to examine temporal trends controlling for age, race/ethnicity, region, payer, severity, and number of diagnoses at discharge by logistic regression. **RESULTS:** Examination of time trend graphs and regression analyses indicates that overall surgery rates increased overtime from 1998 to 2011. Among those who received one type of surgery, BCS decreased while mastectomy increased since 2003, when the American Cancer Society screening guideline was published. Elderly (>60 years), black patients with axillary lymph node dissection who received care in Northeast were most likely to choose BCS over mastectomy. Medicare recipients had higher overall surgery rates, and patients covered by private insurance were more likely to choose mastectomy over BCS. **CONCLUSIONS:** Overall surgery rates have increased overtime in women with breast cancer. Patient demographic and clinical characteristics play a significant role in the choice between breast conserving surgery and mastectomy.

TP4

GEOGRAPHIC VARIATION OF INAPPROPRIATE PRESCRIPTION OPIOID USE AMONG DISABLED MEDICARE BENEFICIARIES

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OBJECTIVES: To address the opioid epidemic in the US, the Pharmacy Quality Alliance (PQA) recently developed quality measures of inappropriate prescription opioid use that address 1) high-dose use, 2) receipt of prescriptions from multiple providers, and 3) concurrent benzodiazepine use. Our objective was to examine the patterns of inappropriate opioid use among disabled Medicare beneficiaries across regions from 2011 through 2013. **METHODS:** Among 186,055 non-cancer, disabled Medicare patients who had >2 opioid prescriptions, we identified patients with high-dose use (>120 daily morphine milligram equivalents for ≥90 consecutive days) and multiple providers (having prescriptions from ≥4 prescribers and ≥4 pharmacies) each year; and concurrent benzodiazepine use (≥30 cumulative days) in 2013 when Part D began coverage for benzodiazepines. We used multivariable logistic regression to obtain adjusted annual rates of problematic opioid use across 306 hospital referral regions (HRRs), adjusting for sociodemographic, health status, and access-to-care factors. **RESULTS:** Adjusted annual rates of high-dose use (~9%) and having multiple providers (~5%) remained stable over three years. In 2013, 33.6% of beneficiaries used benzodiazepines concurrently. The ratios of 75th percentile to 25th percentile rates of inappropriate use across HRRs were 1.89 for high-dose use, 1.86 for having multiple providers, and 1.38 for concurrent benzodiazepine use. The top 5 HRRs with the highest rate of high-dose use were Sarasota, FL(17.2%), Sun City, AZ (17.2%), Lawton, OK(16.1%), New Brunswick, NJ(15.8%), and Pueblo, CO(15.8%); of multiple providers were Arlington, VA(11.6%), St Cloud, MN(8.7%), Pueblo, CO(7.8%), Provo, UT(7.7%), and Anchorage, AK(6.9%); and of concurrent benzodiazepine use were Miami, FL(50.0%), Slidell, LA(48.1%), Panama City, FL(47.5%), Clearwater, FL(47.3%), and Paterson, NJ(46.6%). **CONCLUSIONS:** Substantial concurrent benzodiazepine use and geographic variation in problematic prescription opioid use exist among disabled Medicare beneficiaries. Areas with high rates of problematic use may benefit from targeted interventions (e.g., lock-in programs) to reduce inappropriate opioid use.

BREAKOUT SESSION 5

DIABETES STUDIES

DB1

DIFFERENCES IN DISEASE PROGRESSION, RESOURCE UTILIZATION, AND HEALTH OUTCOMES RELATED TO INITIAL ADHERENCE TO ORAL ANTIDIABETIC MEDICATIONS AMONG VETERANS WITH INCIDENT DIABETES

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OBJECTIVES: To examine the impact of oral antidiabetic medication (OAD) adherence on clinical measures, macrovascular events, and microvascular complications among veterans with incident diabetes mellitus (DM) in the first year of OAD therapy. **METHODS:** The VA Corporate Data Warehouse was used to identify the first diagnosis for uncomplicated DM during 2002-2014. OAD use was assessed by proportion of days covered (PDC) for the first year of therapy using outpatient VA pharmacy records, and those with a PDC>80% were deemed adherent. Changes in clinical measures, outpatient visits and inpatient admissions, and the odds of cardiovascular outcomes, cerebrovascular events, revascularization, and microvascular complications were assessed during the first year of therapy with a focus on differences due to OAD adherence while controlling for baseline demographic and clinical characteristics. **RESULTS:** A total of 159,032 veterans were included and 99,430 (62.5%) were deemed initially adherent to OADs. Adherent patients had significantly larger unadjusted decreases in hemoglobin A1C, systolic blood pressure, and estimated glomerular filtration rates (all p<0.0001) over the first year. When adjusted for baseline characteristics, those nonadherent to OADs had significantly fewer outpatient visits (IRR: 0.84; 95%CI: 0.8310.849) but a higher number of inpatient admissions (IRR: 1.29; 95%CI: 1.230-1.343). Few macrovascular events were observed but nonadherent patients had a higher adjusted odds of having a stroke or transient ischemic attack (OR: 1.4; 95% CI: 1.10-1.74). Those nonadherent to OADs were also more likely to be diagnosed with nephropathy (OR: 1.1; 95%CI: 1.05-1.19) or experience a hypoglycemic event (OR: 1.7; 95%CI: 1.27-2.25) but less likely to have been diagnosed with neuropathy (OR: 0.65; 95%CI: 0.62-0.688) or retinopathy (OR: 0.78; 95%CI: 0.731-0.837) within the first year of OAD use after adjusting for baseline characteristics. **CONCLUSIONS:** Adherence to OADs has important consequences among patients starting DM therapy and suboptimal use can lead to complications, even in the first year of treatment.

DB2

RACIAL DISPARITY IN ACCESS TO NEWER CLASS ANTI-DIABETICS AMONG ADULT PATIENTS WITH DIABETES IN THE U.S.

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OBJECTIVES: Poorer diabetes care and outcomes that are common in racial and ethnic minority populations, may partially be attributed to more barriers to medications among minority populations than whites. This study aimed to examine racial differences in the use of newer class pharmacological treatments in the US, using a nationally representative sample of non-institutionalized population. **METHODS:** This cross-sectional study analyzed the 2014 Household Component and Prescribed Medicines files of the Medical Expenditure Panel Survey (MEPS). Use of newer class pharmacological treatment was defined as any record of prescription fill for type 2 sodium-glucose co-transporter (SGLT2) inhibitors, dipeptidyl peptidase 4

(DPP-4) inhibitor and glucagon-like peptide-1 (GLP-1) in 2014. The use rate was reported and compared between non-Hispanic whites and minorities. Estimates were weighted to the total American non-institutionalized population (WTP). Logistic regression models were employed to assess the association of racial groups and use of any newer anti-diabetics. **RESULTS:** 2,591 (WTP: 24,272,685) individuals with diabetes were identified in 2014. Among those treated with pharmacologic therapy (96.2%, WTP: 23,359,737), 4.0% (WTP: 931,236) used GLP1, 6.6% (WTP: 1,538,691) used DPP4 and 1.8% (WTP: 417,955) used SGLT2 respectively, yielding 11.7% (WTP: 2,735,890) who had used at least one class of these newer anti-diabetics in 2014. A higher proportion of non-Hispanic whites were found to receive newer anti-diabetics than minorities (13.5% versus 8.8%, $p=0.0036$). After controlling for age, education, insurance coverage and diabetes duration, minorities were still less likely to use newer anti-diabetics compared to their white counterparts (OR=0.69, 95%confidence interval=0.49, 0.98). Consistent racial disparity was found within each of SGLT2, DPP-4, GLP-1 classes. **CONCLUSIONS:** Racial disparity in access to newer treatment options among Americans with diabetes is observed. Persistent difference in barriers to new health technology between racial/ethnic groups needs to be examined in broader socioeconomic context and addressed promptly and effectively.

DB3

RESULTS, RATIONALES, AND TRENDS IN HEALTH TECHNOLOGY ASSESSMENTS FOR NOVEL DIABETES AGENTS

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OBJECTIVES: As the global prevalence of diabetes continues to rise, the emergence of newer mechanisms of action, like sodium-glucose cotransporter-2 (SGLT-2) inhibitors, glucagon-like peptide-1 (GLP-1) receptor agonists, and dipeptidyl peptidase-4 (DPP-4) inhibitors, has increased the number of treatments available to patients. By balancing clinical benefit alongside cost, health technology assessment (HTA) decisions aim to prudently manage access to diabetes therapies. The objective of this analysis was to evaluate recent HTA decisions and their rationales to identify trends in selected countries. **METHODS:** HTA surveillance was conducted for Australia, Canada, France, Germany, and the United Kingdom (UK) from January 1, 2012 to October 31, 2016 (58 months). HTAs for diabetes therapies were evaluated by therapeutic area, drug class, decision, and rationale for the decision. Decisions were categorized as favorable, unfavorable, mixed (both favorable and unfavorable), and neutral (neither favorable nor unfavorable). **RESULTS:** 109 diabetes HTAs were published in the study timeframe. Across the studied nations' HTAs, 49 (45%) were favorable, 41 (38%) unfavorable, 16 (15%) mixed, and 3 (3%) neutral. Australia had the highest number of favorable decisions (26/39; 67%), followed by Canada (6/9; 67%), France (15/26; 58%), the UK (2/6; 33%), and Germany (0/29; 0%). Favorability among selected product classes were as follows: DPP-4, 46% (23/50); SGLT-2, 41% (13/32); and GLP-1, 37% (7/19). Mixed decisions, which were more common in the UK and France (67% and 31%, respectively), primarily depended upon whether there was a contraindication to a preferred treatment option or which anti-diabetic agents were to be used in combination. Nearly all of the HTA submissions in markets that evaluate cost-effectiveness used cost-minimization analyses, and those favorable decisions that did provide an incremental cost-effectiveness ratio (ICER) were within the typical range. **CONCLUSIONS:** As the SGLT-2, GLP-1, and DPP-4 classes become more crowded, quality pharmacoeconomic evidence highlighting cost offsets becomes increasingly important.

DB4

POSTPRANDIAL GLUCOSE CONTROL AND HEALTH CARE RESOURCE UTILIZATION

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OBJECTIVES: Postprandial glucose (PPG) control is considered necessary to achieve recommended glycemic goals for people with diabetes, but there is yet limited research on the impact of PPG control on patients' daily lives and healthcare use. The purpose of the study was to investigate the association between PPG control and healthcare resource utilization among adults diagnosed with diabetes. **METHODS:** A web-based self-reported survey of adults with type 1 or type 2 diabetes, treated with basal and bolus insulins, was conducted in Italy, UK and USA. Recruiting targets ensured inclusion of respondents with differing levels of PPG control and PPG monitoring behavior. Average highest PPG was estimated from the two highest PPG values measured in the past week. Respondents were asked about resource use specifically related to having elevated PPG. Negative binomial regression analyses were used to predict healthcare resource use counts. Analyses controlled for demographic characteristics, duration of diabetes and diabetes-related complications. **RESULTS:** Among respondents regularly measuring PPG ($n=691$), 5.5% reported having been hospitalized overnight in the past 12 months, 15.9% visited their healthcare practitioner (HCP) in the past 6 months and 15.1% called/emailed their HCP in the past 6 months, specifically related to elevated PPG. Respondents who regularly measured PPG experienced elevated PPG an average of 4.4 times (SD, 4.9) per week, and mean average highest PPG in the past week was 11.9 mmol/L (SD, 4.0). On average, holding other variables at means, a one-mmol/L PPG increase was associated with significant increases in predicted rates of healthcare resource use related to elevated PPG: overnight hospitalizations, 14.4% ($p<0.001$); HCP visits, 14.1% ($p<0.001$); and HCP calls/emails, 12.3% ($p<0.001$). **CONCLUSIONS:** Inadequate PPG control is associated with increased healthcare resource utilization, and additional education regarding PPG control may be helpful in efforts to improve diabetes management and reduce healthcare costs.

MEDICAL DEVICE AND DIAGNOSTICS STUDIES

MD1

COST EFFECTIVENESS OF THE LEFT ATRIAL APPENDAGE CLOSURE DEVICE COMPARED WITH ORAL ANTICOAGULANTS IN PATIENTS WITH NONVALVULAR ATRIAL FIBRILLATION

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OBJECTIVES: To determine the cost-effectiveness of the left atrial appendage closure (LAAC) device compared with warfarin or novel oral anticoagulants (apixaban, dabigatran, rivaroxaban) in patients with nonvalvular atrial fibrillation (NVAF) from an Ontario, Canada, public payer perspective. **METHODS:** A microsimulation model was adapted to assess the cost-effectiveness of the LAAC device compared with apixaban, dabigatran, rivaroxaban, and warfarin over a lifetime horizon. Patients' baseline characteristics were obtained from an Ontario new onset atrial fibrillation cohort ($n=35,143$). The analysis incorporated CHA2DS2VASc and HAS-BLED risk scores to determine baseline risks of thromboembolic and hemorrhagic events. Treatment effects and adverse events for the LAAC device were obtained from the PROTECT AF and PREVAIL trials. Clinical event costs were primarily obtained from Ontario costing studies and adjusted to 2016 Canadian dollars. Monte Carlo simulation was performed using 1,000 inner loops and 10,000 outer loops to determine the average base case incremental cost, incremental QALYs, and incremental cost-effectiveness ratio of the LAAC device relative to the oral anticoagulant alternatives. Deterministic, probabilistic, and scenario-based sensitivity analyses were performed to examine uncertainty in the results. **RESULTS:** Over a lifetime horizon, the LAAC device was not cost-effective (ICER: \$272,216/QALY) relative to warfarin and was dominated (higher costs, lower QALYs) by each apixaban, dabigatran, and rivaroxaban. In the majority of sensitivity analyses the device remained not cost-effective. The device was shown to be cost-effective relative to warfarin and rivaroxaban when a decreased risk of ischemic stroke for LAAC patients was examined. **CONCLUSIONS:** The LAAC device was not cost-effective relative to warfarin or novel oral anticoagulants in patients with NVAF. These values for money results ought to be considered when making funding recommendations concerning the adoption of this technology in the health care system.

MD2

COST EFFECTIVENESS OF PERCUTANEOUS CLOSURE OF A PATENT FORAMEN OVALE TO REDUCE THE RISK OF RECURRENT ISCHEMIC STROKE IN PATIENTS WHO HAVE HAD A CRYPTOGENIC STROKE DUE TO A PRESUMED PARADOXICAL EMBOLISM IN THE UNITED STATES

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OBJECTIVES: FDA has recently approved a first percutaneous patent foramen ovale (PFO) occluder indicated for transcatheter closure of a PFO to reduce the risk of recurrent ischemic stroke in patients who have had a cryptogenic stroke due to a presumed paradoxical embolism. The objective of this study was to evaluate the cost-effectiveness of this therapy compared with medical therapy in the US. **METHODS:** A Markov cohort model consisted of 4 health states (stable state, post mild and moderate acute recurrent stroke state, and death) was developed to simulate the projected clinical and economic outcomes based on US payer perspective. Event rates were extracted from a randomized clinical trial (RESPECT) with a median 5.9 years follow-up. Health utilities and direct medical costs were obtained from the published sources. One-way, probabilistic sensitivity and scenario analyses were performed to assess the robustness of the model. Monte Carlo simulations were used to estimate the 95% confidence intervals (CI) of the modeled outcomes. The model took a lifetime horizon, discounted at 3% and reported in 2016 dollars. **RESULTS:** Compared with medical therapy alone and using the commonly accepted willingness-to-pay (WTP) threshold of \$50,000, PFO closure reached the cost-effectiveness in less than 3 years (year 2.684). The cost-effectiveness ratios (ICERs) at year 3, 6 (the median trial followup) and 10 were: \$44,335 (95%CI: \$35,295-\$54,803), \$20,996 (95%CI: \$16,139-\$26,487) and \$12,110 (95%CI: \$8,824-\$15,737), respectively, per each quality-adjusted life-year (QALY) gained. Cost-effectiveness acceptability curve indicated 85.3% probability that the ICERs would be lower than the WTP threshold at year 3 and 100% after year 3. Sensitivity analyses showed that the model was robust. **CONCLUSIONS:** In carefully selected young to middle-aged patients with PFO and history of a cryptogenic ischemic stroke, percutaneous PFO closure therapy is cost-effective in the long term compared to medical therapy alone in the context of US healthcare system.

MD3

SPINAL CORD STIMULATION INFECTION RATE AND RISK FACTORS: RESULTS FROM A US PAYER DATABASE

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OBJECTIVES: Surgical Site Infections can result in significant negative clinical and economic outcomes. The objectives of this study are to define the infection rate for SCS implants, to identify patient characteristics that increase the risk for SCS

infection. **METHODS:** Data from the Truven MarketScan® Commercial Claims and Medicare Supplemental databases were used to identify patients with a SCS neurostimulator generator implant during the calendar years 2009–2014. Patients were continuously enrolled for at least 12-months before generator implant. Kaplan-Meier curves were conducted to compare the SCS infection rates between the initial implant group and the replacement implant group. COX proportional hazard regression was performed to characterize the risk factors for SCS infection based on patient demographics, common comorbidities, and other clinical characteristics. **RESULTS:** A total of 13,214 patients were identified. The SCS infection rates were 3.15% in the initial group and 2.96% in the replacement group at the end of 1 year after SCS generator implants. The result of log-rank test showed the difference of infection rates between two groups was not statistically significant (p -value=0.7916). Risk factors for SCS infection included a comorbidity of lumbar disk disease (Hazard Ratio (HR), 1.302; 95% CI: 1.015–1.671; p -value=0.0381) as well as a history of prior all-cause infection (HR, 1.770; 95% CI: 1.342–2.336; p -value <0.0001). In addition, elderly patients were less likely to have a SCS infection (HR, 0.974; 95% CI: 0.962–0.986; p -value <0.0001). **CONCLUSIONS:** The approximate 3% device-related infection rate within 12-months of SCS implant determined from a large administrative database further emphasizes the need for improvement in SCS infection control practices. Based on these results, research is warranted on methods to limit SCS infection rates in patients with a lumbar disk disease or a history of prior all-cause infection. Further research is needed to evaluate these patient factors in a prospective manner for SCS.

MD4

COMPARISON OF ECONOMIC AND CLINICAL OUTCOMES BETWEEN THE DERMABOND® PRINEO® SKIN CLOSURE SYSTEM AND SKIN STAPLES IN PATIENTS UNDERGOING KNEE REPLACEMENT IN REAL WORLD CLINICAL PRACTICE

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OBJECTIVES: To compare economic and clinical outcomes between patients undergoing knee replacement with use of the DERMABOND® PRINEO® Skin Closure System vs. skin staples. **METHODS:** Retrospective, observational study using the Premier Hospital Database. Patients (aged ≥18 years) selected for study had an elective hospital admission, with discharge occurring between 1/1/2012–9/1/2015, carrying primary ICD-9-CM procedure and diagnosis codes for knee replacement and osteoarthritis (first qualifying=index admission). Patients were classified into two mutually-exclusive groups based on billing records during the index admission: those with billing record(s) for use of PRINEO (PRINEO group); those with billing record(s) for skin staples (staple group). Primary outcomes were index admission's length of stay (LOS), total hospital costs, and discharge status (skilled nursing facility [SNF]/other vs. home/home health care); exploratory outcomes included operating room time (ORT) during index admission and 30, 60, and 90-day readmissions. The PRINEO and staple groups were propensity score matched (1:1/nearest neighbor/caliper=0.10) on patient, hospital, and provider characteristics. Multivariable regressions accounting for hospital-level clustering after matching were used to compare outcomes between study groups. **RESULTS:** Each group comprised 971 patients (1,942 total patients; mean age=65.3y; % females=63.5%). The groups were generally well-balanced on matching covariates: mean standardized difference calculated across 49 covariates=0.049. Compared to the staple group, the PRINEO group had statistically significant: shorter LOS (2.8d vs. 3.2d, $P=0.002$), lower probability of discharge to SNF/other vs. home/home healthcare (26.4% vs. 38.5%, $P=0.011$), and lower probability of 30, 60, and 90-day readmissions (30-day, 1.8% vs. 4.4%, $P=0.006$; 60-day, 3.0% vs. 5.4%, $P<0.001$; 90-day, 5.4% vs. 7.4%, $P=0.016$). Differences between the groups for other outcomes were not statistically significant. **CONCLUSIONS:** Among patients undergoing knee replacement in real world clinical practice, use of PRINEO vs. skin staples was associated with shorter LOS, less resource intensive discharge status, and lower probability of readmission.

BREAKOUT SESSION 6

COST-EFFECTIVENESS STUDIES

CE1

COMPARATIVE COST-EFFECTIVENESS OF EARLY-STAGE BREAST CANCER TREATMENTS IN THE ELDERLY

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OBJECTIVES: The aim of this study was to assess the comparative cost-effectiveness of breast-conserving surgery plus hormonal therapy with or without radiotherapy in the United States (US). **METHODS:** The study was conducted according to a US Centers for Medicare and Medicaid Services (CMS) perspective and an eight-year time horizon. Cost data were expressed in 2015 US dollars while clinical benefits were expressed in terms of quality-adjusted life years (QALYs). Both costs and QALYs were obtained from retrospective studies using the Surveillance, Epidemiology, and End Results linked with Medicare (SEER-Medicare) and Medicare Health Outcomes Survey (SEER-MHOS) as data sources respectively. The incremental cost-effectiveness ratio (ICER) of the addition of radiotherapy to hormonal therapy versus hormonal therapy alone, after breast conserving surgery (BCS), was estimated. Willingness-to-pay (WTP) thresholds were used to establish the cost-effectiveness of these treatments. Sensitivity analyses were conducted through the application of the bootstrapping method to calculate confidence intervals around the ICER estimate. **RESULTS:** The results of our analysis indicated that the addition of radiotherapy to hormonal therapy after

BCS yielded the highest clinical benefits (3.88 QALYs) and costs (\$25,246.06) compared to its hormonal therapy alone after BCS (3.52 QALYs; \$9,345.92). As a consequence, the ICER was estimated to be \$44,167.06 per QALY gained. Sensitivity analyses did not change the direction of the findings of this study. **CONCLUSIONS:** The results of our study has an important implication that a WTP threshold of at least \$44,167.06 needs to be adopted for the combination of radiotherapy and hormonal therapy to be cost-effective in the US.

CE2

LOCAL ANAESTHETIC WOUND INFILTRATION IN ADDITION TO STANDARD ANAESTHETIC REGIMEN IN TOTAL HIP AND KNEE REPLACEMENT: LONG-TERM COST-EFFECTIVENESS ANALYSES ALONGSIDE THE APEX RANDOMISED CONTROLLED TRIALS

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OBJECTIVES: The Arthroplasty Pain Experience (APEX) studies are two randomised controlled trials in primary total hip (THR) and total knee replacement (TKR) at a large UK orthopaedics centre (ISRCTN96095682, 29/04/2010). APEX investigated the effect of local anaesthetic wound infiltration (LAI), administered before wound closure, in addition to standard analgesia, on pain severity at 12 months. This article reports results of the within-trial economic evaluations. **METHODS:** Cost-effectiveness was assessed from the health and social care payer perspective in relation to quality adjusted life years (QALYs). Resource use was collected from hospital records and patient-completed postal questionnaires, and valued using unit cost estimates from local NHS Trust finance department and national tariffs. Missing data were addressed using multiple imputation chained equations. Costs and outcomes were compared per trial arm and plotted in cost-effectiveness planes. The economic results were bootstrapped incremental net monetary benefit statistics (INMB) and cost-effectiveness acceptability curves. One-way deterministic sensitivity analyses explored any methodological uncertainty. **RESULTS:** In both the THR and TKR trials, LAI was the dominant treatment: cost-saving and more effective than standard care. Using the £20,000 per QALY threshold, in THR, the INMB was £1,125 (95%BCI, £183 to £2,067) and the probability of being cost-effective was over 98%. In TKR, the INMB was £264 (95%BCI, -£710 to £1,238), with only 62% probability of being cost-effective. Considering a NHS perspective only, LAI was no longer dominant in THR, but still highly cost-effective, with an INMB of £961 (95%BCI, £50 to £1,873). **CONCLUSIONS:** Administering LAI is a cost-effective treatment option in THR and TKR surgeries. The evidence, because of larger QALY gain, is stronger for THR. In TKR, there is more uncertainty around the economic result, and smaller QALY gains. Results, however, point to LAI being cheaper than standard analgesia, which includes a femoral nerve block.

CE3

LONG-TERM COST-EFFECTIVENESS OF ADHERENCE TO ASPIRIN FOR SECONDARY PREVENTION OF CARDIOVASCULAR EVENTS

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OBJECTIVES: Adherence to antiplatelet medications for secondary prevention of cardiovascular (CV) events remains suboptimal. The aim of this study is to determine the clinical and economic implications of aspirin non-adherence in patients with prior primary CV events. **METHODS:** We developed a Markov model to estimate the cost-effectiveness of aspirin adherence from a payer perspective over five-year time horizon. The costs and rates of non-fatal events including adverse events, peripheral arterial disease-related amputation, myocardial infarction (MI) and stroke were gathered from published literature to populate the model. We applied the model separately to a low risk population with no comorbidities (low-risk model) and a high risk population with type II diabetes (high-risk model). The outcome was incremental cost-effectiveness ratio (ICER) measured as cost (\$) per quality adjusted life year (QALY). A one-way sensitivity analysis was done to determine the stability of our results, and a tornado diagram was used to determine parameters that will highly affect our results. **RESULTS:** Adherent patients lived 0.25 and 0.36 QALY longer than non-adherent patients in the low-risk model and high-risk model, respectively. Adherence to aspirin had an ICER of \$25 per QALY in the low risk population, while adherence to aspirin saved \$2,303 in the high risk population. Our results were more sensitive to alteration of parameters in the low-risk model compared to the high-risk model. The two models were highly sensitive to the rates of non-fatal events in non-adherent and adherent patients. A higher event rate in the non-adherent population significantly impacted the models. **CONCLUSIONS:** This analysis demonstrates that aspirin adherence is a cost-effective strategy for promoting CV health, potentially cost saving outcomes for patients with comorbid conditions. While additional research is needed to validate these results in a clinical setting, payers may need to increase the use of strategies to promote adherence.

CE4

HEALTH ECONOMIC IMPACT OF A 17-GENE PANEL PREDICTING AGGRESSIVE DISEASE IN MEN WITH NEWLY DIAGNOSED PROSTATE CANCER

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OBJECTIVES: Active Surveillance (AS) is increasingly recommended as a viable management option for many patients with clinically low risk prostate cancer (PCa). Genomic testing assesses tumor biology, provides an independent and

individualized risk assessment, and has the potential to optimize care. Here, we assessed the economic impact of genomic testing by assessing the influence of a 17-gene panel (Oncotype DX[®] Genomic Prostate Score[™], GPS) on treatment selection and healthcare costs in patients with NCCN Very Low, Low, and Intermediate risk PCa. **METHODS:** We conducted a chart based analysis for 1087 men with NCCN Very Low, Low, and Intermediate risk PCa managed in four large urology practices (LUP). Shared treatment decisions, with GPS testing, were captured through electronic health records from May 2014 through July 2016. Active Surveillance (AS) was defined as documented AS or lack of treatment documentation within six months of prostate cancer diagnosis. We estimated economic outcomes using peer-reviewed and published cost numbers from baseline (untested) and tested patients from a fifth LUP. **RESULTS:** Baseline (untested) practice patterns in the LUP from which cost data was available included 32% of men following AS, 37% receiving Radical Prostatectomy (RP) and 29% Radiation Therapy (IMRT). In the 5 LUPs with GPS testing, AS, RP and RT were utilized by 59%, 20% and 9% of patients, respectively. In these practices, utilization of GPS was calculated to result in a total savings of \$5.574M (\$5,128 per-patient) over the first 180 days post-diagnosis, including GPS list price. We estimate that a 2M member commercial payer that tests all appropriate localized PCa patients with GPS would result in approximately \$4.5M in savings. **CONCLUSIONS:** In this economic assessment, using real-world cost data and GPS guided treatment selection, we project that GPS utilization would decrease direct healthcare spend through appropriate treatment selection for clinically low-risk PCa patients.

CARDIOVASCULAR STUDIES

CV1

BIOLOGICAL AND PSYCHOSOCIAL RISK FACTORS OF STROKE IN AFRICAN AMERICANS ENROLLED IN THE JACKSON HEART STUDY

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OBJECTIVES: To examine the impact of biological, psychosocial and other socio-economic risk factors on incident stroke and to estimate the population attributable risk (PAR) of factors associated with stroke in African Americans enrolled in the Jackson Heart Study (JHS). **METHODS:** This is a nested case-control study of a cohort of African Americans enrolled in the JHS. Cases were patients with incident stroke during a 10 year follow up period. Five controls were selected for each case using incidence density sampling and matched with cases on person-years spent in the cohort. Odds ratios (OR) and PARs were calculated to understand the impact of different risk factors on incident stroke. **RESULTS:** From a cohort of 5,302 patients, 129 cases of incident stroke and 590 controls were identified. Hypertension and diabetes were found to be the two strongest risk factors of stroke, with an OR of 1.8 (95% CI 1.1 - 3.1) for hypertension and 1.7 (95% CI 1.1 - 2.7) for diabetes, followed by the Framingham stroke risk score, where the risk of stroke increased by 4% for every 1% increase in the Framingham stroke risk score (OR 1.04, 95% CI 1.01 - 1.08). Psychosocial risk factors including depression (OR 0.7, 95% CI 0.4-1.2), stress (OR 0.9, 95% CI 0.9-1.0), and major life events (OR 1.0, 95% CI 0.9-1.1), were not significantly associated with incident stroke in this population. The overall PAR for biological and psychosocial risk factors combined accounted for 77.5% of incident stroke. **CONCLUSIONS:** African Americans with hypertension and diabetes were at a higher risk of developing stroke. However, findings on the association between depression and stroke were somewhat inconsistent with previous JHS studies due to the way depression was measured.

CV2

ECONOMIC EVALUATION OF ALTERNATIVE ANTICOAGULANT DRUGS FOR THE PREVENTION OF STROKE AMONG 65-YEAR OLD ATRIAL FIBRILLATION PATIENTS IN TAIWAN

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OBJECTIVES: Atrial fibrillation (AFib) patients have a higher risk of ischemic stroke and anticoagulants are widely used in stroke prevention. Recently, three new oral anticoagulant drugs (NOACs) have been made available in Taiwan (Apixaban, Dabigatran, and Rivaroxaban). This study aims to calculate the cost-effectiveness of them, comparing to Warfarin, in 65-year old patients with AFib from a perspective of Taiwan national healthcare insurance (NHI). **METHODS:** A Markov model, Monte Carlo simulation, and sensitivity analyses were used to assess the costs and quality-adjusted life years (QALYs) of the three NOACs and Warfarin in a Taiwanese setting. All parameters populated were obtained from the literature review and NHI database. The thresholds of the willingness to pay (WTP) at 1 and 3 times GDP per capita (\$22,288 and \$66,864) were used to assess the cost-effectiveness. **RESULTS:** In a base-case analysis, Rivaroxaban produced the most QALYs at 10.32, followed by Apixaban (9.97), Dabigatran (9.26), and Warfarin (8.91). Warfarin had the fewest costs at \$30,251; Rivaroxaban cost the most at \$65,665, followed by Dabigatran (\$52,991) and Apixaban (\$48,223). The costs per QALY gained for each NOAC (Apixaban, Dabigatran, and Rivaroxaban) versus Warfarin were \$16,954, \$64,931, and \$25,116. Dabigatran was dominated by Apixaban and the ICER (Rivaroxaban versus Apixaban) was \$49,834. In a Monte Carlo probabilistic sensitivity analysis, Apixaban, Dabigatran, and Rivaroxaban were cost-effective in 36.8%, 13.4%, 36.2% of \$22,288, and 31.3%, 15.2%, 48.1% of \$66,864. **CONCLUSIONS:** From a Taiwan NHI perspective, if affordable, and the WTP threshold is at least 1 x GDP per capita (\$22,288) per QALY gained, Apixaban

would be preferred to Warfarin. However, if decision-makers are willing to pay up to 2.25 x GDP per capita (\$50,000) per QALY gained, then Rivaroxaban would be the optimal replacement for Warfarin in the Taiwanese setting.

CV3

A HIGH PERCENTAGE OF NEWLY INITIATED DIRECT ORAL ANTICOAGULANT USERS SWITCH BACK TO TRADITIONAL THERAPY

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OBJECTIVES: The objective of this study is to evaluate patterns of prescription switching in atrial fibrillation (AF) patients initiated on a direct oral anticoagulant (DOAC) and previously naïve to anticoagulation (AC) therapy. **METHODS:** Data was obtained from Truven Health MarketScan[®] Commercial and Medicare Supplemental Databases from January 1, 2009 to December 31, 2013. AC naïve (those without prior anticoagulant use) AF patients initiated on a DOAC, with 6 months of continuous health plan enrollment before and after index date and maintained on continuous therapy for a minimum of 6 months were included. **RESULTS:** A total of 34,022 AC naïve AF patients initiating a DOAC were included. Of these, 6,613 (19.4%) patients switched from an index DOAC prescription to an alternate anticoagulant and 27,409 (80.6%) remained on the DOAC (age: 68.5±11.7 vs. 67.1±12.7 years, p<0.001; males: 3,781 (57.2%) vs. 17,160 (62.6%), p<0.001, respectively). A majority of patients received dabigatran as their index DOAC (N=23,521; 69.1%), followed by rivaroxaban (N=9,875; 29.0%) and apixaban (N=626; 1.8%). Amongst those that switched their medication, 3,196 (48.3%) did so within the first 6 months of therapy and 4,574 (69.2%) within the first 12 months. Overall, 2,945 (44.5%) patients switched to warfarin, 2,912 (44.1%) switched to another DOAC and 756 (11.4%) switched to an injectable anticoagulant. The highest proportion of patients switched from dabigatran to warfarin (N=2,320; 35.1%) or rivaroxaban (N=2,252; 34.1%). The median time to switch to another DOAC was 309.5 days vs. 128.0 days (p<0.001) to switch to warfarin. **CONCLUSIONS:** In AF patients newly initiated on DOAC therapy, one in five patients switch to an alternate anticoagulant and one of every two patients do so within the first six months of therapy. Switching from an initial DOAC prescription to traditional anticoagulants occurs as frequently as switching to an alternate DOAC. Further investigation is warranted to assess the potential causes of switching.

CV4

WHY HAVE WE BEEN DYING LESS FROM CORONARY HEART DISEASE IN THE UNITED STATES?

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OBJECTIVES: To replicate a widely cited Ford et al. study (NEJM 2007) that concluded that the decline in CHD mortality in the U.S. between 1980-2000 could be equally attributed to: (1) medical therapies; and (2) changes in CHD risk factors outside of medical therapies. Our replication corrected for one element that could affect (2) above: changes in CHD-related medication rates from 1980-2000. **METHODS:** Ford et al. used average changes in blood pressure and cholesterol in untreated populations to estimate the total deaths prevented or postponed (DPP) from these risk factor reductions outside of medical therapy. However, treatment rates increased from 1980-2000, so it is possible that reductions in average blood pressure or cholesterol among untreated individuals were (at least partially) an artifact of this methodological approach. We adjusted for changing treatment rates by adding back systolic blood pressure (18.8 mmHg) and LDL cholesterol (1.09 mmol/L) to some (for blood pressure) or all (for cholesterol) treated individuals (treatment rates of 18.3% and 7.7%, for blood pressure and cholesterol, respectively) in 2000 to approximate treatment rates in 1980 (6.0% and 0%, respectively). Otherwise, we used the same methods and data sources, such as individual-level data from the National Health and Nutrition Examination Study, as Ford et al. **RESULTS:** In our replication, we estimated total DPP of 236,728 between 1980-2000, with 159,330 (66.3%) attributable to medical therapies and 81,092 (33.7%) from risk factor changes outside of medical therapies. Results were sensitive to assumptions around the levels of blood pressure and cholesterol added back to treated individuals in 2000. **CONCLUSIONS:** After correcting for changes in treatment rates, approximately two thirds of the decline CHD mortality in the U.S. from 1980-2000 could be attributed to medical therapies, with changes in risk factors outside of medical therapies accounting for one third of the CHD mortality decline.

BREAKOUT SESSION 7

MEDICATION ADHERENCE STUDIES

AD1

EXPLORING LENGTH OF THERAPY AND FACTORS ASSOCIATED WITH HIV PRE-EXPOSURE PROPHYLAXIS MEDICATION ADHERENCE USING PHARMACY CLAIMS DATA

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OBJECTIVES: To characterize use of once-daily emtricitabine and tenofovir disoproxil fumarate for HIV pre-exposure prophylaxis (PrEP) by examining length of therapy, gaps in therapy, and adherence using real-world pharmacy claims data. To examine factors associated with PrEP adherence, including demographic variables and use of Walgreens HIV specialized pharmacies (HIV-sp), which support adherence through personalized medication adherence counseling. **METHODS:** We

conducted a retrospective cohort study using Walgreens prescription pharmacy claims data. A random sample of PrEP users from calendar years 2013 to 2016 were included if they filled a PrEP prescription for $>=90$ days in the index year. Patients were excluded if they had evidence of combined ARV therapy during the study period. Average length of therapy and the proportion of patients with gaps in therapy were calculated. Medication adherence, measured as proportion of days covered (PDC), was calculated and analyzed by demographic variables and use of HIV-sp. **RESULTS:** On average, patients used PrEP for 157 days consecutively without gaps; 55.6% of users had a >7 day gap in consecutive days of PrEP coverage during the index year. The mean PDC was .88 and 64.0% of users achieved high adherence (PDC $>=90\%$). HIV-sp users were more likely than non-HIV-sp users to be highly adherent (OR=1.39, 95% CI: 1.27-1.52, $p<.0001$). Those 50 or older were 2.70 times more likely to be highly adherent than those 18-24 years old (CI: 2.34-3.14, $p<.0001$). Women were less likely to be highly adherent than men (OR=0.67, CI: 0.56-0.80, $p<.0001$) as were urban vs. rural PrEP users (OR=0.86, CI: 0.77-0.95, $p=.0052$). **CONCLUSIONS:** PrEP adherence was significantly associated with age, gender, store type, and urban-rural MSA. These results highlight the importance of adherence counseling among specific populations and illustrate differences in adherence by service setting. Future research should investigate improved methods for calculating adherence and length of therapy for PrEP.

AD2

FREE MEDICATIONS: A SYSTEMATIC REVIEW OF THE EFFECT OF ZERO COST SHARING ON ADHERENCE TO THERAPY

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OBJECTIVES: Behavioral economic studies have suggested that people may place lower value on free goods, an argument used to justify copayments or coinsurance by insurers. The purpose of this study was to examine the effect of zero cost sharing compared to usual cost sharing on medication adherence or persistence. **METHODS:** A systematic literature review was performed using Medline, EMBASE, CINAHL, IPA, Cochrane Library, Scopus, Web of Knowledge, PsychINFO, and Clinicaltrials.gov. Included original articles were English language comparative studies with cost as the main exposure. Each article was assessed by two independent reviewers; disagreements were resolved by consensus. Data on study design, population, intervention, adherence/persistence outcomes, and study quality were abstracted. **RESULTS:** The search identified 1941 unique records meeting preliminary inclusion; 19 articles met full inclusion criteria representing 16 independent studies. Two studies were randomized controlled trials (RCTs) with superior methodological quality. Most studies were conducted in the United States and involved a payer-based program or intervention. Among studies using self-reported measures, zero cost sharing significantly decreased cost-related non-adherence, but only had a small negative effect on overall non-adherence. In observational studies, zero cost sharing was associated with sustained or small increases in adherence. Among the RCTs, zero cost sharing had a positive effect on adherence in one study with an insurance policy change, and no effect in one study with an incentive-based program. Overall, few studies evaluated the effect of zero cost sharing on adherence with high methodological quality. Increases in adherence were small and may be related to the program design and population demographics. **CONCLUSIONS:** No important differential zero price effect could be identified in this literature. Insurers should carefully consider that cost sharing may have a small negative impact on medication adherence, potentially impacting those with cost-related non-adherence most.

AD3

IMPACT OF MEDICATION ADHERENCE ON TOTAL MEDICAL COSTS

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BACKGROUND: Existing literature suggests that medication adherence leads to lower health care utilization and reduced medical costs despite increased drug spending. While the impact of adherence on total medical costs is more pronounced in some conditions than in others, the consensus is that optimal adherence will reduce health care costs as well as improve health outcomes. **OBJECTIVES:** To estimate the impact of medication adherence on the total annual medical costs for chronic conditions in commercial health plan beneficiaries. **METHODS:** We examined the pharmacy and medical claims for beneficiaries who were continuously eligible in 2015 and with at least two prescriptions for at least one of the following conditions - Diabetes, Hypertension, Depression and Hyperlipidemia. Adherence was calculated using the interval-based Proportion of Days Covered (PDC) method. Generalized linear model with gamma distribution was utilized to examine the association between adherence and total medical costs while adjusting for the factors such as comorbid conditions, demographic, and socioeconomic characteristics. **RESULTS:** The study sample consisted of approximately 121,781 antidiabetic beneficiaries, 378,511 antihypertensive beneficiaries, 375,442 antidepressant beneficiaries and 307,650 antihyperlipidemics beneficiaries included after applying inclusion/exclusion criteria. On average, non-adherent beneficiaries have their average PDC in the 52%-55% range, while adherent beneficiaries have their average PDC around 92%-94%. For antidiabetics, antihypertensive and antidepressants classes, the average cost for non-adherent group was significantly higher than those in the adherent group ($p<0.001$) after controlling for demographic variables and comorbid conditions. On average there is a \$100 - \$150 PMPY TMC saving as adherence increases in antidepressants and antihypertensive drug classes. **CONCLUSIONS:** Improvement in adherence leads to cost savings in some therapeutic classes, and the savings vary depending on the demographic characteristics and comorbid conditions. Increasing adherence in cases where the medication costs are higher than the resulting visit rate at a hospital or emergency room may not save costs.

AD4

ADHERENCE TO DRUG THERAPY IN THE PATIENTS WITH CHRONIC KIDNEY DISEASE: A SYSTEMATIC REVIEW AND META-ANALYSIS OF OBSERVATIONAL STUDIES

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OBJECTIVES: Medication non-adherence can lead to treatment failure; increased hospitalization, morbidity, and cost of care; and decrease patients' quality of life. The evidence on the medication adherence in the patients with chronic kidney disease (CKD) is lacking. The aim of the present systematic review is to evaluate the medication adherence in the patients with CKD. **METHODS:** Published literature was searched via PubMed, Cochrane library databases, Elsevier ScienceDirect, and Google scholar (from 1990 to Dec 2016). Further, relevant studies were found out by using reference list. Patients of all ages, gender, and diagnosed with CKD and/or on hemodialysis were included. Adherence was defined according to the questionnaires/scales/methods used in different studies. A funnel plot was used to assess the publication bias. Heterogeneity was assessed by using Cochran Q and I² statistics. Random effect model was used. **RESULTS:** A total of fifteen studies (prospective-5, retrospective-1, and cross-sectional-9) were included. Pill count (PC) was the most common used method followed by Morisky medication adherence scale (MMAS), self-reported questionnaire (SRQ), and others (5, 4, 3, and 3, respectively). Others include serum phosphate level, interdialytic weight gain, and simplified medication adherence questionnaire. The pooled prevalence of medication adherence was found to be 50.1% (95% Confidence Interval 41.6-59.9). Adherence in patients on 'medications' and 'medication with dialysis' was found to be 49.8% (95% CI 37.9-61.8) and 52.5% (95% CI 39.0-65.6), respectively. Medication adherence reported using PC was 48.7% (95% CI 29.7-68.1); MMAS was 33.4% (95% CI 14.6-59.6); SRQ was 67.4% (95% CI 49.2-81.6); and others was 59.4% (95% CI 28.2-84.5). **CONCLUSIONS:** This systematic review demonstrated a poor medication adherence in the patients with CKD on 'medications' and 'medications with dialysis'. The 'pill count' was found to be most commonly utilized method. Steps to improve the medication adherence could be helpful in decreasing hospitalization, morbidity, and cost of care; and improving patients' quality of life.

PATIENT PREFERENCE STUDIES

PP1

COMPARISON OF PATIENT, ONCOLOGIST, AND ONCOLOGY NURSE PREFERENCES FOR ATTRIBUTES OF DRUG THERAPY IN ADVANCED MELANOMA

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OBJECTIVES: New treatments options are available for patients with advanced melanoma, which can vary in their efficacy, safety and dosing schedules. The objective of this study was to compare different stakeholder perspectives (patients, oncologists, and oncology nurses) on the importance of drug treatment attributes in advanced melanoma. **METHODS:** Online panels were used to conduct a series of discrete choice experiments (DCEs) in US-based patients, oncologists and oncology nurses. In a series of scenarios, respondents were asked to choose between two hypothetical treatments, each with 7 attributes: mode of administration, dosing schedule, duration of therapy (3, 8, and 12 months), objective response rate (ORR) (15%, 33% and 65% chance of response), progression free survival (PFS) (3, 5, and 11.5 months), overall survival (OS) (45, 55, and 75% survival to 12 months), and grade 3/4 toxicities/adverse events (AEs) (10%, 32%, and 55% likelihood). Each attribute had 3 levels except dosing schedule (8 levels). Bayesian logistic regression models were used to estimate preference weights. **RESULTS:** Participants included 200 patients with advanced melanoma, 226 practicing oncologists, and 150 oncology nurses. The relative importance estimates of attributes by oncologists, patients and nurses were, respectively, as follows: OS (34%, 33%, 28%), AEs (49%, 29%, 26%), ORR (12%, 25%, 27%), PFS (3%, 12%, 15%), dosing schedule (3%, 2%, 3%), median duration of therapy (0%, 0%, 0%), and mode of administration (0%, 0%, 0%). Oncologists significantly differed from nurses and patients in the weights assigned to ORR, PFS and AEs (p -values <0.001). **CONCLUSIONS:** Patients and nurses have similar views on the relative importance of treatment attributes for advanced melanoma, while oncologists assigned greater importance to AEs, and less importance to ORR and PFS. Future research could seek to qualify how these differences impact treatment selection.

PP2

CARER SOCIAL CARE-RELATED QUALITY OF LIFE OUTCOMES: ESTABLISHING PREFERENCE WEIGHTS FOR THE ADULT SOCIAL CARE OUTCOMES TOOLKIT FOR CARERS

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OBJECTIVES: There is an increasing interest in how well informal carers are supported within their caring role. When assessing support, it is important to consider informal carer's quality of life. The Adult Social Care Outcomes Toolkit for Carers (ASCOT-C) was developed and validated to capture the effect of social care on the quality of life (QoL) of informal carers. One objective when developing the ASCOT-C was that it could be preference weighted for use in economic evaluation. Currently there is no set of preference weights established for the

ASCOT-C. The aim of this study was to generate a set of preference weights for the ASCOT-C. **METHODS:** An online survey was developed, which included the Best-Worst Scaling task (BWS) to elicit preferences for ASCOT-C QoL states. The BWS task was based on a fractional-factorial design, consisting of 32 tasks, which were blocked into four segments. The online survey was administered to a representative sample of the general adult population in England ($N = 1,000$). Participants were asked to put themselves into the hypothetical state of being a carer and indicated which QoL situation they thought was the best and worst. Multinomial logistic regression was used to analyse the data. **RESULTS:** Results showed that participants rated having 'no control over their daily life' as the worst domain level of all those presented. The second lowest rated domain level was 'I don't do anything I value or enjoy' from the occupation domain. The most valued aspect by participants was the occupation domain at its highest level closely followed by the top level of control. Findings also showed that the position of the domains influenced participants' best and worst choices. **CONCLUSIONS:** This study has established a set of preference weights for the ASCOT-C. We reflect on the value of these weights for policy and practice.

PP3

PATIENTS' PREFERENCES OVER TREATMENT SIDE-EFFECTS REFLECT A LATENT "OPTIMISM" CHARACTERISTIC

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OBJECTIVES: To identify a quantifiable, latent patient characteristic associated with a propensity to view the side-effects of chemotherapy treatment as minimally bothersome and to investigate its properties with respect to patient reported quality-of-life (QoL) and satisfaction with treatment choice. **METHODS:** 64 women diagnosed with stage 3 or 4 ovarian cancer (a rare cancer) were given access to a web-based decision-aid, which includes educational modules and a preference elicitation exercise, and is designed to help patients choose between routes of chemotherapy administration. Patients provided QoL data and preferences about side-effects before starting treatment. Preferences were measured using a visual analog scale for 4 side effects, each with 3 possible severity levels, for a total of 12 side-effect/severity dyads. Following chemotherapy choice, satisfaction with treatment choice was measured. Item response theory (IRT) was used to identify a latent "optimism" characteristic of patients based on their tendency to rank all side-effects/severities as likely to be either of little bother or a lot. Regression techniques were used to test the relationships between QoL, its component subscales, "optimism", and satisfaction with the treatment choice. **RESULTS:** Lower scores assigned by the IRT analysis indicate the patient's higher propensity to rank all side-effects/severities as of little concern. Sensitivity analysis suggested a score of 0.2 as the cut-off between "optimistic" and "non-optimistic" patients. Patients who had a higher QoL at baseline were found to be more "optimistic" ($OR=1.06$ $p<0.05$). "Optimism" had a large effect size (of about 0.75 standard deviation $p<0.001$) on being satisfied with the chemotherapy treatment choice. **CONCLUSIONS:** This study found that ovarian cancer patients exhibited consistent preferences over 12 side-effects/severities and that these are associated with other attitudes towards the disease. Further studies to evaluate this phenomenon for other cancer patients and with respect to other attitudes which may affect care, is indicated.

PP4

VALIDATION OF A QUESTIONNAIRE TO ASSESS PATIENT PERCEPTIONS OF INJECTION DEVICES FOR TYPE 2 DIABETES

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OBJECTIVES: Characteristics of injection devices used for administering medication for type 2 diabetes (T2D) could impact patient preference. Previous research has examined patient perceptions of insulin injection devices. However, a range of injectable medications other than insulin are now used to treat T2D. No patient-reported outcome (PRO) instruments have been developed taking into account the perceptions of patients using newer injection devices, which are often different from those used in the past. Therefore, the purpose of this study was to validate a new PRO instrument focusing on patients' experiences with injection devices, including those used for newer treatments such as GLP-1 receptor agonists. **METHODS:** Patients with T2D treated with non-insulin injectable medications were recruited via advertisements and six clinical sites in the US and completed the draft 20-item Diabetes Injection Device - Experience Questionnaire (DID-EQ) and additional measures administered for validity assessment. Analyses focused on item reduction (item performance, factor analysis, IRT), reliability, and validity. **RESULTS:** 142 patients (mean age = 63.0y; 56.3% female) participated. Item reduction yielded a 10-item version of the DID-EQ, including a 7-item device characteristics subscale and three global items assessing satisfaction, ease of use, and convenience of the injection device. The DID-EQ demonstrated good internal consistency reliability (Cronbach's alpha of device characteristics subscale = 0.80) and 7-day test-retest reliability (ICCs: 0.92 for device characteristics subscale; 0.65 to 0.91 for the three global items). Construct validity was demonstrated via correlations with previously validated instruments

(e.g., correlations with the DTSQ treatment satisfaction subscale ranged from 0.56 to 0.60, all $p < 0.0001$; correlations with the TRIM-D Device ranged from 0.63 to 0.77, all $p < 0.0001$). **CONCLUSIONS:** This psychometric validation study supports the reliability and validity of the DID-EQ. This questionnaire may be useful in clinical trials and observational research assessing and comparing patient perceptions of injection devices.

BREAKOUT SESSION 8

MENTAL HEALTH STUDIES

MH1

THE POTENTIAL ECONOMIC VALUE OF DISEASE-MODIFYING TREATMENTS IN ALZHEIMER'S DISEASE: PATIENT-LEVEL SIMULATION OF PREDEMENTIA SYMPTOM TRAJECTORIES

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OBJECTIVES: Development efforts for disease-modifying treatments (DMTs) in Alzheimer's disease (AD) are increasingly focused on the prodementia stages of the disease, where efficacy endpoints are less established and may include a combination of biomarker levels and more sensitive cognitive scales than are used in clinical practice. Demonstrating the economic value of DMTs indicated for the prodementia stages of AD requires a modeling approach that translates these sensitive endpoints to long-term disease progression and AD dementia onset. **METHODS:** A natural history microsimulation model of AD was developed to generate lifetime patient-level trajectories for cognitive, behavioral, and functional symptoms for patients who are asymptomatic, at-risk for developing Alzheimer's dementia (ARAD), defined by elevated beta-amyloid levels but not yet meeting mild cognitive impairment due to AD criteria. A targeted literature review was conducted to estimate trajectories prior to AD dementia onset, after which published AD dementia trajectories were used. The natural history model was validated against published epidemiological studies and used to estimate the potential impact of DMTs for ARAD patients on clinical outcomes that drive costs in AD. **RESULTS:** Compared with natural history, a DMT for ARAD that reduces the rate of progression by 20-50% decreases the lifetime likelihood of AD dementia (29-38% vs. 43%) and AD-related institutionalization (11-17% vs. 21%). A DMT that halts progression for 5 years reduces the lifetime likelihood of AD dementia to 27% (12% institutionalization), with a further reduction to 17-23% (6-9% institutionalization) if the halt in progression is followed by a 20-50% reduction in progression rate. **CONCLUSIONS:** DMTs for ARAD have the potential to reduce progression to AD dementia and institutionalization and thus to reduce AD-related costs. Studies relating biomarker and sensitive cognitive endpoints to long-term progression patterns are essential, as the specific form of these relationships significantly influences the economic value of DMTs for ARAD.

MH2

HEALTH CARE UTILIZATION AND EXPENDITURES AMONG ADULTS WITH BIPOLAR DISORDER IN THE UNITED STATES

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OBJECTIVES: Bipolar disorder (BD) is a manic depressive illness that affects more than 5.7 million of the US adult population. The economic burden of BD in the US was estimated to be \$45 billion in 1991. Increasing availability of novel and more expensive therapy for BD suggests a need of assessing healthcare utilization and treatment costs in current environment. The objective of this study was to estimate the healthcare utilization and total healthcare expenditures including inpatient healthcare cost, prescription drug cost, emergency room visit and outpatient cost among US adults with BD. **METHODS:** The Medical Expenditure Panel Survey (MEPS) data of 2008-2012 was used to identify patients with BD using International Classification of Diseases (ICD9-CM) codes. Adults aged 21 years or older were included in the analysis. Data were analyzed using STATA14 for descriptive statistics and differences using the Student t-test and Chi-square test. Regression analysis was performed to predict associations between demographic characteristics; healthcare utilization and healthcare expenditures. Expenditures were adjusted to 2016 US dollars using Consumer Price Index (CPI). **RESULTS:** The final sample consisted of 1729 adults with a mean age was 43.7 yrs. Majority of adults were non-Hispanic white (77%) and were female (67%). Patients had average 23 days of hospital inpatient stay, 1597 medical provider visits, 83 outpatient visits and 15 emergency room visits per year. The total annual healthcare expenditure was estimated to be \$11839, which included \$3238 of inpatient health care cost, \$4026 of prescription drug cost, \$473 of emergency room visit and \$709 of outpatient cost. Gender and age was good predictor of high healthcare expenditures, prescription drug and outpatient costs ($p < 0.05$). **CONCLUSIONS:** Treatment of bipolar disorder poses significant economic burden. Cost effective delivery of medical and psychiatric care is vital for patients with BD to reduce its economic burden on healthcare system and the society.

MH3

HOW WELL DO THE EQ-5D-3L AND 5L PERFORM IN ASSESSING CHANGES IN MENTAL HEALTH?

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OBJECTIVES: To examine the performance of the anxiety/depression (A/D) dimension of the EQ-5D-3L and 5L in assessing changes (improvement vs.

deterioration) in mental health. **METHODS:** Data from two patient populations were used: 495 adults post-discharge from general internal medicine ward (EQ-5D-3L), and 225 type 2 diabetes patients who screened positive for depressive symptoms (EQ-5D-5L). Anchor-based approach along with effect sizes (ES) and ROC analysis were used. Anchors included Patient Health Questionnaire 9-items "PHQ9" and Generalized Anxiety Disorder 2-item questionnaire "GAD2" for EQ-5D-3L, and PHQ9 and SF-12 physical and mental composite summary scores (PCS, MCS) for EQ-5D-5L. A/D change was quantified as the difference between follow-up and baseline levels. **RESULTS:** For the EQ-5D-3L, ES of PHQ9 and GAD2 changes were larger for symptom improvement vs. deterioration (e.g., ES of PHQ9 worsening on A/D 2 levels =1.8 and for 2 level improvement=0.2). The A/D was useful in detecting changes in worsening depressive symptoms with an optimal cut-off point of 1 (C-index=0.61), but not for improving depressive symptoms or any change in anxiety. For the EQ-5D-5L, ES of PHQ9, PCS and MCS changes were larger for symptom improvement vs. deterioration (e.g., ES of PHQ9 worsening on A/D 2 levels =3.3 and for 2 level improvement =1.3). The A/D was useful in detecting changes in improving depressive symptoms with an optimal cut-off point of 1 (C-index=0.64), in worsening MCS with an optimal cut-off point of 1 (C-index=0.74), but not for worsening depressive symptoms, improving MCS, or any change in PCS. **CONCLUSIONS:** Although the A/D of both EQ-5D-3L and 5L was limited in capturing changes in mental health in these populations, the 5L was more responsive than the 3L. While the performance was better for depressive symptoms than anxiety, it varied by the direction of change. Further evidence in other populations using other measures of mental health is warranted.

MH4

DEPRESSION SCREENING AMONG OLDER ADULTS WITHOUT DEPRESSION IN AMBULATORY SETTINGS IN UNITED STATES

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OBJECTIVES: Objectives of this study were to examine national patterns and predictors of depression screening among older adults without a diagnosis of depression in the United States (US). **METHODS:** This study used a cross-sectional design utilizing pooled data from National Ambulatory Medical Care Survey (NAMCS, 2005-2013). The study sample consisted of ambulatory visits among older adults (age ≥ 65 years) without a depression diagnosis. Visits were excluded if they listed depression diagnosis using ICD-9-CM codes of 296.2-296.36, 300.4 or 311, or if the answer to the question "Regardless of the diagnoses written-does the patient now have: depression?" was "yes." Depression screening (yes/no) was the dependent variable for this study. Depression screening was identified by the variable "DEPRESS", which represented depression screening exam, from the NAMCS data. All analyses were adjusted for the complex survey design of NAMCS. Weighted percentages of visit estimates were reported in terms of descriptive statistics. Multivariable logistic regression analyses were conducted to examine predictors of depression screening among older adults without a depression diagnosis adjusting for predisposing, enabling and need factors. **RESULTS:** National depression screening rate was only 0.86% [95% Confidence Interval (CI), 0.7%-1.05%] of all ambulatory visits by older adults without depression. Physician specialty, metropolitan status, geographic region, and time spent with physician were significantly associated with depression screening. For example, receipt of depression screening was four times more likely during a psychiatrist visit [Odds Ratio=4.04; 95% CI, 1.60-10.23] and 50% less likely during a neurologist visit (OR=0.50, 95% CI, 0.26-0.97) compared to visits to other physician specialties. **CONCLUSIONS:** Depression screening remains low in ambulatory care settings for older adults without prior diagnosis of depression in the US. Given the high benefit of treatment and little to no harm of screening, healthcare providers should routinely screen older adults for depression.

RESEARCH ON METHODS STUDIES

RM1

LESSONS LEARNED IN IDENTIFYING RELAPSING-REMITTING MULTIPLE SCLEROSIS IN US INTEGRATED DELIVERY NETWORK HEALTH CARE CLAIMS AND ELECTRONIC HEALTH RECORD DATA

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OBJECTIVES: To develop and validate operational EHR- and claims-based algorithms for RRMS patient identification in a US Integrated Delivery Network (IDN) healthcare system. **METHODS:** IDN data (2010-2014) were queried for the study inclusion criteria: MS diagnosis, age ≥ 18 years, ≥ 1 year baseline history, and no other demyelinating diseases. The EHR-based algorithm used natural language processing (NLP). The claims-based algorithms were developed using (1) combinations of: MS diagnosis, specific symptoms during a neurology visit, disease modifying therapies (DMT), brain/spinal MRI; and (2) rule out progressive MS (P-MS) through: (option A) medications for P-MS; (option B) MS severity/progression from adapted Kurtzke Functional Systems Scores; and (option C) P-MS defined by Gilden, 2011. Random samples of NLP-based medical chart reviews were the "gold standard" for algorithm validation and positive predictive value (PPV) calculations. **RESULTS:** Of 3,111 MS patients identified, 2,960 (95%) were by claims-based, 990 (32%) by EHR-based, and 839 (27%) by both algorithms. RRMS was established in 2,213 (71%) patients overall. Of 2,960 claims-based, the three algorithm options identified 2,271 (77%) RRMS patients. Of 990 EHR-based patients, RRMS was identified in 837 (85%). An average 19.3 documents per patient were included for NLP-based chart review. The combined claims- and EHR-based algorithms had a

PPV (95% CI) of 93% (82%-98%). The claims-based algorithms to identify RRMS had PPV (95% CI) of 88% (78%-94%), 89% (76%-95%), and 89% (79%-95%) for options A, B and C, respectively. **CONCLUSIONS:** Both the combined claims- and EHR-based and the claims-based algorithms had excellent PPV for identifying RRMS among patients with documented MS subtypes. Traditional medical chart reviews will support the NLP-based chart reviews, particularly for patients without clinical notes of MS subtypes. The claims- and EHR-based algorithms to identify RRMS and NLP-based chart reviews are promising methods for future research.

RM2

THE PSYCHOMETRIC EVALUATION OF THE CHINESE VERSION HEARTQOL QUESTIONNAIRE AMONG PATIENTS WITH ISCHEMIC HEART DISEASE IN CHINA

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OBJECTIVES: This study evaluated the psychometric properties of the Chinese Mandarin HeartQoL Questionnaire (C-HeartQoL), an ischemic heart disease (IHD) specific health-related quality of life instrument, among Mainland Chinese patients with angina, myocardial infarction (MI) and heart failure (HF). **METHODS:** The English version HeartQoL questionnaire was translated into Chinese using the forward-backward translation approach. A cross-sectional study was then conducted in patients with angina, MI and HF using C-HeartQoL, SF-12, and HADS. Internal consistency reliability was evaluated. Convergent validity was assessed with Pearson correlations. Divergent validity was determined using age, gender, SF-12 general health status, HADS anxiety and depression, and functional status as predictor variables. **RESULTS:** In total, 406 IHD patients (angina=111; MI=150; and HF=145) were enrolled in China. Patients with MI (2.04 ± 0.72) had higher HeartQoL scores than patients with angina (1.99 ± 0.75) or heart failure HF (1.27 ± 0.83). Cronbach's α internal consistency reliability was ≥0.90. The correlations between the physical subscales and the emotional subscales in C-HeartQoL and SF-12 were strong ranged from 0.52 to 0.82. Higher HeartQoL scores were reported by younger than older patients and by male than female patients. Higher HeartQoL scores were observed consistently in patients reporting 'Excellent/very good' health status than by those reporting 'Good/fair' or 'Poor' status and by patients reporting 'Good/fair' health status than by patients with 'Poor' status and by patients without anxiety or depression than patients with anxiety or depression. Patients with functional class 'III/IV' angina or heart failure had higher HeartQoL scores than patients classified as functional class 'III/IV'. **CONCLUSIONS:** The C-HeartQoL demonstrates good internal consistency reliability and construct validity in patients with IHD and in each diagnostic subgroup. The data support the use of the Chinese HeartQoL by researchers and clinicians to assess and compare health-related quality of life in Chinese patients with IHD.

RM3

USE OF MULTIPLE SURROGATE ENDPOINTS IN ADVANCED COLORECTAL CANCER

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OBJECTIVES: Regulatory and reimbursement agencies increasingly base their decisions on surrogate outcomes especially if they can be measured early compared to the final clinical endpoint. Progression free survival (PFS) has been investigated as a surrogate endpoint for overall survival (OS) in advanced/metastatic colorectal cancer, however the outcome of these investigations has not been conclusive. In recent years, meta-analytic methods allowing for use of multiple surrogate endpoints jointly have been proposed. The aim of this research was to assess if PFS and response to treatment used jointly as surrogate endpoints to OS improve their predictive value. **METHODS:** Data were obtained from a systematic review of randomised control trials in advanced/metastatic colorectal cancer on effectiveness of pharmacological therapies (systemic chemotherapy (SC), anti-EGFR and antiangiogenic). Multivariate meta-analysis was used to model the association between treatment effect on both surrogate (PFS and response) and final (OS) endpoints, on all data and in subgroups of subclass therapy. **RESULTS:** Bivariate meta-analysis showed significant association between treatment effects on PFS and OS, which was only minimally improved in the trivariate analysis modelling the effect on two surrogate outcomes jointly. For subclass therapies, there was a moderate improvement in the association for SC, with increased precision by 9% of the regression coefficient between effects on OS and PFS, but not for the other two subclasses. Predicted treatment effects on OS were obtained with higher precision only for SC and antiangiogenics (reduction in uncertainty on average 1.7% and 2.4% respectively) when using both surrogates jointly. **CONCLUSIONS:** Joint use of two surrogate endpoints did not lead to much improvement in the association between treatment effects on surrogate and final endpoint but in some subclasses led to improved precision of the predicted effects on OS, likely due to the more accurate estimation of PFS when both surrogates were modelled jointly.

RM4

IDENTIFICATION OF PATIENTS WITH HIGH CARE CONTINUITY TO IMPROVE VALIDITY OF COMPARATIVE EFFECTIVENESS AND SAFETY RESEARCH USING ELECTRONIC HEALTH RECORDS

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OBJECTIVES: Electronic health records (EHR) have been widely used for comparative effectiveness research. Care-discontinuity (i.e., receiving care outside of an

EHR system) was associated with substantial information bias when using EHR as the sole data source. We aimed to develop and validate a prediction score for having high care-continuity to reduce such bias. **METHODS:** Study cohort comprised all patients ≥ 65 in EHR from two large US provider networks linked with Medicare insurance claims data from 2007/1/1 to 2014/12/31. Based on the linked EHR-claims data, we measured care-continuity by the Mean Proportion of Encounters Captured (MPEC) by the EHR system. With predictors available in EHR, we built a prediction model for MPEC by Lasso regression, using the two EHR systems as training and validation set, respectively. Within deciles of predicted continuity, we quantified misclassification by Mean Standardized Differences between the proportions of 40 key variables based on EHR alone vs. linked claims-EHR data (MSD_40_variables, <0.1 was used to indicate satisfactory variable classification). We compared patient characteristics in those with high vs. low predicted EHR continuity. **RESULTS:** Based on 104,403 patients in the training and 79,336 in the validation set, we developed a prediction score that was highly correlated with the measured care-continuity in both training and validation sets (Spearman correlation=0.81, 0.83, respectively). In the training set, MSD_40_variables (misclassification based on EHR alone) in the worst predicted continuity decile was 7.8 (95% confidence intervals 6.8-9.1) fold greater than that in the best predicted continuity decile. Those with top 20% predicted continuity were found to have satisfactory variable classification (MSD_40_variables <0.1) and comparable patient characteristics, compared to the rest of population. We found similar results in the validation set. **CONCLUSIONS:** Restriction to patients with high predicted care-continuity may reduce misclassification of key characteristics and improve validity of drug research relying exclusively on EHR.

RESEARCH POSTER PRESENTATIONS – SESSION I

HEALTH CARE USE & POLICY STUDIES

HEALTH CARE USE & POLICY STUDIES – Consumer Role in Health Care

PHP1

A GLOBAL ASSESSMENT OF THE ALIGNMENT OF VALUE BASED HEALTHCARE IN ORTHOPAEDICS USING DATA FROM THE ECONOMIST INTELLIGENCE UNIT

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OBJECTIVES: Value-based healthcare (VBHC) is a patient-centric framework to improve performance in healthcare systems. Value is commonly defined as the health outcomes benefiting the patient over cost. The field of orthopaedics is well placed to introduce VBHC principles into practice given the high volume of discrete conditions and procedures. The aim of this study was to assess the alignment of VBHC in orthopaedics globally. **METHODS:** Data from the Economist Intelligence Unit (EIU) was used. EIU researched, assessed and scored 25 countries across a set of 17 original qualitative indicators (scored on an integer basis). These span four domains: enabling context, policy and institutions for value in healthcare; measuring outcomes and costs; integrated and patient focused care; and outcome based payment approached. **RESULTS:** (1) Most developed countries have moderate alignment with VBHC. Only Sweden emerges with very high alignment and the UK is the only country with high alignment. (2) Whilst India and China generally have similar results, they diverge strongly on health coverage: just 18% of India's population covered by some form of health insurance while in China more than 95% of the population is covered by public health insurance. (3) Strong policy support is generally found in wealthier countries, which helps the transition towards VBHC. (4) The advantage of bundled payments for co-ordinating care and focusing on the patient is increasingly being recognised. In six of the 25 countries assessed, one or more payers are implementing bundled payments. (5) Moving from fragmented single-provider-based care to co-ordinated, team-based care remains challenging. Many countries lack coordinated care pathways, which are not nationally standardised. **CONCLUSIONS:** Some countries are coming closer to aligning their health systems to the VBHC model, but the majority are still in the early stages. Often lower income countries have other priorities such as increasing access to basic health service and improving quality.

PHP2

TRENDS IN PRESCRIPTION OPIOID MEDICATIONS: EMPIRICAL ANALYSIS OF MILLIGRAM MORPHINE EQUIVALENT PER DAY

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OBJECTIVES: Prescription opioids (POs) are often prescribed to those suffering pain. The United States is facing an epidemic, with an increasing number of overdose deaths each year. This study looks at recent trends in POs, particularly milligram-morphine-equivalent-per-day (MME/day) prescribed and price elasticity of demand (PED) for MME/day. **METHODS:** Data from the Medical Expenditure Panel Survey (MEPS) was analyzed to examine recent trends in POs. This study looks at the last five years of available data (2010-2014) from the Prescribed Medicines files of MEPS. MME/day is calculated using the Centers for Medicare and Medicaid Services provided conversion factors. The length a patient has taken a medication (LPTM) is calculated from the survey round and panel data. PED for MME/day is estimated using self-reported out-of-pocket-pay (OOP). **RESULTS:** Throughout 2010-2014, there is an average of 59.1 MME/day for prescriptions, decreasing on average by -3.19 MME/day per year. Only 67.17% of patients receive prescriptions within the 50 MME/day threshold recommended by the Centers for Disease Control and Prevention (CDC). There was a similar proportion of prescriptions between 50 and 100 MME/day (16.35%) and greater than 100 MME/day (16.48%) found across all five years. Similarly, on average, there is almost no correlation between MME/day and LPTM (0.00048), however, there is

an increasing trend in the correlation for every year (0.031 each year). There is a small but significant correlation between MME/day and OOP (0.087). The PED for MME/day is approximately 0.102 with a slight 0.013 average increase in elasticity each year. **CONCLUSIONS:** Many patients receive prescriptions well above the CDC threshold. As expected, POs are significantly inelastic. Despite the small upward trend in elasticity, OOP is unlikely to have an effect on demand for MME/day. This study shows that while there is progress in reducing the average MME/day, using OOP and LPTM may not be effective as methods to decrease the proportion of patients receiving POs over the CDC threshold. https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf

PHP3

OVER-THE-COUNTER MEDICATION USE AND DECISION-MAKING AMONG RESIDENTS OF SENIOR LIVING COMMUNITIES: A QUALITATIVE STUDY

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OBJECTIVES: Older adults are regular consumers of over-the-counter (OTC) medications. OTC medications are generally considered safe, and convenient to use without requiring a prescription. However, the safety of an OTC medication and the final health outcome depends in part upon consumers' perceptions and beliefs, and how they make decisions about OTC use. The primary objective of this study was to explore the knowledge, attitudes, beliefs and experiences about OTC medications among older adult residents of senior living communities. The secondary objective was to elicit the OTC decision-making process in this population. **METHODS:** Focus groups (N=10) were conducted at two senior living facilities in Richmond, Virginia. Overall, 80 people participated (7-8/group) in the 90-minute group discussion. A set of open-ended questions were asked to facilitate a rich discussion about OTC medication use and decision-making. All focus groups were recorded, transcribed verbatim, and analyzed qualitatively using NVivo software. **RESULTS:** Most participants considered OTC medications safe and effective to use, if following the drug-label instructions appropriately. Age and chronic health conditions were considered two important factors that might influence the safety and efficacy of OTC medications. Two major patterns of decision making about OTC purchase and use were identified: (1) Consumers actively look for different OTC options, compare them, and buy them to self-treat, or (2) Consumers, either base their decision on their previous experience or their physician's suggestion, buy the same OTC medications and use them consistently. Participants also reported using OTCs inappropriately and experiencing side effects. Aspirin was observed as the most abused OTC medication in this population. **CONCLUSIONS:** Older adult residents of senior living communities feel positive and satisfied with their OTC use, in general. Considering the self-reported abuse, and experiences of facing side effects, education focused toward older adults should be encouraged to aid in safe and responsible decision-making for self-medication with OTCs.

PHP4

ASSESSMENT OF SELF MEDICATION PRACTICES AMONG URBAN SRI LANKAN ADULTS

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OBJECTIVES: To access the self-medication practices among urban Sri Lankan adults and their perception regarding self-medication. **METHODS:** A descriptive cross sectional study was done on 227 Sri Lankan Urban adults, who are over 20 years of age using convenient sampling using an online data collection form based on a questionnaire. **RESULTS:** Self-medication practices were reported by 69% of the surveyed respondents (n=227). Analgesics was reported as the most commonly used drug for self-medication (80.8%). Significant relationship between the educational level and the use of self-medication was observed (p=0.001). The relation between status of employment and the use of self-medication was significant (p=0.001). Majority of the respondents (68.6%) used the previous prescriptions given by a doctor to obtain drugs on their own, for a subsequent illness. The most commonly reported reason for self-medication practices was the insignificant nature of minor illnesses (59%). Inability to understand the instructions provided in the package insert of the drugs was reported by 67.1% of the respondents. 35.5% of the respondents affirmed the efficacy of 'self-medication drugs' by marking 5 on a scale of 1-5, 5 being most positive. **CONCLUSIONS:** It was revealed that self-medication is a common practice among the Urban Sri Lankan population and a range of drugs are being used for this purpose. But the capability of the individuals to practice "responsible self-medication" was unsatisfactory so it is crucial to enforce the required regulations and strategies related to drug use and to raise awareness regarding potential implications of the same among the public.

PHP5

ATTITUDE TOWARDS BLOOD DONATION IN HUNGARY

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OBJECTIVES: The willingness to donate blood in Hungary decreased gradually in the last decades. The aim of the study is to assess the practice, knowledge and attitude of donors' towards blood donation. **METHODS:** A cross-sectional, quantitative study with non-probability, convenience sampling was performed in Kecskemét between 2016. 07. 01 – 2016. 09. 31. All responders were between 18-65 years, and had a residence in Bács-Kiskun county (N=200). Responders who filled out less than 70% of the questionnaire were excluded. The questionnaire

used in the study had questions about socio-demographic data; health status; locations, amount, frequency of blood donations; knowledge and attitude towards blood donations. For analysis we used SPSS 22.0. Besides descriptive statistics (mean, median, mode, standard deviation, frequency) we calculated Spearman correlation, Kruskal-Wallis test, Mann-Whitney U test, linear regression, χ^2 -test and ANOVA ($p < 0.05$). SPSS 22.0 was used for calculation. **RESULTS:** Mean age of donors was 41.43 years ($SD=11.27$, $min=18$ years, $max=65$ years). Mean score of the knowledge test was 14.44 ± 1.58 points ($min=11$, $max=19$). Socio-demographic data do not have an effect on knowledge, nor regularity of blood donations ($p > 0.05$). Fear of needle, pain and infection shows a negative correlation with the number of donations. Low haemoglobin level is the most frequent reason to be excluded from donation. There is no connection between knowledge level and attitude towards blood donation ($p > 0.05$). **CONCLUSIONS:** Based on our results we conclude the following: good cooperation with the donors are important; interests of young people must be increased; opportunity of donation on week-ends and afternoons (after morning shift schedules) must be given; maintain people's motivation and expand knowledge about blood donation is necessary.

PHP6

NAVIGATING ACCOUNTABLE CARE AND OTHER PAYER-PROVIDER ORGANIZATIONS: AN ASSESSMENT OF EMERGING INSTITUTIONAL STAKEHOLDERS BEHIND VALUE-BASED HEALTHCARE TRANSFORMATION

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OBJECTIVES: Payers are increasingly tying payment for healthcare to quality and value. Within this context, providers are committing to and pursuing systematic solutions to become value-based organizations. This transformation is driving changes in the leadership and organizational structures of hospitals and health systems. This research examines emerging institutional stakeholders behind value-based healthcare transformation; the scope of their responsibilities; and implications for manufacturers seeking to engage accountable care and other payer-provider organizations to drive market access. **METHODS:** A survey of 64 administrators and executives of integrated networks (27%) and hospital systems (73%) was conducted. Represented systems included on average 29 acute care hospitals and 83% were Accountable Care Organizations. Respondents included C-Suite/President (17%), Vice President (28%) and Director (55%) titles. The survey assessed institutional priorities related to value-based healthcare transformation; and leadership and organizational structure related to these priorities. **RESULTS:** Many domains of value-based healthcare transformation were considered, and each was widely reported to be a priority for represented institutions today. Furthermore, dedicated roles have been or will be established with focus primarily or exclusively on each: 68% of organizations have an executive function focused on Payment Transformation; 74% on Population Health Care Coordination and/or Clinical Integration; 75% on Quality; and 76% on Customer Experience. These functions operate at the enterprise (system) level in nearly half of organizations and at the affiliate level in others. **CONCLUSIONS:** As institutions have taken on a greater role in defining and assessing value and in operationalizing value-based decision making in healthcare, there has been a proliferation of relevant stakeholders involved in carrying out these responsibilities. Manufacturers seeking to demonstrate the value of their product within these settings must be prepared to target these emerging customers; including a tailored value proposition which considers the specific scope of their responsibilities.

PHP7

LANDSCAPE OF PATIENT-ENGAGEMENT ACTIVITIES ACROSS THIRTEEN VALUE-ASSESSMENT BODIES

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OBJECTIVES: Understanding the current landscape of patient-engagement activities among value-assessment bodies (VABs) is an important step toward establishing "best practices" in patient-centric value assessments. The objective of this study was to identify and compare patient-engagement practices across VABs. **METHODS:** A sample of North American and European organizations involved in developing clinical and/or economic value assessment was chosen for representativeness. The sample included national health technology assessment bodies (HTA's; $n=6$), professional organizations (PO; $n=4$), and collaborations/independent organizations (CO; $n=3$). Information was gathered between September-October 2016 through a targeted web search and soliciting information from the organizations directly. Data collected included: (1) terms and definitions used to describe patient engagement; (2) types of patient-engagement opportunities offered; (3) evidence that opportunities offered are employed and impact decision-making. **RESULTS:** Tremendous variation exists in terms, processes, and impact of patient engagement across sampled organizations. Seventeen different terms were identified for describing patient engagement activities (e.g., patient input, patient-group submitted information). Opportunities vary widely and include: patient questionnaires (HTA=2); comment periods (HTA=1; CO=1); participation on committees (HTA=3; PO=3); ability to propose topics (HTA=1); draft guidance (HTA=1); general stakeholder forum (CO=1). While many organizations describe engagement opportunities in their documents, only two organizations had clear evidence of engagement impacting decision-making or being consistently incorporated. There is also wide variation in the types of individuals or groups allowed to contribute the patient voice. **CONCLUSIONS:** There is substantial heterogeneity in what is considered patient engagement across VABs. While some seek out patients directly by advertising patient-specific opportunities via social media, others refer to comment periods open to any stakeholder

as patient engagement. Completed value assessments also depict wide variation in impact of the approaches, from descriptions of how patient engagement was directly incorporated into decision-making to no mention of any patient participation.

PHP8

INFLUENCING FACTORS OF YOUNG ADULT ROMANTIC RELATIONSHIPS

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OBJECTIVES: Many conflicts can be observed in relationships, the poor management of which can cause the relationships to end. The objective of our study is to examine young adult romantic relationships and to explore what factors affect them. **METHODS:** The participants were full-time BSc students at Hungarian universities (University of Pécs, Semmelweis University, Pázmány Péter Catholic University) and their age ranged between 18 and 26 years ($N=362$). They were chosen for the quantitative, cross-sectional, descriptive research by convenience sampling. The anonym, self-completion questionnaire was delivered to participants via Internet. For data analysis SPSS v 13 was used. Besides descriptive statistics (average, variability, frequency), mathematical statistics (χ^2 test, Fisher's Exact Test) were also used ($p < 0.05$). **RESULTS:** 55.24% of the students had 1 to 4 one-night stands, 30.93% had 5 or more and only 13.81% have never had one-night stands. Those who meet their partner every day judge the quality of their relationship to be better ($p < 0.01$). Couples that are having a shared view of their future think of breaking up more rarely ($p < 0.01$). Those who met their partner in a club have had more one-night stands than the others ($p < 0.01$). Couples with poor conflict resolution skills think of ending their relationship more often than those who apply proper conflict resolution techniques ($p < 0.01$). In case of relationship problems, those couples who try to resolve them together are more successful than those who rely on external help ($p < 0.01$). **CONCLUSIONS:** It is a message for parents and also for health visitors that young adults frequently switch their partners; therefore more emphasis should be put on sexual education, especially on its affective side. It is not enough to focus only on the somatic factors. It is necessary to extend the topics of school health education with that of successful conflict resolution techniques.

HEALTH CARE USE & POLICY STUDIES – Diagnosis Related Group

PHP9

DRG BASED EVALUATION OF TERTIARY LEVEL INPATIENT CARE IN HUNGARY

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OBJECTIVES: Our objective is to determine the tendencies of the capacity for active inpatient care (the number of beds) and determining the DRG based performance volume limit (TVK) based on nationwide data on the one side and regarding the active inpatient care at tertiary level University Medical Centers on the other part. **METHODS:** The data derive from the DRG based financial database of the National Health Insurance Fund Administration, the only health care financing agency in Hungary. We examined the output volume capacity data of active inpatient care expressed in numbers (DRG cost-weight) and the data of capacity expressed in the number of beds for the period of 2013 and 2017. The financial ceiling of hospitals resulted from the performance volume limit/number of beds indicator has been determined. **RESULTS:** Regarding the number of active beds, the number of beds at Universities (in the period under review fell by -3.4%, -224 beds) and the others hospitals in the country (fell by -2.2%, -721 beds) continuous decline is observed with respect to the universities greater frequency. The performance volume limit -determined by the National Health Insurance Fund Administration- shows different trends. Universities experienced -4.4% decline in their financial budget. The others hospitals in Hungary realized an increase (+ 2.9%), but in the last year the volume decline to the 2013 level (-0.2% decrease). The performance volume limit calculated to one hospital bed decreased by 1.1% at University Medical Centers, from 64.4 to 63.7. **CONCLUSIONS:** Determining the performance volume limit is partly independent of the current capacities and the demand, since there are different trends in the data and getting the appropriate therapy often takes a lot of time because of the long waiting lists. Supervising the performance volume limit based on needs and adjusting the capacities are required.

HEALTH CARE USE & POLICY STUDIES – Disease Management

PHP10

GENE THERAPIES DEVELOPMENT: SLOW PROGRESS AND PROMISING PROSPECT

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OBJECTIVES: In 1989, the concept of human gene therapies has emerged with the first approved human gene therapy trial of Rosenberg et al. Gene therapies are considered as promising therapies applicable to a broad range of diseases. The objective of this study was to review the descriptive data on gene therapy clinical trials conducted worldwide between 1989 and 2015, and to discuss potential success rates of these trials over time and anticipated market launch in the upcoming years. **METHODS:** A publicly available database, 'Gene Therapy Clinical Trials Worldwide', was used to extract descriptive data on gene therapy clinical trials: (1) number of trials per year between 1989 and 2015; (2) countries; (3)

diseases targeted by gene therapies; (4) vectors used for gene delivery; (5) trials status; (6) phases of development. **RESULTS:** Between 1989 and 2015, 2,335 gene therapy clinical trials have been completed, were ongoing or approved (but not started) worldwide. The number of clinical trials did not increase steadily over time; it reached its highest peak in 2015 (163 trials). Almost 95% of the trials were in early phases of development and 72% were ongoing. The United States undertook 67% of gene therapy clinical trials. The majority of gene therapies clinical trials identified targeted cancer diseases. **CONCLUSIONS:** The first gene therapy was approved in the European Union in 2012, after two decades of dashed expectations. This approval boosted the investment in developing gene therapies. Regulators are creating a specific path for rapid access of those new therapies, providing hope for manufacturers, healthcare professionals, and patients. However, payers are increasingly scrutinizing the additional benefits of the new therapies. The potential budget impact may become the actual hurdle for gene therapies, leading to restricted access and lost opportunities for many patients.

PHP11

HOW THE PURCHASE AND USE OF A FDA PRIORITY REVIEW VOUCHER AFFECT PRODUCT UPTAKE AND VALUE CONVERSION

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OBJECTIVES: To understand the commercial, evidence generation, and health technology assessment implications of using an FDA Priority Review Voucher (PRV) to shorten the pre-market authorisation timeline. **METHODS:** The study employed a literature review, including academic journals, pharmaceutical industry news sources, FDA data, and manufacturer press releases to assess the use and transfer of priority review vouchers, as well as their impact on timing to market authorisation, associated effects on evidence generation, and the eventual effect on health technology assessment. **RESULTS:** There have been 12 PRVs that have been granted by the FDA for the development of a treatment for either a neglected tropical disease or a rare pediatric disease. Of the 12 vouchers, four have been transferred for a price \$68 million - \$350 million. Economic models predict the value of an expedited review process could be worth \$50 million - \$300 million depending on a variety of factors, including the treatment algorithm in effect, the competitive environment, and stakeholder perception of unmet need. The first manufacturer to employ a priority review voucher received a decision within six months; however, the application was denied due to insufficient safety data. Only two of the transferred vouchers have been successfully used to achieve both an expedited review and FDA approval. For alcurumab, the voucher provided a competitive advantage to advance its launch date and beat its main PCSK9 competitor to market. However, this advanced timeline also affected the maturation of long-term safety data, and also the approach to reviewing the clinical and economic attributes of the two PCSK9s. The PCSK9 case shines a light on the advantages and disadvantages from evidence generation and appraisal standpoints. **CONCLUSIONS:** While the acquisition of the voucher provides the product with some degree of competitive advantage with regard to timing, the longer-term effect on evidence and health technology appraisal counter-balance these benefits.

PHP12

CHALLENGES OF INTEGRATED PALLIATIVE CARE IN THE HEALTH CARE SYSTEM

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OBJECTIVES: The aim of our study was to estimate the relationship of the chances of dying in hospital or at home, based on demographic data, social support, healthcare categories and additional service needed in palliative care provided by multidisciplinary teams. **METHODS:** The study is a retrospective, quantitative analysis. Through a purposive sampling we analyzed records of tumor- and terminal stage patients who were involved in the service of the Pécs-Baranya County Hospice Foundation and met enroll criteria. (N=1389). Descriptive (absolute- and relative frequency, variance, mean, modus, and mathematical statistics (correlation, chi-square test, variance-analysis (ANOVA), T-test) were done on the sample (p<0,05) using MS Excel and SPSS 22.0. **RESULTS:** Men are more likely to die in hospice care unit (OR = 1.369) compared with those who die at home. The county town living (69.10%, OR = 0.625), however, are less likely to die in hospice care. The number of days spent in care of 30.5% of a maximum of six days, and average length of stay in home care was 23.84 days (SD = 29.98) and 46.1% of patients die in home care. We found significant positive correlation between the role of the healthcare scene and social support (p=0.024), while the tumor disease type, deterioration of general status of the patient is significantly rise the chance of the integration into the intramural than home care (p=0.002). The team providing complementary homecare tasks increase the outcome of optimal hospice-palliative care, chance of dying at the patient's home and the length of survival time (p=0.027). **CONCLUSIONS:** Providing an optimal hospice-palliative care needs a complex, holistic, integrated model of care to be implemented.

HEALTH CARE USE & POLICY STUDIES – Drug/Device/Diagnostic Use & Policy

PHP13

TWO TRANSPARENT METHODS FOR ESTIMATING DRUG RESEARCH AND DEVELOPMENT COSTS

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OBJECTIVES: Current estimates on the cost of developing a new drug are largely based on proprietary data limiting other researchers from validating or testing underlying assumptions. This study presents two transparent methods for

estimating the cost of developing a new drug using publicly available data. **METHODS:** The first approach is a micro approach that utilizes drug company specific levels of research and development expenditures, sales, and drugs on the market. A series of calculations uses this input data and estimates the cost per marketed drug for each company. The second approach is a macro approach and utilizes industry aggregate research and development expenditures and recent approved drugs from the Food Drug Administration (FDA). This data is inputted into a quasi-Markov model of a drug's pre-approval life cycle and calculates the cost per FDA approved drug. A cost of capital is estimated for both approaches using an amortization model. The rates for the cost of capital were either the weighted average cost of capital rate or the rate as suggested by the Congressional Budget Office. **RESULTS:** The micro approach yields a direct cost of \$1.65 billion, and the cost was similar across the three large pharmaceutical companies. The macro approach yields \$1.43 billion. Using a 3% cost of capital rate, the indirect cost is another \$3.1 billion and \$2.6 billion for the micro and macro approach respectively. Using the industry weighted average cost of capital rate, 7.72%, increases the indirect cost to \$5.7 billion using the micro approach and \$6.2 billion using the macro approach. **CONCLUSIONS:** Our results were similar to previously reported cost estimates for developing a new drug with one caveat-we had much lower cost of capital. Understanding the level of investment necessary to develop a drug is critical for policymakers who attempt to balance innovation with price regulation.

PHP14

APPROVALS AND DISCONTINUATIONS OF NEW MOLECULAR ENTITIES AND THERAPEUTIC BIOLOGIC LICENSE APPLICATIONS IN THE UNITED STATES (1986-2015)

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OBJECTIVES: The objective of this study was to describe trends in approvals and discontinuations of new molecular entities (NME) and therapeutic biologic license applications (BLA) during the period 1986-2015. **METHODS:** Data for all FDA-approved NME and BLA marketed in the US during the study period were collected from the Drugs@FDA database, and each NME or BLA discontinued was evaluated to determine whether discontinuation was associated with a safety issue. Descriptive statistics and chi-squared tests were used in the analysis. **RESULTS:** The FDA approved 1,017 drugs during the study period, including 903 NME and 114 BLA. Among the total number of new drugs approved, the percentage of BLA increased from 3.6% the period of 1986-1989 to 8.0% in the 1990s, 15.9% in the 2000s, and 19.4% during the period of 2010-2015. Anti-neoplastic and immunomodulating agents represented 53.5% of all the BLA approved during the study period. The rate of market discontinuation was higher for NME (n=181, 20.0%) than for BLA (n=12, 10.5%) (p= 0.01). As of August 15, 2015, a total of 84 (8.3%) new drugs, including 6 (5.3%) BLA and 78 (8.6%) NME (p=0.22) were withdrawn from the market for safety reasons. **CONCLUSIONS:** The number of BLA and their proportion among the total number of new drugs approved by the FDA increased over time. BLA were concentrated in certain therapeutic categories, especially anti-neoplastic and immunomodulating agents. The majority of the drugs approved in the US remained in the market. NME were more likely to be discontinued. Drugs withdrawn from the market for safety reasons affected one in twelve drugs approved during the study period.

PHP15

PAYERS' ACCEPTANCE OF SURROGATE AND PATIENT-RELEVANT END POINTS IN OUTCOMES-BASED MARKET ACCESS AGREEMENTS

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OBJECTIVES: Costly drugs are often not reimbursed by health care payers via the regular pathway but can be subject specific arrangements called Market Access Agreements (MAAs). MAAs are financial (Commercial Agreements) or outcomes-based (Payment-for-Performance Agreements or Coverage-with-Evidence-Development Agreements). Outcomes in outcomes-based MAAs are assessed through changes in surrogate end points (EPs) or patient-relevant EPs. **METHODS:** We reviewed published and grey literature on MAAs between manufacturers and payers from all geographies in May 2015. We classified the schemes by MAA type. Outcomes-based MAAs were further categorized by the EP used. **RESULTS:** We identified 143 MAAs. 56 (39.2%) were pure Commercial Agreements, 53 (37.1%) were Coverage-with-Evidence-Development Agreements and 34 (23.8%) were Payment-for-Performance Agreements. Among Coverage-with-Evidence-Development Agreements, 49 were patient-relevant EP Coverage-with-Evidence-Development Agreements and four were surrogate EP Coverage-with-Evidence-Development Agreements. In 34 Payment-for-Performance Agreements, there were 29 surrogate EP Payment-for-Performance Agreements for 30 drugs and five patient-relevant EP Payment-for-Performance Agreements for at least six drugs. Among 87 outcomes-based MAAs (Coverage-with-Evidence-Development Agreements + Payment-for-Performance Agreements), patient-relevant EP Coverage-with-Evidence-Development Agreements were the most common (56.3%), followed by surrogate EP Payment-for-Performance Agreements (34.1%). **CONCLUSIONS:** Payers have high acceptance for surrogate EPs when used in Payment-for-Performance Agreements. In contrast, patient-relevant EPs are predominantly accepted for use in Coverage-with-Evidence-Development Agreements. Therefore, Payment-for-Performance Agreements are not used by payers to reduce uncertainty about real-life effectiveness. They can constitute an outcome guarantee for payers if they are based on patient-relevant EPs or validated surrogate EPs. In contrast, Coverage-with-Evidence-Development Agreements employ patient-relevant EPs and can be used by payers to reduce uncertainty about a drug's clinical outcomes or real-life use. They can enable payers to align a product's price with its value.

PHP16

CHANGES OF YOUNG ADULTS' DISABILITY DAYS AFTER THE AFFORDABLE CARE ACT EXTENDED DEPENDENT COVERAGE

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OBJECTIVES: This study aimed to evaluate changes in disability days among young adults after the implementation of the extended dependent coverage under the Affordable Care Act (ACA) in September 2010. **METHODS:** A retrospective study was conducted by using the 2008-2012 Medical Expenditure Panel Survey. Rate of disability days from January 2008 to December 2012 were analyzed using interrupted time series Poisson regression models. Adjustment for over-dispersion and seasonality were also used in the analysis. Young adults were identified as respondents aged 19 to 25 years old. Disability days were defined as the numbers of times the person lost at least a half of day from work or school and the additional days the person spent in bed because of a health problem. **RESULTS:** A total of 56,291 disability days occurred in young adults during the study period. The preliminary model showed a reduction in disability days following the policy, with a decrease of 33% [relative risk 0.713; 95% confidence interval (CI) 0.689-0.737; $P < 0.01$]. Adjusted model for seasonality and over-dispersion showed a 25% reduction in disability days following the policy [relative risk 0.776; 95% confidence interval (CI) 0.610-0.988; $P < 0.04$]. **CONCLUSIONS:** The extended dependent coverage under the Affordable Care Act was associated with a reduction in the number of disability days in young adults. These findings suggest an improvement in health outcomes for young adults after the implementation of the policy.

PHP17

ROLE OF INFORMATION ANXIETY AND LOAD ON THE PROCESSING OF PRESCRIPTION DRUG INFORMATION LEAFLETS

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OBJECTIVES: In this study we evaluate the role of information anxiety and information load on intention to read information from prescription drug information leaflets (PILs). These PILs were developed based on principals of information load and consumer information processing. **METHODS:** This was an experimental prospective repeated measures study where University students were recruited. PILs included a single page information material developed for three drugs namely, Celebrex® (celecoxib), Ventolin HFA® (albuterol) and Prezista® (Darunavir). Information anxiety was measured as anxiety experienced by the individual when encountering information using a 5-point likert scale. To operationalize information load, adults (≥ 18 years) in a university setting answered the survey questionnaire after reading a scenario followed by viewing three product information sources categorized as existing current practice, pre-existing one-page text only leaflets, and one-page PILs. The outcome variable considered was intention to read which was defined as the likelihood that the patient will read the information. Objectives were analyzed by performing a repeated measures MANOVA using SAS version 9.3. **RESULTS:** A total of 360 consumers participated with a 62% response rate. The mean age was 23 (± 6.04) years and 72.50% were taking a prescription medication. Compared to pre-existing and text only leaflets, PILs had significantly lower scores on information anxiety ($p < 0.001$) and information load ($p < 0.001$). The intentions to read scores were highest and significantly different ($p < 0.001$) for PILs as compared to existing current practice or text only leaflets. Information anxiety and load significantly impacted intention to read ($p < 0.001$). **CONCLUSIONS:** There is a need to balance the amount of prescription information presented to patients in order for them to process it appropriately. Newly developed PILs increased patient's intention to read by decreasing information anxiety and information overload. Several implications of the study are important for researchers of consumer information programs and the US FDA.

PHP18

PHARMACEUTICAL PRICES IN THE UNITED STATES VERSUS EUROPE: HOW DO DIFFERENT TYPES OF US PRICES COMPARE?

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OBJECTIVES: Against the background of recent pharmaceutical pricing controversies in the United States, this analysis seeks to provide a more comprehensive and nuanced comparison of prices in the US with those in Europe, including how they evolve over time and how list prices compare to negotiated prices. **METHODS:** Two samples were used: 30 innovative pharmaceuticals approved between 2012 and 2016 by the FDA, and available in each of the EU Top 5 countries. Indices derived from manufacturer prices per pack and unit of strength in January 2017 were compared. Price changes from time of launch to January 2017 were analysed. 20 pharmaceuticals approved earlier, from 2006, to compare different price levels in January 2017 (ASP, FSS, Big4). **RESULTS:** List prices were higher in the United States by an average of 67% over those in the EU Top 5. In the US, manufacturer prices increased by 23% over the period examined. Prices increased for 76.7% of the sample. In the EU top 5, prices of these same pharmaceuticals decreased from 1% in Spain down to 17.8% in Germany. Negotiated pharmaceutical prices are slightly lower than manufacturer prices. Interestingly, the price premium in the United States over Europe was higher in the second sample (of older pharmaceuticals) than in the first sample, although prices tend to increase over time in the US (and decrease in Europe). **CONCLUSIONS:** Price comparisons between the US and Europe often paint a skewed picture in the absence of non-estimated data on net and discounted prices. Pharmaceutical prices across the full spectrum of available prices in the US are still higher than in Europe and continue to increase

over time. The trend in Europe is opposite: prices are lower and tend to decrease. The difference is less pronounced among pharmaceutical prices that are negotiated in the United States.

PHP19

IRP IS DEAD, LONG LIVE IRP: AN ANALYSIS OF RECENT IRP REFORMS AROUND THE WORLD

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OBJECTIVES: International reference pricing (IRP) has been used extensively to regulate pharmaceutical prices. It has been debated whether this policy sows the seeds of its own demise by incentivizing industry and payers to negotiate confidential concessions, prompting scholars to ask whether we will soon face the "end" of IRP. Within this context, the present study updates a 2014 analysis examining IRP policy changes around the world in order to ascertain whether there is any evidence that IRP is becoming less influential. **METHODS:** The study draws upon the same set of 38 countries in which in-depth qualitative interviews were completed with 50 stakeholders (37 payers/policymakers and 13 industry representatives) in 2014. It also expands that list to include 14 additional countries. A qualitative and semi-quantitative analysis of policy changes made throughout 2015 and 2016 was undertaken to identify trends in how IRP policy frameworks have evolved in recent years. **RESULTS:** A total of 12 discrete policy changes were observed across eight of the countries having introduced IRP before the end of 2014 (16%). Of these eight, six belong to the 22 countries (75%) making one or more such changes from time of IRP introduction through end of 2014. The most frequent changes involved modifications to the composition of the reference basket (71%) and frequency with which referencing is performed (43%). Changes to basket composition did not appear motivated by availability of net prices but rather of lower list prices. Three countries were found to have implemented IRP since the end of 2014. **CONCLUSIONS:** Despite recent debates over the end of IRP, it continues to represent a popular tool for regulation of drug prices, and there is currently no evidence of a declining influence - quite the opposite. Policymakers continue to adapt regulations to cope with some of the challenges engendered by this very policy framework.

PHP20

PATENT LINKAGE AND ACCESS TO GENERIC DRUGS IN SOUTH KOREA

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OBJECTIVES: As a result of Korea-US Free Trade Agreement, patent linkage (PL) of pharmaceuticals was newly implemented in South Korea on March 15, 2012. PL incorporates such components as registration of patents, notification of application for marketing approval of generics, and patentees' prohibition of generic marketing. This study aimed to explore the effect of PL on access to generic drugs and drug expenditures in South Korea. **METHODS:** Delay of access to generic drugs was measured by extended market exclusivity period, defined as the period between the date of conditional market approval of generics and expiry of marketing prohibition, during which generic drugs were not allowed to be sold. Changes in drug expenditures were measured by comparing actual and hypothetical market share of generic drugs, the latter of which meant that the market share of generics had been like if marketing prohibition had not been implemented. The market share of generics was estimated by using a logistic function based on monthly utilization of 856 drugs obtained from National Health Insurance claims database. **RESULTS:** In the cases of two brand-name drugs where marketing prohibition of their generics was put to an end, it appeared that extended effective market exclusivity period was 1.4 month, compared to a maximum of 9 months regulation. This meant that, due to the extended market exclusivity, market entry of 19 generic drugs was delayed for 1.4 month and drug expenditures increased by \$150,000~\$290,000 in the short run. **CONCLUSIONS:** Though it is too early to generalize what effect PL had on access to generic drugs and drug expenditures, it appeared that not only PL itself but also many other factors including drug pricing, generic substitution, and patent litigation played a key role in influencing access to generic drugs and drug expenditures.

PHP21

NAIVE AND EXPERT PATIENTS' KNOWLEDGE, ATTITUDES AND BELIEFS ABOUT BIOSIMILARS

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OBJECTIVES: Biosimilars are being approved and included in drug plans. In some countries, clinicians are being asked or mandated to start patients exclusively on biosimilars and even to switch from the originator biologic, citing economic reasons and "no evidence of harm." Given that biologic medicines require patient engagement to use appropriately, this research sought to learn how naive and "informed" patients feel about biosimilar usage. **METHODS:** A questionnaire, sent to 2000 patients in Canada representing multiple diseases, asked about biosimilar knowledge, attitudes and beliefs. The survey also provided some basic education. About 200 patients who had exposure to biologics were probed further about how biosimilars should be used in routine care. **RESULTS:** More than 40% reported no previous knowledge about biosimilars. Only 20% said they were very familiar. Based on information provided, 68% said they expected different efficacy and 84% expected different adverse effects. While 57% agreed that unexposed patients could be prescribed biosimilars, 78% objected to switching with most opposition from naive patients. Oncology patients objected most to approval based on extrapolation. **CONCLUSIONS:** Patients are not receiving education about biosimilars and are reluctant to switch with implications for adherence to and confidence in their use.

PHP22

REDUCING PRESCRIPTION DRUG SPENDING: A REVIEW OF POLICY OPTIONS

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OBJECTIVES: High prices for pharmaceuticals have restricted access to branded drugs because some public programs are rationing care and many private insurers, including Medicare drug plans, are placing specialty drugs on high cost sharing tiers. Ongoing concerns over high prices and limited access to pharmaceuticals have generated a wide range of proposed solutions. **METHODS:** We convened a small group of experts in the field and had them identify policy options that are available to reduce either branded drug costs or spending. Their discussion identified seminal articles. Based on these seminal articles, we constructed a preliminary list of policy options and key words that served as a format for conducting a structured literature review to identify additional policy options. **RESULTS:** We identified forty-one solutions in the peer reviewed literature that can be classified into five broad categories: revising the patent system; encouraging research to increase development of new drugs; altering pharmaceutical regulation; decreasing market demand; and developing innovative pricing strategies. We discuss the rationale for these five approaches and summarize the proposed solutions. We also discuss four unresolved empirical issues are particularly important in any discussion of policy options. **CONCLUSIONS:** Many have argued that the high levels of spending for branded prescription drugs are unsustainable. Others are more concerned about the problems many people have accessing the drugs they need or the impact on the health status of the population. Given the interest in the topic, it is likely that one or more of the policy proposals will be implemented in the coming months and years. However, it is likely that no single policy alternative will be a clear "winner". Resolution of specific empirical issues that we identify may assist policymakers to select policies that are most likely to achieve their stated aims while minimizing the likelihood of unintended consequences.

PHP23

MARKET ACCESS OF CELLULAR AND GENE THERAPY PRODUCTS IN THE US AND EU5

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OBJECTIVES: Examine current market access landscape for cellular and gene therapies in the US and EU5 as well as future implications. **METHODS:** Assessed market access path for all cellular and gene therapies with FDA and EMA approval as of December 31, 2016. Analyzed HTA assessments and funding mechanisms of these therapies in the EU5. **RESULTS:** In the US, cellular and gene therapy products are regulated by the FDA's Center for Biologics Evaluation and Research (CBER) whose Office of Cellular, Tissue and Gene Therapies (OCTGT) has approved 16 cellular therapies and 0 gene therapies for marketing. 50% of all approved cellular therapies are based on Hematopoietic Progenitor Cells (HPC) from cord blood. In Europe, cellular and gene therapy products are assessed by the EMA's Committee for Advanced Therapies (CAT) to confirm whether specific criteria are met by the products to be defined as advanced therapy medicinal products (ATMP). So far, the EMA has approved for marketing 8 ATMPs: 2 gene therapies (alipogene tiparvovec; autologous CD34+ cells transduced to express ADA) and 6 cellular therapies. Of all approved therapies, one was suspended and another two withdrawn. In comparing cellular and gene therapy products approved by FDA and EMA, only the cell therapy talimogene laherparepvec is currently marketed in both US and Europe, while sipuleucel-t and porcine collagen membrane are available in the US but have been withdrawn in Europe. Analysis of HTA assessments and funding mechanisms of these therapies in the EU5 countries showed market access and reimbursement challenges related to uncertain clinical evidence and high costs. **CONCLUSIONS:** Cellular and gene therapy products situation is still in "early days" and constantly evolving. The expected increase in the approved number of these therapies could benefit both patients and pharmaceutical companies, but these expectations will depend on solid clinical evidence and access to them.

PHP24

FUNDING OF GENE THERAPIES IN EUROPE & THE UNITED STATES

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OBJECTIVES: Gene therapies (GT) are promising treatments able to potentially cure chronic and disabling diseases after single or short-course administration. Such products deliver long-term benefits after administration. The short-course administration associated to long-term high value lead to high upfront costs that challenge the sustainability of national health insurance systems. As an important number of gene therapies are expected to reach the market, finding a sustainable funding model for GT is needed. The aim of this study is to identify potential funding models for gene therapies in the large 5 EU countries: Germany, United Kingdom, France, Italy, and Spain as well as US. **METHODS:** A literature review was conducted in PubMed, congress abstracts, Health Technology Assessment bodies' websites and grey literature. **RESULTS:** There is no specific path for GT pricing and reimbursement. However, several methodologies have been proposed to set GT price. Four funding models were proposed: "technology leasing reimbursement strategy", high-cost drug mortgages, high-cost drugs reinsurance, and high-cost drug patient rebates. Some authors suggested that this may jeopardize the future

health insurance resources and cannot constitute a generalizable model; they proposed discounts according to the turnover. Other authors proposed constraint optimization models for GT pricing, while others considered those models inapplicable to US as patients change health plan regularly thus disconnecting initial investment and future value. **CONCLUSIONS:** Current pricing models based on unit price are too one-dimensional for the future needs of the market assuming GT successful arrival to the market. Performance driven managed entry agreements are unlikely to address the short course treatment and long-term value. Many proposed models may be inadequate; they may be too costly on long term or lead to inappropriate return on investment. While GT started reaching the market, no clear research enlightens payers on optimal funding models.

PHP25

IMPACT OF HEALTH INSURANCE BENEFIT DESIGN ON GENERIC DRUG USE IN THE UNITED STATES: A SYSTEMATIC REVIEW

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OBJECTIVES: Use of generic drugs can reduce the growing spending on prescription drugs. In 2014 \$227 billion was saved because of generic drugs in the United States. Appropriate policies are imperative to promote the use of generics. This study aimed to understand the influence of health insurance benefit design (copayment, coinsurance, and deductible) on generic drug use. **METHODS:** We systematically searched the literature between January 2006 and September 2016 using PubMed and Business Source Premier for potentially relevant studies. The search was limited to articles written in English, with human subjects, and conducted in the United States. The PRISMA guideline was used for reporting of evidence. **RESULTS:** 125 articles were identified and 11 articles were included in the qualitative analysis. Overall, a majority of studies showed lower cost sharing improved the use of generics and reduced non-adherence to treatment. Adherence improves by 2.7-3.4% when copays for generics are eliminated and copays for brands are reduced, corresponding to an estimated \$5.7 million reduction in total non-medication expenditures. Charging a copay decreases the probability of using a generic by about 13% while with lower or no copays, there is an 11% increase in generic dispensing rates. Tiered copay systems increase generic filling by 20%, and a change from a single or 2-tier formulary to a 3-tier formulary corresponds with a 5-15% decrease in drug spending. While evidence supports the role of copayment design and copayment amount on generic use, other drug benefit design approaches such as coinsurance or deductibles need further investigation. **CONCLUSIONS:** Use of generics can be improved through health insurance policies such as low cost-sharing. Eliminating or having very low generic cost-sharing can reduce total healthcare spending and non-adherence to treatment. However, further study is needed to identify the optimal design structure to maximize generic use.

PHP26

THE ASSOCIATION BETWEEN PATIENT SOCIODEMOGRAPHIC CHARACTERISTICS AND GENERIC DRUG USE - A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: Generic drugs are bioequivalent and cost effective alternatives to brand name drugs. In 2014, \$227 billion was saved because of generic drugs in the U.S. To inform the development of educational outreach for improving generic drug use among patients, we sought to critically assess evidence on the association between patient characteristics and generic drug use. **METHODS:** We systematically searched the literature between January 2005 and December 2015 using PubMed, Web of Science, OVID-Medline, Google Scholar, and EBSCO IRA-Medline for potentially relevant studies. The titles and abstracts of identified articles were assessed independently by two reviewers. Titles and abstracts that were not written in English, published prior to 2005, not empirical, did not contain socio-demographic data, or were not policy or methodologically relevant to generic drug use were excluded. Data were pooled in meta-analysis using Rstudio software to assess the association of patient-related factors with generic drug use. **RESULTS:** Our searches resulted in 11 articles on patient-level factors, and 6 of these articles had sufficient information to conduct meta-analyses in the domains of patient sex, age, race/ethnicity, and income. Quantitative analysis indicated no differences in generic drug use existed between subgroups of patients defined by sex, age, or race/ethnicity. However, patients with lower income (i.e., <200% federal poverty level (FPL)) were more likely to use generic drugs than those with higher income (≥200% FPL) (pooled odds ratio (OR) = 1.32, 95% confidence interval (CI) = 1.15-1.52). Heterogeneity was high (I² > 75%) for all analyses but income. **CONCLUSIONS:** Patients with lower income were more likely to use generic drugs, whereas we don't have adequate evidence to draw conclusion on the association of generic use with sex, age, or race/ethnicity. Educational outreach targeting patients with higher incomes to understand their perspectives in generic drugs might help improve generic drug use.

PHP27

MONOCLONAL ANTIBODIES BIOSIMILARS IN THE US: WHAT LESSONS CAN BE DRAWN FROM THE RECENT EUROPEAN, SOUTH KOREAN AND JAPANESE EXPERIENCE?

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OBJECTIVES: This study aims to assess the level of competition between the first monoclonal antibodies (mAbs) biosimilars, i.e. infliximab biosimilars (BIOSIM-INFLIX) and their originator (Remicade/infliximab, J&J/Merck) (ORIGIN-INFLIX) by analyzing the key global infliximab markets and the drivers of the BIOSIM-INFLIX uptakes. **METHODS:** Data on medicine volumes, values and ex-manufacturing prices for BIOSIM-INFLIX and ORIGIN-INFLIX in the EU, in South Korea and in Japan from January 2016 to June 2016 were provided by IMS Health. Volumes were calculated in DDD (Defined Daily Doses) and Weighted Average Price (WAP) in Euros/DDD. **RESULTS:** In the first half of 2016, the highest BIOSIM-INFLIX uptake was found in Denmark (96.4%), while the lowest was reported in Japan (1.7%). In EU countries where BIOSIM-INFLIX were marketed in 2015, their uptakes are between 10% and 30% (e.g. France, Germany, Spain, Italy and the UK with respectively 11.5%, 16.9%, 20.8%, 25.5% and 25.6%), in the same way as for countries where BIOSIM-INFLIX have been marketed since 2013 (e.g., Czech Republic and Portugal with respectively 24.9% and 23.0% uptakes), except Finland (66.4%) and Norway (86.7%). All countries have dominant hospital distributions for infliximab except Germany, Japan and Czech Republic, which have mixed retail/hospital distributions. Germany is the country where BIOSIM-INFLIX is the most expensive (WAP=€21.8/DDD) and Norway the country where it is the cheapest (WAP=€4.8/DDD with a 66.2% discount versus ORIGIN-INFLIX). However, the relative price of BIOSIM-INFLIX versus ORIGIN-INFLIX does not always seem correlated to BIOSIM-INFLIX uptakes (e.g. in South Korea, the BIOSIM-INFLIX uptake was 28.6%, whereas the WAP difference between BIOSIM-INFLIX and ORIGIN-INFLIX was of -4.3%; in Japan, the BIOSIM-INFLIX uptake was 1.7% whereas this difference amounts to -33.5%). **CONCLUSIONS:** Infliximab markets have proven to be highly country-specific. Today, the competition between BIOSIM-INFLIX and ORIGIN-INFLIX does not seem to be mainly based on prices, but on local decision-making and purchasing process.

PHP28

BIOSIMILAR INFLIXIMAB: FEEDBACK AFTER A ONE-YEAR USE IN 37 PARIS PUBLIC HOSPITALS

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OBJECTIVES: In 2015, the Committee on Medicinal Products of the 37 Paris Public Hospitals (AP-HP, the largest hospital group in Europe – €1 billion of drug expenditures and 7 million patients hospitalized annually) authorized the tender between two infliximab biosimilars (BIOSIM-INFLIX) and their originator (ORIGIN-INFLIX) only for naïve-patients, as the current French law did not allow the switch from originator biologics to biosimilars for pretreated-patients. A BIOSIM-INFLIX won the tender and the ORIGIN-INFLIX has been listed in the AP-HP hospital drug formulary (HDF) since September 2015 for pretreated-patients. This study analyzes the spread of BIOSIM-INFLIX and of ORIGIN-INFLIX in AP-HP one year after the tender. **METHODS:** Infliximab consumption and expenses data were analyzed over the 2015-2016 period to retrospectively assessed BIOSIM-INFLIX and ORIGIN-INFLIX market shares within the 37 hospitals. **RESULTS:** infliximab expenses in AP-HP in 2016 were down 13.5% compared to 2015 (€34.8 vs. €39.5 million), while infliximab consumption in volume globally increased by 8.8%. The rise in infliximab consumption was offset by a negative price effect due to the competition of BIOSIM-INFLIX (-45% and -34.5% price discounts for BIOSIM-INFLIX and for ORIGIN-INFLIX respectively). In 2016, infliximab products were used in 20 AP-HP hospitals and the average of BIOSIM-INFLIX uptakes in volume reached 28.4% in AP-HP (vs. 11.5% in France). However, BIOSIM-INFLIX uptakes are heterogeneous among AP-HP hospitals: [80%-90%] (n=2), [60%-40%] (n=2), [30%-10%] (n=9), <10% (n=7). The 3 pediatric AP-HP hospitals decided to list only the ORIGIN-INFLIX in their local HDF. No correlation was found between hospitals' infliximab consumption and BIOSIM-INFLIX uptakes. **CONCLUSIONS:** Until a new law governing the substitution for patients receiving biologics in France develops, the BIOSIM-INFLIX uptakes today depend on the will of hospital physicians to switch from biosimilars to originators. The therapeutic indications in which BIOSIM-INFLIX and ORIGIN-INFLIX are used and the naïve/pretreated status of patients must now be explored.

PHP29

ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE OF PHARMACY PROFESSIONALS TOWARDS GENERIC MEDICINES: A CROSS SECTIONAL STUDY

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OBJECTIVES: To assess knowledge, Attitude and practice of pharmacy professionals toward generic products **METHODS:** The study was conducted in all medicine retail outlets in Mekelle city, from April 10, 2016-May 12, 2016. Facility based cross-sectional study was used and the data collection tool were self-administered questionnaire. Statistical test binary logistic regression has been done to determine predictors of knowledge and attitude toward generic medicines. **RESULTS:** From the current study more than half of the respondents 52.9% (agree=32.2%, 20.7% strongly agree) claimed that they have had knowledge on the concept of generic medicine. Pharmacy professionals with experience of from 2 to 5 years (AOR= 25.620 [1.954-335.896]) and those with more than 5 years (AOR= 106.543 [2.375-4779.542]) were more likely to have positive attitude toward generic medicines compared to those with work experience of up to 2 years. **CONCLUSIONS:** More than half of the study participants have had knowledge on the concept of generic medicine and their right to perform generic substitution. The professionals with more experience in the sector could have better view on generic product.

PHP30

INAPPROPRIATE MEDICATION USE AMONG THE ELDERLY POPULATION IN PUNJAB, PAKISTAN

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OBJECTIVES: To estimate the inappropriate medication use among the elderly hospitalized patients in Punjab, Pakistan. **METHODS:** A descriptive, non-experimental, cross-sectional study was carried out from December 2015 to March 2016 in six tertiary-care hospitals of the Punjab province of Pakistan. The population under study was patients aged ≥60 years and being hospitalized in the selected tertiary-care hospitals. In this study, data was collected from 600 elderly patients (100 patients per hospital). All medicines prescribed in each in-patient chart were noted on a pre-designed performa and were evaluated according to the 2015 American Geriatrics Society Beers Criteria. Statistical Package for Social Sciences (SPSS) was used to analyze the data. **RESULTS:** In 600 hospitalized in-patient (male 52.7% and female 47.3%) charts, 3,179 medicines were prescribed. The most commonly prescribed drug classes were: alimentary tract and metabolism 80%, nervous system 66.3%, anti-infectives for systemic use 62.2% and cardiovascular system 48.3%. The most commonly prescribed inappropriate medications were: omeprazole 51.3%, metoclopramide 14.3%, aspirin 9%, diphenhydramine 7.7%, ibuprofen 4%, famotidine 3.3% and chlorpheniramine 1.8%. **CONCLUSIONS:** The rational use of medicines is of utmost importance, most particularly in the elderly population. It is highly recommended that more consideration should be given to the elderly patients.

PHP31

COMPARING HTA OUTCOMES FOR CENTRALLY AUTHORISED MEDICINAL PRODUCTS IN GREAT BRITAIN 2011-2015

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OBJECTIVES: Marketing authorisation is the first step in making new medicines available in national health systems. Most new substances are approved in the European Union via the centralised procedure (coordinated by the European Medicines Agency), which was designed to facilitate access to new and efficacious therapies. Many health care systems in Europe then evaluate new technologies according to their effectiveness and cost effectiveness. We compared the outcomes of HTA evaluations for centrally authorised products (CAPs) in Great Britain. **METHODS:** The Medicine Tracker is a proprietary database of products, which includes detailed and structured information on CAPs, e.g. indications (initial and extensions), regulatory and HTA outcomes and dates of decisions. We analysed and compared the outcomes of evaluations conducted by the National Institute for Health and Care Excellence (NICE), the All Wales Medicines Strategy Group (AWMSG) and the Scottish Medicines Consortium (SMC) for all the CAPs which received an authorisation (initial or extension) between 01/01/2011 and 31/12/2015. **RESULTS:** 416 authorisations (excluding generics, hybrids, biosimilars) were granted between 2011 and 2015 (including 67 orphan medicinal products). 171 (30%) are for anti-cancer medicines. 50% of the 416 CAPs were referred to NICE including 60% (103) of the anti-cancer medicines. 75% of NICE appraised CAPs received a positive recommendation and only 21 products (13%) were rejected. Anti-cancer medicines were disproportionately affected by NICE negative recommendations (OR of receiving a negative recommendation compared with other products 4.19 [2.26, 7.75]). The odds of receiving a positive recommendation from the SMC was significantly lower for orphans compared with non-orphan medicinal products; OR 0.42 [0.21, 0.83]. 25 products were appraised in all 3 countries, there was low agreement in terms of recommendations, Kappa 0.479, p<0.001. **CONCLUSIONS:** Despite the centralised procedure increasing the availability of new medicines, this does not systematically translate into wider access in Great Britain.

PHP32

REVIEW OF ECONOMIC EVIDENCE ON THE IMPACT OF SUBSTANDARD AND FALSIFIED MEDICINES IN LOW AND MIDDLE INCOME COUNTRIES

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OBJECTIVES: To examine the extent of substandard and falsified medicines in low and middle income countries (LMIC) and assess evidence of their economic impact. **METHODS:** Five databases were searched for articles containing data on prevalence and/or economic impact of substandard and falsified medicines in LMICs: PubMed, EconLit, Global Health, EMBASE, and SCOPUS. The search used variations of two keywords: "substandard and falsified medicines" and "low- and middle-income country." Additional gray literature sources were incorporated through reference mining. Studies that did not seek to quantify either prevalence or economic impact of substandard and falsified medicines, or that pertained only to high income countries, were excluded. Two reviewers independently assessed articles for inclusion. Data describing the setting, medicine, disease target, prevalence, and economic impact were extracted from selected articles. **RESULTS:** While the final article count is still underway, we identified more than one hundred articles describing the prevalence of substandard and falsified medicines in LMICs. Results from country studies suggest considerable variation across regions, specific medicines and facilities (hospitals vs. pharmacies), as well as in the source of the evidence (active vs. passive surveillance). In comparison, very few articles described the economic impact of substandard and falsified medicines in LMICs. The economic impact presented often did not clearly describe the methodology, or used a limited scope focusing on immediate impacts. The

final counts and full results of the review will be presented at the ISPOR conference. **CONCLUSIONS:** This review documents current evidence showing the prevalence of substandard and falsified medicines is a substantial problem in LMICs. It further highlights key gaps in the available literature at estimating the economic impact of substandard and falsified medicines, what further studies are needed to evaluate the broader economic impact of poor medicines in LMICs, and makes a case for investing in evidence-based solutions to address this problem.

PHP33

THE BEST WAY TO HTA? QUEBEC VERSUS THE REST OF CANADA

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OBJECTIVES: The Canadian Agency for Drugs and Technologies in Health (CADTH) makes reimbursement recommendations to provincial public drug plans to help guide drug funding decisions. The exception is Quebec, where the Institut National d'Excellence en Santé et en Services Sociaux (INESSS) conducts separate assessments. This research compares drug recommendations between CADTH and INESSS. **METHODS:** Publicly available CADTH (including both Common Drug Review [CDR] and pan-Canadian Oncology Drug Review [pCODR] processes) and INESSS reports on drug assessments were identified between 01/31/2015 and 11/30/2016, and key data were extracted and compared. **RESULTS:** 144 appraisals were conducted by CADTH (104 under CDR and 40 pCODR) compared with 337 by INESSS. 83% CADTH appraisals resulted in positive decisions (defined as a full [4%] or restricted recommendation [79%]) with 17% not recommended. Recommendation rates were similar under CDR versus pCODR processes. 48% INESSS appraisals resulted in positive decisions (including restrictions and those from re-assessments) with 37% not recommended and 14% other. 44% INESSS oncology drug appraisals were positive decisions. 96 drugs had been assessed by both CADTH and INESSS in the same indication. Only 55% were concordant ($\kappa=0.17$); however, this is a higher rate than expected by chance (24%). **CONCLUSIONS:** INESSS has appraised many more technologies than CADTH over the past 2 years but issued less frequent positive decisions. Concordance in decisions between agencies is low ($\kappa=0.17$), largely due to the higher recommendation rate for CADTH. Although CADTH offers a single pan-Canadian assessment of the clinical and economic impact of a new drug, their very high rate of positive recommendations that are non-binding (and hence need subsequent provincial assessments) may question their effectiveness in supporting efficient and consistent provincial drug reimbursement. However, these positive recommendations are typically conditional on demonstrating acceptable cost-effectiveness, and unlike INESSS, CADTH conducts horizon scanning, potentially filtering out technologies unlikely to be recommended.

PHP34

UNDERMINING THE GOLD STANDARD? THE ROLE OF NON-COMPARATIVE EVIDENCE IN HEALTH TECHNOLOGY ASSESSMENT

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OBJECTIVES: Many health technology assessment (HTA) agencies express a preference for 'gold standard' randomized controlled trial (RCT) evidence against a relevant comparator when appraising new health technologies; however, it is not always feasible to design and conduct a clinical trial that meets these criteria. The objective of this study was to assess the current role of non-comparative evidence in HTA decision-making. **METHODS:** The websites of three HTA agencies: NICE (UK), CADTH (Canada), and IQWiG (Germany) were searched for single HTA reports published between January 2010 and December 2015. The product, indication, outcome, and clinical evidence presented (comparative vs non-comparative) were double-extracted, with any discrepancies reconciled. Multiple technology appraisals, medical devices, vaccination programmes, and requests for advice were excluded. A 'non-comparative' study was defined as any study not presenting results against another treatment (including placebo or best-supportive care), regardless of Phase or setting, including dose-ranging studies. **RESULTS:** 549 appraisals were extracted. Non-comparative evidence was considered in 38% (45/118) NICE submissions, 13% (34/262) CADTH appraisals, and 12% (20/169) IQWiG appraisals. Evidence packages based exclusively on non-comparative evidence were presented in only 4% (5/118) NICE appraisals, 6% CADTH appraisals (16/262), and 4% (6/169) IQWiG appraisals. The majority of drugs appraised solely on the basis of non-comparative evidence were indicated for cancer or hepatitis C. Positive outcome rates (encompassing recommended/restricted/added benefit decisions) for submissions presenting only non-comparative evidence were similar to overall recommendation rates for NICE (84% vs 80%, respectively) and CADTH (68% vs 69%), but were notably (though not statistically) lower for IQWiG (38% vs 22%) ($p > 0.05$ for all). **CONCLUSIONS:** The role of non-comparative evidence in HTA is currently limited. Non-comparative studies can be viewed as acceptable clinical evidence by NICE and CADTH when these study designs are justifiable and when treatment effect can be convincingly demonstrated using these methods; IQWiG will rarely consider non-comparative studies.

PHP35

IMMEDIATE DISCOUNTS VERSUS DELAYED REBATES: A SURVEY OF U.S. PAYERS

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OBJECTIVES: Delay discounting describes the tendency to prefer an immediate reward, even when a delayed reward is greater. This phenomenon has been consistently demonstrated in several studies across a variety of populations. This

study aimed to assess whether the delay discounting model is applicable among U.S. healthcare payers. **METHODS:** An online survey was conducted with U.S. pharmacy and medical directors who worked at managed care organizations (MCOs) and served as active members of pharmacy and therapeutics committees. Participants were given 27 different scenarios based on the Monetary Choice Questionnaire. Each scenario offered two options from a fictional drug manufacturer wishing to contract with an MCO. Participants chose between a smaller immediate discount off invoice and a larger delayed rebate. The cost savings and length of delay varied in each of the scenarios. A published scoring tool was used to calculate the individual and overall rates at which the subjective value of the delayed reward decreased over time (k). A delay discounting curve plotted the relative subjective value of the delayed reward versus the length of delay. **RESULTS:** The overall median k value across all 54 participants was 0.00254, yielding a shallow hyperbolic delay discounting curve. Subgroup analyses revealed equivalent median overall k values between pharmacy and medical directors. Overall, 54% of all decisions were in favor of a delayed rebate. A magnitude effect was observed, where increases in rebate amounts from small to large coincided with increased favorability towards delayed rebates (50% to 59%, respectively). **CONCLUSIONS:** While payers in this study displayed an expected pattern of discounting delayed rewards, discounting appears to be minimal compared to previously published discounting rates of non-payer populations. Results suggest payers in general are willing to wait for larger, delayed rebates over smaller, immediate discounts when engaging in contracting opportunities.

PHP36

ASSOCIATION BETWEEN EXTERNAL REFERENCE PRICING AND PER CAPITA SPENDING ON PHARMACEUTICALS IN EUROPE

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OBJECTIVES: External reference pricing (ERP) is a cost-containment tool employed by many European countries to manage pharmaceutical prices. The study objective was to explore the association of ERP and related factors with per capita pharmaceutical spending in 28 European countries. **METHODS:** The outcome variable was annual per capita spending on prescription and over-the-counter (OTC) pharmaceuticals. Potential explanatory variables included the number of countries contained in each country's "basket" of countries referenced when establishing price; number of times each country was referenced in other countries' baskets; price type referenced (manufacturer or purchasing power parity); frequency of re-referencing; Eurozone membership; country population and life expectancy, and gross domestic product (GDP) per capita. All analyses were conducted with SAS v9.3. Explanatory variables were assessed for correlation with the outcome variable, normality, and multicollinearity. Linear regression with backwards elimination was performed to delineate the factors with greatest impact on pharmaceutical spending. **RESULTS:** Mean per capita pharmaceutical spending was €367. While the average number of countries in a given country's basket was 13.2, the average number of times a country itself is referenced in another's basket is 12.0. The number of times each country was referenced and life expectancy were statistically significantly associated with pharmaceutical spending. As the times a country is referenced increases by one, per capita pharmaceutical spending increases by €37. As life expectancy increases by one year, pharmaceutical spending per capita increases by approximately €21.90. **CONCLUSIONS:** This study showed that the number of times a country is referenced by other countries is significantly associated with per capita pharmaceutical spending in the referenced country, indicating that countries with higher per capita spending impact pricing in other countries. Logically, life expectancy is positively correlated with per capita pharmaceutical spending – the longer a person lives, the more he or she will spend on pharmaceuticals in a given year.

PHP37

GENERIC COMPETITION IN THE US (1980-2016)

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OBJECTIVES: This study assessed trends in generic drugs approved by the US FDA in the period 1980-2016. **METHODS:** Study data were derived from the FDA webpage. We assessed the first generic entry for new molecular entities (NMEs) and new therapeutic biologic license applications (BLAs) approved during the study period. We estimated the time from BLA/NME approval to biosimilar/generic approval. Descriptive analysis, t-test and Chi-Square were used in the analysis. Stata 13.1 was used for the analysis. **RESULTS:** The FDA approved 1033 new drugs in the period 1980-2016 including 914 NMEs and 119 BLAs. Nine BLAs and 137 NMEs were discontinued from the market as of December 31, 2016. There were 4 BLAs that experienced biosimilar competition. There were 156 (15.1%) NMEs discontinued from the market and 249 (23.5%) that had patent or exclusivity listed by the FDA, resulting in 528 NMEs that candidates to generic competition of which 392 (74.2%) experienced generic competition during the period of analysis. There were 312 (78.0%) non-orphan NMEs and 91 (49.5%) of orphan NMEs with generic competition. The BLAs with biosimilar competition had a period of single source of 18.3±4.26 years. The NMEs with generic competition had a period of single source of 13.3±4.3 years. The single source period of NMEs was 13.5 years in 1980-1984, 13.8 years in 1985-1989, 12.3 years in 1990-1994, and 11.9 in 1995-1999. Data for the period 2000-2016 is right censored as drugs are expected to experience generic competition in the future. **CONCLUSIONS:** Only a small number of BLA experienced biosimilar competition due to the recent implementation of a pathway for biosimilar approval. A significant number of drugs, especially orphan drugs did not experience generic competition in spite of having not patent or exclusivity protection. The single source period of NMEs declined over time.

PHP38

THE MANAGEMENT OF THE HUNGARIAN HEALTH INSURANCE PHARMACEUTICAL BUDGET BETWEEN 2006-2015

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OBJECTIVES: At the end of 2006, there was an important reform in the Hungarian pharmaceutical market, including serious changes in the health insurance reimbursement of medicines. In 2008, the world economic crisis significantly affected the public expenditures in many countries. The aim of our study is to analyze the changes in the Hungarian health insurance pharmaceutical budget between 2006-2015. **METHODS:** Data were derived from the nationwide administrative dataset of the National Health Insurance Fund Administration (OEP), the only health care financing agency in Hungary. We analyzed the changes of the pharmaceutical budget between 2006-2015. Results are given in Hungarian Forint (HUF) and US dollars (USD). The annual average currency exchange rates were applied according to the data of the Central Bank of Hungary. **RESULTS:** In the first year, the Hungarian pharmaceutical budget decreased from 388.7 billion HUF (2006) to 323.6 billion HUF (2007) by 65.1 billion HUF (16.7%). This decrease was a bit moderate in USD dollar (0.1 billion USD, 4.7%) due to the stronger Hungarian currency. For 2011, the pharmaceutical budget slightly increased compared to 2007 up to 376.9 billion HUF (1.88 billion USD). The increase was moderate in USD due to the weakening Hungarian currency. Between 2012-2015, the pharma budget remained in the range of 296-326 billion HUF (1.17-1.3 billion USD). **CONCLUSIONS:** Due to the reform of the whole Hungarian pharmaceutical market and as the effect of economic crisis, the Hungarian health insurance pharmaceutical budget significantly decreased between 2006-2015. Between 2006-2009 this decline became higher as the Hungarian currency weakened compared USD during the world economic crisis. Between 2012-2015, the pharma budget have been stabilized.

PHP39

THE EXCHANGE OF HEALTHCARE ECONOMIC INFORMATION IN THE US: PAYER AND MANUFACTURER EXPERIENCES WITH FDAMA 114 AND FUTURE DIRECTIONS

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OBJECTIVES: To understand US payer and manufacturer experiences with Section 114 of the Food and Drug Administration (FDA) Modernization Act of 1997 (FDAMA 114) and how this experience could influence implementation of new legal provisions and FDA guidance on healthcare economic information (HCEI). **METHODS:** Payers and manufacturers completed surveys assessing the importance of HCEI and application of FDAMA 114 prior to changes resulting from implementation of 21st Century Cures and recent draft FDA guidance. **RESULTS:** Payers (N=59) were largely from managed care organizations (75%) and most (64%) were voting Pharmacy and Therapeutics Committee members. Manufacturers (N=81) represented small- to large-sized companies, with representation primarily from Health Economics and Outcomes Research functions (35%). Most payers (54%) had a person/group responsible for HCEI, with 46% conducting in-house HCEI evaluations. Nearly half (49%) reported that formulary decision-making was at least somewhat limited by the amount and type of HCEI shared by manufacturers; 56% reported receiving HCEI only sometimes or rarely and 29% agreed very much or completely that conservative action by manufacturers limits HCEI access. Some payers (42%) noted variation among manufacturers with respect to proactive sharing of HCEI. Similarly, most manufacturers (53%) rated FDAMA 114 decisions within a brand/therapeutic area as only somewhat consistent. Approximately half of payers rated real world observational studies comparing adherence rates (47%) and retrospective studies assessing quality measure achievement (58%) as very or extremely useful for informing formulary or medical policy decisions. However, manufacturers reported that it is very or extremely difficult to gain approval for proactive dissemination of these studies (38% and 32%, respectively). **CONCLUSIONS:** Despite its utility in payer decision-making, availability and communication of HCEI by manufacturers is varied and limited. Recent approval of 21st Century Cures and draft FDA guidance may improve the effective exchange of HCEI. This research may help to influence implementation of these changes.

PHP40

PAYING FOR INNOVATION: PRIVATE PAYER COVERAGE OF BREAKTHROUGH THERAPIES

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OBJECTIVES: The Breakthrough Therapy Designation provides an expedited Food and Drug Administration (FDA) review pathway for novel pharmaceuticals that treat serious or life-threatening disease and show preliminary clinical evidence of substantial improvement over existing therapies. The aim of this research is to determine whether that clinical data is sufficient for US payer coverage and reimbursement. **METHODS:** We compared characteristics of all novel pharmaceuticals approved with and without a breakthrough therapy designation using publicly available information provided by Drugs@FDA. Benefits documents and coverage policies were extracted from the 20 largest US private insurance companies. Coverage status and prior authorization criteria were then compared to FDA approval. **RESULTS:** Between 11/1/2013 and 12/31/2015, FDA CDER approved 90 novel pharmaceuticals; 22 new molecular entities/new biological products that received Breakthrough Therapy Designation and 68 novel pharmaceuticals that did not receive Breakthrough Therapy Designation. We identified 684 coverage policies issued by private payers for the included new drugs. Almost no payers denied access to any of the included novel drugs; 96.78% of all coverage policies provided at least some degree of patient access. Breakthrough therapies were universally covered by all payers. Private payer coverage of breakthrough

therapies was equivalent to the corresponding FDA label in 79.17% of cases, more restrictive in 8.33%, less restrictive in 10.19%, and varied in 2.31%. All 'less restrictive' or 'varied' breakthrough therapies were cancer drugs. Breakthrough therapies were significantly more likely to be equivalent to corresponding FDA approval than other novel pharmaceuticals (79.17% vs. 56.4%). Novel pharmaceuticals that did not receive breakthrough therapy designation were significantly more likely to have additional restrictions applied. **CONCLUSIONS:** Although the Breakthrough Therapy Designation leads to faster regulatory approval, payer coverage remains a significant hurdle for drug manufacturers as they bring novel pharmaceuticals to market. For patients, coverage inconsistencies can mean variable access to breakthrough therapies.

PHP41

DYNAMIC REIMBURSEMENT WORKING IN PRACTICE? CANCER DRUGS FUND REFORMS IN THE UK

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OBJECTIVES: Expedited regulatory pathways increasingly grant marketing authorization for treatments at earlier stages of clinical development. In contrast, payers in Europe, Canada, and Australia are increasingly demanding more robust data to justify reimbursement. Dynamic reimbursement, defined as varying the price as further evidence emerges, provides one route for reimbursement where considerable uncertainty exists. However, in practice, attempts to remove coverage/reduce the price of already reimbursed treatments have been challenging (e.g. Conditional Financing in the Netherlands). Reforms to the Cancer Drugs Fund (CDF) in England have effectively created a dynamic reimbursement scheme whereby drugs reimbursed under the CDF (originally set up in 2011 with free-pricing for qualifying drugs) will only maintain reimbursement if they achieve positive NICE guidance. This research aims to evaluate how these CDF reforms have impacted drug coverage and pricing. **METHODS:** Drugs covered under the CDF (as of 07/29/2016) were identified from the NHS England website. Corresponding subsequent NICE appraisal guidance was screened up to 01/13/2017. **RESULTS:** Thirty-three drug-indication pairings were covered under the CDF; 10 have subsequently received final NICE guidance (100% positive); all recommendations were associated with a PAS (all simple discount schemes). 7 drug-indication pairings were approved through rapid re-appraisals and 3 were approved through full NICE submissions. 18 submissions are undergoing NICE appraisals, of which 7 have draft guidance (2 positive, 4 negative, and 1 recommended for inclusion in the reformed CDF). 3 drug-indication pairings were deferred to the CDF 'off-label process', 1 was withdrawn by the manufacturer, and 1 has unknown status. **CONCLUSIONS:** Under the recent CDF reforms, the NHS has arguably successfully implemented a form of dynamic reimbursement whereby manufacturers have had to reduce their prices or lose reimbursement. However, this is not an ongoing scheme but a one-off set of changes that were a consequence of broader oncology reimbursement reforms.

PHP42

DO PAYERS COVER CANCER AND NON-CANCER DRUGS DIFFERENTLY?

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OBJECTIVES: Evidence suggests that health technology assessment agencies across the globe may use different assessment criteria for cancer and non-cancer drugs. Our objective was to compare coverage decisions for cancer and non-cancer drugs issued by US private health care payers to determine if cancer drugs are subject to fewer coverage restrictions. **METHODS:** We identified coverage decisions for cancer and non-cancer drugs from the Tufts Medical Center Coverage Determination database which includes 3,432 coverage decisions issued by 17 of the largest commercial payers (in terms of covered lives). We compared each payer's coverage decision for each drug against the drug's corresponding FDA label. We categorized each coverage decision as: (a) more restrictive than the FDA label (the payer placed conditions on coverage beyond the FDA label); (b) consistent with the FDA label; (c) less restrictive than the FDA label (the payer covered the drug for a broader patient population than the FDA label); or (d) mixed (the payer's coverage decision was more restrictive than the FDA approval in one way but was less restrictive in another). We compared the restrictiveness of coverage of cancer and non-cancer drugs using a chi-squared test. **RESULTS:** The database contains 2,507 coverage decisions for non-cancer drugs, and 925 coverage decisions for cancer drugs. For non-cancer drugs, coverage was more restrictive on 35% (n=877) occasions, consistent on 53% (n=1,324) occasions, less restrictive on 4% (n=109) occasions, and mixed on 2% (n=51) occasions. For cancer drugs, coverage was more restrictive on 5.3% (n=49) occasions, consistent on 70.7% (n=650) occasions, less restrictive on 21.9% (n=201) occasions, and mixed on 1.2% (n=11) occasions. We found a statistically significant (p<0.05) difference between the restrictiveness of coverage of cancer and non-cancer drugs. **CONCLUSIONS:** Our study suggests that payer coverage of cancer drugs is less restrictive than coverage of non-cancer drugs.

PHP43

RATES OF PRESCRIPTIONS FOR HIGH OPIOID DAILY DOSES ACROSS MULTIPLE EMPLOYER GROUP PLANS IN EASTERN TENNESSEE

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OBJECTIVES: CDC has released guidelines for providers on appropriate opioid use which identify potentially unsafe opioid daily doses (≥50 morphine milligram

equivalents (MME) and ≥ 90 MMEs). This study used a multi-employer dataset in eastern Tennessee to identify the proportion of opioid prescriptions that exceeded these thresholds. **METHODS:** Prescription and medical claims data were obtained from the data warehouse of HealthCare 21, the employer coalition in eastern Tennessee. A cross-sectional analysis was conducted including beneficiaries with continuous eligibility from July 2014 to June 2015 who were ages 18-64. Individuals with a cancer diagnosis were excluded. Filled opioid prescriptions were identified and daily doses in MMEs were calculated. Daily doses of ≥ 50 MMEs and ≥ 90 MMEs were identified as these were thresholds described in CDC guidelines. **RESULTS:** The final sample included 63,648 beneficiaries. The median age was 44 and 58% were female. Of these beneficiaries, 14,115 (22%) filled at least one opioid prescription. A total of 47,508 opioid prescriptions were filled. Among the population who filled at least one opioid prescription, the median number of prescriptions was 1, the mean was 3.4, and the maximum was 45. The median daily dose for all opioid prescriptions was 32 MMEs, the mean was 51 MMEs while the 90th and 95th percentiles were 90 and 135 MMEs, respectively. Nearly one third of opioid prescriptions were for daily doses ≥ 50 MMEs (30%) and 12% were for daily doses ≥ 90 MMEs. **CONCLUSIONS:** Despite CDC recommendations against the use of high daily doses of opioids, nearly one in three opioid prescriptions in this study were found to be for daily doses ≥ 50 MMEs. Further research is warranted to better understand factors contributing to the prevalence of high dose opioid prescriptions and how exposure to these potentially dangerous doses can be reduced.

PHP44

MEDICATION ADHERENCE AND DISCONTINUATION IN MEDICAID PATIENTS WITH DUAL DIAGNOSES OF SCHIZOPHRENIA AND BIPOLAR WHO INITIATED LONG ACTING INJECTABLE ANTIPSYCHOTIC VERSUS THOSE WHO CHANGED ORAL ANTIPSYCHOTICS

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OBJECTIVES: To compare medication adherence and discontinuation between patients with dual diagnoses of schizophrenia and bipolar disorder (BPD) who initiated a long-acting injectable antipsychotic (LAI) and those who changed to a different oral antipsychotic monotherapy. **METHODS:** This retrospective cohort analysis used the Truven Health Analytics MarketScan® Medicaid claims database. Of the identified schizophrenia patients (≥ 18 years) with co-morbid BPD (dual diagnoses), two mutually exclusive cohorts were created: "LAI", patients initiating LAI therapy between 01/01/2013 and 06/30/2014 (the identification period); and "oral", patients who changed to a different oral antipsychotic monotherapy during the same period. The first day of initiating LAI or new oral was the index date. Primary outcome measures were medication adherence [proportion of days covered (PDC)] during the 1-year follow-up and medication discontinuation (continuous medication gap ≥ 60 days) during entire follow-up. General linear regression and Cox regression models were used to estimate adjusted medication adherence rate and risk of discontinuation, respectively, adjusting for patient demographic and clinical characteristics, baseline medication, and baseline emergency department visits or hospitalizations. **RESULTS:** The study sample consisted of 1,028 (45.1%) LAI initiators and 1,250 (54.9%) oral monotherapy users. Compared with oral users, LAI initiators had better medication adherence (adjusted mean of PDC: 0.52 vs. 0.48; $p=0.023$). LAI initiators also had a significantly longer time to medication discontinuation than the oral cohort. Median time to discontinuation of index LAI was 38 days, compared with 30 days in the oral cohort ($p=0.025$). Adjusting for covariates, the risk of discontinuing index treatment in the oral cohort was higher than in the LAI cohort (hazard ratio: 1.14; $p=0.01$). **CONCLUSIONS:** This real-world study suggests that among patients with dual diagnoses of schizophrenia and BPD, use of LAI was associated with slightly better medication adherence and lower discontinuation risk compared with use of oral antipsychotic monotherapy.

PHP45

RELATIVE RISK OF ANTI-PSYCHOTIC USE IN FOSTER CHILDREN BENEFICIARIES ENROLLED IN THE MISSISSIPPI DIVISION OF MEDICAID (DOM)

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OBJECTIVES: Increasing use of antipsychotic medications in children, especially outside of FDA approved uses has become a topic of national concern. Higher utilization of antipsychotic medications in foster children has raised questions about treatment disparities. This study assesses the relative risk of antipsychotic use in foster children compared to non-foster children in Mississippi Medicaid. **METHODS:** We employed a retrospective observational design. Mississippi DOM pharmacy claims for all children from ages 4-18 years and continuously enrolled for 2015 were analyzed for antipsychotic use. Antipsychotic use was identified by using NDC codes for all first and second-generation antipsychotics. Foster children were identified using eligibility codes, which excluded children who received long-term care or had dual eligibility. Poisson regression with log link was used to assess the unadjusted and adjusted relative risks of antipsychotic use amongst foster versus non-foster care children. **RESULTS:** We identified 4,626 foster children and 274,043 non-foster children continuously enrolled in 2015. Foster children had higher rates of mental disorders such as psychosis, ADHD, conduct disorder, and disruptive behavior disorder. The unadjusted relative risk of antipsychotic use in foster children was 3.6 times higher compared to non-foster children (95% CI, 3.303-4.013, $p<0.0001$). When adjusting for demographics and mental health disorders, the relative risk of antipsychotic use dropped to 1.4 (95% CI, 1.272-1.603, $p<0.0001$). **CONCLUSIONS:** The use of antipsychotic medications was significantly higher among foster children. After adjusting for mental health

and developmental conditions, the relative risk of use was still significantly higher but much lower. The drop in adjusted relative risk indicates that higher rates of use in foster children might be explained by higher rates of trauma and mental health disorders. Future work examining additional confounding variables may be needed to determine whether a treatment disparity actually exists between foster and non-foster children.

PHP46

ALL-CAUSE INPATIENT HOSPITALIZATIONS IN MEDICAID PATIENTS WITH DUAL DIAGNOSES OF SCHIZOPHRENIA AND BIPOLAR WHO INITIATED LONG ACTING INJECTABLE ANTIPSYCHOTICS

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OBJECTIVES: To compare all-cause inpatient hospitalizations among Medicaid patients with dual diagnoses of schizophrenia and bipolar disorder who initiated long-acting injectable antipsychotics (LAIs). **METHODS:** This retrospective cohort analysis used the Truven Health Analytics MarketScan® Medicaid claims database. Schizophrenia patients ≥ 18 years with comorbid bipolar disorder (dual diagnoses) and having at least one claim for one of the following four LAIs were identified between 01/01/2013 and 06/30/2014: aripiprazole, haloperidol, paliperidone, and risperidone. The first day of initiating LAI was considered the index date. We compared all-cause hospitalization rates during the 1-year follow-up and time to first all-cause hospitalization during the entire follow-up across the four LAI cohorts. Logistic and Cox regression models were used to estimate risks of inpatient hospitalization, adjusting for baseline patient demographic and clinical characteristics, medication use, and emergency department use/hospitalizations. **RESULTS:** Of the identified Medicaid patients with schizophrenia and bipolar dual diagnoses, 935 initiated an LAI: 49.3% received paliperidone, 23.3% haloperidol, 16.4% risperidone, and 11.0% aripiprazole. Controlling for covariates, the adjusted post-index 1-year hospitalization rate in aripiprazole (36.8%) was lower than in paliperidone (41.9%), haloperidol (45.6%), and risperidone (47.3%). The median time to first hospitalization in aripiprazole was 647 days, vs. 507 days in paliperidone, 426 days in haloperidol, and 419 days in risperidone. With the aripiprazole cohort as the reference group, the risk of having any inpatient hospitalizations during the entire follow-up was higher in haloperidol, paliperidone and risperidone cohorts. However, none of these differences were statistically significant ($p>0.05$). **CONCLUSIONS:** This is the first study to compare inpatient hospitalizations among Medicaid patients with dual diagnoses of schizophrenia and bipolar who initiated LAIs. Our findings suggest that patients treated with aripiprazole have a numerically lower risk of having any hospitalizations, compared with those treated with haloperidol, paliperidone, and risperidone, although the difference was not statistically significant.

PHP47

PATIENT CHARACTERISTICS RELATED TO SPECIALTY MEDICATION USE

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OBJECTIVES: To identify characteristics associated with specialty medication use by employing a large, nationally representative sample of patients using specialty medications for their chronic conditions in the U.S. **METHODS:** This study used Medical Expenditure Panel Survey (MEPS) data from 2000 through 2013. Among the MEPS respondents aged 18 or older who received at least one medication during the years 2000 through 2013, those who used any specialty pharmaceuticals were considered as specialty medication users (SMUs). Accordingly, adults 18 or older who used only pharmaceuticals other than specialty medications were considered traditional medication users (TMUs). Those who used not only specialty medications but also traditional medications concurrently were labeled as both medication users (BMUs). Andersen's Health Services Utilization model was used to identify potential factors related to specialty medication use. Associations between the variables identified by Andersen's model and specialty medication use were analyzed using logistic regression in a hierarchical fashion. Sampling weights were considered and standard errors were adjusted to account for the complex survey design. **RESULTS:** A fully adjusted model suggested that older adults or individuals using mail order services were more likely to use specialty medications regardless of whether they used traditional medications concurrently. Behaviors of using specialty medication(s) were positively associated with married and active working status and negatively associated with middle or high income and having a usual source of care (visiting a doctor's office, clinic, or health center they usually go when sick) when comparing TMUs and SMUs. In addition, when comparing TMUs and BMUs, behaviors of using specialty medication(s) were positively associated with female gender, having drug insurance, worse health state and more comorbidities and negatively associated with other race/ethnicity (not Caucasian/African American). **CONCLUSIONS:** This study identified characteristics of patients using specialty medication(s). Some sociodemographic, economic, and clinical factors were related to specialty medication use among U.S. adults.

PHP48

KNOWLEDGE, ATTITUDE AND PRACTICE: STUDY OF GENERIC MEDICINES AMONG STAKE HOLDERS IN BAHAWALPUR CITY

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OBJECTIVES: This study aimed to assess public knowledge and attitudes toward generic medicine usage within a government hospital and community setting in

Bahawalpur which could serve as baseline data for future studies. **METHODS:** A cross-sectional survey involving 600 respondents was conducted using a validated questionnaire among the stake holders of Bahawalpur City, Punjab; Pakistan. The data was collected from 150 pharmacists and 150 doctors by using self-administered questionnaire, while 300 patients were questioned verbally. The data was collected using pre-tested semi structured questionnaire. The data was analyzed using SPSS version 15 and the results were tabulated. **RESULTS:** Out of 150 pharmacist, 102 (68%) had knowledge that generic medicines show same effects as branded medicines. Out of 150 doctors, 67 (44.7%) considered that generic medicines were as effective as branded medicines. Out of 300 patients, 277 (93.3%) considered that branded medicines were safer than generic medicines. Patients 268 (89.3%) were not interested to know about cheaper alternative of prescribed medicines. Patients 296 (98.7%) were not asked by doctors or pharmacist to switch from branded to generic medicines. Pharmacists 113 (75.3%) showed positive attitude to have awareness about shops where generic medicines were available while who suggested the patient regarding use of generic medicines were 102 (68%). Doctors 140 (93.3%) needed information about safety and efficacy of generic medicines and 118 (78.1%) doctors said that their prescribing decision was influenced by advertisements of drug companies. **CONCLUSIONS:** It was concluded from current study that there was gap of knowledge among respondents towards generic medicines. Most of the respondents showed negative attitude towards generic medicines and generic substitution.

PHP49

A CROSS-SECTIONAL STUDY TO EVALUATE THE FACTORS INFLUENCING THE PRESCRIBERS TO PRESCRIBE AN EXPENSIVE BRAND IN BAHAWALPUR, PUNJAB, PAKISTAN

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OBJECTIVES: To promote economic treatment option in the society by reducing treatment cost and by supporting generic prescribing trends. **METHODS:** A descriptive, cross-sectional and non-experimental study was conducted among the prescribers of Bahawalpur, using a pre-tested questionnaire. Statistical Package for Social Sciences (SPSS) was used to analyze the data. **RESULTS:** A total of 250 of the prescribers were selected for the study including general prescribers (134) and specialists (116). 93.7% of the prescribers agreed the cost difference between generic and branded medicines, 52.1% of the prescribers disagreed that generic and branded drugs were equally effective, 73.1% of the prescribers believed that branded medicines followed more safety standards than the generic medicines and 61.1% of the prescribers agreed that advertisements have great impact on prescribing behavior. **CONCLUSIONS:** This study concluded that poor knowledge about safety, efficacy, quality and cost difference, and advertisements by the pharmaceutical companies are the major factors that force the prescribers to prescribe branded medicines rather economical generic. The study showed that lack of standard guidelines and policies divert the prescribing behavior from generic drugs to branded drugs.

PHP50

EXPLORING ANTIMICROBIAL DRUG UTILIZATION REVIEW PROGRAMS IN SAUDI HOSPITALS

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OBJECTIVES: Antimicrobial drug utilization review (DUR) is one of the essential tools to optimize the therapy and minimize the risks that are associated with irrational use of this therapeutic group including the Antimicrobial drug resistance. The aim of the study is to explore how Saudi hospitals setup DUR program for Antimicrobial drugs use. **METHODS:** A cross-sectional survey targeted managers at hospital pharmacies in both governmental and private hospitals in Riyadh City in 2014. The survey gathered information about the Pharmacy & Therapeutics Committee (P&TC) activities and adopted therapeutic guidelines by the hospitals. Descriptive statistics and nonparametric techniques were utilized for the analysis. **RESULTS:** Of the 30 hospital pharmacy managers, 23 (76.6%) responded, and only 21(70%) hospital pharmacies met the inclusion criteria, of which 15 governmental and 6 private hospitals. 20(95.2%) hospitals have P&TC, of these 20 hospitals, 16(80%) have subcommittee dedicated for DUR of Antimicrobial medications. 9 (45%) of these subcommittees meet five times or more annually to discuss Antimicrobial DU related issues. 17(85%) of the hospitals have Antimicrobial use guidelines. The main P&T committee at 11 (55%) hospitals that have both dedicated subcommittees and Antimicrobial use guidelines conduct at least 12 meetings annually. The governmental hospitals are more likely to dedicate subcommittee to review Antimicrobial use and have higher frequency of meetings than the private hospitals. **CONCLUSIONS:** The adoption and implementation of Antimicrobial use guidelines is still not optimal in the Saudi hospitals which might have negative impact not only on the patient outcomes but also in public health as a result of irrational use of Antimicrobial drugs which eventually will develop Antimicrobial resistance. The effectiveness of the Antimicrobial DUR program has not been tested in this study, therefore, further studies should be conducted to ensure the effectiveness of the DUR programs in Saudi hospitals.

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A LANDSCAPE ASSESSMENT OF TWO ANESTHETICS (PROPOFOL & ETOMIDATE) IN THE HOSPITAL INPATIENT POPULATION DEMONSTRATES MARKED DIFFERENCES IN PATIENT CHARACTERISTICS AND COST

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OBJECTIVES: In the last decade the population undergoing medical procedures is older and sicker. However, anesthetics (sedatives/hypnotics) administered during these procedures have not changed significantly during that time. This study sought to gain a better understanding of the sedative/hypnotic landscape in inpatient hospital procedures by examining populations receiving some of the more common drugs. **METHODS:** Adult inpatients with a procedure, discharged in 2014 who received etomidate or propofol, alone or in combination with other anesthetic agents were identified in the Premier hospital database. Data from 01/2013 to 09/2015 was used for trend analysis. Descriptive statistics were employed to understand patients' demographics, therapeutic characteristics, resource utilizations and outcomes. Costs were adjusted to 2015 dollars. **RESULTS:** A total of 3,631,719 adult patients underwent a procedure in the hospital setting in 2014. Of which, 120,304 (3.3%) received etomidate and 1,246,093 (22.4%) received propofol. Compared to propofol patients etomidate patients were: older (64.7 vs. 60.2), sicker, with mean Charlson Comorbidity Index (CCI) 2.7 vs. 1.7, with higher percentage of patients in Mortality/Severity of Major or Extreme groups (73.0% vs. 26.2% and 78.6% vs. 35.7%). The etomidate population had higher resource utilization (LOS 10.9d vs. 6.0d; total cost \$37,685 vs. \$20,586); and higher death rate (15.8% vs 3.0%). For the 3 year period, both populations demonstrated similar trends for mean age, CCI, LOS, Cost, and Mortality/Severity). **CONCLUSIONS:** In this assessment of propofol and etomidate, procedural administration of propofol is the dominant sedative/hypnotic of use but there are marked differences in patient characteristics between the two agents. Etomidate patients are older, sicker, have a longer LOS and use more health care resources. Further research is necessary to understand if these factors may be influenced by technique or concomitant medications.

PHP52

DRUG REVIEW OF CLASS I - ANTINEOPLASIC AND IMMUNOMODULATING FOR TREATMENT OF APLASTIC / HEMOLYTIC ANEMIA AND APLASTIC PURPURA ACQUIRED

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OBJECTIVES: To evaluate the therapeutic indication of 25 mg, 100 mg and 200 mg injectable lyophilized powder antithymocyte immunoglobulin (rabbit) for the treatment of aplastic anemia. **METHODS:** A literature search was carried out on February 2015 in the following databases: BMJ - Best Practice, Dynamed and UpToDate. The search strategy adopted the vocabulary of structured Descriptors in Health Sciences (DeCS) and Medical Subject Headings (MeSH) to better identify the references of interest. Indexed search terms used were: "Anemia, aplastic" and "Antithymocyte Globulin rabbit". **RESULTS:** According to evidences in BMJ, the use of antithymocyte immunoglobulin is indicated as first-line treatment in patients with aplastic anemia in groups of patients with non-severe, severe or very severe acquired disease over the age of 50 years. According to Dynamed database, the use of antithymocyte immunoglobulin at a dose of 15 mg/kg/day for 5 days with prednisolone and cyclosporine 5 mg/kg/day for 6 months improves the response rate and the free time of blood transfusions. Since the evidence synthesis found in UpToDate base demonstrates that for the treatment of severe or very severe aplastic anemia there should contain a combination of: removing potentially offending agents (for acquired aplastic anemia), additional supportive care (for example, transfusion and antibiotics) and some form of definitive therapy (e.g., transplantation of hematopoietic cells or immunosuppressive regimens). Since 2014, none of the published studies comparing horse and rabbit immunoglobulin showed superiority of the latter. It should only be used when the horse derivative is not available. **CONCLUSIONS:** Because human antithymocyte equine immunoglobulin is not available in Brazil, we recommend the inclusion of rabbit antithymocyte immunoglobulin in dosages of 25 mg, 100 mg and 200 mg, in the form of injectable lyophilized powder in the National List of Essential Medicines of Brazil.

PHP53

EVALUATION OF DRUG-DRUG INTERACTIONS IN THE PRESCRIPTIONS OF HOSPITALIZED PATIENTS IN LAHORE, PUNJAB, PAKISTAN

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OBJECTIVES: To identify the prevalence of potential drug-drug interactions (DDIs) in the prescriptions dispensed in a tertiary-care hospital of Lahore, Punjab, Pakistan. **METHODS:** A retrospective analysis of 600 prescriptions fulfilling inclusion criteria was conducted in a tertiary-care hospital, from November 2015 to March 2016. The collected data contain demographics, medications, diagnosis, comorbid conditions and length of hospital stay. Medscape database was used for the therapeutic and/or pharmacological classification of prescribed drugs. The prescriptions were analyzed for potential DDIs by using the drug interaction checker. The DDIs were also classified on severity basis as major, moderate and minor. For statistical analysis SPSS version 21.0 was used. **RESULTS:** Overall prevalence of DDIs was 71.3%. Out of 600 sample size, approximately 428 prescriptions have potential DDIs. Average of 3 DDIs was found in each prescription. The prevalence rate of major interactions were 14.3%, moderate 50.3% and minor were 28.7%. Maximum number of major interaction in a prescription was 4, moderate 9 and minor was 6. Highest percentage of interactions was found in the prescriptions of cardiology ward (53.1%). The DDIs were significantly associated with increased number of drugs prescribed (P-value 0.000). **CONCLUSIONS:** Potential DDIs occurrence was significant. Patients admitted to cardiology ward and those with large number of prescribed drugs need to be monitored more closely.

PHP54

EFFECT OF CASH PRESCRIPTIONS ON ADHERENCE PERFORMANCE MEASURE ESTIMATES USED IN MEDICARE STAR RATINGS

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OBJECTIVES: Medicare Star Ratings evaluate the quality of Medicare Advantage plans with Part-D coverage (MA-PDs) and stand-alone Part-D plans (PDPs) via multiple measures, including adherence metrics developed by the Pharmacy Quality Alliance (PQA). The objective of this study was to assess the impact of missing cash prescriptions on PQA-adherence calculations for statin, angiotensin system antagonists (RASA), and antidiabetic medications. **METHODS:** The Medical Expenditure Panel Survey 2010-2014 was used for this study. Proportion of days covered (PDC) was calculated for all prescriptions, as well as noncash-only prescriptions, when stratified by drug class. Patient adherence was defined as PDC $\geq 80\%$. Index date was defined as the first noncash prescription fill date or the round-start-date of the first noncash prescription. Patients were included if they had 2 or more noncash claims, were continuously enrolled in a MA-PD or PDP, and were age ≥ 65 . Patients with multiple insurance types, not in scope, with a measurement period < 91 days, with end-stage renal disease, and diabetic patients with any insulin claim, were excluded. **RESULTS:** Of PDP-enrollees taking a statin (N=16,325,696) the proportion considered adherent decreased from 65.2% for all prescriptions to 59.7% when measuring noncash-only claims. MA-PD-enrollees using statins (N=17,407,689) displayed similar results, and the proportion considered adherent decreased from 62.9% to 56.6%. For those on RASA-therapy, the proportion of PDP-enrollees (N=13,224,287) considered adherent decreased from 67.2% to 57.7%, and the proportion of MA-PD-enrollees (N=13,625,655) considered adherent decreased from 63.1% to 56.6%. For patients taking antidiabetics the proportion of PDP-enrollees (N=3,804,912) considered adherent decreased from 72.8% to 62.6%, while the proportion of MA-PD-enrollees (N=4,792,802) considered adherent decreased from 75.0% to 65.1%. On average 1 million MA-PD/PDP enrollees per year were incorrectly classified as nonadherent when using noncash-only claims. **CONCLUSIONS:** Cash-only prescriptions represent a significant source of drug-exposure misclassification bias for adherence calculations in MA-PD/PDP enrollees using statin, RASA, or antidiabetic medications.

PHP55

KEY GROUPS INFLUENCING GENERIC DRUG USE IN THE U.S. AND THE NATURE AND EXTENT OF THEIR INFLUENCE

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OBJECTIVES: Research to better understand the key influencers of generic drug use – including their knowledge base and perceptions toward generic drugs – is needed to effectively design and deliver communications to these key groups that impact consumer acceptance and use of generic drugs. In order to address this important regulatory science need, this qualitative study that identifies the informational needs of these key groups regarding generic drugs was conducted. **METHODS:** Key informants in each of the following 6 groups were interviewed between 9/16/2016 and 11/30/2016: 1) patients/caregivers; 2) prescribers; 3) pharmacists; 4) formulary managers; 5) policymakers; and 6) large purchasers of drugs. Participant screeners differed by group. All interview guides focused on the participant's drug prescribing, dispensing, and utilization backgrounds, roles in generic drug use, beliefs about safety and effectiveness of generic drugs, and informational needs related to generic drugs. Trained interviewers conducted 48 phone interviews. Interviews were audio recorded and transcribed. Qualitative data derived from the transcripts were analyzed with the assistance of NVivo 10 software. Initial themes were identified and discussed until all research team members agreed on major themes. **RESULTS:** While participants are likely to prescribe, dispense, or utilize generic medications, many suggested that because generic drug information is dispersed across multiple sources, it may be challenging to obtain generic drug information from one source. Likewise, policymakers, large purchasers, and formulary managers participating in the study believe generic drugs to be as safe and effective as their brand name counterparts, but find information difficult to obtain. Participants provided suggestions to improve accessibility of information, including electronic mailings that include information on drug safety, effectiveness, and approval process. **CONCLUSIONS:** Data collected from these key informant interviews will be used to inform the development of educational materials to address the key groups' knowledge gaps regarding generic drugs.

PHP56

ASSESSMENT OF PAEDIATRIC PHARMACOTHERAPY AT A PRIVATE HEALTHCARE FACILITY

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OBJECTIVES: This study evaluated the prescription at a private paediatric outpatient setting and estimated the cost of treatment in paediatric patients. **METHODS:** A cross-sectional study was conducted in the outpatient department of private paediatric hospital for a period of six months. Children below 18 years of age were included in the study. The prescribing pattern for 624 patients was analyzed by using WHO recommended prescribing indicators. The cost of the drugs was obtained from current index of medical specialities (CIMS). **RESULTS:** Of 624 patients, 366 were male and 258 were female. Most of the patients were preschoolers and toddlers. The average number of drugs prescribed was 2.78 \pm 0.05; and, only 4.69% of drugs were prescribed by their generic name. In this study, 7.69% of patients were prescribed with antibiotics and the use of injections was

minimal. Nearly half of the drugs were prescribed from the National List of Essential Medicines, 2015. The most common dosage form was syrup (40%). Viral infection was the most common diagnosis (26.12% of the patients). Amoxicillin and clavulanic acid fixed dose combination was the most commonly prescribed antibiotics. In this study, the average cost of drug per encounter was found to be INR139.39 \pm 5.20. **CONCLUSIONS:** There is a scope of prescribing medications by their generic name. This, may, help in keeping the cost of drug therapy low and possibly better compliance.

PHP57

UTILIZATION OF PRESCRIPTION MEDICATIONS AND MEDICATIONS LABELED FOR SUICIDE RISK AMONG VETERANS WITH POST-TRAUMATIC STRESS DISORDER, BIPOLAR AFFECTIVE DISORDER, MAJOR AFFECTIVE DISORDER AND/OR SCHIZOPHRENIA IN A PRAGMATIC RANDOMIZED TRIAL

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OBJECTIVES: To describe the prescription drug utilization of 243 Veterans with post-traumatic stress disorder, schizophrenia, bipolar disorder or major affective disorder who both enrolled and completed at least 2 assessments for a pragmatic randomized trial of blister packaging versus dispensing as usual of all prescribed medications in Denver, Colorado between 2012 and 2014. The intervention was designed to improve adherence and reduce suicide risk. **METHODS:** Trial records were linked to VHA Corporate Data Warehouse (CDW) prescription fill records for the study period by unique patient ID. This study was reviewed and approved by the VISNs 2 and 19 Human Subjects Review Boards and the Department of Defense Human Research Protections Office. **RESULTS:** 236 (97.1%) of these Veterans filled at least one prescription for a tablet or capsule drug product at the VA outpatient pharmacy while enrolled in the study. Subjects were enrolled for a mean of 9.4 months during which time they filled a total of 5,939 tablet and capsule prescriptions. The most prevalent drug classes were antidepressants (CN609) (17%) and anticonvulsants (CN400) (12%). The most frequent drug products dispensed were trazodone (6%), sertraline (5%), prazosin (5%), omeprazole (4%), and gabapentin (4%). **CONCLUSIONS:** This pragmatic randomized trial was designed to improve medication adherence among Veterans who may be at elevated risk of suicide or overdose due to schizophrenia or bipolar disorder, for example. Both are associated with increased risk of suicide. The most prevalent prescription medications in this pragmatic trial were antidepressants and anticonvulsants, all of which are labelled for risk of suicidal ideation and behavior. Further examination of combination prescribing refinement of warning labels for suicide risk may support future adherence and prevention efforts. **LIMITATIONS:** Prescription fills outside of VA were not observed.

HEALTH CARE USE & POLICY STUDIES – Equity and Access

PHP58

A WELLNESS PRODUCTION FUNCTION ALLOCATING SCARCE DOLLARS FOR HEALTH OR LEISURE

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OBJECTIVES: To assess and quantify a wellness production function that demonstrates the optimal allocation of money to specific illnesses or leisure, an actual quality adjusted dollar spent. **METHODS:** Medical Expenditure Panel Survey (MEPS) 2014 data were used to estimate a Cobb-Douglas production function with the Physical and Mental Composite Scores as the dependent variables and medical conditions, log-transformed healthcare expenditures and income among other factors as covariates. **RESULTS:** The MMEPS data contained approximately 33,000 interviewees. The intercepts for PCS and MCS were 36.29 (P < 0.01) and 38.38 (P < 0.01). Expenditures for all healthcare and pharmaceuticals were statistically significant, (All P < 0.01). Income elasticities were 1.8884 for PCS and 1.60889 (Both P < 0.01). **CONCLUSIONS:** This analysis is not a drug to drug comparison of value. Rather, it is a multi-disease and wellness measure of producing change in PCS and MCS either by spending on a specific health condition (e.g., cancer) or something other than health that optimizes PCS and MCS.

PHP59

IMPLEMENTATION OF HOSPITAL-BASED HEALTH TECHNOLOGY ASSESSMENT IN THE REPUBLIC OF KAZAKHSTAN (2 YEARS' EXPERIENCE)

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OBJECTIVES: to introduce the results of the first experience of Hospital-based Health Technology Assessment (HTA) in Kazakhstan. At the opening of new Hospital of the Medical Center of the President's Affairs Administration of the Republic of Kazakhstan (Hospital) in March 2015, Innovation Management Department (IMD) was established. One of the main functions of IMD is to evaluate clinical effectiveness, safety and economic effectiveness of new (innovative) health technologies, which are planned for implementing in Hospital practice. **METHODS:** IMD staff have the knowledges and skills in the field of HTA, including 1) the use of systematic search strategy; 2) analysis of reliable information from the evidence-based medicine databases; 3) clinical and economic analysis; 4) analysis of diagnosis-related groups. **RESULTS:** During the reporting period, IMD conducted activities such as: 1) Guideline for implementation of new technologies in Hospital

practice and System of staff motivation for implementation of new technologies were developed; 2) During the years 2015-2016 82 mini hospital-based HTA reports were done for opportunity to make informed managerial decisions about viability of implementing and using new health technologies in Hospital practice; 3) A database of health technologies was established for monitoring and analysis of effectiveness of using implemented technologies, and for development and improvement healthcare quality in Hospital; 4) 20 new health technologies were submitted for inclusion in the Guaranteed volume of free medical care formed by the Ministry of Healthcare. **CONCLUSIONS:** 1) Carrying out of Hospital-based HTA was the basis for making informed managerial decisions about viability of implementing and using new health technologies in Hospital practice; 2) Refusal of implementation of clinical and/or economical non effective health technologies is allowed to optimize Hospital's financial expenses and to fund the most clinical and economic effective health technologies; 3) We consider that the first experience of Hospital-based HTA in Kazakhstan is quite successful and effective.

PHP60

DIFFERENCES IN THE HUNGARIAN AND CHINESE HEALTH PROFILES

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OBJECTIVES: The aim of our study is to compare Hungary's and China's health profile and to have a full picture about their similarities and differences. **METHODS:** A quantitative descriptive study was carried out with document analysis. Data derived from the database of World Health Organization and from the year 2012-2013. The indicators are the following: (the number of live births/deaths, leading causes of death, health care expenditure, adult risk factors, drinking water supply, sewage rate). **RESULTS:** The proportion of people over 60 years is 24% in Hungary and 14% in China. There is a big difference in the proportion of urban population (HU: 70%, CN: 53%). The number of deaths per year is higher than the number of births per year factor in Hungary (death: 129.100/year, birth: 98.100/year). However there is a natural increase in China (death: 10,044,900, birth: 18,513,700). There is difference in the ratio of causes of deaths among under-five in 2013 - the maternal mortality (HU: 37%; CN: 16%) occurs more than congenital anomalies (HU: 29%; CN: 13%). In China, the births asphyxia ratio (CN: 15%; HU: 6%) and the acute respiratory infections are higher (CN: 14%; HU: 5%). The frequency of elevated BP (HU: 25.6-42.7%; CN: 23.7-29.8%) and obesity (HU: 20.4-26.2%; CN: 4.6-6.8%) are more important from adult risk factors than the others in Hungary. The leading cause of death in 2012 was stroke (2,331,300 death) in China and ischemic heart diseases (34,300 deaths) in Hungary. We found difference in the rate of health care spending per capita between China (> 600 USD) and Hungary (> 2000 USD). **CONCLUSIONS:** There are significant differences in the health profile of Hungary and China. However, higher expenditure in health care does not necessarily result in a better health status.

PHP61

REASON FOR CONCERN: GROWTH AND CHANGE IN COMMUNITIES SERVED BY THE 340B PROGRAM

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OBJECTIVES: The rapid growth of the 340B program has led to increased scrutiny by Congress, federal agencies, policy experts, and drug manufacturers, who have questioned the regulation and oversight of the program. A primary concern is how well the program targets medically needy patients, consistent with the intent of the law. Hospitals and their affiliated outpatient sites can charge full price for 340B drugs to commercially insured patients and retain the difference between the charged and discounted acquisition price, without further mandate on how profits are spent. We examine the growth and change in the socioeconomic profile of communities served by DSH, affiliated sites, and Federally Qualified Health Centers (FQHCs) participating in 340B over the last 23 years. **METHODS:** Location data for DSH, child sites, and FQHCs were extracted from the 340B program database and were linked to 2010-2014 socioeconomic data (latest available) from the American Community Survey by ZIP code. We used regression to examine the effect of time on ZIP code-level socioeconomic characteristics for the three facility types. **RESULTS:** About 92% of child sites were registered since 2012, an increase from 1,025 (by the end of 2011) to 15,021 (as of December 2016). Child sites registered since 2012 are in wealthier communities with lower unemployment and higher rates of private insurance, relative to the DSH themselves and communities whose facilities were registered between 1993-2011. Child sites registered since 2012 are also in communities that are significantly more advantaged than communities with FQHCs. **CONCLUSIONS:** Our findings are consistent with concerns cited by prior research and Congress that the growth in the 340B program is largely among facilities that may not be serving the vulnerable population for whom the program is intended to benefit.

PHP62

FACTORS MILITATING AGAINST EFFICIENT SUPPLY CHAIN MANAGEMENT OF MEDICINES FOR IMPROVED MEDICINES ACCESS AND HEALTH OUTCOMES IN NIGERIA

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OBJECTIVES: Access to affordable quality essential medicines in developing countries like Nigeria continues to be a challenge despite interventions by

relevant stakeholders. Inadequate management of the medicines supply chain is a major contributing factor. Hence, this study aims at identifying factors that may be militating against efficient supply chain management (SCM) of medicines in Nigeria. **METHODS:** A mixed methods approach was used to obtain data from logistics companies and pharmacists in Nigeria. Structured questionnaires were administered to logistics companies while in-depth interviews were conducted for pharmacists purposively selected to capture a diverse range of experiences, practice areas and opinions. Quantitative and qualitative data were analyzed using descriptive statistics and thematic analysis respectively. **RESULTS:** Logistics companies are not adequately equipped and no monitoring is in place to ensure that standards are set and followed. 84% of logistics companies had no set of standard operating procedures for medicines logistics. 37% are capable of providing cold chain logistics depending on the duration. 47% had no temperature monitoring devices. There was no form of regulation enforcing standards for medicines logistics, with implications for treatment failure. Pharmacists' views suggest that poor logistics and SCM practices, poor health statistics, weak regulation and policy implementation and lack of support for in-country medical logisticians are factors affecting efficient SCM of medicines. **CONCLUSIONS:** Factors militating against effective logistics and SCM of medicines were identified. Hence the need for establishing measures to improve the situation. Such measures may include more political will in implementing policies, financing SCM of medicines, building in-country skills and capacity in SCM of medicines, individualizing and segmenting medicines supply chains, and creating a regulatory body for certifying and professionalizing medical logistics companies, medical logisticians and supply chain managers in Nigeria, amongst others. These may lead to improved patient outcomes through better access to quality and affordable medicines

PHP63

THE DYNAMIC RELATIONSHIPS BETWEEN ECONOMIC INDICATORS AND PHYSICAL HEALTH MEASURES AMONG WORKING-AGE ADULTS IN THE UNITED STATES

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OBJECTIVES: To examine the dynamic relationships between various measures of economic status and physical health using a sample of working-age adults (18-64 years) in the US. The study examined the effect of positive and negative changes in economic status on health, and improvement and decline in health on economic status. **METHODS:** The study utilized a retrospective observational longitudinal design with repeated measures of economic indicators and health for a period of 14 years using 8 waves of the Panel Study of Income Dynamics: 1999, 2001, 2003, 2005, 2007, 2009, 2011, and 2013. Health measures were self-rated health (SRH) and functional limitations; economic indicators were family income, labor income and net wealth. Four approaches of panel models: 1) System-Generalized Method of Moment (system-GMM); 2) first-difference; 3) first-difference with instrumental variables (IV); 4) Lagged fixed effects; and two standard models: 1) ordinary least squares regression (OLS) and 2) IV OLS were used to evaluate the dynamic relationships between economic indicators and health measures. **RESULTS:** Standard models revealed significant positive relationships between all economic indicators and SRH and negative relationships between all economic indicators and functional limitations. System-GMM estimators revealed that SRH was positively associated with family income ($\beta=0.871$, $p < 0.05$), labor income ($\beta=0.868$, $p < 0.001$) and net wealth ($\beta=0.317$, $p < 0.001$). Nevertheless, only labor income ($\beta=-0.515$, $p < 0.001$) and net wealth ($\beta=-0.142$, $p < 0.05$) were negatively associated with functional limitations. SRH declined due to losses in family income; decreases in SRH resulted in losses in family income, labor income and net wealth. **CONCLUSIONS:** Our findings suggest the need for integrating the economic and health policies and programs to prevent the adverse effects on health whenever an individual experiences either a decline in economic status or decline in health.

PHP64

QUALITY OF PHARMACOLOGIC CARE BY PHYSICIANS, NURSE PRACTITIONERS AND PHYSICIAN ASSISTANTS IN THE UNITED STATES

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OBJECTIVES: Nurse practitioners (NPs) and physician assistants (PAs) have increasingly broad prescribing authority in the United States, yet little is known regarding whether they deliver the same quality of pharmacologic care as physicians. We sought to compare the quality of ambulatory pharmacologic care provided by NPs, PAs and physicians. **METHODS:** We used a serial cross-sectional analysis of 2006-2012 National Ambulatory Medical Care Survey (NAMCS) and National Hospital Ambulatory Medical Care Survey (NHAMCS) to examine ambulatory care services in physician offices, hospital emergency departments and outpatient departments. Participants included a nationally representative sample of patient visits to physicians, NPs and PAs and main outcome measures included thirteen validated outpatient quality indicators focused on pharmacological management of chronic diseases and appropriate medication use. **RESULTS:** A total of 701,499 sampled patient visits were included during the study period, which represented an estimated 8.33 billion visits nationwide. Physicians were the primary provider for 96.8% of all outpatient visits examined, while NPs and PAs each accounted for 1.6% of these visits. The proportion of eligible visits where quality standards were met ranged from 34.1% (angiotensin converting enzyme [ACE]-inhibitor use for congestive heart failure) to 89.5% (avoidance of inappropriate medications among elderly). The median

overall performance across all indicators was 58.7%. On unadjusted analyses, there were statistically significant differences in quality of care between non-physicians and physicians for each indicator. After adjustment for potentially confounding patient and provider characteristics, the quality of pharmacologic care delivered by non-physician providers was similar to the care delivered by physicians for ten of the thirteen indicators evaluated, and there was no consistent directional association between provider type and indicator fulfillment for the remaining measures. **CONCLUSIONS:** While there were significant shortfalls in the quality of ambulatory pharmacologic care among these visits, the quality of care delivered by non-physicians and physicians was generally comparable.

HEALTH CARE USE & POLICY STUDIES – Formulary Development

PHP65

THE 2017 US PAYOR LANDSCAPE: TRENDS AND RESULTS FROM SURVEYS OF MEDICAL AND PHARMACY DIRECTORS ON FORMULARY MANAGEMENT

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OBJECTIVES: To determine the types of approaches preferred by Medical and Pharmacy Directors (MDs+PDs) of US health plans, insurers, and pharmacy-benefit managers to enhance the P&T decision-making process and understand formulary reviews/coverage and changes from prior surveys. **METHODS:** Online survey sent to 459 US MDs+PDs on: advisor+plan information; formulary coverage and restrictions. **RESULTS:** The survey was completed by 52 MDs+PDs (11.3%); 55.8% were MDs and worked for: health plans/IDNs/PPOs/IPAs=57.7% ; PBM=9.6%; Government=3.8%; the remainder consultants. Advisors/plans could cover multiple member-types: Commercial (54.2%=FFS; 70.8%=HMO/PPO), Medicaid (Traditional=22.9%,HMO/PPO=62.5%);Medicare (66.7%;Traditional=22.9%; PDP-only=45.8%) and Employer/Self-funded lives=66.7%. Clinician-administered products were always covered under the medical-benefit (55.6%,previously 64.3%), 4.4% (previously 5.4%) exclusively under the pharmacy-benefit, the remaining 35.6% (previously 32.7%) benefit coverage was threshold/plan-design based, changes were: not anticipated (77.8%,previously 70.9%); expected by 12/17=4.4%; by 12/18=13.3%;or by 12/19=4.4%. Parity policies were in place for self-administered and clinician-administered agents for: no plans=33.3%; select-plans=28.2%; all-members=25.6%; members in mandated-states=10.3%; commercial plans=7.7%; Medicaid plans=7.7%.Mental health [MH] products were carved-out by 35.9 of plans (previously 25.9%), conditions with multiple MH-therapies required: generics-first (41.2%,previously 50%), step-therapy (41.2%,previously 31.5%) or psychiatrist/specialist care (17.6%,previously 18.5%). MH parity policies were in place for: All=62.5%;None=10%;Mandated-states=15%; Commercial-plans=15%;Select-plans=10%;Medicaid-plans=7.5%; Never heard of=7.5%. Respondents involved in decisions for: prescription-drugs (All=75.0%, Some=18.2%,None=6.8%) and Medical-devices (All=43.9%,Some=41.5%, None=14.6%). Budget impact models were used in 73.2% of pharmaceutical and 63.2% of medical-device reviews. Biosimilar use is expected for all reference-product indications (59.5%), while 31.0% will restrict biosimilars to approved indications (31.0%). Most respondents were happy with their medical-benefit, the most request change was moving all drugs to the pharmacy-benefit. Top concerns today and in the future included Oncology, Diabetes and Cardiovascular diseases. **CONCLUSIONS:** The managed care P&T Committee decision-making process is undergoing a series of changes. Medical and pharmacy directors, who commonly serve as P&T Committee members, have distinct opinions as to how to alter the process to adapt to these influences.

PHP66

THE MANAGEMENT OF SPECIALTY DRUGS, SPECIALTY PHARMACIES AND BIOSIMILAR DRUGS IN THE UNITED STATES

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OBJECTIVES: A better understanding of health-plan management of specialty pharmacy (SP), SP-products and biosimilars of SP-products. **METHODS:** Online survey sent to 459 US medical+pharmacy directors (MDs+PDs) on: advisor+plan information; specialty-pharmacies/pharmaceuticals, expected biosimilar coverage/restrictions/co-pays. **RESULTS:** The survey was completed by 52 MDs+PDs (11.3%): 55.8% were MDs and worked for: health plans/IDNs/PPOs/IPAs=57.7%; PBM=9.6%; Government=3.8%; the remainder consultants. Plans were National=41.9%;Regional=34.9%;or Local=23.3%. 51% restrict Specialty Providers (SPs). SPs were: PBM-owned 45.7%; 34.8% owned by the healthplan; 17.4% independent; 10.9% hospital/IDN-owned. 65.9% of plans restricted SPs to those under contract; 6.8% only restricted SPs available through multiple SPs; 6.8% allowed any SP handling the agent. Specialty product co-pays continue to move from fixed to percentage with more plans using group+benefit design to determine the co-pay. Plans covered clinician-administered products under the medical-benefit (MB=15.2%, previously 64.3%); under the pharmacy-benefit (PB=67.4%, previously 5.4%); the remainder varied based on price and plan-design and 89.1% do not expect this to change. Biosimilar use is expected for all reference-product indications (59.5%), while 31.0% will restrict to their approved indications (31.0%). Plans expect biosimilar co-pays to be indication-based (9.5%), discounted off the innovator (45.2%); to vary based on the approval timing (33.3%) or be the only product available (21.4%). Member+provider biosimilar education will be provided through: different co-pays=68.3%; prescriber-mailings=63.4%;

patient-mailings=53.7%; prescriber-calls=39.0%; and patient-calls=19.5%. Biosimilars savings are expected to be: <10% in 2017 (52.4%); 60.5% expect 10-20% by 2020; and 61.9% expect >20% by 2025. **CONCLUSIONS:** Costs associated with specialty pharmacies/pharmacy products have shifted and are expected to grow and require appropriate coverage. The switch from the medical benefit to the pharmacy benefit for oral biologics and self-injected agents represents a significant change as SP management has grown. Biosimilars are expected to provide some cost growth relief but only over after the introduction of more than 2 competitive Biosimilars.

PHP67

A REVIEW OF PUBLIC COVERAGE OF CDR REVIEWED DRUGS

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OBJECTIVES: This PMPRB study analyzes the coverage of drugs reviewed by the CDR across Canadian public drug plans, and examines both the number of drugs and the extent of reimbursement. **METHODS:** The drugs reviewed by the CDR from December 2003 through June 2015, along with their listings as of December 2015, were obtained from IMS Brogan's iMAM and public formularies. The sales data for 2015 was retrieved from the IMS Brogan Private Drug Plan and IMS AG MIDAS™ databases. The coverage rates for 10 provincial drug plans and the NIHB were calculated as simple and weighted percentages of all select drugs. The analysis also includes an inter-jurisdictional comparison using simple agreement descriptive statistics. **RESULTS:** The CDR issued positive recommendations for 55% of the analyzed drugs, with provinces following the CDR recommendation in 78% of the cases. With sales weighting, most provinces listed all major drugs. An inter-jurisdictional comparison of all CDR drugs indicates medium to high rates of coverage agreement, ranging from 50% to 86% across all pairs of the public drug plans. When weighted by sales, the percentage of coverage agreements notably increases. **CONCLUSIONS:** The study results suggest a relatively high coverage and inter-jurisdictional agreement of the CDR drugs, and highlights differences across public drug plans. These findings are expected to inform policy discussions around a national formulary.

HEALTH CARE USE & POLICY STUDIES – Health Care Costs & Management

PHP68

ESTIMATING THE STATE BURDEN OF MENTAL DISORDERS IN THE US OVER NEXT 15 YEARS USING A MICROSIMULATION MODEL

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OBJECTIVES: Mental disorders have become the most costly health conditions in the United States. The aim of this study is to estimate the health and financial burdens of five major mental disorders to each of 50 US state governments, through 2030, and quantify the potential benefits from improvements in treatment coverage and medical advancements. **METHODS:** We identified three target population cohorts—state employees, Medicaid beneficiaries and state inmates—from a baseline population synthesized from National Health and Nutrition Examination Survey, American Community Survey, Behavioral Risk Factor Surveillance System, and National Nursing Home Survey data. A published Markov-based microsimulation model was used to simulate the prevalence, incidence, progression, and potential treatment effects of depression, bipolar, schizophrenia, anxiety disorder and Alzheimer's disease at the individual level. The baseline scenario assumes current population behavior and treatment states continue into the future, while an 'improvement' scenario assumes higher treatment adherence, timely diagnosis, insurance coverage expansion, better life style plus certain treatment advances. **RESULTS:** The burden to state governments' spending varies depending on the size of its covered cohorts, prevalence of mental disorders and population health profile of each specific state. Using Ohio for illustration, if current trends continue, mental disorders will result in \$14 billion in medical expenditures and \$371 million of indirect costs annually. Approximately 911,000 people will have at least 1 of the listed mental conditions. By 2030, it will cost each state resident on average \$1,200 in health expenditures to treat the target populations. The modeled 'improvement' scenario could reduce mortality by 165,000 and generate \$25 billion in medical savings cumulative through 2030. **CONCLUSIONS:** Mental disorders impose substantial financial costs to state governments. Efforts to expand mental health coverage and improve treatment could effectively reduce the future burden of mental disorders.

PHP70

COST ANALYSIS OF HEALTH EXPENDITURES ASSOCIATED WITH DEPRESSION AMONG INDIVIDUALS WITH DIABETES

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OBJECTIVES: Diabetes is still one of the serious and expensive health problems in the US and often associated with comorbidities. Compared with the general population, individuals diagnosed with diabetes are 60% more likely to be diagnosed with depression. The goal of this study is to conduct cost analysis estimating excess health care expenditures associated with depression among adults with diabetes by comparing them to those with diabetes and without depression. **METHODS:** In this cross-sectional study, the 2013 Medical Expenditure Panel Survey (MEPS) was used to analyze data on 2,771 adults with diabetes. Individuals with depression were identified using ICD-9-CM and clinical classification codes. Adjusted mean direct health care utilization and expenditures

associated with ambulatory visits, emergency department visits and prescription drugs per person in 2013 were estimated using analysis of covariance after adjusting for age, gender, race/ethnicity and number of comorbidities. **RESULTS:** Out of 2,771 individuals with diabetes, approximately 16% (N=443) had depression. Adjusted mean health care utilization analysis showed that depressed adults with diabetes had more ambulatory visits (10 vs 6) and used more number of prescription medications (47 vs 22) as compared to non-depressed individuals. Unadjusted mean expenditures for diabetic individuals with depression were \$11,572 relative to \$8,576 for no depression. After controlling for demographic and number of comorbidity covariates, it was found that an individual with diabetes and depression had significantly greater annual mean health care expenditure of \$4,192 compared to that of \$2,012 for an individual with diabetes but no depression. Expenses related to ambulatory visits (\$1,415 vs \$1,041) and prescription medications (\$2,769 vs \$968) found to be major contributing factors in excess health care expenditure associated with comorbid depression. **CONCLUSIONS:** Depression is a significant contributor to the economic burden among individuals with diabetes, such incremental expenditures can be due to increased health care utilization.

PHP71

PREVALENCE AND PREDICTORS OF PRIMARY NONADHERENCE TO CHRONIC DISEASE MEDICATIONS AMONG THE ELDERLY

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OBJECTIVES: Previous work on primary nonadherence has used a wide range of follow-up periods from 30 days up to 18 months, making results difficult to compare. We sought to evaluate primary nonadherence by measuring time until filling in a cohort of elderly patients. **METHODS:** Data comes from a linked database of electronic health records (EHR) and claims for patients aged ≥ 65 years enrolled in Medicare Parts A/B/D. From these data, we identified patients receiving a new prescription for a chronic disease medication. We then followed patients for a fill of the index prescription for one year. Cox models were used to assess differences in time until filling across patient and therapeutic characteristics. **RESULTS:** In 28,770 new medication orders, the majority (58%) were filled within 1 day, 81% were filled within 30 days, and 93% were filled by the end of one year. The rate and timing of filling was similar across therapeutic areas except for insulin, where filling rates were much lower. Within therapeutic areas, time until filling was generally similar across medication classes. Prescriptions with supply > 30 days had a 13% (11%-15%) lower rate of filling than prescriptions with supply < 30 days. Patients with increasing numbers of current medications were much more likely to fill their new prescription. Patients with 3-4 medications had a 71% (65%-77%) higher rate of filling than patients with 2 or fewer medications. Patients with 5-7 medications had twice the rate of filling (HR: 2.06 [1.99-2.14]), and patients with more than 7 current medications had 2.4 (2.3-2.5) times the rate of filling. **CONCLUSIONS:** With the exception of insulin, rates of primary nonadherence were low, and the majority of prescriptions were filled quickly. Focusing interventions on patients with few current medications or those initiating specific medications, such as insulin, may be a promising approach to improve medication adherence.

PHP72

ASSESSING TRENDS IN PHARMACY COST IN SUPER-UTILIZERS AND HIGH-COST PATIENTS IN THE U.S. FROM 1996 THROUGH 2013: EVIDENCE FROM MEDICAL EXPENDITURE PANEL SURVEY DATA

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OBJECTIVES: To analyze trends in pharmacy costs among super-utilizers and very high-cost non-institutionalized U.S. patients. **METHODS:** This was a retrospective analysis using Medical Expenditure Panel Surveys (MEPS) administered by Agency for Healthcare Research and Quality (AHRQ). MEPS data from 1996 through 2013 were used to construct the top 1% of the costliest patient cohorts. Super-utilizers were defined according to AHRQ definition: Medicare or Medicaid patients with four or more hospitalizations per year; or, privately insured patients with three or more hospital admissions per year. Healthcare costs were inflated to 2013 prices. Multivariate quantile regression was used to estimate pharmacy cost for the top 1%, and generalized linear modeling (GLM) was used to estimate mean pharmacy cost for super-utilizers. **RESULTS:** The share of top 1% of the costliest patients steadily grew from 0.73% of the U.S. population to 1.35% (~4.26 million) during the study period. The average age for these patients varied between 51 and 56 during the study period. Mean pharmacy cost rose from \$2,275 in 1996 to a high of \$16,831 in 2011, then declined to \$11,962 in 2013. Mean out-of-pocket pharmacy cost during this period rose from \$676 to a high of \$2,122 in 2004, and then declined to \$743 in 2013. For super-utilizers, mean pharmacy cost rose from \$2,618 to a high of \$6,901 in 2007 and then declined to \$5279 in 2013. Mean out-of-pocket pharmacy cost for super-utilizers started with \$930 in 1996, peaking to \$1,720 in 2003 then declined to \$677 in 2013. Both quantile regression of pharmacy costs for the top 1% and the GLM regression for super-utilizers confirm these descriptive findings. **CONCLUSIONS:** Mean pharmacy cost increased by 425% for the top 1% of the high-cost patients in the U.S. while it rose by 102% for the super-utilizers during the study period.

PHP73

ECONOMIC BENEFIT OF PROCESS OPTIMIZING IN BLOOD COLLECTION CENTER WITH LEAN SIX SIGMA APPROACH

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OBJECTIVES: Patients at Zhongshan Hospital have complained a lot about the long waiting time and crowded environment of out-patient blood collection center for years. To improve the total efficiency and reduce non-value-added cost, the blood collection center launched a process optimization project with consultancy support from Becton, Dickinson Company during March to July in 2016. **METHODS:** Lean Six Sigma methodologies are used in this project. Process map and spaghetti diagram are used to understand current work flow and patient traveling flow. Data of patient distribution by time, average patient waiting time and per capita blood collection time were collected from LIS (laboratory information system). The cause of prolonged waiting time was analyzed using Ishikawa diagram. The failure mode and effects analysis (FEMA) was applied and 9 root of cause were identified. 5S tools were also used to make an organized environment. Improvement actions were taken in 3 areas: environment and layout, patient education, shift and duty arrangements of staff. The outcome was quantified to evaluate economic impact on the organization. **RESULTS:** With an investment of \$58 (\$580 in total, 10 years straight-line depreciation), the average patient waiting time dropped from 14.5 to 9 minutes and the per capita blood-collecting time dropped from 1.4 to 1.31 minutes. Due to the work efficiency improvement, we were able to save the workload by 1.5 man-year, which equals to a labor cost saving of \$24,710 annually. The rejecting rate of blood samples dropped from 0.0421% to 0.0245%, results in a cost saving of \$4,166. In total, the net benefit of the project was \$28,876 per year. At the same time, patient satisfaction rating increased from 4.59 to 4.97 as a result of improved waiting environment and shorter waiting time. **CONCLUSIONS:** Hospital can economically benefit from Lean Six Sigma project through efficiency improvement and reduction of unqualified blood samples.

PHP74

COST DRIVERS IN PUBLIC DRUG PLANS IN CANADA, 2015/16 - COMPASSRX

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OBJECTIVES: After several years of low or negative growth, drug expenditures in public drug plans increased sharply by 12.2% in 2015/16. The 3rd edition of the CompassRx provides insight into the factors that contributed to this remarkable growth in cost. **METHODS:** The analysis uses claims-level public drug plan data from the Canadian Institute for Health Information's NPDUIS Database for the 2011/12 to 2015/16 fiscal years. A sophisticated cost-driver model isolates the key factors contributing to changes in drug and dispensing costs: the mix of drugs, drug prices, dispensing fees, the volume of drugs, and changes in the demographic profile of the beneficiaries. **RESULTS:** The striking growth in drug costs in 2015/16 was due to the combined effect of limited generic savings and an increased use of high-cost drugs. The hepatitis C drugs Harvoni, Sovaldi and Hologic alone contributed 7.3% toward this increase in growth, while other high-cost drugs continued to put pressure on costs. The generic drug use and lower prices, which markedly pulled down drug costs in recent years, had a diminished cost saving impact from -9.2% in 2012/13 to -4.1% in 2015/16 and was no longer able to offset the effect of higher-cost drugs. **CONCLUSIONS:** A greater understanding of the forces driving expenditures in Canadian public drug plans will inform policy and stakeholder discussions and aid in anticipating, managing and responding to evolving cost pressures.

PHP75

AN EVALUATION OF INJECTABLE DRUG PRICES DURING TIMES OF SHORTAGE IN THE UNITED STATES

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OBJECTIVES: To examine trends in drug prices for injectable products listed on the American Society of Health-system Pharmacists (ASHP) drug shortage list. **METHODS:** Medications were identified using the American Society of Health-Systems Pharmacists Current Drug Shortages list and if the shortage limited supply to a large academic medical center in the US. National Drug Codes (NDCs) for affected and available products were retrieved from the ASHP Current Drug Shortages updates pages. Wholesale acquisition cost (WAC) and historical average whole sale prices (AWP) price for each NDC was obtained from Red Book. Price changes were based on the defined daily dose (DDD). A WAC per DDD (or alternate dose) was calculated for each NDC and changes in AWP between January 1, 2015 and March 22, 2016 were identified. **RESULTS:** There were 25 drug products identified with cost data for 454 NDCs. The WAC per DDD ranged from \$1.23 to \$234.60 for the 207 medications on shortage and from \$1.40 to \$139.09 for the 247 available products. Seventy-five of 454 NDCs (16.5%) had price changes in 2015 or 2016 (38 products on shortage and 37 products without shortages). Changes in price ranged from decreases of 87.5% to increases of 197.6% with the majority (87%) of products having an increase in AWP. Increases greater than 50% in AWP were observed in 9 drugs on the shortage list but only two products widely available. **CONCLUSIONS:** Injectable medication prices appeared to be unaffected by drug shortage status. Few products experienced decreases in AWP or increases greater than 50% while on the drug shortage list. Further research is needed to identify other factors associated with drug price changes.

PHP76

REDUCING OUT-OF-POCKET COST BARRIERS TO SPECIALTY DRUG USE UNDER MEDICARE PART D: ADDRESSING THE PROBLEM OF "TOO MUCH TOO SOON"

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OBJECTIVES: Medicare Part D specialty drug users who do not qualify for low-income subsidies (non-LIS beneficiaries) face high and variable cost sharing during the calendar year. We examined their out-of-pocket (OOP) cost patterns under the existing Part D cost-sharing policies and under proposed changes to these policies. **METHODS:** Using 2012 100% Medicare claims data, we examined mean annual and monthly OOP drug costs for Medicare Part D patients who were full-year users of Part D specialty drugs for rheumatoid arthritis (RA, n=1,063), multiple sclerosis (MS, n=2,256), or chronic myeloid leukemia (CML, n=1,135) under existing policy. Using the same data, we simulated costs under both proposed MedPAC policy recommendations and our own recommendations. **RESULTS:** In 2012, our sample faced mean annual cumulative OOP drug costs (for all medications) of \$3,949 (RA), \$5,238 (MS), and \$6,322 (CML). Mean OOP costs were \$977 (RA), \$1,613 (MS), and \$2,456 (CML) in January alone. A substantial proportion of total annual OOP prescription spending also occurred during the catastrophic coverage phase (RA=\$1,229 [31%], MS=\$2,456 [47%], CML=\$3,546 [56%]). Under proposed MedPAC changes, patients would have faced maximum annual OOP spending of \$4,700, but mean OOP costs in January and February would have been higher compared to existing policy. Under our proposed strategy, OOP costs would have been spread evenly over 12 months (\leq \$392 per month). The potential incremental costs of our proposed strategy would have been \$23.55 per non-LIS Part D beneficiary per year. **CONCLUSIONS:** The existing Part D cost-sharing structure creates substantial financial burden for specialty drug users, especially early in the year. Implementing both annual and monthly OOP maximum spending limits would result in lower, more consistent OOP costs, potentially increasing patients' ability to access treatments for life-threatening, chronic, and rare diseases.

PHP77

LATE-TO-REFILL REMINDER CALLS HAVE GREATER IMPACT ON MEDICATION ADHERENCE IN MEDICARE PART D PATIENTS WITH A 90-DAY FILL

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OBJECTIVES: To study whether late-to-refill reminder calls (LTR) from pharmacists are more effective on medication adherence, in patients with 90-day fill than patients with 30-day fill, within Medicare Part D (Med D) population. **METHODS:** A total of 735,218 Med D patients who were 3 days late for their refills at Walgreens retail pharmacy in January 2015 were randomized into an intervention group to receive LTR reminder calls or a control group. Patients were categorized into two subgroups based on days of supply for prescription that triggered LTR: 30-day (28-34 day supply) subgroup (n=395,560) and 90-day (84-100 day supply) subgroup (n=288,211); patients with other days of supply were excluded. We compared the LTR effect on medication adherence for the 90-day subgroup to the 30-day subgroup. Within each subgroup, the LTR effect is measured as the difference in medication adherence between the intervention and control group. Medication adherence was measured as Proportion Days Covered (PDC) and the percent of patients with optimal adherence (OA) PDC \geq 80% over a 365-day period. Difference-in-difference regressions and t-tests were used to test differences. **RESULTS:** The LTR effect on average PDC is significantly higher by 1.1 percentage points (67.0% vs. 65.9%) for the 90-day subgroup and 0.8 percentage points (49.7% vs. 49.0%) for the 30-day subgroup. The LTR effect on proportion of OA patients is significantly higher by 1.5 percentage points (45.9% vs. 43.4%) for the 90-day subgroup and 0.6 percentage points (28.1% vs. 27.5%) for the 30-day subgroup. The LTR effect on average PDC and proportion of OA patients for the 90-day subgroup was significantly greater than the 30-day subgroup by 0.3 and 0.9 percentage points respectively. **CONCLUSIONS:** Pharmacists initiated late-to-refill reminder calls had a greater impact on adherence in Medicare Part D patients with 90-day fills than 30-day fills.

PHP78

RISK SCORE, COST & UTILIZATION IN THE HEALTH INSURANCE EXCHANGE POPULATION: OPEN ENROLLMENT VS. SPECIAL ENROLLMENT PERIODS

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OBJECTIVES: To examine differences in risk scores, cost and utilization between Affordable Care Act (ACA) health insurance exchange plan members enrolled during open enrollment period (OEP) to those who enrolled during a special enrollment period (SEP). **METHODS:** This study used claims data from ACA plans from January-September 2015. Descriptive analyses were conducted to examine differences in risk scores, per member per month cost, and health care utilization between members enrolled during OEP compared to SEP. The sample consisted of 1.7 million enrollees (11% SEP). **RESULTS:** Average risk scores were 20% (1.12 vs. 1.40) lower in SEP versus OEP enrollees. Cost was 5% (\$407 vs. \$398) higher in SEP. The ratio of cost to risk score (cost-risk ratio) was 31% (\$363 vs. \$278) higher in SEP enrollees. This pattern was consistent across metal levels, except for Catastrophic. The high cost of SEP enrollees were driven by hospitalizations (45% higher) and emergency room visits (24% higher). Rates of primary care visits and prescription drug fills were lower in SEP enrollees. Discontinued enrollees had a slightly higher cost-risk ratio for both OEP (\$282 vs. \$277) and SEP (\$383 vs. \$361) than those with continuous enrollment. Across the OEP (January-March), the cost-risk ratio was 6% lower for members enrolled in February. Cost-risk ratio was steadily increasing from \$321 for members enrolled in April to \$516 for those enrolled in September. The increase was mainly due to a 46% increase in hospitalizations. **CONCLUSIONS:** Members who enrolled in on-exchange plans during a SEP had higher cost, yet lower risk scores on average compared to those who enrolled during OEP. The difference in cost-risk ratio was driven more by month of enrollment

and less influenced by month of disenrollment. During the SEP, cost-risk ratios steadily increased for members who enrolled closer to the end of the benefit year.

PHP79

PRICE TRAJECTORIES ASSESSMENT FOR INJECTABLE MEDICARE PART B GENERIC DRUGS

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OBJECTIVES: To assess price changes with time following launch for Medicare part B injectable, generic drugs and to understand how drug characteristics influence price trajectories. **METHODS:** We included all Medicare part B drugs that were reported in both 2006 and 2016. Vaccines, biologics, oral agents and inhalers were excluded. Patent expiration dates were attached using the Medicare Drug Patent Expiration engine and drugs with a patent expiration date later than 2006 were removed. We used the Anatomical Therapeutic Chemical (ACT) code for each drug to identify an indication. For each drug we extracted the Average Sales Price (ASP) history from October 2006 to October 2016, published by the Center for Medicare and Medicaid services (CMS). US inflation rates were obtained from the United States Department of Labor, and prices were adjusted for inflation. For each drug we calculated the cumulative ASP change during the follow-up period. Data was analyzed using IBM SPSS Statistics software. **RESULTS:** We identified 166 injectable, generic drugs that fulfilled our inclusion and exclusion criteria. During our follow-up period 56 (34%) drugs had increases in price of more than 100% and 13 (8%) had increases of more than 1000%. The most common indications in the group of drugs with price increases were nervous system (25%) and anti-infectives (14%). When analyzing the price trajectory of the top increasing drugs, we found both gradual price increases and price hikes. There was no association between drug indications and price trajectory patterns. **CONCLUSIONS:** Generic drug costs may change substantially throughout time. Gradual price increases or acute price hikes may be due to the lack of generic substitution in the market or competitor substitution shortages due to quality, production and marketing reasons. New regulations may be needed to prevent further increases in generic drug costs.

PHP80

BURDEN OF COST OF ADVERSE DRUG REACTION IN PSYCHIATRIC PATIENT—AN ACTIVE SURVEILLANCE FROM A DEVELOPING COUNTRY

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OBJECTIVES: To determine the incidence and estimate the direct cost incurred for the management of adverse drug reaction in ambulatory psychiatric patients **METHODS:** This prospective active surveillance pharmacovigilance study carried out over a period of two year. Patients of any age presented with psychiatric illness receiving at least one psychotropic agent were included. Economic burden associated with the management of ADRs was calculated by considering the cost of medications, medical devices, bed charges, laboratory investigations charges and other relevant charges. **RESULTS:** Of the total 1913 patients observed, 763 were identified with 1058 ADR, which translates to an ADR rate of 39.8%. The average number of ADRs in a patient was 1.3 (range 1 to 8). Majority of ADRs were observed in females [n=456 (59.7%)], patients receiving 3-4 drugs [n=323 (42.3%)], and in patient with co-morbid medical condition [n=386 (50.5%)]. Of the total ADRs, 27.9% of the ADR resulted in economic burden to patients. Total direct cost incurred in the management of 296 ADRs was INR 144731.00 (2,125.00 USD). Average cost incurred per ADR was INR 488.95 (7.17USD) [range: INR 10 (0.14USD) to INR 7846 (115.2 USD)]. Bed charge [INR 75460.00 (1108.11 USD)] and other charges [INR 3430.00 50.36USD] were observed as the highest and lowest burden of cost to the patient. The average cost incurred in the management of 'mild', 'moderate' and 'severe' reactions were INR 166.6 (2.44 USD), INR 427.47 (6.27USD) and INR 5280(77.54 USD) respectively. **CONCLUSIONS:** In our study Adverse drug reactions added an economic burden in patients. Educating the patient and the care giver for early detection and management of ADRs may give a more favorable outcome in psychiatric practice.

PHP81

RETROSPECTIVE DATABASE ANALYSIS OF HOSPITAL LENGTH OF STAY (LOS) AND COST PER HOSPITAL DAY IN PATIENTS UNDERGOING COMMON SURGICAL PROCEDURES IN THE UNITED STATES

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OBJECTIVES: Hospital length of stay (LOS) is an important contributor to healthcare costs in surgical patients, but surgery-specific estimates of daily costs are lacking. We aimed to describe hospital LOS and cost per day in patients undergoing inpatient surgical procedures. **METHODS:** This study evaluated data available via the Premier Perspective® Database which includes administrative data from more than 600 hospitals in the United States. Data on discharges from 10/1/2014 to 9/30/15 with a primary ICD-9 procedure code for one of the 10 most common surgical procedures performed in adults (total knee and hip replacement; laparoscopic cholecystectomy and appendectomy; cervical fusion; open fracture reduction of the femur and tibia/fibula; lumbar/sacral fusion; total abdominal hysterectomy; and excisional wound/burn debridement) were included. Maternal or neonatal hospitalizations and those with any intensive care unit stay were excluded. Outcomes included LOS, total and daily hospitalization costs, and total and daily room and board costs by surgical procedure. All outcomes were summarized descriptively using means and standard

deviations. **RESULTS:** A total of 307,236 hospital discharges of interest occurred during the study period. Of these, one third were total knee replacements, with a mean length of stay of 2.7 days, room and board cost of \$677 per day, and total costs of \$4808/day. Mean LOS was shortest for cervical fusion (1.9 days) and longest for excisional wound/burn debridement (7.1 days). Cost per hospital day was highest for cervical fusion (room and board \$594/day; total \$6860/day) and lowest for excisional wound/burn debridement (room and board \$793/day; total \$1883/day). **CONCLUSIONS:** tal cost per hospital day varied over 3-fold among the 10 most common surgeries performed in US hospitals, likely reflecting the acuity of the patient population and surgery. Shortening LOS by one full day could reduce room and board costs by \$594 to \$793.

PHP82

COST-UTILITY OF BLISTER VERSUS BULK PACKAGING ALL MEDICATIONS FOR VETERANS WITH POST-TRAUMATIC STRESS DISORDER, BIPOLAR AFFECTIVE DISORDER, MAJOR AFFECTIVE DISORDER OR SCHIZOPHRENIA: RESULTS OF A PRAGMATIC RANDOMIZED TRIAL

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OBJECTIVES: To estimate the cost-utility of blister versus bulk packaging of all prescribed medications for 303 Veterans with post-traumatic stress disorder, major affective disorder, bipolar affective disorder, and/or schizophrenia during a 12-month pragmatic randomized trial in Denver, Colorado, 2012-2014 (NCT01118208). **METHODS:** The perspective is that of the US Department of Veterans Health Affairs. Quality adjusted life years (QALYs) were calculated as the area under the SF-6D curve as derived from baseline and monthly SF-36 assessments for 243 subjects (80.2%) who completed at least 2 assessments. The intervention was expected to improve adherence to prescriptions for indications beyond the eligibility criteria. Therefore, all VA utilization and costs were extracted from the VA Corporate Data Warehouse for the intervention period and expressed in 2012 dollars. Costs were estimated at \$0.46 - \$0.52 per blister card per 30 - 90 day prescription and \$0.02 per bottle per prescription. Labor to fill blister cards was estimated at 10 - 15% more. The incremental cost effectiveness ratio (ICER) was calculated. **RESULTS:** The ICER point estimate was negative and blister packaging dominant, with both lower mean total costs (\$19,170 vs \$21,113) and higher mean QALYs (0.59 versus 0.58). Next steps include bootstrap replications and net benefit calculations to ascertain confidence in this point estimate. **CONCLUSIONS:** In this group of 236 Veterans, the point estimate suggests that blister packaging all prescription medications is both less expensive and produces higher quality of life than dispensing in bottles. **LIMITATIONS:** Blister packaging costs are based on cold seal and small-scale production and are likely higher than would be expected with mass production technologies and economics of scale. Medications filled outside of the VA system were not observed.

PHP83

TRENDS IN PRICES OF NEW SYSTEMIC ANTIBIOTICS APPROVED BY THE FDA (1999-2016)

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OBJECTIVES: Antibiotic resistance is considered a main public health concern. The price of new antibiotics must be sufficient to recover the investment. This study assessed trends in the cost per course of therapy of new systemic antibiotics approved by the FDA in the period 1999-2016. **METHODS:** A list of new antibiotics marketed in the US in the period 1999-2016 was extracted from the FDA webpage. Average wholesale prices (AWP) were extracted from the RedBook (Truven Health). Daily doses and duration of the treatment were extracted from the FDA-approved label. The AWP cost per course of antibiotic drug therapy were calculated. Prices were adjusted by the consumer price index to 2016 dollars. The compound annual growth rate (CAGR) was calculated for each price from market entry to December 31, 2016. Descriptive analysis were done in the study using Excel 2013. **RESULTS:** The FDA approved a total of 19 new systemic antibiotics in the period 1999-2016. The antibiotics had an average±standard deviation of 3.0±2.1 indications (range 1-8). Price information was available for all drugs with the exception of obiltoximab (2016). The cost of a course of drug therapy at market entry varied by drug, indication and population subgroup. The median cost per course of drug therapy was \$1,305.64. Gatifloxacin had the lowest CPI-adjusted cost per course of drug therapy at market entry (\$50.09 in 1999) and avibactam/ceftazidime had the highest cost (range: \$1,801.10-\$5,043.08 in 2015). The median cost of a course of drug therapy at market entry was \$136.41 (range: \$50.09-\$1,639.74) in the period 1999-2004, and \$1,703.81 (\$538.75-\$5,401.45) in the period 2005-2016. The CPI-adjusted median AWRP CARG was 6.91%. **CONCLUSIONS:** Prices of antibiotics at market entry increased during the study period. The prices of the marketed antibiotics also increased faster than the inflation.

PHP84

DISCHARGE DESTINATION AFTER TOTAL JOINT ARTHROPLASTY AND POST-ACUTE CARE COSTS

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OBJECTIVES: Post-acute care accounts for substantial amount of 90-day episode costs after joint replacement of the lower extremity. This study evaluated the impact of the

first discharge destination on costs within 90-days of hospital discharge after primary total knee arthroplasty (TKA) or total hip arthroplasty (THA). **METHODS:** This retrospective cohort study included health care claims from the Centers for Medicare and Medicaid Services Standard Analytic Files, limited data sets (LDS). Patients aged 65 or older who had an inpatient TKA or THA between January 1, 2012 and October 1, 2014 were included. Patients' discharge status (to home with or without home care versus skilled nursing facility) was the primary exposure variable and post-acute care costs was the outcome of interest. A multivariable linear regression model was used to estimate post-acute costs after adjusting for patient demographic and clinical characteristics, type of surgery (TKA vs THA), and the costs of index surgery. **RESULTS:** A total of 881,197 patients with total joint arthroplasty were identified. Of these, 37.1% were 75 years of age or older, 63.9% were women and 66.4% had TKA. The average Charlson comorbidity index of the population was 0.71. Most patients were in the South (36.7%) followed by Midwest (28.4%), West (18.5%) and Northeast (16.4%) regions. More than half of the patients (57.2%) were discharged home after their index surgery. Total post-acute costs were \$9,400 lower (\$3,975 vs \$13,375, P<0.0001) for patients discharged home versus other settings of care. **CONCLUSIONS:** Costs for Medicare patients discharged directly to home (with or without home care) were 70% lower compared to those for patients discharged to other settings. Further work is required to determine the extent to which social, economic, and clinical factors allow for safe discharge home after joint replacement.

PHP85

COST-EFFECTIVENESS OF THE INITIAL TREATMENT OF VENOUS THROMBOEMBOLISM FROM THE BRAZILIAN PRIVATE HEALTHCARE SYSTEM PERSPECTIVE

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OBJECTIVES: To assess the cost-effectiveness of apixaban versus other anticoagulants in the initial treatment of venous thromboembolism (VTE) from the Brazilian Private Healthcare System (PHS) perspective. **METHODS:** An economic evaluation of apixaban versus other anticoagulants (dabigatran, rivaroxaban and standard of care (SOC) - enoxaparin and warfarin) was performed using a Markov-associated decision tree model that accompanied patients with VTE over a 5-year time horizon. For all comparators, a single treatment of 6 months was considered. The clinical and economic outcomes considered were, respectively, life years saved (LY) and medical direct costs. An annual discount rate of 5% was considered for the latter. A probabilistic sensitivity analysis (PSA) was also performed, considering variations in efficacy, risks of long-term events and costs. The cost-effectiveness acceptability curve ranged from BRL 0 to 100,000. **RESULTS:** Total costs of dabigatran, rivaroxaban, apixaban and SOC were, respectively, BRL 2437, BRL 1464, BRL 1427 and BRL 684, with effectiveness of 4.45 LY for all treatments. In the PSA, the efficiency of all treatments had little variation because of the low incidence of thromboembolic events or bleeding. The acceptability curve indicated a 100%, 70% and 0% probability in apixaban to be more cost-effective versus dabigatran, rivaroxaban and SOC, respectively, regardless of willingness to pay. **CONCLUSIONS:** It was possible to observe similar efficacy among all comparators, with apixaban being the treatment with the lowest cost, that is, more efficient compared to dabigatran and rivaroxaban, but not to SOC, in the treatment of VTE in the Brazilian PHS.

PHP86

CONTRASTING NON-EMERGENT CARE DELIVERED IN EMERGENCY DEPARTMENTS AND URGENT CARE CENTERS TO ARKANSAS MEDICAID AND PRIVATE OPTION ENROLLEES

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OBJECTIVES: Urgent care centers (UCC) are alternatives to care delivered at emergency departments (ED) that might reduce health expenditures for non-emergent care. As part of the Affordable Care Act, Arkansas expanded coverage to poor and near poor individuals by purchasing qualified health plan (QHP) coverage for non-frail persons with incomes between 17-138% of FPL instead of traditional fee for service Medicaid. This study compared the utilization and costs of UCC and ED services in traditional Medicaid FFS and QHP and assesses the geographic variation. **METHODS:** Non-institutionalized newly enrolled individuals 19-64 years of age in 2014 with 180 days or more of continuous enrollment in either Medicaid or commercial plan were analyzed. ED and UCC visits were classified as emergent, non-emergent and unmeasurable using the NYU ED algorithm. The per visit costs and geographical distribution across 7 health insurance regions of the state were analyzed for non-emergent UCC visits and compared with non-emergent ED visits. **RESULTS:** There were a total of 11.35 UCC and 782.25 ED visits per 1000-person years for QHP recipients of which 67.36% and 25.75% were for non-emergent care respectively. There were 1309.64 ED visits per 1000-person years (45.16% for non-emergent care) and virtually no UCC visits for traditional Medicaid recipients. The average costs for non-emergent UCC visits for QHP was \$136 compared to \$531 for non-emergent care delivered in the ED for QHP compared to \$169 for non-emergent ED care in traditional Medicaid. The Central metropolitan region had the highest rate of non-emergent UCC visits (10.91 per 1000 person years) compared to the West Central rural region (0.91 per 1000 person years). **CONCLUSIONS:** There is considerable ED utilization for non-emergent care and significant cost savings could be realized if this care is shifted to UCC. Geographic access may hinder utilization of UCC in rural areas.

PHP87

SHORT-TERM COSTS OF WHOLE GENOME SEQUENCING IN CARDIOLOGY AND PRIMARY CARE: FINDINGS FROM THE MEDSEQ PROJECT

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OBJECTIVES: To determine the short-term cost impact of integrating whole genome sequencing (WGS) into cardiology and primary settings. **METHODS:** A cost analysis was conducted alongside a randomized controlled trial. Cardiology patients with diagnoses of hypertrophic or dilated cardiomyopathy (n=100) and ostensibly healthy primary care patients (n=100) were randomized to review family history alone (control arm) or with WGS reports (WGS arm). To estimate the cost of WGS from consent through results disclosure, study staff tracked personnel time and resource use. To estimate the costs of follow-up health care, study staff identified services ordered after disclosure sessions by reviewing medical records and survey data, and then applied cost weights per CMS fee schedules. Costs were assessed in 2015 dollars. **RESULTS:** Per-patient costs through 6 months post-disclosure averaged \$13,799 and \$10,086 in the WGS and control arms, respectively, in cardiology settings ($\Delta=3,713$, $p<0.001$); and \$7,956 and \$2,771, respectively, in primary care settings ($\Delta=5,185$, $p<0.001$). Costs in WGS arms included an average of \$5,315 for WGS. Among the 49 cardiology randomized to WGS, sequencing identified genetic variants associated with cardiomyopathy diagnoses in 24 patients (49%), secondary monogenic disease risks in 8 patients (8%), and carrier status for autosomal recessive conditions in 41 patients (84%). Among the 50 primary care patients randomized to WGS, sequencing identified monogenic disease risks in 13 patients (26%) and carrier status in 50 patients (100%). All sequenced patients also received pharmacogenomic information about 5 drugs and risk information about 8 cardiometabolic traits. **CONCLUSIONS:** WGS increased short-term costs in both cardiology and primary care settings, but differences were almost due to the costs of sequencing itself. Longer time horizons are needed to understand the impact of WGS on patient health, but early evidence about its cost impact are encouraging given expectations that prices will continue to fall rapidly.

PHP88

HEALTH ECONOMIC IMPLICATIONS AND CONSUMER PREFERENCE DISTORTIONS OF NEGATIVE INTEREST RATE POLICY

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OBJECTIVES: Monetary policy has evolved, in some countries, to the form of a negative interest rate policy (NIRP). The objective of this research is to review the cost-effectiveness literature to identify examples of negative discounting within CEA analyses, and examine the theoretical implications of such discounting on potential care preferences between acute costs – potentially descriptive of one-time procedures – and chronic costs – potentially descriptive of long-term pharmaceutical treatment. **METHODS:** A review of the Tufts CEA Registry, examining the reported discount rate of all CEAs that reported a discount rate. A theoretical model was developed to estimate the value of a 5- and 10-year stream of future, chronic costs, discounted by several scenarios – (0.5%), 0%, and 3% – to examine how these changes in discount rates may alter the evaluate of these chronic costs, relative to a one-time acute cost. **RESULTS:** Zero analyses were identified within the Tufts CEA Registry with a negative interest-/discount-rate. 60% of articles reporting a discount rate utilizing a 3% discount rate; the lowest identified interest rate was 1%. At a NIRP of (0.5%), the economic model suggests indifference between acute costs equal to 5.08-times chronic costs over a 5-year period, or 10.28-times over a 10-year period. At 0%, those multiples become 5x and 10x, respectively. At 3%, those multiples become 4.57x and 8.49x. Thus, the alternation of the discount rate from 3% to (0.5%) potentially allowed acute costs to increase by 11% and 21% compared to a 5-year and 10-year chronic cost, respectively. **CONCLUSIONS:** NIRP is not yet reflected in the cost-effectiveness literature. As NIRP continues and potentially impacts health economic decision makers, there exists potential for preferences to be altered towards acute costs such as procedures over more chronic costs, such as pharmaceutical requiring long-term chronic or even lifetime use.

PHP89

IMPACT OF ARGININE-BASED IMMUNONUTRITION ON INPATIENT TOTAL COSTS AND HOSPITALIZATION OUTCOMES FOR PATIENTS UNDERGOING COLORECTAL SURGERY

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OBJECTIVES: We assessed the impact of arginine-based immunonutrition intervention for patients undergoing elective colorectal surgery on post-surgical utilization and cost outcomes. **METHODS:** This analysis is based on data from two Washington State databases: Surgical Care and Outcomes Assessment Program (SCOAP) linked to the Comprehensive Hospital Abstract Reporting System (CHARS). The sample (N=722) comprised adult patients from Washington State hospitals that participated in the Strong for Surgery (S4S) initiative between

January 1, 2012 and December 31, 2013. A generalized linear model was used to predict the outcomes, adjusting for demographic characteristics and patient health conditions within a multivariate regression framework. **RESULTS:** Our findings indicate significantly fewer re-admissions (-0.18; $p<0.01$) and hospital days (-1.3; $p<0.10$) for the intervention group during the 180 days following index hospitalization. Clinical benefits included decreased risk of infections ($p<0.05$) and venous thromboembolism ($p<0.01$). There was a similar pattern toward lower total costs (-\$4,675; $p\geq 0.10$) in the immunonutrition patients group; however, these were not statistically different compared to the control group at any time point. Savings in the immunonutrition group were substantial—mean total costs per patient less by approximately \$2,500 at index hospitalization, \$3,500 less through 30 days of follow-up, and \$5,300 less over 180 days compared to control group. **CONCLUSIONS:** Among the significant drivers of total costs during the 180-day follow-up period were post-operative complications. Overall, the findings suggest that arginine-based immunonutrition should be thoroughly evaluated for incorporation into clinical practice for elective surgery patients. Moreover, there is a need to assess the impact of the intervention in other hospitals both within and outside Washington.

PHP90

PRICE ANALYSIS OF THERAPEUTIC BIOLOGICS MARKETED IN THE UNITED STATES

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OBJECTIVES: The objective of this study was to evaluate trends in manufacturer-listed prices of therapeutic biologics approved by the FDA for chronic use and marketed in the US during the period 1986–2015. **METHODS:** Regulatory information for therapeutic biologics was extracted from the FDA website. The FDA recommended adult defined daily dose (DDD) was collected from the first FDA-approved label of each biologic. The average wholesale price (AWP) history was collected from the RedBook. Prices were adjusted to the first semester of 2016 using the consumer price index (CPI) US city average, all items. Descriptive statistics and Wilcoxon rank sum tests and t-tests were performed. The significance level was set at 0.05. **RESULTS:** The analytical sample included 58 biologics (representing 51.3% of all FDA-approved therapeutic biologics during the period 1986–2015). The median market entry inflation-adjusted AWP per DDD was \$113.10 (n=2, interquartile range [IQR]=47.70) in the 1980s, \$64.80 (n=7, IQR=99.70) in the 1990s, \$105.90 (n=24, IQR=294.60) in the 2000s, and \$213.00 (n=25, IQR=504.10) during the period 2010–2015. The median inflation-adjusted AWP per DDD for therapeutic biologics for chronic use at market entry was higher for FDA-priority review (\$389.20, n=34, IQR=636.00) than for standard review (\$88.50, n=24, IQR=105.30; $p<0.05$). **CONCLUSIONS:** The FDA approved an increasing number of therapeutic biologics for chronic use during the period 1986–2015. Median AWP prices at market entry increased over time, and the increase in the prices of therapeutic biologics at market entry exceeded the inflation rate.

PHP91

ECONOMIC BURDEN ASSOCIATED WITH TEMPERATURE DYSREGULATION

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OBJECTIVES: Thermoregulatory mechanisms are often disrupted in patients with critical neurological injury, leading to increased complications and resource use. Previous studies have found that early initiation of mild-moderate hypothermia (32–34°C) was associated with improved survival and neurologic outcomes. A structured literature review was performed to identify the economic burden associated with temperature dysregulation. The assumed costs associated with temperature dysregulation included potential cooling procedures, hospital length of stay (LOS), rehabilitation, and labor costs. **METHODS:** Review of published studies indexed on Medline was performed in December of 2016 without a date restriction. Only English studies were considered. The search strategy included the key words “temperature management” or “therapeutic hypothermia” plus terms including but not limited to: (1) “fever”, “cardiac arrest”, “hypoxic-ischemic encephalopathy”, “stroke”, “intracerebral hemorrhage”, “Glasgow coma scale”, “cerebral performance category”, “traumatic brain injury”, “subarachnoid hemorrhage”, or “cerebral injury”, and (2) “cost”, “economic”, “nursing care”, “reimbursement”, “resource”, “societal”, or “labor”, including MeSH terms where appropriate. Additional references were obtained by reviewing bibliographies. **RESULTS:** Over 2000 titles and abstracts were screened, 146 studies were considered potentially relevant (i.e., included clinical and/or economic outcomes), and 29 of these studies focused on costs, resource use, or public health/economic impact. In patients with critical neurological injury, fever indicated poor prognosis, and was often associated with increased LOS, mortality, and costs. However, reported outcomes and costs varied considerably depending on region, definition, perspective, neurological status, and disease state. For example, reported LOS ranged from 2.5 to 35 days. Long-term societal costs associated with rehabilitation and nursing care, as well as specific costs comparing temperature management methods were limited. **CONCLUSIONS:** Studies have evaluated cost of temperature dysregulation in the hospital setting and have suggested some methods for cost savings. Further research quantifying the longer term economic impact of temperature dysregulation and how temperature regulation methods can avert these is warranted.

PHP92

A COMPARISON OF ONCOLOGY AND NON-ONCOLOGY ORPHAN DRUG PRICES IN EUROPE

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OBJECTIVES: This study aimed to assess price differences of oncology and non-oncology orphan drugs in France, Germany, Italy, Norway, Spain, Sweden, and UK by comparing the annual treatment cost per patient of similarly available drugs. **METHODS:** Orphan drugs granted market authorisation up to June 13, 2016 were extracted from the European Medicines Agency website and divided into oncology and non-oncology. The annual treatment costs per drug were calculated based on the summary of product characteristics (SmPC) using ex-factory prices from IHS POLI and country price databases. The treatment cost in the each country (comparator country) was compared to the UK (reference country) and ratios were analysed for both oncology and non-oncology drugs. The absolute value of the median annual treatment costs of non-oncology and oncology orphan drugs within each country was also analysed. **RESULTS:** 120 orphan drugs were included in the analysis. Compared to the UK, the average annual costs of non-oncology drugs were minimally more expensive in France (averaged ratio 1.03), Germany (1.09), Italy (1.05), similar in Sweden (1.0), and were cheaper in Spain (0.94), and Norway (0.86). The cost differences (ratios) for oncology orphan drugs did not differ greatly with non-oncology (FR 1.04, DE 1.11, IT 1.1, ES 1.01, NO 0.83, SE 0.98). In absolute values, the median annual treatment cost of non-oncology orphan drugs were more expensive than oncology orphan drugs in UK, France, Spain, and Norway, while oncology drugs were more expensive in Germany, Italy and Sweden. The absolute cost differences only amounted from €1,700 to €19,400 per patient per year. **CONCLUSIONS:** In Europe, the price differences of oncology and non-oncology orphan drugs are negligible within and among countries. Moreover, oncology orphan drugs are not generally more expensive than non-oncology orphan drugs.

PHP93

HEALTH CARE USE AND EXPENDITURES AS COMPARED BETWEEN SPECIALTY MEDICATION USERS AND TRADITIONAL MEDICATION USERS

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OBJECTIVES: To investigate health care use and expenditures in specialty medication users compared with traditional medication users. **METHODS:** This was a retrospective cohort study of US adults aged 18 or older using Medical Expenditure Panel Survey (MEPS) data from 2000 through 2013. MEPS respondents aged 18 or older who used any specialty medications were considered specialty medication users (SMUs). Individuals who used pharmaceuticals other than specialty medications were considered traditional medication users (TMUs). Outcomes of health care use included the number of prescription medications as well as the annual number of emergency department visits, hospitalizations, office-based visits, and hospital outpatient visits. Outcomes of health care expenditures included total health care expenses, total prescription medication expenses, out-of-pocket (OOP) expenses for prescription medications as well as spending on emergency department visits, hospitalization, office-based visits, and hospital outpatient visits. For outcomes of health care use, a negative binomial model (or a zero-inflated negative binomial regression model for the outcomes with excessive zeros) was employed. To analyze the outcomes of health care spending, a generalized linear model (GLM) with a log link function and gamma distributed errors (or a two-part model for zero-inflated expenditure data) was used. **RESULTS:** After controlling for the various covariates, SMUs used about 65% fewer prescription medications (incidence rate ratio [IRR] = 0.35, 95% CI = 0.18-0.67) and had 68% fewer hospital outpatient visits (IRR = 0.32, 95% CI = 0.16-0.68) compared with TMUs. However, SMUs spent about \$3,600 more on prescription medications while their OOP medication spending was about \$100 less than TMUs. **CONCLUSIONS:** Compared with TMUs, SMUs used less prescription medications and had less hospital outpatient visits. Spending on prescription medications was higher by SMUs than TMUs, unlike OOP spending.

PHP94

A MODEL TO EVALUATE THE CLINICAL AND ECONOMIC BURDEN OF INTRAVENOUS COMPOUNDING ERRORS

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OBJECTIVES: Pharmacies in hospital have adopted volumetric measurement for compounding intravenous (IV) medication for years, which is a multi-step process manually carried out by pharmacists and technicians. Compounding errors in each step can lead to consequences, such as medication wastage and additional time for re-compounding. In addition, compounding errors that go undetected and reach the patient can lead to preventable adverse drug events (pADEs). An Excel model was developed to articulate the clinical and economic burden during the IV compounding process. **METHODS:** A targeted literature review on IV medication errors (ME), medication wastage, and IV compounding labor was conducted using Medline (2003-2015), identifying seven key articles related to the incidence rates of compounding errors during the process for both chemotherapy and non-chemotherapy preparations. A literature review investigating cost of pADEs, medication wastage, and labor was also incorporated. **RESULTS:** A base scenario for a pharmacy with an annual 15 million USD spending on IV medication, and a total of 100,000 manually prepared IV admixtures was evaluated. The model estimated that of 7,100 compounding errors, 5,574 of the errors would be detected by the pharmacy, resulting in the re-compounding of 1,784 IV preparations. The re-compounded preparations are associated with costs of \$241,024 in medication wastage and \$23,537 in labor. The 1,527

compounding errors not detected by the pharmacy could result in 359 pADEs, with a total cost of \$1,369,222. **CONCLUSIONS:** This model demonstrated the substantial impact of IV compounding errors that lead to pADEs, medication wastage, and unnecessary labor. The consequences were estimated to cost more than \$1,633,783 per year, which is estimated to be >10% of the total hospital IV medication spending. Process standardization and evaluation of new IV preparations measurement methods, such as gravimetric-based medication workflow solutions, are needed to mitigate compounding errors at pharmacies.

PHP95

A COST-EFFECTIVENESS ANALYSIS OF SELF-DEBRIEFING VERSUS INSTRUCTOR DEBRIEFING FOR SIMULATED CRISES IN PERIOPERATIVE MEDICINE IN CANADA

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OBJECTIVES: High-fidelity simulation training is effective for learning crisis resource management (CRM) skills, but cost is a major barrier to implementing high-fidelity simulation training into the curriculum. The aim of this study was to examine the cost-effectiveness of self-debriefing and traditional instructor debriefing in CRM training programs and to calculate the minimum willingness-to-pay (WTP) value when one debriefing type becomes more cost-effective than the other. **METHODS:** This study used previous data from a randomized controlled trial involving 50 anesthesiology residents in Canada. Each participant managed a pretest crisis scenario. Participants who were randomized to self-debrief used the video of their pretest scenario with no instructor present during their debriefing. Participants from the control group were debriefed by a trained instructor using the video of their pretest scenario. Participants individually managed a post-test simulated crisis scenario. We compared the cost and effectiveness of self-debriefing versus instructor debriefing using net benefit regression. The cost-effectiveness estimate was reported as the incremental net benefit and the uncertainty was presented using a cost-effectiveness acceptability curve. **RESULTS:** Self-debriefing costs less than instructor debriefing. As the WTP increased, the probability that self-debriefing would be cost-effective decreased. With a WTP ≤Can\$200, the self-debriefing program was cost-effective. However, when effectiveness was priced higher than cost-savings and with a WTP >Can \$300, instructor debriefing was the preferred alternative. **CONCLUSIONS:** With a lower WTP (≤Can\$200), self-debriefing was cost-effective in CRM simulation training when compared to instructor debriefing. This study provides evidence regarding cost-effectiveness that will inform decision-makers and clinical educators in their decision-making process, and may help to optimize resource allocation in education.

PHP96

COSTS OF CONTRACEPTIVE METHODS FOR THE PUBLIC HEALTH SYSTEM

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OBJECTIVES: Hormonal contraceptive methods are important to effective family planning. They can be used in the form of an oral or injectable drug, vaginal ring, subcutaneous implant and intrauterine device. The aim of this study is to describe the prices of different contraceptive methods available for users of the Brazilian public health system. **METHODS:** Cost data was obtained from the Brazilian Drug Market Regulation Chamber (CMED), through the maximum cost of sale to the government. The efficacy data was taken from the Brazilian Federation of Gynecology and Obstetrics (FEBRASGO) for comparison between different methods. The calculations were conducted for a 5-year time horizon and a discount rate of 5% was applied for costs. Cost data was converted through PPP to 2015 USD using the Campbell and Cochrane Economics Methods Group's Evidence for Policy and Practice Information and Coordination Centre Cost Converter tool (CEMG-EPPI-Centre Cost Converter). **RESULTS:** The costs associated to pills were ethinylestradiol 0.03mg + levonorgestrel 0.15mg (135.72 USD, 99.7% efficacy); cyproterone + ethinylestradiol (307.97 USD, 99.7% efficacy); norethisterone 0.35mg (143.62 USD, 99.0% efficacy). The costs associated to long-acting formulations were: norethisterone 50mg + estradiol valerate 5mg (350.33 USD, 99.0% efficacy) and medroxyprogesterone 150mg (158.18 USD, 99.7% efficacy); and IUD (264.20 USD, 99.9% efficacy). The transdermal patch was associated with higher costs: norelgestromin 0.06mg + ethinylestradiol 6mg (1525.03, 99.7% efficacy). **CONCLUSIONS:** The decision about which products to offer in a country should not only consider efficacy outcomes, but also the costs associated to the technology. The efficacy of the hormonal contraceptive methods vary between 90 and 99.95% and the cost of different method varied between 135.72 and 1525.03 USD.

PHP97

ANALYSIS OF HOSPITAL COSTS BY DAY OF ADMISSION IN PATIENTS UNDERGOING COMMON SURGICAL PROCEDURES IN THE UNITED STATES

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OBJECTIVES: Shortening length of stay (LOS) following inpatient surgery may reduce hospital costs, but quantifying cost savings requires isolation of the fixed surgery costs typically incurred on hospital Day 1 from variable costs incurred on subsequent days. We aimed to describe cost per day of hospital admission in patients undergoing inpatient surgical procedures. **METHODS:** We evaluated data available via the Premier Perspective® Database which includes administrative data from more than 600 hospitals in the United States. Data on discharges from 10/1/2014 to 9/30/15 with a primary ICD-9 procedure code for one of the 10 most

common surgical procedures performed in adults (total knee and hip replacement; laparoscopic cholecystectomy and appendectomy; cervical fusion; open fracture reduction of the femur and tibia/fibula; lumbar/sacral fusion; total abdominal hysterectomy; and excisional wound/burn debridement) were included. Maternal or neonatal hospitalizations and those with any intensive care unit stay were excluded. The primary outcome was daily total hospital cost, stratified by day of hospital admission and surgical procedure. All outcomes were summarized descriptively using means and standard deviations. **RESULTS:** A total of 307,236 hospital discharges of interest occurred during the study period. Total daily costs in all surgeries were highest on the first day of admission (Day 1) and declined thereafter. The differences in total hospital costs for the first 3 days of hospitalization were most pronounced in lumbar/sacral fusion (\$23,749, \$1862, and \$1359 on Days 1, 2, and 3) and cervical fusion (\$13,914, \$1174, and \$1453). Total costs on Day 3 were less than \$1500 for all surgeries except laparoscopic cholecystectomy (\$2132) and open fracture reduction of the femur (\$2794) and tibia/fibula (\$1936). **CONCLUSIONS:** Hospital costs in surgical patients were heavily weighted toward the first day of admission. Shortening LOS by one full day could reduce total hospital costs by up to \$2794, depending on the type of surgery.

PHP98

WHEN COST EFFECTIVE INTERVENTIONS ARE UNAFFORDABLE

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OBJECTIVES: Interventions deemed cost-effective in academic literature are not always affordable. Specifically, interventions may provide high benefit for low cost, but adopting them may necessitate elimination of other more beneficial expenditures. One tool to assess affordability is budget impact analysis (BIA), which estimates a program's short-term costs and savings from the payer's perspective. We examined how BIA has been employed in the global health cost-effectiveness analysis (CEA) literature and explored how to incorporate affordability information alongside CEA. **ANALYSIS:** We investigated BIA in 384 articles from the Global Health Cost-Effectiveness Analysis (GHCEA) Registry, developed by the Tufts Center for the Evaluation of Risk in Health. Three percent (n/N = 12/384) of articles performed a formal BIA. Most of these (n/N = 9/12) noted that cost-effective interventions might be prohibitively expensive for government budgets. In practice, the conclusions of CEA and BIA can differ because: the CEA willingness to pay threshold may be too high; CEA measures societal costs while BIA measures payer costs; CEA considers a time horizon long enough to accrue all benefits while BIA considers budgeting for 1-5 years; and CEA discounts costs and benefits while BIA does not. We argue that researchers should report both CEA and BIA with information about why the two may diverge in a given context. Policymakers should be wary of binary classifications of cost effectiveness, as high-value programs may require substantial new resources. They might seek support from external funders or lenders to adopt programs that have a favorable incremental cost-effectiveness ratio but high upfront costs. **CONCLUSIONS:** Currently, there is a dearth of budget impact information for proposed global health interventions. Researchers should report both cost-effectiveness and budget impact estimates. Policymakers should interpret information about cost effectiveness in the context of their budget and other available funding sources.

PHP99

A SYSTEMATIC REVIEW OF COST-OF-ILLNESS STUDIES ON MULTIMORBIDITY

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OBJECTIVES: To describe the methods of cost-of-illness (COI) studies on multimorbidity; and to summarize the economic outcomes of multimorbidity. **METHODS:** A systematic search for COI studies of multimorbidity published in English from 2000 to 2016 was performed. Inclusion criteria: peer-reviewed cross-sectional, cohort and modeling COI studies of multimorbidity; exclusion criteria: studies focusing on the index disease. Data extracted for each eligible study included definition, measure, prevalence of multimorbidity; number of included health conditions; age range of sample; methodology of COI; proportion of multimorbidity costs and average costs per capita. The adapted British Medical Journal Checklist was used to assess the study quality. Costs were converted to 2016USD using the 2016 exchange rate for each currency, with adjustments over time based on the Consumer Price Inflation. **RESULTS:** 26 articles were included, of which, the definition used in the 14 studies that clearly defined multimorbidity was limited to a simple count of 2 or more conditions. Methodology used to derive costs differed markedly among the studies. Average annual costs per patient of multimorbidity ranged from \$49-\$252,313; the ratios of multimorbidity over non-multimorbidity costs ranged from 2-16. The highest costs (\$252,313) were found in a study of American children. Using a cut-off of 3 or more conditions, average costs were 7%-85% higher than 2 or more conditions within 14 available studies. Among 10 studies providing a breakdown on costs, the largest proportion for multimorbidity was spent on inpatient (95%) or medicines (64%) costs in non-societal perspective studies, while on social care cost from societal perspective (56%). **CONCLUSIONS:** COI studies of multimorbidity are highly heterogeneous. Multimorbidity was associated with considerable economic burden even in children. Costs of different definitions of multimorbidity were limited by the data available. Standardized methods are required for improving accuracy, enhancing

interpretation and facilitating comparisons between studies from different perspectives.

PHP100

COST-EFFECTIVENESS OF VENOUS THROMBOEMBOLISM PROPHYLAXIS AFTER TOTAL KNEE AND HIP REPLACEMENT FROM THE BRAZILIAN PRIVATE HEALTHCARE SYSTEM PERSPECTIVE

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OBJECTIVES: To access the cost-effectiveness of apixaban versus other anticoagulants in the venous thromboembolism (VTE) prophylaxis after total knee (TKR) and hip (THR) replacement in the Brazilian private healthcare system (PHS). **METHODS:** A cost-effectiveness analysis of apixaban versus other anticoagulants (dabigatran, rivaroxaban, warfarin and enoxaparin) was performed using a Markov-associated decision tree model that followed patients who had undergone TKR and THR (56% of the cohort underwent THR) over a 12-month time horizon. The clinical outcome considered was life years saved (LY). The economic outcome considered was medical direct costs, considering an annual discount rate of 5%. A probabilistic sensitivity analysis (PSA) was also performed, considering variations in efficacy, risks of long-term events and costs. The cost-effectiveness acceptability curve ranged from BRL 0 to 100,000. **RESULTS:** Total costs of enoxaparin, dabigatran, rivaroxaban, apixaban and warfarin were, respectively, BRL 881, BRL 463, BRL 383, BRL 348 e BRL 292, with effectiveness of 1.18 LY for all treatments. In the ASP, the efficiency of all treatments had little variation because of the low incidence of thromboembolic events or bleeding. The acceptability curve indicated a 100% probability in apixaban to be more cost-effective versus all comparators, except for warfarin, regardless of willingness to pay. **CONCLUSIONS:** It was possible to observe similar efficacy among all anticoagulants for VTE prophylaxis after TKR and THR, with apixaban being the treatment with the lowest cost, that is, more efficient compared to all comparators, but not to warfarin, in the Brazilian PHS.

PHP101

ECONOMICS OUTCOMES OF MEDICATION SAFETY PROGRAM AT PUBLIC HOSPITAL IN RIYADH, SAUDI ARABIA

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OBJECTIVES: Medication safety program started at Ministry of Health in 2014. The pharmacist should prevent all drug related problems. The objective of this study to estimate cost-avoidance of Medication Safety program at the public hospital in Riyadh city, Saudi Arabia by using American model. **METHODS:** It is a simulation of a 9-month (Dec 2014-Aug 2015) at 300-bed Public Hospital through preventing and documentation of medication errors in adults and pediatrics of inpatient pharmacy services. The program Led by trained pharmacist and delivered Basic medication safety education to all health professional. The estimated cost calculated by using International Study Model (Ling et al., Am J Health Syst Pharm 2005). It expressed in USD, the cost considered were the expected results of medication errors sequel if not stopped; starting from Physician visit, additional laboratory test, further treatment, hospital admission, Critical care admission to death stage. **RESULTS:** The total number of prevented medication errors were 3,378 in 805 prescriptions and patients inside the hospital. The estimated cost avoidance of preventing medication errors was (98,195.97 USD) for the study period and (10,910.USD) per month. The cost avoidance was (29 USD) per each mistake, and (122 USD) per prescription and patient. The highest cost avoidance (90%) came from adults (18-more than 65) while (10%) from pediatrics. The greatest drug of cost avoidance was from prevented Paracetamol Injection errors (7,108 USD), followed by prevented Omeprazole Injection errors (1,525.85 USD). The estimated cost avoidance of preventing medication errors was (130,927.96 USD). **CONCLUSIONS:** Medication safety program is cost-avoidance at the public hospital. Expanding medication safety overall hospital health care services associated with preventing drug-related problems, and avoiding unnecessary cost

PHP102

THE ECONOMIC CONTRIBUTION OF PHARMACEUTICAL CLINICAL TRIALS TO HEALTH CARE AND HEALTH RESEARCH IN ALBERTA, CANADA

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OBJECTIVES: Clinical trials are recognized as drivers of economic activity as well as mechanisms of scientific evidence. Industry-sponsored trials alleviate health-care costs. We sought to examine the economic contribution of industry-sponsored trials in Northern Alberta, Canada. **METHODS:** We selected all phase two and three industry-sponsored trials that started in 2012 in Northern Alberta, Canada. We used trial-specific budget documents to estimate billing costs into three major groups: administration, ethic review and patient costs. We used the trial protocol obtained from the website ClinicalTrials.gov to identify drugs, average dosages and treatment lengths in each trial. Alberta Health Drug Benefit List (ADBL) and the US Department of Veteran Affairs Drug List (VADL) (adjusted for currency differences) were used to obtain drug prices. Price of a close substitute was used if the experimental drug was not listed in either ADBL or VADL. **RESULTS:** There were 40 trials initiated in Northern Alberta in 2012. The mean (standard deviation (SD)) trial length was 29.7 (SD: 14.5) months. 251 patients (75% on experimental arms) were enrolled. Five trials had an open label phase for 28 patients. 55 drugs were evaluated; of which, 15 were biological

products. Total healthcare cost avoidance was Canadian \$29 million. Of which, operating costs were \$5.2 million, drug costs were \$13.5 and \$10.3 million during the trial period and the open label phase, respectively. **CONCLUSIONS:** In addition to the medical advancement benefits, industry-sponsored clinical trials in Northern Alberta contribute a significant dollar amount to the Alberta healthcare system. Policy to motivate industry-sponsored trials should be in place to help alleviate health care costs.

PHP104

ASSESSING THE FINANCIAL VALUE OF PATIENT ENGAGEMENT

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OBJECTIVES: While patient groups, regulators, and sponsors are increasingly considering engaging with patients in the design and conduct of clinical development programs, sponsors are often reluctant to go beyond pilot programs due to uncertainty in the return on investment. The objective of this work was to develop an approach to estimate the financial value of patient engagement. **METHODS:** Expected net present value (ENPV) is a common technique that integrates the key business drivers of cost, time, revenue, and risk into a summary metric for project strategy and portfolio decisions. We describe an approach to assess the impact of patient engagement on ENPV for a medical treatment development program, then apply it to a typical oncology development program entering phase 2 (cost to launch \$121MM, NPV \$493MM) or phase 3 (cost to launch \$114MM, NPV \$640MM). **RESULTS:** For a pre-phase 2 project, the cumulative impact of a patient engagement activity that avoids one protocol amendment and improves enrollment, adherence, and retention is an increase in net present value (NPV) of \$62MM (\$65MM for pre-phase 3) and an increase in ENPV of \$35MM (\$75MM for pre-phase 3). Compared with an investment of \$50,000 in patient engagement, the NPV and ENPV increases exceed 1000-fold the investment. This ENPV increase is the equivalent of accelerating a pre-phase 2 product launch by 2½ years (1½ years for pre-phase 3). **CONCLUSIONS:** Risk-adjusted financial models can assess the impact of patient engagement. A combination of empirical data and subjective parameter estimates shows that engagement activities with the potential to avoid protocol amendments and/or improve enrollment, adherence and retention may add considerable financial value. This approach can help sponsors assess patient engagement investment decisions.

PHP105

PRICES OF TUBERCULOSIS DRUGS MARKETED IN THE US (1973-2016)

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OBJECTIVES: This study describes trends in average wholesale prices (AWP) at market entry of drugs and vaccines approved by the FDA for the treatment and prevention of tuberculosis (TB) and marketed in the US in the period 1980-2016. **METHODS:** The AWP information was collected from the Redbook (Truven Health) for the drugs approved by the FDA to treat TB. Defined daily dose information was collected from the World Health Organization. The AWP was collected from the effective date to January 2017, and price at market entry was converted to 2016 USD using the consumer price index (CPI). Descriptive statistics were conducted in the analysis. **RESULTS:** Twenty-six TB drugs and vaccines approved by the FDA were included in the analysis. There were seven products approved by the FDA in the period 1973-1989, 8 in 1990-1999, and 11 in 2000-2016. The market entry Cost Per Treatment was \$207.20 for hydrocortisone and \$147.73 for Bacillus of Calmette and Guerin (BCG vaccine). The highest TB drug prices for the period 1973-1989 were \$58.65 for rifampin (intravenous), \$3.29 for hydrocortisone (topical), \$1.61 for a combination of isoniazid and rifampin (oral), \$1.3 for prednisolone acetate (ophthalmic), \$2.08 for tuberculin (intradermal) and, \$36.54 for methylprednisolone sodium succinate (intravenous or intramuscular). In 1990-1998, the costs were \$147.73 for the BCG vaccine, live, \$5.15 for hydrocortisone (topical), \$3.74 for aminosalicylic acid (oral), \$8.58 for ciprofloxacin (ophthalmic), and \$5.51 for streptomycin (intramuscular). Prices in the period and for the 2000-2016 period included \$5408.41 for gatifloxacin (ophthalmic), \$168.59 for the BCG vaccine, live (intradermal), \$175.27 for capreomycin (injection), \$214.6 for rifampin (intravenous), and \$191.79 for bedaquiline fumarate (oral). **CONCLUSIONS:** The FDA approved a large number of products for treatment and prevention of TB during the study period. Prices of TB drugs at market entry increased during the same period.

PHP106

COST-EFFECTIVENESS ANALYSIS OF THE USE OF SIU-LNG AGAINST LONG- AND SHORT-ACTING CONTRACEPTIVES, AS CONTRACEPTIVE METHODS FOR WOMEN OF FERTILE AGE IN COLOMBIA

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OBJECTIVES: To estimate the cost-effectiveness ratios of the use of SIU-LNG against the use of T-copper, Implants, patch injectable, oral contraceptives and vaginal ring as contraceptive use for women of childbearing age. **METHODS:** Markov model was developed to estimate the differences in the main outcomes, as avoided pregnancies and total costs, including first and second lines of contraceptive treatment, as well as costs for the presentation of pregnancies. The horizon utilized was 5 years, under monthly cycles, thus were estimated, abandonments / changes method, failures, presence of adverse events, no use of any method or presentation of pregnancy. Technology costs were estimated with national databases; and insurance costs for events. **RESULTS:** Long-acting methods-LARCS- (T-Copper, Implants and SIU-LNG) are

considered dominant over all short-acting methods, that is, more effective in terms of reducing unwanted pregnancies and are less expensive. Compared to LARCs, on average they represent 32.8% more unwanted pregnancies and an over-cost of 51.9% in 5 years. Among LARCs, cost differences are narrow, but in avoided pregnancies, it is estimated that SIU-LNG has the lowest number of pregnancies (19), compared to 49 with T-copper and 37 with implants under a cohort of 100 women. In the temporal horizon, from the second year, the implants shows ICER of dominance over the T-Copper; while the SIU-LNG shows the very first 3 years as a dominant option vs all other technology evaluated but shows versus copper T, a cost-effectiveness ratio for avoided pregnancy of \$ 5,845,273 in the second year, in the third year of \$ 1,104,713, and from the fourth year, a dominance relationship on T-copper. **CONCLUSIONS:** Long-acting contraceptive methods have a dominance relationship over short-acting methods, because they have high levels of adherence. In general, SIU-LNG is a dominant technology over all competitors evaluated over a five-year horizon.

PHP107

THE PRICE RISE OF GENERIC DRUGS IN US MARKET

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OBJECTIVES: After amendments were made to the law in the favor of generic drug makers, this market saw an influx of new players, which brought generic prices further down. Currently, on average, the cost of a generic drug is **80 to 85 percent lower than the brand name product**. As prices declined, usage of generics picked up rapidly. The main objective is to determine the extent to which generic drug price increases and to determine which drug classes has the most cost in order to discover the challenge and the barriers behind generic drug prices increase. **METHODS:** The difference with generic prices has been obtained by the Medicaid file using National Average Drug Acquisition Cost (NADAC) Weekly reference file. The NADAC for prescription and over-the-counter covered outpatient drugs is reported at the 11-digit National Drug Code level. **RESULTS:** Most extraordinary price increases were between 100 and 200 percent. 48 were 500 % or higher. 15 were 1,000 % or higher. Clomipramine HCL/50mg/capsule/oral, 2,000 % in 1 year, \$0.34 per capsule in the first quarter of 2013 to \$8.43 per capsule in the first quarter of 2014. 183 out of the 351 extraordinary price increases were less than 200 % Hydrocortisone/20mg/tablet/oral. 160 % in 1 year, \$0.16 per tablet in the first quarter of 2012 to \$0.41 per tablet in the first quarter of 2013. **CONCLUSIONS:** Based on the analyses conducted to date, a vibrant generic market can exert downward pressure on overall drug prices. Generic drugs account for majority of prescriptions filled in US and represent lower costs to healthcare system. Factors such as drug shortages, the ability to obtain new market exclusivities, the distribution system, small market size, and consolidation in the generic drug industry present potential barriers to ongoing competition in the generic drug market, and will be subject of continued study.

PHP108

PRICES OF BIOSIMILARS IN THE US

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OBJECTIVES: The Affordable Care Act of 2010 defined a pathway for the approval of biosimilar biologic drugs by the FDA. This study assessed trends in prices of biosimilars and biologic drugs in the US as of January 1, 2017. **METHODS:** A list of biosimilars and therapeutic biologics approved in the US was extracted from the FDA webpage. Average wholesale prices (AWP) were extracted from the RedBook (Truven Health). Average sales price (ASP) used for Medicare Part B reimbursement was collected from the CMS. Descriptive statistics were conducted in the study. **RESULTS:** The FDA approved a total of 4 biosimilar drugs for therapeutic biologics as of January 1, 2017. The single source life of the originator biologic drugs from initial approval to first biosimilar approval was 13.7 years for adalimumab, 17.6 infliximab, 17.8 etanercept, and 24.0 filgrastim. Infliximab biosimilar entered the market with an AWP representing 88.3% of the biologic originator. The AWP of the infliximab originator continued to increase, and the biosimilar represented 85.0% of the originator in Jan 1, 2017. The infliximab biosimilar had an ASP price of 122.0% of the originator biologic ASP at market entry. Filgrastim biosimilar entered the market with an AWP representing 85.9% of the originator biologic. The filgrastim biosimilar had an ASP price of 97.0% of the corresponding originator biologic in October 1, 2015, and decrease to 71.0% in January 1, 2017. Prices for adalimumab and etanercept were not available. **CONCLUSIONS:** Biosimilar prices at market entry were equal or higher than the prices of the corresponding biologics. The ASP for the originator filgrastim remained constant after biosimilar entry, while the ASP for the biosimilar declined. Savings from biosimilars could result from lower biosimilar prices at market entry and from lower biologic and biosimilar price increases.

PHP109

COST ANALYSIS OF DELIVERY ADULT MEDICATION THERAPY SERVICES AT MINISTRY OF HEALTH IN SAUDI ARABIA

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OBJECTIVES: To explore the estimation of cost calculations for delivery drug therapy services for adults' population by using American Model with local cost. **METHODS:** It is a cross-sectional 6-months 2016 analysis of drug distribution services for adult patients. It was at 300-Bed Maternity and Pediatrics Hospital in Riyadh, Saudi Arabia. The cost calculated Adults drug therapy management services delivered to 144 beds. The physician prescribed the medications. The pharmacist reviews and prepared drugs and distributed through unit dose system, floor stock distribution, and discharge medications services. The fast moving oral and topical medications

included in the study. The cost Model calculated based on variable expenses including personal cost, material, and supply cost. Fixed cost was including direct cost, non-salary cost, and overhead cost. All cost used of US dollar currency and local prices. **RESULTS:** The estimated cost of delivery of drug therapy services for all total number adults beds per day was (1,191.9 USD). It contained three types; the unit dose system (761.35 USD), drug floor stock distribution system (334.99 USD), and discharge medication system (95.62 USD). The cost of delivery of medicines to single bed per day was (13.99 USD) with highest estimated cost of delivery from discharge medication (6.37 USD), followed by unit dose services (5.29 USD) and floor stock therapy (2.33 USD). The majority of cost came from overhead cost, and material and supply in floor stock services and discharge medication delivery; while the personal cost in unit dose services delivery. The total estimated annual expenditures of drug distribution services were (435,067.15 USD). **CONCLUSIONS:** In this Adults Medication therapy services cost-estimation the first study at MOH in Saudi Arabia. It is an essential basic element of the PharmacoEconomic program and implements Saudi future vision 2030 for drug therapy health care services.

PHP110 GENERIC DRUGS IN CANADA, 2015

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OBJECTIVES: Generics360 is a PMPRB publication series that compares the price of generic drugs in Canada with those in other industrialized countries. This edition focuses on the 2015 calendar year and includes an analysis of the OECD market. **METHODS:** The analysis compares the manufacturer ex-factory generic prices of a large sample of drugs in Canada with their corresponding international prices. International comparisons focus on the seven countries the PMPRB considers in reviewing the prices of patented drugs (PMPRB7): France, Germany, Italy, Sweden, Switzerland, the UK and the US, as well as select countries in the Organisation for Economic Co-operation and Development (OECD). Data was collected from the IMS AG MIDAS™ Database. **RESULTS:** Generic prices in Canada have been reduced by half over 2010 to 2015, markedly narrowing the gap between Canadian and foreign prices. Both provincial generic pricing policies and the depreciation of the Canadian dollar contributed to the decrease in the difference between foreign and Canadian prices. This gap was wider for molecules with higher sales and those with a greater number of domestic suppliers. **CONCLUSIONS:** While the Canadian provinces markedly reduced the prices of generic drugs for all Canadians through the implementation of generic pricing policies, prices in other countries continue to be lower. This analysis is designed to inform policy discussions related to the Canadian prices of generic drugs.

PHP111 COST-ANALYSIS AND FORECASTING DURING (2016-2020) OF TOTAL PARENTERAL NUTRITION PREPARATIONS IN SAUDI ARABIA

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OBJECTIVES: The Total Parenteral Nutrition (TPN) preparations cost estimation and forecasting is a part of the pharmacy strategic planning at MOH in Saudi Arabia. The study investigated the cost analysis of TPN preparations and forecasting in 2016-2020. **METHODS:** Simulation of 6-month 2015 cross-sectional of TPN (2 in 1) preparations for neonates, pediatrics, and adults patients. It was at 300-Bed Hospital (King Salman Hospital) in Riyadh, Saudi Arabia. The pharmacist reviews and prepared TPN. TPN developed through sterile 797 standards and automated compounding facilities. The cost drives from Ministry of Health information database. All price used US dollar currency and local prices. **RESULTS:** The total number patients were 112 with 1631 TPN orders. The estimated cost of TPN bag for adult per day was (265.95 USD). The estimated cost of TPN preparations for pediatrics per day was (284.35 USD). The estimated cost of TPN preparations for neonates was (250.64 USD). The average break-even points after establishment TPN room was 4-months only. The forecasting cost with additional 30% revenues. TPN prices for adults was (345.73 USD), pediatrics (369.65 USD), and neonates (325.8 USD). The break-even points after new price occur after 3-months only. The automated TPN compounding system should use for hospital if at least had an average of eight to ten TPN preparations per day. **CONCLUSIONS:** Cost analysis and forecasting of Total Parenteral Nutrition prices is part pharmaco-economics program and vision future 2030 at MOH in Saudi Arabia. It is an essential tool for TPN strategic plan, forecasting of new TPN services, and cost estimated of TPN-related health care services.

PHP112 COST OF PEDIATRICS DRUG THERAPY SERVICES AT MINISTRY OF HEALTH IN SAUDI ARABIA

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OBJECTIVES: To explore the estimation of cost calculations for delivery drug therapy services for pediatrics by using American Model with local cost. **METHODS:** It is a cross-sectional 6-months 2016 analysis of drug distribution services for pediatric. It was at 300-Bed Maternity and Pediatrics Hospital in Riyadh, Saudi Arabia. The cost calculated pediatrics drug therapy management services delivered to 144 beds. The physician prescribed the medications. The pharmacist reviews and prepared drugs and distributed through unit dose system, floor stock distribution, and discharge medications services. The medications prepared through ASHP standards and facilities. The fast moving oral and topical medications included in the study. The cost Model calculated based on variable expenses including personal cost, material,

and supply cost. Fixed cost was including direct cost, non-salary cost, and overhead cost. All cost used of US dollar currency and local prices. **RESULTS:** The estimated cost of Delivery of drug therapy services for all total number adults beds per day was (1,214.72 USD). It consisted of three types; the unit dose system (771.9 USD), drug floor stock distribution system (350.34 USD), and discharge medication services (92.5 USD). The majority of cost came from overhead cost, and material and supply in floor stock services and discharge medication delivery; while the personal cost in unit dose services delivery. The total estimated annual expenditures of Drug distribution services were (443,371.83 USD). The highest budget expenditures from unit dose services 63.54 % (281,743.01 USD), followed by floor stock medication delivery 28.8 % (127,872.64 USD), and discharge drug therapy 7.6 % (33,756.17 USD). **CONCLUSIONS:** The estimation cost of delivery pediatrics drug therapy is the first study in the Middle East, Gulf countries, and Saudi Arabia. It is basic element of cost calculation of Pediatrics -related health care services.

PHP113 DEVELOPMENT OF THE PUBLIC HEALTH PRODUCT TAX IN HUNGARY BETWEEN 2011-2015

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OBJECTIVES: Several countries has been already established taxes placed upon unhealthy foods and beverages, to increase health awareness. Hungary's public health product tax ('fat tax') has been established in 2011, and its entire amount is a revenue source of the National Health Insurance Fund (NHIF). The aim of our study is to introduce Hungary's public health product tax and reviewing the amount of tax received between 2011-2015 grouped according to taxable products. **METHODS:** A quantitative, retrospective study was carried out to assess the products that have public health tax placed on to. Amount of tax bases (units in liter or kilogram) and amount of tax income (USD) was determined between 2011 and 2015. Data derived from the National Tax and Customs Administration of Hungary. **RESULTS:** Both amount of income and number of taxable products increased over the years. Amount of public health tax income increased by 51% since 2012, due to the Act's extension to alcoholic beverages in 2015. Most of all income came from prepackaged sweetened products (34.24%, ~34,756,809.8 USD) and alcoholic beverages (28.09%, ~28,512,272.9 USD) in 2015. Prepackaged sweetened products (72.49%) and salty snacks (13.31%, 12,288,313.89 USD) were the biggest tax bases (in kilogram). Soft drinks was the main product in tax bases (in liter) (81.04%), although only 15.78% of income can be linked to this item. Alcoholic beverages with 35-45% v/v had the greatest income (49.21% of income from alcoholic beverages, 13.82% of all income, ~14,031,990.27 USD), however this means only 1.66% of all tax bases (in liter). **CONCLUSIONS:** Public health product tax's primary goal was to become a small, but stable source of revenue for the NHIF. It can also be a significant factor from a public health perspective. It is important to assess its affect on population's health awareness in the future.

PHP114

THE IMPACT OF THE FDA'S UNAPPROVED DRUGS INITIATIVE ON EXPENDITURES FOR ORAL COLCHICINE IN THE UNITED STATES

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OBJECTIVES: It has been suggested that some recent price increases of older generic medications may be attributed to the FDA Unapproved Drugs Initiative (UDI), a program to improve safety by removing unapproved drugs from the market. Colchicine is a good example of a previously unapproved drug marketed for many years at a low price. In 2009, a New Drug Application (NDA) was approved for colchicine (Colcrys) in accordance with FDA's UDI, and in 2015 a FDA approved branded generic became available. This study assessed the impact of FDA's UDI on expenditures for oral colchicine before and after the NDA by conducting a descriptive analysis of expenditures over time. **METHODS:** Data on drug expenditures, adjusted for inflation using the Consumer Price Index, and units sold from January 1, 2006 to December 31, 2015 were obtained from the IMS Health National Sales Perspective database. Expenditures (in 2015 \$), units sold, and expenditures/unit ("price") by year were plotted graphically to observe trends over time. Percentage change of each over time was also examined. **RESULTS:** The most volatile time period observed was 2010 to 2014, during which there was a 437% increase in total expenditures, a 574% increase in total expenditures/unit, and a 20% decline in total units sold (total = unapproved and approved products). During the same period, Colcrys expenditures and units sold exhibited a 1,096% and 941% increase respectively. Meanwhile, unapproved oral colchicine expenditures and units sold declined 100% to zero in 2014 due to market exit prompted by FDA's UDI. Subsequently, in 2015, the branded generic oral colchicine entered the market, which lead to a decline of approximately 60% in expenditures and units sold for Colcrys. **CONCLUSIONS:** Expenditures for oral colchicine rose substantially following FDA approval, driven largely by increased price, suggesting a substantial market impact of FDA's UDI on expenditures.

PHP115

AN INCREASE OVER TIME IN PUBLISHED REAL-WORD/HEALTH-ECONOMIC EVIDENCE IN CLINICAL JOURNALS ACROSS DIFFERENT THERAPY AREAS

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OBJECTIVES: Insights from real-world/health-economic (RW/HE) research are becoming increasingly important to clinical decision-making in a number

of therapy areas. This study quantifies the publication of RW/HE evidence in clinical journals over ten years (2005–2015) and across different therapy areas. **METHODS:** Five therapy areas were selected: cardiology, diabetes, neurology, oncology, and nephrology. Within each therapy area, three journals were identified based on impact factor (high) and clinical editorial focus. For these journals, a literature analysis was performed using EMBASE to identify published RW/HE original research articles – as defined by ISPOR – using a search string based on previously published recommendations. We used chi-square tests to compare the proportion of RW/HE articles grouped by therapy area in 2005, 2010, and 2015, and pair-wise tests to compare changes from 2005–2010 and 2010–2015. We also compared the proportion published in society journals versus non-society journals. **RESULTS:** Among all therapy areas, the proportion of RW/HE publications increased over time, but especially during the period 2010–2015. Overall, the proportion of RW/HE publications increased from 6.6% in 2005 to 9.0% in 2010 and 17.1% in 2015 ($p < 0.001$). The proportion of RW/HE publications was different between therapy area ($p < 0.001$ in all 3 time points), with the highest proportion in 2015 for diabetes (23.3%), cardiology (21.0%), and nephrology (20.1%), and the lowest for neurology (8.4%) and oncology (11.7%). Compared with non-society journals, society journals published a higher proportion of RW/HE publications (5.9% vs 20.1% in 2015; $p < 0.001$) and had a stronger increase over time (growth rate 74.3% vs 99.9% for 2010–2015; $p < 0.001$). **CONCLUSIONS:** During the period 2005–2015, the proportion of RW/HE articles in top clinical journals increased across all therapeutic areas investigated. These results could suggest an increasing willingness to publish RW/HE evidence for health-care decision-making, with some notable differences between therapy areas.

PHP116

STAKEHOLDER DEMAND FOR INFORMATION RELATED TO PIPELINE PRODUCTS AND UNAPPROVED USES OF APPROVED MEDICINES

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OBJECTIVES: This study sought to better describe payer and physician interest, perceptions, and use of information about pipeline products and unapproved uses of approved medicines. **METHODS:** We conducted a series of 15-minute online surveys in November 2016 with specialist physicians (cardiologists, oncologists, endocrinologists, neurologists, psychiatrists, and rheumatologists) and payer executives (representing managed care organizations, pharmacy managers, and large integrated delivery networks). **RESULTS:** 178 specialist physicians and 39 payer executives participated in the study. More than 80% of respondents indicated they would like to receive more information on products in the biopharmaceutical pipeline. Among those interested in pipeline information, 72% of payer executives and 53% of physicians indicated they would like this information at least 6 months pre-approval. The majority of payer executives (82%) and physicians (85%) say they would like to receive more information from biopharmaceutical companies on unapproved uses of approved medicines, provided that the evidence is scientifically sound. Respondents saw the most value in receiving information that underwent peer review and disclosed information about study design and limitations. Respondents also acknowledged the value of FDA approval; 79% of payers agreed that even if companies were able to proactively share more information regarding unapproved uses of a medicine, they would still want to see the manufacturer take steps to have the use approved as an indication on the product labeling. Two-thirds (66%) of physicians thought that if they had more information on unapproved uses they would more often refer patients to clinical trials studying those uses. **CONCLUSIONS:** Payers and specialist physicians are interested in receiving additional information about unapproved uses of medicines from biopharmaceutical companies, provided that the quality of the information is scientifically sound. These stakeholders do not view the sharing of information outside of product labeling as precluding the need for clinical trials, particularly for unapproved uses.

PHP117

IMPACT OF AGING ON THE COLOMBIAN HEALTHCARE SYSTEM

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OBJECTIVES: Our objective was to review, based on the official 2014 Colombian healthcare registry (known as RIPS), the crude figures of resource use (number medical consultations and hospitalizations) by age group. **METHODS:** The RIPS database provides demographic information (of which we used age and gender) of each patient's contacts with the health system, on the number of hospitalizations, and on the length of stay (LOS). Based on DANE (the official Colombian statistics agency) we calculated the proportion of subjects in each age group that contacted the system on that particular year, the average number of contacts, hospitalization rate and average length of stay. **RESULTS:** According to RIPS 25,880,817 subjects (54.3% of Colombian population) contacted the health system in 2014, on average 12.2 times. Coverage was high in the first year of age (96% of population), reached its lowest point in the 10 to 14 year age group, and then rose consistently with age. The number of contacts, the hospitalization rate and the LOS increase with age (average LOS is around 5 days at ages 5 to 25, but then rises progressively, up to 11 days at age 80). An interesting finding was that according to DANE's projections, based on the last census (in 2005) there should be 669,643 Colombians age 80 or more, and according to RIPS 921,727 contacted the health system in 2014. **CONCLUSIONS:** Our results give face validity to our RIPS information system and support its potential use both for research purposes and for decision making. Our health system has to be prepared for dealing with chronic conditions, with more comorbidities and with other characteristics of an older population. Additionally, our results suggest that the aging population process has been underestimated by our official statistics agency.

PHP118

CHANGES IN THE PERFORMANCE INDICATORS OF CHRONIC INPATIENT CARE IN HUNGARY BETWEEN 1990 AND 2015

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OBJECTIVES: The aim of our study was to demonstrate the changes in the performance indicators of chronic inpatient care in Hungary between 1990 and 2015. **METHODS:** The study involved the most significant performance indicators of chronic hospital capacities in the period examined, and we used descriptive statistics. The data derived from the financial database National Health Insurance Fund Administration, the single health care financing agency in Hungary. We analysed the period between 1990–2015. **RESULTS:** The number of chronic hospital beds decreased from 30,784 in 1990 to 27,314, in 2015. The lowest number of chronic beds was 19,295, in 2001. Conversely, the number of acute care beds decreased with 31,660 beds. The rate of the active/chronic number of beds changed from 70/30 to 60/40 in the period examined. The internal rates considering chronic beds changed to a great extent. Nursing homes were closed, the number of beds in Pulmonology decreased significantly and that of beds in Psychiatry reduced to a lesser extent. According to new challenges, the number of rehabilitation beds increased by 4.5-fold, to 15,107 beds. Permanent nursing capacities increased by 185%. The increase was not shown in the number of discharged patients, because fewer than 9,696 patients were discharged from chronic beds in the period examined. Despite the decrease in the number of beds, the number of discharged patients from active beds increased by 141,734. This fact shows the development of the technologies in active care. Considering chronic care, slight development could be observed. The number of nursing days decreased to 30.3 days in 15 years. Bed occupancy indicators within chronic care accounted for approximately 84%. **CONCLUSIONS:** According to international trends, the significance of chronic inpatient care capacities increased in Hungary. The internal rates of the number of chronic beds are consistent with the types of disorders; their necessity is supported by the bed occupancy indicators.

PHP119

EXPLORING FACTORS ASSOCIATED WITH MEDICATION SELF-SYNCHRONIZATION

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OBJECTIVES: To explore factors associated with medication self-synchronization. **METHODS:** This observational study includes established Walgreen patients who filled 4 unique maintenance medications in July 2016. Logistic regression is used to evaluate variables associated with medication self-synchronization defined as having just 1 trip (measured as unique prescription sold date) for all maintenance medications in the month. The independent variables include age, gender, payment type, copay amount, total number of prescriptions, maintenance medications indicators, and days supply indicator. **RESULTS:** Out of 613,405 patients in the study, 168,441 (27.46%) are self-synchronized and 444,964 are not (37.86% with 2 trips; 26.77% with 3 trips; and 7.91% with 4 trips). Younger patients are more likely to self-sync than older patients: odds ratios (OR) range from 1.37[1.33, 1.40] to 1.81[1.73, 1.91] compared to patients > 65 years old. Patients with low copays are more likely to self-sync than patients with high copays: odds ratios range from 1.09[1.04, 1.14] to 1.61[1.55, 1.66] compared to patients with copays > \$80. Patients taking selected maintenance medications are more likely to self-sync than patients who are not: odds ratios are 1.08[1.06, 1.10] for anti-diabetic, 1.34[1.31, 1.36] for anti-hypertensive, and 1.33 [1.30, 1.35] for anti-hyperlipidemic medications. Compared to patients who had both 30-day and 90-day fills, patients who had only 30-day fills or 90-day fills are more likely to self-sync: odds ratios are 1.52[1.49, 1.56] and 2.29[2.21, 2.38] respectively. Finally, patients with more prescriptions are less likely to self-sync (OR= 0.91[0.906, 0.915]). **CONCLUSIONS:** Medication self-synchronization is associated with age, copay amount, selected maintenance medication indicators, day supply indicators, and total number of prescriptions. Understanding the underlying factors of medication synchronization helps pharmacies design and deliver more effective patient support programs.

PHP120

THE PREVALENCE AND TYPE OF POTENTIALLY INAPPROPRIATE PRESCRIBING AMONG HOSPITALIZED GERIATRICS IN MALAYSIA

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OBJECTIVES: To identify the prevalence and types of potentially inappropriate medications (PIMs) and potentially prescribing omissions (PPOs) among community-dwelling geriatrics pre- and post-hospitalization. **METHODS:** A prospective cohort study involving patients ≥ 65 years old, on at least one medication for a minimum of 3 months prior to hospitalization, in a tertiary hospital in Malaysia. Data was collected from patients and their records after a signed consent form has been obtained. Patients were followed up until discharge. Medications at admission and discharge were reviewed to identify PIMs/PPOs using STOPP/START criteria Version 2. **RESULTS:** Of 300 patients, 44.3% (n=133) were females, with a mean age of 72 ± 6 years, length of hospital stay was 5.4 ± 3.7 days with a cumulative number of comorbidities upon admission of 3 ± 1.25 diseases. The prevalence of PIMs at admission was 35.3% (106 patients, 134 PIMs), which reduced at discharge to 31.6% (95 patients, 123 PIMs) (p=0.80). The three most common PIMs at admission and discharge were drugs that increase the risk of falls in patients with persistent postural hypotension, non-steroidal anti-inflammatory drugs (NSAIDs) used in patients with creatinine clearance CrCl < 50 mL/min, and metformin used in patients with CrCl < 30 mL/min. The prevalence of PPOs at admission was 47.6% (143 patients, 207 PPOs), which increased at discharge to 48% (144 patients, 201 PPOs) (p=0.99). The three most common PPOs at admission and

discharge were the omission of vitamin D supplement in patients with a history of falls, and the omission of angiotensin converting enzyme (ACE) inhibitor and β -adrenergic blocker in patients with documented coronary artery diseases. **CONCLUSIONS:** PIMs and PPOs are prevalent among community-dwelling geriatrics and hospitalization did not change their prevalence or type significantly.

PHP121

NATIONAL SURVEY OF PHARMACY PRACTICE AT MOH HOSPITALS IN SAUDI ARABIA 2016: DRUG MONITORING AND PATIENT EDUCATION

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OBJECTIVES: To explore the drug monitoring and patient education at Ministry of Health (MOH) hospitals in Saudi Arabia. **METHODS:** It is a 4-months cross-sectional national survey of drug monitoring and patient education at MOH hospitals in Saudi Arabia. The study consisted of two-part; a demographic information and the second part contained eighty-five questions divided into six domains drawn from American Society of Health-System Pharmacists (ASHP) survey. The parts were pharmacy management and resources, prescribing and medication management, preparation of drugs and dispensing, technology and clinical pharmacy services, drug monitoring and patient education, and pharmacy education and training. The 5-points Likert response scale system closed and ended questions used. An electronic questionnaire distributed to the one hundred eighty-five directors of pharmacies at MOH hospitals, and it analyzed the drug monitoring and patient education section through survey monkey system. **RESULTS:** The total responders were seventy hospital pharmacies; the response rate was (37.73%). The highest estimated number of drug monitoring was a prevented medication error per hospital per year (139,816.79), the drug information inquiries per hospital per year were (69,703.23), the adverse drug reaction was (61,905.16). The average number of patients counseling per hospital per year was (58,643.33), the number of pharmacist intervention per hospital per year (58,628.13). The patient education services existed in 52 (74.3%) hospitals. The patient education services were given through outpatient services 59 (84.3%), and at the bedside during discharge 19 (27.1%). The patient education provides to adults patient followed pediatrics and geriatrics patient at outpatient and inpatient setting. The most hospital pharmacies shared in national diabetic day 45 (64.3%) and national asthma day 23 (32.9%). **CONCLUSIONS:** The pharmacist had the active role in drug therapy monitoring and patient counseling. Expanding those services with regular documentation is recommended to improve the quality of the services and patient health care outcomes.

PHP122

THE IMPACT OF A PHARMACY OPERATIONS MODEL ON IMPROVING MEDICATION ADHERENCE

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OBJECTIVES: Suboptimal medication adherence continues to be a recognized issue. In recent years, one emerging pharmacy operations approach to improving adherence has been the appointment-based medication synchronization model. We evaluated the available literature to summarize the impact of medication synchronization model on relevant outcomes and identify gaps for future research. **METHODS:** A comprehensive literature search was conducted using PubMed and EMBASE since database inception. English studies were included if they were peer-reviewed observational and/or interventional studies that investigated impact of medication synchronization on outcomes. References of included studies were screened to identify additional articles for inclusion. Each study was screened by two independent reviewers. Discrepancies were resolved through a third reviewer. **RESULTS:** The search yielded a total of 271 records. After screening for relevance, inclusion criteria, and duplicates, a total of 9 articles were included for data extraction. The majority of studies (7/9) found a significant improvement in the CMS Medicare Star Ratings measures for adherence to oral anti-hyperglycemics, anti-hypertensives, and anti-hypercholesterolemics. One study assessed patient experience to this synchronization model; finding that patients were highly satisfied. One study concluded that medical savings per additional dollar spent on medications ranged from approximately \$1-37, depending on the medication. **CONCLUSIONS:** Medication synchronization has improved adherence across a series of chronic medications. However, even with these positive results, there is a paucity of peer-reviewed evidence evaluating the impact of medication synchronization on healthcare resource utilization (e.g., hospitalizations, ED visits), associated economic outcomes, and adherence to other medications outside of the CMS Star Ratings (e.g., COPD medications). Additionally, most studies were conducted using small sample sizes. Future research is needed that investigates the impact of medication synchronization on other priority conditions (e.g., COPD), other outcomes (e.g., hospitalizations, ED visits, and associated costs), and the overall impact on Star Ratings for Medicare Part D plans.

PHP123

EFFECT OF THE ORDER OF DRAW FOR MULTIPLE BLOOD COLLECTION TUBES ON DIAGNOSTIC PARAMETERS

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OBJECTIVES: There are numerous international standards and recommendations by pharmaceutical manufacturers for the order of draw to avoid contamination of the

sample caused by additives in blood collection tubes. Our goal was to examine whether changing the order of draw results in biases in the analyzed diagnostic parameters. **METHODS:** The quantitative, cross-sectional study was carried out in Karolina Hospital, Mosonmagyaróvár, Hungary between September 1. and November 31, 2016. We used non-randomized, purposive sampling in both experimental and control groups (N1=30, N2=30). In the experimental group, four incorrect orders of draw for phlebotomy tubes were used (Clot-activator, Na-citrate; Li-heparine, Na-citrate; K3 EDTA, native; Na-citrate, native). In the control group, the correct order of draw was followed (Na-cytrate, native, K3 EDTA). The following parameters were examined: prothrombin, INR, Potassium, Calcium, Magnesium, ALP. Data were analyzed using descriptive (absolute and relative frequencies, median with interquartile range [IQR]) and mathematical (χ^2 -test, Mann-Whitney U tests, linear and logistic regressions) statistics ($p < 0.05$). **RESULTS:** Incorrect order of draw (K3EDTA-serum tube) resulted in significantly decreased calcium levels in the experimental group compared to the control group (2.39 mmol/l [IQR: 2.33-2.46] vs. 2.60 mmol/l [IQR: 2.57-2.63], $p < 0.001$). Any other deviation in the order of draw failed to show significant biases. **CONCLUSIONS:** Incorrect order of draw for the sampling tubes during phlebotomy resulted in decreased level of calcium ion, which is a statistically significant difference, however, the value still remained in the normal clinical range.

PHP124

OUTCOMES ANALYSIS OF A SPECIALTY PHARMACY PROGRAM

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OBJECTIVES: To evaluate whether, compared with retail services, the use of specialty home delivery pharmacy services embedded in a health plan's operations is associated with improved medication adherence and reduced overall healthcare costs. **METHODS:** A retrospective, matched cohort study using administrative claims data was conducted using pharmacy and medical claims for patients receiving specialty medication from a specialty home delivery pharmacy and those filling at retail. Based on sample size and potential for differences in outcomes, subpopulations taking inflammatory, multiple sclerosis, oncology, HIV and renal transplant medications were selected. Patients were identified based on their first condition-related medication fill in 2014 and followed for one year. The cohorts were matched on confounders including demographics, Charlson comorbidity score and baseline use of pharmaceutical therapy, as well as condition-specific factors. Statistically significant differences were evaluated using T and chi-squared tests. **RESULTS:** The final analysis included 3,910 patients per cohort. The mean medical cost per patient was 10.8% lower in the home delivery group (\$11,928 v \$10,639; difference = \$-1,289; $P = 0.0176$) in the follow-up period. The home delivery group had lower mean inpatient hospital costs (\$2,640 v \$1,809, difference = \$-832; $P < .0001$). Patients in the home delivery group were more adherent to therapy, 62.9% v 72.1% had PDC > 80%, ($P < 0.0001$). Further, patients in the home delivery pharmacy group had higher levels of engagement in case management and other disease management programs 22.2% vs 25.2% ($P = 0.0019$). **CONCLUSIONS:** After adjusting for measured confounders, individuals who filled their oral and self-injectable specialty medications through mail order pharmacy had higher adherence rates and lower medical cost. This was accompanied by improved engagement in disease/care management programs. These results provide evidence of the effectiveness of patient education, refill management, and clinical management of adverse effects and drug interactions provided by specialty pharmacy services.

PHP125

PERCEPTION OF IRON DEFICIENCY IN MULTIDISCIPLINARY CLINICAL PRACTICES IN ALGERIA IN 2016: SUPFER DZ SURVEY

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OBJECTIVES: The aim of this survey was to assess the diagnostic modalities and the management of iron deficiency (ID) or iron deficiency anemia (IDA) in clinical practices in Algeria. **METHODS:** Physicians were selected from a professional database. They reported, on a self-administered questionnaire, the estimated frequencies of ID and IDA among their patients, the diagnostic modalities and treatments. They have also reported the conditions of use of oral or intravenous (IV) iron and erythropoiesis-stimulating agents (ESA). The survey analysis was performed on 349/400 questionnaires of physicians from different therapeutic areas (anesthesia, intensive care, surgery, n=43; gynecology, obstetrics, n=111; oncology, hematology, n=58; gastroenterology, n=64; cardiology, n=36; internal medicine, n=25; others, n=12). **RESULTS:** Out of 82% (290/349) of physicians reported cases of ID. Among them 20% (75/349) reported a frequency of ID $\geq 50\%$. Physicians were 97% (335/349) to report IDA among their anemic patient. For 71% (250/349) of them, frequency of IDA was > 30%. Physicians were 25% (88/349) to systematically explore ID (57% in gynecology-obstetrics) and 67% only if there is an anemia. Physicians (90%) mainly use oral iron as primary treatment of ID and are 29% who are using IV iron if hemoglobin (Hb) level ≤ 8 g/dL (median). Survey responders were 49% (170/349) to report transfusion for severe IDA (48% in the post-partum). In contrast with Hb level (89%), serum ferritin and transferrin saturation, were insufficiently performed: 66% (232/349) and 36% (125/349), respectively. The use of ESA was reported by 25% (60/238) of physicians [72% (42/58) in oncology and hematology]. **CONCLUSIONS:** This survey provides an initial source of information on the frequency of ID and IDA based on the routine clinical practices from a multidisciplinary sample of Algerian physicians. It appears that the monitoring of iron status parameters is advised to better optimize treatment and reduce blood transfusion.

PHP126

COMPARISON OF ADVERSE DRUG REACTIONS BETWEEN OLDER AND YOUNGER PATIENTS IN KOREA: USING ADVERSE EVENT REPORTING SYSTEM DATABASE FOR 2013-2015

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OBJECTIVES: Although older adults appear to be more prone to experience adverse drug reactions (ADR), a comparison of the health consequences of ADR between older (e.g., over 65 years of age) and younger (e.g., 65 years of age and under) adults has not been performed in the South Korean population. The aim of this study was to identify the characteristics of MEs between older and younger adult patients in South Korea using the Korea Adverse Event Reporting System (KAERS). **METHODS:** The KAERS database contained a total of 754,231 ADR reports from 38,974 patients with average 1.99 reports per patient. KAERS collects ADR reports that include patient demographics, concomitant drugs, patient outcome, reaction severity and the results of causality assessments. We conducted analyses with geriatric ADR reports from the KAERS database covering 2013 to 2015. Reporting odds ratio (ROR) was calculated to examine whether the number and types of ADR reports were statistically different between the two groups: (under vs over 65 years old). **RESULTS:** The proportion of ME reports for older adults was 1.38 times (95% CI = 1.207-1.578) greater than that of the young adults. In the 327 geriatric ADR reports examined, 18 different types of MEs were identified according to WHO-ART code. Of the most frequently reported types of geriatric ADRs, the number of reports of "off label use" (n=166, 50.8%) and "accidental overdose" (n=21, 6.4%) was 1.5 times (95% CI = 1.14, 1.96) and 2.96 times (95% CI = 1.48, 5.90) greater, respectively, in the older patients compared to younger adults. In addition, frequently used drugs and underlying diseases in the 327 older adults ADR reports were "prucalopride" (n=82, 25.1%) and "unspecified primary hypertension" (n=32, 11.0%), respectively. "Carcinoma in situ of stomach" (n=30, 8.3%) was the most frequently reported disease condition for which medicines that caused ME was prescribed. **CONCLUSIONS:** Older adult patients are more likely to experience ADRs because of off label medication use and accidental overdose than younger patients. This finding suggests the need for healthcare professionals to continuously monitor medication use to prevent possible ADRs.

PHP127

MULTIMORBIDITY AND POLYPHARMACY AMONG MEDICAID BENEFICIARIES – A MULTI-STATE ANALYSIS

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OBJECTIVES: Multimorbidity is highly prevalent among young adults and these adults often use multiple medication classes known as polypharmacy. Current definitions of polypharmacy are limited because they do not measure daily use of multiple medication classes. To examine the relationship between multimorbidity and polypharmacy, polypharmacy was estimated with the commonly-used measure and a novel measure. **METHODS:** In this cross-sectional study, data on fee-for-service Medicaid recipients (N = 54,907) were derived from 2010 Medicaid Analytic Extract files of Maryland and West Virginia. Nineteen chronic conditions based on the US Department of Health and Human Services framework were selected. Medication classes were identified using the National Drug Codes. Commonly-used polypharmacy measure was defined as number of drug classes (within an arbitrary 90-day time period) that was 1 standard deviation above the mean. The novel approach integrated the number of drug classes and duration of use to calculate simultaneous daily use medication classes. The simultaneous use of 5 or more different medication classes for a 60-day consecutive period was defined as polypharmacy. The association between multimorbidity and polypharmacy was examined with Chi-square tests and logistic regressions. **RESULTS:** Polypharmacy was estimated at 17.1% under the commonly-used approach and 38.1% under the novel measure. Individuals with multimorbidity had higher rates of polypharmacy under both definitions (33.3% -commonly-used measure vs. 64.5% -novel measure). Adults with multimorbidity were more likely to have polypharmacy for both measures (AOR = 8.6, 95% CI = 8.1 -9.2 -commonly-used measure; and AOR = 6.3, 95% CI = 6.0 -6.5 -novel measure), compared to those without multimorbidity. **CONCLUSIONS:** Polypharmacy was highly prevalent among adults with multimorbidity regardless of the definition used, although the commonly-used definition may underestimate the rate of polypharmacy.

PHP128

90-DAY INDEX FILLS AT RETAIL PHARMACY CONTRIBUTE TO HIGHER CMS STAR QUALITY MEASURES

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OBJECTIVES: To determine if 90-day fills at retail pharmacy are associated with greater adherence to medications included in the CMS Star quality measures. **METHODS:** This observational cohort study includes new and established Medicare Part D (Med D) patients 18 years or older who had at least one prescription fill for any of the three CMS Star drug classes (diabetes, hypertension, or cholesterol) at Walgreens retail pharmacy in January 2016. Patients who filled their first Star drug prescription (index fill) with a 90-day supply are included in the 90-day group and all others are in the 30-day group. To minimize the differences between groups, we propensity score matched patients in the 90-day group, one-to-one, to patients in the 30-day group on age, gender, copay, comorbidities, and past

medication adherence history. We evaluate two measures of medication adherence during the period from the index fill to the end of 2016: proportion of days covered (PDC) and optimal adherence (OA): the percent of patients with PDC ≥ 80%. Student's t-tests and Chi-square tests were used to evaluate differences in the 2 adherence measures. **RESULTS:** The study cohorts consist of 41,704 diabetes patients, 90,034 hypertension patients, and 80,164 cholesterol patients. Average PDCs in all 3 Star drug classes were significantly (p < 0.001) higher for the 90-day group than the 30-day group: diabetes: 82.44% vs. 75.84%, hypertension: 79.83% vs. 72.74%, and cholesterol: 77.09% vs. 70.45%. Percent of patients with PDC ≥ 80% in all 3 Star drug classes were also significantly (p < 0.001) higher for the 90-day group than the 30-day group: diabetes: 66.40% vs. 59.99%, hypertension: 60.22% vs. 53.98%, and cholesterol: 60.16% vs. 52.55%. **CONCLUSIONS:** When Med D patients start the calendar year with a Star drug class 90-day prescription at retail pharmacy they have significantly greater adherence measured in CMS Star ratings.

PHP129

CLINICAL AND ECONOMIC OUTCOMES OF CLINICAL PHARMACIST AT ADULTS CRITICAL CARE OF PRIVATE HOSPITAL IN SAUDI ARABIA

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OBJECTIVES: To explore the clinical and economic outcomes of clinical pharmacist at critical care units at private hospital in Riyadh city, Saudi Arabia **METHODS:** It is a 6-months cross-sectional study from January to June 2016 in adults critical care unit at Dr. Alhabib Group Chain Hospitals. It is one of the biggest private chain hospitals in Kingdom of Saudi Arabia. It was a thirty-bed critical care bed consisted of trauma, medical, surgical and maternity critical care cases. The pharmacist monitored all patients through daily medical round and documents any pharmacist intervention. The pharmacist intervention system used an international study model (Kinky et al., Ann Pharmacother 1999), measure level of activity, rational of clinical intervention, recommendation, patient outcome and pharmacoeconomic impact. The estimated cost avoidance of prevents drug-related problems. **RESULTS:** The total number of pharmacist interventions were (1,222). Among pharmacist intervention 956 (78.2%) was Saudi and 266 (21.8%) was non-Saudi. The gender distribution 540 (44.2%) was female, and 682 (55.8%) was male. The majority of them in age 65 or older 459 (37.6%) and age (18-40) 368 (30.1%). The most drug classification had interventions was Anti-infective drug 363 (29.7%) followed by musculoskeletal and joint disease medications 199 (16.3%). The highest interventions were potentially significant 610 (49.9%) and potentially serious 360 (29.5%). The most rationale of intervention was inappropriate dose 245 (20%), and therapeutic duplications (11.3%). The most patient outcome was unknown 539 (44.1%), patient condition improved 408 (33.4%), and therapeutic end point reached 133 (10.9%). The most pharmacoeconomic impact was the reduction in cost drug therapy 884 (72.3%). The estimated cost avoidance (220,882.1 USD), the total annual estimated cost avoidance (441,764.2 USD) **CONCLUSIONS:** The clinical pharmacist at critical care units of the private hospital is crucial and essential. The pharmacist prevent drug-related problems and saving additional cost of pharmacy services and health insurance system

PHP130

NATIONAL SURVEY OF PHARMACY PRACTICE AT MINISTRY OF HEALTH HOSPITALS IN SAUDI ARABIA 2016: PHARMACY MANAGEMENT AND RESOURCES

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OBJECTIVES: To explore pharmacy management and resources at Ministry of Health (MOH) hospitals in Saudi Arabia. **METHODS:** It is a 4-months cross-sectional national survey of pharmacy management and resources at MOH hospitals in Saudi Arabia. The study consisted of two-part demographic information, and the second part contained eighty-five questions divided into five domains drove from American Society of Health-System Pharmacists (ASHP) survey. The parts were pharmacy management and resources, prescribing and medication control, preparation of medications and dispensing, technology and clinical pharmacy services, drug monitoring and patients education. The 5-points Likert response scale system closed and ended questions used. An electronic questionnaire distributed to the one hundred eighty-five directors of pharmacies at MOH hospitals, and it analyzed the pharmacy management and resources section through survey monkey system. **RESULTS:** The total number of responders was sixty-five hospital pharmacies; the repose rate was (35.13%). The majority of pharmacy services consisted of outpatient pharmacy 55 (96.5%), pharmacy store 49 (81.67%), inpatient pharmacy 48 (80%) and emergency pharmacy 40 (70.18%). The seldom finding of pharmacy services were satellite pharmacy 4 (8.16%), and clinical pharmacy 7 (13.73%). The total number prescriptions dispensed were (53,125) per day with an average (1,080,45) prescriptions per hospital. The total number of pharmacists were (618), and pharmacy technicians were (818) with a mean (11.14) pharmacists and (14.26) pharmacy technicians per hospital respectively. The majority of hospital pharmacies had job description 45 (73.77%), vision 44 (68.75%), and mission 42 (68.75%). While the tiny percentages found were pharmacy annual plan 23 (38.98%), and pharmacy strategic plan or competency of pharmacy staff 26 (43.33%). **CONCLUSIONS:** Most of the hospital pharmacies missed some an essential of pharmacy practice with emphasis on Human Resources and clinical pharmacy services. Implementing of the MOH pharmacy strategic plan with close monitoring is required for all hospitals in Saudi Arabia.

PHP131

CAUSALITY, SEVERITY AND PREVENTABILITY PROFILING OF ADVERSE DRUG REACTIONS AMONG MEDICINE INPATIENTS IN A TERTIARY CARE PUBLIC TEACHING HOSPITAL, INDIA

Dar MA

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OBJECTIVES: This study was aimed to characterize the ADRs and to assess their causality, severity and preventability. **METHODS:** This prospective observational study was conducted in the patients admitted to medicine wards of a hospital. Patients either gender admitted in medicine wards were included in this study. The causality of ADRs was assessed using Naranjo's scale and WHO-UMC criteria. Severity and Preventability were assessed using modified Hartwig's severity scale and modified Schumock & Thornton criteria, respectively. **RESULTS:** Over the period of six months, data from 808 patients was collected. Of which 776 were analysed as they met the inclusion criteria. Out of 776 patients with complete documentation, 77 patients (45 male, 32 female) developed 82 ADRs (9.9%). 65.8% ADRs were observed in adults and 34.2% in geriatrics. Maximum number of ADRs were observed in age group of 40-49 years (25.6%). The highest number of ADRs were associated with antimicrobial drugs (24.4%) followed by diuretics (15.80%), opioid analgesics (14.6%), anticoagulants (14.6%) and antidiabetics (13.4%). Among the organs affected, approximately half of the ADRs were associated with GIT (46.3%) followed by metabolic (35.3%), haematological (14.6) and cutaneous (9.7%). Constipation (19.5%) followed by hypokalaemia (19.5%), coagulopathy (14.6%), hypoglycaemia (13.4%) and hypersensitivity reactions (9.7%) were most commonly observed ADRs. Causality assessment by Naranjo's scale revealed 13.4% of ADRs were 'definite', 52.4% were 'probable' and 34.2% were 'possible' in nature. WHO-UMC criteria showed 15.8% of ADRs were 'certain', 37.8% were 'probable' and 46.2% were 'possible'. Of the 82 ADRs, 31.7% were 'mild' and 68.3% were 'moderate'. Preventability assessment showed that 34.2% of ADRs were 'definitely preventable', 46.3% were 'probably preventable' and 19.5% were 'not preventable'. **CONCLUSIONS:** ADRs encountered in this study were either 'definitely preventable' or 'probably preventable'. A regular mechanism to monitor the patients may be an option to minimise the ADRs.

PHP132

CLINICAL OUTCOMES OF PHARMACOKINETICS SERVICES MANAGED BY PHARMACIST AT MINISTRY OF HEALTH HOSPITAL IN SAUDI ARABIA

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OBJECTIVES: To explore the clinical outcomes of pharmacist-managed Pharmacokinetics services at Ministry of Health Hospital in Saudi Arabia **METHODS:** It is a prospective study of pharmacokinetics services impact managed by a pharmacist over a period of six months at King Saud Medical City (KSMC). The study divided into two phases, each of 3-month duration for data collection and evaluation. The first phase (Phase I) was the Pre-intervention phase; the second was the intervention phase (phase II). Any patient received Gentamicin followed up by trained pharmacist. The pharmacist all pharmacokinetics parameters such as weight, height, culture sensitivity, and any adjustments in dosage, trough and peak levels and duration of administration recorded on a pharmacokinetics form on a regular basis at each phase. **RESULTS:** The total number of patients were 162 in phase I and 136 in phase II, the was no difference in age or gender. In the intervention phase, the adherence of labeled indication increased from 67 (41.4%) to 73 (53.7%) patients while adherences of non-labeled indications decreased from 95 (58.6%) to 63 (46.3%) patients. The sub-therapeutic trough levels of Gentamicin statistically significantly decreased from 22(13.6%) to 12 (8.8) patients ($p < 0.5$). The therapeutic level of gentamicin significantly statistically increased from 22 (13.6%) to 63 (46.3%) patients ($p < 0.05$). The sub-therapeutic peak levels of Gentamicin statistically significantly decreased from 40 (24.7%) to 18 (13.2%) patients ($p < 0.05$), while the therapeutic level of Gentamicin statistically significantly increased from 2 (1.2 %) to 55 (40.4%) patients ($p < 0.05$). All patients 136 (100%) were compliance of Gentamicin duration of administration time in the intervention phase. **CONCLUSIONS:** There is a significant impact of the pharmacist in the pharmacokinetics services, more compliance to indication guidelines, and decrease drug-related problems. Expanding the role of the pharmacist in therapeutic drug monitoring services is required at all hospitals in the Kingdom of Saudi Arabia.

PHP133

IMPACT OF CONVERSION IN RECTAL RESECTION FOR NON-RECTAL CANCER PATIENTS

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OBJECTIVES: This study aimed to assess the impact of conversion from minimally invasive surgery (MIS) to open surgery in rectal resection for non-rectal cancer patients. **METHODS:** Patients who underwent rectal resection in Premier Hospital Perspective® Database from 2008/01 to 2015/09 were included. Cases with rectal cancer ICD-9 diagnosis codes were excluded. Conversions were identified by ICD-9. Multivariate regressions were used to estimate the impacts of conversion through comparing converted vs. 1)non-converted cases; 2)open cases. Outcome measurements included postoperative complications, length of stay(LOS), operation time, total hospitalization cost. Further stratification analyses by surgeon speciality and teaching status were performed. **RESULTS:** Among 20385 non-rectal cancer patients with rectal resection in the study, 33.8% were done with MIS and 23.5% of those MIS were converted to open procedure. For non-rectal cancer patients, conversion to

open surgery had significant higher odds of postoperative complications(OR1.41, 95%CI[1.23-1.62]), longer LOS(0.89days, 95%CI[0.56-1.22]) and operation time (50.70mins, 95%CI[27.04-74.35]), higher total cost(\$2546.14, 95%CI[1503.10,3589.19]) than non-converted cases. Comparable LOS and total costs were observed among converted and open cases, but converted cases were associated with significantly higher risk of postoperative complications(OR1.13, 95%CI[1.01-1.28]), and longer operation time(71.22mins, 95%CI[48.43-94.02]). Among cases performed by non-colorectal surgeons, odds of having postoperative complications were significantly higher in the converted cases than non-converted cases(OR1.51, 95%CI[1.27, 1.79]) and open cases(OR1.15, 95%CI[1.00, 1.32]). In contrast, the impact of conversion on postoperative complication among colorectal surgeons' cases was insignificant. In community hospitals, total hospitalization cost for converted cases was significantly higher than open cases (\$2300.05, 95% CI[1131.05,3470.86]); whereas in teaching hospitals, cost for converted cases were lower yet insignificant than open cases. **CONCLUSIONS:** Conversion of rectal resection among non-rectal cancer patients is associated with higher risk of complication and longer OR time than non-converted cases and open cases. There are variations among surgeon specialties and hospital teaching status.

PHP134

ANTIMICROBIAL DRUG CONSUMPTION IN AMBULATORY CARE CLINICS AND EMERGENCY UNITS AT NORTH WEST (TABUK) REGION HOSPITALS, SAUDI ARABIA

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OBJECTIVES: To explore the Antimicrobial medication use in Ambulatory care clinics and Emergency Units at North West Region Hospitals, Ministry of Health, Saudi Arabia **METHODS:** It is 12-month antimicrobial drug consumption by ambulatory care clinics and Emergency department at North West region hospitals. It included all adults, pediatrics, and neonatal population. The medications selected by Central Antibiotics committee at MOH as part of the National Antimicrobial stewardship program. The consumption-is driven from pharmacy database and calculated base on of stranded unit of antimicrobial per each hospital. The cost of antibiotics consumption calculated by used Ministry of Health National Cost database. All cost used as US currency. **RESULTS:** The total number of Antimicrobial standard units at Ambulatory care clinics and Emergency were (25,116) and (8,687) with average (5,023.2) and (1,737.4) per hospital respectively. The highest drug consumption at Ambulatory care was Azithromycin tablet (10,932), followed by Azithromycin syrup (7,760), and Moxifloxacin tablet, while at Emergency department Azithromycin syrup (4,357) followed by Ceftriaxone injection (805) and Gentamicin 80 mg injection. The total cost of Antimicrobial consumption at Ambulatory care and Emergency were (37,620.13 USD) and (24,822.61) USD) respectively. The highest medication cost at ambulatory care was Levofloxacin injection, Linezolid tablet, and Azithromycin syrup while the Emergency they were Meropenem, Azithromycin syrup, and Moxifloxacin injection. **CONCLUSIONS:** An Ambulatory care clinics and Emergency department had a high consumption of antimicrobial drugs with burden cost. Antimicrobial stewardship program at Ambulatory care clinics and Emergency are necessary to prevent bugs related resistance, improve patient outcome and avoid especially adults Department is a mandate and necessary.

PHP135

POPULATION HEALTH STATUS OF BENEFICIARIES IN NARROW NETWORKS

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OBJECTIVES: To compare Medicare Advantage beneficiary population health status for patients utilizing provider services solely with narrow networks (NN) which are plans with relatively low copays and premiums, but where provider options are considerably constrained, or with Patient Centered Medical Home (PCMH) providers. **METHODS:** This retrospective cohort study used data from Strenuus, a managed care data aggregator, to identify providers participating in NN and PCMH product. Five insurers were selected based on size and variety of products, and their NN and PCMH product were identified. The patient population of Medicare Advantage (MA) members was extracted from a large nationally representative and statistically identified administrative claims database. Members were divided into three groups based on their provider: 1) members receiving services solely within a NN/PCMH ("In"); 2) members receiving services solely outside NN/PCMH ("Out"); and 3) members receiving services both in and outside of NN/PCMH ("Control"). CMS-HCC Risk Scores (version 22) were calculated for each member. The study sample consisted of MA beneficiaries who were continuously enrolled for 12 months within 2014 (N=1.4 million) and in 2015 (N=1.1 million). **RESULTS:** The distribution of members across the groups (In, Out and Control,) was 40%, 10% and 51%, respectively, and was consistent across years. In 2014, mean risk score (and standard deviation) for In, Out and Control, groups respectively were: 0.78 (0.56), .88 (.70), and 1.18 (.98). Similarly, in 2015, these results were 0.88 (0.51), 1.18 (0.70) and 1.44 (0.88). The mean risk scores across the three groups within each year were significantly different ($p < .01$). **CONCLUSIONS:** Data suggest that beneficiaries receiving all of their care

from NN/PCMH providers are healthier than those entirely outside NN/PCMH. Further, beneficiaries receiving a mix of in- and out-network are the least healthy of the three groups.

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PATIENTS' SATISFACTION OF AMBULATORY CARE PHARMACY SERVICES IN RIYADH CITY, SAUDI ARABIA

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OBJECTIVES: To explore the patient's satisfaction with ambulatory care pharmacy services at Riyadh city in Saudi Arabia. **METHODS:** It is 4-months cross-sectional survey of Patients satisfaction of Ambulatory care pharmacy services at Riyadh city in Saudi Arabia. The survey consisted of Forty-Eight questions divided into two-part demographic information and the second part with eleven domains. It included medication availability, patient counseling, pharmacist and patient relationship, medication reconciliation, medication aberrance, pharmacy location. Pharmacy waiting area, pharmacy communications, pharmacy waiting time, overall patient satisfaction of pharmacy services. The 5-points Likert response scale system closed and ended questions used. The survey distributed through three public, pediatrics, and emergency hospitals ambulatory care patient. The authors did the interview with the patient with electronic survey documentation. It analyzed through survey monkey system. **RESULTS:** The total responders were (606) Patients. Of those 509 (84.3%) was Saudi and 95 (15.7%) was non-Saudi. The gender distribution 338 (55.8%) was female, and 268 (44.2%) was male and the majority of them in age (18-44) 65.3%. The scores of medication availability domain were (3.35), patient counseling was (3.2), pharmacist and patient relationship were (3.7), and medication reconciliation was (1.96). The medication adherence was (1.8), pharmacy location was (3.7), pharmacy waiting area was (3.25), pharmacy communications was (2.14), pharmacy waiting time was (3.61), pharmacy recommends to others was (3.54). General evaluation of pharmacy services was very good-excellent with 381 (62.87%) of responders, while 369 (60.9%) advised the pharmacy to his family or friend and 315 (52.5%) of responders prefer to visit pharmacy again. **CONCLUSIONS:** A half of patients satisfied with ambulatory care pharmacy services at Riyadh city. The patients were not happy with medication reconciliation services, medication adherence, and pharmacy communications system. Improving ambulatory care pharmacy services will prevent drug misadventures, avoid additional cost, and raise patient satisfaction of pharmacy services.

PHP137

PHARMACIST INTERVENTION OF PREVENTION MEDICATION ERRORS AT PEDIATRICS, OBSTETRICS, AND GYNECOLOGY HOSPITAL, EAST PROVINCE, SAUDI ARABIA

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OBJECTIVES: The pharmacist intervention system started at East Province of Ministry of Health in 2013. The pharmacist interprets and prevents all drug related problems. The objective of this study was to explore pharmacist intervention and prevented medication errors at Pediatrics, Obstetrics and Gynecology hospital in East province, Saudi Arabia. **METHODS:** It is a cohort study of 12-months, 2015 of pharmacist intervention and prevention medication errors. The system established at 500-bed Pediatrics, Obstetrics and Gynecology Hospital in 2013. This system was a part of medication safety program. The hospital had medication safety officer with medication safety committee. Any intervention should document through medication error form. The structure consisted of patient information, the sources of medication errors, time of mistakes. The type of medication errors, description of errors, causes of errors, recommendation to prevent the errors, and the outcome of medication errors by using National Coordinating Council (NCC) for Medication Error Reporting and Prevention (MERP) system. **RESULTS:** The total number of prevented medication errors were 1654 in 827 prescriptions. The majority of medication errors committed through physicians followed by nurses. The most error stopped with Pediatrics (1-month to 6 years) followed by young adults (18-40 years). The majority type of mistakes was prescriber-related 1216 (73.52%) followed by patient-related errors 426 (25.75%). The outcome of medication errors were near miss 1651 (99.82%). The most medications prevented errors were Paracetamol syrup, Iron tablet, Folic acid tablet, and Calcium tablet. There were three errors of high-risk medications were avoided included Insulin, Enoxaparin, and Heparin. **CONCLUSIONS:** The pharmacist plays a significant role in preventing medication errors, especially in pediatrics populations. The necessity of pharmacist provides basic medication safety education to all health care providers. Expanding pharmacist role in preventing medication errors associated with patient safety and avoid the unnecessary cost.

PHP138

NATIONAL SURVEY OF DRUG INFORMATION CENTERS PRACTICE IN SAUDI ARABIA: MEDICATIONS-USE EVALUATION SERVICES AT MINISTRY OF HEALTH

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OBJECTIVES: To explore Drug Information Centers practice in Saudi Arabia: with emphasis on Medication-Use Evaluation services at MOH. **METHODS:** It is a

national survey of Drug Information Services at MOH. It consisted of a demographic section and ten domains with 181 questions. The ten areas included; Leadership and Practice Management, Medication Addition and Deletion System, Hospital Formulary System, Medication Safety System, Professional, and Public Education. The Evidence Based Medicine-Therapeutics Guidelines, Medication-Use Evaluation (MUE), Pharmacoeconomics System, Investigational Drug Services (IDS) and Professional Publications Services (PPPS), and Ethical and Legal Issue. It drove from International pharmacy standard and best practice guidelines. The domain of Medication-Use Evaluation explored and analyzed. **RESULTS:** The survey distributed to forty-five of hospitals, the response rate, was 40 (88.88%) hospitals. Of that, 35 % were large hospitals and 37.5 % were medium-sized hospitals. The organizational authority for the MUE process found at 26 (65%) of hospitals and the indicators for comprehensive surveillance of the medications use system existed in 24 (60%) hospitals. The priorities aspects of MUE existed in 24 (60%) hospitals. The informality of health-care professionals objectives and expected benefits of the MUE process exist in 25(62.5%). The Criteria, guidelines, treatments protocols and standards of care for specific medications existed in 26 (65%) hospitals applied 25-100% the elements. Educate health-care professionals to promote the use of criteria, guidelines, treatment protocols, and standards of care existed in 27 (67.5%) hospitals. The implementation plan for improvement of the medications uses exist in 25 (62.5%) hospitals. **CONCLUSIONS:** There was an incomplete implementation of Medication-Use Evaluation in drug information centers practice. Establishing strategic planning of Medication-Use Evaluation system and set up an educational program for drug information pharmacist, will improve Medication-Use Evaluation practice.

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NATIONAL SURVEY OF PHARMACY PRACTICE AT MOH HOSPITALS IN SAUDI ARABIA 2016: TECHNOLOGY AND CLINICAL PHARMACY SERVICES

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OBJECTIVES: To explore pharmacy technology and clinical pharmacy services at Ministry of Health (MOH) hospitals in Saudi Arabia. **METHODS:** It is a 4-months cross-sectional national survey of technology and clinical pharmacy services at MOH hospitals in Saudi Arabia. The study consisted of two-part a demographic information, and the second part contained eighty-five questions divided into six domains drove from American Society of Health-System Pharmacists (ASHP) survey. The parts were pharmacy management and resources, prescribing and medication management, preparation of drugs and dispensing, technology and clinical pharmacy services, drug monitoring and patient education, and pharmacy education and training. The 5-points Likert response scale system closed and ended questions used. An electronic questionnaire distributed to the one hundred eighty-five directors of pharmacies at MOH hospitals, and it analyzed the pharmacy technology and clinical pharmacy services section through survey monkey system. **RESULTS:** The total responders were seventy hospital pharmacies; the response rate was (37.73%). Pharmacy computerized and technology in drug distribution network found in 14 (20%) hospitals only. The computerized physician order entry (CPOE) found at (13.14%) hospital pharmacies and alarming medication system at (10.27%) hospital pharmacies. The majority of hospital pharmacies 60 (85.7%) was not used new technology for drug distribution network. The most clinical pharmacy activities found were medication error preventing and monitoring 59 (89.39%), patient drug counseling 52 (78.79%), and provide drug information services 49 (75.38%). The hospital pharmacies provided clinical activities to adult Emergency section 39 (62.9%), adult medicine and surgery 40 (62.5%) units. The most clinical services measured clinical outcome, and cost avoidance was patient drug counseling 33 (55%), medication errors prevention 32 (52.46%), adverse drug reaction prevention 28 (46.67%), drug information inquiries 26 (44.07 %). **CONCLUSIONS:** Pharmacy computerization and technology seldom implemented at MOH hospitals. The clinical pharmacy services are high demand to all medical and surgical for pediatric, adults, and geriatrics patients.

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ANTIMICROBIAL DRUG CONSUMPTION IN INTENSIVE CARE UNITS AT NORTH WEST (TABUK) REGION HOSPITALS, SAUDI ARABIA

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OBJECTIVES: To explore the Antimicrobial medication use in Intensive care units at North West Region Hospitals, Ministry of Health, Saudi Arabia. **METHODS:** It is 12-month antimicrobial drug use by Intensive care units at North West region hospitals. It included critical care for adults, pediatrics, and neonates. The medications selected by Central Antibiotics committee at MOH as part of the National Antimicrobial stewardship program. The consumption-driven from pharmacy database and calculated base on of stranded unit of antimicrobial per each hospital. The antimicrobial consisted of antibacterial drugs, antifungal, and antiviral medications. The cost of antimicrobial consumption calculated by used Ministry of Health National Cost database. All cost used as US

currency. **RESULTS:** The total number of Antimicrobial standard units was (14,305) and average (2,861) per hospital. The highest drug consumption was Ceftriaxone 1 gm injection (2724) followed by Imipenem 500 mg injection (1251) and Vancomycin 500 injection (1165). The total cost of Antimicrobial consumption was (53,884.95 USD) and (10,777 USD) per each hospital. The highest cost medication consumption from Adults critical care (39,562.33 USD) followed by pediatrics critical care (9,779.93 USD) and Neonates critical care (4,542.68 USD). The highest medication cost was Imipenem, Meropenem, and Moxifloxacin. It consumed more than 50% of the cost burden. **CONCLUSIONS:** The study is the first in Saudi Arabia, Gulf and Middle East countries. Health system pharmacies leaders are targeting apply antimicrobial stewardship program, and National Drug Utilization Evaluation system to control unnecessary medication expenditures and prevent misuse of medicines.

PHP141

NATIONAL SURVEY OF PHARMACY PRACTICE AT MOH HOSPITALS IN SAUDI ARABIA 2016: PHARMACY EDUCATION AND TRAINING SERVICES

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OBJECTIVES: To explore the pharmacy education and training services at Ministry of Health (MOH) hospitals in Saudi Arabia. **METHODS:** It is a 4-months cross-sectional national survey of pharmacy education and training services at MOH hospitals in Saudi Arabia. The study consisted of two-part; a demographic information and the second part contained eighty-five questions divided into six domains from American Society of Health-System Pharmacists (ASHP) survey. The parts were pharmacy management and resources, prescribing and medication management, preparation of drugs and dispensing technology and clinical pharmacy services, drug monitoring and patient education, and pharmacy education and training. The 5-points Likert response scale system closed and ended questions used. An electronic questionnaire distributed to the one hundred eighty-five directors of pharmacies at MOH hospitals, and it analyzed the pharmacy education and training section through survey monkey system. **RESULTS:** The total responders were seventy hospital pharmacies; the repose rate was (37.73%). The most hospital pharmacies had a continuing medical education (CME) required 41 (58.6%), and allowed paid time off continuing education program was 31 (41.3%). The policy of CME existed in 33 (47.1%) only while not lived in 37 (52.9%) hospital pharmacies. The most affiliated training program was the pharmacy technician student training program 40 (57.1%) with a total number of candidates (176) annually, and pharmacy students training program 28 (40%) with a total number of candidates was (189) annually. The most courses delivered to health care providers by pharmacists were basic medication safety, cardiopulmonary resuscitation drugs, and an emergency medicine. **CONCLUSIONS:** The hospital pharmacies had adequate an education and training services for pharmacists and pharmacy technicians while missed of Pharm D student and post-graduated residency programs. Review of strategies for pharmacy education and training is highly recommended.

PHP142

ANALYSIS OF ANTIMICROBIAL MEDICATION CONSUMPTION IN INPATIENT UNITS AT NORTH WEST (TABUK) HOSPITALS, SAUDI ARABIA

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OBJECTIVES: To explore the selected Antimicrobial medication consumption in inpatient units at North West Region Hospitals, Ministry of Health, Saudi Arabia. **METHODS:** It is 12-month antimicrobial drug use by inpatients at North West region hospitals. It included inpatient department for adults, pediatrics, and neonates. The medications selected by Central Antibiotics committee at MOH as part of the National Antimicrobial stewardship program. The consumption-driven from pharmacy database and calculated base on of stranded unit of antimicrobial per each hospital. The antimicrobial consisted of antibacterial drugs, antifungal, and antiviral medications. The cost of antimicrobial consumption calculated by used Ministry of Health National Cost database. All cost used as US currency. **RESULTS:** The total number of Antimicrobial standard units was (25,845) and average (5,169) per hospital. The highest drug consumption was Ceftriaxone 1 gm injection (8,572) followed by Ceftazidime 1 gm mg injection (2,147) and Imipenem 500 mg injection (1,347). The total cost of Antimicrobial consumption was (6,829,003.42 USD) and (1,365,800.68 USD) per each hospital. The highest cost medication consumption from Adults inpatient departments (6,803,229.92 USD) followed by pediatrics inpatient (16,087.6 USD) and Neonatal inpatient departments (9,685.9 USD). The highest medication cost was very broad spectrum antibiotics like Meropenem, Imipenem, and Ceftriaxone. It consumed more than 50% of the cost burden. **CONCLUSIONS:** There was very high consumption of antimicrobial drugs inpatient department with huge cost burden. Urgent application of antimicrobial stewardship program especially adults inpatients departments is a mandate and urgent.

PHP143

NATIONAL SURVEY OF PHARMACY PRACTICE AT MOH HOSPITALS IN SAUDI ARABIA 2016: PREPARATION OF MEDICATIONS AND DISPENSING

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OBJECTIVES: To explore the preparation of medications and dispensing at Ministry of Health (MOH) hospitals in Saudi Arabia. **METHODS:** It is a 4-months cross-sectional national survey of preparation of drugs and dispensing at MOH hospitals in Saudi Arabia. The study consisted of two-part a demographic information, and the second part contained eighty-five questions divided into six domains from American Society of Health-System Pharmacists (ASHP) survey. The parts were pharmacy management and resources, prescribing and medication management, preparation of drugs and dispensing, technology and clinical pharmacy services, drug monitoring and patient education, and pharmacy education and training. The 5-points Likert response scale system closed and ended questions used. An electronic questionnaire distributed to the one hundred eighty-five directors of pharmacies at MOH hospitals, and it analyzed the preparation of medications and dispensing section through survey monkey system. **RESULTS:** The total responders were seventy hospital pharmacies; the repose rate was (37.73%). The pharmacy services were the drug distribution unit dose 26 (37.1%), an extemporaneous preparation 14 (20%), repacking medication 14 (20%), and Intravenous admixture 6 (8.6%) only. The hospital home infusion therapy provided from 4 (5.7%) hospital pharmacies only. The most outpatient prescriptions dispensed to hospital employees 48 (68.8%), general public 42 (60%), hospital clinic or patients discharged or emergency room 40 (57.1%), and home healthcare services 22 (31.4%). The most pharmaceutical services were decentralized with distributive function 41 (61.4%) and centralized with pharmacist visiting patient care areas 17 (24.3%). The most system founded to assure the accuracy of preparations and dispensing was one pharmacist checks drug order before dispensing 33 (47.1%), and two pharmacists review high-risk drugs 17 (24.3%). **CONCLUSIONS:** The essential elements of pharmacy practice were weak at MOH hospitals. Annual survey of pharmacy services with improving drug distribution system prevent drug-related problem and improve patient care at Hospitals in Saudi Arabia.

PHP144

WORKLOAD ANALYSIS OF PHARMACEUTICAL CARE SERVICES AND STAFFING REQUIREMENTS AT MINISTRY OF HEALTH HOSPITALS DURING MASS GATHERING HAJJ-2016 IN SAUDI ARABIA

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OBJECTIVES: To explore the pharmaceutical care services workload analysis and staffing needs at Ministry of Health Hospitals during mass gathering (Hajj -2016) in Saudi Arabia. **METHODS:** It is 15-days cross-sectional of Pharmaceutical care services workload analysis during mass gathering Hajj period 2016. The pharmacist and pharmacy technicians provide pharmaceutical care to all patient either Pilgrim or non-pilgrim at Makkah region. It included Mona holy places hospitals; Arafah holy places hospitals, and Makkah city. The workload drives as central pharmacy services, patient specific pharmacy activities, and general administration specific pharmacy activities. **RESULTS:** The total number of hospitals was sixteen hospitals. They located at Mona holy places were four hospitals, Arafah holy places were four hospitals, and Makkah city was eight hospitals. The total number of prescriptions was (156,053). Of those (95,460) were Ambulatory care prescriptions, while (54,903) were Emergency Prescriptions, and (5690) were inpatient orders. The average number of Ambulatory prescription per day (6,364) contained (286,380) medications, the mean number of Emergency orders was (3,660.2) per day included (164,709) medications, and the average of an inpatient order was (379.33) per day provided (17,070) drugs. The average time of dispensing inpatient prescription was 6 minutes; while Ambulatory care and emergency were 4 minutes. The number of pharmacists needed (5.84 FTE) for inpatient services per day, (37.54 FTE) for Emergency services per day, and (65.27 FTE) for Ambulatory care services per day. There were not any central pharmacy activities, and clinical pharmacy services or administrative pharmacy activities. **CONCLUSIONS:** The workload analysis of pharmaceutical care services is a part of total quality indicators tool during mass gathering Hajj. Clinical pharmacy activities missed with emphasis on patient-specific clinical pharmacy. There is a highly demand of pharmacists and clinical pharmacists workforce during mass gathering Hajj period.

PHP145

AMINOGLYCOSIDE THERAPEUTICS MONITORING COMPLIANCE AT MINISTRY OF HEALTH HOSPITAL IN SAUDI ARABIA

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OBJECTIVES: To explore the adherence of Aminoglycoside (Gentamicin, Tobramycin, Amikacin) with basic pharmacokinetics and therapeutic monitoring guidelines in Saudi Arabia. **METHODS:** It is a prospective cross-sectional of Aminoglycoside (Gentamicin, Tobramycin, Amikacin) basic pharmacokinetics and therapeutic monitoring guidelines adherence. It conducted over a 3-Month at King Saud Medical City (KSMC) surgical wards. The guidelines based on basic pharmacokinetics and therapeutic monitoring guidelines. Any patient received Gentamicin followed up by trained pharmacist and supervised clinical pharmacist. The pharmacist measures the adherence of the following elements including; the USA FDA (Food and Drug Administration) labeled indication, all details such as weight, height, bugs culture sensitivity. Moreover, any adjustments of dosage, trough and peak levels and duration of administration recorded on a therapeutic drug monitoring (TDM) form on a systematic basis. All data gathered were statistically evaluated using SPSS version 22. **RESULTS:** The total number of

patients were 162, which 126 (77.7%) were male and 36 (22.2%) were female and a mean age of 34.34 ± 15.71 (M \pm SD) years. Of those 22 (13.8%) patients located from general surgery wards and 138 (86.3%) was from orthopedic wards. All patients received Gentamicin only. Ninety-Five (58.6%) non-adherence to FDA labeled indications while 67 (41.4%) adherence to FDA labeled indication. All patients 162 (100%) were non-compliance of Gentamicin duration of infusion administration time. The trough levels of Gentamicin were sub-therapeutic level in 22(13.6%) patients, 3(1.6%) patients' toxic levels, and 115 (71 %) patients have not checked the drug levels. While the peak levels were sub-therapeutic level in 40 (24.7%) patients, 1(0.6%) patients toxic levels, and 119 (73.5%) patients have not checked the drug levels. **CONCLUSIONS:** There was a poor adherence to Gentamicin basic pharmacokinetics and therapeutics monitoring guidelines. For aiming compliance, and the guidance leads to decrease Gentamicin resistance, prevent the Gentamicin-related problem, improve Gentamicin therapeutic outcome, and avoid the unnecessary additional cost.

PHP146

COMMUNICATIONS AND RELATIONSHIP FACTORS ON PHARMACY CAREER SATISFACTION IN SAUDI ARABIA

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OBJECTIVES: To explore the communications and relationships factors of Pharmacist Job satisfaction in Saudi Arabia. **METHODS:** It is a 4-months cross section survey of communication and relationships factors on Pharmacist Job satisfaction in Saudi Arabia. The study consisted of forty-three questions divided into two-part demographic information and the second part was the questions about communication and relationships factors of pharmacy job. It included pharmacy supervisors, relationship with coworkers, and pharmacist interaction with other healthcare providers, the customer interaction, and overall job satisfaction. The 5-points Likert response scale system closed and ended questions used. The survey made as an electronic format, and it analyzed through survey monkey system. **RESULTS:** The total responders were two hundred and forty-two. Of those 214 (91.8 %) was Saudi and 33 (8.2%) was non-Saudi. The gender distribution 169 (70.7%) 55.8% was male, and 70 (29.3%) was female. The majority of them 202 (84.2%) were in age (20-39). The most educational level of the responders was pharmacy diploma level was 97 (40.6%) and pharmacy bachelor degree 98 (41%). Most of the current position was pharmacy technician 78 (34.1%) and staff pharmacist 78 (34.1%) and worked at inpatient pharmacy 73 (34.9%), and outpatient pharmacy 83 (39.7%). The average satisfaction score of pharmacy supervisors' factors was (2.99) the pharmacist relationship with coworkers was (3.68), pharmacist interaction with other healthcare providers' factors was (3.34), and the customer interaction factors were (3.29). Most of the pharmacist found the challenges at their job were (78%). Some responders wished to change their pharmacy career (43.4%) while (63.4%) liked to stay in the pharmacy field. **CONCLUSIONS:** Most of the pharmacists not satisfied with their job because of the supervisor relationship. The pharmacy supervisors of hospital pharmacies demanded of management tools and communication skills with their colleagues

PHP147

HOW IS HEALTH RESOURCE ALLOCATED IN NIGERIA?

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OBJECTIVES: To evaluate the methods of priority setting used in Nigeria and how it compares with that used in other Low and middle income countries (LMICs). **METHODS:** A systematic literature review on the process of prioritization in LMICs was carried out at the initial phase of the study. Following the review, a mixed method study comprising of an in-depth interviews of health policy makers (N=22) and the distribution of self-administered questionnaire to health workers (N=77/150) was conducted at the 3 tiers of health care - national, state and local levels. The participants at all levels were sampled purposively for the interviews and the questionnaire distribution to the health-workers at each level. The qualitative data was analysed thematically as an iterative process. The self-administered questionnaires were analysed quantitatively. **RESULTS:** The predominant form of financial resource allocation was through budgeting, guided by needs (21%) and political consideration (23%), as typified by this quote - "...and based on the priorities...that will now go through the process of budgeting and approval by the state executive council and then to the state assembly". Further exploration of the priority setting process revealed a lesser defined process at the state level compared to the federal level. There was a strategic relationship between the states and the federal system through a concurrent listing system. In contrast, the local and institutional level of prioritization was more inclusive of stakeholders and its allocation of financial resources was performance-based and largely influenced by the state level policy makers. In the literature, only 2 studies (one central and one decentralised health system) examined this process at all levels in a LMIC, which differed in context, from the Nigerian health system. **CONCLUSIONS:** Health care prioritization is a highly context specific process, that requires a tailoring of approaches, to suit each organisational level of care.

PHP148

CALCULATING RETURN-ON-INVESTMENT FOR A MEDICATION THERAPY MANAGEMENT PROGRAM

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OBJECTIVES: To calculate the return-on-investment (ROI) for a medication therapy management (MTM) program. **METHODS:** Patients were included if they:

i) started a MTM pilot program during Jul 1, 2014 to Sep 1, 2014, and ii) were continuously enrolled six months before and after their index date, defined as the date on which a patient started the MTM program. Using claims data from a commercial payer, mean and median healthcare utilization and cost in the six months before the index date were compared with that in the six months after the index date. A comparison group was randomly selected from eligible candidates for the MTM program who were not contacted. ROI was calculated in two ways: i) by taking the mean pre-post savings, or difference in costs in the six months before versus after the index date, and dividing by program costs, and ii) by taking the difference in pre-post savings between the intervention group and comparison group, and dividing by program costs. **RESULTS:** There were 75 patients in the intervention group and 99 patients in the comparison group. Using the first method, the ROI for the MTM program was calculated as approximately \$2.50 savings for every \$1 spent. Using the second method, the ROI for the MTM program was calculated as approximately \$4 savings for every \$1 spent. **CONCLUSIONS:** There are various methods in calculating ROI for MTM programs; one must be careful to understand the strengths and weaknesses of each method.

PHP149

PATIENT AND PRIMARY KNOWLEDGE ABOUT MEDICATIONS IN SAUDI ARABIA

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OBJECTIVES: To explore the patients and basic understanding of medicines in Saudi Arabia. **METHODS:** It is a 4-months cross-sectional survey of patient and basic knowledge of medicines. The questionnaire consisted of two-part demographic information, and second part forty-nine questions divided into four domains. It included basic information about medication, patient information about the drug related problem, patient information about drug-related cost, and patient perception of medications. MedlinePlus and DailyMed health information used. The 5-points Likert response scale system used. The survey distributed through social media and at 500-bed pediatrics and maternity hospital in Asir region, at ambulatory care pharmacy. The survey made an electronic format, and it analyzed domain one through survey monkey system. **RESULTS:** The total responders were (614) Saudi patients. The gender distribution 523 (86.7%) was female, and 91(13.3%) was male. The majority of them in age (18-44) 78.3% and located at Asir region 325 (115%) and Riyadh region 163 (46.9%). The most type of medications used was anti-diabetic and anti-hypertension medicines, Skin medications, and drugs for Respiratory diseases. The responders showed poor knowledge either they do not know or weak information about the generic name of Medicines 300 (54.8%), the trade name 146 (46.8%), drug strength 182 (34.2%). The responder showed adequate knowledge about medications with complete information about drug indication 333 (56.8%), how to use medications 419 (71.6%), the administration time 419 (72%), the potential to adhere medication 325 (55.7%), and the time to stop drugs 293 (50%). The majority of responders used health care providers 346 (57%), drug bulletin 341 (56.2%), and Internet 221 (36.4%) as sources of drug information. **CONCLUSIONS:** The finding showed indigent essential drug information knowledge. Targeting of public awareness of basic information about their medications and patient counseling system will prevent drug misadventures and drug-related morbidity and mortality in Saudi Arabia.

PHP150

PATIENTS AND HEALTHCARE PROVIDERS' ATTITUDES AND PERCEPTIONS ON DRUG -RELATED PROBLEMS IN SAUDI ARABIA

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OBJECTIVES: To explore the patients and healthcare providers' attitudes and perceptions on drug-related problems in Saudi Arabia. **METHODS:** It is a 4-months cross-sectional survey of drug related problem information in Saudi Arabia. The study consisted of two-part a demographic data, and second part contained the questions about the knowledge of drug-related problems, the frequent occurrence, the type of medication-induced those problems, and the resources information used about drug related problem. American Society of Health-System Pharmacist definitions of drug-related problems were used. The 5-points Likert response scale system used. The survey distributed through social media. The questionnaire made of an electronic format, and it analyzed through survey monkey system. **RESULTS:** The total responders were two hundred and one. The gender distribution was female 180 (89.6%), and male was 21 (10.4%). The majority of them in age (18-44) 88%. Of those 44 (22.1 %) were health care providers. The majority of responders showed good knowledge about medication non-compliance 150 (75.76%), and medication without indication 147 (73.1%), while an adequate revealed information of adverse drug reaction 128 (64%), and an indication without medication 124 (62%). The poor information found about drug interaction 75 (37.5%) and drug poisoning 89 (44.5%). The most frequent drug-related problems occurred with the patient last year at least once; it was drug non-compliance 142 (71.4%), indications without medication 100 (50%), and adverse medication events 80 (40%). The most type of medications induced the problems were Antibiotics, the drugs for pain, and dermatology drugs. The most resources information of drug-related problems used were the internet, medicine leaflet, and health care practitioners. **CONCLUSIONS:** Drug-related problems occurred at a high rate in Saudi patients. The knowledge of drug-related problems is not adequate. It is very demanding and comprehensive public education about medication and urgent implementation of the patient medications counseling program in Saudi Arabia.

PHP151

ECONOMIC OUTCOMES OF PHARMACIST MANAGED NEONATAL TOTAL PARENTERAL NUTRITION SERVICES AT MINISTRY OF HEALTH IN SAUDI ARABIA

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OBJECTIVES: The National Total Parenteral Nutrition Program started in 2013 at General Administration of Pharmaceutical Care in Saudi Arabia. The pharmacist-managed Neonates Total Parenteral nutrition (TPN) services. The study objective was stimulation of estimated cost avoidance of pharmacist-managed neonates TPN services by used American Model with local cost. **METHODS:** Simulation of 17-hospitals had Neonates TPN services. A 300-Bed Hospital with 6-month TPN services for infants in 2015. The cost of TPN services estimated by variable expenses including personal cost, material and supply cost. Fixed costs including overhead cost and non-salary cost. The cost derived from Ministry of Health information database. TPN services started from prescribing, preparation, dispensing, administration, and follow-up, and discounted the TPN order. Cost avoidance stimulation of pharmacist running neonates TPN services at seventeen hospitals in Saudi Arabia calculated of all TPN stages. All cost calculation used by US dollar currency. **RESULTS:** The total number of TPN prescription was (176 per day) and (74,240 TPN orders per year) for a total seventeen hospitals. The total estimated cost of TPN services managed by a physician was (863.74 USD) per day; while the cost of (786.75 USD) per day if the TPN services run by the pharmacist. The total estimated expenditures of TPN services by a physician (64,124,057.6 USD) annually. The total estimated costs of TPN services managed by the pharmacist (58,408,320 USD) annually. The estimated cost avoidance was (5,715,737.6 USD) annually and (13,550.24 USD) per day. The estimated cost saved was (76.99 USD) per each TPN prescription. **CONCLUSIONS:** In this Neonatal Total Parenteral Nutrition cost-Avoidance simulation for Saudi Arabia, it is with cost savings per each prescribing TPN order. Expanding of pharmacist-managed TPN services for neonates associated cost avoidance simulation for healthcare services.

PHP152

CLINICAL OUTCOMES OF VANCOMYCIN THERAPEUTIC MONITORING SERVICES AT MINISTRY OF HEALTH HOSPITAL IN SAUDI ARABIA

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OBJECTIVES: To explore the clinical outcome of Vancomycin therapeutic monitoring services at Ministry of Health Hospital in Saudi Arabia. **METHODS:** It is a cross-sectional clinical outcome of Vancomycin therapeutic monitoring over a period of 9-months at King Saud Medical City (KSMC). The study divided into three phases, each of 3-month duration for data collection and evaluation. The first phase (Phase I) was the Pre-intervention phase; the second was the intervention phase (phase II), the third phase Post-intervention phase (Phase III) without any pharmacist. Any patient received Vancomycin followed up by trained pharmacist. The pharmacist followed a labeled indication, all pharmacokinetics parameters such as weight, height, bug culture sensitivity, and any adjustments in dosage, drug level and duration of administration recorded on a therapeutic drug monitoring form on a regular basis at each phase. **RESULTS:** The total number of patients 53 in phase I, 22 in phase II, and 31 in phase III respectively. The labeled indication adherences increased significantly from phase I to phase II 24 (45.3%) to 19 (86.4%) respectively while significantly decreased in 21 (67.7%) patients in phase III ($p < 0.05$). The non-labeled indications adherences decreased from phase I to phase II 29 (54.7%) to 3 (13.6%) patients respectively. The levels of Vancomycin as sub-therapeutic level significantly decreased from 23 (43.4%) to 0 (0.0%) in patients ($p < 0.5$), the therapeutic Vancomycin level significantly increased from 11 (20.8%) to 20 (90.9%) in patients ($p < 0.05$). The wrong sampling time significantly decreased from 22 (41.5%) to 7 (31.8%) in patients ($p < 0.05$). **CONCLUSIONS:** There is a significant adherence to Vancomycin therapeutic guidelines. Targeting to expanding the role of the pharmacist in Vancomycin therapeutic monitoring is required to improve patient outcome and prevent Vancomycin drug-related problems, and avoid the unnecessary additional cost.

PHP153

NATIONAL SURVEY OF PHARMACY PRACTICE AT MOH HOSPITALS IN SAUDI ARABIA 2016: PRESCRIBING AND MEDICATION MANAGEMENT

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OBJECTIVES: To explore the prescribing and medication management practice at Ministry of Health (MOH) hospitals in Saudi Arabia. **METHODS:** It is a 4-months cross-sectional national survey of prescribing and medication management at MOH hospitals in Saudi Arabia. The study consisted of two-part a demographic information, and the second part contained eighty-five questions divided into six domains drove from American Society of Health-System Pharmacists (ASHP) survey. The parts were pharmacy management and resources, prescribing and medication management, preparation of medicines and dispensing, technology and clinical pharmacy services, drug monitoring and patient education, and pharmacy education and training. The 5-points Likert response scale system closed and ended questions used. An electronic questionnaire distributed to the one hundred eighty-five directors of pharmacies at MOH hospitals, and it analyzed the prescribing and medication management section through survey monkey system. **RESULTS:** The total responders were seventy hospital pharmacies; the response rate was (37.73%). The highest score of committee shared by the hospital pharmacy was the pharmacy and therapeutic committee (4.32), quality management committee (4.21), and patient or medication safety committee (4.03). Also, the hospital pharmacies actively participated in the antibiotics team (3.19)

and pain management team (2.07). The most therapeutic guideline available in the hospital pharmacies were antibiotics guidelines (2.93) and infection control guidelines (2.81). The majority formulary management method used was restricted prescribing 23 (32.9%), and review of non-formulary drugs prior approval 13 (18.6%). The pharmacist had the privilege to write medication orders were 14 (20%) only. The pharmacist commonly prescribed over the counter medications 14 (58.3%) and antibiotics 13 (50%) through the prescription con-signed by physicians 38 (54.3%) and drug prescribing protocol 28 (40%). **CONCLUSIONS:** The pharmacist seldom participated in the therapeutic committees or teams although he had an excellent role of providing medication information. Expanding pharmacy activities will improve the prescribing system, patient clinical outcomes, and prevent drug misadventures.

PHP154

DETERMINANTS OF THE MEDICAL SALARY LEVEL IN THE PUBLIC HEALTH SECTOR: EVIDENCE FOR ARGENTINA

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OBJECTIVES: To contribute to the informed debate about the determinants of medical salaries in the public health sector in a middle-income country under a decentralized health system context. **METHODS:** A multiple response questionnaire was developed for 631 physicians in 25 public health institutions in 5 Argentine cities: Buenos Aires City, Salta, La Rioja, Chaco and Neuquén, in the year 2014. By means of the estimation of a ordered multinomial logit model we identified the personal, union and institutional determinants, among others, that explain the salary levels perceived by the doctors surveyed. **RESULTS:** The length of the working day, the presence of a medical specialty and the years of experience in the institution by the physician show positive signs, and are statistically significant, when explaining the salary levels perceived. Having a labor contract with contributions and working at the Hospital Materno Infantil de Salta (private management) are associated in a positive and statistically significant way, while the gender of the physician does not seem to be associated with the remunerative level. On the other hand, the union action variables show a positive sign and are statistically significant in the income level of medical professionals. **CONCLUSIONS:** A salary scheme that is aligned with the technical knowledge, effort and motivation of medical professionals in the public health sector is of great importance in order to achieve an equitable and efficient health system. The results obtained here contribute to the informed debate on wage policy in health in a context of middle-income countries, although more research is needed.

PHP155

FINANCIAL IMPACT OF ALTERNATIVE PRICING BENCHMARKS FOR PHYSICIAN DISPENSED SIMPLE PRESCRIPTION AND ADMINISTERED DRUGS IN CALIFORNIA WORKERS' COMPENSATION SYSTEM

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OBJECTIVES: Determine financial impact and liability of implementing an alternative price benchmark for the reimbursement of physician dispensed drugs (PDD) and physician administered drugs (PAD) drugs in California Workers' Compensation System (CWCS). **METHODS:** A retrospective large database analysis using physician dispensed and administered billing information from CWCS to re-price drug component of claims processed from 2011 to 2013. To price claims under alternative benchmarks, the billed drug was matched to benchmark unit prices and multiplied by the billed quantity to generate an alternative claim payment. Price benchmarks were acquired from both commercially and publicly available sources. Reimbursement methodology implemented by other states' workers' compensation systems were identified and applied to CWCS claims to project the financial impact of adopting a new reimbursement mechanism. **RESULTS:** To maintain drug spend on PDD claims, implementation of Federal Upper Limit (FUL), National Average Drug Acquisition Cost (NADAC), Wholesale Acquisition Cost (WAC), and Average Wholesale Price (AWP) would require an adjustment factor of 2.66, 1.97, 1.27, and 0.49, respectively. FUL, NADAC, WAC, and AWP provides a price for 78.9%, 86.1%, 80.0%, 99.9% of drugs among PDD claims, respectively. To maintain drug spend on PAD claims, implementation of NADAC, WAC, Direct Price (DP), and AWP would require an adjustment factor of 0.92, 0.68, 0.72, and 0.52, respectively. NADAC, WAC, DP, and AWP provides a price for 66.3%, 99.5%, 78.6%, and 89.5% of drugs among PAD claims, respectively. **CONCLUSIONS:** To ensure CWCS continues to be a prudent payer for drugs, a combination of two reimbursement methods may be the best to maintain costs and patient access for CWCS.

PHP156

THE EXPERIENCE AND IMPACT OF BUNDLED PAYMENT IN ORTHOPAEDIC SURGERY: A SYSTEMATIC REVIEW

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OBJECTIVES: Bundled payment is a per-capita, per-episode of care reimbursement system, which aims to incentivise the delivery of high-quality, coordinated care at the lowest possible cost. We systematically reviewed the literature to assess the impact and experiences of bundled payment systems in the field of orthopaedic surgery. **METHODS:** A systematic search of the electronic databases, including PubMed, Web of Science and the Cochrane Library was performed. Results were grouped into specific outcomes of bundle payment systems: costs of episode of care; length of stay; readmission rates; and qualitative experiences. **RESULTS:** A total of 74 articles were retrieved with our search of which 19 studies were included in our analysis. The following outcomes were extracted: (1) The total episode of care costs of primary total joint arthroplasty (TJA) (both knee and hip) was reduced following introduction of bundled payment systems, but there was

no significant difference for those undergoing revision surgery. (2) Average length of stay decreased significantly for primary and revision TJA in bundled payment systems. (3) There was a small and non-immediate decrease in the readmission rate after TJA under a bundled payment system, but there was no significant difference for those undergoing revision TJA. (4) Qualitative survey analysis suggests bundled payment strategies are perceived positively by doctors, and may be sufficient to alter physician behaviour, but concerns included disincentives to operate on high-risk patients and uncertainty about revenue sharing. **CONCLUSIONS:** Bundled payments appear to be effective in reducing costs, length of stay and readmission rates for primary joint arthroplasty. This systematic review is limited by the paucity of studies in the literature and the restriction of all current studies to the US healthcare system. This study warrants more thorough analysis on the specific outcomes of bundled payment systems across multiple geographies and for different procedure types.

PHP157

DO FRENCH HEALTH ECONOMICS AND CLINICAL HTA COMMITTEES HAVE COHERENT APPRAISALS OF CLINICAL TRIALS?

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OBJECTIVES: In France, the Economic and Public Health Assessment Committee (CEESP) and the transparency committee (TC) are 2 independent committees affiliated to the French health authority (Haute Autorité de Santé: HAS). TC assesses medicinal products clinical evidences and provides recommendations on reimbursement for public authorities whereas CEESP provides recommendations on health economics evaluations. These 2 committees operate in parallel without any coordination or communication of information which constitutes a specificity of the French system. The aim of this study was to evaluate the consistency in evaluating clinical trials between CEESP and TC. **METHODS:** All available CEESP published opinions were searched in HAS website, then the TC opinions for the same products were downloaded. Major comments on clinical trials were extracted from both reports by two different analysts. Comments were classified as limited number of included patients (<50), non-comparative trials, and insufficient data based on CEESP opinion and then compared to TC opinion. **RESULTS:** Twenty published CEESP opinions were identified. Aside health economics comments, CEESP had no comments on clinical trials in 11 reports, while TC identified limitations in 8 reports. In 2 CEESP reports insufficient data was claimed, 4 had a limited number of included patients and 3 non-comparative trials. Out of the 9 comments reported by CEESP, 8 were mentioned also on TC opinions. However, TC presented more detailed evaluation and discussion of all the product clinical trials. **CONCLUSIONS:** A strong coherence in the assessment of clinical trials can obviously be concluded from this comparison. These results raise the issue of effort and work duplication due to the parallel and independent work between the 2 committees. On the other hand, this coherence reveals the homogeneity of the HAS assessment culture.

PHP158

THE EFFECT OF THE PAN-CANADIAN PHARMACEUTICAL ALLIANCE ON PROVINCIAL LISTING TIMES AND UNIFORMITY

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OBJECTIVES: Analyze the impact of the collective negotiating body, the pan-Canadian Pharmaceutical Alliance (pCPA), on important metrics of relevance for manufacturers and patients, including the delays to reimbursement and level of concordance between three of the largest provincial public drug plans in Canada. Considerable variability exists in provincial listing decisions and time to reimbursement, and the explicit goals of the pCPA are to create greater consistency and improved access to drugs. This analysis sought to quantify the effect of the pCPA on the public drug plans of Ontario, Alberta and British Columbia. **METHODS:** We extracted multiple data points from publicly-available reimbursement recommendations, provincial listing decisions and health technology assessment reports. This data was then analyzed to estimate the time to provincial listing (i.e. reimbursement), before and after the development of the pCPA in 2011. The average post-HTA duration for the 5-year period before 2011 was compared with the period after the introduction of the pCPA using Student's-t-tests for each province. We further analyzed the level of agreement between the provinces in a pair-wise fashion, using kappa coefficients as a measure of concordance. The drug plans of Ontario, Alberta and BC were selected both for the sizes of their populations and the transparency and suitability of their reporting processes, which eliminate certain confounding effects seen in other provinces. **RESULTS:** The pCPA appears to have had a beneficial effect on the length of time between HTA recommendations and drug plan listing decisions, improving the absolute duration of delays and also harmonizing the time for each of the 3 provinces examined ($p < 0.05$). The level of agreement between the provinces also improved significantly after the introduction of the pCPA. **CONCLUSIONS:** The pCPA is achieving its desired effect of improving access to new drugs and creating greater consistency between the public plans.

PHP159

REIMBURSEMENT LAG OF INNOVATIVE NEW DRUGS UNDER TAIWAN'S NATIONAL HEALTH INSURANCE SYSTEM

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OBJECTIVES: Reimbursement lag of new drugs is a crucial barrier for patients to fulfill their unmet medical needs. The objectives of this study are to investigate

the reimbursement lag under Taiwan's National Health Insurance (NHI) system and to examine factors associated with the reimbursement lag. **METHODS:** This is a retrospective study using data from the National Health Insurance Administration (NHIA) in Taiwan. Total 193 new drugs reimbursed by NHIA from 2007 to 2014 were included in the analysis. Generalized linear models (GLMs) were adopted to estimate factors associated with the reimbursement lag of new drugs. **RESULTS:** We found that the median reimbursement lags in Taiwan were 378 days [standard deviation (SD)=923] during the "first-generation NHI" period and 458 (SD=529) days during the "second-generation NHI" period, respectively. Adjusted GLMs found that a higher budget impact (drug expenditure) and the introduction of the "second-generation NHI" were associated with a longer reimbursement lag among new drugs in the L group (antineoplastic and immunomodulating agents) of Anatomical Therapeutic Chemical (ATC) classification system. For new drugs in the non-L groups (alimentary tract and metabolism, blood and blood forming organs, nervous system and general anti-infectives for systemic use), we found that the original application price suggested by the pharmaceutical company and the adoption of price-volume agreement were associated with a longer reimbursement lag. Besides, this study demonstrated that the main determinant of reimbursement lag was the waiting time for a new drug to be listed in the Drug Benefit Committee meeting, which could be solved by increasing the human resource. **CONCLUSIONS:** The determinants of reimbursement lag were different for drugs in different ATC categories. For this reason, we suggested building up a specific review process for antineoplastic and immunomodulating drugs to improve the efficiency of their reimbursements.

PHP160

REVISITING ROLE OF PHARMACOECONOMICS IN DRUG PRICING AND REIMBURSEMENT IN CHINA: A GOVERNMENT PERSPECTIVE

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OBJECTIVES: In China, Pharmacoeconomics has long been a hot academic area, which is also drawing closer and closer attentions from government decision makers. Our study aims to provide updates on the role of pharmacoeconomics in drug pricing and reimbursement in China. **METHODS:** Comprehensive search of related literature or official documents was conducted within "CNKI", "Wanfang data" and government's official websites. In addition, expert interviews were carried out as needed. All published governmental documents or regulations related to pharmacoeconomics for drug pricing and reimbursement were included for further analysis. **RESULTS:** 6 governmental documents were included. Drug pricing: in 2009, "state council's opinions on deepening healthcare reform" released by state council first says "pharmacoeconomic evaluation should be gradually implemented in pricing of new drugs". Then in 2010, NDRC published "administration of drug pricing (exposure draft)", saying "price adjustment can refer to results of pharmacoeconomic evaluation". However, NDRC cancelled regulation of drug ceiling price from Jul 2015. In the end of 2015, NHFPC's "pilot scheme for establishing drug price negotiation system (exposure draft)" pointed out "negotiation team should perform EBM and pharmacoeconomic evaluation and integrate international price information before official negotiation." NRDL review: "working scheme for NRDL review (2009)" by MOHRSS says "for inclusion of drug, pharmacoeconomic principle should be used to compare price and efficacy; for exclusion, drugs demonstrated to be not cost-effective should be excluded". then in 2016, "working scheme for NRDL review (2016)" by MOHRSS also emphasized the importance of pharmacoeconomics. NEDL review: "administration methods on NEDL (2015)" by NHFPC says "advisory expert group must conduct technology assessment on included drugs following EBM and pharmacoeconomic principles". **CONCLUSIONS:** Pharmacoeconomics has not been mandatory in drug pricing and reimbursement in China, however, government have realized the great importance of scientific decision making. Pharmacoeconomics is expected to play an important role in pricing and reimbursement in the future.

PHP161

TEN YEAR REVIEW OF THE FINANCIAL PERFORMANCE OF ONTARIO'S SMALL AND RURAL HOSPITALS AND FACTORS FOR PATIENT-BASED FUNDING

METHODS

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OBJECTIVES: Ontario has 55 small and rural hospitals funded through global budgets. Total annual operating budget of \$750M with an annual increase of approximately 1% in the last 3 years. Ontario's 18 billion dollar hospital system has undergone a funding transformation with the introduction of patient-based funding methodology for 85 large community and academic hospitals. This research investigates the financial performance of Ontario's small hospitals from 2005/06 to 2015/16 and explore factors affecting the cost structure to consider for developing a funding formula. **METHODS:** Financial and operational indicators including Total Margin, Current Ratio, Working Capital, Sick Time, Overtime, Debt to Equity, Unit Cost Efficiency measure and operational indicators were developed and trended for all hospitals in Ontario. Using descriptive statistics and financial benchmarks, a peer group analysis was performed comparing small hospitals to large community and academic hospitals. Utilization patterns and factors such as rurality or isolation, health services for aboriginal populations and the cost structure for administrative and operational support services were investigated. Using an advisory panel of hospital CEOs and CFO, cost drivers affecting the actual costs, efficiency and productivity were identified. **RESULTS:** The financial performance of small hospitals have been deteriorating at a faster rate than other hospitals with liquidity declining at a rate which forecasts a current ratio less than 1.0 in 2017/18. 17 hospital were in deficits in 2015/16 of \$3.97M Administrative and support expenses as a percent of total expenses are significantly higher in small

hospitals. Small hospitals have higher overtime and staffing costs associated with transportation of patients. Small hospitals provide 24/7 emergency services, acute in-patient services and laboratory/diagnostic services. Additional services at some sites include dialysis, obstetrics and surgery. A conceptual funded model for funding was developed using the cost drivers identified. **CONCLUSIONS:** A patient-based funding model must take into consideration some of the unique cost structure and utilization patterns of these hospitals.

PHP162

MECHANISMS TO MITIGATE HEALTHCARE COSTS IN THE US – AN INTERNATIONAL COMPARATIVE ANALYSIS OF THE EVOLVING ROLES OF HTA

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OBJECTIVES: Due to increasing health care cost containment pressures in the United States, various evidence-based evaluations are in development that can be used to influence reimbursement coverage decisions. Since a wide range of different models exist for pricing and reimbursement (P&R) evaluation of drugs internationally, we aimed to compare clinical evidence-based ratings (CEBR) and cost-effectiveness ratios (CER) between the Institute for Clinical and Economic Review (ICER) in the United States (US) and key systems in the ex-US markets. **METHODS:** A targeted literature review was conducted using six published ICER reports as a reference document to extract corresponding forty-nine HTA reports in France, Germany, Australia, Canada, and the United Kingdom (UK) in diabetic macular edema (DME), heart failure, hepatitis-C, hypercholesterolemia, multiple myeloma, and non-small cell lung cancer (NSCLC). **RESULTS:** For CEBR analysis, similar ratings were seen for drugs evaluated in NSCLC (**high: immunology drugs, low: non immunology drugs**), hypercholesterolemia (**low**) and DME (**low**), whereas variations were seen in CEBR between countries for remaining drugs in heart failure, hepatitis-C, and multiple myeloma. For economic comparisons, ICER reports CER for 22% (2/9) drugs below a threshold of \$100k/quality-adjusted life year (QALY) and 56% (5/9) below a threshold of \$150k/QALY. For the same indications evaluated by ex-US HTA agencies, there was a high variation in terms of overall final positive recommendations [Australia: 67% (4/6), Canada: 63% (5/8), and the UK: 100% (8/8)]. Similar observations were made for assessments where the CER was below/equal to literature-based threshold [Australia (AUD 45k-75k/QALY): 83%, Canada (CAD 50k/QALY): 25% and the UK (£30k-£50k/QALY): 37%]. **CONCLUSIONS:** Many ex-US markets continue to use a structured approach to influence P&R decisions at a national level. Although ICER uses value-based approach by conducting clinical and economic assessments to evaluate drugs, their decisions are currently non-binding and their role in informally/formally influencing reimbursement coverage requires further research.

PHP163

RELATION BETWEEN POLISH HTA RECOMMENDATIONS AND REIMBURSEMENT DECISIONS

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OBJECTIVES: The aim of the study was to assess the influence of public advisory bodies (the Transparency Council, the President of the AOTMiT; The Polish Agency for Health Technology Assessment and Tariff System) involved in the process on final reimbursement decisions performed by the Ministry of Health. **METHODS:** We have analyzed all statements, recommendations and final reimbursement decisions in Poland for the period of two years: 2014 and 2015. For each recommendation we collected data on decisions as well as potential additional requirements regarding the reimbursement; data was presented for the whole analyzed period and separately for each year, to assess the general tendencies in the reimbursement decision-making in Poland. The tau Kendall measurement of agreement was used to assess the compliance between statements, recommendations and reimbursement decisions. **RESULTS:** We collected 187 records, including 183 Transparency Board statements and 186 recommendations by the President of the AOTMiT, of which 74% and 79%, respectively in the year 2014 and 55% and 42%, respectively in the year 2015, were positive. The President of the AOTMiT was compliant with the statement of the Transparency Board in 95% of cases in the year 2014 and in 76% of cases in the year 2015. Of all drugs, 44% have already gained a positive reimbursement decision (53% in 2014 and 33% in 2015). Agreement between the recommendation and reimbursement status was 0.3188, which represents only moderate agreement. 24% of drugs with negative recommendation obtained positive final reimbursement decision. **CONCLUSIONS:** We observed that final reimbursement decisions did not reflect statements and recommendations issued by the advisory boards. Positive recommendations issued by the AOTMiT did not guarantee positive reimbursement status, and negative recommendations in some cases did not result in the lack of reimbursement.

PHP164

RELATION OF POLISH HTA RECOMMENDATIONS AND DECISIONS ISSUED BY SELECTED NATIONAL HTA AGENCIES

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OBJECTIVES: The aim of this research was to assess the agreement between recommendations issued by the Polish HTA Agency (AOTMiT) and recommendations published by other national HTA agencies chosen for reference by the Polish HTA Agency. **METHODS:** All recommendations produced by the AOTMiT for years

2013–2015 were collected and scanned for references to corresponding recommendations issued by selected national HTA agencies. The agreement in type of recommendation between the AOTMiT and other HTA agencies was measured using Kappa coefficient. Odds for positive recommendations of the AOTMiT assuming positive recommendations of other national HTA agencies were estimated using logistic regression. **RESULTS:** In total 265 recommendations by the AOTMiT were analysed of which 174 were positive (and suggest reimbursement). Six national agencies were considered (NICE, CADTH, SMC, PBAC, HAS, AWMSG) of which significant agreement was observed only for: CADTH (kappa of 0.2393 (95%CI: 0.0111 - 0.4675)) and PBAC (kappa of 0.2319 (95%CI: 0.0615 - 0.4022)). Significant odds for positive recommendations by the AOTMiT for drugs with positive recommendation by other agency were revealed just for the same national HTA agencies: CADTH (3.09 (95%CI: 1.06 - 9.45)) and PBAC (3.55 (95%CI: 1.46 - 8.89)). **CONCLUSIONS:** Agreement between AOTMiT and other agencies was significant only for CADTH and PBAC. The regression analysis showed that in all cases positive recommendation by the national HTA agency outside Poland was associated with the greater odds for the positive recommendation by the AOTMiT, however only in case of CADTH and PBAC the statistical significance was revealed.

PHP165

REGULATORY, PRICING AND REIMBURSEMENT LANDSCAPE OF BIOSIMILARS IN AUSTRALIA

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OBJECTIVES: To understand the dynamics of regulatory approval, pricing, and reimbursement of biosimilars in Australia. **METHODS:** Publicly available documentation of biosimilar appraisals by the Therapeutic Goods Administration (TGA) and Pharmaceutical Benefits Advisory Committee (PBAC) were reviewed to obtain data on the following variables: indication extrapolation, time taken for reimbursement after TGA approval, economic analysis in PBAC submission, and interchangeability at physician/pharmacy level of biosimilars. **RESULTS:** The literature search identified 13 biosimilars approved by TGA. Of which, three biosimilars were not considered relevant for the review due to non-availability of data. Out of 10 biosimilars, 8 got approval for multiple indications corresponding to the reference biologics based on their comparable clinical results in a subset of the approved indications. However, etanercept received approval only in four of six indications. Additionally, one remaining biosimilar (insulin glargine) got approval in line with its reference biologic (there was no need for indication extrapolation). 7 of 10 biosimilars were appraised and recommended by PBAC within 6 months of TGA approval except one (somatropin: 20 months). Of these seven, five submitted cost-minimization analysis in PBAC and demonstrated potential net savings at 5th year and/or over 5 years (Australian Dollar: 10-60 million and 100-150 million, respectively). With respect to the adoption of biosimilars at the provider level, only three biosimilars received interchangeable status (2- Prescriber and 1- Pharmacist). Differences in route of administration and dosage strength to the reference biologics were cited as key reasons for non-interchangeability. **CONCLUSIONS:** Biosimilars in Australia go through standard regulatory, pricing and reimbursement appraisal process. Further, the majority of biosimilars have been recommended on the basis of cost-minimization by PBAC, thereby highlighting their role in the reduction of overall health care costs. Additionally, more initiatives would be needed to drive adoption of biosimilars at patient and provider level.

PHP166

WILL THE REVISED HHS RISK ADJUSTMENT METHODOLOGY IMPROVE ACCURACY IN PREDICTING COSTS FOR DISEASES WITH NON-UNIFORM PATIENT USE OF SPECIALTY THERAPEUTICS?

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OBJECTIVES: To assess the accuracy of the Affordable Care Act's (ACA) Risk Adjustment Program, which will include additional adjustment for prescription drugs for select diseases in the 2018 plan year, in predicting costs for patients with diseases that have significant cost variance due to non-uniform use of specialty therapeutics. **METHODS:** This study compares actual patient costs, as reported by 2015 claims data in the Truven Marketscan database, to estimated disease-related costs as predicted by the ACA Risk Adjustment Program's revised 2018 methodology, which incorporates additional adjustment for prescription drug users. Errors in estimated costs for specialty therapeutic users and non-specialty therapeutic users (including non-drug users) were determined for Rheumatoid Arthritis (RA), Multiple Sclerosis (MS), and Inflammatory Bowel Disease (IBD). Monte Carlo simulation was used to calculate errors in estimated costs for five plan sizes (1250, 3750, 7500, 37500, 100000). **RESULTS:** Using the 2018 methodology, the median error among RA patients taking a specialty therapeutic is \$6,982 and \$39,075 for non-specialty drug users. The median error for IBD specialty therapeutic users is \$11,226.73 and \$50,236.24 for non-specialty users. MS patients have a median error of \$7,855.24 among specialty drug users and \$13,251.32 for non-specialty therapeutic users. At the plan level, these errors translate to an absolute dollar error ranging from \$163,429.03 (1,250 covered lives) to \$12,212,832.30 (100,000 covered lives) for RA. The average absolute dollar error per plan for IBD and MS range from \$60,170.65 to \$3,552,171.29 and \$23,249.45 to \$1,154,468.70 respectively. **CONCLUSIONS:** The Risk Adjustment Program's revised methodology does not take into account differing cost structures for drugs, which may result in the substantial over-estimation of costs for patients taking less expensive therapies. This significant difference in predicted risk could lead to harmful incentives for payers, including limiting access to specialty therapeutics and engaging in adverse selection practices.

HEALTH CARE USE & POLICY STUDIES – Health Care Research & Education

PHP167

DOES PATIENT-PROVIDER COMMUNICATION INFLUENCE PATIENT'S RATINGS OF HEALTH CARE QUALITY?Kakade A¹, Sam Z², Dutta S³¹Independent Consultant, Hoboken, NJ, USA, ²Independent Consultant, Fords, NJ, USA, ³Independent Consultant, Amundale, NJ, USA

OBJECTIVES: Evidence supports that a strong patient-provider interaction and patient engagement in health care decision making improves health outcomes and quality of care. We aimed to explore factors related to patient's rating of quality care in relation to patient-provider communication. **METHODS:** Sociodemographic and patient-provider communication variables were assessed from cycle 4 (4th edition) of Health Information National Trends Survey using a self-administered mailed questionnaire. We analyzed N=3063 subjects with at least one provider visit in the past 12 months from 3,677 records for the year 2015. Univariate logistic regressions were performed followed by multivariate logistic regression. **RESULTS:** In the univariate logistic model, adults with at least one provider visit were more likely to be satisfied with the healthcare quality they received, if they were 50+ years ($p=0.0482$), had a household income \geq 50,000 ($p=0.0072$), had health insurance ($p=0.0041$), had good general health ($p<.0001$) and were more confident about their ability to take care of their own health ($p=0.0004$). Hispanic adults were less likely to be satisfied with healthcare quality, compared to non-Hispanic Whites ($p=0.0014$). Patients who had providers involving them in making health-decisions ($p<.0001$), had providers who allowed them to ask questions ($p<.0001$), and spent enough time ($p<.0001$), were more likely to give high quality ratings. In the multivariate logistic model, adults who were over 50+ (OR=2.31; 95%CI 1.16-4.62), had providers involving them in making health-decisions (OR=4.28; 95%CI 1.18-15.56), were allowed to ask questions (OR=5.07; 95%CI 2.26-11.41) and spent enough time with patients (OR=5.32; 95% CI 1.70-16.68) were more likely to give high healthcare quality ratings, after controlling for sociodemographic determinants. **CONCLUSIONS:** These findings suggest that the patient-provider communication positively influences patient's ratings of health care quality and satisfaction. The results confirm importance of patient-provider engagement, patient's involvement in decision making and patient's self-efficacy in health management.

PHP168

ADJUSTING FOR DIFFERENTIAL ITEM FUNCTIONING IN THE EQ-5D-5L USING EXTERNALLY-COLLECTED VIGNETTESLorgelly P¹, Knott R²¹Office of Health Economics, London, UK, ²Monash University, Melbourne, Australia

OBJECTIVES: There is a growing concern that responses to questions on subjective scales will be inaccurate if certain groups of people systematically differ in their interpretation and use of the response categories - known as differential item functioning (DIF). It has been shown that it is possible to correct for DIF by using vignette responses collected externally to the main dataset of interest. We apply this approach to the EQ-5D-5L to demonstrate how this adjustment-method can be used in practice to obtain QALY measures that are comparable across different population groups. **METHODS:** We adjust for DIF in the Multi Instrument Comparison (MIC) study (our main dataset of interest) using vignettes collected in an online survey of Australian respondents (the vignettes sample). We restrict our analysis in both samples to individuals aged 55 years and above (656 respondents in the MIC sample, and 914 in the vignettes sample). To adjust for DIF we use a special case of the HOPIIT, where the likelihood functions index two different samples - the vignettes sample and the MIC data - which are linked through common parameters in threshold equations. DIF-adjusted profiles are obtained, and tariffs are applied to calculate DIF-adjusted EQ-5D indices. **RESULTS:** Differences in indices between the lowest and highest educated individuals increased from 0.054 before adjustment to 0.079 post DIF-adjustment, which is above a suggested minimally important difference (MID) of 0.074. The difference between employed individuals and those not employed increased from 0.093 to 0.141 after adjusting for DIF. Differences between married and non-married individuals also increased from 0.065 to 0.096, which is also above the MID. Differences across subgroups in the unadjusted and DIF-adjusted indices were not substantive across subgroups according to gender, migrant status or age group. **CONCLUSIONS:** Ignoring DIF could potentially bias conclusions regarding subgroup comparisons in health-related quality of life if left unadjusted.

PHP169

US PAYER VIEWPOINTS ON, AND USE OF, REAL WORLD EVIDENCE (RWE)Kelly K¹, Martin M², Roberts T³¹InVentiv Health Consulting, New York, NY, USA, ²inVentiv Health, London, UK, ³inVentiv Health Consulting, Morristown, NJ, USA

OBJECTIVES: The term Real-World Evidence (RWE) is frequently used but its interpretation can differ substantially depending on the audience. The objective of this study was to gain a better understanding of what US payers receive with respect to RWE, what evidence is useful, what are key gaps in the evidence provided by industry. **METHODS:** We surveyed twenty US payers, medical directors or pharmacy directors, spread over the US, from national or regional MCOs, representing 172 million lives using a structured interview guide including 17 questions related to their understanding and their use of RWE. **RESULTS:** The survey indicated that payers are familiar with the term RWE and are using RWE to make management decisions. RWE is seen as most influential for diabetes management decisions, while payers are split on how RWE impacts PCSK-9s. RWE is shown to be a key value driver in justifying access in RA, but is shown to be somewhat ineffective in reducing competitive contracting rivalry in categories where there is perceived to be a class effect. The

most important benefits of RW data are better understanding cost implications, identification of unexpected AEs and the validation of adherence. As the largest drawbacks of RW data, payers indicated actionability of results, controlling study bias and the fact that often RW study populations are perceived as not reflective of the population in the health plan. Furthermore, payers indicate that RWE is primarily influencing decisions in crowded therapeutic areas such as diabetes and rheumatology. Most payers expected RWE to be more important in the future and expect RWE to be especially valuable for high cost and chronic diseases. **CONCLUSIONS:** RWE is seen as providing important information for decision making by payers in the US and is expected to be even more important in decision making in the future.

PHP170

METHODOLOGICAL ISSUES IN MCDA FOR TRAINING NEED: ELICITING STAKEHOLDERS' VALUE PREFERENCES IN UKRAINEPiniazhko O¹, Zalis'ka O¹, Brezden O²¹Danylo Halytsky Lviv National Medical University, Lviv, Ukraine, ²Jagellonian University, Krakow, Poland

OBJECTIVES: Currently in Ukraine new National Drug Policy and National list of essential medicines are developing due to the reforming process in health care. The study aimed to elicit values and stakeholders' preferences in the decision making process on financing of medicines for the treatment of cancer and rare diseases in Ukraine. **METHODS:** Multiple criteria decision analysis (MCDA) model was designed adhering to ISPOR MCDA Task Force Reports 1, 2 (Value in Health, 2016). A decision workshop was organized within the training session on MCDA for 24 stakeholders of national level, which were divided into 5 groups in October 2016. Criteria were selected using the structure of "value trees" (Kanavos, Angelis, 2013) and weighing was performed in the deliberative process. The criteria were ranked of their relative importance by allocating a total of 100 weight points between them. The mean values and standard deviations were estimated in MS Excel. **RESULTS:** We ranked the criteria due to their importance comparison and weighing for oncology treatment: therapeutic effect - 33 (SD±6.83), cost of treatment -23.6 (SD±13.59), burden of disease - 17.4 (SD±9.0), safety - 15 (SD±6.45), innovation level -11 (SD±4.47), where weights sum to 100 ($\sum=100.0$). The ranked criteria for rare diseases treatment were identified: therapeutic effect - 37 (SD±17.22), cost of treatment - 30.8 (SD±20.26), safety - 18.8 (SD±7.95), innovation level - 9 (SD±3.42), burden of disease - 4.4 (SD±3.03), where weights sum to 100 ($\sum=100.0$). **CONCLUSIONS:** We found high interest to participate and intention to implement the rational and consistent decisions by stakeholders. It was found that criteria for therapeutic benefits and costs had the highest values for stakeholders for both treatment options. Importantly, there is a necessity to implement international requirements to HTA and MCDA in Ukraine in order to prioritize procurements of medicines, financing by government and reimbursement decisions.

PHP171

ASSESSMENT OF EQ-5D DERIVED POPULATION NORMS OF GENERAL POPULATION OF BALOCHISTAN PROVINCE BY DEMOGRAPHIC CHARACTERISTICSNasim A¹, Haq N¹, Rizwan S², Riaz S¹, Yasmin R¹, Razzaq G¹, Khan S¹¹University of Balochistan, Quetta, Pakistan, ²Surgery Unit III, Quetta, Pakistan

OBJECTIVES: This study aimed to measure and analyze EQ-5D derived population norms of general population of Balochistan province by demographic characteristics. **METHODS:** A cross-sectional study was conducted in Balochistan. Population sample (n=3892) was collected by using stratified sampling approach from Quetta, Sibi and Loralai. The EQ-5D 3L tool was used to measure health-related quality of life (HRQOL) of healthy population of Balochistan by socio-economic demographic characteristics. The descriptive and inferential statistics have been done by using SPSS version 20. **RESULTS:** Result showed that mean age of respondents was 30.07 years. Maximum respondents 57.1% were male. Majority of respondents 38.1% had no any income. Most of respondents 34.6% were having bachelor education. Occupation wise maximum respondents 22.9% were government employee. Maximum were 88.4% were from urban locality. Sixty-three percent were single and most of respondents 87.4% had their own house. Total of 46 health states reported by the respondents of which most prevailing was having no problems in any domain. EQ-5D descriptive score and EQ-VAS score were 0.80 ± 0.25 and 0.79 ± 0.21 respectively. The percentage of people responding to any problems in the five EQ-5D-3L dimensions increased with age and males have better health as compared to female in all age groups. Comparison of mean score and inferential statistics shown all demographics were significantly associated ($P<0.01$) with mean EQ5D score and VAS. **CONCLUSIONS:** This study showed Balochistani population HRQOL data measured by the EQ-5D tool. Current study concluded that health status of Balochistan people have same EQ5D trend in which younger age have better health states which reduced as age increasing. Similarly, pain and anxiety is seen more in elderly as compared to earlier ages.

PHP172

PATIENT AND HOSPITAL CHARACTERISTICS RELATED TO LIVER AND KIDNEY DONATIONS IN THE UNITED STATESZacherle E¹, Nair AG², Noone JM¹, Blanchette CM¹, Zenarosa GL², Howden R²¹Precision Health Economics, Davidson, NC, USA, ²University of North Carolina at Charlotte, Charlotte, NC, USA

OBJECTIVES: Throughout the past several decades, demand for organ transplantation has largely outweighed organ supply. In 2016, over 76,000 people in the US were active waiting list candidates, but only 33,596 transplants were performed from 15,951 organ donors. While donation rates have slowly risen each year, with kidney and liver being the most common, little is known about the hospitalization characteristics of these donors. The purpose of this study was to evaluate

differences between living and deceased kidney and liver inpatient donors with respect to their demographics and hospitalization characteristics. **METHODS:** The study used data from the 2009-2012 National Inpatient Sample. Hospitalized kidney and liver donors were identified using ICD-9 diagnosis codes V594 and V596, respectively, and grouped into living and deceased cohorts. Both demographics (e.g., age and sex) and hospital factors (e.g., charges, length of stay, and hospital location) were compared using t-tests for means and Wilcoxon Rank Sum tests for medians. **RESULTS:** 3,739 kidney donors were identified, of which 98% were living and 2% were deceased. Among liver donors (n=291), 74% and 26% were living and deceased, respectively. Median age was lower for living kidney donors (41 vs. 48 years; $p=0.005$) and liver donors (35 vs. 47 years; $p<0.001$) vs. their deceased counterparts. Average hospital charges were higher for deceased kidney donors (\$60,757) vs. living kidney donors (\$42,466; $p=0.002$), but the contrary was seen among liver donors (\$48,141 deceased vs. \$88,572 living; $p<0.001$). Living kidney and liver donors had longer lengths of stay (kidney 2.7 days; liver 4.3 days) than their deceased counterparts (kidney 1.4 days; liver 1.2 days; both $p<0.001$). **CONCLUSIONS:** Inpatient liver donors had higher mortality vs. kidney donors, and living liver donors had greater lengths of stay and hospital charges vs. their deceased counterparts. Additional research is needed to confirm these findings and identify causes of these differences.

PHP173

ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE (HRQOL) OF GENERAL POPULATION OF SINDH, PAKISTAN

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OBJECTIVES: This study aimed to measure and analyze Health-Related Quality of Life (HRQOL) of general population of Sindh, Pakistan. **METHODS:** A cross-sectional study was conducted in Karachi, Hyderabad and Sukkur. Population sample (n=3069) was collected by using stratified sampling approach. The EQ-5D 3L tool was used to measure health-related quality of life (HRQOL) of healthy population by socio-economic demographic characteristics. The descriptive and inferential statistics have been done by using SPSS version 20. **RESULTS:** Result showed that mean age of respondents was 29.06 years. Maximum respondents 60.4% were female. Majority of respondents 22.8% had 10k-20k PKR income. Most of respondents 35.1% were having bachelor education. Occupation wise maximum respondents 30.9% were doing private job. Maximum 87.5% were from urban locality. 55.5% were single and most of respondents 75.5% had their own house. Total of 66 health states reported by the respondents of which most prevailing was having no problems in any domain. EQ-5D descriptive score and EQ-VAS score were 0.80 ± 0.27 and 0.80 ± 0.22 respectively. The percentage of people responding to any problems in the five EQ-5D-3L dimensions increased with age and males have better health as compared to female in all age groups. Comparison of mean score and inferential statistics shown all demographics were significantly associated ($P<0.01$) with mean EQ5D score and VAS. **CONCLUSIONS:** This study showed Sindh population HRQOL data measured by the EQ-5D tool. Current study concluded that health status of Sindh province of Pakistan people has somewhat better EQ5D index score compared to other cities of Pakistan.

PHP174

THE DIRECT MEDICAL COST OF SUCCESSFUL FERTILITY TREATMENT CASES USING THE IN-VITRO FERTILIZATION AT TU DU HOSPITAL IN HO CHI MINH CITY, VIETNAM BETWEEN JUNE 2014 - DECEMBER 2015

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OBJECTIVES: To describe the direct medical cost of using the in vitro fertilization at Tu Du hospital in Ho Chi Minh city, Vietnam. **METHODS:** A cross-sectional study was carried out on the medical data of the 295 couples having successful fertility treatment by in vitro fertilization from 06/2014 to 12/2015 at Tu Du hospital in Ho Chi Minh city. **RESULTS:** Among 295 couples, mean (\pm SD) wife and husband ages were 31.0 (± 4.3) and 34.4 (± 5.5) years old, respectively. The mean infertility duration of the sample was 5.3 (± 3.1) years. The proportions of primary and secondary infertility were 70% and 30%. The cycles of treatment noted in this study sample varied from one to four, in which 90% cases had successful treatment after one cycle. The median of the sample's total cost was 2188 USD (range 1292 - 21127 USD). According to the property of the treatment, the procedural steps included ovum preparation, embryos preparation and transferring, and sperm preparation which respectively constituted 59%, 39%, and 2%. The costs were also categorized based on types of service or procedure which consisted of the medicine cost (56%), the procedural and medical services (37%), and the diagnostic tests (7%). **CONCLUSIONS:** This is one of the very first researches studying the direct medical cost of in vitro fertilization in Vietnam. The result shows that the cost of preparing the ovum and the medicine cost were the largest proportions in the direct cost for a fertility treatment case using the in vitro fertilization at Tu Du hospital in Ho Chi Minh city, Vietnam.

PHP175

THE INFLUENCE OF EXPANDING MEDICAID THROUGH COMMERCIALY OBTAINED INSURANCE VERSUS TRADITIONAL MEDICAID ON INPATIENT UTILIZATION: A COMPARISON OF ARKANSAS AND KENTUCKY

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OBJECTIVES: The Affordable Care Act provided financial incentives for states to expand health coverage to all uninsured individuals earning below 138% of the

federal poverty level. Kentucky adopted a managed care Medicaid expansion with aggressive outreach efforts, whereas Arkansas used federal funds to purchase commercial insurance through the federal marketplace and prohibited state-funded outreach efforts after June 30, 2014. Our objective was to determine if these alternate methods of Medicaid expansions had a differential impact on all-cause and preventable hospitalizations and racial and ethnic disparities. **METHODS:** The state population was obtained from the census data and stratified into cohorts based on county of residence, age (18-24, 25-34, 35-44, 45-54, 55-64), gender and race/ethnicity. We used the State Inpatient Databases for 2013 and 2014 from Arkansas and Kentucky to calculate all-cause and preventable hospitalizations for each county-demographic strata. A difference in difference model was used to estimate the effect of expansion type and a difference in difference in difference model was used to estimate racial and ethnic disparities. **RESULTS:** The rate of change of all-cause and preventable hospitalizations were 2.4% ($p=0.017$) and 4.4% ($p=0.102$) higher in Arkansas compared to Kentucky. There was no significant difference in the rate of change of all-cause and preventable hospitalizations amongst blacks ($p=0.094$; $p=0.338$) and whites ($p=0.117$; $p=0.351$) in Arkansas and Kentucky. However, the rate of change of total and preventable hospitalizations among Hispanics in Arkansas was 160% ($p<0.001$) and 130% ($p=0.015$) higher compared to Kentucky. **CONCLUSIONS:** The Kentucky Medicaid expansion appears to be more successful in reducing the rate of increased inpatient hospitalizations which is in part explained by smaller rates of change in preventable hospitalization amongst Hispanics. This may be attributed to their aggressive outreach efforts which may have had more Hispanics acquire coverage through expansion and get care in an outpatient setting to avoid preventable hospitalizations.

PhP176

ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE OF HEALTHY POPULATION OF PAKISTAN

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OBJECTIVES: This study aimed to measure and analyze EQ-5D derived population norms for Pakistani general population by demographic characteristics. **METHODS:** A cross-sectional nationwide study was conducted. Population sample (n=16672) was selected from Federal Territory, Punjab, Sindh, Khyber Pakhtunkhwa, Balochistan, Azad Jammu and Kashmir and Gilgit Baltistan by using stratified sampling approach. The EQ-5D tool was used to measure health-related quality of life (HRQOL) of healthy population of Pakistan by socio-economic demographic characteristics. The descriptive and inferential statistics have been done by using SPSS version 20. **RESULTS:** A total of 121 health states reported by the respondents. EQ-5D descriptive score and EQ-VAS score were 0.74 ± 0.32 and 0.75 ± 0.25 respectively. The percentage of people responding to any problems in the five EQ-5D-3L dimensions increased with age and males have better health as compared to female in all age groups. Comparison of mean score and inferential statistics shown all demographics were significantly associated ($P<0.01$) with mean EQ5D score and VAS except residence ($p>0.05$). Regression model reported Age, City, Gender, Education, Occupation, Residence and House occupancy significantly associated with HRQOL. However, house occupancy (Beta= 1.745) and Age (Beta= 1.1331) were rated as predictors of HRQOL in the current cohort. **CONCLUSIONS:** This study provides Pakistani population HRQOL data measured by the EQ-5D tool, based on a national representative sample. Current study concluded that health status Population norms are useful in making health status of general persons of Pakistan. Socioeconomically deprived groups have inferior health status than more advantaged. The trends detected in high income nations were usually similar to the Pakistan.

PHP177

THE RELATIVE WEIGHT OF INDICATORS OF MULTIDIMENSIONAL POVERTY AND THEIR ASSOCIATION WITH SELF-REPORTED HEALTH: THE CASE OF CHILE

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OBJECTIVES: Chile has included recently the measurement multidimensional poverty (MDP) in population surveys This considers 12 indicators in 4 dimensions measured at the level of household. About 20% of the population is located in MDP. Objective: To explore the relative weight of each indicators of MDP on self rated health (SRH). **METHODS:** The CASEN survey 2013 estimated distribution of income in Chile. Using data of the population greater of 15 years of CASEN 2013 (n = 85139 equivalent to N = 6.718.477) we estimated multiple models of logistics regressions using as dependent variable the SRH (2 categories: good / bad) and independent each one of them indicators of MDP if only. Each model of regression was also adjusted for sex, age, household income and rurality. **RESULTS:** Only 5 of the 12 indicators of MDP was associated with poor health. These were: i) educational absenteeism (OR = 1, 58 CI95%=[1.15-2.17]); (ii) schooling less than that provided for by law (OR = 1, 8 CI95%=[1.54-2.1]); (iii) lack of healthcare attention (OR = 1, 68 CI95%=[1.32-2.13]); (iv) housing in poor condition (OR = 1, 6 CI95%=[1.39-1.85]); (v) lack of basic services (OR = 0 78 CI95%=[0.62-0.97]). The most striking result was that households with at least one member with less than secondary schooling are 69% more chance to present a bad health versus homes without these individuals **CONCLUSIONS:** Live in homes with people with low schooling affects the SRH in greater magnitude than other indicators. This evidence is relevant from a perspective of social determination and health in all policies to raise poverty to many families in Chile and other countries in developing.

PHP178

DETERMINATION OF IMPORTANCE FOR NEW VACCINE ADOPTION: A BEST-WORST SCALING METHOD

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OBJECTIVES: To determine vaccine attributes importance to various stakeholders in new vaccine adoption in Thailand, using the best-worst scaling (BWS) method. **METHODS:** The vaccine attributes and levels identified from a literature review and semi-structured interviews were categorized into burden of disease, age group, budget impact, fever from vaccine, severity of disease, vaccine effectiveness and cost of vaccine. Main-effects orthogonal design was used to identify 18 best-worst scenarios. A postal survey was conducted among policy makers, healthcare professionals and healthcare administrators during October 2013 and January 2014. Respondents were asked to choose the most important and the least important choices in each scenario. Importance weights were estimated by a conditional logistic regression. Then the relative attribute importance was calculated by the difference between the maximum and minimum coefficient for each attribute divided by the sum of all differences. **RESULTS:** A total of seventy respondents completed the questionnaires. The attribute with highest importance for all groups was severity of disease (35.86%). Fever from vaccine (16.71%), burden of disease (13.48%) and budget impact (12.81%) were not much different importance from each other. For policy makers and healthcare professionals, the attributes with high importance were severity of disease (35.03% and 35.89%), fever from vaccine (22.88% and 16.08%) and burden of disease (14.82% and 15.25%), respectively; whereas the attributes with high importance for healthcare administrators were severity of disease (32.53%), budget impact (15.07%) and fever from vaccine (14.99%), respectively. **CONCLUSIONS:** The BWS method makes it possible to take into account multiple criteria from multiple stakeholders for new vaccine adoption. The results revealed the alignment of a desire for high protection against severe disease in vulnerable groups together with concerns about vaccines with high budget impact and low safety.

PHP179

WHEN WORDS COLLIDE: USE OF THE TERM ‘SELECTION BIAS’ IN COMPARATIVE DRUG SAFETY AND EFFECTIVENESS RESEARCH

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OBJECTIVES: In the epidemiologic methods literature, the term ‘selection bias’ is typically used to describe collider-stratification bias. Yet, many investigators who conduct comparative drug safety and effectiveness research use the term inconsistently when describing other phenomena that lead to bias in, or lack of generalizability of, observational research findings. We surveyed the past five years of comparative drug safety and effectiveness literature to enumerate the various uses of the term ‘selection bias’ in studies using secondary healthcare databases. **METHODS:** A search of PubMed for observational studies featuring the following terms appearing in the title, abstract, or body was performed for publication dates between 01 January 2011 and 31 December 2015: selection bias AND (comparative effectiveness OR comparative effectiveness research OR comparative safety). Review articles or studies not involving medications, of non-English language, of randomized trials, or involving non-human subjects were excluded. **RESULTS:** The initial search yielded 117 articles, of which 43 met the inclusion criteria. Of the 43 articles reviewed, 34 (79%) used the term ‘selection bias’ when describing confounding, 2 (5%) to describe generalizability concerns, and 4 (9%) to describe collider-stratification bias. We were unable to categorize use of the term in 3 (7%) articles due to ambiguity regarding the phenomenon to which it referred. Of 4 included articles appearing in health economics and outcomes research or pharmacoepidemiology-focused journals, only 1 (25%) used the term to describe collider-stratification bias. **CONCLUSIONS:** Despite agreement in the epidemiology methods literature that the term ‘selection bias’ refers to collider-stratification bias, comparative drug safety and effectiveness researchers continue to use the term to describe other phenomena that lead to biased or non-generalizable treatment effect estimates. Inconsistent use of terminology might lead to methodological misunderstandings and conflicting interpretations of research findings.

PHP180

TECHNIQUES FOR TAILORING AN INTERVIEW GUIDE FOR PEDIATRIC CONCEPT ELICITATION AND COGNITIVE DEBRIEFING INTERVIEWS

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OBJECTIVES: To provide specific recommendations for improving pediatric interview guides (IGs) used in concept elicitation and cognitive debriefing interviews for clinical outcome assessment (COA) development. **METHODS:** A pediatric concept elicitation IG and a pediatric cognitive debriefing IG were selected from previously conducted studies for review. Prior to being reviewed, both IGs were anonymized in order to remove any information which might disclose the client and/or drug program being evaluated. The IGs were then critically examined in relation to several recent COA best practice publications. Recommendations were made for (1) specific text revisions, (2) adjustments to interviewer instructions, and (3) techniques for supporting continued patient engagement throughout the interview session. Revisions to the IGs are displayed visually in figures to demonstrate clearly where edits were made to the original documents. **RESULTS:** Recommendations for specific text revisions included tailoring the language to the target age group reading level, and refraining from the use of slang/colloquialism. Interview instructions which were added to the IGs included asking children to “visualize” and/or draw their experiences in order to enhance data quality from the concept elicitation process, giving direct instructions to

caregivers to sit behind their child during the interview process in order to not influence their child’s answers, and reminding caregivers not to interrupt their child. For cognitive debriefing IGs, additional instructions were added and techniques suggested for children to highlight any difficult words when reading a question or set of response options. In order to support continued patient engagement, example rapport-building questions were added to the beginning of and throughout both sets of IGs. **CONCLUSIONS:** Both interview guide and procedural enhancements, in accordance with best measurement practices, can reduce interviewer burden and improve data quality from pediatric interviews.

PHP181

TRENDS IN QUALITY, COST AND PRODUCTIVITY IN SURGICAL CARE

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OBJECTIVES: U.S. hospitals have improved their productivity in recent years, but the drivers of these gains are unclear. This study investigates the potential contribution of surgical care, documenting trends in quality, cost and productivity and exploring innovation in treatment among Medicare beneficiaries from 2002 through 2013. **METHODS:** We consider 11 classes of surgery, characterized by AHRQ’s Clinical Classification System; the surgical classes studied range from tracheostomy to heart valve procedures to colorectal resection to wound debridement. For each surgical class, we assess trends in treatment costs and outcomes among Medicare beneficiaries receiving these procedures during hospital stays. Outcomes include 30-day survival and the avoidance of unplanned readmissions; outcomes and costs are adjusted for patient severity based on demographics, comorbidities, and community context. Productivity is measured by the ratio of the number of high-quality stays (survival without readmissions) to total hospital costs. Surgical innovations are operationalized as clinically distinctive procedures with nonexistent or limited use in 2002, identified using ICD-9 procedure codes. **RESULTS:** Preliminary analysis finds significant and positive productivity growth for 5 surgical classes, tracheostomy 4.96% per year, wound debridement (2.09%), small bowel resection (0.77%), excision of lysis peritoneal adhesions (0.49%), and colorectal resection (0.44%). For each of these surgical classes, the rate of 30-day survival without an unplanned readmission increased from 2002 to 2013, while inflation-adjusted treatment costs decreased. Substantial treatment innovation occurred with respect to surgical procedures utilized for colorectal resection. **CONCLUSIONS:** In 5 out of 11 surgical classes, the quality of surgical care improved while treatment costs declined, thus contributing to improved productivity among U.S. hospitals. However, these trends were associated with measurable innovation in treatment for only 1 surgical class.

PhP182

TRENDS IN UTILITY ELICITATION METHODS: DO ANALYSES ADHERE TO RECOMMENDATIONS?

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OBJECTIVES: To identify trends and adherence to pharmacoeconomic recommendations in the use of direct and indirect utility elicitation techniques in published cost-effectiveness analyses from seven countries with clear guidelines on a preferred utility method. **METHODS:** We analyzed data extracted from cost-effectiveness analyses (CEAs) included in the Tufts Medical Center CEA Registry, a database with detailed information extracted from CEAs published in peer-reviewed medical and economic journals. Using studies published from 2000-2014 in the US, UK, the Netherlands, Sweden, Italy, Belgium, and France, we analyzed the proportion of utility weights elicited by different methods of direct or indirect elicitation. We excluded utilities that did not have an elicitation method stated in the CEA study (48%; n=5,853), and utilities used in multi-country studies (3.7%; n=475). **RESULTS:** From 2000-2014, the EQ-5D was the lead and trending utility elicitation method cited in CEAs published across all countries, including those that recommended the method in their guidelines (US, UK, Netherlands, Sweden and Belgium) and those that did not (Italy, France). In 2010-2014, most utilities from studies based in countries that recommended the EQ-5D method adhered to guidelines (70.5% in the UK, 83.8% in the Netherlands, 79.9% in Sweden, and 52.5% in Belgium). The US, which recommends a generic instrument, also predominately used EQ-5D (32.3%), followed by time trade-off (19.7%), standard gamble (13%), and the visual analog scale (5.2%). The EQ-5D remained the leading utility elicitation method cited even in CEAs from countries that advocated for use of alternative methods in their guidelines (45% in France and 29.9% in Italy; 2010-2014). **CONCLUSIONS:** The EQ-5D has become the most cited utility elicitation method in published CEAs, despite alternative recommendations in certain countries including Italy and France. This could have important implications for decisions about resource allocation.

PHP183

PATIENT AND KNOWLEDGE ABOUT COST OF MEDICATIONS IN SAUDI ARABIA

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OBJECTIVES: To explore the patients and Knowledge about cost of medicines in Saudi Arabia. **METHODS:** It is a 4-months cross-sectional survey of patient and basic knowledge of medicines. The questionnaire consisted of two-part demographic information, and second part of forty-nine questions divided into four domains. It included basic information about medication, patient information about the drug related problem, patient information about drug-related cost, and patient perception of medications. MedlinePlus and DailyMed health information used. The 5-points Likert response scale system used. The survey distributed through social media and

at 500-bed pediatrics and maternity hospital in Asir region, at ambulatory care pharmacy. The survey made an electronic format, and it analyzed domain three through survey monkey system. **RESULTS:** The total responders were (614) Saudi patient. The gender distribution 523 (86.7%) was female, and 91(13.3%) was male. The majority of them in age (18-44) 78.3%, and located at Asir region 325 (115%) and Riyadh region 163 (46.9%). The type of medications used was for Diabetic and Hypertension, Skin, Respiratory diseases. The responders showed good knowledge about drug storage at room temperature 380 (64.7%) or refrigerator 378 (64.7%), and how to behave with an expired medication 328 (59.85%). The patient had adequate information about drug and light exposure 335 (57.56%) while incomplete information about prescription prices 265 (44.9%). The responders showed that a missing of medication knowledge lead them to visit doctor clinic (20%), visit the pharmacy (32.4%), visit hospital emergency (7.4%), hospital admission (13.9%) or intensive care admission (4.3%). **CONCLUSIONS:** The missing of drug information knowledge is burden cost on health care system. Drug-related prices and medication cost awareness are demanding for Saudi patient to prevent drug-related hospital admission, improve patient clinical outcomes and quality of life.

PHP184

UPDATED CODING ALGORITHMS FOR DEFINING CHARLSON COMORBIDITIES USING LARGE RETROSPECTIVE HOSPITAL ADMINISTRATIVE DATA

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OBJECTIVES: To update Deyo's International Classification of Disease, 9th revision, Clinical Modification (ICD-9) coding algorithm for Charlson Comorbidity Index (CCI) with corresponding ICD-10 codes and assess the concordance between algorithms using a large retrospective hospital administrative database. **METHODS:** Deyo's ICD-9 algorithm for CCI was updated referencing Quan's modified version of Deyo's algorithm and clinical judgment made by the Premier team. The ICD-10 algorithm for CCI was developed using the mapped ICD-10 codes based on the Centers for Medicare and Medicaid Services (CMS) 2016 General Equivalence Mappings, with further adjustment according to the 2016 CMS ICD-10 codes tabular list. The ICD-10 algorithm was validated by a concordance analysis using data from hospitals that submitted both ICD-9 and ICD-10 data to the Premier Healthcare Database during Quarter 4 of 2015. Descriptive analysis was conducted to compare the distribution of CCI scores and prevalence for the individual conditions between the two algorithms. Concordance was assessed by Kappa statistics calculated for each of the CCI comorbidities. **RESULTS:** The analysis included 26,792 inpatient discharges from 79 hospitals that reported both ICD-9 and ICD-10 diagnoses codes between 10/1/2015-12/31/2015. Modification to Deyo's ICD-9 algorithm included: 1) inclusion of 294.1x (dementia in conditions classified elsewhere) and 294.2x (dementia, unspecified) to Dementia codes; 2) removal of 250.7x (Diabetes with peripheral circulatory disorders) from Diabetes without chronic complication group and inclusion of 250.7x, 250.8x (diabetes with other specified manifestations) and 250.9x (Diabetes with unspecified complication) to Diabetes with chronic complication group. Mean CCI was 1.42 with standard deviation of 2.10 for both algorithms. The Kappa statistics ranged from 0.82 for diabetes with chronic complications category to 0.98 for AIDS, chronic heart failure, dementia, and myocardial infarction. **CONCLUSIONS:** The ICD-10 CCI score had excellent concordance with the ICD-9 algorithm and both algorithms are available for use in outcome studies.

PHP185

HEALTH RELATED QUALITY OF LIFE FOR GENERAL POPULATION IN CHINA BASED ON EQ-5D-3L: A SYSTEMATIC REVIEW

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OBJECTIVES: Health related quality of life (HRQoL) for Chinese general population is important to decision-maker. The aim of this study was to conduct a systematic review which is based on an EQ-5D-3L questionnaire in China to evaluate HRQoL for general population. **METHODS:** To identify studies related to HRQoL for general population in China, both English and Chinese literatures published from January 1990 to August 2015 were systematically searched by using PubMed, Embase, the Cochrane Library, VIP WanFang Data and CNKI databases. A descriptive analysis was performed to study health utility, VAS scores, and proportion of people who have problems in five dimensions of EQ-5D-3L. **RESULTS:** In total, 17 studies were identified in this research, all age population and elderly population were included. As for all age population, the health utility ranged from 0.80 to 0.96 while VAS scores ranged from 77 to 86. In the majority studies, the dimension with highest proportion of people having problems was "Pain/discomfort", followed by "Anxiety/Depression", while "Self-Care" dimension was the lowest one. For male, the utility values and VAS scores were higher than female, suggesting a better HRQoL of men. People living in rural areas were with lower health utility than urban residents, but VAS score was on the contrary. As for aged population, the utility values ranged from 0.79 to 0.89. The findings of that dimensions with highest and lowest proportion of people having problems for aged population were the same in all age population. **CONCLUSIONS:** EQ-5D-3L is widely used in HRQoL studies for Chinese general population. The sample source and the usage of different utility value set might have influence on measurement results.

PHP187

TRANSITIONING TO ICD-10 FROM ICD-9 PROCEDURES FOR RETROSPECTIVE STUDIES IN THE SURGICAL FIELD

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OBJECTIVES: In September 2015, the United States implemented ICD-10 code system which tends to affect large database analyses based on codes. This study explored the

code change from ICD-9 to ICD-10 in select surgical procedures and tested the viability of the Centers for Medicare and Medicaid Services (CMS) ICD9 to ICD-10 converter. **METHODS:** We reviewed the Premier® Hospital Discharge Database from 2014 Q1 to 2016 Q2 for a low volume cancer surgical procedure (prostatectomy) and a high volume general surgical procedure (ventral hernia repair). ICD-9 codes for the procedures and their surgical approaches (robotic-assisted vs. non-robotic) were converted into ICD-10 via CMS converter. The quarterly volume trend of the procedures and the proportions by surgical approach were compared before and after the ICD-10 implementation. **RESULTS:** Prostatectomy procedure volume was 3406 in Q1 2014 and 3261 in Q1 2015 using ICD-9, vs. 3733 in Q1 2016 using ICD-10. As a well-established procedure primarily performed robotically, the proportion of robotic-assisted prostatectomy was 82.4% in Q1 2014, 85.1% in Q1 2015 using ICD-9, vs. 61.6% in Q1 2016 using ICD-10. Ventral hernia repair procedure volume was 21,149 in Q1 2014 and 19,723 in Q1 2015 using ICD-9, vs. 9,936 in Q1 2016 using ICD-10. As an emerging robotic-assisted procedure for which the proportion of robotic cases was expected to increase, the proportion of robotic-assisted ventral hernia repair was 2.81% in Q1 2014 and 4.52% in Q1 2015 using ICD-9, vs. 5.2% in Q1 2016 using ICD-10. **CONCLUSIONS:** The study suggests inconsistency of volume trends and proportion of surgical approaches when using the CMS ICD-9 to ICD-10 converter alone. There are challenges of this new coding system that impact large database research. Further collaborations among database researchers, clinicians and billing experts are necessary to understand the challenges and to implement appropriate solutions.

PHP188

MULTIDIMENSIONAL POVERTY, SELF-RATED HEALTH AND BARRIERS TO ACCESS TO HEALTHCARE IN CHILEAN ADULTS

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OBJECTIVES: Chile has recently included a multidimensional poverty (MDP) index in population surveys. It considers 12 indicators gathered into 4 dimensions for household level MDP. About 20% of the population has multidimensional poverty. We explored the relationship between Self-Rated Health (SRH), MDP and barriers of healthcare access in Chilean adults during 2013. **METHODS:** Using data of > 15 years old from the 2013 CASEN survey (n=85139, equivalent to N=6.718.477), we estimated multiple ordinal regression models with partial proportional odds and log complementary link, where SRH (3 categories: good/regular/bad) was the dependent variable; MDP (poor/non-poor) and barriers to access to healthcare (yes/no) were the independent variables. We then adjusted for covariates (sex / age / educational level / immigrant status / ethnicity / occupation / marital status / household income). **RESULTS:** SRH was associated with MDP (OR=0.86, 95%CI [0.88-0.91]) and with barriers to access to health. Individuals with barriers to access to healthcare were less likely to move from a "poor health" to a "moderate to good health" (OR=0.68, 95%CI [0.66-0.69]). This was even more accentuated when moving from "bad or moderate" to "good health" (OR=0.54, 96%CI [0.52-0.55]). The association between SRH, MDP and barriers of access was maintained after multivariate adjustment for socio-demographic covariates. **CONCLUSIONS:** Barriers to healthcare showed a strong association with SRH in Chilean adults, even after adjusting for MDP and other socio-demographic covariates. Both MDP and barriers to access are potentially modifiable determinants of SRH that need urgent attention at health policy level in this country.

PHP189

THE ROLE OF PATIENT-POWERED RESEARCH NETWORKS IN COMPARATIVE EFFECTIVENESS RESEARCH AND DECISION-MAKING

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OBJECTIVES: To elicit views on the potential future role of data collected by patient-powered research networks (PPRNs) and the usefulness, acceptability and future role in comparative effectiveness research (CER) and HTA assessments. **METHODS:** PPRNs are online platforms where patients share their health data with other people or organisations of their choice. Key opinion leaders (KOLs) with interest in PPRNs and decision makers working in regulatory, payer or HTA areas were identified and interviewed by phone. Summary transcription of interviews were analysed in 3 different ways: a) exceptional comments were highlighted; b) answers were coded to and grouped; c) categories were collated and summarised as counts or percentages. **RESULTS:** Invitations were sent to 282 participants. Interviews were conducted in spring 2016 with 21 KOLs and 19 decision makers (overall response rate 14.2%). All KOLs had heard of PPRNs, compared with only 15% of the healthcare decision makers. Most participants (90% of KOLs and 84% of decision makers) thought that PPRNs could be useful for comparative effectiveness research and were able to provide a variety of advantages. Most healthcare decision makers reported that they thought the use of effectiveness evidence from PPRNs was acceptable. However limitations were expressed, such as the burden around ethics and regulations and lack of systematic or standardised data collection and validation of self-reported data. These obstacles need to be addressed in order to make PPRNs more useful for the collection of data for CER. **CONCLUSIONS:** PPRNs are still in their infancy. In the short term, both decision makers and KOLs believe they could be used to better understand the patient point of view. In the longer term, once advancements are made, they could also be used in comparative effectiveness research.

PHP190

MEDICAL NUTRITION TERMINOLOGY AND REGULATIONS IN THE US AND EUROPE: A SCOPING REVIEW

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BACKGROUND: Medical nutrition (MN) is comprised of parenteral nutrition (regulated in pharmaceutical legislation) and all forms of enteral nutrition that are regulated as “foods for special medical purposes” (FSMP), as defined by the European Commission. Standardized MN terms and definitions are needed to facilitate comparative and cost-effectiveness research of MN in disease management and health outcomes. **OBJECTIVES:** Conduct a scoping review to identify MN terminology, definitions and regulations in the United States and Europe. **METHODS:** The ISPOR Nutrition Economics Special Interest Group’s Medical Nutrition Working Group identified 19 MN terms and developed a systematic keyword search and inclusion/exclusion criteria to review relevant literature published from 1/2000 to 8/2015. The following databases were searched: Embase; MEDLINE; Cochrane Clinical Trials Registry; Centre for Reviews and Dissemination; the Cumulative Index to Nursing and Allied Health Literature, as well as pertinent professional and regulatory websites. Two-person teams extracted, reviewed and compared results for accuracy and completeness using a two-step screening process (ie, title/abstract, then full-text review). **RESULTS:** Of the 1,687 titles/abstracts identified, 671 full-text articles were reviewed and 473 articles were included in the final analysis, as well as an additional 222 records from 94 websites. Sixty-five percent of the articles mentioned MN terms, of which less than 35% provided a definition. The most common ICD codes/indications for MN were: symptoms, signs, abnormal clinical/laboratory findings (30%); endocrine, nutritional and metabolic diseases (15%), and digestive system diseases (13%). Less than 5% of the articles referenced a MN regulation, with few (<8%) reporting a health or nutrition economics analysis. **CONCLUSIONS:** MN terminology is not consistently defined and applied in the literature. This lack of clarity makes it challenging to interpret existing research findings and hampers effective assessment of the impact of MN on health outcomes and disease management.

PHP191

FREQUENCY OF AND PERCEPTION TOWARDS CESAREAN SECTION: AN EXPLORATORY ANALYSIS FOCUSING PREGNANT WOMEN ATTENDING PUBLIC HOSPITAL OF QUETTA CITY, PAKISTAN

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OBJECTIVES: The literature reports an increased prevalence of cesarean section (CS) worldwide that is related to various reasons as well as to patients’ perception towards. Therefore, the aim of this study was to determine the frequency prevalence of CS (one year retrospective analysis), and explore patient’s perception towards CS attending public hospital of Quetta city, Pakistan. **METHODS:** A retrospective, cross sectional study design was adopted. The retrospective study was conducted to assess the frequency of CS over one year time period. The cross sectional study was conducted to evaluate patients’ perception towards CS whereby a self administered questionnaire was used for data collection. SPSS v.22 was used for data collection and both descriptive and inferential statistics were used for data analysis. **RESULTS:** For the year 2015, the prevalence rate of CS was 13.03% (3044 CS cases out of 23346 deliveries). From 728, seven hundred and seventeen patients responded to the survey. Although 565 (78.8%) perceived CS as a dangerous procedure [education (p=0.004), locality (p=0.001) and employment status (p<0.001)], 534 (74.5%) patients were in agreement that this is the best manner to save mother’s and baby’s life. Sixty two percent of the respondents reported that they would like to avoid CS due to the post operative pain and 422 (58.9%) preferred to have a normal delivery. Additionally, significant associations were reported among education (p=<0.001) and locality (p=<0.001), whereby respondents considered normal vaginal delivery as painful. **CONCLUSIONS:** The present study reports that the frequency of CS is almost equal to what is recommended by the World Health Organization. However, when it comes to perception towards CS, we conclude that women of the current cohort had less information about CS and there is a need to provide them education during antenatal.

PHP192

PARENT-REPORTED HEALTH STATUS AND ITS ASSOCIATION WITH MULTI-DIMENSIONAL POVERTY AMONGST CHILDREN IN CHILE: A POPULATION-BASED, STRUCTURAL EQUATION MODELLING STUDY

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OBJECTIVES: There are 4.5 million <18 years old living in Chile; about 22% living in multidimensional poverty. The aim was to explore, through structural equation modelling (SEM), the relationship between multidimensional poverty and parent-reported health status; and to explore whether access to health care could mediate this relationship in this population. **METHODS:** We used data from CASEN 2013 national survey (n=56,811, weighted N=4,413,728). SEM Model 1 considered the crude relationship between household multidimensional poverty, parent-reported health status and access to health services (healthcare provision) of the child. SEM Model 2 we adjusted Model 1 by five covariates (sex, age, being an immigrant, household income and rurality). In both cases direct and mediated relations were explored. Both models were

assessed using RMSEA<0.05 and CFI>0.95. **RESULTS:** Models 1 and 2 fitted the data appropriately. Model 1: a significant direct effect was observed between multidimensional poverty and parent-reported health status (Bstd=0.04, p-value=0.003). Children living in multidimensional poverty had lower parent-reported health state. Access to healthcare also had a direct and significant effect (Bstd=0.072, p-value<0.001). However, no mediator effect was found for access to healthcare in the relationship between poverty and children’s health status (p-value=0.102). Model 2: the direct effect of multidimensional poverty on health of the children was maintained, but the effect of access on children’s health disappeared (p-value=0.77). **CONCLUSIONS:** This is the first study in Chile to assess the relationship between multidimensional poverty and parent-reported health status of children. Findings prove the strong relationship between household poverty and health status in children.

PHP193

DO PAYERS VALUE RARITY IN DRUG PRICING OF ONCOLOGY VERSUS NON-ONCOLOGY ORPHAN DRUGS IN EUROPE?

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OBJECTIVES: To assess if there is a difference on how payers value rarity in drug pricing between oncology and non-oncology orphan drugs in France, Germany, Italy, Norway, Spain, Sweden, UK. **METHODS:** Approved orphan drugs with their respective disease prevalence were extracted from the European Medicines Agency website and were divided into oncology and non-oncology. The annual treatment costs for each drug were computed based on the summary of product characteristics (SmPC) using ex-factory prices from IHS POLI and country price databases. The relationship between the prevalence (rarity) and the annual treatment cost of (price) in each country was analysed using simple regression analysis. The correlation coefficient (r) for oncology and non-oncology drugs were averaged and compared in each country. **RESULTS:** A total of 120 orphan drugs were analysed. For both oncology and non-oncology orphan drugs, results show an inverse correlation between annual treatment cost and disease prevalence in all countries, with the treatment being more expensive the rarer the disease. For non-oncology drugs, statistical significance was reached in all countries except Spain and Sweden (France: r=-0.41, p=0.01; Germany: r=-0.41, p=0.01; Italy: r=-0.38, p=0.01; Spain: r=-0.37, p=0.08; UK: r=-0.40, p=0.002; Sweden: r=-0.47, p=0.06; Norway: r=-0.41, p=0.01). Oncology drugs had a weaker correlation except Spain (France: r=-0.36, Germany: r=-0.18, Italy: r=-0.25, Spain: r=-0.49, UK: r=-0.23, Sweden: r=-0.47, Norway: r=-0.29; all p<0.05 except Spain p=0.03). **CONCLUSIONS:** This study shows an inverse correlation between annual treatment cost and disease prevalence in orphan drugs. A weaker correlation in oncology supports the idea that in this disease area, payers value other drivers aside from rarity which may include severity, the availability of treatment options, the size of clinical benefit, and incremental cost-effectiveness ratio. Pricing is a complex process where different attributes are assessed, however rarity is valued by payers in pricing decisions in all the countries.

PHP194

RELIABILITY AND VALIDITY OF A PATIENT-REPORTED SYNDROME SCALE: PHELEM SYNDROME (PRS-PS)

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OBJECTIVES: We have developed a patient-reported syndrome scale: phlegm syndrome (PRS-PS) for efficacy assessment of Traditional Chinese Medicine (TCM). This study was conducted to evaluate the reliability and validity of the scale. **METHODS:** A cross-sectional survey was conducted for the 9-item PRS-PS. The patients with phlegm syndrome which is defined as a viscous, turbid pathological product causing a variety of diseases were recruited. After 24-48h, 30 patients were randomly selected to complete the PRS-PS again for retest reliability. For the patients with hyperlipidemia, triacylglyceride(TG) and total cholesterol (TC) were recorded to evaluate the criterion validity of the PRS-PS. The internal consistency and construct validity were analyzed according to Cronbach’s coefficients, Spearman correlation and exploratory factor analysis. **RESULTS:** A sample of 115 patients (average age: 59, 47 males) completed the PRS-PS. The PRS-PS was easy to accept for patients, of which 96.6% completed the scale. The median completion time was 2min, which showed the convenience of the scale. There is no floor and ceiling effect on each item. The retest reliability of the scale was 0.896, of all items range 0.739 from 0.920. Cronbach’s coefficient the scale was 0.643, and it declined after deleting any item. The Spearman correlation coefficients of these nine items and the global score were between 0.409-0.722. Exploratory factor analysis identified 3 primary dimensions that were consistent with the conceptual framework construction. TG was positively associated with the item of expectoration (p<0.05), and the correlation coefficient was 0.320. **CONCLUSIONS:** These results suggest that the PRS-PS is a reliable and valid self-rating instrument for efficacy assessment of phlegm syndrome in TCM. Due to the deficiency of a commonly acceptable criterion for phlegm syndrome assessment, the criterion validity of the PRS-PS will be explored in the further research.

PHP196

A CROSS-SECTIONAL STUDY TO EVALUATING KNOWLEDGE, AND ATTITUDE OF FINAL YEAR PHARMACY STUDENTS TOWARDS PHARMACOVIGILANCE IN ABBOTTABAD, PAKISTAN

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OBJECTIVES: To explore the knowledge and attitude of final year pharmacy students towards ADR reporting in Abbottabad, Pakistan. **METHODS:** A cross-sectional study

was conducted in three universities of Abbottabad from April 1 to May 31st 2016. The questionnaire comprised of questions aimed to explore knowledge, attitude and perception of pharmacy students. **RESULTS:** A total of 93 students responded giving the response rate of 83.4%. Among the respondents 67% were females. More than half 60.4% of the respondents indicated that they had read formal topic on Pharmacovigilance concept. The mean knowledge score of Pharmacovigilance and ADR reporting for the final year pharmacy students was 6.26. 60.4% of students do not know how to report an ADR. Surprisingly, 24.2% believe that reporting of ADR makes no significant contribution to the reporting system. Majority of respondents 93.4% believed that ADR reporting should be made compulsory. 94% of students thought that proper Pharmacovigilance course should be included in pharmacy curriculum. **CONCLUSIONS:** Although majority of students have positive attitude towards Pharmacovigilance but have insufficient knowledge about Pharmacovigilance concept and adverse drug reactions reporting process. There is need to include course of Pharmacovigilance in pharmacy curriculum.

PHP197

UNDERSTANDING DISEASE BURDEN AND OUTCOMES FROM THE PATIENT'S PERSPECTIVE USING DISEASE-FOCUSED INTERNET FORUM DATA

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OBJECTIVES: This research examines what value disease-focused internet forum data offers GSK, including characterizing data elements and whether linked discussion threads provide longitudinal insights into disease and patient perspectives. **METHODS:** This study was a retrospective analysis using deidentified Inspire patient forum data for 2 disease areas: systemic sclerosis ("SS") and rheumatoid arthritis ("RA"). The dataset consisted of English language posts (n=62,806), comprising 5,606 threads, spanning Jan-01-2015 to Nov-30-2015 and representing 6,548 distinct authors. A third party vendor removed PII and discussion threads were programmatically linked by a unique identifier. A random sample of 2,817 threads (50%) consisting of 21,313 posts (34%), representing 3,601 unique authors (55%) was created for curation and analysis. **RESULTS:** Of the 3601 unique authors curated, 870 (24%) indicated they had been diagnosed with SS, 267 (7.4%) indicated they had RA and 54 (1.5%) indicated they had both RA and SS. For 1,975 authors (55%), we were unable to determine a diagnosis. Of the 435 (12%) remaining authors, 203 (5.6%) had other autoimmune disease as diagnosis and 232 (6.4%) were probable RA or probable SS. Patients discussed disease duration in 722 posts, and of those posts 296 (41%) indicated they had the disease for more than 10 years. 26% (n=5541) of posts were made by the patient. 13% gave medication information. 3% discussed non-medical treatments. 5% discussed medical history. 2% provided lab/imaging results. 5% were seeking information. 8% discussed burden of disease. **CONCLUSIONS:** Disease-focused internet forum data provides valuable patient insights and information including: disease burden, duration of disease, medication and non-medication treatments, co-morbidities, and information being sought/provided. Additional research is required to further assess the value of longitudinal data for understanding the patient disease journey and how best to leverage these insights for drug development and safety.

PHP198

THE PATIENT VOICE IN VALUE: REVIEW AND APPLICATIONS OF PATIENT PREFERENCE ELICITATION METHODS

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OBJECTIVES: Patient preference elicitation methods can increase the patient-centeredness of medical decision making by measuring benefit and value. Patients' perspectives on treatment benefits and risks can be different from those of regulators and care providers. This study aimed to conduct a comprehensive review and evaluation of methods used to assess patient preferences for different treatments in three therapeutic areas: oncology, immunology, and central nervous system (CNS) diseases. **METHODS:** A search of electronic databases and grey literature identified published articles on patient preference methods and applications. The methods were critically appraised and the literature review was conducted on patient preference studies on pharmaceutical interventions in oncology, immunology, and CNS. **RESULTS:** Discrete choice experiments (DCE) and conjoint analysis (CA) were the most commonly used methods for patient preference elicitation. Heterogeneity of patient preferences and sample size were key in determining the choice of method. Among the 30 studies included in the final literature review, safety, efficacy, and convenience (dosing and route of administration) were used most often in patient preference surveys to differentiate between different treatment options. Cost attributes were also included in patient preference studies in oncology and immunology, while quality-of-life related attributes were used in oncology and CNS preference studies. **CONCLUSIONS:** Quantitative methods to elicit patient preferences such as DCE and multicriteria decision analysis (MCDA) are becoming increasingly acceptable by regulatory and payer bodies as part of benefit-risk assessments and health economic evaluations. Considering patient preferences for efficacy, safety, and convenience can help inform regulators' and payers' value judgments, increase the patient-centeredness of decision-making, and differentiate products in competitive markets.

PHP199

CHANGES IN THE HEADCOUNT OF HEALTH CARE PROFESSIONAL IN HUNGARY

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OBJECTIVES: After Hungary joined to the European Union in 2004, health care professionals were allowed to enter onto the European labour market. The higher

salaries in Western European countries are important motivating factors for Hungarian health care professional to go abroad. The aim of our study was to analyze the changes in the headcount of health care professionals in Hungary. **METHODS:** Data derive from the database of the Hungarian Central Statistical Office. The following health care professional – working in hospitals – were included into the analysis: physicians, dentists, pharmacists, nurses, dieticians, physiotherapists, ambulance men, midwifery, health visitors, and occupational health professionals. We calculated the average headcount between 2003-2012. **RESULTS:** Between 2003-2012 the average increase of the headcount of all health care professionals was 12%. We observed the highest increase in the headcount of nurses (+84%) midwifery (+67%) and physiotherapists (+61%), while we found the highest decrease in the headcount of occupational health professionals (-76%), dentists (-43%) and pharmacists (-35%). In 2003, we observed the highest headcount for specialist physicians (8109), physicians (3822) and health visitors (3631). We found the highest headcount in 2012 for specialist physicians (7114), health visitors (3830) and physicians (3329). **CONCLUSIONS:** Between 2003-2012 there was a remarkable increase in the the headcount of health care professionals in Hungary. The changes showed significant differences among different professions. In order to prevent well trained health care professionals leaving Hungary for working abroad, further increase of salaries is needed.

PHP200

AVAILABILITY, PRICE AND AFFORDABILITY OF SELECTED MEDICINES FOR NON-COMMUNICABLE DISEASES IN IRAN; A COMPARISON OF 2007 AND 2014 REPORTS

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OBJECTIVES: The global and national burden of non-communicable diseases (NCD) continues to rise making access to essential medicines increasingly important. The objective was to compare the results of two national reports conducted in 2007 versus 2014 in Iran in terms of price, availability and affordability. **METHODS:** The data for selected medicines for NCD were collected from public and private sector retail pharmacies and from private pharmacies located in public hospitals in six cities of Iran. The data was collected using standardized methodology developed by the World Health Organization (WHO) and Health Action International (HAI). Medicines that were common in both surveys with the same strength and dosage form were gathered. The outcome measures were percentage availability of drugs, drug price ratios to international reference prices and affordability. Availability of medicines was compared in forms of originator brand (OB) and Lowest Priced Generic (LPG). While affordability was defined as the number of days' wages needed by the lowest-paid unskilled worker to afford one month supply of chronic treatment. The median price ratios didn't alter after adjusting for annual inflation. **RESULTS:** Affordability of essential treatments was reasonable (<1) in both years and there was no significant change in affordability of common treatments between 2007 and 2014. A negligible decrease in affordability of generic Metformin (0.1 to 0.2 wage) and Salbutamol inhaler (0.2 to 0.3 wage) and a little increase in affordability of statins (0.3 to 0.2 wage) can be ignored due to high and variable inflation. Across all three pharmacy settings, the availability of OB has increased while the availability of LPG has decreased. The comparison of the price of surveyed medicines reveals a reduction in median prices of both OB and LPG in all three settings. **CONCLUSIONS:** Although NCD treatments are mostly available and affordable in Iran during past years, more improvements are still needed.

PHP201

PREMIUM-PRICING STRATEGIES AND REPUTATIONAL COSTS FOR MANUFACTURERS: INCENTIVES AND CONSTRAINTS IN THE EVOLVING US PRICING AND REIMBURSEMENT ENVIRONMENT

Enev T

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OBJECTIVES: Manufacturers seeking high prices for new or in-line agents are leveraging incentives that all but guarantee coverage in certain "sensitive" indications. Recent high-profile cases include the launch of Sovaldi (curative benefit), Sarepta (data issues), the price increase of the EpiPen (no competitors), some new oncology therapies. In "sensitive" indications, what are the constraints on "the sky is the limit" pricing incentives? This paper presents a conceptual model that seeks to explain and identify key factors driving manufacturer pricing behavior and payer reactions to it. **METHODS:** Combined deductive / inductive approach; conceptual pricing-strategy model based on small-n qualitative analysis and comparison of salient cases of price-premium strategies. **RESULTS:** Moderately high prices in large population indications (Sovaldi launch), have led to tighter payer scrutiny and stronger public reaction than substantially higher prices in smaller population orphan diseases, or in oncology indications supported by compendia listings. Superior clinical benefits are leveraged by manufacturers to justify high prices, while inferior clinical benefits are leveraged by payers for coverage rejections. As drug pricing has become a salient issue in the US, manufacturers are increasingly considering "reputational costs" in their pricing strategies. **CONCLUSIONS:** When seeking high prices in "sensitive" indications, manufacturers face three strategic choices: 1) Maximize price – which potentially maximizes revenue but imposes reputational & PR costs and possible payer scrutiny/rejection (data issues-Sarepta); 2) Restrain price – which boosts the company's goodwill, creating reputational & PR capital, but has the downside of "leaving money on the table;" 3) Optimize price (to highest level below the payer radar) – which results in capturing significant revenue and maintaining goodwill,

while sacrificing some revenue gain. Reputational costs / benefits are a new factor with significant influence on choice of premium-pricing strategy by manufacturers and a tool for payers and other system actors to indirectly contain costs through PR exposure.

PHP202

ASSESSMENT OF ESSENTIAL DRUGS IN THE MEDICINES FORMULARY HOSPITAL
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OBJECTIVES: Essential medicines are those that satisfy the priority health care needs of the population. Morocco has a national list of essential drugs, which the last revision was carried out at the end of 2011. The pharmaceutical products covered by this list have an annual budget allocated by the Ministry of health (MOH) to ensure their availability in public hospitals. The aim of our study is to assess the part of essential medicine defined by the MOH in the formulary of a Moroccan tertiary hospital. **METHODS:** We have used the medicines formulary Ibn Sina University Hospital Center in Rabat, It was updated on 2016, which includes nine hospitals and contains all the medical specialties; we have analyzed the part of essential medicines according to the WHO list of 2015 and the national list of 2012. **RESULTS:** Of the 818 articles analyzed, we found that essential drugs account for 28.1% according to the WHO list and 37.7% according to the national list. Essential medicines belong mainly to the N, J and B therapeutic classes (ATC classification) according to the WHO list (27.9%, 15.3%, 13.9%) and Moroccan list (25.3%, 17.8% and 9.4%). **CONCLUSIONS:** Our results show that the rate of essential drugs in our hospital is not large enough. In order to adhere to the policy of the Ministry of Health which aims to ensure a harmonious and sustained health development based on the availability of essential medicines, our institution is asked to review the part of these drugs in the hospital formulary.

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MINING ADVERSE EVENTS IN TWITTER: EXPERIENCES OF ADALIMUMAB USERS
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OBJECTIVES: Multiple methods to identify post-marketing adverse events related to medications exist, yet identifying and reporting adverse drug events (ADEs) remains problematic. The advent of social media platforms provides a robust source to mine pharmacovigilance data. The purpose of this study was to automatically identify associations of ADEs and adalimumab from Twitter accounts using natural language processing techniques and compare ADE tweet rates to known ADE sources. **METHODS:** Data were collected from Twitter Public API using keywords Humira, adalimumab, and common misspellings. The Twitter API makes available a sample of all posted tweets. Collected tweets were processed by the information extraction system ADRMine, designed to extract potential ADE mentions. Extracted ADRs were mapped to the standard Unified Medical Language System (UMLS) concepts automatically, using a custom-built lexicon. UMLS concept names were categorized by frequency. Disproportionality analyses were conducted to determine the relation of ADR signals to tweets. Rates of UMLS concept names were compared to ADEs reported in the drug compendia Clinical Pharmacology, Micromedex, and Lexicomp. **RESULTS:** A total of 10,188 tweets mentioned adalimumab; 1382 contained mention of an ADE. Many tweets mentioned medication names but not ADEs. Of ADE tweets, 192 unique UMLS codes were identified. "Pain" (15.5%), "sick" (8.1%), and "tired" (4.6%) were the top three ADE mentions. Pain rates agreed with ADE rates in compendia (6 to 20%) but "sick" and "tired" were not specifically reported as such. Disproportionality analysis resulted in proportional ADR reporting ratio (PRR) of 0.011, 0.013, and 0.011 and lift of 0.012, 0.014, and 0.012 for the top three respectively. **CONCLUSIONS:** ADRMine identified frequently mentioned ADEs and found reporting rates of some UMLS concepts similar to ADEs catalogued in drug compendia. This study suggests that automatically mining social media and resulting disproportionality metrics can yield promising results for further quantification of ADEs.

PHP205

EFFICACY OF INTERNATIONAL APPROACHES TO MEDICINE PRICE REGULATION AND CONTROL: A SCOPING REVIEW

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OBJECTIVES: Policies drafted and being implemented for regulating and containment of medicine prices, but still "access to affordable medicines" is a significant issue for all especially for the world's poor, where the lowest priced medicines are unaffordable for them. Therefore, the aim was to identify and review the literature on international comparative approaches related to medicine price regulation, control, and its effectiveness. **METHODS:** In this scoping review to analyze the strengths and weaknesses of international approaches towards medicine cost containment and price regulation an extensive search was carried out to collect peer-reviewed research and review articles, discussion papers, public documents relating to medicine pricing policies. STARLITE principles were set as an indicator for search strategy. Key search terms used were "medicine prices", "causes of high medicine prices", "approaches towards medicine prices control", "national medicine policies", "international approaches towards medicine price control", "containment policies", and "effects of pricing policy on medicine". **RESULTS:** Multiple methods such as supply-side regulations and demand-side regulations/incentives, reference-based pricing, equity pricing and WHO recommended policy options for

improving medicine affordability and availability, value-based pricing to regulate medicine prices was reviewed. However, inadequate proof of actual policy impact was found that result in affordability, which indicates that access to affordable medicine is a distant goal. These policies or regulations were either less comprehensive, outdated and fell short in implementation especially in low and middle-income countries due to lack of funding, infrastructure or trained professional task force. Overall, none of the policy options was preferred considering its desired outcome. **CONCLUSIONS:** The authors found gaps in the literature and propose that international and national organizations to perform critical evaluation and research. We propose that pro-poor policies should be developed to have a real impact on the lives of the vulnerable population by paying less for, and access to affordable medicines.

PHP206

THE DISCRIMINANT VALIDITY EVALUATION OF A PATIENT-REPORTED SYNDROME SCALE: QI-DEFICIENCY SYNDROME (PRS-QDS) IN PATIENTS WITH QI-DEFICIENCY

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OBJECTIVES: A patient-reported syndrome scale: Qi-deficiency syndrome (PRS-QDS) had been developed for efficacy assessment in Traditional Chinese Medicine (TCM). This study aimed to evaluate the discriminant validity of the PRS-QDS. **METHODS:** The patients with Qi-deficiency syndrome (QDS) and healthy subjects were recruited. All the subjects were divided into young, middle-aged and aged groups determined by age. Studies have found that there was a correlation between QDS and hemoglobin concentration (Hb), Hb was recorded for patients with anemia to analyse the relationship of QDS and Hb. All the patients with anemia were divided into two subgroups of mild and moderately severe anemia determined by Hb. T test was applied to compare the PRS-QDS scores between healthy subjects and patients with QDS. **RESULTS:** A total of 207 subjects [77 health (age: 51, 30 males) and 130 patients (age: 54, 46 males)] completed the PRS-QDS (ranging from 0-40, high score means less healthy). The total score of healthy people was 7.44±5.16, and the patients with QDS was 19.44±7.30. These total scores of young, middle-aged and aged subgroups for those patients were 19.60±5.86, 19.39±7.36, 19.42±7.67 compared to 8.91±5.15, 7.00±5.82, 4.47±3.12 for those healthy population respectively. The ten item scores of the patients with QDS were obviously higher than those of healthy population (P<0.001). The total score for the mild anemia subgroups was 14.36±7.89 compared to 23.00±7.07 for those moderately severe anemia. T test results showed that the ten item scores of the patients with mild anemia were clearly lower than those of moderately severe anemia. **CONCLUSIONS:** The results expected differences in the PRS-QDS scores by the degree of anemia and known groups showed a good discriminant validity of the PRS-QDS. The evaluation of efficacy assessment for the PRS-QDS will be needed in the further research.

PHP207

ANALYSIS OF THE MEDICINES FORMULARY IN A MOROCCAN HOSPITAL CENTER ACCORDING TO THE ATC CLASSIFICATION

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OBJECTIVES: The Anatomical Therapeutic Chemical (ATC) classification system has been recommended by the WHO for several years for studies on the use of drugs. It is currently widely used internationally and the number of its users is increasing gradually. The aim of this study is to analyze the medicines formulary of the University Hospital Center according to this classification. **METHODS:** We carried out an analytical study of the 2016 drugs formulary of the University Hospital Center IBN SINA - RABAT MOROCCO- where the ATC classification was one of the main parameters studied. **RESULTS:** We analyzed 818 drugs; Belonging to 21 classes according to the pharmacological classification and to 14 classes according to the ATC classification. The results showed that cardiology drugs occupy the most important place (14.18%), followed by anti-infectives (13.08%) and anesthesia-ICU drugs (9.16%). The less represented classes were stomatology (0.12%), antispasmodics (0.24%) and gynecological drugs (0.73%). Regarding the ATC classification, the results showed that drugs belonging to class N (nervous system) occupy the first place (21.9%), followed by class B (blood drug; 13.5%) and Class J (anti-infectives = 12.6%) respectively. The least represented classes were; class G (Genitourinary system and sex hormones: 0.6%) and class P (pesticides, insecticides and revulsives: 0.7%). **CONCLUSIONS:** Drug classification systems provide a useful means of drug description and a uniformity standard for the collection and use of drug use data. The results show a significant difference between the ordinary pharmacological classification and the new ATC classification which appears to be more precise, hence the interest of its adoption in the future referencing of drugs at our establishment.

PHP208

PRACTICAL ISSUES OF DETERMINING WEIGHTS FOR CRITERIA TO BE USED IN AN MCDA FRAMEWORK - BASED ON A CASE-STUDY

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OBJECTIVES: This study aimed to evaluate the different practical issues with determining the criteria weights of a multiple-criteria decision analysis (MCDA) framework and provide recommendations for the future based on a case-study. **METHODS:** An MCDA workshop was held in Kyiv, Ukraine in October 2016.

The 20 participants with various healthcare-related backgrounds were asked to assign weights to five criteria (Burden of disease, Therapeutic effect, Safety, Innovation, Costs) individually, considering two decision scenarios: assessing pharmaceuticals to treat oncological diseases and rare diseases. The sum of the criteria weights was set to 100. The same participants were later assigned into 5 groups with 4 members each, to have discussions and finally agree on a set of weights that represented the joint opinion of their group. The sets of criteria weights of individuals and groups from this workshop were assessed with descriptive statistical methods. **RESULTS:** The means of the criteria weights of individuals and groups differed noticeably in some cases, e.g. 9.25 and 4.4 were the average values for individuals and from groups in the case of the 'Burden of disease' criterion for oncological drugs. The 'Costs' criterion had the highest standard deviation values in both decision scenarios and both in the case of individual and group-based weighting. Contrary to expectations, the smallest weight assigned a criterion was not always lower in the case of individuals than in the case of groups. Intra-group differences were also significant, e.g. one group assigned the weight of 5 to the 'Therapeutic effect' criterion while another group set this weight to 60. **CONCLUSIONS:** These findings indicate the presence of different value judgements when the same people are put in different situations. It can be recommended to consider the potential behavioural biases and limitations when constructing an MCDA framework in practice.

PHP209

IMPACT OF VERBAL AND PHYSICAL AGGRESSION TOWARDS PARAMEDICS IN HUNGARY

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OBJECTIVES: Aggressive behavior from patients and relatives is a serious risk factor for health care workers. Verbal and physical aggression has a negative effect on their work, it can even cause inability to work and career changing in extreme cases. The aim of our study was to assess the frequency of verbal and physical aggression towards paramedics and their impact. **METHODS:** A quantitative, cross-sectional study was carried out with non-probability convenience sampling. Our sample consists of paramedics working in health care for more than one year (N=100). Demographic data, number of verbal and physical aggression coming from patients or their relatives, assumed cause of aggressive behavior and type of help paramedics received was assessed with a self-made questionnaire. SPSS 22.0 was used for calculating descriptive statistics, χ^2 -test and Mann Whitney U test ($p < 0.05$). **RESULTS:** Mean age of responders is 38.57 ± 10.73 years. Large part of the sample has experienced some kind of aggressive behavior during their career (verbal: >91%, physical: >49%). Number of conflicts containing verbal aggression is more frequent (from patient: 10.50 ± 10.52 ; from relative: 9.5 ± 11.06), than physical (from patient: 3.21 ± 4.85 ; from relative: 1.55 ± 0.50). Paramedics who experienced aggressive behavior are more likely to consider career changing, whether it is verbal (from patient: $p=0.016$; from relative: $p=0.045$) or physical (from patient: $p < 0.001$; from relative: $p < 0.001$). Main causes of aggression according to paramedics are psychotropic drugs (72.73%), toxic condition (63.64%) and psychological disorders (30.30%). None of the responders (0%) received any kind of conflict management training or training for trauma processing, although 60% of them would like to participate. **CONCLUSIONS:** Paramedics are put at a great risk of being confronted by aggressive patients or relatives. It is important to help them at their workplace, training them how to manage conflicts and process trauma.

PHP211

MODERNIZING THE 14-ITEM TREATMENT SATISFACTION QUESTIONNAIRE FOR MEDICATION USING RASCH MEASUREMENT THEORY

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OBJECTIVES: The Treatment Satisfaction Questionnaire for Medication (TSQM) Version 1.4's psychometric properties have been demonstrated. The primary objective of this study was to review and to psychometrically evaluate the TSQM using Modern Test Theory Methods. **METHODS:** Patients with Multiple Sclerosis completed the TSQM electronically. Descriptive statistics were used to characterize the participants. Floor and ceiling effects were calculated per item. To evaluate the scaling properties and construct validity of the TSQM, Rasch measurement theory (RMT) was used and the following examined: 1) Fit to the RMT model; 2) Internal reliability; 3) Item category thresholds; 4) Unidimensionality; 5) Response dependency; 6) Differential item functioning (DIF); and 7) Targeting. A partial credit Rasch polytomous model was used. **RESULTS:** 283 patients completed the TSQM. The majority of patients had some college education, were female, and were on average 50 years old. Fit to the RMT model was examined which resulted in rescoring items with disordered thresholds. Item residual and person residual were of 0.0 ± 2.14 and -0.12 ± 1.54 respectively. The Person Separation Index was 0.88. DIF was assessed for gender using analysis of variance and non-uniform DIF was observed for 7 items. Unidimensionality was assessed using independent t-tests between subsets of items identified by a principal component analysis of the residuals, and 12.5% of t-tests were statistically significant (at the recommended alpha level of 5%). Finally, we assessed targeting, and person to items threshold distributions showed a reasonable targeted scale to person thresholds. Items' order from lowest to highest treatment satisfaction was examined. **CONCLUSIONS:** The TSQM has undergone extensive psychometric assessments leading to several versions. An examination of the psychometric properties using mixed methods is granted to improve the scoring and psychometric properties of the measure.

PHP212

ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE (HRQOL) OF GENERAL POPULATION OF KHYBER-PAKHTUNKHWA (KPK) BY DEMOGRAPHIC CHARACTERISTICS

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OBJECTIVES: This study aimed to measure and analyze Health-Related Quality of Life (HRQOL) of general population of Khyber-Pakhtunkhwa (KPK). **METHODS:** A cross-sectional study was conducted in KPK. Population sample (n=1971) was collected from Peshawar and Sawat by using stratified sampling approach. The EQ-5D 3L tool was used to measure health-related quality of life (HRQOL) of healthy population of KPK by socio-economic demographic characteristics. The descriptive and inferential statistics have been done by using SPSS version 20. **RESULTS:** Result showed that mean age of respondents was 24.15 years. Maximum respondents 59.1% were female. Majority of respondents 53.3% had no any income as most of the respondents 42.8% were students. Maximum 81.4% were from urban locality. Eighty percent were single and most of respondents 85.5% had their own house. Total of 60 health states reported by the respondents of which most prevailing was having no problems in any domain. EQ-5D descriptive score and EQ-VAS score were 0.80 ± 0.24 and 0.78 ± 0.20 respectively. The percentage of people responding to any problems in the five EQ-5D-3L dimensions increased with age and females have better health as compared to male in all age groups. Comparison of mean score and inferential statistics shown all demographics were significantly associated ($P < 0.01$) with mean EQ5D score and VAS. **CONCLUSIONS:** This study showed KPK population HRQOL data measured by the EQ-5D tool. Current study concluded that health status of KPK people have same EQ5D trend in which younger age have better health states which reduced as age increasing. Better female health states were observed which showed males are more prone to disease and sickness.

PHP213

WHAT IS BEING MEASURED IN PATIENT-REPORTED OUTCOME MEASURES? SYMPTOM QUESTIONS MAY OFTEN REVEAL IMPACT ANSWERS

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OBJECTIVES: To determine the cognitive retrieval process utilized by patients when asked to describe symptom severity. **METHODS:** 419 subjects with diabetes (n=104), chronic obstructive pulmonary disease (COPD) (n=104), depression (n=107) and osteoarthritis (OA) (n=104) were recruited through Boston media sources; eligible subjects were screened to confirm diagnosis. Subjects were provided a verbal descriptor scale ("none", "mild", "moderate", "severe", "very severe"), and "as bad as I can imagine") at the research site and were asked to describe for their most bothersome symptom, in free text, what each response option meant to them. The data was then coded and analyzed using Atlas.ti. **RESULTS:** Subjects with depression, diabetes, COPD and OA most often reported their most bothersome symptom at each severity level in terms of the impact it had on them (62.6%, 39.4%, 28.8% and 32.7% respectively). In contrast, fewer depression, diabetes, COPD and OA subjects indicated the severity descriptors were associated with more traditional symptom descriptors (4.7%, 14.4%, 16.3% and 29.8% respectively). For example, subjects with OA were more likely to assign impact descriptors as: "none"="I feel great", "mild"="walk faster with a cane", "moderate"="take short breaks", "severe"="take more breaks when walking", "very severe"="stay home and watch TV", "as bad as I can imagine"="stay in bed listen to radio" versus traditional symptom descriptors such as "none"="no pain", "mild"="annoying", "moderate" can deal with it", "severe"="hurt", "very severe"="hurt badly", "as bad as I can imagine"="like dying". **CONCLUSIONS:** In most cases across four disease areas, when subjects were asked to think about the severity of their most bothersome symptom, they considered the impact of their disease rather than symptom severity. Questionnaires that purport to capture information on symptom severity may actually be capturing the impacts of a disease.

PHP214

CONDITIONS WITH LOW MEDICATION ADHERENCE AND ASSOCIATED OUTCOMES: AN ASSESSMENT OF THE UNITED STATES POPULATION

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OBJECTIVES: Medication nonadherence is a concern to physicians and stakeholders, as it is often associated with poorer health outcomes. The aims of this analysis are to (1) assess which conditions have the lowest rates of medication adherence, (2) compare adherence by age and by number of conditions, (3) assess health outcomes by adherence. **METHODS:** This analysis utilized results from the US National Health and Wellness Survey 2016. A stratified random sampling based on gender, age, and race/ethnicity was used to ensure representativeness to the adult (age 18+) population (based on US Census Bureau). Descriptive analyses were conducted to assess condition prevalence. Adherence to prescription treatments (using the Morisky Medication Adherence Scale, ©MMAS-8)1 was assessed among the more prevalent conditions as well as some lower prevalent conditions. Adherence was analyzed by age group and by number of conditions. Healthcare utilization, costs, and productivity impairment were also assessed by adherence levels. **RESULTS:** Among the conditions profiled, the ones with the lowest rates of adherence included: acne (55%), headache (46%), allergies (44%), dry eye (43%), migraine (41%), asthma (inhalers) (40%), social anxiety disorder (40%), bipolar disorder (40%), generalized anxiety disorder (38%), anxiety (37%) and heartburn (36%). Among the more prevalent conditions, the percentage of low adherence decreases as age increases. In assessing the general

trends by condition, compared to adults with high adherence, adults with lower adherence had: higher rates of emergency room visits, higher rates of hospitalizations, and greater work/activity impairment. **CONCLUSIONS:** Conditions that garner low adherence could suggest there is an unmet need. Since low adherence is associated with greater levels of resource utilization and impairment, understanding which conditions have low adherence could help inform stakeholders which conditions present opportunities for decreasing disease morbidity and improving outcomes. Further, understanding the reasons could also help determine appropriate measures for improving adherence.

PHP215

THE VARIABILITY AND COMPLIANCE OF PRESURGICAL IMMUNE ENHANCING SUPPLEMENTS OF PATIENTS ACROSS FOUR SURGICAL DISCIPLINES - A RETROSPECTIVE STUDY

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OBJECTIVES: Surgical procedures are invasive by nature and trigger a complex neurohumoral stress response which is critical to initiate physiologic recovery and tissue healing. Preoperative nutritional optimization with immune enhancing supplements containing arginine, omega-3 fatty acids and nucleotides modulates the stress response and reduces postoperative complications. Despite overwhelming evidence verifying the importance of preoperative nutritional intervention, preoperative nutrition protocols are not implemented consistently to promote patient compliance. The objective of this study was to evaluate the variability and compliance of surgical patients to their preoperative nutritional regimen. **METHODS:** A database including four surgical disciplines (major spine, bariatrics, total hip and knee replacement, and gastrointestinal malignancy) was developed to track variability and compliance with the nutritional supplementation. All patients were prescribed a five (5) day preoperative oral immunonutrition protocol. Patients undergoing bariatric or total joint replacement surgery were given a separate pre-operative class. On the day of surgery, the patient self-reported the number of cartons consumed. Using SAS, these records were analyzed to evaluate patient variability and compliance. **RESULTS:** 2,283 patients records were included in this analysis. Compliance varied among the disciplines. Patients undergoing total joint replacement (n=982) or bariatric surgery (n=267) had the highest compliance rate of 52% and 48% respectively. The lowest compliance rate was seen in those having major spine (n=833, 28.9%) or GI malignancy (n=201, 12.9%) surgery. **CONCLUSIONS:** Patient compliance did vary among the surgical disciplines. In addition, those patients who received a separate pre-operative class had higher compliance rates. Future research is needed regarding the source of the variability of compliance, including the impact of preoperative education, as well as the impact of compliance with preoperative nutritional regimens on outcomes.

PHP216

AVAILABILITY OF ECONOMIC DATA FOR THERAPEUTIC BIOLOGIC DRUGS IN THE US

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OBJECTIVES: 1) to evaluate changes in product package inserts (PPIs) labeling and indications, 2) to evaluate the availability of economic evaluations assessing indications of biologics license applications (BLAs) marketed in the US in the period 1986-2015. **METHODS:** The FDA website was used to obtain information regarding the history of FDA approvals and labeling changes for BLAs in the study period. The labeling changes represent alterations of any section on a PPI including: indications, precautions, warnings, and adverse events. A search using FDA approved label and Micromedex was performed to identify changes in BLAs uses. For the economic evaluations, electronic search was done on Medline and Embase (1986 through August 15, 2016) for CEAs and CUEs studies assessing therapeutic biologics in the US. Key words included BLAs generic and branded names and "cost." Descriptive statistics were estimated using Microsoft Excel 2013. **RESULTS:** A total of 177 economic evaluations published in the period 1989-2015. The FDA approved 114 BLAs in the study period. The BLAs had an average of 4.3±6.0 indications, with an average 2.4±2.0 FDA-approved indications and 2.0±4.7 off-label indications. An estimated 39% of the therapeutic biologics, 29% of the FDA-approved indications and 8% of the off-label indications had at least one economic evaluation published in an indexed journal. There were a total of 882 labeling changes for BLAs in the study period, representing an average of 0.68±0.95 labeling changes for every year a BLA was available on the market. The most common FDA approval label changes for BLAs were supplements (59.64%) followed by labeling revisions (28.57%), and efficacy supplement with clinical data (8.96%). **CONCLUSIONS:** The economic information available for BLAs is limited and no economic evaluation was conducted for more than half of the BLAs marketed in the US. More BLAs economic evaluations are required for use by decision-makers.

PHP217

HEALTHCARE NEEDS OF INTERNATIONAL MIGRANTS IN RELATION TO NATURAL DISASTERS: THE CASE OF CHILE

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OBJECTIVES: Chile is Latin American country prone to natural disasters (NDs). Despite efforts to improve knowledge and effective strategies for prevention and control of NDs in this population, little has been explored related to international migrants (2.5% total population, N=550,000). We explored healthcare related needs of international migrants towards NDs in Chile. **METHODS:** Qualitative case study of

the city of Valparaíso, one of the immigrant-densest cities in Chile and with one of the highest rates of NDs. We conducted 23 individual semi-structured interviews (12 women/11 men), until data saturation was reached. We transcribed interviews verbatim and conducted thematic analysis in NVivo Software. Ethical approve from UDD Ethics-Committee. **RESULTS:** We found two types of participants, those who had not had a NDs experience before (immigrants from bordering countries) and those who did (Central American/Caribbean countries). In both cases there was little knowledge around this topic. Healthcare needs towards NDs were: being trained on how to safely evacuate, how to cope with own and relative's distress, understand the location of safe zones, and what the exact role of the healthcare system is, especially given that the largest response comes from unprepared community members and not experts/authorities. They request for official communication channels with authorities/healthcare experts at all times. **CONCLUSIONS:** International migrants have clear and urgent healthcare related needs in relation to NDs in Chile. This data should be integrated with ongoing strategies in the country, in order to protect the life and health of all residents in the country, including immigrants.

PHP218

PATIENT REPORTED OUTCOMES WITHIN THE FDA COA QUALIFICATION PROGRAM

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OBJECTIVES: Patient-reported outcomes (PROs) are increasingly important in drug development, HTA and patient care. FDA guidance on PROs was issued in 2009 and PROs were included in the FDA January 2016 Pilot Clinical Outcome Assessment (COA) Compendium. The objective of this analysis was to characterize the PROs in the Compendium to add to our understanding of which PROs are more likely to achieve regulatory acceptance. **METHODS:** The Compendium reports outcomes by FDA review division from COA Qualification Program submissions and approved NME labeling from 2003 to 2014; including outcome of interest, outcome assessment(s) and assessment type [PRO, observer-reported (ORO), clinician-reported (CRO), and performance (PO)]. The Compendium was reviewed to characterize PROs in the context of all outcomes within the review division and in aggregate. Frequency of outcome assessment type was determined. PRO outcome assessment tools were identified and characterized by "level" (e.g. generic, disease specific), type of data and collection method. **RESULTS:** Approximately 1/4 of Compendium outcomes had COA submissions, implying the majority of outcomes were from label claims. Outcome assessments were most frequently PROs (48%) or CROs (39%); POs (11%) and OROs (3%) were infrequent. All OROs were parent observations in pediatric studies. The number of PRO assessments was greatest in Pulmonary, Allergy & Rheumatology (22) and Gastroenterology & Inborn Error (21). As a percent of total outcome assessments, PROs were least frequent in Dermatology & Dental (13%) and Psychiatry (10%). Most PRO assessments measured signs and symptoms of disease. Pain and less frequently fatigue were measured in multiple disease states. Patient satisfaction with treatment was reported once, as was the SF-36. **CONCLUSIONS:** Within the FDA Pilot Clinical Outcome Assessment Compendium, patient-reported outcome assessments were frequent; however they were generally disease specific. A health-related quality of life instrument that could be used to compare outcomes across disease states was only listed once.

PHP219

EVALUATION OF IMPACT OF EDUCATIONAL INTERVENTION ON ADVERSE DRUG REACTION REPORTING BEHAVIOUR OF COMMUNITY PHARMACISTS IN SOUTH INDIA

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OBJECTIVES: To assess the impact of educational intervention on ADR reporting behaviour of the community pharmacists in selected practice settings of south India. **METHODS:** A cross sectional study was conducted after educational program to assess impact of intervention on knowledge, attitude and practice of community pharmacists towards ADR reporting. A series of training programs were conducted to improve the awareness and to provide education to community pharmacists on ADR detection and reporting. Training program included basic concepts of ADRs, importance and application of ADR reporting, safety reporting methods, ADR reporting and documentation process as per national requirements, management of common ADRs, possible barriers in reporting. The impact of educational intervention was measured by reviewing number and quality of ADRs reported. Quality of ADR was assessed using prepared checklist. Barrier Assessment Questionnaire (BAQ) was administered to assess the barriers if any in ADR reporting. **RESULTS:** About 68 community pharmacists with mean age of 39.69 ± 8.65 years, with a practicing experience of 15 ± 2.5 years had participated in this study. During the 6 month regular follow-up, 82 ADR reports received from 23 (28%) trained pharmacists. Quality of ADRs were satisfactorily only for 68% of reports. However, remaining reports were not of satisfactory quality. Major barriers identified for under reporting were lack of time (83%), forgetfulness (68%), and shortage of time from patients (46%). **CONCLUSIONS:** The study findings suggest that educational intervention improved the ADR reporting culture among community pharmacists. However, quality of reported cases should be routinely reviewed to further strengthen reporting culture.

PHP220

PERCEPTION OF YOUNG ADULTS TOWARDS PREMARITAL MEDICAL SCREENING IN QUETTA CITY, PAKISTAN

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OBJECTIVES: The aim of this study was to investigate the perception of young adults toward premarital medical screening in Quetta city,

Pakistan. **METHODS:** A cross sectional, descriptive study design was adopted. Perception of young adults towards premarital medical screening was assessed through a pre-validated questionnaire. The questionnaire was distributed to 1260 respondents of both genders. Descriptive and inferential statistics were used for data analysis. All analyses were performed by SPSS v. 20 and $p < 0.05$ was taken as significant. **RESULTS:** Twelve hundred and sixty young adults participated in study with a response rate of 99.4%. Seven hundred and eighteen (57.0%) respondents were males and 924 (73.3%) belonged to age group of 18-23 years. Nine hundred and sixty four (76.5%) had no family history of heredity diseases. Although 1074 (85.2%) of the respondents had information about genetic diseases, 65% had little idea about premarital blood screening. Interestingly, while premarital screening was perceived as a good practice (996, 79.0%) and a method to save generations from genetic diseases (1152, 91.4%), 927 (73.6%) of the respondents still reported that they will not opt for premarital blood screening before their marriages. However, 828 (65.7%) were in favor of premarital screening only if a law is approved by the healthcare authorities. The Chi square test was used for cross tabulation and no significant association was reported among study questions and demographic variables ($p > 0.05$). **CONCLUSIONS:** The current study concluded that majority of the participants had little idea about premarital blood screening. Additionally, premarital screening was not perceived as an important procedure before marriages. This reflects the lack of information towards premarital screening and the need of providing health education in order to improve the perception towards premarital screening among young adults in Quetta city, Pakistan.

PHP221

WILLINGNESS TO PAY FOR HEALTH CARE IN THE US: WHOSE PERSPECTIVE IS IT ANYWAY?

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OBJECTIVES: There is substantial attention on value in health care. The value of a health technology may vary depending on the perspective used. We reviewed and analyzed willingness to pay (WTP) studies to understand the perspectives used for eliciting the value of health care. **METHODS:** We searched PubMed for English-language articles related to WTP for health technologies in the US published from 2006 through 2016. We extracted key features of studies, including the type of health technologies, disease category, and importantly, methodological differences including perspectives, elicitation methods, and mode of administration. **RESULTS:** Of 4,810 articles identified by our search, 104 relevant WTP studies were included. Thirty-three focused on a drug or treatment, 18 investigated diagnostics, and 53 investigated others including technologies, vaccines, and health programs/policies. Seventeen looked at infectious diseases, 16 focused on oncology, and 71 investigated other conditions including neurology and musculoskeletal diseases. Fifty-two studies surveyed patients, 13 included family members, and 25 studies used the general population to assess WTP out-of-pocket for a health intervention from an individual perspective. Seventeen studies used payment card method, 11 used discrete choice, and 14 used bidding game approach. Ninety-five studies estimated WTP from the individual perspective and nine from the societal perspective. **CONCLUSIONS:** There has been substantial variation in studies with respect to the type of technologies and diseases assessed and respondent characteristics. Almost all studies assessed technologies from the individual perspective. As perspectives influence the perceived value of the technologies, it is important to conduct WTP from both the societal and the individual perspectives.

PHP222

IS REDDIT A USEFUL SOCIAL MEDIA DATA SOURCE FOR DRUG OVERDOSE DISCUSSIONS AND OUTCOMES?

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OBJECTIVES: To identify the strengths and limitations of Social Media for toxicovigilance, and to establish the extent to which relevant overdose discussions can provide safety-related outcomes. **METHODS:** This study was a retrospective analysis, conducted using English language Reddit posts ($n=3579$) spanning a 1 year period. Noise was removed from the data via key words, natural language processing, and crowd sourcing via Amazon Turk, to identify in-scope posts prior to making posts available for manual curation. **RESULTS:** Of the 3579 total posts evaluated, 60.7% (2172) were discussing events other than overdose (e.g. drug abuse, illicit drug use); 39.3% (1406) contained overdose discussions- 16% (573) of the posts were determined to be intentional overdoses, 6.6% (236) were unintentional/accidental overdoses and 16.7% (597) were unknown. 61% (858) of the 1406 posts were posted by the patient; 38% (534) were unknown/other and 0.9% (13) was posted by Healthcare Providers. Overdose symptoms were discussed in posts 58% of the time (815), co-morbidities 8% of the time (112) and dose information was provided 4% of the time (56). 27% (390) posts mentioned overdose help and the action taken as a result of the overdose included going to the hospital 20% (78), calling healthcare provider 8% (31) and other 45% (175). 210 (15%) overdose posts contained various overdose treatments. 271 posts (19%) mentioned overdose outcomes and included death in 10% of the cases (27), 11% recovering/resolved (30), 10% not recovered/resolved (27) and 69% of cases (187) recovered/resolved. The 3 most commonly discussed drugs were: Amphetamine and dextroamphetamine (156), Acetaminophen (89) and Diphenhydramine (60). **CONCLUSIONS:** Social media (Reddit) data provides relevant, data rich discussions on drug overdose including: overdose symptoms, drugs involved, comorbidities, treatments and patient outcomes. Additional research is required to further assess the value of this data for various toxicovigilance activities.

PHP223

DIGITAL TRACKERS SHOW THAT HIGH INTENSITY EXERCISING AND CONSISTENT SLEEP PATTERNS ARE ASSOCIATED WITH POSITIVE SELF-REPORTED HEALTH STATUS

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OBJECTIVES: Behavioral data (e.g., steps and sleep patterns) from activity trackers can provide valuable insights into an individual's overall health and wellness. However, the relationship between behavioral characteristics and perceived health and quality of life (QoL) in the general population has not been quantified. In this analysis, we examined the association between behavioral traits inferred from passive trackers and self-reported overall health, physical health, mental health and QoL. **METHODS:** Members of an online health community were invited to participate in a survey that included ratings of perceived overall health status, physical health, mental health and QoL on a 5-point Likert scale, as well as characteristics such as age and gender. We used their activity information recorded from health trackers and apps over the past five months to compute per-patient daily mean and standard deviation of step and sleep metrics such as step count, sleep duration, maximum steps taken in a continuous 30-minute interval per day, and sleep efficiency. Weight was also collected from connected scales. For 7,261 individuals, we used the various computed behavioral characteristics as explanatory variables in standard regression models to predict perceived overall health, physical health, mental health and QoL while controlling for age and gender. **RESULTS:** On average, the study population took 10,588 steps per day and slept 6.6 hours per night. Weight was negatively associated with perceived overall health status, physical health and QoL. High intensity exercise and consistent sleep length had statistically significant associations with positive perception of overall health, physical health and mental health, and high self-reported QoL. **CONCLUSIONS:** Our results indicate that individuals who frequently engage in rigorous exercising and sleep a consistent amount nightly also have positive perceptions of their health, wellness and QoL. Further research should be conducted to determine if these relationships hold true among disease-specific populations.

PHP224

PATIENTS CONSIDER TRAINING A NECESSARY PART OF CLINICAL TRIALS, PREFERRING READILY-ACCESSIBLE INTERACTIVE ELECTRONIC TRAINING

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OBJECTIVES: As patient-reported outcomes (PROs) are often primary or secondary endpoints in clinical trials, regulatory PRO guidance recommend patient training to improve data quality and reduce variability. This study explored patients' views on the importance of training and their preferred mode for training. **METHODS:** 437 Participants reported on an online survey their opinions regarding 1) the necessity of training during clinical trials, 2) preferred training material format, and 3) accessibility of materials for the duration of the trial. Participants were also asked how they would handle questions that may arise when completing questionnaires. Demographic information, including age, education level, and household income were recorded. **RESULTS:** 95.4% of participants indicated that educational materials and training were "definitely needed" (75.5%) or "somewhat needed" (19.9%). With modes of training, 71.6% of participants reported they preferred completing interactive training on mobile electronic devices or the internet as opposed to 27% who preferred paper guides to take home. 89.9% of respondent considered accessibility to the training to refresh on the information during the trial "definitely needed" (58.2%) or "somewhat needed" (31.7%). Should they have questions completing a questionnaire, 46.2% stated they would ask the trial doctor, 40.5% would look up information online or in reference materials, and 12.6% would try to pick the best answer. **CONCLUSIONS:** Our study found that the vast majority of participants considered educational materials and training a necessary part of clinical trial participation. Moreover, most participants preferred electronic modes of training and the ability to refresh on training materials. Less than half of the respondent would ask site staff to clarify questions, which may introduce inconsistency in PRO measures unless training is used to provide standardized instructions and key definitions. Our findings are consistent with regulatory PRO guidance and suggest that electronic interactive training could be used as an approach to improve data quality.

PHP225

ASSESSMENT OF PATIENT SATISFACTION AND PERCEPTION TOWARDS PHARMACIST AND PHARMACY SERVICES IN TERTIARY CARE HOSPITALS QUETTA, BALOCHISTAN

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OBJECTIVES: The Study aimed to assess patient satisfaction and perception towards pharmacist and pharmacy services in tertiary care hospitals Quetta, Balochistan. **METHODS:** Cross sectional study was conducted in tertiary care hospitals of Quetta to assess patient satisfaction and perception towards pharmacist and pharmacy services. The research instrument is designed and validated by Pakistan Institute of Medical Sciences and translated into Urdu by using standard translating procedure, comprises of 19 questions. Data collected from 1013 patients from January to September 2016. All analyses were done by using SPSSv20. **RESULTS:** Result showed that mean age of respondents were 43.95 years. 1013 respondents do not know about pharmacist. Majority of respondents ($n=556$, 54.9%) were male. Majority of respondents ($n=179$, 17.7%) matric as education. Most

of respondents (n=637, 62.9%) were have no income. Majority of respondents (n=837, 82.6%) were married. Majority were (n=647, 63.9) lived in their own house and from urban locality. Majority of respondents (n=290, 28.6%) were prescribed 6 medicines and large number of respondents (n=188, 18.6%) were dispensed 2 medicines. Maximum patients (n=693, 68.4%) showed poor satisfaction towards Pharmacists and pharmacy services provided to them. Comparison of mean score with demographics showed that there is no statistical significant difference found among demographics. **CONCLUSIONS:** Study concluded that patients were not satisfied with Pharmacy services provided to them and ultimately it results in patients show poor satisfaction, perception and appreciation of the pharmacists' role in the health care team. Pharmacists need to be able to reach out to patient, evaluate their reluctances and promptly offer explanation which was valued by the patients.

PHP226

EXPLORATION OF FEMALE WORKFORCE AND THEIR JOB SATISFACTION IN PUBLIC SECTOR HOSPITALS IN QUETTA, PAKISTAN

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OBJECTIVES: To assess the female workforce and their job satisfaction in government hospitals in Quetta, Pakistan. **METHODS:** Mixed method Prospective and Retrospective study conducted on total of 579 female healthcare professionals in Government hospitals of Balochistan, Quetta from July-2015 to April-2016. All the female health care professionals (medical doctors, pharmacists, nurses) working in government hospitals targeted for the study. Study tool consists of Questionnaire for job satisfaction consists of domains i.e. Authority, Promotion, relation with patient, Relation with other health care provider, Pay and Professional development along with socio-demographic variables. All female employees present on their duties on time who agree to participate in study were included. Descriptive and inferential statistics have been done by using SPSS version 20. **RESULTS:** Majority of participants (n= 304, 52.5%) were nurses. having majority (n=155, 51.0) ranges between 25 - 30 years. Majority of them were married (n=184, 60.5%). Maximum respondents 97 (31.9%) were have experience of 1 - 5 years. Overall satisfaction score demonstrated that maximum respondents (n=500, 86.4%) were satisfied, association of mean satisfaction score with demographics was performed, none of demographics was significantly associated with overall satisfaction (i.e. $p > 0.05$) except to job place ($p=0.001$) and Department ($p=0.019$). **CONCLUSIONS:** It is concluded that overall satisfaction was found to be satisfied, however it is showed that early career level in respondents were more satisfied, as the age level was increased there is low gradient of satisfaction with job.

PHP227

THE ASSOCIATIONS OF MULTIMORBIDITY ON HEALTH-RELATED LOST PRODUCTIVITY TIME IN A LARGE AND DIVERSE AUSTRALIAN PUBLIC SECTOR WORKFORCE: A CROSS-SECTIONAL SURVEY FROM AN EMPLOYEE PERSPECTIVE

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OBJECTIVES: Multimorbidity adversely affects health-related productivity loss. Sex may influence this relationship. This study aims to evaluate absenteeism, presenteeism and total lost productive time (LPT) due to multimorbidity from an employee perspective. **METHODS:** A 2013 Partnering Healthy@Work survey of state government employees in Tasmania, Australia (N=3,228, mean age 47 years, 71.9% women) was conducted as part of an evaluation of workplace health and wellbeing programs. Multimorbidity was defined as the co-occurrence of 2+ chronic conditions out of a pre-specified list of 20. Measures of absenteeism, presenteeism and LPT were obtained from employees' self-reported data over a 28-day period. Analyses were stratified by sex, and two-part models were used to estimate the associations between multimorbidity and productivity loss. **RESULTS:** This study included 3,086 respondents. The mean age of the sample was 47 years (SD=10). The majority of the respondents were female (71.7%). The average number of health-related total LPT was 0.8 (SD=2.3) and 1.0 (SD=2.7) days for men and women with multimorbidity, respectively. Both women and men with multimorbidity had greater odds of productivity loss due to absenteeism or presenteeism compared to those without, but women with multimorbidity had 40% and 30% more LPT due to absenteeism (RR=1.4, 95%CI 1.1-1.8) and presenteeism (RR=1.3, 95%CI 1.0-1.6), respectively, in women with day lost. However, there was no significant difference in men with day lost. **CONCLUSIONS:** This study identified the negative influence of multimorbidity on LPT and significant differences in LPT between men and women reporting multimorbidity. Female employees with multimorbidity were less likely to engage in their work due to presenteeism and absenteeism, and thus may require more attention in regards to planning preventive health care intervention strategies in a diverse, public sector workforce, particularly in female dominated occupations.

PHP228

AN ANALYSIS OF THE EVOLVING USE OF RWE BY IDNS TO INFORM CLINICAL DECISION MAKING

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OBJECTIVES: Availability of robust real world data (RWD) is quickly evolving; simultaneously, incentives driving use of RWD and RWE are changing clinical decision making. This study assesses what data IDNs are using to generate RWE and

how they are using RWE. **METHODS:** A quantitative survey of 70 US IDNs and payers about RWD sources and uses of RWE. We assessed the type of evidence generated, therapeutic areas of greatest interest, analytic approaches used to generate RWE, and willingness to partner with different healthcare stakeholders. **RESULTS:** Despite having improved sources of RWD (95% have some integrated EMRs), only 18% of IDNs use these data in clinical decision making. Key challenges include the expense of generating and applying the evidence and lack of skills to generate the evidence. The IDNs surveyed indicated that they would like more guidance on how to generate RWE cost effectively. About a third of the surveyed IDNs indicated they would partner with pharma to achieve this. The TAs for which they use RWE most frequently are anti-infectives, cardiovascular / metabolic, critical care, inflammation, and oncology. In the future, IDNs indicated future use to include neurology, women's health and nephrology. **CONCLUSIONS:** IDNs make little use of RWE in their decision making, but their needs for RWE to manage clinical decisions effectively grows. IDNs' ability to generate and leverage RWE lags the increasing availability of RWD. They would like to use more RWE, but more cost-effectively than the current model. Because a meaningful number are open to collaborating with third parties including pharma, pharma has an opportunity to engage with IDNs to accelerate their evidence generation and make more efficient.

PHP229

ICER'S GENERALIZED BUDGET IMPACT MODELLING METHODOLOGY IS CONTRARY TO ISPOR TASK FORCE GUIDELINES AND THE METHODS OF OTHER HTA AGENCIES

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OBJECTIVES: Budget Impact Analysis (BIA) is an important tool used in pharmaceutical pricing and reimbursement. We compared the BIA methods of the Institute for Clinical and Economic Review (ICER) to those of influential Health Technology Assessment (HTA) agencies. The aim was to determine whether they share similar BIA methods and goals and whether ICER is aligned with ISPOR's 2012 BIA recommendations. **METHODS:** We examined BIA methods guidelines of NICE, SMC, G-BA/IQWiG, PBAC, HAS, and CADTH, comparing them to each other and to ICER's methodology framework. We used ISPOR's 2012 BIA report on good practices as a benchmark for comparison. We assessed each set of HTA guidelines and methodologies to determine who conducts the BIA, the perspective of the BIA, and how the analysis is used. **RESULTS:** HTA agencies and ISPOR's guidance are consistent in their BIA approach, requiring assessments which address specific payers and policymakers and using real-world costs and populations. ICER uses a generic perspective, generally assuming wholesale acquisition costs, an unmanaged healthcare system (excluding cost-offsets or other resource considerations), with populations and uptake patterns that lack the specificity and applicability of those used by HTA agencies. ICER also uses a uniform budget cap in its analysis, potentially creating a bias towards lower cost drugs, regardless of effectiveness. ICER uses BIA and cost-effectiveness to determine whether the drug is affordable and provides good value to the healthcare system, and whether discounts are needed for the product-price to be "value based." HTA agencies primarily use BIA to aid in implementing their decisions. **CONCLUSIONS:** HTA agencies are more consistent with ISPOR BIA guidance than ICER. ICER's generic perspective and broad assumptions call into question the validity and usefulness of their BIA analyses, especially when used by ICER to make determinations about value and not, like most HTA agencies, solely to guide implementation.

PHP230

DEVELOPMENT OF A CONCEPTUAL FRAMEWORK OF "GOOD HEALTHCARE" FROM THE PATIENT'S PERSPECTIVE

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OBJECTIVES: Research is lacking on the most important aspects of care and clinician performance from the patient's perspective. Utilizing concept mapping (CM), a mixed method (qualitative and quantitative), the primary objective of this study was to conceptualize "good healthcare" and aspects of healthcare that matter most to patients. Secondary objectives evaluated differences in prioritizing aspects of healthcare among (1) various patient populations and (2) patients and stakeholders. **METHODS:** This study consisted of two phases, (1) statement generation, and (2) CM. Statements about what constitutes "good healthcare" were generated from literature review, stakeholder interviews (clinicians, researchers, purchasers, measure developers, health IT) and survey of patients (n=157) and stakeholders (n=17), via the online Open Research Exchange platform of PatientsLikeMe (a social network for patients with life-changing medical conditions). The majority of patients in phase I self-identified as female (71%), White (85%), and Non-Hispanic (92%) with a mean age of 56 years, and reported 68 different primary diagnoses. The statement pool (n=1300) was reduced to 79 statements for CM. In the second phase, using ConceptSystems software, stakeholders (n=15) and patients (n=172) rated these statements on importance and sorted the statements into meaningful categories. The majority of patients in phase II self-identified as female (64%), White (82%), Non-Hispanic (86%) with a mean age of 57 years, and reported 51 different primary diagnoses. **RESULTS:** Preliminary results produced an 8-factor solution: (1) Doctor-Patient Communication, (2) Doctor Characteristics and Behavior, (3) Appropriate Care, (4) Outcomes, (5) Patient as an Active and Informed Participant in Their Care, (6) Office Attributes, (7) Team Communication, and (8) Insurance Limitations. Pattern matching (cluster ratings of importance) across various demographic/clinical variables (e.g., gender) revealed similar results across groups. **CONCLUSIONS:** The conceptual model generated from this study is the first step towards developing patient-reported performance measures, and may also have public policy implications.

PHP231

CURRENT SITUATION AND PROSPECT OF PRIVATE HOSPITAL IN CHINA

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OBJECTIVES: To provide advices and future development directions for Chinese private capital invested medical institutions by analyzing the development of health resources from 2011 to 2015 in China. **METHODS:** The data of health resources were collected from National Health and Family Planning Commission of China. The data were divided into group public hospital (groupPub) and group private hospital (groupPvt). Descriptive analysis was applied by Excel. **RESULTS:** There were 27,587 thousand hospitals, 5.33 million beds and 5.071 million medical personnel in china in 2015. The number of groupPub institution is 13,069 thousand and accounted for nearly half (47.4%) in 2015. But groupPub accounted more than 60% of institutions in 2011. The groupPub is decreasing while the groupPvt is increasing from 2011 to 2015. The groupPvt increase around 15%. The number of beds in hospital is still increasing in both groups. The groupPub-bed was 4 times (4.3 : 1.03) as groupPvt-bed in 2015 and in 2011 even reached 7 times (3.24 : 0.46). The growth rate of groupPub-bed is around 6%. The growth rate of groupPvt-bed is still remained at 23%. From 2011 to 2015, the number of medical personnel increased fast in both groups. The groupPub-PPL was 5 times (4.28 : 0.79) as many as groupPvt-PPL in 2015 and reached 8 times (3.28 : 0.42) in 2011. The growth rate of groupPub-PPL is 7% and the rate of groupPvt-PPL is still remained at 17%. **CONCLUSIONS:** Private hospital has a significant gap from results than public hospital in China. Although government has been raising private capital invested medical institutions, but because of condition and the health environment, the development of private hospitals is still difficult. But private capital can coordinate with tired medical service of health care reform policy and transition into a specialist hospital. Private hospital will be occupied a place in the future medical environment.

PHP232

DISCRIMINANT VALIDITY OF A PATIENT-REPORTED SYNDROME SCALE: PHEGEM SYNDROME (PRS-PS) IN PATIENTS WITH PHEGEM SYNDROME

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OBJECTIVES: The study was conducted to compare the scores of a patient-reported syndrome scale: phlegm syndrome (PRS-PS) in patients categorized by baseline disease species, with a priori assumption that the primary phlegm symptoms of patients in different diseases were diverse from each other. **METHODS:** Healthy volunteers and patients with phlegm syndrome which mainly manifest as poor appetite, abdominal distension, greasy mouth, expectoration, heaviness in the body and sticky greasy coating, were enrolled. All the subjects were divided into young, middle-aged and aged subgroups determined by age. Patients with phlegm were separated into different groups according to baseline diseases. PRS-PS scores were compared between healthy subjects and patients and in different diseases. **RESULTS:** A total of 201 participants [86 health (age: 55, 40 males) and 115 patients (age: 59, 47 males)] completed the PRS-PS (ranging from 0-36, high score means less healthy). There were a variety of diseases concerning patients with phlegm syndrome, such as cardiovascular (29 cases), digestive (24), respiratory (14), urinary (11), endocrine (7) and other diseases (30). These total scores of young, middle-aged and aged subgroups for those patients were 13.3±5.02, 14.74±6.17, 12.55±5.4 compared to 1.91±1.35, 1.92±1.73, 2.53±2.23 for those healthy population respectively (P=0.000). The score of expectoration-item was the highest (2.57±1.16) in patients with respiratory diseases. The patients in digestive diseases showed the highest score (1.83±1.34, 2.63±1.10) in the item of poor appetite and abdominal distension. The score of the item of lost of taste and greasy mouth were high in patients with digestive (1.46±1.02, 1.67±1.20), respiratory (1.71±1.49, 1.43±1.40) and urinary diseases (1.60±1.51, 1.50±1.18), daytime somnolence (2.29±1.11) and sticky stool (2.14±1.35) high in endocrine diseases, heaviness in the body (2.40±1.35) high in urinary diseases. **CONCLUSIONS:** The measurement of expected differences in the PRS-PS scores by disease species and known groups supports the discriminant validity of the PRS-PS.

PHP233

AREA-LEVEL SOCIOECONOMIC STATUS INDICATORS FOR OBSERVATIONAL STUDIES OF MEDICATION USE: A COMPARISON OF ZIP CODE AND CENSUS-BLOCK GROUP BASED AGGREGATION

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OBJECTIVES: Electronic healthcare data are critical for evaluating medication outcomes in routine care. However, they typically do not record information on socioeconomic status (SES), which may be an important confounder in observational studies. Therefore, we merged area-level SES data from the US Census Bureau with patient-level electronic healthcare data and compared broader-level ZIP code-based aggregation with more granular census-block group-based aggregation in an illustrative cohort of generic versus brand-name atorvastatin initiators. **METHODS:** We identified a cohort of generic or brand-name atorvastatin initiators between November 30, 2011 and December 31, 2013 from Medicare claims linked to electronic health records from the Partners healthcare system in Boston. Using geocoding, patient addresses were spatially linked to data from the American Community Survey to assign area-level SES variables to each patient based on the census block group and the ZIP code of his/her address. These variables were used to compute a validated deprivation measure, the RTI SES index, which incorporates measures of unemployment, education, poverty, and housing in a single measure (range 0-100). Correlation between block group-based SES index (SESBG) and ZIP

code-based SES index (SESZC) was reported. Differences in the SES index between generic and brand-name atorvastatin initiators were evaluated using t-tests. **RESULTS:** Among 7,109 eligible patients, the mean (+/- standard deviation) SESZC (58.98 +/- 5.52) was similar to the mean SESBG (59.08 +/- 6.34), with a Pearson correlation coefficient of 0.81. When the SES index between generic atorvastatin initiators was compared to brand-name atorvastatin initiators, both SESZC (58.88 +/- 5.50 vs. 59.79 +/- 5.65) and SESBG (58.98 +/- 6.35 vs. 59.89 +/- 6.28) suggested that brand-name initiators had higher SES than generic initiators (p<0.001 for both). **CONCLUSIONS:** Aggregated SES data based on ZIP codes, which are easily accessible in most data sources, reasonably approximate SES data based on census block groups, which require availability of street-level addresses.

PHP234

BRAZILIAN EQ-5D-3L POPULATION NORMS

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OBJECTIVES: The EQ-5D is a widely used generic health-related quality of life measure commonly applied to describe health outcomes and to measure disease burden. This study aims to generate Brazilian population norms for EQ-5D-3L. **METHODS:** We performed a multicenter cross-sectional study was performed in three Brazilian urban areas. The final sample consisted of 5772 respondents, aged from 18 to 64 years. Amongst other information, respondents were asked to self-report their health status using the EQ-5D-3L descriptive system and visual analogue scale (EQ-VAS). Data on socio-demographic characteristics was obtained through specific questionnaires. The Brazilian TTO scoring algorithm was used to derive the utility values. **RESULTS:** Mean values were computed for both weighted index scores and self-rated health status (EQ-VAS), and stratified by gender and age groups. Health status declines with age, ranging between 0.87 for the youngest group 18-29 year-olds and 0.76 for 60-64 year-old. Men (0.85) reported higher scores than woman (0.79). Lower education levels were associated with lower EQ-5D index score in most age groups. **CONCLUSIONS:** This study provides EQ-5D reference values for the Brazilian population. These values can be used by local decision makers and researchers on economic evaluations and population health studies.

PHP235

INTERNATIONAL COMPARISON OF EQ-5D TARIFF SCORES BETWEEN THE UK AND JAPAN

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OBJECTIVES: Japanese researchers have insufficient health utility data on the Japanese population. Thus, they often resort to using parameters based on UK data in economic evaluations. Therefore, a need exists for an international comparison of EQ-5D tariffs between the UK and Japan as a fundamental validation analysis. The aim of our research is the evaluation of the differences in elicited EQ-5D-3L and -5L tariff scores across the range of different health states derived from the UK and Japanese populations. **METHODS:** Utility values are acquired from published database. (<https://www.ohe.org/publications/valuing-health-related-quality-life-eq-5d-5l-value-set-england> and <http://www.niph.go.jp/journal/data/64-1/supplement.xls>) Tariffs derived from the two countries are compared using mean and standard deviation as well as the correlations between countries. **RESULTS:** The Japanese EQ-5D-3L score was 0.423±0.217, and that for the UK was 0.147±0.312. In the case of EQ-5D-5L, the Japanese score was 0.449±0.154, and that for the UK was 0.391±0.228. The corresponding correlations between countries were 0.74 and 0.91. **CONCLUSIONS:** We identified that the Japanese and UK EQ-5D-5L tariff are more highly correlated than are the EQ-5D-3L tariffs. One reason for the EQ-5D-3L tariffs being different is that the N3 score, which is a constant that is added if any level-three value is scored, varies substantially between the countries; specifically, the UK N3 score was 19.2 times higher than that of Japan. Although the role of EQ-5D-5L differs from that of EQ-5D-3L, utility data from EQ-5D-5L can be better extrapolated than can EQ-5D-3L utility values.

PHP236

ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE (HRQOL) OF GENERAL POPULATION OF FEDERAL TERRITORY OF PAKISTAN

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OBJECTIVES: Assessment of Health-Related Quality of Life (HRQOL) of General Population of Federal Territory of Pakistan. **METHODS:** A cross-sectional study was conducted in Islamabad and Rawalpindi. Population sample (n=2582) was collected by using stratified sampling approach. The EQ-5D 3L tool was used to measure health-related quality of life (HRQOL) of healthy population of by socio-economic demographic characteristics. The descriptive and inferential statistics have been done by using SPSS version 20. **RESULTS:** Result showed that mean age of respondents was 29.12 years. Maximum respondents 69.1% were male. Majority of respondents 19.7% had 20k-30k PKR income. Most of respondents 34.3% were having bachelor education. Occupation wise maximum respondents 26.2% were doing private job employee. Maximum 94.9% were from urban locality. Sixty-one percent were single and most of respondents 75.2% had their own house. Total of 56 health states reported by the respondents of which most prevailing was having no problems in any domain. EQ-5D descriptive score and EQ-VAS score were 0.58 ± 0.45 and 0.63 ± 0.33 respectively. The percentage of people responding to any problems in the five EQ-5D-3L dimensions increased with age and males have

better health as compared to female in all age groups except elder age group where females have better health as compared to males. Comparison of mean score and inferential statistics shown all demographics were significantly associated ($P < 0.01$) with mean EQ5D score and VAS. **CONCLUSIONS:** This study showed federal territory population HRQOL data measured by the EQ-5D tool. Current study concluded that health status of federal territory of Pakistan people have lower EQ5D index score compared to other cities of Pakistan. Concern should be made to improve general health status of healthy people.

PHP237

ASSESSMENT OF THE QUALITY OF PHARMACOECONOMIC EVALUATION LITERATURE IN CHINA

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OBJECTIVES: To evaluate the quality of Chinese pharmacoeconomic evaluation literatures published between 2012 to 2014 retrieved from the Chinese National Knowledge Infrastructure (CNKI) to assess their adherence to the recommendations of the Chinese Pharmacoeconomic Guidelines. **METHODS:** Identified literature was screened according to pre-specific criteria to access legibility for inclusion. Each included literature was systematically compared against the recommendations proposed by the Chinese guideline. The level of adherence was expressed descriptively as percentage. **RESULTS:** After culling, 259 literatures were included in the comparative analysis. When compared to a previous study evaluating the quality of similar literature published between 1997 and 2007, our results showed improvements in certain technical aspects over the years. Particularly, the improvement was seen in more diverse evaluation methods being used, increased use of cost-utility analysis (2.43% in 2012–2014 vs. 0.26% in 1997–2007) and use of discounting (45.00% in 2012–2014 vs. 4.35% in 1997–2007). In addition, small number of studies were starting to apply modelling. **CONCLUSIONS:** The quality of economic evaluation literature had improved in recent years, with more researchers realizing the importance and necessity of using discounting, sensitivity analysis and modeling when conducting economic evaluation. Our study also highlights certain important areas when conducting economic evaluation needing further attention in China. These include the ICER threshold of economic analysis, more detailed guidance in performing sensitivity analysis and modelling as well as transferability of cost data across different regions. Overall, our results would support the positive contributing role of the Chinese Economic Guideline in promoting economic evaluation in China.

PHP238

A SURVEY OF THE NEED OF SLEEPING AND RESTING AMONG ICU PATIENTS

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OBJECTIVES: The aim of the research was to measure the changes in sleeping qualities and quantities in hospital and determine those factors what have the worst and best effects on sleeping. **METHODS:** Our research was retrospective, quantitative on the Cardiac Surgery Department of Pecs's hospital. The formula of admission criteria were the age above 18, the time/place orientation, longer staying in intensive care unit (ICU) than 3 days (N=82). Beside a standard and own-structured questionnaire we examined the medical datas of the patients as well. To statistical analysis we used the Ms Excel 2010 and SPSS 22.0. programmes, Chi-square-probe, T-probe, linear regression statistic method, Mann-Whitney-U probe, descriptive statistics, and it came out that the $p < 0.05$. **RESULTS:** In comparison of the sleep quality and quantity, both variables changed in negative direction in ICU. The most common factors that influence sleep are: thirst, uncomfortable posture, changed sleeping-program, existing disease, probes and catheters and environmental noises. There is a significant difference between the sleep quality and quantity at home, in the ICU and on standard department ($p < 0.001$). We found medium, positive connection between the feeling of pain and sleep quality at home ($r = 0.266$, $p = 0.015$), the sleep quantity in ICU and existing disease ($r = 0.314$, $p = 0.004$), probes and catheters ($r = 0.332$, $p = 0.002$), and noises ($r = 0.317$, $p = 0.003$). The ICU related factors (fright, closeness, detection of not real things) mostly influence the ICU sleep quality, quantity and the slept through hours amount. **CONCLUSIONS:** In changed environment, mainly in the ICU, the sleep quality and quantity are poor compared to home's and standard department's. The patients complain of many factors what have influenced the sleeping, including thirst and the uncomfortable posture.

PHP239

PROXIMAL VERSUS DISTAL IMPACTS OF DISEASE: DRIVERS OF BOTHERSOMENESS RATINGS IN PATIENT-REPORTED OUTCOME (PRO) STUDIES

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OBJECTIVES: To understand the rationale behind subjects' selections of their most bothersome symptom in PRO qualitative research. **METHODS:** 419 subjects were sampled in the areas of diabetes, chronic obstructive pulmonary disease (COPD), osteoarthritis (OA) and depression. Recruitment employed free-media-advertising-based population sampling methods in Boston. Eligible adult subjects were screened to confirm diagnosis and disease severity. Subjects in all four groups were asked to report the most bothersome symptom related to their disease and then indicate a reason for why they selected that symptom. **RESULTS:** Subjects in all four diseases most frequently chose their most bothersome symptom based on the impact it had on their lives. Subjects with diabetes (n=104) most commonly reported that a symptom was the most bothersome due to loss of productivity (14.4%) and that they felt a need for

medication (11.5%). Subjects with COPD (n=104) most commonly reported that a symptom was the most bothersome due to it causing them to be less productive (26.9%). Subjects with OA (n=104) most commonly reported that a symptom was the most bothersome due to functional limitations (37.5%). Subjects with depression (n=107) most commonly reported that a symptom was the most bothersome due to it causing them to be less productive (17.8%) and that it negatively affected their activities of daily living (8.4%). That is, in depression subjects, limitations at work and home bothered subjects more than traditional symptoms of depression (e.g., feeling sad) or for COPD subjects, shortness of breath. **CONCLUSIONS:** The majority of patients across diseases reported a way in which the disease limited some aspect of their life. This implies that patients consider how their symptoms bother them in terms of impacts, and the impact of the disease matters to patients, rather than the symptom itself.

PHP240

SOCIOECONOMIC DISPARITIES IN MEDICATION ADHERENCE AMONG PRIVATELY INSURED PATIENTS IN THE UNITED STATES

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OBJECTIVES: Socioeconomic Disparities in Medication Adherence Among Privately Insured Patients in the United States. **METHODS:** This study analyzed the drug prescription history of patients enrolled in healthcare plans provided by a large private insurance provider from 2011 to 2013. We identified patients younger than 65 years old by the end of 2013, who were prescribed an oral antidiabetic (N=57,133), antihypertensive (N=159,227), or antihyperlipidemic (N=144,761) medication and filled it at least twice. We followed these patients for at least a year after their first fill and measured patients' adherence using proportion of days covered (PDC). We then studied the relationship between patients' adherence and their income, education and race using regression analysis to understand how much patients' characteristics (age, gender, geographic area of residence, and comorbidity), copay, income and education explains the racial disparity in medication adherence by type of medication. **RESULTS:** Across all three types of medications studied, we found significant disparities in medication adherence by socioeconomic status of the patients. White patients were more adherent than non-White (Asian, Black and Hispanic) patients. Medication adherence improves with patients' education attainment and income level. Socioeconomic disparities were largest for those on antihyperlipidemic medications. Our regression analysis on racial disparities shows that racial disparities persist, after we control for patients' characteristics, copay, education and income. We were able to explain more of the black and white gap in adherence compared with that between Hispanic and white beneficiaries. **CONCLUSIONS:** Privately insured patients from lower socioeconomic backgrounds are less likely to adhere to their medications. Reducing copay and improving patient's education could potentially reduce these disparities. However, more research and efforts should be made to understand their reasons for nonadherence and effective intervention mechanisms.

PHP241

MULTIPLE CHRONIC CONDITIONS IN OLDER PEOPLE AND THEIR EFFECTS ON HEALTH CARE UTILIZATION: A NETWORK ANALYSIS APPROACH USING SHARE DATA

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OBJECTIVES: The presence of multiple coexisting chronic diseases in individuals and the expected rise in chronic diseases over the coming years are increasingly being recognized as major public health and health care challenges. At present, the common belief is that persons with multiple diseases have high rates of health care utilization (Starfield, 2006; Glynn et al., 2011; Salisbury et al., 2011). In our article we want to study the influence of multiple diseases to health care utilization of the elderly, using network analysis and regression methods. **METHODS:** In our article we use SHARE dataset of Wave 5, including data on 14 European countries and Israel. We model the presence of multiple coexisting chronic diseases as a network analysis problem, controlling for endogenous network formation (Goyal and Joshi, 2003; Soramaki et al., 2007). This has special scientific relevance as, to our knowledge, network analysis has not been used so far to study this problem, and, also, very seldom before in the analysis using SHARE data. To appropriately model the presence of multiple chronic diseases we also use tools from multivariate analysis. To verify the effects of multiple diseases on the rates of health care utilization we construct several different health care utilization variables and model the effects of different combinations of most commonly connected diseases on the health care utilization using econometric models from causal inference (controlling for endogeneity). **RESULTS:** Preliminary results confirm that a) the method of network analysis can be used for this purpose and provides a set of 6 main groupings/clusters of diseases with common prevalence among the elderly; b) the groupings have strongly statistically significant effects on the health care utilization. **CONCLUSIONS:** The analysis provides a new statistical method and model with extensive applications for the analysis of multiple coexisting diseases in health economics and medical sciences in general in future.

PHP242

THE INFLUENCE OF TIME HORIZON ON RESULTS OF COST-EFFECTIVENESS ANALYSES

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OBJECTIVES: To document variations in time horizons used in published cost-effectiveness analyses (CEAs) that assume a US payer perspective, and examine

how the assumed time horizon influences results. **METHODS:** We systematically reviewed the Tufts Medical Center Cost-Effectiveness Analysis (CEA) Registry. We included all US-based studies that used a healthcare payer perspective, were published during 2005-2014, and received a Registry quality score of 4 or better on a seven-point scale. We classified the identified CEAs as short-term (time horizon ≤ 5 years) and long-term (> 5 years). We analyzed associations between study characteristics (e.g., intervention type, prevention stage, and funding sources) and the specified time horizon. Finally, we developed case studies with selected interventions to illustrate the association between the time horizon and the cost-effectiveness estimates. **RESULTS:** The literature review identified 782 articles that met our inclusion criteria. Among the identified studies, 552 studies (74%) utilized a long-term time horizon while 198 studies (25%) used a short-term horizon. Of 32 studies that employed multiple time horizons, we reviewed 23 intervention-specific incremental cost-effectiveness ratios (ICERs). The extension of the time horizon yielded more favorable ICERs in 19 cases, and less favorable ICERs in 4 cases. In our case studies, the use of a longer time horizon also yielded more favorable cost-effectiveness ratios. **CONCLUSIONS:** The time horizon used in CEAs can substantially influence the value assessments of medical interventions. To capture broad societal impacts on costs and health effects, we encourage the use of time horizons that extend sufficiently into the future.

PHP243

EVALUATION OF MEDICATION ADMINISTRATION ERRORS BY PHARMACIST IN PEDIATRIC INPATIENTS

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OBJECTIVES: The study was designed to evaluate the frequency of administration errors and prevention Strategy in a pediatric ward of a teaching hospital, Quetta, Pakistan. **METHODS:** The study was prospective observational based, assessment of all the treatment chart of admitted patients by Pharmacist during the study period and analyzed the medication administration errors as per WHO guidelines. Data was collected from pediatric ward Bolan Medical Complex Hospital, Quetta from the period of October - November 2015 in a data collection form. Data was analyzed by using SPSS version 20. **RESULTS:** The total number of 287 patients treatment chart were assessed and the total drug administration were 8179, out of which drug administration to male patients were 5156 (63%) and female patients 3023 (37%). The total administration errors were recorded 6718 (82.13%), which include 6607 (98.34% of total errors) were omission errors, followed by 43 (0.64%) wrong time error, and 41 (0.61%) un-authorized drug error. **CONCLUSIONS:** There was a high percentage of administration errors in inpatient settings in which omission error was most frequent administration error made by nurses during the process of medicines administration. The only solution is that the educational training should be provided to nurses improve their administration process skills according to World Health Organization guidelines and Pharmacist intervention is needed in this regard.

PHP244

SATISFACTION WITH LIFE AMONG GENERAL POPULATION OF PUNJAB. PAKISTAN

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OBJECTIVES: To evaluate the satisfaction with life of general population of Punjab. Pakistan. **METHODS:** The study was designed as a cross sectional, online survey. Satisfaction with life was assessed by using Ed diener Satisfaction with Life Scale. Descriptive analysis was used to elaborate people's demographic characteristics while inferential statistics were applied to report the association among study variables. $P < 0.05$ was taken as significant. **RESULTS:** A total of 960 participants responded to the survey. The cohort was equally distributed in terms of gender and was dominated by participants of 20-25 (44.5%) years old. Seven hundred and twenty (75.0%) were unmarried and 392 (40.8%) had graduate level of education. Overall 682 (71.05%) participants reported satisfaction with their lives. Two hundred and fifty-six (26.7%) participants were dissatisfied from their lives respectively. People in urban locality have positive trend of satisfaction when compared with the rural ones. No significant association was reported among other study variables. **CONCLUSIONS:** This study provides baseline assessment for the Satisfaction with life of general population of Punjab, Pakistan. The study revealed the impact of the following conditions on the various satisfaction with life domains measured: Education, work, personal income & Locality. Overall the percentage of study correspondents who are satisfied with their life (71.05%) is more as compared to the percentage of dissatisfied people. satisfaction with life could be further improved if better job and education opportunities are provided.

PHP245

RELIABILITY AND VALIDITY EVALUATION OF A PATIENT-REPORTED SYNDROME SCALE: Qi-DEFICIENCY SYNDROME (PRS-QDS): QUALITATIVE METHODS

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OBJECTIVES: A self-rating scale for patients with Qi-Deficiency syndrome was established. This study was aimed to evaluate the reliability and validity of the PRS-QDS. **METHODS:** The reliability was assessed by retest reliability and intrinsic consistency reliability. The scale was filled again after 24-48 hours to evaluate the retest reliability. The Cronbach's α coefficient was used to assess the intrinsic consistency reliability. Content validity was assessed through the normative, rational

and accurate study of the scale. Exploratory factor analysis was used to assess the construct validity. Studies have found that there was a correlation between Qi deficiency syndrome and hemoglobin concentration (Hb), Hb was used as the criterion validity of Qi deficiency syndrome. **RESULTS:** A sample of 130 patients (average age: 54, 46 males) completed the PRS-QDS. 96% of the patients completed the scale, and the median completion time was 2.2 min. The retest reliability of the scale was 0.954, and ranged from 0.872 to 0.972 for the 10 items. The Cronbach's α coefficient of the scale and three dimensions: fatigue, shortness of breath and spiritlessness were 0.827, 0.674, 0.768 and 0.614 respectively. The correlation coefficients of 3 dimensions and their respective dimensions were 0.771-0.866. Spearman correlation coefficients between total score and 10 items were 0.369-0.761. Three common factors were extracted through the maximum variance rotation method consisting with the theoretical framework. The correlation coefficient between hemoglobin concentration and the scale was -0.718. The global score, three dimensions and all items were negatively correlated with Hb. Higher PRS-QDS scores were associated with a lower hemoglobin concentration. **CONCLUSIONS:** The PRS-QDS was proved to have a good reliability and validity. Through this study, a practical, self-rating tool was provided for patients with Qi-Deficiency syndrome.

PHP246

ANALYSIS OF THE PART OF THE GENERIC DRUGS IN THE MEDICINES FORMULARY OF A MOROCCAN HOSPITAL CENTER

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OBJECTIVES: The aim of this study is to determine the rate of generic drugs in tertiary hospital **METHODS:** In this study we carried out a qualitative and quantitative analysis of the part of brand name and generic drugs in the hospital medicines formulary of the Ibn Sina University Hospital Center of Rabat updated in 2016. **RESULTS:** From the 520 articles studied in the 2016 formulary, only 372 articles are retained in call for tenders of drugs (71.5%). The qualitative analysis showed a slight dominance of the brand name compared to the generics with 52% and 48% respectively. Regarding the quantitative analysis, generic drugs account for 59% of the global budget of the call for tenders. according to the ATC classification, The L, B and J class consume respectively the largest part of the budget allocated to the brand name (22.8%, 19.7%, 17%). Whereas for the generic, we find mainly the classes A, J and B (39.2%, 38.4%, 13.5 %) **CONCLUSIONS:** According to this study, we find that despite the procedure for the acquisition of medicines by tender, within our hospital center, the penetration rate of the first medicines exceeds half even if this mode of acquisition is in favor Of the lowest-priced drug that is the generic.

PHP247

POTENTIAL FACTORS ASSOCIATED WITH INTERVIEW QUALITY IN EQ-5D VALUATION PILOT STUDY IN TAIWAN

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OBJECTIVES: Following EuroQol EQ-5D valuation study protocol, Taiwan pilot study was just finished. The responses and quality control findings were obtained for quality improvement of interview. The aim of this study was to explore the other indicators to evaluate the QC and its potential associated factors in pilot study. **METHODS:** In addition to evaluate the main QC criteria in EuroQol EQ-5D valuation study protocol, we intend to explore the other QC parameters and its potential factors in EQVT study in Taiwan. While interviewers were informed to demonstrate the 3 practice time-trade off (TTO) tasks, the corresponding final answers could be the reference to anchor and compare the logic of participants' responses. Concerning Asian people tended to give up life in the worst health state, the responses toward the TTO final answers of the worst health status were compared and contrasted with that for the 3 practice TTO tasks. The associated factors of background questions using the descriptive analysis, independent tests and appropriate bivariate analysis were also evaluated. **RESULTS:** In the pilot study, 10 trained interviewers have completed 50 pilot interviews. 26% of them ever experienced severe illness, 62% had their family members experience severe illness and 46% chose to give up 20 out of 20 years in the worst health state. While the TTO final answers for the worst health state was strongly correlated with that of severe practice of TTO task ($r=0.56$), those who experienced with severe illness in caring for others and disagreed that "bad living better than good death" tended to give up more time than the counterparts ($ps < 0.05$). **CONCLUSIONS:** The associations of TTO final answers between the worse health state and the practice severe task and the participants' experience of severe illness and belief about "death" could be other potential factors to evaluate the quality of interview in EQ-VT study.

PHP248

NUTRITION INTERVENTIONS POSITIVELY IMPACT HEALTH OUTCOMES OF COMMUNITY-BASED ADULTS: A SYSTEMATIC REVIEW

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OBJECTIVES: Although ample research supporting the positive effects nutrition interventions have on hospitalized patients exists, less is known about the role nutrition interventions play on the health outcomes of community-dwelling adults. This review paper aims to systematically evaluate the literature exploring the association between nutrition and health outcomes among community-based patients, including free-living individuals and home care residents.

METHODS: PRISMA guidelines were followed for the literature review. Articles including original studies, pilot programs, and analytical reports of previously published papers were sourced from MEDLINE, EBSCO, Embase®, Foodline®, SCIENCE, and Google Scholar. After selection criteria were employed, only 24 of 401 (6.0%) articles were deemed eligible. **RESULTS:** Of the reviewed studies, majority explored nutritional interventions including oral nutritional supplementation (ONS), dietary advice, and nutritional counselling implemented for a minimum of 3 months. Majority of patients were free-living adults at-risk of or diagnosed with malnutrition. Most common study population were surgical patients; other populations included patients with oncology diagnosis, Alzheimer disease, gastrointestinal issues, chest infection, decompensated alcoholic liver disease, or disease-associated malnutrition complications. Among the improved health outcomes reported, anthropometric measures including less weight loss were the most common. Improved well-being/health status utilities, increased protein/energy intake, reduced readmission or postoperative morbidity or complications, and improved handgrip strength were frequently reported. Inconclusive results were reported regarding nutrition support impact on patient quality of life. **CONCLUSIONS:** Overall, nutrition interventions were found to have improved health outcomes among community-based patients. However, the reported studies are limited by their retrospective design, study setting heterogeneity, relatively small sample size, and lack of standardized measurements for assessing malnutrition and reported outcomes. Future research using more rigorous methods is needed to provide further support for the impact nutrition-based interventions can have on health outcomes of adults living in different community settings, and informing the design of new nutrition interventions.

PHP249

FROM RUSSIA WITH LOVE: VALUATION OF EQ-5D HEALTH STATES USING AVAILABLE DATA

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OBJECTIVES: To calibrate EQ-5D using an extant Russian data sources. **METHODS:** The 2005 Russia Longitudinal Monitoring Survey (RLMS) contains data from 10,140 respondents (56.9% female) who self-reported problem levels on EQ-5D dimensions. An overall self-assessment of health (SRH) was also captured using a 5-point categorical rating scale (very good-very bad). Each respondent is represented by a vector of 6 elements – 5 indicating the level of problem on each of the EQ-5D dimensions and 1 indicating SRH status. Data were analysed using an ordinal regression with SRH as the dependent variable; each EQ-5D dimension/level was represented by a pair of dummy variables. The value decrements identified by the regression coefficients were rescaled so that full health scored 1 and the worst defined health status scored zero. A summary EQ-5D index score for each respondent was computed and used to test psychometric robustness including capacity to differentiate between known groups. **RESULTS:** 31% of respondents reported having no problems on ANY dimension. 94/243 EQ-5D health states were observed in the data. Pain/discomfort produced the highest decrements (level 2/3 = 0.149/0.291 respectively), followed by usual activities and mobility. The mean EQ-5D index in those with diagnosed cardiovascular or respiratory conditions was significantly lower (0.611 & 0.669 respectively) than the mean of corresponding population without (0.829). The index is higher for respondents who use healthcare resources less frequently. **CONCLUSIONS:** As in other countries, HTA in Russia, requires a value metric to quantify health benefits; however there are currently no Russian social preference weights for use in economic evaluation. Although the methodology used here is somewhat at odds with that used in other health jurisdictions, it is based on a standardised descriptive classification (EQ-5D) that has worldwide coverage. This study demonstrates the feasibility of calibrating EQ-5D using data that maintain national domestic integrity thereby avoiding reliance on values imported from 3rd party countries.

PHP250

DISCRIMINANT VALIDITY FOR A PATIENT-REPORTED SYNDROME SCALE:

BLOOD-STASIS SYNDROME (PRS-BSS)

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OBJECTIVES: In a previous study, we had established a patient-reported syndrome scale: blood-stasis syndrome (PRS-BSS) which had satisfactory reliability and validity. This study aimed to assess the discriminant validity of the PRS-BSS for distinction in the two groups of patients and healthy people. **METHODS:** A sample of 50 cases of patients (age: 57±13years, 17 males) with blood stasis were enrolled. The patients mostly come from the department of cardiology, spleen and stomach, rheumatology. The patients completed the PRS-BSS and changhai pain feet pain score at the same time. 30 cases of healthy population (age: 53±11years, 11 males) completed the PRS-BSS. The discriminant validity of the PRS-BSS were examined by using statistical methods such as correlation coefficient, T test and analysis of variance. **RESULTS:** The scale was composed of 4 dimensions (activity, sleep, mood, and aggravation) and 10 items. The correlation coefficient of 4 dimensions and pain score were 0.703, 0.342, 0.461 and 0.495, respectively. The correlation coefficient of the PRS-BSS score and pain score was 0.741 (P=0.000<0.05). It was found that higher PRS-BSS scores were associated with the higher degree of pain. T test results showed that the scores of the patients with blood-stasis syndrome were obviously higher than those of healthy subjects (P<0.001), which indicated the PRS-BSS could distinguish the known people. **CONCLUSIONS:** The discriminant validity was good. Two groups of the patients and healthy people can be distinguished clearly. The efficacy assessment of the PRS-BSS will be needed to evaluate in the further research.

PHP251

ERRORS IN PATIENT REPORTED OUTCOMES (PROS): PATIENTS' UNDERSTANDING OF HOW TO RECORD A HEADACHE DAY

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OBJECTIVES: Patient-reported outcomes (PROs) collected as endpoints in clinical trials often require patients to report symptom severity, frequency, or the impact of symptoms on quality of life. It is generally accepted that variability in PROs should be reduced to ensure data quality, however, assessment variability due to the subject's interpretation of measurement parameters may be overlooked. **METHODS:** We collected data from 485 individuals who were asked to respond to the following scenario, "If you were participating in a clinical trial that asked you to report how many days you had a headache in a week, and you had a headache from 8:00 pm Sunday night to 8:00 am Monday morning, does it count as 1 or 2 days with a headache?". In addition, demographic data, as well as whether patients have ever participated in clinical trials, were also collected. **RESULTS:** Among the total participants, 434 people responded to this question. A strong majority of responders (76.5%, n = 332) answered the question incorrectly. Only 23.5% (102 patients) answered the question correctly ("2 days. I had a headache on Sunday and Monday"). Of those that answered incorrectly, 27.1% (n = 90) felt that there was not enough information to answer the question. Interestingly, among this majority of 332 patients (76.5%) who chose incorrect answers, 94 (28.3%) also reported that they have participated in a clinical trial at some point. **CONCLUSIONS:** These findings suggest that without standardized training, patients have a wide-range of interpretations and would report highly variable data during a clinical trial. FDA guidance states that "the headache diary should be shown to be well defined and reliable for the target population." Therefore, custom training including specific guidance on headache diary completion and understanding of trial expectation would be highly beneficial in improving clinical trial data quality while complying with the FDA's recommendations.

PHP252

FATHERS IN CHILDBIRTH EDUCATION

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OBJECTIVES: Childbirth as one of the most beautiful events in an individual's life, has been integrated into the „healthcare machinery”, being involved to the labor/delivery is unnatural to many fathers today. Our aim was to discover influencing factors of the fathers participating in childbirth education and the effect of their perceptions of the delivery. **METHODS:** Our study was set up in Veszprém, Hungary, in 2014 amongst families having the delivery the father involved. (N=100) We used mean, prevalence and Chi2 test to statistical analysis. Evaluation of the questionnaires was done by MS Excel software. **RESULTS:** Fathers with lower qualification has less knowledge on expecting a baby, and the awarding of childbirth education is also low (p<0.05). The higher the father is qualified, the earlier is his decision on the presence at the labor/delivery. Participation in childbirth education is depending on the baby's place in the birth-hierarchy (p<0.05), the qualification of the father (p<0.05), but not influenced by the fact if the child was planned or not in the family (p>0.05). Those with higher levels of education, prepare more consciously for having a baby. 94.5% of the mothers had positive experience about their partner's support in the labor/delivery, while after childbirth, 43% of the couples experienced positive change in their relationship. 29% of the interviewed mothers answered that the father becomes more understanding, 14% of them experienced better communication. Childbirth is a positive change of quality in family relationships (p<0.05), perceptions are strong and determining in the couple's life. **CONCLUSIONS:** Early involving the father in the prenatal care is important for their later relationship to their child. It is essential and necessary to provide more information to the lower qualified individuals, and also to emphasize the importance of childbirth education to fathers as well.

PHP253

HEALTHCARE PROFESSIONAL'S PERCEPTION WITH PHARMACIST'S RELATIONSHIP AND COUNSELING IN SAUDI ARABIA

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OBJECTIVES: To explore the healthcare provider's perception of pharmacist's relationship and counseling in Saudi Arabia. **METHODS:** It is a 4-months cross-sectional survey of healthcare professional's perception and attitude toward pharmacists. The questionnaire consisted of two-part demographic information, and second part Sixty-Six questions divided into four domains. It included general understanding ideas about the pharmacist, healthcare professional's perception, and attitude during pharmacy visit, health professional's opinion with pharmacist's relationship and counseling, and healthcare provider's perception challenges and improves pharmaceutical care. The 5-points Likert response scale system, and closed, ended questions used. The survey distributed through social media to more one thousand lists through what's up an application. The study made an electronic format, and it analyzed domain three through survey monkey system. **RESULTS:** The total responders were (170) healthcare providers. Of those 150 (93.8%) was Saudi and 10 (6.3%) was non-Saudi. The gender distribution 129 (75.9%) was female, and 41 (24.1%) was male. The majority of them in age (18-44) 95.8% and located at Riyadh region 69 (41.6%), and East Province region 36 (21.7%). Most of the healthcare providers were pharmacist 81 (59.55%), nurses 27 (19.85%), and physician 24 (17.6%). The highest score of statements was the pharmacist

delivers the medication in a polite way (3.96), the pharmacist answer questions in an excellent way (3.67), all pharmacists characterized with courtesy and respect (3.45), and the pharmacists had carefulness and competency skills (3.23). The lowest statements scores were the pharmacist follow up and call the about patient conditions after dispensing (1.86), the pharmacist asks about medication compliance (2.71) and the pharmacist check about medication reconciliation (2.79). **CONCLUSIONS:** The healthcare professional's perception about communication and counseling need to improve with emphasis on medication follow-up, medication adherence, and medication reconciliation. Corrections of healthcare care provider's needs will improve the perceptions, the communications, and avoid the unnecessary additional cost.

PHP254

THE HEALTH STATUS AND COHERENCE- FEELING OF NURSES WORKING IN DIFFERENT WORK SCHEDULE

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OBJECTIVES: The coherence-feeling is the main element of salutogenesis which is a valid factor of health. The different work schedule influences the nurses circadian rhythm and health condition. The aim of this research is to find the least stressful work schedule, to measure the health status and coherence-feeling of the nurses. **METHODS:** During the quantitative, cross-sectional research we used convenient sampling method to take the data from four hospitals of the Southern Transdanubian region and in the breaks of the advanced trainings held by the Faculty of Health Sciences, University of Pécs. Altogether 355 nurses from standard departments filled the Sense of Coherence questionnaire. Data were analysed with t-test, chi-square test, ANOVA, Kruskal-Wallis and linear regression in SPSS 22.0. **RESULTS:** The 76.6 % of the responders thought that the irregular work schedule is more stressful than the regular ones. Out of the regular work schedules the best is: 1 daytime shift followed by 1 night shift and 2 days of break (62.5 %). The average point of the coherence-feeling is 61.76. The coherence-feeling of those who work in daytime shift is better than those who work in shift work ($t=2.933$; $p=0.004$). Irregular work schedule nurses' coherence-feeling is lower than the flexible shift workers's ($p=0.04$). The most favourite regular multiwork schedule workers' coherence-feeling is higher than the secondly more frequent regular schedule workers' ($p=0.022$). Psychosomatic symptoms incidence is higher among nurses working in shift work than working in daytime work schedule ($p=0.031$). **CONCLUSIONS:** The irregularity of the work schedules are very stressful for nurses. Because of the health condition of the nurses- and the patient care- it is really practical to create the less stressful work schedule.

PHP255

EXPOSING PHYSICIANS TO RESEARCH METHODOLOGIES TO GAIN PROVIDERS' PERCEPTIONS AND PERSPECTIVES ON IMPROVING REAL-WORLD EVIDENCE (RWE): AN IN-PERSON PHYSICIAN FORUM METHOD

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OBJECTIVES: The generation and utilization of real-world evidence (RWE) are reliant on the providers of healthcare, who make treatment decisions, assess results, and participate in research via pre- and post-marketing studies. To improve the value of analytical insights which inform clinical decision-making, researchers must help expose physicians to RWE research methods and then understand with physician perceptions and perspectives on the value of the generated data. The purpose of the research was to evaluate the value of live physician forums for these purposes. **METHODS:** Attendees are screened via online survey to achieve broad representation of geography, practice type and affiliations and preserve unique audience. Each forum has a RWE research topic focus e.g., patient reported outcome (PRO) methods, medical record reviews, database studies, limitations of clinical trials. Presentations to attendees and open forum discussions at each summit conference are used to gather instant feedback via an audience response system (ARS). **RESULTS:** Five forums were conducted with 320 oncology physicians between February 2014 and October 2016. An average of 64 physicians attended each forum. Most (85%) physicians attended a single forum, but others attended more than one. Almost all (94%) providers attending one forum believed that RWE studies are necessary to inform clinical practice due to the limitations of RCTs. In the same forum, 97% believed that RWE can drive efficiency and improve healthcare quality. Although >90% of providers in another forum believed that PROs are very/somewhat valuable for patient treatment, only 20% reported the ability to gather PRO data. A majority (86%) of physicians in another forum reported no previous involvement in any HEOR research, although most were willing. **CONCLUSIONS:** Understanding the perceptions and perspectives on evidence generation, including RWE, PROs, and RCTs is essential as medicine transitions to value based care. In-person physician forums facilitate information exchange between treating physicians and researchers.

PHP256

PATTERN OF MARKET EXCLUSIVITY AND THE ENTRY OF ABBREVIATED NEW DRUG APPLICATIONS

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OBJECTIVES: The Office of Generic Drugs (OGD) publishes bioequivalence (BE) guidances for specific products to support generic drug development.

Each guidance describes the studies recommended for abbreviated new drug applications (ANDAs) that reference a particular new drug application (NDA). The purpose of this study was to evaluate the impact of BE guidance availability on the entry of generic competition when the reference product for a new molecular entity (NME) loses exclusivity. **METHODS:** A cross-sectional study using exclusivity and patent data from the Orange Book published in 12/2016 was conducted. Other sources include product-specific BE guidances, Drugs@FDA, and National Drug Code directory. Exclusivity patterns, distribution of ANDAs approved after loss of exclusivity (LOE), patent term-related to NME NDAs, and BE guidances-related to NMEs were examined using descriptive statistics and chi-squared tests. **RESULTS:** A total of 171 NME-associated NDAs with LOE between 7/28/2015-3/06/2027 were identified. The number of NMEs with LOE was highest in 2017 ($n=34$). As of 12/2016, LOE has happened for 33 NME NDAs; whereas 138 NME NDAs are still under their exclusivity period. Of the NME NDAs where LOE has happened, 12.5% have a generic approved/tentatively approved and the average number of ANDAs approved (\pm SD) per NDA is 2.25 (± 1.89). For the remaining NME NDAs in this group with no generics, 82.14% are still under their patent term. Further, findings demonstrate that BE guidances were published prior to ANDA approval. On a yearly basis, BE guidances have been published for an average of 86.33% ($\pm 15.44\%$) of all NME NDAs. **CONCLUSIONS:** Although BE guidances cover for the majority of NDA with NME exclusivity, exclusivity period, as well as patent term, may determine the entry of ANDAs into the market after LOE has happened. Further studies are warranted to analyze other factors that may impact ANDA entry.

PHP257

DOES PROVIDING MORE SERVICES INFLUENCE HEALTHCARE UTILIZATION RATES AND PROCESSES OF CARE AMONG MEDICAL HOMES?

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OBJECTIVES: To evaluate whether variability of healthcare utilization metrics and process of care exists in Medical Homes (MHs) depending on the extent of services offered. **METHODS:** A retrospective study was conducted using the 2015 population-based healthcare database of residents in Parma Local Health Authority, Emilia-Romagna, Italy. Data were analyzed for 118,356 patients ≥ 14 years receiving care from primary care physicians in small, medium and large MHs. Health care utilization metrics and process of care were computed for all patients across MH types. Healthcare utilizations encompassed hospital admissions, including ambulatory care sensitive conditions (ACSCs) hospitalizations, emergency department (ED) visits, specialty visits, pharmacy, 30-day and 90-day readmissions. Process of care measures comprised diabetes care metrics (e.g., HbA1c monitoring, microalbumin, lipid panel, eye exam). Negative binomial GEE regression models compared healthcare utilization rates and logistic GEE regression models compared the prevalence of process of care measures between MH sizes. **RESULTS:** Of all 16 MHs in Parma, 5 were classified as large MHs, 6 as medium MHs, and 5 as small MHs. There was no significant difference in healthcare utilizations across MH types, except for 90-day congestive heart failure readmissions that were higher in small and medium sized-MHs compared to large MHs (RR small vs large: 2.71, 95%CI:1.48-4.99; RR medium vs large:1.79, 95%CI:1.11-2.89). No significant differences for rates of recommended diabetes care processes were found, except for microalbumin tests that were more commonly performed in small and medium MHs (OR small vs large: 1.43, 95%CI:1.03-1.99; OR medium vs large:1.96, 95%CI:1.50-2.57). **CONCLUSIONS:** This early evaluation of recently implemented MHs found little evidence of differences in healthcare utilization metrics and processes of care among MHs depending on the scope of services offered. Further research is needed to characterize the relationship between healthcare metrics and organizational structures of MHs.

HEALTH CARE USE & POLICY STUDIES – Health Technology Assessment Programs

PHP258

PAYER PERCEPTIONS AND UTILIZATION OF THE INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW (ICER) VALUE ASSESSMENT FRAMEWORK

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OBJECTIVES: This study aimed to evaluate payer perceptions and utilization of the Institute for Clinical and Economic Review (ICER) Value Assessment Framework in coverage decisions. **METHODS:** A double-blinded, web-based survey was disseminated to 57 individuals within managed care organizations, health systems, and academic institutions in November 2016. The survey assessed payers' experience and involvement with the ICER Framework, their perceived strengths and limitations of the Framework, and the level of influence the Framework had in recent coverage decisions. **RESULTS:** 55 payers representing 47 organizations completed the survey. All respondents were active members of a pharmacy & therapeutics committee. The majority of payers (67%) were familiar with the ICER Framework methodology and 36% reported reviewing one or more ICER evaluations within the preceding 12 months. Few participants (11%) reported that their organization actively engaged in a prior ICER review (eg, providing public comments, meeting attendance). 51% of respondents said that ICER's recommendations had not influenced decisions, 44% noted occasional influence on decisions, and 5% said the recommendations often influenced decisions within their organization. As a whole, respondents indicated that use of real-world evidence (60%), transparency of methodology (53%), and choice of clinical outcomes (44%) were strengths of the Framework. Limitations noted by payers included: timing of evidence reporting vis-a-vis decision making needs (45%), lack of stakeholder engagement (38%), and use of fixed thresholds for cost per quality-adjusted life year and budget impact (35%). Regardless of current application, the

majority of respondents (96%) agreed the Framework has potential to be more influential in future decision-making. **CONCLUSIONS:** While many payers are familiar with the ICER Framework and recognize its potential impact, its actual application in the decision-making process has been limited. Findings from this survey indicate that utilization for decision-making may be increasing, though additional studies will be needed to confirm anticipated trends.

PHP259

CROSS-COUNTRY VARIATION IN HTA PREFERENCES; QUALITATIVE EVIDENCE FROM AN INTERNATIONAL SURVEY OF STAKEHOLDERS

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OBJECTIVES: Several interviews with stakeholders have compared how Health Technology Assessment (HTA) activities, evidentiary requirements and approaches to dealing with uncertainty differ across countries. Nevertheless, no studies have elicited cross-country, HTA stakeholders' preferences on criteria that shape coverage decisions. We aimed to identify the extent to which prioritization of criteria, uncertainties and other factors that inform HTA decision-making differs across countries. **METHODS:** HTA stakeholders in Brazil, England, France, Italy, Netherlands, Spain and Sweden were invited via email to complete a survey. A number of clinical, economic and other criteria (i.e. rarity/orphan status and stakeholder input, among others) considered in HTAs, along with factors related to clinical evidence uncertainties, unmet need and innovative nature of treatment were ranked in terms of their importance on a 7-point-Likert-scale. Responses were anonymised and analysed using descriptive statistics. **RESULTS:** Responses were received from Brazil(n=9), England(n=7), France (n=10), Italy(n=6), Netherlands(n=3), Spain(n=3) and Sweden(n=3). "Achievement of/Concerns around clinical benefit" was the only clinical criterion/uncertainty ranked as 6(=high) and/or 7(=very high) in importance by 100% of respondents in each country. The requirement for/uncertainty around "Appropriate comparators" was highly important overall but country preferences fluctuated; i.e. ranked above 6 by more than 80% of respondents in all countries apart from Spain and Sweden (50% and 33% respectively). "Budget impact analysis" was the most important economic criterion overall, although not consistently ranked across countries; i.e. ranked above 5 by 100% of respondents in all countries apart from Italy and France (78% and 57% respectively). More subtle differences were identified in the priorities of innovation, disease severity and stakeholder input towards HTA decision-making across countries. **CONCLUSIONS:** We demonstrated cross-country variation in HTA stakeholders' preferences, especially for economic and other criteria related to innovation and unmet need, possibly underlying differences in HTA recommendations. Further investigations are required to map the patterns that differentiate coverage decisions across countries.

PHP260

DOCUMENTATION OF SYSTEMATIC REVIEW OR META-ANALYSIS IN NATIONAL PHARMACOECONOMICS GUIDELINES

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OBJECTIVES: To survey how much systematic review or meta-analysis (SR/MA) related items were addressed in national pharmacoeconomics guidelines. **METHODS:** We searched pharmacoeconomics guidelines by way of a repository of them from 33 countries (<https://www.ispor.org/peguidelines/index.asp>), public literature databases, and a paper dealing with a comparison of eight national guidelines for network meta-analysis (Value Health 2014;17:642-54). Excluding method reviews, indirect comparison specific guidelines, unreadable documents, 16 general pharmacoeconomics guidelines were selected as a study population. They include Portugal (1998), Hungary (2002), France (2004), Austria (2006), Canada (2006), Taiwan (2006), Belgium (2008), Poland (2009), Ireland (2010), United States (2012), Norway (2012), United Kingdom (2013), Australia (2013), Germany (2013), South Africa (2013), Scotland (2014). We developed 26 checklists of SR/MA including 14 basic and 12 technical ones. **RESULTS:** Guidelines have been published from 1998 to 2014. All came from Western countries except Taiwan. SR/MA term and RCT/observational studies term were most commonly used in 13 of 16 (81%). Literature search was addressed in 10 of 16 (63%). Indirect comparison was addressed in 9 of 16 (56%). Guidelines of top 3 acceptance rate came from Germany (17/26=65%), United Kingdom (15/26=58%), and Scotland (13/26=50%) which were relatively recent ones. French and Portuguese guidelines did not accept any item related to SR/MA. Median acceptance rate was 5.5/26 (21%). **CONCLUSIONS:** Although national pharmacoeconomics guidelines have been published in many countries, only 21% of the SR/MA related items were addressed. Yet, it seems to be increasing in recent guidelines.

PHP261

THE CHANGING ROLE OF COST-EFFECTIVENESS IN COMMON DRUG REVIEW RECOMMENDATIONS

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OBJECTIVES: We sought to understand the changing role of cost-effectiveness analysis (CEA) at the Common Drug Review (CDR), the health technology assessment agency providing reimbursement recommendations to all provinces in Canada outside Quebec. The emergence of the pan-Canadian Pharmaceutical Alliance (pCPA) for collective price negotiation has changed the way CEA is used by CDR. Our analysis sought to characterize the use of threshold analysis, (i.e. explicit suggested price discounts calculated using HTA methods), the impact of elimination of

confidential pricing, disagreement between submitted ICERs and re-analyses by CDR reviewers, and the fate of cost-effective drugs in negotiations with the pCPA. **METHODS:** Our analyses relied on publicly-available source documents, obtained primarily from the HTA agency's website. Documents included reimbursement recommendations, process updates and provincial public plan drug listing updates. We compared the percentage of drugs considered cost-effective, according to the text of the reimbursement recommendation, and its change over time since the introduction of new recommendation codes in 2012. We also determined the percentage of recommendations which included explicit threshold analyses, and also those with more general price recommendations. We also recorded the ICERs submitted and reported by CDR, and those considered plausible by CDR reviewers. Finally, we analyzed the time from HTA recommendation to completion of pCPA negotiations, focusing on the success of drugs considered cost-effective by CDR. **RESULTS:** Use of threshold analysis has increased dramatically, from 2.70% to 37.21% of recommendations between 2012-2016. Confidential pricing has been used in 25-44% of submissions since 2012. 105/116 submissions receiving conditional recommendations since 2012 featured some form of price control. Disagreement between submitters and CDR reviewers is frequent and substantial, and only a minority of drugs are considered cost-effective. These drugs actually take longer to get through the pCPA negotiation process. **CONCLUSIONS:** CEA is used rigorously by CDR to secure substantial discounts for innovative treatments.

PHP262

AN ANALYSIS OF REAL WORLD DATA USE BY GLOBAL MARKET ACCESS STAKEHOLDERS

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OBJECTIVES: There are clinical and financial impacts of not having real-world data (RWD) upon market entry such as delayed approval, suboptimal reimbursement, and unfavorable re-evaluation. We aimed to assess the use of RWD for market access (MA) decisions globally and trends in the number of RWD studies to evaluate growing interest in RWD. **METHODS:** A global search was conducted in the HTA Accelerator@database from 2008 to 2016 for any recommendation of conditional reimbursement or approval requiring collection of RWD. An online search was conducted in the United States, United Kingdom, Australia, and Canada for uses of RWD by regulators and payers. Clinicaltrials.gov was searched for trends in the number of "observational" studies in the US and UK registered from 2010 to 2016. **RESULTS:** 17 HTAs recommended reimbursement or approval conditional on providing additional economic (7) or clinical (10) RWD. In the UK, the National Health Service is ramping up RWD capabilities by integrating clinical datasets. In Australia, the Pharmaceutical Benefits Advisory Committee is supporting risk-based approaches that condition reimbursement on RWD collection. The Canadian Agency for Drugs and Technologies in Health recently published a framework that suggests RWD may play a role in recommendations for orphan diseases. In 2016, the US issued a draft guidance on the use of RWD to support regulatory decision-making for medical devices. There was an increase in RWD studies in the UK, from 15.7% in 2010 to 21.5% in 2016 of all observational and interventional studies. RWD use declined in the US over the same period, from 18.2% to 15.1%. **CONCLUSIONS:** With the recognized value of RWD in MA decisions, there is a need to monitor stakeholders' use of RWD to optimize treatment access. There is also a need to approach evidence generation systematically to differentiate assets beyond approval and initial P&R.

PHP264

OPTIMIZING ICER'S 'CARE VALUE' FRAMEWORK: AN ANALYSIS OF STAKEHOLDERS' PROPOSALS FOR IMPROVEMENT

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OBJECTIVES: The Institute for Clinical and Economic Review (ICER) evaluates the value of medical technologies according to a proprietary 'care value' framework, which takes a third-party United States payer perspective. In 2016, ICER held a national call for suggestions for framework improvements. Herein is a critical assessment of publicly available stakeholder responses that were submitted to ICER. **METHODS:** 50 responses were submitted, 46 of which were publicly available. Suggestions/criticisms were extracted and classified by category (framework structure, framework methodology, parameter estimation, analysis perspective, or assessment) and respondent type (manufacturer, trade group, patient advocacy, consultancy, payer, or individual). Descriptive statistics were used to analyze trends. **RESULTS:** 17 patient advocacies, 12 manufacturers, 11 trade groups, 4 individuals, 1 payer, and 1 consultancy publicly responded to ICER's national call. 39 unique suggestions/criticisms of the framework were documented. The most commonly cited (>50% of respondents) included the limitations of a 'QALY-only methodology', the arbitrary nature of ICER's 'affordability cap', the lack of early and broad stakeholder engagement, and a lack of focus on the patient. Manufacturers and trade groups were most similar in their critiques, additionally focusing on the framework's lack of transparency, the conflation of 'value' with budget impact, the use of a static willingness-to-pay threshold across disease areas, the biases inherent with a short-term analysis horizon, and the lack of clinical expertise on the assessment panels. Patient advocacies were most likely to focus on the optimal role of the patient in ICER's assessment. **CONCLUSIONS:** Diverse stakeholders provided suggestions regarding ICER's value assessment of medical technologies. There is consensus among stakeholders that the framework's methodology should be revised, with a goal of focusing on the patient perspective of value, and that ICER's value assessment process should be modified to promote increased transparency and broad stakeholder engagement.

PHP265

REVIEW OF PUBLICLY AVAILABLE ECONOMIC EVALUATION REPORTS BY HAS

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OBJECTIVES: In 2013, Economic and Public Health Assessment Committee (CEESP) was asked to review economic evaluations of innovative and high-budget-impact drugs/medical devices, and to publish efficiency opinions. The purpose of these efficiency opinions is to inform the price committee on methodological compliance of manufacturer's cost-effectiveness dossier, when confronted to French Health National Authority (HAS) recommendations. The objective of this study is to review and summarize deviations formulated by CEESP in dossiers published until December 2016. **METHODS:** All available published efficiency opinions published by CEESP were reviewed. Based on developed extraction table, a three-level classification was proposed to identify main CEESP deviations. Study objectives, structural choices, measurement and valorization of health states and costs, modeling, results presentation and sensitivity analyses were addressed as the principal dimensions with further split. Descriptive analysis was conducted for each assessed product depending on the type of CEESP deviation, and results were aggregated by topic. **RESULTS:** Overall, 19 efficiency opinions were identified on the official HAS website, among which 7 presented results that were invalidated by CEESP. All assessment reports included minor deviations and 90% of them reported at least one major or important deviation. Overall, 236 deviations were reported, the majority (62%) being minor, while 33% were considered important and 5% considered major. Main identified issues concerned results presentation and sensitivity analyses (55% of all major and 29% of all important deviations), as well as modeling methodological approach (27% of major and 34% of important deviations). **CONCLUSIONS:** CEESP considers an accumulation of methodological deviations to invalidate results. Our findings suggest that pharmaceutical industry could be more efficient in their initial submissions and during the dialogue with HAS, by avoiding most commonly identified problems in previous CEESP submissions. However, the lack of threshold leads to uncertainty on how these results impact price of intervention.

PHP266

VALUE FRAMEWORKS TO SET TONGUES WAGGING: ANALYSIS OF OPINIONS AND DISCUSSIONS ON THE MOST POPULAR VALUE FRAMEWORKS

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OBJECTIVES: Value frameworks are a new and emerging field in the United States (US). Since the establishment of the Institute for Clinical and Economic Review (ICER), there has been much online debate on the use of value frameworks. We aimed to explore online discussions and opinions on five existing value frameworks. **METHODS:** A pragmatic literature review was conducted in Google using search terms for the ICER, American Society of Clinical Oncology (ASCO), Memorial Sloan Kettering Cancer Center DrugAbacus (MSKCC), and National Comprehensive Cancer Network (NCCN) value frameworks and the National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK). The first 60 results for each term were screened against inclusion criteria. Eligible records included journal articles, blogs and open letters. Independent opinions were extracted for analysis and classified as positive/negative/neutral. **RESULTS:** A total of 67 records were included, providing 252 opinions for analysis. ICER was the most frequently discussed framework (50% of all opinions), yet 82% of comments on ICER were negative. Commonly cited criticisms were lack of transparency and reproducibility of economic models and need for more patient-centered evidence. The majority of negative comments were from patient representatives, clinicians and pharmaceutical companies. NICE, ASCO and MSKCC had 62%, 58% and 50% negative opinions, respectively. In contrast, the NCCN framework had the highest percentage of positive opinions (76%) related to being of significant value to physicians, transparent for patients and affiliated with outstanding research. **CONCLUSIONS:** ICER was the most discussed framework, but had the most negative comments, possibly due to ICER's call for feedback in July 2016. NCCN appeared to be the most positively received framework. Despite NICE being well established in the UK, the majority of opinions were negative. Limitations of this study include use of Google only and subjective opinion selection.

PHP267

HEALTH TECHNOLOGY ASSESSMENT NUCLEUS IN A REFERENCE PUBLIC HOSPITAL IN BRAZIL

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Health Technology Assessment Nucleus (NATS) nested in reference hospitals nationwide distributed in Brazil were created in 2011-2012. Hospital de Clinicas de Porto Alegre (HCPA) a reference university public hospital in the southernmost province of Brazil established its nucleus in 2012, before this decentralized committees performed HTA evaluations. **OBJECTIVES:** Evaluate the results of NATS implementation at HCPA, by reviewing its technical production and analyzing the decisions referent to incorporations requests. **METHODS:** We reviewed all requests for inclusion of health technologies sent to NATS and Drugs and Therapeutics Committee (COMEDI) since October, 2012. The database evaluated included the online requests of health technologies filled during the time and the register of both committee meetings. The results of the requests for health technologies inclusion were categorized as accepted or rejected and also classified (according UK-NHS Innovation Center criteria and to 'Morgan et al' criteria) as innovation or not. **RESULTS:** During the period of time (Oct/2012-Dec/2016) there were in total 75 requests for inclusion of new health technologies (equipment, vaccines, health products and medicines) in the HCPA.

Thirty-three of these requests concern the inclusion of equipment, vaccines or 'health products' and forty were related to medicines. Of the 73 requests 30 (13 equipment/vaccines/health products and 17 medicines) were accepted—41% of all requests. Also 41% of all inclusion requests regarded innovative products and 43% of all incorporated technologies were considered innovations. **CONCLUSIONS:** Of all requests for health technology inclusion, less than half were accepted after evaluation. Considering the aspect innovation only 43% of incorporated health technologies represented innovative products, this proportion was even lower between the medicines. Possible causes are the high cost of these products and what does the term innovation could represent, notable when discussing innovate drugs—the variability of the 'level' of innovation is an important variable to consider.

PHP268

PERSPECTIVE USE OF HTA IN THE DECISION-MAKING PROCESS IN UKRAINE

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OBJECTIVES: HTA introduction and implementation for the development of the National list of essential medicines (NLEM) took place in Ukraine in 2016 in the context of National Drug Policy for the time period until 2025. The regulation states that the selection of medicines should be based on HTA approaches. Consequently, HTA and pharmacoeconomic analysis is highly relevant currently in the decision making process in line with the international requirements. The study aimed to outline the main steps in HTA development in Ukraine in 2016 and future directions. **METHODS:** Systematic review, expert interviews within deliberative process with main stakeholders were conducted. A legislation, scientific publications on the study question were analyzed and presented. **RESULTS:** In Ukraine a legal framework was developed in 2016 for the elaboration of the National list of essential medicines. HTA should be used for the inclusion of medicines based on the applied evidence of quality, efficacy, effectiveness, safety and economic evaluations adhering to the Order of MOH No. 84 dated 11.02.2016 and Order of MOH No. 1050 dated 07.10.2016. HTA implementation in 2016 consisted of legislation, capacity building regarding HTA training for members of Expert committee of MOH and development of NLEM. Reimbursement programs for cardiovascular disease, T2D, asthma are going to be started in April 2017 due to the adopted regulations. **CONCLUSIONS:** HTA use in the decision-making in Ukraine will provide an access to innovative treatments for patients and transparent, consistent decision-making process in assessing the health technologies for inclusion on regulatory lists and reimbursement programs.

PHP269

INFORMING THE PROCESS OF INNOVATIONS UPTAKE IN HOSPITALS IN TUNISIA

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OBJECTIVES: Informing about decisions taken is crucial in order to reduce variability in practice and inequities in the access to health care services in the same country. In many countries and regions, hospitals are autonomous in their decisions around the incorporation of health technologies, and different decisions could be taken about the same technology. Tunisia recently implemented a HTA agency (INASanté) to inform decisions around health technologies and it should have an impact in obtaining information around what has been implemented in real world practice and why. **METHODS:** An analysis of how decisions were taken for different technologies (drugs, procedures and medical devices) and which were the key elements of this decision-making process was performed. This comprised a SWOT analysis and direct contact with stakeholders for "in depth" interviews according to best practices in qualitative research. Based on this analysis, a flow chart of decisions was built and the main pitfalls were identified in order to make proposals to bridge the gap and structure the information around innovations uptake in hospitals. **RESULTS:** Weaknesses were: the inexistence of standardized forms for the inclusion of health technologies in the hospital formularies, the inexistence of explicit grids with criteria and the lack of information among hospitals around the decisions. The stakeholders identified INASanté as an opportunity to structure the process of technology uptake in hospitals, to standardize the processes and to centralize information around decisions. **CONCLUSIONS:** Hospitals in Tunisia require a structured and informed process of health technologies uptake. This process should include: a standardized form for proposals submission, criteria for prioritization, a defined timetable for resolutions, a grid that includes criteria for decision-making and a centralized database of proposals and final decisions. Without compromising hospitals' independency, INASanté could propose a manual and centralize the information in order to avoid duplicates and reduce inefficiencies.

PHP270

PERSPECTIVE OF HEALTH TECHNOLOGY ASSESSMENT IN CHILD HEALTH CARE IN JAPAN

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OBJECTIVES: In Japan, the allocation of public health resource is expected to be based on a rational judgement on the social value, and Health Technology Assessment (HTA) serves as a powerful tool for the value assessment. Child health care is inevitably influenced by such the tendency of value-based approach. This

study aims to provide an overview and perspective of HTA in child health care, under a context of epidemiological transition, health care system and social changes in Japan. **METHODS:** Narrative review of health issues of children in epidemiological transition, child health care financing and provision system, challenges to evaluate pediatric health outcomes, and the expected role of value-based approach in policy making. **RESULTS:** The decrease of the overall child mortality has on aggregate led to relative increase in priority of two issues in child health care: a largely expended need of the long-term care for survivors saved by advanced neonatal and pediatric medicine but with disabilities and chronic diseases, even though the incidence is very rare; and an integrated support to child health and development targeting the majority of population at the community. A geographical disparity remains in child health care financing and provision. Adequate and effective resource allocation is expected to strengthen the child health care provision system by addressing its problems on sustainability. For effective resource allocation and the reform of the current provision system of child health care, a value-based approach is urgently necessary, even though compared to that in adult, the standard methodology for evaluation of health utility and outcomes in children is still waiting for the establishment. For child health care, the current standard methodology on cost-effectiveness have a limitation. **CONCLUSIONS:** HTA is expected to play a crucial role on evidence-based pediatric policy making. The evaluation methodology specific for children's health outcomes needs to be developed.

HEALTH CARE USE & POLICY STUDIES – Patient Registries & Post-Marketing Studies

PHP271

POSTMARKETING COMMITMENT TRENDS IN PEDIATRIC PATIENT POPULATIONS

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OBJECTIVES: In 2003, the Pediatric Research Equity Act (PREA) was passed to improve the quality of pediatric information in drug labeling. This legislation authorizes FDA to require pediatric studies of marketed drugs that are not adequately labeled for children after other opportunities to obtain data on a voluntary basis have been exhausted. The requirement for such studies may be waived if studies in children are impossible; there is evidence suggesting the drug will not be safe in children; the drug does not represent a therapeutic benefit over existing therapies for children or the drug is not likely to be used in a substantial number of children. We evaluated the trends in post-marketing commitments/requirements (PMC/Rs) in pediatric populations. **METHODS:** Publicly available FDA databases were analyzed to identify all new molecular entities approved between January 1, 2011 and January 1, 2016 and associated PMC/Rs in pediatric populations. Study designs were categorized as safety/non-safety, observational/interventional research, and drugs/biologics. **RESULTS:** Between 01/01/2011 and 01/01/2016, there were 414 newly approved products. Of these, 305 (74%) included at least one PMC/R, 157 (38%) included at least one pediatric PMC/R, and 154 (37%) were labeled for pediatric use. Among those labeled for pediatric use, 139 (90%) were drugs and 15 (10%) were biologics. There were 1,153 PMC/Rs in total. Among these, 555 (48%) were pediatric PMC/Rs. Of these pediatric PMC/Rs, 493 (89%) were drugs, 62 (11%) were biologics, 509 (44%) were safety studies, and 102 (9%) were observational studies. The greatest number of pediatric PMC/Rs was seen in infectious disease 140 (25%) and general medicine 68 (12%). **CONCLUSIONS:** Following passage of the PREA, many pediatric PMC/Rs have been required by the FDA. In the future, we should expect to see more pediatric PMC/Rs in drugs, safety studies, and for infectious disease and general medicine therapeutic areas.

PHP272

REFERENCE GROUPS USED IN PREGNANCY EXPOSURE REGISTRIES: CHALLENGES AND OPPORTUNITIES

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OBJECTIVES: Pregnancy registries monitor pregnancies exposed to specific drugs to determine risk of major birth defects. Ideally, registries should be designed to include internal reference groups. When this is not practical, external reference groups should be carefully selected. This study sought to examine reference groups used by pregnancy registries in 2017 versus 2009 and discuss pros and cons of each. **METHODS:** We collected data on all currently ongoing pregnancy registries identified on the FDA pregnancy website and compared data from 2017 with 2009. Sources of data included the FDA website, registry publications or websites, clinicaltrials.gov, and registry staff. In the two time periods, we descriptively evaluated the number of ongoing registries, their characteristics, and reference groups employed. **RESULTS:** In 2009 we identified 38 pregnancy registries and obtained data on 79%. In 2017, we identified 103 registries and obtained data on 92%. In 2009 only 63% used an internal comparator versus 86% in 2017. Also, in 2009 only 73% used 2 or more comparators versus 81% in 2017. Internal comparators included unexposed women with/without the disease. External comparators included population-based rates, data from other studies and the literature. Each comparator has advantages and disadvantages; an external population-based comparator can provide stable estimates for specific malformations, whereas internal comparators usually have limited sample size to assess specific malformations but can provide more comparable estimates of overall malformations. **CONCLUSIONS:** Data from the FDA website indicate a 2.7-fold increase in pregnancy registries from 2009-2017. We noted a trend toward use of 2 or more comparators and toward use of internal comparators. Internal comparators may be scientifically superior but can be challenging and costly. While there is no ideal comparator for a pregnancy registry, using more than one generally improves overall validity and statistical power.

HEALTH CARE USE & POLICY STUDIES – Population Health

PHP273

CLINICAL AND HEALTH CARE USE IMPLICATIONS OF IMPROVING POPULATION HEALTH

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OBJECTIVES: This research quantifies the impact of achieving select population health improvements on disease prevalence and healthcare use. Such information can help inform how population health policies and practices might affect future patient outcomes and health system needs. **METHODS:** Using a previously published Markov-based microsimulation approach, we modeled a hypothetical scenario of sustained 5% body weight loss for overweight and obese adults; improved blood pressure, cholesterol, and blood glucose levels for adults with elevated levels; and smoking cessation. Published clinical trials and observational studies informed model parameters and achievable clinical improvements. Relationships between patient characteristics and healthcare use came from Poisson and logistic regression analysis estimated from the 2010-2014 Medical Expenditure Panel Survey and 2014 Nationwide Inpatient Sample. A nationally representative adult sample from the 2013-2014 National Health and Nutrition Examination Survey was extrapolated to national totals using Census Bureau population projections. **RESULTS:** Cumulative between 2015 and 2030, achieving these lifestyle and clinical goals results in 9.6 million fewer people with heart disease, 3.3 million fewer strokes, 2.4 million fewer heart attacks, and reduced incidence of cancer and other diseases. Per capita inpatient days, emergency visits, and ambulatory care declines. Reduced mortality suggests an additional 6.3 million adults alive in 2030. Cumulative over the first three years, national inpatient days decline by 4.3 million days and emergency visits by 3.4 million. By 2030, annual inpatient days are 6 million higher and emergency visits 1.7 million higher. By 2030 an additional 16,400 physicians would be required to support the extra 6.3 million people. **CONCLUSIONS:** The long term implications of achieving the modeled population health outcomes is reduced morbidity and mortality, but increased use of healthcare services to support a larger population. Health system planning should reflect that improved population health causes short term reductions in demand for healthcare services but long term demand will rise.

PHP274

UTILIZATION PATTERN OF ORAL ANTICOAGULANTS IN HIP AND KNEE REPLACEMENT PATIENTS IN UNITED STATES, 2010-2016

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OBJECTIVES: Since their introduction to the US market in 2010, non-Vitamin K oral anticoagulants (NOACs) have sought to address the issues of not only efficacy, but also safety, ease of use, and patient compliance. However, little is known about the trends in the utilization of these medications after hip or knee replacement surgery. In this study, we analyzed changes in prescription volumes for oral anticoagulants since the introduction of NOACs in United States in major orthopedic surgery patients. **METHODS:** Using Truven Health MarketScan data, we analyzed prescription volumes for warfarin, dabigatran, rivaroxaban, and apixaban from January 2010 to September 2016 in patients undergoing total knee or hip replacement surgery. The total prescription volume was calculated quarterly and included new fills and refills for these medications. **RESULTS:** The overall volume of oral anticoagulant prescriptions in hip and knee replacement surgery patients in United States has increased annually since 2010. Since the availability of the NOACs, the proportion of total oral anticoagulant prescriptions attributable to warfarin in these patients has steadily decreased, from 99% in 2010 to 72% by September 2016. The largest increase in NOAC prescribing occurred between 2012 and 2014, which corresponds to the timeframe when rivaroxaban was first listed on most formularies. By September 2016, rivaroxaban held a 19% share of the oral anticoagulant market in orthopedics, whereas dabigatran and apixaban together accounted for approximately 9%. **CONCLUSIONS:** Since their approval, the NOACs have represented a growing share of total OAC prescriptions in orthopedic surgery patients in United States. This trend is expected to continue because the NOACs are given preference over warfarin in guidelines on venous thromboembolism prevention in major orthopedic surgery patients. An understanding of the current prescribing patterns will help to influence health policy and reimbursement strategies.

HEALTH CARE USE & POLICY STUDIES – Prescribing Behavior & Treatment Guidelines

PHP275

STUDY OF POLY PHARMACY AT A TERTIARY CARE TEACHING HOSPITAL BANGALORE

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OBJECTIVES: The study was designed to study the extent of polypharmacy among the prescriptions received at Out Patient pharmacy in St.Philomena's Hospital, Bangalore, to identify the most common class of drugs prescribed in polypharmacy prescription, to identify the drug interactions among the prescribed drugs, to identify the various therapeutic classes involved in major drug interactions. **METHODS:** A prospective hospital based observational study was carried out in the outpatient department of St.Philomena's hospital. The research student, collected all the prescriptions received at OP pharmacy. All the prescriptions were carefully analyzed for polypharmacy and the data were pooled and analyzed. **RESULTS:** A total number of 200 polyphonic prescriptions were found in the outpatient pharmacy of St.Philomena's Hospital. During the study period of 6 months, it was found that the majority of the prescriptions were prescribed to female 101(50.50%) and 99(49.50%) were prescribed to male. Among 200 prescriptions it was found that 134(67%) contain 5 drugs followed by 42(21%) contain 6

drugs, 15(7.50%) contain 7 drugs and 9(4.50%) contain more than drugs. The most common therapeutic class was found to be Analgesics pertaining to 122(61%) drugs followed by antibiotics, which were 65(32.50%) drugs and 55(27.50%) drugs were Vitamins. It was found that the majority of polypharmacies have been occurred in the age group of adults 113(56.50%) patients followed by neonates and infants 52(26%) patients and geriatrics 19(9.50%) patients. Among 200 prescriptions, 82 drug interactions were observed which were found to be 43(52.43%) major followed by 36 (43.90%) moderate and 3 (3.65%) minor. Among the Major interactions, anti-inflammatory drugs were found to be the most commonly participating therapeutic class of drug in interactions. **CONCLUSIONS:** only 10% of prescriptions were found to have polypharmacy which was commonly observed in female patients. Among polypharmacy prescriptions less than 50% had drug interactions, majority of which were major drug interactions.

PHP276

IMPACT OF DISPLAYING INPATIENT PHARMACEUTICAL COSTS AT THE TIME OF ORDER ENTRY: LESSONS FROM A TERTIARY CARE CENTER

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OBJECTIVES: Expensive medicines are often utilized when there are comparable alternatives available at a lower cost. Increasing prescriber awareness of medication cost at time of ordering may help promote cost-conscious use of medications in the hospital. Our objective was to evaluate the impact of cost messaging on the ordering of nine expensive medications. **METHODS:** This was a retrospective analysis of an institutional cost-transparency initiative in a 1,145-bed tertiary care academic medical center (The Johns Hopkins Hospital). Prescribers who ordered medications through the computerized provider order entry system at the Johns Hopkins Hospital. Each medication was compared to its pre-intervention baseline utilization dating back to January 1, 2013. For the seven medications with alternatives offered, we also analyzed use of the suggested alternative during these time periods. Interrupted time series and segmented regression models were used to examine prescriber ordering before and after implementation of cost messaging for nine high-cost medications. **RESULTS:** Following the implementation of cost messaging, no significant changes were observed in number of orders or ordering trends for intravenous formulations of ecuzimab, calcitonin, levetiracetam, linezolid, mycophenolate, ribavirin, and levothyroxine. An immediate and sustained reduction in medication utilization was seen in two drugs that underwent a policy change in addition to the drug cost messages during our study, intravenous pantoprazole and oral voriconazole. Intravenous pantoprazole became restricted at our facility due to a national shortage (-985 orders per 10,000 patient days; $p < 0.001$) and oral voriconazole was replaced with an alternative antifungal in oncology order sets (-110 orders per 10,000 patient days; $p = 0.001$). **CONCLUSIONS:** Provider cost transparency alone did not significantly influence medication utilization at our institution. Active strategies to reduce ordering resulted in dramatic reductions of ordering.

PHP277

EVALUATION OF EFFECTIVENESS OF HEALTH CANADA'S DEAR HEALTHCARE PROFESSIONAL LETTERS ON PRESCRIBING PRACTICE IN CANADA

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OBJECTIVES: Health Canada's Dear Healthcare Professionals Letters (DHPLs) are used to communicate health risks information to healthcare practitioners. Since DHPLs may contain critical health risks information, they may result in measurable shifts in the prescribing practice. However, current research suggests that DHPLs may not be effective in communicating safety-related information. Continuing on a previous 2012 research conducted by Risk Sciences International that evaluated Health Canada's DHPLs' impact on prescribing practice, this study performed a qualitative descriptive analysis to identify: the attributes of DHPLs that result in a significant change in prescribing habits and; to develop recommendations and a conceptual framework for the communication of information on safely use of prescription drugs in Canada. **METHODS:** Health Canada's DHPLs issued from 2005 to 2015 were obtained. Relevant attributes of the DHPLs that are most likely to result in a change in prescribing practice were identified and examined using descriptive analysis. **RESULTS:** A total of 280 DHPLs were identified. Letters varied in terms of clarity of key information, format, content and length. Results suggest that 65% of DHPLs were warnings on drug side effects with the majority were considered serious adverse reactions; 12% of DHPLs were informative of new indications; 18% were warnings about product impurity and 5.7% of letters were warnings about drugs having the potential to lead to medication errors; only 33% of letters reported references. The target population was precisely described in 68% of the DHPLs. Fifty-four percent of the letters provided new recommendations, while 25% advised the close monitoring of patients to reduce the drug-related risks. **CONCLUSIONS:** This study suggests several attributes related to content and format of DHPLs could affect their effectiveness on the prescribers' behavior. Further research is needed to examine the correlation between these attributes in DHPL and changes in prescribing rates.

PHP278

ADHERENCE TO TREATMENT GUIDELINES AFTER OPIOID DEPENDENCE HOSPITALIZATION IN MEDICAID AND COMMERCIALLY INSURED POPULATIONS

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OBJECTIVES: To evaluate adherence to recommended evidence-based treatment guidelines and receipt of FDA-approved opioid addiction medications in Medicaid and commercial patients within 30-days of discharge from an opioid hospitalization. **METHODS:** The patient population was extracted from a large nationally

representative and statistically de-identified administrative claims database. Our cohort included members aged 18-64 between Jan. 1, 2010 and Sept. 30, 2014 who were hospitalized for opioid abuse, dependence or overdose and continuously enrolled at least 90-days prior to hospitalization and at least 30-days post-discharge. Use of FDA-approved medication was defined as receipt of buprenorphine, naltrexone or methadone. We also evaluated use of benzodiazepines (contraindicated), antipsychotics and antidepressants (prevalent use). **RESULTS:** We identified 76,611 patients with an opioid misuse hospitalization; 16,859 (22%) with commercial insurance and 59,752 (78%) with Medicaid. Medicaid beneficiaries were more likely to be female (57% vs 44%) and older on average. A similar proportion filled an opioid prescription following hospitalization (20%). The percent receiving recommended treatment post-discharge was low for both cohorts, but significantly lower for Medicaid patients (8.6% vs 18.5%). Overall, a higher proportion of Medicaid patients did not fill a prescription for any of the medications evaluated (41% vs 28%). **CONCLUSIONS:** There is an unprecedented opioid epidemic in the U. S. leading to healthcare and social costs estimated at \$55 billion annually. The U.S. Department of Health and Human Services has made expanding use of medication addiction treatment a top priority, but this study found >90% of Medicaid beneficiaries do not receive recommended dependence medications and found disparities in treatment between Medicaid and commercial patients. These findings point to the need to identify and limit barriers to prescribing opioid treatment medications like buprenorphine—such as physician certification requirements and restrictions on the number of patients they can treat—in order to reduce opioid overdoses and deaths in the U. S.

HEALTH CARE USE & POLICY STUDIES - Quality of Care

PHP279

REMS SURVEY RESPONSE RATE BY METHOD OF RECRUITMENT

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OBJECTIVES: REMS surveys seek to assess survey participants' awareness and understanding of key risk messages of REMS programs and are thus critical to maintaining effective REMS programs. This study sought to examine REMS survey response rates by method of patient recruitment (i.e., mode of invitation delivery and source of patient contact information). **METHODS:** This retrospective analysis of patient survey data, collected from all five REMS surveys conducted by a major CRO from 2014-2016, examined recruitment and survey completion metrics. Response rates were compared across two modes of invitation delivery and sources of patient contact information. Mode 1: sponsor-provided list of patients willing to be contacted regarding the product, but not necessarily product users; patient survey invitations were delivered via email with the survey link embedded. Mode 2: pharmacy claims data from a nationwide retail pharmacy chain; patient survey invitations were delivered via hardcopy mail to a targeted group of patients who filled prescriptions for the product in the last year. Surveys were available both online and via telephone. **RESULTS:** Using Mode 1, 19,650 surveys were distributed and 10,800 were distributed using Mode 2. Only 4.3% (n=1314) responded to the surveys. Regardless of recruitment method, the majority of patients (85%) completed the surveys online rather than via telephone. Response rates were higher for surveys using Mode 2 (7.4%) compared to surveys using Mode 1 (2.6%). **CONCLUSIONS:** This study was limited in its ability to separate source of participant contact information from mode of invitation delivery. However, results suggest that specifically targeting product users (Mode 2) may play a larger role in survey response than consent or ease of participation - embedded link in emailed invitations (Mode 1). Further research is needed to compare response rates for pre-consented patients with and without product exposure.

HEALTH CARE USE & POLICY STUDIES - Regulation of Health Care Sector

PHP280

EXPLORATION OF KNOWLEDGE AND PERCEPTION OF REGULATORY PHARMACIST REGARDING DRUG REGULATION IN PAKISTAN

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OBJECTIVES: The Study aimed to explore the knowledge and perception of Regulatory pharmacists regarding Drug Regulation in Pakistan. **METHODS:** A cross sectional descriptive study was conducted to evaluate the Knowledge and perception of Regulatory Pharmacist regarding Drug Regulation in Pakistan from November - June 2016. The study was carried out in Pakistan major cities of Pakistan where regulatory pharmacists were practicing. Study tool comprised of Demographics and six main domains including; Amendment in Existing Drug regulation, Procedural flaws and delay, Lack of knowledge and Training, Lack of budget and other facilities, Political Influence and security Issues, Poor communication and administration between different bodies. All analyses were done by using SPSSv20. **RESULTS:** Result showed that maximum respondents 155 (57.2%) age ranges between 32-41 years. Most of respondents 185 (68.3%) were male having B-Pharmacy. Majority 123 (45.4%) of respondents were Drug inspectors. maximum of respondents 148(54.6%) were disagreeing in that Drug act1976 is complete and comprehensive for drug regulation in Pakistan and provide complete and comprehensive leverage to Provincial Government to made rules. Majority of respondents 119(43.9%) were disagree that Drug act provide proper procedure for all regulatory activities. While 95(35.1%) were disagree in that Academic learning provides proper knowledge to Regulatory Pharmacist during study. Most of pharmacists 145(53.5%) were agree that they have security issues when they go for inspection. Majority of respondents 138(50.9%) were disagree that information which is present by one authority is not disseminate to other. **CONCLUSIONS:** Study concluded that regulatory pharmacists in Pakistan had mixed perceptions towards drug regulations. The findings showed that misapprehensions about certain sections/subsections of drug law persist among regulatory pharmacists. It is high time that the policy makers and regulatory pharmacists should sit together for mutual consensus development regarding the discrepancies in the current drug act.

PHP281

PATIENT ACCESS OPPORTUNITIES AND CHALLENGES FOR BIOSIMILARS: A REVIEW OF THE UNITED STATES MARKETPLACE

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OBJECTIVES: Rising health care budgetary pressures combined with an aging patient population and increasing incidence of chronic diseases provide great opportunities for biosimilars. The 2010 Affordable Care Act includes a Biologics Price Competition and Innovation Act. The government initiatives balance the stringent regulatory environment to reduce the complex, costly issues creating high barriers for manufacturers. This research reviews the current US biopharmaceutical regulatory pathway, definitions and status of the US marketplace. **METHODS:** A search strategy using the term “biosimilars” AND “US FDA” was used to identify peer-reviewed literature published from 2010–2016 reporting the current state of the US biosimilar marketplace. Additionally the “grey” literature (e.g., government publications, reports, newsletters, fact sheets) were also reviewed. **RESULTS:** A biological product is approved by showing it is highly similar to an FDA-approved biological reference product. The biosimilar must have no clinically meaningful safety and effectiveness differences from the reference product. Only minor differences in clinically inactive components are allowable. An interchangeable biological product is biosimilar to an FDA-approved reference product and meets additional standards for interchangeability. An interchangeable biological product may be substituted for the reference product by a pharmacist without the intervention of the prescriber of the reference product. The first US biosimilar pharmaceutical product (i.e., filgrastim-sndz) launched in September 2015. There are only four biopharmaceuticals currently approved for sale in the US. **CONCLUSIONS:** Historically multiple regulatory pathways existed (e.g., section 505(j) of the Food Drug & Cosmetics Act, 351(k)) for guiding the development of biopharmaceuticals. However, even given the current improved legislation ambiguity still exists, for example, regarding the definition of “highly similar” and “no clinically meaningful differences”. Thus these and other questions persist about the pathway that are likely slowing product development and market uptake. Continued analytical, pharmacological, and clinical research should improve our knowledge and development of these products.

HEALTH CARE USE & POLICY STUDIES – Risk Sharing/Performance-Based Agreements

PHP282

CHARACTERISTICS OF MANAGED ACCESS AGREEMENTS FOR MEDICINES IN AUSTRALIA

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The Australian Pharmaceutical Benefits Advisory Committee (PBAC) recommends subsidy of a medicine for an indication (MIP) based on appraisal of the evidence for comparative clinical effectiveness, cost effectiveness and financial cost. PBAC advises what uncertainties exist in the evidence. Where uncertainties exist, the Australian Government uses a wide range of managed entry agreements (MEAs) to make medicines available in the national Pharmaceutical Benefits Scheme (PBS). **OBJECTIVES:** To describe the characteristics of all MEAs established by type of action, source of recommendation, and therapeutic area (ATC). **METHODS:** Extracted information for all MEAs implemented between January 2012 and May 2016. A typology for the type of action was developed. **RESULTS:** Eighty-six MIPs were PBS-listed with 171 MEAs. 74% of MIPs had two or more MEAs. 51% of MIPs provided additional health benefit (cost effective) and 49% the same benefit (cost minimised) over comparators. 51% of MIPs treated cancers or immune diseases (ATC L). PBAC recommended MEAs for 90% of MIPs. 82% of MEAs were simple financial agreements; of the 8 possible financial actions 33% were discounts, keeping the actual price confidential, and 43% required reimbursement if financial caps were exceeded. 13% of MEAs relied on performance measures linked to reimbursement; most of the 6 possible MEAs limiting subsidised continuation to patient response. Coverage with evidence development (CED) MEAs were least common (5%); 5 of the 8 CED required review of outcomes from clinical trials already underway. **CONCLUSIONS:** The Australian Government relies on financial agreements to manage access. There may be barriers to implementation of more complex MEAs. The PBAC is involved in implementing many MEAs through the evaluation and appraisal of evidence.

PHP283

CURRENT AND FUTURE USE OF OUTCOMES-BASED CONTRACTING BY US PAYERS

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OBJECTIVES: U.S. payers are increasingly using outcomes-based contracts with pharmaceutical companies to place greater financial risk on therapies' ability to demonstrate real-world clinical success. This study examines payer's current and future use of outcomes-based contracts (OBCs), drivers of their use, overall design, and challenges encountered to identify the future of these arrangements. **METHODS:** In the U.S., 41 health plan pharmacy and medical directors were surveyed about their current or expected use of outcomes-based contracts, including 15 already operating OBCs and 13 expecting to do so in the next 12 months. In addition, 100 cardiologists were surveyed over the impact of OBCs on their prescribing. **RESULTS:** 68% of surveyed payers either currently or expect to have OBCs in place in the next year, typically based on pharmacy and medical claims data. Existing OBCs were most commonly driven by cost-saving goals (47%) while payers planning OBCs in the next year also cite client demands (23%) and a desire for the pharmaceutical industry to justify prices (23%). Under existing OBCs, physicians are required to report

patient-level data on drug usage (53%), medical utilization (53%) and hospital discharges (40%). Among surveyed cardiologists, 73% reported being more willing to prescribe a drug shown by OBCs to be as clinically or cost-effective as presumed. However, 53% of payers identified trusting and verifying the integrity of the pharmaceutical company's data as their largest challenge. **CONCLUSIONS:** OBCs appear poised for continued growth, driven by a desire to better align efficacy with price. Physicians report they are monitoring OBCs and are likely to reward therapies that demonstrate presumed effectiveness with increased prescribing. However, the relative newness of many of these agreements suggest their design will evolve in the coming decade. In addition, payer skepticism for the quality of data reported by the drug industry represents a stumbling block on their expanded use.

PHP284

RISK-SHARING MODELS IN HEALTH CARE SYSTEMS: LITERATURE REVIEW

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OBJECTIVES: To review the current risk-sharing and pay-for-performance models in indexed literature and to describe characteristics and outcomes obtained after the implementation of these models. **METHODS:** We conducted a review of the literature in Medline, Embase and Lilacs, using the free terms “risk sharing”, “risk management” and “pay for performance”, without language or publication date limits. Economic studies, systematic and non-systematic reviews of the literature, as well as descriptive studies about risk-sharing and international payment models were included. **RESULTS:** Of the 1009 articles initially identified, 35 were included for the analysis. Most studies come from United States and the UK, but there are also experiences from Belgium, Italy, Spain, South Africa, Sweden; there are also documented experiences from Philippines, Tanzania, Zambia, Rwanda, Burundi, Democratic Republic of Congo, Vietnam, Peru, and China. Implementation of risk-sharing models had good overall performance and most papers show a significant improvement in different variables, such as decreased mortality and improvement in quality of care provided to patients mostly with chronic diseases. Payment arrangements between health care providers and pharmaceutical industry facilitated the implementation of new technologies in different health care systems. **CONCLUSIONS:** Due to the diversity of interventions and of healthcare system structures, the evidence available is still insufficient to draw conclusions. “Risk sharing” includes a wide range of approaches, is far from a uniform intervention, and depends on the interaction of numerous variables, including the magnitude and distribution of the incentives, and the amount of technical support available.

PHP285

ASSESSMENT OF MANAGED ENTRY AGREEMENTS IN EUROPE AND THE US

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OBJECTIVES: Managed entry agreements (MEAs) provide manufacturers and payers the opportunity to work together, provide new contracting and payment mechanisms, and improve patient access. This is particularly relevant in the US, where drug costs are rising and the healthcare system is complex, with multiple payers and payer types. While theoretically promising, MEAs are often multi-faceted and difficult to implement. This research aims to assess the successes and failures of MEAs in UK, Italy, France, and the US to identify key learnings and barriers for expansion in the US. **METHODS:** Secondary research identified managed entry agreements in UK, Italy, France and US from 2007 to 2017. A review of publicly available health authority websites, peer-reviewed journals, and news sources was conducted to identify MEAs, the types of agreements (i.e., risk share, evidence based pricing, etc.), outcomes, and the perceived level of success. Data were then analyzed to understand the successes and key characteristics that may have supported the program's success. **RESULTS:** Type of MEA varied significantly within and throughout countries. In the UK and Italy, most MEAs were considered to have been successful, whereas French MEAs had neutral outcomes. Successful programs typically identified benefits for both the manufacturer (i.e., decreased time to review by NICE in UK) and the payer (lower overall cost to NHS in UK). Few MEAs in the US have publicly available information or data. Of those, all but one considered the program to be successful, while all simultaneously noted that MEAs require significant additional effort, sometimes stymying the perceived success. **CONCLUSIONS:** Most MEAs were successful at decreasing cost to the intended health system and improving manufacturer relations with payers. Increased transparency in the US could improve local learnings from existing MEAs. Linking health outcomes to payments was a chief driver of success in most MEAs.

PHP286

RISK-SHARING AGREEMENTS (RSA) IN EMERGING MARKETS: IS IT A WAKE-UP CALL OR IS IT INNOVATION TOO LATE?

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OBJECTIVES: Recent years have witnessed emerging market (EM) countries adopting various forms of RSAs in order to manage public financing of innovative pharmaceuticals. South Korea, Taiwan, and Russia have either provided guidance or executed pilot programs in the recent past. This research aimed to analyse existing RSA structures across these countries and identify commonalities and divergences to postulate future of RSAs in EMs. **METHODS:** A pragmatic review of literature (in English and local language, as appropriate) and government resources on the RSA policies was undertaken for this research. Implementation examples, including completed pilots and proposed disease priorities were also reviewed to identify key differences from the developed markets. Guidance on implementation (South Korea),

pilot examples (Taiwan) and legislation and regional diversity (Russia) were analyzed. **RESULTS:** Common themes for RSAs in EM included evolution of legislative guidance to reflect drug development trends, infrastructure availability, industry engagement and healthcare financing uniformity across the country. In Korea, industry groups and payers have initiated discussions on evolving RSAs to include combination drugs. Financing infrastructure and data governance capabilities will reflect the agreements' designs, as seen in Taiwan's pilot programs. Potential restrictions on the orphan drug RSAs in Russia can arise due to the regional financing principles, limited by lack of interlinked data collection across institutions and regions. In the future, maturity of the RSAs will enable linkage to HTA requirements, such as in Korea and Taiwan, while the Russian RSAs being developed in parallel with the local HTA methodology leave uncertainty to the industry regarding their evaluation principles. **CONCLUSIONS:** Clear legal framework, data privacy, ownership, accessibility and evaluation principles, remain the cornerstone of success likelihood among RSAs in EMs. Several country-specific factors, including existing infrastructure and financing systems will impact the emerging RSAs, and should be taken into account to tailor implementation in any EM.

PHP287

EVALUATING THE EFFICIENCY OF COVERAGE WITH EVIDENCE DEVELOPMENT IMPLEMENTATION

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OBJECTIVES: The coverage with evidence development (CED) program within the Center for Medicare and Medicaid Services (CMS) is used to generate additional data to support national coverage decisions for medical technologies. Coverage for patients is provided, but only in the context of approved clinical studies including clinical trials or observational registries. In this study, we evaluated the time to implementation of clinical studies for CMS CED programs. **METHODS:** We reviewed CMS's website for data on CED National Coverage Determinations (NCD) and abstracted the release date, date of first approved clinical study, and last modified date for each case. We estimated the mean time to study implementation overall and by type of study. We also used linear regression to assess the trend in mean time to implementation, as well as the impact of recency (NCD with past 5 years) on mean time to implementation. **RESULTS:** We found 22 CED NCDs among which 17 had a study implemented. The mean time to implementation or end of study was 731 days. Among NCDs with a study implemented, the mean time was 405 days (clinical trials: 515 days; registries: 48 days). We found a trend toward a shorter time to CED implementation over time (155 days shorter each year, $p = 0.035$). Recent cases had a time lag 944 days shorter than older cases ($p = 0.039$). The majority of recent cases have their first related clinical study approved within 200 days after the release of NCD. **CONCLUSIONS:** Our findings suggest some difficulty implementing clinical studies following a CED determination, but less so with registries. However, these difficulties may be lessening over time.

PHP288

REDEFINING "REASONABLE AND NECESSARY"? AN EMPIRICAL, COMPARATIVE ASSESSMENT OF MEDICARE'S COVERAGE WITH EVIDENCE DEVELOPMENT

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OBJECTIVES: Medicare employs coverage with evidence development (CED) to provide conditional coverage for an intervention to allow for the collection of evidence of its effectiveness. In this study, we examined how private payers cover interventions for which Medicare has employed CED. **METHODS:** First, we identified all drugs, medical devices, clinical therapies, and diagnostic technologies that are covered under CMS's Coverage with Evidence Development (CED) program. Second, we located coverage policies for CED interventions issued by the largest private payers that make their coverage policies publicly available. Third, to categorize coverage policy restrictiveness, we compared private payer coverage to corresponding FDA labels and categorized coverage as equivalent to, less restrictive, or more restrictive than the labeled indication. **RESULTS:** Between September 1998 and February 2016, CMS completed 246 national coverage analyses, 18 of which (7.3%) applied Coverage with Evidence Development. We identified 258 coverage policies issued by private payers for these CED technologies. We identified significant variation in both the number of policies payers' issued and their coverage of CED technologies. Private payers did not cover the majority of CED technologies (138 of 258 policies; 53.5%). Health Net and Highmark were the payers that most often covered CED technologies (62.5%). Private payer coverage was equivalent to corresponding FDA approval in 68.3% of cases, more restrictive in 25.0%, and less restrictive in 6.7%. **CONCLUSIONS:** When covering health care technology, the conventional wisdom is that private payers follow Medicare's lead. However, we found significant variation in private payer coverage of this set of innovative medical technologies. Overall, these findings provide insight into Medicare's application of CED and suggest that patients enrolled in different health plans may have variable access to innovative medical technologies.

PHP289

IQWiG VERSUS THE G-BA – FREQUENCY OF DIVERGENT OPINIONS IN GERMANY AND THEIR IMPACT ON GLOBAL PRICING

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OBJECTIVES: Since 2011, under the Pharmaceutical Market Restructuring Act (AMNOG), new pharmacological therapies in Germany are subject to an early

benefit assessment (EBA) upon launch. The Institute for Quality and Efficiency in Health Care (IQWiG) usually conducts an initial assessment, followed by the Federal Joint Committee (G-BA) issuing a final verdict. If a newly approved drug is not deemed to offer an additional benefit over available therapies, it is not granted premium-pricing, instead being subject to reference pricing. This research assesses how the G-BA's assessments differ from IQWiG's. **METHODS:** All EBA resolutions were extracted from the English-language G-BA website alongside corresponding IQWiG press releases (01/01/2012-01/13/2017) and key information compared. For extracted outcome data, the focus was the subgroup of greatest additional benefit. **RESULTS:** Of 100 identified G-BA and IQWiG EBA assessments, 68% (68/100) did not differ in their additional benefit. The G-BA concluded on an additional benefit where IQWiG deemed none in 10% (10/100) of cases, G-BA and IQWiG both agreed that additional benefit was offered but differed in its extent in 20% (20/100); 15 cases: G-BA's rating was lower, 5 cases: G-BA's was higher). In the 2 cases where IQWiG's verdict was 'lesser benefit', the G-BA ultimately concluded no additional benefit was proven. As for the level of certainty with which additional benefit was demonstrated, in 85% (39/46) the G-BA's verdict matched IQWiG's assessment; in 4% (2/46) of cases, the G-BA's certainty rating was higher, in 11% (5/46) it was lower. **CONCLUSIONS:** Even after an unfavourable IQWiG assessment, companies should fully engage with the EBA consultation process, as the G-BA has frequently shown the flexibility to deviate from IQWiG's initial assessment. As many countries use external reference pricing for price-setting and Germany is one of the most frequently referenced countries, this has global revenue implications.

PHP290

THE NICE CRUNCH? CAPACITY CONSTRAINTS LEADING TO POTENTIAL INCONSISTENCIES IN THE ASSESSMENT OF DRUGS IN ENGLAND

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OBJECTIVES: When developing Single Technology Appraisal (STA) guidance, the National Institute for Health and Care Excellence (NICE), commissions an independent academic centre (Evidence Review Group [ERG]) to develop a report that critically appraises the manufacturer's submission and review published evidence. This research aims to compare the work of different ERGs and whether this may affect STA outcomes, particularly in light of recent reforms to the Cancer Drugs Fund (CDF), which have increased the number of NICE STAs to be undertaken. **METHODS:** All final appraisal determinations (FADs) resulting from STA processes were screened and the outcome, disease area (classified by ICD10 category), and academic centre was extracted (up to 11/20/2016). Statistical comparisons were conducted using a Chi-squared test. **RESULTS:** 272 NICE STAs were identified, supported by 12 different ERGs (highest: 33 [Southampton], lowest: 1 [Schering]). Rates of positive recommendation (defined as 'recommended' or 'optimised') varied numerically but not significantly by appraisal centre ($p=0.79$, highest: BMJ-TAG [93%, 14/15], lowest: Schering [0%, 0/1]). However, there were notable variations in recommendation rates by therapy area and the considered therapy areas varied substantially between different ERGs. An annual average of 23.5 STAs were undertaken (highest: 42 [2016], lowest: 4 [2006]) with a large upsurge in the last two years driven by increased oncology submissions. This has coincided with an increased number of ERGs supporting oncology appraisals (average: 8.0 [2015-2016] vs. average: 4.2 [2006-2014]), including in cancer types they had not previously appraised. **CONCLUSIONS:** To date, the likelihood of a positive recommendation has not significantly varied by ERG, with numerical differences largely due to variations in therapy areas appraised. However, NICE are conducting increasing numbers of submissions, resulting in ERGs increasingly supporting TAs in therapy areas for which they have no prior experience, potentially introducing a risk for non-uniform implementation of NICE's methodology.

PHP291

A REVIEW OF US BIOSIMILAR APPROVALS: WHAT EVIDENCE IS FDA REQUIRING, AND HOW ARE MANUFACTURERS RESPONDING?

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OBJECTIVES: To identify the types and quantities of evidence the FDA is requiring for biosimilar approval, and the corresponding evidence manufacturers have provided in their 351(k) biosimilar approval applications. **METHODS:** We searched through FDA general guidances, drug-specific approval documents, and webcasts to collect data. The following data were collected: approval indications and dates, reference product names, manufacturer names, evidence on similarity in analytical and functional characteristics, pharmacokinetics, pharmacodynamics, efficacy, safety, and immunogenicity, evidence used for extrapolation claims, and other notable points of discussion during FDA Advisory Committee meetings. **RESULTS:** There are currently four biosimilars approved in the United States. For these biosimilars, a large evidence base is provided to demonstrate similarity in analytical and functional characteristics, while fewer clinical studies are provided to demonstrate efficacy. Extrapolation allows biosimilars to be approved for indications in which clinical studies were not conducted, as long as they show similar analytical and functional characteristics relevant to the known or likely mechanism of action for the extrapolated indication(s). **CONCLUSIONS:** As increasingly more biosimilars go through the 351(k) biosimilar approval pathway, we will better understand what evidence is required for biosimilar approval in the United States.

PHP292

PAYERS' FAMILIARITY AND UTILIZATION OF CURRENT VALUE ASSESSMENT FRAMEWORKS AND OPINIONS ON IDEAL VALUE FRAMEWORK CRITERIA

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OBJECTIVES: Organizations, such as the Institute for clinical and economic review (ICER), the American Society of Clinical Oncology (ASCO) and the national comprehensive cancer network (NCCN), have developed value assessment frameworks to determine "value" of drug therapies. These frameworks are being incorporated into clinical guidelines and may serve as the basis for purchasing and insurance coverage decisions. The purpose of this study is to determine payer perspectives of all 5 value frameworks, compare value frameworks with payers' own value assessment methods, and reach a consensus on payer opinions of the ideal value framework. **METHODS:** A Delphi study with 12 managed care pharmacists was performed to determine payers' opinions of the value frameworks and the characteristics of the ideal value framework. The study included 2 electronic anonymous surveys and a teleconference to discuss the results. Results are reported descriptively. **RESULTS:** Participants most familiar (somewhat familiar, familiar, and very familiar) with NCCN (89%), followed by ACC/AHA (78%), ICER (67%), ASCO (44%) and MSKCC DrugAbacus (33%). ICER, NCCN and ACC/AHA are currently being used by the participants, mainly as additional sources of clinical information, and each value framework is being considered for use in the future. The main reason for not utilizing value frameworks was more information was needed. The most participants (38%) said their company's drug evaluation was similar (somewhat similar and very similar) to NCCN, followed by ICER (33%). All respondents agreed that drug evaluations will become more transparent with increased utilization of value frameworks. Most participants reported that the ideal framework should be an online tool (67%) updated each time a new drug in a class is approved (55%). **CONCLUSIONS:** All participants agree that value frameworks would contribute to transparency of drug evaluation but the health plans need more information about the value frameworks before they will be widely utilized.

HEALTH CARE USE & POLICY STUDIES – Conceptual Papers

PHP293

IS LONGER SURVIVAL MORE VALUABLE THAN BETTER QUALITY OF LIFE? INSIGHTS FROM REAL OPTIONS THEORY

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The quality-adjusted life-year (QALY) combines expected survival and quality of life into a single composite measure, and assumes that a QALY gain from life extension is equivalent to a QALY gain from quality-of-life (QoL) improvement. However, a recent systematic review (Ryen 2015) provided empirical evidence that willingness-to-pay (WTP) estimates for a QALY were consistently higher when the QALY gain was from life extension as compared to from QoL improvement. Originating from corporate finance, real options theory recognizes that in some cases initial investments may create opportunities (options) for subsequent investments. Such initial investments therefore have two value elements: the static or passive net present value of direct cash flows and the option value of operating flexibility and strategic interactions. Similarly, a treatment that prolongs survival creates options as it opens up opportunities for patients to benefit from future treatments should they become available during the extended life. In a stated-preference study, survey respondents may consider this additional benefit from longer survival and factor that into their WTP, which could be the reason for a higher WTP for life extension. One of the implications of this is that in a value-based reimbursement system where "a QALY is a QALY is a QALY", the option value of life-extending treatments may be omitted, thus resulting in under-reward of such innovations. Current cost-effectiveness modeling practice has generally not factored in the impact of (unknown) new future treatments. Accounting for option value in technology assessment requires modeling arrivals of new treatments and their health benefits and costs, and/or patient's preference and WTP on attributes of potential future treatment opportunities (such as efficacy, time of arrival, likelihood of arrival, etc.). Further research is needed on the methods for operationalizing real option value and its implications on the cost-effectiveness of a treatment and optimal resource allocation.

PHP294

HEALTH IMPACT FRAMEWORK FOR CURES AND HIGH IMPACT MEDICAL TECHNOLOGIES

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Objective: A number of recent treatment advances have been labelled cures but a consistent definition of cure does not exist in research or clinical practice. Further, no single framework exists that can capture key factors in the evaluation of medical technologies and cures. Our objective was to develop a general framework for characterizing the health impact of medical products that can cover high impact technologies and cures. **Methods:** We performed a systematic literature review to identify uses of the word cure in five high burden disease areas: heart disease, human immunodeficiency virus, diabetes, depression, and cancer (prostate and breast). We then applied Walker and Avant's concept analysis to identify key factors contained within cure definitions. We then developed a comprehensive framework that captures key factors related to a medical technologies' clinical and economic impact and which includes curative technologies. **Results:** The key concepts that we identified were: 1) clinical impact, which could be measured using the QALY shortfall or proportional QALY shortfall, 2) economic impact, which can be measured as the incremental net total costs and 3) the timing of the clinical or economic impacts. The key factors that are captured in the framework are: disease burden alleviated, net incremental treatment costs, timing of clinical effects and costs, and the distribution of clinical and economic outcomes for the target population. **Conclusions:** We developed a comprehensive framework that captures the key factors in the evaluation of medical technologies and cures. The

framework can be used to illustrate an individual technology's impact relative to an alternative as well as facilitate comparative evaluations across technologies.

PHP295

CONSTRUCTING DISCRETE CHOICE INSTRUMENTS FOR REGULATORY ASSESSMENT OF MEDICAL DEVICES

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Objective: FDA's Center for Devices and Radiological Health (CDRH) shows commitment to integrating patient voice into device benefit-risk determinations, but the methods are largely undeveloped. We suggest specific methods to follow to integrate device-development and patient outcomes as attributes for conjoint analysis. **Methods:** We developed patient attributes for a choice based conjoint and a standard gamble tool for use in regulatory approval of new technologies for upper limb prosthetics. There are ground breaking innovations in prosthetics, that theoretically could increase the ability of those missing an upper limb to control their hand/arm movement by thought or muscle movements and with potential to also feel sensation through the prosthetic. However, at least 30% of those who adopt new upper limb prosthetics do not end up using the devices. We suggest the steps that can be used to guide the quantitative translation of highly technical outcomes into patient centered outcomes. **Results:** We provide the measurement tools for a choice based conjoint and a standard gamble tool for adoption of upper limb prosthetic devices such as osteointegration and myoelectric control. We show how pictures and videos can better convey a complex motion and a functional ability. We describe an activity by both patients with upper-limb loss and device-developers that can help translate electrical based metrics into larger grouped patient life-skills for improved patient-centered regulatory decision making. **Activity:** Prioritization of functional life skills most needed, and selection of the mix of device technical attributes (grip strength, closure speed, degrees of freedom of motion) and deficiencies (failure, weight) required to perform different levels of each functional skill). **Conclusion:** Integrating device developers and potential device users together to translate the technical outcomes into patient-centered outcomes is essential for selection of attributes for discrete choice experiments which will result in useable information for regulatory approval decisions.

PHP296

THE PATIENT VOICE IN VALUE ASSESSMENT: A RUBRIC TO INCREASE PATIENT CENTRICITY

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OBJECTIVES: Professional societies and other organizations have recently taken a visible role in the US defining treatment value and providing recommendations to payers and clinicians via value assessments. While patient perspectives routinely differ from those of other stakeholders, it is not always apparent patients were engaged in value framework development or assessments. If value frameworks are to be used to inform decisions affecting treatment access, the patient community wants robust processes in place to incorporate the patient voice. To aid stakeholders in achieving patient-centered value assessments, the National Health Council (NHC), with stakeholder input, created the Patient-Centered Value Model Rubric (Rubric). **METHODS:** The NHC held a multi-stakeholder, invitational roundtable in early 2016. Participants reviewed existing patient-engagement rubrics; discussed experiences with value frameworks; debated and thematically grouped hallmark patient-centeredness characteristics; and developed illustrative examples of the characteristics. These materials were organized into the Rubric, and vetted via multi-stakeholder peer-review. **RESULTS:** The Rubric describes two complementary, direct and indirect, pathways for addressing the six domains of patient-centered value frameworks: Partnership, Transparency, Inclusiveness, Diversity, Outcomes, and Data Sources. Specific examples were created to illustrate how patient engagement and centeredness can be operationalized. While direct patient engagement is the ideal goal, where the patient community has an active role, indirect means of engagement can also contribute to patient-centeredness. Indirect means include using existing data sets that capture patient views and preferences. **CONCLUSION:** The Rubric is intended to assist all stakeholders, especially the patient community, in assessing the level of patient-centeredness and engagement in a given value framework or model used to conduct a value assessment. It can be a guide to support developers in conceptualizing plans for meaningfully engaging patients. The Rubric will be refined over time based upon feedback from patient, patient group, framework developer, and other stakeholder-use experiences.

PHP297

CONCEPT ANALYSIS ON CURES FOR ILLNESSES WITH HIGH DISEASE BURDEN

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OBJECTIVES: A number of recent treatment advances have been labelled cures but a consistent definition of cure does not exist in research or clinical practice. The purpose of this study was to review the term cure and establish an operational definition. **METHODS:** We conducted a systematic literature review to identify uses of the word cure. All relevant definitions were collected in five disease areas of high disease burden: heart disease, human immunodeficiency virus, diabetes, depression, and cancer (prostate and breast). Walker and Avant's concept analysis method was applied. Frequently used attributes of cure within each disease area were compared and reduced to the fewest number of defining attributes that would differentiate cure from similar concepts. Subsequent steps included

identifying ideal, borderline, and related cases, as well as antecedents and consequences of cure. **RESULTS:** Three defining attributes were identified: complete and permanent remission, reversing or eliminating the underlying cause of disease, and treatment or other interventions no longer being necessary. These attributes of cure set a high benchmark, making cure difficult to be achieved and measured, especially at the individual level. One potential operational definition may be statistical cure—when a patient's mortality risk returns to that of the general population. This definition is used in epidemiologic modeling studies given sufficiently long follow-up. However, this does not capture the quality-of-life dimension inherent with disease. The recent concept of the quality-adjusted life-year (QALY) shortfall, i.e. the difference between the quality-adjusted life expectancy of a patient with disease versus that of the general population may provide the best operational definition—alleviation of the QALY shortfall. **CONCLUSIONS:** The concept of cure was assessed to establish an operational definition as more treatments are expected with “curative” intent. Although difficult to measure, we suggest that the best operational definition for cure is the alleviation of the QALY shortfall.

PHP298

MARKET ACCESS CHALLENGES FOR VACCINE LAUNCHES

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Objectives: Vaccine launch from a market access perspective could be more complex than launching general drugs. The study was conducted to assess the complexities of launching various types of vaccines and differences in market access pathways. Factors of modes to include in the National Immunization program (NIM), procurement dynamics, evidence requirements, value elements influencing access were assessed. The project was focussed in selected European countries including France, Italy, Germany, UK, Spain, Norway and Belgium. **Methods:** The project was conducted through in depth secondary research including assessment of pathways and critical analysis of HTA outcomes of selected vaccines through analogue analysis. **Results:** The analysis confirmed that there are several stakeholder institutions in addition to those involved in general drug assessments who influence the success of a vaccine. Most importantly NITAG (national immunisation technical advisory groups) in various countries play an important role. There is variance in how different countries approach the inclusion of vaccines in the national immunisation program. Not all countries have clearly defined criteria making it difficult for vaccine manufacturers to understand how to develop a market access strategy for vaccines. They could follow either a vaccine pathway, generally defined by national immunisation program or a therapeutic pathway, which is similar to the standard drug access pathway. Also the modes of procurement vary including direct purchase by hospitals to national or regional tendering. Elements such as efficacy of the vaccine, its influence on the individual and global population, schedule, target population, price, unmet need and target disease carry different weightings influencing the success of vaccine from a market access perspective. **Conclusions:** The study gave clear strategy for a pharmaceutical company wanting to launch a vaccine. HTA agencies in general have a positive perspective towards vaccines and have support systems that could be explored for their successful market access launch.

PHP299

US NATIONAL HEALTH CARE PLAN ABSTRACT

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Abstract Objectives: National public healthcare programs have been topics of discussion during presidential elections in the United States of America (US) since 1945. This paper examines the claims and counterclaims of the Medicare for All (MfA) healthcare plan proposed during the 2016 US presidential primaries from a social, health economic perspective. **Methods:** A narrative literature review was conducted of English-language public domain sources published between January 1, 2015 and January 1, 2017 using PubMed, EMBASE, CINAHL, and Google Scholar utilizing the following search terms: “national”, “health”, “plan”, “universal”, “insurance”, “single”, “payer”, “federal”, “United States”, “Medicare for All”. The “federal” and “plan” search terms were least useful for generating additional, non-redundant content. **Results:** The two most common issues raised with MfA were economic viability and political possibility; administrative impact: service delivery system, payment policies, benefit design and utilization management issues, was less frequently addressed. The economic critiques of MfA frequently involved federal payers and budget impact perspectives, while the MfA proposal was based upon a broader, social perspective. Administrative impact critiques focused greatly on short-term considerations or potential pit-falls left unaddressed in MfA and identified large information gaps. **Conclusions:** The recent MfA debate was extremely similar to its predecessors; no overarching consensus was reached, with a clear trend toward negative MfA assessments. The quality of the counterclaims presented was often greatly limited and did not address the ethical issues of the wealthiest country in world history not providing universal, comprehensive healthcare for its citizens when other countries of lesser means can.

PHP300

EVOLUTION OF REGULATORY REQUIREMENTS FOR RETROSPECTIVE OBSERVATIONAL STUDIES USING MEDICAL RECORDS IN FRANCE, GERMANY, SPAIN AND THE UK

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Background: While clinical trials remain the gold standard for drug approval, additional information is required on how specific drugs perform in a real-world setting. Observational studies providing Real World Evidence (RWE) help fill the knowledge gap between clinical trials and actual clinical practice and are

increasingly demanded for submission by health authorities. By providing information on real-world environment, the analysis of retrospective data from medical records addresses the needs of key stakeholders before and after the drug approval. To harmonize legislation across European countries, the European regulatory framework is evolving (EU CRT N° 536/2014) and requires each local country legislation to follow. According to the European Medicines Agency (EMA) (statement Dec 2015) this new regulation should come into effect by October 2018 at the latest. In the interim, country specific legislation must be respected resulting in a high level of complexity for multi-country observational studies. **Methodology:** Documentary Method – critical analysis of country specific legislations, government body requirements and recommendations. **Results:** In France, the Loi Jardé became effective in November 2016, but will require a new amendment for observational studies in order to conform with the forthcoming EU law. In Germany, studies involving the collection of retrospective medical records are mainly classified as ‘Anwendungsbeobachtungen (AWB)’, and require only the notification to central entities. Spain has a straightforward regulatory classification system for observational studies, but requires site-based Research Ethics Committee (REC) approvals. Even though the current legislation of the UK for observational studies is probably the most straightforward (e.g. service evaluation), the future evolution of regulations is highly uncertain due to BREXIT. **Conclusions:** Although EU harmonization of legal requirements for observational studies is supposed to take place in October 2018, we can expect many twists and turns until this is translated in real-world practice!

PHP301

APPROPRIATENESS AND LIMITATIONS OF COST-EFFECTIVENESS METHODOLOGIES IN ONCOLOGY

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There is strong evidence to suggest that the quality-adjusted life-year (QALY) and its use in cost-effectiveness analysis (CEA) to determine the incremental cost-effectiveness ratio (ICER) has important limitations in oncology, and alternative analyses of value should be considered. The ICER is the incremental cost associated with a new intervention versus an existing intervention, divided by the change in effectiveness measured in QALYs. In some countries, if the ICER for a new product meets a pre-defined threshold then it receives access and reimbursement. When this CEA method is used to assess new oncology agents, they often fail to meet these thresholds, and have limited public use. This CEA method only determines a drug's value for a particular place in therapy at first regulatory approval, and not the value for evolving therapeutic uses as commonly seen in oncology. Recommended health-related quality of life instruments used to develop the QALY were not designed for measuring health status change within disease states where vitality is important, thereby inaccurately reflecting cancer-related quality of life. Finally, this CEA method does not routinely account for societal issues, such as cost offsets, lost productivity, or caregiver requirements. There is evidence suggesting that countries using the ICER and QALY reimburse fewer cancer drugs, take longer to provide access for patients, have subsequent lower and slower clinical adoption rates of new cancer medicines, and have lower cancer overall survival. Alternative approaches presently used abroad to value oncology therapies involve clinical innovation scores, flexible thresholds, special end-of-life criteria, pragmatic decision-making and patient access schemes. In the United States, market-based solutions like risk-sharing agreements, value-based contracting, and considerations of Multi-Criteria Decision Analysis are growing. CEA using the ICER and QALY should be only one criterion amongst many to be considered when deciding access and reimbursement for oncology therapies in the US.

PHP302

OVERVIEW OF HORIZON SCANNING PROCESSES FOR MEDICAL TECHNOLOGIES: RATIONALE AND REQUIREMENTS

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Given ongoing medical innovation, it is essential that healthcare policy makers prepare for the costs of emerging health technologies that will enter the market. Horizon Scanning is an important tool used by such policy makers, which enables them to predict costs and prepare the necessary national budgets and resources required for health technology reimbursement. Horizon Scanning organizations generally use two main approaches: 1) Routine scanning, whereby ongoing ‘horizontal’ scans are performed to identify significant and urgent healthcare advances regardless of healthcare area; and 2) In-depth ‘vertical scanning’ which focuses on healthcare areas with known significant or unmet needs. Horizon Scanning organizations rely on regular communication with manufacturers in order to ensure that both routine and in-depth Horizon Scanning can be carried out efficiently. Using the information obtained from Horizon Scanning, the organizations put together technology briefings, alerts and in-depth Horizon Scanning reports which can be made publicly available minus confidential information. Horizon Scanning organizations in different countries require information on emerging technologies at different times. Some require information once phase III clinical trials have been initiated, whilst others can range in requiring information from three to one years prior to expected market entry. The data requested across European Horizon Scanning organizations broadly include some or all of the following: product name, indication, regulatory status, mechanism of action, epidemiology, likely comparator products, current clinical research evidence, potential product benefits, costs of product and comparators, estimated net budget impact, information and service implications. If manufacturers proactively engage with Horizon Scanning organizations, it allows healthcare reimbursement agencies to optimally prepare for the arrival of new healthcare technologies, thus increasing the likelihood of patients with unmet needs gaining access to new technologies in a timely manner.

PHP303

REDUCING THE IMPACT OF MENTAL HEALTH-RELATED COSTS IN THE WORKPLACE WITH A PROGRAM TARGETING COGNITION

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Depression is recognised as the major cause of mental illness worldwide, affecting an estimated 22.7% of the U.S. working population (Evans-Lacko S. 2016). Depression significantly affects performance and undermines productivity with high rates of presenteeism and absenteeism (estimated annual costs of \$5,524 and \$390 respectively per person; total costs of ~\$90-100 billion (Evans-Lacko S. 2016; Greenberg et al. 2015)). Sixty-two per cent of costs are associated with co-morbid mental disorders, such as anxiety, stress, and sleep disorders (Greenberg et al. 2015). These disorders are related to cognitive issues that depression-affected people experience in attention, memory, and executive functions, leading to complications in concentrating, solving problems, or making decisions, and are the main factors determining a presenteeism-associated lack of productivity. Solutions that specifically target depression-related, co-morbid disorders associated with presenteeism will be cost-saving. A project recently launched in a London-based, world-wide organisation, aiming to investigate, prevent, and manage potential cognitive employee health-related issues, adopts a cognitive assessment and training software, already tested in psychiatric populations (Domen A. et al. 2015; Nieman D. et al. 2015; Domen A. et al. 2016), in combination with a behavioural program targeting employees' habits in sleep, exercise, diet, and hydration. The 15-minute online assessment used allowed employees to monitor their cognitive health from their own digital devices, while employers received an anonymised and aggregated view of cognitive health trends in their organisation. The assessment may help to raise awareness of the risk of mental illness in the workplace, enabling an evaluation of the outcomes of the combined solutions that were adopted. Assuming that a combined cognitive and behavioural program may reduce costs by 10%, U.S. employers should be able to realise a savings of around \$550 per person in presenteeism costs alone.

PHP304

MONOPSONY OF ORPHAN DRUGS

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One of the challenges facing any health authority is the marketing of orphan drugs. Orphan drugs are those medicines used to treat patients with rare diseases. The scarcity of the rare disease makes it a non-attractive area for research and development to investigate new molecules, and for industry to invest in the marketing of orphan drugs. In most countries, the government is the provider for those services to rare diseases. Although many of these diseases like Gaucher, Willson's and more were discovered long ago, there is no variability in medicines available to treat those diseases. The number of companies investing in the market of orphan drugs is known and that leads to the control of the market. Monopoly takes place in most cases of orphan drugs with high prices and low availability. Non Profit organizations exist in a parallel performance to governments to provide a unified voice and support people living with rare diseases. The model shouldn't be left to the Non Profit Communities and charity organizations. All Governments in collaboration with World Health Organization must have an entity to support, care, and treat people with rare diseases. In the market dynamics, when demand side is one stakeholder, the prices will fall. This is called monopsony where prices can be controlled by the buyer. People living with rare diseases are all the same regardless of the geographic borders they are behind especially in the small open world. There should be no dependence on governments, charity organizations to provide the healthcare and orphan drugs to people living with rare diseases. The entity created under the umbrella of WHO should compile all rare diseases and orphan drugs to support and provide the one demand for the world to treat all rare diseases.

PHP305

TAKING PATIENTS AS PARTNERS IN RESEARCH

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Despite the increasing number and scope of patient involvement initiatives, there is no accepted master framework for systematic patient involvement in pharmaceutical medicines development. Patient engagement is more productive, but inconsistent and fragmented on a broader level. Incorporating the patient's perspective in healthcare research is strongly promoted by policy makers, funding bodies and international regulators. Patients have a personal experience of disease that is not available to most researchers, which complements researchers' analytical skills and scientific perspective. Involving patients in research projects improves both the methodology and outcomes of the research, and also offers invaluable additional insights. Contributions by patients to the design, implementation and evaluation of research leads to effectiveness, credibility, and often to more cost efficiency as well. It is essential to ensure that high quality research brings real benefits for patients and their daily lives. Increasing number of studies are now being conducted involving patients in the research. Effective patient engagement is a time consuming process and involves significant investment. The research team and patient partners need to be open to the risks and be flexible in this work together. Mutual trust and integrity are key components to keep open conversation flowing and offers the possibility of allowing the patient voice to impact research studies, which can be incredibly valuable in providing end-use of research results. Future studies with a direct impact on patient-centered outcomes research would directly benefit from engagement with patients as full-team members in their research programs.

PHP306

THE IMPLEMENTATION OF AN EDUCATIONAL PATIENT PROGRAM IN A SPECIALIZED CENTER FOR RHEUMATOID ARTHRITIS IN COLOMBIA

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Rheumatoid arthritis (RA) is a chronic, inflammatory autoimmune disease of unknown etiology, it is a long term condition that causes pain, disability and affects the quality of life (1). In countries like the United Kingdom has been demonstrated how patient education can empower the individual giving as a result a better decision making between the practitioner and patient in order to obtain better health care outcomes compared to patients that are not involved in educational activities (1). In a specialized RA center in Bogotá Colombia during 2016 we started a patient and caretaker oriented program to support the clinical treatment in patients with RA. The structure of the program was an educational-recreational strategy where we integrated health education (disease activity, pharmacovigilance, psychology and nutrition) and recreational activities such as crafts, yoga, aerobics and dance lessons with a periodicity of two times per week. We called the program "Gest-Art". As a result of this pilot program we obtained a positive impact and perception among patients and care takers; we had the participation of 600 people during the whole year. From this experience we can conclude that the implementation of this educational program opened the opportunity to empower and motivate our patients and care takers to be actively participative with the disease management and health care, also the program has been a space for the patients to share their experiences and to propose new strategies to improve the program which opens the communication channels to build in 2017 a multi-participative program where the patients and care takers are a fully participative component. References 1. Prothero L, Georgopoulou S, de Souza S. Patient involvement in the development of a handbook for moderate rheumatoid arthritis. 2016.

PHP307

UTILIZING HEOR METHODS TO SUPPORT QUALITY DATA AND DECISION-MAKING FOR BETTER HEALTH OUTCOMES THROUGH COMPLEMENTARY AND INTEGRATIVE HEALTH APPROACHES

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The 1994 Dietary Supplement and Health Education Act (DSHEA) has been a key factor in influencing the use of Complementary and Integrative Health (CIH) approaches. Along with natural products or dietary supplements, there has been an increase in the use of mind-body approaches such as yoga, osteopathic and chiropractic manipulations, etc., with estimates of approximately 36% of the US population having used at least one such approach in prior two years¹ and 33.2% of the US population using it for pain management as per the National Health Information Survey (NHIS).² From patient perspective, there has been a consistent increase over the last two decades in the use of CIH approaches for various disease indications despite this being out-of-pocket expenditure. This is because it is at odds with the Commercial Payers' perspective that focuses on elements like evidence-based improvements in health outcomes, specific clinical endpoints and lower cost (decreased hospitalizations, medication use, emergency room visits). CIH approaches that include conventional treatment along with complementary practices, may augment patient health experience positively, reducing health disparities and provide better health outcome at potentially lower cost, satisfying both the patient and commercial payer's perspective. 1 For conventional healthcare systems to adopt truly integrated CIH approach, the major drivers will have to include clinical and cost-effectiveness parameters. Outcomes research assessing impact on quality of life, can be pivotal in bringing this approach to the commercial payer's domain. We also propose an organized database accessible to the relevant stakeholders, mapping the use of CIH approaches by patients in the real world. Such information linking specific approaches to specific therapeutic areas can lead to better understanding and help in devising strategies to selectively bring CIH approaches to the mainstream. Kinser PA, et al. Evidence based Complementary and Alternative Medicine, Vol 2016, Article ID 2156969 <https://ncchih.nih.gov/health/integrative-health> accessed on 18th Jan 2017

PHP308

OVERCOMING THE CHALLENGES OF ESTABLISHING EXPANDED ACCESS PROGRAMS IN EUROPEAN MEMBER STATES – A REGIONAL REVIEW

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OBJECTIVES: To review current status and challenges associated with mechanisms governing the provision of unlicensed pharmaceutical compounds in areas of high unmet need outside of clinical trials. Recommendations for avoiding common pitfalls will be provided based on review of actual case studies in selected markets. **DISCUSSION:** While the European Medicines Agency (EMA) provides recommendations through the Committee for Medicinal Products for Human Use (CHMP), Expanded Access Programs (EAPs) are mainly regulated at country level. The main markets (EUS, Austria, Belgium, The Netherlands, Portugal and some Nordic countries) have defined EAP procedures. Most Eastern European countries do not, or are currently developing legislation. The EU directive does not set requirements for charging of investigational medicinal product, Member States set their own pricing and reimbursement rules. This lack of a common legal framework has led to national programs that differ widely due to differences in clinical practices, hospital structures, national insurance systems, pricing and reimbursement and funding pathways. The possibility of charging for these products is different from one country to another. Furthermore,

future price can be influenced by the price of the product in an EAP and by the timing of the negotiations. The complexity of managing these programs has increased, particularly in countries where it can take over 20 months to agree reimbursement after marketing authorization, delaying patient access. Under-estimation of the set-up complexities, language issues, cost and duration of an access program, failure to reliably predict demand and ensure that sufficient drug is available, and failure to define an appropriate exit strategy are common challenges. **CONCLUSIONS:** Implementation of an EAP requires a multidisciplinary strategic approach and allocation of substantial resources. It is important to work with local representatives to understand the specific regional requirements in each country to mitigate potential risks e.g. inadvertently establishing price precedents or benchmarks.

PHP309

IMPACT OF HEALTH SECTOR REFORMS ON HOSPITAL PRODUCTIVITY IN TURKEY: A DATA ENVELOPMENT ANALYSIS (DEA) BASED MALMQUIST INDEX APPROACH

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OBJECTIVES: Health sector reforms are policy changing processes designed to solve efficiency, quality and equity problems associated with the delivery of health services. Health sector reforms create sustained, purposeful and fundamental changes in the health sector (Berman, 1995). As pointed out by Cassels (1995), governments of developing countries have to ensure that an appropriate share of public revenue is allocated to health, that the benefits of publicly-funded health care are equitably distributed; and that resources are used as efficiently as possible, both in terms of maximum health gain for the fund invested and minimum cost for the range of health services provided. Since 2003, the Turkish Ministry of Health (MoH) has embarked upon the implementation of a Transformation Program (HTP) to design a human (i.e., patient) centered health system (Akdağ, 2003). **METHODS:** The Authors used Data Envelopment Analysis and Malmquist index to measure hospital efficiency and productivity in Turkey, after the Turkish government healthcare Reform. **RESULTS:** That study found that the hospital sector in Turkey improved in efficiency and productivity since the implementation of health care reform. This has contributed to lower healthcare spending. **CONCLUSIONS:** Healthcare sector in Turkey has improved overtime bringing Turkey one step closer to joining the European Union, although the service, quality, and productivity are other values that need attention

PHP310

THE TOWWERS PROGRAM: A PILOT PROGRAM TO CAPTURE REAL-WORLD EVIDENCE IN A POPULATION ENVIRONMENT - THE QUEBEC EXPERIENCE

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In the province of Quebec, over the past 30 years, the proportion of healthcare cost has increased significantly, regardless of all the cost containment policies that have been implemented within the system. Today, healthcare represents 48% of the government expenses. Health is a priority but it is not the only one. International organizations are searching to solve the puzzle of coping with patient access - patient centeredness - clinical relevance - affordability - breaking the silos - real world evidence as a mean to optimize patient health and control cost increase. In the province of Quebec, a pilot project is underway to address these issues: the TOWWERS program. The TOWWERS program is a dynamic, interactive, web clinical registry that shares the patient clinical summary (the DOC-P) amongst healthcare professionals and the patient. The ultimate goal of the TOWWERS program is to transform healthcare policymaking paradigm based on budgets towards clinical results, increasing accountability and collaboration of the various actors to develop relevant market access strategies and track the efficiency of treatment plans for the various actors. During this conference, we will share our ongoing experience of a major public-private health partnership of healthcare professionals, patients and their advocacy groups, payers, governments and industry.

PHP311

CHALLENGES FACING PHARMACEUTICAL PRICING IN EGYPT AFTER CURRENCY DEVALUATION HOW TO REACH EQUILIBRIUM

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The central bank of Egypt announced the floatation of the Egyptian pound in November 2016 leading to a significant devaluation against the USD. The pharmaceutical industry was critically affected by the floatation because; ● Pharmaceutical products are subject to compulsory pricing and They represent 31 % of total health spending. ● many of the Products In The Market Had Been Priced Years Earlier at a much Lower Exchange Rate. Which lead to pharmaceutical industry facing the following challenges: ● products went below profitability ● business size shrank by 50% overnight. Consequences were: ● Inability to maintain supply to fulfill tender requirements that were awarded before the devaluation. ● All Patient access programs were reassessed & in many cases suspended. ● Products shortage due to exit of suppliers from Egyptian market and due to distributor and pharmacist holding back stock in anticipation of a price increase. Which create an urgent need from stakeholder (pharma industry - regulatory body) to address the following: ● How the repricing process could achieve the equilibrium between a fair price for the industry and patient

accessibility. ● How to control drug shortage. ● With 71% out of pocket for health expenditure how to minimize the effect of price increase on public. Methods: The following strategies should be implemented : ● Developing clear & fair pricing guidelines that enhance value recognition. ● establish a price elasticity model that accommodates market equilibrium between supply & demand ● (re)pricing policy should be a multi criteria decision including (profit margins for supplier-socioeconomic factors - life saving products -orphan drugs -) ● Enhancing perfect competition elements like(Property rights, exit and entry to the market large number of buyers and sellers, transparent information) ● Expanding health services packages for new social layers to minimize the impact of price increase

PHP312

EQUITY, LAW AND SOCIAL JUSTICE IN THE CONTEXT OF COLOMBIAN HEALTH SYSTEM

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The present work is the result of a perspective exercise that aims to reflect from the conception of human rights to the consequences of a health system centered more on the treatment of diseases that ultimately becomes inefficient. This study is a perspective paper about equity, justice and rights in the context of the Colombian Health System, going from a philosophical conception of first- and second-order rights, to finally characterize the current Health System to which the Colombian population is "exposed". With real examples it is shown that Colombia fails at being a welfare State, focusing in first-order rights more than in second-order rights. This work demonstrates not-favorable outcomes on collective rights of the Colombian population, partly due to the lack of morality of its implicit actors, to the fragile structure for a true regulation of the health system, and corruption in health, among other causes. With all of these issues, there is no space for a true social justice, leading to a worsening status of health inequities. The importance of this work is to generate and to promote new policy efforts to change the current weak and unstable Colombian health care system that could finally lead to an improvement of social justice and inequities in health.

PHP313

"THE PICKWICKIAN SYNDROME" A STORY OF BULG AND THE ROLE OF PROBIOTICS

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In the present scenario, the health of Homo sapiens is drastically deteriorating due to man's desire for rapid industrialization and urbanization. The heart-warming conditions like cardiovascular disease remain the world's main cause of mortality and are linked to high blood cholesterol and chronic low grade inflammation. The emerging trends of multidrug resistance among several groups of microorganisms against different classes of antibiotics led to use of probiotics for cholesterol lowering has been extensively studied and is considered a prospective option to prevent cardiovascular diseases like pickwickian syndrome which is also known as the Obesity hypoventilation syndrome (OHS). The use of probiotics for cholesterol lowering has been extensively studied and is considered a prospective option to prevent cardiovascular disease. In this study we report the causes of Pickwickian syndrome, clinical safety and efficacy of cholesterol lowering probiotics like *Lactobacillus reuteri* and other strains. **KEYWORDS:** Cardiovascular disease, biotechnology, probiotic, *Lactobacillus reuteri*, Obesity Hypoventilation Syndrome (OHS)

PHP315

THE IMPORTANCE OF CHARACTERISING UNCERTAINTY IN MODEL-BASED ECONOMIC EVALUATIONS OF STRATIFIED MEDICINE

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Stratified medicine requires that treatment decisions are informed by a strategy (usually a test) that reveals previously unobserved heterogeneity within a patient population. The relative costs and benefits of a stratified medicine can be evaluated with a model-based cost-effectiveness analysis (CEA). Understanding the type and impact of the uncertainty inherent in model-based CEA is necessary to inform the appropriate allocation of health care budgets. In contrast to conventional pharmaceuticals, there is frequently a lack of evidence that demonstrates the relationship between a test result and the treatment-related health outcome, which can, among other factors, contribute towards greater uncertainty. The objective of this conceptual study is to discuss the importance of characterising the types of uncertainty in model-based CEA relevant to stratified medicine. Four types of uncertainty were defined, using systematic searches of the literature and supported by identifying relevant examples of uncertainties within appraisals for the NICE Diagnostics Assessment Programme: methodological, structural, parameter, and decision uncertainty. Methodological uncertainty is apparent when decision-makers and analysts consider whether the CEA evaluative framework is appropriate for a stratified medicine. Structural uncertainty arises from different views about the relevant test-and-treatment pathways and the appropriate choice of model type needed to reflect the positioning, frequency, and consequence of test combinations. Consideration of parameter uncertainty is essential given the relatively poor evidence base available to populate model-based CEA. The interpretation of value of information analyses within model-based economic evaluations of stratified medicine should be made with reference to both parameter and structural uncertainties. Decision uncertainty associated with recommendations for stratified medicine may be greater than for conventional pharmaceuticals resulting from limitations in the support-

ing evidence base. It is vital that decision-makers are aware of the influence of all types of uncertainty to fully understand the opportunity cost and relative value of introducing stratified medicine into practice.

PHP316

IMPLICATIONS FROM HEOR AND RWE MODELS FOR BIOPHARMACEUTICAL COMMERCIAL ANALYTICS TO DEMONSTRATE DRUG VALUE THROUGH SALES AND MARKETING OF SPECIALTY MEDICINES

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Biopharmaceutical industry trends show an increased focus on specialty medicines. Specialty medicines account for 35% of US drug total spending, half of total spending growth is on new drugs available for <2 years, and with oncology comprising 35% of all 2015 new drug launches. However, biopharma pricing of specialty medicines is not economically sustainable. There is a growing gap between rising costs of pharmaceutical R&D for drug innovation and individual/societal willingness and ability to pay for this innovation. Numerous complications arise from specialty medicines catering to orphan drug-like patient populations. Drug pricing and demonstration of value problems are acute with targeted personalized anti-cancer medicines. What can biopharma companies do to demonstrate value for specialty medicines when conducting sales and marketing? Traditional commercial model design that emphasizes unit sales growth will not suffice. The literature lacks practical mechanisms companies can use to bridge implications from HEOR/RWE models with commercial operations for successful demonstration of drug value that benefits patients and the healthcare system. This proposed research presentation will provide a conceptual framework that combines traditional HEOR/RWE models with commercial analytics (defined as commercial model design, payer/patient/sales/marketing analytics, commercial analytics innovation center, and cloud information management) to support informative sales and marketing activities of specialty medicines. The result will be a more effective demonstration of drug value through sales and marketing by improving health outcomes, cost-effectiveness, and overall healthcare spending. Commercial analytics activities are becoming interdependent as opposed to distinctly-operating functions. Payer/patient analytics will be the principal emphasis and drive all commercial decisions leveraging outcomes from HEOR/RWE modeling. All remaining analytics will be to support payer/patient outcomes. A new approach to commercial analytics is needed, requiring greater alignment among these activities, an open-system framework in solving commercial problems, data environment constructed to support these activities, and leadership/organizational changes.

DISEASE-SPECIFIC STUDIES

INFECTION – Clinical Outcomes Studies

PIN1

ANALYSIS OF ADVERSE DRUG REACTIONS IN PATIENTS WITH TUBERCULOSIS ALONE AND IN COMBINATION WITH HIV COINFECTION : A PROSPECTIVE OBSERVATIONAL STUDY

Name HM3

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OBJECTIVES: The main objective of the study is to monitor and detect adverse drug reactions during treatment of pulmonary tuberculosis, and to compare their incidence, frequency and severity with patients having TB-HIV co-infection. **METHODS:** We conducted a prospective study on patients who visited DOTS center between December 2014 and November 2016 in Govt. Infectious Disease Hospital, Guntur, Andhra Pradesh, India. Any symptomatic adverse event observed by the clinician or reported by the patient was recorded in the standard patient treatment booklet of the National Tuberculosis and Leprosy Programme. **RESULTS:** One hundred and thirty two patients completed the study. Maximum number of ADRs observed in one patient is 13. Twenty six patients (19.6%) had TB-HIV co-infection. Majority (53.1%) of the events are moderate. All the serious events occurred in TB-HIV group. Out of 132 patients, the commonly occurring ADRs were neuropathy (n=40, 10.3%) followed by anorexia (n=39, 10%) and polydipsia (n=36, 9.25%). Gastrointestinal ADRs were highest in number followed by the nervous system related reactions. Type A reactions were more common in TB group (p < 0.001). **CONCLUSIONS:** ADRs are more likely to occur and to persist in HIV co-infected patients than in HIV uninfected patients. Clinicians should employ various strategies for preventing drug-induced patient discomfort and harm, such as reducing the dose or stopping the suspected offending medicine.

PIN2

ACTIVE VERSUS PASSIVE PHARMACOVIGILANCE: ADALIMUMAB-RELATED INFECTIONS REPORTED IN OBSERVATIONAL STUDIES COMPARED WITH THE FDA'S ADVERSE EVENT REPORTING SYSTEM CASES

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OBJECTIVES: To compare adalimumab-related infections reported in observational studies to those reported in the U.S. FDA's Adverse Event Reporting System (FAERS). **METHODS:** Using MedDRA® preferred terms (PTs), infection and infestation cases in FAERS with adalimumab as the primary suspect drug were extracted through Evidex™. Completed observational studies with results reported on ClinicalTrials.gov (OS-CTs) were extracted. Exclusion criteria for observational studies were: 1) did not assess safety, 2) contained duplicate data from another observational study and 3) reported only serious adverse events. For each

infection PT, the percentage of the total number of infections from each source was determined. **RESULTS:** In FAERS, 58,012 cases with 824 different infection PTs were found. The 10 most frequently reported PTs in FAERS were nasopharyngitis (15.5%), sinus (7.8%), pneumonia (6.2%), bronchitis (5.6%), influenza (4.5%), urinary tract infection (3.9%), Herpes Zoster (3.3%), upper respiratory tract infection (2.6%), cellulitis (2.2%) and ear infection (1.8%). Twenty-four OS-CTs were included, comprising 2,284 cases with 272 infection PTs. The 10 most frequently reported PTs in OS-CTs were nasopharyngitis (15.7%), bronchitis (13.7%), urinary tract infection (10.8%), pneumonia (5.7%), respiratory tract infection (4.2%), upper respiratory tract infection (2.8%), Herpes Zoster (2.2%), sinusitis (1.9%), sepsis (1.7%) and pharyngitis (1.7%). Thus, 7 of the top 10 infection PTs matched and 3 were reported at rates within 0.5% of each other. Respiratory cases accounted for 6 and 7 of the top 10 infection PTs in FAERS and OS-CTs, respectively. **CONCLUSIONS:** The study demonstrates good comparability between adalimumab-related infection cases reported in FAERS and OS-CTs. Differences in the percentages of cases may relate to severity, as likely only the most severe infections would be reported to FAERS. Results indicate that passive (FAERS) and active (observational studies) pharmacovigilance provide similar results for common infections. This finding supports the usefulness of FAERS in post-marketing drug safety assessment.

PIN3

ANTIBIOTIC UTILIZATION, TREATMENT OUTCOMES, AND ECONOMIC IMPACT IN SEPSIS PATIENTS: RETROSPECTIVE ANALYSIS OF A LARGE US ELECTRONIC HEALTH RECORD DATABASE

Peyerl FW, Khangulov VS, Hayashi DE, Talaga AK, D'Souza FT

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OBJECTIVES: Approximately 7% of total healthcare expenditure in the US is due to hospitalizations for severe infections. Treatment of sepsis patients accounts for 1.15 MM hospital admissions every year. The objective of this study was to examine antibiotic utilization and associated outcomes and cost in a large sample of US sepsis patients. **METHODS:** An electronic health record dataset (Cerner Health Facts®) containing over 600 hospitals and 272MM patient visits was examined for this retrospective study. Adult inpatients and outpatients diagnosed with sepsis during an emergency admission between January 2010 and March 2015 were retrospectively analyzed. **RESULTS:** The final study population included 47,842 patient visits. The most common antibiotics used were vancomycin (14.4%), piperacillin-tazobactam (14.3%), and levofloxacin (12.8%). Based on median severity of illness scores, gentamicin and piperacillin-tazobactam were prevalently used to treat severe infections. Patients with severe infections were observed to have high length of stays (LOS), with gentamicin (median LOS 7.5 days), metronidazole (median LOS 8.7 days), and linezolid (median LOS 8.7 days) patients having the highest LOS of the top ten antibiotics. Patients on linezolid experienced the highest mortality rates (17%) and cost per patient (mean total cost of \$40,226), despite having similar severity of illness scores to other commonly used antibiotics. In contrast, patients treated with levofloxacin experienced the lowest median cost per visit (\$22,902) and mortality rate (6%). **CONCLUSIONS:** Sepsis patients treated with levofloxacin experienced the lowest patient cost per visit and mortality rate compared to sepsis patients treated with other antibiotics. Severe patients, treated with other antibiotics such as piperacillin-tazobactam, gentamicin, and linezolid, experienced higher mortality rates, longer length of stays, and higher treatment costs.

PIN4

ANTIBIOTIC UTILIZATION, TREATMENT OUTCOMES, AND ECONOMIC IMPACT IN PNEUMONIA PATIENTS: RETROSPECTIVE ANALYSIS OF A LARGE US ELECTRONIC HEALTH RECORD DATABASE

Peyerl FW, Khangulov VS, Hayashi DE, Talaga AK, D'Souza FT

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OBJECTIVES: In 2014, the US healthcare spending surpassed \$3.0 trillion with nearly 1/3 (\$971 billion) spent on hospitalizations. An estimated 1.14 MM patients are admitted to the hospital every year for treatment of pneumonia. The objective of the present study was to examine the current antibiotic utilization and associated outcomes and cost in a large sample of US pneumonia patients. **METHODS:** We examined prospectively collected data from a US electronic health record dataset (Cerner Health Facts®) representing 614 US hospitals and over 272MM patient encounters. Inpatient and outpatient encounters between January 2010 and March 2015 involving adult patients diagnosed with pneumonia during an emergency admission were retrospectively analyzed. **RESULTS:** The final study population included 103,502 patient encounters. The most common antibiotics used were levofloxacin (19.7%), ceftriaxone (13.8%), and azithromycin (11.0%). Gentamicin, ciprofloxacin, and piperacillin-tazobactam were commonly used to treat more severe infections, based on median severity of illness score. Severe patients treated with these antibiotics were observed to have a high median length of stays (LOS) compared to patients treated with the other top ten antibiotics, with gentamicin (median LOS 9.0 days), metronidazole (median LOS 8.9 days), and ciprofloxacin (median LOS 7.0 days) patients having the highest LOS. Patients on gentamicin had higher mortality rates (18% vs. 13% as the next highest in top ten) and cost per patient (median total cost of \$80,682 vs. \$39,314 as the next highest in top ten), potentially due to high median severity of illness scores compared to other commonly used antibiotics. **CONCLUSIONS:** This analysis identified key trends in antibiotic usage in pneumonia patients. Gentamicin was used to treat severe patients, resulting in longer length of stays and higher costs per patient. Conversely, patients treated with other commonly used antibiotics such as levofloxacin, ceftriaxone, and azithromycin, were less severe and experienced shorter length of stays and lower mortality rates.

PINS

TREATMENT OUTCOMES AMONG HIV/AIDS PATIENTS TREATED DURING HAART THERAPY AT INFECTIOUS DISEASE CLINIC

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OBJECTIVES: Current study is aimed to explore and to observe clinical treatment outcomes during HAART therapy among HIV/AIDS patients. **METHODS:** An observational retrospective study of all patients diagnosed of HIV infection and on HAART therapy from Jan 2007 to Dec 2012 was conducted at infectious disease department of Hospital Pulau Pinang, Malaysia. Data was descriptively analyzed by using statistical package for social sciences (SPSS 20). **RESULTS:** Out of 792 patients that underwent HAART therapy, 607 (76.6%) were male and 185 (23.3%) were female patients. The treatment outcome of the total study population (792) on the basis of recovery of CD4 cells count to the normal range was (≥ 350 cells/mm³). Out of total patients (792), 645 (81.4%) patients improved their CD4 cells count under the treatment of HAART therapy out of which 488 (61.6%) male and 157 (19.8%) female patients were improved to a normal range of CD4 cells count. On binary logistic regression both Malay (OR 2.32, $p < 0.001$) and Chinese patients (OR 0.37, $p < 0.001$) were found to be statistically significant. Patients having age less than 30 years (OR 0.58, $p 0.09$), with secondary education level (OR 0.44, $p 0.001$), and Graduate patients (OR 0.50, $p 0.09$) were also have a significance association with treatment outcomes. Non-smokers (OR 2.16, $p 0.001$), non-alcoholic (OR 1.42, $p 0.05$) and non-drug abusers were also found to be statistically significant. **CONCLUSIONS:** The study indicates the clinical treatment outcomes in non-smokers, non-alcoholics and non-drug abusers HIV patients were higher. Also indicate a significant treatment outcomes on educated patients which may be due to the awareness about the infection. However, a multicenter study with a large sample size may provide us with better understanding of this relationship

PING

OUTCOMES AND ECONOMIC BURDEN OF ANTIBIOTIC-RESISTANT SEPSIS

PATIENTS: RETROSPECTIVE ANALYSIS OF A LARGE US ELECTRONIC HEALTH RECORD DATABASE

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OBJECTIVES: Hospitalizations for severe infections account for approximately \$212 billion in annual spending, at an average cost of \$15,500 per occurrence. Sepsis accounts for approximately 12% of all hospital stays and over 40% of bacterial sepsis cases are caused by drug resistant organisms. The objective of the present study was to examine the outcomes and costs associated with drug resistant sepsis in a large sample of US patients. **METHODS:** We examined an electronic health record (EHR) database with information collected from 614 hospitals across the US. Encounters involving adult inpatients and outpatients diagnosed with sepsis during an emergency admission between January 2010 and March 2015 were retrospectively analyzed. **RESULTS:** The final study population included 47,842 patient visits. The most common bacterial species in sepsis infections were *Escherichia coli* (19%), *Staphylococcus aureus* (10%), and *Staphylococcus sp.* Coag Negative (7%). Sepsis patients with drug resistant infections experienced higher median hospital costs (\$14,088) compared to patients with drug susceptible infections (\$11,084). Acute kidney injury was 16% more prevalent in patients with drug resistant sepsis (drug resistant 26.8%; drug susceptible 23.0%). Patients with drug resistant infections experienced 22% longer length of stays (LOS) in the intensive care unit (ICU) and 26% longer LOS in the hospital (median ICU LOS 4.4 days vs. 3.6 days; median hospital LOS 9.0 days vs. 7.1 days). We observed a similar trend for mortality rate, as patients with drug resistant pneumonia were over 300% more likely to die in the hospital (mortality rate 5.64% vs. 1.27%). **CONCLUSIONS:** This analysis identified important differences in clinical outcomes, LOS, and cost in sepsis patients with drug resistant bacterial species and drug susceptible bacterial species. Drug resistant bacterial infections resulted in higher mortality rates, longer hospital stays, and higher treatment costs.

PIN7

OUTCOMES AND ECONOMIC BURDEN OF ANTIBIOTIC-RESISTANT PNEUMONIA

PATIENTS: RETROSPECTIVE ANALYSIS OF A LARGE US ELECTRONIC HEALTH RECORD DATABASE

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OBJECTIVES: Approximately 13.7 million hospital discharges in 2013 (~30% of all hospital discharges) involved treatment of infectious organisms. An estimated 1.14 MM patients are admitted to the hospital every year for treatment of pneumonia and over 20% of bacterial pneumonia cases are caused by drug resistant organisms. The objective of the present study was to examine the outcomes and costs associated with drug resistant pneumonia in a large sample of US patients. **METHODS:** This retrospective study examined prospectively collected data from a large, de-identified US electronic health record database covering >49M patient encounters from >600 participating facilities. We retrospectively analyzed encounters involving adults diagnosed with pneumonia during an emergency inpatient or outpatient admission between January 2010 and March 2015. **RESULTS:** The final study population included 103,502 patient visits. The most common bacterial species in pneumonia infections were *Staphylococcus aureus* (9%), *Staphylococcus sp.* Coag Negative (9%), and *Escherichia coli* (9%). Drug resistant infections resulted in higher median hospital costs per patient compared to drug susceptible infections (\$16,171 vs. \$11,451). Patients with drug resistant pneumonia were 26% more likely to experience acute kidney injury (drug resistant 24.6%; drug susceptible 19.5%). Length of stays (LOS) in the intensive care unit (ICU) and hospital were 26% and 33% higher, respectively for patients with

drug resistant pneumonia (median ICU LOS 7.5 days vs. 6.0 days; median hospital LOS 11.9 days vs. 9.0 days). Additionally, patients with drug resistant pneumonia had higher mortality rates (3.40% vs. 0.81%). **CONCLUSIONS:** This analysis identified greater hospital costs, longer length of stays, and higher mortality rates in pneumonia patients with drug resistant bacterial species compared to patients with drug susceptible bacterial species. These findings provide insights into resource allocation for treatment of drug resistant infections and support the importance of developing treatment options to circumvent established antibiotic resistances.

PING

CONCOMITANT UTILIZATION OF COMPLEMENTARY AND ALTERNATIVE MEDICINE, AND ANTIRETROVIRAL THERAPY AMONG HIV-INFECTED PATIENTS: PREVALENCE, PATTERNS AND OUTCOME

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OBJECTIVES: To evaluate the prevalence and patterns, and covariates of concomitant use of complementary and alternative medicine (CAM) and Antiretroviral Therapy (ART) and the impact on ART adherence and viral load suppression among HIV-infected patients engaged in care in Houston/Harris County, Texas. **METHODS:** Data used for this study were obtained from the Medical Monitoring Project (MMP) survey conducted in Houston/Harris County, Texas between 2009 and 2013. We estimated the prevalence and patterns of concurrent use of CAM and ART among persons receiving HIV medical care in the past 12 months, and determined the relationship with ART adherence and viral load suppression. The data obtained were subjected to descriptive and inferential statistics using the SAS software version 9.4. **RESULTS:** Concomitant use of CAM and ART (CAM-ART) was significantly ($p < 0.0001$) more prevalent among Whites (44.9%, 95% CI: 33.4-56.4) than blacks (34.0%, 95% CI: 24.6-43.4) and Hispanics (17.1%, 95% CI: 9.3-24.9). CAM-ART use increased significantly ($p < 0.0001$) with age and education, peaking at age 45-54 years (42.1%, 95% CI: 32.7-51.6) and among those educated beyond high school (62.0%, 95% CI: 49.9-74.1). More males than females used this self-management approach (79.3% vs. 18.7%, $p < 0.0001$). Common CAM modalities used include biologically based therapies (84.5%), mind-body medicine/manipulative body-based therapies (25.4%), spiritual healing (14.2%), and energy therapies (2.4%). Among CAM-ART users, 83.5% ($p < 0.0001$) were adherent to ART. We noted no significant variations in viral load suppression among CAM-ART users and non-users. **CONCLUSIONS:** The use of these therapies is suggestive of complementary roles rather than as substitutes for ART. However, it is very important that CAM-ART users consult with their clinicians to avoid any potential side effects or interactions with ART, and to ensure patient safety. Further research is needed to explore reasons for use and the possible health benefits or risks associated with long term use of CAM.

PING

BURDEN OF INVASIVE PNEUMOCOCCAL PNEUMONIA AMONG INDIAN

CHILDREN: A SYSTEMATIC REVIEW AND META-ANALYSIS OF OBSERVATIONAL STUDIES

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OBJECTIVES: Pneumococcal pneumonia is a vaccine preventable disease. Despite this fact, it is one of the leading causes of childhood morbidity and mortality in Indian children. Limited data on its burden and serotype prevalence is one of the reasons for non-inclusion of the vaccine in national immunization schedule. The aim of the present study is to estimate the overall prevalence of invasive bacterial pneumonia caused by *Streptococcus pneumoniae* in Indian children. **METHODS:** This systematic review was performed using Cochrane Library; Pubmed; Google Scholar and Science Direct. Further, the reference list of related papers was also screened for additional studies. Patients under 12 year of age and diagnosed with invasive bacterial pneumonia caused by *S. pneumoniae* was included. Published studies up to JANUARY 2016 were included. Publication bias was assessed by using the Egger's and Begg's tests along with funnel plot. Newcastle-Ottawa scale was used to assess the study quality. Heterogeneity was assessed using Cochrane Q-statistics test and I² statistics. Random-effects model was used to report the pooled prevalence with 95% confidence intervals (CI). **RESULTS:** A total of 6 studies, covering a total of 40083 patients and from different geographical regions in India were included. The number of study participants ranged from 132-37070. And, the period of surveillance ranged from 1-2 years. The pooled prevalence of bacterial pneumonia caused by *S. pneumoniae* in Indian children under 12 year of age was found to be 24.5% (95% confidence interval 11.2%-45.4%). The pooled prevalence of bacterial pneumonia caused by *S. pneumoniae* 45.9% (30.6%-62%) was found to be higher in children under 6 years of age. **CONCLUSIONS:** Bacterial pneumonia caused by *S. pneumoniae* has a significant burden among Indian children. The inclusion of pneumococcal vaccine in the Indian public health programme may help in decreasing this burden.

PIN10

INCIDENCE OF PERTUSSIS AMONG INDIVIDUALS AGED 0-64

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OBJECTIVES: Pertussis is an infectious respiratory disease which affects individuals of all ages. Pertussis incidence has increased in recent decades, despite established childhood vaccination programs. To better understand recent trends in pertussis disease, and the impact of new adult vaccination recommendations, we used administrative health care claims data to estimate the incidence of pertussis among individuals aged 0-64 from 2006 to 2015. **METHODS:** Individuals aged 0-64 years with evidence of a pertussis diagnosis from 1/1/2006-12/31/2015 were identified from commercial claims in the Optum Research Database (ORD). Annual pertussis incidence was calculated as the ratio of newly diagnosed pertussis cases

over the total person-time at risk. Incidence rates were standardized to the 2010 US Census on age, sex and geographic division. **RESULTS:** From 2006-2015, 17,350 pertussis cases aged 0-64 were identified with 61.3% of cases among adolescents or adults. The overall standardized incidence of pertussis was 14.6 cases/100,000 person-years (PY). The incidence of pertussis among all age groups peaked in 2012 at 23.3/100,000 PY (178.9/100,000 PY among infants <1) and declined to 12.9/100,000 PY in 2015 (infants: 96.5/100,000 PY), consistent with trends reported by the CDC using nationwide surveillance data. On average, standardized incidence rates estimated from the ORD were more than twice as high as those reported by the CDC. **CONCLUSIONS:** Our results suggest that pertussis incidence may be higher than previously estimated, and that medical claims data can provide an important alternative perspective on disease incidence. Incidence of pertussis has been declining since the CDC recommended vaccination for all adults in 2012, with more rapid declines among infants. Findings from this study highlight the continued importance of pertussis management and prevention strategies among individuals from all age groups, especially adolescents and adults as they are known to represent a main source of transmission to infants.

PIN11

INCIDENCE AND TREATMENT OUTCOME OF TUBERCULOSIS AMONG MALAYSIAN PRISONERS

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OBJECTIVES: To assess the incidence of TB among prison inmates in four Malaysian states and evaluate their treatment outcomes. **METHODS:** A multicenter, cross-sectional, retrospective study was conducted in the eleven prisons in four Malaysian states, which were selected based on high burdens of TB in Malaysia (Sabah, Sarawak, Pulau Pinang, and Selangor). Patients with confirmed TB were selected for the study based on tuberculin skin testing, and further established by chest radiograph (CXR), sputum positive and culture positive test. **RESULTS:** A total of 405 inmates were diagnosed with TB. The majority were male inmates (n=397, 98%). The mean age of inmates with TB was 39.28 (SD ± 10.12) years. The sample was ethnically diverse and consisted mainly of Malays (n = 203, 50.1%) followed by Chinese (n = 98, 24.2%), Indians (n = 64, 15.8%), and other ethnicities (n = 40, 9.9%). Of the 405 inmates with TB, the majority were in Selangor state prison (n= 312, 77%); the incidence rate was 755/100,000. The overall incidence of TB among the four state prisons in Malaysia was 440/100,000. The treatment outcomes of 279 (68.8%) inmates with TB was successful; 31 (7.7%) were defaulters; 12 (3%) were transferred to other prisons, 34 (8.4%) died, and treatment was continued in 49 (12.1%) inmates with TB. TB, age group (p 0.002), marital status (0.001), duration of sentence (p 0.005), and other factors were independently associated with the tuberculin skin test. **CONCLUSIONS:** A high incidence of TB was among the prison inmates in four Malaysian states indicates that the existing medical care in prisons requires improvement in order to address the spread of TB in prison.

PIN12

CHANGING EPIDEMIOLOGY OF PNEUMOCOCCAL MENINGITIS IN THE UNITED STATES, 2008-2013

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OBJECTIVES: The purpose of this study was to characterize U.S. national trends of the incidence of pneumococcal meningitis (PM), with an interest in differences prior- and post-licensure of the 13-valent pneumococcal conjugate vaccine (PCV13). The objectives were 1) to describe the incidence and related outcomes of PM patients and 2) to evaluate risk factors for PM among adults with selected chronic medical conditions. **METHODS:** This was a retrospective analysis of the National Inpatient Sample from 2008 to 2013. Patients were identified with the International Classification of Diseases, Ninth Edition, Clinical Modification diagnosis code for PM (320.1). Three periods were observed: 2008-2009 (pre-PCV13), 2010 (transition year), and 2011-2013 (post-PCV13). Data were weighted to generate national estimates and hospitalizations were reported per 100,000 discharges. In-hospital mortality and length of stay (LOS) were presented descriptively and a multivariable logistic model was utilized to identify risk factors associated with PM. **RESULTS:** During 2008-2013, there were 9283 hospitalizations due to PM in the U.S. Incidence of PM remained steady up to the introduction of PCV13 following which PM incidence increased from 3.96 hospitalizations/100,000 in 2011 to 4.14/100,000 in 2013. From 2011-2013, similar increases were seen for median LOS (8.64 days to 9.3 days) and in-hospital mortality (9.55% to 11.19%). In children aged <2 years the rate of PM hospitalizations increased from 2011-2013 (0.18/100,000 to 0.22/100,000) with a similar increase among children aged 2 to 4 years (0.06/100,000 to 0.18/100,000). Significant risk factors for PM in adults aged 19-64 years included alcoholism (aOR=2.89; 95% CI: 2.16, 3.86), diabetes (aOR=1.80; 95% CI: 1.44, 2.25), and chronic heart failure (aOR=2.44; 95% CI: 1.64, 3.63). **CONCLUSIONS:** Following the introduction of PCV13, incidence of PM increased in the U.S. with a similar trend in patient mortality and hospital LOS. Selected chronic medical conditions in which PCV13 is not indicated are risk factors for PM.

PIN13

COMPARISON OF ADVERSE PREGNANCY OUTCOMES BETWEEN ANTI-MALARIAL DRUGS: A BAYESIAN NETWORK META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS AND COHORT STUDIES

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OBJECTIVES: Head to head comparison studies are difficult to conduct in pregnant women. Bayesian network meta-analysis can be used to estimate the differences

between treatment arms, between studies. The present study is a network meta-analysis of safety of anti-malarial drugs used to treat malaria in pregnant women. **METHODS:** A thorough literature search was conducted in electronic databases for either randomized controlled trials or prospective cohort studies in pregnant women with malaria, prescribed two different classes of anti-malarial drugs and reported adverse pregnancy outcomes such as still birth, miscarriage and congenital abnormalities. Odds ratio with 95% confidence interval was used as the effect estimate. Random-effects model was chosen and the Markov Chain Monte Carlo method was used to run 10,000 iterations. Step plots, rankogram using surface under the cumulative ranking curve (SUCRA) and inconsistency in results between direct and indirect comparisons were evaluated. **RESULTS:** A total of 1242 papers were obtained with the search strategy, of which nine evaluating 15 treatment arms in a total of 9476 participants were found eligible for this meta-analysis. No significant differences in risk of adverse pregnancy outcomes were observed between the different anti-malarial drugs evaluated in the present review. The combination of amodiaquine with sulphadoxine-pyrimethamine was found to be the safest anti-malarial agent. **CONCLUSIONS:** The anti-malarial drugs recommended by various guidelines as well as those assessed in randomized controlled trials and prospective cohort studies in pregnant women with malaria have comparable effect on adverse pregnancy outcomes.

INFECTION – Cost Studies

PIN14

A BUDGET-IMPACT ANALYSIS OF QUADRIVALENT INFLUENZA VACCINE USE IN THE UNITED STATES

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OBJECTIVES: Influenza causes annual epidemics whose clinical and economic impacts show large seasonal variability. Although quadrivalent influenza vaccines (QIVs) provide broader protection against circulating influenza B lineages, use of trivalent influenza vaccines (TIVs) in the United States (US) persists. The objective of this study was to estimate the clinical and budgetary impact of converting remaining TIV market share to QIV in the US, while accounting for influenza's seasonal epidemiologic variability more precisely than previous models. **METHODS:** A budget-impact model was constructed using season-specific epidemiological parameters (e.g., attack rates, hospitalization rates) derived from Centers for Disease Control and Prevention published data for eight recent seasons; previous modeling approaches used average parameter values across seasons, including average attack rates from vaccine clinical trials conducted over limited seasons. The base-case estimates the annual budget impact (2016 US\$) of converting 100% of current TIV market share to QIV in the US population aged ≥6 months. Influenza cases prevented were estimated using 2015/2016 vaccine coverage estimates, as well as influenza A/B type-specific vaccine efficacy data. Influenza-related outcomes and costs were then estimated using a decision-tree framework. Scenario analyses considered different payer perspectives and TIV market share conversions. **RESULTS:** Using mean parameter values across the eight influenza seasons, converting TIV market share to QIV resulted in 84,272 fewer influenza cases, 1,354 fewer hospitalizations, and 67 fewer deaths annually, with a corresponding budget impact of \$0.013 per-person per-month (PPPM). Results varied substantially based on the epidemiological data from individual seasons, ranging from 211,557 fewer influenza cases and a PPPM cost of \$0.001 using data from 2007/2008 to 11,904 fewer influenza cases and a PPPM cost of \$0.025 using data from 2006/2007. **CONCLUSIONS:** The model estimated that conversion of TIV to QIV results in decreased clinical burden and deaths while slightly increasing costs. Using season-specific epidemiological inputs demonstrated outcome variability by season.

PIN15

BUDGET IMPACT OF ELBASVIR/GRAZOPREVIR (EBR/GZR) FOR THE TREATMENT OF CHRONIC HEPATITIS C (CHC) GENOTYPES 1 AND 4 IN A UNITED STATES (US) HEALTH PLAN

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OBJECTIVES: To assess the financial consequence to a US health plan's direct pharmacy budget when EBR/GZR is added to the formulary for the treatment of G1 and 4 CHC patients. **METHODS:** The budget impact model (BIM) compared two scenarios, without EBR/GZR (scenario 1) and with (scenario 2) EBR/GZR on the formulary. The impact of the addition of EBR/GZR to the formulary was assessed within the context of other FDA-approved treatments for CHC G1 and 4 infection, which were assumed to be on formulary. Regimens and treatment durations were assumed to follow FDA-approved labeling and differed by genotype, presence of cirrhosis, and presence of chronic kidney disease (CKD) stage 4/5. Costs included medication wholesale acquisition costs and RAV testing, and were calculated over a 3-year time horizon. The incremental pharmacy cost of adding EBR/GZR to the formulary was estimated by calculating the total and per-member-per-month (PMPM) costs, with or without EBR/GZR in patients with and without CKD. **RESULTS:** Using an assumed plan size of 4,000,000 members, it was estimated that 11,465 patients with G1 or 4 CHC would be treated over 3 years. The total cumulative direct pharmacy budget was estimated at \$1,062,307,272 (scenario 1) without EBR/GZR, and \$1,002,922,056 after adding EBR/GZR to the formulary (scenario 2), a reduction of \$59,385,216 (5.59%) over 3 years. PMPM cost decreased from \$7.38 to \$7.16 (-3.00%) in year 1, \$6.94 (-5.87%) in year 2, and \$6.79 (-7.90%) in year 3. In CKD stage 4/5 patients, total direct pharmacy budget was estimated at \$14,930,787 (scenario 1) before adding EBR/GZR and \$14,871,236 after adding EBR/GZR to the formulary (scenario 2), a 0.40% reduction. **CONCLUSIONS:** Based on the inputs and assumptions used in the BIM, the introduction of EBR/GZR to the formulary was projected to be cost savings to direct pharmacy budget of a health plan over a 3-year period.

PIN16

RETURN OVER INVESTMENT ANALYSIS ON PNEUMOCOCCAL 13-VALENT CONJUGATE VACCINE CAMPAIGN IN PATIENTS OVER 50 YEARS IN BRAZILIAN PRIVATE HEALTHCARE

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OBJECTIVES: Evaluate the estimated time to achieve breakeven point in a pneumonia vaccination campaign using 13-valent conjugate vaccine in a Brazilian Private Healthcare System (BPHS). **METHODS:** A model developed to measure the time to achieve the breakeven point in a vaccination campaign. For this analysis were taken in consideration pneumococcal diseases epidemiologic data (DATASUS); mortality rates, demographic data (IBGE) and vaccine effectiveness, in a cohort of 2 million lives (based on average of top 10 largest Brazilian Private Health Plans). Were considered direct costs regarding patient treatment and indirect costs such as loss working day. For comparison were produced two scenarios: Scenario 1 the campaign was financed in 50% by the healthcare plan and scenario 2, where the cost is 100% with no cost for the patient. **RESULTS:** Applying the demographic rate of age groups were obtained the target population to be vaccinated (N=455,600). The total investment cost of the vaccination campaign for scenario 1 was BRL 30.2 million, and approximately BRL 60.5 million in scenario 2. The total cost of the pneumococcal diseases events were BLR 179.9 million direct expenses; including indirect costs were BLR 255.7 million. The breakeven point of investment in scenario 1 was under 2 years considering only direct costs and approximately 1 year, when including indirect costs. For scenario 2 the point was reached in approximately 3.5 years considering only the direct costs and approximately 2.5 years when including the indirect costs. **CONCLUSIONS:** The vaccination campaign using the 13-valent conjugate vaccine may represent an alternative medium-term investment improving overall health of the policyholder's portfolio, reducing the number of claims. Vaccine properties of immunological memory guarantee that a greater investment is needed only once, at the outset, requiring a lower maintenance cost for new entrants

PIN17

ECONOMIC OUTCOMES OF DENGUE FEVER IN HOSPITALIZED CASES IN VIETNAM: A CROSS-SECTIONAL STUDY

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OBJECTIVES: Dengue is the most rapidly-spreading mosquito-borne viral disease in the world. The disease is now endemic in more than 100 countries in the World Health Organization (WHO) regions. In 2014, Vietnam had recorded 43,000 cases in 53 provinces with 28 deaths. **METHODS:** A cross-sectional study was conducted in six months between September 2015 and March 2016 at Cu Chi Provincial General Hospital. Cost-of-illness (COI) in this study is estimated under the incidence-based approach from the societal perspective. **RESULTS:** Among 168 patients were interviewed, proportion of adults suffering dengue fever are almost double that of children (64.3% vs 35.7%). The day loss of patient and caregiver were 7.8 ± 2.9 days and 7.6 ± 2.1 days, respectively. Study also found out the average cost per case was 139.3 ± 61.7 USD. The average cost per child was not significantly higher than per adult (151.0 ± 63.5 USD and 132.7 ± 59.9 USD, respectively; $p = 0.068$). The component with the highest proportion of total cost was the cost of hospital bed (50.2%). According to the sensitivity analysis, if the cost of hospital bed and ultrasonic cost was reduced by 10%, the total treatment cost of dengue fever will fall by 5% and 1.6%, respectively. **CONCLUSIONS:** This study can be the basis for formulating investment plans and allocating funds for the treatment and prevention of this disease. In order to estimate the entire socioeconomics burden of disease due to dengue virus, a larger study including both dengue fever and dengue hemorrhagic fever, in several hospitals is needed.

PIN18

DIRECT MEDICAL COST OF INFLUENZA IN VIET NAM: A RETROSPECTIVE STUDY

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OBJECTIVES: Influenza which is imposed a considerable economic and social burden is a common cause of influenza-like illness among children. This study was conducted to estimate cost of illness based on provider perspective of influenza. **METHODS:** A retrospective study was conducted between January 2013 and December 2015 at at Ho Chi Minh city Hospital of Tropical Diseases. Demographic and clinical information was collected from medical records. Treatment cost are composed of cost of hospital bed, cost of diagnosis test, cost of X-ray/Imaging, cost of operation, cost of pharmaceuticals and cost of consumable material. **RESULTS:** Average cost per episode of all aged group was 112.58 ± 239.60 USD, the highest cost was contributed by Adults group (313.28 ± 560.50 USD), whereas the lowest cost was Children group (80.62 ± 120.83 USD). According high risk factor group, average cost per day is 42.14 USD for any cardiovascular disorders group; diabetes-cardiovascular patient (41.15 USD), and elderly patient groups (48.52 USD). **CONCLUSIONS:** Direct medical cost of influenza-related hospitalizations imposes a heavy burden on patients and their families in Vietnam. Further study is needed to provide more comprehensive evidence on the economic burden of influenza.

PIN19

GENERATING DEMAND ESTIMATES TO INFORM THE VALUE OF DENGUE VACCINE INTRODUCTION IN 6 DIFFERENT COUNTRIES IN LATIN AMERICA AND THE CARIBBEAN

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OBJECTIVES: The first dengue vaccine was approved at the end of 2015 and has been authorized in 11 countries so far around the world. We estimated the

potential vaccine demand using different introduction scenarios for two different vaccines in 6 different endemic countries in Latin America and the Caribbean to enable vaccine producers and public health agencies to have better strategies for a timely introduction of the vaccine. **METHODS:** We developed an Excel-based model and calculations were based on 2016-2045 population projections for our selected countries. For each of these countries, we considered 4 different introduction scenarios assuming a country-wide routine vaccination and catch-up vaccination campaigns. Assumptions on expected vaccination coverage were based on country-specific public sector immunization performance. We estimated the potential demand and costs of introducing a dengue vaccine in 6 different Latin American countries, based on key stakeholder preferences. We explored the impact of vaccine demand when the price drops faster and countries introduce sooner. **RESULTS:** Under our assumptions, Mexico would require the largest amount of annual doses in the first 5 years with 70.74 million doses and El Salvador the lowest with 3.88 million doses to vaccinate adults and children under any scenarios. The total vaccine cost for 30 years' projection varies by country. Mexico has the highest cost with \$10.1 billion USD and El Salvador the lowest with \$566 million USD. For these countries, if we experience an early price drop from \$20 to \$10 USD per dose in the first two years, the annual vaccine program costs (cost per dose, vaccination equipment, fixed and variable implementation cost) would increase by 50%. **CONCLUSIONS:** Our results project an upper-limit estimate of vaccine demand, with actual demand depending on each country priorities, cost and product profile. Policymakers in these selected countries should consider appropriate implementation strategies

PIN20

BUDGET IMPACT AND COST-EFFECTIVENESS ANALYSES OF NEWLY AVAILABLE TREATMENTS FOR CHRONIC HEPATITIS C INFECTION IN HONG KONG

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OBJECTIVES: To evaluate the cost-effectiveness and the budget impact of introducing oral direct-acting antivirals (DAAs) to the hospital formulary in Hong Kong. **METHODS:** We developed a decision analytic model to compare short-term costs and health outcomes of chronic HCV genotype 1 infection in Hong Kong patients on the current standard treatment (triple therapy of pegylated interferon, ribavirin and boceprevir) to new treatments (sofosbuvir, ledipasvir/sofosbuvir or ombitasvir/paritaprevir/ritonavir and dasabuvir). Costs, sustained viral response (SVR) and incremental cost-effectiveness ratio (ICER) defined as incremental cost per treatment success were estimated for the cost-effectiveness evaluation. Five-year healthcare expenditures before and after the introduction of new treatments were compared to assess the budget impact to the public healthcare system. **RESULTS:** Medication costs accounted for >85% of overall treatment costs for all treatments. Compared to the current standard treatment, new treatments improved the SVR from 59-66% to 82.3-99.8% upon patient treatment history and cirrhosis conditions. New treatments mainly dominated current treatment as cost-saving options given their greater effectiveness and lower costs with ICERs ranged from -\$3,395 to -\$43,643 per treatment success. Introducing new treatments associated with 16.5% (\$99.2 million) budget increase on HCV management over five years. A 50% change in medication costs reflected a change in budget ranging from -\$229.2 to \$426.5 million. **CONCLUSIONS:** New HCV treatments are cost-effective alternatives to current standard care in Hong Kong. Introducing the new treatments to the public hospital formulary yields moderate budget increase in five years.

PIN21

IMPACT OF CARBAPENEM RESISTANCE ON CLINICAL AND ECONOMIC OUTCOMES AMONG INPATIENTS WITH ACINETOBACTER BAUMANNII INFECTION OR COLONIZATION IN A HOSPITAL OF ZHEJIANG PROVINCE CHINA

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OBJECTIVES: The prevalence of carbapenem resistant *Acinetobacter baumannii* (CRAB) was seen a marked increasing in China. There is a significant impact of carbapenem resistance on both clinical and economic outcomes. This study aims to examine hospital mortality, length of stay, intensive care unit stays and average hospitalization expenses among inpatients with CRAB infection or colonization (CRAB/CSAB infection or colonization is replaced with CRAB/CSAB) and carbapenem susceptible *A. baumannii* (CSAB) in a tertiary teaching and general hospital in Hangzhou, Zhejiang Province, China. **METHODS:** Sixty-five percent inpatients, whose clinical specimens were submitted to the microbiological laboratory, between January 1, 2013, and December 31, 2015, were randomly selected every year, due to the large quantity of inpatients. The 1:2 propensity-matched samples were used for analysis to address the selection bias. Univariate analysis was performed to compare the characteristics of inpatients with CRAB versus CSAB. Kruskal-Wallis non-parametric test and multivariate linear regression model was conducted to evaluate the average hospitalization expenses. **RESULTS:** A total of 1007 inpatients with CRAB and 773 inpatients with CSAB were included. Compared to inpatients with CSAB, those with CRAB were significantly associated with a more than 3-fold increase in hospital mortality, a 3-day increase in mean length of stay, an 8-day increase in intensive care units stays and a 2-fold increase in average hospitalization expenses. **CONCLUSIONS:** The results of this study highlight the heavy burden CRAB posing on current Chinese healthcare system, emphasizing the importance of optimizing treatment pathway as early as empirical treatment stage and enhanced efforts in controlling carbapenem resistance, which calls for reliable resistance surveillance data, better prediction of the risk of CRAB infections, and improved antimicrobial stewardship programs in Chinese hospitals.

PIN22

THE HEALTH AND ECONOMIC IMPACTS OF ANDROGENIC ANABOLIC STEROIDS AS ADD-ON THERAPY FOR HIV PATIENTS

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OBJECTIVES: Anabolic androgenic steroids (AAS) are a potential treatment for muscle wasting, a common consequence of advanced HIV. Prevalence of use and health outcomes associated with AAS are not well understood for HIV patients. The purpose of this study was to evaluate economic and health outcomes of HIV patients receiving AAS therapy compared to non-AAS treated HIV patients. **METHODS:** A retrospective cohort analysis was conducted with a large commercial claims database (2009-2014). HIV patients (ICD-9-CM: 042, 043, and 044) who received their first AAS treatment between January 2010 and June 2013 were identified. Patients without AAS treatment were selected if they had a primary diagnosis of HIV between January 2010 and June 2013. For analysis, a 6-month pre-period and a 24-month post-period were used to assess disease related utilization and cost. AAS treated and non-AAS treated patients were matched 1:1 using Greedy propensity score matching. **RESULTS:** 663 HIV patients were identified in the time window, of which 45 (6.8%) received AAS. There were disparities between the AAS and non-AAS groups in age (47.7 ± 7.61 vs 44.9 ± 9.93; p=0.028), proportion that were male (100% vs 81%; p=0.0012), HIV medication days' supply (305.4 ± 237.6 vs 233.6 ± 218.2; p=0.035), and HIV medication cost (\$9192.30 ± 5981.40 vs \$6506.90 ± 5337.00; p=0.001). Fifty-eight patients were matched on demographic and severity indices. Age, gender, and pre-index costs were not different between groups. In 2 years of follow up, healthcare utilization costs were not different. AAS-treated patients tended to have fewer emergency room visits (0.76 ± 1.77 vs 1.21 ± 1.97; p=0.16). **CONCLUSIONS:** HIV patients taking AAS therapy were older, male, and were taking larger amounts of HIV medication. Additionally, AAS-treated HIV patients tended to have less healthcare resource utilization. This study is limited by the small population of HIV patients receiving AAS therapy.

PIN23

COMPARISON OF HIV ANTIRETROVIRAL DRUGS PRICES IN THE US AND CANADA

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OBJECTIVES: To compare the prices of HIV antiretroviral (ARV) drugs in the US and the Canadian provinces Ontario and Quebec. **METHODS:** US wholesale acquisition cost (WAC) prices were collected from the online database RedBook (Truven Health Analytics) on Nov 17, 2016. Prices for public programs of the provinces of Quebec and Ontario were collected from the respective webpages on the same date. The defined daily dose (DDD) for each HIV ARV was extracted from online database of the World Health Organization. Prices for 30 DDD were calculated and converted into US dollars. Wilcoxon Signed rank test was conducted in the analysis using SPSS V21.0. **RESULTS:** There were 38 HIV ARV drugs approved by the FDA and available in the US market, 29 in Ontario and 33 in Quebec. There were 8 drugs with generic competition in the US, and 8 in Ontario and Quebec. The study included 28 brand and 5 generic products that were available in the US, Ontario and Quebec. The median cost of brand HIV ARV drugs per 30-DDD was \$833.50 (range=\$412.20-\$3086.04) in the US, \$357.85 (range=\$58.50-\$1548.54) in Ontario (p<.05 vs. the US), and \$325.81 (range=\$56.80-\$1518.17) in Quebec (p<.05 vs. the US). The median cost of generic HIV ARV drugs per 30-DDD was \$276.49 (range=\$23.15-\$549.57) in the US, \$166.86 (range=\$42.60-\$240.34) in Ontario, and \$166.86 (range=\$42.60-\$240.34) in Ontario. The price of generic nevirapine 200mg was lower in the US than in Ontario and Quebec. **CONCLUSIONS:** The US had more HIV ARV drugs than Ontario and Quebec. Prices of brand HIV ARVs were significantly higher in the US than in Ontario and Quebec. Quebec had non-statistically significant lower prices than Ontario.

PIN24

INPATIENT AND OUTPATIENT COSTS CARE BEFORE AND AFTER A VACCINATION CAMPAIGN IN HIGH-RISK ADULT IN PANAMA IN 2015

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BACKGROUND: Panama Canal Area Benefit Plan (PCABP) is a Benefit Plan administered by AXA Assistance. AXA-Assistance represents around 35-40% of private health market in Panama. Our Plan has more than 10,000 Members and almost of our Members are ≥ 50 years older and suffering multiple comorbidities, mostly related to chronic cardiometabolic disease, as well as, diabetes, hypertension, stroke, arteriosclerosis, arthritis. Before 2015 none of plan's member received 13-Valent Pneumococcal Conjugate Vaccine (PCV13). **OBJECTIVES:** To estimate number of inpatient and outpatient cases included the different cost, before and after vaccination campaign in our high-risk older population from a private perspective (AXA Assistance). **METHODS:** We compared 2 periods: January-July 2015 and January-July 2016. A vaccination campaign was developed during November 2015 and was performed in 1000 high-risk members. **RESULTS:** Period of January-July, 2015 were reported 379 cases of community-acquired pneumonia (CAP) (165 inpatient hospital, 214 outpatient hospital). In a period January-July 2016, 344 cases of CAP were reported (149 inpatient hospital, 195 outpatient hospitals). The average cost of inpatient and outpatient set was \$ 10,879 and \$ 265.56 respectively. Average time of hospitalization 2015 vs 2016 was 16.2 days UCI and 7.8 ward days vs 15.4 days UCI and 7.5 days. The average age hospitalized is 81 years and outpatient 74 years. **CONCLUSIONS:** PCV13 vaccine campaign reduces number of cases, length of stay. This intervention generate saving costs for PCABP administered by AXA Assistance.

PIN25

COST OF HOSPITALIZATION AND OUTPATIENT TREATMENT FOR HERPES ZOSTER IN HONG KONG OLDER ADULTS

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OBJECTIVES: The population at risk for herpes zoster (HZ) is increasing with prolonging life expectancy in Hong Kong. HZ treatment cost data are essential to assist the cost-effective implementation of zoster vaccination program. We aimed to describe HZ clinical outcomes and direct cost in older adult patients treated in Hong Kong inpatient and outpatient settings. **METHODS:** A retrospective, observational study was conducted in two clusters of Hospital Authority, the largest public healthcare provider in Hong Kong. Medical records of patients aged ≥ 50 years with HZ diagnosis at outpatient clinics and general hospitals in January 2011 to December 2013 (prior to zoster vaccine became available in Hong Kong) were reviewed. Outcome measures included HZ-related length of hospital stay (LOS), outpatient visits, treatment cost, and HZ-related complications. **RESULTS:** We reviewed 215 HZ cases (46% male; age 70±12 years), 102 (47%) were hospitalized patients and 113 (53%) were outpatient cases. Of the 102 inpatient cases, 15 (15%) were immunocompromised patients. Median LOS was 4 days (IQR 3-8) days. HZ-related complications occurred in 47 (46%) inpatient cases. Median inpatient treatment cost was HKD21,630 (IQR HKD15,030-38,430) (USD1=HKD7.8). Inpatient cost for immunocompromised patients (HKD49,990; IQR HKD26,125-90,310) was significantly higher than non-immunocompromised cases (HKD20,095; IQR HKD15,030-33,750) (p<0.001). Immunocompromised patient was associated with high (≥75th percentile) inpatient treatment cost (OR 8.88; 95%CI 2.67-29.55; p<0.001). For the 113 outpatient cases, 26 (23%) patients were immunocompromised. 58 (51%) patients used one-time outpatient clinic service and 55 (49%) patients had 4.9±3.2 clinic visits for HZ treatment. Outpatient treatment cost (HKD1,100; IQR HKD1,100-4,785) was significantly lower than inpatient treatment cost (p<0.001). There was no significant difference between the outpatient treatment costs in immunocompromised and non-immunocompromised patients. **CONCLUSIONS:** Inpatient HZ treatment cost was substantially higher than outpatient cost. Immunocompromised patient was associated with high inpatient HZ treatment cost in older Hong Kong adults.

PIN26

AGE-SPECIFIC ECONOMIC BURDEN OF RESPIRATORY SYNCYTIAL VIRUS (RSV) HOSPITALIZATIONS IN THE UNITED STATES, 2009-2013: AN ANALYSIS OF HEALTHCARE COST AND UTILIZATION PROJECT (HCUP) NATIONWIDE INPATIENT SAMPLE (NIS)

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OBJECTIVES: Age-specific economic burden of RSV hospitalizations is poorly documented. We assessed national estimates of age-specific economic burden of RSV hospitalizations in the US. **METHODS:** A retrospective cohort study using the HCUP NIS between January 2009 and December 2013 was conducted. NIS includes discharge data on 20% of all US hospitalizations. Hospital admissions for RSV were identified using records with a principal ICD-9 diagnosis code of 466.11 or 480.1. We analyzed hospitalizations in 5 age categories (<1, 1-4, 5-49, 50-64, and >65yrs). Total inpatient costs (converting charges to cost using cost-to-charge ratio), hospital length of stay (LOS), and mortality during the inpatient visit were assessed. **RESULTS:** A total of 75,427 RSV hospitalizations were identified. The highest hospitalizations were in patients <1yr (72%) followed by 1-4yr age group (25.3%). Mean LOS was highest in the 49-64yr age group (8.3 days, SE 0.6) and lowest in the 1-4yr age group (3.0 days, SE 0.03). Correspondingly, mean cost per stay was highest in the 49-64yr age group (\$29,777.00, SE 4518.0) and lowest in the 1-4yr age group (\$5,639.97, SE 201.6) in <1yr and 1-4yr age groups. Records with a presence of asthma or COPD had 27% and 35% higher mean cost per stay, respectively. Based on weighted frequency, total national hospitalization cost of RSV admissions between 2009 and 2013 was \$2.3 billion of which \$1.5 billion (67.4%) was attributable to patients of age <1yr. Inpatient mortality was highest (5.1%) in the 49-64yr age group. **CONCLUSIONS:** Economic burden of RSV varies dramatically by age groups. RSV hospitalizations are highest in the children <5yrs and accounts for 90% of the total national hospitalization costs of RSV. Elderly patients, though low in numbers, have higher mortality, LOS, and cost per stay compared to young children.

PIN27

ECONOMIC IMPACT OF DENGUE IN LATIN AMERICA: A SYSTEMATIC REVIEW

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OBJECTIVES: Dengue fever affects tropical and subtropical regions, mainly low income areas. The incidence has been increasing steadily in Latin America, and despite costs variation between countries, its economic impact is consistently high. This study reviews papers on economic impact of dengue in Latin America. **METHODS:** We performed a systematic review in Pubmed (Medline), EMBASE and BVS, which includes Latin American databases. Nonpublication date or language limits were used. All papers that considered costs (either direct medical, out-of-pocket, productivity or social) were included. Costs are expressed in 2015 American Dollars (USD). **RESULTS:** From a total of 848 initial references, 16 studies were selected for data extraction (2 each from Brazil, Colombia, Cuba, Mexico, Puerto Rico and Panama; and 1 each from Argentina, Venezuela, and Nicaragua; 2 articles included several countries). In general, the main impact of the disease was caused by productivity costs. Total average annual cost in Latin America has been estimated in more than USD \$3 billion; 60% of which is represented by Brazil, followed by Mexico and Colombia. Direct costs are higher

for hospitalized cases (Brazil \$424 per case, Mexico \$1,216, Colombia \$523). In non-hospitalized patients, which are more than 95% of cases, direct medical costs are low but social costs (both productivity costs and out-of-pocket expenses) are significant (Brazil \$117, Mexico \$109, Colombia \$115). **CONCLUSIONS:** Different social, environmental and political factors have influenced the increasing incidence of dengue fever. Difficulties in application of preventive policies have been a limitation for vector control; therefore, many preventable cases need to receive treatment, generating a high economic impact to the health systems and to society in general. It is essential to develop new public health interventions, such as the vaccination, to decrease the propagation of the disease.

PIN28

ASSESSING THE ECONOMIC BURDEN AND 30-DAY READMISSION RATES AMONG PATIENTS WITH CLOSTRIDIUM DIFFICILE INFECTION IN THE US VETERANS HEALTH ADMINISTRATION POPULATION

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OBJECTIVES: To assess the health care costs, 30-day readmission rates, and predictors of 30-day readmission among patients diagnosed with clostridium difficile infection (CDI) in the US Veterans Health Administration (VHA) population (01OCT2010-30SEP2015). **METHODS:** Patients diagnosed with CDI were identified (International Classification of Disease, 9th Revision, Clinical Modification code: 008.45) from the VHA dataset for the identification period (01OCT2011-30SEPT2014). The initial diagnosis date was designated as the index date. Patients without a CDI diagnosis, who were of the same age, race, and sex as study CDI patients, were identified for comparison. An index date was randomly selected to minimize bias. Adult patients were required to have continuous medical and pharmacy benefits for 1 year pre- and post-index date. Health care costs and 30-day readmission rates during the follow-up period were compared among 1:1 matched patients with and without CDI. Logistic regression was used to examine the predictors of 30-day readmission. **RESULTS:** After matching, there were 18,794 patients in each group. Patients with CDI had higher 30-day readmission rates (25.9% vs 0.6%, $p < 0.0001$) and incurred significantly higher inpatient (\$73,937 vs \$892; $p < 0.0001$), outpatient (\$9,168 vs \$2,035; $p < 0.0001$) and total costs (\$83,106 vs \$2,928; $p < 0.0001$) than those without CDI. The likelihood of 30-day readmission was lower among patients aged 26-34 years as compared to those aged ≥ 65 years (odds ratio [OR]: 0.5; $p = 0.0002$). Readmission was higher among patients with higher mean Charlson Comorbidity Index (CCI) scores (OR: 1.1; $p < 0.0001$). **CONCLUSIONS:** Patients with CDI had a significantly higher economic burden and 30-day readmission rates than those without CDI. Age and CCI scores were significant predictors of 30-day readmission.

PIN29

ECONOMIC IMPACT OF TREATMENT FAILURE IN PATIENTS WITH SKIN AND SOFT TISSUE INFECTIONS TREATED WITH METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA) ANTIBIOTICS IN THE PERSPECTIVE OF BRAZILIAN PRIVATE HEALTHCARE SYSTEM

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OBJECTIVES: To evaluate the economic burden of treatment failure and cure rates in patients with skin and soft tissue infections treated with any anti-MRSA antibiotic in first or subsequent lines. **METHODS:** The Orizon database is an administrative database containing over 18 million lives of the Private System. Eligibility criteria were patients with ICD-10 codes: A26, A26.0, A26.8, A26.9, A46, H60.0, H60.1, K12.2, L00, L02, L02.1, L02.2, L02.3, L02.4, L02.8, L02.9, L03, L03.0, L03.1, L03.2, L03.3, L03.8, L03.9 and L08 from May/2012 to Jun/2013. A total of 531 hospitalizations were identified and stratified in two groups: group I (patients that initiated the treatment with any anti-MRSA) and group II (used an anti-MRSA except in the first line). Direct medical costs (DMC) per patient-year were calculated as the sum of medical claims for each patient with an exchange rate of 1 USD = 3,43 BRL. **RESULTS:** In group I ($n = 322$), the mean length of stay (LOS) was 12.5 days, the mean DMC was USD 8,046.817 and presented a cure rate with any anti-MRSA of 85.7%. In the subset of cured patients ($n = 267$), the mean LOS was 11.0 days with a mean DMC of USD 6,908.877. It was noteworthy that in group II the cure rate with an anti-MRSA was similar in comparison with group I (84.7%). As expected, the costs were much higher, presenting a mean DMC of USD 16,504.46 and a mean LOS of 21.7 days, even in the subset of patients cured with an anti-MRSA ($n = 177$, mean LOS 19.9 days and mean DMC of USD 14,317.02). **CONCLUSIONS:** The cure rates among patients with skin and soft tissue infections that initiated with an anti-MRSA or used after initial failure were high, however the economic impact of delayed appropriate anti-MRSA treatment was associated with an almost doubled resources use and LOS.

PIN30

DIRECT MEDICAL COSTS OF HOSPITALIZATIONS FROM DIABETIC AND NON-DIABETIC PATIENTS ASSOCIATED WITH SKIN AND SOFT TISSUES INFECTIONS IN THE BRAZILIAN PRIVATE HEALTHCARE SYSTEM

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OBJECTIVES: To estimate the mean cost of hospitalizations by diabetic and non-diabetic patients associated with skin and soft tissues infections. **METHODS:** The Orizon database is an administrative database containing over 18 million lives of the Private Health System. Eligibility criteria were patients (≥ 18 years) with ICD-10 codes: A26, A26.0, A26.8, A26.9, A46, H60.0, H60.1, K12.2, L00, L02, L02.1, L02.2, L02.3, L02.4, L02.8, L02.9, L03, L03.0, L03.1, L03.2, L03.3, L03.8, L03.9 and L08 from May/2012 to Jun/2013. We also stratified by age (18 to 35, 36 to 59 and above 60 years) and diabetic comorbidity. Direct medical costs (DMC) per patient-year were calculated as the sum of

medical claims for each patient with an exchange rate of 1 USD = 3,43 BRL. **RESULTS:** A total of 1,846 patients were identified over the analysis period. In the non-diabetic group ($n = 1605$), the mean length of stay was 5.3 days with a mean DMC of USD 2,081.77. In contrast, the diabetic group presented a mean of 11.9 days and a DMC of USD 7,617.88 ($n = 241$). When stratified by age groups, the mean length of stay and DMC for the non-diabetic group were 4.4 days and USD 1,444.45 (18 to 35 years, $n = 771$), 5.5 days and USD 2,110.66 (36 to 59 years, $n = 605$) and 8.1 days and USD 4,151.21 (60 years and above, $n = 229$). In the diabetic group, the mean length of stay and DMC were 8.0 days and USD 3,199.38 (18 to 35 years, $n = 19$), 11.7 days and USD 5,950.39 (36 to 59 years, $n = 95$) and 13.3 days and USD 10,216.39 (60 years and above, $n = 127$). **CONCLUSIONS:** older and diabetic patients affected by skin and soft tissues infections clearly increase the economic burden in the Brazilian private healthcare system.

PIN31

ANALYSIS OF TREATMENT COSTS OF MALARIA IN A TERTIARY CARE HOSPITAL: AN INDIAN PERSPECTIVE

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OBJECTIVES: To study malaria disease prevalence, demographics of patients, and pattern of complications within patients under study and to determine average total cost for inpatient treatment of malaria, and to analyse total cost of treatment with respect to various departmental services of a tertiary care hospital. **METHODS:** A retrospective, cross sectional study was performed at Kasturba hospital (a tertiary care hospital) to determine average total cost of treatment for single episode of malaria. Patients diagnosed with malaria from January 1, 2010 to December 31, 2011 were included in study. Data for treatment costs were obtained from hospital's billing section. Prescribing patterns for anti-malarials were studied and major treatment regimens were evaluated by pharmacoeconomic methods such as cost-effectiveness analysis and cost minimization analysis. **RESULTS:** Out of total 522 patients that were followed, 323 (62%) patients had P.vivax malaria; 189 (36%) had P.falciparum malaria and 10 (2%) had mixed malaria. Malaria cases were further classified into complicated and uncomplicated cases as defined by WHO, NIMR and CDC guidelines. Average total treatment cost for single episode of malaria was found to be INR 11338 (US\$ 220) at our study site. Average length of hospitalization stay was found to be 6 days. Treatment cost of complicated malaria was found to be significantly higher than uncomplicated malaria. Parenteral artesunate was found to be most commonly prescribed anti-malarial, followed by chloroquine. ICER value for parenteral artesunate over quinine was found to be INR 27583 (US\$ 535). **CONCLUSIONS:** Our study estimates high cost of treatment with new anti-malarials. It also proves high cost-effectiveness of parenteral artesunate over quinine for treatment of severe malaria. Treatment costs can be significantly reduced by early conversion from intravenous artesunate to oral artemisinin based combination therapies.

PIN32

COST-EFFECTIVENESS OF ANTIVIRAL PROPHYLAXIS DURING PREGNANCY TO PREVENT PERINATAL HEPATITIS B INFECTION IN SOUTH KOREA

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OBJECTIVES: To analyze the cost-effectiveness of the nationwide Perinatal Hepatitis B Prevention Program (PHBPP) and identify the optimal strategy of eliminating mother-to-child transmission of hepatitis B virus (HBV) in Korea. **METHODS:** A decision tree model with a Markov process was developed and simulated over the lifetime of the 2014 birth cohort in Korea. The current PHBPP was compared against two other strategies, universal hepatitis B vaccination and the PHBPP with antiviral prophylaxis, by their costs and health outcomes. The Korean National Health Insurance (NHI) database was investigated to estimate the costs of HBV-related diseases and utilization of health resources. Costs were assessed from the health care system perspective. Health outcome measures were Quality-adjusted Life Years (QALYs), and the number of HBV-related diseases and deaths. The Incremental Cost-Effectiveness Ratio (ICER) produced from the analysis was evaluated by the amount of Willingness-to-Pay (WTP) in the Korean society. **RESULTS:** The nationwide PHBPP in Korea is cost-saving compared to the universal hepatitis B vaccination. An introduction of antiviral prophylaxis to pregnant women with a high viral load of HBV saved 55 QALYs (ICER: \$19,163 per QALY) and averted 13 HBV-related deaths per 100,000 people compared to the current PHBPP. **CONCLUSIONS:** Considering that the WTP of Korea is \$30,000, the strategy of PHBPP with antiviral prophylaxis is cost-effective. To further decrease the burden of perinatal hepatitis B in Korea, adding antiviral prophylaxis to the current PHBPP is recommended.

PIN33

COST-EFFECTIVENESS OF HUMAN PAPILLOMA VIRUS (HPV) VACCINATION IN NIGERIA: A DECISION ANALYSIS USING PRAGMATIC PARAMETER ESTIMATES FOR COST AND PROGRAMME COVERAGE

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OBJECTIVES: World Health Organisation recommends routine Human Papilloma Virus (HPV) vaccination for girls when its cost-effectiveness in the country or region has been duly considered. We therefore aimed to evaluate cost-effectiveness of HPV vaccination in Nigeria using pragmatic parameter estimates for cost and programme coverage, i.e. realistically achievable in the studied context. **METHODS:** A micro-simulation frame-work was used. The natural history for cervical cancer disease was remodelled from a previous Nigerian model-based study. Costing was based on health providers' perspective. Disability adjusted life years attributable to cervical

cancer mortality served as benefit estimate. Suitable policy option was obtained by calculating the incremental cost-effectiveness ratio. Probabilistic sensitivity analysis was used to assess parameter uncertainty. One-way sensitivity analysis was used to explore the robustness of the policy recommendation to key parameters alteration. Expected value of perfect information (EVPI) was calculated to determine the expected opportunity cost associated with choosing the optimal scenario or strategy at the maximum cost-effectiveness threshold. **RESULTS:** Combination of the current scenario of opportunistic screening and national HPV vaccination programme (CS + NV) was the only cost-effective and robust policy option. However, CS + NV scenario was only cost-effective so far the unit cost of HPV vaccine did not exceed \$5. EVPI analysis showed that it may be worthwhile to conduct additional research to inform the decision to adopt CS + NV. **CONCLUSIONS:** National HPV vaccination combined with opportunist cervical cancer screening is cost-effective in Nigeria. However, adoption of this strategy should depend on its relative efficiency when compared to other competing new vaccines and health interventions.

PIN34

ECONOMIC EVALUATION OF RACECADOTRIL (HIDRASEC®) FOR THE TREATMENT OF PEDIATRIC PATIENTS WITH ACUTE DIARRHEA

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OBJECTIVES: To assess the cost-effectiveness relation between racecadotril (Hidrasec®) adjuvant with electrolytes for the treatment of pediatric patients with acute diarrhea from the Mexico's National Health System perspective. **METHODS:** A cost-effectiveness analysis was conducted through a decision tree. The model structure was taken from the published economic study (Rautenberg et al., 2012). The analysis compared racecadotril (Hidrasec®) plus electrolytes vs electrolytes by themselves. The effectiveness measure was the absent of diarrhea 48 hours after the administration of the treatment and the proportion of patients that did not require hospitalization. Based on the natural history of the disease, the time horizon was of 6 days. The transition probabilities was taken from the clinic literature (Lehert et al., 2011) (Álvarez et al., 2009). It was only considered direct medical costs, which are pharmacological costs and cost of a hospitalization per day, there were obtained from institutional sources. **RESULTS:** In a 1,000 patients cohort, racecadotril (Hidrasec®) adjuvant with electrolytes, resulted in the absent of diarrhea 48 hours after the administration of the treatment in 580 patients, in comparison with only 320 patients a cause of only electrolytes, which means an incremental effectiveness of 320 patients. 97.44% and 73.43% of the patients treated with racecadotril (Hidrasec®) adjuvant with electrolytes and with electrolytes alone, respectively, did not require hospitalization, having an increase of 24% because of the use of racecadotril (Hidrasec®). The average cost per patient treated with racecadotril (Hidrasec®) adjuvant with electrolytes was \$99.41 USD, in comparison with electrolytes alone that was \$354.39 USD, having a saving of \$254.98 USD. **CONCLUSIONS:** From the Mexico's National Health System perspective, racecadotril (Hidrasec®) adjuvant with electrolytes for the treatment of pediatric patients with acute diarrhea, is a dominant therapy vs electrolytes alone, generating a bigger effectiveness with a less cost per patient.

PIN35

A COST-EFFECTIVENESS ANALYSIS OF A WHOLE GENOME SEQUENCING TEST COMPARED TO THE STANDARD CARE IN PATIENTS WITH HOSPITAL-ACQUIRED BACTEREMIA

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OBJECTIVES: Recently researchers at the University of Pittsburgh and University of Pittsburgh Medical Center reported the detection of KPC-positive *K. pneumoniae* from patients undergoing endoscopic retrograde cholangiopancreatography (ERCP) from a single hospital. KPC-positive *K. pneumoniae* isolates are essentially resistant to all the commonly available antimicrobials. Therefore, it is crucial to identify them early with high accuracy to prevent it infecting other patients. With its high sensitivity and significantly lowered price, whole genome sequencing has been considered as a way to help facilitate the identification of KPC-positive *K. pneumoniae*. However, evidence for its cost-effectiveness is lacking. **METHODS:** Here in this study, cost-effectiveness of adopting whole genome sequencing (WGS) following every ERCP procedure was modeled and was compared with the standard of care (SOC, high-level infection). A hypothetical cohort of 1000 patients was simulated for ten years using the four-state Markov model. KPC-positive *K. pneumoniae*-caused infection-related healthcare cost over ten years and quality-adjusted life year (QALY) were estimated for both the WGS strategies and the SOC strategy. **RESULTS:** When the probability of infection of KPC-positive *K. pneumoniae* through ERCP was assumed at 1% in a hospital in the Mid-Atlantic geographic region, and the cost for the WGS was assumed at \$100 per test, the 10-year cost for a cohort of 1000 patients in the SOC strategy is \$1,107,095; while the cohort will gain 8736.6 QALYs during that span. If the hospital adopts the WGS test strategy, the total 10-year cost is \$218,696; while the cohort will gain 9485.9 QALYs. Under these conditions, the SOC strategy was dominated by the WGS strategy. Sensitivity analysis of critical variables indicates the robustness of the model. **CONCLUSIONS:** In summary, from the provider's perspective, the WGS strategy is more cost effective in identifying PC-positive *K. pneumoniae*.

PIN36

THE COST-EFFECTIVENESS OF STRATEGIES TO VACCINATE AGAINST VARICELLA IN MEXICO

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OBJECTIVES: The annual reported incidence of varicella in Mexico between 2010-2014 ranged from 221,000-371,000 cases annually. Seroprevalence data indicates that the true number of cases is likely between 1.6-2.3 M annually. Despite availability of varicella vaccines in the private sector and for selected patients in the public sector since 2000, vaccine uptake remains variable. The objective of this study was to evaluate the cost-effectiveness of possible varicella vaccination strategies in Mexico. **METHODS:** A dynamic transmission model of varicella infection was calibrated to reported age-specific outpatient varicella incidence data from 2003-2011, and adjusted for care-seeking behaviour patterns. Ten experts from Mexican health institutions provided input to summarize patterns of health care resource utilization (HCRU) for natural varicella among patients in different age groups (<1, 1-4, 5-9, 10-14, 15-44, 45-64, 65+). This was combined with local unit cost data to estimate varicella treatment costs. Five vaccination strategies were considered (1 dose; 1 dose + catchup 2nddose; 1 dose + campaign; 2 dose; and 2 dose + campaign). **RESULTS:** All strategies were cost-saving and will vary between 3.17T MXN to 3.5T MXN over 10 years (145B to 162B USD). The 1 dose strategy will reduce varicella cases and deaths by 35% in Year 1, 80% in Year 5, and 90% in Year 3. Higher-order strategies such as 2 dose + campaign will reduce varicella burden more quickly, lead to reductions of 61%, 87% and 92% in years 1,5, and 10. **CONCLUSIONS:** Both one and two dose universal varicella vaccination are cost-saving interventions, due to high use of health care resources for management of varicella in Mexico. Conservative rates of coverage (90% 1st dose and catchup, 80% 2nd dose) were assumed so health benefits could actually be higher. Choosing a vaccination strategy will depend on goals for speed of reduction of disease burden and budget concerns.

PIN37

POTENTIAL COST-EFFECTIVENESS FOR USE OF 13-VALENT PNEUMOCOCCAL CONJUGATE VACCINE IN TAIWANESE ELDERLY AND IMMUNOCOMPROMISED ADULTS

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OBJECTIVES: Use of PCV13 is recommended to the elderly and the adults with immunocompromising conditions. Additionally, use of PCV13 to immunocompromised adults who also receiving a single dose of 23-Valent Pneumococcal Polysaccharide Vaccine (PPV23) before is also recommended (PPV23-PCV13 sequence vaccination). This study is aimed to predict the potential cost-effectiveness of PPV23-PCV13 sequence vaccination to the elderly and immunocompromised adults in Taiwan. **METHODS:** Cost-effectiveness analysis from societal perspective was performed using a micro-simulation model. Cost-effectiveness of PPV23-PCV13 sequence vaccination versus PPV23 alone vaccination to a population of 50,000 was predicted on the time horizon of 70 years. Parameters in the model included demographic, epidemiological data, direct medical costs, indirect costs and vaccine efficacy data were derived from published literatures and Taiwan's National Health Insurance Database. All Results of cost-effectiveness analysis were presented by the incremental cost-effectiveness ratio (ICER) to illustrate the incremental cost (in New Taiwan Dollars, NTD) for one additional life-year (LY) gained. Sensitivity analysis was performed to evaluate the robustness of the results of micro-simulation model. **RESULTS:** Compared with PPV23 alone vaccination, PPV23-PCV13 sequence vaccination definitely increased vaccination cost but it would reduce total costs including vaccination costs, direct medical costs and indirect costs. Overall, PPV23-PCV13 sequence vaccination was more cost-saving than PPV23 alone vaccination. And, PPV23-PCV13 sequence vaccination would save an additional 0.0065 discounted LYs. The ICER for PPV23-PCV13 sequence vaccination for the elderly and immunocompromised adults was estimated about -284,000 NTDs per LY. **CONCLUSIONS:** PPV23-PCV13 sequence vaccination could achieve potential health economic and clinical benefits. For the elderly and immunocompromised adults in Taiwan, PPV23-PCV13 sequence vaccination was considered as the dominant vaccination strategy compared with PPV23 alone vaccination.

PIN38

COST-EFFECTIVENESS ANALYSIS OF COMBINED ANTIRETROVIRAL THERAPIES FOR TREATMENT OF HIV-1 POSITIVE PATIENTS IN BULGARIA

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OBJECTIVES: The aim of this study is evaluation of incremental costs, incremental health benefits and their incremental ratio (ICER) of CART (E/C/F/TAF and E/C/F/TDF) in comparison with most commonly used therapeutic alternatives in clinical practice in Bulgaria for treatment of HIV-1 positive patients in 2016. **METHODS:** A systematic review of published cost-effectiveness analyses data for CART for treatment of HIV-1 positive patients is performed in MEDLINE, EMBASE, Web of Science, Cochrane Library, covering the period January 2010 – June 2016. Data for health benefits in terms of additional QALY are directly transferred for the purposes of this analysis, due to similar population and characteristics of health systems. Data for the costs of CART are based on local reference prices in Bulgaria, published in Positive drug list as of July 2016. **RESULTS:** If we consider a cost-effectiveness threshold of three times GDP per capita in Bulgaria (WTP36 221 BGN, 2015) E/C/F/TDF is cost-effective therapy compared to ABC/3TC/LPV (ICER 34 546 BGN/QALY). **CONCLUSIONS:** In conclusion, CARTs E/C/F/TAF is cost-effective, when compared to commonly used therapeutic alternative in Bulgaria ABC/3TC/LPV and should be recommended as first therapeutic choice, based on HTA pharmacoeconomic analysis.

PIN39

USING CRICKET GAMES TO PREVENT TRANSMISSION OF HIV IN SCHOOL CHILDREN IN CAMEROON

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OBJECTIVES: To evaluate the cost effectiveness of using cricket ambassadors compared to regular sports teachers for training school children on life skills against HIV/AIDS. **METHODS:** We conducted a cluster randomized control trial of 13 schools in the city of Bamenda in Cameroon for change in knowledge and intention on sexually related HIV prevention approach. The 3 arm study consisted of group 1 where a cricket ambassador was attached to a school to further strengthen skills in cricket and HIV/AIDS prevention messages in addition to school sports teacher, group 2 with school sports teacher coaching only and group 3 a control group with standard national approach to HIV prevention. Data was collected at baseline, 1 month, 3 months and 6 months post intervention. We compared cost effectiveness between 3 groups based on cost invested against total number of children recruited. **RESULTS:** A total of 909 students participated in the study. Analysis suggest cricket games increased knowledge by 36.1% when cricket games with ambassadors was used; by 38.2% when teachers only was used and by 2.9% when standard national approach was used. There was no difference in intention. The ambassador schools arm was able to reach out the most of students (444 students) as compared to the cricket only and control arms (250 and 209 students respectively). The various groups cost 135 versus 160 versus 191 XAF per child trained on life skills. **CONCLUSIONS:** Using ambassadors for cricket games will be most cost effective approach for training school kids in life skills.

PIN40

SAUSALIN VS METRONIDAZOLE IN TREATMENT OF GIARDIASIS: PHARMACOECONOMIC ASSESSMENT

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OBJECTIVES: The treatment of giardiasis is a global problem for public health of Asian countries in despite of the low cost of such popular drug as Metronidazole. The treatment with Metronidazole is ineffective in most cases due to adverse effects of this drug and the high level resistance of Giardia intestinalis. Sausalin is the new drug for treatment of giardiasis. It was synthesized by Scientific holding «Phytochemistry» Kazakhstan. The aim of present study was to conduct the cost-effectiveness analysis of Sausalin vs Metronidazole in adults with giardiasis. **METHODS:** A randomized controlled trial that was assessed with pharmacoeconomic methods was undertaken in this study. There were included 70 patients with confirmed giardiasis. Two groups were formed randomly. The patients in the study group received Sausalin, in the second group included patients treated by metronidazole. The rate of eradication of parasites was evaluated as outcome and the cost-effectiveness of Sausalin and metronidazole were determined. **RESULTS:** A high percentage of eradication of the parasite was detected in study group, which amounted to 82% for therapy with Sausalin ($p < 0.01$) and only 56.8% ($p < 0.01$) for therapy with Metronidazole. The indicators of cost-effectiveness were 9.7 for Sausalin therapy and 13.56 for therapy with Metronidazole. The adverse effects were detected in 5 patients of Metronidazole group, such as vomiting and nausea. **CONCLUSIONS:** The use domestic preparation Sausalin is economically feasible taking into account the high level of eradication and the safety profile of the drug.

PIN41

COST-EFFECTIVENESS ANALYSIS OF FIRST-LINE ADMINISTRATION OF TENOFOVIR ALAFENAMIDE (TAF), A NOVEL NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITOR (NRTI), FOR THE MANAGEMENT OF CHRONIC HEPATITIS B (CHB) IN THE UNITED STATES (US)

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OBJECTIVES: To estimate the health and economic value of TAF versus tenofovir disoproxil fumarate (TDF) or entecavir (ETV) in the management of patients with CHB from the third-party US payer perspective. **METHODS:** A lifetime cost-effectiveness model was developed using discretely integrated condition event (DICE) simulation. Health and cost outcomes for the overall population and patient subgroups (e.g. treatment-naïve and treatment-experienced) were analyzed separately. Inputs were obtained from published randomized trials and epidemiological/outcome studies, real-world database analyses and expert opinions. Model structure/assumptions/inputs were agreed by a group of clinical experts and health economists. As observed in the two pivotal trials, the model assumed similar HBV suppression and resistance rates between TAF and TDF, and improved ALT reduction and bone/renal safety with TAF. Efficacy and safety data for ETV were obtained from published studies. **RESULTS:** Over a lifetime, initiation of TAF was associated with fewer hepatic complications (cirrhosis, hepatocellular carcinoma, liver transplantation), renal and bone related events and deaths when compared to TDF and ETV, which resulted in higher quality-adjusted life years (QALYs) per patient (0.02-0.34) on long-term projection. Total costs per patient with TAF were lower (-0.35% to -1.15%) compared with TDF and higher (3.1% to 4.0%) compared with ETV. The model suggested that TAF usage dominated versus TDF in the overall population with greater cost saving and better clinical outcomes in the TE population. Compared with ETV, incremental cost-effectiveness ratios (ICERs) were below the commonly accepted threshold of

\$50,000/QALY in the overall population. Sensitivity analyses showed that results were robust. **CONCLUSIONS:** Driven by its favorable efficacy, safety, and resistance profile, TAF is projected to lead to better health outcomes and to be cost effective compared to TDF and ETV, leading to either dominance or generally favorable cost-effectiveness ratio (i.e., ICER < \$50,000/QALY).

PIN42

COST-EFFECTIVENESS OF HEPATITIS C TREATMENT FOR LEBANESE PATIENTS IN EARLY STAGES OF LIVER DISEASE

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OBJECTIVES: To conduct a cost effectiveness analysis comparing 'early treatment' versus 'delayed treatment' for Lebanese hepatitis C virus patients starting at a given level of fibrosis. **METHODS:** This study was conducted from the payer's perspective to evaluate the cost-effectiveness of using novel Direct Acting Antiviral agents in two treatment strategies, early treatment (initiated at fibrosis stages F2/F1/F0) versus delayed treatment (till fibrosis stages F3/F4). The model followed a typical patient's QALY at each stage and throughout the progression of the disease as reported in the literature. Direct medical cost were identified, measured and valued from third party payers in Lebanon and based on patient case scenario from medical center. Incremental cost effectiveness analysis was then conducted measuring the incremental cost per QALYs gained and per life year extended. **RESULTS:** The initiating of novel treatment soon after early stage diagnosis have led to an incremental cost effectiveness analysis (ICER) of 587 Euros per QALY gained. On the other hand, when outcomes of such treatment were measured over just the one-year duration when patient would receive treatment right after early stage diagnosed instead of delaying treatment until an advanced stage, the ICER was 27,268 Euros per QALY gained. In addition, when extended life year was used as the outcomes, the analysis showed that early treatment is associated with 1,527 Euros per additional life year extended. The one-way Sensitivity Analysis showed that a 25% decrease in the cost of dual drug option or if triple drug option was used, the ICER would significantly decrease to 16,982 Euros per QALY gained when treatment is initiated at early stage. **CONCLUSIONS:** 'Earlier treatment' is cost effective compared to 'delayed treatment' and thus reinforce the need to screen for HCV at early age so that initiation of therapy could be done as soon as confirming diagnosis.

PIN43

EXPLORING ECONOMIC VALUE IN TREATING PSEUDOMONAS AERUGINOSA INFECTIONS IN CYSTIC FIBROSIS – EARLY MODELLING TO INFORM PRODUCT DEVELOPMENT

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OBJECTIVES: To develop an economic model to explore the relative contribution of potential mechanisms driving the value of a new technology to manage Pseudomonas aeruginosa infections in Cystic Fibrosis (CF). **METHODS:** Following a literature review to identify published models in CF, a previously published model (Tappenden et al, 2013) was replicated and adapted to explore a variety of clinically plausible mechanisms by which a new technology could impact upon health-related quality of life, resource use and cost. These included: drug acquisition costs, reduction in inhaled aminoglycoside use, exacerbation risk, exacerbation level (major/minor), exacerbation costs, exacerbation disutility, mortality risk, CF progression and HRQL. The model estimated costs from the perspective of the NHS and health outcomes using quality-adjusted life-years (QALYs) in line with UK guidelines for economic evaluation and was developed probabilistically to account for parameter uncertainty. The new technology was defined as an adjunct to standard of care treatment (in this case inhaled aminoglycosides). **RESULTS:** Model results indicated that the cost-effectiveness of the new technology in CF was highly sensitive to its price with large shifts in incremental cost-effectiveness observed across relatively small changes in the daily acquisition cost. The potential reduction in adjunctive inhaled aminoglycoside therapy was the next most important driver of cost-effectiveness. The third most important driver of cost effectiveness was reduction in risk of exacerbations. **CONCLUSIONS:** The development of an early model allows for a detailed understanding of the mechanisms which drive the potential value of a new technology. This can be used to focus not only technology development but also the design of studies for evidence collection to best capture the value. The wider benefits of reduced inhaled aminoglycoside use, e.g. reductions in resistance and treatment-related side-effects, are an area of uncertainty and warrant further research.

PIN44

COST MINIMIZATION ANALYSIS OF RILPIVIRINE/EMTRICITABINE/TENOFOVIR IN TREATMENT NAÏVE HIV+ PATIENTS WITH ADVERSE EVENTS WHEN TREATED WITH STANDARD THERAPY

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OBJECTIVES: In Mexico, efavirenz/emtricitabine/tenofovir is the standard of treatment for antiretroviral-naïve patients; however efavirenz is highly associated with neurocognitive adverse events due to its central nervous system toxicity. The aim of this analysis was to estimate the annual cost of treatment for rilpivirine/emtricitabine/tenofovir compared to available alternatives for those patients virologically suppressed and intolerant to efavirenz in Mexico. **METHODS:** Nine randomized clinical trials were included to perform a meta-analysis of an unadjusted indirect comparison of alternatives evaluated in terms of the percentage of patients with undetectable viral load (HIV-RNA <50 copies/mL) at 48 weeks of treatment. A cost-minimization analysis was developed to determine the annual cost of treatment for rilpivirine/emtricitabine/tenofovir as single tablet regimen

(STR) compared to dolutegravir, raltegravir, atazanavir/ritonavir and darunavir/ritonavir as part of a highly active anti-retroviral therapy (HAART) with emtricitabine/tenofovir as backbone for patients intolerant to efavirenz in Mexican health-care system. Cost analysis included only acquisition drug costs that were obtained from published sources. Costs are expressed in 2016 USD (\$1USD=\$20MXN). **RESULTS:** The meta-analysis performed suggested comparable efficacy and safety between the alternatives evaluated. Annual cost of treatment for rilpivirine/emtricitabine/tenofovir was estimated in \$2,458 versus \$3,720 and \$4,460 for dolutegravir and raltegravir schemes, respectively; and versus \$3,142 and \$3,475 for HAART that included atazanavir/ritonavir and darunavir/ritonavir, respectively, as third component of the regimen. Annual savings with rilpivirine/emtricitabine/tenofovir ranged from \$684 to more than \$2,000 per patient compared to annual cost of treatment of the other alternatives evaluated. A sensitivity analysis over the acquisition price (+/-10%) showed that even with an increase up to 10% in the cost of rilpivirine/emtricitabine/tenofovir, it remained as the least expensive alternative. **CONCLUSIONS:** The use of rilpivirine/emtricitabine/tenofovir as STR is a cost-saving alternative in patients intolerant to efavirenz compared to other options approved and locally available in the Mexican healthcare system.

PIN45

COST-UTILITY ANALYSIS OF OUTPATIENT DALBAVANCIN FOR ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI) VERSUS INPATIENT VANCOMYCIN FOLLOWED BY ORAL LINEZOLID

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OBJECTIVES: Guidelines support patients requiring intravenous (IV) therapy for acute bacterial skin and skin structure infection (ABSSSI) in the absence of severe infection or unstable comorbidities can be managed effectively in the outpatient setting. The potential cost and quality of life differences associated with a shift in care from inpatient to outpatient care through the use of dalbavancin, a long-acting IV antibiotic, for patients with ABSSSI with no or few comorbidities was examined. **METHODS:** A decision analytic model from a payer perspective was developed to assess direct medical costs (inpatient and outpatient) and quality of life differences for patients with ABSSSI with no or few comorbidities (Charlson Comorbidity Index (CCI) score <1). Patients with ABSSSI received an inpatient treatment pathway of IV vancomycin followed by oral linezolid or outpatient treatment with IV dalbavancin (single infusion). Cost parameters included hospital length of stay (LOS) determined by presence or absence of systemic infection symptoms and CCI score, hospitalization costs, medications, laboratory, diagnostic and therapeutic services delivered to the patient. Inputs were obtained from published literature and evidence-based assumptions. Due to the lack of literature for ABSSSI, we estimated utility weights for inpatient versus outpatient treatment. **RESULTS:** Mean costs for the inpatient treatment pathway were \$10,610. Shifting to outpatient treatment with IV dalbavancin was estimated to save approximately \$3,840 per patient versus an inpatient treatment pathway. The quality-adjusted-life-days (QALDs) associated with the inpatient treatment pathway versus outpatient treatment with IV dalbavancin were 15.4 versus 15.6, respectively. **CONCLUSIONS:** In patients with ABSSSI with no or few comorbidities, shifting IV treatment for ABSSSI to an outpatient setting with dalbavancin resulted in a >36% decrease in medical costs and an incremental QALD gain versus an inpatient treatment pathway. The outpatient treatment with IV dalbavancin dominated the inpatient treatment pathway.

PIN46

SINGLE-DOSE ORITAVANCIN AVOIDS HOSPITALIZATION AND SHORTENS LENGTH OF STAY FOR TREATMENT OF SKIN AND SKIN STRUCTURE INFECTIONS IN US HOSPITALS

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OBJECTIVES: When single-dose oritavancin was introduced in 2014 for the treatment of acute bacterial skin and skin structure infection, it was hypothesized that its single-dose formulation may help US hospitals reduce use of inpatient beds through treatment entirely in the outpatient setting and reduction in length of stay (LOS) for admitted patients. This analysis sought to assess the real world impact of oritavancin to US hospitals. **METHODS:** Data were extracted from the Premier Hospital Database for the first full year of oritavancin availability (2015). Hospital admission rates and LOS were assessed for patients receiving oritavancin for skin infection and compared with patients receiving any other intravenous (IV) antibiotic grouped by infection severity (no systemic symptoms, with systemic symptoms, life-threatening infection) and presence of comorbid conditions using Charlson Comorbidity Index score (CCI). **RESULTS:** There were 208,113 records for patients 18+ with a primary diagnosis of skin infection and administration of IV antibiotic. Among 203 patients who received oritavancin, the average CCI was 1.46; 24.1% patients CCI ≥3; 9.8% life-threatening condition (4.4%) or systemic symptoms (5.4%). 144 (70.9%) oritavancin patients were treated as outpatients. For the 59 patients who were hospitalized (LOS=4.0d), 56 patients received oritavancin after the discharge of hospitalization or on day of discharge. Compared to patients receiving other IV antibiotics, the patients who received oritavancin had consistently lower admission rates (rate reduction up to 45.4%) across all levels of infection severity and CCI. If admitted, oritavancin patients had shorter LOS (LOS reduction up to 1.8 days) across all severity levels except CCI=1 group. **CONCLUSIONS:** This analysis finds that use of oritavancin avoided hospitalization and shortened length of stay for skin infection patients. As skin infections represent 2% of all US hospital admissions, increased use of oritavancin may represent an opportunity to recover several hundred thousand bed days for use with other patients.

INFECTION – Patient-Reported Outcomes & Patient Preference Studies

PIN47

A CLAIMS-BASED ANALYSIS OF HEPATITIS A, B, AND A/B VACCINATION SERIES COMPLETION AND COMPLIANCE AMONG US ADULTS

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OBJECTIVES: Literature on guideline adherence for hepatitis A, B, and A/B vaccines is limited. We assessed hepatitis A, B, and A/B vaccination completion and compliance rates among US adults. **METHODS:** Data were from Truven Marketscan commercial/Medicare and Medicaid healthcare claims (Q1 2007-Q3 2015). Patients had ≥1 claim for a hepatitis A, B, or A/B vaccine, ≥19 years at first claim ("index date"), ≥12 months of enrollment pre-index date, ≥18 months of enrollment post-index date, and <2 hepatitis A or B diagnoses pre-index date. Using CDC guidelines, we defined completion as receiving the correct number of doses separated by minimum intervals and compliance as receiving the correct number of either monovalent or bivalent vaccines within the product labels' specified timeframes. % patients completing and complying with the hepatitis A and B series were presented with % patients completing stratified by monovalent versus bivalent vaccine as initial dose. **RESULTS:** 395,323 commercial/Medicare and 13,822 Medicaid patients were included. Patients were on average 43.4 years old and mostly female. Among commercial/Medicare patients with a monovalent-vaccine initial dose, completion rates were 32.0% and 39.6% for hepatitis A and B, while 65.1% received at least a second dose of hepatitis B vaccine. Among patients initiating with a bivalent vaccine, 47.3% and 47.2% completed the hepatitis A and B series, with approximately 74.6% receiving at least two doses of hepatitis B vaccine. Among Medicaid patients, completion rates for hepatitis A, B, and A/B vaccines ranged from 21.0%-24.1%. Compliance rates for hepatitis A, B, and A/B vaccines were 27.9%, 12.2%, and 23.9% in commercial/Medicare patients, and 18.4%, 5.6%, and 9.9% in Medicaid patients. **CONCLUSIONS:** Adult completion and compliance rates for hepatitis A, B, and A/B vaccines are suboptimal. Research investigating completion and compliance predictors is needed.

PIN48

ASSESSING THE LEVEL OF ADHERENCE IN TUBERCULOSIS TREATMENT AMONG PATIENTS ACCESSING DIRECTLY OBSERVED TREATMENT SHORT-COURSE (DOTS) IN TERTIARY HOSPITALS IN NSUKKA, ENUGU STATE, NIGERIA

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OBJECTIVES: To assess the level of adherence in tuberculosis treatment amongst patients accessing the Directly Observed Treatment Short-course (DOTS) in Nsukka tertiary hospitals, and to determine patient related factors that influence adherence. **METHODS:** The study was a cross-sectional prospective study, conducted using data from questionnaires administered on tuberculosis patients (n=250) accessing the DOTS treatment in 3 tertiary hospitals, namely: Bishop Shanahan Hospital, Nsukka; District Hospital, Nsukka; and General Hospital, Enugu-Ezike. The instrument used in this study was a modified Morisky medication adherence scale-eight (MMAS-8). Chi-square was used to determine the relationship between demographic factors with the level adherence at P < 0.05. **RESULTS:** Study showed that 84% of the participants had high adherence, 12% had medium adherence; while 4% of the participants had poor adherence. Results showed that the severity of the symptoms as significantly ($\chi^2=6.031$; p= 0.049), associated with the level of adherence among patients in TB treatments. **CONCLUSIONS:** The DOTS therapy is cost-efficient; and has high efficacy level when the positive factors that influence high adherence level: good relationship with health care workers to patients and easy access to medications are present. Poor relationship with health care workers to patients, long distance to DOTS facility, alcoholism, poor patients behavior, lack of understanding of treatment regimen, and lack of motivation to tuberculosis regimen have negative impacts on the level of adherence among TB patients accessing the DOTS therapy in Nsukka tertiary hospitals.

PIN49

PARENTS' ADHERENCE, KNOWLEDGE AND ATTITUDES TOWARDS CHILDHOOD VACCINATION PROGRAM IN SAUDI ARABIA

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OBJECTIVES: To assess parents adherence, knowledge, and attitudes on childhood vaccination program among Saudi population. **METHODS:** A cross-sectional study was conducted during November 2016 in Riyadh, Saudi Arabia. Convenient method of sampling was adopted. Parents with children of 0-2 years old were invited to participate. Data was collected through face-to-face interview method using Arabic validated questionnaire to collect demographic data, education level, time of vaccination, adherence, knowledge about childhood vaccination program and attitudes of the parents. **RESULTS:** A total of 180 parents were participated. The mother was interviewed in 99 % of cases, Infant's ages ranged between 2-24 months (mean 10.7 months, standard deviation (SD) 8.2). 28.2 % of sample reported their child is a first child, and this is first exposur to vaccination program. Parents had good adherence to vaccination program rched up to (87%) on time without delay, main reason for not-adhere to vaccination program was lack of education. On other hand knowledge on aspects related to the general role of vaccination in prevention of some infectious diseases and important of timing of the first dose in vaccination schedule (95.2%), (86.9%). However, poor knowledge was documented among parents in other aspects like the importance of administration of multiple doses of the same vaccine to child immunity (41.6%), administration of multiple vaccines at the same time have no negative impacts on child immunity (47%). The Physicians representing the main

source of information for patients about vaccination (77.6 %). Parents attitudes towards immunization was positive, 98% reported the important of vaccination, only 10 % of participants thought that vaccination one of risk factors induced autism. **CONCLUSIONS:** Although parents had good adherence, knowledge and positive attitudes on some aspects related childhood immunization, gaps in both studied domains were identified. Educational interventions are needed to upgrade parents' knowledge.

PIN50

IMPACT OF A DENGUE EPISODE ON QUALITY OF LIFE OR DALYS: SYSTEMATIC REVIEW

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OBJECTIVES: With about 4,000 times as many symptomatic non-fatal dengue cases as dengue deaths, quantitative disability assessments are critical to assessing the cost-effectiveness of dengue control interventions. Yet, most cost-effectiveness studies assess disability only subjectively or through proxy conditions (e.g., any acute infection). To strengthen the needed evidence base, we conducted a systematic literature review of the disability or quality of life lost from a symptomatic dengue episode. **METHODS:** We searched major data bases for entries in English, Spanish, Portuguese or French through 2016 with "dengue" combined with "quality of life" or disability, quality-adjusted life year, QALY, disability-adjusted life year, DALY, or foreign equivalents. We first examined titles and abstracts from Cochrane Database of Systematic Reviews, PubMed, POPLINE, EconLit, and Google Scholar for relevance. We next excluded duplicates, obtained the full text of relevant entries, and analyzed entries with numerical quality-of-life assessments. We scored these entries' relevance using a 6-attribute scale (0-100%). Fitting level of disability (0.00-1.00) as a function of time from the dengue episode's start until recovery, we computed the average duration, average loss per day, and episode loss in DALYs (area under the disability curve). **RESULTS:** We identified 4,335 entries, reviewed full text of 17, and found 6 meeting our criteria (Armen, 2008; Lum, 2008; Luengas, 2016; Martelli, 2011; Nguyen, 2013; Whitehorn, 2016). Their median score was 76% (range 58-89%). All but Luengas studied acute cases, giving the following medians (with ranges) for ambulatory episodes: duration in days 10.2 (9.5-20.0), disability weight 0.500 (0.235-0.800), and area 0.0162 (0.0041-0.0367). For studies including hospitalized episodes, disability ranged 16%-47% higher than for ambulatory episodes. **CONCLUSIONS:** As the burden of dengue episodes varies across sites, pooled results are more robust. This systematic review should contribute to evidence-based effectiveness measures for cost-effectiveness studies of vaccination, vector control and other dengue control interventions.

PIN51

EVALUATION OF THE PERFORMANCE PROPERTIES OF THE INFLUENZA PATIENT-REPORTED OUTCOMES INSTRUMENT (FLU-PRO) IN PATIENTS WITH INFLUENZA-LIKE ILLNESS (ILI)

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OBJECTIVES: Test the reliability, validity, and responsiveness of the FLU-PRO for evaluating presence and severity of symptoms in adults with influenza-like illness (ILI). **METHODS:** Analyses of data from subjects testing influenza-negative participating in the prospective, observational study used to develop and evaluate the FLU-PRO. Adults (≥ 18 years with ILI) were recruited through outpatient settings in the US, UK, Mexico, Peru, and Argentina, and completed the 37-item draft FLU-PRO daily for up to 14-days. Laboratory tests confirmed the presence/absence of influenza. The performance of the final 32-item FLU-PRO, developed and validated with data from influenza-positive subjects, was tested. The FLU-PRO assesses signs/symptoms across six body systems: Nose, Throat, Eyes, Chest/Respiratory, Gastrointestinal, Body/Systemic. Reliability was estimated using Cronbach's alpha (α ; Day 1) and intraclass correlation coefficients (ICC; 2-day reproducibility). Convergent and known-groups validity were assessed using patient global assessments of symptom severity (PGA; none, mild, moderate, severe, very severe). Patient report of return to usual health was used to assess responsiveness (Day 1-7). **RESULTS:** N=220 ILI patients, mean age=39.3, 64.1% female, 88.6% white. N=61 (28%) were hospitalized at some point in their illness. Reliability: α Total score = 0.90; α subscales = 0.72 to 0.86; ICC (Day 1-2) Total score = 0.64; ICC subscales = 0.46 to 0.78. At Day 1, FLU-PRO scores correlated (≥ 0.30) with the PGA (except Gastrointestinal). FLU-PRO scores were significantly different across PGA severity groups (Total: $F=81.7$, $p<0.001$; subscales:

$F=6.9-62.2$; $p<0.01$). Mean improvement in FLU-PRO scores from Day 1 to 7 was significantly greater in patients reporting return to usual health compared with those who did not ($p<0.05$ for Total and all subscales, except Gastrointestinal and Eyes). **CONCLUSIONS:** Results suggest FLU-PRO total and domain scores are reliable, valid, and responsive in studies of adults with ILI, with or without documented influenza virus infection.

PIN52

DEVELOPMENT OF A DAILY DIARY TO ASSESS SIGNS AND SYMPTOMS OF GENITAL HERPES

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OBJECTIVES: Genital herpes (GH) is a common and highly contagious infection typically spread through sexual contact. GH affects more than 600 million people worldwide (CDC, 2016). New treatments in development are designed to reduce frequency, duration and severity of signs and symptoms. In order to accurately assess these treatment benefits, fit for purpose measures are required. **METHODS:** In alignment with the FDA PRO Guidance (FDA, 2009), a rigorous qualitative research study was undertaken to identify concepts of relevance and importance to patients with GH. Specifically, following a targeted literature review, semi-structured interview guides were created: one for use with clinical experts and a second for use with adult patients with GH. Individual interviews were conducted by trained staff and concept saturation was tracked. Diary items were generated following standard qualitative evaluation and pilot-tested in two rounds of interviews with a new sample of GH patients. **RESULTS:** Four clinical experts participated in individual interviews. Experts endorsed concepts identified in the literature and described challenges/proposed solutions for the measurement of signs and symptoms for GH. Patient input was gathered via in-depth interviews (n=20) of individuals with varying disease duration, severity and a mix of educational background and ethnicity. The result was a preliminary list of patient derived disease state attributes and an initial version of a conceptual framework. Items were tested and refined utilizing cognitive debriefing interviews with a new sample. The result is an 8-item diary (GH-SSD) designed for daily administration in a clinical trial setting with three items to assess the presence of GH lesions, lesion type, and the presence of prodrome symptoms. The remaining items assess itching, pain, pain with urination, draining/discharge, and swelling. **CONCLUSIONS:** The GH-SSD is a brief PROM developed in full alignment with the FDA PRO guidance. Content validity was supported, and psychometric assessment is underway.

PIN53

CONTENT VALIDATION OF A NEW PATIENT-REPORTED OUTCOME (PRO) INSTRUMENT IN HOSPITAL-ACQUIRED BACTERIAL PNEUMONIA (HABP)

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OBJECTIVES: Currently no PRO instrument has been developed to capture HABP patients' symptoms and functioning. The goals of this study were to identify patient-reported HABP symptoms and impacts to develop items for a new HABP PRO instrument. **METHODS:** Patients were recruited at four US clinical sites. The study was conducted in two stages via telephone interviews. One-on-one concept elicitation (CE) interviews were conducted until concept saturation was achieved. In developing items for the new HABP PRO instrument, our previously developed Community-Acquired Bacterial Pneumonia (CABP) PRO instrument item pool was utilized given observed overlap of concepts between the two patient populations. Combined CE/cognitive debriefing (CD) interviews were then conducted with additional HABP patients to further explore the HABP disease experience and assess relevance and understanding of items, response options, instructions, and recall period of the new instrument. Data were analyzed using an iterative process to identify themes and concepts documented according to FDA PRO Guidance. **RESULTS:** Eighteen patients participated in CE (n=8) and combined CE/CD (n=10) interviews. Mean age of the sample was 62 years (SD = 12, range: 41-84); 50% were male. Similar to CABP, the most common spontaneously reported symptoms among HABP patients were difficulty breathing (72%), cough (56%), chest pain (56%), fever (50%), and lack of energy (50%). Significant impacts on physical (72%) and emotional (67%) functioning were also reported. Analysis of CD data indicated all 10 patients interpreted the large majority of items on the HABP PRO as intended, and reported the concepts covered were comprehensive and relevant to their illness. **CONCLUSIONS:** Results support the content validity of the HABP PRO items within a HABP population. Future research will assess the measurement properties of this new instrument.

PIN54

ANTIVIRAL THERAPY IMPROVES THE HEALTH-RELATED QUALITY OF LIFE OF PATIENTS WITH CHRONIC HEPATITIS B VIRUS INFECTION IN CHINA

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OBJECTIVES: This study aimed to evaluate the effect of antiviral therapy on patients' health-related quality of life (HRQL) in an observational clinical study of

nucleos(t)ide analogue (NUC) treatment for chronic hepatitis B (CHB) in China. **METHODS:** NUC naïve CHB patients were recruited from 63 hospitals across China. The HRQoL of the patients was assessed using the EQ-5D-3L questionnaire prior to initiation of NUC treatment and reassessed at 24, 48, 72, and 96 weeks after treatment initiation. Changes in 'poor' HRQoL status, defined as reporting any of the five EQ-5D health problems, and the EQ-VAS score were examined, with missing data imputed using the last-observation-carried-forward method. **RESULTS:** Of 3438 patients (mean age: 39.5 years; female gender: 26.2%) enrolled, the majority was inpatient (53.6%) and treated with entecavir (53.1%). The proportion of patients (95% confidence interval [CI]) in poor HRQoL monotonically decreased from 24.9% (23.4% to 26.3%) before treatment to 18.1% (16.8% to 19.3%) at 24 weeks, 16.6% (15.4% to 17.9%) at 48 weeks, 15.1% (13.9% to 16.3%) at 72 weeks, and 14.3% (13.1% to 15.4%) at 96 weeks after treatment initiation. The mean EQ-VAS score (95%CI) increased from 83.3 (82.9 to 83.8) before treatment to 86.5 (86.1 to 86.9) at 24 weeks, 86.9 (86.5 to 87.4) at 48 weeks, 87.4 (86.9 to 87.8) at 72 weeks, and 87.9 (87.5 to 88.3) at 96 weeks after treatment initiation. Among 854 patients who were in poor HRQoL before treatment, only 33.6% remained in poor HRQoL at 96 weeks after treatment; the mean EQ-VAS score (95%CI) increased from 75.3 (74.3 to 76.3) before treatment to 84.2 (83.3 to 85.2) at 96 weeks after treatment. **CONCLUSIONS:** The HRQoL of CHB patients in mainland China continuously improves in their first two years of antiviral therapy. The treatment effect is more salient among patients in poor health.

PIN55

DESCRIPTIVE ANALYSIS OF HEALTH-RELATED QUALITY OF LIFE IN HIV/AIDS PATIENTS AT A HEALTH INSURER IN COLOMBIA

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OBJECTIVES: To measure health-related quality of life (HRQoL) and to explore its determinants in a HIV/AIDS patients sample at a health insurer. **METHODS:** A cross-sectional descriptive study was performed out with the application of EuroQol 5 dimensions system (EQ-5D-5L) and Visual Analog Scale (VAS). Proportional non - probabilistic sampling was carried out, with distribution in 8 cities. Clinical data were obtained from medical history and sociodemographic data through an annex to the survey. HRQoL index values were obtained based on the literature. A Spearman correlation analysis was performed between the dependent variables (EQ-5D-5L index and mean EQ-VAS). The means were compared by stratum among clinical and sociodemographic variables using the Kruskal-Wallis test. IBM-SPSS 22[®] statistical package was used. **RESULTS:** Analyzable data were obtained from 265 patients. The mean (SD) of EQ-5D-5L index was 0.95 (0.09) and the EQ-VAS 86.99 (16.10). We obtained 59 health states and the most frequent were 11111 (48.30%) followed by 11112 (6.04%). The correlation between the dependent variables was positive ($r = 0.53$). The mean EQ-5D-5L index was lower as age increased. HRQoL values between clinical variables were not different, while at socio-demographic level showed significant differences ($p < 0.05$) by socioeconomic stratum with a EQ-5D-5L index 0.92 (0.11) in stratum 1, and 0.97 (0.04) in strata 3 to 5; while in employment the mean EQ-VAS was 75.33 (25.25) in unemployed and 90.08 (11.71) in dependent employees. **CONCLUSIONS:** Regarding the clinical conditions of the patients, there were no significant differences in HRQoL, however, this analysis suggests that sociodemographic conditions such as employment and income affect the well-being of these patients. It is recommended to carry out complementary studies to evaluate the validity and psychometric properties of EQ-5D-5L in this population.

PIN56

A COMPARISON OF PATIENT REPORTED OUTCOME MEASURES DESIGNED OF USE IN HEPATITIS C VIRUS

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OBJECTIVES: Chronic hepatitis c virus infection (HCV) affects over 150 million people worldwide and an estimated 2.7-3.9 million people in the US. HCV is the most common chronic blood borne viral infection in the US and the leading cause of chronic liver disease and transplantation. The objective of this study was to compare and contrast the psychometric properties of disease-specific patient reported outcome measures (PROMs) used in HCV. **METHODS:** Comprehensive literature review was conducted to identify self-administered PROMs in English with at least one publication citing psychometric properties. Selected instruments were evaluated based on: conceptual model, practicality (≤ 15 minutes to complete), depth (floor and ceiling effects $\leq 15\%$), reliability (internal consistency and test retest), construct validity (convergent and divergent or confirmatory factor analysis), and responsiveness for group level decision making. **RESULTS:** Ten instruments were evaluated: Chronic Liver Disease Questionnaire (CLDQ), Chronic Liver Disease Questionnaire-HCV (CLDQ-HCV), hepatitis c virus patient reported outcomes instrument (HCV-PRO), chronic hepatitis c virus treatment satisfaction (HCVTSAT), hepatitis quality of life questionnaire (HQLQ), liver disease quality of life (LDQOL), liver disease symptom index version 1 and 2 (LDSI V1/V2), Patient Reported Outcome Quality of Life survey for HCV (PROQOL-HCV), and liver disease and care specific patient satisfaction instrument (QUOTE-LIVER). All instruments except HQLQ and LDQOL did not meet practicality criteria. CLDQ-HCV, HCV-PRO and HQLQ met study criterion for reliability and construct validity. Reliability data was not available for most scales. Criterion for construct validity was also met for CLDQ, LDSI-V1/V2, LDQOL and HCVTSAT. Lack of meeting study criteria was due predominantly to unavailable psychometric data. **CONCLUSIONS:** If health related quality of life is the study objective CLDQ-HCV met all study criteria, followed by HCV-PRO; however, if patient satisfaction is the goal, HCVTSAT met most study criteria. PROM instrument choice must also consider study objective in addition to psychometric properties.

PIN58

QUALITY OF LIFE OF PERSONS LIVING WITH HIV IN A BIG CITY: SEARCHING FOR PREDICTORS

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OBJECTIVES: Identify the most significant predictors affecting the quality of life (QoL) of persons living with HIV (HIV Persons) in a big city. **METHODS:** There was conducted three-stage study. At the first stage HIV morbidity and mortality follow up indicators of the HIV Persons who is living in megalopolis (Astana) were analyzed in comparison with the republican indicators for the 10 years period (2004-2013). At the second stage through the use of earlier developed by our force questionnaire, which is including 49 questions. At the third stage the QoL of HIV-infected persons was studied. The SF-36 questionnaire was chosen as the main tool for QoL research. The selection sample size has included 170 respondents. **RESULTS:** It was found that HIV-infection morbidity indicators of the capital city were significantly lower than the countrywide indicators. Despite the stick-slip nature, a morbidity steady growth was marked, then that rate stabilized and became 1.11 per 100 000 of population in 2013. Comparison of QoL indicators by gender in relation to the majority of the scales of physical health component (PHC) as well as the total PHC in general revealed that men QoL indicators were higher than women QoL indicators. In the meantime the mental health component (MHC) indicators in relation to the total MHC and to the most scales were higher in women, but statistical differences between all scales were not significant ($p > 0.05$). Comparison of QoL indicators showed no dependence on the time of the establishment of HIV status. It was found that the drug use significantly reduces the QoL. **CONCLUSIONS:** Results of the study revealed the multivalued role of predictors that influence the quality of life of persons living with HIV in a big city. HIV morbidity risk reduced factors allow to carry out practical recommendations on the prevalence of the disease containment.

INFECTION - Health Care Use & Policy Studies

PIN59

PATIENT AND PHYSICIAN DIRECTED SURVEY ON HUMAN PAPILLOMAVIRUS VACCINE IN MUMBAI, INDIA

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OBJECTIVES: i. An adult-directed survey to assess the knowledge of Human Papillomavirus (HPV), Cervical Cancer and Human Papillomavirus Vaccine, the perception and intent to vaccinate. ii. A health practitioner-directed survey regarding the provision of HPV Vaccination at the principal practice site. **METHODS:** The survey was carried out among willing participants ($n=327$) from Mumbai, India, 18 years of age or older. A structured questionnaire was distributed via email and other social networking sites. Another short survey was conducted among paediatricians, gynaecologists and general practitioners in Mumbai, India to gauge their practice methods and attitudes towards HPV vaccination. **RESULTS:** About 60% participants had a general understanding of HPV while 24% were familiar with the HPV vaccine. It was found that 3 out of every 5 doctors administer the vaccine, but only about 14% female participants had taken it. Due to lack of proper knowledge, 74% of the participants were apprehensive about taking the vaccine. Of the participants initially unaware, 40% were willing to take it after obtaining some information provided through the survey. **CONCLUSIONS:** The utilization of the recently introduced HPV vaccine is challenged not only by lack of education, but also by the high cost, feasibility and logistics of the three-dose regimen. The need of the hour is to increase awareness about HPV as a major cause of cervical cancer in young and middle-aged women and the availability of this vaccine as an effective prophylactic method. With proper patient counselling and management strategies, healthcare professionals can play a vital role in increasing the acceptability of the vaccine in adolescents, parents and the community.

PIN60

HEPATITIS C TREATMENT IN PATIENTS WITH HEPATITIS B VIRUS/HEPATITIS C VIRUS CO-INFECTION

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OBJECTIVES: Recently, FDA is warning about the risk of hepatitis B virus (HBV) reactivation among hepatitis C virus (HCV) patients under direct-acting antivirals (DAA) therapy, who had current or previous HBV coinfection. Understanding HCV treatment pattern among HBV/HCV coinfecting population is important. This study aimed to examine HCV treatment uptake for patients with HCV/HBV coinfection compared to HCV mono-infection. **METHODS:** A retrospective cohort study was conducted using Truven Health MarketScan Commercial Claims Database (2008-2014). Patients $>=18$ years old with newly diagnosed HCV and had no use of HCV treatment before the first HCV diagnosis (index date) were included. HCV/HBV coinfection was defined as any HBV diagnosis within 12 months prior to index date. HCV treatment uptake was compared between HBV/HCV co-infected and HCV mono-infected patients by multivariate logistic regression, controlling for age, gender, region, payer, drug abuse and comorbidities (e.g. HIV, cirrhosis, etc.). Treatment types and initiation time were compared by Chi-square tests and two-way ANOVA. **RESULTS:** A total of 60,538 HCV patients were identified, with 1.3% HBV/HCV co-infection ($n=788$, mean age= 52yrs, 69.5% male) and 98.6% HCV mono-infection ($n=59,750$, mean age= 53yrs, 60.0% male). Only 4.6% of co-infected patients ($n=36$) initiated HCV treatment, whereas 17.2% mono-infected patients ($n=10,281$) did. Among HBV/HCV co-infected patients, 44.4%, 36.1% and 19.4% received interferon/ribavirin, DAA plus interferon/ribavirin, and all oral therapy, respectively; the corresponding percentages were 40.8%, 35.4%, and 23.8% for HCV mono-infected patients ($p=0.81$). The average time (months) to

initiating interferon/ribavirin, DAA plus interferon/ribavirin, and all oral therapy were 8.8, 17.6, and 13.8 for coinfection, and 7.5, 12.6, and 25.0 for mono-infection ($p < 0.05$). After adjusting for baseline characteristics, HBV/HCV co-infected patients were 76% less likely to initiate HCV treatment (OR=0.24 95%CI 0.17-0.33). **CONCLUSIONS:** A lower rate of HCV treatment initiation was observed even in the era of direct-acting antivirals in HBV/HCV co-infected patients.

PIN61

IMPROVING FACTORS OF PPV23 VACCINE COVERAGE RATES IN ADULTS AGED 65 YEARS IN JAPANESE MUNICIPALITIES –NATIONWIDE COMMUNITY-BASED SURVEY

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OBJECTIVES: In the vaccination program for the 23-valent pneumococcal polysaccharide vaccine (PPV23) for elderly in Japan, various measures are taken by municipalities to raise PPV23 coverage rates. These measures include notification of program eligibility through newsletters, broadcasting and financial support to reduce out-of-pocket costs. We investigated whether both notification methods and financial support raise the PPV23 coverage rates in Japan. **METHODS:** A postal and web-based nationwide survey was sent in May 2015 to all municipalities of Japan (n=1741). We used a self-administered questionnaire to collect the PPV23 coverage rates in adults 65 years, which is the main outcome in this study. Details on notification method (number of times and type) and out-of-pocket costs for vaccination (financial support) were also collected by the questionnaire. Additional municipality-level variables (potential modifiers of vaccination) were collected from the national statistics in Japan, including demographic (population age), socio-economic (income, unemployment) and health system indicators (physician supply). Multiple regression was used to explore the effect of the notification methods and out-of-pocket costs on PPV coverage rates adjusting for municipality-level factors. **RESULTS:** 1022 responded to the survey (response rate 58.7%). Median PPV coverage rate among municipalities was 41.3% (IQR: 32.2-48.5%). In multiple regression, PPV coverage increased with the number of notifications sent to an eligible individual ($p < 0.001$, adjusted means; none; 23.7%, once; 42.8%, twice; 49.2%, three times and more; 47.4%). PPV23 coverage decreased by 3.0% (2.3-3.7%) per 1000 Yen increase in out-of-pocket costs ($p < 0.001$). The type of notification was not significantly associated with PPV23 coverage ($P=0.60$). **CONCLUSIONS:** This study provides insight into factors that influence PPV23 vaccine coverage in Japanese municipalities. We found that the number of notifications sent to eligible adults, as well as out-of-pocket costs, were significantly associated with vaccine uptake.

PIN62

IMPLEMENTATION STATUS OF COST-EFFECTIVE VACCINES IN GAVI-ELIGIBLE COUNTRIES

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OBJECTIVES: To examine implementation status for vaccine interventions evaluated in studies using “cost-effectiveness” measured in terms of cost-per-DALY averted, and catalogued in Tufts Medical Center’s Global Health Cost-Effectiveness Analysis (GHCEA) Registry. **METHODS:** We reviewed the GHCEA Registry, which includes 479 cost-per-DALY averted studies published through 2015. We limited our search to vaccine-related interventions in countries eligible at some point from 2000 to 2016 for financial aid from the Global Alliance for Vaccines and Immunizations (GAVI). The 62 identified studies reported 590 incremental cost-effectiveness ratios (ICERs), each of which compares an intervention’s cost and health impacts to a comparator program (or to no action). We classified ICERs as “cost-saving” (lower costs, better health), “highly cost-effective” (ICER < 1x per capita GDP), or “cost-effective” (ICER from 1x to 3x per capita GDP). Finally, for interventions with implementation status information (as characterized by GAVI and in-country sources), we used the Fisher exact test to assess the relationship between implementation and favorable cost-effectiveness (“highly cost-effective” or “cost-saving”), vs. unfavorable cost-effectiveness (at least one ICER not “highly cost-effective” or better). This last analysis restricted attention to studies pertaining to 2016 GAVI-eligible countries. **RESULTS:** The Registry catalogs articles on vaccines for 10 diseases. The most frequently reviewed interventions addressed HPV (49% of ICERs) and rotavirus (33%). Regions most studied included the WHO Africa Region (43%) and Southeast Asia (21%). The most common study sponsors were the Gates Foundation (40%) and government institutions (31%). The 590 ICERs were “cost-saving” (10%), “highly cost-effective” (80%), “cost-effective” (6%), or not cost-effective (4%). We had implementation information for 101 favorably “highly cost-effective” interventions and for 8 interventions with unfavorable cost-effectiveness. The implementation odds ratio for favorable vs. not favorable cost-effectiveness was 20 ($P < 0.001$). **CONCLUSIONS:** Favorably “highly cost-effective” vaccine interventions are most likely to be implemented.

PIN63

AVAILABILITY AND USE OF MALARIA RAPID DIAGNOSTIC TEST IN HEALTH FACILITIES IN GOMOA WEST DISTRICT, GHANA

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OBJECTIVES: The objective of the study was to assess availability and use of malaria RDT in health facilities in the Gomoa West district and investigate adherence patterns of clinicians to the incorporation of malaria RDT results in case management. **METHODS:** A cross-sectional study was carried out in selected health facilities to review stock records for malaria RDT, and to assess malaria RDT availability over one year period. A pretested data extraction sheet was used to extract data on the proportions of suspected malaria cases tested with malaria RDTs. A structured

questionnaire was administered to prescribers to collect data on adherence to RDT use and incorporation of RDT results in case management. Data were analyzed and chi square test was used to assess associations. Detailed analysis was done with logistic regression model to assess strength of associations. **RESULTS:** Least malaria RDT availability of 87.7% was recorded in 3 facilities. Three facilities recorded 100% availability. Overall, 256(73.6%) out of 348 suspected malaria cases were tested with malaria RDT. No significant associations were found between malaria RDT testing and age (below 5 years and 5 years and above), temperature and caseload per day. However there was significant association between facility type and malaria RDT testing (p value < 0.001). Out of 137 positive malaria RDT results, 132(96.3%) received antimalarial. 68 (37.1%) out of 119 negative results did not receive antimalarial while 51(42.9%) received antimalarial. There was significant association between malaria RDT results and prescribing of antimalarial (p value < 0.001). **CONCLUSIONS:** Malaria RDT availability and RDT testing rates were optimal in all health facilities with testing rates better in CHPS and health centers than district hospital. However, given the proportion of patients receiving presumptive treatment is high (26.4%) and some negative malaria RDT cases receive treatment, there is the need to intensify education if success in adherence to guidelines is to be achieved.

PIN64

WELL-CHILD VISITS AND HPV VACCINATION IN PRETEENAGERS AGED 11-12 YEARS DURING 2007-2015 IN THE UNITED STATES

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OBJECTIVES: Well-child visits (WV) provide the best opportunities for vaccinations in the US. The Advisory Committee on Immunization Practices (ACIP) recommends vaccination of 11-12 year old (y/o) females and males with HPV (Human Papillomavirus) vaccine. This study aimed to estimate the % of preteenagers aged 11-12 years who had WV and who received the first dose of HPV vaccine (HPV1st) from 2007 to 2015 and to estimate, for those preteenagers who did not receive HPV1st, the % of them who would have another scheduled WV. **METHODS:** This was a retrospective database (Market-Scan®) study. Eligible subjects were 11-12 y/o females and males who had continuous health plan enrollment since January 1, 2007 or January 1 of the year they turned 9 y/o and did not have HPV vaccine previously. Females were excluded if they had medical claims for pregnancy, delivery, cervical cancer, or hysterectomy. Percentages of WV and HPV1st, overall and during WV, were estimated. Descriptive analyses were used in assessing the study’s objectives. **RESULTS:** There were a total of 2,363,820 eligible subjects; 56.8% 11 y/o and 43.2% 12 y/o; 63.5% female and 36.5% male. From 2007-2015, 53.4% of 11 y/o and 56.0% of 12 y/o had WV; 8.9% of 11 y/o and 12.8% of 12 y/o initiated HPV1st. Among those who initiated HPV1st, 57.3% and 55.5% were during WV for 11 y/o and 12 y/o, respectively. For those who did not receive HPV1st at 11-12 y/o, it was less likely they would have another scheduled WV, ranging from 39.7% at 12-13 y/o to 11.5% at 19-20 y/o and less likely they would initiate HPV1st, ranging from 9.2% at 12-13 y/o to 1.1% at 19-20 y/o. **CONCLUSIONS:** This analysis suggests that WV at 11-12 y/o provide the best opportunity to maximize the potential of the HPV vaccination program in the US.

PIN65

IMPACT OF DOLUTEGRAVIR AND TENOFOVIR ALAFENAMIDE ON HIV REGIMEN SWITCHING TRENDS

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OBJECTIVES: With the introduction of the dolutegravir (DTG) single-tablet regimens (STRs) and emtricitabine tenofovir alafenamide (FTC/TAF) STRs, physicians have more prescribing options to treat HIV. The objective of this study is to identify whether the availability of these new treatments has impacted the frequency of switching therapy in the United States (US). **METHODS:** Data from the Ipsos HIV US Therapy Monitor (TM) and HIV Scope Study (Scope) were used. Both the TM and Scope are retrospective medical chart reviews of patients with HIV conducted in 3-month intervals (N=200 and N=100 physicians per interval, respectively). The TM study includes a sequential selection of 20 HIV patients per physician whereas Scope includes a sequential selection of 6 HIV patients initiating therapy and 6 HIV patients switching therapy (i.e., all other patients would not be included in the Scope study). Both studies included data on demographics, disease history and treatment patterns. **RESULTS:** TM had a total of N=296 physicians and Y=30,991 patients and Scope N=154 physicians and Y=7,348 patients. In the TM, the rate of switching HIV therapy significantly increased from Q3 2014 (7.4%) to Q3 2016 (14.1%) ($p < .01$), coinciding with the launches of the DTG STR (Q3 2014) and the first FTC/TAF STR (Q1 2016). During the same timeframe, Scope showed the top reasons for switching HIV therapy were ‘implementation’ and ‘preemptive switch to avoid side effects’ which increased from 2.1% to 20% ($p < .01$) between Q3 2014 and Q3 2016. **CONCLUSIONS:** Switching therapy was less common among HIV patients until the launch of DTG and FTC/TAF based STRs, which doubled the rates of switching. Physicians reported that simpler and more tolerable regimens were the key reasons for increased switching.

PIN66

ASSESSMENT OF A PHARMACIST-LED EDUCATIONAL PROGRAMME ON COMMUNITY RESIDENTS’ KNOWLEDGE AND PERCEPTIONS OF ANTIBIOTIC RESISTANCE IN PENANG, MALAYSIA

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OBJECTIVES: To assess the impact of an educational programme on community residents’ knowledge and perceptions of antibiotic resistance in Jelutong District,

Penang, Malaysia. **METHODS:** A single cohort pre/post-intervention study was conducted among the community residents from 30th January to 30th April 2016. Using convenience sampling, 70 residents (aged ≥ 18 years) were invited to participate in an educational programme on antibiotic resistance. The programme included a talk, video presentation and the distribution of a booklet regarding this issue. The participants were asked to complete a validated, pre-tested self-administered questionnaire before the programme, immediately after the programme, at 1 month and 3 months follow-up. The questionnaire consisted of six statements assessing their knowledge of antibiotic resistance and four statements to assess their perceptions of this issue. The primary outcome measures were an increase of their antibiotic resistance knowledge and perception scores after participating in the programme. Data was analysed using the Statistical Package for the Social Sciences version 22.0 and was presented as mean \pm standard deviation. **RESULTS:** Sixty eight of the 70 residents participated in the study (response rate = 97.14%), but six of them (8.82%) dropped-out at 3 months follow-up. Their knowledge scores were 1.24 ± 0.81 , 5.41 ± 0.50 , 5.03 ± 0.67 and 4.39 ± 0.95 before the programme, immediately after the programme, at 1 month and 3 months follow-up, respectively ($p < 0.001$). Their perception scores were 1.24 ± 0.81 , 3.82 ± 0.38 , 3.50 ± 0.50 and 3.13 ± 0.34 before the programme, immediately after the programme, at 1 month and 3 months follow-up, respectively ($p < 0.001$). **CONCLUSIONS:** The educational programme significantly increased the knowledge and positively changed the perceptions of the community residents towards antibiotic resistance. Therefore, further initiatives should include the scaling up of the programme to combat antibiotic resistance at the community level in Malaysia.

PIN67

IMPACT OF AN EDUCATIONAL INTERVENTION ON COMMUNITY RESIDENTS' KNOWLEDGE AND ATTITUDES TOWARDS ANTIBIOTICS IN PENANG, MALAYSIA

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OBJECTIVES: To assess the impact of an educational intervention on community residents' knowledge and attitudes towards antibiotics in Jelutong District, Penang, Malaysia. **METHODS:** A single cohort pre/post-intervention study was conducted among the community residents between 30th January and 30th April 2016. Using convenience sampling, 70 residents (aged ≥ 18 years) were invited to participate in an educational intervention that included a talk, video presentation and the distribution of an antibiotic booklet about the responsible use of antibiotics. Pre-intervention, the participants were asked to complete a validated, pre-tested self-administered questionnaire. Then, they were asked to complete the same questionnaire immediately post-intervention, at 1 month and 3 months follow-up. The questionnaire consisted of nine statements assessing their knowledge of antibiotics and six statements to assess their attitudes towards antibiotics. The primary outcome measures were a post-intervention increase of their antibiotic knowledge and attitude scores. Data was analysed using the Statistical Package for the Social Sciences version 22.0 and was presented as mean \pm standard deviation. **RESULTS:** Sixty eight out of 70 residents participated in the study (response rate = 97.14%), but six of them (8.82%) dropped-out at 3 months follow-up. Their knowledge scores were 2.50 ± 0.92 , 8.24 ± 0.74 , 7.85 ± 0.78 and 7.23 ± 0.42 at the pre-intervention, immediately post-intervention, at 1 month and 3 months follow-up, respectively ($p < 0.001$). Their attitude scores were 2.32 ± 0.72 , 5.82 ± 0.38 , 5.50 ± 0.50 and 5.13 ± 0.34 at the pre-intervention, immediately post-intervention, at 1 month and 3 months follow-up, respectively ($p < 0.001$). **CONCLUSIONS:** The educational intervention significantly increased the knowledge and positively changed the attitudes of the community residents towards antibiotics. Hence, further initiatives should include the scaling up of the intervention to promote the responsible use of antibiotics among community residents in Malaysia.

PIN68

PREVALENCE AND FACTORS ASSOCIATED WITH COMPLETING MMR VACCINATION SERIES IN A RECENTLY RESETTLED REFUGEE POPULATION

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OBJECTIVES: Approximately 70,000 refugees are resettled to the US each year, and it is important that refugees receive immunizations to prevent communicable disease. The measles, mumps, rubella (MMR) vaccination is a two-part vaccination that protects against three diseases. This study sought to identify factors associated with MMR vaccination series completion in a refugee population resettled in the US. **METHODS:** We analyzed data from the Jefferson Longitudinal Refugee Health Registry, which contains clinical, demographic, and immunization data. The study population included refugees resettled to the US who received an initial domestic medical examination and follow-up care from a primary care clinic in Philadelphia from 2008-2014. Those not eligible for MMR vaccination per Advisory Committee on Immunization Practices guidelines were excluded. Prevalence of MMR completion was computed. Binomial logistic regressions were used to estimate the association of clinical and demographic factors with MMR series completion. **RESULTS:** Of the 1,150 refugees included in the study, 69% were 18-45 years old and 11% were under the age of 18. Forty-six percent of refugees had documentation of MMR vaccination series completion. Age group was significantly associated with MMR completion. Patients 4-11 years old were most likely to complete the series (OR 136, 95%CI: 45-419) compared to 65+ year-old patients. Country of origin was associated with increased MMR completion for patients from Myanmar who transited through Thailand (OR 4.7, 95%CI: 2.7-8.4), Myanmar who transited through Malaysia (OR 2.9, 95%CI: 1.8-4.7), Bhutan/Nepal (OR 5.5, 95%CI: 3.6-8.2), and Eritrea/Ethiopia (OR 2.2, 95%CI: 1.2-3.8) compared to Iraqi patients. Hypertension and diabetes diagnoses were not found to be significantly associated with MMR series completion. **CONCLUSIONS:** Age and country of origin were significantly associated with MMR

completion. These findings can be used to identify quality improvement projects to ensure vaccination completion within a recently resettled refugee population.

PIN69

ANALYSIS OF ECONOMIC BURDEN OF INFLUENZA AND ARI IN UKRAINE

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OBJECTIVES: Every year in Ukraine 15-17% of the total population suffers from influenza and ARI. In Ukraine the treatment cost is 6 USD during 5 days without complications. **METHODS:** We used data of the MoH of Ukraine about the incidence of influenza, data of the rate of influenza vaccination, cost analysis for influenza vaccine, modeling method. **RESULTS:** Number of patients with influenza and ARI in Ukraine in 2015-2016 year amounted to 5.8 mln people. The total treatment cost during 5 days without complications is 34.8 mln USD. The cost of flu vaccination is 6.87 USD (1 USD=27,5 UAH) per 1 patient in Ukraine. The rate of flu vaccination is 0.3% of the total population 2015-2016. The rate of flu vaccinations among the medical worker is 20%. Indirect costs for sick list and employee absence at work significant economic burden for the budget constitute. The minimum payment per patient for 1 day is 6 USD. It means, that the minimum payment for sick list for 5 days per patient is 30 USD and it refers to the expenses of institution. In 2016 the number of economically active population was 16 million peoples. In modeling situations when 15% of people (2.4 million) is sick, the costs of sick list will be 72 mln USD, and the cost of vaccination will be 16,49 mln USD. **CONCLUSIONS:** Therefore, to reduce the economic burden on the health care system and reduce indirect costs necessary to increase the rate of vaccination among the working peoples of population. Rate of benefit amount to 4,4 times higher.

PIN70

EVALUATION OF CLINICAL AND ECONOMIC OUTCOMES ASSOCIATED WITH POTENTIAL MISCLASSIFICATION OF CLOSTRIDIUM DIFFICILE INFECTION

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OBJECTIVES: The Centers for Medicare and Medicaid Services (CMS) require public reporting of Clostridium difficile infection (CDI) rates as part of the Inpatient Quality Reporting Program. Under-performing hospitals may be at risk for significant financial penalties. This study evaluated incremental health care resource use and costs associated with potential misclassification of CDI. **METHODS:** This was a retrospective, observational study of inpatient adults with a positive stool sample for Clostridium difficile from January 1, 2015 to March 31, 2016 at a community hospital. Patients were classified as definite community-onset CDI (positive stool sample within 3 days of admission) or healthcare facility-onset (positive stool sample at least 3 days post-admission). The healthcare facility-onset group was analyzed to identify symptomatic patients within 3 days of admission but had a ≥ 3 day delay in sampling stool for Clostridium difficile. This group was defined as the possible community onset CDI group. Cost to the hospital was calculated as the sum of the cost of the additional days of hospital stay and the estimated cost of the CMS-imposed payment penalty using data from Georgia non-profit hospital estimates and CMS. The definite and possible community-onset groups were compared with respect to costs, demographics, admission diagnoses, laboratory findings, treatment, length of stay, re-admission, and death. **RESULTS:** A total of 130 patients were evaluated: definite community-onset CDI group (n=105) and possible community-onset CDI group (n=25). The possible community-onset group had a longer total length of stay (10.8 vs. 7.6 days, P=0.0075) and duration of inpatient CDI treatment (5.5 vs. 3.5 days, P=0.0352). Length of stay translated to \$148,640 in total costs and financial penalties, due to a 1% reduction in total CMS payment, translates to \$13,150. **CONCLUSIONS:** Inpatient misclassification of CDI may be associated with longer hospital stay and treatment duration, leading to significant economic consequences and implications for reporting and reimbursement metrics.

PIN71

EVOLUTION OF THE MARKET FOR INTEGRASE INHIBITORS FOR HIV INFECTION AMONG ADULT PATIENTS IN CANADA

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OBJECTIVES: Human immunodeficiency virus (HIV) infection, which leads to the progressive destruction of CD4+ lymphocytes essential for the immune system, is still a concern in Canada. Cases of acquired immunodeficiency syndrome have however decreased over the last 20 years mainly due to the introduction of highly active antiretroviral therapy (HAART). The objective of this study was to evaluate the Canadian market for integrase inhibitors in the last five years. **METHODS:** Data on retail prescriptions and drugstore and hospital purchases of antiretroviral drugs including integrase inhibitors for the treatment of HIV infection in Canadian adults were obtained from QuintilesIMS. The number of prescriptions and purchases (in \$Can) were collected for 12-month periods ending November for the last five years (2012-2016). **RESULTS:** The contribution of integrase inhibitors to the total HAART market has been increasing steadily in the last five years; in terms of number of prescriptions and purchases, from 5.7% and 7.1% in 2012 to 22.1% and 32.4% in 2016, respectively. In 2016, second in the HAART purchase market was nucleoside reverse transcriptase inhibitor (NRTI) combinations (21.2%) followed by protease inhibitors (14.8%), combination NRTIs/non-NRTIs (NNRTIs; 14.3%), NRTIs (13.1%), NNRTIs (3.2%), entry inhibitor (0.9%) and fusion inhibitor (0.1%). In the integrase inhibitor class, marked increases in both prescriptions and purchases were observed in the last four years for elvitegravir/ cobicistat/emtricitabine/tenofovir disoproxil fumarate, in the last three years for dolutegravir and in the last two years for dolutegravir/lamivudine/abacavir while prescriptions and purchases for raltegravir

only increased slightly from 2012 to 2016. **CONCLUSIONS:** HAART for HIV infection in adults represents a market of almost three quarters of a billion dollars in Canada. In the last five years, market share of integrase inhibitors has increased markedly representing in 2016 one third of the total HAART market in Canada.

PIN72

ASSESSMENT OF AWARENESS REGARDING SWINE FLU (INFLUENZA A) AMONG MEDICAL AND PHARMACY STUDENTS OF PAKISTAN

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OBJECTIVES: The study aimed to assess the awareness among medical and pharmacy students of different colleges and universities of Pakistan toward Swine flu (Influenza AH1N1). **METHODS:** A descriptive, cross sectional study design was adopted to conduct the study. A self-administered questionnaire was administered in 500 students of both urban and rural community of Pakistan during January 2016 to October 2016. Respondents were selected by using convenient sampling method. Data was analyzed using IBM SPSS version 20. Descriptive statistics were applied to evaluate the data and chi square test was used to check association between dependent and independent variables. **RESULTS:** Among the participants, 221 (44.2%) were male and 279 (55.8%) were female. Almost all respondents 455 (91.0%) had knowledge about origin of disease, genotype: H1N1 268 (53.6%), H1N2 198 (39.6%), mode of transmission: human 221 (44.2%), pigs 298 (55.8%) and preventive measures 475 (95%) of swine flu. Participants were having less knowledge about vaccination 285 (57%), lab screening, and availability of facilities to practitioner and patients by government regarding swine flu. **CONCLUSIONS:** Knowledge regarding swine flu pandemic was good among participants but need further improvement as well. Government should focus on providing isolated ward facility, special diagnostic and treatment facility to swine flu patients. Government should focus on facilitating mask availability to practitioners as protective measure

PIN73

KAP STUDY REGARDING HIV/AIDS PATIENTS CONDUCTED AMONGST PAKISTANI UNIVERSITY STUDENTS

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OBJECTIVES: HIV/AIDS is a high risk disease with a little prevalence currently in Pakistan but due to low health budget, less educational programs, drug abusers, poverty, illiteracy, social and moral constraints. The main aim of this study is to design a study which assesses the knowledge and perception of young generation about HIV/AIDS especially the university students. **METHODS:** This study consists of a random cross sectional study design involving 200 university students. Data collection was done via validated questionnaire and SPSS 21.0 was used for statistical analysis. Independent and dependent variables were analyzed using odds ratio significant at 95% CI (P < 0.05). Pearson Chi-square was performed for finding association between dependent and independent variables. **RESULTS:** Overall response rate to our questionnaire was good. Gender and age showed a significant relationship (P < 0.05) with the knowledge of HIV/AIDS. Age of the students has a significant influence on the course of the available treatment options. Health information dissemination via different sources had a major role and demonstrated a significant relationship (P < 0.05) with the knowledge of the students. **CONCLUSIONS:** The response from different students was quite interesting and diverse. The desire to gain knowledge is inevitably shown from this study. The knowledge, their perception and their behavior and attitude towards an infected patient shows the need for health training and education regarding HIV/AIDS. The need of budget allocation towards initiating HIV/AIDS programs targeting awareness and education, by a Government or a government funded organization becomes vital to improve the literacy regarding HIV/AIDS. Campaigns regarding improvising the current knowledge and beliefs should be initiated. Certain health policy reforms will ascertain an increased positive perception about this dreadful disease and young generation equipped with education and knowledge will promote towards a healthier disease free and safe future.

PIN74

A COMPARISON OF THE PRICES OF HIV ANTIRETROVIRAL DRUGS MARKETED IN KUWAIT AND THE US

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OBJECTIVES: This study compared the prices of HIV antiretroviral (ARV) drugs marketed in Kuwait and the US in December 31, 2015. **METHODS:** A list of HIV antiretrovirals approved in the US was extracted from the FDA webpage on December 31, 2015. Average wholesale prices (AWP) were extracted from the RedBook (Truven Health). Prices of HIV ARV drugs in Kuwait was collected for the Ministry of Health list of drug prices. Descriptive statistics and Wilcoxon Signed rank test were conducted using Stata 13.1. **RESULTS:** The FDA approved a total of 28 single active ingredients and 12 fixed dose combinations (FDC) of HIV ARV drugs in the period of analysis. There were 7 single active ingredients (lamivudine, saquinavir, raltegravir, darunavir, zidovudine, atazanavir, and nevirapine) and 2 FDC (lopinavir/ritonavir and lamivudine/zidovudine) included in the Kuwait Ministry of Health pricing list. Those 9 drugs had a total of 11 formulations and 13 strengths. Those 13 products were also available in the US. The median Kuwait

prices for HIV drug products as a percentage of the US prices was 23.8% (range: 13.5%-31.9%). The difference in prices between the two countries was statistically significant (p < .001). Generic bioequivalent alternatives were available in the US for the HVI ARV drugs lamivudine/zidovudine and lamivudine. Kuwait did not list any of those generic alternatives. However, the prices of the US HVI ARV generic drugs were higher than the prices of the Kuwait brands. **CONCLUSIONS:** The Kuwait Ministry of Health list of prices included less than one fourth of the HIV ARV drugs available in the US. The prices of brand HIV ARV in Kuwait were significantly lower than the corresponding brand and generic drug prices in the US.

PIN75

COMPARATIVE STUDY OF FUNDING OPPORTUNITY FOR AN EXPENSIVE INNOVATIVE OUTPATIENT TREATMENT IN EMERGING MARKETS

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OBJECTIVES: To evaluate the funding opportunity for an innovative Hepatitis B treatment in six emerging markets with differently advanced public funding systems: South Korea, Turkey, Indonesia, Philippines, Thailand and Nigeria. **METHODS:** 1) Search in grey literature, on health authorities' and health insurance websites to establish country-specific market access policies. 2) Interviews with healthcare system and funding experts (4 experts per country) to understand funding opportunities. **RESULTS:** In all countries researched the funding of this innovative Hepatitis B drug can go through either a public route or a private one. Turkey and South Korea have the most advanced public coverage systems of the countries. The research found that countries could be grouped as markets where funding were perceived by the experts as going through primarily a) public coverage: Turkey and South Korea, b) out of pocket (OOP): Philippines and Thailand or c) private insurance: Indonesia and Nigeria. The opportunity for getting funding at a price similar to feasible price level in EU was greatest in private insurance markets (Indonesia and Nigeria). Lowest opportunity was seen in public coverage markets (Turkey and South Korea). OOP markets (Philippines and Thailand) offered a medium opportunity. **CONCLUSIONS:** This research shows that countries with less advanced public funding systems provide greater opportunity for funding new expensive this new drug than those with more developed public coverage systems due to high requirements on cost-effectiveness. Funding in countries with less developed public coverage is done through either private insurance pathways or by OOP payment. Though access to expensive drugs in countries with less developed public funding systems is not equitable it nevertheless provides the countries an opportunity to gain experience in the country-specific setting of a new drug. Emerging countries with more advanced public funding systems may be deprived of that opportunity.

PIN77

IMPACT OF EDUCATION STATUS OF MOTHER ON IMMUNIZATION OF YOUNG CHILDREN

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OBJECTIVES: The present study was conducted to find out the impact of mother's education on immunization status of children. **METHODS:** The study was a cross-sectional questionnaire based survey performed in different immunization centers of South Punjab, Pakistan. Total 424 parents with 12-23 months old children were interviewed about the vaccination status of children. Vaccination coverage was assessed by both vaccination card and parent's recall methods. SPSS version 20.0 was used to analyze the data. Appropriate statistics was applied to summarize and analyze the data. **RESULTS:** Complete immunization coverage was seen in 69.5% children while 30.5 % children were found incompletely immunized. Knowledge regarding immunization was also assessed and majority of parents were found with an average level of knowledge and mean knowledge score was 9.13±2.90. However a significant association (p=0.001) was observed between the maternal education and vaccination status of children. **CONCLUSIONS:** Results of the study concluded that complete vaccination trend was more common in educated mothers as compared to illiterate mothers. So vaccination coverage can be improved by educating and providing awareness to parents about immunization.

PIN78

UNDERSTANDING LOW UTILIZATION OF THE 8 WEEK SOFOSBUVIR/LEDIPASVIR SINGLE-TABLET REGIMEN AMONGST ELIGIBLE HEPATITIS C PATIENTS IN THE UNITED STATES

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OBJECTIVES: This research aims to estimate the proportion of hepatitis C (HCV) patients on sofosbuvir/ledipasvir (SOF+LED) that are eligible to finish treatment in 8-weeks and expected to finish the regimen in this timeframe. An additional aim was to identify factors associated with the use of the 8-week regimen. **METHODS:** Data from the Ipsos HCV Therapy Monitor was used. The HCV Therapy Monitor is a prospective medical chart review of patients with HCV conducted by hepatologists, gastroenterologists, infectious disease specialists, and internists in the United States. Physicians randomly selected eligible patient charts and abstracted data on demographics, disease history and treatment patterns. Only US data from December 2015 to November 2016 was used (N=4,431 patients from N=168 physicians). Eligibility for 8 weeks of SOF+LED was defined as being genotype 1, non-cirrhotic, naive to previous HCV treatment, and a HCV viral load below 6 million IU/mL. Logistic regressions were used to predict use of an 8-week SOF+LED regimen (versus a longer duration) from

demographics and clinical characteristics. **RESULTS:** 67.5% of the sample was male, and the mean age was 51.5 years (SD = 12.5). 41.8% of the 4,431 patients in the study were eligible for 8 weeks of SOF+LED. Of these eligible patients, only 46.1% were currently treated and 32.6% were treated with SOF+LED regimen (35.2% of those treated with SOF+LED were expected to finish in 8 weeks). Substance abuse (OR = 2.7) and HIV co-infection (OR = 7.4) were significantly associated with SOF+LED expected treatment durations >8 weeks versus 8 week (both $p < .05$). **CONCLUSIONS:** A minority of currently treated eligible HCV patients were prescribed 8-weeks of SOF+LED. The low levels of use are partially a function of specific concomitant disorders and substance abuse issues. Despite the approval and access to SOF+LED for 8 weeks, utilization remains low.

PIN79

LONGITUDINAL BEHAVIOR CHANGE AND RISKS OF SEXUALLY TRANSMITTED DISEASE INFECTIONS/HUMAN IMMUNODEFICIENCY VIRUS INFECTION AMONG YOUNG AFRICAN AMERICANS: A LATENT TRANSITION ANALYSIS

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OBJECTIVES: The aim of this study was to explore changes in risky sexual behaviors of African Americans (AA) from adolescence to adulthood and the associations of these changes with the risk of contracting sexual transmitted Infections (STI)/Human Immunodeficiency Virus (HIV). **METHODS:** Three waves (wave 1, 3 and 4) of the National Longitudinal Study of Adolescent to Adult Health were used. Five indicators (drinking, Lysergic-acid-diethylamide use, injection drug use, condom use, and number of sexual partners) and one predictor (living with both parents or not) were included to develop a latent profile of young AA's sexual behavior patterns utilizing latent transition analysis performed with SAS software version 7.3. **RESULTS:** A total of 960 AAs with 59.2% females in all waves were included in this study. Latent class and transition probabilities identified four sub-groups: Multiple Risk Behaviors (Class 1), Condomless Sex (Class 2), Less Sexual Activity (Class 3), and Condom Use (Class 4). Compared to those living with a single parent or other relatives, the individuals living with both parents were less likely to locate at class 1, 2, and 4 (odds ratios [ORs] for males respectively: 0.53, 0.44, and 0.67; ORs for females: 0.49, 0.61 and 0.15 respectively). The family structure was a significant predictor of individual's behavior pattern at their age of 14 years ($p=0.0024$). The majority of the AAs were at class 3 at the age of 14 years (male: 65.2%; female: 84.3%). Most young men switched to class 1 (32.3% at 21 years, 43.2% at 28 years); women relocated to class 4 (48.0% at 21 years, 45.5% at 28 years). The results of latent class and transition probabilities were confirmed with the individual's STI/HIV infection status during the past 12 months. **CONCLUSIONS:** Findings of this study highlight the need for tailored intervention programs that target different subpopulations at different points in time.

PIN80

THE INFLUENCE OF SOCIAL DETERMINANTS AND FAMILY STRUCTURE ON SEXUAL BEHAVIORS AMONG ADOLESCENTS FROM AN ECODEVELOPMENTAL PERSPECTIVE

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OBJECTIVES: The aim of this study was to examine the differences in the influence of social determinants, modified by family structures, on sexually transmitted infection (STI)/Human Immunodeficiency Virus (HIV) related sexual behaviors among African American (AA) and non-Hispanic White American (WH) adolescents using the Ecodevelopmental theory. **METHODS:** A total of 5,908 adolescents in Wave I of the Add Health data were identified. Predictors were developed under four systems of the Ecodevelopmental theory. Sexual behavior was measured using a health score generated with six STD/HIV-related sexual behaviors. A higher health score indicates less risky sexual behaviors. An advanced linear regression analysis was employed using SAS software 9.3. **RESULTS:** Family structures were significantly different between the two groups ($p < 0.0001$); 71% of WH lived with both parents, whereas 48% of AA were raised by single mothers. School bonding, feeling the love from mother and father, mother's attitude toward youth's sexual behavior, getting older, and youth's knowledge about condom use influenced health score of those who lived with at least one parent. Safety of the living environment was only associated with the health score of the youth living with single parent ($\beta = -0.353$, $p = 0.0191$), while household income significantly modified the health score of the youth living with both parents ($\beta = 0.001$, $p < 0.0001$). The differences in health scores between WH and AA youth raised by a single-parent ($\beta = 0.263$, $p = 0.0007$) and both parents ($\beta = 0.201$, $p = 0.0004$) remained even after controlling for family structures. Specifically, the level of neighborhood satisfaction, mother's attitude toward youth's sexual behavior, father's attitude toward youth's use of birth control, and if father received public assistance are significant predictors of the health score of the youth brought up by relatives other than parents. **CONCLUSIONS:** These findings highlight the differences in factors influencing STD/HIV-related sexual risk behaviors among two young populations and can contribute to future intervention program development.

PIN81

IMPACT OF 9-VALENT HUMAN PAPILLOMAVIRUS VACCINE ON VACCINATION OF ADOLESCENTS AND YOUNG ADULTS IN THE PACIFIC NORTHWEST

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OBJECTIVES: Describe human papillomavirus (HPV) vaccine uptake, initiation, completion, compliance, and missed vaccination opportunities among patients

before and after introduction of 9-valent HPV vaccine (HPV9). **METHODS:** A retrospective patient cohort, males & females aged 9 to 26 years, enrolled in the Kaiser Permanente Northwest health plan between April 2012 and June 2016 was selected (N = 244,491). Vaccination and health care utilization data from electronic medical records and state-wide immunization registry were analyzed. Vaccine uptake (number of doses administered) was assessed during 4-month periods. Vaccine initiation, completion, compliance (received 3 doses within a 9 month period), and missed opportunities (eligible patient visits with no vaccination) were assessed over the entire study period and over 1-year periods pre- and post-HPV9 introduction in July 2014. **RESULTS:** Approximately 9,000 doses were administered during each 4-month period, with increases during periods spanning August through November (approximately 11,000 doses administered). During the study period, initiation was highest among patients aged 13 to 21 years, at 55%. Among those who initiated the series, 71.1% of patients completed two doses and 48.2% completed three doses of HPV vaccine; 28.2% were compliant with guidelines during the study period. Compliance was slightly lower prior to HPV9 introduction than during the post-period (21.3% and 28.0%, respectively). The proportion of patients with at least one missed vaccination opportunity was similar pre- and post-HPV9 introduction (56.0% and 53.6%, respectively). **CONCLUSIONS:** Uptake peaked at the start of the academic year. Among initiators, less than half completed three doses and few complied with dose-spacing recommended by the ACIP during the study period. Missed opportunities were common; reducing such occurrences may lead to higher completion and compliance as well as earlier immunization. Further analysis of reasons for missed opportunities and adolescent/young adult resource utilization may inform health care systems on improving HPV vaccine uptake and schedule compliance.

PIN82

ESTIMATING THE IMPACT OF UNIVERSAL VARICELLA VACCINATION IN JORDAN

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OBJECTIVES: More than 50% of the Levant population has access to universal varicella vaccination (UVV). In order to avoid changes in the age-distribution of varicella cases, and significantly reduce disease burden, it is important for other countries in the region to consider UVV. The objective of this study is to assess the magnitude of current varicella disease burden and the potential impact of UVV in Jordan. **METHODS:** A dynamic transmission model of varicella infection was calibrated to available varicella seroprevalence data within the region and validated against local epidemiological data. The current burden was assessed by converting the calibration into age-specific incidence and mortality rates, and the impact of one-dose UVV administered at 12 months of age with 90% coverage (concurrent with MMR vaccination which is >95% coverage) was estimated. Alternative vaccination strategies were examined as sensitivity analyses. **RESULTS:** The model estimates the current burden of varicella to be 188,000 cases per year, an incidence rate of 2,475/100,000 persons. Varicella incidence is projected to decrease by 38% at 1 year, 79% at 5 years, 86% at 10 years, and 90% at 25 years. After 5 years of UVV, 743,000 cases and 93 deaths due to varicella will be prevented; over a 25 year period, more than 4 million cases and 500 deaths due to varicella will be prevented. Importantly, the public health benefits extend beyond vaccinees, with a 92% disease reduction in unvaccinated infants and an 84% reduction in unvaccinated adults. At low coverage levels (10%), such as might be seen with private-sector only varicella vaccination, slight shifts in the age-distribution of cases to older adults are likely. **CONCLUSIONS:** UVV in Jordan will significantly reduce varicella disease burden and protect against possible age-shifts in varicella case distribution that could be caused by synergies of private-sector only vaccination and high UVV rates within the region.

PIN83

THE IMPACT OF METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA) AND METHICILLIN-SENSITIVE STAPHYLOCOCCUS AUREUS (MSSA) INFECTION ON HOSPITAL READMISSIONS AMONG PATIENTS WITH PNEUMONIA

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OBJECTIVES: To explore and quantify the association between MRSA/MSSA infection and readmission risk among patients with pneumonia. **METHODS:** Healthcare Cost and Utilization Project-State Inpatient Databases were used to identify all inpatient admissions with a primary diagnosis of pneumonia in Florida (2009-2013), Massachusetts (2010-2012) and California (2009-2011). Readmissions were measured by the CMS validated algorithm. MRSA and MSSA infections as secondary diagnoses were identified with ICD-9-CM codes. All pneumonia patients were categorized into three subgroups: MRSA-infected, MSSA-infected and non-MRSA/MSSA. Descriptive analysis was performed to compare demographic differences across three groups, and multivariate logistic regression was applied to evaluate the association between MRSA/MSSA infection and probability of readmission. **RESULTS:** Among 450,793 inpatient admissions with pneumonia, 2,285 (0.51%) had MRSA and 996 (0.22%) had MSSA. Compared to patients in the non-MRSA/MSSA group, patients in the MRSA group had higher Medicare coverage (72.56% vs 66.47%) and longer length of stay (LOS) (7.17 vs 5.36 days), while patients in the MSSA group were younger (65.51 vs 68.43 years old), predominantly male (56.48% vs 47.56%), had higher Medicaid coverage (12.25% vs 9.90%) and longer LOS (8.84 vs 5.36 days) (all $p < 0.05$). Compared with non-MRSA/MSSA group (18.09%), the readmission rates were higher in the MRSA (28.45%) and MSSA groups (23.80%) (all $p < 0.001$). Controlling for demographic and illness factors, MRSA infection was associated with a higher risk of readmission (OR=1.497, $p < 0.001$), while MSSA infection was also a risk factor for readmission (OR=1.201, $p < 0.018$). Older age (OR=1.006, $p < 0.001$), African American (OR=1.202, $p < 0.001$, ref=whites), homeless status (OR=1.935, $p < 0.001$) and longer LOS (OR=1.058, $p < 0.001$)

were associated with greater readmission risk, while female (OR=0.883, $p<0.001$) and private insurance (OR=0.668, $p<0.001$, ref=Medicare) were associated with lower readmission risk. **CONCLUSIONS:** MRSA/MSSA infection among pneumonia patients was associated with a higher risk of readmission. Programs to reduce the risk for MRSA/MSSA infection at discharge would likely reduce readmissions.

PIN84

RESPIRATORY ILLNESS AND RESPIRATORY SYNCYTIAL VIRUS (RSV)-RELATED HOSPITALIZATION (RSVH) IN INFANTS WITH CONGENITAL AIRWAY ANOMALIES (CAA) IN THE CARESS REGISTRY (2005-2016)

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OBJECTIVES: Infants < 2 years of age with congenital airway anomalies (CAA) may experience increased risks of respiratory illness-related (RIH) and RSV-related hospitalization (RSVH). This study compared RIH and RSVH hazards in infants with CAA versus infants prophylaxed for standard, approved indications (SD) and other serious underlying medical disorders (MD) in the Canadian RSV Evaluation Study of Palivizumab (CARESS). **METHODS:** CARESS is a prospective, observational study of children who received ≥ 1 injection of palivizumab across 32 Canadian hospital sites. Neonatal and demographic data were collected at enrolment. Post-injection data was collected monthly, including utilization and adherence, and outcomes related to respiratory illness events. **RESULTS:** 23,597 infants (95% CAA, 3346 MD, and 19296 SD) were enrolled. Group demographic differences ($p<0.05$) were found in: enrolment and gestational age, birth and enrolment weight, proportion of Caucasians, daycare attendance, smoking exposure, siblings, multiple births, household crowding, and family history of atopy. Palivizumab adherence, including inter-dose interval lengths, was 74.15% overall, and was similar across indications. 1655 infants were hospitalized 1970 times. CAA infants had an overall crude RIH rate of 11.6% (MD [10.1%], SD [6.3%]) and a significantly increased RIH hazard relative to MD (HR=1.59, 95%CI 1.30-1.94, $p<0.0005$) and SD (HR= 1.39, 95%CI 1.22-1.57, $p<0.0005$). Crude RSVH rates were: 1.75% (CAA), 1.45% (MD), and 1.30% (SD). Using Cox proportional hazard analysis, after adjusting for proportion of Caucasians, daycare attendance, siblings, smoking exposure, crowding, and atopy, the model was significant ($\chi^2=75.98$, $df=6$, $p<0.0005$); however, based on indications for palivizumab the model was found to be insignificant ($p=0.93$). **CONCLUSIONS:** RIH risks were higher in CAA infants relative to MD and SD infants. However, hazard for RSVH appeared to be similar across indications, possibly due to the smaller CAA sample size compared to MD and SD.

PIN85

DOES THE INFORMATION-MOTIVATION-BEHAVIORAL SKILLS (IMB) MODEL ACCOUNT FOR ADHERENCE PROMOTION ACTIVITIES TARGETING PERSONS LIVING WITH HIV IN AMBULATORY-BASED SETTINGS?

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OBJECTIVES: A substantial number of persons living with HIV (PLWH) have suboptimal ART adherence (<90%), which has implications for health outcomes. Despite empirical evidence that pharmacist interventions can increase ART adherence, pharmacists are underutilized resource in promoting ART adherence. Our objective was to examine how ambulatory-based pharmacists' knowledge, motivation, and behavioral skills influence the provision of adherence promotion activities (APA) to PLWH. **METHODS:** 188 ambulatory-based pharmacists providing HIV patient care rated 27 APA items and another 27 items related to the information-motivation-behavioral skills (IMB) model. We used Exploratory Factor Analysis (EFA) to identify latent constructs (APA, Information, Motivation, Behavioral Skills) and Structural Equation Modelling (SEM) with 2000 bootstrapping to assess the direct and indirect effects of IMB predictors on APA. We hypothesized that each IMB factor independently predicted APA, and that information and motivation indirectly predicted APA through Behavior Skills. **RESULTS:** EFA generated 1 APA factor (eigenvalue (λ)=5.11, variance explained (R²)=58%, Cronbach alpha (α)=0.92) and 3 IMB-factors having $\lambda>1$ (1.25 $\leq\lambda\leq$ 4.35; R²=77%; 0.76 $\leq\alpha\leq$ 0.90). Initial SEM chi-square of $p<0.001$ suggested the model failed to fit the data. Modification Indices suggested that Information was not a significant predictor of APA. After respecifying the model to exclude Information, all model fit indices fit the data well. All coefficients were statistically significant ($p<0.05$), with correlations among factors ranging from -.29 to .33. The respecified model explained 58% of the variance in APA. **CONCLUSIONS:** Our findings provide partial support for the IMB model, since Information does not predict APA. Information influences APA indirectly through motivation and behavioral skills. Motivation is a significant predictor of both behavioral skills and APA. Ambulatory-based pharmacists' provision of APA is largely influenced by motivation-related factors. Thus, pharmacist-level interventions to promote ART adherence among PLWH in ambulatory-based settings should focus on increasing pharmacist motivation (e.g., reimburse for APA services).

PIN86

QUALITY IMPROVEMENT PRACTICES AND INNOVATIONS TO REDUCE VENTILATOR-ASSOCIATED PNEUMONIA

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OBJECTIVES: To perform a systematic review of practices, research, and innovations to reduce ventilator-associated pneumonia (VAP) rates in acute care facilities. **METHODS:** A systematic PubMed and Google search was conducted to identify publications that describe practices and innovations designed to decrease the rate of

VAP from 2008 to present in the U.S. Identified sources were reviewed by independent reviewers to determine inclusion status. **RESULTS:** 489 publications were identified, of which 40 were judged to be relevant. The 40 included publications described 17 distinct practices or innovations that had been implemented to reduce the rate of VAP. Interventions that were demonstrated to be particularly effective were: prophylactic chlorhexidine mouth rinse, use of copper-infused bed linens, improved bronchial drainage, universal decolonization, critical care physicians available 24-hours a day, integration of efforts within a health-system, early and ongoing evaluation for ventilator weaning, and regular pulmonary and dental evaluations. In the pediatric population, a bundle of care that included elevating the head of the bed, daily sedation vacations, daily assessment of readiness to extubate, peptic ulcer disease prevention, and regular oral care has been shown to decrease VAP rates by 63-87 percent across a group of three hospitals that implemented the bundle. **CONCLUSIONS:** Healthcare institutions nationwide are conducting a variety of initiatives to reduce the incidence of VAP. These efforts include initiatives at the patient, provider and health-system levels. These practices should be embraced by acute care facilities to reduce the rate of VAP.

PIN87

ADULT VACCINATION MARKET UPTAKE, 2009-2015

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OBJECTIVES: Adult vaccine-preventable diseases in the US are a major healthcare burden and vaccination is an important strategy to protect individuals, in particular those at higher risk of complications, from infectious diseases. Over the past several years, new adult vaccines along with changes in adult-vaccination guidelines have increased the number of vaccines recommended for adults. Adult vaccination rates in the US are measured by the Centers for Disease Control and Prevention using the National Health Interview Survey, however, there is no study examining adult vaccination trends among the US insured population. **METHODS:** Using commercial and Medicare Advantage with Part D (MAPD) data (2009-2015) for individuals aged ≥ 19 from the Optum Research Database, claims for pneumococcal vaccine (PPV and PCV), herpes zoster (HZ), tetanus/diphtheria booster (Td) and tetanus/diphtheria/pertussis (Tdap) were captured. The denominator was the average number of members enrolled annually. Vaccinations were examined over time by age group and insurance type (commercial or MAPD). **RESULTS:** From 2009 to 2015, per-member PPV use was low (1.3%-1.5%), Td use decreased (1.2%-0.5%); and HZ use increased (0.6%-1.1%). Increases were larger for Tdap (3.7%-5.6%) and PCV (3.8%-8.4%). As expected, PCV use varied by age-while low ($\leq 1.2%$) among members aged 19-59; use increased 241-, 770- and 2183-fold among members aged 60-64, 65-69, and 70+, respectively, driven predominantly by use of PCV13. By 2015, 3.3%, 26.1% and 34.9% of annual membership aged 60-64, 65-69, and 70+, respectively, received a PCV13 vaccine. **CONCLUSIONS:** Consistent with recent market and guideline changes, PCV13 use increased significantly among insured patients in 2015, and Tdap vaccine use is also increasing moderately over time. Use of other adult vaccines remains relatively stable, highlighting the need for additional strategies to promote adult vaccination.

RESEARCH POSTER PRESENTATIONS – SESSION II

DISEASE – SPECIFIC STUDIES

CANCER – Clinical Outcomes Studies

PCN1

RISK FACTORS ASSOCIATED WITH ORAL MUCOSITIS FOLLOWING HEAD AND NECK CANCER TREATMENT

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OBJECTIVES: Oral mucositis (OM), a debilitating side effect of chemotherapy treatment among patients with head and neck cancer (HNC), can impact quality of life and disrupt cancer treatment plans. Our goal was to assess the risk factors associated with OM among patients with HNC who undergo treatment with chemotherapy. **METHODS:** Using the Medicare 5% Standard Analytical Files from 1/1/2010-12/31/2014, elderly (≥ 65 years of age) patients were identified based on first-observed treatment with chemotherapy (index), a diagnosis of HNC within 3 months prior to index, and continuous eligibility ≥ 12 months pre- and ≥ 1 month post-index. The proportion of patients with an OM diagnosis within 30 days following index chemotherapy treatment and the setting of OM care were assessed. A logistic regression model was conducted to assess predictors associated with OM following chemotherapy treatment. **RESULTS:** 2,453 patients met inclusion criteria (mean age 73.4 (± 6.4), 69% male, 90.5% White). Baseline mean Charlson Comorbidity Index score excluding cancer was 4.67 (± 3.40), 49.9% of patients received concurrent radiotherapy within ± 14 days of index, and 50.3% were diagnosed with >1 HNC location within 3 months before index. 7.6% of patients were diagnosed with OM within 30 days following index (mean 17 (± 18.3) days from index to OM diagnosis), with the most common settings of OM-related care being outpatient hospital (47.3%), inpatient hospital (29.0%), and physician office (18.8%). Adjusted results indicated that >1 HNC location (adjusted odds ratio (OR): 1.56; 95% confidence interval (CI): 1.10-2.22), baseline gingival and periodontal disease (OR: 2.67; 95% CI: 1.24-5.38), and concurrent radiotherapy (OR: 4.63; 95% CI: 3.09-7.18) were significantly associated with an OM diagnosis. **CONCLUSIONS:** Our findings indicate that HNC disease burden, manifested by tumor site and treatment with radiotherapy, is associated with OM. Future research can examine the specific nature of chemotherapy and radiation therapy that may correlate with the risk of developing OM.

PCN2

PATTERN OF CHEMOTHERAPY-RELATED ADVERSE EFFECTS AMONG ADULT CANCER PATIENTS TREATED AT GONDAR UNIVERSITY REFERRAL HOSPITAL, ETHIOPIA: A CROSS-SECTIONAL STUDY

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OBJECTIVES: Adverse drug reactions (ADRs) are a global problem and constitute a major clinical problem in terms of human suffering. The high toxicity and narrow therapeutic index of chemotherapeutic agents makes oncology pharmacovigilance essential. The objective of the present study was to assess the pattern of ADRs occurring in cancer patients treated with chemotherapy in a tertiary care teaching hospital in Ethiopia. **METHODS:** A cross-sectional study over a 2-year period from September 2013 to August 2015 was conducted on cancer patients undergoing chemotherapy at Gondar University Referral Hospital Oncology Center. Data were collected directly from patients and their medical case files. The reported ADRs were assessed for causality using the World Health Organization's causality assessment scale and Naranjo's algorithm. The severities of the reported reactions were also assessed using National Cancer Institute Common Terminology CTCAE version 4.0. The Pearson's chi-square test was employed to examine the association between two categorical variables. **RESULTS:** A total of 815 ADRs were identified per 203 patients included in the study. The most commonly occurring ADRs were nausea and vomiting (18.9%), infections (16.7%), neutropenia (14.7%), fever and/or chills (11.3%), and anemia (9.3%). Platinum compounds (31.4%) were the most common group of drugs causing ADRs. Of the reported ADRs, 65.8% were grades 3–4, (severe level) 29.9% were grades 1–2, and 4.3% were grade 5 (toxic level). Significant association was found between age, number of chemotherapeutic agents, as well as dose of chemotherapy with the occurrence of grades 3–5 toxicity. **CONCLUSIONS:** The high incidence of chemotherapy-related ADRs among cancer patients is of concern. Setting up an effective ADR monitoring and reporting system (onco-pharmacovigilance) and creating awareness among health care professionals regarding the importance of ADR reporting may help prevent the problem.

PCN3

SORAFENIB TOLERANCE AND ADVERSE EVENTS IN THE FIRST LINE TREATMENT OF HEPATOCELLULAR CARCINOMA

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OBJECTIVES: Sorafenib has demonstrated improved overall survival in hepatocellular carcinoma (HCC). Many patients (80%) taking sorafenib experience adverse events (AEs) leading to dose reductions (26%) and drug discontinuation (38%). First line (1L) utilization of sorafenib among patients in the US with HCC, real-world dosing, AEs, and tolerance of sorafenib are described below. **METHODS:** US patients with two separate diagnoses of HCC receiving 1L treatment with at least two prescriptions of sorafenib between July 1, 2007 and September 30, 2015 were retrospectively analyzed in the Truven Marketscan® Commercial and Medicare Supplemental claims databases. Descriptive statistics characterized baseline demographics, clinical attributes, prescribed and calculated average daily dose (ADD) of sorafenib, tolerance of sorafenib (calculated ADD of sorafenib >285mg/day), and AEs. **RESULTS:** Among 1,861 patients diagnosed with HCC receiving sorafenib 1L treatment, 1,157 (62%) patients received at least two pharmacy claims for sorafenib. Of the 1,157 patients, the mean age was 63 years (SD=10.15), and 81.6% were male. Of those (n=934) with complete prescription claims, the mean calculated ADD was 621.6mg/day (SD=223.7) (78% of the labeled dose), and 91.5% were tolerant to sorafenib (>285mg/day). The median time from initial diagnosis to sorafenib initiation was 44 days, and median duration of sorafenib treatment was 83 days. Most patients (86.9%) did not receive subsequent anti-cancer therapy. Anorexia/weight loss, nausea/vomiting, and musculoskeletal/joint pain were the most common AEs (>15%) during sorafenib treatment. **CONCLUSIONS:** Less than two thirds of patients with HCC in the US receiving 1L treatment with sorafenib receive a second prescription, and most do not receive subsequent drug therapy. These patients have lower calculated ADD than recommended per label, and experience a variety of adverse events demonstrating unmet medical need. Factors associated with dose reduction and discontinuation and whether these have an impact on real-world effectiveness of 1L sorafenib should be investigated.

PCN4

CHARACTERISTICS AND ADVERSE EVENTS OF PATIENTS WITH HEPATOCELLULAR CARCINOMA RECEIVING ONE SORAFENIB PRESCRIPTION

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OBJECTIVES: Sorafenib has demonstrated improved overall survival in patients with hepatocellular carcinoma (HCC). Many patients (80%) taking sorafenib experience adverse events (AEs) leading to dose reductions (26%) and drug discontinuation (38%). The objective of this retrospective analysis is to describe patients in the US with HCC who cease sorafenib treatment after one prescription. **METHODS:** The study cohort was US patients with two separate diagnoses of HCC receiving first line (1L) treatment with one or more sorafenib pharmacy claims between July 1, 2007 and September 30, 2015 in the Truven Marketscan® Commercial and Medicare supplemental claims databases. Descriptive statistics characterized patient baseline demographics, clinical characteristics, sorafenib treatment-related variables, and AEs. **RESULTS:** Among 1,861 patients in the study cohort, 704 (38%) patients received only one sorafenib claim. Of the 704 patients, the mean age was 63.5 years (SD=10.74), and 78.8% were male. Non-alcoholic liver disease, cirrhosis, and hepatitis C were the most common (>25%) hepatic-related comorbidities. The mean prescribed average daily dose of sorafenib was 713.3mg/day (SD=179.45) (89% of the labeled dose) among patients with complete prescription claims (97.4%). The median time from diagnosis to sorafenib initiation was 35 days. Nausea/vomiting, anorexia/weight loss, fatigue, and

musculoskeletal/joint pain were the most common AEs (>5%) during sorafenib treatment. Most patients (93.3%) did not receive subsequent therapy with an alternative anti-cancer agent, however, for those who did the median time to initiation of subsequent therapy was 49 (Range: 1-456) days after sorafenib initiation. **CONCLUSIONS:** Over one-third of patients with HCC in the US fill only one sorafenib 1L prescription, and most do not receive subsequent drug therapy, demonstrating unmet medical need. Some patients receive less than the labeled dose. Factors associated with dose reduction and discontinuation and the impact on real-world effectiveness of first line sorafenib should be investigated.

PCN5

ASSESSMENT OF DOSE PER CYCLE OF DEXAMETHASONE IN LENALIDOMIDE-DEXAMETHASONE REGIMEN TO TREAT RELAPSED/REFRACTORY MULTIPLE MYELOMA PATIENTS IN THE UNITED STATES

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OBJECTIVES: While high-dose dexamethasone (Dex; 480 mg/cycle) is effective in combination with lenalidomide (Len) in relapsed/refractory multiple myeloma (RRMM) patients, emerging evidence points to increased use of low-dose (≤160 mg/cycle) Dex in this combination regimen. We assessed frequency of use of high- vs low-dose Dex in RRMM patients in real-world practice in the US. **METHODS:** Patients who received treatment for myeloma between July 2012–September 2014 were identified from a large US claims database. Index date was defined as the first diagnosis of multiple myeloma or claim for a myeloma drug during the study period. Patients were stratified into two groups: Group (G)1 if they had continuous enrollment and prescription eligibility for a 12-month period prior to index date (indicating newly diagnosed, treatment-naïve status); G2 if they did not have 12-month continuous enrollment prior to index date. Dex dose per cycle in the first four cycles of Len-Dex treatment in RRMM patients was evaluated. **RESULTS:** Overall, 8891 and 16,489 patients were identified in G1 and G2, respectively. In total, 6620 distinct lines of treatment (LOTs) were identified in G1 and 29,287 in G2. Len-Dex RRMM LOTs accounted for 4.6% (n=304) in G1 and 7.1% (n=2080) in G2. The median (Q1–Q3) Dex dose per cycle across the first four cycles in RRMM LOTs was 121 (75–156) mg in G1 and 102 (70–154) mg in G2. In G1, median dose was consistent across LOTs 2, 3 and 4 (137, 113 and 114 mg/cycle, respectively). More than two-thirds of these LOTs showed a Dex dose of ≤160 mg/cycle. **CONCLUSIONS:** This real-world study of Len-Dex use among RRMM patients shows that the majority receive low-dose Dex, and confirms the growing use of low-dose Dex in this combination regimen. Additional analyses may inform revision of treatment guidelines for RRMM.

PCN6

INDIRECT COMPARISONS OF SAFETY OF TARGETED THERAPIES FOR METASTATIC RENAL CELL CARCINOMA: A NETWORK META-ANALYSIS

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OBJECTIVES: Renal cell carcinoma (RCC) is the most common type of kidney cancer. Disease specific survival for metastatic RCC (mRCC) was significantly improved with the introduction of the targeted agents since 2005. However, there are not enough head-to-head clinical trials comparing the safety between several pairs of targeted therapies. This study aimed to compare toxicity outcomes among targeted agents in patients with mRCC by using network meta-analysis (NMA). **METHODS:** The PubMed, MEDLINE, Cochrane Library, and Web of Science were searched to identify phase II or III randomized clinical trials (RCTs) of targeted therapies in patients with mRCC published between January 2000 and September 2016. Discontinuation rates due to severe adverse events were compared using risk ratios (RRs) and 95% confidence intervals (CIs). A network of the RCTs involving targeted agents was constructed to conduct the Bayesian NMA. The surface under the cumulative ranking curve (SUCRA) of each treatment was calculated to assess the probability of the best treatment. **RESULTS:** A total of 11,265 patients with mRCC were included from 28 RCTs. Among the first-line therapy, the RRs of discontinuation were not significantly different among treatments, except that the combination therapy of temsirolimus/bevacizumab was associated with a higher risk of discontinuation due to severe adverse events compared to everolimus, placebo/interferons, and temsirolimus (RR=2.69 (95% CI=1.18-6.13), RR=2.99 (95% CI=1.58-5.66), and RR=3.60 (95% CI=1.40-9.25), respectively). For second-line therapy, axitinib had significantly lower relative risks of discontinuation compared to cabozantinib, everolimus, lenvatinib, and other treatments. In RRs of discontinuation, the largest values of SUCRAs were found in temsirolimus among the first-line therapy (83.1) and axitinib among the second-line therapy (95.1). **CONCLUSIONS:** Regarding medication safety, temsirolimus and axitinib may be appropriate options in the first-line and second-line therapy in patients with mRCC, respectively.

PCN7

RACIAL DIFFERENCES AND COMPARATIVE EFFECTIVENESS OF RITUXIMAB-BASED THERAPIES AMONG ELDERLY FOLLICULAR LYMPHOMA (FL) PATIENTS – A RETROSPECTIVE COHORT STUDY USING SEER-MEDICARE LINKED DATABASE

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OBJECTIVES: Follicular Lymphoma (FL) is the most common indolent lymphoma (15,000 cases diagnosed in US, 2016). Limited evidence exists on racial differences in treatment and the comparative effectiveness of rituximab-based chemo/immunotherapy treatment regimens among elderly FL patients. Herein, we examined the differences in treatment utilization for elderly FL patients stratified by race and characterized the comparative effectiveness of treatments on cancer-specific and all-cause mortality. **METHODS:** We conducted a retrospective cohort

study of patients (age ≥ 66 years) diagnosed with first primary FL from 2001-2011, using the SEER-Medicare database. Differences in risk of all-cause and cancer-specific mortality by race were examined using Cox proportional hazards models. Adjusted hazard ratios and 95% CIs were also estimated to determine the comparative effectiveness of rituximab-based chemotherapy versus observation only. **RESULTS:** Among 4,849 elderly FL patients, treated patients tended to be younger than patients receiving observation only. African-American patients were less likely (44%) to receive treatment versus Caucasian patients (53%). Our findings suggested benefit of rituximab-based chemo/immunotherapy across all races, although only statistically significant for Caucasian patients, for cancer-specific mortality (Caucasian: HR=0.55, 95% CI:0.44-0.68; African-American: HR=0.62, 95% CI:0.30-1.41; Hispanic: HR=0.69, 95% CI:0.42-1.28; Asian/Pacific Islander : HR=0.65, 95% CI:0.27-1.40) and all-cause mortality (Caucasian: HR=0.53, 95% CI: 0.46-0.62; African-American: HR=0.61, 95% CI:0.28-1.93; Hispanic: HR=0.51, 95% CI:0.23-1.10; Asian/Pacific Islander : HR=0.54, 95% CI:0.20-0.94). Further subgroup analyses suggested similar benefits of rituximab plus chemotherapy and rituximab monotherapy when compared to observation (log-rank $p < 0.001$). **CONCLUSIONS:** We found racial differences in the treatment utilization and comparative effectiveness of therapies in elderly FL patients. Some socio-demographic predictors may have an important role for treatment decisions. In this preliminary analysis it remains unclear if racial differences exist in the effectiveness of rituximab-based chemotherapy and monotherapy on cancer-specific and all-cause survival. Further analyses are planned to extend our analysis to all elderly indolent lymphoma patients.

PCN8

SPINAL SURGERY IN PATIENTS WITH MALIGNANT AND BENIGN BONE CANCER OF THE VERTEBRAL COLUMN – PREVALENCE AND RISK FACTORS

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OBJECTIVES: Spinal fusion (SF) is performed to address pain and loss of function. However, the frequency of SF and incidence of repeat SF for patients with benign or malignant bone tumors of the vertebral column (BTVIC) is not well documented. **METHODS:** Using the Truven CCAE and Truven Medicare databases, patients with SF (International classification of disease (ICD-9): 81.0X or 81.61-4) from 2010 to 2014 were identified and all diagnoses concurrent to SF were analyzed. A patient subset that had ≥ 12 -month enrollment pre- and post- SF and no prior spine surgery within 12 months of index SF were categorized for comorbidities at index. The presence of benign (ICD-9 213.2) or malignant (ICD-9 170.2) BTVIC was documented. Comorbidities at surgery included diabetes (ICD-9 250.X), osteoporosis (ICD-9 733.0X) and obesity (ICD-9 V85.35-45; 278.00, 278.01). Occurrence of repeat SF (new or revision - for revision: ICD-9 81.3X) within the 12 months follow-up period was evaluated. **RESULTS:** 61% of patients who underwent SF had spinal stenosis, 41% had spondylolisthesis, 36% had DDD and less than 1% had malignant or benign BTVIC. The study cohort included 122,589 patients, with a total 12-month rate of repeat SF of 4.86% (4.63%, 4.02% and 6.19% in the non-cancer, benign and malignant BTVIC populations, respectively). Logistic regression indicated that risk of repeat SF was significantly associated with obesity (Odds ratio (OR): 1.273 – 95% Wald confidence interval (CI) 1.161-1.396), osteoporosis (OR: 1.192 – 95% CI: 1.087-1.307) and diabetes (OR: 1.086 – 95% CI: 1.002-1.177), but not with benign (OR: 0.876 – 95% CI: 0.539-1.424) or malignant BTVIC (OR: 1.356 – 95% CI: 0.804-2.288) versus no BTVIC. **CONCLUSIONS:** Risks for repeat SF in patients with BTVIC are similar to those for patients without BTVIC. Our results suggest that the risk of repeat SF is associated with baseline comorbidity status, rather than the presence of BTVIC.

PCN9

COMORBIDITY MEASURES TO PREDICT OVERALL SURVIVAL TIME AMONG ELDERLY GYNECOLOGIC CANCER SURVIVORS IN THE US: AN ANALYSIS OF SEER-MEDICARE DATA

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OBJECTIVES: To examine relationships between different comorbidity indices and overall survival time, and to compare the performance of these indices in predicting survival time among elderly gynecologic cancer survivors. **METHODS:** This retrospective study used 2007-2010 Surveillance, Epidemiology, and End Results (SEER)-Medicare database. The primary independent variables were comorbidity indices, including diagnosis-based indices [Deyo-Charlson Comorbidity Index (CCI), Romano CCI, D'Hoore CCI, Original Elixhauser Comorbidity Index (EI), AHRQ EI, and National Cancer Institute comorbidity index] and medication-based indices [Chronic Disease Score (CDS)-1, CDS-2, and RxRisk]. The CCIs and EIs were included as both score and categorical/indicator variables. The dependent variable was overall survival time. Cox models with a time-dependent covariate were used to assess the relationships between comorbidity measures and survival time. The Akaike Information Criterion, Bayesian Information Criterion, and Likelihood ratio tests were used to compare the predictive ability of the indices. **RESULTS:** The mean age of the 4,063 gynecologic cancer survivors studied was 78.0 (SD=7.4) years; 27.6% died within one year after diagnosis. Uterine cancer was most common (48.5%), followed by ovarian cancer (30.0%). All diagnosis-based indices were significantly positively associated with risk of death, while none of the medication-based indices were associated with risk of death after controlling for covariates. Regarding predictive ability of comorbidity indices, the score versions of the diagnosis-based indices tended to outperform the categorical/indicator versions of the diagnosis- and medication-based indices. **CONCLUSIONS:** This study found meaningful associations between

different comorbidity indices and overall survival among the elderly gynecologic cancer population in the US. Study findings suggest using the score versions of the diagnosis-based indices in predicting survival-related outcomes in this population. This study may help clinicians identify conditions where better treatment plans could improve health outcomes, and health scientists choose the better comorbidity indices to use in their epidemiologic research.

PCN10

IMPACT OF CRYOTHERAPY AND CONSERVATIVE MANAGEMENT ON DEPRESSION AND ANXIETY DISORDERS IN MEN WITH PROSTATE CANCER

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OBJECTIVES: To compare rates of subsequently diagnosed mental health issues (MHI), and time to develop any MHI in men with localized prostate cancer who underwent conservative management (CM) or cryotherapy. **METHODS:** The Surveillance, Epidemiology and End Results (SEER)-Medicare linked data from 2000-2013 was used. Patients' aged 65 years or older with stage I and stage II cancer diagnosis and no prior MHI were included. Patients in the CM cohort were identified as those who did not receive any immediate treatment within 6 months of diagnosis of localized prostate cancer. Patients in the cryotherapy cohort were identified using ICD-9 procedure code, Healthcare Common Procedure Coding System (HCPCS) code/ Current Procedural Terminology (CPT) code. The diagnoses of any MHI (major depressive disorder, anxiety, depression-not otherwise specified (NOS), neurotic depression, and adjustment disorder with depressed mood) were identified using the ICD-9 codes. Rates of each of the MHI were assessed. A cox proportional hazard model was used to estimate time to develop MHI in the cohorts. All analyses were performed using SAS (version 9.4). **RESULTS:** There were 13,161 and 3,533 patients in the CM and cryotherapy cohort, respectively. Rates of MHI were lower in the CM compared to cryotherapy cohort: neurotic depression (0.25% and 0.42%, respectively); major depressive disorder (0.49% and 0.58%, respectively); anxiety disorders (2.38% and 2.69%, respectively), adjustment disorder with depressed mood (0.17% and 0.25%, respectively), and depression NOS (2.05% and 2.41%, respectively). Median time to develop any MHI in the CM and cryotherapy cohort were 62.9 months and 54 months, respectively, and the risk of being diagnosed was 16.5% higher in the cryotherapy cohort (hazard ratio [HR] = 1.17 [1.02 – 1.41]). **CONCLUSIONS:** Findings suggest that the burden of MHI is greater with cryotherapy treatment in comparison to CM. Patients who receive cryotherapy may need additional mental health monitoring and treatment to avoid negative outcomes.

PCN11

TREATMENT PATTERNS AND MEDICATION ADHERENCE AMONG PATIENTS DIAGNOSED WITH MULTIPLE MYELOMA AND TREATED WITH PANOBINOSTAT

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OBJECTIVES: Examine treatment patterns and sequence, combinations, dosing, medication adherence, and persistence in adults with multiple myeloma (MM) treated with panobinostat in the US. **METHODS:** Using a nationwide administrative claims database, a cohort of MM patients aged ≥ 18 years treated with panobinostat from 02/01/2015-07/31/2016 was evaluated. Three months continuous enrollment was required prior to the first panobinostat claim (index date) and variable length post-index follow-up was used. Lines of therapy (LOT) were defined as the number of prior chemotherapeutic and/or immunotherapy regimens administered within 60 days. Adherence was measured using the medication possession ratio (MPR). Descriptive analyses were used to examine differences by LOT and treatment combination. **RESULTS:** Seventy-seven patients treated with panobinostat were included (mean age 61.4 (SD=9.1) years; 50.6% male). Patients had an average of 237.6 (SD=144.0, 25th-75th interquartile range [IQR]=140.8-335.2) days continuous enrollment following panobinostat. The majority of patients received panobinostat as the 4th (19.5%) or 5th (15.6%) LOT compared to the 2nd (10.4%) or 3rd LOT (11.7%). The most common treatment combinations were bortezomib/dexamethasone/panobinostat (33.8%), bortezomib/panobinostat (14.3%), and dexamethasone/panobinostat (9.1%). Most patients (71.4%) received the recommended dose of 20 mg at index. Approximately 77.9% of panobinostat users remained on a stable dose throughout follow-up. The average number of panobinostat cycles was 3.9 (SD=3.2) with an average duration of 97.5 days (SD=82.0). Medication adherence was high across 3, 6, and 9 month follow-up (MPR of 0.89, 0.89, and 0.88, respectively). Persistence among patients treated with panobinostat was approximately 75.3% with an average time to non-persistence of 94.1 days (SD=88.2). **CONCLUSIONS:** Panobinostat was most often used in fourth or fifth LOT. Most patients received the recommended dose at index and treatment regimen in combination with bortezomib and dexamethasone. Adherence was high among panobinostat users; however, the limited duration of follow-up may have affected the number of cycles observed in this population.

PCN12

EPIDEMIOLOGY OF METASTATIC MELANOMA AND FREQUENCY OF MUTATION TESTING IN THE U.S. MEDICARE POPULATION

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OBJECTIVES: To quantify the population of metastatic melanoma patients in the US Medicare population, and assess the frequency and timing of newly available mutation testing. **METHODS:** A retrospective claims study was conducted using the Medicare FFS Database. Patients included were aged ≥ 65 years with at least 2 claims for malignant melanoma in the identification period

1/1/2013 to 12/31/2014, and continuously enrolled in medical and hospital benefits from 1/1/2013 until 12/31/2015 or death. A newly metastatic cohort was further identified based on (1) having at least 2 claims for a metastatic disease on or following the date of the first melanoma claim; and (2) absence of any metastatic claims in the 12 months prior to the initial metastatic claim. For every patient defined as having metastatic melanoma, mutation testing claims were identified using the CPT codes for panel testing (81445, 81450, 81455) and BRAF single mutation testing (81210). **RESULTS:** 9,656 melanoma patients were identified as prevalent in 2014, 347 (3.6%) of whom were identified as newly metastatic in 2014. Among metastatic melanoma patients, 98 (28.2%) underwent diagnostic testing for mutations. Of these, 96 (98.0%) were administered a BRAF single mutation test. Of all 98 patients tested for mutations, 74 (75.5%) were tested after their diagnosis of metastases; the median time between mutation testing and diagnosis was 18.5 days. Majority of testing (78.4%) was done within the first 3 months of diagnosis of metastases. **CONCLUSIONS:** Despite the launch of multiple therapies targeting BRAF+ mutations since 2011, analysis of a large melanoma population suggests that diagnostic mutation testing rates remained low even in 2014. These findings raise important questions about why diagnostic tests to drive treatment decisions were not used or accessed more broadly, and merit additional research as new targeted therapies for metastatic melanoma are coming to market.

PCN13

COMPARATIVE COMPARISON OF CLINICAL AND ECONOMIC OUTCOMES OF HAND-ASSISTED LAPAROSCOPIC RECTAL RESECTION FOR RECTAL CANCER

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OBJECTIVES: Laparoscopic rectal cancer resection is a technically challenging surgery. Hand-assisted laparoscopic surgery (HALS) was common to avoid conversion to open surgery and potential intra-operative complications. This study aims to compare the clinical and economics outcomes of four surgical approaches for rectal cancer resection: HALS, non-HALS, convert-to-open surgery, and open surgery. **METHODS:** Rectal cancer patients underwent rectal resection from 01/2008-09/2015 in Premier Hospital Perspective® Database were included. HALS approach was defined by billing texts, and other surgical approaches were defined by ICD-9 procedure codes. Multivariate regression was used to examine the difference of postoperative complication rate, length of stay (LOS), operation-room (OR) time, hospitalization cost between HALS cases and patients with non-HALS, convert-to-open surgery, or open surgery, respectively. Further stratification analyses were performed by surgeon specialty or hospital teaching status. **RESULTS:** Among 25814 rectal cancer patients in study, 66.4% were open surgery, 7.59% were converted to open surgery, 17.35% were non-HALS, and 8.43% were HALS. After adjustment, compared with convert-to-open cases, HALS cases had lower odds of post-operative complications (OR 0.77, 95%CI [0.66-0.94]), shorter OR time (-36.71 mins, 95%CI [-52.81, -20.60]) and lower hospitalization cost (\$-1394.977, 95%CI [-2684.51, -105.44]). Compared to open surgery, HALS cases had lower odds of post-operative complications (OR 0.89, 95%CI [0.90-0.99]), and shorter LOS (-0.44 days, 95%CI [-0.75, -0.14]). However, compared to non-HALS, HALS had longer LOS (0.69 days, 95%CI [0.33, 1.04]) and higher direct cost (\$805.54, 95%CI [204.16, 1406.91]) with shorter OR time (-22.48mins, 95%CI [-37.19, -7.76]). Similar trending was observed when stratifying by surgeon specialty and teaching hospital status. The gap of direct cost between HALS and non-HALS MIS were bigger among cases in teaching hospitals and colorectal surgeons, compared with community hospitals and non-colorectal surgeon. **CONCLUSIONS:** HALS approach is associated with lower complications and shorter LOS compared to convert-to-open and open approach, yet is associated with longer LOS and hospitalization costs when compared to non-HALS in rectal cancer resection.

PCN14

META-ANALYSIS ON MICROWAVE ABLATION IN CHINESE PATIENTS WITH LIVER CANCER >3CM

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OBJECTIVES: Percutaneous microwave ablation (pMWA) is a highly prevalent therapy to treat primary or metastatic liver cancer patients in China. However, the clinical safety and effectiveness of MWA in treating large liver lesions (LLL) > 3cm are debatable. The objective of this meta-analysis was to retrospectively evaluate the clinical safety and effectiveness of pMWA for Chinese patients with LLL. **METHODS:** A systematic search of the MEDLINE, Embase, Cochrane library, CNKI and WanFang databases using relevant keywords for liver, hepatocellular, carcinoma, cancer, tumor, percutaneous, ablation and microwave was performed. Only studies on Chinese patients were included. Meta-analysis was conducted using non-comparative binary data in RevMan Software for the following variables: technical success rate (TSR), local recurrence rate (LRR) and 1-year survival (1YS). The data type was generic inverse variance, and random-effects model was used. All statistics are mean (95% CI). **RESULTS:** 14 studies, including 1,035 patients with primary or metastatic LLL, were analyzed. The TSR was 67% (50%-84%). Subgroup analysis showed a TSR of 96% (94%-99%) in patients with lesion size 3-5cm, while the rate was 60% (38%-83%) in patients with lesions > 5cm. 29% (10%-47%) of patients with LLL had local recurrence. The LRR of patients with lesion 3-5cm and above 5cm were 27% (9%-64%) and 41% (22%-60%) respectively. The 1YS was 84% (77%-91%) with 89% (86%-93%) in the 3-5cm group and 62% (52%-71%) in the >5cm group. 8% (3%-14%) of patients experienced major complications (e.g. liver abscess) post-operatively. The post-operative complication rate was 3% (1%-5%) in 3-5cm patients, and 12% (6%-18%) in the >5cm group. **CONCLUSIONS:** The clinical safety and effectiveness of pMWA drops significantly in the treatment of Chinese patients with primary or

metastatic liver cancer when the size of lesion increases from 3-5cm to >5cm. New technology should address these unmet needs in large lesion ablation.

PCN15

EFFICACY OF TREATMENTS IN CHILDREN WITH RELAPSED/REFRACTORY ACUTE LYMPHOCYTIC LEUKEMIA (R/R ALL): A SYSTEMATIC LITERATURE REVIEW AND META-ANALYSIS

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OBJECTIVES: Pediatric ALL is the most common childhood leukemia, with 20% of children experiencing relapse after initial complete response (CR) to first-line treatment. A systematic literature review (SLR) and meta-analysis (MA) were conducted to determine the effects of treatments for pediatric r/r ALL. **METHODS:** EMBASE, MEDLINE, and CENTRAL databases were searched from 01/01/2000-12/31/2016 using keywords for pediatric r/r ALL paired with terms for relevant treatments to identify studies reporting efficacy and safety data. Proceedings from recent oncology conferences were also searched. Statistical analysis was limited to studies with comparable populations and treatments. Random-effects MA of single-arm data were performed to determine 6- and 12-month OS rates, median OS, and CR rate (timepoint not reported) for pediatric r/r ALL patients treated with clofarabine + cyclophosphamide + etoposide (CCE). **RESULTS:** Studies included in the SLR were heterogeneous, only five of the 46 studies identified were sufficiently comparable for MA in terms of outcomes and populations (median age 8-14 years, median 2 prior lines of therapy). All five were single-arm studies in primarily B-cell immunophenotype evaluating CCE, a treatment with pooled 6-month OS of 43.5% (95% CI: 32.6%-55.1%), 1-year OS of 26.7% (95% CI: 17.5%-38.3%), and median OS of 5.2 (95% CI: 3.2-8.6) months. The CR rate was 43.2% (33.7%-53.3%) across the five studies (timepoint not reported). **CONCLUSIONS:** This is the first SLR and MA to be conducted on treatment of pediatric r/r ALL and evidence was heterogeneous. MA were only possible for single-arm trials examining CCE. Pediatric r/r ALL patients treated with CCE had poor survival, with a low 1-year OS rate of less than 30% and short OS duration (median 5.2 months). Lack of data on timepoint of assessment make the CR rate results difficult to interpret. New treatments are needed to better manage pediatric r/r ALL.

PCN16

A BAYESIAN NETWORK META-ANALYSIS (NMA) OF THERAPIES FOR TREATMENT-NAÏVE CHRONIC LYMPHOCYTIC LEUKEMIA (TN-CLL) PATIENTS INELIGIBLE FOR FULL-DOSE FLUDARABINE THERAPY

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OBJECTIVES: RESONATE-2 showed that ibrutinib is a well-tolerated treatment and superior to chlorambucil (chl) for TN-CLL patients who are elderly or unfit for full-dose fludarabine therapy. However, no head-to-head comparisons exist of ibrutinib with other treatments in this population. An NMA was conducted to assess the efficacy of ibrutinib vs. regimens licensed for TN-CLL. **METHODS:** A systematic literature review identified randomized controlled trials (RCTs) in TN-CLL patients ineligible for full-dose fludarabine-based treatment. The feasibility of NMA was assessed by evaluating whether variability of trial design, population, treatment regimen, and outcome definition could affect the estimated relative treatment effects. Both random and fixed-effects Bayesian NMAs were conducted to assess (i) hazard ratios (HR) of overall survival (OS) and progression-free survival (PFS) and (ii) odds ratios (OR) for treatment discontinuation (TD) and TD due to adverse events (TDAEs). Sensitivity analyses of subgroup data were conducted to evaluate the impact of variations in patient characteristics. **RESULTS:** Five RCTs met all pre-defined NMA inclusion criteria and had populations comparable to RESONATE-2 with respect to key characteristics. Based on fixed-effects analyses, ibrutinib had favorable HRs and the highest pairwise probability of being the best treatment (P) in terms of OS and PFS versus bendamustine (HR=0.21/0.71; P=99.5%/84.8%; results for OS and PFS, respectively), rituximab+chl (HR=0.25/0.35, P=98.2%/99.9%); ofatumumab+chl (HR=0.18/0.28, P=99.6%/100%), obinutuzumab+chl (HR=0.40/0.85, P=91.1%/69.2%); and bendamustine+rituximab (HR=0.25/0.67, P=96.7%/85.2%). Ibrutinib had the highest probability of being the best treatment in the network in terms of OS (89.9%), PFS (62.7%), TD (99.4%), and TDAEs (78.9%). Sensitivity analyses confirmed that ibrutinib's treatment benefit persisted in subgroups of patients ≥65 years and patients without 17p deletion in all evaluable outcomes. **CONCLUSIONS:** This Bayesian analysis showed that ibrutinib has the highest probability of being the best treatment in terms of survival and tolerability outcomes versus existing treatments for elderly or unfit TN-CLL patients.

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OBJECTIVES: The relationship between treatment sequence and outcomes in mCRPC is unclear. This retrospective cohort study assessed if second-line taxane-based chemotherapy vs alternative ARTA is associated with improved clinical

PCN17

CLINICAL RESPONSE AND TIME TO PROSTATE-SPECIFIC ANTIGEN (PSA) PROGRESSION IN PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (mCRPC) RECEIVING SECOND-LINE CHEMOTHERAPY VERSUS ALTERNATIVE ANDROGEN RECEPTOR-TARGETED AGENTS (ARTA) AFTER A LACK OF RESPONSE TO FIRST-LINE ARTA IN US COMMUNITY ONCOLOGY PRACTICES

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OBJECTIVES: The relationship between treatment sequence and outcomes in mCRPC is unclear. This retrospective cohort study assessed if second-line taxane-based chemotherapy vs alternative ARTA is associated with improved clinical

response and time to PSA progression in patients with a lack of response to first-line ARTA in the US community oncology setting. **METHODS:** Using Altos electronic medical records, 345 mCRPC patients were identified who lacked response to first-line ARTA (abiraterone: N=289; enzalutamide: N=56) and received second-line chemotherapy (docetaxel: N=128; cabazitaxel: N=19), or alternative ARTA (enzalutamide: N=170; abiraterone: N=28) from 05/2011 to 10/2014. Outcomes were evaluated from second-line therapy initiation and compared between the two cohorts using one-sided tests. Clinical response (clinical note, ECOG performance status (PS) reduction by ≥ 1 , $\geq 5\%$ weight increase, or $\geq 2\text{g/dl}$ hemoglobin (Hb) increase over ≥ 3 months) and time to PSA progression ($\geq 25\%$ increase over nadir concentration) were assessed using logistic and Cox regressions adjusted for year, age, metastases, opioid use, ECOG PS, PSA, Hb, alkaline phosphatase (ALP), lactate dehydrogenase (LDH) and albumin (Alb) levels. **RESULTS:** At start of second-line therapy, patients receiving chemotherapy vs ARTA were younger (median age, 74 vs 79 years) and had a poorer prognosis: higher mean PSA (439 vs 231 ng/mL), LDH (344 vs 234 $\mu\text{g/L}$) and ALP (241 vs 166 $\mu\text{U/L}$) levels, lower mean Hb levels (11 vs 12 g/dL), higher mean Halabi risk score (159 vs 137; JCO 2014:32;671-7), and more patients had Alb levels <lower limit of normal (25% vs 15%); all $p < 0.01$. Patients in the chemotherapy vs ARTA cohort were more likely to have a clinical response (adjusted odds ratio=1.78, $p=0.020$) and longer time to PSA progression (adjusted hazard ratio=0.66, $p=0.010$). **CONCLUSIONS:** Second-line taxane-based chemotherapy vs second-line ARTA may be more suitable for patients with a lack of response to first-line ARTA and therefore should be further investigated in a prospective randomized trial.

PCN18

IMPACTS OF CONVERSION IN RECTAL RESECTION FOR RECTAL CANCER PATIENTS - DOES CONVERSION MATTER?

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OBJECTIVES: Conversion to open surgery is an intra-operative outcome indicating failed to complete a planned minimally-invasive surgery (MIS). Conversion in rectal cancer resection is high yet the associated clinical and economic impacts of conversion are less understood. **METHODS:** Rectal cancer patients underwent rectal resection in Premier Hospital Perspective® Database were included. Conversion and surgical approaches were defined by ICD-9. Multivariate regression was used to estimate the impacts of conversion through comparing converted vs. (1)non-converted cases; (2)open cases. Outcomes included post-operative complications, length of stay(LOS), operation-room time, and hospitalization cost. Stratification analyses were conducted by surgeon specialties and hospital teaching status. **RESULTS:** Among 25,814 rectal cancer patients with rectal resection, 33.4% were done with MIS and 22.8% of those MIS were converted to open surgery. Patients who converted to open surgery had significantly higher risk of postoperative complications(vs. non-converted: OR 1.47, 95%CI[1.29, 1.66]; vs. Open OR: 1.16 95%CI[1.04,1.29]), longer operation time (vs.non-converted: 21.26mins, 95%CI[6.15, 36.38]; vs. Open: 60.14mins, 95%CI[3.46,116.83]), and higher hospitalization cost (vs.non-converted: \$2270.47, 95%CI[\$11251.99, 3288.95]; vs. Open: \$1942.48 95%CI[880.41, 3004.54]); LOS of converted cases is significantly longer than non-converted cases (0.85days, 95%CI[0.51-1.19]) after adjusted for covariates. Stratifying by community or teaching hospital, the converted cases in community hospital had significantly higher risk of postoperative complication, longer operation-room time and higher hospitalization cost compared with both non-converted and open cases; while in teaching hospital, the outcome differences between converted and open cases became insignificant. Similar results were found after stratification by non-colorectal or colorectal surgeon. **CONCLUSIONS:** Conversion to open surgery for rectal cancer resection is associated with higher risk of complications, longer LOS, operation-room time and higher hospitalization cost. The impacts of conversion vary in different types of surgeons and hospitals. Further research is warranted for prevention of conversion and how to tailor the prevention method to different archetypes of care providers.

PCN19

COMPARATIVE EFFECTIVENESS OF SURGICAL VERSUS NONSURGICAL THERAPY FOR LARYNGEAL AND OROPHARYNGEAL CANCER

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OBJECTIVES: The treatment of patients with laryngeal and oropharyngeal cancer includes surgery or concurrent chemoradiation (CRT). Although CRT has become more common in recent years, the effectiveness of complete CRT in improving survival over surgery is not clear. The aim of this study was to evaluate the impact of CRT on mortality rates for laryngeal and oropharyngeal cancer using a validated approach. **METHODS:** This was a hospital-based cancer registry (HBCR) study carried out at a referential cancer hospital in Sao Paulo, Brazil, between 2008-2012. Records were retrieved and information about patients with head and neck squamous cell carcinoma (oropharynx and larynx), over 18 years old, were included in the analysis. A propensity score-matched logistic regression analyses were conducted to compare overall mortality rates between treatment modalities, adjusting for patient sociodemographic and clinical characteristics (age, gender, year of diagnose, tumor site and clinical staging). Conditional logistic regression for vital status as outcome was performed after matched by propensity scores. **RESULTS:** Of the 694 patients in the study cohort, 34% underwent surgery and 66% underwent CRT. In traditional analysis, patients who underwent CRT had almost three-fold to die compared with patients in surgical treatment (OR [odds ratio] 2.9; 95%CI 1.9-4.3). Using propensity score approach, the odds for CRT was 3.6 (95%CI 1.8-6.9). **CONCLUSIONS:** Patients who underwent complete CRT were found to have overall mortality rates different to those of patients undergoing surgery.

Although CRT provides organ preservation, the benefits and trade-offs of CRT and total laryngectomy should be discussed fully with patients.

PCN20

EFFICACY, EFFECTIVENESS, SAFETY AND COST-EFFECTIVENESS OF THE USE OF SORAFENIB IN DIFFERENTIATED THYROID CANCER. A SYSTEMATIC REVIEW

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OBJECTIVES: Treatment options for patients with differentiated thyroid cancer (DTC) locally advanced or metastatic refractory to radioactive iodine (RAI) are limited. The aim of this study was to review the evidence on efficacy, effectiveness, safety and cost-effectiveness of sorafenib administered in radioiodine-refractory DTC patients. **METHODS:** A systematic review was conducted through a systematic search of indexed scientific literature in the main databases (PubMed and Embase). The search terms "thyroid cancer", "differentiated" and "sorafenib" were used to identify the relevant literature. Full-text articles published in the last 10 years that included patients > 18 years were selected. No language restriction was performed. Clinical response (partial response, disease progression in patients with stable disease) and survival (mean progression-free survival and/or overall long-term survival) were the outcomes analyzed in the efficacy and effectiveness epidemiological analysis. For safety analysis, adverse events associated to sorafenib were evaluated. Treatment costs, years of life gained (YLG), incremental cost per year of life earned, incremental cost per disability adjusted life years (DALY), and quality-adjusted life-year (QALY) were analyzed in the economic analysis. **RESULTS:** We identified 597 studies (PubMed=133, Embase=464). 427 were excluded after screening. We full-text reviewed 54 studies (PubMed= 17, Embase= 37) after reviewing titles and abstracts. A total of four studies met the inclusion criteria and were included in the analysis (systematic reviews= 2, meta-analysis=1 and clinical trials=1). In the analyzed studies, sorafenib resulted to significantly increase the progression-free survival between 10-35 months in radioiodine-refractory DTC patients. Hand-foot syndrome (4-6%), fatigue (5.3-16%), hypertension (7.3-9.7%), diarrhea (5.8-6.8%), rash (4.8-6.8%) and weight loss (5.2-5.8%) were the most frequently reported severe adverse events caused by sorafenib. No cost-effectiveness studies related to DTC were found in the review. **CONCLUSIONS:** Our results suggest that sorafenib represents a new and effective treatment option for patients with progressive RAI-refractory DTC.

PCN21

THE TREATMENT EFFECT ON EARLY STAGE HEPATOCELLULAR CARCINOMA IN JAPANESE POPULATION: LITERATURE REVIEW

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OBJECTIVES: Liver resection (LR) is standard of care for Hepatocellular carcinoma (HCC) in Japan. Since 2004 Local-treatment for smaller HCC is covered under Japan's health insurance and literatures is now available. This study aimed to understand treatment effects of radiofrequency ablation (RFA), microwave coagulation (MW), LR and transcatheter arterial chemoembolization (TACE) for HCC from Japanese literatures. **METHODS:** The Ichushi-Web search was performed on 4th October 2016. Except case studies, all study design indicated short-term outcomes (Intra OR Bleeding, OR time, length of stay, Post OR complication) and long-term outcomes (survival rate, Relapse-free survival rate, etc.) of HCC patients excluding HCC with vessel invasion, recurrent or metastasis HCC, published in Japanese were searched. **RESULTS:** 32 literatures involving 15672 patients: 19 reported on LR, 9 on RFA, 3 on TACE, 1 on MW and TACE vs LR, 2 on RFA vs LR, with relevant outcomes were included. Seven studies reported the challenges in HCC: high rate of Cirrhosis population which increases risk in bleeding, recurrent rate in remittent-liver and decreased remittent-liver function, tumor location or low liver function limits eligibility of LR, complications include SSI is high in LR, and requiring frequent re-intervention. One study states that the current treatment guideline is not up to date with the technology improvement of coagulation therapy such as RFA and MW. 5 studies suggested that local ablation treatments (MW, RFA) was equivalently safe and effective to LR (in which, 2 studies suggest Laparoscopic RFA approach for tumors >2cm). There are no record of Local therapy used for tumors size >3cm. **CONCLUSIONS:** In the tumors size <3cm, numbers of literatures are confirming safety and efficacy of Local-treatment. With the described characteristics of HCC and challenge in LR, the minimally invasive interventions such as RFA and MW are considered safe and effective, an important alternative to LR.

PCN22

RENAL CELL CARCINOMA REAL WORLD OUTCOMES WITHIN THE BRAZILIAN HEALTH CARE SETTING: A LONGITUDINAL PATIENT ANALYSIS BASED ON MEDICAL CLAIMS DATABASE (DATASUS)

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OBJECTIVES: To evaluate clinical outcomes of renal cell carcinoma (RCC) patients within the Brazilian health public health care setting using secondary data from a real world longitudinal patient database (DataSUS) **METHODS:** Hospital (SIH) and ambulatory (SIA) information from Brazilian health care information system (DataSUS) were used to frame up a longitudinal patient database based on record linkage algorithms. The cohort for analysis is composed of de-identified patients with any ICD C64 records from 2008 to 2016. Surgery (Stx), radiotherapy (RTx) and chemotherapy (Ctx) are considered as treatments and clinical outcomes

calculated using longitudinal patient records timeframes. Time to treatment is considered the period from last diagnosis method and first treatment records. Also, overall survival (OS) consist of claims record gaps between a treatment line and patient death. **RESULTS:** The overall analysis cohort results 34,167 patients considering datasets intersection obtained through record linkage. On the period between jun/16 and jul/15, the average time to treatment was 5.8 months among 7,566 patients in treatment: 3,279 in STx, 600 in RTx and 1401 in CTx, being 246 on TKIs/mTORs/MABs and 1,179 on another CTx regimen. Considering first line patients, overall OS was 19 months; carving up into disease staging results in stage I/II/III 34 and stage IV 8 months. Finally, considering CTx patients, 5.6% were prior exposed to RTx and 31.0% to STx and 3.1% to both. **CONCLUSIONS:** Framing patient-centric medical claim databases using record linkage algorithms provides a powerful asset for analyzing calculated clinical outcomes in oncology under the real world environment. Furthermore, both demographic and socioeconomic analysis can be shaped bring up a better understanding of RCC dynamics in Brazil.

PCN23

FULVESTRANT: A TREATMENT OPTION IN METASTATIC BREAST CANCER AFTER TWO LINES OF HORMONAL THERAPY, THE EXPERIENCE IN COSTA RICA

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OBJECTIVES: In Costa Rica, Caja Costarricense de Seguro Social (CCSS) doesn't include fulvestrant in its basic drug list, however it's authorized for individual cases of women with metastatic breast cancer after receiving two lines of hormone therapy. This study aims to assess the results obtained in patients that received treatment with fulvestrant in CCSS between 2012 and 2015, and the cost-effectiveness (efficiency) of intervention. **METHODS:** This is an observational, retrospective, descriptive study, that includes the patients that were authorized to receive treatment with fulvestrant, according to the data base of the Central Pharmacotherapy Committee, between January 2012 and December 2015. Clinical records were accessed to retrieve information on diagnosis, hormone receptors, ECOG, treatment duration, progression-free and overall survival, and cost of treatment. **RESULTS:** 26 clinical records were available for review. All patients that received fulvestrant were woman, average age was 67.8 years (IC95% (63.9; 71.6). 77% (n=20) are dead. Hormone receptors were registered in 65% of patients, 50% (n=13) had both estrogen and progesterone and 15% (n=4) had positive estrogen and negative progesterone receptors. All patients received an initial dose of 500mg IM on day 1, 15 and 29, followed by 500mg each month. Median time of treatment was 6.5 months, IC95% (5.6; 7.4). Median progression-free survival was 6.5 months, IC95% (5.0; 8). Median overall survival was 13.8 months, IC95% (10.8; 16.7). Considering cost of treatment and the median time of treatment, we obtained a cost per patient of US \$7,893, that if divided by the median overall survival (1.15 years) gives us a cost of US \$6,881 per year gained, that represents the 65% of GDI per capita in 2015 for Costa Rica (approx. US\$10,500). **CONCLUSIONS:** Giving treatment with fulvestrant in patients with metastatic breast cancer, progressive to two lines of hormone therapy is an efficient intervention in the context of Costa Rica's Social Security.

PCN24

RACE DIFFERENCES IN PATTERN OF CARE AND SURVIVAL IN MEN DIAGNOSED WITH PRIMARY PROSTATE CANCER

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OBJECTIVES: To understand the impact of race on shared decision-making on the first course of treatment in patients with newly diagnosed prostate cancer (PCa). This study explored the difference in treatment patterns and clinical outcome in PCa patients by race, risk categorization and clinico-pathologic characteristics. **METHODS:** This study consisted of a retrospective cohort of 1,545 patients, 141 African American Men (AAM), 1,404 Non-Hispanic white(NHW), who were newly diagnosed with adenocarcinoma of the prostate after calendar year 2006 at Moffitt Cancer Center (MCC) or elsewhere, and received all or part of first course treatment at MCC. Logistic regression was used to evaluate primary treatment choice by race. Survival Analysis was used to analyze the difference in PCa specific mortality (PCSM) and overall survival (OS). **RESULTS:** AAM had a higher preoperative Prostate Specific Antigen (PSA) compared to NHW ($p < 0.01$). There was a trend in high risk category as more AAM (24.8%) were at higher risk compared to NHW (20.6%) ($p = 0.1$). In bivariate analysis, 40.4% of AAM received radiation therapy compared to 31.2% of NHW ($p = 0.02$). Furthermore, surgery was a more favourable treatment modality among younger men (72.8%) compared to radiation (27.1%) ($p < 0.01$). In a logistic regression model AAM were more likely to choose radiation therapy as the primary treatment modality compared to surgery (OR=2.22, 95% CI: 1.38 to 3.55, $p < 0.01$). There was no significant difference in PCSM and OS by race. However, among the low grade PCa (Gleason 6 and 3+4), AAM had poor PCSM compared to NHW ($p = 0.03$). **CONCLUSIONS:** AAM men were more likely to choose radiation therapy as the primary treatment modality while younger men were more likely to have surgery. Decreased survival among AAM with low grade PCa may suggest biological differences in this patient population.

PCN25

EFFICACY AND SAFETY PROFILE OF COMBINED TARGETED THERAPY INHIBITING EGFR AND VEGF PATHWAYS IN PATIENTS WITH ADVANCED NON-SMALL-CELL LUNG CANCER: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: The objective was to evaluate the clinical efficacy and safety of combined targeted therapy against epidermal growth factor receptor (EGFR) and

vascular endothelial growth factor (VEGF) pathways in patients with advanced Non-small-cell lung cancer (NSCLC). **METHODS:** Literature searches were conducted in Embase, PubMed and The Cochrane library databases using relevant search strategies. Studies retrieved from the databases were screened and extracted by two independent reviewers. Discrepancy was resolved by third reviewer. Randomized controlled trials which compared combined targeted therapy with control groups (placebo, chemotherapy, single EGFR or VEGF inhibition therapy or a combination of them) for the treatment of advanced NSCLC were included in the meta-analysis. Outcomes assessed included, progression free survival (PFS), objective response rate (ORR), and adverse events (AEs). Data was analyzed using Review Manager (v5.3). **RESULTS:** Of the 608 studies identified, 12 studies with 5485 patients were included for meta-analysis. Overall, combined targeted therapy was resulted in better PFS (HR: 0.86 [95%CI: 0.71-1.04]; n=11) and ORR (RR: 1.09 [95%CI: 0.81-1.47]; n=11) compared with control groups. However, no improvement was seen in OS with combined therapy (HR: 0.98 [95%CI: 0.91-1.05]; n=10). The subgroup analysis based on treatment line showed that combined therapy significantly improved PFS (HR: 0.77 [95%CI: 0.66-0.89]; n=8), and ORR (RR: 1.39 [95%CI: 1.01-1.93]; n=7) in the second-line treatment of NSCLC. Compared with control therapy, combination therapy had significant risk for grade 3/4 rash (RR: 2.63 [95%CI: 1.31-5.30]; n=10), diarrhea (RR: 4.03[95%CI: 2.17-7.50]; n=10) and hypertension (RR: 2.44[95%CI: 0.77-7.78]; n=9). **CONCLUSIONS:** The combined inhibition therapy against EGFR and VEGF pathways can significantly improve PFS and ORR in the second-line treatment of NSCLC. However, combined therapy has increased risk for grade 3/4 adverse events such as rash and diarrhea. Further large-scale trials would be helpful to validate these findings.

PCN26

EFFICACY AND SAFETY OF BEVACIZUMAB PLUS CHEMOTHERAPY VERSUS CHEMOTHERAPY ALONE IN THE TREATMENT OF NON-SMALL-CELL LUNG CANCER IN ASIAN PATIENTS: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: Over the past few years, there have been considerable advances in the treatments available to patients with metastatic or locally advanced non-small cell lung cancer (NSCLC). The objective of this review is to evaluate the efficacy and safety of bevacizumab plus chemotherapy versus chemotherapy alone for the treatment of NSCLC in Asian patients. **METHODS:** All randomized controlled trials (RCTs) examining the efficacy and safety of bevacizumab plus chemotherapy in adult patients with histologically confirmed NSCLC in Asian patients were included. We looked into overall survival (OS) and progression free survival (PFS) as the primary outcomes. Secondary outcomes were response rate, complete response, partial response, stable disease, progressive disease, disease control, and adverse events. Literature searches were conducted in MEDLINE and the Cochrane Library. In addition, references of included studies and clinicaltrials.gov were searched for relevant studies. No language or date restrictions were imposed. Study quality of included trials were assessed using the Cochrane Risk of Bias Tool. Two authors independently selected papers, extracted data and assessed quality. **RESULTS:** Four RCTs involving a total of 652 patients were included in this meta-analysis. The combination of bevacizumab with carboplatin & paclitaxel (BCP regimen) showed improved response rate (RR=1.87, 95% CI 1.50 to 2.30) and improved clinical benefit (RR=1.16, 95% CI 0.96 to 1.39) when compared to CP regimen. Further, BCP regimen led to less disease progression as compared to CP (RR=0.22, 95% CI 0.09 to 0.53). Bevacizumab when combined with other chemotherapy also showed improved PFS and OS. Leukopenia and neutropenia were most common haematological adverse events observed with bevacizumab. **CONCLUSIONS:** Bevacizumab plus chemotherapy is associated with significant improvement in OS, PFS, response rate and clinical benefit when compared to chemotherapy alone among patients with NSCLC.

PCN27

EFFICACY AND SAFETY OF OXALIPLATIN/CAPECITABINE BASED CHEMOTHERAPY PLUS BEVACIZUMAB AS FIRST-LINE TREATMENT FOR ADVANCED COLORECTAL CANCER: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: Colorectal cancer (CRC) is the fourth most frequently diagnosed cancer and the second leading cause of neoplasm-related death in the United States. Over the past 10 years, various combinations of chemotherapy were investigated for the treatment of metastatic CRC. The objective of this review is to evaluate the efficacy and safety of oxaliplatin or capecitabine -based chemotherapy plus bevacizumab as first-line treatment for advanced CRC. **METHODS:** All randomized controlled trials (RCTs) examining the efficacy and safety of oxaliplatin/capecitabine based chemotherapy plus bevacizumab in adult patients with advanced CRC were included. Primary outcome that we looked into were overall survival (OS) and progression free survival (PFS). Secondary outcomes were response rate (RR), complete response (CR), partial response (PR), stable disease (SD), progressive disease (PD) and adverse events. Literature searches were conducted in MEDLINE, Embase and the Cochrane Library. In addition, references of included studies and clinicaltrials.gov were searched for relevant studies. No language or date restrictions were imposed. Study quality of included trials were assessed using the Cochrane Risk of Bias Tool. Two authors independently selected papers, extracted data and assessed quality. **RESULTS:** Three RCTs with 1902 patients were included in this meta-analysis. Oxaliplatin/

capecitabine based chemotherapy plus bevacizumab (OCB) regimen showed improvement in OS (odds ratio [OR]=1.14, 95% CI 0.68 to 1.92), which was not statistically significant, when compared to other chemotherapy. Further, the OCB regimen also showed higher RR, CR, PR and SD (OR=1.30, 95% CI 0.80 to 2.11, OR=1.99, 95% CI 0.49 to 8.05, OR=1.57, 95% CI 1.05 to 2.36 and OR=1.34, 95% CI 0.96 to 1.86) respectively. Most common adverse events reported with bevacizumab included bleeding, hypertension, and venous thromboembolic events. **CONCLUSIONS:** Bevacizumab plus Oxaliplatin/capecitabine based chemotherapy showed improvement in OS and RR as compared to other chemotherapy in patients with advanced CRC.

PCN28

EFFICACY AND COST-EFFECTIVENESS OF SECOND-LINE CHEMOTHERAPY IN ELDERLY PATIENTS WITH ADVANCED GASTRIC CANCER

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OBJECTIVES: Second-line chemotherapy has been shown to benefit patients with advanced gastric cancer (AGC), extending the overall survival (OS) and progression-free survival (PFS). This study aimed to assess the efficacy and cost-effectiveness of second-line treatment for elderly patients with AGC. **METHODS:** Medical records and follow-up information of elderly patients (≥ 70 years) with AGC who received second-line chemotherapy were collected. A Markov model comprising three health states PFS, progressive disease (PD), and death was developed to simulate the process of AGC. Cost was calculated from the perspective of Chinese society. Sensitivity analyses were applied to explore the impact of essential variables. **RESULTS:** Forty-three elderly patients with AGC receiving second-line chemotherapy were included in our study. The median OS was 6.0 months (95% confidence interval [CI], 3.90-8.10) and PFS was 3.1 months (95% CI, 1.38-4.82), respectively. Treatment with second-line chemotherapy was estimated to increase costs by \$1,980.82 compared with best supportive care (BSC), with a gain of 0.103 quality adjusted life years (QALYs). Thus, the incremental cost-effective ratio was \$19,231.21/QALY for second-line chemotherapy versus BSC, which was below the threshold of 3x the per capita GDP of China, \$23,970.00. The Utility scores of PFD state and PD state were the most influential factors to the model. **CONCLUSIONS:** Second-line chemotherapy was an optimal strategy for elderly AGC patients in China from the efficacy and cost-effectiveness perspective.

PCN29

COMPARATIVE EFFECTIVENESS OF PLATINUM PLUS PACLITAXEL, PLATINUM PLUS LIPOSOMAL DOXORUBICIN, TOPOTECAN, AND LIPOSOMAL DOXORUBICIN FOR SECOND-LINE CHEMOTHERAPY AMONG PLATINUM-SENSITIVE PATIENTS WITH RECURRENT ADVANCED OVARIAN CANCER IN TAIWAN

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OBJECTIVES: This study aims to evaluate the comparative effectiveness of using platinum-based versus non-platinum-based regimens in treating patients with recurrent advanced ovarian cancer in Taiwan. **METHODS:** The data source was 2000-2013 National Health Insurance Research Database. The including criteria were patients who (1) received surgeries related to early stage ovarian cancer during 2000-2011; (2) received 6-9 cycles of platinum plus paclitaxel (PT) treatment within 60 days after the surgery as the first-line chemotherapy; and (3) had ≥ 6 months of clinical remission before receiving the 2nd treatment after disease relapse. Eligible patients were grouped into four treatment regimens according to their second line treatment: platinum plus paclitaxel (PT) (n=605), platinum plus liposomal doxorubicin (PD) (n=204), topotecan (n=109), and liposomal doxorubicin (n=120). The Kaplan-Meier method and the Cox proportion hazard model were used to estimate the overall survival (OS) and survival after recurrence (SR) among different treatments. **RESULTS:** When compared with PT, the adjusted HRs of the 5-year SR for PD, topotecan, and liposomal doxorubicin were 0.82 (95% CIs: 0.65-1.03), 1.47(95% CIs: 1.14-1.89), 1.64(95% CIs: 1.28-2.08), and the adjusted HRs of the 5-year OS were 0.88 (95% CIs: 0.68-1.13), 1.55(95% CIs: 1.18-2.03), 1.81(95% CIs: 1.40-2.34), respectively. **CONCLUSIONS:** When compared with non-platinum based regimens, platinum-based regimens significantly improve the treatment outcomes as the second line chemotherapy in terms of SR and OS for platinum-sensitive patients with recurrent advanced ovarian cancer.

PCN30

EFFECTIVENESS OF ABIRATERONE IN THE POST-DOCETAXEL SETTING ON THE SURVIVAL OF METASTATIC CASTRATION-RESISTANT PROSTATE CANCER PATIENTS IN QUEBEC

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OBJECTIVES: Abiraterone was introduced in Quebec in 2012 for metastatic castration-resistant prostate cancer (mCRPC) in the post-docetaxel setting. This study described abiraterone utilization in the early post-approval period and its clinical effectiveness in Quebec, for both post-chemotherapy patients and patients unfit for chemotherapy. **METHODS:** A retrospective cohort study was conducted using Quebec public healthcare administrative databases. Our cohort consisted of mCRPC patients receiving abiraterone from 2012-2013 (N=303). The abiraterone group was stratified into abiraterone post-chemotherapy (N=99) and abiraterone without chemotherapy (N=204, unfit for chemotherapy and qualified for abiraterone with the "exception patient" measure). Study outcomes included overall survival, abiraterone duration, and hospitalization days. Cox proportional hazard regression was used to estimate the effectiveness of abiraterone in the post-docetaxel setting adjusted for several covariates. **RESULTS:** Our cohort consisted of 303 mCRPC patients treated with abiraterone (abiraterone post-chemotherapy: 99 and

abiraterone "exception patient": 204). The median age was 75.0 for the abiraterone post-chemotherapy group and 80.0 for the abiraterone "exception patient" group. Median duration of abiraterone was 6 months (abiraterone post-chemotherapy: 5.3 months, abiraterone "exception patient": 5.9 months). The corresponding median survivals were 12 and 14 months, respectively (log-rank test p-value=0.815). Risk of death was similar in the abiraterone post-chemotherapy and abiraterone "exception patient" groups (hazard ratio: 0.99; 95%CI 0.64-1.52). Hospitalization days were higher for abiraterone post-chemotherapy patients compared to abiraterone "exception patients" (13.7 vs 10.9 days, p-value=0.0096). **CONCLUSIONS:** Effectiveness of abiraterone in older patients who were chemotherapy ineligible was similar to that of patients with prior docetaxel exposure. Overall, real-world survival benefits of abiraterone were similar to the results of the COU-AA-301 trial.

PCN31

REAL-WORLD OUTCOMES AMONG PATIENTS WHO INITIATED PAZOPANIB OR SUNITINIB AS FIRST TARGETED THERAPY FOR ADVANCED RENAL CELL CARCINOMA (ARCC): A RETROSPECTIVE ANALYSIS OF MEDICARE DATA

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OBJECTIVES: This study assessed real-world overall survival (OS), time on treatment (TOT), and dose intensity among ARCC patients who initiated pazopanib or sunitinib, two commonly-used first targeted therapies (TT). **METHODS:** Patients aged ≥ 65 with ARCC who initiated pazopanib or sunitinib as first TT (index date) were identified from the 100% Medicare data + Part D linkage (1/1/2006-12/31/2014). Patients were stratified by first TT and matched 1:1 using propensity scores based on age, sex, race, year of RCC diagnosis, metastatic sites, and baseline comorbidities and costs (assessed 1 year before index date). OS was defined as the time from index date to death from any cause; TOT as the time from index date to the earliest of treatment discontinuation (a prescription gap of > 90 days) or death from any cause. For both outcomes, patients were censored at the earliest of end of eligibility or data cut-off. Dose intensity was defined as the ratio of days that the patient had received drug supply to TOT. OS and TOT were compared between matched cohorts using Kaplan-Meier analyses and univariable Cox models; dose intensity was compared using Wilcoxon signed-rank tests. **RESULTS:** Before matching, the pazopanib cohort (N=526) was associated with higher outpatient visits and costs and lower pharmacy costs than the sunitinib cohort (N=1,185; all p<0.05). After matching, all baseline characteristics were balanced (N=522 for both). First TT with pazopanib was associated with significantly longer OS (median: 18.2 vs. 14.6 months, p<0.05; hazard ratio [HR]=0.83, 95% confidence interval [CI]: 0.72-0.97), similar TOT (median: 4.8 vs. 4.1 months, p=0.16; HR=0.90, 95% CI: 0.78-1.04), and lower dose intensity (mean: 0.91 vs. 0.94, p<0.01) compared with the sunitinib cohort. **CONCLUSIONS:** Among Medicare patients with ARCC, first TT with pazopanib compared to sunitinib was associated with significantly longer OS, similar TOT, and lower dose intensity.

PCN32

A META-ANALYSIS AND META-REGRESSION OF THE EFFICACY OF FRONT-LINE TREATMENT COMBINATIONS WITH PONATINIB VERSUS 1ST- AND 2ND-GENERATION TYROSINE KINASE INHIBITORS FOR PH+ ACUTE LYMPHOBLASTIC LEUKEMIA

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OBJECTIVES: To compare the effectiveness, as measured by complete molecular response (CMR) and 2- and 3-year overall survival (OS), of ponatinib versus first- and second-generation TKIs (i.e., imatinib, dasatinib, and nilotinib) for treatment of de novo Philadelphia-positive acute lymphoblastic leukemia (Ph+ ALL). **METHODS:** Twenty-six studies of front-line Ph+ ALL treatment with a TKI in combination with chemotherapy or corticosteroids were identified from published targeted literature reviews and recently published trials. Study arms in which patients received chemotherapy or corticosteroids only, a single TKI agent, or autologous stem cell transplant exclusively, were excluded. The proportions of patients achieving CMR (no detectable BCR-ABL1 transcripts) and 2- and 3-year OS were extracted from all study arms and summarized by TKI group (ponatinib versus earlier-generation TKIs) using pooled estimates with 95% confidence intervals (CIs) from a random-effects meta-analysis. Multivariate logistic meta-regressions adjusting for age and gender estimated the association between TKI-treatment group and percent CMR, 2-year OS, and 3-year OS. Odds ratios (OR) and 95% CIs were reported. **RESULTS:** Thirty-two TKI treatment arms were analyzed. The pooled proportion of patients achieving CMR with ponatinib was higher than that with earlier-generation TKIs (79% versus 34%). The pooled estimates of 2- and 3-year OS were also higher with ponatinib than with earlier-generation TKIs (2-year: 83% versus 58%; 3-year: 79% versus 50%). The OR for ponatinib versus earlier-generation TKIs for CMR (N=25) was 6.09 (95% CI: 1.16-31.90, p=0.034); for 2-year OS (N=27) 3.70 (95% CI: 0.93-14.73, p=0.062); for 3-year OS (N=19) 4.49 (95% CI: 1.00-20.13, p=0.050). **CONCLUSIONS:** Compared to earlier-generation TKIs, ponatinib was associated with a > 6 -fold, > 3 -fold, and > 4 -fold increase in the odds of achieving CMR, 2-year OS, and 3-year OS, respectively. Ponatinib in combination with chemotherapy may represent an effective front-line treatment option in newly diagnosed Ph+ ALL compared with combination therapy with earlier-generation TKIs.

PCN33

AN OUTCOMES MODEL ASSESSING THE IMPACT OF EARLY DISCONTINUATION OF EVEROLIMUS (EVE) DUE TO STOMATITIS ON HEALTH AND PATIENT-REPORTED OUTCOMES IN POSTMENOPAUSAL WOMEN WITH HR+/HER2- ADVANCED BREAST CANCER (ABC) RECEIVING EVEROLIMUS-EXEMESTANE COMBINATION THERAPY (EVE-EXE)

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OBJECTIVES: To explore the impact of early discontinuation of everolimus (EVE) due to stomatitis on health and patient-reported outcomes among everolimus-exemestane combination therapy (EVE-EXE) users with HR+/HER2- aBC. **METHODS:** The current model was adapted from a published cost-effectiveness model using a US third-party payer perspective comparing EVE-EXE with other endocrine therapies and focused on only the EVE-EXE arm. Specifically, efficacy data were obtained from a published clinical trial; utility and disutility data were obtained from published literature. The base case scenario were 61-year-old patients. The model time horizon was 10 years. A distinct patient subgroup – patients who prematurely discontinued everolimus due to stomatitis - was created from the overall intent-to-treat (ITT) EVE-EXE arm and the outcomes were compared with the ITT sample. As 90% of stomatitis events upon everolimus use occurred prior to 8 weeks, the average time to treatment discontinuation in the aforementioned subgroup was assumed to be 8 weeks. Exposure-outcome ratios were calculated to quantify the relationship between time on everolimus and outcomes. The outcomes of interest included progression free survival (PFS), overall survival (OS), and quality-adjusted life months (QALMs) gained. Deterministic sensitivity analyses were applied to understand the relative impact of different parameters to study findings. **RESULTS:** In the base-case scenario, relative to the ITT sample, patients who prematurely discontinued everolimus due to stomatitis on average was projected to experience 2.0 months (17.8 vs. 19.8 months), 1.3 months (37.4 vs. 38.8 months), and 1.2 (22.7 vs. 23.9) shorter PFS, OS, and QALM respectively. Deterministic sensitivity analyses showed that time on everolimus and exposure-outcomes ratio are the two major input parameters influencing study findings. **CONCLUSIONS:** Patients initiating EVE+EXE and discontinuing everolimus early due to stomatitis was projected to experience shorter PFS, OS, and QALMs compared with the ITT sample. There is a need to prevent stomatitis to ensure better patient outcomes.

PCN34

USE PATTERNS OF FIRST-LINE INHIBITORS OF TYROSINE KINASE AND TIME TO CHANGE TO SECOND-LINE THERAPY IN PATIENTS WITH CHRONIC MYELOID LEUKEMIA

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OBJECTIVES: Chronic myeloid leukemia (CML) has a low incidence but a high burden of disease, and is treated with high-cost tyrosine kinase inhibitors (TKI). To determine the time from the start of a first-line TKI until it passes to second-line, and to establish the reasons for the change of therapy time. **METHODS:** Retrospective cohort study, in patients with Philadelphia-positive CML between January 1 2007 and July 31 2015 treated with some TKI. With information obtained from medical records, the time to change initial drugs to second-line therapy, and the reasons for change, were identified. Kaplan-Meier survival analysis was carried out. **RESULTS:** A total of 247 patients treated were found in 22 cities in Colombia with a mean age of 53.2 ± 15.2 years. The drug most used as initial therapy was imatinib; 53.8% of cases had to change to another TKI. Fifty percent of patients changed therapy in 42 months, the men in 24 months and women in 67 months (95%CI: 14.314–33.686; p = 0.001). Being male (OR: 2.23; 95%CI: 1.291–3.854; p = 0.004) and receiving hydroxyurea (OR: 3.65; 95%CI: 1.601–8.326; p = 0.002) were associated with a higher probability of switching to nilotinib or dasatinib, while receiving a new-generation TKI (OR: 0.15; 95%CI: 0.071–0.341; p < 0.001) reduced this risk. **CONCLUSIONS:** This cohort of CML patients were treated with drugs of high therapeutic value at recommended doses, but a high proportion needed to change to a second line with nilotinib and dasatinib management.

PCN35

CALCULATING EPIDEMIOLOGY ESTIMATES IN ACUTE MYELOID LEUKEMIA (AML) FOR AUSTRALIA, CANADA AND SWITZERLAND USING A TOP DOWN VS. BOTTOM UP APPROACH

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OBJECTIVES: To compare how the incidence rates of AML in Australia, Canada and Switzerland differ depending upon the calculation approach taken (detailed bottom up or top down). **METHODS:** A comprehensive literature review was undertaken to identify incidence data for AML; this included available databases, registries, clinical trials and research papers. Detailed bottom up studies were reviewed for sample size, date of data collection, breadth of geographic coverage and representation. The incidence of AML has been reported as between 32% - 33% of all leukemia cases, which was applied to a top down calculation using national reported leukemia rates. **RESULTS:** For Switzerland, in a bottom up calculation based on data from 128 medical records of adult patients (> 16 years) diagnosed with de novo AML during the period 1984-2003, the incidence was 2.6/100,000. Swiss incidence of leukemia was 8/100,000 in 2012, and when the top down calculation rate of 32% (UK proportion) was applied, the incidence was 2.6/100,000. For Australia, the incidence of AML has been reported as 3.4/100,000 in a study from Western Australia for 898 patients diagnosed between 1991-2005. This aligned with the Australian cancer registry reported incidence of 3.8/100,000 (2012). In Canada, 3.7/100,000 people were diagnosed with AML in 2013, falling

well below the draft guidelines for orphan designation of 5/10,000 people. In 2012, Canadian total leukemia incidence was 9.5/100,000. Applying the top down calculation based on 33% (US proportion) translated to an AML rate of 3.1/100,000. **CONCLUSIONS:** Variation in the incidence rates using a top down or bottom up approach for the three countries ranged between no difference and 0.6/100,000. Across all countries, regardless of approach the AML incidence numbers were well below the incidence rates required for orphan designation. Using both approaches serves to validate the numbers reported.

PCN36

BURDEN OF MERKEL CELL CARCINOMA: A TARGETED LITERATURE REVIEW

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OBJECTIVES: Merkel Cell Carcinoma (MCC) is a rare, lethal cutaneous skin cancer with no approved drug therapies and limited treatment options. Our objective was to conduct a comprehensive review of MCC disease burden. **METHODS:** We conducted a targeted literature review of studies published from 2010 to 2016 to assess epidemiology, patient burden, and unmet needs associated with MCC. An article was retrieved for full review if the abstract met each of the following criteria: reported incidence, natural morbidity or mortality of MCC; derived from a peer-reviewed journal; and reported in English-language published since January 2010. **RESULTS:** The incidence of MCC (per 100,000 persons per year) is reported highest in Australia (0.82-1.60), followed by the US (0.6), Netherlands (0.35), Sweden (0.18-0.33), Finland (0.24-0.25), Spain (0.28), Denmark (0.22), South East Scotland (0.133), France (0.13). Inadequate data available from countries like Canada, UK, and Germany. Typically, stage I-II MCC is observed in approximately 60% - 75% patients, stage III in 10% - 30% patients, and stage IV (metastatic) in 2% - 16% patients. The 5-year and 10-year survival is 0% - 68%, and 21% - 65% respectively, based on factors such as disease stage and gender. Although less than 20% patients progress to advanced metastatic stage IV MCC, they experience the highest unmet need due to lack of effective therapeutic options. **CONCLUSIONS:** The current treatment options usually include a combination of surgery, radiotherapy, and chemotherapy, but there is a significant need of newer, better treatments which can increase the survival. No evidence is found in the literature that reports the humanistic and economic burden related to MCC. Future research is warranted to adequately quantify the burden-of-illness of MCC and assess comparative effectiveness of evolving treatment options to better inform patients, prescribers and payer organizations concerning optimal modalities of disease management.

PCN37

THE ROLE OF EPIDEMIOLOGY IN HEALTH ECONOMIC AND OUTCOMES RESEARCH: A THYROID CANCER, RETROSPECTIVE, POPULATION-BASED COHORT STUDY

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OBJECTIVES: Changes in-points in trends (joinpoint) of disease incidence and mortality inform decision makers to design health programs, determine the area where more research is needed and can also be used in health economics and outcomes research. This study goal was to detect change-points in trends (joinpoint) of thyroid cancer incidence and mortality in the period 1969-2013. **METHODS:** Surveillance, Epidemiology, and End Results (SEER18) and the National Center for Health Statistics (NCHS) databases were used to extract the data. A joinpoint regression and least square method was used to identify the best fit model. Sequences of permutation tests were used to determine the goodness of fit. **RESULTS:** The incidence of diagnosed malignant thyroid cancer reached 132,988 cases in the period 2000-2013. One joinpoint and two segments were identified based on the joinpoint (2000-2009 and 2009-2013). The annual percent change (APC) from 2000-2009 was 6.63, 6.09 and 6.80 for both genders, male and female, respectively. The APC from 2009-2013 significantly decreased to 2.45, 2.80 and 2.37, respectively. A total of 53,773 died from the thyroid cancer between 1969-2013. One joinpoint and two segments were determined (1969-1988 and 1988-2013) based on the number of change-points for both sex combined and for female with APCs= -2.12, 0.73, respectively, and APCs= -2.65, 0.38, also respectively. Two segments were specified for male (1969-1986 and 1986-2013) with APCs= -1.48, 1.29 respectively. **CONCLUSIONS:** The thyroid cancer incidence rate increased from 2000 to 2009 and then significantly decreased until 2013. The mortality rates decreased from 1969 until 1988 and then significantly increased until 2013. The results of the changes in joinpoints can be applied as inputs in economic models and in more accurate estimations of budget impact analyses.

PCN38

INCIDENCE OF LYMPHOMA IN TAIWAN, 1998-2012

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OBJECTIVES: To estimate the annual incidence of lymphoma in Taiwan population. **METHODS:** We conducted a cross-sectional analysis using 1998-2012 Taiwan National Cancer Registry. Patients with the following 4 different types of lymphoma were identified: Hodgkin's lymphoma, aggressive or indolent B-cell lymphoid neoplasm, and T/NK-cell lymphoid neoplasm. Annual incidence was reported per 100,000 individuals as crude rate and age-standardized rate. Sex-specific incidence and age of diagnosis were also reported. **RESULTS:** The crude incidence rate of aggressive B-cell lymphoma was highest among all 4 lymphoma types, which was 2.02 per 100,000 persons in 1998 and surged to 5.68 per 100,000 persons in 2012.

Indolent B-cell lymphoma were less frequently occurred (crude incidence rate 0.66 per 100,000 persons in 1998 and 2.13 per 100,000 persons in 2012), followed by T/NK-cell lymphoma (crude incidence rate 0.34 per 100,000 persons in 1998 and 1.63 per 100,000 persons in 2012). As other countries, the incidence rate of Hodgkin's lymphoma was much lower than non-Hodgkin's lymphoma (crude incidence rate 0.38 per 100,000 persons in 1998 and 0.75 per 100,000 persons in 2012). The incidence trends during 1998–2012 were similar among men and women. However, the incidences of most lymphoma were higher in males than in females, especially for T/NK-cell lymphoma. Besides, Hodgkin's lymphoma tended to occur at a younger age of life than non-Hodgkin's lymphoma. **CONCLUSIONS:** The incidences of all 4 types of lymphoma yielded increasing trends during 1998–2012 among Taiwanese population and aggressive B-cell lymphoid neoplasms increased fastest.

PCN39

HERPES ZOSTER INCIDENCE, DISEASE BURDEN AND COST AMONG PATIENTS WITH SOLID TUMOR MALIGNANCY RECEIVING CHEMOTHERAPY 2010–2014 IN A LARGE, INSURED US POPULATION

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OBJECTIVES: Chemotherapy places patients with solid tumor malignancy (STM) at risk for herpes zoster (HZ). HZ incidence among STM patients is 23–48/1,000 person-years (PY) vs. 3–5/1,000 PY in the general population. We aimed to assess HZ incidence and HZ-associated healthcare resource utilization (HRU) and cost among STM patients. **METHODS:** Claims were analyzed for adults aged ≥ 18 years with STM between 01/2010–06/2014 in Optum Research and Impact National Benchmark Databases. Subjects with prior HZ or <18-month continuous enrollment, or hematological cancers or Zostavax were excluded. Incidence was calculated as HZ cases observed over accrued time-at-risk in PY. To assess all-cause HRU and costs, index date was HZ onset date for HZ cases, and an assigned date for controls. 3,004 cases and 15,020 controls were propensity-score matched at 1:5 ratio. HRU and per-patient-month (PPM) costs were assessed from 21 days pre-index through up to 364 days post-index. Total 1-year cost was analyzed with Lin's regression to account for censor. **RESULTS:** There were 3,100 HZ cases among 155,480 STM patients, yielding incidence of 14.90/1,000 PY (95% CI: 14.38–15.44). Females had significantly higher incidence than males (15.55 vs. vs 13.76 /1,000 PY). Incidence was higher for chemotherapy with moderate or high immunosuppression vs. low or no immunosuppression 17.06 (16.24–17.92) vs. 11.81 (11.10–12.55) /1,000 PY. Incidence rate varied across cancer type. HZ cases had greater HRU in all treatment settings. Mean unadjusted PPM cost was significantly greater for cases (\$5,258 (SD \$9,184)) vs. controls (\$4,203 (SD \$8,005)) ($P < 0.001$). The adjusted 1-year excess cost for cases was \$6,432 (\$3,481–\$9,383) ($P < 0.001$). **CONCLUSIONS:** HZ incidence was significantly greater with increasing immunosuppression. HZ cases experienced significantly greater HRU and costs. A safe and effective HZ vaccine for STM patients receiving chemotherapy could be a useful prevention tool to improve outcomes and reduce costs.

PCN40

A REVIEW OF EPIDEMIOLOGY, PROGNOSIS, AND TREATMENT OPTIONS FOR RECURRENT OR METASTATIC HEAD AND NECK SQUAMOUS CELL CARCINOMAS (HNSCC)

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OBJECTIVES: To review the epidemiology, prognostic factors, and treatment guidelines for recurrent or metastatic HNSCC, to better understand and describe patient groups and the corresponding treatment options. **METHODS:** Targeted literature reviews of published epidemiology studies in the past five years and current clinical guidelines from Europe, North America, and Australia indexed in the National Guideline Clearinghouse or International Guideline Library were conducted. **RESULTS:** Of 265 hits, 25 epidemiology studies and 12 guidelines were selected. Global incidence and one-year prevalence rates in 2012 were 1.9 and 1.7 per 100,000 (oropharynx/hypopharynx), 2.1 and 2.2 (larynx), and 4.0 and 3.9 (lip/oral cavity), respectively. Changes in annual incidence rates (-3.7% to +5%) vary by tumor site, gender, and country. Risk factors for advanced HNSCC include age, gender, and alcohol or tobacco use, whereas risk factors for recurrence or death include tumor characteristics and treatment outcome. Five-year survival rates for metastatic HNSCC ranged widely between 3–36% across tumor sites and studies. In Europe and the United States, depending on tumor site, 2–16% of HNSCC are diagnosed at distant stages. Reportedly, 35% of regional cases develop distant metastases, including 25% of complete responders. Epidemiological data on recurrent vs. metastatic disease, or relapse vs. refractoriness to prior therapies is scarce, fragmented by tumor site/subsite, and limited to single study sites/countries. Newer guidelines recommend combined platinum/5-fluorouracil FU/cetuximab for recurrent/metastatic HNSCC. However, no recommendations are based on prior systemic therapy, nor differentiate recurrent and refractory disease. **CONCLUSIONS:** Epidemiological data on HNSCC sub-populations not amenable to curative treatment is scarce and fragmented by country and disease site, resulting in low generalizability. A more comprehensive systematic review or chart reviews may provide further informative epidemiological data. However, we can conclude that in non-curative disease, there remains high unmet need with limited systemic treatment options available and poor overall survival.

PCN41

ASSESSING VARIATION IN THE INCIDENCE OF ACUTE MYELOID LEUKEMIA (AML) FOR FRANCE, GERMANY, ITALY, SPAIN, UK AND CANADA

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OBJECTIVES: To compare how the incidence rates of AML vary across France, Germany, Italy, Spain, UK and Canada. **METHODS:** A comprehensive literature

review was undertaken to identify incidence data for AML using databases, registries, clinical trials and publications. Detailed bottom up studies were reviewed for sample size, data collection dates, geographic coverage and representation. **RESULTS:** The highest rates of AML for target countries were for the UK where incidence was 4.1/100,000, in 2016. This was based on clinical and lab data from Yorkshire and Humber regions, and national health data. A study of patients from south east England between 1999–2000 reported 3.0/100,000. The lowest estimated rates were reported in France with 2.3 and 2.6/100,000 cases for males and females respectively in 2012. However, this data was sourced from registries which only cover ~20% of France. Italian rates were 3.7 and 2.6/100,000 for males and females respectively based on registry data covering 43% of Italy. In Germany, according to 11 population-based cancer registries, there were 13,810 new AML cases (≥ 15 years) during 2007–2011. AML rates were not retrieved, although crude rates could be calculated based on total population estimates. Coverage in Spain was limited to regional AML studies (north-east Catalonia) where incidence was 3.1/100,000. In Canada, 3.7/100,000 people were diagnosed with AML in 2013 based on registry data with almost complete national coverage. The annual crude incidence rate for Europe was reported as 3.7/100,000 based on the RARECARE project using patients diagnosed between 1995–2002. **CONCLUSIONS:** Rates were consistent across the target countries, ranging from 2.3–4.1/100,000. Robust data regarding the incidence of treatment naive and relapsed or refractory patients was not identified, but would be expected to have a lower incidence than the overall AML population.

PCN42

PREVALENCE OF ANAPLASTIC LYMPHOMA KINASE POSITIVE NON-SMALL-CELL LUNG CANCER IN SELECTED POPULATION OF PATIENTS IN BULGARIA

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OBJECTIVES: Lung cancer is the most common cause of death from cancer worldwide with 1.8 million people diagnosed/year. The disease remains as the most common cancer in men worldwide. The purpose of the article is to evaluate the prevalence of ALK mutations in NSCLC patients in Bulgaria. **METHODS:** A systematic review of the published data on prevalence of ALK positive NSCLC conducted in other countries and compared to local data, were being carried out. Between January 2016 and June 2016, 132 patients with NSCLC, previously screened for EGFR mutation were selected for ALK mutation analysis. **RESULTS:** Data is available for 124 patients, for 8 patients tumor mass was insufficient for analysis. ALK mutation was confirmed in 5 patients, 119 patients were diagnosed with ALK wild type. From all ALK positive patients, 3 were with adenocarcinoma, 1 with squamous NSCLC and 1 with other type NSCLC. All ALK mutations were observed in non smoker and ex-smoker patients. ALK mutations were presented only in patients with stage III and IV NSCLC. Histologic examination showed that almost half of the patients were with stage IV NSCLC; 12.9% were with stage III NSCLC; one patient with stage IIa; one with stage IIb NSCLC and two patients with confirmed relapse. Most of the patients were with adenocarcinoma (82 patients), 11 patients were with squamous NSCLC and 2 patients were with other type of NSCLC. **CONCLUSIONS:** In our study we found that the prevalence of ALK mutation in EGFR negative NSCLC patients is 3.8%.

PCN43

RATES AND PREDICTORS OF POLYPHARMACY IN CANCER SURVIVORS IN THE UNITED STATES

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OBJECTIVES: Polypharmacy among individuals with cancer is an alarming issue. We aimed to determine the rates of polypharmacy and predictors among cancer survivors in the United States. **METHODS:** This cross-sectional analysis included responses to survey questions collected as part of the Medical Expenditures Panel Survey (MEPS) for the survey years 2008, 2010, 2012, and 2014. The total number of prescriptions per person/household response were determined by picking the panel with the most reported medications. Polypharmacy was defined as having five or more classes of medications. We chose to include only those cancer survivors who had a single tumor. Descriptive statistics were used to determine significant differences in characteristics among those with and without polypharmacy, and logistic regression was employed to identify predictors of polypharmacy in a multivariate framework. **RESULTS:** An estimated 46.5 million cancer survivors cumulative for the four years comprised our study sample. Of these, 49.3% met our definition of polypharmacy while 50.7% had four classes of medications or less. Older age (65+ vs. 18–39, adjusted odds ratio (AOR)= 1.62, confidence interval (CI): 1.15–2.29), female gender (AOR= 0.75, CI: 0.59–0.95), number of chronic conditions (1 vs none, AOR= 2.26, CI: 1.83–2.80 and 2+ vs none, AOR= 8.28 CI: 6.63–10.35), and increased number of total visits (10 to 19 visits compared to 0 to 4, AOR= 1.82, CI: 1.44–2.30 and 20+ visits compared to 0 to 4, AOR= 3.59 CI: 2.72–4.74) were significant predictors of polypharmacy. **CONCLUSIONS:** Polypharmacy is highly prevalent among cancer survivors in the United States, suggesting greater surveillance of adverse drug interactions among this vulnerable group.

PCN44

TARGETED LITERATURE REVIEW OF ADVANCED/METASTATIC TRIPLE-NEGATIVE BREAST CANCER BURDEN OF ILLNESS

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OBJECTIVES: To summarize literature on the burden of illness in patients with advanced or metastatic triple-negative breast cancer (TNBC) and identify information that may inform a cost-effectiveness analysis. **METHODS:** Searches of MEDLINE, Embase, EconLit, and the NHS Economic Evaluation Database were conducted to identify relevant literature describing the epidemiology (January 2006–July 2016), economic burden, quality-of-life (QoL) burden, and treatment guidelines (January 2011–July 2016) associated with TNBC. Search strategies included disease terms for breast cancer, advanced/metastatic disease, and hormone receptor/human epidermal growth factor receptor 2 status. Abstract review, full-text review, and data extraction were conducted by a single reviewer and validated by a second, independent reviewer. **RESULTS:** A total of 3140 publications were identified; following screening, 36 studies were selected for review (21 epidemiology, two economic, 13 guidelines). Across 11 studies, reported prevalence of the triple-negative (TN) subtype among advanced/metastatic breast cancer ranged from 1.3% to 25.6% (nine out of 14 patient groups had prevalence >15%). Incidence rates were reported to have a similar range (nine studies), and rates of the TN subtype were shown to be higher for younger patients and African-American patients. Among 10 studies reporting overall survival, all but one reported a median of <9 months. Economic evidence was limited (two studies), but indicated increased resource use and higher treatment costs compared with non-TNBC patients. No QoL studies were found for a TNBC population; supplemental searches identified two additional studies in a general metastatic breast cancer population to provide context. Disease progression has the largest impact on QoL in this population; chemotherapy-related adverse events also showed a significant QoL burden. Treatment guidelines generally recommended anthracycline- and taxane-based chemotherapy as initial treatment for TNBC. **CONCLUSIONS:** This review highlights the paucity of literature available to inform cost-effectiveness evaluations of advanced/metastatic TNBC, indicating a need for further research.

PCN45

INCIDENCE, PREVALENCE, AND SURVIVAL OF MALIGNANT PLEURAL MESOTHELIOMA (MPM) IN THE UNITED STATES

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OBJECTIVES: Malignant Pleural Mesothelioma (MPM) is a rare, aggressive cancer with poor prognosis, currently accounting for 0.10% deaths annually in the United States (U.S.). The current treatment options are limited, including surgery and chemotherapy with pemetrexed, cisplatin, and bevacizumab. There is limited recent information on disease epidemiology and baseline estimates of occurrence and characteristics in a large U.S. cohort. Therefore, the objective of this analysis was to describe the long-term trends in incidence rates and survival in MPM. **METHODS:** The prevalence, incidence, and overall survival of MPM patients by sex, year of diagnosis, and geographical location for all races were evaluated using data from 18 cancer registries with SEER from 1973–2013 for MPM patients by ICD-O code 9050/3 and C38.4. Cancer-directed surgery and outcomes were also examined over time. **RESULTS:** The prevalence of MPM increased with age, but decreased over time. Age-adjusted incidence rates per 100,000 were higher in patients 65 years and older (3.0) vs 24–64 years old (0.1), and in males (0.9) vs females (0.2). Incidence rates were higher in geographical locations with higher asbestos exposure. The incidence of patients receiving surgery per 100,000 decreased over time, from 1.2 to 0.43. Observed survival was lower in patients greater than 65 years old, with a median survival of 1 year, and remained relatively unchanged after the FDA approval of pemetrexed in 2004. **CONCLUSIONS:** The trend in prevalence rates demonstrates a delay in disease onset from asbestos exposure to disease diagnosis. This decrease in prevalence over time is expected with stringent laws imposed around asbestos usage and removal. Very few patients received surgery, which suggests a higher usage of chemotherapy. There was minimal change in survival before and after the FDA approval of pemetrexed for MPM, demonstrating an unmet need for additional treatment options.

PCN46

ASSOCIATION BETWEEN ASTHMA AND RISK OF PROSTATE CANCER – A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: Evidence indicates that systemic inflammatory response, not only prostate inflammation, contributes to prostate cancer etiology. Therefore, it is possible that males with long-term inflammatory responses such as asthma are at increased risk of prostate cancer. However, there are existing knowledge gaps in the association between comorbid asthma and prostate cancer. **METHODS:** A systematic review with meta-analysis was conducted to examine the association between asthma and risk of prostate cancer. An initial search of the bibliographic databases PsychINFO, CINAHL and Pubmed from January 1966 to January 2016 was completed by using a combined text word (“Asthma”[Mesh] OR Asthma[tiab] AND “Prostatic Neoplasms”[Mesh] OR Prostat[tiab] AND (Cancer” [tiab]OR Neoplasm”[tiab])) and MESH/subject heading search strategy. The electronic search was restricted to studies written in English and carried out in human subjects. The meta-analysis was further limited to studies with reported quantitative effect estimates, expressed as an odds ratio, relative risk ratio (RR), standardized mortality ratio, or standardized incidence ratio. **RESULTS:** A total of 25 studies were included in the systematic review. Of these, 12 studies (including 12,866

individual participants) were considered eligible for meta-analysis, involving 4 case-control studies and 8 cohort studies. The summary of combined RR from the random effects model for developing prostate cancer was 1.02 (95% CI: 0.89–1.13) for asthma with high heterogeneity (94.4%). **CONCLUSIONS:** The present meta-analysis of observational studies indicates that there is no association between asthma and risk of prostate cancer. Further subgroup analysis in different patient characteristics needs to be investigated.

PCN47

REAL-WORLD OUTCOMES IN PATIENTS WITH METASTATIC MERKEL CELL CARCINOMA TREATED WITH FIRST-LINE CHEMOTHERAPY IN THE UNITED STATES: RESULTS FROM A RETROSPECTIVE ANALYSIS

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OBJECTIVES: This retrospective study examined therapeutic outcomes to first-line (1L) chemotherapy in patients with distant metastatic Merkel cell carcinoma (mMCC). MCC is a rare, aggressive skin cancer associated with poor prognosis in patients with metastatic disease. Advanced MCC is typically treated with chemotherapy, but there is no approved standard-of-care treatment. **METHODS:** Data were obtained from the US Oncology Network/McKesson Specialty Health electronic health record database and medical charts. Qualifying patients were adults with distant mMCC who had received 1L chemotherapy between 11/2004 and 9/2014 with follow-up until 6/2015. Patients who received treatment with any drug targeting T-cell coregulatory proteins were excluded, among other eligibility criteria. Objective response rate (ORR) to 1L chemotherapy was assessed using RECIST v1.1 as a guide, and duration of response (DOR), time to treatment discontinuation (TTD), progression-free survival (PFS), and overall survival (OS) were estimated using Kaplan-Meier methodology. The primary analysis population was patients with immunocompetent status. **RESULTS:** Of 686 patients identified to have MCC, 67 qualified for analysis (76% immunocompetent/24% immunocompromised). In immunocompetent patients (n=51) at start of 1L chemotherapy, median age was 78 years, 84% were male, 49% had an ECOG performance status of 1, and 69% were diagnosed initially with stage I–III disease. The most common 1L regimen was carboplatin + etoposide (63%). ORR was 29.4% (95% CI, 17.5–43.8), median DOR was 6.7 mos (95% CI, 1.2–10.5; interquartile range, 2.3–12.1), median TTD was 2.4 mos (95% CI, 2.2–2.9), median PFS was 4.6 mos (95% CI, 2.8–7.7), and median OS was 10.5 mos (95% CI, 7.2–15.2). Results in the overall population were consistent with those in the immunocompetent population. **CONCLUSIONS:** In patients with distant mMCC treated with 1L chemotherapy, responses were of limited duration. The median survival was less than 1 year, highlighting the need for novel therapies.

PCN48

SURVIVAL ASSOCIATED WITH COPD AMONG SEER-MEDICARE BENEFICIARIES WITH NSCLC

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OBJECTIVES: Lung cancer and chronic obstructive pulmonary disease (COPD) are among leading causes of morbidity and mortality worldwide. We investigated the impact of pre-existing COPD and its subtypes, chronic bronchitis and emphysema, on overall survival among Medicare enrollees diagnosed with non-small cell lung cancer (NSCLC). **METHODS:** Using SEER-Medicare data, we included patients >= 66 years of age diagnosed with NSCLC at any disease stage between 2006 to 2010 and continuously enrolled in Medicare Parts A and B in the 12 months prior to diagnosis. Pre-existing COPD in patients with NSCLC were identified using ICD-9 codes. Kaplan-Meier method and log-rank tests were used to examine overall survival by COPD status and COPD subtype. Multivariable Cox Proportional Hazards models were fit to assess the risk of death after cancer diagnosis. **RESULTS:** We identified 66,963 lung cancer patients. Of these, 22,497 (33.60%) had documented COPD before NSCLC diagnosis. For each stage of NSCLC, median survival was shorter in the COPD compared to the Non-COPD group (stage I: 692 days vs 1130 days, P<0.0001; stage II: 473days vs 627 days, P<0.0001; stage III: 224 days vs 229 days; P<0.0001; stage IV: 106 days vs 112 days, P<0.0001). For COPD subtype, median survival for patients with pre-existing chronic bronchitis was shorter compared to emphysema across all stages of NSCLC (stage I: 672 days vs 811 days, P<0.0001; stage II 582 days vs 445 days, P<0.0001; stage III: 255 days vs 229 days, P< 0.0001; stage IV: 105 days vs 112 days, P<0.0001). In cox proportional hazard model, COPD patients exhibited 11% decreased time to death than Non-COPD patients (Hazard Ratio: 1.11, 95%Confidence Interval: 1.09–1.13). **CONCLUSIONS:** NSCLC patients with pre-existing COPD had shorter survival with marked differences in early stages of cancer. Chronic bronchitis demonstrated a greater association with time to death than emphysema.

PCN49

AGE DISPARITIES IN INFLAMMATORY BREAST CANCER SURVIVAL BY RACE AND HORMONAL RECEPTOR STATUS: AN ANALYSIS OF 1990–2013 SEER DATA

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OBJECTIVES: Inflammatory breast cancer (IBC) is a rare and aggressive form of cancer with poor outcomes. This study aims to assess age differences in IBC survival among all, white, black, estrogen receptor positive (ER+) and estrogen receptor negative (ER-) patients. **METHODS:** Using the Surveillance, Epidemiology,

and End Results (SEER) data, IBC female patients diagnosed between 1990 and 2013 were identified. Patients were divided into five groups according to their age at diagnosis: 18-34 (younger patients), 35-49, 50-64, 65-74 and 75 and above (older patients). The 36-month inflammatory breast cancer-specific survival (IBCSS) was estimated using the Kaplan-Meier method and compared across groups using the log-rank test. Stratified multivariable Cox proportional hazard ratios (HRs) were used to assess the association between age and survival among all, white, black, ER+ and ER- patients after adjusting for patient and tumor characteristics. **RESULTS:** A total of 13,748 IBC patients were identified; 3.8% were diagnosed between the ages of 18-34, 25.0% between 35-49, 38.8% between 50-64, 16.9% between 65-74, and 15.5% aged 75 and above. The 36-month IBCSS Kaplan-Meier curves showed younger patients had a better crude survival compared to older patients among all (58% vs 52%), white (60% vs 52%), ER+ (76% vs 64%) and ER- (48% vs 41%) subgroups, and the same survival among the black subgroup (48% vs 48%). The adjusted HRs were higher for older versus younger patients for all, white, ER+ and ER- patients, but not for black patients. Compared to younger patients, the adjusted HRs for older patients were 1.28(95%CI:1.11-1.47), 1.32(95%CI:1.12-1.56), 1.07(95%CI:0.79-1.45), 1.28(95%CI:1.01-1.63) and 1.31(95%CI:1.06-1.61) for all, white, black, ER+ and ER- patients respectively. **CONCLUSIONS:** This study suggests increased age may be associated with poorer survival among all, white, ER+ or ER- patients, but not associated with poorer survival among black patients. Further research is needed to examine other variables that may affect these findings.

PCN50

THE EFFECT OF CACHEXIA ON SURVIVAL IN LUNG CANCER PATIENTS

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OBJECTIVES: Lung cancer is the leading cause of cancer death in the United States. It is estimated that 60% of lung cancer patients are afflicted with cancer-cachexia and approximately 10% of these patients will die due to cancer-cachexia. We examined the impact of cachexia on survival among lung cancer elderly patients. **METHODS:** We conducted a retrospective study using SEER-Medicare data. Patients were included if diagnosed with first primary lung cancer between January 1, 2005 and December 31, 2010, at least 66 years of age, and continuously enrolled in Medicare Parts A and B in the 12 months prior to diagnosis. We identified cachexia in lung cancer patients using ICD-9 codes. Descriptive statistics were used to identify population characteristics. Propensity score (1:1 nearest neighbor) matching was performed between cachectic and non-cachectic lung cancer patients to compare survival. **RESULTS:** We identified 84,518 lung cancer patients. Of these, 2,536 (3%) developed cachexia after lung cancer diagnosis. The most common comorbid conditions among cachectic and non-cachectic groups were chronic obstructive pulmonary disease (50% versus 45.62%), congestive heart failure (8.56% versus 13.38%), diabetes (7.41% versus 14.75%), peripheral vascular disease (3.82% versus 6.85%), and renal disease (3.63% versus 6.14%). Adjustment for immortal time bias resulted in a cohort of 3734 matched patients. Eighty-eight percent of patients in the cachectic group died during the follow-up period compared to 78% in the non-cachectic group. Median survival time among non-cachectic lung cancer patients was significantly longer than cachectic lung cancer patients (log-rank $p < 0.0001$). Specifically, median survival in non-cachectic patients was 201 days compared to 92 days among cachectic patients. **CONCLUSIONS:** The occurrence of cachexia is independently associated with a significant decrease in survival among lung cancer elderly patients. The results of this study may be useful for identifying healthcare burden and planning treatment modalities for this population.

PCN51

RE-DEFINING LONG-TERM SURVIVAL: SURVIVAL ENDPOINTS WITHIN HEMATOLOGICAL CANCERS – A TREND ANALYSIS OF THE PIPELINE PRODUCTS

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OBJECTIVES: The long-term survival (LTS) benefits of candidate therapies is increasingly being assessed in clinical trials. As this data is generally not available for pivotal studies at time of pricing and reimbursement review it does not influence initial access decisions. We conducted a trend analysis of landmark survival endpoints, particularly LTS, in hematological cancer indications to inform considerations for future clinical trial designs and the potential impact on P&R reevaluations. **METHODS:** A targeted review using Citeline's Trialrove database was conducted to extract landmark survival data (≥ 3 months) for progression free survival (PFS) and overall survival (OS) for products across leukemia, lymphoma, multiple myeloma (MM), and myelodysplastic syndromes (MDS) between June 2014 and June 2016. **RESULTS:** A total of 961 observations were extracted across phase I/II (n=265), phase II (n=552), phase II/III (n=20) and phase III (n=124) across MDS (n=105), MM (n=162), leukemia (n=346), and lymphoma (n=348). Overall, 53% (516/961) of trials included landmark OS and PFS across indications, 64% (329/516) included long-term endpoints of ≥ 1 year PFS and 66% (340/516) ≥ 1 year OS across immune oncologic (IO) (n=135) and non-IO (n=370) trials. The most commonly seen long-term endpoints across 516 trials were PFS at years 1 (10%, n=51), 2 (23%, n=117), 3 (11%, n=59) and 5 (10%, n=52), and OS at years 1 (17%, n=86), 2 (22%, n=115), 3 (17%, n=86) and 5 (11%, n=57), and the proportion did not differ significantly between IOs and non-IOs. Interestingly, 5% (n=27) of trials measured PFS between years 6 and 15, 8% (n=43) measured OS between years 6 and 16, and about 2% (n=11) trials measured PFS and/or OS until progression or death. **CONCLUSIONS:** LTS endpoints are becoming an increasingly frequent inclusion in hematologic cancer therapy trials. Future monitoring and primary research would be required to understand if newer drugs will be re-evaluated in light of long-term data becoming available.

PCN52

OVERALL SURVIVAL WITH NIVOLUMAB FOR PATIENTS WITH ADVANCED, PREVIOUSLY TREATED RENAL CELL CARCINOMA

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OBJECTIVES: Nivolumab was the first immunotherapy to demonstrate a significant overall survival benefit versus standard of care for previously treated patients with advanced or metastatic renal cell carcinoma (RCC) in a phase III trial setting. While conclusive phase III trial evidence for the immunotherapeutic benefit of nivolumab on overall survival beyond 3 years is not yet available for RCC, phase I/II data support a clinical rationale that some nivolumab patients will achieve long-term overall survival. Such benefit has also been seen in melanoma with other immunotherapy drugs. The objective of this research is to illustrate the importance of immunotherapeutic assumptions for long-term survival estimates and the potential impact on health technology appraisal decisions. **METHODS:** Alternative extrapolations of pivotal phase III (CheckMate 025) and supportive phase I (study 003) survival data for nivolumab in RCC were compared to illustrate the importance of long-term survival assumptions for value projections. **RESULTS:** Long-term survival projections vary depending on dataset and model choice, and whether clinical expectations based on key evidence and rationale are incorporated. For RCC patients treated with nivolumab who survive to 3 years, projected survival for an additional 10 years is 8% using the generalized gamma model extrapolation of CheckMate 025 data, versus 46% when quantified clinical expectations are incorporated into this projection, and 42% using the Gompertz model extrapolation of study 003 data. In England, these different survival assumptions cause the incremental cost-effectiveness ratio for nivolumab versus axitinib to range from below £25,000 to over £50,000, based on list price. **CONCLUSIONS:** Using clinical expert estimates to inform long-term survival projections is pertinent in the absence of long-term patient data. This approach becomes essential when the immunotherapeutic mechanism of action of a treatment and early evidence suggest a survival plateau that is not offered by other currently available treatments.

CANCER – Cost Studies

PCN53

CONCEPTUALIZATION OF AN EXCEL-BASED INDICATION-SPECIFIC PRICING (ISP) MODEL TO ASSESS POTENTIAL SAVINGS TO A U.S. HEALTH PLAN

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OBJECTIVES: Value based pricing has become a topic of increasing public attention and scrutiny. An Indication Specific Pricing (ISP) model allows price setting relative to the level of benefit provided in a given indication and patient population, with the potential for price to vary based on value in the concerned indication(s). We quantified the impact of deploying an ISP scheme on 5-year Afinitor (everolimus) expenditures for a hypothetical health plan of 5M covered lives in the U.S., taking into account three indications: HER2- breast cancer, renal cell carcinoma, and pancreatic cancer. **METHODS:** We constructed an Excel-based model to understand future expenditures on an annual basis utilizing an ISP scheme against a more traditional single contracted price. Key inputs for the model include price per pill (average selling price (ASP)), forecasted annual number of patients per indication (based on 5M covered lives), and compliance rate. Results from the Sloan Kettering "DrugAbacus" pricing project were leveraged to estimate indication-level prices based on their assessment of efficacy, tolerability, and unmet need for Afinitor in each of the indications; actual ISP prices originally used by Sloan Kettering in their model were reweighted and adjusted. **RESULTS:** As the DrugAbacus price calculated for each indication was lower than the current ASP for Afinitor, use of an ISP methodology resulted in a 9.3% decrease in five year expenditures for Afinitor (\$136.9M for a traditional single price vs. \$124.1M for an ISP model). **CONCLUSIONS:** US Payers could consider assessing the value a therapeutic intervention brings to each approved indication using ISP in an effort to lower total pharmaceutical-related healthcare costs. Drug manufacturers may benefit from considering relative product value in each potential indication to assess commercial attractiveness and focus evidence generation strategies on those indications seen as most valuable, to support price negotiations.

PCN54

BUDGET IMPACT ASSESSMENT (BIA) OF INTRAOPERATIVE RADIOTHERAPY (IORT) IN THE GERMAN EARLY BREAST CANCER PATIENTS

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OBJECTIVES: To evaluate the potential budget impact of early breast cancer treatment using IORT to inform the reimbursement policy decisions. The IORT (as definite dose or as boost) eliminates the need for numerous radiation center visits and minimizes radiation exposure to healthy tissue and organs. **METHODS:** An incidence-based budget impact model in MS Excel was developed over a five-year time horizon employing the German health care system perspective. Epidemiologic data were used to quantify the proportion of patients diagnosed with early breast cancer in Germany. Two scenarios were examined; one with progressive uptake of IORT over the time horizon and other with 100% uptake of IORT from the introduction year. Diagnosis Related Group based IORT base case cost was varied in a reasonable range for the sensitivity analysis. **RESULTS:** With the progressive introduction of IORT the total annual cost of treatment for early breast cancer patients in Germany gradually decline from

244 Million Euros in the first year to 189 Million Euros in the fifth year. Therefore, introduction of IORT in phasic manner could save 241 Million Euros over the next five years. In the alternative scenario, where all patients are treated with IORT from the introduction year, the annual cost saving for the payer would be 78 million Euros. Therefore, aggressive introduction of IORT would save 389 Million Euros over the tie horizon which translates to the additional cost saving of 148 Million Euros in comparison with the phasic introduction. **CONCLUSIONS:** IORT (boost and single treatment) is the cost saving treatment strategy for patients with early-stage breast cancer. The impact of IORT treatment decision extends beyond these model results as the implementation of this shorter radiation course could improve quality of life by sparing patients from the protracted course of conventional radiotherapy, improve compliance, prevent unnecessary mastectomies and save valuable health care resources.

PCN55

BUDGET IMPACT MODEL OF PEMBROLIZUMAB IN PREVIOUSLY TREATED ADVANCED PD-L1 NSCLC POSITIVE IN COLOMBIA

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OBJECTIVES: Lung cancer is the second leading cause of cancer-related death in Colombia. The aim of this Budget Impact Model (BIM) is to evaluate the impact of adding pembrolizumab for the treatment of PD-L1 positive advanced NSCLC with disease progression on or after platinum-containing chemotherapy in Colombia. **METHODS:** Based in the National Health Technology Agency (IETS), the perspective of the model is from the payer over a period of 3 years. Inputs are based on epidemiologic, market research, and cost data from Colombia. Comparators were nivolumab and other regimens recommended for use in the pembrolizumab-eligible population. The market share is based on local KOL's assumptions, and the market of pembrolizumab is based on a Merck model. Costs included drug acquisition, administration, prophylaxis, adverse event, and PDL-1 test. **RESULTS:** Considering Colombian population of 48,747,632 (1.3% annual growth rate), 3,042 advanced NSCLC patients will receive a PD-L1 test in year 1 (9,911 patients: 3 years), and 692 PD-L1 positive advanced NSCLC patients are expected to be eligible for pembrolizumab as 2L+ treatment in year 1 (2,256: 3 years). The total budget impact of pembrolizumab is estimated at US\$22,865,707 over three years. In a second scenario comparing the population size treated with pembrolizumab vs. nivolumab (no test and treating all patients), and the total cost associated, the total cost impact to the healthcare payer is much lower for the pembrolizumab treatment approach (US\$26,715,299) compared to nivolumab (US\$ 47,586,330), a cost saving of approximately US\$20,871,032. **CONCLUSIONS:** The addition of pembrolizumab to the National formulary may result in a moderate increase in current expenditures, which means an impact 3% less of the total expenditures in cancer drugs over 3 years. When compared to nivolumab, pembrolizumab will likely result in cost savings for the health system in Colombia, considering the optimization of resources by selecting patients.

PCN56

BRENTUXIMAB VEDOTIN (ADCETRIS®) ECONOMIC EVALUATION ON PATIENT'S TREATMENT WITH RELAPSE OR REFRACTORY HODGKIN LINFOMA

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OBJECTIVES: To assess the budget impact of brentuximab vedotin in patients with relapsed or refractory Hodgkin lymphoma (HL) from the perspective of México's National Healthcare System (NHS). **METHODS:** A budget impact analysis of brentuximab vedotin, an orphan drug for patients with relapsed or refractory HL, was conducted. The current treatment alternatives in Mexico include the following: 1) ICE (ifosfamide, carboplatin, etoposide), 2) MINE (mesna, ifosfamide, mitoxantrone, etoposide) 3) ESHAP (etoposide, methylprednisolone, cytarabine, cisplatin), and 4) IGEV (ifosfamide, gemcitabine, vinorelbine). The analysis was performed from the institutional perspective, with a five year time horizon. Target population estimates were based on projections of the Mexican population reported by CONAPO (Consejo Nacional de Población) and HL incidence obtained from the literature. The direct costs were taken from institutional sources in 2016, primarily drug costs of the current treatment schemes of the NHS. The results are presented as the budget impact for the NHS and for each public healthcare institution (IMSS, ISSSTE, Seguro Popular, PEMEX, SEMAR, SEDENA). The results are also expressed as percentage of the total drug budget of the institutions. Finally, a univariate deterministic sensitivity analysis was conducted. **RESULTS:** The budget impact analysis shows that the incorporation of brentuximab vedotin to the NHS generates an incremental investment of \$169,322 USD in 2016, reaching a total of \$893,529 USD in 2020, with an average of 49 new patients annually. An annual average investment of \$526,914 USD, or 0.016% of México NHS's drug budget in 2016, will be required. **CONCLUSIONS:** Given the high mortality of relapsed or refractory HL, there is a need for alternative treatments for patients in this setting. Brentuximab vedotin is a viable treatment option with a limited budget impact affordable to the Mexico NHS.

PCN57

BUDGET IMPACT OF COMPREHENSIVE GENOMIC PROFILING OF PATIENTS WITH ADVANCED LUNG CANCER IN EUROPE

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OBJECTIVES: To estimate the budget impact of comprehensive genomic profiling that interrogates the entire coding sequence of 315 cancer-related genes plus select introns from 28 genes to identify targeted treatment in patients with advanced lung carcinoma in Europe. **METHODS:** A 5 year budget impact model was developed to determine the financial implications of incorporating genomic profiling of biopsy samples in patients with advanced lung carcinoma. Costs included testing and associated costs and treatment costs. Testing results were obtained from in house data and also literature, costs were identified from technology assessment reports and literature. Sensitivity analyses were conducted on proportion of testing and costs. Results are compared with a mix of current testing including Polymerase Chain Reaction (PCR), Fluorescence in situ Hybridisation (FISH) and no testing. **RESULTS:** The incremental budget impact varied from between €0.20 to €0.80 per person within a population dependant on mix of type of testing and cost of drug treatments. Total budget impact (per person cost x population) was country dependant, for the UK the result was between £12.75 million and £42 million after 5 years. **CONCLUSIONS:** Comprehensive genetic profiling may be an affordable option to identify the most appropriate targeted therapy for an individual patient. Further research is warranted on the potential gain in survival outcomes when treatment is optimised. Furthermore health systems may need to move from a tumour type based treatment approach to a mutation specific based indication as recommended therapies may be approved for another tumour type and not the one tested.

PCN58

BUDGET IMPACT ANALYSIS OF AXITINIB IN THE TREATMENT OF METASTATIC RENAL CELL CARCINOMA AFTER THE FAILURE OF ONE PRIOR SYSTEMIC THERAPY IN THE BRAZILIAN PRIVATE HEALTH SYSTEM

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OBJECTIVES: To evaluate the budget impact of axitinib, an oral angiogenesis inhibitor, in the second line treatment of metastatic renal cell carcinoma (mRCC) in the Brazilian private health system. **METHODS:** A budget-impact model comparing a world with vs world without axitinib [sorafenib, everolimus, sunitinib, temsirolimus, pazopanib or best supportive care (BSC)], was calculated based on published data on incidence estimate of RCC (0,009%) and assumptions from estimate of new diagnosed cases of non-metastatic RCC (81%) [A], diagnosed non-metastatic RCC cases in progress to mRCC (40%) [A x 40% =B], new diagnosed cases of mRCC (19%) [Population estimate of RCC x 19%=C], mRCC cases receiving 1st line therapy (74%) [B+C=D] and eligible cases of 2nd line therapy (52%) [52% x D=population eligible for the analysis]. The Analysis was performed in a three year time horizon, from perspective of the Brazilian private health system, and included only direct costs of medicines. The estimates were applied considering a health plan with 2 million lives (based on average of top 10 largest Brazilian Private Health Plans). Medicines cost data were taken from MoH's price in November 2016. **RESULTS:** The total number of patients with RCC was 170 while the number of mRCC patients in 2nd line therapy was 34. Costs of treatment with axitinib were BRL 4,714,490, BRL 4,734,597 and BRL 4,877,913 in years 1, 2 and 3 versus BRL 4,475,391, BRL 4,047,948 and BRL 3,950,505 without axitinib, respectively. Over a three year time horizon, the incremental budget impact was BRL 1,853,156 (15% of RCC patients) or BRL 0.31 per member per year from total lives of the Brazilian Private Health Plan. **CONCLUSIONS:** Axitinib is a targeted anticancer agent to mRCC treatment in 2nd line. Considering only the costs of drug acquisition, the treatment with axitinib were associated with low budget impact to the Brazilian Private Health System.

PCN59

BUDGET IMPACT ANALYSIS OF CRIZOTINIB IN THE TREATMENT OF ALK-POSITIVE NON-SMALL CELL LUNG CANCER IN THE BRAZILIAN PRIVATE HEALTH SYSTEM

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OBJECTIVES: To evaluate the budget impact of crizotinib, an oral inhibitor of anaplastic lymphoma kinase (ALK), in the treatment of ALK-positive non-small cell lung cancer (ALK+NSCLC) in the Brazilian private health system. **METHODS:** A budget-impact model was developed to compare the cost of treatment with crizotinib in ALK+NSCLC patients to that of chemotherapy (bevacizumab, carboplatin, cisplatin, docetaxel, erlotinib, gefitinib, gemcitabine, paclitaxel, pemetrexed and vinorelbine). Analysis considered a three year time horizon from the perspective of the BPHS, and has included only direct costs of medicines. Based on published data, the incidence rates considered to the Brazilian population were 0,014% of lung cancer (LC), 89,5% of NSCLC, 70,6% of advanced NSCLC and 5% of ALK+NSCLC, applied considering a health plan with 2 million lives (based on average of top 10 largest Brazilian Private Health Plans). Was applied an annual population growth rate of 0,09% after first year. Medicines cost's data were taken from MoH's price in November 2016. **RESULTS:** The total numbers of patients with LC were 280, 305 and 333 while the numbers of ALK+NSCLC patients were 9, 10 and 11 in years 1, 2 and 3 respectively. Costs of treatments, including crizotinib were BRL 34.722.255, BRL 37.847.258 and BRL 41.253.511 at years 1, 2 and 3 versus BRL 32.986.119, BRL 35.954.870 and BRL 39.190.808 only with chemotherapy, resulting in an incremental budget impact of BRL 1,736,136, BRL 1,892,388 and BRL 2,062,703, respectively. Over a three year time horizon, the incremental budget impact was BRL 5,691,227 (5% of LC patients) or BRL 0.07 per member per month from total lives of the Brazilian private health plan. **CONCLUSIONS:** Crizotinib is a novel targeted anticancer agent that favors ALK+ NSCLC patients. Considering only the cost of drugs,

the treatment of ALK+NSCLC's patients with crizotinib were associated with low budget impact to the Brazilian private health system.

PCN60

LAWSUITS TO RECEIVE FREE DRUGS: FEDERAL EXPENDITURES FOR THE BRAZILIAN PUBLIC HEALTH SYSTEM (SUS)

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OBJECTIVES: Due to the increasing demand for Lawsuits to receive free medication in Brazil, it is estimated that the increase in costs may compromise the sustainability of SUS. The aim of this work is to analyze Federal expenditures for the Brazilian Public Health System (SUS) with drugs obtained through lawsuits between the years 2011-2014. **METHODS:** Cross-sectional study, with descriptive and analytical characteristics. Data collected from the DW / COMPRASNET platform. **RESULTS:** In total 12,578 lawsuits were identified at the federal level and 15 drugs with the highest acquisition value were extracted. Of these, seven drugs corresponded to US\$ 452.644.065.68 million dollars of the federal budget, which represented 87% of the total expenditure of the actions studied, most of them were oncologic and rare diseases drugs. Of the 15 drugs / year studied, 14.28% (n = 4) were registered at the National Brazilian Surveillance Agency (ANVISA), were incorporated by the National Commission for the Incorporation of Technologies in SUS (CONITEC) and were part of the List of essential drugs (RENAME); 46.42% (n = 13) were registered with ANVISA, but not incorporated by CONITEC and not members of RENAME; 3.57% (n = 1) registered in ANVISA, incorporated by CONITEC and non-RENAME members and 35.71% (n = 10) without ANVISA registration, not incorporated by CONITEC and not RENAME members. **CONCLUSIONS:** With the Lawsuits to receive free medication, the acquisitions are carried out without planning or establishing minimum criteria such as: the presence of registration at ANVISA, incorporation in SUS and presence in RENAME, may compromise SUS sustainability. It is urgent that the Judiciary approaches the Executive stakeholders to initiate a responsible commitment to the health rights of the Brazilian population.

PCN61

LAPATINIB WITH LETROZOLE AS A TREATMENT STRATEGY FOR PATIENTS WITH METASTATIC BREAST CANCER (HER2+) UNDER THE PERSPECTIVE OF BRAZILIAN PUBLIC HEALTHCARE SYSTEM: A BUDGET IMPACT ANALYSIS

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OBJECTIVES: The goal of this study was to estimate the budget impact of lapatinib with letrozole as a therapy for metastatic breast cancer with HER2+ status into Brazilian Public healthcare system (SUS). **METHODS:** Epidemiological data were from Ferlay, et al., 2013. Drugs costs were from Health Price Bank (BPS) of Brazilian Ministry of Health (MOH), a public purchasing database. The analysis looked into 5 years under the perspective of MOH. Only drug costs were considered for analysis. We have also performed sensibility analyses, in parameters of prices (ex-factory, Maximum price for MOH, and negotiated prices) and taxes from different states perspectives. **RESULTS:** The budget impact was estimated to a population of 86,789, considering 50% limitation (43,395 and 38,293) of women for the 5th year, with ages from 50-64 years old, diagnosed with breast cancer HER2+. The budget impact analysis under the reference case (market share of 100% of letrozol), in five years, would represent US\$18 MI, allowing for an annual growth rate of the total number of patients. The adoption of the newer strategy, for the lapatinib and letrozol (3 alternative scenarios lapatinib + letrozol, scenario 1 (25% of market share), scenario 2 (45%) and scenario 3 (65%)), adjusted for the inflation, represent a budget impact of approximately, US\$ 941 milhões. This increase of 307% would occur in the 5 years perspective. **CONCLUSIONS:** Under the perspective of Brazilian SUS the incorporation of lapatinib and letrozol is not recommended due to high budget impact to SUS. Further, cost effectiveness and budget impact studies can give stronger evidence to decision making.

PCN62

BUDGET IMPACT OF INCREASED UTILIZATION OF PALONOSETRON FOR THE CONTROL OF CHEMOTHERAPY INDUCED NAUSEA AND VOMITING IN MANAGED CARE

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OBJECTIVES: Currently, several branded and generic serotonin-3 receptor antagonists (5HT3RAs) are indicated for chemotherapy induced nausea and vomiting (CINV). While these medications differ in efficacy and acquisition cost, palonosetron is a second generation 5HT3RA commonly recommended by treatment guidelines (e.g., NCCN, MASCC, ASCO). Using a decision analytic model, this study examined the financial impact of a 5% increase in the utilization of palonosetron vs. a generic 5HT3RA (ondansetron) in cancer treated with a highly (HEC) or moderately emetogenic chemotherapy (MEC). The results illustrate the costs to manage CINV from a payer perspective. **METHODS:** The model generated outputs for a hypothetical one-million member healthplan. The eligible population was determined from national rates of cancer and chemotherapy. Antiemetic-specific rates of CINV were based on retrospective analyses defining CINV by ICD9 codes or use of rescue antiemetics. Other inputs included current 5HT3RA market share, medication acquisition costs, and per-patient costs to treat

CINV. Model outputs predicted pharmacy and medical costs in the base year and following the 5% utilization increase. **RESULTS:** The model predicted a population of 968 patients, 282 (14.1%) treated with HEC and 686 (34.3%) with MEC. Increasing the utilization of palonosetron by 5% (59% to 64% in HEC, 51% to 56% in MEC) resulted in an increase in pharmacy acquisition costs from \$1.00 million to \$1.02 million. CINV treatment costs, however, would decrease from \$2.41 to \$2.35 million. Overall, net costs for the MCO decreased by \$73.4K, or \$0.01 PMPM. **CONCLUSIONS:** As expected, this model predicted an increase in pharmacy costs from the increased utilization of palonosetron relative to generic ondansetron. However, because the rate of CINV control associated with palonosetron was lower than with ondansetron, CINV treatment costs decreased. Increasing the utilization of palonosetron in MEC and HEC, then, may result in an overall net savings to a health plan.

PCN63

BUDGET IMPACT ANALYSIS OF RITUXIMAB IV VERSUS SC FROM PUBLIC BRAZILIAN HOSPITAL

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OBJECTIVES: The analysis aimed to compare the total cost of rituximab IV versus SC in both indications approved by ANVISA[i] for rituximab SC: follicular lymphoma (FL) first line and maintenance and diffuse large B-cell lymphoma (DLBCL) first line. **METHODS:** Budget impact analysis was conducted based on the direct cost of Hospital Geral de Curitiba (HGEC), active healthcare professional (HCP) time from a time and motion study, [ii] wage paid from Paraná, and the treatment cost of rituximab. In order to quantify the cost per professional involved in the administration and manipulation of the drugs, the wage paid and active HCP time were used to monetize labor. As HGEC has only pharmacists and nurses involved in the procedure, the time and motion study was adapted to HGEC scenario. The total cost of rituximab was calculated according to drug information leaflets, assuming 20 and 8 cycles for FL and DLBCL, respectively. The results were expressed as cost difference per patient between rituximab IV and SC and were calculated according to the puncture: peripheral or catheter. **RESULTS:** The saving generated by switching IV to SC was R\$ 12.091,66 and R\$ 12.960,91 per patient (peripheral and catheter, respectively) for FL, whereas for DLBCL the saving generated was R\$ 4.454,82 and R\$ 4.775,07 per patient (peripheral and catheter, respectively). **CONCLUSIONS:** Use of rituximab SC is less costly compared to rituximab IV, and switching IV to SC can bring resource savings to HGEC. Other institutions can also use this analysis as a model and quantify their savings from switching IV to SC. [i] Produtos Roche Químicos e Farmacêuticos S.A. MabThera IV e MabThera SC (rituximabe) [Bula]. 2016. p. 1-65. [ii] Cock, E., D., et al., Time Savings with Rituximab Subcutaneous Injection versus Rituximab Intravenous Infusion: A Time and Motion Study in Eight Countries. PLOS ONE. 2016; 11(6):e0157957. doi: 10.1371/journal.pone.0157957.

PCN64

COST-EFFECTIVENESS AND BUDGET IMPACT ANALYSIS OF IMATINIB AS FIRST-LINE TREATMENT OF CHRONIC MYELOID LEUKEMIA IN CHINA

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OBJECTIVES: Nilotinib has been recently approved as the 1st-line treatment of chronic myeloid leukemia (CML) in China. This study aimed to evaluate the long-term cost-effectiveness and budget impact of nilotinib used as the 1st-line tyrosine kinase inhibitor (TKI) in China. **METHODS:** A two-part Markov model was designed to evaluate the lifetime cost and health outcomes of 1st-line nilotinib versus 1st-line imatinib in CML patients. A distinction was made between patients who were still on treatment and who discontinued treatment at the 12th month. Patient's response was assessed for those still on treatment, and the level of response was assumed as the predictor of long-term outcomes. Clinical effectiveness was obtained from ENESTnd trial. Costs were obtained from Chinese literature review and a panel of local clinical experts and only the direct medical cost was included. A budget impact model was used to calculate the change in CML-related expenditures from a single payer perspective after nilotinib was introduced as the 1st-line TKI, compared to imatinib as 1st-line TKI. A discounted rate of 3% was used for both effectiveness and cost. **RESULTS:** The results of cost-effectiveness analysis indicated that 1st-line nilotinib was associated with longer survival (1.78 discounted life years), more QALY (1.77 discounted QALYs) and higher costs (CNY66,317), compared to 1st-line imatinib. The increased cost-effectiveness ratio was CNY37,454 per QALY gained, which was less than the GDP per capita of China in 2015. The direct medical cost decreased in each of the 5 years after nilotinib was introduced as 1st-line treatment. The total budget of 5 years decreased by 1.99% compared to the current scenario. **CONCLUSIONS:** The introduction of nilotinib as 1st-line treatment of CML in China is a highly cost-effectiveness strategy compared to the current scenario. Meanwhile, the total budget for the payer decreased in a substantial rate.

PCN65

ASSESSMENT OF COSTS ASSOCIATED WITH ADVERSE EVENTS IN PATIENTS WITH CANCER

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OBJECTIVES: This study assessed the incremental costs associated with adverse events (AEs) in a range of malignancies. **METHODS:** Using Truven Health Analytics

MarketScan® databases (2000:Q1-2015:Q3), patient-level treatment episodes for breast, gastrointestinal, genitourinary, lung, hematologic, and skin cancers were identified. Based on current National Comprehensive Cancer Network Treatment Guidelines, 104 prescribing labels were reviewed to identify 36 AEs of interest. Episodes with a claim for an AE were matched with episodes without the AE on a 1:1 ratio based on demographics, insurance plan type, therapy line, treatment regimen, cancer characteristics, and episode duration. Healthcare costs (2015 USD) were compared between episodes with and without each AE using multivariate generalized linear regression models adjusting for the presence of other AEs. **RESULTS:** A total of 794,243 episodes were identified; mean patient age was 62.8 years; 58.1% were female; and 45.3% were first, 24.3% second, and 30.4% third or later line therapy following primary diagnosis. The number of matched episodes for each AE ranged from 878 to 115,754, with mean duration ranging from 4.7 to 16.4 months. The most prevalent AEs were pain (prevalence: 28.2%; incremental adjusted costs per episode: \$4,576), hypertension (27.5%; \$2,416), anemia/pallor (17.8%; \$4,826), psychiatric disorders (13.9%; \$3,458), and cough/upper respiratory infections (13.6%; \$393); all $p < 0.05$. The most costly AEs were central nervous system hemorrhage (0.2%; \$26,904), sepsis/septicemia (2.5%; \$25,562), gastrointestinal perforation (0.2%; \$24,141), pancreatitis (0.1%; \$17,987), and gastrointestinal fistula (0.1%; \$15,881); all $p < 0.05$. **CONCLUSIONS:** The prevalence and cost of AEs in patients with cancer tended to have an inverse relationship, with some of the most prevalent AEs being less costly and some of the most costly AEs being fairly rare. Treatment AEs may add a significant amount of cost to a treatment. Cancer therapies that are well tolerated are needed to further reduce the economic burden on patients and the health care system.

PCN69

COST OF IMMUNOTHERAPY TO TREAT LOCALLY ADVANCED OR METASTATIC UROTHELIAL CANCER (MUC) AND METASTATIC NON-SMALL CELL LUNG CANCER (MNSCLC)

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OBJECTIVES: Immune checkpoint inhibitors represent important options for mUC and mNSCLC patients. Given increasing emphasis on economic value, this study examines cost differences when atezolizumab (ATEZO), nivolumab (NIVO) or pembrolizumab (PEMBRO) are used per label in these indications. **METHODS:** We calculated the cost of ATEZO (1200mg Q3W, 60min initial, 30min subsequent infusion), NIVO (240mg Q2W, 60min infusion), and PEMBRO (200mg Q3W, 30min infusion) based on 2017 wholesale acquisition costs (WAC) and CMS average sales price (ASP) payment rates. Dosing does not differ for the two indications. Infusion administration (ADMIN) costs were based on CMS Physician Fee Schedule (\$136 for up to 60min). Since treatment durations from clinical trials have not been published, standardized costs are presented per month (30.44 days) and per 24 weeks. This analysis does not account for discounts/rebates, which is not publicly available information, and could affect the net cost to individual payers. **RESULTS:** Monthly costs were: ATEZO: WAC \$12,449, ASP \$12,427, ADMIN \$198; NIVO: WAC \$13,089, ASP \$12,827, ADMIN \$297; PEMBRO: WAC \$12,895, ASP \$12,733, ADMIN \$198. Over 24-weeks, ATEZO patients have 4 fewer visits and 7.5 fewer infusion hours compared with NIVO; equal visits and 30min more infusion time for the first cycle compared with PEMBRO (equal after first infusion). Total (WAC+ADMIN) 24-week costs were \$3,802 higher for NIVO and \$2,184 higher for PEMBRO compared with ATEZO. ASP-based total 24-week costs (ASP+ADMIN) were \$2,756 and \$1,691 higher for NIVO and PEMBRO, respectively, compared with ATEZO. **CONCLUSIONS:** Immunotherapies are valuable in mUC and mNSCLC. This analysis suggests ATEZO may be less costly among cancer immunotherapies in these indications, with potential time savings for patients (fewer office visits and less infusion time vs. NIVO). Additional research is required to characterize real-world utilization and outcomes (including AEs) of immunotherapies, which might have an impact on the total cost of treatment.

PCN70

COST COMPARISON OF TREATMENT CHOICES FOR ADVANCED NON-SMALL CELL LUNG CANCER: AN OBSERVATIONAL STUDY

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OBJECTIVES: Pharmacotherapy has improved survival for non-small cell lung cancer (NSCLC) but is limited by financial burden in resource poor settings. National list of essential medicines (NLEM) and drug price control in India intend to reduce this burden. This study was planned to compare costs among advanced NSCLC patients who get essential vs non-essential medicines. **METHODS:** Patients diagnosed with advanced NSCLC from July 2016 to January 2017 were enrolled in this prospective, observational study. Data on demography, quality of life and estimate of treatment related costs (direct and indirect) was collected. Group A patients received essential medicines (NLEM) and group B received medicines outside NLEM. Indian costs were converted to USD (per patient per month) and data is expressed as mean±SD/ median (range). **RESULTS:** Forty advanced NSCLC patients (age 55.4±10.5 years; 33% females; 38% nonsmokers; 25% local residents) were enrolled. Median treatment duration was 2.75 (0.33–14) months in group A (n=16) and 6.5 (0.5–72) months in group B (n=24). Average cost incurred was 750.1 (235–5304) in group A and 541.1 (40–4258) in group B. Cost of medicines was 55.6 (0.5–2731) and 87.2 (3.6–2517) respectively. Cost of hospitalization did not differ significantly but cost of investigations was 103.3 (0–1175) and 69.1 (6.1–1468) respectively. Indirect costs were 398.9 (54.3–2564) and 234.3 (5.1–1777) respectively. Among these, transportation for outstation patients and work loss for young accounted for major expenditure. **CONCLUSIONS:** There has been a great emphasis on affordability of anticancer medicines in India. However, medicines accounted for only 1/5th costs in our study. Medical investigations and/or indirect costs substantially add to the

overall financial burden. Additional measures such as judicious use of investigations and optimizing outpatient treatment are required to ensure treatment access in the absence of widespread medical insurance.

PCN71

THE COST OF OSTOMY CREATION DURING COLORECTAL RESECTION: ANALYSIS OF A NATIONAL HOSPITAL BILLING DATASET

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OBJECTIVES: Colorectal resection procedures often involve planned or unplanned creation of an ostomy that brings one end of the large/small intestine out through an opening made in the abdominal wall for passage of bowel contents. The study objective was to estimate the incremental hospital costs of patients undergoing ostomy formation in real world clinical practice. **METHODS:** We reviewed the Premier Perspective® Database containing billing data from over 600 hospitals in the U.S. Patients >18 years of age, undergoing a left hemicolectomy, sigmoidectomy, or lower anterior resection between 2008 through 2014 were included. Ostomy cases were identified using ICD-9 CM procedure codes for intestine exteriorization, colostomy, and ileostomy. Billing data were used to obtain hospital costs in 2014 US dollars. Multivariable Generalized Estimating Equation (GEE) models controlling for differences in patient, provider, and hospital characteristics were used to estimate the incremental hospital cost in patients with an ostomy compared to those who did not need an ostomy. Models accounted for clustering of hospitals; results were provided for the overall sample and by elective status. **RESULTS:** Of the 108,311 patients in the study, 30,625 (28%) had an ostomy. Results of the multivariate analysis indicated that the adjusted hospital costs were: \$33,812 [95% CI: \$32,844–\$34,809] for patients with ostomy and \$19,501 [95% CI: \$19,026–\$19,988] for patients without ostomy. This represented a 73.4% higher hospital cost (\$14,311 higher) for patients with an ostomy ($p < 0.01$). Breakdown of results by elective status showed that in patients undergoing elective colorectal surgery, the incremental cost of ostomy was 80.1% higher (\$15,963 higher; $p < 0.001$) and in non-elective surgeries, the incremental cost of ostomy was 34.4% higher (\$ 11,701 higher; $p < 0.01$). **CONCLUSIONS:** Nearly 30% of colorectal procedures involved an ostomy and the incremental impact on hospital costs was significant. Future research should include cost of reversal surgeries and the impact of these procedures on patient productivity and quality of life.

PCN72

TREE ANALYSIS OF FACTORS INFLUENCING THE COST OF SURGICAL RECTAL CANCER PATIENTS

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OBJECTIVES: Colorectal cancer is one of the most common malignant gastrointestinal tumor in China, and rectal cancer accounts for about 70%. Rectal cancer has brought a great social burden in Beijing, but the economic burden still need to be identified. This study aimed to analyze the hospitalization expenses and fund reimbursements. **METHODS:** A retrospective analysis was conducted using the electronic database from Peking University Cancer Hospital. Patients (n=358) who were hospitalized for rectal cancer with surgery record during January 2014 to December 2015 were identified. The study applied Decision Tree Analysis to construct pivotal factors of hospitalization expenses and fund reimbursements. **RESULTS:** The average age was 62.28±12.06 years, the proportion of Urban Employee Basic Medical Insurance (UEBMI) was 94.97%, and the male accounted for 62.57%, the proportion of radical operation and fistula operation accounted for 91.34%, 50.28%. According to the CN-DRGs, patients were mainly classified into GB25 group and GB23 group, and accounted for 53.91%, 37.43%. The cost of per inpatient was 83206RMB, and there were no statistical differences in gender, age and medical insurance schemes, but there was a significant difference in operation radical or not ($P < 0.001$); the cost of per inpatient with radical operation was 85102RMB, and the cost of per inpatient with palliative operation was 27876RMB. The fund reimbursement of per inpatient from government was 51675RMB, and there were significant differences in medical insurance schemes ($P = 0.024$) and in operation fistula or not ($P = 0.001$); the fund reimbursement of per inpatient with UEBMI and other insurance scheme was 52528, 40057RMB respectively; and the fund reimbursement of per inpatient with operation fistula or not was 53699, 50172 RMB respectively. Fitted by SPSS TREE model, the operation of the fistula or not and DRGs grouping were the main criteria for the patient's financial burden. **CONCLUSIONS:** Medical insurance schemes, types of surgical procedure and DRGs grouping affected the burden of patients; for tumor specialty, the government should give full play on the leverage role of health insurance, the medical institutions should refine the cost management strategies.

PCN73

EVALUATING THE ECONOMIC BURDEN AND HEALTH CARE UTILIZATION OF PROSTATE CANCER PATIENTS IN THE US DEPARTMENT OF DEFENSE POPULATION

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OBJECTIVES: To examine the economic burden and health care utilization of Prostate Cancer (PC) in the US Department of Defense population.

METHODS: Patients diagnosed with PC (International Classification of Diseases, 9th Revision, Clinical Modification diagnosis code: 185) were identified using DoD data from 01OCT2010-31OCT2015. The first diagnosis date was designated as the index date. A comparison cohort was created for patients without PC but of the same age, gender, race, index year, and with similar baseline Charlson Comorbidity Index scores. The index date was chosen randomly for the comparison cohort to minimize selection bias. Patients in the disease and control cohorts were required to have continuous medical and pharmacy benefits for 1 year before and 1 year after the index date. Study outcomes, including health care costs and utilization, were compared between the disease and comparison cohorts using 1:1 propensity score matching (PSM) and were adjusted for baseline demographic and clinical characteristics. **RESULTS:** Eligible patients (N=14,428) with and without PC were identified. After 1:1 PSM matching, 6,378 patients were identified in each cohort; the baseline characteristics were well balanced. Patients with PC had a greater mean number of inpatient (0.48 vs 0.16; $p < 0.001$), emergency room (ER) (0.63 vs 0.45, $p < 0.001$), ambulatory (30.13 vs 14.88; $p < 0.001$) and pharmacy (17.12 vs. 13.68, $p < 0.001$) visits. Higher all-cause health care costs were also observed for PC patients, including mean inpatient (\$6,275 vs \$2,302; $p < 0.001$), ER (\$439 vs. \$315; $p < 0.001$), ambulatory (\$14,376 vs \$4,860; $p < 0.001$), pharmacy (\$1,095 vs. \$1,036; $p = 0.414$), and total costs (\$22,185 vs \$8,513; $p < 0.001$). **CONCLUSIONS:** During a 12-month period, DoD beneficiaries diagnosed with PC had higher health care utilization and costs than their matched controls.

PCN74

REGULATORY APPROVAL AND PRICE ANALYSIS OF ANTI-ANDROGEN DRUGS MARKETED IN THE UNITED STATES AND USED IN HORMONAL THERAPY IN ADVANCED PROSTATE CANCER

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OBJECTIVES: To assess the drug prices' and drug approval trends of Anti-androgen drugs approved for advanced prostate cancer until December 2016. **METHODS:** Luteinizing-hormone releasing hormone (LHRH) agonists, LHRH antagonists and Non-Steroidal Anti-Androgen drugs were included and information on approval of these drugs, approval date, type of review, active ingredient, route of administration, and indication were collected from Food and Drug Administration website. Drug prices were collected from Redbook issued by Truven Health Analytics. **RESULTS:** There are 4 medications of LHRH agonists in the US market and all of these medications are given parenterally. LHRH agonists' prices are based on frequency (Monthly, 2-months, 3-months, 4-months and 6-months) and route of administration (subcutaneous, intramuscular and subcutaneous implant). The price of Leuprolide given subcutaneously amount to only 37% of price of the drug given intramuscular for the same strength. Based on Defined Daily Dose, Histrlin has the lowest price of LHRH agonist (336 \$/month) and is given by subcutaneous implant. There is only one drug from LHRH antagonist group in the US market (degarlix) (594 \$/ month) after the discontinuation of abarelix in 2005 due to low sales. Non-Steroidal anti-androgen class includes 4 drugs taken orally and have more than 21 approved generics and represent about 53% of drugs approved for hormone therapy for prostate. **CONCLUSIONS:** The route of administration and frequency of taking medication may explain the variation in prices between LHRH agonists. Implant dosage form is the highest price over LHRH agonists, but its the lowest price based on defined daily dose per month. High number of generics approved may explain low price for non-steroidal anti-androgens compared to other groups of anti-androgen classes.

PCN75

A COST COMPARISON OF TREATMENT WITH ABIRATERONE ACETATE PLUS PREDNISONE IN THE PRE-CHEMOTHERAPY SETTING FOLLOWED BY ENZALUTAMIDE IN THE POST-CHEMOTHERAPY SETTING VERSUS THE OPPOSITE TREATMENT SEQUENCE IN METASTATIC CASTRATION RESISTANT PROSTATE CANCER PATIENTS WITH NON-VISCERAL METASTASES IN COLOMBIA

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OBJECTIVES: To estimate and compare the costs associated with post androgen deprivation (post-ADT) therapy abiraterone acetate plus prednisone followed by post-chemotherapy enzalutamide ('AA+P → ENZ sequence') versus the opposite treatment sequence ('ENZ → AA+P sequence') in patients with non-visceral metastases. **METHODS:** A health-state transition cost consequence model was developed to assess patients with castration resistant prostate cancer who had non-visceral metastases. The model compares two treatment sequences: AA+P → ENZ versus ENZ → AA+P. Patients enter the model to receive AA+P or ENZ as post-ADT treatment. Those who discontinue treatment enter the active monitoring phase until they initiate docetaxel chemotherapy. Patients receiving chemotherapy are allowed to discontinue treatment and progress through active monitoring, post-chemotherapy ENZ or AA+P treatment, and palliative care states. Patients are subject to death at all times. The proportion of patients occupying a particular health state is assessed every month. Twenty years of time horizon was used to capture the whole life expectancy of patients. Costs and life-years were discounted at 3.5%. The payer's perspective was used. Drug acquisition costs, adverse events costs, drug administration costs, monitoring costs, and terminal care costs were taken into account. **RESULTS:** The total life time costs of the sequence AA+P → ENZ was less costly than sequence ENZ → AA+P; total savings per patient treated were USD\$15,339.90 (Exchange rate USD \$1 = COP\$3,000). Most costs were generated during the post-ADT state (AA+P: USD\$34,112.99 representing 69% of total life time costs; and ENZ: USD\$52,368.60,

representing 80%). Costs during docetaxel chemotherapy were USD\$5,452.40 (11% for AA+P and USD\$5,791.40 (9%) for ENZ. Post-chemotherapy costs were USD\$10,196.73 (20%) for AA+P → ENZ and USD\$6,942.02 (11%) for ENZ → AA+P. **CONCLUSIONS:** Using currently available data and the presented modeling approach, the cost comparison treatment sequences suggests that starting treatment with AA+P may result in lower total life time costs than starting treatment with ENZ, and may yield to substantial savings per patient treated.

PCN76

COST THRESHOLD ANALYSIS OF GENOTYPE-GUIDED ASPIRIN USE FOR COLORECTAL CANCER PREVENTION

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OBJECTIVES: Colonoscopy is the "gold standard" for colorectal cancer (CRC) screening. However, adherence rates are low and detection is not optimal. Concomitant aspirin chemoprevention is recommended by the US Preventive Task Force, but bleeding complications can be limiting. Variant genotypes in genes of aspirin metabolism can modify CRC and adenoma risk. Genotype-guided aspirin use can identify a targeted average risk population for maximal aspirin benefit, while minimizing adverse events rates compared to the general population. We conducted a cost threshold analysis of genotype-guided aspirin use for primary chemoprevention of CRC in healthy average risk individuals. **METHODS:** Our Markov de novo decision analytical model compared genotype-guided aspirin use to no intervention, and to colonoscopy ± general aspirin use. The model incorporated 5 possible health states based on the natural history of CRC progression; no cancer or polyps, adenoma, pre-clinical CRC, CRC, and death. Model probabilities for prevalence and likelihood of developing cancer were estimated using the SEER database and published literature. A microsimulation of 10,000 individuals aged 50-64 years was conducted to estimate the cost-effectiveness of genotype-guided ASA use for CRC prevention from a US payer perspective over a lifetime. **RESULTS:** When genetic testing costs were below \$63, colonoscopy + genotype-guided aspirin use became the dominant strategy (i.e. lower cost and higher efficacy). When the costs for genetic testing were between \$63-283, the costs of using genotype-guided aspirin per quality adjusted life year gained remained below \$100,000, a commonly acceptable threshold for reimbursement in many countries. **CONCLUSIONS:** Genotype-guided aspirin use with colonoscopy can maximize benefit and decrease adverse event rates for preventing CRC compared to other screening strategies. The economic value of genotype-guided aspirin is dependent on the genetic testing costs.

PCN77

RELAPSED OVARIAN CANCER TREATMENT COSTS COMPARISON IN SPAIN

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OBJECTIVES: To investigate, within the context of relapsed Ovarian Cancer's (OC) treatment, the associated costs to the Spanish National Healthcare System (NHS), using a patient segmentation based on platinum sensitivity: refractory/resistant (PR), partially Sensitive (PPS), fully sensitive (FPS); and the ones who are not suitable to receive further platinum treatments after previous relapse. Treatment ranks, based on cost-efficacy (CE) ratios, are then provided for all the above populations. **METHODS:** Survival data was collected from randomized controlled trials involving the main therapies approved on the relapsed OC setting. Acquisition and medical resource costs were sourced from the 2016 NHS price list. Health economics outcomes were the associated Incremental Cost Effectiveness Ratio (ICER) of every therapy compared to an appropriate reference by sensitivity. **RESULTS:** In PR patients, gemcitabine alone -followed by PLD- is the most cost-effective therapy, with an associated median cost of €47.1 per median survived month. In PPS patients, trabectedin plus DLP followed by a platinum based chemotherapy at relapse remains on top of the results, with an estimated ICER of €19,294 to €20,462 compared to DLP alone (with/out following platinum. Bevacizumab-based therapy rises to an ICER of €42,595; and the olaparib-based schema offers an estimated ICER of €24,841. Within the FPS stratum, carboplatin or paclitaxel plus PLD, are, by far, the cheapest treatment options, with estimated median costs per median survived month ranging from €84.1 to €166.7. Trabectedin plus PLD remains a cost-effective option for those with allergy or intolerance to platinum compounds-, with an estimated ICER of €46,095 vs. the reference therapy (PLD plus carboplatin). **CONCLUSIONS:** To our knowledge; this is the first study showing a comprehensive review on the relapsed OC treatment associated costs from the NHS perspective in Spain. Results assert the value of trabectedin plus PLD as therapy of choice for both OC PPS and intolerant to platinum patients.

PCN78

HEALTHCARE UTILIZATION AND COSTS AMONG POST-MENOPAUSAL WOMEN ON ADJUVANT ENDOCRINE THERAPY

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OBJECTIVES: Although aromatase inhibitors (AIs) have been shown to be more effective than tamoxifen (TMX) in delaying disease progression, reducing risk of recurrence, and improving survival among post-menopausal women with a history of breast cancer, both classes of drugs are recommended options for adjuvant endocrine therapy. We aimed to compare healthcare utilization and expenditures between the two drug classes. **METHODS:** This retrospective study

utilized 2010-2014 data from the Medical Expenditure Panel Survey and included women aged ≥ 55 years with a history of breast cancer who were treated with an AI or TMX within the past 5 years. Health care utilization and annual expenditures were compared between cohorts using linear and log-transformed regression. **RESULTS:** The cohorts contributed 221 patient-years (Weighted $N = 2,610,777$) with 182 (Weighted $N=2,099,698$) for AIs and 39 (Weighted $N = 511,079$) for TMX. In the unadjusted analysis, there was no statistical difference between both groups in overall annual expenditure (\$16,030 (Standard error, SE=\$1,931) vs \$16,092 (SE=\$1,573), $p>0.05$) and in mean number of events and expenditure for inpatient services, outpatient services, office-based visits, emergency room services, prescription drugs, and home health services ($p>0.05$). After adjusting for race/ethnicity, marital status, poverty category, smoking status, and comorbidities, the following expenditures were significantly ($p<0.001$) higher for women on AIs, compared to women on TMX: overall (62%; $RR=1.62$, 95% confidence interval (CI)=1.33-2.00) and for office-based visit expenditures (156%; $RR=2.56$, 95% CI=1.88-3.47), prescription drugs (75%; $RR=1.75$, 95% CI=1.33-2.32), and home health services (96%; $RR=1.96$, 95% CI=1.58-2.43). Number of office visits (35%; $RR=1.35$, 95% CI=1.17-1.56) and home health services use (19%; $RR=1.19$, 95% CI=1.13-1.26) were also higher for women on AIs compared to those on TMX ($p<0.001$). **CONCLUSIONS:** Among post-menopausal women with a history of breast cancer, being on an AI was associated with higher health-related expenditure, with office-based visits having the strongest influence.

PCN79

HEALTHCARE EXPENDITURES AMONG COMMUNITY-DWELLING ADULTS WITH THYROID CANCER IN THE UNITED STATES: A PROPENSITY SCORE MATCHED ANALYSIS

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OBJECTIVES: This study assessed the excess healthcare expenditures and factors associated with it among community-dwelling adults with thyroid cancer compared to non-cancer controls in the United States (US). **METHODS:** We adopted a retrospective, cross-sectional, matched case-control study design by pooling Medical Expenditure Panel Survey (MEPS) data (2002-2012). The eligible study sample comprised of adults (age ≥ 21 years), who were alive during the calendar year and reported positive healthcare expenditure. We identified adults with thyroid cancer (cases) with Clinical Classification System code of "36". The control group consisted of adults who did not have any form of cancer. The case and control groups were matched on propensity score generated based on age, gender, race/ethnicity, smoking status and Body Mass Index. We conducted a series of Ordinary Least Square (OLS) regressions on log-transformed expenditures to elucidate the influence of different factors on healthcare expenditures (total, emergency room, inpatient, prescription, outpatient, home healthcare and other) among adults with thyroid cancer. We used semi-logarithmic equation ($e^{\beta} - 1$) to calculate the percent difference in costs between cases and controls. **RESULTS:** The yearly average total healthcare expenditures among adults with thyroid cancer was significantly higher compared to propensity score matched controls (\$9,734 vs. \$6,329, $p<0.001$). Similar observations were found in terms of inpatient (\$3,164 vs. 2,314, $p<0.05$), outpatient (\$4,208 vs. 1,663, $p<0.001$), and prescription expenditures (\$1,613 vs. 1,468, $p<0.001$). Functional status as well as comorbid conditions were significantly associated with excess expenditures among the case group compared to matched controls. For example, difference in total healthcare expenditures decreased from 182% to 90% when functional and health status and comorbidities were added to the OLS regressions. **CONCLUSIONS:** Our findings suggest that in this nationally representative sample of adults with thyroid cancer, functional and health status as well as comorbidities significantly influence the excess expenditures.

PCN80

ECONOMIC AND HUMANISTIC BURDEN OF HEPATOCELLULAR CARCINOMA IN THE UNITED STATES

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OBJECTIVES: Hepatocellular carcinoma (HCC) has an increasing incidence in the US, with 29,000 new cases in 2016. To better understand the burden on the healthcare system, patients, and families/caregivers, published data were evaluated to document HCC-related economic and humanistic burden. **METHODS:** A targeted literature review was conducted, searching MEDLINE (2007-2016) as well as grey literature, public-use databases/websites, and conference proceedings; manual backward-citation tracking was also employed. Searches used disease-specific terms for HCC (any-stage) combined with terms for economic and humanistic burden. While the review focused on US studies, global studies were consulted where gaps existed. Costs are adjusted to 2016 US dollars. **RESULTS:** Initial search yielded 1,446 non-duplicate citations. Following title/abstract and full-text review, 43 studies met inclusion criteria. Patients receiving no proven treatments are common in the HCC population (39-60%) at all ages and levels of co-morbidity and liver dysfunction. One study reported 60% of patients were untreated, of which 23% were diagnosed with early disease, 13% with stage III, and 19% with metastatic disease. Quality of life (QoL) is notably worse in advanced-stage patients, with symptoms (particularly pain) associated with significant QoL decrement. Annual direct medical costs of HCC range from ~\$40,000-70,000; with the highest costs reported in advanced disease (>\$140,000 annualized). Indirect costs have been estimated at 10.8% of annual overall costs. Patients with advanced disease receiving no treatment incurred \$27,067 in total medical expenses after diagnosis;

this figure doubled for systemic chemotherapy and radiation, while patients treated with liver-directed therapies accumulated \$79,136. **CONCLUSIONS:** These findings underscore the growing economic and humanistic burden of HCC. Patients diagnosed with advanced disease appear to have larger QoL decrements and incur significantly higher costs. To better guide treatment and reimbursement decision-making, additional research is needed to understand resource use, costs, and treatment consequences associated with advanced HCC.

PCN81

THE DIRECT COST OF BLADDER CANCER TO THE BRAZILIAN PUBLIC HEALTHCARE SYSTEM (SUS)

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OBJECTIVES: To identify direct costs of bladder cancer management in the Brazilian public health system. **METHODS:** Direct costs referring to inpatient and outpatient treatment for bladder cancer were obtained from national databases available at official information systems in 2014 (Hospital Information System, SIH/SUS and Outpatient Information System, SIA/SUS). Bladder cancer patients were identified using ICD-10 code. **RESULTS:** In 2014, 85,302 outpatient procedures were performed for bladder cancer treatment, resulting in direct outpatient costs of US\$8,455,086. The Southeast region was responsible for major proportion of procedures performed in the country (45%). The intravesical chemotherapy was accounted for the highest share of total direct outpatient costs (more than US\$4.8 million). Regarding inpatient procedures, there were 15,341 procedures performed, resulting in direct inpatient costs of US\$21,424,079. The proportion of inpatient procedures among men was 2-3 higher than women. Of note, only US\$6,231,257 of costs were related to treatment of female patients. The inpatient procedure performed more often was the resection of vesical lesion (more than 9,000 times); resulting in the highest share of direct inpatient costs (US\$11,295,324). **CONCLUSIONS:** Considering the prevalence of bladder cancer in Brazil, the disease has significant economic impacts in the Brazilian public health system with a total direct medical cost of US\$29,879,165. Although this amount corresponds to most of treatment cost, including for example chemotherapy, resection and radiotherapy, it is still underestimated by not including the costs related to adverse effects management. The results presented have potential to contribute to support strategic actions of public policies in health directed towards prevention and early diagnosis of bladder cancer.

PCN82

DIRECT NON-MEDICAL COSTS OF PATIENTS WITH TRACHEA, BRONCHUS AND LUNG CANCER IN RUSSIA

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OBJECTIVES: The aim of the study was to assess the annual direct non-medical costs of patients with trachea, bronchus and lung (TBL) cancer in Russia in 2015 from the social perspective. **METHODS:** Direct non-medical costs were calculated for subgroups of TBL patients, stratified by the stages of cancer process using the cost-of-illness modeling. Total direct costs included disability pension and temporary social disability payments due to TBL cancer. Parameters of the model were obtained from the number of sources: National statistic surveillance system and National vital registration system (Federal State Statistics Service), National cancer registry, the Pension Fund of the Russian Federation, expert survey and metadata from the literature sources. The data was extracted according to the triangulation-combining method. The assessment of direct non-medical costs was made by the bottom-up costing approach. **RESULTS:** The total annual direct non-medical costs of patients with TBL cancer in Russia in 2015 were about \$67.8 million (\$506 per patient). Disability support pension payments were about \$65.5 million (97% of direct non-medical costs), while temporary social disability payments were about \$2.3 million (3% of direct non-medical costs). The total costs by newly diagnosed patients (\$20.6 million) were in 2.3 times lower than for the patients diagnosed in previous years (\$47.2 million). **CONCLUSIONS:** The results of the economic study demonstrate that TBL cancer impose a considerable economic burden on the economic system of Russian Federation. The support pension payments almost equal the total direct non-medical costs. These findings demonstrate the importance of further development and improving the TBL cancer treatment approaches and care of patients with disability due to TBL cancer.

PCN83

THE ECONOMIC BURDEN OF ILLNESS OF TREATING ADULT ACUTE LYMPHOBLASTIC LEUKEMIA IN CANADA

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OBJECTIVES: Acute lymphoblastic leukemia (ALL) is the most common malignant disease in pediatric patients, but is rare in adults. Thus, many adult treatment regimens and costing analyses are based on, or adapted from, pediatric protocols. This analysis aims to capture the costs of standard of care treatment regimens for adults who receive front-line therapy for Philadelphia chromosome-negative B-cell precursor ALL. **METHODS:** In Canada, HyperCVAD and Dana Farber Cancer Institute (DFCI) protocols represent the current standard of care regimens for adult ALL patients. This analysis collected drug, administration, physician services, laboratory tests and hospitalization costs. Resource use and costs were informed by published protocols, expert clinician experience, QuintilesIMS

DeltaPA, Ontario Case Costing Initiative and Ontario fee schedules. Costs were reported by treatment phase of each regimen. Uncertainty was explored through probabilistic and deterministic sensitivity analyses. **RESULTS:** The complete HyperCVAD and DFCI protocols are estimated to cost \$51,863 and \$35,036, respectively. Drug costs accounted for 18% of total costs in the HyperCVAD regimen as compared to 46% in the DFCI regimen; the remaining costs were driven by hospitalization (\$31,965 vs. \$13,770, respectively). Results were robust to the probabilistic sensitivity analysis. **CONCLUSIONS:** By using current cost data and recently modified chemotherapy regimens, this analysis represents the most up to date estimation of the cost of treating adult ALL patients. Both HyperCVAD and DFCI protocols pose considerable financial burden; the DFCI treatment protocol is estimated to cost the healthcare system more in drug costs but substantially less in hospitalization costs compared to the HyperCVAD protocol.

PCN84

INDIRECT COSTS AND BURDEN OF LUNG CANCER IN TERMS OF DISABILITY ADJUSTED LIFE YEARS DURING 2015 IN RUSSIA

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OBJECTIVES: The study was aimed to evaluate the total indirect costs of lung cancer (LC) and burden of disease during 2015 in Russia. This data could help to improve reimbursement processes and decision-making. **METHODS:** A systematic literature review was performed to obtain the following information: employment, length of hospital stay, average value of a statistical life, indicators of morbidity and mortality by age group and stage of LC. Finally, obtained data were used in cost-of-illness analysis. The total indirect costs of LC were calculated using two different approaches: the human-capital and friction-costs method. The cost of illness was calculated by a bottom-up approach. The global burden of LC was also assessed in terms of DALYs. The rate of discounting was 5%. **RESULTS:** In 2015, the indirect costs of LC were estimated at \$1 689 million (\$12 621 per patient) using human-capital method. The costs were more than six times higher in males than in females. Total annual indirect costs were evaluated at \$14 million (\$506 per patient) using friction-cost method. The DALYs burden for LC reached 1 307 837 years, including years of life lost due to premature mortality (14 744) and years lost due to disability (1 293 093). The cost in terms of DALYs was also estimated using the average cost of a statistical life, which was \$73 484. The global burden of LC using DALYs and the average cost of a statistical life was estimated at \$1 344 million. **CONCLUSIONS:** LC is a leading cause of cancer mortality and represents a significant burden of disease. The results suggest that LC deserve more attention from policymakers.

PCN85

REVIEW OF BURDEN OF ILLNESS DATA FOR FOLLICULAR LYMPHOMA AND MARGINAL ZONE LYMPHOMA

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OBJECTIVES: Indolent Non-Hodgkin Lymphomas (NHL) including follicular lymphoma (FL) and marginal zone lymphoma (MZL) compromise approximately 12% of all NHLs worldwide. The aim of this review is to synthesize the global burden of disease for FL and MZL by characterizing the epidemiology, natural history, economic and societal impact of these indolent NHLs. **METHODS:** We ran searches in the EMBASE, Medline, NHSEED and ECONLit databases from January 2006 to November 2016. Outcomes of interest were incidence, prevalence, quality of life, costs and resource use, mortality and long-term prognosis. 1,946 potentially relevant abstracts were retrieved and reviewed. From this 54 full texts were reviewed, with 31 studies finally included in the review. **RESULTS:** We found that the age-standardised incidence rates of FL ranged from 2.1/100,000 to 4.3/100,000 while for MZL it varied geographically from 0.5/100,000 in Australia to 2.6/100,000 in the UK. The cumulative total direct health care costs for FL/MZL varied by whether patients experienced progressive disease (PD) or not, with a higher mean overall cost for PD patients compared to non-PD patients (\$30,890 vs. \$8,704 at 12 months). There was a clinically meaningful difference in quality of life between patients with PD and newly diagnosed patients (FACT-LYM total score 109.7 vs. 136.0 [score range 0-168]). Mortality rates of FL patients at 5 years differed according to age at diagnosis (≤ 60 years: ranging 7.8-8.8%, ≥ 60 years: 17.9% and > 80 years ranging 41.5-51.1%) and disease stage (21% at Ann Arbor stages 1-2 and 28% at Ann Arbor stages 3-4). Limited outcome data for MZL patients was identified. **CONCLUSIONS:** This comprehensive burden of illness review demonstrates that FL/MZL contribute significant burden on the health care systems and patients globally and delays in progression could lead to potential cost savings. New treatments are needed to improve patient outcomes and reduce the global burden of disease for FL/MZL patients.

PCN86

THE DIRECT COST OF HEAD AND NECK CANCER TO THE BRAZILIAN PUBLIC HEALTHCARE SYSTEM (SUS)

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OBJECTIVES: Since head and neck cancer (HNC) is known to have a high incidence and often demands invasive treatments, this study aimed to identify the direct costs

of HNC management in the Brazilian public health system. **METHODS:** Inpatient and outpatient costs of HNC treatment in 2014 were obtained from databases available at official information systems in health (Hospital Information System, SIH / SUS and Outpatient Information System, SIA / SUS). HNC patients were identified by the ICD-10 code. **RESULTS:** In 2014, the treatment of HNC resulted in 41,386 inpatient procedures (approximately 30,000 patients), with a cost of US\$39,697,795; from which 66% was attributed to male patients. Resection of tumors/lesion was performed 5,197 times, resulting in a cost of more than US\$4 million and the admission for continuous administration chemotherapy resulted in add cost of almost US\$2 million. Regarding outpatient care, US\$18,972,113 were spent in a total of 59,545 procedures, in which 81% was spent with male patients. The most outpatient procedures were chemotherapy applied to sinuses/larynx/hypopharynx/ oropharynx/oral cavity, with a total of 21,724 events and US\$8,405,026. **CONCLUSIONS:** As expected, HNC is a group of diseases associated with high costs and very invasive treatments, leading to a high economic and social burden. The total medical direct cost of HNC treatment in 2014 was US\$58,669,908 for the Brazilian public healthcare system. However, this amount is still underestimated by not including costs with adverse effects management, since this is a hallmark of head and neck cancer.

PCN87

HEALTH INSURANCE COST OF BRAIN CANCER IN HUNGARY: A COST OF ILLNESS STUDY

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OBJECTIVES: The aim of our study is to calculate the annual health insurance treatment cost of brain cancer in Hungary. **METHODS:** The data derive from the financial database of the Hungarian National Health Insurance Fund Administration (NHIFA), the only health care financing agency in Hungary. We analyzed the health insurance treatment cost and the number of patients for the year 2010. The following cost categories were included into the study: out-patient care, in-patient care, CT-MRI, PET, home care, transportation, general practitioner, drugs and medical devices. Brain cancer was identified with the following codes of the International Classification of Diseases 10th revision: C70-C72, D32-D33, D42-D43. **RESULTS:** The Hungarian National Health Insurance Fund Administration spent 3.071 billion Hungarian Forint (HUF) (14.758 million USD) for the treatment of patients with brain cancer. The annual average expenditure per patient was 145673 HUF (699.9 USD) while the average expenditure per one inhabitant was 307 HUF (1.7 USD). Major cost drivers were acute inpatient care (49.2 % of total health insurance costs), pharmaceuticals (35.7%) and CT-MRI examinations (8.5 %). The number of patients with brain cancer was 21.1 per 10000 populations. We found the highest patient number in outpatient care (21088 patients) general practitioners (8915 patients) and pharmaceuticals (6620 patients). **CONCLUSIONS:** Brain cancer represents a significant burden for the health insurance system. Reimbursement of acute inpatient care and pharmaceuticals are the major cost drivers for brain cancer in Hungary.

PCN88

COSTS OF BREAST CANCER RELATED CARE AMONG WOMEN IN THE UNITED STATES INSURED COMMERCIALLY, AND BY MEDICARE AND MEDICAID – A SYSTEMATIC REVIEW

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OBJECTIVES: Breast cancer is the second most common cancer among women in the US. The objectives of this study were to conduct a systematic review of recent publications that evaluated the costs of care of women with breast cancer in active treatment and stratify the costs by payer type. **METHODS:** A systematic review of PubMed from January 2010 to December 2016 was conducted to identify relevant publications. The initially identified abstracts were reviewed to select full text manuscripts containing details of breast cancer costs and cost estimating methodology. From the identified publications, cost data were extracted and reviewed by 2 independent researchers. The extracted data contained breast cancer related cost information during active cancer treatment among women with specific payer types. All retrieved cost data were inflation adjusted to 2016 USD. **RESULTS:** Of the studies included (n=15), 4 were from a commercial payer perspective, 8 were from a Medicare perspective (4 evaluated radiation therapy cost only), and 3 were from a Medicaid perspective. For commercial payers and Medicare, breast cancer related care costs during 12 months of active treatment averaged \$61,420 per patient (standard deviation (SD): \$7,166, median: \$58,648) and \$28,906 per patient (SD: \$6,741, median: \$27,760), respectively. Costs for outpatient care (\$39,905 per patient, SD: \$14,195, median: \$38,448) contributed most to the overall costs of breast cancer related care for commercially-insured patients. Outpatient care was inconsistently defined across studies of Medicare-insured women, but reported radiation therapy costs averaged \$12,482 per patient (SD: \$4,444, median: \$11,347). Cost data for breast cancer related care among Medicaid beneficiaries is limited. **CONCLUSIONS:** The cost of breast cancer related care varies across payer types, with commercial payers having the greatest burden per patient in the US. For more reliable cost estimates, especially from the perspective of Medicaid, further study is warranted.

PCN89

DIRECT MEDICAL COSTS FOR STAGE-SPECIFIC BREAST CANCER IN JORDAN

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OBJECTIVES: This study aimed to estimate the direct medical costs associated with the care of breast cancer patients by disease stage. **METHODS:** A retrospective analysis of a cohort of patients with BC treated for 12 months in 2015 in KAUH.

Demographic, clinical and economic data was collected. Statistical analysis will be performed using SPSS/STATA for Windows and a p value of < 0.05 is defined as statistically significant. **RESULTS:** A total of 119 female patients with BC were identified. Their mean age was 50.82 ± 10.22 years. The total cost for the sample was JD 1,393,325. Mean cost per patient from stage I to IV was JD 6,696; 9,183; 11,970 and 15,073; respectively. Medications (mainly chemotherapy) were the most expensive healthcare resource used, accounting for 75% of total cost, followed by laboratory and diagnostic test. **CONCLUSIONS:** This study is the first to examine the impact of breast cancer on health system resources in Jordan. Direct medical costs associated with BC are substantial. The vast majority of the cost was devoted for medications. Stage IV was associated with the highest cost and the largest number of patients.

PCN90

ADHERENCE TO CANCER THERAPIES AND THE IMPACT ON HEALTHCARE COSTS AMONG PATIENTS WITH ADVANCED MELANOMA IN THE USA

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OBJECTIVES: To evaluate adherence to cancer therapies among patients with advanced melanoma and quantify the impact of drug adherence on healthcare costs. **METHODS:** Patients (≥ 18 years) with a diagnosis for stage III/IV melanoma who initiated cancer therapies were identified from the MarketScan Commercial and Medicare databases (1/1/2011-8/31/2015). Demographic and clinical characteristics were evaluated at baseline (12 months pre-index). Medication adherence and persistence were examined during a variable length follow-up period for up to 24 months. Patients were grouped into 2 study cohorts: those with high adherence (medication possession ratio, $MPR \geq 0.8$) and those with low adherence ($MPR < 0.8$) to the index cancer therapy. All-cause and melanoma-related costs were measured as per patient per month (PPPM, 2015 USD) at follow-up and compared among study cohorts. A multivariate generalized linear model was used to evaluate the impact of adherence status on healthcare costs, while controlling for key patient characteristics. **RESULTS:** In the overall study population ($N=2,671$), the mean[\pm SD] age of the patients was $60.9[\pm 13.3]$ years, 63.6% were male, with a mean[\pm SD] Charlson comorbidity index score of $8.8[\pm 2.0]$, and 85.5% had stage IV melanoma. 49.1% of the patients were on an immunotherapy and 94.7% of those patients received ipilimumab. The mean[\pm SD] MPR of patients decreased as the duration of follow-up increased, ranging from $0.75[\pm 0.24]$ at 3 months to $0.44[\pm 0.29]$ at 24 months of follow-up. Nearly three-fourths (72.4%) of the patients discontinued their index therapy within 3 months. After controlling for patient characteristics, those with high vs. low adherence had lower mean PPPM all-cause total cost (\$41,830 vs. \$51,991; $p < 0.001$) and melanoma-related total cost (\$37,549 vs. \$48,263; $p = 0.006$). **CONCLUSIONS:** A majority of patients with advanced melanoma have low adherence and discontinue therapy in ≤ 3 months. Patients with high adherence to cancer therapies have lower all-cause and melanoma-related total costs than patients with low adherence.

PCN91

COSTS OF MANAGING PATIENTS WITH RELAPSED OR REFRACTORY HODGKIN LYMPHOMA (RRHL) IN THE USA

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OBJECTIVES: Treatment options for RRHL patients post-autologous stem cell transplant (ASCT) are limited. Newer therapies including brentuximab vedotin (BV) may improve outcomes. Understanding contemporary use of these medications is important, as they may be costly. We identified costs of care for a cohort of RRHL patients treated with ASCT in the USA, according to timing of BV treatment. **METHODS:** We identified 401 adult RRHL patients treated with ASCT after failing first-line therapy between 2006-2015, using the Truven MarketScan databases. Line of therapy was classified based on dispensations and chemotherapy administration, and duration of line of therapy was considered from initiation of one therapy line until initiation of the next (or until censoring). All-cause healthcare resource use during each therapy line was used to estimate mean (standard deviation) per patient monthly and total costs, inflated to 2015 US dollars (\$). **RESULTS:** Three hundred and seventy (92.3%) patients were BV-naïve, 8 (2.0%) had BV pre-ASCT, and 23 (5.7%) had BV post-ASCT. Mean monthly costs among BV-naïve patients were \$28,580 (48,202) over a median follow-up of 77 weeks post-ASCT, \$53,767 (51,272) for those with BV prior to ASCT over 51 weeks, and \$27,976 (17,241) for those with BV after ASCT over 88 weeks. Mean monthly costs for BV-naïve patients increased with lines of therapy post-ASCT, but were relatively stable among those with BV post-ASCT. Total costs from time of ASCT to end of follow-up were \$381,810 (388,888) for BV-naïve patients, \$560,927 (295,827) for those with BV pre-ASCT, and \$422,741 (184,194) for those with BV post-ASCT. **CONCLUSIONS:** Mean monthly costs for managing RRHL patients are approximately \$28,000, and total costs are \$380,000 per patient treated. Small samples and shorter follow-ups limit the relevance of estimates from those with BV pre-ASCT. These data highlight the high economic burden associated with managing RRHL patients.

PCN92

COMORBIDITY MEASURES TO PREDICT HEALTHCARE COSTS AMONG ELDERLY GYNECOLOGIC CANCER SURVIVORS IN THE US: AN ANALYSIS OF SEER-MEDICARE DATA

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OBJECTIVES: To examine relationships between different comorbidity indices and healthcare costs, and to compare the performance of these indices in predicting

healthcare costs among elderly gynecologic cancer survivors. **METHODS:** This retrospective study used 2007-2010 Surveillance, Epidemiology, and End Results (SEER)-Medicare data. The primary independent variables were comorbidity indices [Charlson Comorbidity Index (CCI), Elixhauser Comorbidity Index (EI), National Cancer Institute (NCI) index, Chronic Disease Score (CDS) and RxRisk]. The dependent variables were costs for emergency room (ER)/inpatient visits, outpatient visits, office-based practitioner visits, prescriptions, and total healthcare. Gamma regressions with a log link were used for the analyses. The Akaike Information Criterion, Bayesian Information Criterion, and Likelihood ratio tests were used to compare the predictive ability of the indices. **RESULTS:** The mean total annual healthcare cost for the 4,063 survivors studied was \$40,605 (SD=\$34,014). In the unadjusted models, indices (except the CDS-2 and RxRisk) were positively significantly associated with ER/inpatient visit and total healthcare costs. In the adjusted models, CCI and CDS-1 scores and several EI indicators were positively significantly associated with higher ER/inpatient visit and total healthcare costs after controlling for covariates. None of the indices (except a few EI indicators) were associated with outpatient visit, office-based practitioner visit, or prescription costs in the models. CCI and CDS-1 scores outperformed other indices in predicting ER/inpatient visit and total healthcare costs. **CONCLUSIONS:** This study found meaningful associations between different comorbidity indices and ER/inpatient visit and total healthcare costs among elderly gynecologic cancer survivors in the US. Study findings suggest using the CCI and CDS-1 scores in predicting ER/inpatient visit and total healthcare costs in this population. This study may help payers in their budgeting by identifying comorbid conditions associated with higher costs, and health economists choose the better comorbidity indices to use in their research.

PCN93

HEALTHCARE RESOURCE UTILIZATION AND COSTS OF SKELETAL-RELATED EVENTS IN PATIENTS WITH MULTIPLE MYELOMA

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OBJECTIVES: Skeletal-Related Events (SREs) (defined as spinal cord compression, pathological fracture, radiation or surgery to bone) are common bone complications of patients with multiple myeloma (MM). Clinical guidelines recommend prophylactic management for prevention of SREs, as SREs can be debilitating, and are associated with poor clinical outcomes and high costs. This study estimated economic burden of SREs in MM. **METHODS:** In this retrospective cohort study, adults with ≥ 1 inpatient or ≥ 2 outpatient MM diagnoses between 01/01/2010 and 12/31/2014 were identified from the QuintilesIMS' PharmetricsPlus healthcare claims database. First SRE date on or after first MM diagnosis was the index date. All patients had ≥ 12 -months of continuous enrollment pre-index and ≥ 1 month post-index. Patients with SRE(s) were propensity score matched 1:1 to MM patients without SREs (controls) using pre-index demographic, clinical characteristics, and costs. Patients were followed until the earliest of last enrollment date, or 12/31/2015. The average per-patient per-year (PPPY) healthcare resource utilization (HRU) and costs were measured during follow-up. McNemar's test and Wilcoxon test were conducted to assess HRU and cost. **RESULTS:** A total of 848 patients with SREs and 848 matched controls met the study criteria (mean age: 61 years; male: 57%; mean follow up: 22 months). SRE and control groups were well-matched. Compared to controls, SRE patients had significantly higher proportions and frequency of hospitalizations (72.4% vs. 41.2%; and 1.7 vs. 0.7, respectively), emergency room visits (55.5% vs. 42.9%; and 1.1 vs. 0.7, respectively), and higher all-cause total costs (\$188,723 vs. \$108,160) PPPY [$p < 0.0001$]. Primary cost drivers were hospitalizations and outpatient ancillary costs, PPPY cost differences between matched cohorts were \$36,775 and \$16,646, respectively. **CONCLUSIONS:** Significant economic burden was observed with SREs in patients with MM (almost 2-fold more hospitalizations and \$80K PPPY additional cost). This study demonstrates the importance of prophylactic management of SREs in MM.

PCN94

CLINICAL AND COST OUTCOMES ASSOCIATED WITH MULTIPLE OPEN SURGICAL PROCEDURES FOLLOWING PERCUTANEOUS BREAST BIOPSY

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OBJECTIVES: This study estimated the proportion of patients requiring multiple open surgical procedures following percutaneous breast biopsy, including associated complications and incremental medical costs. **METHODS:** Healthcare claims data from the Truven Commercial Research database (2009 - 2014) was used to identify patients undergoing percutaneous biopsy in an outpatient setting for this retrospective database analysis. Patient selection criteria included: female; continuous health plan enrollment; no previous history of cancer, chemotherapy, radiation, or breast cancer surgery. Open procedures were defined as an open biopsy or lumpectomy. Study follow-up was defined as 90 days from initial percutaneous biopsy; or until the first date of chemotherapy, radiation, or mastectomy—to limit analysis to diagnosis-related costs. **RESULTS:** 143,771 patients were identified for analysis with mean age 47 to 54 years. Eighty-five percent of patients underwent only a percutaneous biopsy, 12.4% underwent one open procedure, and 2.5% had multiple open procedures. Incidence of any complication was significantly lower among those with no open procedure (9.3%) versus patients with one open (15.6%) or multiple open procedures (25.3%, $P < 0.001$). Mean incremental breast-related medical costs were \$14,257 greater among patients with one open procedure versus none (\$18,828 vs. \$4,571, $P < 0.001$); and \$4,982 greater among patients with multiple open procedures versus one (\$23,811 vs. \$18,828). In logistic regression, factors associated with multiple open procedures included: diagnosis of breast cancer, any complication, region, ages 41-50 (vs ≤ 40), initial percutaneous biopsy procedure setting, and

initial open procedure setting. **CONCLUSIONS:** This study demonstrates there are a proportion of women that require multiple open procedures following initial percutaneous biopsy for diagnosis of a suspicious lesion. There is a need for more patient-centered approaches for the diagnosis of suspicious lesions to minimize the use of open diagnosis-related procedures.

PCN95

REAL-WORLD TREATMENT PATTERNS AND COSTS IN MEDICARE BENEFICIARIES NEWLY DIAGNOSED WITH ACUTE MYELOID LEUKEMIA

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OBJECTIVES: Little is known on treatment patterns and costs of acute myeloid leukemia (AML) management in US clinical practice. This study describes induction therapy and consolidation cycles in terms of settings, duration, and costs of Medicare beneficiaries with AML who are candidates for standard chemotherapy. **METHODS:** Using the SEER-Medicare databases, Medicare beneficiaries newly diagnosed with AML from 2007-2011 who received standard induction chemotherapy in an inpatient setting were selected. Patients were observed from induction therapy initiation to the first event among hematopoietic stem cell transplant, death, end of Medicare coverage/data availability, or 180-days after the end of the induction episode. AML treatment episodes, including induction therapy and consolidation cycles, were identified using DRG/procedure codes. AML treatment episode settings, duration, and costs (USD2015, public payers' perspective) were analyzed. **RESULTS:** Of the 563 Medicare beneficiaries (mean age=66 years; 54% male) with a first induction episode, 193 (34%) patients had 2 cycles of induction therapy during this episode. The median duration of inpatient stays with 1 cycle of induction therapy was 28 days and mean costs were \$64,680. The median duration of inpatient stays with 2 cycles of induction therapy was 47 days and mean costs were \$126,096. Following induction therapy, 297 (53%) patients had ≥ 1 consolidation cycle, 231 (40%) ≥ 2 , 148 (26%) ≥ 3 , and 87 (15%) ≥ 4 . 65% of consolidation cycles were administered in an inpatient setting and 35% in an outpatient setting. In the inpatient setting, the median duration per cycle was 6 days and mean costs were \$28,843. In the outpatient setting, the median duration per cycle was 5 days and mean costs were \$5,803. **CONCLUSIONS:** This is the first exploratory study reporting recent treatment patterns and costs of Medicare beneficiaries newly diagnosed with AML. These findings suggest that, there is substantial heterogeneity in the consolidation therapy setting and costs.

PCN96

HOSPITAL BURDEN FOR TREATING PROSTATE CANCER (PCA) WITH BONE METASTASIS (WBM) PATIENTS IN THE BRAZILIAN SUPPLEMENTARY HEALTH SYSTEM: RESULTS FROM A RETROSPECTIVE ANALYSIS OF AN ADMINISTRATIVE DATABASE

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OBJECTIVES: Prostate cancer places a high economic burden on healthcare systems globally. International studies demonstrated significant impact to the health system, mainly due to increased hospitalization of advanced disease patients. In Brazil, a cohort study evaluated PCa medical-cost in an HMO resulting in R\$4,640/year, with most of patients in earlier treatment stage. This study aims to evaluate medical-costs for the treatment of patients with PCa-wBM in the Brazilian Supplementary Health System (SHS). **METHODS:** This was designed as a retrospective database cohort study from an administrative database (Orizon) that covers part of the Brazilian SHS, during the period of Jan/2010-Dec/2015. The analysis focused on hospital costs and medical resources consumption of patients registered in the database with prostate cancer and bone metastasis according to selection criteria: ICD-10:C-61 register followed by ICD-10:C795 or M907 or register of bone-metastasis procedures; at least one PCA treatment and hospitalization or ambulatory admission. Study outcomes were: annualized overall hospital cost per patient, prostate cancer treatment types distribution, average hospital visits and Length of Stay (LOS). Currency rate: US\$1=R\$3,23. **RESULTS:** A cohort of 181 patients met the selection criteria for the study. During the follow-up period 21.5% of the patient cohort had exclusively one type of treatment, whereas 37.5% had Radiotherapy (RT), Hormonotherapy (HT) and Oncologic-therapy. Average cost/entrance was R\$10,300, hospitalization and ambulatory costs were R\$36,853 and R\$5,627 respectively. Patient had entered the hospital 8,04-times per year, of which 4,20-times was hospitalized with an average LOS/hospitalization of 10,64-days. Annualized hospital cost/patient was R\$128,607. Sub-group analysis had shown RT average cost/entrance of R\$3,001 and oncologic-therapy of R\$4,340. HT average cost/entrance was R\$16,614, with disparity between ambulatory and hospitalization, R\$4,538 and R\$42,140 respectively. **CONCLUSIONS:** This cohort study showed high economic burden of hospital treatment of PCa wBM in the Brazilian SHS compared to previous study, mainly due to advanced disease stage that requires frequent hospital entrance and stay.

PCN97

UTILIZATION OF TARGETED THERAPIES WITH COMPANION DIAGNOSTICS IN MEDICARE CANCER PATIENTS 2011 - 2015

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OBJECTIVES: Targeted therapy attacks specific types of cancer cells. Companion diagnostics (CDx) aid in the identification of candidates who may benefit from a

targeted therapy. This analysis was conducted to understand the trend of targeted therapy/CDx utilization under Medicare, 2011-2015. **METHODS:** Therapies were selected based on FDA cleared/approved CDx. We analyzed Medicare Part D drug spending (2011-2015) published by CMS in 2016 for each therapy. Analysis was limited to therapies with a single cancer indication requiring CDx. Further analysis considering all targeted therapies with CDx were conducted to understand impacts of the therapy exclusion criteria. **RESULTS:** From 2011 to 2015, the number of targeted cancer therapy beneficiaries increased from 498 to 7,133. The Medicare spend increased from \$9,547,737 to \$293,607,643, also increasing as part of the overall Medicare Part D spend (0.01% to 0.21%). PMPM increased from \$0.0163 to \$0.4408. In 2011, the total spend as part of the overall spend on these included therapies was led by melanoma (61.24%), followed by non-small cell lung cancer (NSCLC) (33.76%) and colorectal cancer (CRC) (5.00%). This trend has changed and by 2015, there was increased utilization of targeted therapies for NSCLC (51.58%), followed by melanoma (36.32%), ovarian cancer (9.65%), breast cancer (2.03%) and CRC (0.42%). In 2015, the annual spend per beneficiary ranged from \$15,919 (Gefitinib) to \$70,967 (Crizotinib), and the cost sharing was 0.0045-0.5110% for beneficiaries who qualified for a Low Income Subsidy (LIS), and 5.1%-17.1% for those who do not qualify for LIS. Further analysis demonstrated a similar trend in the therapy utilization. **CONCLUSIONS:** The Medicare spend on targeted cancer therapies requiring CDx increased 2011-2015, and also increased as part of the overall Medicare Part D spend. It is expected that this trend may continue, driven by the increasing adoption of targeted therapies in clinical practice, and the target therapies currently under development.

PCN98

PRICE ANALYSIS OF THYROID CANCER- TYROSINE KINASE INHIBITOR DRUGS MARKETED IN THE US

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OBJECTIVES: Tyrosine kinase inhibitor therapy (TKI) is a type of targeted therapy that inhibit signals needed for cancer cells to grow and divide. In this study we assessed the trends in average wholesale prices (AWP) at market entry for thyroid cancer - targeted therapy approved by the US Food and Drug Administration (FDA). **METHODS:** Regulatory information was derived from the FDA website. AWP per unit at market entry data were derived from the RedBook (Truven Health Analytics, Inc.). The AWP history was collected from year of approval to January 2017. The daily defined dosage (DDD) for adult patients was obtained from FDA approved labels. AWP per DDD and 30 DDD were computed. AWP were adjusted to for inflation by using the consumer price index (CPI). Descriptive statistics were performed in this study. **RESULTS:** The FDA approved 6 tyrosine kinase inhibitor drugs for the indication of thyroid cancer in the period 2005-2016. The first TKI for thyroid cancer was approved in 2005 and the deactivated in January 2008 with an AWP of \$174.90 per DDD, and then returned to the market on July 2008 with the same strength and package and with an AWP of \$604.50 which represents a 246% increase in the previous price. The median AWP per DDD at market entry was \$391.43. The FDA-approved TKIs typically increased their AWP prices twice a year. The AWP per DDD at market entry of the last approved TKI in 2015 was 552% higher than the AWP per DDD at market entry of the first approved TKI in 2005. The AWP per DDD at market entry were \$163.01, \$372.96, \$409.91, \$1,358.58, \$363.96, and \$1,063.60 respectively during the time of study. **CONCLUSIONS:** The market entry prices of TKIs for thyroid cancer substantially increased over the period of study.

PCN99

DIRECT MEDICAL COSTS OF LUNG CANCER PATIENTS TREATED IN FIRST LINE WITH GEFITINIB OR ERLOTINIB IN THE BRAZILIAN PRIVATE HEALTHCARE SYSTEM

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OBJECTIVES: To evaluate the direct medical costs (DMC) in patients with lung cancer treated with gefitinib or erlotinib in first line and subsequent therapies. **METHODS:** The Orizon is an administrative database containing over 18 million lives of the Brazilian Private System. Eligibility criteria were patients treated in first line with any TKI with ICD-10 code C34 from 2013 to 2015. Monthly DMC were calculated as the sum of medical claims for each patient during treatment and all results were represented by the mean values with an exchange rate of 1 USD = 3.23 BRL. **RESULTS:** A total of 55 patients were treated with any TKI in first line. Results of DMC in gefitinib group was USD 1,463.32 (BRL 4,726.54) per month, while the erlotinib group was USD 4,369.77 (R\$ 14,114.37), resulting in an average cost increase of 2.9 times, mainly due to the higher erlotinib cost and hospitalizations. In terms of length of treatment (LOT) results were similar between both medicines, patients were on gefitinib therapy for 7.6 months and erlotinib for 7.9 months. We also evaluated 26 patients in second line, after TKI therapy, where the most common were pemetrexed monotherapy or in combination with other drugs resulting in a monthly DMC of USD 5,492.50 (R\$ 17,740.78) with a LOT of 5.0 months and bevacizumab plus chemotherapy with a monthly DMC of USD 11,134.98 (R\$ 35,966.01) and a LOT of 4.8 months. **CONCLUSIONS:** Monthly costs with patients treated in first line with gefitinib were lower than erlotinib and presented a similar mean length of treatment duration. It was noteworthy that monthly costs of precision medicine therapies were much lower than chemotherapy schemes in the Brazilian private setting.

PCN100

PALBOCICLIB DOSING, WASTAGE AND COSTS AMONG POST-MENOPAUSAL WOMEN WITH HORMONE RECEPTOR POSITIVE AND HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 NEGATIVE (HR+/HER2-) METASTATIC BREAST CANCER (MBC): A CLAIMS ANALYSIS

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OBJECTIVES: To examine dosing patterns among HR+/HER2- mBC patients treated with palbociclib during second or later lines of therapy in real-world medical practice. **METHODS:** Postmenopausal women with HR+/HER2- mBC treated with palbociclib-based second (2L), third (3L) or fourth (4L) lines of therapy were identified from MarketScan US claims databases during 1/1/2013- 7/31/2016 (earliest secondary malignancy diagnosis was index). Patients had continuous health plan enrollment for at least 6 months pre-/post-index and valid data for dose calculations. Dose modification was defined as a change in daily dose of > 25 mg compared to the prior prescription. Patients with an overlap in supply preceding a modification were identified to estimate cost of potential drug wastage. Wastage costs were computed by applying wholesale acquisition costs (January 2017) to each day of overlap. **RESULTS:** Of 811 eligible mBC patients treated with palbociclib (mean age 58.8 + 11.5), there were 249, 172, and 102 with a 2L, 3L, and 4L of therapy respectively. Initial mean dose in mg was 94.8 + 13.9 during 2L, 96.5 + 13.1 during 3L, and 90.7 + 16.1 during 4L. The proportion of patients with dose modification was 41.8% (2L), 37.2% (3L) and 22.5% (4L) driven by dose decreases (35.7% in 2L to 19.6% in 4L). Of patients with modification, 41-44% had an overlap in supply prior to the change (10.9 + 9.0 days in 2L to 14.2 + 7.7 days in 4L) which lead to \$5,418 - \$7,063 costs of potential drug wastage per patient during a median duration of 3.9 months for each line. **CONCLUSIONS:** This analysis found that 19.6%-35.7% of patients with palbociclib-based treatment during a second or later line of therapy had a dose reduction over a median time of 3.9 months resulting in potential drug wastage of \$5,418-\$7,063 per patient during each line.

PCN101

AN INVESTIGATION OF THE CORRELATION BETWEEN PRICE MIGRATION AND MOLECULE SIZE OF ONCOLOGY DRUGS AVAILABLE IN THE US

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OBJECTIVES: This study aims to evaluate if there is a correlation between the magnitude of cancer drug price increases and their molecule size (small molecule vs. mAb) **METHODS:** All oncology drugs approved by the FDA from January 1, 2004 to October 31, 2015 were included for analysis (N=72). The Wholesale Acquisition Cost (WAC) prices at launch, and subsequent price increases were extracted from AnalySource. We evaluated how the magnitude and frequency of price increases for each drug were impacted by different product characteristics like route of administration, launch date, molecule size, etc. **RESULTS:** The correlations between price migration and a number of different drug characteristics were studied, of which molecule size was found to have a distinctly strong impact on price increases. Of the 72 drugs studied, 58 were small molecules and 14 were monoclonal antibodies (mAbs). The average CAGR for small molecules was 6.1%, and that for mAbs was 1.4%. On average, annual price increases were also more frequent for small molecules compared to mAbs at 1.1 times and 0.6 times, respectively. When stratified by indication, the average CAGR of small molecules indicated for blood tumors was 6.0% compared to a 2.6% growth rate of mAbs. Within solid tumors, small molecules had 6.1% CAGR versus 0.9% for mAbs. For each tumor type, the magnitude and frequency of price increases were consistently higher for small molecules compared to mAbs with the exception of brentuximab, a mAb indicated for lymphoma, at 7.0% CAGR and 1.8 annual price increases, compared to 4.4% CAGR and 1.0 annual increases for small molecule lymphoma drugs. **CONCLUSIONS:** Small molecules appear to have larger and more frequent price increases than mAbs. Molecule size appears to be an important influencer on price for new drugs and should be introduced into the ongoing dialogue on cancer drug pricing.

PCN102

DIRECT MEDICAL COSTS OF MAINTENANCE THERAPY IN BRAZILIAN PLATINUM-SENSITIVE OVARIAN CANCER PATIENTS OF PRIVATE HEALTHCARE SYSTEM: RETROSPECTIVE ANALYSIS OF AN ADMINISTRATIVE DATABASE

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OBJECTIVES: The aim of this study was to determine the direct medical costs (DMC) of maintenance therapy in Brazilian platinum-sensitive ovarian cancer (PSOC) patients based on the Private Healthcare System. **METHODS:** The Orizon database, an administrative database containing inpatient and outpatient claims representing 34% of the total Private Health System, was evaluated from Jan/2011 to Dec/2015. Eligibility criteria were patients with ICD-10 code C56 that started treatment among Jan/2012 to Dec/2014, unresectable stages III or IV, treated in first line with any platinum scheme. Platinum sensitive patients were defined as relapse ≥ 6 months after first platinum-based chemotherapy. DMC of maintenance therapy were calculated as the sum of medical claims for each patient included in the analysis (conversion rate of 1 USD = 3.45 BRL). **RESULTS:** Of the 243 patients identified in the database, 62 (25.5%) did maintenance therapy where bevacizumab monotherapy was the most common of all schemes, corresponding to 96.6%. Total maintenance DMC in the subgroup (n = 64) was USD 4,035,872.72 (mean cost = USD 63,060.51/maintenance) and a mean monthly cost of USD 6,917.06. Medicines represented 95.4%, materials 3.1%, exams 0.5%, fees (expenses related to other medical costs) 0.4% and others 0.5% of total costs during the

maintenance phase. **CONCLUSIONS:** The benefit of maintenance therapy in PSOC patients was already demonstrated in clinical trials. Understanding the local current maintenance costs will help payers in decision making specially when novel targeted agents are coming such as olaparib, an oral PARP inhibitor and selective for BRACm patients only, which is already registered and will soon be available in Brazil, not incurring in costs associated with in-clinic infusions.

PCN103

ROBOTIC-ASSISTED THORACOSCOPIC PULMONARY RESECTION VERSUS VIDEO-ASSISTED THORACOSCOPIC PULMONARY RESECTION FOR EARLY STAGE NON-SMALL CELL LUNG CANCER: A HEALTHCARE UTILIZATION ANALYSIS

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OBJECTIVES: The objective of this study was to compare robotic-assisted thoracoscopic (RATS) pulmonary resection to video-assisted thoracoscopic (VATS) pulmonary resection for early stage Non-Small Cell Lung Cancer (NSCLC) with respect to healthcare resource utilization. **METHODS:** Patients who underwent anatomic lung resections using the RATS (n=42) or VATS (n=96) technique for early stage NSCLC between April 2014 and March 2015 at a single institution were identified. Data on demographics, clinical characteristics, cancer stage, operative metrics, and morbidity were collected. **Patient-level case-costing data**(direct medical and non-medical) for hospital and homecare-associated resource variables were recorded. The economic evaluation adopted a health care payer perspective and 30-day post-hospital discharge/death time horizon. Parametric or non-parametric tests were used as appropriate and incremental cost difference using 10,000 bootstrap samples using bias corrected and accelerated method to generate 95% confidence intervals for total cost. **RESULTS:** Baseline demographic and clinical characteristics were comparable between the two groups. The median total hospital cost per patient was \$15,247.79 (95% confidence interval, \$15,643.87 to \$18,945.28) in the RATS cohort, compared to \$12,131.31 (95% confidence interval, \$13,218.05 to \$15,879.67) in the VATS cohort (n=96) (p<0.001). Longer operating times were the main cost-drivers for higher hospital costs for patients undergoing RATS pulmonary resections compared with the VATS group (p=0.000). Resource utilization and costs for the post-operative services were similar between the two groups. The operative and post-operative morbidity were also similar, however, VATS had a higher likelihood of conversion to thoracotomy (10/96, 10.4%) as compared to RATS (3/42, 7.1%). **CONCLUSIONS:** This is the first micro-costing study comparing the in-hospital and homecare-related resource utilization and cost for the RATS and VATS pulmonary resection. The RATS pulmonary resection for early stage NSCLC was associated with higher healthcare resource dollars when compared to VATS, but offered similar perioperative outcomes. Multicenter cost-effectiveness studies are required to justify use of robotic surgery.

PCN104

THE ECONOMIC IMPACT OF DELAYING BRAIN METASTASES IN ALK-POSITIVE NON-SMALL CELL LUNG CANCER IN THE COMMERCIALLY INSURED US POPULATION

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OBJECTIVES: To describe the occurrence of brain metastases (BMet) and cost offsets of delaying or preventing BMet in ALK+ non-small cell lung cancer (NSCLC) patients in the US. **METHODS:** Patients with ALK+ NSCLC were identified from a stacked database of PharMetrics Plus and MarketScan claims data from Jan 2008 to Mar 2016 and Dec 2015, respectively. Early BMet was defined as a BMet within 6 months after the first lung cancer diagnosis (index date). The occurrence of a BMet after 6 months was defined as a delayed BMet. Patients with an ALK inhibitor, ≥ 18 years old, with ≥ 6 months preindex and ≥ 30 days follow up were included. ALK+ NSCLC patients were categorized into cohorts of no BMet, early BMet, and delayed BMet. Costs were measured for each BMet category over 12 months, and standardized to per patient per month. **RESULTS:** The study included 207 (48.7%) patients with no BMet and 218 (51.3%) with BMet. Baseline demographics were similar for age (57 and 54), gender (50% male), and Charlson comorbidity index (mean 1.1). The mean time to a BMet was 210 days (median 39). Among patients with BMet, 140 (64.2%) had early BMet, and 78 (35.8%) had delayed BMet. On average, healthcare costs per month in patients with a BMet was \$4,390 higher (median \$3,844) compared to no BMet. Among patients with a BMet, the cost of delayed BMet was \$12,395 lower per month (median \$7,692) than early BMet. **CONCLUSIONS:** BMet is an important indicator of poor prognosis, and is associated with substantial economic burden. The majority of NSCLC patients are diagnosed early with BMet. Delaying the occurrence of BMet in patients may substantially reduce healthcare cost. This study demonstrates an unmet need for therapies that may prevent or delay the occurrence of BMet in ALK+ NSCLC patients.

PCN105

EVALUATION OF A PATIENT ASSISTANCE PROGRAM FOR PEMETREXED AS A MAINTENANCE THERAPY FOR NSCLC IN CHINA

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OBJECTIVES: The study is to evaluate the costs, clinical and social benefits of a patient assistance program (PAP) implemented by the China Primary Health Care

Foundation for the use of pemetrexed in first-line non-squamous non-small cell lung cancer (NSCLC) maintenance therapy in China. **METHODS:** A survival analysis was conducted on the clinical data of 1,366 patients who participated the PAP and treated with pemetrexed from January 1, 2015 to June 30, 2016. The progression free survival (PFS) and median maintenance treatment cycle of pemetrexed were analyzed. A 36-month Markov model from a payer's perspective was constructed to analyze the cost and effectiveness associated with the PAP for pemetrexed. The inputs of the model were sourced from the PAP clinical data and published literatures. The study estimated the incremental quality adjusted life-years (QALYs) (pemetrexed plus best supportive care (BSC) vs. BSC only), the cost saving of the PAP, and the impact on the percentage of catastrophic medical expenditures (CHE) and poverty headcount ratio (HCR). **RESULTS:** The median of PFS and treatment cycles were 187 days and 5 cycles (total 9 cycles, which included 4 cycles of induction therapy), respectively. The pemetrexed plus BSC treatment with PAP resulted in an additional 0.16 QALYs over BSC only (0.78 QALYs vs. 0.62 QALYs). The total cost was \$56,180 and \$79,043 for the patients who have or have not joined the PAP, respectively. Compared to patients without PAP, the percentage of CHE and HCR of PAP was reduced from 95.17% to 71.34% and 80.38% to 44.17%, respectively, indicating that the PAP decreases the number of patients who fall into poverty due to NSCLC treatment. **CONCLUSIONS:** To conclude, pemetrexed PAP is resulted significant clinical and economic benefits to society, and to increase patients' compliance with chemo protocols by allowing patients, for whom the pemetrexed treatment was unaffordable, to continue receive it.

PCN106

COST PER RESPONDER OF BIOLOGIC DRUGS FOR RHEUMATOID ARTHRITIS

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OBJECTIVES: Evaluate the estimated time to achieve breakeven point in a pneumonia vaccination campaign using 13-valent conjugate vaccine in a Brazilian Private Healthcare System (BPHS). **METHODS:** A model developed to measure the time to achieve the breakeven point in a vaccination campaign. For this analysis where taken in consideration pneumococcal diseases epidemiologic data (DATA-SUS); mortality rates, demographic data (IBGE) and vaccine effectiveness, in a cohort of 2 million lives (based on average of top 10 largest Brazilian Private Health Plans). Were considered direct costs regarding patient treatment and indirect costs such as loss working day. For comparison were produced two scenarios: Scenario 1 the campaign was financed in 50% by the healthcare plan and scenario 2, where the cost is 100% with no cost for the patient. **RESULTS:** Applying the demographic rate of age groups were obtained the target population to be vaccinated (N=455,600). The total investment cost of the vaccination campaign for scenario 1 was BRL 30.2 million, and approximately BRL 60.5 million in scenario 2. The total cost of the pneumococcal diseases events were BLR 179.9 million direct expenses; including indirect costs were BLR 255.7 million. The breakeven point of investment in scenario 1 was under 2 years considering only direct costs and approximately 1 year, when including indirect costs. For scenario 2 the point was reached in approximately 3.5 years considering only the direct costs and approximately 2.5 years when including the indirect costs. **CONCLUSIONS:** The vaccination campaign using the 13-valent conjugate vaccine may represent an alternative medium-term investment improving overall health of the policyholder's portfolio, reducing the number of claims. Vaccine properties of immunological memory guarantee that a greater investment is needed only once, at the outset, requiring a lower maintenance cost for new entrants.

PCN107

COST-EFFECTIVENESS OF DRUGS TO TREAT RELAPSE/REFRACTORY MULTIPLE MYELOMA IN THE U.S

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OBJECTIVES: New three-drug regimens have been developed and approved to treat multiple myeloma (MM). The absence of direct comparative data and the high cost of treatment support the need to assess the relative clinical and economic outcomes across all approved regimens. Our objective was to evaluate the cost-effectiveness of treatments for relapsed refractory MM from a U.S. health sector perspective. **METHODS:** We developed a partition survival model with three health states, progression-free, progression, and death. 2nd line regimens included lenalidomide (LEN) + dexamethazone (DEX), Carfilzomib (CAR)+LEN+DEX, elotuzumab (ELO)+LEN+DEX, ixazomib (IX)+LEN+DEX, and daratumumab (DAR)+LEN+DEX, bortezomib (BOR)+DEX, and DAR+BOR+DEX. 3rd line regimens included the above plus panobinostat (PAN)+BOR+DEX. To estimate relative treatment effects, we developed a network meta-analysis and applied progression free survival (PFS) hazard ratios to baseline parametric PFS functions derived from pooled data on LEN+DEX. We estimated overall survival using data on the relationship between PFS and OS from a large meta-analysis of MM patients. Modeled costs included those related to drug treatment, administration, monitoring, adverse events and progression. Utilities were from manufacturer and publicly available data. **RESULTS:** Model results showed regimens containing DAR yielded the highest expected life years and QALYs, with DAR+BOR+DEX (2nd line) and PAN+BOR+DEX (3rd line) being the most cost-effective options. The PAN+BOR+DEX results were subject to data limitations and if removed, DAR+BOR+DEX becomes the most cost-effective option. Model results were most sensitive to the PFS hazard ratios, followed by the estimated link between PFS and

OS, and drug costs. In the probabilistic sensitivity analysis, DAR+BOR+DEX and PAN+BOR+DEX had an 89% and 87% probability of being cost-effective at the \$150,000/QALY threshold, respectively. **CONCLUSIONS:** The new three-drug regimens appear to improve clinical outcomes relative to standard options, however only the addition of DAR or PAN to BOR+DEX may be considered cost-effective at commonly used willingness-to-pay thresholds.

PCN108

COST-EFFECTIVENESS ANALYSIS OF AFATINIB VERSUS GEFITINIB AS FIRST LINE TREATMENT IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC EPIDERMAL GROWTH FACTOR RECEPTOR MUTATION-POSITIVE NON-SMALL CELL LUNG CANCER IN THE BRAZILIAN PRIVATE HEALTHCARE SYSTEM

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OBJECTIVES: To compare costs and effectiveness of afatinib versus gefitinib, as first line treatment of patients with locally advanced or metastatic epidermal growth factor receptor mutation-positive (EGFR+) non-small cell lung cancer (NSCLC) in the Brazilian private healthcare system. **METHODS:** A disease cohort model was used to estimate 7-year progression-free life years (PFLY), life years (LY), Quality-adjusted life years (QALY) and clinical outcomes of afatinib versus gefitinib in the Brazilian setting. The model was fit using partitioned survival data from the LUX-Lung 1, 3 and 6 trials, safety data from the LUX-Lung 1 and 3 trials, and utilities from the LUX-Lung 6 and LUCEOR trials. Comparative effectiveness versus control was estimated using Bayesian indirect treatment comparison. Resource use was estimated by an expert panel consisting of Brazilian oncologists and parameterized using cost estimates from official Brazilian databases. Indirect costs were not considered in this evaluation. Costs and benefits were discounted at a 5% annual rate. **RESULTS:** Base case analysis showed that afatinib was associated with increased progression free survival (0.53 PFLY), increased survival (0.37 LY) and higher quality of life (0.34 QALY) and increased cost (BRL 24,890; 1USD = BRL3,483) versus gefitinib, resulting in an incremental cost-effectiveness ratio of BRL 46,709/PFLY, BRL 67,548/LY and BRL 73,757/QALY. Considering 3 PIB per capita as a threshold (BRL 86,628 per PFLY, LY or QALY), afatinib is a cost-effective technology versus gefitinib. Sensitivity analyses indicated that the conclusion was robust across relevant scenarios. **CONCLUSIONS:** Findings suggest that afatinib is a cost-effective option versus gefitinib as first line treatment in EGFR+ NSCLC patients under the Brazilian private healthcare system.

PCN109

COST-EFFECTIVENESS ANALYSIS OF TRANSCATHETER ARTERIAL CHEMOEMBOLIZATION WITH OR WITHOUT SORAFENIB FOR THE TREATMENT OF UNRESECTABLE HEPATOCELLULAR CARCINOMA

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OBJECTIVES: Transcatheter arterial chemoembolization (TACE) and TACE in combination with sorafenib (TACE-sorafenib) have shown a significant survival benefit for the treatment of unresectable hepatocellular carcinoma (HCC). Adopting either as a first-line therapy carries major cost and resource implications. The objective of this study was to estimate the relative cost-effectiveness of TACE against TACE-sorafenib for unresectable HCC using a decision analytic model. **METHODS:** A Markov cohort model was developed to compare TACE and TACE-sorafenib. Transition probabilities and utilities were obtained from systematic literature reviews, and costs were obtained from West China Hospital, Sichuan University, China. Survival benefits were reported in quality-adjusted life-years (QALYs). The incremental cost-effectiveness ratio (ICER) was calculated. Sensitivity analysis was performed by varying potentially modifiable parameters of the model. **RESULTS:** The base-case analysis showed that TACE cost \$26,950.90 and yielded survival of 0.71 QALYs, and TACE-sorafenib cost \$44,541.70 and yielded survival of 1.01 QALYs in the entire treatment. The ICER of TACE-sorafenib versus TACE was \$57,459.13 per QALY gained, which was above threshold for cost-effectiveness in China. Sensitivity analysis revealed that the major driver of ICER was the cost post TACE-sorafenib therapy with stable state. **CONCLUSIONS:** TACE is a more cost-effective strategy than TACE-sorafenib for the treatment of unresectable HCC.

PCN110

TIMING OF COST-EFFECTIVENESS ANALYSIS IN BREAST CANCER: AN ANALYSIS OF PEER-REVIEWED LITERATURE

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OBJECTIVES: To review the time frame between drug approval dates and their cost-effectiveness analysis publications in breast cancer treatment from a US and European perspective. **METHODS:** A literature analysis was performed using EMBASE to identify cost-effectiveness analyses published from January 2000-December 2016 in breast cancer using the following search criteria: "original articles", "English", "human", "breast cancer", "cost effectiveness analysis" and "drug therapy". The following information was extracted from the identified publications: publication date, type and phase of tumor, type of therapy, country, primary drug, and pharmaceutical sponsor. Drug approval dates were retrieved from Citeline and the regulatory bodies' websites. The time frame between the drug approval date and the publication date of the cost-effectiveness analysis (i.e. delay period) was calculated. **RESULTS:** The initial search yielded 16 publications from the US and 33 from Europe. The most common tumor types were HER2 positive (13/49) and HR positive (7/49); 24 publications did not specify the tumor type. Among the 21 drugs identified in these publications, trastuzumab was the

most common (11/49), followed by anastrozole (5/49) and exemestane (5/49). Twenty-three sponsored (10 US-based, 13 Europe-based), 16 non-sponsored (6 US-based, 10 Europe-based), and 1 publication with unknown sponsorship status were eligible for calculating the delay period. A mean delay of 40.5 months between drug approval and their cost-effectiveness analysis publication dates (SD = 37.4) was found for industry sponsored publications and 33.0 months (SD=28.0) for non-industry sponsored publications. A trend of shorter delay for US publications (29.1 months, SD = 42.4) compared to European publications (43.2 months, SD = 35.3) was observed, regardless of sponsorship. **CONCLUSIONS:** Many healthcare decision makers depend on the peer-reviewed cost-effectiveness analysis literature to make informed value-based decisions. With scarce information available, there is a need for more and timely publications, which could improve drug therapy appraisal of breast cancer treatment.

PCN111

THE COST-EFFECTIVENESS OF PRECISION MEDICINE TREATMENT STRATEGIES FOR DIFFUSE LARGE B-CELL LYMPHOMA

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OBJECTIVES: Diffuse large B cell lymphoma (DLBCL) is comprised of germinal center B cell-like (GCB) and activated B cell-like (ABC) subtypes; the latter is associated with worse survival with standard rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (RCHOP) therapy. Preliminary evidence suggests that novel agents can improve ABC DLBCL survival when added to RCHOP, which motivates the implementation of precision medicine treatment strategies stratified by subtype. Our objective was to project the cost-effectiveness of subtype-based treatment strategies from a US payers' perspective. **METHODS:** We developed micro-simulation models to compare three first-line treatment strategies for DLBCL: (1) standard treatment with RCHOP; (2) lenalidomide+RCHOP (R2CHOP); and (3) subtype-based treatment with subtype testing using immunohistochemistry (IHC) algorithms followed by RCHOP for GCB and R2CHOP for ABC (or non-GCB) DLBCL. Relapsed patients received salvage chemotherapy followed by autologous stem cell transplant as the current standard of care. Subtype-specific survival data were drawn from published clinical studies, and drug and administration costs were based on average wholesale price and Medicare physician fee schedule. We performed one-way and probabilistic sensitivity analyses to assess model robustness. **RESULTS:** RCHOP on average provided 6.2 QALYs (8.1 LYs) at a cost of \$65,700; and subtype-based treatment improved health outcomes by providing 7.9 QALYs (10.2 LYs) at a cost of \$86,400, leading to an incremental cost-effectiveness ratio of \$12,500/QALY (\$9,600/LY). R2CHOP provided 7.8 QALYs (10.5 LYs) at the highest cost of \$123,300, which is dominated by subtype-based treatment. Sensitivity analyses demonstrated that our findings were robust with variations in model parameters. **CONCLUSIONS:** We demonstrated that subtype-based treatment has the potential to be cost-effective across variations in survival benefit and additional cost for the novel treatment. Data from randomized trials are needed to validate the cost-effectiveness profile and to guide the optimal use of standard and novel therapies for DLBCL in clinical practice.

PCN112

COST-EFFECTIVENESS OF PEDIATRIC-INSPIRED VS HYPER-CVAD PROTOCOLS FOR FIRST-LINE TREATMENT OF ADOLESCENT AND YOUNG ADULT (AYA) PATIENTS WITH PHILADELPHIA-NEGATIVE ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)

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OBJECTIVES: Different protocols exist for 1st-line treatment of adolescents and young adult (AYA; 16-39 years) patients with acute lymphoblastic leukemia (ALL). Recent evidence suggests that pediatric-inspired treatment protocols for ALL—which include asparaginase in combination with chemotherapy—are associated with improved clinical outcomes, especially when compared to conventional regimens such as Hyper-CVAD (hyperfractionated cyclophosphamide, vincristine, doxorubicin, dexamethasone). Evidence is, however, limited regarding the cost-effectiveness of pediatric-inspired protocols versus Hyper-CVAD in AYA patients. This analysis estimates the cost-effectiveness of a pediatric-inspired protocol vs. Hyper-CVAD for the first-line treatment of AYA patients with Philadelphia-negative (Ph-) ALL from the US payer perspective. **METHODS:** A 6-state Markov model was developed to estimate expected overall survival, treatment-related costs, and quality-adjusted life years (QALYs) in the 1st-line treatment of ALL over a lifetime horizon. Modeled health states were: no first complete remission, first complete remission, first relapse, second complete remission, second relapse, and death. Model inputs for survival, adverse events, health utility, and costs were obtained from literature. Cost-effectiveness was measured by the incremental cost-effectiveness ratio (ICER; incremental costs/QALY gained). Deterministic and probabilistic sensitivity analyses were performed to evaluate uncertainty around model input values. **RESULTS:** The base-case analysis suggested that, compared with Hyper-CVAD, the pediatric-inspired protocol resulted in increased QALYs and reduced costs (total QALYs gained, 2.05; total cost savings, \$41,685). Sensitivity analysis indicated that the key driver of cost-effectiveness was the probability of stem cell transplantation at second complete remission. At a willingness-to-pay threshold of \$50,000/QALY, the probability of the pediatric-inspired protocol being cost-effective relative to Hyper-CVAD was 92%. **CONCLUSIONS:** A pediatric-inspired protocol including asparaginase for the first-line treatment of AYA patients with Ph- ALL is cost-effective compared to Hyper-CVAD. Cost should not be a barrier to the use of a pediatric-inspired protocol in AYA patients. **Ref:**1. Ram R., et al. *Am J Hematol.* 2012.

PCN113

NUMBER NEEDED TO TREAT AND ASSOCIATED INCREMENTAL COSTS OF TREATMENT WITH ENZALUTAMIDE VERSUS ABIRATERONE ACETATE PLUS PREDNISONE IN CHEMOTHERAPY-NAÏVE PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER IN SPAIN AND THE UNITED KINGDOM

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OBJECTIVES: A number-needed-to-treat (NNT) analysis comparing treatment with enzalutamide (ENZ) with abiraterone acetate plus prednisone (ABI+P) for chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC) concluded that ENZA is cost-effective compared with ABI+P in a US setting. The analysis utilized the payer perspective and explored the incremental costs to achieve one additional patient free of radiographic progression, chemotherapy, or death over a 1-year time horizon. The analysis was adapted to Spain and the UK and estimated the difference in costs between therapies, respectively. **METHODS:** Differences in treatment patterns between countries were adjusted using locally sourced data from reimbursement and treatment guidelines; US unit costs were replaced with 2016 country-specific costs. Also, NNT and clinical outcomes were based on ENZ and ABI+P clinical trial data included in the original US analysis (Massoudi 2016). **RESULTS:** Total cost per treated patient for ENZ was lower than for ABI+P in both Spain (€34,610 versus €36,631) and the UK (£32,531 versus £32,669). Compared with ABI+P, treating 14 patients with ENZ resulted in one additional patient free of progression/death over 1 year at a cost saving of €28,879 (Spain) or £1962 (UK), treating 26 patients with ENZ resulted in one additional patient with chemotherapy delayed over 1 year (cost saving: Spain €53,199; UK £36,151), and treating 91 patients with ENZ resulted in one additional patient surviving over 1 year (cost saving: Spain €183,777; UK £12,487). Thus, ENZ is less costly and more effective for all three outcomes. The models' results suggest that ENZ potentially decreases the risk of disease progression and death and delays chemotherapy initiation in chemotherapy-naïve patients. Results were confirmed among multiple sensitivity analyses. **CONCLUSIONS:** Consistent with the original US analysis, results modeled here for Spanish and UK contexts also suggest that ENZ is cost-effective versus ABI+P for treating chemotherapy-naïve patients with mCRPC.

PCN114

COST-EFFECTIVENESS ANALYSIS OF ENZALUTAMIDE FOR PATIENTS WITH CHEMOTHERAPY-NAÏVE METASTATIC CASTRATION-RESISTANT PROSTATE CANCER IN JAPAN

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OBJECTIVES: To evaluate the cost-effectiveness of enzalutamide in chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC) patients in the Japanese healthcare setting. **METHODS:** A Markov model was developed to capture time spent by patients in various health states: stable, progression, and death. Abiraterone acetate plus prednisone and docetaxel were set as active comparators. Clinical outcomes were obtained from the PREVAIL, COU-AA-302, and TAX327 trials. Treatment sequence, concomitant drugs in each treatment regimen, and therapies for both palliative care and adverse events were estimated from responses to a survey for medical resource consumption by 14 prostate cancer experts. Analytic perspective was public healthcare payer and the time horizon was 10 years. Incremental cost-effectiveness ratio (ICER) was estimated from quality-adjusted life years (QALY) and Japanese public healthcare costs. Both costs and outcomes were discounted by 2%. Probabilistic sensitivity analysis was performed to assess the robustness of the findings. **RESULTS:** According to the survey, the most common treatment sequences (first → second → third) were as follows: 1) enzalutamide → docetaxel → cabazitaxel, 2) abiraterone → enzalutamide → docetaxel, 3) docetaxel → enzalutamide → cabazitaxel. The following sequence was included in a scenario analysis as an alternative sequence of 1: 4) enzalutamide → abiraterone → docetaxel. In the base-case analysis, sequence 1 saved JPY 1.74 million compared with sequence 2, with a 0.129 utility gain (dominant). Sequence 1 had a cost increase of JPY 4.44 million over sequence 3, with a 0.371 utility gain. The ICER of sequence 1 versus sequence 3 was estimated as JPY 11.95 million/QALY gained. Similar results were obtained by the replacement of sequence 1 with sequence 4. Probabilistic sensitivity analysis demonstrated that, compared with sequence 2, the probability of sequence 1 being dominant was 87.4%. **CONCLUSIONS:** The results modeled in the present study suggest that the enzalutamide-first sequencing (1 and 4) is more cost-effective than the abiraterone-first sequencing, but less cost-effective than the docetaxel-first sequencing, for chemotherapy-naïve patients with mCRPC.

PCN115

COMPARISON OF VALUE EVALUATIONS USING DRUG ABACUS AND TRADITIONAL COST-EFFECTIVENESS ANALYSIS FOR AN IMMUNO-ONCOLOGY DRUG IN AN ORPHAN INDICATION

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OBJECTIVES: Extensive research has been conducted to optimally estimate the value of a drug. The Memorial Sloan Kettering Cancer Center (MSKCC)-proposed Drug Abacus and incremental cost effectiveness ratio (ICER) frameworks attempt to estimate the value of oncology drugs, with the latter particularly useful in population medicine. The utility of these frameworks in assessing value of an immune-oncology (IO) agent in an ultra-orphan tumor is not well-documented. **METHODS:** A survival partition model was developed to compare

costs, life years and QALYs for an IO drug vs chemotherapy over the patient's lifetime. A threshold of \$156,000 per QALY and per life year gained was used for the ICER and MSKCC frameworks, respectively. User-modifiable premiums for each dimension for Drug Abacus were varied from 1-3, whilst allowing corresponding variation in the thresholds from \$84,000 to \$226,000 per life year or QALY gained. Conservative assumptions (e.g. no premium for Research and Development) were employed throughout the analyses. **RESULTS:** The monthly value of the drug using the ICER framework ranged from \$4,033-\$14,978 when only survival was considered. Incorporating quality of life decreased the value by \$1,315-\$3,537, whilst the inclusion of toxicity increased the value by \$1,687. Using Drug Abacus the value of the drug related to survival and strength of evidence ranged from \$4,129-\$11,209. Incorporating each of novelty, rarity, population health burden, unmet need and prognosis dimensions were estimated to increase the value by up to a maximum of \$7,669, \$15,338, \$1,534, \$15,338 and \$12,599, respectively. **CONCLUSIONS:** For an ultra-orphan tumor, the additional value dimensions related to disease and drug-specific factors influence the value assessment. Overall, holistic assessment is needed to capture true value of a new IO therapy in rare diseases.

PCN116

COST-EFFECTIVENESS ANALYSIS OF ADDITIONAL BEVACIZUMAB TO CHEMOTHERAPY AS INDUCTION AND MAINTENANCE THERAPY IN METASTATIC NONSMALL-CELL LUNG CANCER

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OBJECTIVES: According to the BEYOND trial, the addition of bevacizumab(B) to paclitaxel-carboplatin (PC) chemotherapy provided a significant clinically benefit in Chinese patients with metastatic nonsquamous non-small cell lung cancer (NSCLC). This study aimed to evaluate the cost-effectiveness of additional B to first-line induction and continuation maintenance therapy from Chinese perspective. **METHODS:** A Markov model was developed to estimate the cost and effectiveness of B plus PC in the induction and maintenance therapy for patients with metastatic nonsquamous NSCLC. Costs were calculated in the Chinese setting and health outcomes derived from the BEYOND trial were measured as quality-adjusted life year (QALY). A one-way sensitive analysis was conducted to explore the impact of parameters in the study. **RESULTS:** The B plus PC group was more costly (\$112,950.19 versus \$32,182.19) and more effective (1.07 QALYs versus 0.80 QALYs) compared with the PC group. Adding B to the PC regimen for nonsquamous NSCLC results an incremental cost-effectiveness ratio \$299,140.78 per QALY, which exceed the accepted societal willingness to pay threshold (\$23,970.00) of China. In the sensitive analysis, duration of progression-free survival (PFS) state for B+PC group, cost of PFS state for B+PC group and the price of B were considered to be the most sensitive factor on the model considered to be the most influential factor. **CONCLUSIONS:** The addition of B to the first-line PC induction and maintenance therapy is not assessed to be a cost-effective strategy for metastatic nonsquamous NSCLC in China, even an assistant program was provided.

PCN117

COST-EFFECTIVENESS OF OLARATUMAB IN COMBINATION WITH DOXORUBICIN FOR THE TREATMENT OF LOCALLY ADVANCED OR METASTATIC SOFT TISSUE SARCOMA IN THE UNITED STATES

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OBJECTIVES: Soft tissue sarcomas (STSs) are rare cancers with poor outcomes for patients with advanced disease (median overall survival [OS] is 12 - 16 months) for which the standard first-line treatment has changed little in 40 years. Recently, the United States (US) Food and Drug Administration conditionally approved olaratumab in combination with doxorubicin (OlaDox) based on a randomized, phase 2 trial in 133 patients (JGDG) that reported a significant OS benefit over single-agent doxorubicin (Dox). We investigated the cost-effectiveness of OlaDox versus Dox and five other standard-of-care regimens for patients with advanced or metastatic STS, from a US payer perspective. **METHODS:** A partitioned survival model comprising three health states (Progression-free, Progressed, and Dead) was developed to estimate costs and outcomes over patients' lifetimes. Efficacy data were based on the JGDG study and a network meta-analysis. Adverse-event rates and costs were from published sources. Progression-free survival was estimated from Kaplan-Meier curves. OS was estimated using parametric functions and age-specific mortality adjusted for STS, assuming no treatment-effect after trial follow-up. One-way sensitivity analyses (OWSAs), probabilistic sensitivity analyses, and scenario analyses were performed to evaluate the uncertainty in all model parameters. Costs and outcomes were discounted at 3% per annum. **RESULTS:** The incremental cost-effectiveness ratio (ICER) estimate for OlaDox versus Dox was \$105,408 per life-year (LY) saved (95% credible interval: \$62,501-\$245,354). Mean costs and LYs for OlaDox increased by \$133,653 and 1.27, respectively. In a fully incremental analysis, all other regimens were dominated or extendedly dominated. In OWSAs and scenario analyses, the ICER per LY saved ranged from \$78,669 to \$190,662. **CONCLUSIONS:** Results suggested a substantial improvement in OS with OlaDox (1.27 LYs versus Dox), and an ICER of \$105,408 per LY. Analyses were based on a small phase 2 trial; an ongoing phase 3 trial is expected to reduce uncertainty in future estimates.

PCN118

COST-EFFECTIVENESS OF IBRUTINIB AS FRONTLINE TREATMENT FOR ADULT PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA IN BELGIUM

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OBJECTIVES: This study aimed to assess the cost-effectiveness of ibrutinib vs. current frontline treatments for elderly/unfit patients with chronic lymphocytic leukemia (CLL), from a Belgian healthcare payer perspective. **METHODS:** A state transition model with three health states (progression-free survival [PFS], post-progression, and death) was used to capture ibrutinib's benefits and costs over patient lifetime. Ibrutinib was compared to chlorambucil monotherapy, chlorambucil + obinutuzumab; bendamustine + rituximab; and physician's choice (PC), a mix of the above treatments, as used in Belgian clinical practice. Data sources for efficacy outcomes included the RESONATE-2 trial (Burger et al. 2015) and results of a network meta-analysis which estimated treatments' relative efficacy based on data from a systematic literature review (SLR). Long-term health outcomes were extrapolated based on trial data; utilities were based on EQ-5D-5L data collected in RESONATE-2 whenever possible, and supplemented by data identified in an SLR; Belgium-specific costs for drugs, administration, monitoring, resource use, and adverse events were used to estimate the incremental cost-effectiveness ratio (ICER). **RESULTS:** Ibrutinib showed incremental health gains of up to 7.13 life years (LYs) and 4.74 quality-adjusted LYs (QALYs). Ibrutinib was also associated with higher costs, largely driven by ibrutinib's superior PFS, which led to longer time on treatment. The resulting ICER was €65,760/QALY gained versus PC and ranged between €51,641 and €76,451/QALY gained versus other comparators. The ICER versus PC was €42,540/LY gained and ranged from €34,361 to €49,424/LY gained versus other treatments. Sensitivity analyses showed that results were influenced by a few drivers, including discount rates for health and cost outcomes, and ibrutinib treatment duration. **CONCLUSIONS:** Results of our analysis indicate that ibrutinib offers a pronounced benefit over comparators for frontline CLL. ICERs are in line with general willingness-to-pay thresholds, demonstrating that ibrutinib represents a cost-effective use of resources for elderly/unfit frontline CLL patients.

PCN119

COST-EFFECTIVENESS OF SUNITINIB VS. PAZOPANIB IN METASTATIC RENAL CELL CARCINOMA (mRCC) IN CANADA USING REAL-WORLD DATA

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OBJECTIVES: Outside of controlled clinical studies, the understanding of the effectiveness and cost associated with targeted therapies for mRCC is limited in Canada. The purpose of this study was to assess the cost-effectiveness of targeted therapies for clear-cell mRCC patients using real-world data from a Canadian database. **METHODS:** First and second-line TTT (time to treatment termination) was determined from the time of initiation of the therapy until discontinuation of therapy. Survival curves (Kaplan-Meier and direct adjusted survival curves) were used to estimate the overall survival by treatment. Cox regression was used to examine the effect of treatment controlling for variables. The costs of drugs were estimated by using the average duration of treatment in each line of therapy based on results from the database. Incremental cost-effectiveness ratio (ICER) was obtained by dividing the difference between the cost of sunitinib and pazopanib and the difference between the mean survivals of sunitinib compared to pazopanib. **RESULTS:** As of June 2016, there were 4314 patients entered in the database as prospective patients with kidney cancer. 376 patients received targeted treatment as part of the management of their disease and were included in the final analysis. 83% of patients were treated with sunitinib and 17% with pazopanib. The median TTT in first line for sunitinib and pazopanib patients was 7.7 and 5.9 months respectively (p=0.0027). The adjusted OS with sunitinib was 33 months compared to 24 months with pazopanib, but there was not a statistically significant difference between the 2 groups (p=0.08). The median cost of therapy for sunitinib and pazopanib was \$57,792 (95%CI : 23,063-119,456) and \$47,872 (95%CI: 28,039-89,041) respectively. The ICER of sunitinib is \$11,905/Life-year gained compared to pazopanib. **CONCLUSIONS:** This incremental survival is linked to a \$11,905/Life-year gained. Based on our real-world evidence, sunitinib is a cost-effective option compared to pazopanib in Canada.

PCN120

COST-EFFECTIVENESS ANALYSIS OF COMPARING GEFITINIB VERSUS CARBOPLATIN-PACLITAXEL AS FIRST-LINE THERAPY FOR ADVANCED NON-SMALL CELL LUNG CANCER WITH SENSITIVE EGFR GENE MUTATIONS FROM A CHINESE PERSPECTIVE

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BACKGROUND: Lung cancer is the leading cause of cancer death. Non-small cell lung cancer (NSCLC) is the most common type of lung cancer, responsible for about 85% of the cases. EGFR tyrosine kinase inhibitors such as gefitinib improved survival for patients with NSCLC, but inevitably increased monetary burden. The people's Republic of China National Health and Family Planning Commission announced the results of the first batch of national drug price negotiations in 2016, the price of gefitinib cut over 50%. **OBJECTIVES:** To evaluate the cost-effectiveness of gefitinib versus carboplatin-paclitaxel as first-line therapy for advanced NSCLC with sensitive epidermal growth factor receptor (EGFR) gene mutations after cost reconciliation in China. **METHODS:** A Markov decision tree based on NEJ002 study was created, comparing gefitinib to carboplatin-paclitaxel in as the first-line treatment for NSCLC harboring an EGFR mutations. Three health states (progression-free survival, progressive disease and death) were analyzed in a Markov model. The costs were calculated from the Chinese societal perspective. Results were reported in Quality-adjusted life year (QALY) and incremental cost-effectiveness ratios (ICERs). **RESULTS:**

Gefitinib was estimated to increase the cost by \$4757.02, with a gain of 0.26 QALY. Gefitinib came at an ICER of \$18296.23 per QALY, which are less than the accepted willingness-to-pay (WTP) threshold of \$23970.00 per QALY in China. **CONCLUSIONS:** Gefitinib is a cost-effective first-line treatment for NSCLC with mutated EGFR when compared with carboplatin–paclitaxel in China.

PCN121

THE COST EFFECTIVENESS ANALYSIS OF CAPOX VERSUS FOLFOX-4 REGIMENS WITH OR WITHOUT BEVACIZUMAB IN THE FIRST LINE MANAGEMENT OF METASTATIC COLORECTAL CANCER (MCR) IN HONG KONG

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OBJECTIVES: This study aimed to investigate if the addition of bevacizumab to CAPOX/FOLFLOX4 was cost-effective as a first-line treatment of MCR in Hong Kong. **METHODS:** This was a retrospective observational study conducted in two public hospitals in Hong Kong. Patients received either CAPOX or FOLFLOX4 with or without bevacizumab from Jan 2011 to Dec 2014 as first-line treatment were included. Direct medical costs were estimated based on Hong Kong Gazette and internal systems in both hospitals. Cost analysis was performed from the healthcare-payer perspective. All costs were expressed in Hong Kong dollar (1USD=7.8HK\$) and 2014 was the base year. QALY were calculated by the product of utility scores from previous literature and PFS from the medical records. Probabilistic sensitivity analysis was conducted to estimate the most cost-effective treatment. **RESULTS:** A total of 105 patients were included. Base case analysis revealed that the total cost for CAPOX and CAPOX with bevacizumab were HKD103,961.35 and HKD180,386.56 respectively while the PFS were 155.5 days and 199.5 days. The total cost of FOLFLOX4 was HKD137,105.81 and HKD322,608.76 for FOLFLOX4 with bevacizumab whereas the PFS is 85 days and 259.5 days respectively. The ICER is HKD1,074,545/QALY when comparing CAPOX with or without bevacizumab and HKD732,103/QALY for FOLFLOX4 counterpart. PSA revealed that there are a 28% and 22% chance for bevacizumab to be cost effective when added to CAPOX and FOLFLOX4 respectively at a willingness-to-pay of HKD935,505, which is three times the GDP per capita of Hong Kong in 2014. **CONCLUSIONS:** The current study demonstrated that adding bevacizumab to FOLFLOX4 was cost-effective but not to CAPOX. However, further studies are required in view of the different limitations encountered in the current study.

PCN122

PATIENT-BASED COST-EFFECTIVENESS ANALYSIS OF FOLFIRI VERSUS FOLFOX7 FOR ADVANCED GASTRIC ADENOCARCINOMA IN CHINA: A FOUR-YEAR PROSPECTIVE RANDOMIZED PHASE II STUDY

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OBJECTIVES: According to the four-year follow-up results of an open, randomized, phase II study, this patient-based cost-effectiveness analysis compares mFOLFIRI (irinotecan, 5-fluorouracil and leucovorin, IRI arm) with mFOLFOX7 (oxaliplatin, 5-fluorouracil and leucovorin, OXA arm) as first-line treatments in patients with locally advanced gastric adenocarcinoma(GC). **METHODS:** A Markov model was created based on previous results reported on 2016 Gastrointestinal Cancers Symposium to evaluate mFOLFIRI and mFOLFOX7 for advanced GC. Quality-adjusted life years (QALY) and incremental cost-effectiveness ratios (ICERs) were examined as the primary outcomes. **RESULTS:** For evaluable 128 patients, treatment efficacy was 0.59 QALYs for IRI arm and 0.70 QALYs for OXA arm, with a total cost of \$13,861.34 for IRI arm and \$14,127.30 for OXA arm. Hence, OXA arm had lower cost per QALY compared with IRI arm contributing to an ICER of \$2,417.82 per QALY for OXA arm, which was below the threshold of 3× per capita GDP of China. For subgroup analysis of those receiving mFOLFIRI followed by mFOLFOX7 (IRI arm) and the reverse (OXA arm), OXA arm gained 0.44 more QALYs compared with IRI arm with a total cost of \$28,890.09 for IRI arm and \$31,147.30 for OXA arm. However, the cost per QALY was also lower for OXA arm compared with IRI arm, leading to an ICER of \$5,129.55 per QALY for OXA arm, which was also below the threshold. **CONCLUSIONS:** Both mFOLFIRI and mFOLFOX7 are affordable for the first-line treatments of advanced GC, but mFOLFOX7 is more cost-effective. Additionally, mFOLFOX7 followed by mFOLFIRI was an optimal sequence with more effectiveness and acceptable cost.

PCN123

COST-EFFECTIVENESS ANALYSIS OF AFATINIB VERSUS ERLOTINIB AS FIRST LINE TREATMENT IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC EPIDERMAL GROWTH FACTOR RECEPTOR MUTATION-POSITIVE (EGFR+) NON-SMALL CELL LUNG CANCER IN THE BRAZILIAN PRIVATE HEALTHCARE SYSTEM

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OBJECTIVES: To compare costs and effectiveness of afatinib versus erlotinib, as first line treatment of patients with locally advanced or metastatic epidermal growth factor receptor mutation-positive (EGFR+) non-small cell lung cancer (NSCLC) in the Brazilian private healthcare system. **METHODS:** A disease cohort model was used to estimate 7-year progression-free life years (PFLY), life years (LY), Quality-adjusted life years (QALY) and clinical outcomes of afatinib versus erlotinib in the Brazilian setting. The model was fit using partitioned survival data from the LUX-Lung 1, 3 and 6 trials, safety data from the LUX-Lung 1 and 3 trials, and utilities from the LUX-Lung 6 and LUCEOR trials. Comparative effectiveness versus control was estimated using Bayesian indirect treatment comparison. Resource use was estimated by an expert panel consisting of Brazilian oncologists and parameterized using cost estimates from official

Brazilian databases. Indirect costs were not considered in this evaluation. Costs and benefits were discounted at a 5% annual rate. **RESULTS:** Afatinib was associated with additional progression free survival (0.46 PFLY), longer survival (0.13 LY) and increased quality of life (0.20 QALYs) with lower total cost (- BRL21,327; 1USD = BRL3,483) versus erlotinib, therefore, afatinib is dominant versus erlotinib. Sensitivity analyses indicated that the conclusion was robust across relevant scenarios. **CONCLUSIONS:** Findings suggest that afatinib is a cost-saving option versus erlotinib as first line treatment in EGFR+ NSCLC patients in the Brazilian private healthcare system.

PCN124

COST-EFFECTIVENESS ANALYSIS OF THE DRUGS REIMBURSED BY THE MEXICAN PUBLIC HEALTH SYSTEM (MPHS) FOR THE SECOND-LINE TREATMENT OF PD-L1 POSITIVE, ADVANCED NON-SMALL-CELL LUNG CANCER (NSCLC)

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OBJECTIVES: This study sought to determine which of the drugs reimbursed by the Mexican Public Health System (MPHS) for the second-line (post platinum-containing chemotherapy) treatment of PD-L1 positive, advanced Non Small-Cell Lung Cancer (NSCLC, target population) is the most efficient, according to health technologies assessment literature. **METHODS:** Through expert consultation, international/national guidelines of treatment review, and Mexican National Formulary assessment, it was determined that the relevant drugs for the analysis were Docetaxel, Pemetrexed and Gemcitabine. A systematic review of the literature was performed to identify relevant phase-III Randomized Controlled Trials (RCTs) and meta-analyses. Fourteen published articles were identified and a random-effects meta-analysis was performed using WINBUGS. A three-state Markov Model (Stable Disease, Progressing Disease and Death) was developed using a parametric fitting of Survival Curves, through a Constant Hazard-Ratio Model. The costs included were cost of the drug (CoD), administration/monitoring, grade 3/4 adverse events attention and Best Supportive Care (BSC) for progressed patients. Costs were obtained from published sources from Mexican government, except for BSC, which was obtained from a modified-Delphi expert panel. The time horizon was 2 years. A Public Payer's perspective was considered. Health outcome assessed was Life Years (LY). Discount rate was 5% for health and costs outcomes. A probabilistic sensitivity analysis (PSA) through Monte Carlo simulations was performed. **RESULTS:** The total cost of Treatment (CoT, in USD) for Docetaxel, Pemetrexed and Gemcitabine was \$10,590, \$16,500 and \$9,850, respectively, where 21%, 37% and 4% was associated with the CoD. The number of LY for Docetaxel, Pemetrexed and Gemcitabine was 0.79, 0.87 and 0.91 respectively. These results were statistically-significant only for costs in the PSA. **CONCLUSIONS:** Gemcitabine is a dominant, thus efficient strategy for the second-line treatment of PD-L1 positive advanced NSCLC from the MPHS perspective. Even under uncertainty, gemcitabine is a cost-saving alternative compared to Docetaxel and Pemetrexed.

PCN125

COST-EFFECTIVENESS OF AFATINIB VERSUS PEMETREXED PLUS CISPLATIN AS FIRST LINE TREATMENT IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC EPIDERMAL GROWTH FACTOR RECEPTOR MUTATION-POSITIVE (EGFR+) NON-SMALL CELL LUNG CANCER (NSCLC) IN THE BRAZILIAN PRIVATE HEALTHCARE SYSTEM

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OBJECTIVES: To compare costs and effectiveness of afatinib versus pemetrexed plus cisplatin, as first line treatment in patients with locally advanced or metastatic epidermal growth factor receptor EGFR mutation-positive (EGFR+) non-small cell lung cancer (NSCLC) in the Brazilian private healthcare system. **METHODS:** A disease cohort model was used to estimate 7-year progression-free life years (PFLY), life years (LY), Quality-adjusted life years (QALY) and clinical outcomes of afatinib versus pemetrexed plus cisplatin in the Brazilian setting. The model was fit using partitioned survival data from the LUX-Lung 1, 3 and 6 trials, safety data from the LUX-Lung 1 and 3 trials, and utilities from the LUX-Lung 6 and LUCEOR trials. Resource use was estimated by an expert panel consisting of Brazilian oncologists and parameterized using cost estimates from official Brazilian databases. Indirect costs were not considered in this evaluation. Costs and benefits were discounted at a 5% annual rate. **RESULTS:** Afatinib was associated with increased progression free survival (0.41 PFLY), increased survival (0.16 LY) and increased quality of life (0.22 QALY) with an incremental increase in cost (BRL8,549; 1 USD = BRL 3,483), resulting in an incremental cost-effectiveness ratio of BRL 20.639/PFLY, BRL 53.280/LY and BRL39.162/QALY. Considering 3 PIB per capita as a threshold (BRL 8,628 per PFLY, LY or QALY), afatinib is a cost-effective technology versus chemotherapy. Sensitivity analyses indicated that the conclusion was robust across relevant scenarios. **CONCLUSIONS:** Findings suggest that afatinib is a cost-effective option as first line treatment for patients with EGFR+ NSCLC versus pemetrexed plus cisplatin in the Brazilian private healthcare system.

PCN126

VALUE DEMONSTRATION OF IMMUNO-ONCOLOGY THERAPIES IN A RARE TUMOR COMPARING ASCO, NCCN, AND TRADITIONAL COST-EFFECTIVENESS ANALYSIS

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OBJECTIVES: Assessing drug “value” is typically based on the trade-off between its clinical benefit using quality-adjusted life-years (QALYs) relative to cost.

Recently, the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN) have proposed alternative frameworks to evaluate the value of oncology drugs. This analysis applies these frameworks vs traditional cost-effectiveness analysis to compare a new immuno-oncology (IO) therapy to chemotherapy in an ultra-rare tumor. **METHODS:** A survival partition model was developed using the approach proposed by the Institute for Clinical and Economic Review (ICER). Under the ASCO framework, net health benefit (NHB) scores between the IO agent vs chemotherapy were compared using survival, toxicity, and bonus points. NCCN Evidence Blocks of efficacy (E), safety (S), consistency (C), quality (Q) of evidence, and affordability (A) were assessed based on benchmarking to IO therapies in other indications and other therapies in the same indication. **RESULTS:** Under ICER, incremental life-years were estimated to be 0.74, with a corresponding increase in QALYs of 0.59, with most gains associated with pre-progression improvement in life-expectancy. Under ASCO, the incremental NHB was estimated to be 189, comprising 157 clinical benefit points, 12 toxicity points, and 20 bonus points for improved survival at the tail of the curve. Efficacy contributed to 94% of the NHB. Under NCCN, the IO therapy scored (E:5, S:4, Q:3, C:2, A:4). Chemotherapy scored lower on all domains apart from affordability (E:1, S:2, Q:2, C:3, A:4). **CONCLUSIONS:** ASCO and NCCN include oncology-specific measures important to patients, whereas ICER is payer focused. Overall, multiple or more holistic value assessments should be considered to capture the true value of an IO therapy in a rare disease space.

PCN128

CAN DOSE ALTERNATING OF SUNITINIB REGIMEN ENHANCE PATIENT'S OUTCOMES AS A FIRST LINE TREATMENT FOR METASTATIC RENAL CELL CARCINOMA?

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OBJECTIVES: Using Sunitinib for treating metastatic renal cell carcinoma (mRCC) is often associated with toxicity necessitating dose reduction. Maintaining adequate dosing & drug levels are essential for optimizing clinical efficacy and these toxicity has negative impact on patient's outcomes and resources which raise a question how Alternative dosing of Sunitinib regimen can enhance patient's outcomes & utilize resources? The main objective for conducting this study is to evaluate the impact of changing Sunitinib regimen to 50 mg once daily, two weeks on and one week off against continuous pazopanib 800 mg once daily for enhance patient's outcomes & resources utilization for metastatic renal cell carcinoma over a time horizon of five years. Cost effectiveness study was conducted for measuring and evaluating outcomes **METHODS:** Markov chain model was applied with three health states. Quality of life data were incorporated. Costs were that of the fund list. Results presented in term of ICER and QALYs. One-dimensional sensitivity analyses were employed. **RESULTS:** During the five-year time horizon, the total cumulative cost for sunitinib 50 mg is 134,079 EGP (exchange with a 1.85 cumulative QALY gained). The total cost for pazopanib was 136,214 EGP with a 1.81 QALY gained. The difference is -2,135 EGP in cost and 0.04 in QALY. The calculated ICER is -55,448. Sensitivity analyses found the results to be most sensitive to utility values during treatment, the progression free survival data and the cost of both Sunitinib and pazopanib **CONCLUSIONS:** Introducing Sunitinib regimen to 50 mg once daily, two weeks on and one week off as a first line for treatment of metastatic renal cell carcinoma was likely to be cost saving. With significant positive impact on patient outcome including

PCN129

COST-EFFECTIVENESS ANALYSIS OF APATINIB COMPARED WITH BEST SUPPORTIVE CARE IN CHEMOTHERAPY-REFRACTORY ADVANCED OR METASTATIC GASTRIC CANCER IN CHINA

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OBJECTIVES: Gastric cancer is the second most common cancer and the second leading cause of cancer-related death in China. It is estimated that approximately half of the new cases are in China. Apatinib, a novel vascular endothelial growth factor receptor 2 tyrosine kinase inhibitor, shows survival benefits in treating chemotherapy-refractory advanced or metastatic gastric or gastroesophageal junction adenocarcinoma in the phase III trial. The objective of this study was to evaluate the cost-effectiveness of apatinib from a Chinese payer's perspective. **METHODS:** A Markov model was developed to simulate disease progression and determine costs and outcomes over a 5-year time horizon. Incremental cost-effectiveness ratio (ICER) of apatinib to best supportive care (BSC) was calculated. Current apatinib patient assistance program (PAP) that offers donation after 3 cycles of treatment is available in China and therefore was taken into consideration in the present analysis. Data of BSC was collected from direct medical record. The model parameters and utilities were derived from previously published trials or literatures, and costs data were obtained from public sources. A 5% annual discount rate was applied to both costs and outcomes. **RESULTS:** Compared with BSC, the improvement following apatinib PAP in life-years (LYs), progression-free life-years (PFLYs), and quality-adjusted life years (QALYs) were 0.303, 0.193 and 0.237 years, respectively. The incremental cost with apatinib was \$4868, yielding the ICER of \$20,540 per QALY gained, which was lower than the willingness-to-pay threshold of \$24,000 per QALY gained. Sensitivity analysis showed that the major drivers of cost effectiveness were treatment-related utility and cost of apatinib. **CONCLUSIONS:** The present analysis suggests that apatinib therapy is cost-effective alternative for patients with advanced or metastatic gastric or gastroesophageal junction adenocarcinoma who failed at least two lines of prior chemotherapy in China.

PCN131

TRABECTEDIN-BASED VERSUS PLATINUM-BASED TREATMENT ON RELAPSED, PARTIALLY PLATINUM SENSITIVE OVARIAN CANCER: AN INDIRECT, ADJUSTED SURVIVAL COMPARISON

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OBJECTIVES: To demonstrate that, on relapsed ovarian cancer (ROC) patients with partially platinum sensitive (PPS) tumors; a non-platinum based treatment - trabectedin plus PEGylated liposomal doxorubicin (T-PLD) - is, at least, as clinically efficacious as a platinum-based strategy (C-PLD). **METHODS:** We performed a MAIC to adjust for differences in baseline characteristics between two phase-III randomized trials involving ROC, PPS patients: IPD was obtained from OVA-301 (T-PLD) whilst aggregated data from CALYPSO (C-PLD). A survival analysis followed, in order to analyze adjusted Overall Survival and Progression Free Survival; ultimately leading towards an adjusted Cox-proportional hazards model to test the non-inferiority hypothesis of T-PLD versus a platinum based therapy. **RESULTS:** After performing the MAIC methodology, T-PLD was found to be, at least, as efficacious when compared to C-PLD as treatment of choice following first progression: adjusted Cox proportional HR for overall survival was 0.90 (95% CI: 0.72-1.14) and for Progression Free Survival 1.18 (95% CI: 0.82-1.26). The adjusted median overall survival values were 25.6 and 23.4 months for T-PLD and C-PLD, respectively. In one particular key subset of patients - those treated with a further platinum-based line after T-PLD -; benefit was more pronounced: with an adjusted median survival of 29.6 months, T-PLD would provide a median life extension of 6.2 months versus C-PLD; whilst still the non-inferiority hypothesis was met (adjusted overall survival HR= 0.85, p > 0.05). **CONCLUSIONS:** Awaiting results from ongoing head to head trials (INOVIATYON), this study strongly points out to a trend towards a significant survival improvement -within the PPS stratum- when a non-platinum combo (T-PLD) is prescribed. The incremental survival -more than 6 months- is an encouraging data for future research, given the poor prognosis and clinical management difficulties observed in this population.

PCN132

HEALTH ECONOMIC EVALUATIONS OF TARGETED THERAPIES FOR METASTATIC RENAL CELL CARCINOMA - A SYSTEMATIC REVIEW

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OBJECTIVES: The availability of several targeted therapies (TTs) since 2005 has improved survival among metastatic renal cell carcinoma (mRCC) patients. However, their high cost imposes a significant burden on patients and healthcare systems. In order to provide an overview of economic value of TTs, we systematically reviewed cost-effectiveness studies of TTs in the U.S and other countries. **METHODS:** We searched Medline/PubMed and CINAHL databases using search terms, MeSH and CINAHL headings related to economic analysis and TTs in mRCC. We included original research published in English from the 2005 to 2016. While screening abstracts, we excluded studies unrelated to economic analysis and studies not comparing TTs to a comparator. We reviewed full texts to exclude commentaries, reviews, resource utilization and cost of illness studies. Study quality was assessed using Quality of Health Economic Studies (QHEs) instrument. **RESULTS:** Of 228 studies found during the initial search, we reviewed 15 that met pre-defined selection criteria. Eight studies assessed first-line and 7 assessed second-line therapies. Two of four studies, which compared first-line TTs to cytokine therapy, found TTs to be cost effective (CE) over cytokine therapy. Three studies had direct comparisons of first-line therapies. Sunitinib was CE compared with bevacizumab and sorafenib in U.S and Sweden while pazopanib dominated sunitinib in the U.S and Canada. Five studies compared TTs to best supportive care (BSC). Only sunitinib was CE compared to BSC. Among second-line direct comparisons, everolimus (in the U.S) and axitinib (in Cyprus) were CE compared with sorafenib. Of 15 studies, 12 were good quality studies (QHEs-score ≥ 75 of 100) with mean score of 81.8 (SD: ± 10.1). **CONCLUSIONS:** No drug was CE consistently across all studies. Evidence varied by country and accepted willingness to pay thresholds. Few direct comparisons of first and second-line therapies are available to draw conclusions among targeted therapies.

PCN133

COST-UTILITY OF OBINUTUZUMAB IN PREVIOUSLY UNTREATED FOLLICULAR LYMPHOMA

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OBJECTIVES: Follicular lymphoma (FL) is the most common subtype of indolent non-Hodgkin lymphoma, typically treated with a rituximab-containing immunochemotherapy regimen. The randomized, phase 3 GALLIUM trial showed an increase in progression-free survival (PFS) for patients with previously untreated FL when receiving obinutuzumab plus chemotherapy (G-chemo) compared to rituximab plus chemotherapy (R-chemo). The objective of this study is to assess the cost-effectiveness of G-chemo versus R-chemo for previously untreated FL from a US payer perspective. **METHODS:** A three-state partition survival model was developed using GALLIUM PFS and overall survival (OS) data to model long-term outcomes over a 30-year time frame. CDC life tables were used to inform background mortality rates for patients with FL. Adverse event frequencies were obtained from trial data, and costs were calculated using Average Sales Price (ASP) and Medicare reimbursement rates. Utility estimates for pre-progressive and post-progressive states were obtained from literature. **RESULTS:** Treatment with G-chemo resulted in an incremental gain of 0.84 life-years, or 0.68 quality-adjusted life years (QALYs) compared to R-chemo. The total costs over a 30-year horizon were \$308,527 for G-chemo and \$293,356 for R-chemo, resulting in an incremental cost of \$15,171. Treatment with G-chemo was associated with higher treatment costs, which were offset somewhat by lower post-progression costs. Adverse event frequencies and costs were also higher for G-chemo. The incremental cost-effectiveness ratio (ICER) for G-chemo versus R-chemo

was \$22,161 per QALY gained, which is cost-effective at a \$50,000 per QALY threshold. The one-way sensitivity analysis showed that model results were most sensitive to PFS parameters for G-chemo and R-chemo, followed by drug costs and patient utilities. **CONCLUSIONS:** Treatment with G-chemo is likely cost-effective compared to R-chemo from a US payer perspective in the setting of previously untreated FL. The higher treatment costs of G-chemo are offset by gains in QALYs and delayed progression of disease.

PCN134

COST-EFFECTIVENESS OF RITUXIMAB IN ADDITION TO STANDARD OF CARE CHEMOTHERAPY FOR ADULT PATIENTS WITH ACUTE LYMPHOBLASTIC LEUKEMIA

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OBJECTIVES: Acute lymphoblastic leukemia (ALL) is an aggressive but potentially curable form of leukemia. Rituximab, an anti-CD20 monoclonal antibody, in addition to standard chemotherapy represents a novel therapeutic option for adults with the Philadelphia chromosome-negative, CD20-positive, B-cell precursor ALL sub-type (CD20+ Ph- BCP-ALL). The objective of this analysis is to determine the economic impact to the Canadian public provincial healthcare payer of rituximab in addition to standard of care (SOC) chemotherapy vs. SOC alone in newly diagnosed CD20+ Ph- BCP-ALL. **METHODS:** A decision analytic model included the following health states over a 15-year time-horizon: event-free survival, relapsed/resistant disease, cure and death. SOC was with the two most widely used chemotherapy regimens in Canada: Hyper-CVAD or Dana Farber Cancer Institute (DFCI). Both regimens contained multiple treatment phases. Event-free survival, overall survival and serious adverse event (SAE) rates were taken from a recent major randomized controlled trial. Costs of the model included: first-, second- and third-line treatment and administration; disease management; palliative care; and SAE-related treatments. Model inputs were sourced from public data, literature and cancer agency input. **RESULTS:** Rituximab in addition to SOC resulted in 1.33 greater life-years, 1.16 greater quality-adjusted life-years (QALYs) and \$51,679 incremental costs. The resulting mean ICER was \$39,563/QALY. At a willingness-to-pay threshold of \$100,000/QALY, the probability of being cost-effective was 96%. Decision outcomes were robust to the probabilistic and deterministic sensitivity analyses. **CONCLUSIONS:** For adults with CD20+ Ph-BCP-ALL, rituximab in addition to SOC was found to be a cost-effective intervention, compared to SOC alone from a Canadian public payer perspective.

PCN135

AN ECONOMIC EVALUATION OF CABOZANTINIB VS. EVEROLIMUS IN THE SECOND-LINE TREATMENT OF ADVANCED RENAL CELL CARCINOMA

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OBJECTIVES: The objective of this economic evaluation was to determine the cost-effectiveness of cabozantinib versus everolimus in the treatment of advanced renal cell carcinoma using a United States payer perspective. **METHODS:** A partitioned survival model was developed that contained three health states: 1) Stable (progression-free), 2) Progressed, and 3) Death. Data for the model with regard to survival, costs, and utilities was gathered via a variety of sources, including the METEOR trial, national databases, and existing literature. Methods described by Hoyle and Henley et al. were used to derive parametric survival functions from the available Kaplan-Meier curves. Model outcomes included total life-years, quality-adjusted life-years (QALYs), total costs, cost per life-year gained and cost per QALY gained. Sensitivity analyses were performed to evaluate the impact of parameter uncertainty on model results. **RESULTS:** Individuals treated with cabozantinib gained on average an additional 0.44 LYs compared to those treated with everolimus. In addition, individuals treated with cabozantinib gained on average an additional 0.32 QALYs compared to those treated with everolimus. However, treatment with cabozantinib was associated with a greater cost of \$49,811 compared to treatment with everolimus. This resulted in incremental cost effectiveness ratios of \$112,318/LY and \$154,194/QALY. Model results were most sensitive to cabozantinib cost, everolimus cost, utility for the stable (progression-free) state, utility for the progressed state, and cost associated with the progressed state. **CONCLUSIONS:** These results suggest that cabozantinib may not represent a cost-effective option in the second-line treatment of advanced renal cell carcinoma compared to the standard-of-care option everolimus based on common willingness-to-pay thresholds.

PCN136

MOLECULAR PROFILE SELECTION IN ADVANCED HEAD AND NECK CANCER: A COST-EFFECTIVENESS ANALYSIS

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OBJECTIVES: Relapsed/metastatic head and neck squamous cell cancer patients are offered a combination of platinum-based chemotherapy (PF, cisplatin-fluorouracil) plus cetuximab regimen (PF+C) according to results of the Extreme trial. However, two economic evaluations showed that addition of cetuximab was not cost effective. This study aims at evaluating the cost-effectiveness of a putative predictive molecular test (MT) to identify and treat only patients potentially responsive to cetuximab when added to PF. **METHODS:** A Markov model was developed to compare both health and economic outcomes of PF+C regimen administered to all patients (PF+C ALL) versus the regimen administered only to MT-positive patients (PF+C POS). The model considered partial/complete

response with or without mild/severe adverse events (AEs), progression and death. Rates of progression and survival, response rates to systemic treatment and adverse events were retrieved from the Extreme trial. Baseline utility coefficients for disease control and progression were retrieved from the literature (0.67 and 0.52, respectively). Only direct costs estimated from the Italian Health Service perspective were included (tariffs and DRGs reimbursements). The model was evaluated according to a cut-off of MT sensitivity at 85% and specificity at 70%. A 3 years horizon was chosen. Life expectancy, QALYs and costs were discounted at 3.5% annually. **RESULTS:** Applying the WHO cost-effectiveness threshold of 3 times the gross domestic product for Italy (66,402€), PF+C POS resulted a cost-effective choice in comparison to PF+C ALL for a MT cost lower than 5,750€. **CONCLUSIONS:** Adding cetuximab to PF only to patients positive to a predictive test may be cost-effective. Efforts should be spent to build such a test upon existing evidences in order to save resources for the health systems and spare unnecessary toxicities to patients.

PCN137

A REVIEW OF GLOBAL COST-EFFECTIVENESS STUDIES IN RENAL CELL CARCINOMA FOR AXITINIB

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OBJECTIVES: Renal cell carcinoma (RCC) is a kidney cancer with an estimated worldwide incidence of 338,000. Five year survival for patients diagnosed with late-stage RCC is estimated to be < 10%. This study reviewed the literature to find studies estimating the cost-effectiveness of axitinib globally. **METHODS:** A search of the literature was conducting using PubMed, the Tufts CEA Registry, and the ASCO and ISPOR abstract databases. The search string in PubMed was: "Renal Cell Carcinoma[title] AND Cost-Effectiveness[title]". The Tufts CEA Registry was searched using only: "Renal Cell Carcinoma". Both conference abstract databases were queried using: "Renal Cell Carcinoma[title] AND Cost-Effectiveness[title]". Studies returned in the searches were then reviewed by two independent researchers for inclusion into our study. Included studies were examined and the indication, setting, sponsor, perspective, model type, discount rate, comparators, and results were extracted. **RESULTS:** A total of 6 cost-effectiveness studies were included. Two studies focused on the United States, while the other four examined the cost-effectiveness in Colombia, the Czech Republic, the United Kingdom, and Cyprus. Five of the six studies were funded by the pharmaceutical industry (Novartis, Pfizer, and Bayer), and one was an academic study. All studies examined axitinib as a second-line therapy. Axitinib was compared to everolimus in three studies and sorafenib in three studies. When compared to everolimus, axitinib was dominant in one study (Czech Republic) and dominated in the other two studies (Colombia and UK). When compared to sorafenib, axitinib had higher costs and higher health outcomes in all three studies. ICERs ranged from 87,936 euros per QALY (Cyprus) to \$683,209 USD per life year (U.S.). **CONCLUSIONS:** Axitinib had higher incremental health outcomes in four of six studies. The cost-effectiveness of axitinib is dependent on the study setting, perspective, and comparator.

PCN138

PHARMACOECONOMIC EVALUATION OF Nilotinib VERSUS Imatinib IN THE FIRST-LINE TREATMENT OF CHRONIC MYELOID LEUKEMIA: A SYSTEMATIC REVIEW

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OBJECTIVES: To give an overview of available evidence on cost-effectiveness of nilotinib (NL) versus imatinib (IM) for the first-line treatment of chronic myeloid leukemia (CML) as well as the quality of these studies. **METHODS:** All studies were searched in 3 electronic databases (PubMed, ScienDirect and Cochrane) with key words through the MeSH tool. After searching, screening identified studies with inclusion and exclusion criteria, data extraction and summary of results into pre-specified information table were undertaken. The studies were included if they were an original economic evaluation of NL versus IM in the first-line treatment of CML, written in English and conducted in the newly diagnosed patients. Abstracts of citations found that met the specified inclusion criteria were also reviewed. To compare and overview the results of studies, all currency values were transferred into \$USD in 2015 based on Consumer Price Index. The report's quality of the studies was evaluated by 3 blinded reviewers based on the Quality of Health Economic Studies (QHES) tool with 16 questions. **RESULTS:** From a total 159 detected papers, 10 studies were extracted data and 3 studies were selected to evaluate the quality. Cost-effectiveness analysis, Markov model and sensitivity analysis were mostly used methods in these studies. Most researches used direct costs and used QALY as outcome. The converted ICUR/QALY of studies reached \$866,436/QALY. Based on WTP threshold, 8/10 studies concluded that NL was cost-effectiveness compared with IM in the first-line of CML. Using QHES it has been shown the high quality of these studies with the mean score of 97 (1.73) on a scale of 100. **CONCLUSIONS:** Most studies suggested that NL was cost-effective compared with IM in the first-line treatment of CML patients and the report's quality of studies was very high.

PCN139

A RETROSPECTIVE ANALYSIS OF GENOMIC RISK STRATIFICATION ASSAYS FOR COLON CANCER

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OBJECTIVES: Multi-gene assays and microarray technologies are being used increasingly for risk stratification of stage II colon cancer patients to predict disease relapse and guide adjuvant therapy decisions. Our objective was to

evaluate the outcomes and cost-effectiveness of using ColoPrint (Agendia Inc., Irvine, CA) as compared with Oncotype DX Colon Cancer Assay (Genomic Health Inc., Redwood City, CA) in the treatment of stage II colon cancer patients. **METHODS:** As part of a larger study to develop a Markov model, we conducted a review of the literature from January 2005 to December 2016 to assess data on risk classification; recurrence rates, transition probabilities, utilities and costs used for GEP assays in patients with stage II colon cancer. We investigated outcomes in three stages - no recurrence, recurrence, and death. For costs, we considered gene test costs; the costs of adjuvant chemotherapy, costs associated with adverse events and treatment, the cost of treating recurrence, and end-of-life care costs. **RESULTS:** A retrospective data analysis of 6,064 patients for both multi-gene assays in stage II or III colon cancer was conducted. We found that the recurrence score (RS) and microsatellite (MSI) status are the most reliable factors for prognosis of stage II colon cancer patients. For 5,307 patients using Oncotype DX, we found RS of 780 patients (14.69%) were in the low risk group, 990 patients (18.65%) in the intermediate risk group and 950 patients (17.90%) in the high-risk group. For 757 patients using ColoPrint, we found that the MSI status of 485 patients (64.06%) was in the low risk group and 272 patients were (35.93%) in the high-risk group. **CONCLUSIONS:** Multi-gene assays can predict the development of distant metastasis of patients with stage II colon cancer and may improve prognostic accuracy for safe therapeutic management of patients in treatment decisions about chemotherapy.

PCN140

COST-EFFICACY ANALYSIS OF THE PHARMACOGENETICS TEST FOR THE TPMT IN ACUTE LYMPHOBLASTIC LEUKEMIA

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OBJECTIVES: The potential impact of pharmacogenetics on healthcare are still uncertain. Toxicities derived from the use of 6-mercaptopurine can be prevented by the genotyping of the thiopurine-methyltransferase (TPMT) enzyme. The aim of this study is to elaborate a cost-efficacy analysis for the determination of TPMT genotype in children with Acute Lymphoblastic Leukemia(ALL) using an economic and simple method for the pharmacogenetic determination. **METHODS:** We perform this analysis using the Ramos(2015) method from a dried blood drop deposited in collection cards for the genomic-DNA extraction. Genetic variants of TPMT analyzed were: 2*,3A*,3B*,3C* and 4*. Polymorphisms determination was performed by PCR using fluorescent probe. The sensitivity of our method is 99% (data not show). The cost of each genetic determination was 1.16€. Therefore the genotyping of a patient was 4.64€. Leucopenia is the most severe adverse event(AE) associated with thiopurine treatment. For the economic analysis we considered that the frequency of occurrence of AE would be 3% (Sanderson-2004), and 1/3 of this AE are related to TPMT decreased activity (Marra (2002)). 2/3 of patients suffering significant leucopenia could be managed as out-patients, requiring two additional visits (132€). The mean hospital stay of a child with ALL with severe myelosuppression is 10 days (480€/day). The health-costs were taken from the Official Bulletin of Canary-Islands, 2015. The cost-efficacy analysis was done for a hypothetical cohort of 2.000 children with ALL. **RESULTS:** For the study population are estimated 60 patients will develop severe myelosuppression. In 20 patients this AE are related to TPMT deficiency with a cost associated: 7 hospitalized patients (70 days/33.600 €), 13 out-patients (1.716€). The TPMT genotyping costs for 2000 patients will be 9.280€. So the cost saving will be 26.036€. **CONCLUSIONS:** Our analysis indicates that TPMT genotyping could be considered as an integral part of healthcare prior to the initiation of therapy with thiopurine drugs.

PCN141

A COST MINIMIZATION ANALYSIS OF ORAL VINORELBINE VERSUS IV CHEMOTHERAPIES FOR THE TREATMENT OF NON-SMALL CELL LUNG CANCER AND METASTATIC BREAST CANCER FROM CHINESE SOCIETAL PERSPECTIVE

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OBJECTIVES: Consideration of medical costs as well as effectiveness and adverse events is becoming an important factor in the selection of chemotherapy regimens. Oral vinorelbine is recently approved for use of advanced non-small cell lung cancer (NSCLC) and metastatic breast cancer (mBC) in China. We conducted a cost minimization analysis for oral vinorelbine versus selected IV chemotherapies in treating advanced NSCLC and mBC from Chinese societal perspective for the purpose of facilitating evidence-based decision-making process. **METHODS:** Literature review indicated a comparable clinical efficacy between oral vinorelbine and its IV comparators (pemetrexed, gemcitabine and docetaxel in NSCLC; paclitaxel, gemcitabine and docetaxel in mBC). Thus, a cost-minimization analysis that assumes the same efficacy was conducted. Total costs for oral vinorelbine included drug acquisition price, adverse events (AEs) treatment cost, travel/delivery expense, medical examination cost, premedication and other costs. Total costs for IV comparators included drug acquisition price, AEs cost, travel expense, medical examination cost, hospitalization bed fee/ IV chair fee, medical supplies, premedication, patients' productivity loss and HCP labor cost. Cost information were retrieved from a previously completed time and motion analysis as well as a KOL survey. The model simulated total costs for four cycles of treatment. Only single-agent chemotherapy was considered. **RESULTS:** In NSCLC, the total

treatment costs per treatment (four cycles)for oral vinorelbine, pemetrexed, gemcitabine and docetaxel were ¥61,848.68, ¥117,864.87, ¥71,060.94, and ¥64,162.87 respectively. Oral vinorelbine achieved cost reduction of ¥56,016.19, ¥9,212.26 and ¥2,314.19 respectively. In mBC, the total treatment costs per treatment for oral vinorelbine, paclitaxel, gemcitabine and docetaxel were ¥61,848.68, ¥66,509.64, ¥68,077.14, and ¥62,600.67 respectively. Oral vinorelbine achieved cost reduction of ¥4,660.96, ¥6,228.46 and ¥751.99 respectively. **CONCLUSIONS:** Oral vinorelbine leads to a much lower total cost compared with pemetrexed, gemcitabine, docetaxel and paclitaxel in treating NSCLC and mBC from Chinese societal perspective.

PCN142

ROBOT-ASSISTED RADICAL PROSTATECTOMY: A COST-UTILITY ANALYSIS

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OBJECTIVES: Use of the robotic surgical system for radical prostatectomy (also called Robot-assisted radical prostatectomy (RARP)) is rapidly diffusing as an alternate to open radical prostatectomy (ORP). We assessed the economic implications of RARP compared with ORP in patients with localized prostate cancer. **METHODS:** We conducted a cost-utility analysis with a one-year time horizon from the perspective of the public payer in Ontario, Canada. Cost and utility parameters were mainly based on a recently published randomized controlled trial comparing the perioperative, functional, and oncological outcomes of patients receiving RARP or ORP at early 12 week follow-up. Potential long-term effects of RARP were evaluated in a scenario analysis using a 10-year Markov model. Budget impact was assessed assuming an increased RARP uptake in the next 5 years. **RESULTS:** Compared with ORP, RARP was associated with higher costs (\$6,234 CAD) and small gains in quality-adjusted life years (QALYs) (0.0012), resulting in a base case incremental cost-effectiveness ratio (ICER) of \$5.2 million/QALY gained. Key variables that influenced the ICER included post-surgery utilities, the service life of the robotic surgical system and the costs of disposables for the RARP. Results from the probabilistic sensitivity analysis were consistent with the base case. If RARP was assumed to have substantially better functional and oncological outcomes in the long term, the ICER could decrease below \$100,000/QALY. The annual budget increase was estimated to be \$0.8 million to \$3.4 million CAD over the next five years, assuming an increased uptake of RARP (40% to 60% in Year 1 to 5 respectively versus current uptake rate of 34%). **CONCLUSIONS:** The robotic surgical system is not likely to be cost-effective for radical prostatectomy compared with ORP. If the diffusion rate of RARP continues to increase, it would lead to a considerable budget increase if this device was publicly funded.

PCN143

COST-UTILITY ANALYSIS OF GEFITINIB AND EGFR MUTATION TESTING AS THE FIRST-LINE TREATMENT FOR NON-SMALL CELL LUNG CANCER IN VIETNAM

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OBJECTIVES: Gefitinib is an orally administered epidermal growth factor receptor tyrosine kinase inhibitor (EGFR-TKI). The combination of gefitinib and EGFR mutation testing was approved as a standard first-line therapy for non-small cell lung cancer (NSCLC) patients. This research evaluated the cost-utility of this targeted therapy to standard chemotherapy in Vietnam. **METHODS:** A three-state Markov model was developed based on the perspective of the insurance organization to achieve objectives. The quality-adjusted life year (QALY), direct medical cost, incremental cost-utility ratio (ICUR) were estimated. One-way sensitivity analysis was performed to evaluate uncertainties of parameters. **RESULTS:** The combination of EGFR mutation testing and gefitinib saved 43.5% cost of treatment compared to that of standard chemotherapy (111.34 millions VND and 196.94 millions VND, respectively). Patients treated with gefitinib-contained regimen gained more 0.3 QALY than those with standard chemotherapy (8.66 QALY and 8.36 QALY, respectively). These results suggested that gefitinib and EGFR mutation testing was totally cost-effective compared with standard chemotherapy in Vietnam. These results were supported by the one-way probabilistic sensitivity analysis. **CONCLUSIONS:** Based on the analysis, the combination of gefitinib and EGFR mutation testing was considered a cost-effective first-line therapy compared to standard chemotherapy such as paclitaxel plus carboplatin for NSCLC in Vietnam.

PCN144

COST-UTILITY OF NIVOLUMAB AGAINST DOCETAXEL FOR THE TREATMENT OF ADVANCED NON-SQUAMOUS NON-SMALL CELL LUNG CANCER (NSCLC) IN UNITED ARAB EMIRATES (UAE)

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OBJECTIVES: This study aims to evaluate the cost-utility of nivolumab after prior chemotherapy compared with docetaxel in patients with locally advanced or metastatic non-squamous NSCLC from a UAE healthcare payer perspective. **METHODS:** A partitioned survival analysis model with 1-week cycle length was developed to simulate patients flowing through three main health-states: 'Progression-free', 'Progressive-disease', and 'death'. Survival, clinical and utilities input data for the comparison of nivolumab and docetaxel were derived from CheckMate-057 clinical trial. Local cost and resource utilization were estimated based on local institutions price indices and expert opinion Delphi exercise. A 20-year time-horizon and discount rates of 5% for costs and 3.5% for outcomes were used. **RESULTS:** In the base case analysis, the model estimates nivolumab to

provide 1.59 QALYs and 2.25 LYG vs. 0.76 QALYs and 1.04 LYG by docetaxel. A higher proportion of patients in the nivolumab cohort were estimated to be alive at years 1 and 2 compared with the docetaxel cohort; 48% at year 1 and 29% at year 2 on nivolumab vs. 41% and 13% on docetaxel, respectively. Total cost of the nivolumab cohort was estimated at AED 399,792 vs. AED 134,403 for docetaxel; which resulted in an estimated ICER at AED 318,653/QALY. Assuming a UAE willingness-to-pay threshold of AED 445,231/QALY (3GDP per capita) gained, nivolumab would be considered cost-effective against docetaxel. The results were robust to all parameters tested in sensitivity analysis with the discount rate of outcomes and average body weight being the main influential variables. Probabilistic sensitivity analysis indicated that nivolumab had a 92% chance of being cost-effective against docetaxel at the assumed willingness-to-pay threshold. **CONCLUSIONS:** Given the substantial improvement in clinical efficacy and a favorable ICER, nivolumab constitutes a cost-effective second line treatment option when compared to docetaxel from a UAE healthcare payer perspectives under the current model assumptions.

PCN146

PRODUCTIVITY LOSS AMONG PATIENTS WITH NEWLY DIAGNOSED MULTIPLE MYELOMA IN THE UNITED STATES

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OBJECTIVES: To evaluate workplace productivity loss among U.S. adult patients in the six months following an initial diagnosis with multiple myeloma (MM) who were treated with MM-directed drug therapies alone (DT) versus with autologous stem cell transplant (SCT). **METHODS:** A retrospective analysis was conducted using the Truven Health Analytics MarketScan Commercial Claims and Encounters (CCAE) and Health and Productivity Management (HPM) databases. Employed patients with six months of continuous enrollment in their medical benefits plan and for disability benefits (long term disability (LTD), short term disability (STD), workplace absenteeism (WAB)) were included in the analysis. **RESULTS:** 698 patients (mean age=52.8 years) met inclusion/exclusion criteria and were included in the study cohort. Of these, 323 patients (46%) used some form of disability benefit in the 6 months after initial diagnosis, compared to 193 (28%) in the six months prior to diagnosis (RR: 1.7, 95% CI: 1.4-1.9, p<0.001). Patients who used any disability benefit after diagnosis used a median of 18.5 disability days. Workplace absenteeism after initial diagnosis was the most common disability benefit used (85% of patients with absenteeism eligibility), followed by short term disability (14% of eligible patients), and long term disability (4% of eligible patients). The median number of disability days was higher among patients receiving SCT vs. DT (138.5 vs. 105.5 days, p=0.5 by Kruskal Wallis test). In sensitivity analysis using a cohort with 12 months follow-up after diagnosis, patients receiving SCT had significantly more disability days versus DT (145 vs. 112 days, p=0.01 by Kruskal Wallis test). **CONCLUSIONS:** Diagnosis of multiple myeloma is associated with significant productivity loss, as measured by use of disability benefits. Nearly half of all patients diagnosed with MM experience productivity loss. Both SCT and drug treatment are associated with productivity loss. Future work will assess the economic impact of this productivity loss.

PCN147

ECONOMIC BURDEN AND SURVIVAL ANALYSIS OF RELAPSE FOLLOWING HLA IDENTICAL ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION FOR THE MANAGEMENT OF ACUTE LEUKEMIA AND MYELODYSPLASTIC SYNDROME

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OBJECTIVES: Relapse following allogeneic hematopoietic stem cell transplant (aHSCT) is usually associated with poor outcomes. The impact of treatment choice on costs and survival remains unknown. The objective of this study was to measure the economic burden associated with the management of relapse following aHSCT and the impact of treatment on survival and healthcare costs. **METHODS:** A retrospective medical chart review was conducted in a HSCT specialized center in Montreal (Canada). Eligible patients were diagnosed with acute leukemia (AL) or myelodysplastic syndrome (MDS) and relapsed following a human leukocyte antigen (HLA) identical aHSCT between January 2011 and December 2014. Patients and disease characteristics as well as relapse-related healthcare resources were collected from date of relapse until death or last follow-up. Canadian unit costs for each resource were obtained from literature and governmental publications. **RESULTS:** A total of 36 patients were included in the analysis. Of these, 4 were diagnosed with MDS and 32 with AL. Treatment approaches following aHSCT relapse were divided in three groups: group 1 received supportive care (n=9), group 2 received chemotherapy or tyrosine kinase inhibitors (n=21) and group 3 received a cellular based therapy, either donor lymphocyte infusion or a second aHSCT (n=6). The mean cost per patient per month was C\$20,239 (SD=17,079). The mean survival following relapse was 12.4 months (SD=2.8). For group 1, 2 and 3, the mean cost per patient per month was C\$17,436 (SD=16,447), C\$22,914 (SD=18,474), C\$15,082 (SD=12,954), respectively. For group 1, 2 and 3, the mean survival was 4.0 months (SD=2.0), 7.2 months (SD=1.6), and 44.6 months (SD=8.4), respectively. **CONCLUSIONS:** Results demonstrate that compared to other treatments, cellular therapy following aHSCT is associated with a prolonged survival at a similar cost per patient per month and appear cost effective. Further studies with larger sample sizes are needed to confirm these findings.

PCN148

CAN SURGICAL TECHNIQUE IMPACT LENGTH OF STAY AND POST-OPERATIVE OUTCOMES IN BREAST RECONSTRUCTION?

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OBJECTIVES: Pre-pectoral breast reconstruction is a less invasive technique compared to dual plane technique and shows promise in improving patient outcomes. This study compares hospital length of stay (LOS) and post-operative outcomes of pre-pectoral (PP) and dual plane (DP) techniques of breast reconstruction. **METHODS:** This single-site, retrospective cohort study included data from breast reconstruction procedures from June 2013 to March 2016. Data collected included demographics, chemotherapy/radiation exposure, surgical technique, LOS, drain usage, post-operative incision care and 90 day post-operative complications. Two-sided T-test and Chi-square or Fisher's Exact tests were performed at $\alpha = 0.05$. **RESULTS:** The study included data on 176 patients (DP=117, PP=59) and 335 breasts (DP=225, PP=110). The PP group had a higher BMI (29.5 vs. 26.3 kg/m²; p=0.0017), and a significantly higher proportion of patients with diabetes (13.6% vs. 2.6%; p=0.0073), hypertension (35.6% vs. 17.1%; p=0.0061), and prior breast surgery (36.8% vs. 22.2%; p=0.0415). A higher proportion of PP patients received cINPT (57.6% vs. 25.6%; p<0.0001) compared to the DP group. There were no differences in complication rates between the two groups. The PP group had a significantly lower LOS compared to DP (mean: 1.1 vs. 1.8 days, p<0.0001). Nearly 95% of PP patients were discharged after 1 hospital day compared to only 25.6% of the DP patients (p<0.0001). Results of multiple regression models were similar to the univariate analyses after controlling for effects of age, BMI, cINPT use, diabetes, hypertension and prior breast surgery. **CONCLUSIONS:** This study demonstrated a significantly lower hospital LOS in the PP group compared to DP technique. Complication rates were similar between the two groups even though the PP group was more complex. Studies with a long-term follow up will be critical in understanding the true differences between surgical technique and clinical outcomes.

PCN149

ANALYSES OF HEALTHCARE RESOURCE UTILIZATION (HCRU) IN CHECKMATE 141, A PHASE 3 STUDY OF NIVOLUMAB VERSUS INVESTIGATOR'S CHOICE (IC) IN PATIENTS WITH RECURRENT OR METASTATIC (R/M) PLATINUM-REFRACTORY SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK (SCCHN)

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OBJECTIVES: In CheckMate 141 (NCT02105636), nivolumab was shown to have survival and health-related quality-of-life benefits versus IC of single-agent therapy (methotrexate, docetaxel, or cetuximab) in patients with platinum-refractory R/M SCCHN. Using data from CheckMate 141, we assessed the impact of treating platinum-refractory R/M SCCHN with nivolumab versus IC on HCRU and associated costs. **METHODS:** Using non-protocol-specified hospitalization and medical visit data from CheckMate 141, the number of HCRU events and percentage of patients who experienced those events were compared between treatment arms from baseline through end of safety follow-up. Negative binomial regression adjusting for patient differences in length of study follow-up was used to examine differences in HCRU by treatment arm, with coefficients transformed to incidence rate ratios (IRRs). Using a US perspective, economic burden of HCRU was extrapolated by attaching unit costs from the Medical Expenditure Panel Survey to per-patient average numbers of events. Costs were calibrated to 2011 values (USD). **RESULTS:** Nivolumab-treated patients had a 29% lower rate of hospitalization than those treated with IC (IRR=0.71 [95% confidence interval (CI): 0.50-0.99]; P=0.046). Rates for emergency department visits (IRR=0.72 [95% CI: 0.24-2.13]), hospital outpatient visits (IRR=0.87 [95% CI: 0.38-1.99]), and other visits (IRR=0.86 [95% CI: 0.39-1.91]) were qualitatively lower for nivolumab versus IC. Using the United States as a base case, average per-patient costs for nivolumab versus IC were lower for all forms of HCRU except physician office visits. The total per-patient HCRU cost for nivolumab (\$21,779) was 13% lower than that for IC (\$24,961). **CONCLUSIONS:** In CheckMate 141, nivolumab-treated patients had a lower rate of hospitalization than IC-treated patients. Differences in rates of hospitalization and other events translated into substantial differences in estimated costs of care. The full economic implications of these differences should be interpreted carefully as not all potentially related costs were assessed.

PCN150

TREATMENT PATTERNS, HEALTH CARE RESOURCE UTILIZATION AND COST ASSOCIATED WITH THE MANAGEMENT OF RELAPSED/REFRACTORY INDOLENT NON-HODGKIN LYMPHOMA

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OBJECTIVES: Indolent non-Hodgkin lymphoma (iNHL) is a hematologic malignancy characterized by slow progression. Although response rates to first-line therapy are

high, patients often relapse repeatedly. There are no guidelines for the treatment of relapsed/refractory iNHL and the economic impact in Canada is unknown. The objective of this study was to understand treatment patterns, health care resource utilization and cost for the management relapsed/refractory iNHL in Canada. **METHODS:** A retrospective chart review was conducted in 3 Canadian Oncology centers. Patients included were ≥ 18 years, diagnosed with follicular lymphoma, small lymphocytic lymphoma, lymphoplasmacytic lymphoma or marginal zone lymphoma, received prior treatment with ≥ 2 chemotherapy- or immunotherapy-based regimens and were refractory to rituximab and an alkylating agent. Data were collected from iNHL diagnosis until end of study (i.e. death, loss to follow-up or March 31, 2015), with the index date defined as the date at which patients met all eligibility criteria. Mean monthly cost per patient was calculated from index date to end of study. Canadian unit costs were obtained from the literature and government publications. **RESULTS:** A total of 40 iNHL patients met the eligibility criteria. Of these, 24 (60%) had a diagnosis of follicular lymphoma. The median age at index date was 64 years. With each line of treatment, the proportion of unique regimens administered increased while the number of patients receiving therapy decreased. Furthermore, the median time to relapsed/refractory diagnosis decreased with each subsequent line of treatment. Mean monthly cost per patient was C\$5,420 including hospitalizations (43%), treatments (38%), medical procedures (17%) and medical visits (1%). **CONCLUSIONS:** This study demonstrates that the management of relapsed/refractory iNHL becomes increasingly challenging throughout the course of the disease and generates considerable costs. Patients become less responsive to therapies over time and there is no consistent standard of care for relapsed/refractory iNHL patients.

PCN151

RESOURCE USE FOLLOWING GENE EXPRESSION PROFILE TESTING IN UVEAL MELANOMA PATIENTS: A U.S. PRIVATE PAYOR MODEL

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OBJECTIVES: Early detection of metastases is crucial in uveal melanoma patients, as nearly 50% metastasize within five years, primarily to the liver. However, <3% of all patients present with metastases at diagnosis. DecisionDx-UM is a validated prognostic gene expression profile test that categorizes a patient's metastatic risk as low, medium or high, allowing them to be followed with a surveillance program of corresponding intensity and minimizing over- or under-treatment. U.S. private payors cover more than half of uveal melanoma patients; we developed a decision tree model to assess the impact of DecisionDx-UM on resource utilization in this population. **METHODS:** Surveillance costs (outpatient visits, liver function testing, and imaging) were compared for the previous framework in which 80% of patients received high-intensity surveillance regimens, and the current scenario in which patients are tested with DecisionDx-UM and receive a low-, medium- or high-intensity regimen based on their individual risk. Regimens and model structure were based on literature review and U.S. clinical practice; cost inputs were based on 2016 private payor rates. The model assumes 1,650 diagnoses per year and survival rates for each risk group based on results of the first Collaborative Ocular Oncology Group study. Model predictions included the number and cost of surveillance procedures. **RESULTS:** Based on this model, DecisionDx-UM was associated with a 50% reduction in the number of surveillance procedures performed at two years compared to the previous framework (14,459 procedures with DecisionDx-UM vs. 28,846 without), with an overall 60% reduction at five years (29,158 procedures with DecisionDx-UM vs. 72,155 without). Overall cost savings per patient was \$3,733 per patient per year with total cost savings of \$20,164,682 at five years. **CONCLUSIONS:** DecisionDx-UM allows clinicians to tailor surveillance programs based on each individual patient's risk, greatly reducing resource utilization and resulting in meaningful cost savings for private payors.

PCN152

CLINICAL UTILITY, COVERAGE, AND REIMBURSEMENT FOR NEXT-GENERATION SEQUENCING IN PEDIATRIC ONCOLOGY PRACTICE

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OBJECTIVES: Next-generation sequencing (NGS) has the potential to transform the paradigm for diagnosing and treating cancer. Widespread adoption is predicated on demonstrating the clinical utility/clinical impact of NGS and developing evidence-based reimbursement policies. A review of clinical utility, coverage and reimbursement from third-party payers was conducted in a cohort of pediatric oncology patients as part of a clinical NGS program. **METHODS:** NGS was performed in a CLIA-certified laboratory at Columbia University Medical Center. Testing included whole-exome sequencing (WES) of matched tumor-normal tissue, transcriptome analysis and copy number variation. WES of patient-parent DNA was performed when a constitutionally encoded disease or syndrome was suspected. Targeted sequencing of 48 or 467 cancer-associated genes was used when tumor tissue was limited. **RESULTS:** 105 patients received NGS (WES: n=82, 78%; targeted panels: n=23, 22%). Clinical utility/clinical impact was demonstrated in 62/105 patients (59%); druggable targets (17/62), diagnostic/prognostic (26/62); other clinically-impactful findings (19/62). WES identified 54/62 (87%) of the clinically-impactful findings. 78 patients (74%) received partial reimbursement. In 16/27 patients denied coverage (59%), a clinically-actionable result was found. Reimbursement was provided by commercial plans to 35/52 patients (67%) and to 43/50 patients (86%) by managed-government plans. Government plans provided no coverage for 3 patients. Insurers without a specific coverage plan or considered NGS "experimental", denied coverage for all or part of testing. On average, insurers reimbursed

33% of the total NGS service charges: 30% (range, 0-89%) from commercial plans; 37% (range, 0-61%) from managed-government plans. The average reimbursement was: \$3,426 (range, \$750-\$7,227) for WES; \$837 (range, \$82-\$1,399) for targeted 48-gene panel sequencing; and \$2,586 (range, \$444-\$4,149) for targeted 467-gene panel sequencing. **CONCLUSIONS:** NGS provided clinically-impactful information for 59% of patients but only one-third of charges for testing were reimbursed by insurers. Evidence-based reimbursement policies are needed to promote the adoption of NGS technologies that benefits patients into clinical practice.

CANCER – Patient-Reported Outcomes & Patient Preference Studies

PCN153

THE EFFECT OF DEPRESSION ON ADHERENCE TO HORMONE THERAPY IN BREAST CANCER PATIENTS

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OBJECTIVES: Breast cancer patients with depression before or after their diagnosis have been shown to have increased cost, shorter survival time and reduced adherence to hormone therapy. Currently, no study has determined the association of concurrent depression while adjusting for a history of depression with adherence to hormone therapy. The objective of this study is to determine the association of concurrent depression with adherence to hormone therapy adjusting for a history of depression. **METHODS:** Breast cancer patients with hormone receptor positive cancers diagnosed from 2006 to 2009 were identified in the linked SEER-Medicare dataset. Patients must have started hormone therapy within a year of cancer diagnosis to be included and have at least 1 year and up to 4 years of follow up. Patients who had an ICD-9 code for depression within a year of cancer diagnosis were classified as currently depressed. Adherence was measured using percent days covered (PDC) and was calculated for each quarter during follow up. A generalized linear model with repeated measures was used to determine the association of concurrent depression with adherence to hormone therapy. **RESULTS:** 10,471 hormone receptor positive breast cancer patients who took hormone therapy were identified. Of these, 10% were currently depressed. Those with depression consistently had lower PDC values for each quarter during follow up. Current depression was associated with a 19% reduction ($p < .01$) in the odds of adhering to hormone therapy after adjusting for a prior history of depression in addition to other confounders. A prior history of depression was also associated with a 15% reduction ($p < .01$) in the odds of adhering to hormone therapy after adjustment. **CONCLUSIONS:** Concurrent depression is associated with significantly reduced adherence to hormone therapy in breast cancer patients.

PCN154

KNOWLEDGE OF WOMEN ON HUMAN PAPILLOMA VIRUS

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OBJECTIVES: The main objective of our study was to assess the knowledge of women in Siklós and its region about the human papillomavirus and also learn their attitudes about the vaccine. **METHODS:** A quantitative, cross-sectional survey was carried out in 2016 by using non-random sample selection method in Siklós and its region. 180 questionnaires were distributed, of which 166 proved to be evaluable. The questionnaire included the following groups of questions: socio-demographic profile, knowledge on human papilloma virus and willingness to vaccination. Data were processed by SPSS 22.0 program, using descriptive statistical analysis, χ^2 -test, Mann-Whitney-test and Logistic regression ($p < 0.05$). **RESULTS:** 81.9% of the women knew the meaning of the acronym, HPV. Significantly more women with higher education ($\chi^2=24.960$; $p < 0.001$), with health education ($\chi^2=16.738$; $p < 0.001$), and with knowledge of the acronym, HPV ($\chi^2=16.427$; $p=0.001$) knew the promoting factors of the infection. Women giving birth later in life were likely to give a wrong answer on diseases caused by HPV ($\beta=0.167$; OR= 1.182; 95% CI[1.032;1.353]). Women with health education (Mann-Whitney U=1005.500; $p < 0.001$) had a significantly higher level of knowledge than those without it. In total, 33.7% of the women could be considered as persons with high level of knowledge on HPV. Women with higher education significantly knew more on HPV ($\chi^2=35.111$; $p < 0.001$). 81.9% of the respondents had some knowledge on HPV vaccination and 4.2% of them received vaccination. 30.7% of them may have vaccination later, especially those who consider their states of health good ($\chi^2=20.120$; $p < 0.001$) or those who attend cervical screening regularly ($\chi^2=15.147$; $p=0.019$) in a higher rate. **CONCLUSIONS:** To enhance knowledge is the best way to express the importance of infection. Acquired knowledge may determine the participation in screening and willingness to vaccination.

PCN155

GASTROINTESTINAL SYMPTOMS AND NUTRITIONAL CHALLENGES OF PATIENTS (PTS) AFTER TREATMENT FOR GASTRIC OR GASTROESOPHAGEAL JUNCTION (GEJ) CANCERS

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OBJECTIVES: Patients with gastric or GEJ cancers frequently experience gastrointestinal symptoms and face nutritional challenges, particularly during and immediately after treatment. We sought to identify these symptoms and challenges, and obtain insight about how patients consequently adapted their eating. **METHODS:** Patients

with gastric or GEJ cancer were systematically interviewed about their medical history (diagnosis, treatment[s], medications, comorbidities, deficiencies, and receipt of dietary recommendations); symptoms; elimination patterns; impact of certain foods and beverages, including aversions, triggers, and avoidances; and daily food and beverage intake. **RESULTS:** Patients (4 men, 5 women; 34–70 years old) had diagnoses ranging from stage I to IV gastric±GEJ cancer and had undergone various treatments (partial esophagectomy±partial/total gastrectomy±chemotherapy±radiation). Some but not all patients received meaningful dietary advice during or immediately after treatment. No patient tolerated commonly recommended nutritional shakes. Most patients experienced dumping syndrome/diarrhea, particularly after consuming liquids with solids, and most had ≥ 1 (mainly vitamin B12) deficiency. Patients occasionally experienced constipation. In general, patients used a trial-and-error approach to identify optimal eating parameters (eg, timing, volume, and palatable, non-symptom-evoking foods and beverages). All patients ate frequent, small meals that included a protein; drank frequent, small volumes of liquid; did not co-consume solids and liquids; introduced new foods and beverages slowly and repeatedly; and increased consumption volumes over time. Frequent symptom triggers were high-sugar and/or carbonated beverages, raw vegetables, and high-sugar, spicy, high-fat, and fried foods, and variable triggers were caffeinated beverages, alcohol, and red meat. **CONCLUSIONS:** Patients are concerned about subpar nutrition after treatment for gastric or GEJ cancers. Though foods and beverages impact patients differently, commonalities exist. Providing behavior and healthy dietary recommendations can help manage patients' expectations and optimize nutritional intake. Diet and consequent nutritional intake, which may impact medication compliance and/or adherence, should be considered within clinical trials.

PCN156

HEALTH UTILITIES IN ACUTE MYELOID LEUKEMIA: A COMPREHENSIVE LITERATURE REVIEW

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OBJECTIVES: Acute myeloid leukemia (AML) is a rare hematologic malignancy characterized by proliferation of myeloid blasts which is associated with poor outcomes (25.8%, 5-year survival; SEER, 2016). While AML treatment has not changed meaningfully in the past four decades, new therapies in advanced development have the potential to improve outcomes in AML. Health utilities are an important component in economic evaluation to assess the value of new treatment options. This literature review aims to identify health state utility values in adult patients with AML. **METHODS:** A literature search strategy for AML and health state utility values was implemented across MEDLINE, PubMed, EMBASE, PsycINFO, HTA databases, NHS Economic Evaluation Database, Cochrane Central Register of Controlled Trials, Database of Abstracts of Reviews of Effects, Cost-Effectiveness Analysis Registry, SchARRHUD, EQ-5D database, ISPOR Scientific Presentations Database, and ISOQOL conference abstracts. 2284 records were identified. Following exclusion of records based on title and abstract, two researchers independently assessed the 52 full texts of selected articles and extracted data for eligible studies. **RESULTS:** Eighteen studies met the eligibility criteria. Of the studies assessed, four reported values for descriptive analyses of HRQoL, one was a review of utilities in different leukemia types, and the remaining publications used utility values in economics models. Utilities were derived from multiple methods, including proxies from other health conditions (e.g., CML, MDS; n=5), mapping (n=2), EQ-5D (n=5), physician visual analog scale ratings (n=2), reference to other publications (n=2), or was not specified (n=2). Overall, utility values for AML health states varied widely by publication: baseline AML 0.52–0.77; remission 0.74–0.99; relapse 0.3–0.8. **CONCLUSIONS:** Overall, this review indicates that there is a scarcity of robust utility data in AML patients. Further studies are needed to delineate better defined AML health utilities to inform the economic value of AML treatment strategies.

PCN157

ASSESSMENT OF UTILITY VALUES FOR TREATMENT-RELATED HEALTH STATES OF ACUTE MYELOID LEUKEMIA IN THE UNITED KINGDOM

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OBJECTIVES: Acute myeloid leukemia (AML) is a genetically heterogeneous hematologic malignancy associated with reduced quality of life (QoL) among patients. Considering the morbidity and mortality associated with AML treatment, improvement in QoL is critical in establishing the non-survival benefits of AML therapies. Information on AML health-state utilities is currently limited. This study assessed how members of the general public in the United Kingdom (UK) value AML health states. **METHODS:** A Time Trade Off (TTO) approach was used in this study, which has been widely used to obtain utility values for use in the economic evaluation of health technologies. Health state descriptions were developed based on the literature, which included elements of symptoms and aspects of physical, functional, and emotional well-being, as well as key adverse events of AML treatment. Ten health states included in the study were: newly diagnosed AML, induction, consolidation, maintenance, long-term follow-up, relapsed/refractory, stem cell transplant (SCT) procedure, SCT recovery, SCT long-term follow-up with and without complications. Descriptions were validated by haematologists and nurse specialists for clinical accuracy and completeness. Subsequently, 210 members of the general UK public participated in the main TTO interviews. Descriptive statistics were used to analyse the utility values. **RESULTS:** One hundred and twenty-nine (61.4%) participants were female. Mean age of the participants was

44.0 years (SD 14.9, range 18 to 81 years). The following utility values were obtained: newly diagnosed AML 0.63; induction 0.16; consolidation 0.57; maintenance 0.89; long-term follow-up 0.89; relapsed/refractory 0.51; SCT procedure -0.21; SCT recovery 0.75; SCT long-term follow-up with and without complications 0.37 and 0.94, respectively. **CONCLUSIONS:** The utility value is low, as expected, for the health states induction and SCT procedure. The TTO methodology can be employed to elicit utilities for AML health states which can be used in cost-effectiveness models of AML treatments for HTA submissions.

PCN158

HEALTH STATE UTILITY VALUES FOR HER2+ METASTATIC BREAST CANCER

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OBJECTIVES: Health state utility values (HSUV) are commonly used to derive quality adjusted life years in economic evaluations. The objective of this study was to estimate health utilities for HER2+ metastatic breast cancer patients who have failed on least two regimens of HER2 directed therapies. **METHODS:** We analysed data from a large (n=602), repeated measure (3,767 observations), EQ-5D-3L dataset from the TH3RESA trial to estimate utility values. The EQ-5D was converted into utility value using the UK tariff. A mixed (random-slope) models using unstructured covariance structure were fitted to predict utility values according to baseline patient characteristics and key clinical outcomes. The set of variables considered for the model included: treatment allocation, disease progression, hospitalisation due to adverse event (AE), baseline age, baseline ECOG, sex, baseline BMI, number of prior regimen (<=3 or >3), visceral disease, and patient proximity to death. Final set of variables were selected using clinical opinion. **RESULTS:** The median number of follow up visit was 7 (range: 0–27). Time was included as a random effect. Included variables demonstrated evidence of an important association with HRQoL outcomes based on magnitude and significance of effect (p<0.1). Visceral disease and number of prior regimen was forced into the model to make HSUV more generalisable. Our model showed a substantial statistically significant utility decrement of 0.33 in the 14 weeks leading to patient's death. Lastly, hospitalisation due to AEs and disease progression was associated with utility decrement of 0.06 and 0.04, respectively. **CONCLUSIONS:** An event based analysis using a mixed model better explained variation in EQ-5D data according to key clinical outcomes and patient characteristics.

PCN159

A TRIAL-BASED EUROQOL EQ-5D HEALTH UTILITY ANALYSIS IN PATIENTS WITH PREVIOUSLY UNTREATED METASTATIC NSCLC

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OBJECTIVES: This study evaluated health-related quality of life utility in previously untreated non-small cell lung cancer (NSCLC) patients. **METHODS:** This study examined the EQ-5D-3L data collected from patients enrolled in the KEYNOTE-024 trial, a multicenter, worldwide, randomized Phase III trial comparing pembrolizumab to standard-of-care platinum-based chemotherapy (SoC) in patients with previously untreated metastatic NSCLC with PD-L1 positive (Tumor Proportion Score [TPS] $\geq 50\%$) tumors. Two approaches of defining health states are considered in analysing utility: time-to-death reflecting decline in cancer patient's quality of life as they approach death, and progression-based health states. Generic health statuses assessed from the EQ-5D-3L questionnaire were converted to population-based utility values using published algorithms. The utility scores from the pooled treatment groups are reported. **RESULTS:** Data came from 283 patients who had at least one evaluable EQ-5D record. Mean utility score for patients in progression-free and progressive disease state is 0.78 (95% CI 0.77, 0.79) and 0.69 (95% CI 0.66, 0.72), respectively. Mean utility showed a decrease on disease progression of 0.09, which is considered as clinically meaningful. Patients were split into four groups based on their time to death after the EQ-5D questionnaire was taken - over 360 days, 180–360 days, 30–180 days, and under 30 days. Mean utility in each time-to-death category is 0.81(95% CI 0.77, 0.84), 0.73 (95% CI 0.68, 0.77), 0.63(95% CI 0.59, 0.67), and 0.54 (95% CI 0.43, 0.65). The results showed a large decrease in utility by time to death category. **CONCLUSIONS:** The results showed that quality of life for metastatic NSCLC patients rapidly deteriorates during the end of life period. Considerable deterioration of utility in NSCLC patients is associated with disease progression and time to death. The utility values estimated from the study will inform economic evaluations of treatments in previously untreated metastatic NSCLC.

PCN160

HEALTH UTILITY IN MYELOFIBROSIS PATIENTS AND COMPARISON BETWEEN HEALTH UTILITY VALUES MEASURED BY TIME TRADE OFF AND VISUAL ANALOGUE SCALE

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OBJECTIVES: To elicit utility for health states of myelofibrosis patients and calculate mean differences and correlation between health outcomes measured by time trade off (TTO) method and visual analogue scale (VAS). The effects of socio-demographic characteristics on TTO ratings were also explored. **METHODS:** Four health states of myelofibrosis were created: early disease state without treatment (HS1); late disease state without treatment (HS2); treatment with best available therapy (BAT) (HS3); and off BAT (HS4). Detailed health state descriptions were developed based on literature searches for myelofibrosis and the

health states were assessed using TTO and VAS. Based on a stratification sampling method, participants were selected to represent the population of South Korea. Paired t-tests and correlation were used to compare VAS and TTO. A generalized linear model was used to find the demographic factors influencing TTO values. **RESULTS:** A total of 126 participants, with an average age of 46.7 (± 10.8) and of which 49.2% were women, were interviewed. The mean utility values using TTO were: 0.90(± 0.08) for HS1; 0.22(± 0.24) for HS2; 0.41(± 0.26) for HS3; and 0.36(± 0.26) for HS4. Significant mean value differences between TTO and VAS were found in HS2, HS3, and HS4; 0.108, 0.107 and 0.125 ($p < 0.000$), respectively. Correlations between TTO and VAS were found in HS1, HS3 and HS4; $r = 0.244$ ($p < 0.01$), $r = 0.263$ ($p < 0.01$) and $r = 0.189$ ($p < 0.05$), respectively. Small variances in TTO were explained by VAS in HS1 (6%), HS3 (7%) and HS4 (4%). Demographic factors did not significantly affect TTO utility values. **CONCLUSIONS:** This study found that there were differences in myelofibrosis patient's utility values according to four different health states. Values measured by TTO and VAS were significantly different in HS2 through HS4, and weak correlations were found in HS1, HS3 and HS4. The findings could serve as a valuable resource for future research when comparing the impacts of previous and/or new treatments.

PCN161

CLINICIAN PREFERENCES FOR CANCER TREATMENT OUTCOMES: DOES PERSONALITY INFLUENCE CHOICE?

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OBJECTIVES: To (1) determine whether Conscientiousness or Agreeableness was associated with different treatment outcome preferences and (2) examine whether the choice between Dead and moderate or severe health differed by levels of personality traits. **METHODS:** An online survey was administered to a convenience sample of doctoral pharmacy students. Respondents completed a personality inventory to measure levels of Big Five personality traits (Extraversion, Agreeableness, Conscientiousness, Emotional Stability, and Openness to Experience), then categorized by tertiles (low, moderate, high) for each trait. Treatment outcome preferences were quantified using profile-based (case 2) best-worst scaling (BWS) where profiles were described using the EQ-5D-Y descriptive system and framed with a hypothetical cancer scenario. In two additional items, respondents were asked to choose between Dead and moderate and severe health states. Count analysis obtained preference scores for each treatment outcome. Analysis of variance (ANOVA) and Kruskal-Wallis test (KWT) examined preference differences across Conscientiousness and Agreeableness tertiles. Logistic regression models evaluated the association between higher levels of Conscientiousness and Agreeableness and choosing Dead over the moderate and severe health states. **RESULTS:** A total of 185 respondents were recruited. Preferences were significantly different across Conscientiousness tertiles for "no problems" in Usual Activities (ANOVA $p = 0.03$, KWT $p = 0.06$), Pain/Discomfort, and "a lot of problems" in Pain/Discomfort (p -values < 0.05). No differences in treatment preferences were observed across Agreeableness tertiles. Higher levels of personality traits were not significantly associated with choosing Dead over moderate health (Conscientiousness: odds ratio [OR] 3.9, 95%CI 0.4-34.7; Agreeableness: OR=0.2, 95%CI 0.02-1.7); nor severe health (Conscientiousness: OR 0.8, 95%CI 0.4-1.6; Agreeableness: OR 0.7, 95%CI 0.3-1.3). **CONCLUSIONS:** Conscientiousness appears to be a factor in treatment outcome preferences among future pharmacists. Conscientiousness and Agreeableness may impact choosing Dead over health states based on the effect magnitude; however, larger studies are needed to confirm this association.

PCN162

STATED PREFERENCES FOR LUNG CANCER TREATMENT: A SYSTEMATIC REVIEW

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OBJECTIVES: The selection of therapeutic schemes for advanced stages of lung cancer patients often involves weighing beneficial and deleterious outcomes of each available alternative, as well as their costs. Patients and relatives preferences about established therapeutic options and innovative medical solutions may be a key information to support decision-making across its multiple spheres. This study aims to identify stated-preferences studies that elicited lung cancer patient's preferences regarding treatment and outcomes. **METHODS:** The search was performed using MEDLINE, EMBASE, Econlit and RePec. In addition, the references of articles that meet the inclusion criteria were scanned in an effort to identify further relevant literary production. Articles published until June 2016 were included in this systematic review. Studies that reported stated preferences experiments, on the topic of lung cancer therapies and/or outcomes were included. Reports of any variation of stated preferences experiments were considered eligible (e.g. Choice-based conjoint, willingness-to-pay (WTP)). **RESULTS:** Ten out of 1,155 references retrieved met the inclusion criteria. The total sample size was composed by 1,302 patients. Studies were conducted in the USA (4) and Europe (4), Asia (1) and Australia (1). The studies used choice-based conjoint (4), willingness-to-pay (5) and time trade-off (1). WTP studies explored how much patients were willing to pay to avoid one single side effect or to be cured of the disease. The remaining studies looked at the valuation of health outcomes or at the trade-off between health outcomes and processual attributes. Overall, relief of symptoms related to secondary effects of chemotherapy and to the tumor appeared to be more important than processual attributes. When included, disease-free survival or overall survival were considered the most important attributes. **CONCLUSIONS:** The identified literature found that the cost, efficacy and symptom relief are important drivers of choice.

PCN163

DEVELOPING ATTRIBUTES AND ATTRIBUTE-LEVELS FOR A DISCRETE CHOICE EXPERIMENT ON LUNG CANCER PATIENT'S PREFERENCES FOR DRUG THERAPIES

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OBJECTIVES: Stated preferences experiments validity depends largely on the proper specifications of attributes and levels. Hence, patients and physicians engagement is critical to assure that the information being valued on the experiment is both important to patients and decision-relevant. This study reports the systematic approach undertaken targeting the definition of attributes and attribute levels for a discrete choice experiment created to elicit lung cancer patient's preferences for drug therapies. **METHODS:** A literature review was undertaken aiming to identify conceptual attributes and attribute-levels. The finding of this review helped to define the qualitative component. The qualitative component included 3 focus groups, on which 8 patients and 3 oncologists were engaged on discussions aiming to identify context specific attributes. All interviews were recorded, transcribed and analyzed by the research team. The resulting draft-proposal of attributes and attribute-levels was thoroughly discussed and further developed by a group of experts. **RESULTS:** The first round of results derived 10 attributes. Attribute-levels were defined according with the literature, the results from the qualitative component and experts opinions. After a round of discussion with experts on the field three attributes were discarded. The final proposal consists in seven attributes that were defined as follows: Fatigue/tiredness, diarrhea, skin rash, risk of hospitalization, mode of administration (route of drugs administration), access and overall survival. **CONCLUSIONS:** The results reported in this manuscript will add to the body of knowledge on the application of qualitative methods to derive attributes and attribute-levels for a stated preferences experiment.

PCN164

EXPLORING CANCER SURVIVOR PERSPECTIVES ON THE VALUE OF LIFE AND TIME POST-DIAGNOSIS

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OBJECTIVES: The objectives of this study were to explore cancer survivors' perspectives on the value of life and time and to gather preliminary data to guide future research through a pilot survey. **METHODS:** A convenience sample of survivors was reached with an online survey instrument via sharing a link on two US cancer survivor Facebook groups. A dataset was downloaded for analysis after 48 hours of collection. **RESULTS:** 104 individuals responded, and 99 complete responses were analyzed. Year of cancer diagnosis were 1975 to 2015. Tumor types included breast cancer (25%), leukemia (15%), Hodgkin lymphoma (13%) and many others. The majority of respondents had completed active treatment (81%). A majority (76%) rated post-diagnosis years as having more value than years prior to diagnosis. (23% assigned same value, 2% less value). When asked about the value of time pre- and post-diagnosis, 81% of all respondents agreed with: "Time is more valuable now because of my experience" as opposed to less valuable, or no change in perspective. 26 respondents (26%) rated post-diagnosis years as more valuable even though they are now partially limited ($n = 22$) or significantly limited ($n = 4$) in what they are able to do. **CONCLUSIONS:** Cancer survivors' perspectives on the value of time and years post-diagnosis have not been heavily researched. Common methods in health economic evaluation use metrics such as the Quality Adjusted Life Year (QALY) that place a value on life years based as a function of time and Health Related Quality of Life (HRQoL). Data from this survey suggests that the outputs of QALY functions, which reflect lower values for post-diagnosis years, may not accurately reflect survivor perspectives, which could place greater value on post-diagnosis years even when physical limitations are present. As value is increasingly emphasized in oncology policy, these patient perspectives merit further investigation and attempts at quantification.

PCN165

COMPARING CANCER-SPECIFIC PREFERENCE-BASED OUTCOME MEASURES: THE SAME BUT DIFFERENT

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OBJECTIVES: Disease-specific outcome measures for use in economic evaluations are growing in popularity. Within cancer there are now two preference-based measures, the EORTC-8D and the QLU-C10D. Both map responses from the EORTC QLQ-C30, a questionnaire which measures the quality-of-life of cancer patients. They share some commonalities in the C30 items that they draw from and the analytical approach applied in selecting their item dimensions, but they differ in other areas (the clinical characteristics of the patient group within which they conducted their analysis and the valuation approach). This is the first analysis comparing the two measures in an external dataset. **METHODS:** Cancer 2015, a longitudinal prospective population-based cancer genomic cohort, was utilised in the analysis. Both the EQ-5D-3L and the EORTC QLQ-C30 were asked at baseline (diagnosis) and at various follow-up points (3, 6, 12 months). The respective algorithms were applied to generate health state values for the EORTC-8D and the QLU-C10D. Cancer-specific baseline values were evaluated and compared. Quality adjusted life-years (QALYs) were estimated and assessed. Validity, ceiling effects, agreement and sensitivity in the instruments were also evaluated. **RESULTS:** Complete case analysis of 1663 patients found that the EORTC-8D and QLU-C10D are highly correlated (0.947), yet the EORTC-8D values at baseline were significantly higher than the QLU-C10D values (0.830 vs 0.736, $p < 0.001$). There is strong agreement between the instruments at baseline (ICC=0.770). EORTC-8D QALY estimates were significantly higher than

QLU-C10D QALYs (0.911 vs 0.821, $p < 0.001$). Differences in QALY estimates appear to be sensitive to the site of the cancer. **CONCLUSIONS:** It is well known that generic preference-based measures often produce different conclusions, this analysis confirms that disease-specific measures also suffer from the same variability, even when drawn from the same quality-of-life instrument. Further research is required to understand the reasons for the variability, particularly if recommendations for reimbursement change in light of using one instrument over another.

PCN166

SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK (SCCHN) PATIENT REPORTED SATISFACTION WITH CANCER THERAPY

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OBJECTIVES: To understand SCCHN patient satisfaction with cancer therapy. **METHODS:** Real world data was gathered using Adelphi's Disease-Specific Programme (DSP) - a cross-sectional survey administered to physicians and patients in the USA, France, Germany and the UK (April - September 2016). 182 physicians (54 US, 128 EU) provided data on consulting SCCHN patients regarding treatment patterns and staging. 373 current stage IV SCCHN patients (60 US, 313 EU) completed the Cancer Therapy Satisfaction Questionnaire (CTSQ), a 16-attribute tool assessing patient satisfaction with and preference for treatment. Summary statistics were reported and differences between sub-groups assessed using chi-square tests. **RESULTS:** Overall 44% of patients stated satisfaction (very/satisfied) with their most recent cancer therapy. No notable difference was observed based on current stage (%sat) - stage IVA/B (47%) vs. stage IVC (41%), or current regimen (%sat) - platinum-based (50%) vs. cetuximab-based (46%). Further analysis of side effects being as expected (%somewhat/much worse) also sees no marked difference between those on platinum-based (29%) vs. cetuximab-based (28%) regimens. The only difference in platinum-based vs. cetuximab-based scores is in how worthwhile (%very) patients feel cancer therapy has been (22% vs. 16% ($p=0.0108$)). A notable overall satisfaction difference (%sat) was observed between those currently receiving 1st line drug therapy (51% vs. 2nd line (38%) ($p=0.0224$)). Differences were also seen between the cohorts in terms of whether therapy has been as difficult as expected (% much/somewhat more difficult - 1st line 36%, 2nd line 48% ($p=0.0265$)) and whether the benefits of therapy have met expectations (% somewhat/much worse than expectations - 1st line 16%, 2nd line 30% ($p=0.0025$)). No difference was seen in side effects scores (%somewhat/much worse - 1st line 27%, 2nd line 32%). **CONCLUSIONS:** Patients on 2nd line SCCHN drug therapy have lower satisfaction than those on 1st line, highlighting a need for improved drug treatments at later lines.

PCN167

CHEMOPREVENTION RATES AMONG WOMEN WITH HIGH RISK OF BREAST CANCER: A SYSTEMATIC REVIEW

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OBJECTIVES: This study summarizes the uptake rates of chemoprevention drugs among postmenopausal women at high risk of being diagnosed with breast cancer. **METHODS:** A systematic literature review was conducted for articles published between January 1996 and October 2016, using databases Medline (Ovid), and PubMed (NLM). Chemoprevention was defined as the use of tamoxifen or raloxifene or exemestane. The eligibility criteria considered in this study were, post-menopausal women at a high risk of breast cancer. Only articles published in English from peer reviewed journals were included in this review. Two reviewers independently screened a random sample of 25 titles and abstracts. A moderate agreement (Cohen's $\kappa = 0.65$) was obtained. The elements of PICOS were reviewed within each article. **RESULTS:** A total of 10 full text articles were included in this review. The overall decision to initiate chemoprevention ranged from 4.7% - 47.0% affirmative in the articles included in the review. An average of 70% women declined chemoprevention. Only one study measured the uptake of chemoprevention immediately after an intervention, while nine studies measured the uptake after a follow up of 3-14 months. The presence of a control group indicates a stronger study design and only three studies had a control group. The chemoprevention uptake rates were about 10% on an average in the target population. The most common reasons for refusal of chemoprevention were chemoprevention side effect profile and the duration of therapy. **CONCLUSIONS:** Chemoprevention uptake rates were low among post-menopausal women with high risk of breast cancer. Since risk of adverse events and duration of therapy were the most cited reasons of low chemoprevention uptake, appropriate patient counselling with focus on chemoprevention risk-benefit profile may be designed and implemented.

PCN168

IDENTIFYING PREFERENCES FOR APPROACHES TO BREAST CANCER SURGICAL TREATMENT BEYOND TRADITIONAL CLINICAL BENCHMARKS OF SURVIVAL

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OBJECTIVES: To identify preferences for breast cancer surgical treatments. **METHODS:** A computerized adaptive choice-based conjoint survey was administered in December 2016 to a sample of healthy women ≥ 18 years old from the Army of Women registry. The survey quantified the importance of clinical and humanistic outcomes and surgical treatment characteristics using a hierarchical Bayes model. Preferences for each treatment attribute were ranked by importance and part-worth utilities were used to perform a simulation of preference for treatment options including breast conservation surgery with radiation and uni- and bi-lateral mastectomy with or without

reconstruction. **RESULTS:** A total of 522 subjects returned the survey. Age ranges were 0.2%, 20.3%, 49.6% and 29.9% for those 18-25, 26-44, 45-64, and ≥ 65 years old, respectively with majority being Caucasian (96.7%). Mean (\pm standard deviation) ranking of surgical treatment attribute importance, in decreasing order, were physician recommendation, 21.4 (± 13.6); 20-year survival, 20.5 (± 9.8); number of surgeries and recovery time, 14.3 (± 10.6); 10-year recurrence, 14 (± 7.3); out of pocket (OOP) costs, 8.7 (± 5.5); nipple preservation and sensitivity, 7.8 (± 6.5); breast look relative to before surgery, 6.1 (± 4.4); radiation use, 5.2 (± 4.8) and annual following imaging requirements, 2.2 (± 1.8). Simulation results when testing common surgical approaches (equal survival and physician recommendation), showed that 65.07% of simulation resulted in preference for bilateral mastectomy (22.2% without reconstruct, 42.9% with reconstruction). **CONCLUSIONS:** The findings validate that survival is a key driver, but ~80% of the decision was based on other factors including doctor's recommendation, the risk of recurrence, cost burden, OOP costs and aesthetic related factors. The majority of subjects preferred bilateral mastectomy with reconstruction when comparing preferences among 5 possible surgical intervention approaches. Understanding preferences may help focus education material and physician approaches to information sharing and decision making.

PCN169

PATIENT PREFERENCES REGARDING TRADEOFFS BETWEEN EFFICACY AND ADVERSE EVENTS FOR METASTATIC COLORECTAL CANCER TREATMENTS

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OBJECTIVES: To evaluate patient preferences and their willingness to accept risks of specific adverse events (AEs) associated with metastatic colorectal cancer (mCRC) treatments for expected survival benefits associated with these treatments. **METHODS:** We administered an online questionnaire to 100 patients with CRC and 150 with mCRC, which asked each respondent nine discrete choice experiment (DCE) questions. Each question was designed to elicit relative preferences for clinically relevant levels of four attributes of treatments for mCRC—the chance of living at least 3 years after starting therapy, the risk of severe skin rash, the risk of any gastrointestinal (GI) bleeding, and the risk of any other bleeding problems. Preference weights for the levels of these attributes were elicited using a random-parameters logit model. These preference weights were used to calculate the maximum acceptable risk (MAR) of each AE that patients were willing to accept for a 10% increase in 3-year survival. **RESULTS:** Results from a chi-square test identified no statistically significant differences in the preferences of patients with metastatic and nonmetastatic disease. Thus, a single preference model was used with both groups for the analysis. For an increase from 24% to 34% in the chance of 3-year survival with treatment, the MARs (95% confidence interval—CI) were as follows—severe skin rash, 77.3% (62.0%–92.6%); any GI bleeding, 49.4% (39.5%–59.4%); and any other bleeding problems, 40.9% (27.8%–54.0%). **CONCLUSIONS:** Patients were willing to accept a higher risk of developing a severe skin rash than suffering from any GI bleeding or any other bleeding problems for a given increase in survival benefit. This research shows substantial differences in patient preferences for treatment-specific AEs, making patient preference an important factor in the choice of mCRC treatment.

PCN170

PATIENT PREFERENCE AND SATISFACTION WITH ORAL ONCOLYTICS: A REVIEW OF AVAILABLE INSTRUMENTS AND THEIR PSYCHOMETRIC PERFORMANCE

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OBJECTIVES: An increasing number of patients now take oral therapies to treat cancer, thereby highlighting the importance of patient preference and satisfaction with these therapies. As key outcomes in the oncology quality framework, there is a need to identify preference and satisfaction-related instruments in oral oncolytics and report their psychometric properties. **METHODS:** A literature search was conducted according to PRISMA guidelines using PubMed database to identify relevant articles in English up until October, 2016. Non English studies, case reports and other review articles were excluded. Controlled search terminology included oral oncolytic therapy names in combination with satisfaction, preference and related terms. Psychometric properties of the instruments were extracted for qualitative synthesis. **RESULTS:** Among 803 articles identified, 46 studies were included in the final review, of which, 18 had used validated instruments. The population ranged from 18 to 95 years and was being predominantly treated for breast and colorectal cancers. Most studies indicated that convenience and outcomes compared to intravenous drugs promoted the use of oral oncolytics whereas high cost and medication adherence were potential barriers influencing patient preference and satisfaction. A total of 15 standardized instruments (11 satisfaction and 4 preference) were reported. The most commonly used were Cancer Therapy Satisfaction Questionnaire (CTSQ) which evaluated 7 domains (expectations of cancer therapy, feelings about side effects, oral cancer therapy adherence, convenience, satisfaction with cancer therapy, stopping cancer therapy, and reasons for nonadherence) and Therapy Preference Questionnaire which evaluated 2 domains (characteristics interfering with daily activities and factors influencing treatment preference). These instruments also reported good psychometric properties. **CONCLUSIONS:** Patient preference and satisfaction are crucial variables in medication adherence and are valuable when comparing treatments. With oral oncolytics being increasingly prescribed, it will be important to include validated preference and satisfaction instruments to document the changes in outcomes, thereby influencing treatment decisions in oncology care.

PCN171

HOW CAN WE ASSESS THE IMPACT OF COST ON PATIENT TREATMENT PREFERENCES IN CLL TREATMENT?

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OBJECTIVES: To develop a method to assess the impact of cost on patient preferences in chronic lymphocytic leukemia (CLL) treatment. **METHODS:** Assessing the impact of cost on treatment preferences in a discrete-choice experiment (DCE) can be difficult, especially for drugs with long treatment durations. When costs are high, respondents may either ignore the cost attribute or focus only on cost, reducing the value of the study. As an alternative, we first administered a DCE that did not include cost as an attribute. After the DCE, respondents answered one additional question where cost was added as attribute to pre-defined Medicines A and B. Respondents were randomly assigned to the high-cost version (\$400 per month difference in cost between the medicines) and the low-cost version (\$75 per month difference in cost between the medicines). Using the DCE results, we computed posterior preferences for each individual conditional on the pattern of observed choices and based on Bayes' theorem without cost and forecast the share who would choose each of the two medicines. The forecast was compared to the percent who selected Medicine A or B in the two cost questions. **RESULTS:** 384 patients with self-reported CLL took a DCE survey on treatments for CLL (mean age 65 years, 23% first line, 39% relapse, 53% received financial aid to pay for treatments). Using the method described above, we forecasted that 91% of the sample would prefer the medicine with the longest PFS when cost was not included, compared to 50% and 26% who actually selected that option for the low-cost and high-cost follow-up questions, respectively. **CONCLUSIONS:** The fixed follow-up questions including cost provided preference information when high costs were not feasible as a DCE attribute. Respondents were very sensitive to modest changes in treatment cost, pointing to the importance of gathering this information.

PCN172

WOMEN'S PREFERENCES AND WILLINGNESS-TO-PAY FOR SINGLE NUCLEOTIDE POLYMORPHISMS GENE TESTING IN A MULTI-ETHNIC ASIAN POPULATION

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OBJECTIVES: Single Nucleotide Polymorphisms (SNPs) gene tests have demonstrated potential for stratifying women into distinct breast cancer risk categories, thereby facilitating personalised screening regimens. We studied screening-age women preferences and willingness-to-pay for SNPs gene testing in Singapore. **METHODS:** English-speaking Singaporean women aged 40 to 69 years old without history of breast cancer were enrolled via door-to-door recruitment with quota sampling by age and ethnicity to participate in a discrete choice experiment (DCE). DCE comprises: (i) sample type (buccal swab, dried blood spot), (ii) person conducting pre-test discussion (nurse educator, non-specialist doctor, specialist doctor), (iii) test location (private family clinic, public primary-care clinic, hospital) and (iv) out-of-pocket cost (approximately US\$35, US\$125, US\$210). Conditional Logit (CL) and Hierarchical Bayes (HB) were used to estimate preference weights and willingness-to-pay. Associations between sociodemographic characteristics and attribute levels were studied by including interaction terms in CL model. **RESULTS:** 300 women aged 52.6 ± 7.6 years completed the survey (100 Chinese, Malay and Indian women respectively). Using HB, relative attribute importance is highest for cost (75.6%), followed by pre-test discussion (14.6%), test location (5.5%) and sample type (4.4%). Using CL, cost and pre-test discussion appeared to be significant (p-value < 0.0001 for both). Interaction effect between ethnicity and test location was significant (p-value = 0.0001). As compared to Chinese, Malays and Indians attached smaller disutility to taking the test at public primary-care clinic. Women were willing to pay the most to discuss with specialist doctor instead of non-specialist doctor (approximately US\$34; 95% CI: US\$24 to US\$44), and the least to switch from dried blood spot to buccal swab (about US\$0.44; 95% CI: US\$-5.38 to US\$6.25). **CONCLUSIONS:** Test cost was the main determinant of preferences, while sample type was of least concern. To promote uptake, the design of personalized breast cancer screening programmes may be tailored accordingly to these preferences.

PCN173

DISCORDANCE OF ACUTE MYELOID LEUKEMIA SYMPTOMS REPORTED BY US PHYSICIANS AND PATIENTS

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OBJECTIVES: Little is known about the level of agreement between physician- and patient-reported symptoms in the acute myeloid leukemia (AML) population. The objective of this analysis was to assess the level of agreement on reported AML symptoms between treating physician and AML patients. **METHODS:** Data from an Adelphi AML Disease Specific Programme, a real-world, cross-sectional survey involving 61 US hematologists/hemato-oncologists and their AML patients were analyzed. The survey, conducted between February–May 2015, covered population characteristics and treatment regimens with both physician- and patient-reported data captured at

the same time. Physicians provided information on patients' current symptomatology from a symptom list and invited their patients to complete a questionnaire containing the FACT-LEU tool. Patient-reported symptomatology was taken from the 'Additional Concerns' section, where the level of importance informed whether the symptom was experienced (3 [Quite a bit], 4 [Very much]) or was not experienced (0 [Not at all], 1 [A little bit], 2 [Somewhat]). The kappa-statistic measure of inter-rater agreement (adjusting for random agreement) was calculated for the presence of key AML symptoms. Kappa values near 0 indicate low agreement, while values approaching 1 indicate high agreement. **RESULTS:** For the 82 patients included in the analysis, most of whom were receiving first-line treatment (n=56), approximately a third (n=26) were reported as asymptomatic by their physician. Kappa analysis indicated low agreement between physician and patient on the presence of 6 key reported symptoms: (loss of appetite [agreement=29.3%; kappa=-0.02], fatigue/tiredness [agreement=62.2%; kappa=0.08], weight loss [agreement=70.7%; kappa=0.08], bruising [agreement=70.7%; kappa=0.13], bleeding [agreement=76.8%; kappa=0.02], and fever [agreement=87.8%; kappa=0.31]). **CONCLUSIONS:** Disagreement was observed between physician- and AML patient-reported symptoms, with patients being considerably more likely to report experiencing symptoms to some degree. Shared decision making tools that can facilitate improved communication between physicians and AML patients about their symptoms may lead to more effective management.

PCN174

TREATMENT SATISFACTION AND BURDEN OF ILLNESS (BOI) WITH ORAL VS INJECTABLE MULTIPLE MYELOMA THERAPY IN PATIENTS WITH RELAPSED OR REFRACTORY DISEASE

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OBJECTIVES: Compare patient-reported satisfaction and BOI with oral vs. injectable therapy for multiple myeloma (MM) among patients with relapsed/refractory (RR) disease. **METHODS:** Patients within the patient-powered research network, Patient-LikeMe (PLM; www.patientslikeme.com) were surveyed about their treatment experience and BOI. Eligible patients were ≥ 18 years, resided in the USA, and were currently on a treatment regimen comprised of either an all-oral therapy (oral users) or injectable therapy with or without oral medication (injectable users). Those with concomitant amyloidosis or other cancers in the past 5 years were excluded. Patients were classified as RR if they ever changed treatment due to disease progression or recurrence. Patients completed a web based self-administered survey using the Treatment Satisfaction Questionnaire for Medication (TSQM) and BOI questions related to MM. Outcomes of interest were compared in univariate analyses between oral and injectable users. **RESULTS:** In this interim analysis, among 32 respondents, mean age was 60 years (SD: 9), 86% were Caucasian, 15% were Hispanic, and 57% and 25% had an ECOG PS 0-1 and 2, respectively. Current use of an all-oral regimen was 44% (n=14/32), whereas 56% (n=18/32) were on an injectable regimen. Oral users tended to report better mean effectiveness (70 vs. 65, p = 0.465) and global satisfaction (56 vs. 51, p = 0.386), and significantly greater convenience (83 vs. 64, p < 0.01) with therapy than injectable users. Oral users had fewer provider treatment visits in the past 30-days (median: 1 vs. 3) and less time spent per visit (median: 68 vs. 120 minutes) compared with injectable users. **CONCLUSIONS:** Emerging data suggests that an all-oral regimen is associated with a higher level of convenience and a trend towards greater treatment satisfaction and lower healthcare resource use than an injectable regimen in RRMM. Patient productivity will be reported in the final analysis.

PCN175

EVALUATING PATTERNS OF COGNITION, DEPRESSION AND FATIGUE AMONG CHILDREN WITH CANCER

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OBJECTIVES: Cognitive dysfunction is a common late effect for children with brain tumor or who received neurotoxic treatments. Cognition reported by parents (PCF-p) and/or children with cancer (PCF-c) have been used by clinicians to refer children for further cognitive testing. Since PCF-c has been suggested to be related to fatigue and depression, clinicians have tended to rely more on PCF-p. The current study explored the relationship among cognition reported by parents and children and fatigue and depression in children with cancer. **METHODS:** 515 patients (53% BT; 47% non-BT) aged 7-21 (mean=14 yrs; 56% males) were recruited. 34% received radiation therapy, 72% chemotherapy, 71% surgery. Years since last treatment (mean=3.3) was divided into: <1 year (n=34.3%), 1-2 years (12%), and >2 years (53.4%). PCF was measured using a validated 43-item pediatric PCF item bank (pedsPCF-p and pedsPCF-c). Patients also completed NeuroQOL Depression, PedsQL Fatigue, and neuropsychological tests. Z-scores were created for all scales (mean=0; SD=1) for ease of comparisons. Latent class analysis was used to classify patients based on depression, fatigue, pedsPCF-p and pedsPCF-c. Higher scores meant better PCF, more fatigue and more depressed. Logistic regression was used to identify significant predictors of these classes. **RESULTS:** Three latent classes were identified: 1) normal PCF-p (z=0.194), PCF-c (z=0.139), non-fatigue (z=-0.296) and non-depression (z=-0.451); 2) mild PCF-p (-0.968) and PCF-c (z=-0.696), moderate fatigue (z=1.331), and severe depression (z=3.141); 3) mild PCF-p (z=-0.565), normal PCF-c (z=-0.373), mild fatigue (z=0.909) and moderate depression (z=1.118). Working memory, gender, parent-reported QOL of the child, and Hispanic origin were significant predictors of class membership. **CONCLUSIONS:** This study identified three classes among patterns of cognition, fatigue, and depression and identified predictors of class membership. Future studies should be done to explore clinical implications of these results.

PCN176

EFFECT OF ENZALUTAMIDE ON SPECIFIC SYMPTOMS AND FUNCTIONAL AREAS IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: A NOVEL ANALYTIC APPROACH

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OBJECTIVES: Enzalutamide has a positive impact on outcomes assessed by the Functional Assessment of Cancer Therapy-Prostate (FACT-P) instrument, including slower overall decline in total FACT-P scores among patients with metastatic castration-resistant prostate cancer (mCRPC). This research aimed to describe specific benefits of enzalutamide through novel exploratory analyses of individual symptom and functioning items of FACT-P in mCRPC clinical trials. **METHODS:** FACT-P was administered at baseline and every 12 weeks during placebo-controlled trials of enzalutamide in chemotherapy-treated (AFFIRM) and chemotherapy-naïve (PREVAIL) mCRPC patients. Scores on FACT-P 0-4 scales were transformed to 0-100% to facilitate interpretation; higher scores indicated reduced symptoms and better functioning. Descriptive analyses were performed on change from baseline scores. **RESULTS:** In both trials, the impact of enzalutamide on items related to pain was relatively robust compared with other symptom items. In AFFIRM, at week 25, men receiving enzalutamide reported a median decrease (deterioration) of 3% across all FACT-P pain items, compared with a 16% decrease in those receiving placebo. Throughout both studies, enzalutamide delayed worsening in various aspects of social, physical, and emotional functioning versus placebo, including ability to work and enjoy life, worrying about dying, and feeling sad. Throughout both trials, there was little impact of enzalutamide on symptom and functioning items assessing urinary and sexual symptoms compared with placebo. **CONCLUSIONS:** The exploratory analysis indicates enzalutamide preserves mCRPC patients' level of symptomatology and physical functioning, supporting overall health-related quality-of-life scores previously reported. The analyses suggest enzalutamide may prevent a progression in pain and preserve patients' standard of living, ability to work, and emotional views of their disease. Given a lack of decline in the context of a chronic condition, patients may deem these effects as positive. Analyses of individual items are an innovative and valuable approach to interpreting treatment effects from broad patient-reported outcome measures.

PCN177

UNDERSTANDING KEY SYMPTOMS, SIDE EFFECTS AND IMPACTS OF HR+ AND HER2- ADVANCED BREAST CANCER: LITERATURE REVIEW AND EXPERT INTERVIEWS

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OBJECTIVES: While patients with HR+/HER2- advanced breast cancer experience a wide range of disease-related symptoms, side effects, and impacts, identifying the most important and relevant concepts of interest can allow for generalization of the patient experience. This study sought to describe these commonalities based on a review of the literature and interviews with therapeutic experts. **METHODS:** Literature reviews were conducted in MEDLINE®, Embase, and PsycINFO® to identify articles relevant to study goals (search terms included "breast cancer," "metastatic," "advanced," and "symptoms OR side effects OR impacts"; articles published from March 2005 to February 2016 were considered for inclusion). Individual telephone interviews were conducted with five US-based breast cancer oncologists. **RESULTS:** Literature reviews identified 13 eligible studies. Disease-related symptoms were described for six metastatic sites. Six treatment types and their side effects were described. Nausea/vomiting, pain, weight changes, and diarrhea were reported in at least half of these treatments. Emotional and physical impacts of cancer and treatment were reported most frequently. Interviews with experts identified disease-related symptoms for 10 metastatic sites. Pain, fatigue, loss of appetite, and nausea were reported as symptoms generalizable to all HR+/HER2-breast cancer patients, regardless of location of metastasis. Pain and fatigue were reported by three experts as both the most severe and most bothersome disease-related symptoms. Four types of treatment were discussed. Fatigue was reported by three experts as generalizable to all metastatic sites discussed, and relevant to all treatments discussed. The majority of reported impacts focused on physical functioning. **CONCLUSIONS:** Literature and expert perspectives suggest that patients with HR+/HER2- advanced breast cancer commonly experience pain and fatigue as disease-related symptoms; nausea/vomiting, pain, weight changes, diarrhea, and fatigue as treatment-related side effects; and impacts on physical functioning, regardless of the location of their metastases.

PCN178

EXPERIENCES OF TREATMENT-RELATED SIDE EFFECTS AND SUPPORTIVE CARE WITH KOREAN MEDICINE IN WOMEN WITH BREAST CANCER - A FOCUS GROUP STUDY

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OBJECTIVES: In some countries, clinical practice guidelines have included acupuncture as supportive care for breast cancer survivors (BCS). This study aimed to explore experiences of treatment-related side effects and supportive care among Korean BCS. **METHODS:** Focus group interview was conducted with six Korean women with breast cancer at stage I-III. Participants were recruited through snowballing. Interview was audio-recorded and transcribed verbatim. NVivo-11 was used to code the data into themes. **RESULTS:** Two major themes were identified:

(1) experiences of the Western-medicine, including side effects, communication with doctors, and costs; (2) experiences of Korean-medicine, including the same as above. Participants had mean age of 48.7 (SD 6.8) years and had survived for 1-7 years without recurrence. All participants experienced Western-medicine in treatment phase and reported impairment of physical, emotional, and social functioning during and after Western-medicine treatment. Korean-medicine was used after treatments ended. The negative responses from Western-medicine doctors were the most important factor keeping participants from accessing Korean-medicine when treatment-related side effects occurred. For this reason, some participants used Korean-medicine without disclosure. Participants usually acquired information about Korean-medicine from online community or other BCS, which was another important factor because it raised concerns about side effects and credibility of Korean-medicine. High cost of Korean-medicine was also reported as barrier in using Korean-medicine. When getting the cancer treatment, participants tended to endure their treatment-related side effects rather than to resolve them or express needs. Needs of information about effective and economical supportive care were identified. **CONCLUSIONS:** Korean BCS may be at risk of greater physical or emotional distress during treatment period. Findings suggest that there is a high need for supportive care to relieve treatment-related side effects and improve patients' quality-of-life. Furthermore, developing a systematic guidance or credible information sources is warranted to help patients find the best supportive care options.

PCN179

IMPUTING MISSING VALUES TO ESTIMATE HEALTH-RELATED QUALITY OF LIFE (HR-QOL) IN METASTATIC PANCREATIC CANCER (MPC) TREATED WITH 5-FLUOROURACIL AND LEUCOVORIN, WITH AND WITHOUT LIPOSOMAL IRINOTECAN (NAL-IRI)

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OBJECTIVES: The survival benefits of nal-IRI+5-fluorouracil/leucovorin vs fluorouracil/leucovorin in MPC patients who progressed after prior gemcitabine-based therapy were demonstrated in a phase 3 study (NAPOLI-1); preplanned analyses of QoL demonstrated no differences between treatment groups. Post hoc analysis of NAPOLI-1 EORTC-QLQ-C30 questionnaire results showed that HR-QoL change was improved with nal-IRI+5-fluorouracil/leucovorin. However, about half of randomized patients had missing scores. We investigated how imputation of missing values would affect initial findings. **METHODS:** A principal component (PC) analysis was performed on EORTC-QLQ-C30 scales week-6 changes. For patients with missing information, clinical data-based imputation was performed using either regression predictors or median value of study population-matched controls. **RESULTS:** Of 266 randomized patients, 122 had baseline and week-6 EORTC-QLQ-C30 scale measures and were used for PC analysis and imputation model development. Four PCs explaining 59% of variance were retained. With positive weights on Global Health Status/Quality of Life (GHS/QL) and functioning scales and negative weights on financial difficulties and symptoms scales, the first PC (PC1: variance explained 34%) reflected general HR-QoL. Prior to imputation, patients treated with nal-IRI+5-fluorouracil/leucovorin had better HR-QoL PC score week-6 increments vs 5-fluorouracil/leucovorin (PC1: +0.45 vs -0.34, P=0.0478; 4-PC multivariate comparison: P=0.0051). The baseline predictors included in the imputation model were Karnofsky performance status ≥90, albumin ≥4g/dL, CA19-9 ≥40U/mL, stage IV cancer at diagnosis, presence of liver metastases, and ≥40 days since prior anticancer therapy. The population was matched using these predictors, excluding CA 19-9 (94% patients with ≥1 match). Comparable results were found using either predictive model (PC1: +0.30 vs -0.14, P=0.0214; 4-PC multivariate comparison: P=0.0015) or population-matched values (PC1: +0.34 vs -0.10, P=0.0271; 4-PC multivariate comparison: P=0.0007). **CONCLUSIONS:** The improvement in HR-QoL with nal-IRI+5-fluorouracil/leucovorin observed in the post hoc analysis of NAPOLI-1 results remained comparable after imputation of missing values in this imputation exercise.

PCN180

NON-PROGRESSION ON TREATMENT WITH AVELUMAB CONTRIBUTES TO GAINS IN HEALTH UTILITY SCORES IN PATIENTS WITH METASTATIC MERKEL CELL CARCINOMA

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OBJECTIVES: Patient-reported outcomes are an important component of drug benefit/risk and reimbursement evaluation, but limited data are available from patients with rare tumors, such as Merkel cell carcinoma (MCC). This study aimed to assess differences in health utility scores between non-progressing and progressing patients with metastatic MCC treated with anti-PD-L1 avelumab. **METHODS:** EQ-5D data collected from a phase 2 single-arm trial (NCT02155647) of 88 patients with chemotherapy-treated metastatic MCC were analyzed. The EQ-5D was assessed at baseline, week 7, every 6 weeks thereafter, and at the end-of-treatment visit. At each assessment, tumor response was determined by radiologically by an independent review committee per RECIST v1.1 performed within approximately 7 days of the EQ-5D assessment. EQ-5D utilities were calculated based on US and UK value sets. Linear mixed models were fitted to EQ-5D data, including progressive disease (vs complete response/partial response/stable disease) as a single time-varying covariate. In sensitivity analyses, estimates were adjusted for grade 3-4 adverse events (AEs) ongoing at EQ-5D assessment and treatment-related AEs of any grade. **RESULTS:** Among 70 evaluable patients, 247 observations were analyzed. Utility based on the US (UK) value sets was 0.8058 (0.8327) in the non-progression health state and 0.7120 (0.7130) in the

progression health state. Differences between health states were statistically significant ($p < 0.0001$) and clinically relevant. Adjusting for the presence of AEs had minimal impact. Parameter estimates of dis-utilities associated with experiencing ≥ 1 grade 3-4 AE based on US (UK) value sets were -0.02191 (-0.02439). Dis-utilities for treatment-related AEs of any grade were smaller (-0.00532 and -0.01028 for US and UK value sets). **CONCLUSIONS:** In patients with metastatic MCC, non-progression during treatment with avelumab contributed to gains in health utility scores. The dis-utility impact of AEs during treatment with avelumab was minimal, suggesting a manageable safety profile from a patient perspective.

PCN181

ASSOCIATION OF PATIENT-PHYSICIAN COMMUNICATION WITH FINANCIAL BURDEN AND QUALITY OF LIFE OF CANCER PATIENTS

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OBJECTIVES: Cancer is one of the most prevalent diseases in the United States. Approximately 39% of men and women are diagnosed with cancer based on 2011-2013 data. The objective of our study is to compare the quality of life (QOL) and financial burden of cancer patients who had good patient-physician communication to patients who had poor/no communication. **METHODS:** This was a retrospective study using 2011 Medical Expenditure Panel Survey (MEPS) data. The full year consolidated file was used. The sample consisted of all individuals who experienced cancer after the age of 18. The QOL and financial burden of cancer patients who reported having detailed discussions with their physician were compared with those with brief/no discussions. Chi-square tests were used for all comparisons. **RESULTS:** The sample consisted of 1592 cancer patients. Of these, 58.86% were females, 54.71% were married, 49.75% were in the 65-85 years' age group, with a typical cancer patient having a median total income of \$21334 (Interquartile range = 31681). Of those patients with higher QOL, a higher percentage (65.20% vs. 8.77%) reported good patient-physician communication as compared to those who had no communication. A larger percentage (66.84% vs. 8.05%) of patients with no financial burden had good patient-physician communication as compared to those with no communication. All results were statistically significant at $p < 0.05$. **CONCLUSIONS:** Patients with good communication with their doctors were more likely to have lower financial burden and a better quality of life.

PCN182

MULTIVARIATE ANALYSIS OF HEALTH-RELATED QUALITY OF LIFE (HR-QOL) IN METASTATIC PANCREATIC CANCER (MPC) TREATED WITH 5-FLUOROURACIL AND LEUCOVORIN, WITH AND WITHOUT LIPOSOMAL IRINOTECAN (NAL-IRI)

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OBJECTIVES: The survival benefits of nal-IRI+5-fluorouracil/leucovorin vs 5-fluorouracil/leucovorin in mPC patients who progressed after prior gemcitabine-based therapy were demonstrated in a phase 3 study (NAPOLI-1); preplanned analyses of QoL demonstrated no differences between treatment groups. While chemotherapy causes toxicities that impair HR-QoL, its clinical benefits may improve HR-QoL. We conducted a post hoc analysis of NAPOLI-1 EORTC-QLQ-C30 questionnaire measures to compare overall HR-QoL change. **METHODS:** A principal component (PC) analysis was performed on the EORTC-QLQ-C30 scales week-6 changes. PC scores were compared between groups, and correlations between EORTC-QLQ-C30 scale increments examined. **RESULTS:** Of 266 randomized patients, 122 had baseline and week-6 EORTC-QLQ-C30 scale measures and were included in the analysis. EORTC-QLQ-C30 increments in pain (-8.0 vs $+9.0$; $P=0.0060$), insomnia (-10.3 vs $+9.5$; $P=0.0023$), role functioning (-0.3 vs -11.7 ; $P=0.0346$), and Global Health Status/Quality of Life (GHS/QL; $+0.6$ vs -8.2 ; $P=0.0318$) favored patients receiving nal-IRI+5-fluorouracil/leucovorin vs 5-fluorouracil/leucovorin alone. No differences favored patients receiving 5-fluorouracil/leucovorin (P -values ≥ 0.1039), although diarrhea scores were numerically lower ($+15.4$ vs $+6.7$). GHS/QL increments were not correlated with diarrhea ($P=0.8487$), nausea/vomiting ($P=0.3787$), constipation ($P=0.3255$), or dyspnea ($P=0.3253$); pain ($P < 0.0001$), fatigue ($P < 0.0001$), insomnia ($P < 0.0002$), and appetite loss ($P < 0.0002$) were. Role functioning change had the strongest positive correlation with GHS/QL increment ($+0.39$, $P < 0.0001$). Multivariate comparison of the first 4 EORTC-QLQ-C30 scales changes PCs (variance explained: 59%) found treatment groups to be different ($P=0.0051$). With positive weights on functioning and GHS/QL scales, and negative weights on symptoms and financial difficulties scales, the first PC (explained variance: 34%) reflected general HR-QoL. nal-IRI+5-fluorouracil/leucovorin patients (vs. 5-fluorouracil/leucovorin) had higher first PC score ($P=0.0478$). **CONCLUSIONS:** Results of this post hoc analysis suggest that nal-IRI+5-fluorouracil/leucovorin improves HR-QoL vs 5-fluorouracil/leucovorin alone, and that certain chemotherapy adverse effects are not associated with HR-QoL detriments.

PCN183

QUALITATIVE INTERVIEWS TO UNDERSTAND THE PATIENT EXPERIENCE OF SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK AND EXPLORE THE CONTENT OF PATIENT REPORTED OUTCOME MEASURES

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OBJECTIVES: To understand the patient experience of squamous cell carcinoma of the head and neck (SCCHN) and guide selection of relevant measurement concepts for clinical trials. Patient reported outcome (PRO) instruments (EORTC QLQ-C30 and H&N-35) were also assessed for their suitability in this population. **METHODS:** A literature review and clinician interviews were conducted to inform in-depth

semi-structured telephone interviews with patients who had received treatment in the past 12 months for metastatic and/or recurrent SCCHN. Interview transcripts were analysed thematically in ATLAS.ti v7; patient quotes were coded to identify concepts and themes to develop a conceptual model of SCCHN experience. **RESULTS:** Thirteen patients were interviewed (77% male, aged 35-84); the majority diagnosed for > 1 year. Patients reported few symptoms pre-diagnosis; commonly a neck lump/swelling ($n=7$) and/or difficulty swallowing ($n=3$). Treatment generally comprised of surgery and chemotherapy and/or radiotherapy. Key side effects included pain ($n=8$), fatigue ($n=8$), and weight loss ($n=8$). These impaired health-related quality of life (HRQoL) including work ($n=6$), socializing ($n=7$), and emotional wellbeing ($n=11$). Tumour location, surgery and radiation particularly affected difficulty speaking ($n=7$) and difficulty eating/drinking ($n=9$). This was most severe in patients who had a feeding tube in-situ. Patients generally found the QLQ-C30 and H&N-35 content to be understandable and conceptually relevant; some additions were suggested including excessive mucous production and neuropathic symptoms. Patient data generally corroborated with the clinician interview and the literature review findings. **CONCLUSIONS:** SCCHN diagnosis, symptoms, and treatment impacts patients' physical functioning, emotional wellbeing, and overall HRQoL. PRO instruments included in clinical trials should assess the effect of novel therapies on fatigue, pain and oral problems including swallowing. The QLQ-C30 and H&N-35 appeared generally relevant and suitable to capture symptoms and impacts associated with SCCHN. However, some items could be amended/added to ensure conceptual comprehensiveness.

PCN184

EVALUATING CLINICALLY MEANINGFUL CHANGE OF THE EORTC QLQ-C30 IN PATIENTS WITH NSCLC

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OBJECTIVES: The EORTC QLQ-C30 has been extensively validated in cancer patients, but its responsiveness to individual changes in clinical outcomes in anaplastic lymphoma kinase (ALK+) non-small cell lung cancer (NSCLC) was not previously evaluated. The ALK in Lung Cancer Trial of brigatinib (ALTA trial; NCT02094573), an open-label, Phase 2, randomized, multicenter, international study, evaluated the efficacy and safety of brigatinib (Arm A: 90 mg qd and Arm B: 180 mg qd with a 7-day lead-in at 90 mg) in patients (pts) with locally advanced or metastatic ALK+ NSCLC whose disease had progressed on prior therapy with crizotinib. To interpret meaningful change in patient-reported outcomes (PROs), the responder definition (RD) threshold for the minimum individual pt change representing treatment benefit was established. **METHODS:** PRO data collection included the EORTC QLQ-C30 at baseline and first day of each cycle. The RD of the Global Health Status (GHS)/QoL scale of the QLQ-C30 was examined with anchor and distribution-based methods. Anchors included time point response per RECIST v.1.1 criteria and ECOG performance status. **RESULTS:** Of 222 randomized pts, 208 (94%) completed PRO data at baseline and at least one subsequent on treatment visit. The ANCOVA adjusted (sex and age) mean group difference between pts with stable disease ($n=76$) vs. complete or partial response ($n=99$) in change from baseline to cycle 3 in GHS/QoL was 9.8. Distribution-based estimates of the RD were 5.04, 12.6 and 17.6 (0.2 SD, 0.5, SD, and 1.0 SEM). A change of 8.33 (1 point on the raw scale, the minimum change possible) was selected as the RD threshold for GHS/QoL based on corresponding changes in response at cycle 3. **CONCLUSIONS:** A change of 8.33 points from baseline to cycle 3 can be interpreted as a meaningful score change in GHS/QoL indicative of treatment benefit for an individual patient with ALK+ NSCLC.

PCN185

PATIENT REPORTED HRQOL IN PATIENTS WITH STAGE IV SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK (SCCHN)

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OBJECTIVES: To evaluate the quality of life (QoL) reported by stage IV SCCHN patients. **METHODS:** Real world data was gathered using Adelphi's Disease-Specific Programme (DSP) - a cross-sectional survey administered to physicians and patients in the USA, France, Germany and the UK (April - September 2016). 182 physicians (54 US, 128 EU) provided data on consulting SCCHN patients regarding treatment patterns and staging. 373 current stage IV SCCHN patients (60 US, 313 EU) completed the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30), SCCHN-specific module (QLQ-HN35) and EQ-5D. Summary statistics were reported and differences between sub-groups assessed using pairwise t-tests. **RESULTS:** Patient global QoL, indicated by the EORTC QLQ-C30 global health scale, was poor with a (mean) score of 46.9. Some difference was observed between stage IVA/B and IVC patients (48.6 vs. 45.0 ($p=0.0997$)), most notably in physical function scores (69.4 vs. 63.8 ($p=0.0150$)). The most commonly reported symptoms were weight loss (61.3), less sexuality (54.9) and trouble with social eating (42.9). EORTC QLQ-C30 global QoL scores based on primary tumour site showed differentiation (mean) - floor of mouth (38.9), larynx (42.4), lip/tongue/gum (47.3), hypopharynx (49.4) and oropharynx (52.4). This was seen again in social function scores - floor of mouth (50.6), larynx (54.2), lip/tongue/gum (53.0), hypopharynx (61.0) and oropharynx (61.9). The reported EQ-5D score (mean) also showed low QoL (0.57), with no difference between stage IVC (0.57) and stage IVA/B patients (0.57). Some differences were seen based on primary tumour site (mean) - floor of mouth (0.46), larynx (0.51), lip/tongue/gum (0.58), hypopharynx (0.60) and oropharynx (0.64). **CONCLUSIONS:** Overall QoL for stage IV SCCHN patients is low, although not significantly lower for stage IVC vs. IVA/B patients.

Primary tumour site impacts QoL, most notably for patients with a floor of the mouth tumour.

PCN186

UNDERSTANDING THE SYMPTOMS, IMPACTS, AND TREATMENT SIDE-EFFECTS OF ADVANCED BLADDER CANCER FROM THE PERSPECTIVE OF THE LITERATURE, CLINICIANS, AND PATIENTS

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OBJECTIVES: The primary objective was to identify, define and substantiate concepts of measurement that reflect the symptoms, impacts and treatment side-effects of advanced bladder cancer (BC) from the literature, clinician, and patient perspective. **METHODS:** Symptoms, impacts, and treatment side-effects of advanced BC were elicited through a literature review and interviews with clinicians and patients. Articles were identified via OvidSP and results were summarized in extraction tables. Clinicians were identified using literature and peer recommendations. Patients were recruited via agencies and clinical sites. Patient study materials were approved by an Ethics Committee. Each interview (clinician/patient) was audio-recorded, transcribed, anonymized, and analyzed quantitatively and qualitatively. Concepts identified across research stages were organized into a disease conceptual model and compared to PRO measures for conceptual coverage. **RESULTS:** Of the twelve articles reviewed, 12 signs/symptoms of advanced BC, 33 side-effects, and 33 impacts were identified across seven domains. Five clinicians elicited 15 signs/symptoms, 31 side-effects, and 25 impacts across seven domains. Ten patients with advanced BC (mean age: 72.1 years and 60.0% male) primarily receiving chemotherapy (n=5, 50%) reported 22 BC symptoms, 19 treatment-related side-effects, and 27 BC or treatment-related impacts across nine domains. The most frequently reported symptom across the BC experience was blood in urine (n=8, 80.0%). The most frequently reported side-effect was fatigue/tiredness (n=5, 50.0%) attributed to various treatments. The most frequently reported BC or treatment-related impact domain was activities of daily living (n=9, 90.0%). **CONCLUSIONS:** Results demonstrate the deleterious burden of advanced BC and treatment. Although no one PRO measure captures the multiple symptoms, impacts and side-effects of the disease, the EORTC QLQ-BLM30, FACT-G, FACT-BL, and NFBISI-18 might be considered for assessing symptoms and impacts, and the PRO-CTCAE for assessing side-effects. This research underscores the importance of capturing patients' experience of symptoms, tolerability, and impacts when evaluating new treatment options.

PCN187

THE EFFECTS OF DISEASE AND TREATMENT-ASSOCIATED CANCER SYMPTOMS ON HEALTH-RELATED QUALITY-OF-LIFE: THE MEDIATING EFFECT OF FATIGUE IN NON-SMALL CELL LUNG CANCER AND METASTATIC BREAST CANCER

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OBJECTIVES: Recent research has shown complex and indirect associations of disease and treatment-associated cancer symptoms with health-related quality-of-life (HRQoL) constructs (e.g., functioning and QoL). Evident from this work are the causal cascades of symptoms flowing to distal HRQoL outcomes, and that these pathways are often mediated by patient-reported fatigue. We developed models and tested their correspondence in 1st line non-small cell lung cancer (NSCLC) and 3rd line or greater metastatic breast cancer (mBC) settings. **METHODS:** Data come from two randomized clinical trials (RCTs) of 1st line locally advanced or metastatic NSCLC and a single one-arm clinical trial of 3rd line or greater mBC. Structural equation modeling (SEM) of direct and indirect symptom effects on distal HRQoL outcomes was conducted using questionnaires included in these trials; the EORTC QLQ-C30 was supplemented with the EORTC QLQ-LC13 in the NSCLC RCTs and with the Brief Pain Inventory short form (mBPI-sf) in the mBC clinical trial. We ran and interpreted goodness-of-fit tests to evaluate the extent that hypothesized conceptual models corresponded with the observed data. Estimates of standardized direct, indirect, and total effects of symptom on HRQoL showed the relative strengths of the cascade path components. **RESULTS:** There was a logical and consistent ordering, and effect magnitudes, of the causal cascade path components across the NSCLC and mBC trials. Specifically, the effects of symptoms (e.g., pain, dyspnea, and appetite loss) on HRQoL (i.e., physical, role, cognitive, emotional, and social functioning as well as QoL) were mediated by fatigue. **CONCLUSIONS:** Corroborating across-trial and across-tumor results demonstrate the consistent mediating effect of fatigue which links disease and treatment-associated cancer symptoms to HRQoL. Evaluating only direct effects of symptoms on HRQoL will underestimate the patient symptom burden. Interpretation of causal cascades will better inform patients, families, and clinicians about the HRQoL consequences of the disease and treatment.

PCN188

STRESS-RELATED COMORBIDITIES AND LOSS OF PRODUCTIVITY ASSOCIATED WITH PROVIDING CARE TO ADULTS WITH MULTIPLE MYELOMA

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OBJECTIVES: Little is known about the effect of caregiving for people with multiple myeloma (MM) on work productivity, activity impairment, depression and anxiety. This study examined the burden on caregivers providing care to adults with MM. **METHODS:** A cross-sectional survey of 145 MM caregivers recruited through the Light Speed Research panel was conducted. The IRB-approved survey assessed patient and caregiver demographic characteristics, hours of provider care, and MM

treatment. The study assessed caregiver burden using validated instruments including, the Work Productivity and Activity Impairment (WPAI) questionnaire, the Patient Health Questionnaire-9 (PHQ-9; range 0-27, higher scores indicate greater depression severity) and Generalized Anxiety Disorder-7 (GAD-7; range 0-21, higher scores indicate greater anxiety severity). The results are summarized using descriptive statistics. **RESULTS:** Among the 145 caregiver respondents, 60.7% (n=88) were female and the mean age was 51.9 (SD=12.6) years. Of these, 72.4% were White, 78.6% married, and 65.5% employed. Caregivers, on average, had been providing care to the MM patients for 4.1 years (range=0.2-27.5), and reported providing 31.5 (SD=35.8) hours of care per week. Patient characteristics were as follows: Diagnosed 5.1 (SD=6.6) years prior to study enrollment, 44.8% female, 59.9 (SD=13.9) years old, on a multiple-drug regimen (1.9 drugs (SD=1.0)) for MM. A total of 30.3% were on their third or later treatment regimen. In univariate analyses, caregivers reported a mean (SD) absenteeism from work due to impairment of 14.5% (14.3%), impairment while at work (presenteeism) of 47.0% (31.7%), overall work impairment of 51.5% (33.1%), and activity impairment of 44.4% (31.3%) in the past 7 days. Mean (SD) scores on the GAD-7 and PHQ-9 were 6.6 (4.9) and 7.6 (5.9) respectively. **CONCLUSIONS:** There is a significant caregiver burden associated with caring for a person with MM, impacting productivity and daily activities. Caregivers also experience mild depression and anxiety symptoms.

PCN189

PSYCHOMETRIC VALIDATION OF THE FACT-M QUESTIONNAIRE IN PATIENTS WITH MERKEL CELL CARCINOMA

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OBJECTIVES: Assessment of patient-reported outcomes in oncology clinical trials is required to demonstrate treatment benefit from a patient's perspective. No validated tools exist to capture health-related quality of life (HRQoL) in patients with Merkel cell carcinoma (MCC), an ultra-rare skin cancer. The objective of this research was to assess the reliability and validity of the Functional Assessment of Cancer Therapy-Melanoma (FACT-M) questionnaire in patients with MCC. **METHODS:** Patients with stage IV chemotherapy-refractory MCC completed the FACT-M in a single-arm, open-label, multicenter, international phase 2 trial (NCT02155647). Internal consistency reliability and construct validity of the FACT-M were assessed at baseline and the ability to detect change in tumor size was assessed from baseline to week 7. Minimal important differences (MID) were computed using distribution and anchor-based methods. **RESULTS:** Baseline assessments were available in 70 patients (mean age: 70 years; 74.3% male). FACT-M domains showed acceptable psychometric properties: high internal consistency reliability (Cronbach's alpha: 0.81 - 0.96) and good convergent validity (correlations above 0.4 were observed for 88% of items of the melanoma surgery scale, 75% of items of the melanoma scale and 100% of items of the other FACT-M domains). Higher scores (better HRQoL) on all FACT-M domains were observed in patients with better functioning (assessed by ECOG performance score), with statistically significant difference in physical well-being score (p=0.0221) supporting clinical validity. Despite the small sample for responsiveness analysis (n=37), the majority of FACT-M scores showed sensitivity to changes in tumor size at week 7 with small to moderate effect sizes. Some evidence of floor/ceiling effects and potential mismatch between items and domains (discriminant validity) was found. MID were consistent with previously reported values in the literature for FACT-M domains. **CONCLUSIONS:** The FACT-M demonstrated acceptable psychometric properties in MCC patients, thus making it a potential candidate for assessing HRQoL in MCC trials.

PCN190

ASSESSMENT OF THE ASSOCIATION BETWEEN THE BURDEN OF CARCINOID SYNDROME SYMPTOMS AND THE QUALITY OF LIFE AMONG PATIENTS WITH CARCINOID SYNDROME IN THE UNITED STATES BASED ON THE FACT-G INSTRUMENT

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OBJECTIVES: To assess the association between the burden of carcinoid syndrome symptoms (CSS) and quality of life (QoL) among patients with carcinoid syndrome using the validated Functional Assessment of Cancer Therapy-General (FACT-G) instrument. **METHODS:** Patients with CSS in the US were recruited via Neuroendocrine Cancer Awareness Network for an online, anonymous survey between July and October 2016. Eligible patients were at least 18 years old with CSS and received either somatostatin analogs (SSA) or non-SSA treatments for CSS control. The survey consisted of demographic, clinical, and QoL questions, including FACT-G questionnaire. Descriptive and multivariable regression analyses, adjusting for demographic and clinical characteristics, were performed to assess the association between CSS and total FACT-G score. **RESULTS:** Among 117 patients with CSS, who completed the survey, 76.9% were female and 87.2% were Caucasian with a mean age of 58.0 years. Patients reported experiencing up to 6 CSS (mean±SD: 3.0±1.1) after diagnosis with neuroendocrine tumor. Carcinoid diarrhea (97.4%) and flushing (90.6%) were the most common CSS. Majority of patients (98.3%) reported receiving SSAs in the past month, and the mean±SD FACT-G total score was 67.6±20.0 (possible range: 0-108), which is lower than the general US population (80.1±18.1). Descriptive analysis suggested that FACT-G total score and subdomain scores were negatively associated with CSS burden. Multivariable models revealed that the FACT-G total score was decreased by 3.4 points (P=0.034) for each additional CSS, ≥4 bowel movements/day was associated with a 7.1 point decrease in FACT-G total score as compared to having <4 bowel movements/day (P=0.043), and that reduced activity levels (bed rest at

<50% or ≥50% of the day, compared to normal activity) decreased the FACT-G total score by 25.4 and 35.5 points, respectively (both $P < 0.001$). **CONCLUSIONS:** This study suggests that CSS burden and impaired activity level are associated with lower QoL among patients with carcinoid syndrome.

PCN191

HEALTH-RELATED QUALITY OF LIFE AMONG CANCER SURVIVORS STRATIFIED BY OPIOID EXPOSURE IN THE UNITED STATES

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OBJECTIVES: Health-Related Quality of Life (HRQoL) is critical to cancer patients in terms of care, making treatment decisions and survival. This study aims to measure HRQoL among cancer survivors stratified by opioid exposure in the United States. **METHODS:** Data were obtained annually from 2008-2013 using Medical Expenditure Panel Survey (MEPS). Cancer survivors were identified using survey questions and clinical classification codes excluding non-melanoma skin cancer. The HRQoL was measured in terms of physical component summary (PCS) and mental component summary (MCS) scores using Short Form-12. The HRQoL among cancer survivors with opioid exposure were reported for the following classes: (a) with any opioid use (opioids, narcotic analgesic combinations), (b) no opioid use but at least one prescription for other pain medication (adjuvant analgesics and non-opioids such as NSAIDs, salicylates, non-narcotic analgesic combinations) and (c) without pain medication. Data were analyzed using appropriate statistical procedures for the MEPS with its unique sampling design. **RESULTS:** A total of 23.1 million cancer survivors and 193.5 million individuals without cancer history were identified. The cancer survivors had significantly ($p < 0.001$) lower PCS and MCS scores, 43.9(SE=0.20) and 50.2(SE=0.16) compared to individuals who never had cancer, 50.0(SE=0.07) and 51.2(SE=0.05) respectively. Among cancer survivors, 35.0% had at least one prescription claim for opioids, 18.4% had no prescription for opioids but at least one claim for other pain medication and 46.6% had no prescription for a pain medication. For these three groups the PCS and MCS scores were 39.2(SE=0.31), 43.1(SE=0.42), 47.7 (SE=0.23) and 48.1(SE=0.27), 49.7(SE=0.35), 52.0(SE=0.18) respectively. **CONCLUSIONS:** A high percentage of cancer survivors take opioids for the disease or for treatment. The lower HRQoL scores indicate cancer survivors are in pain and need to be screened appropriately for their physical and psychological concern.

PCN192

HUMANISTIC BURDEN OF DISEASE IN EARLIER STAGE METASTATIC (IIIB/C-IVM1A) VERSUS LATE STAGE METASTATIC (IVM1B/C) MELANOMA PATIENTS IN A REAL WORLD SETTING IN THE US

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OBJECTIVES: To assess melanoma specific health-related quality of life (HRQoL) and health states in patients with earlier stage metastatic (IIIB/c-IVM1a) versus late stage metastatic (IVM1b/c) melanoma. **METHODS:** Data were collected from the Adelphi Real World Advanced Melanoma Disease-Specific Programme®, a cross-sectional survey of 112 physicians and their patients (N=666). Data were collected between March and July 2016 in the US. A subset of 183 patients completed the Functional Assessment of Cancer Therapy Melanoma (FACT-M) and EuroQol-5D (EQ-5D) one time. Patients were classified by stage of melanoma at time of consultation. Descriptive analyses of HRQoL scores between earlier and late stage metastatic melanoma were assessed using Mann-Whitney U tests. **RESULTS:** The mean age of the earlier stage and late stage metastatic patients was 62 and 64 respectively. More earlier stage metastatic patients had an ECOG status of 0 or 1 versus late stage metastatic patients (85%, 75% respectively). A total of 31% of late stage metastatic patients required caregiver support and had a median time since primary diagnosis of 5.0 months whereas earlier stage metastatic patients reported 14% and 5.2 months respectively. Patients with earlier stage metastatic melanoma had better mean EQ-5D index scores versus late stage metastatic melanoma patients (0.81 (n=84), 0.76 (n=93); $p=0.0103$). Higher scores indicating better HRQoL were observed between earlier stage metastatic versus late stage metastatic melanoma patients for the FACT-M (120.7 (n=81), 107.4 (n=91); $p=0.0017$) and subscales (except Social Well Being). Clinically meaningful differences between groups using published minimal important differences (MIDs) were observed in 6/7 FACT-M subscales and EQ-5D VAS. **CONCLUSIONS:** Differences in HRQoL and health states were observed between earlier stage metastatic and late stage metastatic melanoma populations, highlighting the detrimental effect of developing metastatic disease. These results suggest that treatments that delay progression of the disease are important to conserve patients HRQoL.

PCN193

RELATIONSHIP BETWEEN RECEIPT OF A WRITTEN SURVIVORSHIP CARE PLAN AND HEALTH-RELATED QUALITY OF LIFE: AN ANALYSIS OF THE NATIONAL HEALTH INTERVIEW SURVEY

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OBJECTIVES: Little is known about the relationship between cancer survivorship care planning and quality of life outcomes of survivors. The purpose of this study was to examine the association between receipt of written documentation of advice for follow up care or documentation of all cancer treatments on Health Related Quality of Life (HRQoL). **METHODS:** Adults aged 18+ years with a history of cancer were identified from the 2010 National Health Interview Survey. Patients currently receiving cancer treatment and those who were diagnosed with cancer

prior to age 18 were excluded (final sample 2,329). Logistic regression was used to assess the association between receiving advice from a health care professional about routine cancer check-ups after completing cancer treatment in a written format (WA) (n=1327) and receiving a written documentation of all cancer treatments (WTx) (n=1783) and general HRQoL, physical health status, and mental health status. Analyses were adjusted for SES variables, cancer status, and participation in counseling or support groups. The general HRQoL outcome was dichotomized (excellent or very good or good vs fair or poor). All analyses were weighted to account for the sampling scheme. **RESULTS:** Neither WA nor WTx was associated with HRQoL (OR = 1.16, 95% CI 0.74, 1.81; OR = 1.24, 95% CI 0.81, 1.90 respectively). WTx was not associated with mental health status (OR = 1.28 & 95% CI 0.83, 1.98), but WA was associated with a 38% decreased odds of reporting excellent or very good mental health (OR = 0.62, 95% CI 0.40-0.97). Neither WA nor WTx was associated with physical health status (OR = 0.89, 95% CI 0.64-1.24 and OR = 0.78, 95% CI 0.56-1.10, respectively). **CONCLUSIONS:** Receipt of WA is associated with decreased odds of reporting excellent or very good mental health. Future work should investigate this relationship.

PCN194

HUMANISTIC BURDEN OF DISEASE IN EARLIER STAGE METASTATIC (IIIB/C-IVM1A) VERSUS LATE STAGE METASTATIC (IVM1B/C) MELANOMA PATIENTS IN A REAL WORLD SETTING IN 5 EU COUNTRIES

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OBJECTIVES: To assess melanoma specific health-related quality of life (HRQoL) and health states in patients with earlier stage metastatic (IIIB/c-IVM1a) and late stage metastatic (IVM1b/c) melanoma. **METHODS:** Data were collected from the Adelphi Real World Advanced Melanoma Disease-Specific Programme®, a cross-sectional survey of 243 physicians and their patients (n=1881). Data were collected between March and July 2016 in 5 major European countries (FR, GE, SP, IT & UK). A subset of 660 patients completed the Functional Assessment of Cancer Therapy Melanoma (FACT-M) and EuroQol-5D (EQ-5D) one time. Patients were classified by stage of melanoma at time of consultation. Descriptive analyses of HRQoL scores between groups were assessed using Mann-Whitney U tests. **RESULTS:** The mean age of the earlier and late stage metastatic patients sampled was 57 and 59 respectively. More earlier stage metastatic patients had an ECOG status of 0 or 1 versus late stage metastatic patients (80%, 75% respectively). A greater proportion of late stage metastatic patients required caregiver support (42%) and had a longer median time since primary diagnosis (6 months) versus earlier stage patients (30% and 5 months). Patients with earlier stage metastatic melanoma had better mean EQ-5D index scores versus late stage (0.75 (n=325), 0.67 (n=324); $p=0.0120$). Higher scores indicating better HRQoL were observed between the earlier and late stage metastatic melanoma patients for the FACT-M (116.4 (n=315), 108.8 (n=307); $p=0.0014$) and subscales (except Emotional Well Being). Clinically meaningful differences between groups using published minimal important differences (MIDs) were observed for 3/7 FACT-M subscales and the EQ-5D index score. **CONCLUSIONS:** Differences in HRQoL and health states were observed between earlier stage and late stage metastatic melanoma populations, highlighting the detrimental effect of developing late stage metastatic disease. These results suggest that treatments that delay progression of the disease are important to conserve patients HRQoL.

PCN195

QUANTIFYING THE ASSOCIATION BETWEEN HEALTH-RELATED QUALITY OF LIFE (HRQL) SCORES AND WORK-RELATED OUTCOMES IN ONCOLOGY

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OBJECTIVES: The impact of health-related quality of life (HRQL) on work-outcomes, such as absenteeism and presenteeism, has been examined; however, this impact has not been clearly quantified specifically in samples of oncology patients. This study quantified the association between differences in SF-12v2® Health Survey (SF-12v2) physical or mental component scores (PCS and MCS) scores and work-related outcomes among patients with cancer not in remission. **METHODS:** Data came from adult participants in the Medical Expenditure Panel Survey who completed at least one SF-12v2 questionnaire and reported a diagnosis of cancer not in remission (n=548). Generalized linear mixed models were used with absenteeism (percentage of lost days of paid and unpaid work) and presenteeism (serious cognitive limitations) as the outcome. Predictors included SF-12v2 PCS and MCS with sociodemographic factors as covariates. Analyses examined these effects in the entire sample and specifically among employed patients. **RESULTS:** A five-point greater (more favorable) PCS and MCS score was associated with 9% and 20% lower odds, respectively, of having lost work days. Among employed subjects, a 5-point greater PCS and MCS score was associated with 20% and 24% lower odds of missing work days, respectively. A five-point greater PCS and MCS was also associated with 24% and 33% decline, respectively, in the odds of experiencing serious cognitive limitations; among employed subjects, the decline in the odds of experiencing cognitive limitations were 12% and 38%, for a 5-point greater PCS and MCS, respectively. **CONCLUSIONS:** Better PCS and MCS scores were associated with lower odds of missing work days and experiencing serious cognitive difficulties, suggesting a close link between improved HRQL scores and declines in absenteeism and presenteeism. These findings can be a potential guide in evaluation of outcomes in oncology. Future research should explore whether these US based results can be generalized to an international oncology population.

PCN196

EORTC-8D UTILITY VALUES IN PATIENTS WITH PHILADELPHIA NEGATIVE (PH-) RELAPSED/REFRACTORY (R/R) B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA (B-CELL ALL) RECEIVING BLINATUMOMAB VERSUS STANDARD OF CARE (SOC) CHEMOTHERAPY IN A RANDOMIZED, OPEN-LABEL PHASE 3 STUDY (TOWER)

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OBJECTIVES: The TOWER trial demonstrated improved survival and beneficial effects on health-related quality of life (HRQoL) for blinatumomab compared with SOC chemotherapy in patients with Ph- R/R B-cell ALL (Topp, 2016). To inform economic evaluations of blinatumomab in this setting, a post-hoc analysis was conducted to estimate utility values for patients with Ph- R/R B-cell ALL receiving blinatumomab and SOC chemotherapy in TOWER. **METHODS:** Utility values were estimated using the EORTC-8D, a cancer-specific preference-based measure of HRQoL derived from the EORTC QLQ-C30 (Rowen 2011). Utility values were classified into four health states (baseline, initial [post-baseline and pre assessment of response], response, and refractory), and by time to death (≤ 1 vs. > 1 month). Because of small numbers, post-relapse assessments were excluded. GLM/GEE regression was employed with covariates for health states interacting with treatment assignment and time to death. **RESULTS:** Among patients randomized to blinatumomab (N=271) and SOC (N=134), 260 blinatumomab and 105 SOC patients had valid EORTC-8D utility values for one or more assessment for the states of interest (total number of valid assessments=1421 for blinatumomab and 376 for SOC). Baseline utility values were similar for blinatumomab vs. SOC (Mean [SE] 0.750 [0.009] vs. 0.746 [0.014], $p=0.824$). Utility values were higher for blinatumomab vs. SOC for the initial state (0.766 [0.009] vs. 0.688 [0.018], $p<0.001$), response state (0.814 [0.011] vs. 0.747 [0.020], $p=0.003$), and refractory state (0.742 [0.014] vs. 0.673 [0.017], $p=0.001$). There was a nominal decrement in mean [SE] utility during the one month before death (-0.027 [0.015], $p=0.083$), independent of treatment. **CONCLUSIONS:** EORTC-8D utility values in TOWER were higher for patients receiving blinatumomab than SOC chemotherapy for all post-baseline health states. These findings are consistent with the benefits of blinatumomab vs. SOC on survival, response, and HRQoL observed in TOWER.

PCN197

WORK PRODUCTIVITY AND ACTIVITY IMPAIRMENT IN WOMEN WITH HR+/HER2- ADVANCED/METASTATIC BREAST CANCER

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OBJECTIVES: To assess work productivity and activity impairment among women with HR+/HER2- advanced/metastatic breast cancer (ABC/MBC) in a real world setting. **METHODS:** Women with HR+/HER2- ABC/MBC in the US and 5 major EU countries (N=739) were recruited as part of a multicenter study and completed the 6 item Work Productivity and Activity Impairment (WPAI:SHP) questionnaire. For employed patients, the instrument measures work time missed, impairment at work, and overall impairment/ productivity loss. Activity impairment is calculated for employed and unemployed patients. Higher scores indicate greater impairment and less productivity. Results were stratified and compared by receipt of chemotherapy vs. endocrine therapy. Significance was assessed using Kruskal-Wallis tests. **RESULTS:** Patients had mean (SD) age of 65.2 (10.6) and 85% were white/Caucasian. 83% of patients were in metastatic stage and 17% had locally advanced disease. Of the metastatic patients, 61% had visceral disease. Only 11.4% (n=83) of patients were employed at the time of completion of the WPAI. Mean (SD) number of hours missed due to breast cancer (BC) was 8.7 (13.0) while for other reasons it was 2.8 (8.3) hours. Patients missed 26.7% of their work time on average due to BC. When subset to those receiving chemotherapy alone (n=305) or endocrine therapy alone (n=293), chemotherapy patients (11.9% employed) missed a greater percentage of work time (25.7% vs. 16.0%, $p=0.696$) compared to endocrine therapy patients (9.7% employed). Similarly, impairment at work was 28.8% (35.4% chemotherapy vs. 21% endocrine therapy, $p=0.0121$). Overall work impairment was 34.9% (44.2% chemotherapy vs. 25.8% endocrine therapy, $p=0.0107$). Among both employed and unemployed patients, activity impairment was 36.8% (37.8% chemotherapy vs. 34.3% endocrine therapy, $p=0.0343$). **CONCLUSIONS:** Women with HR+/HER2- ABC/MBC have low rates of employment, and among those employed, there is considerable negative impact on productivity and overall activity. Patients receiving chemotherapy had greater negative impact compared to those receiving endocrine therapy.

CANCER – Health Care Use & Policy Studies

PCN198

LOWER ANTERIOR RESECTION (LAR) PROCEDURES AND IMPACT OF KEY COMPLICATIONS ON DIAGNOSIS RELATED GROUP (DRG) SEVERITY LEVELS: A REAL-WORLD DATABASE STUDY

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OBJECTIVES: Diagnosis Related Groups (DRG) for hospitalizations have varying levels of severity that impact hospital reimbursement. This study assesses the distribution of DRG severity levels in lower anterior resection (LAR) procedures among colorectal cancer patients and explores the association of specific complications [bleeding, infection and anastomotic leak (AL)] and DRG severity category of a major comorbidity or complication (MCC). **METHODS:** We reviewed the Premier Perspective® Database containing billing data from over 600 hospitals in the U.S. Included patients were > 18

years of age, had a diagnosis of colorectal cancer and underwent an elective LAR between 2008 and 2014. AL, bleeding and infection were identified using ICD-9 diagnosis codes. Multivariable models were used to estimate the association of each major complication on receiving MCC DRG classification, adjusting for differences in patient, hospital, and surgical characteristics; separate models were run for each complication. **RESULTS:** A total of 8,790 patients underwent elective LAR with a cancer diagnosis during the study period. Of these, 3,450 (39%) were coded as having no complications/comorbidity, 4,465 (51%) were classified into complication or comorbidity (CC) category, and 875 (10%) were classified as the most severe MCC category. Incidence of AL, bleeding and infection was 12.9%, 9.5% and 5.8%, respectively in the overall sample. These complications were disproportionately higher in the MCC category (AL=35.3%, bleeding=24.2% and infection=41.7%). Results of the multivariable models showed that AL, bleeding and infection were associated with higher odds of receiving an MCC classification [AL:Odds Ratio(OR) =4.12;CI:3.42-5.0;Bleeding: OR=2.56;CI:2.08-3.16;Infection:OR=38.19;CI:29.53-49.39]. **CONCLUSIONS:** This study demonstrates that a majority of elective LAR procedures among cancer patients fall under the CC or MCC DRG categorization. Incidence of complications such as AL, bleeding and infection are associated with a greater likelihood of falling under the MCC DRG category and would likely lead to a greater economic burden.

PCN199

EFFECTS OF SCREENING AND TARGETED THERAPIES USE ON COLORECTAL CANCER DIAGNOSIS AND TREATMENT IN TAIWAN

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OBJECTIVES: For early diagnosis, colorectal cancer screening (Fecal Immunochemical Testing) has been promoted and implemented on a large scale by Health Promotion Administration in Taiwan since 2010. Besides, targeted therapies (bevacizumab, cetuximab, panitumumab, regorafenib) have gradually become available for better treatment since 2005. This study aims to explore the effects of large-scale colorectal cancer screening on incidence and diagnosis of colorectal cancer in Taiwan overtime. We also examined the influences of availability of targeted therapies on clinical outcomes of colorectal cancer overtime. **METHODS:** 1994-2013 (20 years) colorectal cancer-related data from Taiwan Cancer Registry Database was accessed. Using an interrupted time series design and segmented regression, we estimated changes in age-standardized incidence rate, proportion of early/late diagnostic stage, five-year survival rates and age-standardized mortality rate of colorectal cancer following the above interventions. **RESULTS:** After the large-scale colorectal cancer screening in 2010, the incidence rate of colorectal cancer increased suddenly but decreased later on. There was a relative decrease of 1.85% in incidence rate at 3 years following the screening. Proportion of early diagnostic stage did not significantly increase as expected, while proportion of late diagnostic stage substantially reduced 15.32% (C.I.: -21.69%, -8.96%) at 3 years after the screening. Following the first targeted therapy (bevacizumab) became available in 2005, the five-year survival rate relatively increased 6.49% (C.I.: 4.59%, 8.39%), however, mortality rate also increased 8.79% (C.I.: 2.28%, 15.30%) at 3 years after the use of targeted therapies. **CONCLUSIONS:** The study found that the implementation of large-scale colorectal cancer screening was helpful to decrease the proportion of late diagnostic stage, no significant increasing of proportion of early diagnostic stage was found though. Despite targeted therapies were beneficial for increasing survival rate, the overall mortality did not reduce. Better use of targeted therapies is needed to be considered in Taiwan.

PCN200

CLINICAL AND ECONOMIC ASSESSMENT OF DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL) THERAPIES USING A PROPRIETARY VALUE ASSESSMENT PLATFORM

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OBJECTIVES: To assess clinical and economic value of current and pipeline projects indicated for DLBCL. **METHODS:** MKTXS Value Assessment Platform (MVAP) was used to evaluate Rituximab, Cyclophosphamide, Hydroxydaunomycin Oncovin, and Prednisone combination (RCHOP), and pipeline agents studied in combination with RCHOP, lenalidomide, ibrutinib, and pembrolizumab. A targeted literature review was conducted (using Pubmed and clinicaltrial.gov) to collect evidence on clinical (efficacy, safety, administration, evidence availability) and economic (need, competition, delivery) categories. Each category consists of attributes driving value, for example, efficacy included, among others, overall survival (OS) and progression free survival (PFS). Categories were weighted by importance to US Payer, therapies were scored against RCHOP, and value plotted on an X-Y axis. **RESULTS:** Clinically, RCHOP (Intravenous (IV)) received the highest score due to its performance on all efficacy attributes, and on safety (manageable adverse events (AEs)). In clinical categories, lenalidomide combination outperformed RCHOP on efficacy (OS, PFS). Ibrutinib and pembrolizumab are in early development, and performed worse than lenalidomide due to lack of evidence (no OS, PFS) and poorer safety (more AEs expected). RCHOP received the highest economic score due to less competition (provider familiarity, uptake). Lenalidomide and ibrutinib offer the next highest value due to easier delivery (oral versus IV), while pembrolizumab lags due to need for an additional IV agent in addition to RCHOP. **CONCLUSIONS:** Effectively communicating superior efficacy and benign safety profile, with an oral formulation can differentiate lenalidomide against DLBCL options, but evidence generated by newer agents should be carefully monitored. Ibrutinib can also leverage its oral formulation, but, due to its, and pembrolizumab early stage in development, the manufacturer should engage in cross functional (including clinical, health economic/market access, commercial) teams to internally assess value, and fine tune future trial designs and strategize evidence generation plans that highlight product value against competitors.

PCN201

METASTATIC CASTRATION RESISTANT PROSTATE CANCER TREATMENT PATTERNS CHANGES WITH THE INTRODUCTION OF ABIRATERONE IN 2012 IN QUEBEC

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OBJECTIVES: This study aimed to describe how real-world clinical practice was changed with the introduction of abiraterone in Quebec in 2012. **METHODS:** We conducted a retrospective cohort study in two of McGill University's academic hospitals. We selected 308 patients treated for mCRPC from January 2010 to June 2014. Data on mCRPC treatments and patients' clinical and demographic characteristics was extracted. Descriptive statistics, Kaplan-Meier method and Cox proportional-hazard regression were used to describe drugs utilization over time, to estimate time to initiate them and to identify predictive factors of receiving them. **RESULTS:** The median age at CRPC was 74.0. 52% of patients were diagnosed with mCRPC before 2012. Half of patients in the pre-2012 group had docetaxel and 1.2% had abiraterone as first-line vs 30% and 26%, respectively, in the post-2012 group. Overall, 84% of patients had docetaxel and 48% had abiraterone in the pre-2012 group versus 55% and 77%, respectively, in the post-2012 group. Patients with metastases at CRPC diagnosis: bone (HR: 2.4; 95%CI 1.4 – 4.1) and visceral (HR: 3.3; 95%CI 1.8 – 6.2), those younger than 80 at CRPC diagnosis (HR: 1.9; 95%CI 1.3 – 2.8) and those diagnosed with mCRPC pre-2012 (HR: 1.7; 95%CI 1.3 – 2.3) were more likely to have docetaxel. Patients with bone (HR: 1.9; 95%CI 1.1 – 3.2) and visceral metastases (HR: 2.4; 95%CI 1.3 – 4.7) at CRPC diagnosis and those diagnosed with mCRPC post-2012 (HR: 5.0; 95%CI 3.3 – 10.0) were more likely to have abiraterone. Median time to initiate docetaxel was delayed in post-2012 group comparatively to pre-2012 (11 (2 – 41) vs 5 (1-16) months, respectively). **CONCLUSIONS:** The introduction of abiraterone reduced docetaxel utilization as first-line and overall and delayed time to its initiation. Metastases extent, age, moment of diagnoses with mCRPC were predictive factors of receiving docetaxel and abiraterone.

PCN202

REAL WORLD DATA ON MULTIPLE MYELOMA IN BRAZIL: PATTERNS OF CARE IN THE PRIVATE HEALTHCARE SYSTEM

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OBJECTIVES: Multiple Myeloma (MM) is a rare malignancy, accounting for only 0.8% of all cancers and 10% of hematologic malignancies. The aim of this retrospective study was to generate real world data (RWD) for MM patterns-of-care in Brazilian private healthcare system. **METHODS:** We searched Evidências-Kantar Health electronic claims private market database Auditor (which represents 7% of Brazilian private healthcare system) for MM patients in treatment between Mar2013-Mar2016. We retrieved data on demographics, disease stage, chemotherapy regimens, supportive treatment, stem cell transplantation (SCT) and laboratory results. Analyses were conducted using descriptive statistics. **RESULTS:** Our search retrieved 254 MM patients, with median age of 65 years (IQR:55-75) of which 53.9% were female. Per Durie Salmon system, 5.5% had stage I disease, 14.9% stage II and 29.5% stage III. First-line therapy data was available for 245 patients. Median treatment time was 168 days (112-224). Bortezomib-containing regimens were reported by 78.8% of patients and preferred regimen was bortezomib+cyclophosphamide+dexamethasone (VCD, 51.4%). For second-line, of 92 patients (median treatment time: 126 days (84-224), 63.5% reported bortezomib-containing regimens and preferred regimen was VCD (29.4%). For later lines, distribution of patients (number of patients, preferred regimen) was: 3rd line (46, BCD); 4th (23, VCD); 5th (6, melphalan+prednisone) and 6th(1, VCD). Forty-one patients (16.1%) received SCT in at least one line. Median age for SCT+ patients were 60 years (IQR:51-63) versus 67 years (IQR:56-77) for the non-SCT group (p<0.05). There was a significant difference between the mean time between 1st and 2nd line therapies for SCT+ (855 days; SD±455) and SCT- patients (520 days; SD±366; p<0.05). **CONCLUSIONS:** RWD from Auditor database showed that bortezomib-containing regimens, especially VCD, are the preferred regimens to treat MM in most therapy lines in Brazilian private healthcare system. As expected, SCT+ patients were younger, and had longer time between 1st and 2nd line of therapy.

PCN203

REAL-WORLD TREATMENT PATTERNS AMONG AN INCIDENT COHORT OF PATIENTS WITH HODGKIN LYMPHOMA IN THE UNITED STATES

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OBJECTIVES: Although most patients with Hodgkin lymphoma (HL) are successfully treated with first-line therapy, patients who fail can require multiple costly, additional treatments. Presently there is little information on how recurrent HL is managed in routine clinical practice, particularly, the progression to new lines of therapy among patients with relapsed/refractory HL (RRHL). We identified treatment patterns for an incident cohort of patients with HL in the USA. **METHODS:** We conducted a retrospective observational study of adults with HL from 2006-2015 using Truven MarketScan databases. Patients were required to be initially treated with a first-line therapy to be eligible. Therapies were classified based on records

of prescriptions and chemotherapy administration. The frequency of individual therapies, and time to initiation of a subsequent therapy, were estimated according to line of therapy. **RESULTS:** The cohort included 4,304 treated incident patients: 55% male, mean age at diagnosis of 42.5 years. Twenty-three percent progressed to second-line therapy, of whom 34% proceeded to a third-line, and 56% of those treated in third line progressed to fourth-line therapy. Of all 4,304 first-line patients, 1.1% (n=48) eventually received a fourth line of therapy. The most common second-line therapies were autologous stem cell transplantation (ASCT; observed in 56% of the cohort), rituximab (18%), and ICE (ifosfamide, carboplatin, etoposide; 13%); third-line therapies were brentuximab vedotin (20%) and rituximab (11%); and fourth-line therapy was bendamustine (15%). The mean time between initiation of first- and second-line therapy was 96.3 weeks; time between lines decreased for subsequent lines of therapy. **CONCLUSIONS:** Patients with HL who fail first-line therapy are treated with a variety of strategies. In addition to ASCT and brentuximab vedotin, rituximab, bendamustine, and ICE were the most frequently used. These data characterize contemporary treatment patterns, and the variability in these confirm the individualized nature of care for RRHL patients.

PCN204

TREATMENT PATTERNS AMONG PATIENTS DIAGNOSED WITH ADVANCED MELANOMA IN A COMMERCIALLY INSURED POPULATION

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OBJECTIVES: The objective of this study is to describe treatment patterns in patients with advanced melanoma since the approval of checkpoint inhibitors (CI) and targeted therapies (TT). **METHODS:** The study used a retrospective cohort design using IMS PharMetrics claims data from 07/01/2011-03/31/2016. Adults with a diagnosis of metastases (index date) and melanoma were eligible for inclusion. Patients were followed for 6-months preindex and a minimum of 1-month postindex or until lost to follow-up. The proportion of patients and duration of therapy during first and second lines of therapy (LOT) were assessed overall, by therapy class (CI, TT, cytokines, and chemotherapy), and by individual treatments. Trends in treatments were assessed across years (2012-2016Q1). **RESULTS:** Of the 4,487 patients included, 41.8% had stage 4 disease, 60.6% were male, mean age 54.9 (±12.8) years, mean Charlson comorbidity index score 0.4 (±0.9), and 33.6% initiated first-LOT and 11.5% second-LOT. From 2012-2016Q1, CI use increased in first-LOT (28.8%-79.5%) and second-LOT (45.7%-90.3%). Among CI users, use of nivolumab monotherapy (first-LOT:4.7%-25.8%; second-LOT:7.3%-44.6%) and in combination with ipilimumab increased (first-LOT:4.1%-13.5%; second-LOT:4.5%-26.8%), whereas use of pembrolizumab monotherapy increased in first-LOT (17.0%-28.1%) and decreased in second-LOT (48.2%-17.9%) from 2015-2016Q1. From 2012-2016Q1, TT use decreased in first-LOT (26.6%-13.4%) and second-LOT (35.8%-6.5%). Among TT users, use of dabrafenib and trametinib combination increased (first-LOT:58.1%-80.0%; second-LOT:15.4%-25.0%), whereas use of vemurafenib/dabrafenib/trametinib monotherapy decreased (first-LOT:84.9%-6.7%; second-LOT:96.6%-50.0%) from 2012-2016Q1. The median duration of CI and TT use was 57 and 121 days for first-LOT, and 64 and 117 days for second-LOT, respectively. Among patients receiving CI first-LOT, 34.7% received second-LOT (58.1% CI; 29.8% TT). Similarly among patients receiving TT first-LOT, 39.8% received second-LOT (50.9% CI; 41.3% TT). **CONCLUSIONS:** Results suggest quick adoption of newly approved treatments for advanced melanoma. Additional data segregated by BRAF status are needed to determine optimal treatment sequencing.

PCN205

TREATMENT PATTERNS AND TRENDS OF PATIENTS DYING OF PROSTATE CANCER IN QUEBEC: A POPULATION-BASED STUDY

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OBJECTIVES: The management of metastatic castration-resistant prostate cancer (mCRPC) has evolved considerably with the inclusion of docetaxel-based chemotherapy, bone-targeted therapies and more recently abiraterone for docetaxel-refractory patients. Our study aimed to analyze contemporary mCRPC management patterns and therapy utilization trends in Quebec, Canada. **METHODS:** The cohort included patients dying of prostate cancer (PCa) between January 2001 and December 2013 and selected from the public healthcare insurance databases, the Régie de l'Assurance Maladie du Québec (RAMQ) and Med-Echo databases. Patient selection was based on PCa-related death and/or therapy utilization according to the Canadian Urological Association guidelines. Multivariate logistic regression was used to identify factors associated with the probability of receiving chemotherapy, bone-targeted therapies and palliative radiotherapy (RT) before death from PCa. **RESULTS:** Overall 3,106 patients were identified in our cohort. The median age of death was 78 years old. Most (83%) received mCRPC-specific treatments: chemotherapy, abiraterone, palliative RT or bone-targeted therapy, while 17% of patients were managed only with maximum androgen blockade, despite diagnosis of PCa-related death. Logistic regression analyses indicate that patients dying after 2005 were more likely to have received chemotherapy (OR 1.51; 95%CI 1.22-1.85) and bone-targeted therapy (OR 1.97; 95%CI 1.64-2.37). Age was a significant predictor of utilization of chemotherapy, bone-targeted therapy and palliative RT (ORs ranged from 0.96 to 0.98, p < 0.05). **CONCLUSIONS:** Patient age seems to be a strong determinant in mCRPC therapy selection, with an impact in the probability of chemotherapy, bone-targeted therapy or palliative RT utilization. While chemotherapy is still used only in a minority of patients, the introduction of new therapies such as bone-targeted therapy, docetaxel and abiraterone affected treatment selection over time.

PCN206

RETROSPECTIVE REVIEW OF CANCER PATIENTS IN INDIA: ANALYSIS OF PATIENT CHARACTERISTICS AND TREATMENT METHODS

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OBJECTIVES: To review the patient characteristics and treatment methods of breast, oral and ovarian cancer patients at a tertiary care hospital in India. **METHODS:** This study was a retrospective review of electronic medical records from a tertiary care hospital in Mumbai, India. Patients ≥ 18 years of age hospitalized for breast (BC), oral (OC) and ovarian cancer (OVC) treatment between Jan 2014 and May 2015 were included in the study. Descriptive and inferential statistics were used to analyze and compare differences between patients. **RESULTS:** A total of 323 cancer patients met the study criteria (BC=146 patients, OC=132 patients, OVC=45 patients). The mean age for OVC patients was the highest (OVC= 52.17+13.0 years, OC=51.81+12.20 years, BC=51.07+13.34 years). Across all three cancer types, majority of them underwent a surgical procedure at the hospital (BC=120,37.2%; OC=106,32.8%; OVC=33,10.2%). The majority of the patients were subscribed to RGJAY payer scheme (RGJAY=224, 69.3%; no insurance (NI)=53, 16.4%; private insurance (PI)=26, 8%; CGHS=20, 6.2%). Abnormal growth was the most common reason for admission into the hospital among BC and OC patients, while it was pain among OVC patients (BC=106, 32.8%; OC=80, 24.8%; OVC=22, 6.8%). 81 (25.1%) patients with hypertension and 64 (19.8%) patients with diabetes were reported as major comorbidities during hospitalization. Among 120 BC patients that had surgery, majority of them (n=90) underwent a modified radical mastectomy or a breast conservation surgery (n=10). Among 106 OC patients that had surgery, majority of them (n=50) underwent a modified radical neck dissection or a combined mandibulectomy and neck dissection operation (n=30). Among 33 OVC patients that had surgery, majority of them underwent a total abdominal hysterectomy bilateral salpingo oophorectomy (n=14). **CONCLUSIONS:** Majority of the cancer patients were subscribed to RGJAY scheme. The common reason for hospital admission was abnormal growth and majority of them underwent surgery.

PCN207

HEALTHCARE RESOURCE UTILIZATION DURING MULTIPLE MYELOMA TREATMENT IN THE STOCKHOLM REGION OF SWEDEN

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¹Karolinska Institutet, Stockholm, Sweden, ²Aarhus University Hospital, Aarhus, Denmark, ³Bristol-Myers Squibb, Rueil-Malmaison, France, ⁴Bristol-Myers Squibb, Solna, Sweden **OBJECTIVES:** To estimate healthcare resource utilization (HRU) by line of therapy (LOT) for multiple myeloma (MM) patients in a high-volume Swedish university clinic. **METHODS:** The study population comprised all MM patients diagnosed January 1st 2010-December 31st 2014 at the Karolinska Institutet, Stockholm, Sweden. Patients were followed from date of treatment initiation to end of study period, death, or change in LOT. HRU was based on hospital admissions and acute/planned outpatient contacts (visits and telephone calls) for MM. We calculated summary descriptive statistics (mean, standard deviation [SD], rates per month) of patient characteristics and HRU by LOT. **RESULTS:** Of 403 MM patients identified, 398 (98.8%) were treated with a 1st LOT (2nd LOT: 193 [47.9%]; 3rd LOT: 86 [21.3%]). 55% were male. Mean age at diagnosis was 69.1 (SD 11.5) years; 68.5% of patients were aged ≥ 65 . Mean duration for 1st, 2nd and 3rd LOT was 17.7, 10.6 and 7.6 months, respectively. During follow-up (all LOTs combined), the mean number of hospital stays and days in hospital were 2.6 and 20.9 respectively. Patients on the 2nd LOT had fewer hospital stays per month (mean for 1st LOT: 0.16, 2nd LOT: 0.11, 3rd LOT: 0.14) and fewer days in hospital per month (mean for 1st LOT: 1.58, 2nd LOT: 1.10, 3rd LOT: 1.64). Mean number of outpatient visits from diagnosis was 19.9, with a slightly higher rate per month in the 2nd and 3rd LOTs compared to the 1st (1st LOT: 0.79, 2nd LOT: 0.88, 3rd LOT: 0.87). **CONCLUSIONS:** In this Swedish MM cohort, the frequency and length of hospitalization was lower during the 2nd LOT after diagnosis than 1st or 3rd. However, a different pattern was observed for outpatient visits. Future research should focus on understanding such patterns, which can be related to the nature of disease or treatment toxicity.

PCN208

REAL-WORLD HEMATOLOGIC AND LIVER FUNCTION-RELATED MONITORING PATTERNS IN FIRST-LINE THERAPY INITIATORS OF POSTMENOPAUSAL WOMEN WITH HORMONE RECEPTOR POSITIVE, HUMAN-EPIDERMAL-GROWTH-FACTOR-RECEPTOR-2 NEGATIVE (HR+/HER2-) METASTATIC BREAST CANCER (MBC)

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OBJECTIVES: To explore monitoring patterns among postmenopausal women diagnosed with HR+/HER2- mBC, initiating first-line treatment. **METHODS:** Postmenopausal women with HR+/HER2- mBC initiating first-line therapy after February 3, 2015 were identified in the PharMetrics Plus database during January 1, 2006 to December 31, 2015, inclusive; index date: therapy initiation date. Patients (n \geq 30) were stratified by initial treatment: chemo-monotherapy (CT), endocrine-monotherapy (ET), chemo-endocrine therapy (CET), and palbociclib-endocrine therapy (PET). Study outcomes: prevalence (%), mean, standard deviation (SD) of complete blood cell (CBC) and liver function test (LFT) monitoring, one month post- vs. pre-index date. **RESULTS:** In total, 742 patients were selected; CT: n=267 (36.4%), ET: n=374 (51.0%), CET: n=30 (4.1%), PET: n=63 (8.6%). Mean age (years) (SD) at index date: 57.3 (9.3); range across sub-groups: 55.8 (8.9) for PET, 58.4 (9.3) for ET. Monitoring outcomes were greater one month post- vs. pre-index date. Overall, n=483 (65.1%), (mean: 2.3, SD: 1.4) vs. n=391 (52.7%), (mean: 1.5, SD: 1.1) had CBC monitoring, and n=481 (64.8%), (mean: 1.9, SD: 1.1) vs. n=369 (49.7%),

(mean: 1.3, SD: 0.8) had LFT monitoring one month post- vs. pre-index date, respectively. For CBC: CT (92.1% vs. 65.9%; mean [SD]: 2.9 [1.5] vs. 1.5 [1.0]), ET (40.4% vs. 39.0%; mean [SD]: 1.5 [0.8] vs. 1.4 [1.1]), CET (96.7% vs. 73.3%; mean [SD]: 2.9 [1.4] vs. 1.6 [0.9]), PET (81.0% vs. 65.1%; mean [SD]: 1.7 [0.8] vs. 1.6 [1.0]). For LFT: CT (92.1% vs. 60.7%; mean [SD]: 2.3 [1.2] vs. 1.5 [1.0]), ET (39.3% vs. 37.4%; mean [SD]: 1.3 [0.6] vs. 1.2 [0.5]), CET (100% vs. 70.0%; mean [SD]: 2.2 [1.2] vs. 1.3 [0.7]), PET (81.0% vs. 63.5%; mean [SD]: 1.4 [0.5] vs. 1.3 [0.7]). **CONCLUSIONS:** There was an increase in monitoring among the study sample following first-line treatment initiation. These data may benefit payers integrating monitoring-related costs in cost-effectiveness calculations.

PCN209

CRITICAL ANALYSIS OF THE "REGIONAL HEALTH TECHNOLOGY ASSESSMENT REPORT ON THE IMPLICATIONS OF BEVACIZUMAB USE IN ADULT PATIENTS WITH METASTATIC COLORECTAL CANCER (DIME, 2015)"

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OBJECTIVES: Analyze the results obtained in DIME-BID HTA for the treatment of metastatic colorectal cancer (mCRC). **METHODS:** a methodological analysis of the HTA presented by the DIME was performed. Focused on three parameters (research question, hypothesis, evidence and economic analysis). **RESULTS:** The efficacy of Bevacizumab for the treatment of mCRC has been tested in a Phase IV clinical trial, seven phase III clinical trials, two meta-analyses and more than 25 scientific papers concluding that Bevacizumab is more effective than chemotherapy in the first line treatment of mCRC. Despite the strong scientific evidence, the HTA published by DIME "Regional Technology Assessment Report on the Implications of the Use of Bevacizumab in Adult Patients with Metastatic Colorectal Cancer (Jul, 2015)" concludes that in first line there is no difference in efficacy between Bevacizumab and chemotherapy. The results obtained were due to poor selection of evidence, a consequence of an inconsistent research question and a structure that did not establish necessary parameters to measure the question. Most troubling is the quality of evidence the authors used. The ITACA trial, despite being phase III, does not have enough external validity due to the small population, which resulted on an efficacy outcome incongruent with previous clinical trials. It is clear that the alarming negative results are a direct result of the inadequate HTA structure and the limitation in the selection of scientific evidence. **CONCLUSIONS:** If the published and accepted evidence reflects a superiority of Bevacizumab in efficacy versus the different forms of chemotherapy for the treatment of first-line mCRC, DIME should have not opted for a cost minimization analysis that implies equivalence in efficacy of Bevacizumab and chemotherapy. Therefore, the DIME decision to opt for a cost minimization analysis is considered a conceptual problem from the point of view of health economics.

PCN210

FACTORS INFLUENCING THE USE OF MASTECTOMY AMONG WOMEN WITH BREAST CANCER IN A COMMERCIALLY INSURED US POPULATION

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OBJECTIVES: The objective of this study was to determine the factors influencing the use of mastectomy as compared to breast conserving surgery (BCS) among women with breast cancer. **METHODS:** The study involved retrospective analysis of the Truven MarketScan Commercial database. Women aged 19-64 years who underwent mastectomy or BCS between July 1, 2011 and September 30, 2014 were identified, with the first date of surgical procedure classified as index date. A breast cancer claim in the six-month pre- and post-index date and continuous enrollment in the one-year pre- and post-index period were required for study inclusion. Multivariable logistic regression analysis was used to examine the factors influencing treatment with mastectomy as compared to BCS. **RESULTS:** The final study sample included 43,597 women with breast cancer. The overall mastectomy rate during the study period was 40.14%, with little variation observed from 2011 to 2014 (range 38.30%-41.38%). Women aged 40-49 years (odds ratio [OR] 0.658; confidence interval [CI] 0.588-0.736), 50-59 years (OR 0.5333; CI 0.478-0.595), and 60-64 years (OR 0.483; CI 0.429-0.544) were significantly less likely to be treated with mastectomy as compared to those aged 19-39 years. Women who were obese (vs. non-obese) were less likely (OR 0.853; CI 0.787-0.924) to be treated with mastectomy. Women with a genetic susceptibility to breast cancer (OR 6.582; CI 5.453-7.946), claim for genetic testing (OR 1.743; CI 1.616-1.880), or with a family history of breast cancer (OR 1.436; CI 1.352-1.525) were significantly more likely to be treated with mastectomy. Factors including geographic region, time period, metropolitan statistical area classification, radiation therapy, chemotherapy, lymph node surgery, plan type, and comorbidity status also had a significant influence on treatment with mastectomy. **CONCLUSIONS:** The proportion of women with breast cancer undergoing mastectomy remained steady during the study period. Demographic, treatment-related, and comorbidity factors were found to influence treatment with mastectomy.

PCN211

ONCOLOGIST PERCEPTIONS OF CANCER CARE TREATMENT ADVANCES, VALUE ASSESSMENT, AND COMMUNICATION OF INFORMATION ON UNAPPROVED USES OF APPROVED MEDICINES

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OBJECTIVES: The aim of this study was to document how oncologists in the United States perceive treatment advances, the communication of information on

unapproved uses of approved medicines, and assessing treatment value. **METHODS:** Data were collected from a 20 minute on-line survey of United States-based oncologists recruited from an online panel. Findings were reported descriptively. **RESULTS:** Oncologists (n=202) believe the greatest progress in cancer care has been with immunotherapies and targeted therapies compared with other innovations and that this trend will continue moving forward; the majority considered immunotherapies (84%) and targeted therapies (82%) "very/extremely" promising. More than three out of four oncologists surveyed (78%) would find it useful if more information about safety and efficacy of unapproved uses was available in their clinical practice.; 85% would be interested in receiving this information from biopharmaceutical manufacturers. A similar proportion (77%) indicated that they would be more likely to refer patients to clinical trials if more information on off-label uses of medicines were available. Oncologists identified the most important attributes of a value framework as the incorporation of the best available evidence, reflection of real-world treatment decision-making, and review by qualified experts. Nearly all respondents (>95%) were familiar with the NCCN Evidence Blocks and the ASCO Value Framework and found them "very/extremely" useful in decision making (71% and 63% respectively), compared to the ICER Value Framework and MSK Drug Abacus (19% and 24% respectively). It should be acknowledged that while the ICER and MSK tools are payer-focused and not developed for use by oncologists or patients, it remains important that those frameworks incorporate attributes that oncologists value. **CONCLUSIONS:** Innovative medicines represent an opportunity for treatment progress in cancer care. Facilitating the exchange of information and addressing gaps in current value assessment tools and can help move towards a value-driven healthcare system that improves patient outcomes.

PCN212

A RETROSPECTIVE REVIEW OF PATIENT CHARACTERISTICS AND TREATMENT METHODS OF BREAST CANCER PATIENTS IN INDIA

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OBJECTIVES: To review the patient characteristics and treatment methods of breast cancer patients at a tertiary hospital in India. **METHODS:** This study was a retrospective review of electronic medical records from a tertiary care hospital in Mumbai, India. Patients ≥ 18 years of age hospitalized for breast cancer treatment between Jan 2014 and May 2015 were included in the study. Descriptive and inferential statistics were used to analyze and compare differences between patients. **RESULTS:** A total of 146 patients met the study criteria. Of these, 120 patients were in the age group of 18 to 64 years. The mean age for all the breast cancer patients was 51.07+13.34 years. The mean age was lowest for patients with private insurance (PI) while highest for patients with CGHS (CGHS=54.69+13.35 years, RGJAY=52.39+12.41 years, NI=46.59+16.43 years, PI=45.64+12.49 years). The majority of the patients (n=120, 82.2%) underwent a surgical procedure during their stay. The majority of the patients were subscribed to RGJAY payer scheme (RGJAY=97, 66.4%; CGHS=13, 8.9%; NI=22, 15.1%; PI=14, 9.6%). Abnormal growth was the most common reason for admission into the hospital (n=106, 72.6%). 49 (33.5%) patients with hypertension and 36 (24.6%) patients with diabetes were reported as major comorbidities during hospitalization. The majority of the patients had early stage breast cancer (108, 74.0%), while 16 (11.0%) patients had locally advanced breast cancer stage 2B and 22 (15.1%) patients had locally advanced breast cancer stage 3A to C. Of the total 120 patients that had surgery, majority of them (n=90) underwent a modified radical mastectomy (MRM) or a breast conservation surgery (n=10). **CONCLUSIONS:** Majority of the breast cancer patients were diagnosed during the early stages of the disease and were subscribed to RGJAY scheme. The common reason for hospital admission was abnormal growth and the common procedure patients underwent was the MRM.

PCN213

PAYER DECISION MAKING FOR PHARMACOGENETIC TESTS: PRELIMINARY RESULTS

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OBJECTIVES: Genetic tests are the fastest growing sector of medicine and medical science, yet there is a dearth of research on access to cancer-related pharmacogenetic tests. The study explored payers' views about management strategies for pharmacogenetic tests, and to describe criteria for coverage decisions, policy challenges and strategies used to overcome these challenges. **METHODS:** We conducted semi-structured interviews with representatives of seven US private payers and two US public payers. Interviews were recorded and transcribed verbatim. Using a directed qualitative content analysis, two members of the research team performed open coding of the transcripts in an iterative process, building a provisional code book as coding progressed. **RESULTS:** Payers may not have established coverage policies for single gene tests but even without a policy in place, these are generally accessible on a case-by-case basis. For coverage decision making for pharmacogenetic tests, payers generally followed coverage decision making processes originally established for pharmaceuticals. Some realize that the evidence requirements, which are established for pharmaceuticals, are not applicable to pharmacogenetic tests, particularly because the field is advancing rapidly. 'Outcomes based' risk sharing agreements with diagnostic companies are recognized as a possible option to collect evidence and limiting coverage. Some payers are introducing prior authorization requirements for pharmacogenetic tests to better manage utilization because an established coding system for tests is lacking. Another key challenge from payers' perspective is managing the use of and payment for gene panels. Laboratories provide different combination of genes in their panel tests, thus knowing which genes are tested is

a challenge. Some payers do not pay for large gene panels. **CONCLUSIONS:** Single pharmacogenetic tests are generally readily accessible. However, as we move from single gene tests to gene panels, payers have identified challenges, and ways of overcoming those challenges as the field evolves.

PCN214

EVALUATION OF DRUG PRICE TRENDING IN THE FEDERAL 340B DRUG DISCOUNT PROGRAM

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OBJECTIVES: The Federal 340B drug discount program provides access to significant drug price discounts for healthcare organizations serving disadvantaged patients. Currently there are no published studies documenting pricing trends in the 340B program. In this project, we analyzed drug price trends in the 340B program over a 10-year period. **METHODS:** Pharmacy purchase records were collected from a 340B-contracted pharmacy system in Los Angeles between 2006 and 2016. Data, including 340B drug price and average-whole-sale price (AWP) were analyzed chronologically to display the price change. Annual average prices were weighted by purchase volume in each year. The results were categorized by American Hospital Formulary Service (AHFS) Therapeutic Classification. All dollar values were reported in 2016 terms. **RESULTS:** 340B prices declined relative to AWP over time across all drug classes. Overall drug price growth rate over 10-years was 16% for AWP and 19% for 340B (p=0.88). The growth rate variations were similar after 2010. Among high cost drug classes, the 10-year price growth rates were: 11% in AWP and 5% in 340B in antiretroviral drugs (p < 0.01), 58% in AWP and 32% in 340B in antineoplastic drugs (p=0.37), 16% in AWP and -6% in 340B in disease-modifying antirheumatic drugs (DMARD) (p=0.07) and 14% in AWP and 15% in 340B in anti-diabetic drugs (p=0.97). For specialty drug classes, such as antineoplastic drugs, antiretroviral drugs and DMARDs, the 340B price growth rates were smaller than AWP growth rates after 2014. **CONCLUSIONS:** The relatively low drug price in the 340B program provides significant financial savings for eligible healthcare organizations. Eligible organizations with high specialty drug volume would benefit the most from the 340B program.

PCN215

DELAYS IN CLINICAL TRIAL DATA RELEASE ACROSS ONCOLOGY

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OBJECTIVES: Although much of the clinical trial data generated by pharmaceutical companies in oncology are eventually released, there are concerns regarding the speed at which this information is disseminated. Thus, we conducted a study examining the delays in publication of clinical trial results and the availability of clinically actionable data in company press releases. **METHODS:** We identified peer-reviewed publications and meeting presentations for all clinical trials mentioned in press releases issued by the top five companies in oncology between January 2011 and June 2016. Time to first publication from the availability of trial results was calculated. Availability of results was the earliest date among: initial press release, meeting presentation (minus either 120 or 90 days for regular or late-breaking abstract submission, respectively) or publication (minus 120 days). We conducted survival analyses using the log-rank test and Cox proportional hazards models. **RESULTS:** Across our sample of 76 clinical trials, the median time from the availability of trial results until the first journal publication was 363 days. The vast majority (79%) of releases reported positive results. For those which reported negative results, there was a longer delay to publication (median of 559 vs. 348 days, log-rank p<0.001) and the press releases were significantly less likely to include quantitative data (p<0.01). This result remained significant in a model controlling for company. **CONCLUSIONS:** Our study reveals that there is a tremendous amount of information emanating from human subjects research on cancer drugs that is not finding its way into the public domain in a timely fashion. These delays negatively affect both patient outcomes and scientific innovation. We propose two solutions to ensure rapid dissemination of data, including more consistent use of independent scientific preprinting and rigorous enforcement of regulations requiring that sponsors post trial results on public domains such as ClinicalTrials.gov.

PCN216

PCODR UNDER CADTH - WHAT'S CHANGED?

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OBJECTIVES: The pan-Canadian Oncology Drug Review (pCODR) was established in 2010 to assess oncology drugs and bring consistency to the assessment across provinces/territories. In April 2014, pCODR was transferred to the Canadian Agency for Drugs and Technologies in Health (CADTH). This research aims to see what effect this transfer has had on the number of appraisals and recommendation rates conducted by pCODR. **METHODS:** All publically available pCODR reports were extracted up to 30th November 2016 and the drug, indication, date and outcome were extracted. Statistical comparisons were made using Student's t-test. **RESULTS:** 76 appraisals have been conducted by pCODR, reflecting an average of 15.5/year (10 in 2012, 18 in 2013, 9 in 2014, 24 in 2015, and 15 in 2016). No significant change in the rate of appraisals was observed pre-CADTH transfer (14.2/year [32 from January 2012 to March 2014]) versus post-CADTH transfer (16.5/year [44 from April 2014 to November 2016]) (p=0.588). Overall, 79% of pCODR outcomes have been positive recommendations (defined as full recommendations [12%] or restricted recommendations [67%]) with the remaining 21% being

“not recommended”. Annually, the highest recommendation rate was observed in 2013 (89%) and the lowest in 2012 (70%). There were no significant differences in recommendation rates since pCODR was transferred to CADTH (81% positive recommendations pre-CADTH versus 77% post-CADTH, $p=0.427$). **CONCLUSIONS:** The number of technologies appraised by pCODR and recommendation rates for these have fluctuated from year to year, but no meaningful trends have been observed since the transfer of pCODR to CADTH. However, this transfer began in April 2014, with a second phase aimed at aligning pCODR and CADTH review criteria and best-practice review processes that only commenced in April 2015. Thus, the full effects of this transfer may not yet be clear.

PCN217

CHANGE IN THE UTILIZATION OF BLOOD TRANSFUSION AFTER THE NATIONAL COVERAGE DETERMINATION FOR ERYTHROPOIESIS-STIMULATING AGENTS IN CANCER

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OBJECTIVES: Erythropoiesis-stimulating agents (ESAs) are commonly prescribed for cancer patients with chemotherapy-induced anemia or chronic kidney disease (CKD) patients with low levels of hemoglobin. ESAs are efficacious in increasing hemoglobin levels and reducing future requirements of blood transfusion. Due to safety concerns found in clinical trials, Centers for Medicare and Medicaid Services issued a National Coverage Determination (NCD) for ESAs in cancer to regulate ESA use. The objective of this study is to examine the utilization of blood transfusion in cancer patients before and after the NCD. **METHODS:** This study used the Surveillance, Epidemiology, and End Results (SEER)-Medicare linked database. A repeated cross-sectional design was implemented. Percentages of patients received blood transfusion in each month were compared before and after the NCD. This study used an interrupted time series (ITS) design with a control group, which is a valuable design to evaluate the effectiveness of policy at a clearly defined point in time. The ITS could examine two types of change: intercept change and slope change. **RESULTS:** During the study period, the utilization of blood transfusion was decreased before the NCD and remained stable after the NCD in the treatment group. In the control group, the utilization of blood transfusion was similar before and after the NCD. According to the ITS, the utilization (intercept) was increased by 0.10% ($P=.0186$) and the trend (slope) was increased by 0.01% per month but was not statistically significantly ($P=.0524$). **CONCLUSIONS:** The NCD only had a one-time effect on the utilization of blood transfusion. The monthly utilization of blood transfusion was increased by 0.10% (about a 10% increase). In addition to the impact on the utilization of ESAs, the NCD have resulted in an unintended consequence of increased utilization of blood transfusion.

PCN219

EFFECTS OF PHYSICIAN-HOSPITAL INTEGRATION ON TREATMENT PRODUCTIVITY: EVIDENCE FROM CHEMOTHERAPY IN LUNG CANCER

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OBJECTIVES: Over the past several years, hospitals in the United States have increasingly acquired physician-based oncology care. The more vertically integrated form of organization triggered by such changes can internalize the effects of decisions made by physicians and hospitals who once independently provided complementary services, potentially leading to gains in treatment productivity. This study examines the impact of physician-hospital consolidation on productivity growth, using chemotherapy claims for patients with lung cancer in the 20% Medicare Outpatient Research Identifiable Files (2009-2013). **METHODS:** While prior studies have relied on self-reported binary measures of integration available in hospital-level surveys, we instead identify oncologists who switched from being office-based to being hospital-based, using the billing structure of Medicare, and define a continuous measure of change in the share of services provided by these “switched” oncologists for each hospital. The total factor productivity of hospitals, obtained from a patient-level log health production function, is then regressed on this measure of integration, controlling for hospital fixed effects and a comprehensive set of time-varying hospital characteristics. **RESULTS:** A 10 percent increase in the share of services provided by the switched oncologists is associated with a 2.1 percent increase in productivity in treating Medicare beneficiaries with lung cancer. **CONCLUSIONS:** These study findings highlight the importance of understanding the effects of organizational changes in the provision of chemotherapy. More attention is needed, as the expansion of accountable care organizations and drug discount programs for hospitals are likely to accelerate the trend toward vertical integration.

PCN220

PATTERNS OF CARE FOR HODGKIN LYMPHOMA IN BRAZIL: REAL WORLD DATA (RWD) FROM A PRIVATE HEALTHCARE SYSTEM

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OBJECTIVES: Hodgkin Lymphoma (HL) is a rare hematologic malignancy with an estimated 2,470 new cases projected for 2016 in Brazil. RWD on patterns of care for HL in the private healthcare sector in Brazil are scarce; thus, we aimed to evaluate patient characteristics and treatment patterns for HL patients in a private setting in Brazil. **METHODS:** This was a retrospective analysis of demographic, disease-related and treatment-related data for patients with HL. Patients were required to

have a diagnosis for HL in Evidencias-Kantar Health claims database (Auditron, which covers 3+ million lives, ~7% of Brazilian private sector) between March/2013-March/2016. Data were analyzed using descriptive statistics. **RESULTS:** 147 patients with HL met study eligibility: mean age was 36 years (± 17), 51.7% were females and 74.8% were from the Southeast/South Regions. At diagnosis, 40.2% were stage II and 28.6% stage III. First-line treatment for 134 patients (91.1%) was ABVD for a mean of 6 cycles. The other 13 patients received 11 different first-line regimens. There were 42 patients (28.6%) who received second-line treatment. Most patients received ICE in second-line (20 patients, 47.6%) for a mean of 4 cycles or DHAP (12 patients, 28.6%) for mean 3 cycles. Twenty-nine (19.7%) patients received third-line treatment, the most frequent being GDP (24.1%), followed by DHAP (20.7%). For further lines of treatment the numbers were: fourth-line (20 patients- 6 on brentuximab vedotin [BV]), fifth-line (9 patients - 4 on BV) and sixth-line (5 patients- 3 on BV). Time to first relapse was available for 27 patients: 33.3% relapsed in ≤ 12 months and 37.1% in ≤ 3 months. **CONCLUSIONS:** ABVD was the most common first-line treatment regimen in this cohort of HL patients from the private healthcare setting in Brazil. Treatment patterns in second-line or later lines were heterogenous and patients did not receive BV until third or later lines.

PCN221

TREATMENT PATTERNS OF METASTATIC TRIPLE-NEGATIVE BREAST CANCER (MTNBC) IN US COMMERCIAL PLANS

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OBJECTIVES: A generally accepted standard of care does not exist for the management of TNBC. Common recommendations include taxanes and/or anthracyclines as frontline treatment (FT) for metastatic disease and non-cross resistant agents (e.g., capecitabine) for resistant or progressed patients. We analyzed real-world treatment patterns of US commercially insured mTNBC patients. **METHODS:** Adult females with ≥ 1 breast cancer ICD9-CM and ≥ 1 distant secondary malignant neo-plasm ICD9-CM diagnoses, continuously enrolled for 6-months pre- and 1-month post-metastatic diagnosis (mDx) were identified from the IMS LifeLink Claims database (2011-2015). mTNBC status was approximated by receipt of any chemotherapy post-mDx in the absence of pre- and post-mDx use of hormonal therapy or trastuzumab. Kaplan-Meier survival curves were used to estimate time-to-treatment and proportion of patients starting each treatment regimen. **RESULTS:** 2,949 mTNBC patients (median [interquartile range] age, 53 [47-61] years) were included. Taxanes and/or anthracycline were the most commonly (45%) used FT, often in combination with other agents (30% of FT). Median [interquartile range] time from mDx to FT initiation was 20 (6-49) days. Progression to a second regimen occurred in 54% and 68% of patients after 12 and 36 months of FT initiation, respectively. Median (95% confidence interval [CI]) time from FT to a second regimen was 273 (249-305) days. Of 1,283 second regimen recipients, 52% and 64% progressed to a third regimen within 12 and 36 months of second regimen initiation, respectively; median (95% CI) time from second to third regimen initiation was 296 (263-366) days. Non-cross resistant agents (paclitaxel, capecitabine, gemcitabine, ixabepilone) were most common second regimen (64%). Median (95% CI) therapy durations were 67 (63-70) and 63 (56-65) days for FT and second regimen. **CONCLUSIONS:** Real-world treatment patterns indicate that mTNBC patients often start with a taxane- and/or anthracycline-containing combination therapy and move on to non-cross resistant therapy as a second regimen.

PCN222

BICALUTAMIDE TREATMENT PATTERNS IN ELDERLY PROSTATE CANCER PATIENTS: A HISTORICAL COHORT STUDY USING THE SURVEILLANCE, EPIDEMIOLOGY AND END RESULTS PROGRAM (SEER)-MEDICARE DATABASE

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OBJECTIVES: Bicalutamide (BIC), an androgen receptor inhibitor, is indicated for the treatment of stage D2 metastatic prostate cancer as a combination treatment with luteinizing hormone-releasing hormone (LHRH) analog (a form of androgen deprivation therapy [ADT]). Although newer hormonal agents have been approved since 2010, BIC remains part of the National Comprehensive Cancer Network guidelines for advanced disease. Our objective was to characterize contemporary real-world use and duration of BIC treatment before and after ADT in elderly prostate cancer patients. **METHODS:** The SEER-Medicare database was used to identify men aged ≥ 66 years enrolled in Medicare and diagnosed with primary prostate cancer between 1/1/2007 and 12/31/2011. Patients treated with BIC after diagnosis were selected and followed until 12/31/2013 or death. Descriptive statistics were used to evaluate patient demographics, disease characteristics, and therapies. **RESULTS:** In a cohort of 7919 patients treated with BIC, 70.7% were non-Hispanic white and 16.6% had metastatic disease at time of diagnosis. Upon initial treatment with BIC, 25.4% of patients had been diagnosed with metastatic prostate cancer. Among all cohort members, 9.8% never had ADT, 1.9% underwent bilateral orchiectomy, 0.4% were ever treated with LHRH antagonists alone, 85.6% received LHRH agonists, and 3.0% received both LHRH antagonists and agonists after diagnosis. Of the total cohort, 36.0% (2852/7919) were treated with BIC only during the “potential testosterone flare prevention” period (6 months pre- to 2 months post-LHRH agonist initiation). For the remainder of the cohort ($n = 5067$; 64.0%), median duration of BIC use was 6.9 months (mean [standard deviation], 10.7 [11.1] months). **CONCLUSIONS:** Almost two-thirds of prostate cancer patients treated with BIC identified in the SEER-Medicare

database had a median treatment duration of < 7 months, for androgen suppression beyond flare prevention. Research on BIC use patterns and duration after the introduction of newer hormonal agents is warranted.

PCN223

AN ASSESSMENT OF ATTITUDINAL AND BEHAVIORAL TRENDS RELATED TO CONSIDERATION OF TREATMENT COST AND VALUE AMONG PROVIDERS IN ONCOLOGY CARE MODEL PARTICIPATING PRACTICES

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OBJECTIVES: The Oncology Care Model (OCM) is one of several alternative payment models developed by the CMS Innovation Center (CMMI). OCM practices have entered into payment arrangements that include financial and performance accountability for episodes of cancer care. This research assesses attitudinal and behavioral trends related to consideration of treatment cost and value among providers in OCM practices. It also considers emerging evidence needs in the context of value-based oncology and how these may be served by manufacturers. **METHODS:** There are 190 practices participating in the OCM. Primary research was conducted with providers including medical oncologists and nurse practitioners from a subset of these practices. Respondents completed a survey assessing attitudinal and behavioral trends related to consideration of treatment cost and value within their practices. This included: awareness of cost and health economic evidence; referencing of emerging oncology value frameworks; discussion of these elements with peers and patients; and consideration of these elements in development of oncology pathways and/or prescribing. **RESULTS:** Providers in OCM practices indicated growing awareness, discussion and consideration of treatment cost and value. Although drugs were not currently considered to be a top focus area for cost savings, providers nonetheless indicated greater appetite for health economic evidence to support decision-making. Moreover, they expect that these elements will become more important, with introduction of two-sided risk for OCM and/or eventual reform to Medicare Part B payment policies. **CONCLUSIONS:** There is a gradual but important shift in mindset among oncologists in which treatment cost and value is becoming a better understood quantity and this trend is more pronounced in OCM sites. These providers seek health economic data and analysis to support their clinical decision-making. This may include medical resource utilization and patient-reported outcomes (e.g., functionality) in well-defined patient populations.

PCN224

TREATMENT PATTERN OF CETUXIMAB FOR COLORECTAL CANCER IN REAL WORLD SETTING BY USING CHINESE ADMINISTRATIVE DATABASES

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OBJECTIVES: The differences in treatment patterns for metastatic colorectal cancer (mCRC) patients have not been extensively studied in Chinese practice setting. This study evaluated the treatment patterns of cetuximab in the real-world setting in China. **METHODS:** This study used administrative data from the Qingdao City and Zhejiang Province from 2015 to 2016. All patients with metastatic colorectal cancer (mCRC) treated with cetuximab were included. The outcome of cetuximab was monitored during this period, and the combining regimens and agents were analyzed for 2 years following the initiation of chemotherapy. **RESULTS:** There are 105 cases that received cetuximab treatment. The median time of adding cetuximab is 359 days (quartile range: 85.0 – 571.0 days). When health insurance or patients assistant program was provided, frequency of receiving cetuximab treatment at the initiating chemotherapy would be increased. The combination regimens were FOLFIRI(49.10%), Other(17.10%), Capecitabine(17.6%), FOLFOX(10.50%), Capecitabine+Oxaliplatin(6.30%), mFOLFOX6(1.80%), FOLFOXIRI(0.60%). There are 26 cases that received two combining regimens, including 8 cases with the regimens switched from FOLFIRI to Capecitabine, 3 cases from FOLFIRI to FOLFOX. There are 6 cases that received three combining regimens. **CONCLUSIONS:** Our findings suggest that patients with mCRC could gain health benefits from the Chinese health insurance or patients assistant program covering cetuximab. The combining regimens were varied in Chinese practice, which should be evaluated for their difference in efficacy and safety.

PCN225

IMPACT OF PAYER ON HEALTHCARE RESOURCE UTILIZATION AND COSTS AMONG BREAST CANCER PATIENTS IN INDIA

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OBJECTIVES: To evaluate the impact of the type of payer on health care utilization and the costs of patients treated for breast cancer at a tertiary hospital in India. **METHODS:** This study was a retrospective review of electronic medical records from a tertiary care hospital in Mumbai, India. Patients ≥ 18 years of age hospitalized for breast cancer treatment between Jan 2014 and May 2015 were identified and included in the study. Descriptive and inferential statistics were used to analyze and compare differences between patients. Regression models were also used to determine predictors of total costs for all patients. **RESULTS:** A total of 146 patients met the study criteria. The mean length of stay (LOS) for all patients was 5.3+2.5 days. The mean LOS was highest for RGJAY scheme patients and lowest for patients with no insurance (NI). (RGJAY=6.4+1.8 days, private insurance (PI) =4.3+3.5, CGHS=3.5+2.28, NI=2.6+1.8; p<0.001). Patients with NI went into surgery the earliest (1.2+0.6 days) while CGHS patients were discharged from the hospital the earliest (2.6+1.3 days). Patients with PI received the highest

number of per patient clinician visits compared to other patients (PI=16.3 visits/patient, NI=11.8, CGHS=2.7, RGJAY scheme=2.2; p<0.001). Patients with NI (unit doses=3435) and PI (unit doses=1863) received the highest unit doses of drug while RGJAY scheme patients (unit doses=649) received the least. Mean hospital costs were highest for patients with PI and lowest for RGJAY scheme patients (PI=\$2381.03+1739.31, NI=\$1558.70+1342.56, CGHS=\$723.19+731.57, RGJAY=\$637.41+118.20). Clinician visits (r=0.576, p<0.01) and having PI (r=0.334, p<0.01) were found to be significant predictors of costs in the regression model. **CONCLUSIONS:** Significant differences were found in resource utilization and costs among breast cancer patients. Patients covered by private insurance and no insurance incurred higher costs but received more resources, which could lead to better care, compared to patients with other insurances.

PCN226

IMPACT OF PAYER ON HEALTHCARE RESOURCE UTILIZATION AND COSTS AMONG ORAL CANCER PATIENTS IN INDIA

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OBJECTIVES: To evaluate the impact of the type of payer on health care utilization and the costs of patients treated for oral cancer at a tertiary hospital in India. **METHODS:** This study was a retrospective review of electronic medical records from a tertiary care hospital in Mumbai, India. Patients ≥ 18 years of age hospitalized for oral cancer treatment between Jan 2014 and May 2015 were included in the study. Descriptive and inferential statistics were used to analyze and compare differences between patients. Regression models were also used to determine predictors of total costs for all patients. **RESULTS:** A total of 132 patients met the study criteria. The mean length of stay (LOS) for all patients was 9.1+5.13 days. The mean LOS was highest for private insurance (PI) patients and lowest for patients with no insurance (NI). (PI =11+2.82, RGJAY=9.3+5.04 days, CGHS=9+4.94, NI=5.5+4.46; p=0.006). Patients with PI went into surgery (2+0 days) and also got discharged the earliest (10+2.8 days). Patients with NI received the highest number of per patient clinician visits compared to other patients (PI=36.5 visits/patient, NI=24.6, CGHS=8, RGJAY scheme=1.2; p<0.001). Patients with NI (unit doses=3674) and PI (unit doses=508) received the highest unit doses of drug while RGJAY scheme patients (unit doses=1415) received the least. Mean hospital costs were highest for patients with PI and lowest for RGJAY scheme patients (PI=\$5132.61+6158.41, NI=\$1998.52+2057.81, CGHS=\$1178.21+309.23, RGJAY=\$795.77+\$314.92). Clinician visits (r=0.485, p<0.01), having NI (r=0.128, p<0.01), undergoing surgery (r=0.379, p<0.01) and gender (r=-0.152, p<0.001) were found to be significant predictors of costs in the regression model. **CONCLUSIONS:** Significant differences were found in resource utilization and costs among oral cancer patients. Patients covered by private insurance and no insurance incurred higher costs but received more resources, which could lead to better care, compared to patients with other insurances.

PCN227

IMPACT OF PAYER ON HEALTHCARE RESOURCE UTILIZATION AND COSTS AMONG OVARIAN CANCER PATIENTS IN INDIA

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OBJECTIVES: To evaluate the impact of the type of payer on health care utilization and the costs of patients treated for ovarian cancer at a tertiary hospital in India. **METHODS:** This study was a retrospective review of electronic medical records from a tertiary care hospital in Mumbai, India. Patients ≥ 18 years of age hospitalized for ovarian cancer treatment between Jan 2014 and May 2015 were included in the study. Descriptive and inferential statistics were used to analyze and compare differences between patients. Regression models were also used to determine predictors of total costs for all patients. **RESULTS:** A total of 45 patients met the study criteria. The mean length of stay (LOS) for all patients was 9.4+4.55 days. The mean LOS was highest for RGJAY patients and lowest for private insurance (PI) patients. (RGJAY=10.5+3.85, no insurance (NI)=9.5+6.02, CGHS=8.5+0.70 days, PI=7.2+4.18; p=0.289). Patients with CGHS went into surgery (2+0 days) the earliest while private insurance patients got discharged the earliest (6.5+2.64 days). Patients with NI received the highest number of per patient clinician visits compared to other patients (NI=35.9 visits/patient, CGHS=19.5, RGJAY=1.1, PI=30.3; p<0.001). Patients with NI (unit doses=3926) and PI (unit doses=1980) received the highest unit doses of drug while RGJAY scheme patients (unit doses=208) received the least. Mean hospital costs were highest for patients with NI and lowest for RGJAY scheme patients (NI=\$3843.77+\$2735.89, PI=\$2735.89+2454.62, CGHS=\$1849.73+1023.56, RGJAY=\$653.01+\$257.18). Clinician visits (r=0.826, p=0.004), having NI (r=0.532, p=0.025), undergoing surgery (r=0.224, p=0.044) were found to be significant predictors of costs in the regression model. **CONCLUSIONS:** Significant differences were found in resource utilization and costs among ovarian cancer patients. Patients covered by private insurance and no insurance incurred higher costs but received more resources, which could lead to better care, compared to patients with other insurances.

PCN228

REAL WORLD DATA ANALYSIS OF TREATMENT PATTERNS AND COSTS ASSOCIATED WITH NON-SMALL CELL LUNG CANCER (NSCLC) IN ITALY

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OBJECTIVES: To describe treatment patterns/costs for patients with stage IV NSCLC in Italy. **METHODS:** Retrospective database analyses were conducted for 3

Local Health Units (LHUs) from 3 separate regions: Veneto, Tuscany and Lombardy. Resource use/costs were estimated from administrative databases provided by the LHUs from Tuscany and Lombardy, and chemotherapy regimens from hospital electronic medical records (EMR) provided by the LHU from Veneto. **RESULTS:** A total of 306 patients were enrolled: 248 (81.0%) non-squamous (non-sq) NSCLC, 58 (19.0%) squamous (sq) NSCLC. For the non-sqNSCLC and sqNSCLC patients, respectively, the average age was 66.9, 68.8 years, 64.1%, 81.0% were male, the most common co-morbidities were cardiovascular disease: 34.3%, 48.3% and metabolic disorders: 12.9%, 20.7%. Among non-sqNSCLC patients, 193/248 (77.8%) received chemotherapy. In the LHU from Veneto, the most common first-line therapy was pemetrexed+platinum (42/93 (45.2%) patients). 46/93 (49.5%) received second line treatment. Erlotinib was most commonly used (23/46 patients). Among sqNSCLC patients, 46/58 (79.3%) received chemotherapy. In Veneto, the most common first-line therapy was a gemcitabine+platinum (18/23 (78.3%) patients). 9/23 (39.1%) received second line treatment. Docetaxel monotherapy was most commonly used (7/9 patients). 106/124 (Tuscany and Lombardy) non-sqNSCLC patients (85.5%) had a NSCLC inpatient hospitalisation. Mean number of inpatient days was 34.0 days per patient. Total health care cost related to the first line of chemotherapy was €7,435 of which €3,812 was for NSCLC hospitalisations. 21/28 (Tuscany and Lombardy) sqNSCLC patients (75.0%) had a NSCLC inpatient hospitalisation. Mean numbers of inpatient days was 29.2 days per patient. Total health care cost related to the first line of chemotherapy was €5,257 of which €3,716 was for NSCLC hospitalisations. **CONCLUSIONS:** LHU databases provide an important means for assessing patient treatment patterns and resource use/costs and are encouraged to make their data available

PCN229

EFFICACY AND SAFETY OF DIFFERENT PHARMACEUTICAL ETOPOSIDE PRESENTATIONS USED IN ENDOMETRIAL CANCER TREATMENT

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OBJECTIVES: Etoposide is a chemotherapy drug used to treat small cell lung cancer, ovarian cancer, testicular cancer, leukaemia and lymphoma. The indication to the use of etoposide in the treatment of patients with endometrial cancer is related in the National Therapeutic Form of Brazil 2010. Although not included in the National List of Essential Medicines (RENAME 2014), it should be considered to be included on RENAME 2016. This study aimed to evaluate the therapeutic indication of etoposide 50mg and 100mg in capsule form and 20mg/mL in injectable solution form in the treatment of endometrial carcinoma. **METHODS:** The research was carried out in the specialized literature on February 23, 2015, on Best Practice (BMJ), Dynamed and UpToDate databases, being used the DeCS and MeSH indexed terms: "Endometrial Cancer", "Cancer of the endometrium" and "Etoposide". **RESULTS:** According to the evidence on UpToDate database, agents commonly used in recurrent endometrial cancer treatment include doxorubicin, paclitaxel and bevacizumab. On Micromedex database it was found the use of etoposide in the treatment of endometrial cancer in a phase II study, however, the use of oral 50 mg/m²/day etoposide produced no objective response in patients with advanced endometrial cancer. No evidence was found on BMJ and Dynamed databases. **CONCLUSIONS:** The suggested use of etoposide for endometrial cancer treatment comes from a phase II study with no objective response in patients with advanced endometrial cancer. Until now, other reports do not mention the use of etoposide or recommend it to the treatment of endometrial cancer. In conclusion, the indication of 50mg and 100mg capsule form and 20 mg/ml injectable etoposide is not recommended for the endometrial carcinoma treatment.

PCN230

SOMATOSTATIN AND ANALOGS IN THE TREATMENT OF PANCREATIC TUMOR

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OBJECTIVES: In Brazil, the injectable octreotide is present in the National List of Essential Medicines (RENAME 2014). It is indicated to the treatment of severe diarrhea and flushing caused by certain types of cancer. It is also used to treat acromegaly in certain patients. However, its use has also been identified in the treatment of pancreatic cancer. This study aimed to evaluate the therapeutic indication of octreotide in various pharmaceutical forms, in order to present response to this new inclusion to RENAME 2016. **METHODS:** The research was carried out in the specialized literature on February 15, 2015, on the Best Practice (BMJ), Dynamed and UpToDate databases, being used the DeCS and MeSH indexed terms: "Pancreatic Neoplasms" and "Octreotide". Details on the evidence were identified on the use of 0.1mg, 10mg, 20mg and 30mg/mL injectable octreotide for the treatment of the cited neoplasia. **RESULTS:** No evidence was located on BMJ and UpToDate databases. It was located on Dynamed database that the use of 100µg subcutaneous octreotide three times a day during 7 days is recommended for patients undergoing pancreas surgery. On Micromedex database it was found the use of octreotide and alpha interferon are effective in the treatment of advanced metastatic disease in patients unresponsive to the single use of octreotide. The recommended dosage of octreotide associated with interferon

alpha is 200µg, 3 times a day. **CONCLUSIONS:** There is evidence on the use of octreotide to treat patients with pancreas cancer. Therefore, it is recommended to include its 0.1mg, 10mg, 20mg and 30 mg/mL injected form in RENAME 2016, for the indication evaluated.

PCN231

REAL-WORLD TREATMENT PATTERNS OF SYSTEMATIC COMBINATION THERAPY IN PATIENTS WITH METASTATIC MELANOMA

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OBJECTIVES: First-line systemic combination therapies for metastatic melanoma (MM) include targeted therapy combination such as dabrafenib/trametinib (dab/tram) or vemurafenib/cobimetinib (vem/cobi) for patients with BRAF-mutation, and immunotherapy combination ipilimumab/nivolumab (ipi/nivo) for patients irrespective of BRAF status. Our objective is to describe the real-world baseline characteristics and treatment patterns of ipi/nivo and dab/tram. **METHODS:** Flatiron Oncology electronic health record (EHR) data from Jan 2013 to July 2016 was used. Included patients were ≥18 years and treated with either ipi/nivo or dab/tram after MM diagnosis. Baseline characteristics and treatment patterns were analyzed descriptively. **RESULTS:** 40 ipi/nivo patients (11 BRAF positive) and 98 dab/tram patients were included. 93% of the included patients were white and 64% male. The median age was 65 years for dab/tram and 60 years for ipi/nivo patients. Before receiving combination therapies, 10% ipi/nivo and 29% dab/tram patients had high LDH level. 25% ipi/nivo and 41% dab/tram patients had brain metastasis. 78% ipi/nivo patients and 59% dab/tram patients received combination as first-line. 21/40 ipi/nivo patients did not complete the 4-dose ipi induction therapy, and 23/40 discontinued ipi+nivo during follow-up (median 185 days). The 3 and 6 months discontinuation rates for ipi/nivo were 23% and 40%. 53/98 patients discontinued dab/tram during follow-up (median 235 days). The 3 and 6 months discontinuation rates for dab/tram were 14% and 31%. **CONCLUSIONS:** MM patients receiving combination therapies in real-world were typically aging white male with high disease burden. Dab/tram patients were 3 times more likely to have high LDH before therapy than ipi/nivo patients. The 3 and 6 months discontinuation rates were high (23% and 40% for ipi/nivo, 14% and 31% for dab/tram), mostly due to progression and toxicity.

PCN232

LOW USE OF BIOLOGICS IN FIRST-LINE THERAPY AMONG PATIENTS WITH METASTATIC COLORECTAL CANCER (mCRC)

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OBJECTIVES: Treatment outcomes have improved greatly over the last decade for patients with metastatic colorectal cancer (mCRC) due to the advances in systemic chemotherapies, targeted agents, and supportive care. We aimed to describe contemporary real-world first line (1L) treatment among patients with mCRC. **METHODS:** Patients with mCRC diagnosed from 2012-2014 (ICD-9 codes 153.x, 154.0x, or 154.1x and 197.x-198.x) were identified from a US healthcare claims database consisting of 129 million unique covered patient lives. Patients were classified into treatment groups based on the 1L treatment received. The end of 1L was defined as addition of new drug(s) to the original treatment outside of the first 30 days of treatment; if an additional agent was added to a fluoropyrimidine (FP) backbone within 60 days, then the regimen was classified as a combination instead of incrementing the line of therapy. Time from diagnosis to initiation of 1L was calculated for each treatment group. **RESULTS:** There were 4,527 mCRC patients identified (mean age at diagnosis, 61.2 years; 54% male) who initiated 1L therapy. On average (mean, SD), patients were followed for 12.8 months (8.47 months) after diagnosis. The most common 1L regimen (39%) consisted of FP + chemotherapy, followed by biologic + FP + chemotherapy (36%), FP monotherapy (21%), and biologic + FP (5%). Across treatment groups, half of patients initiated 1L within 39 days of diagnosis (range of medians across treatment groups: 15 days to 43 days; all pairwise comparisons, p<0.05). **CONCLUSIONS:** These real world data show substantial variability in treatments received in 1L and time to 1L initiation among patients with mCRC. Despite published guidelines, just over 1/3 of patients received a chemotherapy doublet plus biologic. Further research is needed to understand the surprisingly low penetration of biologics into 1L.

PCN233

EARLY STAGE BREAST CANCER TREATMENT PATTERNS BY JOINT RECEPTOR SUBTYPE AND INSURANCE STATUS

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OBJECTIVES: Since 2010, HER2 status has been reported to the Surveillance Epidemiology and End Results (SEER) registry for breast cancer (BC) cases. Previous research reported variations in adherence to guideline recommended treatment of early stage breast cancer (ESBC) that were associated with different receptor subtypes and race/ethnicity. This study sought to characterize associations between early stage breast cancer treatment patterns and joint receptor subtype, race/ethnicity, and insurance status. **METHODS:** Females diagnosed with Stage I-II BC from 2010-2013 were identified in the SEER database based on availability of joint receptor subtype data. This population included patients diagnosed at ages 18-64 and excluded patients missing key information about demographics, tumor

characteristics or treatment. Patients were classified as having received or not received guideline-concordant locoregional treatment (GCT) based on receipt of surgery and radiation per NCCN guideline recommendations. Multivariate logistic regression models identified factors associated with receiving GCT. **RESULTS:** The final sample included 74,047 patients from 18 SEER registries. Patients were 67% non-Hispanic white, 11% African American, 10% Asian/Pacific Islanders, and 12% Hispanic white. Two percent were uninsured, 12% were Medicaid beneficiaries, and 85% were insured, non-Medicaid. The prevalence of receptor subtypes at diagnosis was 11% HER2+/HR+, 4% HER2+/HR-, 72% HER2-/HR+, and 12% HER2-/HR-. Overall, 87% of patients received GCT. Insured, non-Medicaid patients were 76% more likely to receive GCT (OR 1.76, 95%CI:1.56-1.98) and Medicaid patients were 25% more likely to receive GCT (OR 1.25, 95%CI:1.10-1.42) compared to uninsured patients. Race/ethnicity of African American was associated with decreased likelihood of receiving GCT (OR 0.77, 95%CI:0.72-0.82). HER2-/HR+ status was associated with increased likelihood of receiving GCT (OR 1.46, 95%CI:1.37-1.55). **CONCLUSIONS:** Insurance status, receptor subtype, and race/ethnicity were significantly associated with receipt of GCT for ESBC. More research is needed to examine how these relationships may be influenced by additional variables not included in the SEER database.

PCN234

HIGHER PATIENT COST SHARING IS ASSOCIATED WITH PRESCRIPTION ABANDONMENT AND DELAY IN FILLS OF NOVEL ORAL ONCOLYTIC PRESCRIPTIONS

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OBJECTIVES: Increased availability of novel oral oncolytics has had important implications for the delivery, financing, and outcomes of cancer care. Oral oncolytics are typically covered under the prescription benefit and are increasingly being subject to high cost sharing, raising the question of whether high out-of-pocket costs may interfere with cancer treatment initiation. Our study is the first to examine this issue for a range of novel oral oncolytics and to use data from recent years wherein aggressive cost-sharing strategies have become more prevalent. **METHODS:** Utilizing 2014-2015 Integrated DataVerse data, we examined patients with a new adjudicated prescription for one of 42 oral oncolytics. We examined associations between out-of-pocket costs for the index oncolytic prescription and abandonment (i.e., failure to purchase index adjudicated prescription, with no alternative oral or infusible oncolytic prescription obtained within 90 days) and delayed initiation (i.e., failure to purchase index adjudicated prescription but same or alternative oncolytic obtained within 90 days). We used logistic regressions controlling for sociodemographic, clinical, and treatment characteristics to estimate adjusted outcome rates. Extensive sensitivity and subgroup analyses were conducted. **RESULTS:** The sample included 38,111 Medicare and commercial insurance enrollees. Risk-adjusted abandonment rates were higher among greater out-of-pocket cost categories: 9% for the ≤\$10 group vs. 13% for the \$50.01-\$100 group, 29% for the \$100.01-\$500 group, 38% for the \$500.01-\$2000 group, and 45% for the >\$2000 group, P<0.001 for all comparisons. Delayed initiation was also more frequent among patients in higher cost-sharing categories (3% in ≤\$10 group vs. 19% in >\$2000 group, P<0.001). Sensitivity and subgroup analyses by type of insurance, pharmacy, and cancer identified similar associations. **CONCLUSIONS:** Higher cost sharing was associated with higher rates of prescription abandonment and delayed initiation of oral oncolytic prescriptions. Our findings suggest cost sharing as a substantial barrier to prompt initiation of lifesaving treatments.

PCN235

CANCER CONCERNS AND ONCOLOGY CARE MANAGEMENT IN THE US

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OBJECTIVES: Cancer is costly, managed by a variety of treatments that include traditional and robotic surgery, radiation, chemotherapy, and immunotherapy. Pharmaceutical treatments are shifting from **METHODS:** Managed care (MC) MDs+PDs completed an online interactive survey. Topics included: advisor+plan information; Ranking (highest=1-to-13=lowest) of cancer-types; Copays; benefit-design; management of cancer; and top concerns today and in 5 years from budgetary and medical points of view. **RESULTS:** The survey was completed by 52 MDs+PDs (11.3%); 55.8% were MDs and 57.7% worked for health plans/IDNs/PPOs/IPAs; 9.6% for PBMs; 3.8% for Government; the remainder consultants. Plans were National=41.9%; Regional=34.9%; or Local=23.3%. Advisors/pPlans could cover multiple types of members: commercial (54.2%=FFS; 70.8%=HMO/PPO), Medicaid (Traditional=22.9%;HMO/PPO=62.5%),Medicare (66.7%; Traditional=22.9%; PDP-only=45.8%) and Employer/Self-funded lives=66.7%. Oncology was tied for the top-ranked Specialty-Pharmacy condition covered 84.4% (vs 64.3% last year) and 34.1% of advisors reported they participated in Oncology accountable care/disease management organizations. Breast cancer received the most #1 rankings, however based on average rankings (out of 13) the most concerning were: Lung Cancer=2.54; Breast Cancer=2.72; Colon and Rectal Cancers=3.64; Prostate Cancer=6.0; Myeloma=6.44; Leukemia=6.97; Melanoma=7.08; Pancreatic Cancer=7.72; Non-Hodgkins Lymphoma=7.82; Kidney Cancer=8.85; Endometrial Cancer=9.76; Bladder Cancer=9.97; and Thyroid Cancer=11.38. When asked about their management of cancer therapies and treatments, 48.7% of the plans/advisors sometimes leave oncology specialists alone; 65.0% of plans/advisors always follow NCCN guidelines; 56.4% sometimes follow other guidelines or pathways; and 38.5% sometimes follow internal protocols. Cancer/oncology was consistently reported the top concern from medical care (50% today, 42.5% in 5

years) and budgetary (35.7% today, 57.5% in 5 years) points of view. **CONCLUSIONS:** The environment for cancer treatment is undergoing a series of changes. The shift from traditional chemotherapies toward targeted immunotherapies and the potential cost implications requires payor medical and pharmacy directors to focus on, adapt and evaluate these newer agents and pathways rapidly as they become available.

PCN236

A DESCRIPTIVE ANALYSIS OF THE HEALTH CARE UTILIZATION AND COSTS OF PATIENTS DIAGNOSED WITH LYMPHOMA IN THE US MEDICARE POPULATION

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OBJECTIVES: Examine the health care utilization and costs incurred by patients diagnosed with lymphoma in the US Medicare population. **METHODS:** Patients diagnosed with lymphoma (International Classification of Diseases, 9th Revision, Clinical Modification diagnosis codes 200.4x, 200.7x, 202.0x, and 202.8x) were identified using 100% national Medicare data from 01JAN2009-31DEC2013. The first diagnosis date was designated as the index date, and patients were required to have continuous medical and pharmacy benefits 12 months pre- and post-index date. Study outcomes included demographic and clinical characteristics as well as health care costs and utilization for patients diagnosed with lymphoma. **RESULTS:** A total of 299,349 lymphoma patients were included in the study. The mean age was 77 years. A majority of the patients were female (53.49%) and white (91.24%). Most patients resided in the South (36.62%), Midwest (25.27%), or Northeast (20.40%) US region. The mean Charlson Comorbidity Index score was 4.86 (standard deviation = 3.40). The most commonly diagnosed comorbid conditions included hypertension (78.13%), and diabetes mellitus (34.52%). Health care utilization was assessed, including the proportion of patients with inpatient (26.71%), emergency room (ER; 26.95%), physician office (94.02%), outpatient hospital (81.22%), skilled nursing facility (SNF; 7.11%), hospice (1.66%), home health agency (HHA; 14.60%), and durable medical equipment (DME; 41.11%) visits. Patients with lymphoma incurred higher mean health care costs, including inpatient (\$6,729), ER (\$279), physician office visit (\$4,835), outpatient hospital (\$9,371), SNF (\$1,519), hospice (\$352), HHA (\$851), DME (\$559), Part D pharmacy (\$2,683), and total costs (\$27,177). **CONCLUSIONS:** During a 12-month period, Medicare patients diagnosed with lymphoma incurred substantial health care utilization and costs.

PCN237

BUDGET IMPACT ANALYSIS OF THE USE OF TRASTUZUMAB SC IN THE TREATMENT OF HER2 POSITIVE IN PUBLIC HEALTH INSTITUTIONS OF ECUADOR

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OBJECTIVES: The standard treatment OF HER2+ breast cancer in Ecuador is Trastuzumab IV+Chemotherapy, however, the pharmaceutical formula Trastuzumab Subcutaneous (SC) has been shown to have the same efficacy, treatment regimen and a higher patient preference, which is why an economic analysis is fundamental for decision making. **METHODS:** We opted for a Budget Impact to reflect the savings that the incorporation of the pharmaceutical formula SC would generate to Ecuador. The analysis proposes a difference of 6% between the price of Trastuzumab IV (\$1821.94) and Trastuzumab SC (\$1712.62), in addition, it includes administration costs (USD, 2015) for patients between 40 and 59 years old with an average weight of 66.7 kg (95% CI 66kg: 68kg) for a population of 515 people (Globocan 2012) and a time horizon of three and five years. Due to the fact that in Ecuador there is no available data on waste management and vial sharing, the following article was used as guide "Drug waste minimization and cost-containment in Medical Oncology: Two-year results of a feasibility study (Fasola G et al., 2014). **RESULTS:** Considering an average of 7% of vial waste in the first year and a 3.5% of vial waste from the second year on, Trastuzumab IV represents an investment of \$15,710,806 in the first year and of \$15,199,073 from the second year while Trastuzumab SC represents an investment of \$14,842,096 per year. The incorporation of Trastuzumab SC would generate savings of \$868,716 the first year and of \$356,978 from the second year on. Savings of \$1,582,665 would be generated in 3 years and of \$2,296,620 in 5 years. **CONCLUSIONS:** The reimbursement of Trastuzumab SC would generate substantial savings to Ecuador (\$2,296,620 in five years) as well as a more efficient drug management and a better health system approval from patients with HER2+ breast cancer who are currently receiving intravenous treatment.

PCN238

A DESCRIPTIVE ANALYSIS OF THE HEALTH CARE UTILIZATION AND COSTS OF PATIENTS DIAGNOSED WITH MYELODYSPLASTIC SYNDROME IN THE US MEDICARE POPULATION

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OBJECTIVES: To examine the health care utilization and costs incurred by patients diagnosed with myelodysplastic syndrome (MDS) in the US Medicare population. **METHODS:** Patients diagnosed with MDS (International Classification of Diseases, 9th Revision, Clinical Modification diagnosis codes 238.72-238.75) were

identified from the 100% national Medicare data population from 01JAN2009-31DEC2013. The first diagnosis date was designated as the index date. Patients were required to have continuous medical and pharmacy benefits 12 months pre- and post-index date. Study outcomes included demographic and clinical characteristics as well as health care costs and utilization for patients diagnosed with MDS. **RESULTS:** A total of 166,545 MDS patients were identified. The mean age was 80 years. The majority of patients were female (53.42%), white (88.06%), and resided in the South (38.99%) or Midwest (24.18%) US region. The mean Charlson Comorbidity Index scores were 4.99 (standard deviation = 3.49). The most commonly diagnosed comorbid conditions included hypertension (78.36%), and diabetes mellitus (33.07%). Health care utilization was assessed, including the proportion of patients with inpatient (26.89%), emergency room (ER; 28.00%), physician office (94.00%), outpatient hospital (80.81%), skilled nursing facility (SNF; 8.07%), hospice (2.04%), home health agency (HHA; 16.27%), and durable medical equipment (DME; 39.91%) claims. Patients with MDS incurred higher mean health care costs, including inpatient (\$6,482), ER (\$285), physician office (\$4,805), outpatient hospital (\$9,237), SNF (\$1,720), hospice (\$429), HHA (\$1,004), DME (\$511), Part D pharmacy (\$2,496), and total costs (\$26,968). **CONCLUSIONS:** During a 12-month period, Medicare patients diagnosed with MDS incurred substantial health care utilization and costs.

PCN240

OPPORTUNITIES FOR HIGH-COST DRUGS IN INDIA

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OBJECTIVES: Healthcare in India is a rapidly expanding sector. Increased urbanisation, better standards of living, a growing middle class, improvements in health standards cumulatively have led to increased longevity and a shift in burden of disease dominated by infectious diseases to non-communicable diseases (NCDs). NCDs like cancer are now one of the leading cause of morbidity and mortality in India. Oncology therapeutics are generally highly priced and recognised as defining the 'high-cost drugs' space in the Indian market. Emerging markets such as India represent untapped revenue potential for the major pharmaceutical companies. We sought to assess market access opportunity for such drugs in India including current disease treatment landscape and reimbursement channels. **METHODS:** Research involved targeted review of literature published on the topic, followed by primary research with senior oncologists involved in formulary decision-making and nationally influential on the field of practice. **RESULTS:** Various public and private health insurance schemes were identified, particularly those that reimburse high cost drugs. Extrapolating from the cover provided under various schemes and affordability across income groups, a threshold of ₹2 lakh (~\$3000) per treatment course was set beyond which any drug was considered high cost. Overall, ~6% of the population receive very comprehensive health cover that reimburse high cost drugs through schemes provided by central government, state government, railway, armed forces. **CONCLUSIONS:** At first glance, opportunities for high cost drugs in India can be considered low considering limited reimbursement options and lack of affordability for majority of the population. However, 6% of the population engaged in the public sector have good health cover which include reimbursement for high cost drugs. Together, this is a substantial market and the opportunity should be considered as 'high'.

PCN241

THE IMPACT OF DIFFERENT TYPES OF PAYER ON HEALTHCARE RESOURCE UTILIZATION AND COSTS AMONG CANCER PATIENTS IN INDIA

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OBJECTIVES: To review the patient characteristics and treatment methods of breast, oral and ovarian cancer patients at a tertiary care hospital in India. **METHODS:** This study was a retrospective review of electronic medical records from a tertiary care hospital in Mumbai, India. Patients ≥18 years of age hospitalized for breast (BC), oral (OC) and ovarian cancer (OVC) treatment between Jan 2014 and May 2015 were included in the study. Descriptive and inferential statistics were used to analyze and compare differences between patients. Regression models were also used to determine predictors of total costs for all patients. **RESULTS:** A total of 323 cancer patients met the study criteria (BC=146 patients, OC=132 patients, OVC=45 patients). The mean length of stay was highest for OVC patients (OVC=9.4+4.55 days, OC=9.1+5.13 days, BC=5.3+2.5 days). Patients with BC went into surgery early and were discharged the early (Pre-surgery: BC=3.6+1.8 days, OVC=4.2+2.32 days, OC=4.6+1.9 days; Post-surgery: BC=3.2+1.2 days, OVC=7.2+2.57 days, OC=6.3+3.3 days) from the hospital. Among BC patients, patients with private insurance (PI) received the highest number of per patient clinician visits (PI=16.3 visits/patient, no insurance (NI)=11.8, CGHS=2.7, RGJAY scheme=2.2; p<0.001). Among OC and OVC patients, patients with NI received the highest number of per patient clinician visits (OC: PI=36.5 visits/patient, NI=24.6, CGHS=8, RGJAY scheme=1.2; p<0.001; OVC: NI=35.9 visits/patient, CGHS=19.5, RGJAY=1.1, PI=30.3; p<0.001). Among BC and OC patients, mean hospital costs were highest for patients with PI (BC: PI=\$2381.03+1739.31, NI=\$1558.70+1342.56, CGHS=\$723.19+731.57, RGJAY=\$637.41+118.20; OC: PI=\$5132.61+6158.41, NI=\$1998.52+2057.81, CGHS=\$1178.21+309.23, RGJAY=\$795.77+\$314.92). While NI patients incurred the highest mean hospital costs among OVC patients (OVC: NI=\$3843.77+\$2735.89, PI=\$2735.89+2454.62, CGHS=\$1849.73+1023.56, RGJAY=\$653.01+\$257.18). Clinician visits was found to be the significant predictor of costs in all regression models across cancer type. **CONCLUSIONS:** Patients with PI and NI incurred higher costs but received more resources, which could lead to better care, compared to patients covered under other insurance schemes.

PCN242

REAL-WORLD TREATMENT PATTERNS AND COSTS AMONG ADVANCED HEPATOCELLULAR CARCINOMA (AHCC) PATIENTS TREATED WITH SYSTEMIC CANCER THERAPIES

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OBJECTIVES: To describe the patient characteristics, pharmacologic treatment patterns and costs among commercially insured patients diagnosed with aHCC. **METHODS:** Newly diagnosed aHCC adults were identified using the Truven MarketScan Research Databases between 1/1/2008-9/30/2015 (ICD-9-CM 155.0.x, 155.2x; on ≥1 inpatient or ≥2 outpatient claims). Continuous enrollment was required 6 months prior- and 1 month post- first diagnosis (index date). A claim for systemic therapy after the index date was required. Patients with prior diagnosis of other primary/secondary cancers were excluded. Outcomes included a descriptive assessment of patient characteristics, patterns of systemic therapy use and monthly/total healthcare costs. **RESULTS:** 4,902 patients met study criteria, mean (±SD) age 60.9 (±11.0) years, 32.6% female, and mean follow-up of 467 days (±466). 25.1% had a pre-index diagnosis of cirrhosis, 16.3% had HCV only, 3.0% had HBV only, 0.7% had both HCV and HBV. 43.6% of patients received sorafenib (SOR) as a first exposure. SOR users were more likely to have cirrhosis (39.5% versus 13.2%), HBV (6.3% versus 1.5%), and HCV (27.6% versus 8.3%) than non-SOR patients (all p>0.01). Among SOR users (n=2,217), 42.5% used target therapies, 5.1% used chemotherapies, and only 1 patient used immunotherapy within 60 days after first SOR use. Overall, mean total per patient per month (PPM) healthcare costs were \$16,148 (±\$14,502). PPM costs for SOR users (vs non-SOR) were significantly lower (\$14,033 (±\$12,488) vs \$17,894 (±\$15,766), p<0.01). Among sub-sets of patients with 6-months (n=3,309) or 12-months (n=2,103) of continuous enrollment, mean total costs were \$101,119 (±\$95,807) and \$164,897 (±\$143,357), respectively. **CONCLUSIONS:** The majority of aHCC patients received SOR (in first-line); however a variety of agents are used post-SOR despite no approved standard of care in second line. Given the limited number of approved treatment options overall and substantial PPM costs, there is a clear need for more effective aHCC treatments.

PCN243

ASSOCIATION BETWEEN CANCER INFORMATION SEEKING VIA INTERNET AND CANCER FATALISTIC BELIEFS AMONG AMERICANS USING HEALTH INFORMATION NATIONAL TRENDS SURVEY

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OBJECTIVES: To determine association between internet cancer information seeking behavior and cancer fatalistic beliefs across people with and without cancer history. We hypothesized that the behavior would mitigate cancer fatalistic thoughts on cancer prevention and treatment. **METHODS:** A pooled cross-sectional study was conducted among US adults (≥ 18 years) using Health Information National Trends Survey 2012 and 2014 data. Participants were categorized into two groups: with and without cancer history. The behavior of interest was whether they sought cancer information for themselves via internet (the eSeekers) in past 12 months (yes/no). Fatalistic beliefs were operationalized by participants' agreement or disagreement with three statements along the lines of everything causes cancer, cancer prevention is not possible, and too many recommendations are available for preventing cancer. Each fatalistic belief was analyzed separately across both groups. Weighted descriptive bivariate analyses were used to explore associations between socio-demographic factors and each fatalistic belief. Adjusted multivariable logistic regression was then employed to examine association between internet cancer information seeking behavior and each fatalistic belief. **RESULTS:** Of the total 5,454 participants, 1,022 (18.7%) reported using internet for seeking cancer information. Greater proportions of the eSeekers were aged 35-64 years, college graduates, urban dwellers, and with either personal or family cancer history. The eSeekers also reported higher agreement on behaviors (such as diet, smoking, exercise) cause cancer (p<0.001). The eSeekers without cancer history were 38% less likely to believe that they were overwhelmed with many recommendations for preventing cancer (Adj. OR: 0.62, 95% CI: 0.44-0.86). However, internet cancer information seeking behavior was insignificantly associated with the other fatalistic beliefs across both groups. **CONCLUSIONS:** Information seeking is a desired behavior for cancer prevention. However, we did not observe significant associations between the behavior and two out of the three cancer fatalistic beliefs across participants with and without cancer history.

PCN244

FDAMA114 LANDSCAPE ASSESSMENT: ARE US PAYER AND PROVIDER ACCESS DECISION MAKERS RECEPTIVE TO HEALTHCARE ECONOMIC INFORMATION CONSIDERING THE RECENT CHANGES TO FDAMA114

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OBJECTIVES: Section 114 of the FDA Modernization Act of 1997 (FDAMA114) provides companies with guidelines to share healthcare economic information (HCEI) with formulary decision makers. However, ambiguity in the phrasing of FDAMA114 has caused companies to exercise caution when distributing HCEI. The enactment of the 21st Century Cures Act in December 2016 aimed to remove this ambiguity in an effort to increase HCEI utilization and standardization, and encourage collaboration in addressing rising healthcare costs. This research

identifies four areas of ambiguity within FDAMA114, seeks to understand if the Cures Act provided sufficient clarity, and captures the Payer and Provider Access Decision Maker (ADM) perspective on the credibility and believability of HCEI. **METHODS:** Secondary research was conducted to identify four phrases in FDAMA114 considered ambiguous to Payer and Provider ADMs. Each identified phrase was analyzed in relation to guidance provided in the Cures Act. Primary research was conducted with Payer and Provider ADMs to understand the extent to which the Cures Act addressed ambiguity in FDAMA114 and impacts the perceived credibility and believability of HCEI. **RESULTS:** The Cures Act stoked new interest in FDAMA114 by pharmaceutical companies. Specifically, the four primary areas of uncertainty in FDAMA114 identified were acknowledged through changes brought by the Cures Act. However, Payer and Provider ADMs do not recognize a meaningful advancement in reducing the ambiguity around HCEI communications. Moreover, stakeholders acknowledged that the lack of coordination and consistency between pharmaceutical companies further enhances the low perception of credibility and believability around HCEI. **CONCLUSIONS:** HCEI continues to present an opportunity to utilize a data-driven approach to confronting rising healthcare costs. Even with recent revisions to FDAMA114 through the Cures Act, ambiguity and uncertainty still remain with Payer and Provider ADMs. Furthermore, the pharmaceutical industry must work towards standardization for the communication of HCEI to improve its overall credibility and believability.

PCN245

ASSESSING THE MOTIVATION FACTORS AND REASONS FOR NON-ATTENDANCE AT CERVICAL CANCER SCREENING AMONG ROMANY MINORITY POPULATION

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OBJECTIVES: The aim of our study was to assess the main reasons for romany women to stay away from cervical cancer screening, factors that affect screening attendance and knowledge about cervical cancer and its screening process. **METHODS:** We carried out a quantitative, cross-sectional study with non-probability convenience sampling in 2016. Our sample consists of romany women living in the agglomeration of Nagyatád, Hungary (N=126). We excluded women with cervical cancer, women receiving treatment for gynecological cancer or women who underwent hysterectomy. In the questionnaire we measured health status, reasons for non-attendance and knowledge with a test consisted of 20 questions. During statistical analysis we calculated descriptive statistics, χ^2 -test and t-test ($p < 0.05$). **RESULTS:** Mean age of responders is 37.45 ± 12.05 years. 26.2% of women have not attended any kind of gynecological screening in their life. Mean age of women when they attended for screening for the first time was 24.05 ± 8.96 years ($n=91$). 76.2% of women who have selected physicians attend screening in every three years. We did not find any significant connection between time of the last attendance or frequency of attendance and socio-demographic data ($p > 0.05$). Main score of the knowledge test is 31.4 ± 3.93 points. Knowledge about HPV and cervical cancer is low in 8.7%, average is in 87.3% of the case and only 4% of the sample has sufficient knowledge. According to knowledge level there is no connection between attendants and non-attendants ($p=0.141$). **CONCLUSIONS:** It is necessary for romany women to be screened for cervical cancer regularly. Expand knowledge is key to increase the frequency of screening attendance.

PCN246

DEVELOPING A PHARMACOECONOMICS PROGRAM IN AN ACADEMIC MEDICAL CENTER

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OBJECTIVES: While the cost of cancer care continues to rise, the traditional approach to formulary management is no longer sustainable. Several FDA approved anti-cancer drugs in development provide marginal impact on patient survival, little or no improvement in quality of life, and raise questions about the true value of the drug. Value is a key consideration in discussions about reducing oncology drug costs. Unlike in other countries, the U.S. lacks a national program that provides comprehensive review of costly oncology medications. By existing standards, most cancer treatments are unlikely to be cost-effective. A national discussion is needed around the economic value placed on a year of life, what a value-based price is and how it is determined. The objective is to develop an evidence-based program in pharmacoeconomics at an academic medical center to look beyond the traditional approach to oncology formulary management. **METHODS:** The oncology pharmacy and therapeutics (P&T) subcommittee was identified as an initial strategic avenue for developing pharmacoeconomic analyses for new drug requests and conversion from one drug to another. The methodology are expected to be transparent and replicable, and key stakeholders from disease teams to billing/reimbursement are engaged in data collection, selection of analytical framework, and applicability of results. Ongoing efforts include educating hospital leadership about the value of pharmacoeconomics. **RESULTS:** Current efforts to identify the value of high cost oncology drugs on formulary include cost-effectiveness and budget impact analyses. Additional areas for development are oncology care model, treatment pathways and medication policy determination. **CONCLUSIONS:** The inclusion of pharmacoeconomics is essential for efficient formulary management. Successful program development requires physician and pharmacy champions in determining guiding principles of the program. Moving toward a pricing system that matches the value of a drug will be challenging. We share these

experiences to encourage a national conversation about the rising costs of cancer care.

PCN247

PARTICIPATION IN CERVICAL CANCER SCREENING AND EXAMINATION OF ITS AFFECTING FACTORS AMONG WOMEN LIVING IN BARANYA COUNTY, HUNGARY

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OBJECTIVES: The aim of our study was to explore the habits and attitudes to cervical cancer screening among women aged between 18 and 70 years. **METHODS:** A quantitative, cross-sectional study was conducted using self-administered questionnaire (socio-demographic data, motivation to take part in screening, participation rate and habits) among women who were selected by non-random sample selection method in Baranya county, Hungary in 2016 ($n=166$). Data were processed by SPSS 22.0 program, using descriptive statistical analysis, χ^2 -test and multivariate logistic regression ($p < 0.05$). **RESULTS:** 51.2% of women attended screening within a year, 17.7% of them continued this practice every two years. Almost 20 % of the women participated in screening less than three years. Women living in reasonably good financial position ($\chi^2=18.563$; $p=0.005$) went to screening more often than their less well-off counterparts. The first examination usually occurred at the age of 20.8 ($SD=4.81$). Early recognition was a motivating factor for screening (94.6%) and for examination of disease in order to prevent a serious illness (92.8%). Motivations for non-attendance are the following: 16.3% of the women did not participate in screening due to fear of examination. Women with lower education kept away screening to a greater extent due to the above reason. ($\chi^2=13.650$; $p=0.008$). 42.2% of them knew that health visitors may perform screening, since they heard of the Cervical Cancer Screening Program significantly to a great extent ($\chi^2=78.949$; $p < 0.001$). 34.9% of the women asked for help from the health visitors on gynecological problems because they had some knowledge on screening given by the health visitor. Those persons who asked for help were usually young women ($\beta=0.044$; $OR=1.045$; 95% CI[1.007;1.084]). **CONCLUSIONS:** The role of health visitors is an extremely important job in health promotion because they can reduce the fear that keeps women away from screening.

PCN248

AVERAGE TIME TO PATIENT ACCESS FROM DRUG APPROVAL: AN ANALYSIS OF ONTARIO & QUEBEC

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OBJECTIVES: This study compares two provinces to provide insight into the time to provincial reimbursement from Health Canada approval for novel oncology drugs. **METHODS:** Health Canada's "Notice of Compliance (NOC)" database was used to identify "new active substances" in oncology approved from January 1, 2012 until December 31, 2016. The pan-Canadian Oncology Drug Review (pCODR) and Institut National d'excellence en sante et en services sociaux (INESSS) databases were used to determine the date that Ontario and Quebec publicly listed each drug. Prescription claims from a private pay direct drug plan database that includes all major insurance providers in Ontario and Quebec were provided by QuintilesIMS to determine the date of first private claim. **RESULTS:** 43 oncology drugs met inclusion criteria. As of January 2017, Ontario had listed 23/43 (53%) and Quebec had listed 21/43 (49%) of the drugs. Of the listed drugs, the median time (range) to provincial listing from NOC was 382 (134-817) days in Ontario and 367 (188-1008) days in Quebec. The median time (range) to first private claim from NOC was 84 (13-411) days and 127 (45-665) days in Ontario and Quebec, respectively. Nine drugs received no private claims in Quebec or Ontario during the study period, and four drugs had a greater than expected time to first private claim. **CONCLUSIONS:** These findings suggest private insurance plans continue to reimburse novel oncology treatments in a shorter timeframe than public programs. There was a trend that time to first private claim in Quebec was longer than that in Ontario, which needs to be investigated further as time to first private claim could be impacted by various confounding factors. A limitation of this study is that access to drugs via clinical trial, compassionate usage and pharmaceutical sponsored programs would not be captured in this analysis.

PCN249

CHALLENGES OF PRICING STRATEGY FOR DRUGS BEING LAUNCHED IN MULTIPLE ONCOLOGY INDICATIONS

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OBJECTIVES: Most oncology drugs have development plans that includes multiple indications and often the value they bring in some indications can be higher than others. This study aimed to understand what the best pricing strategy would be when a drug's value is different across indications and how payer willingness to pay may be impacted when the time between the regulatory approval of the indications takes 1 year or more. **METHODS:** In-depth secondary research was conducted on 18 oncology drugs that were launched in 2 indications or more. This was followed by 1-1 interviews with senior clinicians, policy makers and national and regional payers in EU5. **RESULTS:** Observation of price changes indicated differences in response by market. The key difference was observed in net prices. Factors such as the unmet need in different populations, the magnitude of efficacy (primarily OS and PFS), the size of the population, the time difference between launches were determined to be key decision drivers influencing the price and access of oncology drugs. Although payer concerns were more related to

clinical benefit and budget impact, they were also vary of deliberate delaying tactics by pharma in manipulating launch sequence to influence price. The analysis revealed that in order to ensure the price of one indication is not impacted by that of a follow-on indication, a minimum of 18 months between indications is expected. **CONCLUSIONS:** Even though delaying a drug's initial launch in one indication to obtain a higher price for another may appear to be an attractive strategy, research shows that drugs that employed this strategy have often resulted in a lower price than what they might have achieved by pursuing 'natural' launch sequence. Companies developing drugs in oncology should aim to come to market upon initial approval to maximise revenue and avoid conflicts with regulatory authorities, clinicians and patient groups.

PCN250

ARE HTAS FOR ONCOLOGY AGENTS TAKING LONGER TO COMPLETE? TRENDS IN TIME TO AN HTA DECISION IN 6 MAJOR MARKETS

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OBJECTIVES: To determine how the time required for health technology assessment (HTA) after regulatory approval has changed. **METHODS:** Oncology drugs approved 2005-2015 by the EMA, 2013-2015 by Health Canada, and 2009-2015 by TGA were matched on indication with HTAs from G-BA, HAS, NICE, SMC, pCODR, and PBAC. The analysis included 569 HTAs. Resubmissions were excluded. The date of the first reimbursement decision was subtracted from the date of the regulatory approval to determine the time taken to complete HTA and to issue reimbursement decision. Trends over time were analyzed using regression analysis. **RESULTS:** On average it takes 321 days from regulatory approval to issue a reimbursement decision for oncology drugs. Since 2005, the time from regulatory approval to the first reimbursement decision for has lengthened (increased) by approximately 10 days per year ($p=0.04$). Trends over time varied by HTA agency. PBAC's time to reimbursement has trended upwards (i.e., longer time to issue a decision), while G-BA's time to decision has been steadily decreasing. HAS and SMC's time to reimbursement decisions have increased slightly, with a recent dip in 2016. **CONCLUSIONS:** Delays in patient access to life-saving oncology therapies appear to be getting longer over the past decade. This increase may be due to changes in HTA processes, the time it takes manufacturers to prepare and submit their dossiers, or the time to finalize intense negotiations between companies and payers. For example, negotiating patient access schemes for higher cost cancer therapies may require more time. The cost-effectiveness agencies (i.e., NICE, SMC, pCODR, PBAC) have demonstrated lengthier trends, while G-BA, an agency that does not consider cost during the evaluation, has not.

PCN251

DO LONGER HTA REVIEW TIMES FOR ONCOLOGY PRODUCTS REFLECT WORSE OUTCOMES? A REVIEW OF 482 HTAS ACROSS 5 MARKETS

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OBJECTIVES: To determine how reimbursement decision type affects the time required for health technology assessment (HTA) agencies to issue a decision in oncology. **METHODS:** Oncology drugs approved between 2005-2015 by the EMA, 2013-2015 by Health Canada, and 2009-2015 by TGA were matched on indication with HTAs from HAS, NICE, SMC, pCODR, and PBAC ($n=482$). Resubmissions were excluded. The date of the first reimbursement decision was subtracted from the date of the regulatory approval to determine the time to reimbursement decision. Reimbursement decisions were categorized as "recommend," "recommend with restrictions," or "do not recommend." An analysis of variance test was used. **RESULTS:** On average it took 304, 382, and 353 days to issue "recommend," "recommend with restrictions," and "do not recommend" decisions, respectively. Although demonstrating a trend, there was no difference in the time to a decision by the type of decision ($p=0.16$). All agencies (except SMC) required more time for "recommend with restrictions" decisions than "recommend" decisions. It took longer, on average, for pCODR, HAS, and NICE to issue a "do not recommend" decision than a "recommend" or "recommend with restrictions" decision. **CONCLUSIONS:** The most positive decision ("recommend") takes the shortest time for all agencies, except for SMC; "recommend with restrictions" and "do not recommend" decisions require longer time, reflecting challenges in negotiations with manufacturers or the time needed to determine restrictions. For example, negotiating with manufacturers on patient access schemes or allowing the manufacturer to comment, appeal, or counter a preliminary decision could require additional time to reach a conclusion. The time it takes agencies to issue decisions post regulatory approval can lead to delaying patient's access to oncology treatments.

PCN252

VALUE FRAMEWORKS IN ONCOLOGY: UNDERSTANDING AND IMPLICATIONS TO PHARMA

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OBJECTIVES: GfK reviewed the capabilities and limitations of five of the most notable value frameworks to emerge in recent years, to compare and contrast the relative value that each conveys as well as their application among the intended stakeholders. **METHODS:** GfK contrasted the methodology of the ASCO Value Framework (version 2.0), NCCN Evidence Blocks, MSKCC DrugAbacus, ICER Value Assessment Framework and ESMO Magnitude of Clinical Benefit Scale with

respect to the input, scoring approach and output. In addition, GfK gleaned stakeholder insight on these frameworks and their potential application from dialogues with physicians and payers as well as secondary research and meta-analysis of existing data. **RESULTS:** GfK noted several framework-specific themes related to trial analysis, breadth of evidence, evidence weighting, scoring and value to stakeholders. Our dialogues with physicians and meta-analysis of existing data revealed level of awareness and use of value frameworks in practice. For example, while the ASCO value framework appears nascent in clinical practice, physicians believe they will be more purposeful in the future as they become more established and the outputs more widely accepted. **CONCLUSIONS:** The value of drugs is emerging as a particularly acute concern in oncology, where the cost of cancer care has evoked concerns of "financial toxicity". Along with patients and payers, physicians and policymakers have waded into the discussion, as well as the pharmaceutical industry that seek to understand the impact of these value frameworks as they model the value and financial threshold of innovative, high-cost drugs. Each of these five major value frameworks is geared to a different set of stakeholders. By understanding not only the meaning of the output(s) generated by each framework, but also the value of each framework to each stakeholder, pharma has an opportunity to selectively utilize these fledgling frameworks to shape clinical and commercial development in oncology.

PCN253

EVOLVING TREATMENT PATTERNS IN METASTATIC MELANOMA IN CANADA IN 2016

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OBJECTIVES: Treatment of metastatic melanoma has evolved rapidly with changes to the approval and access status of new therapies. In 2016, several agents became available on compassionate use programs and later through public reimbursement, including Immuno-Oncology (I/O) agents. With open access to all available treatments, our objective is to compare the upfront treatment at centers in Canada prior to and after the availability of these new treatments. **METHODS:** This study used ONCO-CAPPS, a proprietary database of patient chart abstractions collected through regular survey of physician panels. The data includes demographic details, disease markers, and details of patients' cancer treatment by line of treatment. Data from the time periods 2013 to 2016 were used to identify patients with metastatic melanoma and analyze changes in upfront cancer treatment. **RESULTS:** 157 first line-treated (1L) metastatic melanoma patients were reviewed for 2013, and 338 1L patients for 2016. The most important factor in determining the 1L treatment, throughout the time period of data capture, was BRAF mutation status. In 2013, prior to the widespread availability of new agents, 88% of patients known to have BRAF mutation (BRAFM) were treated with a BRAF targeting agent in 1L. In 2016, 78% of 1L BRAFM patients were treated with a BRAF targeted agent, and 11% were treated with I/O agents. For patients without known BRAF mutation (BRAFWT), 87% were treated with chemotherapy in 1L in 2013; in 2016 only 8% of 1L BRAFWT patients were treated with chemotherapy and 88% were treated with I/O agents. **CONCLUSIONS:** With open access to all treatments for metastatic melanoma, there remains a physician preference for upfront targeted treatment in BRAFM patients. In the first line setting, Immuno-Oncology agents have had the effect of replacing chemotherapy for patients without known BRAF mutation.

PCN254

DO ADVANCES IN BREAST CANCER TREATMENT RENDER SCREENING MAMMOGRAPHY NOT COST-EFFECTIVE FOR AVERAGE-RISK WOMEN?

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OBJECTIVES: Researchers have postulated that screening mammography could become less effective in reducing cancer mortalities as breast cancer (BC) treatment improves over time. We evaluated the association between treatment advances and the cost-effectiveness of screening mammography for women at average-risk for BC. **METHODS:** Our microsimulation model includes "no screening" plus 6 other strategies at three initiation (40/45/50) and two cessation ages (75/80). We captured treatment advances by modeling a hypothetical treatment with the same hazard reduction and costs as trastuzumab but would benefit 50% (or 100%) of BC patients, instead of only HER2+ patients. We obtained clinical parameters from the literature or statistical modeling and cost parameters from Medicare fee schedule and SEER-Medicare. Deterministic CEA was based on simulating a birth cohort of 500,000 women and probabilistic CEA from 100 repetitions of the simulation, each with a cohort of 100,000 women. **RESULTS:** The most cost-effective screening strategy in the base case scenario was a hybrid strategy that started screening at 45 and switched to biennial between 55 and 75, yielding ICER \$69,235/QALY. The ICER of the same strategy increased to \$70,612/QALY and \$71,162/QALY in the scenario in which the new treatment benefited 50% and 100% of patients, respectively. At \$50,000/QALY willingness-to-pay, the probability that this hybrid strategy yielded the highest net benefit was 30% at base case, and reduced to 28% and 23% in the 50% and 100% new treatment scenario, respectively. At \$100,000/QALY, the probability that the above hybrid strategy had the highest net benefit stayed around 37% for all three scenarios. **CONCLUSIONS:** Treatment advances reduce the cost-effectiveness of screening mammography, especially in countries with lower CE threshold. For countries with a higher CE threshold, a new treatment would have to be substantially better than trastuzumab and benefit a large proportion of patients to render screening mammography not cost-effective.

PCN255

THE REPORTING OF ADVERSE EVENTS AND DEATHS USED FOR ECONOMIC MODEL INPUTS IS INCONSISTENT THROUGHOUT ONCOLOGY TRIALS

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OBJECTIVES: Cost-effectiveness analyses require accurate and uniform data relating to adverse events (AEs) and deaths. The consistency of reporting of these data in peer-reviewed oncology trial publications was explored. **METHODS:** The consistency of reporting of non-mortality AEs and deaths was evaluated in published articles relating to 21 trials in the last 10 years in previously untreated diffuse large B-cell lymphoma (DLBCL) and 12 in relapsed/refractory small cell lung cancer (SCLC). **RESULTS:** The criteria used to report AEs, and the rate and the severity of AEs that were included, differed across the publications. In the 21 publications for DLBCL, four different criteria were used to report AEs, and 17 papers (81%) clearly stated which criteria were used. The severity of AEs reported ranged from 'all AEs' to 'grade 3-4', and the frequency of AEs ranged from 'all', to 'common AEs'. As a result, AEs were reported in 18 different ways in the 21 studies. For SCLC, most publications (92%) specified the criteria used to report AEs. AEs were reported in seven different ways, ranging from 'all' to 'grade ≥ 3 occurring in $\geq 5\%$ of participants'. The number of deaths was not always reported. In DLBCL, 71% of publications reported the total number of deaths, and 62% reported the number of treatment-related deaths. For SCLC, 67% reported total deaths, and 58% specified toxicity- or treatment-related deaths. **CONCLUSIONS:** Within and across oncology indications, there is variation in the criteria used to report AEs, and the detail to which AEs are reported, making comparisons between treatments difficult. There is also a lack of clear reporting of deaths and treatment-related deaths. Greater consistency in the reporting of these important clinical endpoints would assist decision-making by health technology assessment agencies.

PCN256

BARRIERS TO CONDUCTING CLINICAL TRIALS AND ONCOLOGY RESEARCH IN COMMUNITY ONCOLOGY IN THE US

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OBJECTIVES: Less than 3-4% of cancer patients enroll in clinical trials. While 80% of oncology patients are treated in a community setting, trial patients are mostly enrolled in academic institutions. Understanding barriers to conducting clinical research in the community is essential to increase trial enrollment. **METHODS:** We surveyed 53 community-based oncologists of various geography and practice types to understand barriers to conducting clinical trials. Data were collected at a live meeting with audience response technology. **RESULTS:** Almost 35% of oncologists participated in phase III trials and an additional 31% participated in phase II studies. While 75% of oncologists participated in cooperative groups and/or pharma-sponsored studies, 58% indicated that more than 50% of pharmaceuticals have enrolled no patients. Almost 65% of oncologists were interested in observational trials and 62% stated that they have biomarkers-related studies open. Majority of oncologists (72%) claimed good understanding of required compliance, but 41% needed external advisors to help explain continuous regulatory changes. Barriers to clinical research: difficulty recruiting: 81%, budget/contract negotiations: 77%, IRB processes: 70%, time and resource constraints, 50%, and technology needs: 50%. A majority of the advisors (65%) indicated that clinical trials-related functional requirements and operational concerns moderately influenced their decision to set up a clinical research department. Protocol design was cited by 41% as the main cause for poor enrollment. Notably, 77% of oncologists did not have experience in healthcare economics and outcomes research, but 37% expressed an interest in learning more. Despite limitations, 82% stated that their practice provides added value to patients when clinical research is conducted. **CONCLUSIONS:** Community oncologists are eager to participate in clinical research, which is perceived as high-value to patients. The strength of the barriers is so significant that few trials can fully accrue patients, and few community practices participate broadly. Strategies to overcome barriers are urgently needed.

PCN257

IDENTIFYING THE HIGHEST BUSINESS OPPORTUNITY FOR FUTURE DEVELOPMENT AMONG KEY PATIENT SUBGROUPS IN NON-SMALL CELL LUNG CANCER (NSCLC)

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OBJECTIVES: Lung cancer is an increasingly segmented disease as more targeted and biological therapies are launched every year, particularly for non-small cell lung cancer (NSCLC). Given segmentation is being used by key opinion leaders and Payers in developing guidelines and policies, it is pertinent to assess the current landscape, HTA evidence requirements, and clinical trial design of current/future competitors in order to identify the subgroup(s) with the highest business opportunity for an interested manufacturer. **METHODS:** MKTXXS reviewed published studies of FDA and EMA approved NSCLC drugs using PubMed and clinicaltrials.gov. The latter was also leveraged to extract trial design information for not-yet-approved treatments, such as comparator, outcomes, inclusion criteria, etc. Published HTA reports from NICE, SMC, HAS/CT, and IQWiG were assessed for each recently approved therapy to understand key drivers of decision-making. Current price and access for NSCLC therapies was collated via online country-specific databases. **RESULTS:** Four subgroups within metastatic

NSCLC were identified: ALK+, EGFR-, adenocarcinoma, and squamous cell carcinoma. Within the crowded EGFR- and ALK+ subgroups, multiple therapies have demonstrated meaningful improvements in PFS and are not associated with considerable safety concerns. The adenocarcinoma and squamous cell carcinoma segments have few non-chemotherapy options recommended by NCCN, as a result of a dearth of indicated, highly effective and/or tolerable treatments. From an HTA standpoint, no demonstrated benefit in overall survival (OS) was needed to earn a positive assessment; progression-free survival (PFS) was sufficient. Well-defined and narrow target patient populations, such as the previously treated ALK+ subgroup associated with crizotinib, allowed for a price two to three times greater than other NSCLC therapies. **CONCLUSIONS:** Adenocarcinoma and squamous cell carcinoma represent the most promising future business opportunities within NSCLC. Optimal access in ALK+ or EGFR- will prove difficult without a substantial efficacy benefit or economic incentive (i.e., significant price discount).

PCN258

EXPLORING STAKEHOLDERS' PERSPECTIVES WITH MULTI-CRITERIA DECISION ANALYSIS (MCDA): APPLYING A PARACONSISTENT FRAMEWORK TO HEALTH TECHNOLOGY ASSESSMENT (HTA)

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OBJECTIVES: To assess multi-stakeholder expressed preferences around health care prioritization in the Brazilian National Committee for Technology Incorporation (CONITEC). **METHODS:** In addition to systematic consideration of scientific evidence, healthcare decision making requires reconciliation of all competing interests. For this purpose, paraconsistent multi-criteria decision analysis (MCDA) approach enables exploration of stakeholders' perspectives, regarding imperfect information and contradictory valuation, as well as explicit organization of broad range of criteria on which real-world decisions are made. A pilot MCDA approach was used to access multi-stakeholder concerns about resource allocation based on health technology assessment (HTA) report provided by CONITEC. An appraisal group, at hospital level, was convened and "Erlotinibe for Lung Cancer" was selected as a case study. A by-criterion HTA report was developed to synthesize evidence. The paraconsistent MCDA approach (a framework that can be used as the basis for inconsistent but non-trivial theories) was tested in 3 steps: selection, scoring and weighting of criteria. Interpretation was explored through discussion. **RESULTS:** Four criteria for assessing "Erlotinibe for Lung Cancer" were identified from the HTA report: clinical effectiveness, cost-effectiveness, budget impact and clinical relevance. Scoring was elicited according to standard approach in annotated logics, considering the concepts of magnitude and confidence on the available evidence. Weights for the criterion representing their relative importance, apprehended from the HTA report, were derived from a survey with the 8 members of the appraisal group. Scenario analyses were done varying criteria, scores and weights. The effect of different criteria and weights resulted in distinct recommendation, similar to the ones described in the HTA report. **CONCLUSIONS:** Feedback from participants revealed that the tool could help to promote a more structured and transparent approach to HTA. Further testing and validation are needed to advance the paraconsistent MCDA approach in healthcare decision making.

PCN259

PAYER ACCEPTABILITY OF METASTASIS-FREE SURVIVAL AS PRIMARY ENDPOINT IN NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

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OBJECTIVES: Life expectancy of patients with non-metastatic prostate cancer may exceed 10 years, making overall survival impractical as a primary efficacy endpoint. Therefore, pivotal trials in non-metastatic castration-resistant prostate cancer (M0 CRPC) have proposed metastasis-free survival (MFS) as an intermediate primary efficacy endpoint. While new oncology drugs may be conditionally approved by regulators based on attaining intermediate efficacy endpoints, their acceptance by payers seems to vary widely across regions and agencies. This research aimed to assess the acceptance of MFS by payers to demonstrate clinical benefit to patients. **METHODS:** A targeted search for products with MFS as an endpoint was performed. Health technology assessments (HTAs) of these products and analogs in early-stage oncology indications published from January 2011-March 2016 were obtained from HTA agencies around the globe (NICE, SMC, G-BA, IQWiG, HAS, PBAC, and TLV). **RESULTS:** Six products with MFS as primary endpoint were identified: five in M0 CRPC and one in stage III melanoma; no products had been approved by regulators. Searches for products in analog indications resulted in 40 HTAs of seven products in 10 different indications. Notably, progression-free survival (PFS) was the primary endpoint in most (9/10) indications and its definitions closely resembled MFS in M0 CRPC. No included assessments demonstrated statistically significant survival benefits and all submissions relied on intermediate primary endpoints to demonstrate clinical benefits (36 PFS; four objective response rate). A correlation between PFS gain of ≥ 5 months and positive recommendations was observed for most agencies, except in Germany (IQWiG and G-BA) and France (HAS), where the acceptance of intermediate endpoints remains challenging. **CONCLUSIONS:** Payers' acceptance of intermediate endpoints has increased over time and is mainly driven by the effect size of the demonstrated benefit. However, benefit ratings in France remain low and strict endpoint validation guidelines seem to hinder acceptance in Germany.

PCN260

COMPARISON OF FACTORS INFLUENCING RECENT REIMBURSEMENT DECISIONS OF ADVANCED NON-SMALL-CELL LUNG CANCER THERAPIES ACROSS LEADING HTA AGENCIES

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OBJECTIVES: To compare the factors leading to favorable and unfavorable recommendations for advanced non-small cell lung cancer therapies across six HTA bodies. **METHODS:** We evaluated HTA reports published by NICE, SMC, IQWiG, HAS, PBAC and pCODR on non-small cell lung cancer therapies to identify final decisions and the clinical and economic factors influencing these decisions. The decisions were classified as either positive or negative and to analyze the factors affecting decisions, recommendation summaries of HTA reports were assessed. **RESULTS:** A total of 25 HTA reports published between January 2016 and January 2017 were identified among which the decisions were positive for 68% submissions. Highest percentage of positive decisions were provided by SMC (100%) and pCODR (100%). But in pCODR, all being conditional on cost-effectiveness improvement to an acceptable level. Major factors driving positive decisions were overall survival (OS) and added clinical benefit for IQWiG, pCODR and HAS; and cost-effectiveness versus relevant comparator(s) for NICE and SMC. Highest negative decisions were provided by PBAC (100%) followed by HAS (66.7%) and IQWiG (37.5%). The leading factors for negative decisions included high ICER values mainly due to economic modelling issues for NICE and PBAC; and no added clinical benefit for IQWiG and HAS. The chief issues of economic modelling by HTA bodies involved inappropriate extrapolation of immature OS data, improper cross-over adjustment, non-inclusion of adverse event-related disutility and costs, underestimation of utility and costs due to post-progression, overestimation of comparator drug costs, and underestimation of resource use costs. **CONCLUSIONS:** The current evaluations signified that supporting data on OS benefit versus relevant comparators should be considered for reimbursement submissions by pharmaceutical manufacturers. In addition, robust economic models which incorporate appropriate cost and utility values and utilize sensitivity analysis for adjusting uncertainties could be useful to attain market access approvals.

PCN261

APPLICATION OF ONCOLOGY VALUE FRAMEWORKS TO THE 2ND LINE TREATMENTS IN RENAL CELL CARCINOMA (2L-RCC)

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OBJECTIVES: With multiple recent approvals, substantial progress has been made in the treatment of RCC patients who failed the initial therapy. Recently emerged US oncology value frameworks use heterogeneous methodologies, consider different evidence and target audience. Here we summarize the different approaches and outcomes of National Comprehensive Cancer Network Evidence Blocks (NCCN), American Society of Clinical Oncology Conceptual Framework (ASCO) and Memorial Sloan Kettering Cancer Center DrugAbacus (MSKCC), using examples in 2L-RCC. **METHODS:** PSE curated oncology database identified six FDA-approved treatments with multiple publications of randomized controlled trials (RCTs) in 2L-RCC: axitinib (AXI), cabozantinib (CAB), everolimus (EVE) lenvatinib+everolimus (LEN+EVE), nivolumab (NIV), sorafenib (SOR). Relevant endpoints from PSE database and 30-day costs derived from GPI pulse (averages sales prices/ wholesaler acquisition costs) were used to calculate ASCO Net Health Benefit (NHB) and MSKCC value price; and compare with NCCN approach. **RESULTS:** There were significant differences in the assessment of value by frameworks. NCCN assigned higher efficacy and safety score to NIV (4/5), while ASCO NHB was the highest for LEN+EVE (66/130). All regimens had the same NCCN affordability score (2/5) despite > 3X monthly costs variations. MSKCC does not include combination therapy nor CAB. For the remainder, the MSKCC price fell below the market price only when \$150,000/life year was used for pricing. Using a 20% discount for toxicity and a multiplier of 1.5 for other attributes yielded MSKCC price above the market price for all products except AXI. **CONCLUSIONS:** Although there are common themes among frameworks, heterogeneous methodologies and various data considerations lead to significant variability in value judgement and inconsistent recommendations. Further refinement of each framework is ongoing; however, it is clear that in the dynamic environment where growing evidence may change rapidly, a careful review of such evidence and transparent methodology are important to support clinical decision making.

PCN262

INTERNATIONAL COMPARISON OF HEALTH TECHNOLOGY ASSESSMENT DECISIONS IN PERSONALIZED ONCOLOGY THERAPIES

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OBJECTIVES: To identify the Health Technology Assessment (HTA) decision preferences of targeted therapies across the globe by comparing the decision rates and rationale of government-based HTA between Western and Eastern agencies. **METHODS:** A literature review was conducted to identify decision rates and rationale for targeted cancer therapies from five HTA agencies: NICE in UK, CADTH (pCODR) in Canada, PBAC in Australia, HIRA in South Korea and CDE in Taiwan. This study focused on cancer therapies with biomarkers in the top three cancer types — non-small cell lung cancer (NSCLC), breast, and colorectal cancer (CRC) — based on the GLOBOCAN 2012 report. 17 targeted therapies were selected.

Bevacizumab and Alectinib for NSCLC and Ramucirumab for CRC were excluded due to absence of HTA reports in more than three HTA agencies. Consequently, four therapies in breast cancer and five in NSCLC and CRC were reviewed. **RESULTS:** Seventy HTA reports were identified and reviewed. 15 of 70 HTA reports were not available since the assessments were still in progress or have not been published. The positive decision rate for targeted therapies was 67% (n=37) including the conditional positive decision rate of 29% (n=16). Taiwan had the highest positive decision rate, 100% (n=7/7), while NICE was 50% (n=6/12). CRC therapies had the lowest positive decision rate, 52% (n=11/21), while NSCLC had a positive decision rate of 90% (n=18/20). The reasons of negative decisions included the uncertainty of the clinical outcome (n=6), no comparative effectiveness to standard or current therapies (n=5) and insufficient cost-effectiveness (n=10). **CONCLUSIONS:** Based on the selected countries and cancer areas, Asian countries (Korea and Taiwan) were more favorable to targeted therapies than Western countries. CRC and breast cancer had lower positive decision rates compared to general cancer therapy which was 65% and 79% in NICE and CADTH respectively.

PCN263

EVALUATING VALUE BASED FRAMEWORKS IN THE US MARKETPLACE: CHALLENGES IN REAL WORLD APPLICATION

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OBJECTIVES: To compare and contrast value based framework (VBF) applicability in stakeholder decision making and to describe the challenges and limitations associated with real world application of each VBF. **METHODS:** All available VBFs for oncology therapies were used in a test case for refractory or relapsing multiple myeloma (RRMM). Regimens included carfilzomib, elotuzumab, and ixazomib because they share a common comparator in clinical trials, lenalidomide plus dexamethasone. The output of each VBF was computed according to the most recent guidance from each respective organization and differences in output for treatment decision making were reported. Additionally, we reviewed the challenges and limitations associated with running the test case in RRMM for each VBF. **RESULTS:** The ASCO, ICER, and NCCN VBFs suggest carfilzomib may be the most valued treatment option from payer, provider, and patient perspectives. A number of challenges and limitations of VBFs were identified including evidence limited to clinical practice guidelines and clinical trial data. The ASCO VBF had complexities of drug evidence evaluation, difficult interpretation of “good” or “bad” net health benefit, and limitations of drug comparisons within clinical trials. Due to the limited number of drugs in the tool and low interrater reliability of the eight domain inputs, no output from DrugAbacus was available for the test case. The published ICER report lacks continuous updates, and isn't adjustable to specific populations and clinical applications. Furthermore, it doesn't incorporate indirect benefits/costs of treatment and doesn't make clear suggestions for stakeholder use. NCCN scoring is subjectively rated by consulting disease specialist clinicians. The included affordability block doesn't clarify other factors (e.g., discounts, price adjustments) and doesn't establish thresholds. **CONCLUSIONS:** Although the test case provided a consensus on treatment decision, there is much nuance and limitations with VBFs available for RRMM. Clearer objectivity and better adaptability to specific treatment decisions is warranted.

PCN264

APPLYING THE ASCO VALUE FRAMEWORK NET HEALTH BENEFIT SCORE (NHB) TO METASTATIC PANCREATIC CANCER (mPA) SOC THERAPIES ESTABLISHING CRITERIA FOR ASSESSING NEW NOVEL TREATMENTS

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OBJECTIVES: Pancreatic cancer is difficult to treat effectively and the optimal first-line treatment has not yet been defined. The objective of this research is to provide benchmark reference for the evaluation of newer therapies. The ASCO Value Framework NHB and the NCCN recommended chemotherapy treatment combinations were utilized to assess the clinical benefit of three treatment regimens. **METHODS:** Phase III RCTs based on the NCCN recommended first line therapies for advanced mPC, were selected for analysis: “MPACT”, GEM + nab-Paclitaxel (GN-P); “ACCORD”, FOLFIRINOX and “NCIC-CTG” GEM + Erlotinib (GEM-E). The ASCO framework was applied to calculate the clinical/toxicity and NHB scores of each regimen. We also calculated the monthly drug cost for each of these standard regimes based on the 2016 Medicare Part B Drug Payment Allowance. **RESULTS:** The NCCN guidelines list all regimens in Category 1 preferred chemotherapy combinations. All regimens delivered an NHB over GEM: FOLFIRINOX 23.1 pts; GN-P 21.4 pts; GEM-ER 18.3pts. The clinical benefit score for each regimen, FOLFIRINOX 41pts, GN-P 28pts and GEM-E 23 pts. The toxicity scores based on adverse events were higher in FOLFIRINOX, GN-P and GEM-E and lower in the GEM group. Bonus points were achieved in FOLFIRINOX, GN-P based on overall survival benefit. The cost of drug treatment per month was significantly higher in each group while GEM was the lowest cost treatment: GEM \$278; FOLFIRINOX \$2,975; GN-P \$11,350; GEM-E \$8,320. **CONCLUSIONS:** The ASCO NHB is an attempt to represent therapy value in a single score but can be prejudiced by trial design and treatment cost. The regimens assessed support the NCCN category 1 recommendations for first line mPA treatment. FOLFIRINOX provided the highest NHB and was the least expensive. This assessment provides a reference for stakeholder evaluation and assessment of new therapies and for patient and provider therapy choice decisions.

PCN265

IS NICE BEING NICE IN THEIR RE-EVALUATION OF ONCOLOGY DRUGS IN THE CANCER DRUGS FUND IN ENGLAND?

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OBJECTIVES: Since July 2016, NICE took over responsibility for the Cancer Drugs Fund (CDF) in England, which contained 25 drugs for 35 indications. NICE is currently evaluating all existing treatments in the CDF to determine their cost-effectiveness and if they should be recommended for use by NHS England; retained in the CDF to gather additional evidence or not recommended. This study investigates NICE's evaluation of existing CDF treatments and its potential impact on funding and patient access. **METHODS:** Publicly available data sources were analyzed to determine the outcome of the 35 on-going NICE evaluations for oncology indications previously funded through the CDF. Information was collected on the stage of the evaluation process for each product and the outcome of the NICE assessment (recommended; recommended for use in CDF; not recommended). **RESULTS:** Of the 35 indications, manufacturers agreed to receive transition CDF funding for 34 indications whilst NICE undertakes an evaluation of their treatments. To date, 19 indications have been assessed of which treatments for 12 indications were recommended for NHS use, with seven indications not being recommended. Of the positive recommendations, nine were only recommended on condition of a patient access scheme and four with a restricted patient population. Only one indication was recommended for use within the CDF to generate additional evidence within a two-year deadline. The remaining 15 indications will be reviewed before December 2017. **CONCLUSIONS:** NICE is using cost effectiveness as an assessment criteria for treatments entering the CDF, resulting in limited patient access through removal of some treatments previously funded by the CDF. The removal of treatments for seven indications implies that collation of additional evidence is unlikely to make these treatments cost-effective. Access to the CDF will only occur if there is a realistic chance that additional evidence will reduce the uncertainty of their cost effectiveness.

PCN266

MANUFACTURER REGULATORY SUBMISSION STRATEGIES FOR ONCOLOGY THERAPIES IN THE UNITED STATES AND EUROPEAN UNION, 2012-2016

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OBJECTIVES: To investigate regulatory submission strategies employed by manufacturers of anticancer therapies in the US and EU, we sought to identify any discrepancies between the regulatory dossiers submitted to the FDA and EMA for the period of 2012-2016. **METHODS:** A review of all relevant FDA-approved oncology products granted marketing approval between 01/01/2012 and 07/15/2016 was conducted, followed by a cross-check to identify any associated CHMP opinions. In order to capture all potential submission delays across post-2012 FDA and EMA new drug applications, data for supplemental NDAs or BLAs submitted during the same period were also collected and cross-checked against the EMA database. Any FDA/EMA application pair associated with a submission delay of 6 or more months was selected for deep-dive assessment. FDA Summary Review, EPARs, and CHMP opinion summaries were consulted to extract data on sponsor application evidence packages and submission timelines. All data were then cross-examined to identify any variations between corresponding applications across the two regulatory agencies. **RESULTS:** Of unique NDA and BLA approvals granted by the FDA for the period in question, 41 corresponding conditional or positive CHMP recommendations were identified. 32 additional submissions to the EMA were identified as being associated with FDA approvals for follow-on indications. Three new drug and six follow-on indication FDA/EMA pairs were associated with submission delays of greater than 6 months. Of these nine cases, five were found to have substantial differences in the evidence packages submitted to the respective agencies. **CONCLUSIONS:** The majority of regulatory submissions for anticancer indications were found to be submitted within similar time frames to both the FDA and EMA. However, the identification of multiple instances of more comprehensive data package submissions to the EMA may allude to potential regulatory strategies utilized by manufacturers to obtain optimal product positioning at launch.

PCN267

COMMUNITY ONCOLOGY PERCEPTION AND PERSPECTIVES ON PATIENT REPORTED OUTCOMES (PROs) AND REAL-WORLD EVIDENCE (RWE) RESEARCH IN THE CONTEMPORARY ERA

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OBJECTIVES: PROs and RWE research are vital components in patient-centered care. The recently passed Cures-21 bill named both as important parts of new drug approval processes. Views on RWE and RWE research among community oncologists, where patients are seen most, are not well studied. The purpose of this study was to understand clinician perspectives regarding participation in and use of such research. **METHODS:** This descriptive study identified PROs and RWE-related attitudes among 51 community-based US oncologists. Data were collected at a live meeting with audience response technology. **RESULTS:** While only 13% of oncologists were aware of any oncology drug containing PRO claims in its package insert, and only 25% ever considered PROs in prescribing decisions, 80% agreed that the value of PROs increases if cost savings were shown. Only 11% of

oncologists have ever participated in PRO-research and 74% stated that identifying patients for such studies is somewhat/very difficult. If patients were identified, 64% of oncologists believed that contacting these patients would not be a barrier. Over 80% of oncologists believed that $\geq 25\%$ of their patients would participate in PRO research if compensated. Similarly, 70% of oncologists would participate if compensated. Top barriers to participating in PRO research: staffing (64%), education of patients/staff (57%), and technology (53%). Almost all oncologists believed that RWE drives efficiency and improves quality of care, and 46% believed that RWE is very impactful on their clinical-decision making. Most oncologists believed that "decreasing total healthcare expenditures" and "patients' quality of life" are where RWE research impacts oncology care. Barriers to participating in RWE research: logistics (60%), personnel (58%), and finances (52%). Most (72%) favor participating in RWE and PRO research if the process is made seamless for participating practices. **CONCLUSIONS:** Addressing barriers to PROs and RWE research in community oncology is essential moving forward; logistics and finances are major hurdles.

PCN268

COMMUNITY ONCOLOGISTS' PERCEPTION AND UNDERSTANDING OF BIOSIMILARS' ROLE IN ONCOLOGY

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OBJECTIVES: Biosimilars are highly similar drugs to innovator biologics and are uniquely regulated by the FDA, different from their reference biologic, small molecules, or generics. In light of these regulatory differences, data are needed to understand prescribers' perceptions and barriers to use. The purpose of this study was to gather and elucidate these perceptions from practicing clinicians. **METHODS:** This descriptive study identified biosimilar-related attitudes among 61 community-based US oncologists of various geography and practice types. Data were collected at a live meeting with audience response technology. **RESULTS:** One quarter of respondents stated lack of familiarity with biosimilars. 46% indicated that additional evidence is needed before prescribing them. 23% admitted no knowledge of regulatory processes while 19% stated that regulatory approval is similar to other anti-neoplastics. 78% believed that efficacy of biosimilars will be comparable to the reference product. 90% did not associate lower costs of biosimilars with lesser efficacy. 51% endorsed reference drug mirror labeling. 45% considered familiarity with the manufacturer as essential. Concerns about potential litigation was raised by less than 20%. 33% would treat biosimilars like generics with automatic substitution while 33% expect internal review. 3% were unwilling to prescribe biosimilars unless mandated by a payer. 57% identified cost reduction by prescribing biosimilars as important. 76% believed an 11-30% discount on reference drug necessary to prescribe biosimilars. Likelihood of prescribing a biosimilar to the following reference drugs was: trastuzumab in breast cancer - adjuvant (39%), metastatic (69%); bevacizumab in metastatic colon cancer (75%); rituximab - chronic lymphocytic leukemia (75%), non-Hodgkin lymphoma (60%) versus their reference biologics. **CONCLUSIONS:** While community oncologists appear receptive to biosimilars and are willing to incorporate them into their daily practice, significant educational gaps exist regarding efficacy and toxicity data, cost, reimbursement, and regulatory processes.

PCN269

INITIAL UPTAKE AND UTILIZATION PATTERNS OF FILGRASTIM-SNDZ, THE FIRST US BIOSIMILAR

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OBJECTIVES: The first US biosimilar, filgrastim-sndz (FIL-SNDZ), available since September 2015, is a granulocyte-colony stimulating factor (G-CSF) approved for 5 of 6 filgrastim (FIL) indications. The American Society of Clinical Oncology (ASCO) clinical practice guidelines include FIL-SNDZ among recommended G-CSFs for prevention of treatment-related febrile neutropenia in patients with solid tumors or lymphoma receiving chemotherapy. In January 2017, FIL-SNDZ replaced FIL on the CVS Health formulary. We assessed FIL-SNDZ utilization versus other G-CSFs by quarter (Q) during the first year of FIL-SNDZ availability in the United States. **METHODS:** Patients with claims for FIL-SNDZ, tbo-filgrastim (TBO-FIL), FIL, or pegfilgrastim (PEG); a cancer diagnosis; evidence of antineoplastic therapy; and medical and pharmacy benefits were identified for each Q, October 2015 through September 2016, for fully adjudicated claims. Demographics, plan type, and treatment setting were reported. **RESULTS:** In Q4 2015, 5133 patients received a G-CSF: 31 (1%) FIL-SNDZ; 221 (4%) TBO-FIL; 1315 (26%) FIL; and 3739 (73%) PEG. In Q3 2016, among 2371 patients receiving a G-CSF, 107 (5%) received FIL-SNDZ, 46 (2%) TBO-FIL, 508 (21%) FIL, and 1797 (76%) PEG. Patients could have received > 1 G-CSF. The top 5 diagnoses for FIL-SNDZ were agranulocytosis, encounter for antineoplastic therapy/other aftercare, breast cancer, leukemia, or multiple myeloma. 41% of FIL-SNDZ patients had a commercial payer, exceeding other G-CSFs: 39% (TBO-FIL), 33% (FIL), and 38% (PEG). Similar to other G-CSFs, out-patient use was most common for FIL-SNDZ (44% of claims), while 23% of FIL-SNDZ claims were covered by pharmacy benefit, the highest among G-CSFs. **CONCLUSIONS:** FIL-SNDZ use increased between Q4 2015 and Q3 2016 at the expense of FIL and TBO-FIL and despite an increase in PEG, based on switching between G-CSFs. FIL-SNDZ adoption commercially and by pharmacy benefit managers was higher compared with other G-CSFs. Further evaluation should assess FIL-SNDZ impact on G-CSF market size.

PCN270

UPTAKE OF THE FIRST US BIOSIMILAR: FILGRASTIM-SNDZ UTILIZATION OBSERVED IN A MEDICAL TRANSCRIPTION DATABASE OF PATIENT OFFICE VISITS
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OBJECTIVES: Since September 2015, filgrastim-sndz (FIL-SNDZ), a biosimilar of filgrastim (FIL), has been available in the United States (US) at approximately a 15% discounted price compared with FIL. FIL-SNDZ is approved for 5 out of 6 FIL indications, and is listed among the recommended granulocyte colony-stimulating factors (G-CSFs) in the American Society of Clinical Oncology (ASCO) clinical practice guidelines for prevention of treatment-related febrile neutropenia in patients with solid tumor or lymphoma receiving chemotherapy. Our objective was to identify physician documentation and utilization of FIL-SNDZ during patient office visits, and compare FIL-SNDZ use with other G-CSFs. **METHODS:** Physician records were extracted from January 1, 2016 through December 31, 2016 from RealHealthData, a US nationwide medical transcription database providing data within 72 hours of each patient visit to a participating provider. Records were searched for mention of FIL-SNDZ, tbo-filgrastim (TBO-FIL), FIL, and pegfilgrastim (PEG), then counts were tabulated to identify the most common location (US state) and medical specialty of the providers. Counts will be refreshed in May 2017. **RESULTS:** Counts of each mentioned G-CSF, unique patients, and most frequent provider type and state were: FIL-SNDZ: 72 (33 patients), general practitioner, Kansas; TBO-FIL: 1136 (420 patients), multispecialty, Texas; FIL: 4149 (2347 patients), general practitioner, Texas; PEG: 6496 (3391 patients), general practitioner, Pennsylvania. Most G-CSF mentions originated from general practitioners in Texas, Pennsylvania, and Virginia. **CONCLUSIONS:** Among 11,853 records reporting a G-CSF, only 72 mentions (0.6%) of FIL-SNDZ occurred in the 15 months since entry into the US marketplace. Although provider type was similar, the current data underline the geographic disparity in utilization of FIL-SNDZ from that of other G-CSFs. The May 2017 update will confirm whether FIL-SNDZ utilization has increased, as is anticipated with growing awareness and understanding of biosimilars among US clinicians and payers.

PCN271

USE OF DIETARY SUPPLEMENTS AND CANCER FATALISTIC BELIEFS AMONG AMERICANS

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OBJECTIVES: To explore associations between fatalistic beliefs about cancer and self-reported use of dietary supplements (DS). **METHODS:** A cross-sectional study among American adults was conducted using Health Information National Trends Survey-Food and Drug Administration 2015 data. Primary outcome was DS usage (yes/no) in the past 12 months. Five fatalistic belief (agreement or disagreement) statements including DS prevent cancer, DS treat cancer, behavior/lifestyle causes cancer, everything causes cancer, and cancer prevention not possible were used to explore associations with DS usage. Weighted bivariate descriptive analysis to compare sociodemographics between users/non-users of DS, and adjusted multivariate logistic regression analysis were conducted to examine the associations. **RESULTS:** 2,938 (78.6%) reported using DS (either multivitamins or single vitamin or herbal supplements). Higher proportions of DS users were older age groups, females, married, higher education, former smokers, and higher income. Compared to DS users, a majority of non-DS users disagreed that DS could help prevent or treat cancers. Compared to non-DS users, a majority of DS users agreed that behavior/lifestyle causes cancer as well as everything causes cancer. However, they disagreed that "there's not much you can do to lower your chances of getting cancer." Participants who agreed that "all or some cancers could be avoided through DS" were 100% more likely to use DS (Adj. OR: 2.00, 95% CI: 1.39-2.89), compared to those who disagreed. Participants who perceived that "all or some cancers could be treated through DS" were 90% more likely to use DS (Adj. OR: 1.90, 95% CI: 1.37-2.63), compared to those who thought otherwise. There were no significant associations between other fatalistic beliefs and use of DS. **CONCLUSIONS:** The use of DS is predominantly affected by the perceived belief that cancer can be avoided or treated through DS. These positive findings highlight the need for research in exploring the roles of DS in cancer prevention and treatment.

PCN272

COMMUNITY ONCOLOGISTS' PERCEPTION AND ADAPTABILITY TO EMERGING CAR-T THERAPIES

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OBJECTIVES: Chimeric Antigen Receptors of T cells (CAR-T) are emerging cellular-based therapies with remarkable responses in several hematologic malignancies and solid tumors. Regulatory approval of this technology is expected in less than 12 months. Little is known about barriers to market penetration, oncologists' acceptance, and forecasted use within current patterns of care. The purpose of this study was to understand clinician perspectives regarding these barriers. **METHODS:** This descriptive study identified CAR-T-related attitudes among 87 community-based US oncologists of various geography and practice types. Data were collected at two live meetings with audience response technology. **RESULTS:** Regarding personal experience: 20% referred at least one patient in the preceding 12 months for a clinical trial. Impressions of CAR-T were highly variable: 33% believed it a game changer, 23% another anti-cancer option, 21% similar to other immuno-oncology (i.e. anti PD-1 and PDL-1) and 33% lacked familiarity. Likelihood of prescribing CAR-T: 63% said limited to hematologic malignancies, 50% believed <10% patients eligible, while 20% didn't foresee any potential patient. The top 5 cited barriers to use: logistics (72%), cost (35%), toxicity (35%), clinical trial eligibility criteria (22%), and lack of efficacy (17%). Regarding

site of care 43% plan to refer all eligible patients to academic institutions, 26% plan on referring some, and 30% anticipated treating their patients locally at their own centers. **CONCLUSIONS:** Many community oncologists believe that CAR-T therapy is a game changer. Many perceive logistics, toxicity, and cost as major barriers. The fact that nearly one third expect to personally administer CAR-T exposes a significant education gap regarding the complexity of therapy. Comprehensive education initiatives for community oncologists and scalability of this technology are needed to optimize referral channels which will be essential to wider market adaptability once CAR-Ts are approved for adult malignancy.

PCN273

PATIENT-LEVEL PREDICTORS OF RECEIPT OF WRITTEN CANCER SURVIVORSHIP PLAN: AN ANALYSIS OF THE NATIONAL HEALTH INTERVIEW SURVEY

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OBJECTIVES: Provision of written survivorship care plans for cancer survivors is lower than desired. The purpose of this study was to investigate patient-level predictors of receipt of written documentation of advice for follow up care or documentation of all cancer treatments. **METHODS:** Adults aged 18+ years with a history of cancer were identified from the 2010 National Health Interview Survey. Patients currently receiving cancer treatment and those who were diagnosed with cancer prior to age 18 were excluded (final sample 2,329). Logistic regression was used to assess the association of individual level predictors with two primary outcome variables: receiving advice from a health care professional about routine cancer check-ups after completing cancer treatment in a written format (WA) (n=1327) and receiving a written documentation of all cancer treatments (WTx) (n=1783). All analyses were weighted to account for the sampling scheme. **RESULTS:** After adjusting for all other variables, older age and being male were associated with lower odds of receiving a WTx (OR = 0.98, 95% CI 0.98-0.99 and OR = 0.67, 95% CI 0.52-0.86, respectively). Hispanics and non-Hispanic Blacks were 2.24 (95% CI 1.40-3.59) and 2.40 (95% CI 1.60-3.60) times more likely to receive a WTx compared to non-Hispanic Whites, and survivors who participated in counseling or a support group were 1.78 (95% CI: 1.23-2.58) times more likely to receive WTx compared to those who did not. Compared to non-Hispanic Whites, non-Hispanic Blacks were 2.17 (95% CI 1.29-3.66) times more likely to receive WA. Survivors who participated in counseling or a support group were 1.82 (95% CI 1.21-2.75) times more likely to receive WA. **CONCLUSIONS:** Age, sex, race, and participation in counseling or support groups are all associated with receipt of written advice and/or written statements of treatment received. Future work should investigate provider-level factors and the patient-provider relationship.

PCN274

PRECISE PROGNOSIS, KEY TO END-OF-LIFE PLANNING AND REACHING MEDICARE QUALITY MEASURES; HOW THE VERISTRAT TEST CAN HELP

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OBJECTIVES: The 2015 Medicare Access and CHIP Re-authorization Act (MACRA) will base physician payments on quality-of-care. This system will rely on specific outcomes and patient metrics to assign a composite performance score; however, there are inherent challenges to measuring and improving upon that score. Here, we reviewed the current standing of oncology end-of-life care, and how VeriStrat® testing and other tools can help physicians improve quality care at end-of-life. **METHODS:** This study was conducted through a systematic literature review of clinical trials, survey-based studies, medical practice guidelines and reports on the following oncology topics: Establishing prognosis (including advanced diagnostic laboratory tests), referral to hospice or best-supportive care, and patient quality-of-life. **RESULTS:** The review of Merit-based Incentive Payment System (MIPS) and Oncology Care Model (OCM) Quality measures identified specific quality metrics related to end-of life care for oncology patients - overtreatment at end-of life, late or no hospice referral, and hospital admissions- and underscored the importance of establishing and communicating prognosis. When informed of poor prognosis, patients and physicians were less likely to select aggressive treatments, more likely to engage in early palliative care and focus on comfort, all of which are correlated with decreased hospital admissions and improved quality-of-life. While knowing a patient's prognosis is crucial, studies consistently demonstrate the difficulties of establishing prognosis through clinical factors (tumor stage, performance status). The collective literature shows advanced diagnostic laboratory tests such as the blood-based VeriStrat test (prognostic for survival outcomes in NSCLC patients across treatments) help establish prognosis and guides treatment decisions and referrals to hospice for patients with poor prognosis. **CONCLUSIONS:** Knowledge and communication of prognosis is central to planning end-of life care and optimizing patient quality-of-life. By combining prognostic testing and clinical factors, physicians and practices can optimize end-of-life care and measurement and improvement of composite performance score.

PCN275

ADHERENCE TO 'CHOOSING WISELY' RECOMMENDATIONS FOR RADIATION THERAPY IN A COMMERCIALY INSURED LOW-RISK ENDOMETRIAL CANCER POPULATION

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OBJECTIVES: The American Society for Radiation Oncology (ASTRO) 'Choosing Wisely' (CW) recommendations note radiation interventions lacking evidence of

benefit in cancer care. This study characterizes adherence to the 2014 CW recommendation to 'not recommend radiation following hysterectomy in low-risk endometrial cancer' (Stage I, Grade 1-2) using a novel linkage between the Western Washington Cancer Surveillance System (CSS) and claims from two large commercial insurance plans. No studies have previously evaluated adherence to this CW recommendation in a commercial insurance setting. **METHODS:** CSS records for patients with first primary diagnosis of Stage I (Grade 1-2) endometrial cancer (2008-2015) were linked with Premera Blue Cross and Regence Blue Shield claims. Included cases had coverage for ≥ 12 -months before/after diagnosis and hysterectomy 1 month before to 4 months after diagnosis. We used generalized estimating equations (GEE) clustered by institution to evaluate associations between demographic (age, race) and tumor characteristics (grade, dx year) and receipt of radiation therapy within 1 year of diagnosis. **RESULTS:** Among 2,227 identified endometrial cancer patients, 514 were Stage I & Grade 1/2, and 112 met all inclusion criteria. Mean age was 59.8, 91.9% were white, and 67.0% were Grade 1. Overall, 12.5% were non-adherent. Non-adherence was 10.7% in Grade 1, 16.2% in Grade 2, and was highest (15.8%) after the ASTRO CW recommendation (2014-2015). Most non-adherent cases (78.6%) received brachytherapy. In multivariate analyses, only age in years (continuous) was associated with non-adherence (Odds Ratio=1.05, $p=0.01$). **CONCLUSIONS:** More than 12% of low-risk endometrial cancer cases in our sample were non-adherent to ASTRO CW recommendations. Surprisingly, non-adherence was highest in the time after the ASTRO CW recommendation (2014-2015). This is an important finding because non-adherence may result in side effects and/or substantial cost without commensurate clinical benefit. Future studies should evaluate non-adherence in other regions and patient populations and evaluate strategies to curb overuse.

PCN276

SOMATOSTATIN ANALOG (SSA) DOSE ESCALATIONS AMONG PATIENTS WITH METASTATIC GASTROENTEROPANCREATIC NEUROENDOCRINE TUMORS (GEP-NET) TREATED AT A TERTIARY REFERRAL CENTER

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OBJECTIVES: To describe the frequency and nature of SSA dose escalations among patients with advanced GEP-NET treated at a tertiary referral center. **METHODS:** We conducted a cohort study of patients with GEP-NET recruited between June 2003 and May 2015 from Dana-Farber Cancer Institute's (DFCI) and Brigham and Women's gastrointestinal clinics, by linking an institutional research database to DFCI's outpatient pharmacy dispensation data. Eligible patients had well-differentiated, metastatic GEP-NET and were seen ≥ 2 at DFCI. Dispensation frequency was categorized into weeks (dispensations +/-3 days considered part of the same week) and monthly SSA dosing regimens were derived. Dose escalations were defined as ≥ 2 increases in monthly SSA dosing regimens compared to last 2 SSA monthly regimens. Exposure gaps were dispensations separated by >6 weeks, with dosing regimens before and after the gap considered separately. **RESULTS:** Among 682 patients (mean age [SD]: 58.5 [11.9], 50.1% male, 96.5% white, 44.9% midgut NET, 28.7% pancreatic NET, 26.4% other NET, 38.9% with carcinoid symptoms at baseline, and 62.6% with <1 year since metastatic GEP-NET diagnosis), 341 patients had >1 octreotide (long-acting release) LAR dispensation at DFCI's pharmacy. No lanreotide dispensations were observed as lanreotide was not on formulary during the study period. Over 3.5 patient-years of octreotide LAR exposure, we observed 472 dose escalations among 213/341 (62.5%) patients (range: 1-9). Octreotide LAR dose escalations comprised increases in dose, increases in dispensation frequency, or both in 42.8%, 53.0%, and 4.2% of cases, respectively. The frequency of the most common dose escalations for derived monthly octreotide LAR regimens was 20.8% for 20 to 30 mg, 13.6% for 30 to 40 mg, and 13.1% for 40 to 53 mg (i.e. 40 mg/3 weeks). **CONCLUSIONS:** Octreotide LAR dose escalations in the treatment of metastatic GEP-NET were common and may reflect an increased need for symptom control over the disease course.

PCN277

BEYOND HYPOMETHYLATING AGENTS (HMAs): TREATMENT OF PATIENTS WITH HIGHER-RISK MYELODYSPLASTIC SYNDROMES (HR-MDS) AFTER FIRST-LINE THERAPY (1LT) USING A UNITED STATES (US) ELECTRONIC MEDICAL RECORD (EMR)

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OBJECTIVES: MDS encompasses multiple, rare hematological stem cell disorders resulting in cytopenias and disease-related complications/deaths. Overall of the two HMAs approved, only azacitidine has been shown to impact survival; no approved therapies exist post 1LT progression. We examined treatment patterns after ending 1LT in HR-MDS patients in routine care. **METHODS:** Adult HR-MDS patients initiating 1LT (1/1/2008 - 7/31/2015) were identified from a large US EMR database. As complete cytogenetics were unavailable, HR-MDS was based on: International Classification of Diseases (ICD) coding of HR-MDS (with ³1 HR-MDS code [ICD-9 code: 238.73; ICD-10 codes: D46.20, D46.21, D46.22]) or HR-MDS algorithm based on Revised International Prognostic Scoring System. 1LT was defined as MDS-specific treatment (MDS-Tx) initiated after the first HR-MDS claim; the addition/substitution of an MDS-Tx >28 days post 1LT triggered second-line therapy (2LT). MDS-directed supportive care (MDS-SC) included erythrocyte or platelet transfusions, erythropoietic, and granulocyte-stimulating agents.

Patients were followed until death, progression to acute myeloid leukemia (AML), loss to follow-up, or end of study. **RESULTS:** 218 HR-MDS patients initiating 1LT were identified with HMAs (azacitidine [63.3%]; decitabine [24.8%]) predominating. Post 1LT, 30 patients (13.8%) received MDS-Tx +/- MDS-SC; 56 patients (25.7%) received MDS-SC alone. Most common MDS-Txs in 2LT were HMAs (decitabine [30.0%] and azacitidine [23.3%]), followed by lenalidomide \pm an HMA (23.3%) and antimetabolite chemotherapy (23.3%). Post 1LT, 33.5%, 9.6%, and 9.6% received transfusions, erythropoietic-, and granulocyte-stimulating agents, respectively. Death (33.5%) and progression to AML (22.5%) were the main outcomes post-1LT in patients not initiating MDS-Tx in 2LT. **CONCLUSIONS:** A majority of HR-MDS patients in routine care do not receive 2LT with an MDS-Tx. Of those who receive MDS-Tx, HMAs remain the predominate choice. MDS-SC post 1LT progression is still utilized in most patients. Outcomes in patients not initiating 2LT are poor, highlighting the need for additional treatment options.

PCN278

SIGNIFICANT VARIATION IN FIRST-LINE TREATMENT DURATION AMONG PATIENTS WITH METASTATIC COLORECTAL CANCER (mCRC) TREATED IN THE COMMUNITY SETTING

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OBJECTIVES: Overall survival (OS) has significantly improved over the last decade for patients with metastatic colorectal cancer (mCRC) due to advances in systemic chemotherapy, targeted agents, and supportive care. Duration and sequencing of therapies have correlated with OS. We aimed to describe duration of first line (1L) treatment among patients with mCRC in the community setting. **METHODS:** Patients with mCRC diagnosed from 2012-2014 (ICD-9 codes 153.x, 154.0x, or 154.1x and 197.x-198.x) were identified from a US healthcare claims database consisting of 129 million unique covered patient lives. Patients were classified into treatment groups based on 1L treatment received. Treatment duration (TD) was defined as time from initiation to 30 days prior to initiation of 2L or end of follow-up and calculated by Kaplan-Meier estimator (median and 95% CI). Log-rank test assessed equality of survivor functions (i.e., time to 1L discontinuation). **RESULTS:** There were 4,527 mCRC patients identified (mean age at diagnosis, 61.2 years; 54% male) who initiated 1L therapy. On average (mean, SD), patients were followed for 12.8 months (8.47 months) after diagnosis. Median 1L TD was 211 days (95% CI: 204 days, 221 days) across all treatments. The longest 1L median TD was 250 days (95% CI: 239 days, 262 days) among those treated with a biologic + fluoropyrimidine (FP) + chemotherapy, followed by 217 days (95% CI: 202 days, 237 days) among those treated with FP + chemotherapy, followed by 178 days (95% CI: 148 days, 280 days) among those treated with biologic + FP, and 141 days (95% CI: 133 days, 151 days) among those treated with FP monotherapy ($p<0.0001$). **CONCLUSIONS:** These real world data show significant variability in the duration of 1L treatments among patients with mCRC. The choice of 1L therapy may have an impact on the time to treatment discontinuation.

PCN279

RETROSPECTIVE REVIEW OF ORAL CANCER PATIENTS IN INDIA: ANALYSIS OF PATIENT CHARACTERISTICS AND TREATMENT METHODS

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OBJECTIVES: To review the patient characteristics and treatment methods of oral cancer patients at a tertiary hospital in India. **METHODS:** This study was a retrospective review of electronic medical records from a tertiary care hospital in Mumbai, India. Patients ≥ 18 years of age hospitalized for oral cancer treatment between Jan 2014 and May 2015 were included in the study. Descriptive and inferential statistics were used to analyze and compare differences between patients. **RESULTS:** A total of 132 patients met the study criteria. Of these, 108 patients were in the age group of 18 to 64 years. The mean age for all the oral cancer patients was 51.81+12.20 years. The mean age was lowest for patients with no insurance (NI) while highest for patients with CGHS (CGHS=66.60+7.16 years, PI=61+9.89 years, RGJAY=51.39+12.43 years, NI=49.40+9.53 years). The majority of the patients (n=106, 80.3%) underwent a surgical procedure during their stay. The majority of the patients were subscribed to RGJAY payer scheme (RGJAY=105, 79.5%, NI=20, 15.2%; CGHS=5, 3.8%; PI=2, 1.5%). Abnormal growth was the most common reason for admission into the hospital (n=80, 60.6%). 21 (15.9%) patients with hypertension and 18 (13.6%) patients with diabetes were reported as major comorbidities during hospitalization. The majority of the patients had stage 3 or 4 oral cancer (99, 75.0%), while 30 (22.7%) patients had stage 1 or 2 oral cancer and 3 (2.3%) patients had stage 0 oral cancer. Of the total 106 patients that had surgery, majority of them (n=50) underwent a modified radical neck dissection (MRND) or a combined mandibulectomy and neck dissection operation (n=30). **CONCLUSIONS:** Majority of the oral cancer patients were diagnosed during the advanced stages of the disease and were subscribed to RGJAY scheme. The common reason for hospital admission was abnormal growth and the common procedure patients underwent was MRND.

PCN280

REAL-WORLD TREATMENT PATTERNS AMONG PATIENTS WITH SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK (SCCHN) IN CANADA

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OBJECTIVES: Real-world treatment patterns in patients with SCCHN are largely unknown. In light of emerging therapies, our objective was to elucidate real-world

patterns of drug treatment for SCCHN in Canada. **METHODS:** Real-world data were collected through a cross-sectional survey administered to oncologists across Canada between May and July 2016. Physicians provided data regarding disease history, characteristics, and treatment patterns for 6–8 consecutive patients receiving drug treatment for SCCHN. **RESULTS:** Sixteen physicians provided data on 109 patients receiving first- or second-line drug treatment for SCCHN. The mean (SD) age was 61.8 (8.7) years; 24% were current smokers with a mean (SD) exposure of 26.2 (12.7) pack-years, and 66% were former smokers. The most common primary tumor site was oropharynx (48%); 66% of patients had stage IV cancer; 75% of patients had received radiotherapy, and 32% had undergone surgery. Most patients (83%) received a platinum-based regimen as first-line treatment, with 44% receiving cisplatin monotherapy. Use of cetuximab-based regimens as first-line treatment was limited (17%). Among 53 patients receiving second-line treatment, platinum-based regimen use was markedly lower (13%) than in first-line. The most common second-line regimens included cetuximab (44%), docetaxel (13%), paclitaxel (13%), and methotrexate (8%) monotherapies. A median (interquartile range [IQR]) of 49 (19–149) days between the end of first-line and the beginning of second-line treatment was reported. Among patients receiving second-line treatment, 87% had received a first-line platinum-based regimen. Nearly half (46%) of previously platinum-treated patients received cetuximab monotherapy as second-line treatment, whereas 13% received docetaxel monotherapy, 9% methotrexate monotherapy, and 9% another platinum-based regimen. Patients treated with a first-line platinum-based regimen who progressed to second-line had a median (IQR) of 55 (20–146) days between treatment lines. **CONCLUSIONS:** Real-world data on the treatment of SCCHN in Canada showed high use of platinum-based regimens as first-line. Second-line treatment patterns varied, although cetuximab use was prevalent.

PCN281

PREDICTING TREATMENT STRATEGIES FOR ACUTE MYELOID LEUKEMIA ACROSS THE UNITED STATES, WESTERN EUROPE, AND JAPAN

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OBJECTIVES: National Comprehensive Cancer Network (NCCN) guidelines recommend different treatment strategies for the treatment of acute myeloid leukemia (AML) based on patient age. Patients younger than 60 years are recommended to receive a standard (or high) dose of a cytarabine-based regimen whereas patients older than 60 years are recommended to receive a standard dose of cytarabine or lower intensity therapy (i.e., low dose cytarabine or hypomethylating agents [HMAs]). This study examined how these treatment strategies were implemented in the real world and across various regions. **METHODS:** A retrospective chart review of patients with AML was conducted by physicians in the US, SEU (France, Germany, Italy, Spain, UK), and Japan between Q4 2015 and Q3 2016. Physicians randomly selected patient charts and abstracted data on patient demographics, disease history, and treatment patterns. Only adult AML patients with complete dosing information who were using cytarabine or HMA agents were included (N=1,037; US: N=106, SEU: N=490, Japan: N=441). **RESULTS:** The mean age of the sample was 59.7 years (SD=14.9); 59.8% were male. 32.6% of patients were using high dose cytarabine (> 220 mg/m²), 20.5% were using standard dose cytarabine (> 89 to < 220 mg/m²), 10.0% were using low-dose cytarabine (≤ 89 mg/m²), and 36.8% were using HMAs. The strongest predictors of high dose cytarabine relative to low dose cytarabine were lower ECOG scores (e.g., 0 vs. 3; (odds ratio [OR] = 8.36), age < 60 (OR=6.48), and being treated in an academic center (OR=1.96) (all p < .05). Similarly, the strongest predictors of high dose cytarabine relative to HMAs were being treated in an academic center (OR=6.22), age < 60 (OR=3.62), fewer comorbidities (OR=0.72), and lower ECOG scores. **CONCLUSIONS:** Consistent with NCCN guidelines, age was a strong predictor of high dose cytarabine use relative to other, less intensive therapy options. However, ECOG scores, comorbidities, and setting also played an important role.

PCN282

IMPUTATION OF PERFORMANCE STATUS FROM A CLAIMS-BASED MODEL TO EVALUATE FIRST-LINE THERAPY GUIDELINE COMPLIANCE IN METASTATIC NON-SMALL CELL LUNG CANCER

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OBJECTIVES: Guideline recommendations for first-line non-small cell lung cancer (NSCLC) therapy are partially based upon physician-reported performance status (PS). Lack of PS in claims data limits evaluation of guideline recommended initiation (GRI) of therapy. This study adapted a previously validated claims-based algorithm for PS to assess GRI. **METHODS:** Patients with metastatic NSCLC and Medicare coverage were identified from Humana medical claims and 2013–2014 treatment preauthorizations for infusion therapy. Index was the first infusion date. PS was imputed from a classification model using procedure, diagnosis and durable medical equipment codes one year pre-index. The model predicted poor (PS=3–4) vs good/moderate PS (PS=0–2). Moderate PS (PS=2) was estimated using the top quintile of good/moderate PS. Six-month post-index mortality and hospice status validated PS cut-points. GRI was > 1 cycle of National Comprehensive Cancer Network recommended first-line therapy based on age and PS or targeted therapies regardless of age and PS. Significance was from Chi-square and t-tests. **RESULTS:** For 1,353 eligible patients with metastatic NSCLC, mean (SD) age was 71.4 (6.6), 45.9% were female. After applying the PS algorithm, 75.8% had good, 18.8% had moderate and 5.4% had poor PS. Mean Deyo-Charlson Comorbidity score was 7.98 (3.3) with no difference by PS. Six-month mortality

was 25.7% for good, 33.7% for moderate and 48.4% for poor PS (p=0.015). Hospice was initiated by 8.0% of patients with good PS, 10.5% with moderate PS and 25.8% with poor PS (p=0.0163). GRI was observed in 88.1% of patients with good PS, 11.6% with moderate PS, and 5.1% with poor PS (p < 0.0001). **CONCLUSIONS:** Determining PS from claims data allows assessment of GRI of first-line therapy for metastatic NSCLC. Increased rates of mortality and hospice with worsening PS suggests that cut-points used to distinguish poor, moderate and good levels of PS may offer discrimination of PS categories and determination of GRI from claims data.

PCN283

PREDICTING WATCHFUL WAITING AMONG PATIENTS WITH MULTIPLE MYELOMA IN THE UNITED STATES AND WESTERN EUROPE

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OBJECTIVES: Although there are a number of treatments available for patients with multiple myeloma (MM), a “watchful waiting” approach can often be used among patients who are asymptomatic. This study sought to understand the frequency of “watchful waiting” across regions and identify the strongest predictors of this strategy. **METHODS:** A retrospective chart review of patients with MM was conducted by physicians in the United States (N=6,085) and SEU (France, Germany, Italy, Spain, UK; N=4,379) between Q4 2015 and Q3 2016. Physicians randomly selected patient charts and abstracted data on patient demographics and disease and treatment history. Only patients with complete watchful waiting information were included. Regression models predicted watchful waiting and time spent waiting from available patient and physician variables. **RESULTS:** A total of 8,798 patients were included (mean age = 68.7 years [SD=9.4], 58.2% male). “Watchful waiting” was significantly more common in the SEU (11.4%) than in the US (5.4%) (p < .05). The strongest predictors of engaging in a “watchful waiting” period was being in Spain (odds ratio [OR] = 9.63), being in Germany (OR = 9.40), being treated by an internist (OR = 4.43), being male (OR = 1.19), having a low risk stratification (OR = 1.21), being older (OR = 1.02), and being a non-smoker (OR = 1.51) (all p < .05). Similar factors were associated with length of watchful waiting (mean = 20.5 months, median = 12.0 months). However, although being treated by a hematologist or hematologist/oncologist were not associated with an increased likelihood of “watchful waiting” they were both associated with a longer period if it did occur (bs = 1.32 and 0.55, respectively; ps < .05). **CONCLUSIONS:** “Watchful waiting” was relatively uncommon in the study sample, though more common in Western Europe than in the US. Specific countries, notably Germany and Spain, were the strongest predictors though other physician and patient level factors contributed.

PCN284

EVALUATION OF TREATMENT PATTERNS AMONG PATIENTS WITH DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL)

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OBJECTIVES: Treatment guidelines for DLBCL recommend a combination of chemotherapy agents with rituximab in first-line therapy (1LT). For patients with refractory/relapsed disease, high-dose chemotherapy with stem cell transplant, combination chemotherapy, or single-agent rituximab are considered. This study assessed real-world DLBCL treatment patterns as compared to guideline recommendations. **METHODS:** Patients newly diagnosed with DLBCL were identified between 01/01/08 and 08/31/15 within the Humedica electronic medical record (EMR). The first DLBCL diagnosis date served as the index date. Patients were required to have 12 months of continuous activity in the EMR before the index date, and were followed from index until end of continuous activity, death, or end of study period. DLBCL treatment patterns were assessed during follow-up. **RESULTS:** Of 2,657 patients meeting the inclusion criteria, 1,436 (54%) had evidence of initiating 1LT; median (IQR) time to therapy was 0.5 (0.2–0.9) months. Combination chemotherapy was most common in 1LT (92.1% vs 7.9% single-agent), with rituximab-based therapies dominating (R-CHOP), 58.3%. Rituximab monotherapy comprised ~80% (6.1%) of single-agent use in 1LT. Median duration of 1LT was 4.2 (2.2–4.5) months; 164 patients received second-line therapy (2LT); 29.3% received a single-agent, and 70.7% received combination chemotherapy. 25% of 2LT received stem cell transplant. In 2LT, rituximab (10.4%) remained the top single-agent, while bendamustine+rituximab (11.6%) was the most common combination therapy. Median duration of 2LT was 2.3 (0.8–4.8) months. 24 patients received third-line therapy (3LT); 62.5% received a single-agent, while 37.5% received combination chemotherapy. In 3LT, lenalidomide (29.2%) was the most common single-agent; bendamustine+rituximab (20.8%) remained the most common combination therapy. Median duration of 3LT was 3.4 (0.9–5.2) months. **CONCLUSIONS:** Consistent with guidelines, most first-line DLBCL patients received rituximab-based combinations. A small subset received 1LT monotherapy, which increased during subsequent lines of therapy, with rituximab as the most common 1LT and 2LT monotherapy.

PCN285

TREATMENT AND OUTCOMES IN RECURRENT/METASTATIC SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK: A CHART REVIEW STUDY IN FRANCE

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OBJECTIVES: Real-world treatment and outcomes in patients with recurrent or metastatic (R/M) squamous cell carcinoma of the head and neck (SCCHN) after

platinum therapy are largely unknown. In light of emerging therapies, a retrospective chart review was conducted in France to characterize the experiences of patients with R/M SCCHN who have been previously treated with a platinum-based regimen. **METHODS:** Real-world data were collected through a chart review. Included were patients randomly selected from all adults aged ≥ 18 years diagnosed with SCCHN at treating sites between January 1, 2013 and June 30, 2014 to meet an a priori sample-size calculation. Patients were followed through August 20, 2016 or until death. Clinical trial participants were excluded. Demographics and treatment data were analyzed descriptively. Overall survival (OS) was quantified using Kaplan-Meier analysis censoring for date of chart abstraction in surviving patients. **RESULTS:** Twenty-three oncologists contributed data for a random selection of 204 patients; 86% were men and 97% were current or former tobacco users. The mean (SD) age was 63 (10.5) years at initial R/M SCCHN diagnosis. Most patients (89%) were treated first-line with a platinum-based regimen, and 117 (65%) of these patients progressed to second-line treatment. Second-line treatment among these 117 patients consisted largely of monotherapy with a taxane (33%), cetuximab (21%), or methotrexate (12%) irrespective of disease stage (ie, IVC vs non-IVC), and 98 (84%) patients were identified as being second-line platinum-refractory (ie, did not receive second-line platinum). Among those receiving second-line treatment, median OS from first-line initiation was 14.6 (95% CI: 13.0, 16.3) months. **CONCLUSIONS:** More than half of the patients in this chart review received second-line treatment following first-line platinum-based therapy, but median survival remained well under 1.5 years. This study highlights the need for more effective treatments for a patient population with a significant level of unmet need.

PCN286

RETROSPECTIVE ANALYSIS OF PATIENTS WITH OVARIAN CANCER RECEIVING TREATMENT AT A TERTIARY CARE HOSPITAL IN INDIA

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OBJECTIVES: To review the patient characteristics and treatment methods of ovarian cancer patients at a tertiary hospital in India. **METHODS:** This study was a retrospective review of electronic medical records from a tertiary care hospital in Mumbai, India. Patients ≥ 18 years of age hospitalized for ovarian cancer treatment between Jan 2014 and May 2015 were included in the study. Descriptive and inferential statistics were used to analyze and compare differences between patients. **RESULTS:** A total of 45 patients met the study criteria. Of these, 38 patients were in the age group of 18 to 64 years. The mean age for all the ovarian cancer patients was 52.17+13.0 years. The mean age was lowest for patients with CGHS while highest for patients with RGJAY (RGJAY=56.50+11.57 years, PI=55.8+9.50 years, NI=43.36+12.33 years, CGHS=35.0+18.38 years.). The majority of the patients (n=33, 73.3%) underwent a surgical procedure during their stay at the hospital. The majority of the patients were subscribed to RGJAY payer scheme (RGJAY=22, 48.9%; NI=11, 24.4%; PI=10, 22.2%; CGHS=2, 4.4%). Pain was the most common reason for admission into the hospital (n=22, 48.9%), 11 (24.4%) patients with hypertension and 10 (22.2%) patients with diabetes were reported as major comorbidities during hospitalization. The majority of the patients had stage 2 or 3 ovarian cancer (16, 48.5%), while 11 (33.3%) patients had stage 1 ovarian cancer and 6 (18.2%) patients had stage 4 ovarian cancer. Of the total 33 patients that had surgery, majority of them underwent a total abdominal hysterectomy bilateral salpingo oophorectomy (TAHBSO) (n=14). **CONCLUSIONS:** Majority of the ovarian cancer patients were diagnosed during the advanced stages of the disease and were subscribed to RGJAY scheme. The common reason for hospital admission was pain and the common procedure patients underwent was the TAHBSO.

MUSCULAR-SKELETAL DISORDERS – Clinical Outcomes Studies

PMS1

PREVALENCE OF BISPHOSPHONATE-ASSOCIATED OSTEONECROSIS OF THE JAW USING TRUVEN HEALTH ANALYTICS MARKETSCAN® 2008-2014

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OBJECTIVES: To determine the prevalence of Osteonecrosis of the jaw (ONJ) cases among adult users of Bisphosphonates (BPs) and identify the potential risk factors that contribute to ONJ among BPs users. **METHODS:** In a retrospective cohort study, we used Truven Health Analytics MarketScan® databases from 2008 to 2014 to identify cohort members. The cohort included patients aged ≥ 18 years who received at least one prescription of bisphosphonates (oral or IV) for underlying bone or malignant disorders. We included BPs that were approved in the US for human use. The outcome variable is having ONJ, (ICD 733.45), and the independent variables included BPs types (Alendronate, Risedronate, Ibandronate, Zoledronic acid, Pamidronate and Etidronate), route of administration of BPs (oral Vs. IV), demographic characteristics (age and gender), and comorbidities (diabetes, hypertension, hypercholesterolemia). Multivariate logistic regression analysis was used to examine the association between risk factors and ONJ outcomes. **RESULTS:** We identified a study population of 837867 men and women who aged ≥ 18 years and had at least one prescription of BPs. We found only 66 patients with ONJ, so the prevalence of ONJ among the BPs users is less than 0.01%. We found that there was no statistically significant association between the outcome (ONJ) and BPs' characteristics (BPs type OR=0.751 95% CI 0.419-1.359). Furthermore, there was no statistically significant association between the outcome (ONJ) and patients' characteristics (age OR=1.01 95% CI 0.914-1.104 and gender OR=0.1228 95% CI 0.440-3.43). Moreover, there was no statistically significant association between the outcome (ONJ) and comorbidities (diabetes OR=1.23 95% CI 0.69-5.37, hypertension OR=0.797 95% CI 0.47-1.36 and hypercholesterolemia OR=0.69 95% CI 0.418-1.141). **CONCLUSIONS:** The prevalence of ONJ among the BPs users is less than 0.01% and there is no statistically significance

association between ONJ and BPs type, route of administration, age, gender, diabetes mellitus, hypertension and hypercholesterolemia.

PMS2

BISPHOSPHONATES AND OSTEONECROSIS: ANALYSIS OF THE KOREA ADVERSE EVENT REPORTING SYSTEM

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OBJECTIVES: To examine if bisphosphonate (BP) use is associated with drug related osteonecrosis (osteonecrosis) using adverse drug reaction (ADR) data reported in the Korea Adverse Event Reporting System (KAERS) from 2013 to 2015. **METHODS:** The KAERS database contained a total of 754,231 ADR reports from 38,974 patients, resulting in an average of 1.99 reports per patient; the ADR reports include patient demographics, concomitant drugs, patients' outcomes, reaction severity, reporting centers, and the results of causality assessments. The reporting odds ratio (ROR) was calculated to estimate the association between osteonecrosis and implicated medications. Chi-square tests were also conducted to compare the sociodemographic characteristics of osteonecrosis patients who reported BP use to those using other drugs. **RESULTS:** 230 ADR reports involving osteonecrosis cases were identified from the total 754,231 ADR reports. Among the 230 osteonecrosis reports, 201 reports (87.4%) were attributed to BP use, while 27 reports (11.7%) were attributed to other drug use; 2 reports lacked drug information. The ROR for osteonecrosis and BP use was 82.57 (95%CI, 55.06-123.82), with a majority of cases (n=105) associated to alendronate use among the six different classes of BP. Among the 228 reports of osteonecrosis, females (n=167, 87.6%) were more likely to report BP-related osteonecrosis than males (n=24, 12.6%) (p<0.001). Concomitant medications that were used with BP were rare and included Amlodipine, Calcitriol, Risedronate and Tiotropium bromide (each, n=3, 7.5%). **CONCLUSIONS:** The risk of BP use for drug related osteonecrosis in ADR reports in South Korea were examined. The results imply that BP use needs to be carefully monitored for patients with susceptibility for osteonecrosis.

PMS3

A NETWORK META-ANALYSIS OF THE EFFICACY OF TREATMENTS IN BIOLOGIC NAÏVE PATIENTS WITH MODERATE TO SEVERE RHEUMATOID ARTHRITIS AFTER INADEQUATE RESPONSE TO CONVENTIONAL DISEASE MODIFYING ANTIRHEUMATIC DRUGS

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OBJECTIVES: To compare the efficacy of treatments in moderate-to-severe rheumatoid arthritis (RA) in biologic-naïve patients with inadequate response to conventional disease modifying antirheumatic drugs (cDMARDs). **METHODS:** MEDLINE, Embase, and Cochrane Central Register were searched for RCTs published in 01/1990 to 08/2016. Treatments included were tumor necrosis factor inhibitors (TNFis; etanercept, adalimumab, infliximab, certolizumab pegol, golimumab), rituximab, abatacept, Interleukin 6 inhibitors (tocilizumab, sarilumab), and Janus kinase inhibitors (tofacitinib and baricitinib), each combined with cDMARDs. Outcomes were difference in mean change in modified Total Sharp Scores (mTSS) between each regimen and cDMARDs, and probabilities of $\geq 20\%$ improvement in the American College of Rheumatology response criteria (ACR20) at 6-months and 12-months. A Bayesian network meta-analysis using random-effects models estimated the comparative efficacy for these regimens. **RESULTS:** Up to 72 studies were included in this analysis. At 6-months, the difference in mean change in mTSS (95%CrI) versus cDMARDs ranged from -1.01(-3.70;1.69) for adalimumab to -3.74(-8.07;0.62) for infliximab in TNFis; and from -0.36(-2.80;2.04) for tofacitinib to -1.08 (-3.21;1.01) for tocilizumab in non-TNFis. At 6-months only the etanercept regimen had statistically significant difference in mean mTSS change -2.08(-3.67;-0.52) vs. cDMARDs. At 6-months, ACR20 (95%CrI) in TNFis ranged from 58.8% (47.8%;69.8%) for infliximab to 74.3%(66.2%;81.1%) for certolizumab pegol; and from 52.8%(33.5%;71.7%) for baricitinib to 63.3%(45.1%;80.0%) for sarilumab in non-TNFis. At 12-months, differences in mean change in mTSS ranged from -2.15(-5.41;1.10) for adalimumab to -7.03(-10.34;-3.83) for infliximab in TNFis; and from -1.08(-5.56;3.35) for rituximab to -2.52(-6.36;1.43) for sarilumab in non-TNFis. At 12-months, ACR20 ranged from 62.7%(48.0%;75.9%) for infliximab to 82.5% (56.9%;95.3%) for certolizumab pegol in TNFis; and from 63.6%(41.0%;85.5%) for sarilumab to 73.0%(56.1%;88.3%) for tocilizumab in non-TNFis. **CONCLUSIONS:** Targeted immune modulator in general showed reduced radiographic progression as measured by mTSS compared with cDMARDs. TNFis appear to be the most effective class as measured by the ACR20.

PMS4

COMPARATIVE EFFICACY OF TARGETED IMMUNE MODULATORS AS MONOTHERAPY AND IN COMBINATION WITH CONVENTIONAL DMARDS IN RHEUMATOID ARTHRITIS

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OBJECTIVES: To evaluate the comparative effectiveness of targeted immune modulators (TIMs) in patients with moderately-to-severely active rheumatoid arthritis (RA) who have had an inadequate response to prior conventional disease modifying antirheumatic drugs (cDMARDs) and are TIM-naïve. **METHODS:** Two investigators conducted a systematic literature review of RCTs that evaluated the efficacy of 11 TIMs relative to cDMARDs and to each other: rituximab, abatacept, tocilizumab, sarilumab, tofacitinib, baricitinib, adalimumab, certolizumab pegol, etanercept, golimumab, and infliximab. Outcomes of interest included measures of disease activity, ACR response, and radiographic progression. Bayesian network

meta-analysis (NMA) was also performed to combine direct and indirect evidence on ACR response, which was analyzed using a random-effects, multinomial likelihood model. **RESULTS:** Our literature search identified 68 RCTs, nine of which examined head-to-head comparisons. All TIMs produced statistically- and clinically-significant improvements in disease activity and ACR response relative to cDMARDs alone. In head-to-head studies, tocilizumab and sarilumab monotherapy were superior to adalimumab in rates of clinical remission and ACR response; combination therapy with baricitinib + cDMARD was also superior to adalimumab + cDMARD in ACR20/50/70, but rates of clinical remission were similar between the two regimens. Abatacept, tofacitinib, certolizumab pegol, and adalimumab (all in combination with cDMARDs) showed comparable rates of remission, ACR response, and radiographic progression. Thirty-nine RCTs were included in the NMA; results showed small incremental differences in ACR response between TIMs (for example, rates of ACR50-70 ranged from 16% with rituximab + cDMARD to 22% with tocilizumab monotherapy), and a lack of statistically significant differences in most comparisons. **CONCLUSIONS:** Among patients with an inadequate response to cDMARDs, all TIMs provide substantial benefits relative to cDMARDs alone. Distinguishing the benefits between TIMs is more difficult, although tocilizumab and sarilumab monotherapy were superior to adalimumab in head-to-head studies.

PMS5

REVISION AND RADIOGRAPHIC PROGRESSION IN RHEUMATOID ARTHRITIS: REVIEW OF REGISTRY DATA AND LONG-TERM COHORT STUDIES

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OBJECTIVES: The objective of this review is to synthesize available evidence from long-term cohort studies and registries on remission and radiographic progression of rheumatoid arthritis (RA) and its predictors. **METHODS:** Registry studies published between 2006 and 2015 were systematically identified through the MEDLINE, EMBASE and Cochrane databases. Literature were assessed for eligibility by two independent reviewers based on pre-specified criteria. **RESULTS:** Forty-eight studies reporting remission and 25 reporting radiographic progression were included. Disease duration across cohorts varied between 2 and 15 years. Disease remission rates were reported using 28-joint Disease Activity Score (DAS28), European League Against Rheumatism (EULAR), Clinical Disease Activity Index (CDAI), and Simple Disease Activity Index (SDAI). Remission rates across studies were low, with up to 98% of patients unable to achieve and sustain remission over 12 months (non-remission rates: DAS28, 48%–91%; EULAR 81%–98%; CDAI, 60%–95%; SDAI, 74%–89%). Sharp/van der Heijde, Larsen, and Ratingen scores were the most common measures of radiographic progression. In 20 studies in treatment-naïve patients with early RA, sustained and substantial radiographic progression was observed, with variability in annual rates driven by risk factors (eg, anti-cyclic citrullinated peptide, rheumatoid factor positivity, baseline damage). In 5 studies enrolling patients with established RA (duration at baseline, 5–11 years), patients had received both non-biologics and biologics and annual change in radiographic damage was comparable to early RA studies (before biologics were available). A single study assessed radiographic progression before and after biologic treatment and showed a statistically significant 67% reduction in the annual rate after treatment initiation. **CONCLUSIONS:** This review showed that, while improvements in long-term clinical outcomes could be expected with a treat-to-target approach in combination with biologic therapy, a significant unmet need remains for higher rates of remission over time and inhibition of radiographic progression in RA.

PMS6

SUITABILITY OF A NETWORK META-ANALYSIS OF TARGETED SYNTHETIC OR BIOLOGIC THERAPY FOR PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS DESPITE BIOLOGIC DMARDs

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OBJECTIVES: To assess the suitability of a network meta-analysis (NMA) of targeted synthetic and biologic DMARDs in patients with active RA despite biologic DMARD (bDMARD) treatment. **METHODS:** A systematic literature review was performed to identify relevant randomized controlled trials (RCTs). Efficacy outcomes of interest were ACR20 response and change in DAS28(CRP) at 24±4 weeks. Suitability of a valid NMA was assessed according to the following criteria: 1) presence of 1 connected network where each trial has ≥1 intervention in common with another trial; 2) the distribution of study characteristics, patient characteristics, and contextual factors that are effect-modifiers are balanced across trials; and 3) the ability to overcome bias due to differences in effect-modifiers with statistical analysis. Identification of potential effect-modifiers was based on reported subgroup results in the literature and analysis of patient level data from a sirukumab phase 3 RCT (SIRROUND-T). **RESULTS:** Eight RCTs (2005–2016) were identified. Meaningful between-trial variation was observed, including differences in inclusion criteria, prior bDMARD use, and rescue therapy. Six trials included patients who failed anti-TNFs only, whereas 2 included patients who failed any bDMARD. Percentages of patients failing ≥2 prior bDMARDs ranged from 21%–61%. Where permitted, rescue therapy was administered after 12–18 weeks. Pre-study cDMARD stabilization periods varied (4–8 weeks). Unexplained variability in the placebo response (10%–34% ACR20 response) further highlighted the differences in patient characteristics between trials. A meta-regression analysis attempting to control for between-trial differences in effect-modifiers

or high placebo response was not feasible due to the small number of trials. **CONCLUSIONS:** Available trials in the post-bDMARD population are characterized by meaningful variation in likely effect-modifiers. In the absence of patient-level data to adjust for patient-related between-trial differences, a NMA based on reported study-level data is likely to be biased.

PMS7

INITIATION OF BIOLOGIC DISEASE-MODIFYING ANTIRHEUMATIC DRUG THERAPY AND ASSOCIATED CHANGES IN DISEASE ACTIVITY MEASURES IN ROUTINE CLINICAL PRACTICE

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OBJECTIVES: To evaluate changes in disease activity measures associated with biologic disease-modifying antirheumatic drug (DMARD) therapy in patients with rheumatoid arthritis (RA). **METHODS:** The OMI RA Data include electronic medical record (EMR) data (from a specialized rheumatology EMR) on ~75,000 patients diagnosed with RA, from across the US. This analysis included patients who a) were treated with non-biologic DMARD (nDMARD) between January 2013 and June 2016, b) had not received prior treatment with biologic DMARD, c) either added or switched to another nDMARD or initiated biologic DMARD (bDMARD) during the observation period (date of change in therapy is the index date) and d) had at least 2 disease activity measures. Disease activity measures included RAPID-3, HAQ-II, CDAI, and DAS28 and established American College of Rheumatology cutpoints were used to define remission. To reduce the impact of subsequent treatment changes, data were censored at 12 months. Survival analyses were conducted to evaluate the time to remission as well as time to sustained remission defined as 2 consecutive scores denoting remission. **RESULTS:** There were ~14,000 disease activity measures during the 12 month study period and none of the patients were in remission at index date. Of the 4,005 patients, 2,038 added or switched to another nDMARD and 2,014 added or switched to a bDMARD. A larger proportion of patients in the bDMARD group achieved remission and sustained remission compared to the nDMARD group (23% versus 19%; 14% versus 11%, p<0.05). Time to remission was significantly shorter in the bDMARD group compared to the nDMARD group (mean±SD=5.6±4.4 months versus 6.0±4.4 months, p<0.001). **CONCLUSIONS:** Disease activity improved with changes in DMARD therapy; however, the addition of bDMARDs were associated with significantly shorter time to remission and sustained remission.

PMS8

IMPACT OF SPIRONOLACTONE ON ACR RESPONSE VARIABLES IN NAIVE RHEUMATOID ARTHRITIS PATIENTS

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OBJECTIVES: To determine the ACR response of spironolactone when added to continuing regimen of Disease-Modifying antirheumatic drugs (DMARDs) therapy in 28 naive rheumatoid arthritis (RA) patients, who failed to respond adequately on monotherapy or combination of conventional disease modifying agents. **METHODS:** A distinct study on 28 patients of 24 weeks was designed to gain additional data concern the use of spironolactone (2mg/Kg/OD) in RA patients with active disease despite core standard therapy with DMARDs. American College of Rheumatology (ACR) responses at zero week, 12 week and 24 weeks were calculated statistically. The differences before and after spironolactone treatment were examined by 2-tailed paired student t-test. Results were considered significant at 95% level (p≤0.05) and presented as mean ± SEM. **RESULTS:** All ACR (20, 50, 70, 90) core set variables were significantly improved after 6 months with spironolactone treatment when compared with baseline in 26 patient. Two patients dropped out the study. 23 patients (88.4%) achieved target response (ACR 20% response), measured as composite index which is based on standard criteria set by American College of Rheumatology and is evaluated as 20% improvement in at least 20% reduction of Tender Joint Count (TJC), Swollen Joint Count (SJC) and in addition to a 20% improvement in at least three of the five activity measures; patient & physician assessment of general health on VAS scale, pain intensity assessment, ESR and HAQ functional questionnaire. Sixteen (61.5%), eleven (42.3%), nine (34.6%) and four (15.3%) patients also achieved ACR 50%, 70%, 90% response respectively after 24 weeks treatment. **CONCLUSIONS:** The study suggests that when spironolactone added with DMARDs, impacts both clinically and biologically to the patients with RA. The addition of spironolactone to the treatment of patients who respond incompletely to DMARDs alone or in combination may be distinctly valuable in the management of RA.

PMS9

REAL-WORLD HEALTH OUTCOMES ASSOCIATED WITH INFLIXIMAB FOR MODERATE-TO-SEVERE ANKYLOSING SPONDYLITIS IN A MEDIUM-SIZED CITY OF CHINA

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OBJECTIVES: to assess the real-world impact of infliximab on the disease activity and quality of life in Chinese patients with moderate-to-severe ankylosing spondylitis (AS) in a medium-sized city of China. **METHODS:** A cohort of Chinese patients with moderate-to-severe AS (Bath Ankylosing Spondylitis Disease Activity

Index (BASDAI) score greater than 4) were prospectively followed up at a tertiary care hospital in Zhuzhou, a medium-sized city in the central south of China, for their disease severity and quality of life associated with infliximab-contained therapy (ICT) or conventional disease-modified anti-rheumatic drugs (cDMARD). The disease severity of AS was measured by BASDAI and the quality of life was measured by both EQ-5D & SF-12 score in the study cohort. Conventional linear regression analyses with full adjustment of patient baseline characteristics compared ICT versus cDMARD for the changes of BASDAI, EQ-5D utility values, and SF-12 physical and mental scores over 22-week follow-up. **RESULTS:** A total of 31 patients completed 22-week follow-up (20 patients receiving ICT and 11 patients receiving cDMARD). The ICT group was associated with significantly younger age (34.0 years vs. 43.9 years, $p=0.016$) but a higher proportion of urban resident health insurance plan (54.5 vs. 0.0, $p=0.002$) at baseline than the cDMARD group. Relative to cDMARD, ICT was associated with significantly reduced BASDAI score (coefficient -2.910, $p=0.001$), improved EQ-5D utility value (coefficient 0.383, $p<0.001$), and increased SF-12 physical score (coefficient 15.597, $p<0.001$) in the multiple linear regression analyses with full adjustment of patient baseline characteristics. **CONCLUSIONS:** Patient social economic status could strongly impact the utilization of infliximab for moderate-to-severe AS in Chinese patients. The infliximab treatment led to significantly reduced disease severity and improved quality of life associated with moderate-to-severe AS in a medium-sized city of China.

PMS10

EFFECTIVENESS OF A PATIENT CENTERED CARE MODEL IN PATIENTS WITH RHEUMATOID ARTHRITIS RECEIVING ONLY CONVENTIONAL DMARDS IN COLOMBIA

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OBJECTIVES: The aim of study was to describe the change in Disease Activity Score 28 (DAS28) in patients with rheumatoid arthritis (RA) receiving only conventional treatment under a patient centered care model (PCC) in a specialized rheumatology center. **METHODS:** We carried out a retrospective review of clinical records of patients with RA and treated with conventional treatment in a rheumatology center in Colombia. Patients were followed-up during 24 months using a treat-to-target strategy (T2T); a PCC model means that a patient should be seen by rheumatologist, physical and occupational therapist, physiatrist, nutritionist and psychologist, at least three times a year according to disease severity. Clinical follow-up was according to DAS28: every 3-5 weeks (DAS28 > 5.1), every 7-9 weeks (DAS28 ≥ 3.1 and ≤ 5.1), and every 11-13 weeks (DAS28 < 3.1). Patients were classified into four groups due to DAS28: Remission (REM), low disease activity (LDA), moderate disease activity (MDA) and severe disease activity (SDA). Statistical analysis was done. **RESULTS:** A total of 968 patients were included, 80.2% were women; average age was 63 years (SD 10.7). Regarding conventional treatment, 52.4% received methotrexate, 26.0% leflunomide and 21.6% other DMARDs. At 24 months follow-up, an improvement was observed. At baseline 41% of patients were in remission, 17% in LDA and 42% in MDS/SDA. At the month 24 of follow-up, 66% were in remission, 18% in LDS and 16% in MDS/SDA. Regarding to DAS28, the mean at the beginning of the time analysis was 3.1 (SD 1.0) and after 24-months it was 2.4 (SD 0.7), showing a statistically significant improvement ($p < 0.000$). **CONCLUSIONS:** We observed a global improvement of DAS28 in patients receiving only conventional therapy, followed under T2T strategy and a PCC model. Those results should be used by decision makers in order to do cost-savings for health systems.

PMS11

CONFLICTING COMPARATIVE EFFECTIVENESS EVIDENCE OF HYALURONIC ACID USING REAL WORLD DATA EVIDENCE. AN UPDATE USING A HIGH DIMENSIONAL PROPENSITY SCORE MATCHING APPROACH

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OBJECTIVES: Recent evidence from large observational studies suggest that intra-articular HA injections are associated with a delay in total knee replacement among patients with knee osteoarthritis (OA). However, this recent industry sponsored evidence is limited considering residual confounding and potential selective loss to follow up. The objective of this study was to evaluate the effectiveness of intra-articular HA injections for knee OA management. **METHODS:** A nested cohort of persons with knee OA visiting a specialist and a recent history of pain medication use was created using the Lifelink Plus claims (2010-2015) to compare the risk of composite (any) knee surgical interventions, total (TKR) / unicompartmental knee replacement (UKR) and TKR only among HA users and two comparison groups: corticosteroid (CS) users and HA/CS non-users. A high dimensional propensity score (hdPS) was used to match HA users with HA/CS non-users and with CS users on background covariates. The risk of surgical interventions among HA users relative to the comparison groups was assessed using Cox proportional hazard models. A wide range of sensitivity analyses were also conducted including falsification tests. **RESULTS:** Among 13,849 patients, 797 were HA users, 5,327 were CS users, and 7,725 were HA/CS non-users. After hdPS matching, the risk of composite surgical interventions did not differ between HA users and HA/CS non-users (HR=0.88, 95% CI 0.67-1.16) and CS users (HR= 0.89, 95% CI 0.65-1.12). A sensitivity analysis that restricted the sample to patients who had any type of knee surgery (an approach used in recent studies), showed a significant lower risk of surgery for those using HA relative to HA/CS non-users (HR=0.87, 95% CI 0.79-0.95) **CONCLUSIONS:** There were no significant differences in the risk of surgical interventions among HA users compared to HA/CS non-users and CS users after accounting for residual confounding using a high dimensional propensity score.

PMS12

RISK FACTORS AND ECONOMIC BURDEN OF COMPLICATIONS AFTER AN OSTEOPOROTIC HIP FRACTURE IN CHINA

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OBJECTIVES: To investigate the complication incidence and its risk factors following an osteoporotic hip fracture, and quantify and compare the healthcare resource utilization and direct medical costs among patients with and without complications. **METHODS:** Data was obtained from Tianjin Urban Employee Basic Medical Insurance database (2009-2014). Patients aged ≥ 50 years, had ≥ 1 diagnoses of hip fracture during 2010 and 2012, and had continuous enrollment during 12-month before (baseline) and 24-month after (follow-up) the first identified hip fracture were included. Medical complications were identified within 4-month after the fracture, while surgical complications were identified within the 24-month follow-up. All-cause healthcare resource utilization and direct medical costs were measured and compared between patients with and without complications. Logistic regression was applied to identify risk factors associated with any complication. **RESULTS:** 1,675 patients were identified (mean age=70.5 years, 58.4% female). 66.9% (N=1120) of them had at least one complications during the identified period. Cerebral infarction was the most common medical complication (17.7%), followed by constipation (13.9%) and pneumonia (13.3%), while the most common surgical complications were osteoarthritis (20.9%) and subsequent hip fracture (11.4%). Compared with those without complications, patients with complications had higher all-cause total costs (\$8371 vs. \$5946, $p<0.001$) during the 24-month period, with longer length of hospitalization (39.0% vs. 25.6, $p<0.001$) and more outpatient visits (96.3% vs. 87.2%, $p<0.001$). Patients aged older (Odds Ratio [95% CI]: 1.02 [1.01-1.03]), had comorbidities including chronic heart disease (1.38 [1.04-1.84]), peripheral vascular disease (1.53 [1.05-2.22]), or hemiplegia (5.38 [2.75-10.50]), and had higher baseline all-cause direct medical cost (1.04 [1.00-1.09]) were more likely to have complications. **CONCLUSIONS:** Complication following an osteoporotic hip fracture is associated with increased economic burden in China. The most common complications were cerebral infarction, constipation, pneumonia, and osteoarthritis. Effective strategies should be made to prevent osteoporotic fractures and their complications.

PMS13

MICROVASCULAR COMPLICATIONS AND RISK OF HIP FRACTURE IN PATIENTS WITH TYPE II DIABETES

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OBJECTIVES: People with type II diabetes (T2DM) have increased risk of microvascular complications and fracture. How microvascular complications are related to hip fracture has not been established. We investigated hip fracture risk by numbers of different microvascular complications in T2DM using the Taiwan National Health Insurance Research Database. **METHODS:** Among people with newly diagnosed T2DM, 2000-2005, 247,177 participants (48% female) who developed at least one complication 1-yr after T2DM diagnosis ("exposed") were 1:1 matched at index date to 245,456 participants who never developed complications. Index date referred to the first complication diagnosis date among the exposed. Matching factors included age, sex and T2DM duration. Participants were followed to the first occurrence of inpatient hip fracture diagnosis, disenrollment or 12/31/2013. We calculated hip fracture incidence. Cox proportional-hazards regression modelling estimated hazard ratios and 95% confidence interval (CI) for hip fracture. Sex-specific models included age, T2DM duration and cardiovascular disease. **RESULTS:** Median age for T2DM diagnosis was 57. Among the exposed, first complication occurred at age 62. Over 4.2-year of follow-up, hip fracture occurred in 2258 women and 1034 men without complications (incidence: 42/10,000 person-years, women; 18/10,000 person-years, men) and 3727 women and 2011 men with any complication (incidence: 67/10,000 person-years, women; 35/10,000 person-years, men). In participants with 1, 2 or 3 complications, hip fracture incidence was 47, 126, and 266 per 10,000 person-years in women and 22, 72, to 130 per 10,000 person-years in men. Compared to participants without complications, adjusted hazard ratios for hip fracture in those with 1, 2 or 3 complications was 1.51 (CI: 1.44-1.60), 2.05 (CI: 1.83-2.29) and 3.38 (CI: 2.12-5.40) in women; 1.77 (CI: 1.64-1.90), 2.71 (CI: 2.33-3.16) and 4.03 (CI: 2.10-7.73) in men, respectively. **CONCLUSIONS:** Microvascular complications increase hip fracture risk in T2DM, particularly people with multiple complications. Bone health management should be considered for people with complicated T2DM.

PMS14

365 DAY SURVIVAL ANALYSIS OF PREDICTORS IN PATIENTS WITH SECOND HIP FRACTURE

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OBJECTIVES: Patients with second hip fractures are at increased risk of death. The aim of the study was to analyse the predictors of 365 day survival in patients with second hip fractures. **METHODS:** Patients aged 60 years and over treated with primary femoral neck fractures in the year 2000 and suffered from contralateral hip fractures between 01 January 2000 and 31 December 2008 were selected from the database of the Hungarian National Health Insurance Fund. The following prognostic factors were evaluated: age, gender, comorbidities, location of second hip fracture, type of surgical intervention, local complication after second hip fracture, and day of hospital admission were studied. The 365 day mortality was calculated

for each group. Predictors for 365 day survival were evaluated by Kaplan-Meier survival analysis and log-rank test. Statistical analyses were performed using the SPSS version 19.0. **RESULTS:** 312 patients met the criteria. The mean survival time was 113.22 days. The 365 day mortality rate was 38.4%. There was significantly longer survival ($p=0.004$) found in patients with femoral neck fracture (mean survival time: 135 days) relative to patients with peritrochanteric (mean survival time: 73.28 days) and other fractures (mean survival time: 93.60 days). There was no significant difference found in 365 day survival of patients with gender ($p=0.610$), type of surgical intervention ($p=0.269$), local complication after second hip fracture ($p=0.847$), comorbidities ($p=0.537$), and day of hospital admission ($p=0.698$). **CONCLUSIONS:** The 365 day mortality rate was high. Patients with femoral neck fracture had better survival then those with peritrochanteric fracture location. The worse survival in patients with peritrochanteric fracture could be explained by better blood supply, and higher risk for hemorrhage of this region.

PMS15

30 DAY SURVIVAL ANALYSIS OF PREDICTORS IN PATIENTS WITH SECOND HIP FRACTURE

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OBJECTIVES: Patients with second hip fractures are at increased risk of death. The aim of the study was to analyse the predictors of 30 day survival in patients with second hip fractures. **METHODS:** Patients aged 60 years and over treated with primary femoral neck fractures in the year 2000 and suffered from contralateral hip fractures between 01 January 2000 and 31 December 2008 were selected from the database of the Hungarian National Health Insurance Fund. The following prognostic factors were evaluated: age, gender, comorbidities, location of second hip fracture, type of surgical intervention, complication after second hip fracture, and day of hospital admission were studied. The 30 day mortality was calculated for each group. Predictors for 30 day survival were evaluated by Kaplan-Meier survival analysis and log-rank test. Statistical analyses were performed using the SPSS version 19.0. **RESULTS:** 312 patients met the criteria. The mean survival time was 13.12 days. The 30 day mortality rate was 8.3%. The 30 day survival time was longer in men vs. female (13.57 vs. 12.95 days), in patients with peritrochanteric fracture vs. femoral neck fracture (13.53 vs. 12.22 days), in patients with arthroplasty vs. osteosynthesis (15 vs. 13.41 days), and in patients were admitted to hospital on weekday vs. weekend (13.32 vs. 12.57 days). However there was no significant difference found in 30 day survival of patients with different gender ($p=0.818$), location of second hip fracture ($p=0.805$), type of surgical intervention ($p=0.616$), complication after second hip fracture ($p=0.254$), and day of hospital admission ($p=0.795$). **CONCLUSIONS:** The 30 day mortality rate was high, but the investigated prognostic factors didn't show significant correlation with patients' survival. Further analyses of risk factors are needed to clarifying their role in the survival of patients with second hip fracture.

MUSCULAR-SKELETAL DISORDERS – Cost Studies

PMS16

POTENTIAL IMPACT OF THE BIOSIMILARS INTRODUCTION OF 3 ANTI-TNFS IN THE EUROPEAN MARKET

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OBJECTIVES: Anti-TNFs represent a substantial cost in the European healthcare systems. Patents of infliximab and etanercept have expired in Europe, with patent of adalimumab expected to expire in Europe in 2018. Biosimilars of former two are available in Europe. This study's objective was to assess the potential savings of introducing infliximab, etanercept and adalimumab biosimilars in Europe. **METHODS:** Savings for each anti-TNF were estimated from the year of biosimilar entry in Europe (2015 for infliximab, 2016 for etanercept and 2018 for adalimumab) up to 2020. Annual sales (\$) of originator products in the year prior to biosimilar entry were used assuming these to remain constant in subsequent years (adalimumab from 2015). Infliximab biosimilars average market share (MS) was 20% in 2015 and 45% in 2016 and it was assumed a 10% increase in 2017 and a 5% in subsequent years. Etanercept biosimilars MS was assumed 20% in 2016, 40% in 2017 (2nd biosimilar in the market), 50% in 2018, 55% in 2019 and 60% in 2020. Adalimumab biosimilars MS was assumed 30% in 2018, 50% in 2019 and 60% in 2020. Infliximab biosimilar average discount was 40% in 2015 and 50% in 2016 assuming further 2.5% in subsequent years. Etanercept biosimilar average discount was 35% in 2016 assuming further 10% discount in 2017 and further 2.5% in subsequent years. For adalimumab biosimilar, 35% discount was assumed in 2018 with further 2.5% in subsequent years. Originator prices were assumed to decrease by 10% in first 2 years of biosimilar introduction and by 20% in subsequent years. **RESULTS:** Biosimilar introduction of the 3 anti-TNFs in Europe is likely to result in savings of \$11.44b between 2015-2020; i) infliximab: \$5.31b, ii) etanercept: \$2.95b & iii) adalimumab: \$3.18b. **CONCLUSIONS:** Biosimilars of these 3 anti-TNFs will provide significant savings to the healthcare systems across Europe contributing to their sustainability.

PMS17

BUDGET IMPACT ANALYSIS OF ETORICOXIB IN THE TREATMENT OF OSTEOARTHRITIS IN CHINA

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OBJECTIVES: To estimate the potential budget impact of Etoricoxib in the Treatment of Osteoarthritis from the public health insurance payer's perspective in China from 2017-2021. **METHODS:** A budget impact model was developed in the context of national reimbursement drug list with a five-year time frame in

accordance with the ISPOR BIA guideline. The target patient population of Osteoarthritis patients was estimated with official national population statistics and published epidemiological data. The patient population was then divided into resident and employed groups because of different reimbursement level. The national hospital sales data of last year were used to forecast the annual growth and patient share sizes. Daily dosage of drug was determined by drug instructions' average dose. Two scenarios were modeled: etoricoxib covered or not covered by the public health insurance. **RESULTS:** China's target osteoarthritis patients was estimated to be 10.02 million. Chinese and many international guidelines had established etoricoxib as alternative to the drugs including ibuprofen, naproxen, loxoprofen, diclofenac, sulindac, acemetacin, etodolac, nabumetone, meloxicam, nimesulide, celecoxib, paracetamol, tranadol, hydrochloride tramadol. The annual expenditure of etoricoxib (1,784.12 CNY/patient) was lower than celecoxib (1,984.38 CNY/patient) based on average bidding prices. Thus, including etoricoxib in the national reimbursement list could potentially increase 7.37 million, 15.88 million, 24.00 million, 32.68 million, 41.85 million CNY medical expenditure from 2017-2021. Sensitivity analyses showed the result were robust. **CONCLUSIONS:** Inclusion of etoricoxib in China's national reimbursement list will increase the annual medical insurance expenditure. The reason is that the prices of ibuprofen, loxoprofen, diclofenac and meloxicam are lower than etoricoxib, market share was higher. But compared with ibuprofen, loxoprofen, diclofenac and meloxicam, etoricoxib has the advantages of safety, and saving the use of other medical resources. Because it will increase medical insurance expenditure, appropriately reducing the price can significantly reduce medical insurance expenditure.

PMS18

PHARMACOECONOMIC INSIGHTS TO GUIDE BIOSIMILAR ADOPTION AND EVIDENCE OF COST SAVINGS FOR FOUR FDA-APPROVED BIOSIMILARS

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OBJECTIVES: US health plans have been slow to adopt newer biosimilar (BS) drugs partly due to uncertainties surrounding their safety, efficacy and economic superiority. This study aims to collect evidence of economic value of four new biosimilars that have been FDA-approved for sale so far to provide information that might aid formulary adoption and uptake by health plan decision makers (HPDMs). **METHODS:** A systematic review of pharmacoeconomic studies of four USFDA-approved biosimilars to date (filgrastim, infliximab, etanercept, adalimumab) from PubMed, Embase, and SciDirect databases. Eligible studies included cost-based comparative evaluations of a biosimilar product vs. another biologic, an originator product, or a qualified reference product. Empirical and review studies documenting traditional HEOR results, findings of comparative effectiveness, budget impact analyses (BIA) and resource use projections were drawn from multiple literature databases for final review. **RESULTS:** We identified 44 studies (15 peer reviewed articles and 29 meeting abstracts) that met the eligibility criteria. Nearly all the studies were either simulated models with cost projections or retrospective cost analyses (>90%) with only three real-world utilization studies; only four were US-based studies. BIAs constituted a majority (>75%) and more than half involved multi-national comparisons in EU. QALYs, incremental costs, and projected savings to cover additional lives were the most common outcome measures. Price discounts modeled varied from 20% to as high as 75%, and savings generated were substantial to significant in most cases. **CONCLUSIONS:** US studies demonstrating the value of BS are extremely rare, but the international experience with these products shows strong cost advantages. Market uptake rates and acquisition cost discounts drive savings in most cases and savings are sensitive to jurisdictional variations, interchangeability parameters and clinical factors. Scarcity of real-world performance data in the USA, and the difficulty of using European commercial experience for US adoption and forecasting make immediate BS acceptance challenging.

PMS19

AN EVALUATION OF THE IMPACT OF STATIN DRUG-DRUG INTERACTIONS LEADING TO RHABDOMYOLYSIS REQUIRING HOSPITALIZATION

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OBJECTIVES: This study examined the annual incidence, mortality, and cost of rhabdomyolysis due to the potential drug-drug interactions between statins and other agents in the United States. **METHODS:** This study was a decision model developed based on data from the National Health and Nutrition Examination Survey (NHANES) and the Healthcare Cost and Utilization Project (HCUP) to estimate use of statins, cost, and mortality associated with rhabdomyolysis. The incidence rate of statin-induced rhabdomyolysis was identified using multiple published studies. Estimates of the proportion of statin-related rhabdomyolysis attributable to drug interactions was from a systematic review of 35 trials. Our study evaluated adults forty years of age or more using a statin. The incident rate of hospitalized rhabdomyolysis was estimated for patients on statin monotherapy or combination therapy including a statin. The proportion of drug-drug interaction was incorporated to the total number of annual statin-related rhabdomyolysis patients. One-way sensitivity analyses were conducted to evaluate the robustness of the findings. **RESULTS:** In the primary analysis the incidence of rhabdomyolysis per 10,000 person-years was 0.44 (95%CI:0.20-0.84) for monotherapy and 5.98 (95%CI:1.46-13.68) for combination therapy. An estimated 3,487 patients a year experience severe rhabdomyolysis requiring hospitalized due to drug-drug interactions with statins. The estimated total annual cost was \$21.9 million. At this incidence rate approximately 30 individuals die each year due to the interaction. In the second analysis, a different incidence rate for each statin therapy was utilized. It was estimated that 1,938 patients annually experience

rhabdomyolysis requiring hospitalization due to statin drug-drug interactions and estimated total annual costs of \$17.2 million with an estimated 23 patients expiring. A deterministic one-way sensitivity analysis indicated that incidence rate of hospitalized rhabdomyolysis as the most influential model parameter. **CONCLUSIONS:** Statin drug-drug interactions may result in rhabdomyolysis that has significant costs and mortality.

PMS20

EVALUATING THE ECONOMIC BURDEN AND HEALTH CARE UTILIZATION OF RHEUMATOID ARTHRITIS PATIENTS IN THE US DEPARTMENT OF DEFENSE POPULATION

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OBJECTIVES: To examine the economic burden and health care utilization of rheumatoid arthritis (RA) patients in the US Department of Defense (DoD) population. **METHODS:** Patients diagnosed with RA (International Classification of Diseases, 9th Revision, Clinical Modification diagnosis code: 714) were identified using DoD data from 01OCT2010-31OCT2015. The first diagnosis date was designated as the index date. A comparison cohort was created for patients without RA, but of the same age, gender, race, index year, and with similar baseline Charlson Comorbidity Index scores. The index date was chosen randomly for the comparison cohort to minimize selection bias. Patients in both cohorts were required to have continuous medical and pharmacy benefits for 1 year pre- and 1 year post-index date. Study outcomes, including health care costs and utilization, were compared between the disease and comparison cohorts using 1:1 propensity score matching (PSM), and adjusted for baseline demographic and clinical characteristics. **RESULTS:** Eligible RA and non-RA patients (N=32,512) were included for study. After 1:1 PSM matching, 14,223 patients were identified in each cohort; the baseline characteristics were well balanced. Patients with RA had a greater mean number of inpatient (0.27 vs 0.12; p<0.001), emergency room (ER) (0.81 vs 0.45; p<0.001), ambulatory (26.69 vs 14.11; p<0.001) and pharmacy (21.55 vs 11.7; p<0.001) visits. Higher all-cause health care costs were also observed for RA patients, including mean inpatient (\$3,278 vs \$1,398; p<0.001), ER (\$535 vs \$291; p<0.001), ambulatory (\$7,685 vs \$3,978; p<0.001), pharmacy (\$3,495 vs \$1,142; p=0.4138), and total costs (\$14,992 vs \$6,808; all p<0.001). **CONCLUSIONS:** During a 12-month period, DoD beneficiaries who were diagnosed with RA had higher health care utilization and incurred higher costs than matched control patients.

PMS21

ECONOMIC IMPACT OF BIOLOGIC DMARD TREATMENT FOR APCA+ AND RF+ PATIENTS: A COMPARISON OF ABATACEPT AND TNFI BIOLOGIC DMARDS

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OBJECTIVES: Anti-citrullinated protein antibodies (ACPA) and Rheumatoid Factor (RF) are markers used to diagnose rheumatoid arthritis (RA). Patients that are both RF+ and ACPA+ (hereafter Double+) have more severe disease and improved clinical response to abatacept treatment compared with other patients. This study estimates changes in RA-related medical cost after initiation of treatment with abatacept or tumor necrosis factor inhibitor (TNFi) biologic disease-modifying anti-rheumatic drugs (bDMARDs) among RA patients who have Double+ RA. **METHODS:** In our three-step simulation model, we first measured RA-related costs for Double+ patients using IMS PharMetrics Plus health insurance claims data linked to electronic medical record data (2010-2015). Second, we measured the changes in functional status comparing patients who initiated treatment with abatacept versus TNFi in terms of Clinical Disease Activity Index (CDAI). Finally, we monetized functional status improvement among these patients using the literature. **RESULTS:** Annual RA-associated total expenditure was \$5,335 for Double+ patients compared to \$3,581 for other patients (Δ =\$1,754, p<0.01). Double+ patients who initiated treatment with abatacept had an 8.5 point decrease in CDAI score compared to a 7.2 point decrease among those who initiated a TNFi, a difference of 1.3 (p<0.001). These reductions in CDAI are estimated to reduce mean annual RA-related cost by \$893 (-14.7%) for abatacept users and by \$756 for patients initiating TNFi therapy (-12.4%). Switching all Double+ RA patients that use bDMARDs from TNFi therapy to abatacept would reduce mean annual RA-related medical expenditures by \$14.7 million. **CONCLUSIONS:** Abatacept initiation among Double+ RA patients lead to large improvements in functional status and lower RA-related medical costs compared to TNFi initiation. Harrold et al. *Ann Rheum Dis* 2016; **75**; 123-4 Michaud K, et al. *Arth & Rheum* 2003;**48**:2750-62

PMS22

HEALTHCARE UTILIZATION AND COSTS FOR RA PATIENTS ON BIOLOGICS COMPARED TO THOSE ON CONVENTIONAL SYNTHETIC DMARDS: RESULTS FROM A NATIONWIDE POPULATION-BASED COHORT STUDY IN TAIWAN

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OBJECTIVES: This study aimed at assessing the changes in healthcare utilization and costs between patients treated with conventional synthetic and biological disease modifying antirheumatic drugs (csDMARD and bDMARD) for rheumatoid arthritis (RA) in Taiwan. **METHODS:** Two cohorts of severe RA patients were identified from National Health Insurance claims database. The csDMARD cohort was patients who had medication claim for cyclosporine \geq 50 mg/day with

concomitant use of \geq 2 csDMARDs for \geq 28 days within 56 days after cyclosporine use during 1997-2003 (N=1,569). After csDMARD cohort was determined, the bDMARD cohort was selected if patients had \geq 1 claim for bDMARD during 2003-2011 (N=1,530). The index date was the date with the first qualifying claim. Patients were followed up for maximum of 10 years, or death, switched to bDMARDs (for csDMARD only), or end of 2013, whichever came first. Per-patient-per-year (PPPY) annual healthcare utilization and costs were calculated by bootstrapping with 1,000 nonparametric replications drawn from the source cohorts. Annual incremental utilization and costs for csDMARD and bDMARD cohorts were compared. **RESULTS:** Incremental number of hospitalization days decreased by 75% (from 2.3 days for csDMARD to 0.58 day for bDMARD). The incremental total costs and RA medication costs were increased by 3.66 times (US\$9,081 vs. US\$2,481) and 4.78 times (US\$8,992 vs. US\$1,883), respectively, for bDMARD compared to csDMARD. However, the sum of incremental healthcare utilization costs and incremental non-RA medication costs was decreased by 64% (from US\$1,302 for csDMARD to US\$467 for bDMARD). **CONCLUSIONS:** The introduction of biologics in the treatment of RA has significantly reduced the hospitalization days for RA patients. Incremental costs of healthcare utilization and non-RA medication also decreased for bDMARD compared to csDMARD.

PMS23

TRENDS IN HEALTHCARE EXPENDITURES, UTILIZATION, AND HEALTH STATUS AMONG US PATIENTS WITH RHEUMATOID ARTHRITIS FROM 1998-2014: A REPORT FROM THE MEDICAL EXPENDITURE PANEL SURVEY

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OBJECTIVES: The research was conducted to estimate the annual expenditures, healthcare utilization, and change in health status for patients who sought health care services for rheumatoid arthritis (RA) based on the nationally representative sample from the Medical Expenditure Panel Survey (MEPS). **METHODS:** Adult respondents were sampled from the years 1998, 2002, 2006, 2010, and 2014. Patients with RA were identified and compared to those without RA. Annual total expenditures and utilization were recorded for the inpatient setting, office-based setting, pharmacy, and emergency department. Data were compared to the self-reported health status from short-form 12 for patients each year. Sociodemographic factors were adjusted for, and a generalized linear model was developed to identify factors associated with RA expenditure. The quantity of biologics used and expenditures associated since their initial release in 1998 were estimated. **RESULTS:** The adjusted average total expenditure of the RA population over the five sampled years in 2014 US dollars was \$9363.40 compared to \$7179.30 in the non-RA sample (p<0.0001). Pharmacy accounted for an average expenditure of \$4181.1 in RA patients and \$2291.24 in non-RA patients (p<0.0001). The average total utilization of the RA population over the five sample years was 54.21 in RA patients and 39.86 in non-RA patients (p<0.0001). The mean physical health summary score for was significantly lower for RA patients (31.52) compared to non-RA patients (39.26) (p<0.0001). The number of biologics dispensed for RA treatment increased from 0 per patient in 1998 to 0.35 per patient in 2014. **CONCLUSIONS:** Despite having lower physical and mental health scores, RA-related expenditure represents a considerable economic burden on the US health care system. Pharmacy is the primary area of expenditure.

PMS24

CLINICAL RESPONSE AT WEEK 52 AND COSTS IN PATIENTS WITH RHEUMATOID ARTHRITIS USING BIOLOGICAL THERAPY IN A SPECIALIZED CENTER IN COLOMBIA

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OBJECTIVES: Rheumatoid Arthritis (RA) is a chronic autoimmune disease with a prevalence of 1% in general population. Due to the course of disease patients have progressive disability that causes productivity losses and early retirement leading to great expenses for society. Biological treatment for RA has been proved as an effective treatment but it is associated with high costs. We describe the costs of biological therapy in patients with RA in a specialized center. **METHODS:** We conducted a real-world, retrospective, cross-sectional study, we included patients with biological therapy; they were followed-up during 52 weeks and treated according to Disease Activity Score 28 (DAS28). Descriptive epidemiology was done; means were analyzed using t-Student performing a normality test for DAS28 and overall therapy costs were assessed. **RESULTS:** 684 patients were included; mean DAS28 at beginning of therapy was 3.1 ± 1.1 ; the majority of patients received Adalimumab 16% followed by Etanercept 25 mg 12%, Tocilizumab, Infliximab and Rituximab 11%, Abatacept IV 10%, Etanercept 50 mg 10%, Certolizumab and Golimumab 7%, Tofacitinib 3% and Abatacept SC 2%. The most expensive biologic treatment was Golimumab (USD 12.770/year) followed by Certolizumab (USD 10.357), Etanercept 25 mg and 50 mg (USD 10.347), Tofacitinib (USD 9.811) Adalimumab (USD 9.799), Abatacept SC (USD 9.656) Tocilizumab (USD 8.795). Abatacept IV (USD 8.330 Infliximab (USD 6.564) and Rituximab (USD 4.427). When the progression of the disease was compared at week 52, most of patients went from a DAS28 of 3.1 ± 1.1 to a mean DAS28 of 2.4 ± 0.8 using biological therapy. **CONCLUSIONS:** The use of biologic therapies in the treatment of RA is effective but continues to be associated with high costs of biological therapy is to carefully evaluate patients that will receive these medications, nonetheless further research based on cost-effectiveness analysis is needed to verify these results.

PMS25

ADVERSE EVENT DATA AS PROXY TO DETERMINE TOTAL MEDICAL COSTS FOR TNF-ALPHA INHIBITORS

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OBJECTIVES: Adverse drug events (ADEs) lead to 700,000 ER visits and are the fourth leading cause of death in the U.S. ADE costs are paramount to understanding total medical cost and differential economic impacts between therapies. This study examined downstream medical costs associated with infections from the use of TNF-alpha inhibitors. The goal was to establish whether ADE cost analytics can be compared with claims databases to model safer and more cost-effective drug decisions. **METHODS:** We analyzed ADE and claims data for six TNF-Alpha inhibitors from August 2013 through July 2015. We examined: 1) ADE and outcome-specific medical costs obtained from AHRQ; 2) ADE and outcome data from FAERS; 3) drug usage information from Evaluate Pharma; and 4) claims data from WEA Trust. ICD-9 diagnoses were mapped to each ADE. Focus was limited to EudraVigilance Important Medical Events and "primary suspect" ADE reports. CPT Service Codes were used to establish three cost measurements: ER visits, hospitalizations, and ambulance transportation. Only medical services incurred after a filed pharmacy claim were examined. **RESULTS:** Certolizumab and golimumab were associated with a higher incidence of ADEs compared to other TNF-alpha's (adalimumab, etanercept, and infliximab) in both ADE and claims data. Downstream medical cost per dispense were: \$522, \$256, and \$190 for certolizumab, adalimumab and etanercept, respectively, for ER visits. Hospitalizations costs were \$156, \$79, and \$57 and ambulance transportation were \$30, \$19, and \$19 for certolizumab, adalimumab, and etanercept, respectively. **CONCLUSIONS:** Given that both ADE and claims data suggested that two TNF-alpha inhibitors were more likely to cause infections and higher medical costs, WEA Trust will be working with providers to modulate TNF-alpha inhibitor prescriptions to lower cost and improve safety. Future work will examine other drug classes regarding the use of ADE analytics as a proxy for drug benefit design.

PMS26

COST-EFFECTIVENESS ANALYSIS OF SECUKINUMAB IN PSORIATIC ARTHRITIS: A CANADIAN PERSPECTIVE

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OBJECTIVES: To evaluate the cost-effectiveness of secukinumab, a fully human monoclonal antibody that selectively neutralizes interleukin (IL)-17A, versus currently licensed biologic therapies in patients with active psoriatic arthritis (PsA) from a Canadian healthcare system perspective. **METHODS:** A decision analytic semi-Markov model evaluated the cost-effectiveness of secukinumab 150mg and 300mg compared to certolizumab pegol, etanercept, adalimumab, infliximab, infliximab biosimilar, golimumab, and ustekinumab in biologic-naïve and biologic-experienced patients, respectively, over a lifetime horizon. The response to treatments was evaluated after 12 weeks by PsA Response Criteria (PsARC) response rates. Non-responders or patients discontinuing initial-line of biologic therapy were allowed to switch to subsequent-line biologics. Model input parameters (Psoriasis Area Severity Index [PASI], Health Assessment Questionnaire [HAQ], withdrawal rates, costs, and resource use) were collected from clinical trials, published literature, and other Canadian sources. Benefits were expressed as quality-adjusted life years (QALYs). Costs were reported in Canadian dollars (CAD). An annual discount rate of 5% was applied to costs and benefits. **RESULTS:** In the biologic-naïve population, patients treated with secukinumab achieved the highest number of QALYs (8.54) at the lowest cost (CAD 925,387) over a lifetime horizon compared to all comparators, except for infliximab and its biosimilar, which achieved minimally more QALYs (8.58) than secukinumab. However, infliximab and its biosimilar incurred more costs than secukinumab (infliximab: CAD 1,015,437; infliximab biosimilar: CAD 941,004), resulting in worse cost-effectiveness profiles. Secukinumab dominated all therapies except infliximab, but was cost-effective versus infliximab in this population. In the biologic-experienced population, secukinumab dominated all treatments as it generated more QALYs (8.89) at lower costs (CAD 954,692). Deterministic sensitivity analyses indicated the results were most sensitive to variation in PsARC response rates, change in HAQ, and utility values. **CONCLUSIONS:** Secukinumab is either dominant or cost-effective versus all licensed biologics for the treatment of active PsA in biologic-naïve and biologic-experienced populations in Canada.

PMS27

COST-EFFECTIVENESS OF PHARMACOLOGICAL RHEUMATOID ARTHRITIS TREATMENTS IN THE UNITED STATES: A SYSTEMATIC REVIEW OF THE LITERATURE

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OBJECTIVES: To conduct a literature review to identify cost-effective analysis (CEA) studies for the pharmacological treatment of rheumatoid arthritis (RA) in the United States (US). **METHODS:** A total of four databases were searched to identify articles relevant to CEA of pharmacological interventions for rheumatoid arthritis: (1) Embase; (2) Medline; (3) Tufts CEA registry; and (4) The UK National Institute for Health Research (NIHR) Health Technology Assessment

(HTA) Database; from inception to November 5, 2016. Key search terms included "rheumatoid arthritis" and "cost" or "cost-effectiveness". English, peer-reviewed studies from the US perspective that reported original CEA's were included. **RESULTS:** The search identified a total of 2,882 articles. After the removal of duplicates and title screening, 110 articles remained for full-text review. A total of 11 articles were included in the review. These articles were assessed for quality according to the CHEERS checklist and had scores ranging from 11/24 (46%) to 18/24 (75%). The pharmacological agents most commonly reported in the articles were: methotrexate (n=7), etanercept (n=7), and adalimumab (n=5). The model types of the articles were decision models (n=5), Markov models (n=2), Monte-Carlo simulations (n=2), and individual patient simulations (n=2). The time horizons ranged from 6 months to lifetime, and generally performed discounting at a rate of 3%. The perspectives of the studies were either payer (n=7), societal (n=3), or both (n=1). Incremental cost-effectiveness ratio values reported in the studies ranged from a low of \$4,849/quality-adjusted life-year (QALY) to a high of \$12.5 million/QALY. **CONCLUSIONS:** Overall, there were a total of 11 articles that presented CEA of various pharmacological treatment options for RA in the US. However, since some drugs were analyzed less frequently than others, and they were not all compared against each other, it was not possible to state which was the most cost-effective option overall.

PMS28

AN INTRA-ARTICULAR, EXTENDED-RELEASE FORMULATION OF TRIAMCINOLONE ACETONIDE AS A COST-EFFECTIVE THERAPY FOR TREATING OSTEOARTHRITIS OF THE KNEE

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OBJECTIVES: The present study investigated the cost-effectiveness of a novel, intra-articular, extended-release formulation of triamcinolone acetonide (TA-ER) in comparison to other methods for treating knee osteoarthritis (OA) pain. **METHODS:** Clinical outcome data from 324 patients enrolled in three Phase 2 and Phase 3 randomized trials (NCT01487161, NCT02116972, NCT02357459) evaluating an investigational intra-articular corticosteroid formulation (FX006 40 mg) for treatment of knee OA pain were used. In these studies, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC-A [Pain], -B [Stiffness], -C [Physical Function]) data were assessed at baseline and at 4-week intervals through 12 (one study) or 24 weeks (2 studies) post-treatment. Health Utilities Index Mark 3 (HUI3) scores were calculated from WOMAC values. Cost-effectiveness was assessed using cost per quality-adjusted life years (\$/QALY) and the incremental cost-effectiveness ratio (ICER) versus other knee OA treatments, including conventional care with non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen, physical therapy, and assistive devices (CC); prescription NSAIDs (diclofenac); and hyaluronic acid treatment regimens with 1-5 intra-articular injections (HAs); based upon 2016 WAC pricing. **RESULTS:** TA-ER demonstrated sustained significant improvements from baseline in all WOMAC components through 24 weeks, with concordant improvements in HUI3; peak HUI3 gain from baseline was 0.229 at week 4. Overall, TA-ER treatment produced an average QALY gain from baseline of 0.189 per 6 months, higher than published for CC (0.030), diclofenac (0.078) and HAs (average 0.110). At a hypothetical drug cost of \$500, TA-ER yields a \$/QALY estimate of \$3,201, in comparison to other treatments: diclofenac (\$2,708), CC (\$10,717), and HAs (average \$13,267). TA-ER at this treatment cost provided ICERs of \$1,783 versus CC, \$3,549 versus diclofenac, and was the dominant strategy versus HA injection regimens. **CONCLUSIONS:** Intra-articular TA-ER injection provides sustained positive clinical outcomes, and if priced similarly to HA therapies, will be a cost-effective therapy for treating knee OA pain.

PMS29

ASSESSING THE COMPARATIVE EFFECTIVENESS OF TOCILIZUMAB IN GIANT CELL ARTERITIS WITHIN A DE NOVO HEALTH ECONOMIC MODEL, BASED ON THE GIACTA TRIAL AND DATA FROM MARKET SCAN DATABASE

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OBJECTIVES: To assess the comparative effectiveness of tocilizumab with prednisone vs. prednisone alone, in Giant Cell Arteritis (GCA). **METHODS:** A de-novo cost-effectiveness model was built to reflect the natural history of GCA, with the following health states: remission (on and off steroids), relapse/flare and death. A lifetime horizon was applied. Patient's quality of life was estimated using the EQ-5D results from the GIACTA trial. The model accounts for adverse events (AEs) related to prednisone cumulative dose and GCA related AEs with a flare. Time to first flare Kaplan Meier curves were extrapolated using parametric models, rates of subsequent flares were assessed using Poisson regression. Cumulative prednisone dose for each treatment arm was extrapolated in the long run using a logistic regression and linked with probabilities of prednisone related AEs such as diabetes, fractures and serious infections based on the real world data from US MarketScan. **RESULTS:** In the tocilizumab arm, the median time in steroid free remission was two years longer than patients on prednisone alone. Patients who received tocilizumab had an improved quality of life to those on prednisone alone; this was driven by the reduction in their risk of flare by over 50%. This resulted in a statistically significant (P<0.0001) decrement over baseline utility, equal to 0.13. Furthermore, patients on tocilizumab reduced their cumulative prednisone significantly, as a result, patients on prednisone alone risk for developing glucocorticoids related AEs are 117% higher than tocilizumab patients. **CONCLUSIONS:** Tocilizumab significantly improved the quality of life of patients with GCA compared to the current standard of care through more patients achieving better disease control and by reducing the risk of long term AEs.

PMS30

A COST PER RESPONDER MODEL FOR ORAL TOFACITINIB AND BIOLOGIC TNF INHIBITORS IN RHEUMATOID ARTHRITIS DURING THE INITIAL 24 WEEKS OF THERAPY

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OBJECTIVES: Current therapy for moderate to severe rheumatoid arthritis (RA) often utilizes a subcutaneous or infused tumor necrosis factor (TNF) inhibitor with methotrexate. Tofacitinib is an oral Janus kinase (JAK) inhibitor that is indicated for the treatment of RA. Tofacitinib is priced similarly to injectable biologics and the purpose of this study is to evaluate the cost-effectiveness of tofacitinib, in combination with methotrexate, for the initial 24 weeks of treatment compared to currently available TNF inhibitors. **METHODS:** A cost per responder model was created for the initial 24 weeks of treatment with combination therapy of methotrexate and tofacitinib, infliximab, adalimumab, etanercept, golimumab for infusion, or certolizumab pegol. A number needed to treat (NNT) was calculated from the ACR20 response rate at 24 weeks of treatment in the phase three trials for each drug. Dosing was based on approved prescribing information and includes any recommended loading doses during the initial 24 weeks. Weight based dosing was estimated from CDC reported average adult weights and the gender distribution from the phase three clinical trials of the drugs. Wholesale acquisition costs (WAC) from the FDA Redbook were used for pricing each drug. **RESULTS:** The NNT ranged from 1.41 to 2.00. Infliximab had the lowest cost per responder (\$33,398.10 NNT: 2.00), followed by etanercept (\$34,628.96 NNT: 1.41), tofacitinib (\$40,419.73 NNT: 1.94), golimumab for infusion (\$41,158.51 NNT: 1.70), adalimumab (\$48,274.24 NNT: 1.81), and certolizumab pegol (\$50,066.26 NNT: 1.70). **CONCLUSIONS:** While tofacitinib demonstrates a similar NNT and cost per responder to many biologics, it is less cost effective than infliximab and etanercept. Limitations of the model are that it does not include administration costs or the costs of treating adverse events. Future research is needed to determine the cost-effectiveness of therapy beyond the initial 24 weeks since loading doses are no longer needed.

PMS31

COST SAVINGS ASSOCIATED WITH THE DECREASE OF USE OF BIOLOGICAL THERAPY IN PATIENTS WITH RHEUMATOID ARTHRITIS USING CONVENTIONAL DMARDs DURING A 5 YEAR PERIOD

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OBJECTIVES: Pharmacological therapy in patients with rheumatoid arthritis (RA) include conventional therapy (DMARDs) and biological therapy (BT), but BT is still associated with high costs and has impacted the budget in Colombian Health System. We aim to describe the effectiveness of conventional DMARDs therapy in patients with RA by reducing the Disease Activity Score 28 (DAS28) in patients with moderate-severe disease activity during 5 years in a specialized center in RA and subsequently cost savings obtained. **METHODS:** We conducted a real-world, descriptive cohort study. We included patients who had moderate/severe disease activity in a specialized RA center in Bogotá, Colombia during 2012-2016. These patients were potential candidates for biological therapy and were followed-up under T2T standards. Clinical follow-up was done according to DAS28: every 3-5 weeks (DAS28 > 5.1), every 7-9 weeks (DAS28 ≥ 3.1 and ≤ 5.1), and every 11-13 weeks (DAS28 < 3.1). Therapy had to be adjusted with DAS28 > 3.2 unless patient's conditions don't permit it. Descriptive epidemiology was done; the means were analyzed using Chi2 test performing a normality test for DAS28 distribution. **RESULTS:** 776 patients meet inclusion criteria; 83% were female, mean age was 64 ± 10. At baseline 616 (79%) had moderate disease activity and 160 (21%) severe disease activity, mean DAS was 4.7 ± 1.0. After a 5 year of follow-up, 80% of patients achieved remission/low disease activity. The cost of biological therapy in Colombia finishing 2016 on average was 9201 US dollars/year/patient, and for 613 patients amount in projected costs-savings of preventing use of biologics was approximately 5,640,213 US dollars/year. **CONCLUSIONS:** The results of this cohort showed the effectiveness of conventional DMARDs therapy for the achievement of remission/low disease activity in patients with RA in a model with T2T strategy and a multidisciplinary approach, leading to significant cost savings for health system.

PMS32

COST-EFFECTIVENESS OF THERAPIES FOR EARLY RHEUMATOID ARTHRITIS IN THE CONTEXT OF THE EVIDENCE-BASED CLINICAL PRACTICE GUIDELINE FOR COLOMBIA

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OBJECTIVES: To evaluate the cost-effectiveness of two or more non-biological DMARDs versus biological+MTX in the context of the evidence-based clinical practice guideline for Colombia. **METHODS:** The analysis of cost effectiveness was conducted in development of the clinical practice guideline for early detection, diagnosis, and treatment of the Rheumatoid Arthritis in Colombia. A decision tree was constructed to determine the cost-effectiveness. The patients over the age of 16, with early rheumatoid arthritis or very early, with two or more poor prognostic factors and high activity of the disease during one year. The model compared two or more non-biological DMARDs versus a biological+ methotrexate. Efficacy information was taken from the controlled clinical trial (Goekoop-Ruiterman et al., 2005), and the costs of procedures and medications from national tariff system. The perspective of the General System of Social Security in Health (third payer) was used. The remission of the disease was the outcome. **RESULTS:** The average cost of a case of remission in a year with DMARDs was 448,68 USD, and with biological+MTX was 10,591 USD. One additional case of remission in a year with biological+MTX versus 2 DMARDs has an

incremental cost of 338,063.3 USD. In the sensitivity probability analysis with a threshold of 3 GDP per capita (14,998 USD), the 70,27% of the estimates for biological+MTX was above the threshold, and 29,73% was a dominated strategy, since, it was less effective and more expensive than the alternative with DMARDs. **CONCLUSIONS:** The combination of a biological+MTX is not cost effective in the Colombian context, for the first line treatment of early rheumatoid arthritis in adult patients with high activity and two more poor prognostic factors.

PMS33

COST-EFFECTIVENESS OF SINGLE-DOSE ZOLEDRONIC ACID FOR NURSING HOME RESIDENTS WITH OSTEOPOROSIS

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OBJECTIVES: Hip fracture sustained in nursing homes is an important source of mortality, morbidity, and healthcare expenditure. The study aimed at evaluating the cost-effectiveness of routine administration of single-dose zoledronic acid in nursing home residents with osteoporosis. **METHODS:** A Markov cohort simulation model was developed. The target population was a hypothetical cohort of nursing home residents aged 85 years with osteoporosis. The analysis was conducted from a health care system perspective over a lifetime horizon. Two strategies were compared: a single intravenous dose of zoledronic acid 5mg (ZOL); and usual care (calcium and vitamin D supplementation only). Data sources were published literature. The relative risk of hip fracture was estimated based on a surrogate outcome of bone mineral density in the ZEST (Zoledronic acid in frail Elders to Strengthen bone) trial. The main outcome was incremental cost-effectiveness ratio (ICER) as measured by cost per quality-adjusted life year (QALY) gained. **RESULTS:** Compared with usual care, the ZOL strategy had an ICER of \$220,300 per QALY gained and was not cost-effective at a conventional willingness-to-pay threshold of \$100,000 per QALY gained. The results were robust to a reasonable range of assumptions about incidence, mortality, quality-of-life effects, and the cost of hip fracture and the administration cost of ZOL. The ZOL strategy had a potential to become cost-effective if 6-month mortality in nursing home residents was below 15% or if fracture risk reduction by ZOL was above 25%. Probabilistic sensitivity analysis revealed that the ZOL strategy would be cost-effective in 11%, 24%, and 42% of simulations at willingness-to-pay thresholds of \$50,000, \$100,000 or \$200,000 per QALY gained, respectively. **CONCLUSIONS:** Routine administration of single-dose zoledronic acid in nursing home residents with osteoporosis is not a cost-effective use of resources from a health care system perspective. It would be justifiable in nursing home residents with a favorable life expectancy.

PMS34

EXPLORATORY COST-EFFECTIVENESS EVALUATION OF DIFFERENT TREATMENT STRATEGIES FOR MENISCUS ROOT TEARS

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OBJECTIVES: Medial meniscus root tears are common among patients over 50 years of age, and are the biomechanical equivalent of a total meniscectomy, which typically leads to the rapid advancement of knee osteoarthritis. Studies have documented the clinical consequences of conservative therapy, meniscectomy and meniscus root repair, but limited information is available related to their long-term costs. Our objective was to explore the cost-effectiveness of these differing treatment strategies in the United States. **METHODS:** A Markov model was constructed to project strategy-specific progression to symptomatic osteoarthritis (OA), total knee arthroplasty (TKA) and revision TKA in a cohort of 50-year old patients presenting with no significant OA at time of treatment. Failure rates of repair and meniscectomy procedures were accounted for. Utilities, costs, and event rates were based on literature and public databases. Analyses considered a 10-year timeframe, and explored the effects of parameter uncertainty and of different analysis horizons. **RESULTS:** Over 10 years, 45.8% of the meniscectomy and non-treated patients were projected to have undergone TKA, compared to 29.3% of repair patients. Discounted 10-year costs were \$15,864 for repair, compared to \$17,943 and \$20,972 for no treatment and meniscectomy. Projected quality-adjusted life years (QALY) were 7.03, 6.75, and 6.72, respectively, yielding repair to be associated with most favorable outcomes at concurrent cost savings of \$2,079 compared to next best strategy. Repair was either cost-effective or dominant across a broad range of OA progression and repair failure rates. Analysis horizons of 2 years or longer found repair to be cost-effective, and dominant for horizons of 6 years or more. **CONCLUSIONS:** Our model-based projections suggest that repair of meniscal root tears is associated with improved mid- and long-term outcomes and cost savings relative to both meniscectomy and conservative therapy, making repair the most cost-effective strategy for meniscal root tears.

PMS35

THE COST-EFFECTIVENESS OF XIAN LING GU BAO FOR THE TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS IN CHINA: A DECISION-TREE MODEL

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OBJECTIVES: The multi-component Fufang (non-leguminous traditional Chinese herbal formulas with multi-interactive compounds) Xian Ling Gu Bao (XLGB) in capsular form was officially approved by China FDA for the management of menopausal osteoporosis and related conditions based on its safety and efficacy evidence. This study was conducted to evaluate the cost-effectiveness of XLGB versus placebo in the management of postmenopausal osteoporosis from Chinese

payer's perspective. **METHODS:** A decision-tree model based on the BMD change efficacy information from a randomized clinical trial (RCT) was developed to estimate the outcomes of XLGB treatment over 10 years. After one-year treatment of XLGB or placebo, changes in bone mineral density (BMD) in femoral neck were utilized to predict the 10-year risk of hip fracture and thus the risk of hip-fracture related mortality. The 10-year hip fracture risk was assessed via FRAX[®] WHO Fracture Risk Assessment Tool. The mortality followed by hip fracture was estimated from a large population-based cohort study among Taiwanese. The effects of hip fracture on utilities were estimated based on a systemic review. Cost data, including treatment cost of hip fracture and adverse events were obtained from literature and KOL survey. A one-way sensitivity analysis was conducted. **RESULTS:** The total cost for XLGB and placebo was ¥6,911.77 and ¥5,789.69, respectively. The QALY of XLGB group was 5.302 while that of placebo group was 3.286. The ICER value of 70,396.91 RMB/QALY, which is below the WHO recommended threshold (less than 3 times of GDP) in all Chinese provinces, indicating that XLGB is a cost-effective alternative for treating postmenopausal osteoporosis. The one-way sensitivity analysis of key parameters suggested the robustness of the model. **CONCLUSIONS:** Compared with placebo, XLGB is a cost-effective alternative for the treatment of postmenopausal osteoporosis in China.

PMS36

MODELING THE COST-EFFECTIVENESS OF RITUXIMAB USE COMPARED TO TUMOR NECROSIS FACTOR INHIBITORS (ANTI-TNF) AGENTS AS A SECOND-LINE THERAPY IN PATIENTS WITH RHEUMATOID ARTHRITIS (RA) IN QUEBEC, CANADA USING RHUMADATA REGISTRY DATA

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OBJECTIVES: No guidelines are available for selecting a particular biologic agent for Rheumatoid Arthritis (RA) treatment. We conducted a cost-utility analysis to compare rituximab and three tumor necrosis factor inhibitors (anti-TNF) (adalimumab, etanercept, and infliximab) used as second-line therapy in terms of direct RA-related costs borne by the public health care system and Quality Adjusted Life Years (QALYs) gained. **METHODS:** Four two-state (e.g., "on second-line treatment" and "after failing second-line treatment") Markov models reproduced the 6-years long course of patients treated either with adalimumab, etanercept, infliximab or rituximab. Baseline patient characteristics, transition probabilities, cost and treatment effectiveness were estimated for each group of patients based on the data from a clinical registry RHUMADATA[®]. We included RA patients who started the second-line treatment between January 1st, 2007 and January 1st, 2013. Only patients who had complete data on baseline and follow-up Health Assessment Questionnaire (HAQ) scores were included in this preliminary analysis. Transition probabilities for rituximab and the combined anti-TNFs were obtained from Kaplan-Meier survival estimates of the 6-year drug retention rates. Unit costs (2016 CAD) from Quebec, Canada were applied to value RA-related healthcare resources used (e.g., biologic agent and rheumatologist visits costs) measured on an item-by-item basis. Treatment effectiveness was measured in QALYs calculated from HAQ scores over follow-up time. **RESULTS:** Out of 130 RA patients identified, 96 patients were included in this preliminary analysis. Over 6 year follow-up, rituximab as a second-line treatment was associated with cost of \$18,312 and effectiveness of 2 QALYs and was dominant over treatment with adalimumab, etanercept, and infliximab, which were associated with cost of \$22,022, \$21,976 and \$26,502, and effectiveness of 1.98 QALYs, 1.97 QALYs and 1.76 QALYs, respectively. **CONCLUSIONS:** Based on results of the preliminary analysis, the second-line rituximab therapy was more effective and less costly when compared to adalimumab, etanercept, and infliximab.

PMS37

COST MINIMIZATION ANALYSIS IN THE SWITCH OF INFILIXIMAB FOR ITS BIOSIMILAR IN THE BRAZILIAN PRIVATE HEALTHCARE SYSTEM

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OBJECTIVES: To develop a cost minimization analysis in the switch of infliximab to it biosimilar, in the treatment of rheumatoid arthritis (RA) from the perspective of Brazilian private health system (BPHS). **METHODS:** A cost minimization analysis model was developed to measure the impact of treatment switch from infliximab to its biosimilars. The analysis considered the perspective of the BPHS, and has included only direct costs of medicines (as regulated by the local Ministry of Health), in a cohort of 2 million lives (based on average of top 10 largest Brazilian Private Health Plans). The incidence rates for RA in the Brazilian population (0.46%; N= 9,200), followed by an estimate percentage of patients treated with infliximab (34.15%; N=3,142), for the switch scenario were considered an increasingly switching rate from 30% with additional 5% early, up to 50% at the end of 5 years. The population was adjusted using a growth rate of 0.09% after first year. **RESULTS:** During first year, the "without switch" scenario costs were BRL 151,769 million, followed by BRL 151,905 million, BRL 152,042 million, BRL 152,178 million and BRL 152,315 million in the following years. For the "switch to biosimilar" scenario costs were BRL 136,088 million in the first year, followed by BRL 133,596 million, BRL 131,099 million, BRL 128,594 million and BRL 126,091 million in the following years. The difference between the scenarios generated an economy of BRL 15,6 million followed by BRL 18,3 million, BRL 20,9 million BRL 23,5 million and BRL 26,2 million in the following years resulting in a total economy of BRL 104,7 million. **CONCLUSIONS:** The switch to biosimilar could provide payers an option for expenditures reduction, being a viable alternative for physicians to provide the chosen treatment at a lower cost, increasing the access to the drug, and overall treatment availability.

PMS39

IMPACT OF RHEUMATOID ARTHRITIS ON EMPLOYMENT AND PRODUCTIVITY LOSS AMONG NON-INSTITUTIONALIZED INDIVIDUALS IN THE U.S.

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OBJECTIVES: Rheumatoid arthritis (RA) is a chronic inflammatory condition characterized by chronic pain and joint deformity, which affects function, productivity and overall quality of life. There is limited literature on nationally representative estimates of current RA-related burden. Our objective was to examine the impact of RA on employment and productivity loss among adults in the US. **METHODS:** In this pooled cross-sectional study, we used the Medical Expenditure Panel Survey (MEPS) data for the years 2010-2014. We identified RA patients using the clinical classification code - 202 and ≥ 45 years of age. We measured employment disability, days missed at work for employed and days in bed (2010-2012) for unemployed RA patients. Additionally, we measured productivity loss as limitation in work, housework or any activity. We used multiple logistic and negative binomial regression models to control for covariates such as age, gender, race, education, occupation, comorbidities, and overall health status. The wage estimates are for 2014 and value of home productivity for 2012. **RESULTS:** In descriptive analysis, more RA patients were older, females, not working due to illness, had limitation in work, housework and any activity. In adjusted analysis, compared to non-RA, the RA patients were 74% more likely to have employment disability (95% CI 1.34-2.27) leading to per capita wage loss of \$6,990 (95% CI \$4,418-\$9,994); had 1.52 missed work days (p=0.02) corresponding to \$160 per capita productivity loss. At home, RA patients spent 1.92 days in bed (p<0.01) with per capita productivity loss of \$81. Additionally, RA patients were 24% and 44% more likely to have limitations in housework and any activity respectively. **CONCLUSIONS:** RA is highly associated with productivity loss both at home and in the workplace. These results will help inform interventions aimed at reducing the overall economic burden associated with RA in different at-risk groups.

PMS40

HEALTH CARE RESOURCE USE OF MEDICARE BENEFICIARIES WITH PRIMARY OSTEOARTHRITIS (OA) OF THE KNEE - A CLAIMS DATA ANALYSIS

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OBJECTIVES: To estimate how health care resource use patterns have shifted over time for Medicare beneficiaries with primary knee osteoarthritis (OA) across 5 care delivery settings. **METHODS:** De-identified patient level claims data from 2009 and 2014 were provided by CMS. Datasets for primary care, home-health, inpatient, outpatient, and skilled nursing facilities (SNF) were assessed. 534,004 primary knee OA patients were identified using ICD-9 codes 715.16, 715.36, 715.96, and excluding confounding comorbidities such as rheumatoid arthritis. Submitted costs for each site of care per dataset year were analyzed to report resource utilization trends. A benchmark population without OA will also be generated using demographics-based propensity score matching and the burden of OA will be calculated. **RESULTS:** On average, each OA patient had 1.2 inpatient stays, 7.7 outpatient visits, 9.9 primary care visits, 0.89 home care episodes and 0.16 SNF stays in 2009. In 2014, the number of primary care visits increased to 11.3 and SNF stays tripled to 0.48, while outpatient visits decreased slightly to 7.28 and home care utilization dropped to near-zero. In both years, 95% of OA hospitalizations were for joint replacements with an average length of stay of 3 days. The cost of delivering care increased for most of the settings. In 2009, average cost (inflated to 2014 value) for each episode of care in inpatient, outpatient, and SNF setting was \$52,949, \$1,079, and \$8,236, respectively. In 2014, this changed to \$55,379, \$1,403, and \$8,517, respectively. For primary-care visits, while cost per visit decreased (\$165 to \$147), overall costs for visits increased. **CONCLUSIONS:** Primary knee osteoarthritis is a significant source of economic burden in Medicare patients. Overall, most costs have increased between 2009 and 2014, despite adjustment for inflation. Further research into overall burden and cost drivers will assist in understanding treatment trends in the OA Medicare population.

PMS41

HEALTH CARE RESOURCE USES AND COSTS IN COLOMBIAN EARLY RHEUMATOID ARTHRITIS PATIENTS

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OBJECTIVES: To establish the use of health resources (drugs, clinical laboratory, diagnostic imaging, medical appointments and absenteeism) and costs related to the care of early rheumatoid arthritis (ERA) in a Colombian real world. **METHODS:** A cohort of 345 patients with ERA from two health care institutions in Bogota, Colombia, followed by two years (2013-2015). On the first appointment, patients were classified according to the disease activity (DAS), and were checked every three months. In this period, the use of resources and costs for each patient was identified. **RESULTS:** The total cost for 345 patients was \$2,323,373 USD. According to DAS in the first appointment patients were classified as: remission 13.3%, low 7.8%, moderate 42.9%, and high 35.9%. The 21.2% of the patients received biological treatment, representing a cost of care equivalent to 86.4% of the total cost. In the biological group, distribution of costs by initial DAS was remission 3.1%, mild 1.6%, moderate 30.8%, and high 64.5%; additionally, drugs accounted for 95.6% of the cost of care, followed by work absenteeism with 3.3%. The 78.8% of patients received treatment with DMARDs, its cost of care was 13.6% of the total. The distribution of costs by initial DAS was remission 8.2%, low 8.2%, moderate 40.5%, and high 43.1%. In this group, the drugs represent 42.5% of the cost, and the absenteeism 37.2%. The average cost of care per patient with biologicals was \$27,505 USD and \$1,160 USD DMARDs. The average of work absenteeism by patient days were 64.2 and 31.3 respectively. **CONCLUSIONS:** The most expensive stage was high, followed by the

moderate for the two groups of the study. The group that received biologicals on average is 23.7 times more expensive than the DMARDs group.

MUSCULAR-SKELETAL DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

PMS42

SWITCHING AND MEDICATION PERSISTENCE OF PATIENTS TAKING DISEASE MODIFYING ANTI RHEUMATIC DRUGS (DMARDS): A COMPARATIVE EFFECTIVENESS STUDY

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OBJECTIVES: Rheumatoid arthritis (RA) is a chronic autoimmune disorder that affects small joints of the hands and feet. It usually results in swollen and painful joints. In severe cases, there may be lethargy and weakness which progresses within months. Despite the progress in the area of Rheumatoid Arthritis in terms of prognosis, drug response and treatment modalities can be erratic. Patients are typically switched to agents with similar action and efficacy. This study is aimed at determining the number and proportion of rheumatoid arthritis patients with a new start of a DMARD, switching to another DMARD within a 6 and 12 month period. **METHODS:** This study is a retrospective analysis of a cohort of Rheumatoid Arthritis patients. This study will utilize the Mississippi Medicaid administrative claims database. Patients must be ≥ 18 years identified through a diagnosis of Rheumatoid arthritis with ICD 9 code (714.xx) and ICD 10 code (M06.9). The index date will be the date of a new start for a DMARD within the time period and continuous eligibility in Medicaid for 6 months would be the pre index period. The primary outcome of interest would be to determine the number patients that change from their current DMARD to another within the time frames – 6 months and 12 months following initial therapy. Patients must also be DMARD naïve prior to study. **RESULTS:** 980 patients on 10 different DMARDS were identified using the inclusion criteria, all patients were consistent with their medication for the initial 6 months. However, 63 patients switched to another DMARD or quit their current DMARD therapy within a 12 month period. **CONCLUSIONS:** This study shows that majority of patients currently on DMARDS show tolerability to their current medication, although a significant number of patients do not tolerate therapy after using these medications for some time.

PMS43

ADHERENCE EVALUATIONS FOR TUMOR NECROSIS FACTOR ALPHA INHIBITORS FOR RHEUMATOID ARTHRITIS I

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OBJECTIVES: To characterize one-year follow-up rates of treatment response parameters in new users of tumor necrosis factor (TNF)-alpha inhibitors for rheumatoid arthritis in nationally representative medicare and commercial claims databases. **METHODS:** A retrospective cohort analysis of RA patients in the 2011 Truven MarketScan database was conducted. Subjects were required to have RA based on ICD-9 code, at least one claim for one of the TNF-alpha inhibitors and 12 months continuous enrollment before and after the first TNF-alpha inhibitor claim. Adherence was defined as medication possession ratio of at least 80%. Glucocorticoid equivalent dose of at least 10 mg designated flare management. Analyses conducted using SAS 9.4 (Cary, NC) and Python 9.4.3 (Python Software Foundation). **RESULTS:** In the Medicare cohort (n=8,123), 33.0% of new users experienced a 60 day gap or more or switched TNF-alpha inhibitors. Regarding adherence, 37.2% were non-adherent. In terms of glucocorticoid usage, 7.2% of the cohort failed based on increased glucocorticoid dose and 4.0% failed based on glucocorticoid initiation. In terms of DMARDs, 67.2% of the cohort used a DMARD concurrently with TNF-alpha inhibitor use. Outpatient costs during the study period were an average of \$413 and TNF-alpha inhibitor costs were an average of \$20,516. In the commercial cohort (n=41,244), 41.0% of new users experienced a 60 day gap or more or switched TNF-alpha inhibitors. Regarding adherence, 47.2% were non-adherent. In terms of glucocorticoid usage, 7.7% of the cohort failed based on increased use of glucocorticoid and 4.3% failed based on glucocorticoid initiation. In terms of DMARDs, 73.4% of the cohort used a DMARD concurrently with TNF-alpha inhibitor use. Outpatient costs during the study period were an average of \$518 and TNF-alpha inhibitor costs were an average of \$19,558. **CONCLUSIONS:** Substantial discontinuation and nonadherence present challenges to RA management. Developing means of improving appropriate use are needed.

PMS44

IMPACT OF ABBVIE'S PATIENT SUPPORT PROGRAM (PSP) ON PERSISTENCE WITH ADALIMUMAB THERAPY AMONG PATIENTS WITH RHEUMATOID ARTHRITIS IN URUGUAY

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OBJECTIVES: AbbVie provides a PSP to support adalimumab (ADA)-treated patients with laboratory tests, nurse support, injection training, pen disposal, and medication reminders. We investigated associations between PSP and rate of ADA persistence among ADA-treated patients with rheumatoid arthritis (RA) in

Uruguay. **METHODS:** A retrospective study was conducted (03/2010–11/2014) among adults with RA who initiated ADA and opted-in to the PSP (PSP-users) versus patients who initiated ADA and did not opt-in to PSP (non-users). All patients were evaluated using AbbVie's PSP database and available dispensing data at 12 and 24 months following initiation. For PSP-users, the index date was the date of enrollment. ADA initiation was used to assign index dates to non-users. The difference in persistence (time from index date to ADA discontinuation date) between PSP-users and non-users was evaluated. Discontinuation was defined as no ADA dispensing for 3 consecutive months. No formal statistical tests were required because the full population of ADA-treated patients in Uruguay was analyzed, eliminating the need for hypothesis testing. **RESULTS:** A total of 210 (98 PSP-users, 112 non-users) and 136 (44 PSP-users, 92 non-users) patients were available for the 12- and 24-month analyses, respectively. By 12 months, PSP-users persisted on ADA for an average of 11 months versus 9.98 months for non-users. Persistence on ADA continued to be higher at 24-months with PSP-users using ADA for an average of 20.0 months versus 16.2 months for non-users, resulting in 23% more time spent on therapy for PSP-users. **CONCLUSIONS:** Enrollment in AbbVie's PSP resulted in a higher persistence for ADA among Uruguayan patients with RA, demonstrating that it is an important tool for helping patients adhere to their medication. Additional studies are needed to evaluate PSP impact on disease control, patients' and physicians' preferences, and associated healthcare resource utilization.

PMS45

TRANSLATION AND VALIDATION OF THE CQR-19 FOR ROMANIAN PATIENTS WITH RHEUMATIC DISEASES

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OBJECTIVES: The aim of the study was to translate and validate a Romanian version of the original English edition of the 19th Compliance Questionnaire for Rheumatology (CQR-19) and use it for Romanian patients with rheumatic diseases. **METHODS:** The questionnaire was translated into Romanian by two translators, native speakers of Romanian, familiar with the medical aspects and each translated item was pilot-tested to 10 patients with rheumatic diseases in several community pharmacies in Craiova, Romania. After identifying and resolving the problems in translation, CQR-19 was applied to a sample of 100 patients with rheumatic diseases, with 50 patients completing them again after 3 weeks. Reliability, validity and responsiveness were evaluated. Test-retest reliability was tested by Cronbach's alpha and Intraclass Correlation Coefficients (ICC). The 4-point Likert scale was used to calculate the adherence for each patient. We used SPSS v.19.0 in order to examine the characteristics of the sample and of the questionnaire. Correlations were conducted to evaluate the possible associations between various sociodemographic factors and medication adherence. **RESULTS:** The mean age of the sample was 52.4 years (SD=17.88 years), 46% were male, 88% living in urban, 8% had finished high school, 62% had graduated a faculty, 45% were employed. The mean score for the medication adherence was 61.99 (95%CI, 58.41-65.57). The Romanian version was easily understood by the patients and had good levels of reliability (Scale's reliability analysis revealed a Cronbach's alpha of 0.76) and consistency (ICC=0.88). It was found that age was related to adherence score (rs=0.48, p<0.05), indicating that older people were more likely to adhere to antirheumatic medication. Gender, living place, level of education and job didn't influence adherence's level. **CONCLUSIONS:** The Romanian version of the CQR-19 is a reliable and valid measure to evaluate the adherence for patients with rheumatoid arthritis.

PMS46

HEALTH-RELATED QUALITY OF LIFE FOLLOWING A TRAUMATIC BRAIN INJURY: A RETROSPECTIVE OUTCOMES ANALYSIS FROM SAUDI ARABIA

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OBJECTIVES: In Saudi Arabia, trauma is associated with 18% of all fatalities, representing the leading cause of death. Among the wide spectrum of injuries, traumatic brain injuries (TBI), pose a pervasive threat as they significantly impact health outcomes. If not fatal, TBIs are associated with long-term disabilities and little is known on the burden of trauma-related disability in the country, and specifically due to TBI. Thus, the study aims to examine long-term health outcomes of TBI survivors treated at a level-I trauma center. **METHODS:** We used a dataset from King Abdulaziz Medical City in Riyadh. To be included in the study, patients had to be hospitalized due to a TBI between years 2005-2014. Of the 1,620 patients (age=16-60 years) who met the inclusion criteria, a 50% random sample was selected. Patients were contacted via the phone and information about Activity of Daily Living (ADL) and Instrumental Activity of Daily Living (IADL) was ascertained. Univariate analyses were performed to examine patients' characteristics and to estimate the prevalence of disability. **RESULTS:** Of the 760 patients contacted, 3 patients were deceased. Of the remaining, 260 (34%) patients were reached and agreed to participate in the study. The overall sample was relatively young (mean age= 24.8; SD=9.8) and predominantly males (92.7%). The average time since the injury is 6.8 years (range=3-12, SD=2.6). Of the TBI patients, 25.4% reported at least some limitations in ADL while 19.8% reported IADL limitations. Half of TBI patients in the study received at least one session of rehabilitation services. **CONCLUSIONS:** The fact that one of every four TBI patients becomes disabled poses a significant burden on population health and healthcare institutions. Further studies are warranted to elucidate the reasons for these findings. More importantly, this highlights the need for further investment in injury prevention programs in order to reduce associated disabilities.

PMS47

WORK PRODUCTIVITY AND GENERAL HEALTH STATUS IMPROVEMENTS WITH SIRUKUMAB, AN ANTI-IL-6 CYTOKINE MONOCLONAL ANTIBODY, IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS DESPITE ANTI-TNF THERAPY: RESULTS FROM THE PHASE 3 SIRROUND-T STUDY

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OBJECTIVES: This study evaluated effects of sirukumab, a selective anti-IL-6 cytokine monoclonal antibody, on work productivity/interference and health status in patients with active rheumatoid arthritis (RA) despite treatment with anti-tumor necrosis factor (TNF) therapy. **METHODS:** In this randomized, double-blind, phase 3 trial, 878 eligible patients with active RA who were intolerant/refractory to anti-TNFs were randomized 1:1 to sirukumab subcutaneous (SC) 50mg every 4 weeks (q4w; n=292), sirukumab SC 100mg every 2 weeks (q2w; n=292), or placebo SC q2w (n=294). At Week 18, placebo patients were re-randomized to 1 of the sirukumab doses if insufficient (<20%) improvement; at Week 24, all patients remaining on placebo crossed over to sirukumab. The Work Limitations Questionnaire (WLQ) evaluated health-related job limitations and productivity loss in 4 domains (mental-interpersonal, output, physical demands, time management); the 3-level EuroQol-5 Dimension (EQ-5D) questionnaire measured 5 dimensions of health status (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). **RESULTS:** At Week 24, mean total WLQ scores improved significantly from baseline for sirukumab 50mg q4w and 100mg q2w versus placebo (mean change, -2.2 and -2.3 vs 0.2, respectively; both p<0.001), as did all 4 mean WLQ domain scores (all p<0.01). Improvements from baseline in mean total WLQ and all 4 domain scores were maintained through Week 52 for both sirukumab doses. Mean EQ-5D index and health state visual analog scale (VAS) scores improved significantly from baseline at Week 24 for sirukumab 50mg q4w and 100mg q2w versus placebo (mean index change, 0.2 and 0.2 vs 0.0, respectively; mean VAS change, 13.9 and 15.4 vs 4.8, respectively; all p<0.001); improvements from baseline were maintained through Week 52 with both sirukumab doses. **CONCLUSIONS:** Sirukumab treatment led to significant improvements in work-related productivity and general health status in patients with active RA despite anti-TNF therapy, consistent with demonstrated effects of sirukumab on RA disease improvement.

PMS48

REAL-WORLD, MULTI-SITE, OBSERVATIONAL STUDY OF INFUSION TIME AND TREATMENT SATISFACTION IN RHEUMATOID ARTHRITIS (RA) PATIENTS TREATED WITH INTRAVENOUS GOLIMUMAB (GLM-IV) OR INFliximab (IFX)

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OBJECTIVES: This study assessed infusion times associated with GLM-IV and IFX in RA patients and factors associated with patient satisfaction for these treatments. **METHODS:** An observational study in RA patients at 6 US sites assessed GLM-IV or IFX infusion time variables including: **clinic visit duration** - time from patient's arrival to verbal discharge; **total infusion time** - time from infusion start to completion; and **total infusion process time** - the sum of medication preparation, patient preparation, and medication infusion times. Patient satisfaction was assessed by Treatment Satisfaction Questionnaire for Medication (TSQM-IV) and study-specific questionnaires. Descriptive statistics and comparative tests (analysis of variance for continuous and Fisher's exact test for categorical measures) were summarized. **RESULTS:** RA patients (n=150; 72 GLM-IV; 78 IFX) from 6 US sites were studied. Mean age of GLM-IV cohort was 61 years; 85% were female. The IFX cohort was older (66 years; P=0.0105), had fewer females (76%; not statistically significant—NS) and higher proportion of retirees (64% IFX vs. 40% GLM-IV). Mean weight was 83.8 kg for GLM-IV and 85.4 kg for IFX (NS). Infusions of GLM-IV and IFX averaged 3.7 and 4.9 vials, respectively. Mean clinic visit times were 65.1 (GLM-IV) and 153.1 minutes (IFX; P<0.0001). Mean medication infusion times were 32.8 (GLM-IV) and 119.5 minutes (IFX; P<0.0001). Mean infusion process times were 45.8 (GLM-IV) and 134.1 minutes (IFX; P<0.0001). Higher overall satisfaction ratings were reported by GLM-IV than IFX patients for the following: infusion time (P<0.0001), visit time (P<0.0003), and length of time the IV line was inserted (P<0.0001). **CONCLUSIONS:** Shorter overall clinic, infusion process, and medication infusion times were observed for GLM-IV compared to IFX. These differences were driven primarily by shorter medication infusion time. Shorter infusion time, shorter visit time, and shorter IV insertion time were associated with higher patient satisfaction ratings.

PMS49

RHEUMATOID ARTHRITIS AND PATIENT BURDEN OF DISEASE

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OBJECTIVES: To describe patient reported outcomes (PROs) among those who have initiated targeted biologic treatment in a US observational cohort of patients with Rheumatoid Arthritis (RA). **METHODS:** Eligible patients were from the Corrona RA registry who had initiated a biologic agent between 2001-2016 and had a 6 month follow-up visit post initiation. Outcomes included the Clinical

Disease Activity Index (CDAI), pain and fatigue (visual analog score; 0-100); morning stiffness (yes/no and hours); patient reported depression and anxiety; and others. Participants were grouped by initiation of a biologic: 1st line initiators, (patients initiating their 1st biologic), 2nd line initiators, and 3rd+ line initiators and by Tumor Necrosis Factor inhibitors (TNFi) and non-TNFi therapies. Means (SD) of outcomes are presented as changes between initiation and the 6 month follow-up visit by line of therapy. **RESULTS:** 11,299 patients initiated a biologic agent, 79% were female with mean (SD) age of 56.9 (12.9) years. Mean (SD) CDAI improvements from baseline to follow-up were -8.9 (14.2) 1st line, -6.6 (13.5) 2nd line, -6.4 (14.1) 3rd+ line. Mean CDAI improvements in TNFi initiators were -9.1 1st line, -5.9 2nd line, -5.5 3rd+ line vs -6.9, -7.8 and -6.9 in non-TNFi initiators, respectively. Follow-up average (SD) pain scores by line of therapy were 33.5 (27.5), 39.6 (27.7), 46.9 (27.7) (changes of -10.9, -7.5 and -7.5); fatigue scores: 39.0 (29.8), 43.7 (29.7) and 51.6 (28.6) (changes of -6.8, -4.6 and -5.0). 71%, 78% and 85% still experienced morning stiffness (average 1.5-2.0 hours/day at follow-up). Patient reported anxiety and depression were similar at baseline and follow-up. **CONCLUSIONS:** Despite many therapies to treat RA, patients still experience significant burden of disease. For the majority of outcomes, biologic naïve patients reported the largest improvements; lesser improvements occurred in 2nd and 3rd line initiators. Initiators of non-TNFi had more homogenous changes across lines of therapy.

PMS50

PATIENT REPORTED OUTCOMES AND CHANGES IN DMARD THERAPY FOR RHEUMATOID ARTHRITIS IN ROUTINE CLINICAL PRACTICE

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OBJECTIVES: To examine the role of patient reported outcomes (PRO) as assessed by the RAPID3 in guiding therapy in rheumatoid arthritis (RA) in routine clinical practice. **METHODS:** The OM1 RA Data include electronic medical record (EMR) data (from a specialized rheumatology EMR) on ~75,000 patients diagnosed with RA, from rheumatology practices across the US. This analysis includes 64,663 patients on DMARDs seen between January 2013 and June 2016. RAPID3 scores within 30 days before changes to DMARD drugs were compared with those at other subsequent time points in a linear mixed model. The RAPID3 is scored 0-10 with higher scores associated with higher disease activity. To adjust for differences in follow up, data were censored at 24 months after the first DMARD recorded in the database. **RESULTS:** During the study period, there were 32,635 changes in DMARD therapy among 24,053 patients. 51% of physicians collected RAPID3s on at least 25% or more of their patients. Patients with ≥2 RAPID3 measurements (n=4,856) were more likely to have a DMARD change than patients with ≤1 measurement (n=59,807; 50% vs. 36%, p<0.001 by Chi square test). RAPID3 scores reported in the 30 days prior to a change in DMARD therapy (mean±SD=4.4±2.3) were worse than scores reported at time periods not associated with change in therapy (3.6±2.4) (p<0.001). In a mixed model, with time in months as a fixed effect and patients as a random effect, patients with changes in DMARD therapy had worse RAPID3 scores than those who did not have change in DMARD (p<0.001). **CONCLUSIONS:** Rheumatologists that routinely monitor PROs (e.g., RAPID3) in clinical practice appear to use that information to guide DMARD therapy in patients with RA. Patients reported worse RAPID3 before they changed therapies.

PMS51

ASSOCIATION OF OBESITY WITH PATIENT-REPORTED OUTCOMES IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS: A CROSS-SECTIONAL STUDY IN AN URBAN ASIAN POPULATION

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OBJECTIVES: To determine if obesity is associated with poorer patient-reported outcome (PRO) in patients with Spondyloarthritis (SpA). **METHODS:** We conducted a cross-sectional study using data of the PREcision medicine in SpOndyloarthritis for better Outcomes and Disease remission (PRESPOND) registry from a tertiary referral centre in Singapore between 2011-2015. All patients fulfilled the Assessment of Spondyloarthritis (ASAS) 2009 criteria. Demographics, clinical and PRO variables were collected. Patients were divided into three categories: normal (BMI <23 kg/m²), overweight (23 kg/m² ≤ BMI <27.5 kg/m²) and obese (BMI ≥27.5 kg/m²), using Asian BMI classification. The dependent variables are Pain Score, Bath Ankylosing Spondylitis Patient Global Score (BAS-G), Bath Ankylosing Spondylitis Disease Activity Score (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Health Assessment Questionnaire (HAQ), Medical Outcomes Study Short Form 36 version 2 (SF-36) and Ankylosing Spondylitis Quality of Life questionnaire (ASQoL). Multivariate regression analyses were performed with these dependent variables and obesity categories, adjusting for confounders. **RESULTS:** Amongst 202 patients with SpA, 32% are overweight while 21% are obese. We found that patients in obese category had significantly poorer pain score (β: 12.81, 95%CI: 3.53,22.09) and BAS-G score (β: 10.43, 95%CI: 2.23,18.62) when compared to normal BMI patients. However, obesity was not associated with BASDAI (β: 0.53, 95%CI: -0.15,1.21), BASFI (β:0.36, 95%CI: -0.34,1.06), HAQ (β: -0.05, 95%CI: -0.17,0.07), ASQoL (β: -0.06, 95%CI: -1.60,1.48), Physical Component Summary (β: -1.03, 95%CI: -5.37,3.30) and Mental Component Summary (β: -2.40, 95%CI: -6.90,2.10) of SF-36. **CONCLUSIONS:** Obesity was associated with pain score and BAS-G score but not with BASDAI, BASFI, HAQ, SF-36 and ASQoL. Further study is needed to examine the causal relationship between obesity and poorer PRO.

PMS52

PRO INSTRUMENTS USED IN STUDIES OF ANKYLOSING SPONDYLITIS SINCE 1960

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OBJECTIVES: To create an evidence map of the different patient-reported outcome instruments used in studies of patients with ankylosing spondylitis, the geographical settings in which these studies were conducted and the interventions assessed. **METHODS:** We searched the heoro.com database (www.heoro.com) for PRO studies on ankylosing spondylitis published between 1960 and December 7 2016, and analysed the abstracts identified by the search to determine the different PRO instruments cited across the range of geographical locations and interventions. We presented the findings as an evidence map. **RESULTS:** We found a total of 128 abstracts that reported the use of 64 different PRO instruments. Of these, 22 instruments were specific for ankylosing spondylitis or other inflammatory arthritis, 27 were general instruments used to evaluate quality of life or utilities, 12 assessed non-disease-specific symptoms, in particular fatigue, or other conditions or diseases that were common comorbidities of people with ankylosing spondylitis, and three evaluated the impact of the disease on work productivity. The most frequently used tool was the BASDAI, cited in 66 abstracts, followed by the BASFI (54 abstracts), SF-36 (52 abstracts), AS Quality of life questionnaire (34), Health Assessment Questionnaire (20) and the EQ-5D (14). The Netherlands was the most frequent location for the studies, with 16 abstracts, followed by the United States (14 abstracts), then Germany, Turkey and the United Kingdom (12 abstracts each), then Canada (11 abstracts). Interventions assessed were generally targeted therapies such as TNF inhibitors and physical therapies. **CONCLUSIONS:** A wide range of PRO tools have been used in studies of ankylosing spondylitis from a wide range of locations, but only nine tools and six countries were cited in more than 10 abstracts.

PMS53

TREATMENT PATTERNS FOR PATIENTS WITH RHEUMATOID ARTHRITIS ENROLLED IN ACA EXCHANGE PLANS IN 2015

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OBJECTIVES: Disease-modifying anti-rheumatic drugs (DMARDs) are the standard of care for rheumatoid arthritis (RA). This study aims to identify factors associated with receipt of DMARDs among patients diagnosed with rheumatoid arthritis (RA) and enrolled in an ACA insurance exchange plan in 2015. **METHODS:** Member-level data were extracted from a large nationally representative and statistically de-identified administrative claims database. The sample included 23,278 members. Patients were included in the study if they were (1) 18 years old or older; (2) diagnosed with RA anytime during 2015; (3) continuously enrolled for at least 11 months. **RESULTS:** The sample was approximately 70% females with average age of 52. Twelve percent of RA patients enrolled in 2015 received DMARDs. The 65-69 and 75-79 age groups had proportionately more recipients of DMARDs (14.0% and 14.3%, respectively). Slightly higher proportion of enrollees in households with \$15,000 or less median income received DMARDs (14.2%), followed by households with income of \$100,000 or more (13.4%). There were more recipients of RA treatment drugs in West South Central (27.3%) and at the 'platinum' level (17.9%) Differences among age groups were not significant. The linear model revealed that difference between income of \$15,000 (14.2%) or less and \$30,000 - \$39,999 (9.6%) was significant ($p < .01$). The model showed that receipt of DMARDs differs significantly based on metal level: between 'bronze' (10.4%) and 'platinum' and between 'silver' (10.4%) and 'platinum' ($p < .001$). **CONCLUSIONS:** The probability of receiving DMARDs is associated with metal level and income level among the ACA enrollees. The finding that persons in households with lower incomes significantly receive DMARDs is revelatory and warrants further investigation.

PMS54

A SYSTEMATIC REVIEW OF THE ASSOCIATION BETWEEN OBESITY AND OUTCOME OF RHEUMATIC DISEASES

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OBJECTIVES: To provide a systematic review of current literature on the association of obesity and outcome of rheumatic diseases. **METHODS:** We conducted a literature search using related keywords on three databases: PubMed®, Embase® and PsycInfo®. We categorized the articles found into three categories, namely positive, neutral or negative association of obesity and outcomes of rheumatic diseases. The subject population, country, type of studies, number of patients, measurement of obesity and outcomes assessed were presented. Outcomes assessed were split into two categories, patient reported outcomes and clinical outcomes. **RESULTS:** A total of 3454 articles were screened and 48 articles were found to be relevant to the objective. About half of the studies showed that obesity has a negative association with outcomes of rheumatic disease. No conducted studies on psoriatic arthritis, ankylosing spondylitis, axial spondyloarthritis and polyarthritis showed that obesity has a positive association on outcomes. The disease population of most of the studies found by this systematic review are subjects diagnosed with rheumatoid arthritis (RA). Most of the studies were completed in western populations such as America and Europe **CONCLUSIONS:** A systematic review on the association of obesity and outcome of rheumatic diseases was conducted. Most of the completed studies are based on Western populations. Therefore, to achieve a more precise assessment of the association of obesity on the disease outcome in Asian populations, further studies devoted to examining Asian subjects suffering from various types of rheumatic diseases, in particular those other than RA are warranted.

PMS55

TREATMENT FAILURE, TREATMENT SWITCHING AND HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH ANKYLOSING SPONDYLITIS: RESULTS FROM A REAL WORLD SURVEY IN THE US

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OBJECTIVES: To describe the use and switching of biologics among ankylosing spondylitis (AS) patients, and the correlates of treatment failure. **METHODS:** US Rheumatologists and their AS patients completed surveys capturing reasons for switching biologics, including primary lack of efficacy (1st LE, initial non-response) and secondary lack of efficacy (2nd LE, loss of response over time). Patients reported HRQoL (SF-36, EQ-5D), work productivity and activity impairment (WPAI). Current biologic was determined as 'failed' if, after ≥ 3 months, rheumatologist perceived disease severity had worsened, remained severe, was 'unstable' or 'deteriorating', or they were dissatisfied with disease control, and/or did not consider treatment a 'success'. **RESULTS:** 92 Rheumatologists and 534 patients participated in the study. Of 525 patients with full treatment data, 19.8% had never received a biologic, 65.1% had received 1, 11.4% 2 and 3.6% ≥ 3 biologics. Of 76 patients with known reasons for switching from 1st biologic, 22.4% switched due to 1st LE and 38.2% due to 2nd LE. Despite 1st LE, patients (n=16) continued the 1st biologic for on average 12.6 months. Overall 17.4% patients were determined to be failing biologic treatment; 16.5% (43/261) on 1st biologic, 19.6% (9/46) on 2nd and 26.7% (4/15) on 3rd or later biologic. Failing patients reported significantly worse EQ-5D utility (0.68 vs 0.85) and SF-36 physical component summary (PCS; 37.2 vs 46.2), mental component summary (MCS; 42.4 vs 50.2) and social function domain (SF; 59.0 vs 80.8) scores (all $p < 0.0003$). Patients failing biologics had greater work productivity impairment (higher WPAI scores) than non-failing patients (36.6% vs 17.1%, $p = 0.0003$). **CONCLUSIONS:** Only a minority of biologic patients had ever switched biologic therapies. The main reasons for switching were loss or lack of efficacy. Despite treatment failure some patients did not switch biologics. Failing biologic treatment was associated with worse health utilities and HRQoL scores and lower work productivity.

PMS56

TREATMENT FAILURE, TREATMENT SWITCHING AND HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH PSORIATIC ARTHRITIS (PSA):

RESULTS FROM A REAL WORLD SAMPLE IN THE US

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OBJECTIVES: To describe use and switching of advanced therapy (AT; subcutaneous biologics, and small molecules (apremilast)), and the correlates of failure among PsA patients. **METHODS:** US specialists (Rheumatologists and Dermatologists) and their PsA patients completed surveys capturing reasons for switching AT, including primary lack of efficacy (1st LE, initial non-response), secondary lack of efficacy (2nd LE, loss of response over time). Patients reported HRQoL (SF-36, EQ-5D), work productivity and activity impairment (WPAI) and disability (HAQ-DI). Current AT was determined as 'failed' if, after ≥ 3 months, specialists perceived disease severity had worsened, remained severe, was 'unstable' or 'deteriorating', or they were dissatisfied with disease control and/or did not consider treatment a 'success'. **RESULTS:** 140 specialists and 628 patients participated in the study. Of 601 patients with full treatment data, 29.6% had never received AT, 52.7% 1, 11.3% 2, and 6.3% > 3 ATs. Of 93 patients with known reasons for switching from 1st AT, 36.6% switched owing to 2nd LE and 26.9% due to 1st LE. Despite 1st LE, patients (n=21) continued on 1st AT for on average 12.4 months. Overall 13.6% were determined to be failing AT; 12.0% (28/233) on 1st AT, 7.5% (4/53) on 2nd and 22.2% (6/27) on third or later AT. Failing patients reported significantly worse EQ-5D utility (0.73 vs 0.87; $p = 0.0002$), SF-36 physical component summary (39.8 vs 48.2; $p < 0.0001$), and social function domain (69.4 vs 82.8; $p = 0.0008$) scores than those not failing; mental component summary score was not significantly different (47.6 vs 50.8; $p = 0.0991$). They also reported higher WPAI (24.6% vs 13.4%, $p = 0.0018$) and HAQ-DI (0.60 vs 0.29, $p = 0.0009$). **CONCLUSIONS:** Few patients had ever switched AT, when switches occurred the main driver was loss or lack of efficacy. Some patients persisted with their current AT despite treatment failure; AT failure was associated with poorer health utilities and HRQoL scores and lower work productivity.

PMS57

BURDEN OF DISEASE ASSOCIATED WITH MOOD OR DEPRESSION IN PATIENTS WITH RHEUMATOID ARTHRITIS

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OBJECTIVES: The objective of this review is to synthesise available evidence on the burden of depression in rheumatoid arthritis (RA). **METHODS:** Burden of illness, cost, and health-related quality-of-life studies (2006-2015) were

systematically identified through MEDLINE, EMBASE and Cochrane databases. Literature was screened for eligibility by two independent reviewers based on pre-specified criteria. Studies evaluating relationships between RA outcomes and depression were analysed and findings summarised using descriptive statistics. **RESULTS:** Eighteen studies met eligibility criteria. The reported prevalence of depression in RA patients was in line with previous data (8.9%–47.3%). Overall annual healthcare costs and hospitalisation rates were significantly higher (nearly double) in patients with RA and comorbid depression versus those with RA alone. Depression was a risk factor for sick leave episodes, suggesting an impact on work productivity loss. Depression was significantly associated with increased disease severity at follow-up visits (as measured by 28-joint Disease Activity Scores, tender joint counts, and patient global assessment scores). Depression was also associated with slower clinical improvement (change in Clinical Disease Activity Index) and reduced odds of achieving clinical remission. Higher depressive domain scores on the MOODS-Spectrum were associated with significant worsening of Short Form-36 scores. Elevated Centre for Epidemiologic Studies Depression Scale (CES-D) scores (range, 0–60; higher scores indicate more depressive symptoms) were identified as independent predictors of elevated Pittsburgh Sleep Quality Index scores (indicating poorer sleep quality). A multivariate analysis showed a 2% increased risk of mortality with each 1-point increase on the CES-D. **CONCLUSIONS:** This comprehensive review and synthesis of available evidence showed that depression influences diverse RA outcome measures, including disease activity, response to treatment, quality of life, and sleep measures, suggesting that mental health is an important area to manage in RA. Further evidence is needed to determine whether treating depression improves RA outcomes.

PMS58

THE EFFECT OF GOLIMUMAB, AN ANTI-TNFA MONOCLONAL ANTIBODY, ON GENERAL HEALTH STATUS, DAILY ACTIVITY AND WORK PRODUCTIVITY IN SUBJECTS WITH ACTIVE ANKYLOSING SPONDYLITIS: 28-WEEK RESULTS OF THE PHASE III GO ALIVE TRIAL

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OBJECTIVES: To evaluate health-related quality of life (HRQoL) including general health status, daily activity, and work productivity outcomes of intravenous (IV) golimumab in subjects with active ankylosing spondylitis (AS). **METHODS:** In this randomized, double-blind, Phase 3 trial, adults with AS received golimumab 2 mg/kg (n=105) or placebo (n=103). At Week 16, placebo recipients crossed-over to golimumab. Current health state was measured by EuroQoL-5D index including 5 domains: mobility, self care, usual activities, pain/discomfort, and anxiety/depression; impact of AS on daily productivity was measured by visual analogue scale (VAS); and impact of AS on work productivity was measured by Work Limitations Questionnaire (WLQ) productivity loss score in subjects who work or volunteer, which was converted from the 25-item version. Changes from baseline were summarized at Weeks 8, 16, and 28. Unadjusted p-values of least square mean differences (LSMD) between treatment groups were based on analysis of covariance (ANCOVA) controlling for prior anti-TNF therapy. **RESULTS:** Mean EuroQoL-5D index improvements were greater with golimumab vs. placebo at Week 8 (0.16 vs. 0.04 [LSMD: 0.11, p<0.001]) and Week 16 (0.17 vs. 0.05 [LSMD: 0.11, p<0.001]). Greater mean reductions in impact of AS on daily productivity were observed with golimumab vs. placebo at Week 8 (–2.21 vs. –1.07 [LSMD: –1.18, p<0.001]) and Week 16 (–2.93 vs. –1.08 [LSMD: –1.89, p<0.001]). Likewise, greater mean reductions in WLQ productivity loss score were observed with golimumab (n=56) vs. placebo (n=64) at Week 8 (–2.86 vs. –1.72 [LSMD: –1.14, p=0.04]) and Week 16 (–3.46 vs. –1.87 [LSMD: –1.59, p=0.009]). At Week 28, placebo recipients who crossed over to golimumab had similar mean improvements from baseline in EuroQoL-5D index, productivity VAS, and WLQ productivity loss score as those randomized to golimumab. **CONCLUSIONS:** In active AS, IV golimumab improved HRQoL outcomes.

MUSCULAR-SKELETAL DISORDERS – Health Care Use & Policy Studies

PMS60

FACTORS ASSOCIATED WITH INITIATION OF BIOLOGICS IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS IN AN URBAN ASIAN CITY: A PRESPOND STUDY

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OBJECTIVES: Axial Spondyloarthritis (AxSpA) is a type of inflammatory rheumatic disease that is chronic in nature and can cause severe disability. As biologics play a crucial role in managing AxSpA, it is important for clinicians to understand why biologics are initiated or refused. Hence, we aim to examine if patient's sociodemographic, clinical characteristics, and patient reported outcomes were associated with biologics initiation in patients with AxSpA in Singapore. **METHODS:** Data from a dedicated registry, the PREcision medicine in Spondyloarthritis for better Outcomes and Disease remission (PRESPOND) from a tertiary referral centre in Singapore from January 2011 to July 2016 were used. Initiation of first biologics was the main outcome of interest. Logistic regression analyses were used to explore the association of duration of disease, age, employment status, BASDAI, SF-36 (PCS and MCS), ESR, comorbidities of peptic ulcer disease (PUD) and skin symptoms, as well as responsiveness to NSAIDs on biologics initiation. **RESULTS:** Of 189 eligible patients (age 37.7 ± 13.3 years, 76.2%

males), 30 (15.9 %) were started on biologics during follow-up. In the univariable analyses, higher ESR (OR=1.02; 95%CI 1.00-1.03; p=0.03) as well as presence of PUD (OR=3.78; 95%CI 1.14-12.5; p=0.03) were associated with higher odds of biologics initiation. Older age (OR=0.96; 95%CI 0.93-1.00; p=0.03) and good response to NSAIDs (OR=0.32; 95%CI: 0.14-0.72; p<0.01) were associated with lower odds. In the multivariable model, age (OR=0.93; 95%CI 0.89-0.98; p<0.01), MCS of SF-36 (OR=0.18; 95%CI 0.03-0.89; p=0.04), ESR (OR=1.02; 95%CI 1.00-1.04; p=0.02), presence of PUD (OR=10.4; 95%CI 2.21-48.8; p<0.01) and good response to NSAIDs (OR=0.23; 95%CI 0.08-0.61; p<0.01) were found to be associated with biologics initiation. **CONCLUSIONS:** Age, ESR, MCS of SF-36, comorbidities of PUD and responsiveness to NSAIDs were associated with biologics initiation. Thus, clinicians might consider using these factors to guide biologics treatment in patients.

PMS61

A SYSTEMATIC REVIEW OF THE FACTORS ASSOCIATED WITH THE INITIATION OF BIOLOGICS IN PATIENTS WITH RHEUMATOLOGICAL CONDITIONS

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OBJECTIVES: Rheumatological diseases place a significant burden on patients and society due to their association with multiple comorbidities and functional disability. As biologics play a crucial role in managing some of these diseases, it is important for clinicians to understand why biologics are initiated or refused so as to make better clinical decisions in the course of improving patients' disease outcomes. Although there were many studies investigating factors associated with initiation of biologics for patients with rheumatological conditions, there have been no systematic review that provide a comprehensive summary in this area. The objective of this paper is to provide a summary of factors associated with biologics initiation for patients with rheumatological conditions. **METHODS:** We performed a literature search in PubMed®, Embase® and PsycInfo®. We identified and screened studies according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). Factors were presented according to patient, disease-related, therapy-related, healthcare team-related and system in-place factors. **RESULTS:** A total 1755 articles were being reviewed and 25 articles were found to be relevant to our objective. Forty eight factors reviewed were categorized into five main categories namely patient factors (n=13), disease-related factors (n=12), therapy-related factors (n=10), healthcare team related factors (n=4) and system in-place related factors (n=9). An illustration for biologics initiation was also presented to allow clinicians to better understand the complex nature of decision making. **CONCLUSIONS:** Forty eight factors of five different categories were found to be associated with biologics initiation for patients with rheumatological conditions. Clinicians need to be mindful of the complex nature of these factors to optimize therapeutic outcomes of patients with rheumatological conditions.

PMS62

ASSOCIATION BETWEEN ALLOPURINOL DOSE-TITRATION AND SERUM URIC ACID LEVELS IN GOUT PATIENTS: US ELECTRONIC HEALTH RECORD DATA

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OBJECTIVES: To understand allopurinol dose-titration relative to sUA levels. Allopurinol is a first-line urate lowering therapy for patients with gout. The American College of Rheumatology guidelines recommend allopurinol dose-titration to maintain serum uric acid (sUA) levels <6 mg/dl. **METHODS:** This retrospective study used the de-identified Humedica electronic medical record database. The study included all sUA and allopurinol records among gout patients (ICD-9-CM: 274.xx) ≥18 years old with first gout diagnosis in 2007 – 2015. An episode was defined as an allopurinol initial dose (ID) prior to (closest) and titrated dose (TD) after (within 30 days) an sUA test. Dose-titration was categorized as an episode with a dose-change (up-titration: ID < TD; down-titration: ID > TD), or no-dose-change (ID = TD). For multiple different doses recorded on the same prescription date, the sum of doses was taken as daily dosage. Episodes were considered uncontrolled when sUA ≥6 mg/dl. Descriptive episode-level analyses were performed. **RESULTS:** Within 64,609 episodes, 57% of episodes were uncontrolled (sUA: 6 to <8 mg/dl: 38%; 8 to <10 mg/dl: 15%; ≥10mg/dl: 4%). Seventy-one percent of uncontrolled episodes were no-dose-change, 21% were up-titrated, and 7% were down-titrated. Within no-dose-change episodes, 51% were uncontrolled and lower doses corresponded to higher percentages of uncontrolled episodes (<100mg/day: 88%; 100mg/day: 70%; >100, <300 mg/day: 49%; 300mg/day: 38%; >300mg/day: 36%). Seventy-eight percent of dose-change episodes were uncontrolled, of which 100 to 300 mg/day (39%) was the most frequent dose titration. Overall, the most frequent TD was 300 mg/day (52%) followed by 100mg/day (36%), >100 <300mg/day (8%), >300mg/day (3%), and <100mg/day (<1%). **CONCLUSIONS:** Allopurinol dose is not generally titrated regardless of sUA control. This pattern suggests a need for active management of patients with gout with uncontrolled sUA including consideration of new treatment options in addition to allopurinol.

PMS63

RHEUMATOLOGIST- AND PATIENT-SPECIFIC FACTORS ASSOCIATED WITH CURRENT ADVANCED THERAPY USE IN RHEUMATOID ARTHRITIS

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OBJECTIVES: Identify factors associated with current advanced therapy (AT) use among patients with rheumatoid arthritis (RA). **METHODS:** Data were obtained

from the US 2016 Adelphi RA Disease Specific Programme. Rheumatologists (HCP, N=85) provided details about their RA patients (N=1,003) and patients voluntarily completed a self-reported questionnaire (N=639). The analysis sample consisted of patients with complete data on variables of interest (N=327). AT for RA was defined as current use of a tumor necrosis factor inhibitor (TNFi), non-TNFi, or Janus kinase inhibitor (JAKi). Multivariable logistic regression was used to examine predictors of current AT vs. conventional disease-modifying antirheumatic drug (cDMARD) use. The following variables were included based on clinical relevance and univariable analyses: age, sex, RA duration at initiation of current therapy, accepting of injectables (IV or SC) therapy (HCP-reported); treatment goal set, concern with side effects, cost factor in treatment decision (patient-reported); disease severity prior to treatment initiation, patient engagement/willingness to change therapy (HCP- and patient-reported). Odds ratios (OR) and 95% confidence intervals (95%CI) were assessed. **RESULTS:** Mean±SD age was 54±15y, 74% were female, with duration of RA 88±96 months, 70% were current users of AT [TNFi (69%), non-TNFi (21%), JAKi (10%)], and most (63%) were 1st-line AT. Current AT use was more common among patients whose HCP classified them as accepting of injectable therapies (OR=2.29, 95%CI: 1.21-4.31) and when patients expressed willingness to change therapy to meet treatment goals (OR=2.33, 95%CI: 1.33-4.07). In contrast, HCP perception of patients' engagement/willingness to change therapy was unrelated to current AT use (OR=1.15, 95%CI: 0.64-2.06). **CONCLUSIONS:** Key predictors of AT use are patient willingness to switch and perceived acceptance of injectable therapies. This suggests that the patient voice is important in uptake of AT and may help to counter any inertia in appropriate treatment escalation.

PMS64

ANALYSIS OF FORMULARY COVERAGE AND COST OF BIOLOGIC DISEASE-MODIFYING ANTI-RHEUMATIC DRUGS IN MEDICARE PART D

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OBJECTIVES: This study examined the drug formulary coverage, usage restrictions (i.e. prior authorization, step therapy and quantity limits), and cost-sharing rates of biologic disease modifying anti-rheumatic drugs (DMARDs) in Medicare Part D in the period 2006 to 2015. **METHODS:** Study data were derived from the Centers for Medicare and Medicaid Services (CMS) Medicare Prescription Drug Plan Formulary and Pharmacy Network Files data. National Drug Codes (NDCs) information was derived from the U.S. Food and Drug Administration (FDA) NDC Directory. Descriptive statistics were performed. **RESULTS:** The FDA approved 10 biologic DMARDs in the period 2006 to 2015. In 2006, the mean percentage of Medicare Part D formularies covering all biologic DMARDs was 74.5%. The Medicare Part D prescription drug coverage reached its highest level (85.9%) in 2007 and it went down to 73.8% in December 2015. The percentage of formularies requiring prior authorization across biologic DMARDs ranged from 68.4% in 2006 to 93.1% in 2014. The use of step therapy varied by drug. No formularies required step therapy for adalimumab and rituximab; whereas, over 10% of formularies required step therapy for certolizumab, golimumab, tocilizumab, abatacept, tofacitinib, and etanercept in 2015. The percentage of formularies requiring quantity limits ranged from 0.0% (rituximab) to 47.4% (tofacitinib) in 2015. Placement in tier 5 increased from 7.9% in 2006 to 61.5% in 2015. Placement in tiers 2-4 decreased during the study period. Coinsurance was the most commonly used type of cost-sharing mechanisms; it was required by 62.3% of the plans in 2006 and 68.4% in 2015. **CONCLUSIONS:** All Medicare Part D formularies covered at least one biologic DMARD during the period 2006-2015. The large majority of formularies placed prior authorization, step therapy and quantity limits on the utilization of biologic DMARDs. In addition, biologic DMARDs were increasingly placed in higher specialty tiers that required high cost-sharing rates.

PMS65

ANALYSIS OF THE IMPACT OF AFFORDABLE CARE ACT AND THE 2011 FDA SAFETY COMMUNICATION ON THE UTILIZATION OF BIOLOGIC DISEASE-MODIFYING ANTI-RHEUMATIC DRUGS IN THE MEDICAID OUTPATIENT PHARMACY PROGRAM

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OBJECTIVES: To describe trends in utilization and expenditures of biologic Disease Modifying Anti-rheumatic drugs (DMARDs) in the Medicaid outpatient pharmacy program from 2007 to 2014 and to assess the impact of the 2010 Affordable Care Act (ACA) and 2011 FDA safety communications about anti-tumor necrosis factor (TNF) drugs on the utilization of biologic DMARDs. **METHODS:** Medicaid drug utilization data were collected from Centers for Medicare & Medicaid Services. Biologic DMARDs and national drug codes were collected from the Food and Drug Administration (FDA) databases. An interrupted time series analysis was conducted to assess the association of the ACA and FDA safety communications and the utilization of biologic DMARDs. **RESULTS:** The Medicaid outpatient pharmacy utilization for biologic DMARDs increased from 11,187 claims in first quarter of 2007 to 64,684 in the fourth quarter of 2014. The highest utilization occurred in the second quarter of 2010 (104,996 claims). The Medicaid expenditures of biologic DMARDs increased from \$21.9 million in the first quarter of 2007 to \$202.4 million in the fourth quarter of 2014. ACA led to an increase of 17.4% in the number of anti-TNF claims per quarter in the Medicaid outpatient pharmacy program. After controlling for the effect of ACA, the 2011 FDA safety

communication was significantly associated with a decrease in anti-TNF utilization ($p < 0.001$). In addition, the FDA anti-TNF safety communication was significantly associated with an increase in the utilization of non-anti-TNF ($p < 0.001$). **CONCLUSIONS:** The utilization of biologic DMARDs in the Medicaid outpatient pharmacy program significantly changed over time. The utilization of biologic DMARDs was higher post-enactment of the ACA compared to the period pre-ACA. Likewise, the utilization of Anti-TNF biologics significantly increased after the implementation of the ACA and decrease following the 2011 FDA safety communication.

PMS66

TRENDS IN PRESCRIPTION DRUGS UTILIZATION AMONG INDIVIDUALS WITH ARTHRITIS IN THE UNITED STATES, 2005 TO 2014

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OBJECTIVES: Given the rise in the population of arthritis and advances in the therapeutic options to manage arthritis, there are needs to evaluate the real-world pharmacotherapeutic management of arthritis. Therefore, we evaluated retrospective cross-sectional trends in prescription drugs utilization among adults with arthritis using a nationally representative data, the Medical Expenditures Panel Survey. **METHODS:** Study population comprised of bi-annual cross-sectional cohorts of individuals aged ≥ 18 years during calendar year of 2005 through 2014. Prescription drugs were classified based on therapeutic class and subclass as per Multum Lexicon database. Chi-square statistics were used to examine differences in the proportion of particular prescription drugs utilization between those with and without arthritis. **RESULTS:** An annual-weighted individual with doctor-diagnosed arthritis rose from 44.3 million in 2005/06 to 63.5 million in 2013/14. For arthritis-related medications, we found a gradual increase in single opioid agent use (4.7% vs. 13.3%), a minor increase in glucocorticoids (8.6% vs. 10.0%), as well as topical steroids (4.6% vs. 5.2%) and no changes in overall non-opioid analgesic use (46.3% vs. 45.0%) in 2013/14 as compared to 2005/06. With respect to co-medications, we found a stable use proportion of individuals utilizing cardiovascular agents (56.4%), central nervous system agents (57.0%), antibiotics (34.7%), and proton-pump Inhibitors (19.7%) from 2005/06 to 2013/14, whereas, an increase in proportion of individuals utilizing anticonvulsant (12.8% vs. 18.4%), statins (29.1% vs. 35.0%), and antidepressant (22.8% vs. 24.9%) from 2005/06 to 2013/14 among those with arthritis. Individuals with arthritis were more likely to receive cardiovascular, central nervous system agents, gastrointestinal agents, respiratory agents as compared to those without arthritis throughout 2005/06 to 2013/14. **CONCLUSIONS:** Our study highlights an uptake of opioid analgesic with a relatively stable proportion of other arthritis-related medication. In addition, high use of cardiovascular, psychotherapeutic agents, antibiotics, gastrointestinal and respiratory agents suggest a significant medication burden among individuals with arthritis.

PMS67

INCREASED PREVALENCE IN OPIOID PRESCRIPTION AS A FIRST LINE THERAPY IN OSTEOARTHRITIS

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OBJECTIVES: Concerns regarding the misuse of opioid analgesics are widespread in public health literature, resulting in increased regulations and guidelines suggesting the use of alternative therapy (weight-loss and exercise) as first-line treatment. The objective of this study is to use real-world data to compare the longitudinal prevalence of opioid prescription in patients with newly diagnosed generalized osteoarthritis (OA) (ICD-9-CM 715.0). **METHODS:** The Q-EMR database was used to gather records between 1/1/05 to 4/30/16, with the index event (first diagnosis of osteoarthritis) occurring between 1/1/05 and 4/30/15 to allow for a one-year follow-up. Two outcomes were assessed: 1) opioid prescription within one week after index event and 2) opioid prescription within one year after index event. To detect trends over time, linear regression was used with percentage of patients on opioids as the dependent variable and calendar year as the independent variable. **RESULTS:** There was a total of 100,578 patients newly diagnosed with OA during the study period; 28,947 were prescribed opioids within one year and 14,072 were prescribed opioids within one week of diagnosis. The percentage of patients prescribed opioids within one year of diagnosis ranged from 18% in 2005 to 36% in 2015, significantly increasing by 2% (95%CI: 1.7 to 2.4%; $p < 0.0001$) per year. Similarly, the percentage of patients prescribed opioids within week of diagnosis ranged from 8% in 2005 to 17% in 2015, significantly increasing by 1% (95% CI: 0.8% to 1.3%; $p < 0.0001$) per year. **CONCLUSIONS:** This study used real-world data to assess the longitudinal trend of opioid prescription in newly diagnosed osteoarthritis patients. Results suggest an increase in prescription of opioids both within the first week and year of diagnosis. Despite public health concerns regarding misuse, opioids still appear to be a common and increasingly prescribed treatment for osteoarthritis.

PMS68

NEBULOUS GUIDELINES: CAN PHARMACOECONOMICS SUPPORT THE EVIDENCE?

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OBJECTIVES: To examine the role of pharmacoeconomics in ascertaining the choice of appropriate therapeutics. **METHODS:** This is a retrospective analysis, conducted using the clinical records from a tertiary referral hospital in western Maharashtra, India. Data on patients of ankylosing spondylitis and rheumatoid

arthritis was collected. Biological response modifiers (BRMs) are indicated for NSAID failure and DMARD failure cases, respectively. We compared the input costs and relative benefit of various BRMs. **RESULTS:** Out of 35 patients of ankylosing spondylitis who had NSAID failure, 15 were given etanercept (24 injections/patient) and 20 were given infliximab (8 injections/patient). Mean reduction in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score in etanercept and infliximab group was 1.79 and 2.41 respectively (difference not statistically significant). The total input cost per patient of etanercept and infliximab was INR 1,56,984 and INR 2,55,360 respectively. The average cost incurred for per unit reduction in mean BASDAI score was INR 87,700 (1,56,984/1.79) for etanercept and 105,958 for infliximab. Though the gross input cost of infliximab was 1.62 (2,55,360/1,56,984) times higher, its cost per unit benefit offered was only 1.2 (1,05,958/87,700) times higher than etanercept. Similarly, in 28 cases of DMARD failure RA cases, 15 were given infliximab and 13 were given etanercept. The average cost incurred for per unit reduction in mean disease activity score (DAS-28) was INR 1,22,643 for etanercept and INR 1,78,573 for infliximab. Cost of infliximab per unit benefit offered was 1.4 times higher than etanercept. **CONCLUSIONS:** In view of its lower cost for comparable clinical effect, etanercept appears to be a more appropriate BRM. The case study demonstrates that pharmacoeconomic analysis of competing therapies can single out the appropriate treatment choice. However, for drawing generalizable conclusions, prospective studies with indirect costs and longer time horizon are required.

PMS69

ASSESSING ASSOCIATIONS BETWEEN INSURANCE TYPE AND DRUG THERAPY IN PATIENTS WITH RHEUMATOID ARTHRITIS

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OBJECTIVES: Rheumatoid arthritis (R.A.) is a chronic disease with a large impact on quality of life. Introduction of biologic disease-modifying antirheumatic drugs (TNF-alpha blockers) for treatment of R.A. has yielded significantly improved outcomes, however cost is high. We examined association between insurance coverage and likelihood of biologic therapy in patients with Rheumatoid arthritis. **METHODS:** Patients with R.A. were identified from 2014 Medical Expenditure Panel Survey data using ICD-9M codes (714.xx) as inclusion criteria and combining records from the Medical Conditions and Prescribed Medications file. Patients were classified as biologic users, or non-biologic users. Patients were classified as having poor, fair, or good health based on self-reports. Insurance type was categorized as "Private," "Public," or "Uninsured." SF-12 physical component (PCS) and mental component scores (MCS) were compared across groups using generalized linear models. The SURVEYREG procedure in SAS was used to assess relationship between insurance and medication type with weights adjusting for the MEPS complex survey design. Charlson comorbidity index, health, age and gender were included as covariates. **RESULTS:** A total of 387 individuals met inclusion criteria. Females made up 27.6% of the sample. Mean age was 59.3 ± 14.6 years. Only 5% of the sample used biologics. Patients with private insurance were more likely than uninsured patients to be on biologic therapy, odds ratio=3.94, 95% confidence interval= 1.2 to 13.4. Mean SF-12 physical component scores did not differ among patients using biologics and those not using biologics. However privately insured patients had higher mean PCS (33.7 ± 16.24) than publicly insured patients (27.0 ± 14.44), $P < 0.001$. MCS scores did not differ across groups, $P = 0.63$. **CONCLUSIONS:** Privately insured patients were almost 4 times more likely to be on biologics as compared to uninsured patients ($p < 0.05$).

PMS70

FACTORS ASSOCIATED WITH THE INITIATION OF BIOLOGIC DISEASE MODIFYING ANTI RHEUMATOID DRUGS IN A PRIVATELY INSURED POPULATION WITH RHEUMATOID ARTHRITIS BETWEEN 2004 AND 2013

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OBJECTIVES: Biologic Disease Modifying Anti-Rheumatic Drugs (bDMARDs) have revolutionized the treatment of rheumatoid arthritis. Biologic DMARDs are highly effective but demand extremely high costs. Understanding appropriate timing and risk factors for the use of bDMARDs is a concern for patients, physicians, and payers. The objectives were to identify, describe, and measure the risk factors associated with initiation of a bDMARD in newly diagnosed adult patients with RA between 2004 and 2013. **METHODS:** Patients were selected from a large national private insurance-claims database if they had at least 2 claims for ICD-9 code 714.xx at least 45 days apart and received DMARD therapy between 2004 and 2013. Predictors of initiation of a biologic included first line treatment regimen, ultrasound use, insurance plan generosity, disease severity, age, sex, comorbidities, and year of diagnosis. Cox Proportional Hazard models were used to evaluate the predictors associated with the initiation of a bDMARD. **RESULTS:** A cohort of 20,731 patients with RA was selected, 64% were female, and the median age of onset was 54 years. Earlier initiation of a bDMARD was associated with dual therapy use vs. mono therapy (HR 1.27, 95% CI 1.17-1.38), ultrasound use 3-6 months before diagnosis (HR 5.46, CI 2.60-11.48), high plan generosity (HR 7.23, CI 6.60-7.91), disease severity (HR 1.12, CI 1.10-1.14), and year of diagnosis 2013 vs. 2004 (HR 2.09, CI 1.41-3.12). Protective factors included age at onset (HR 0.984 CI 0.981-0.987), comorbidities (HR 0.93, CI 0.91-0.95), and female sex (HR 0.92, CI 0.87-0.98). **CONCLUSIONS:** Patients that initiated dual therapy, were younger, had more severe disease, had increased ultrasound use, had better drug benefit coverage, and were more recently diagnosed are more likely to initiate bDMARDs earlier in their disease history. Understanding these factors can help ensure bDMARDs are being used appropriately to achieve optimal therapies, and avoiding unnecessary costs and risks.

PMS71

ASSOCIATION BETWEEN DISEASE ACTIVITY LEVEL IMPROVEMENT AND REDUCTION IN HEALTHCARE RESOURCE UTILIZATION IN PATIENTS WITH RHEUMATOID ARTHRITIS RECEIVING TARGETED THERAPY

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OBJECTIVES: To evaluate the impact of change in patient-reported disease activity assessment measured using the Routine Assessment of Patient Index Data 3 (RAPID3) on healthcare resource utilization (HRU) in patients with rheumatoid arthritis (RA) receiving targeted therapy. **METHODS:** Electronic medical records (EMR) from Reliant Medical Group (Worcester, MA, USA) were used to identify adult RA patients with first observed prescription for a targeted therapy ("index") between 1/1/2008 and 6/30/2015. Change in RAPID3 score was calculated as the difference in RAPID3 score (range 0-30) at baseline and 6 (±1) months post-index and was categorized as good, moderate or poor response. All-cause and RA-related medical visits, including inpatient, emergency room, and outpatient visits, as well as prescription drug use was assessed using EMR data in the 6-12 month period following index. A generalized linear model with a log link function and negative binomial distribution was used to assess the association between RAPID3 response category and HRU outcomes, adjusting for RAPID3 score and HRU at baseline. **RESULTS:** The mean age of the study population (N=90) was 59.6 years and 73.3% were female. The mean RAPID3 score was 13.2 at baseline and 10.1 at 6 months post-index; 41 patients (45.6%) had good (N=24) or moderate (N=17) disease response. Compared to patients with poor response, patients with good/moderate response had fewer mean all-cause medical visits (6.1 vs. 11.0, $p = 0.003$), RA-related medical visits (2.5 vs. 5.3, $p = 0.022$), and non-targeted therapy prescriptions (7.3 vs. 12.2, $p = 0.006$). Multivariate regression models showed patients with good/moderate response had significantly reduced all-cause (incidence rate ratio [IRR]=0.68, $p = 0.029$) and RA-related (IRR=0.59, $p = 0.005$) visits, driven mainly by reduction in outpatient visits, compared to poor responders. **CONCLUSIONS:** Patients with good or moderate disease response to targeted therapy, as assessed by RAPID3, have reduced HRU, highlighting the association of patient-reported disease response and economic endpoints.

PMS72

TRENDS IN DIRECT AND OUT-OF-POCKET HEALTHCARE EXPENDITURES AMONG INDIVIDUALS WITH ARTHRITIS IN THE UNITED STATES, 2005 TO 2014

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OBJECTIVES: No up-to-date information since a decade about direct and out-of-pocket (OOP) healthcare expenditures among US adults with arthritis exists. Hence, we evaluated retrospective cross-sectional trends in incremental direct and OOP healthcare expenditures among adults with arthritis using a nationally representative data, the Medical Expenditures Panel Survey. **METHODS:** Study population comprised of bi-annual cross-sectional cohorts of individuals aged ≥ 18 years during calendar year of 2005 through 2014. Total direct and OOP healthcare expenditures per person per year were estimated. Two-part models were used to estimate the incremental total and types of annual direct and OOP healthcare expenditures (adjusted to 2014 US dollars) of arthritis after adjusting for predisposing, enabling, need, personal health practice and external environment factors as per the Anderson Healthcare Behavior Model. **RESULTS:** Annual weighted population of individuals with arthritis rose from 44.3 million in 2005/06 to 63.5 million in 2013/14. The unadjusted annual average direct and OOP expenditure were \$10,963 (Standard Error, SE: \$292, aggregated: \$485.7 billion) and \$1,949 (SE: \$57, aggregated: \$86.3 billion) in 2005/06 while these were \$10,036 (SE: \$237, total: \$37.3 billion) and \$1,177 (SE: \$37, aggregated: 74.8 billion) in 2013/14, respectively, among individuals with arthritis. The incremental direct expenditures among adults with arthritis were \$1,061 (SE: \$198) in 2005/06 which reduced to \$652 (SE: \$172) in 2013/14. As compared to the direct and OOP expenditures in 2005/06, there was a significant decline in these estimates in 2013/2014. **CONCLUSIONS:** Although there was a decline in the intensity of incremental direct and OOP expenditures among individuals with arthritis in the recent years, arthritis still pose significant economic burden to the US.

PMS73

THE CANADIAN MARKET FOR BIOLOGIC RESPONSE MODIFIERS, 2015

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OBJECTIVES: The market for biologic drugs used in the treatment of chronic inflammatory conditions has rapidly evolved over the last two decades. This study provides insight into the uptake in utilization, market shares, pricing, annual treatment costs and the broader drug portfolio of manufacturers operating in this space. **METHODS:** This project was initiated in response to a request from the NPDUIS Advisory Committee in support of the pan-Canadian Pharmaceutical Alliance (pCPA). The drugs considered are Enbrel, Remicade, Kineret, Humira, Rituxan, Orenzia, Simponi, Cimzia and Actemra. International comparisons focus on the seven countries the PMPRB considers in reviewing the prices of patented drugs (PMPRB): France, Germany, Italy, Sweden, Switzerland, the UK and the US, as well as select countries in the Organisation for Economic Co-operation and Development (OECD). The report focuses on 2015 calendar year and provides a retrospective look at trends since 2010. **RESULTS:** The study shows that the sales and use of these biologic drugs are higher in Canada than in most comparable international markets. Despite the availability of lower-cost treatments, the majority of Canadian patients continue to use the drugs with the highest

treatment costs: Remicade, Humira, and Enbrel. Aligning Canadian drug prices with international levels, especially for Remicade, and using less expensive alternative therapies, such as biosimilars, would result in lower drug costs for Canadians. **CONCLUSIONS:** This report is designed to inform policy discussions on the price and reimbursement of this drug class at public and private payer level, including the pricing and uptake of emerging biosimilars.

PMS74

ANALYSIS OF THE FEMORAL FRACTURE REOPERATION RATE IN SÃO PAULO STATE

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OBJECTIVES: To estimate the burden of reoperation rate (clinical and economic) of hip fractures in São Paulo (Brazil). These fractures are associated with different implications to the patient, such as, high mortality rate in the first year (up to 24%), loss of function (after one year less than 40% of patients are able to walk again) and reoperation (6.3%). **METHODS:** A longitudinal analysis was performed (2008-2015), using hospitalization records - without patient identification, the Hospitalization Service (SIH) of DATASUS, which is a real world evidence database. **RESULTS:** 29,188 primary and 1,903 reoperation procedures were performed in the period, resulting in an average reoperation rate of 6.5%. In 91.5% of the cases a second procedure operation was needed. 49% of the reoperation procedures were performed in the first year after primary surgery, 26% in the second year and 24% the third year. The procedures in people over 50 years correspond to 69.9% of primary procedures. Up to 50 years, women represent 40.1% of cases. Over 50 years the relationship man vs. woman is inverted and 77.8% of surgical cases for fracture treatment were performed on women. The average length of stay of patients was 6.7 days. The mortality rate was 3.72 for the surgical treatment of subtrochanteric fracture, 3.68 for transtrochanteric fracture and 1.15 for surgical treatment of delay on consolidation in the trochanteric region. The economic impact of reoperations was R \$ 3.8 million (Reais) in the period studied. **CONCLUSIONS:** The complications related to hip fracture often require reoperation. The reoperation rate found in SUS is similar to the reoperation rate published in the literature, 6.5% vs. 6.3%. Our research shows that hip fractures represent a huge burden in the State of São Paulo in terms of reoperation and it brings a huge cost to the health care system

PMS75

TREATMENT PATTERNS AND HEALTHCARE RESOURCE USE OF RHEUMATOID ARTHRITIS PATIENTS TREATED WITH BIOLOGIC DISEASE-MODIFYING ANTI-RHEUMATIC DRUGS IN SOUTH KOREA: RESULTS FROM THE HIRA HEALTH INSURANCE CLAIMS DATABASE

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OBJECTIVES: To characterize real-world patients, treatment patterns and costs amongst rheumatoid arthritis (RA) patients in Korea, specifically patients on biologic disease-modifying antirheumatic drugs (bDMARDs) since major reimbursement guideline changes in 2013. **METHODS:** Descriptive retrospective analysis of the HIRA health insurance claims database. Patients' baseline demographics, clinical characteristics and persistence, and RA-related annual reimbursement costs per-patient were evaluated. Total per-patient costs were calculated in addition to components of cost relating specifically to hospitalizations, joint replacements, outpatient attendances, bDMARD administrations, serious infections and monitoring. Drug costs were not evaluated as a component of cost. RA-diagnosed patients aged 18+ and initiated on or switched bDMARD were included, indexed between Dec 2013 and Dec 2014 with a 12-month follow-up. An exchange rate of #1=€0.00078 was used. **RESULTS:** In total, 2,835 bDMARD patients were identified, of which 2,173 were initiators (21.4% etanercept, 20.6% adalimumab, 16.1% tocilizumab) and 662 switchers (35.5% tocilizumab, 22.8% rituximab, 12.5% golimumab). Mean (SD) age was 54.04 (12.71), 16.1% were male and mean (SD) Charlson comorbidity score was 3.69 (1.71), across all patients included. Over half of initiators (58.6%) and switchers (50.6%) persisted on the index bDMARD for 12 months. Annual mean RA-related per-patient costs for (initiators, switchers) were #9,446,105 (€7,368), #9,701,216 (€7,567) in total within the follow-up period: hospitalizations accounted for #923,826 (€721), #1,128,228 (€880); joint replacements #126,096 (€98), #176,800 (€138); hospital outpatient attendance #186,053 (€145), #183,024 (€143); bDMARD infusions #12,804 (€10), #17,538 (€14); bDMARD subcutaneous injections #4,538 (€4), #1,857 (€1); serious infections #330,494 (€258), #414,137 (€323); and monitoring costs #212,500 (€166), #233,646 (€182). **CONCLUSIONS:** This is the first Korean study demonstrating real world treatment patterns and costs (over #9,000,000 [€7,000] per-patient per year) of treating RA patients with bDMARDs since 2013 reimbursement guideline changes, and therefore is informative to physicians in Korea.

PMS76

REAL-WORLD COSTS OF RHEUMATOID ARTHRITIS IN A SPECIALIZED CENTER IN BOGOTÁ COLOMBIA: RESULTS OF A REGISTRY DURING FIVE YEARS

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OBJECTIVES: Many studies have investigated socioeconomic and cost issues in rheumatoid arthritis (RA); the introduction of TNF blockers and other biological

therapies since 2000 has proven efficacy, and however it has been associated with high costs compared with established DMARDs. The aim of this study was to analyze the health costs of RA therapy and the effectiveness of therapy evaluated by DAS28 over a 5 year period from the perspective of the health care system. **METHODS:** The data of this study was taken from a registry in a RA specialized center in Colombia. We selected patients who had moderate/severe disease activity and had a minimum of 12 follow visits during 2012-2016. These patients were followed-up under strictly T2T standards. Clinical follow-up was done according to DAS28. Therapy had to be adjusted with DAS28 > 3.2 unless patient's conditions don't permit it. The cost analysis was made considering the cost of medications, consultation with a multidisciplinary team, laboratory and radiological tests. The effectiveness was measured by improvement in DAS28. **RESULTS:** Between 2012 and 2016 1220 patients meet the inclusion criteria, 83% were female, mean age was 62 ± 10. 776 patients were receiving conventional DMARDs and 444 biological therapies; DAS28 average was 4.5 ± 1.0 at beginning; after 5 years 864 patients achieved remission/low disease activity: 70% were receiving DMARDs and 30% biological therapy. The average year costs of therapy during 5 years in order to achieve remission/LDA in the group receiving DMARDs was \$423.313 US dollars, while the average costs to achieve remission/LDA in the group receiving biological therapy was \$2.392.197 US dollars. **CONCLUSIONS:** The results of this registry shows that conventional DMARDs therapy can achieve remission/LDA at a considerably lower costs compared to biological therapy (five/six times) saving costs for the health system over the years.

PMS77

UTILIZATION INDICATORS OF SPECIALIZED THERAPEUTIC SERVICES (NUMBER OF CASES AND VISITS) IN HUNGARIAN HOME CARE

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OBJECTIVES: The primary aim of our study was to analyze the therapy services by speciality focusing the number of cases and visits in Hungarian home care. **METHODS:** Our data came from the database of the National Health Insurance Fund, as the single home health financing agency, which was queried through the Central Statistics Office. The period examined was the year of 2013. The following indicators were analyzed: number of visits, type of visits, number of cases, visits per case. **RESULTS:** The total number of cases in home care amounted to 133.342, the number of visits amounted to 1.298.834 in 2013. Within home care, the number of cases managed by specialized therapeutic service accounted for 64.428 (48.32%). Within this service, the number of cases treated by physiotherapy amounted to 57.509 (43.1%). The number of cases managed by physiotherapy accounted for 6.555 (4.9%), and that of treated by speech therapy amounted was 364 (0.3%). The total number of visits to therapy services by speciality was 532.205 (40.98%). Within these services, physiotherapy amounted to 462.759 (35.6%), physiotherapy accounted for 65.656 (5.0%) and speech therapy amounted to 3.881 (0.3%) visits. The number of visits per case in physiotherapy was 8.04, in physiotherapy, it was 10, and in speech therapy, it was 10.7 visits per case. **CONCLUSIONS:** Within home care, therapy services by speciality play an essential role in the health care of Hungary, among which the request of physiotherapy is extremely high. The number of cases and visits justifies the need of this type of service, currently maximized centrally, to receive more support.

PMS78

UTILIZATION AND FINANCIAL INDICATORS OF SPA SERVICES IN THE SOUTH DANUBIAN REGION, HUNGARY

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OBJECTIVES: Aim of our study was to analyze the utilization and health insurance of physiotherapy-type spa services in Hungary and focusing the data of the South-Danubian region. **METHODS:** Our data were obtained from the Central Bureau of Statistics. The list of spa and other medical care treatment contained 11 activities. The examined period was the year 2014. **RESULTS:** The number of treatments offered by 11 spa funded by the National Health Insurance Fund were 6.839.546. The first three most common treatments included: 1. pool with medicinal water therapy 2.076.148 (30.36%); 2. medical massage 1.642.037 (24.01%); 3. underwater group physiotherapy 686.773 (10.04%). 11.41% of all procedures were enlisted in the South-Danubian region (780.477 treatments), where the most common were: 1. pool with medicinal water therapy 194.976 (24.98%); 2. medical massage 179.003 (22.94%); 3. underwater group physiotherapy 87.176 (11.17%). Sequence of treatments in relation to the Social Insurance (thousand HUF): 1. medical massage 933.229 (21.71%); 2. pool with medicinal water 686.826 (15.98%); 3. complex bath medical-care 621.361 (14.45%). The total National Social Insurance subsidy was 4.299.171, of which 564.838 (13.14%) were in the South-Danubian region. The region's most supported treatments include (thousand HUF): 1. complex bath medical-care 155.707 (27.57%); 2. medical massage 10.334 (18.29%); 3. mud pack 71.613 (12.68%). In the region studied, the majority of patients receiving the above therapeutic possibilities were between 50-79 years of age. **CONCLUSIONS:** There were no differences in the sequence of the most common treatments between the national and South-Danubian region, while there was a significant difference in Social Insurance subsidy. In the South-Danubian region, complex spa medical-care had an extremely high financing rate, while underwater group physiotherapy and pool treatments with medicinal water receive relatively less support reducing overhead costs. Being aware of data can be essential in the organization of regional spa services.

PMS79

UTILIZATION INDICATORS OF THERAPY SERVICES BY SPECIALITY (NUMBER OF PATIENTS AND VISITS) IN HUNGARIAN HOME CARE

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OBJECTIVES: The primary aim of our study was to analyze the therapy services by speciality focusing the number of patients and visits in Hungarian home care. **METHODS:** Our data came from the database of the National Health Insurance Fund, as the single health financing agency, which was queried through the Central Statistics Office. The period examined was the year of 2013. The following indicators were analyzed: number of visits, type of visits, number of patients, visit per case. **RESULTS:** The total number of patients in home care amounted to 59,072, the number of visits amounted to 1,298,834 in 2013. Within home care, the number of patients managed by specialized therapeutic service accounted for 31,739 (53.7%). Within this service, the number of patients treated by physiotherapy amounted to 27,228 (46.1%). The number of patients managed by physiotherapy accounted for 4,340 (7.3%), and that of treated by speech therapy amounted was 171 (0.3%). The total number of visits to therapy services by speciality was 532,205 (40.98%). Within these services, physiotherapy amounted to 462,759 (35.6%), physiotherapy accounted for 65,656 (5.0%) and speech therapy amounted to 3,881 (0.3%) visits. The number of visits per case in physiotherapy was 16.99, in physiotherapy, it was 15.1, and in speech therapy, it was 22.7 visits per case. **CONCLUSIONS:** Within home care, therapy services by speciality play an essential role in the health care of Hungary, among which the request of physiotherapy is extremely high. The number of patients and visits justifies the need of this type of service, currently maximized centrally, to receive more support.

PMS80

EPIDEMIOLOGICAL CHARACTERISTICS OF PATIENTS WITH RHEUMATOID ARTHRITIS IN A SPECIALIZED CENTER IN BOGOTA COLOMBIA

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OBJECTIVES: Rheumatoid arthritis (RA) is a chronic, autoimmune disease manifesting as joint inflammation that, can lead to joint damage, destruction, and disability: RA can affect approximately 1% of the population, with a peak incidence between the ages of 35 and 50 years (1). The objective of this study is to describe the major clinical and epidemiological characteristics in a descriptive cohort of RA patients, in a specialized RA clinic. **METHODS:** We conducted a cross-sectional study, the data was taken from a registry of RA specialized center in Colombia. These patients were followed-up under strictly treat to Target (T2T) standards; clinical follow-up was done according to DAS28; therapy had to be adjusted with DAS28 > 3.2 unless patient's conditions don't permit it. Epidemiology descriptive was done. **RESULTS:** 5214 patients were included in our registry during a 5 year follow-up. The mean age of patients was 64 ± 10 years old, 82% were woman and 18% men. The serum rheumatoid factor and anti-citrullinated protein antibodies were positive in 80% of our patients, 4205 (80%) were under conventional DMARDs. In regards of comorbidities 30% of patients had osteoarthritis, 20% hypertension, osteoporosis 12%, 4% diabetes, Sjogren's syndrome 3%, cerebrovascular disease 1%, and chronic renal disease 1.3%. Mean DAS28 was 3.7 ± 1, regarding disease activity 50% of patients were in remission 12% low disease activity, 31% moderate disease activity and 7% in severe disease activity. **CONCLUSIONS:** The characteristics of the patients in this epidemiological study are similar to others reported in other studies(1), also this data is evidence that may support other research projects in the Colombian context. References 1. Bautista-Molano W, Fernández-Avila D, Jiménez R, Cardozo R, Marín A, Soler MdP, et al. Epidemiological Profile of Colombian Patients With Rheumatoid Arthritis in a Specialized Care Clinic. *Reumatología Clínica (English Edition)*. 2016;12(6):313-8.

PMS81

WHEN CLINICAL AND VALUE EVIDENCE DO NOT STATISTICALLY COINCIDE

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OBJECTIVES: We provide a US case of TNF inhibitors (adalimumab, certolizumab pegol, etanercept, golimumab (iv), and infliximab) in rheumatoid arthritis (RA) where head-to-head clinical evidence did not achieve statistical significance but head-to-head cost-effectiveness evidence achieved variation on probabilistic separation. **METHODS:** We conducted a systematic literature review using best practices for search strategy development and article retrieval. We identified studies that included TNFs in combination with conventional disease-modifying anti-rheumatic drugs such as methotrexate. A network meta-analysis of direct and indirect clinical evidence comparisons across TNFs also used in an economic model primarily included: 1. American College of Rheumatology (ACR) ACR20, 50, and 70, representing at least 20%, 50%, or 70% improvement in tender/swollen joint counts; and 2. The Sharp Score, a measure of radiographic joint damage. We developed an economic model consistent with RA evidence and its uncertainty to generate probabilistic sensitivity analysis findings with adalimumab as the primary comparator. Outputs from the US payer perspective were lifetime costs, quality-adjusted life years (QALYs), and incremental net monetary benefit (INMB), estimated using a willingness-to-pay of \$150,000/QALY. The Bayesian credible

intervals from the network meta-analysis clinical measures and INMB were used to identify statistically significant differences across TNFs as compared to adalimumab. **RESULTS:** At the 95% credible level, no observed differences were detected across the TNFs in comparison with adalimumab for the clinical measures of ACR improvement or Sharp Scores. When this same level of clinical uncertainty was propagated through to cost-effectiveness findings, the INMBs showed separation with high levels of likelihood for two of four TNFs. Specifically, certolizumab pegol, etanercept, golimumab (iv), and infliximab had 50%, 97%, 59%, and 99.9% probability respectively, of achieving a favorable INMB as compared to adalimumab. **CONCLUSIONS:** Findings suggest decision makers may gain value efficiencies even when statistical separation in clinical outcomes is not observed.

PMS82

ASSESSMENT OF KNOWLEDGE REGARDING OSTEOPOROSIS AMONG FEMALE PATIENTS ATTENDING GYNECOLOGICAL WARDS IN DIFFERENT HOSPITALS OF QUETTA, PAKISTAN

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OBJECTIVES: The study aimed to investigate knowledge regarding osteoporosis among female patients attending gynecological wards in different hospitals of Quetta, Pakistan. **METHODS:** A cross sectional study was conducted on female patients in gynecological wards in different hospitals of Quetta from March to October 2016. Knowledge was assessed by a pre-validated questionnaire containing 20 questions regarding osteoporosis, its symptoms and causes. A score level of <11 was considered as poor knowledge while ≥11 was regarded as adequate knowledge. All the analysis was done by using SPSS vs 20. **RESULTS:** A total of 289 female patients were included in the study during the study period. Majority (n= 285, 98.6%) were married with the age group between 26-35 years. Most of the patients (n=259, 86.9%) have not been previously diagnosed of bone related problem or osteoporosis. Overall mean knowledge score related to osteoporosis were 12.61 ± 3.528 (max 20). Majority of respondents 213 (73.7%) had adequate knowledge regarding osteoporosis. Majority (n=117, 40.5%) were not aware about the early symptoms of the disease. **CONCLUSIONS:** The study concluded that although females had adequate knowledge regarding osteoporosis, yet they were not aware with the early symptoms of the disease that can lead to develop the disease in them and condition could become worsen if not diagnosed at earlier stages, therefore, awareness programs should be conducted for better understanding of the disease condition.

SENSORY SYSTEMS DISORDERS – Clinical Outcomes Studies

PSS1

INCIDENCE RATES OF COMORBIDITIES AMONG PATIENTS WITH PSORIASIS IN THE UNITED STATES

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OBJECTIVES: Psoriasis (PsO) is associated with a substantial comorbidity burden. However, limited data on comorbidity incidence are available for PsO patients in the US. This study compared the incidence of newly diagnosed comorbidities among PsO patients versus demographically matched controls. **METHODS:** PsO patients ≥20 years old with ≥1 inpatient or ≥2 nonrule-out PsO diagnoses (ICD-9-CM code 696.1) were identified in the Truven Health MarketScan Commercial and Medicare Supplemental Databases (January 2000–September 2015), with the first PsO diagnosis as the index date. Controls without PsO diagnosis were matched 1:1 to PsO patients on birth year, gender, and geographical region. All individuals were required to have ≥24 months of continuous enrollment prior to index date, and patients with a comorbidity of interest in the prior 24 months were excluded from analysis. Individuals were followed post-index until loss to follow-up, end of continuous enrollment, or end of study period. Incidence rates of PsO-related comorbidities were compared between the PsO and control groups. Hazard ratios were estimated using Cox proportional hazards models adjusted for baseline characteristics including comorbidities and insurance plan type. **RESULTS:** A total of 114,824 PsO patients and matched controls were included; mean age was 53 years and 46% were male. Incidence rates were higher for comorbidities among PsO patients including cardiovascular and metabolic diseases, autoimmune conditions, depression, anxiety, and lymphoma (all P<0.05). The most common comorbidities in both groups were hyperlipidemia (PsO vs control, incidence rate per 1000 person-years: 127.5 vs 102.8), hypertension (94.3 vs 80.6), depression (33.3 vs 24.9), anxiety (32.3 vs 25.1), and obesity (33.1 v. 24.1). In adjusted Cox models, PsO patients were more likely to develop all comorbidities described compared with matched controls, with all hazard ratios >1 (all P<0.05). **CONCLUSIONS:** Compared with demographically matched non-PsO controls, PsO patients were more likely to develop PsO-related comorbidities.

PSS2

RISK OF INCIDENT UVEITIS IN PEOPLE WITH PSORIASIS: A NATIONWIDE COHORT STUDY

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OBJECTIVES: To evaluate the risk of uveitis in people with psoriasis. **METHODS:** We used Taiwan's National Health Insurance Research Database to conduct a

retrospective cohort study, and identified 147,954 people with psoriasis (including 10,107 with concomitant psoriatic arthritis and 137,847 without psoriatic arthritis) and 147,954 nonpsoriatic controls. We used the Cox proportional hazard model to assess the hazard ratio (HR) for incident uveitis in people affected by mild and severe psoriasis with and without psoriatic arthritis with reference to nonpsoriatic controls. **RESULTS:** The severe psoriasis with psoriatic arthritis group had the greatest risk of incident uveitis in comparison to nonpsoriatic controls (adjusted HR 2.40 [95% confidence interval (CI) 1.90–3.02]). The severe psoriasis without psoriatic arthritis and mild psoriasis with psoriatic arthritis groups also had an increased risk of incident uveitis (adjusted HR being 1.42 [95% CI 1.23–1.64] and 1.42 [95% CI 1.03–1.96], respectively). On the other hand, the mild psoriasis without psoriatic arthritis group did not have an increased risk for incident uveitis (adjusted HR 1.09 [95% CI 1.00–1.20]). **CONCLUSIONS:** People with severe psoriasis and those with mild psoriasis but with psoriatic arthritis have an increased risk of uveitis. Clinician may use this finding as a guide for uveitis risk stratification in patients with different inflammatory presentations on the spectrum of psoriatic disease.

PSS3

RISK OF SECOND PRIMARY CANCER IN PEOPLE WITH NON-MELANOMA SKIN CANCER: A NATIONWIDE COHORT STUDY

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OBJECTIVES: To assess the risk of second primary cancer in people with non-melanoma skin cancer (NMSC). **METHODS:** By using data from the National Health Insurance Research Database, we conducted a population-based cohort study to assess the risk of incident second primary cancer in people affected by NMSC. **RESULTS:** We identified 505 subjects with NMSC and 2,020 matched controls. After adjustment for potential confounders including age, sex, urbanization, and Charlson comorbidity index, people who had NMSC had a 1.43-fold (95% CI: 1.05–1.96) risk for the development of second primary cancer as compared with control group. Men with NMSC had a 2.99-fold (95% CI 1.00–9.10) risk for second primary cancer involving the lip, oral cavity, and pharynx and a 3.51-fold (95% CI 1.21–10.17) risk for second primary cancer involving the genitourinary organs when compared to the control group. By contrast, women with NMSC did not have an increased risk of second primary cancer. **CONCLUSIONS:** This study confirmed Asians with NMSC have an increased risk of second primary cancer, but the clinical presentations are different from those in Caucasians. Our findings can be a useful reference for health care for people diagnosed with NMSC.

PSS4

DIAGNOSIS AND TREATMENT HISTORY BEFORE PSORIASIS DIAGNOSIS AMONG PATIENTS WITH MODERATE-TO-SEVERE PSORIASIS

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OBJECTIVES: Psoriasis patients often experience delay in diagnosis. This study examined the diagnoses of skin diseases and treatments before receiving psoriasis diagnosis among patients with moderate-to-severe psoriasis. **METHODS:** Adult patients with at least 2 psoriasis diagnoses (ICD-9-CM code: 696.1) between 01/1998 and 03/2015 were identified in the OptumHealth Reporting and Insights claims database. The index date was the first psoriasis diagnosis date. Eligible patients had continuous eligibility during the 3 years before (baseline period) and 5 years after the index date. Patients with moderate-to-severe psoriasis were identified if they had ≥ 1 systemic therapy or phototherapy during the 5-year post-index period. Diagnoses of other skin diseases, time from the first skin disease diagnosis to the first psoriasis diagnosis and treatments for skin diseases were described over the baseline period. **RESULTS:** The study included 1,098 patients with a mean age of 53 years and 46% female. Common psoriasis-related comorbidities during the baseline period were hyperlipidemia (41%), hypertension (38%), and diabetes (14%). During the baseline period, 474 (43%) patients had ≥ 1 diagnosis of other skin disease, with the most common including contact dermatitis and other eczema (29%), dermatophytosis (13%), and atopic dermatitis and related conditions (7%). The average time from the 1st skin disease diagnosis to the 1st psoriasis diagnosis was 15.9 months. Among patients with a skin disease diagnosis, 91% received treatments related to skin diseases with the most commonly used being steroids (topical: 77%, non-topical: 24%) and antifungals (topical: 39%, oral: 23%). **CONCLUSIONS:** A high proportion of moderate-to-severe psoriasis patients had diagnoses for other skin diseases and was treated with steroids or antifungals before receiving the 1st psoriasis diagnosis. The high rates of other skin disease diagnoses at baseline suggested that some patients may be misdiagnosed. Future studies assessing the association between these skin diseases and psoriasis are warranted.

PSS5

PREVALENCE OF GINGIVITIS AMONG PATIENTS ATTENDED DENTAL DEPARTMENT OF SANDMAN PROVISIONAL HOSPITAL IN QUETTA, PAKISTAN

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OBJECTIVES: The aim of this study was to check prevalence of Gingivitis among patients attended dental department of Sandman Provisional hospital Quetta, Pakistan. **METHODS:** The retrospective based descriptive study was done and data was collected from patients records for the period of 16 months i.e.: January 2015 to

April 2016. The record of patients attended dental department of hospital having any dental disease were included in study. To study population descriptive and cross tabulation were performed and data in this study was analyzed using IBM SPSS v.20. **RESULTS:** Three thousand four hundred six (3406) patient's record data were analyzed during the study period, majority (n=1159, 34.9%), of respondents had age ranges between 17 – 26 years with male dominance, (n= 1746, 51.3%). Results shows that overall prevalence of Gingivitis was 89.6% (n=3052) among all the dental diseases recorded for the patients. Age group was significantly (P < 0.001) associated with the type of different diseases. **CONCLUSIONS:** The present study revealed that the Gingivitis was most prevalent disease in dental patients, it is recommended that conscious efforts should be taken including oral health awareness programs and seminars regarding oral health in city.

SENSORY SYSTEMS DISORDERS – Cost Studies

PSS6

AFLIBERCEPT FOR THE TREATMENT OF NEOVASCULAR AGE-RELATED MACULAR DEGENERATION: A BUDGET IMPACT ANALYSIS UNDER THE PERSPECTIVE OF BRAZILIAN PUBLIC HEALTH CARE SYSTEM

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OBJECTIVES: Age-related macular degeneration (AMD) is a chronic disease that can lead to blindness. The Brazilian public healthcare system (SUS) provides free of cost those drugs incorporated to its Pharmaceutical Assistance Program. The goal of this study is to determine the budget impact of aflibercept for SUS as compared with bevacizumab and ranibizumab. **METHODS:** We have undertaken a budget impact analysis (BIA) following the Brazilian Ministry of Health (MOH) guidelines. The Brazilian population data was obtained from Instituto Brasileiro Geografia Estatística (IBGE) and epidemiological data from Brazilian Society of Retina and Vitreous (SBRV), with the prevalence of 10%. All drugs had their posology based on their Brazilian labels. The prices (ex-factory, maximum price for MOH, and negotiated prices) were from SUS. And other costs from SUS administrative databases, SIGTAP (for medical office, diagnosis tests and pharmaceutical application costs, etc.). We simulated various scenarios of diffusion rates from 10% to 70% penetration. **RESULTS:** We have estimated that about 126,266 Brazilians are potential patients in the first year and 133,826 in the 5th year. The annual cost of treatment, using the maximum price for MOH, with aflibercept was R\$ 20,809.81 (USD\$ 6,120.00) for the first year, R\$ 17,836.98 (USD\$ 5,245.00) (from 2nd to 5th year); bevacizumab was R\$ 15,536.64 (USD\$ 4,519.00); and ranibizumab R\$ 36,410.64 (USD\$ 10,708.00). The total annual budget impact for SUS in the 10% scenarios was R\$ 480 MI (USD\$ 141 MI) for ranibizumab and R \$280 MI (USD\$ 82 MI) for aflibercept, considering that it was R\$219MI (USD\$ 64 MI) for bevacizumab. **CONCLUSIONS:** Under the perspective of Brazilian SUS, ranibizumab had the higher costs, bevacizumab had similar efficacy with lowest costs, and aflibercept had also similar efficacy with intermediated costs between ranibizumab and bevacizumab. Thus, a strong price negotiation is recommended due to large budget impact on SUS.

PSS7

COST-EFFECTIVENESS AND BUDGET IMPACT ANALYSIS OF CLOSTRIDIAL COLLAGENASE OINTMENT COMPARED WITH MEDICINAL HONEY FOR TREATMENT OF PRESSURE ULCERS

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OBJECTIVES: To assess the cost-effectiveness and economic impact of enzymatic debridement with clostridial collagenase ointment (CCO) compared with medicinal honey (MH) for pressure ulcer (PU) treatment from a US payer/Medicare perspective in the hospital outpatient department (HOPD) setting. **METHODS:** A budget impact analysis using Markov health state transitions was developed using a 1-week cycle length across a 1-year time period to estimate the potential economic impact (expressed in 2016 US dollars) after increasing the market share of PU patients treated with CCO. The three health states were: (1) inflammation/senescence; (2) granulation/proliferation (ie, patients achieving 100% granulation); and (3) epithelialization. Data sources included the US Wound Registry, Medicare fee schedules, and published clinical and cost studies about PU treatment. **RESULTS:** In the base-case analysis over a 1-year time horizon, CCO was the economically dominant strategy (ie, simultaneously conferring greater benefit at less cost). Patients treated with CCO experienced 22.7 QALWs at a cost of \$6,161 over one year, while MH patients experienced 21.9 QALWs at a cost of \$7,149. Patients treated with CCO achieved 11.5 granulation weeks and 6.0 epithelialization weeks compared with 10.6 and 4.4 weeks for MH, respectively. The number of clinic visits was 40.1 for CCO vs 43.4 for MH, and number of debridements was 12.3 for CCO compared with 17.6 for MH. Assuming a patient population of 1000 patients, for every 1% of patients shifted from MH to CCO, a cost savings of \$9883 over one year is observed by the payer. Probabilistic sensitivity analyses determined CCO to be dominant in 72% of 10,000 iterations and cost-effective in 91%, assuming a benchmark willingness-to-pay threshold of \$50,000/quality-adjusted life year (\$962/QALW). **CONCLUSIONS:** The results of these economic analyses suggest CCO is a cost-effective, economically dominant alternative to MH in the treatment of patients with PUs in the HOPD setting.

PSS8

ESTIMATING THE ECONOMIC IMPACT OF OPEN-ANGLE GLAUCOMA THERAPY OPTIONS: A SYSTEMATIC REVIEW

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OBJECTIVES: To conduct a systematic review of the economic impact on glaucoma-associated services, comparing topical medications ("drop") vs. laser trabeculoplasty (LT), or any glaucoma surgery ("non-drop") therapies. **METHODS:** We used a structured search of Pubmed to retrieve randomized controlled trials, cohort or case-control studies, and economic models published between January 1996 and August 2016. Inclusion criteria required a direct comparison of a drop vs. non-drop treatment. We extracted data on healthcare resource use and direct costs of glaucoma associated services (ophthalmologist visits, surgical procedures, medications, exams and other services); and indirect costs (production loss and absenteeism) of topical medications drop vs. non-drop therapies. **RESULTS:** Twelve studies met the inclusion criteria (eight economic models, three retrospective cohort studies and one prospective case series). Analyses were from eight countries across four continents (North America, South America, Europe and Africa). Of the non-drop therapies included in the review, LT was the comparator in six studies, traditional surgical procedures were comparators in four, minimally invasive surgeries in one study; and one study assessed either surgery or laser procedures compared with drops. In four studies, the comparison between drops and LT were made in a primary glaucoma diagnosis population, with the other eight in populations with more advanced or refractory disease. All 12 publications reported direct costs, only two of the twelve included indirect costs or reported health care resource utilization. Potential cost-savings with non-drop treatments was seen in eight of the twelve studies, including all four studies comparing a primary laser procedure to initiation of drop therapy. **CONCLUSIONS:** Open-angle glaucoma treatment using non-drop therapies may have the potential to be cost-effective when compared to drop therapy for both initial- and drop-refractory treatment for open-angle glaucoma. However, variability between studies and numerous potential intra-study limitations does not allow for a consensus recommendation and supports the need for further evaluation.

PSS9

TREATMENT PATTERNS AND TOTAL HEALTHCARE COSTS OF METASTATIC MERKEL CELL CARCINOMA IN THE UNITED STATES

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OBJECTIVES: This study describes treatment patterns and total direct healthcare costs among Medicare enrollees diagnosed with advanced Merkel cell carcinoma (aMCC), a rare neuroendocrine carcinoma of the skin. **METHODS:** Surveillance, Epidemiology and End Results (SEER)-Medicare data were used to describe treatment patterns and costs, and 12-month total healthcare costs for patients aged ≥ 65 years diagnosed with aMCC from 2006-11. Patients were required to have non-HMO Medicare eligibility for ≥ 12 months before and ≥ 4 months after diagnosis. Chemotherapy within 4 months after diagnosis was considered first-line treatment. Second-line treatment was assessed from 6 weeks after first chemotherapy up to death or disenrollment. Median per-patient total direct healthcare costs within 12 months post-diagnosis, including diagnostics and imaging, treatment procedures, inpatient and outpatient visits, hospice, home healthcare and durable medical equipment for any condition were calculated in 2015 dollars. **RESULTS:** We identified 154 patients diagnosed with aMCC. At diagnosis, mean age was 81 (SD=7.5) years; 32% (N=60) were women; 39% (N=60) were stage IIIB and 61% (N=94) were stage IV. Within 4 months after diagnosis, 83% (N=128) of patients received treatment, of which 45% (N=70) received surgery, 44% (N=67) radiation therapy and 38% (N=58) chemotherapy. Second-line chemotherapy was identified in 31% (N=18) of patients receiving first line chemotherapy. Median total 12-month direct healthcare costs were \$46,081 (IQR=\$37,488) per patient. Patients receiving no treatment had the lowest median total healthcare costs (\$29,256; IQR=\$13,387), followed by patients receiving surgery and/or radiation but not chemotherapy (\$45,775; IQR=\$37,110); costs were highest in patients receiving chemotherapy, either alone or combined with radiation and/or surgery (\$54,672; IQR=\$70,635). **CONCLUSIONS:** Most aMCC patients receive initial treatment including surgery, radiation and/or chemotherapy and approximately one-third of the latter receive second-line chemotherapy. Total 12-month direct healthcare costs are highest in patients receiving chemotherapy alone or combined with radiation and/or surgery.

PSS10

COSTS OF NONSURGICAL DEFECT SCARS TREATMENT SCHEME AFTER SURGERY ON MAMMARY GLANDS IN REAL LIFE PRACTICE

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OBJECTIVES: Hypertrophic scars and keloids have high influence on quality of life for women after surgery and lead to strong psychosocial impairment. There are numbers of invasive and non-invasive options available for the plastic and aesthetic surgery both to prevent and to treat abnormal scar formation. The objective of this study was to estimate costs of treatment scheme of scars after surgery on mammary glands in real life practice and assess consumption of medicine in out-patient care in Ukraine. **METHODS:** We analyzed 47 medical records of women with scars after surgery on mammary glands at Lviv State Regional Oncology Diagnosing and Treating Centre in 2015 in Ukraine (Lviv Region population 2,5 mln people). We calculated the average costs of medicine treatment course per patient for 3 month duration; and we analyzed the direct cost of treatment using weighted average prices from Morion company database (Ukraine) as of December 1, 2016 (1 USD= 26 UAH) from patients' perspective. **RESULTS:** The

main effectiveness outcomes in the scheme are lower recurrence rates, satisfied patients, absence of additional surgery of defect scars, and short time presence in hospital (Monstrey S, Middlekoop E. et al., 2014). The sample included 47 women with age ranging from 19 to 41 years. The treatment included: dexamethasone solution for injection, local anesthetic (2% lidocaine), silicone patch, elastic bandage. An average costs were 57.86 USD per one woman for treatment course for 3 month. **CONCLUSIONS:** The costs of the treatment are high because they are the patient's out-of-pocket expenses. The analysis shows the actual topic for research of women health and optimization of treatment regimens after surgery.

PSS11

EVALUATION OF THE CHANGE IN VISUAL ACUITY AND RELATED CLINICAL RESOURCE USE IN THE 12 MONTHS PRIOR TO AND POST INTRAVITREAL SURGERY USING THE FLUOCINOLONE ACETONIDE IMPLANT

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OBJECTIVES: To assess visual acuity (VA) and healthcare resource use and costs of treating diabetic macular oedema (DMO) before and after treatment with fluocinolone acetonide (FAC) intravitreal implant in routine practice. **METHODS:** The retrospective ILUVIEN Clinical Evidence study collected data from patient medical records in multiple ophthalmology centres in the UK. Data were collected on patients with DMO prescribed FAC implant in the 12 months before and after implant. Costs were attributed to healthcare resource use using standard UK healthcare costing methods (2014/15 prices). **RESULTS:** 178 people contributing 196 treated eyes were included in the study. Mean age was 68.4 years; 67 (38%) were female. Median (interquartile range, IQR) VA was 0.70 (0.50–1.00) LogMAR units at implant, improving to 0.60 (0.38–0.90) LogMAR units at 12 months post implant ($p < 0.001$). 45% and 20% of patients achieved an improvement in ETDRS score of 5 and 15 letters, respectively, at 12 months. The mean (standard deviation, SD) number of anti vascular endothelial growth factor (anti-VEGF) injections per treated eye in the 12 months prior to implant was 2.8 (2.6), decreasing to 0.6 (1.4) in the same period after implant (unit cost £747 for ranibizumab, £1,012 for aflibercept and £246 for bevacizumab). The corresponding figures for other steroid injections were 0.2 (0.4) before and 0.1 (0.4) after implant (unit cost £1,066 for dexamethasone and £197 for triamcinolone). 20 (10%) and 18 (9%) eyes underwent macular laser therapy (unit cost £137) before and after implant, respectively. Mean (SD) costs of these treatments were £2,049 (£1,869) before and £543 (£1,177) after implant ($p < 0.001$). The unit cost of administering the FAC implant was £5,696. **CONCLUSIONS:** An improvement in visual acuity was observed at 12 months. Excluding the cost of the FAC implant, healthcare costs associated with treatment were significantly reduced in the 12 months post implant.

PSS12

COST-EFFECTIVENESS OF SECUKINUMAB IN MODERATE TO SEVERE PSORIASIS COMPARED WITH OTHER BIOLOGICS IN GERMANY

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OBJECTIVES: Secukinumab (SEC) 300 mg, a fully human interleukin-17A antibody, has demonstrated superior and sustained efficacy in adults with moderate to severe psoriasis compared with ustekinumab (UST), etanercept (ETN), and placebo. This analysis compared the cost per responder of SEC as first biologic treatment with adalimumab (ADA), infliximab (INF), ETN, and UST. **METHODS:** A 52-week decision tree, reflecting response to treatment (defined as Psoriasis Area Severity Index [PASI] reduction of $< 50\%$, 50-74, 75-89, and ≥ 90 ["PASI ≥ 90 "]), led into a Markov model with health states related to treatment continuation, drop-out, and death. Responders (i.e., PASI ≥ 75 and PASI ≥ 90) at week 16 continued initial treatment. Sustained response was defined as 16-week response maintained at week 52. Nonresponders and drop-outs were switched to standard of care. A 10-year German health care system perspective with 3% discount rates was adopted. Clinical data came from a mixed-treatment comparison; 2016 resource unit costs from national sources; and adverse events and discontinuation rates from literature. We calculated cost per PASI ≥ 90 responder over week 16 and over week 52, as well as per sustained responder between weeks 16 and 52. Sensitivity analysis, excluding co-pays, was conducted. **RESULTS:** SEC had the lowest cost per PASI ≥ 90 responder over 16 weeks (€17,907) compared with UST (€18,027), ADA (€23,418), INF (€28,416), or ETN (€33,939). Over 52 weeks, costs per PASI ≥ 90 responder ranged from €42,078 (SEC) to €69,968 (ETN). Likewise, SEC had the lowest cost per sustained 52-week PASI ≥ 90 responder (€22,514) and UST the highest (€31,107). SEC dominated all other biologics on the cost-effectiveness frontier. Sensitivity analysis supported robustness of results. **CONCLUSIONS:** SEC treatment of moderate to severe psoriasis is cost-effective, reducing cost per responder compared with other biologic treatments over 10 years in Germany.

PSS13

COST-EFFECTIVENESS ANALYSIS OF RANIBIZUMAB PRN (AS NEEDED) IN WET AGE-RELATED MACULAR DEGENERATION IN CHINA

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OBJECTIVES: Ranibizumab (RBZ) was the first available anti-vascular endothelial growth factor treatment in China. Monthly treatment is recommended per label; however, pro re nata (PRN) (as needed) is the most widely used dosing regimen in local

routine clinical practice. This study aimed to assess the cost-effectiveness of RBZ-PRN compared to best supportive care (BSC) with the recently revised 2016 manufacturer price from a societal perspective. **METHODS:** A 10-year MS-Excel Markov model with 5 visual acuity levels and 1 death state was used. Two wAMD eye types, predominantly classic (PC) and minimally classic/occult (MC/OC) eyes were analyzed separately given the differences in treatment response observed in clinical trials. Transition probabilities, treatment frequencies and adverse event data were sourced from clinical trials (MARINA, TAP, SUSTAIN, MONT BLANC). Direct medical costs (3.5% discount) were obtained from China's national claims database; utilities (3.5% discount) were from a time-trade-off study. Direct non-medical and indirect costs were sourced from a local disease burden study. One-way and probabilistic sensitivity analyses were performed on baseline age, time horizon, treatment duration, blinding costs and utilities etc. **RESULTS:** Assuming a cost-effectiveness threshold of

PSS14

THE COST-EFFECTIVENESS OF ORAL ALITRETINOIN IN PATIENTS WITH SEVERE CHRONIC HAND ECZEMA IN THE HEALTHCARE SYSTEM OF SOUTH KOREA

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OBJECTIVES: Patients with severe chronic hand eczema (CHE) refractory to steroids have few therapeutic options. Recently, alitretinoin has been suggested as a new treatment option for those patients and its cost-effectiveness has been accepted in European countries. However, the cost-effectiveness outcomes of using alitretinoin have rarely been examined in other countries. Our study aims to assess the cost-effectiveness of alitretinoin compared to previous supportive care from the societal perspective of South Korea. **METHODS:** A markov model was constructed to project the incremental cost effectiveness ratio (ICER) per quality-adjusted life-year (QALY) for every 12-week up to 20 years. Clinical effectiveness outcomes were drawn from previous clinical studies. Costs and utilization patterns of medications were obtained from the survey and focus group interviews with dermatologists and pharmacists. The EQ-5D values were mapped from the Dermatology Life Quality Index according to patients' Physician Global Assessment scores. All costs were converted to 2016 January US dollars of 2016 January. One-way sensitivity analyses regarding discount rate, alitretinoin price, definition of relapse, utility values, and the number of treatment terminated patients were performed. Both costs (\$) and QALY were annually discounted at 5% rate. **RESULTS:** The use of alitretinoin treatment over the supportive care during 3 years yielded in the ICER of \$15,854/QALY. The ICER values kept decreasing from \$31,350/QALY to \$8,917/QALY as the time horizon extended from 1 to 20 years. These results were robust to all sensitivity analyses with ICERs between \$8,525/QALY and \$24,386/QALY during 3 years. **CONCLUSIONS:** Our study projected the cost-effectiveness of using alitretinoin and the results showed that alitretinoin was highly cost effective for patients with severe CHE refractory to topical steroids in South Korea considering the ICER value lesser than the GDP per capita.

PSS15

A COST-PER-RESPONDER ANALYSIS OF SECUKINUMAB COMPARED WITH USTEKINUMAB THROUGH 52 WEEKS IN GERMANY: RESULTS FROM THE CLEAR STUDY OF PATIENTS WITH MODERATE TO SEVERE PSORIASIS

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OBJECTIVES: Secukinumab (SEC) 300 mg, a fully human interleukin-17A antibody, has demonstrated sustained superior efficacy over ustekinumab (UST) 45/90 mg, an anti-interleukin-12/23 antibody, through 52 weeks in adults with moderate-to-severe psoriasis. This analysis compared the cost per responder of SEC versus UST over 1 year from a German payer perspective. **METHODS:** A 52-week decision-tree model reflecting response to treatment, defined as Psoriasis Area Severity Index (PASI)-reduction of < 50, 50-74, 75-89, and ≥ 90% from the CLEAR head-to-head study comparing SEC to UST, evaluated cost per responder (PASI75, PASI90, and PASI100). Responders at week 16 continued initial treatment. Nonresponders and drop-outs were switched to standard of care. Resource unit costs for 2016 were derived from national sources; adverse events and discontinuation rates, from published literature. No discount was applied. Analyses were conducted for responders over week 16 and over week 52, as well as for those with sustained response between weeks 16 and 52. Deterministic sensitivity analyses were conducted to evaluate the impact of drug costs only. **RESULTS:** Estimated cost per PASI90 responder was lower for SEC than for UST over 16 weeks (SEC: €15,648; UST: €16,645), over 52 weeks (SEC: €35,668; UST: €49,280), and for 52-week sustained response (SEC: €19,017; UST: €23,800). Overall, PASI75 and PASI100 results also were lower for SEC than for UST. Time in PASI90-99 or PASI100 was longer with SEC than with UST (0.31 vs. 0.24 years and 0.40 vs. 0.20 years, respectively). Sensitivity analyses confirmed the robustness of results: cost per responder remained lower for SEC than for UST. **CONCLUSIONS:** The strong and sustained efficacy of SEC compared to UST in the treatment of moderate to severe psoriasis reduces the cost per responder over 1 year in Germany.

PSS16

PHARMACOECONOMIC ANALYSIS OF DEXAMETHASONE INTRAVITREAL IMPLANT FOR THE TREATMENT OF DIABETIC MACULAR EDEMA IN RUSSIA

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OBJECTIVES: Diabetic macular edema (DME) is one of the leading causes of vision loss in older adults in Russia, as well as in the United States. Sustained-release

dexamethasone intravitreal implant blocks production of the vascular endothelial growth factor (VEGF) and other inflammatory mediators, inhibits leukostasis, and enhances the barrier function of vascular endothelial cell tight junctions. It was approved for the treatment of DME in Russia in 2016. This is the first pharmacoeconomic evaluation of Ozurdex use in treatment of DME in Russia. **METHODS:** VEGF inhibitors ranibizumab and aflibercept were used as comparators; the mean average best corrected visual acuity (BCVA) improvement was chosen as a primary efficacy endpoint. Thorough literature search was conducted, 12 appropriate randomized clinical trials (RCTs) and 4 observational studies were retrieved. Cost-utility and cost-effectiveness analyses were implemented based on decision tree model. The main scenario incorporated weighted efficacy of dexamethasone, ranibizumab and aflibercept obtained in a Bayesian network meta-analysis of RCTs; an alternative scenario exploited effectiveness of Ozurdex estimated in observational studies. A three year model horizon was used. Probabilistic sensitivity analysis using Monte Carlo simulation was used to estimate uncertainty range for incremental cost-effectiveness and cost-utility ratios (ICER and ICUR). **RESULTS:** Total direct costs of dexamethasone, ranibizumab and aflibercept were 274 729, 792 662 and 1 060 918 rubles accordingly. In the main scenario ICERs for ranibizumab and aflibercept were 2 130 143 and 1 767 862 rubles for three line BCVA improvement; and ICURs were 39 258 845 and 33 667 235 rubles accordingly for 1 additional QALY, which exceeds 1 341 308 rubles society willingness to pay threshold based on per capita gross domestic product. Sensitivity analysis demonstrated low level of uncertainty of these estimates. **CONCLUSIONS:** Dexamethasone intravitreal implant is pharmacoeconomically useful for patients with DME in Russia.

PSS17

COST-EFFECTIVENESS OF TARGETED THERAPY FOR MODERATE-TO-SEVERE PLAQUE PSORIASIS: AN ANALYSIS BASED ON AN INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW (ICER) REPORT

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OBJECTIVES: To determine the likelihood of cost-effectiveness, assessed by cost per quality-adjusted life year (QALY), for several targeted therapies approved to treat moderate-to-severe plaque psoriasis in the United States. Currently marketed drugs included were apremilast, adalimumab, etanercept, infliximab, ustekinumab, secukinumab, and ixekizumab; the newly-approved drug brodalumab was also included. **METHODS:** We constructed a Markov model to simulate the flow of patients from first-line therapy to either second-line therapy or no treatment and, for patients receiving second-line treatment, from second-line therapy to no treatment. Patients were assumed to change treatment if they failed to achieve a 75% improvement in Psoriasis Area Severity Index (PASI-75) over baseline or if their response fell below PASI-75. The wholesale acquisition cost for each drug was discounted by a class-specific, empirically-derived rebate percentage. Brodalumab's price was set to equal the average of secukinumab and ixekizumab, the other two IL-17 agents. Health-related utility on first-line treatment was derived from improvement in PASI score from baseline; second-line treatment used a weighted average of utility on targeted therapy, with a 5% decrement to represent loss of efficacy in patients with prior targeted therapy. We conducted a probabilistic sensitivity and net monetary benefit analysis to estimate likelihood of cost-effectiveness. **RESULTS:** Over a ten year time horizon, at a willingness-to-pay of \$100,000/QALY, secukinumab, ixekizumab, and brodalumab – all IL-17 agents – had a combined probability of 51% of being most cost-effective, while apremilast and infliximab had 11% and 7% probability, respectively. The class-wide probability of cost-effectiveness for IL-17 drugs rose to 94% when willingness-to-pay is \$150,000/QALY. **CONCLUSIONS:** At and above the \$100,000/QALY threshold often cited for the United States, the three IL-17 agents in this study are likely to be the most cost-effective first-line agents.

PSS18

A COST-EFFECTIVENESS AND VALUE OF INFORMATION ANALYSIS OF ALTERNATIVE TREATMENTS FOR PRIMARY AXILLARY HYPERHIDROSIS IN SECONDARY CARE

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OBJECTIVES: To determine the most cost-effective sequence of interventions for the management of refractory primary hyperhidrosis in secondary care in the UK NHS, and to establish the expected value of undertaking additional research on clinical outcome and utility parameters. **METHODS:** A de novo probabilistic model was developed, which modelled sixty-four different treatment sequences for axillary hyperhidrosis. Treatments included: aluminium chloride, medication (M), botulinum toxin (BTX), iontophoresis (I) sponge, curettage (C) and endoscopic thoracic sympathectomy (E). A 48-year time horizon was used, with health outcomes expressed as QALYs. The perspective was that of the UK NHS and Personal Social Services. Sensitivity analyses were conducted, alongside both the population expected value of perfect- and partial perfect-information (EVPI) for model parameters. These were calculated for different willingness to pay thresholds (WTP), incidence rates and effectiveness of treatments. Costs were calculated in GBP (£) for the 2015 price year. **RESULTS:** Base-case results indicated that IBMCE was the most cost-effective sequence; ICER of £9,304/QALY; probability cost-effective 0.8. The next most cost-effective sequences involved medication moving

before BTX or disappearing from the sequence. This reflects the uncertainty in the effectiveness estimate of medication vs placebo. Most sensitivity and scenario analyses had little effect on the results. The population EVPI for medication vs placebo and for curettage vs BTX effectiveness was > £3 million for all scenarios; unless the incidence of axillary hyperhidrosis was 0.5% and WTP was £20,000/QALY. **CONCLUSIONS:** The analysis found that the treatment sequence IBMCE was most cost-effective. Despite the limited evidence, iontophoresis and BTX maintained their position as first- and second-line treatment options in the majority of cost-effective sequences. The value of information analysis suggested that whilst further research of medication vs placebo may be of value, with medication either coming before BTX in the sequence or dropping out altogether.

PSS19

ASSESSING HOSPITAL UTILIZATION OF PATIENTS DIAGNOSED WITH EPIDERMOLYSIS BULLOSA

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OBJECTIVES: Epidermolysis Bullosa (EB) is a group of rare genetic diseases that affects 20 out of every million live births in the United States. Although there are many different variations of EB all have extremely fragile skin that blisters and tears with only minor friction or trauma. EB may also affect internal organs and body systems. The objective of this analysis is to describe EB patients utilizing acute care hospital services and examine drivers of utilization. **METHODS:** A retrospective descriptive study was conducted on a cross-section of EB discharges in the MedAssets health system data for inpatient (N=114) and outpatient (N=866) visits from October 2015 through December 2016. Multivariable logistic regression was used to identify significant drivers of inpatient admission. **RESULTS:** The sample included 431 unique patients from 111 hospitals with an average age of 22.0 years. The population included slightly more females (53.4%) than males and had few comorbidities with an average Charlson comorbidity score of 0.76. The most common comorbid conditions were chronic pulmonary disease (14.4%) and renal disease (10.7%). Disease complications included anemia (24.2%), nutritional deficiencies (12.8%), feeding difficulties such as dysphagia or esophageal obstruction (12.0%), skin infections (5.2%) and other infections (6.0%) such as pneumonia and sepsis. While 26.8% of the sample had a single visit during the study period, 4.8% had five or more visits. Utilization was primarily outpatient (88.4%). The average inpatient length of stay was 11.8 days with average cost \$43,309. The largest predictors of inpatient admission were skin (OR=7.8, p<.0001) and other infections (OR=28.8, p<.0001), diabetes with complications (OR=8.1, p=.0302), and nutritional deficiencies (OR=5.1, p<.0001). **CONCLUSIONS:** EB patients have few non-disease related comorbidities but many disease related complications. Hospital utilization is primarily outpatient based, however disease complications may lead to lengthy and costly inpatient admissions.

SENSORY SYSTEMS DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

PSS20

ADHERENCE AND PERSISTENCE AMONG U.S. PATIENTS INITIATING SECUKINUMAB FOR THE TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS

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OBJECTIVES: Secukinumab is highly effective for the treatment of moderate to severe plaque psoriasis in clinical trials. Little is known regarding how secukinumab is used long term in a real world setting. This study examined adherence and persistence to secukinumab among patients with plaque psoriasis. **METHODS:** Adults with ≥ 1 plaque psoriasis diagnosis since January 1, 2014 who initiated secukinumab between January 1, 2015 and April 30, 2016 (first claim= index) with ≥ 6 months of pre-index continuous enrollment in the MarketScan[®] Commercial and Medicare Supplemental Databases were selected. Adherence was measured by the proportion of days covered (PDC) with secukinumab. Persistence was defined as the number of days from index until a gap of ≥ 90 days without secukinumab (discontinuation), or the end of follow-up if no discontinuation was observed. Further analysis was conducted for non-mutually exclusive subgroups based on available post-index follow-up (≥ 3, ≥ 6, ≥ 9 and ≥ 12 months respectively). **RESULTS:** A total of 1,504 secukinumab patients were examined, with mean age 48.6 years and 54% male. Among all patients, 1,087 (72%), 724 (48%), 355 (24%), and 69 (5%) had ≥ 3, ≥ 6, ≥ 9 and ≥ 12 months of post-index follow-up, respectively. The estimated PDC was 0.79 for all patients and 0.72 for those with ≥ 12 months of follow-up. Overall, 87% of patients persisted on secukinumab, with a mean of 154 days (standard deviation [SD]: 104) persistence prior to discontinuation. Among patients with ≥ 12 months follow-up, 74% were persistent, and the mean days to discontinuation were 295 [SD: 123]. **CONCLUSIONS:** Patients with plaque psoriasis initiating secukinumab were generally adherent to therapy as evidenced by PDC of nearly 80%. Almost three-quarters of patients persisted on treatment over 12 months.

PSS21

OBSERVATIONAL STUDY COMPARING TREATMENT PERSISTENCE IN BIOLOGIC-NAIVE PSORIASIS PATIENTS INITIATING APREMILAST OR ETANERCEPT

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OBJECTIVES: Currently, no comparative data have been published on the persistence among biologic-naive patients with psoriasis who are being treated with apremilast vs. etanercept in a real-world setting. We assessed real-world treatment persistence over 12 months in patients with psoriasis in the United States who were initiated on

apremilast or etanercept. **METHODS:** This descriptive, observational, retrospective cohort study was conducted using MarketScan Commercial and Medicare Supplemental Databases (2013-2016). Adults with ≥ 2 diagnosis codes for psoriasis (ICD-9: 696.1; ICD-10: 40.0) who were initiated on apremilast or etanercept treatment were selected. The index date was defined as the first apremilast or etanercept prescription date, and patients were required to be continuously enrolled for ≥ 12 months pre-index and ≥ 12 months post-index. Time to treatment discontinuation was evaluated descriptively using Kaplan-Meier curves, and defined as the end of days' supply before at least a 60-day gap without medication. At 12 months post-index, the percentage of patients persisting on drug was assessed. **RESULTS:** A total of 1,101 patients initiated on apremilast treatment and 687 initiated on etanercept treatment met the inclusion criteria and had similar baseline characteristics. Mean enrollment follow-up time was 493 days for apremilast and 586 days for etanercept. At 12 months post-index, persistence on the initiated drug was not significantly different between the apremilast and etanercept cohorts (39.5% [apremilast] vs. 35.8% [etanercept]; P=0.109). **CONCLUSIONS:** While apremilast showed numerically higher treatment persistence compared with etanercept, the difference was not statistically significant. Further analyses are needed to explore the impact of higher persistence on clinical effectiveness, that is, to describe the benefit patients are receiving from staying on treatment.

PSS22

A REVIEW OF VISION-RELATED UTILITY VALUES AND THEIR SUITABILITY FOR USE IN COST-EFFECTIVENESS MODELS IN AGE-RELATED MACULAR DEGENERATION

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OBJECTIVES: While therapies for wet age-related macular degeneration (AMD) are well established, therapies in development for dry AMD would be without precedent. Economic evaluations of wet AMD therapies typically have relied on health states and utility values defined by visual acuity (VA), but the mechanisms of dry AMD can impair visual functioning without impairing VA. Our objective was to assess the suitability of VA-based utilities used in wet AMD for use in economic evaluations in dry AMD. **METHODS:** This study reviewed four AMD utility studies and five wet AMD model structures and compared them with two guideline-based visual impairment definitions and the target populations for ongoing clinical trials in dry AMD. A crosswalk of VA ranges and associated utility values was developed to visualize alignment across studies. The AMD utility studies were assessed to determine whether they considered non-VA measures of visual functioning, included dry AMD patients, or controlled for dry AMD severity. **RESULTS:** Lack of alignment in VA ranges was identified: none of the utility studies or model structures were aligned with guideline-based visual impairment definitions, and three of the five model structures used health state definitions that were not aligned with VA-based utility values. The utility studies were all conducted at least ten years ago, and only one utility study considered the interaction of VA and other visual functioning measures. While the utility studies all included dry AMD patients, the percentages of patients with dry AMD were low; moreover, dry AMD severity levels, when reported, were not aligned with dry AMD clinical trial populations. **CONCLUSIONS:** Substantial limitations and inconsistencies were observed in utility values for wet AMD, and key data gaps were identified related to dry AMD. Studies designed specifically for dry AMD are needed to support economic evaluations of future dry AMD therapies.

PSS23

DOES THE CHOICE OF TARIFF MATTER? A COMPARISON OF EQ-5D-5L UTILITY SCORES USING CHINA, UK AND JAPAN TARIFFS ON A PSORIASIS VULGARIS SAMPLE IN MAINLAND CHINA

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OBJECTIVES: To compare and analyze the differences of EQ-5D-5L values derived from UK, Japan and China preference weights using a sample of patients with psoriasis vulgaris in Mainland China. **METHODS:** A convenience sampling framework was adopted and a face-to-face interview approach was used for data collection. The Friedman Test and The Wilcoxon signed-rank tests were used to examine the differences of EQ-5D-5L utility scores derived from three tariffs. The ICCs and Bland-Altman plots were used to study the agreement among the three EQ-5D-5L scores. The Spearman's rho correlation coefficients was adopted to examine the correlation between EQ-5D-5L utility scores and a series of quality of life scores measured based on Visual Analogue Scale (VAS) scores, Psoriasis Area Severity Index (PASI) scores, and Psoriasis Disability Index (PDI) scores. The differences on quality of life scores between different severities of psoriasis vulgaris were tested by using the Mann-Whitney U test. **RESULTS:** A total of 350 patients (aged 16 years or older) were recruited. There were significant differences among the three national tariff sets. The EQ-5D-5L scores using the China weights yielded the largest range (0.30-1.00), whereas those scores derived from Japan and UK preference weights had smaller range (0.45-1.00 and 0.34-1.00, respectively). Overall, three tariffs showed excellent agreement (ICC > 0.90). The EQ-5D-5L scored using the China tariff had better discriminated validity than the other two tariffs. **CONCLUSIONS:** Three country-specific EQ-5D-5L tariffs have shown a high level of agreement based on psoriasis vulgaris patients in Mainland China. Having said that the Chinese-specific tariff had the best the best discriminated validity. It is recommended that the country-specific tariff is preferred for use in Mainland China. If not available, the value sets should be developed, or we also can use UK or other country tariffs with same cultural background. However, more research needs to be done.

PSS24

FACTORS INFLUENCING PATIENT SATISFACTION WITH LOWER REMOVABLE DENTURE

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OBJECTIVES: To determine correspondence between clinician's and patient's appreciation of existing removable dentures and to assess the main determinants of patient satisfaction with the aim of improving treatment outcomes. **METHODS:** This cross-sectional study was conducted over a three-year period among 115 patients with mandibular single remaining teeth, who wore lower removable clasp-retained and overdentures. After detailed examination these patients—67 females (58.3%), 48 males (41.7%) of mean age 63.5 years (SD 13.0), were categorized in Class III—substantially compromised dental status (American College of Prosthodontists Classification System, 2002), ranks of retention and stabilization of a lower denture on its foundation were determined. Oral Health Self-Assessment was aided by the validated translation of the 5-item structured questionnaire (G.D.Slade, 2007). Data were analyzed using Spearman's rho in the SPSS (Statistical Package for Social Sciences) for Windows software (version 12.0). **RESULTS:** Patient dissatisfaction was the most frequently associated with chewing pain (28%) and interrupted meals (27%). These reported causes of denture discomfort were followed by a need of treatment (19%), avoiding speech and laughing (16%) and difficulty relaxing—10% cases. A statistically significant positive correlation was found between the high scores of lower denture instability and chewing pain ($\rho=0.67$), need of treatment ($\rho=0.48$), while stronger-to-weak negative correlation—with interrupted meals ($\rho=-0.35$), avoiding speech and laughing ($\rho=-0.27$) and difficulty relaxing ($\rho=-0.14$). **CONCLUSIONS:** Denture clinical scores and patient perceived comfort have multilateral correlation. In each clinical case attainable prosthodontic goals are helpful in increasing patient satisfaction and improving treatment outcomes.

PSS25

DEVELOPMENT AND VALIDATION OF THE IMPACT ASSESSMENT FOR ROSACEA FACIAL REDNESS (IA-RFR)

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OBJECTIVES: Persistent facial erythema (redness) associated with rosacea has considerable psychosocial impacts that are important components of treatment evaluation. This report describes the development and validation of a patient-reported outcomes (PRO) measure to assess impacts of rosacea facial redness. **METHODS:** The Impact Assessment for Rosacea Facial Redness (IA-RFR) questionnaire was developed consistent with FDA guidance and ISPOR recommendations for validating PROs. The conceptual framework and questionnaire items were generated by literature review, patient concept elicitation interviews (N=31 adults, moderate to severe rosacea-associated erythema; Clinician Erythema Assessment [CEA] grade ≥ 3), and expert opinion. Cognitive interviews (N=20) were conducted to guide revisions. Reliability and validity were examined in a phase 2b study (N=356 adults; 80.1% female; 91.3% Caucasian; CEA severity: 82.0% moderate, 18.0% severe) of oxymetazoline hydrochloride cream 1.0% for treatment of moderate to severe facial erythema associated with rosacea. Test-retest reliability was examined on days 14 and 28 (predose) among patients with the same CEA response. **RESULTS:** Four distinct impact domains were identified, comprising 8 items: Self-perception (self-conscious, low self-esteem, bothered by appearance); Emotional functioning (embarrassment, worry); personal Grooming (avoidance of products, use of cover-up products); and Social functioning (unwanted comments). The IA-RFR and its domains had acceptable Cronbach coefficients ($\alpha \geq 0.83$), with the exception of personal Grooming (Cronbach $\alpha=0.018$). Test-retest reliability was high (intraclass correlation coefficients ≥ 0.80) in 2 different analysis populations. Correlations of items within their respective domains established adequate convergent validity for Self-perception ($r \geq 0.73$) and Emotional domain items ($r=0.72$). Known groups validity was shown for IA-RFR overall, Emotional domain, and worry scores, each of which was significantly higher ($P < 0.05$) among patients with more vs less severe erythema (CEA score). **CONCLUSIONS:** The IA-RFR is a novel tool for assessing the impact of rosacea facial redness that is grounded in patient experience and demonstrates acceptable measurement properties in adults with rosacea.

PSS26

PATIENT-RATED IMPACT ASSESSMENT FOR ROSACEA FACIAL REDNESS (IA-RFR): RESULTS OF TWO PHASE 3 PIVOTAL TRIALS OF OXYMETAZOLINE CREAM 1% VS VEHICLE

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OBJECTIVES: Persistent erythema associated with rosacea has considerable psychological and social impacts that are important to assess when evaluating treatment efficacy. Two phase 3 pivotal trials examined efficacy and safety of oxymetazoline for treatment of moderate to severe persistent facial erythema associated with rosacea. This report describes Impact Assessment for Rosacea Facial Redness (IA-RFR) outcomes from both trials. **METHODS:** In 2 identically designed trials (REVEAL 1 and 2), eligible patients were randomized 1:1 to vehicle or oxymetazoline hydrochloride cream 1.0% (oxymetazoline) applied to the face (QD, 29 days). The impact of erythema associated with rosacea was evaluated using the 8-item IA-RFR, a validated, patient-rated scale. Each item was rated on a 5-point scale (0-4; higher scores indicate more negative impact). Patients completed the IA-RFR at baseline and at hour 6 on follow-up days 1, 15, and 29. Differences between oxymetazoline-group and vehicle-group changes from baseline in IA-RFR total score and Self-perception, Emotional functioning, personal Grooming, and Social functioning domain scores were compared using the van Elteren test. Analyses of item-level changes are ongoing. **RESULTS:** IA-RFR assessments included 440 patients in REVEAL 1 (oxymetazoline, n=222; vehicle,

n=218) and 443 patients in REVEAL 2 (oxymetazoline, n=223; vehicle, n=220). In REVEAL 1, median change from baseline to day 29 was significantly greater with oxymetazoline vs vehicle for total IA-RFR (-0.60 vs -0.50; $P=0.045$), personal Grooming (-0.50 vs 0.00; $P=0.021$), and 1 Self-perception item (self-consciousness; -1.0 vs -1.0; $P=0.024$). In REVEAL 2, median change from baseline to day 29 was numerically greater for oxymetazoline vs vehicle for the total IA-RFR score (-0.70 vs -0.60). Pooled data analyses are forthcoming. **CONCLUSIONS:** Patients with moderate to severe persistent facial erythema associated with rosacea reported greater improvements in impacts of rosacea facial redness when treated with oxymetazoline compared with patients who received vehicle.

PSS27

GEOGRAPHIC ATROPHY DISEASE BURDEN: NEED FOR BETTER CHARACTERIZATION

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OBJECTIVES: To identify knowledge gaps around the burden of illness of geographic atrophy (GA), we conducted a literature review and used findings to guide interviews with GA patients, caregivers, and healthcare providers (HCPs) who treat GA patients. **METHODS:** Peer-reviewed publications describing the use of an instrument, survey, or other assessment tool to report the impact of GA were identified using PubMed (January 2000 to September 2015), a pearl-growing approach, and independent internet searches. Patients with symptomatic GA (n=8), their caregivers (n=6), and HCPs (n=5) were interviewed using tailored guides to identify topics that would further help understand the burden of illness of GA. **RESULTS:** Only 1 out of 318 articles reviewed reported GA-specific findings; other articles reported data for advanced age-related macular degeneration (AMD) and did not differentiate between advanced AMD and GA. A single study described direct medical costs in GA, but there were no GA-specific data on indirect costs related to caregiving, transportation, or lost income. Studies on the mental health burden of GA were lacking. Patients reported that GA affected household chores, visiting restaurants, social outings, sports and outdoor hobbies, participating in religious activities, and long-distance travel. Patients also reported direct out-of-pocket expenses for low vision aids. Caregivers reported modifying schedules, providing transportation, and other assistance. HCPs identified mental health issues and variable compliance with low vision aids as relevant to GA patients. **CONCLUSIONS:** The literature review found very little published information on the impact of GA. There is no consensus on the dimensions of functioning relevant to GA patients or the instruments used to assess them. The interviews highlight the impact of GA on patients' and caregivers' social functioning, quality of life, mental health, indirect resource use, and out-of-pocket costs and provides guidance for designing future burden of GA studies.

PSS28

THE IMPACT OF SOCIOECONOMIC AND CLINICAL CHARACTERISTICS ON HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH PSORIASIS: AN INTERNET-BASED CROSS-SECTIONAL SURVEY

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OBJECTIVES: To determine socioeconomic and clinical characteristics affecting health-related quality of life (QOL) in patients with psoriasis. **METHODS:** A cross-sectional study was conducted between March-June 2015 using data obtained via an Internet-based survey from a psoriasis patients group in Korea. The survey instrument included questions regarding demographic, socioeconomic, and clinical characteristics as well as QOL. Patients' QOL impairment was classified as severe if the dermatology life quality index scores were ≥ 11 . Factors influencing the impairment were identified using multivariable logistic regression analysis. **RESULTS:** Of the 299 respondents, 161 (53.8%) exhibited severe QOL impairment. Patients' dermatology life quality index scores were significantly influenced by gender; annual income; neck psoriasis; psoriasis-related designation from work; and use of oral and herbal medications. QOL in women was two times more significantly impaired than that of men (odds ratio (OR)=2.00, 95% confidence interval (CI): 1.05-3.80). Patients who had psoriasis on the neck had significantly impaired their QOL compared to those who had psoriasis on other areas of their bodies (OR=2.30, 95% CI: 1.20-4.43). In regards to socioeconomic status, patients who earned >40 million KRW (approximately 34,000 USD; high-income group) showed less impairment in their QOL than those who earned less (OR=0.47, 95% CI: 0.28-0.80). Patients who had severe QOL impairment used oral (OR=2.04, 95% CI: 1.20-3.44) or herbal (OR=1.86, 95% CI: 1.04-3.34) medications more often than patients whose QOL impairment was less severe. **CONCLUSIONS:** QOL in patients with psoriasis was significantly associated with demographic and socioeconomic characteristics and working status. The presence of psoriasis on exposed areas may exert a significant effect on patients' QOL and working status. It is recommended that a study evaluating the impact of psoriasis on patient productivity be performed in the future.

PSS29

SYSTEMATIC PSYCHOMETRIC EVALUATION OF DISEASE SPECIFIC HEALTH-RELATED QUALITY OF LIFE INSTRUMENTS IN ACNE VULGARIS

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OBJECTIVES: Acne vulgaris is a chronic skin condition affecting two-thirds of adults and four-fifths of adolescents with significant impact on their health

related quality of life (HRQOL). The objective of this study was to compare and contrast the psychometric properties of acne vulgaris specific HRQOL instruments. **METHODS:** Comprehensive literature review was conducted to identify self-administered instruments in English with at least one publication citing psychometric properties in a peer-reviewed journal. Selected instruments were evaluated based on eight measurement standards: conceptual model, versatility (age, severity, and gender), practicality, breadth, depth, reliability (internal consistency and test-retest), construct validity (convergent and divergent), and responsiveness. **RESULTS:** Seven instruments were evaluated: Acne Disability Index (ADI), Cardiff Acne Disability Index (CADI), Acne-Quality of Life (Acne-QOL), Acne Quality of Life Scale (AQOL), Acne Quality of Life Index (Acne-QOLI), 4-item index of Acne-Quality of Life (Acne-Q4), and Acne Symptoms and Impact Scale (ASIS). All evaluated instruments were designed to be self-administered, versatile (used in men and women, adolescents and adults of varying acne severity), and brief (completed in 5 to 15 minutes), except for ADI. Data to support construct validity was only available for three instruments: CADI, Acne-QOL and ACNE-QOLI, with no data reported for ADI. Depth data was missing for all scales with variability in reliability data reported. Internal consistency and test-rest was reported in most cases for total scores: ADI, CADI, AQOL and Acne-QOLI all meeting study criterion for group level decision making ($>=.70$) (total score), and similarly for Acne-QOL (3/4 scales). **CONCLUSIONS:** Acne-QOL (21 items) was the most widely used instrument, while ADI (48 items) was the longest. Results of the study show strongest support for Acne-QOL, Acne-QOLI, and ASIS, with the latter meeting most study criteria. Instrument choice must also consider study objective, group versus individual level decision making, and domains considered important.

PSS30

DIFFERENTIAL EFFECTS OF SECUKINUMAB VS. USTEKINUMAB FOR TREATMENT OF MODERATE TO SEVERE PSORIASIS ON WORK PRODUCTIVITY AND ACTIVITY IMPAIRMENT: A STRUCTURAL EQUATION MODELLING APPROACH USING THE CLEAR 52-WEEK STUDY

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OBJECTIVES: Moderate-to-severe psoriasis is associated with great impairment in activity and work productivity. However, the causal pathways involving treatment and psoriasis-related symptoms on work productivity and activity impairment (WPAI) are unknown. This analysis examined the differential direct and indirect effects of secukinumab vs. ustekinumab on psoriasis symptoms and patient-reported WPAI at 52 weeks. **METHODS:** Clinical and patient-reported outcomes from CLEAR, a head-to-head, phase 3b study comparing the efficacy and safety of secukinumab vs. ustekinumab in moderate-to-severe psoriasis patients, were examined. Key variables in the analysis included Psoriasis Area and Severity Index (PASI) 50/75/90/100 response (percent improvement from baseline), patient-reported symptoms (pain, itching, scaling), and the WPAI at Week 52. Structural equation modelling (SEM) was used to demonstrate that treatment and selected disease covariates affect WPAI indirectly by first improving symptoms. Model fit was evaluated for each PASI response. Standardized coefficients (β ranging -1 to +1) compared the strength of relationships between covariates. **RESULTS:** Fit of all models to the data was excellent (comparative fit index=0.98). The greater likelihood for secukinumab to achieve PASI 50/75/90/100 response directly resulted in less activity impairment ($\beta=-0.37, -0.35, -0.22, -0.15$, respectively) and work impairment ($\beta=-0.37, -0.33, -0.24, -0.15$, respectively) than ustekinumab (all $P<0.05$). Secukinumab directly improved scaling, and indirectly improved pain and itching, which directly resulted in lower activity impairment and work impairment and indirectly resulted in lower absenteeism. The indirect effects on WPAI resulted from the correlation of absenteeism with activity impairment and work impairment, and correlation of pain and itch with scaling. Results were similar for all PASI levels. **CONCLUSIONS:** SEM allows a detailed understanding of the differential direct and indirect effects of secukinumab vs. ustekinumab on multiple patient-relevant outcomes simultaneously. Secukinumab treatment results in lower activity impairment and work impairment through greater improvements in psoriasis symptoms and greater PASI response vs. ustekinumab.

SENSORY SYSTEMS DISORDERS – Health Care Use & Policy Studies

PSS31

PREVIOUS TREATMENTS FOR PLAQUE PSORIASIS AMONG U.S. PATIENTS INITIATING SECUKINUMAB

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OBJECTIVES: Secukinumab was approved in January 2015 to treat moderate-to-severe plaque psoriasis. The previous treatment of secukinumab patients has not been examined in real world. This study evaluated treatments received by patients with psoriasis prior to secukinumab initiation. **METHODS:** Adults with plaque psoriasis after January 2014 who initiated secukinumab 1/1/2015-4/30/2016 were selected from the MarketScan® Research Databases. Systemic (biologic and non-biologic), topical and non-pharmacological plaque psoriasis treatments utilized prior to secukinumab initiation were measured two ways. First, all treatments used in the 6 months before the first secukinumab claim (index) were flagged. Subsequently, the

one prescription filled closest to index was determined, as an indicator of what treatment patients used just prior to initiating secukinumab. **RESULTS:** Patients initiating secukinumab (N=1,504) had a mean age of 48.6 years and were 54% male. Over the 6-months pre-index, 82.7% of patients were prescribed biologic and/or non-biologic systemic therapy. For the 59.2% of patients with ≥ 1 biologic claims, the most common biologics were ustekinumab (22.9%), adalimumab (21.6%), and etanercept (11.8%). Non-biologic systemic agent claims were observed for 51.4% of patients, with 31.2%, 16.4%, 2.7%, and 18.6% for systemic steroids, apremilast, acitretin, and other systemic agents (methotrexate, cyclosporine), respectively. Among the 26.1% of patients with a biologic claim closest to index, the most commonly prescribed were ustekinumab (9.6%), adalimumab (9.1%), and etanercept (6.0%). About 26% of patients had claim(s) for non-biologic systemic agents closest to index, with 7.4% using apremilast; 31% had a claim for topical agents, 2.6% had photo therapy or laser treatment, 6% had multiple treatments on the same day (e.g., systemic plus topical agents), and 8.4% had no treatment. **CONCLUSIONS:** Some patients used secukinumab as the first-line biologic treatment, but over 80% of patients utilized systemic therapy for plaque psoriasis prior to starting secukinumab, with many having biologic exposure prior to secukinumab initiation.

PSS32

REAL-WORLD HEALTHCARE RESOURCE UTILIZATION IN URTICARIA PATIENTS NEWLY TREATED WITH OMALIZUMAB IN THE UNITED STATES

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OBJECTIVES: To assess healthcare resource utilization (HCRU) among urticaria patients prior to and after omalizumab initiation in a real-world environment. **METHODS:** This retrospective observational cohort study utilized US claims data from the HealthCore Integrated Research Database between 09/20/2013 and 04/30/2016. The study population consisted of urticaria patients newly treated with omalizumab (defined as ≥ 4 omalizumab claims within the first 6 months post-index period; index date=first omalizumab claim date between 03/21/2014 and 10/31/2015), aged ≥ 12 years, and with ≥ 6 months pre- and ≥ 12 months post-index healthcare insurance enrollment. Descriptive and inferential statistics were used to compare all-cause and urticaria-related HCRU within 6 months pre-index (baseline) to months 1-6 and 7-12 post-index. **RESULTS:** The study identified 298 urticaria patients newly treated with omalizumab with a mean (SD) age of 43.5 (± 13.64) years, of which 70.8% were female. The number of patients with all-cause and urticaria-related inpatient hospitalizations remained very low ($n \leq 10$) and was similar across the baseline and post-index periods (for all comparisons, $p > 0.05$). Patients with all-cause emergency department (ED) visits decreased from 19.8% ($n=59$) to 14.4% ($n=43$) ($p=0.066$) and 10.7% ($n=32$) ($p=0.001$) across the baseline, months 1-6, and months 7-12 time periods, respectively. Similarly, a significant trend was observed for urticaria-related ED visits (for all comparisons, $p=0.002$). The number of all-cause and urticaria-related outpatient services and pharmacy claims increased significantly in the post-index period, mainly in months 1-6, when compared to those at baseline (for all baseline to months 1-6 comparisons, $p < 0.05$). **CONCLUSIONS:** Study results showed that urticaria patients newly treated with omalizumab had fewer ED visits and similar inpatient hospitalizations in the post-index period, when compared to those at baseline, in a real-world clinical setting. The observed increase in post-index outpatient and pharmacy claims likely reflect the requirement that omalizumab be administered in a healthcare provider setting.

PSS33

HEALTHCARE UTILIZATION AND EXPENDITURES OF COMMERCIAL/MEDICARE AND MEDICAID PATIENTS WITH HIDRADENITIS SUPPURATIVA

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OBJECTIVES: To understand healthcare resource utilization (HCRU) and expenditures in the hidradenitis suppurativa (HS) Commercial/Medicare and Medicaid populations, before and after the first HS diagnosis (index date). **METHODS:** Retrospective analysis of healthcare claims from the MarketScan Commercial and Medicaid Multi-State Databases identified patients aged ≥ 12 years old with ≥ 3 inpatient (IP) or outpatient (OP) medical claims with a HS diagnosis between January 1, 2009 and December 31, 2014. All-cause costs included any HCRU. HS-specific costs were identified by the presence of a HS diagnosis, boils, fistula, abscesses, or a HS-specific procedure on the claim. HCRU included IP, OP, and pharmacy utilization. **RESULTS:** A total of 16,489 patients, 11,325 Commercial/Medicare and 5,164 Medicaid patients, were identified. All-cause IP services increased between the pre and post-index period for the Commercial/Medicare (10.0% to 13.1%) and Medicaid (17.2% to 19.0%) cohorts. The proportion of patients with HS-specific OP services increased in the post-index period for both Commercial/Medicare (41.2% increase) and Medicaid (34.3% increase) patients. Prior to the index date, OP pharmacy utilization was already above 90% for both cohorts. After index, total all-cause costs increased in the Commercial/Medicare (\$10,646 to \$15,525) and Medicaid (\$9,703 to \$13,167) cohorts. HS-specific OP costs more than tripled in both cohorts (Commercial/Medicare: \$609 to \$2,514, Medicaid: \$404 to \$1,354), and total HS-specific costs increased in the Commercial/Medicare (\$1,349 to \$4,428) and the Medicaid (\$859 to \$2,662) cohorts. **CONCLUSIONS:** For this debilitating disease with significant unmet need, all-cause and HS-specific utilization and healthcare costs substantially increased following diagnosis of HS; the majority of costs were

attributable to OP services, while the cost increases were driven by inpatient services.

PSS34

ECONOMIC EVALUATION OF FUSIDIC ACID IN ADD ON PROTOCOL FOR TREATMENT OF SOFT TISSUE TOPICAL INFECTIONS IN IRAN

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OBJECTIVES: The most pathogenic factors in hospital infections become resistant to antibiotics mostly because of the inappropriate use of them. Considering the risk of increased microbial resistance to Mupirocin, it seems necessary to have another medical treatment for controlling and treating topical infections. This study is conducted to evaluate the economic evaluation of adding Fusidic acid to the current treatment protocol. **METHODS:** A decision tree model with cost-minimization analysis used from the payer's perspective. The model was used for 1,000 hypothetical patients, half of whom assumed as burn patients and the rest as other topical infection and impetigo. The cost of Mupirocin and Fusidic acid was taken from the price list of IrFDA, and the manufacturer respectively. Considering the importance of costs due to microbial resistance and consequence side effects, the costs of systemic antibiotic treatment and hospitalization were calculated as well. One-way sensitivity analysis was performed. **RESULTS:** The treatment cost of 1,000 patients was estimated at 33805.5 US\$ with Mupirocin arm and 11869.5 US\$ with Mupirocin and Fusidic acid arm (50/50 ration for burn vs other hospital wards). Since the efficacy of the both drugs are reported to be equal, the lower cost in the arm with Fusidic acid means that this option is cost saving in comparison with Mupirocin alone (cost reduction 21.9 US\$ per patient). **CONCLUSIONS:** Based on this findings, adding Fusidic acid to current treatment reduced costs dramatically. Therefore, it seems that it is economically reasonable that insurance companies support the prescription and use of Fusidic acid as the second line of treatment for skin infections, which will lower the costs and the risk of antimicrobial resistance as well as improvement in the quality of life of patients.

PSS35

LONG-TERM TREATMENT PATTERNS AMONG PATIENTS WHO DEVELOPED MODERATE-TO-SEVERE PSORIASIS

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OBJECTIVES: To describe the treatment patterns since diagnosis among patients who developed moderate-to-severe psoriasis. **METHODS:** Using the OptumHealth Reporting and Insights claims database between January 1998 and March 2015, adult patients with ≥ 2 psoriasis diagnoses and receiving ≥ 1 systemic (non-biologic or biologic) therapy or phototherapy during the 5 years after the first psoriasis diagnosis date (study period) were selected. Patients were required to have continuous insurance coverage during the 3 years before (baseline period) and 5 years after the index date. During the study period, the percentage of patients who re-initiated the same treatment after a gap of >90 days, changed therapy (initiated a different treatment, added a different agent to the existing treatment, or discontinued an agent from the existing treatment) were examined for the 1st, 2nd, 3rd, 4th and 5th treatment. **RESULTS:** The sample included 1,098 patients with a mean age of 53 years and 46% female. Common psoriasis-related comorbidities over the baseline period included diabetes (14%), depression (10%) and coronary heart disease (10%). Over the study period, 48%, 27%, 16% and 11% of moderate-to-severe psoriasis patients received at least 2, 3, 4, and 5 systemic or phototherapy treatments, respectively. The most common treatment sequences included UVB only (26%), systematic non-biologic only (18%) and biologic only (7%). Overall, the rate of re-initiation was 21% for the 1st treatment, 17%, 21%, 14%, and 12% for 2nd, 3rd, 4th, and 5th treatment, respectively. The rate of therapy change was 27% for the 1st treatment, 39%, 39%, 50%, and 45% for 2nd, 3rd, 4th, and 5th treatment, respectively. **CONCLUSIONS:** Almost half of the moderate-to-severe psoriasis patients received more than 1 treatment during the 5 years after diagnosis. Overall, high rates of re-initiation and therapy change suggested substantial unmet needs in this population.

PSS36

COMPARISON OF TREATMENT PATTERNS AMONG MODERATE-TO-SEVERE PSORIASIS PATIENTS RECEIVING PHOTOTHERAPY, NON-BIOLOGIC AND BIOLOGIC THERAPIES

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OBJECTIVES: To compare time on treatment and time to the next treatment initiation among patients receiving phototherapy, systemic non-biologic therapy (NBT), and biologic therapy after psoriasis diagnosis. **METHODS:** Adults with ≥ 2 psoriasis diagnoses and ≥ 1 systemic or phototherapy claim over the 5 years (study period) after the first psoriasis diagnosis date were selected from a claims database (01/1998-03/2015). Up to 5 treatments (phototherapy, NBT, and biologics) over the study period were assessed. A new treatment was identified as initiating a different treatment, re-initiating the same treatment after a gap of 90+ days, adding a different agent to the existing treatment, or discontinuing an agent from the existing treatment. Time on treatment, time to therapy change, and time from end of treatment to the next treatment initiation were examined. **RESULTS:** A total of 1,098 adults were included with a mean age of 53 years, 54% men, and 38% having preferred provider organization plan. A total of 44%,

38%, and 17% patients received phototherapy, NBT, and biologics as initial treatment, respectively. The mean time (months) on 1st treatment was significantly longer for biologics (20.4), compared with NBT (10.4) and phototherapy (5.2). Similarly, the mean time (months) to therapy change was longer for biologics (16.4) compared to phototherapy (7.0) and NBT (9.9). The mean time (months) from end of 1st treatment to 2nd treatment initiation was longer for phototherapy (9.5) and NBT (6.8) compared to biologics (4.0) (all $p < 0.05$). Similar patterns were observed for some of the subsequent treatments. For all treatments except phototherapy, the mean time on treatment decreased from 1st to subsequent treatments. **CONCLUSIONS:** Among patients with moderate-to-severe psoriasis, those on biologics generally stayed on treatment longer. After discontinuing the 1st treatment, biologics users moved faster to the next treatment. Time on treatment was shorter for later treatments than 1st treatment.

RESEARCH POSTER PRESENTATIONS - SESSION III

DISEASE - SPECIFIC STUDIES

DIABETES/ENDOCRINE DISORDERS - Clinical Outcomes Studies

PDB1

UPDATING RISK ENGINE FOR DIABETES PROGRESSION AND MORTALITY IN THE UNITED STATES: INTERNAL VALIDATION

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OBJECTIVES: Most of the current diabetes prediction models heavily relied on the UKPDS risk engine and Framingham equation, which used data from 1970s on European populations. This study aimed to update a risk engine using a cohort of patients with type 2 diabetes in the United States (US). **METHODS:** A total of 21 equations for forecasting diabetes-related microvascular and macrovascular events, hypoglycemia, mortality, and progression of diabetes risk factors were estimated using data on 10,251 patients from the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial. Left truncated proportional hazard model or accelerated failure time model was applied to fit each event equation using diabetes duration as time index, and a large variety of distributions including Weibull and Gompertz distribution were tested. 10-folds cross-validation or bootstrapped validation was applied to account for overfitting issue. Predicted cumulative incidence rates was plotted against the observed cumulative incidence to serve as internal validation. **RESULTS:** The model's forecast fell within the 95% confidence interval for the observed events at each time point up to 40 years diabetes duration. Our model prediction provides accurate prediction according to the internal validation process, and good face validity on risk factors were established by endocrinologists. Severe hypoglycemia was found to be an important risk factor for congestive heart failure (CHF), myocardial infarction (MI), angina, revascularization surgery, and diabetes-related mortality. Racial factor was included in more than half of the events equations. **CONCLUSIONS:** The updated risk engine for the US diabetes cohort has a good internal validity to simulate events that closely match observed outcomes in the ACCORD trial. With extrapolation over lifetime, a simulation model based on the updated risk engine can also predict a range of long-term outcomes, thus assist making clinical and policy decisions. We are currently conducting external validation of this updated risk engine.

PDB2

DIPEPTIDYL PEPTIDASE-4 INHIBITORS AND RISK OF HEART FAILURE IN TYPE 2 DIABETES: A SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED AND OBSERVATIONAL STUDIES

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OBJECTIVES: To examine the association between dipeptidyl peptidase-4 (DPP-4) inhibitors and the risk of heart failure or hospitalization for heart failure in patients with type 2 diabetes. **METHODS:** We searched Medline, Embase, CENTRAL and ClinicalTrials.gov to identify randomized controlled trials (RCTs) and non-randomized studies of adults with type 2 diabetes that compared DPP-4 inhibitors against placebo or active anti-diabetic medications, and explicitly reported the outcome of heart failure or hospitalization for heart failure. Paired reviewers independently screened for eligible studies, assessed risk of bias, and extracted data. Data from trials and observational studies were pooled separately; quality of evidence was assessed by the GRADE approach. **RESULTS:** A total of 55 studies involving 1,846,133 patients were eligible, including 43 RCTs (n=68,775) and 12 observational studies (nine cohort studies, and three nested case-control studies; n=1,777,358). There was low-quality evidence regarding risk of heart failure between DPP-4 inhibitor use versus control (38 trials, odds ratio (OR) 0.97, 95% confidence interval (95% CI) 0.61 to 1.56); risk difference 2 fewer (95% CI 19 fewer to 28 more) events per 1000 patients over five years). There was moderate-quality evidence for an increased risk of hospital admission for heart failure in patients treated with DPP-4 inhibitors versus control (five trials, OR 1.13, 95% CI 1.00 to 1.26; RD 8 more (0 more to 16 more)). The observational studies provided effect estimates generally consistent with trial findings, but with very low-quality evidence. **CONCLUSIONS:** The relative effect of DPP-4 inhibitors on the risk of heart failure is uncertain, given the relatively short follow up and low quality of

evidence. Both RCTs and observational studies, however, suggest that these drugs may increase the risk of hospitalization for heart failure in type 2 diabetes patients with existing cardiovascular diseases or multiple risk factors for vascular diseases relative to no use.

PDB3

EFFECTS OF SODIUM GLUCOSE CO-TRANSPORTER-2 INHIBITORS ON URINARY TRACT INFECTIONS AND GENITAL INFECTIONS IN PATIENTS WITH TYPE 2 DIABETES: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: To systematically assess the impact of sodium glucose co-transporter-2 inhibitors (SGLT2) inhibitors treatment on urinary tract infections (UTIs) and genital infections in patients with type 2 diabetes. **METHODS:** We searched PubMed, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL), and ClinicalTrials.gov for randomized controlled trials (RCTs) that compared SGLT2 inhibitors with placebo or active antidiabetic drugs with a duration of 12 weeks or longer, among patients with type 2 diabetes. Paired reviewers independently screened citations, assessed risk of bias, and extracted data. We pooled effect estimates using Mantel-Haenszel relative risk with 95% confidence intervals, and used the GRADE method to rate the quality of evidence. **RESULTS:** In total, 77 RCTs involving 50,820 participants were included. The pooled analyses showed no significant difference in urinary tract infections (UTIs) between SGLT2 inhibitors versus control (2,526/29,086 vs. 1,278/14,940; risk ratio (RR) 1.06, 95% confidence interval (CI) 0.99 to 1.13, low quality evidence), but suggested increased risk of genital infections with SGLT2 inhibitors (1,521/24,017 vs. 216/12,552; RR 3.83, 95% CI 3.34 to 4.40, RD 521 more, 95% CI 431 more to 626 more per 1000 over 5 years; high quality evidence). Dapagliflozin - an individual drug of SGLT2 inhibitors - showed increased risks of UTIs (RR 1.34, 95% CI 1.11 to 1.62) and genital infections (RR 3.80, 95% CI 2.57 to 5.62), as well as events suggestive of UTIs (RR 1.33, 95% CI 1.10 to 1.61; high quality evidence) and of genital infections (RR 4.50, 95% CI 3.24 to 6.25; high quality evidence). **CONCLUSIONS:** The impact of SGLT2 inhibitors on the risk of UTIs remains uncertain, high quality evidence shows a clinically important increase in the risk of genital infections in type 2 diabetes patients using this drug class.

PDB4

THE ASSOCIATION OF DIPEPTIDYL PEPTIDASE-4 INHIBITORS USE WITH JOINT PAIN AMONG US ADULTS WITH TYPE-2 DIABETES MELLITUS

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OBJECTIVES: Few recent studies have reported that the use of dipeptidyl peptidase-4 inhibitors (DPP4Is), a class of antidiabetic agents, may be associated with joint pain. The purpose of this study was to examine the association of DPP4i use with joint pain in Type 2 Diabetes Mellitus (T2DM) patients. **METHODS:** This was a retrospective cross-sectional study. We used data from 2012 and 2014 Medical Expenditure Panel Survey. The study sample consisted of adults (≥ 40 years) with T2DM ($n=4,559$). DPP4Is were identified from prescription drug files. Joint pain was identified from medical conditions files using ICD9CM codes. Chi-square test and logistic regression were used to examine the association between DPP4i use and joint pain. **RESULTS:** Among adults with T2DM, 69.9% ($N = 3,185$) reported physician-diagnosed joint pain and 7.4% were DPP4i users. There was no statistically significant difference in DPP4i use among those with and without joint pain (7.8% vs 6.3%). Even after adjusting for other factors that may affect DPP4i use, there was not a statistically significant difference in DPP4i use among T2DM adults with and without joint pain (AOR= 1.04, 95% CI= 0.74-1.48). Adults with prescription insurance (AOR= 1.76, 95% CI= 1.01-3.04) and public health insurance (AOR= 1.76, 95% CI= 1.02-3.03) were significantly more likely to use DPP4i as compared to those with no prescription insurance and private health insurance, respectively. Adults who had a heart disease were significantly more likely to use DPP4Is as compared to those who did not have heart disease (AOR= 1.59, 95% CI= 1.18-2.15). **CONCLUSIONS:** DPP4i use was not affected by the presence of joint pain. However, we found that adults with heart disease were more likely to use DPP4i, despite studies reporting an association between DPP4i use and heart failure.

PDB5

STUDY ON CO-MORBIDITIES IN PATIENTS WITH TYPE II DIABETES MELLITUS

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OBJECTIVES: Study of co-morbidities in patients with type II diabetes mellitus is important as co-morbidities increase the disease burden and cost. It results in poor quality of life and reduced life expectancy. Studies have shown that diabetes is associated with different diseases such as hypertension, cardiovascular diseases, chronic kidney disease, dyslipidemia, tuberculosis, anemia, depression etc. **METHODS:** The study was of prospective and observational type. It was conducted in a teaching hospital in South India for a period of 5 months from July 2016 to November 2016. All the patients diagnosed with type II diabetes mellitus with medical history of it since more than 1 year were included in the study. **RESULTS:** Out of the total 62 patients, majority (56%) were males. The median age was 52. Majority of the patients (27%) had a single co-morbidity, 18% had two co-morbidities and very few patients had three or more co-morbidities. Hypertension (38%) was the most common co-morbidity. Other co-morbidities found were cardiovascular diseases (11%), chronic kidney disease (9%), depression (6%), tuberculosis (6%), anemia (4%) hypothyroidism (3%) etc. **CONCLUSIONS:** Co-morbidities were common in patients with type II diabetes mellitus.

Proper selection of antidiabetic drugs considering co-morbidities can provide better outcome and prevent further complications in patients.

PDB6

IMPACT OF LONG-TERM OPIOID MEDICATION USE ON SUBSEQUENT TYPE 2 DIABETES MELLITUS RELATED HOSPITALIZATIONS

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OBJECTIVES: Patients' adherence to antihyperglycemic medication is an essential component in achieving adequate glycemic control. Non-adherence can lead to macro vascular and micro vascular complications among patients with type 2 diabetes mellitus (T2DM). According to SAMSHA's opioid use guideline, prescription opioid use can negatively impact chronic asymptomatic medication therapy. Thus, antihyperglycemic medication adherence may decrease and subsequently lead to T2DM related hospitalizations. **METHODS:** This was a retrospective cohort analysis using 2003-2004 Truven MarketScan® commercial claims databases. T2DM patients greater than 18 years who were prescribed prescription opioids were included. Adherence to antihyperglycemic medications was calculated among long-term (≥ 90 days) opioid users and short-term (< 90 days) opioid users. Medication adherence (PDC) was estimated with PDC ≥ 0.80 considered adherent. Subsequent T2DM related hospitalizations was estimated using a cox proportional hazard regression model, comparing long-term and short-term prescription opioid users. **RESULTS:** After inclusion criteria was applied, data on 22,212 patients were observed, out of which 7,462 (33.66%) were long-term opioid users. During the 6-month follow-up, risk of T2DM related hospitalization was lower among long-term opioid users with 150 days or less during follow-up (HR = 0.73, 95% CI = 0.69-0.78) as compared to short-term prescription opioid users. Risk of T2DM related hospitalization was higher among patients with long-term prescription opioid use greater than 150 days during the follow-up (HR = 1.25, 95% CI = 0.69- 2.28) as compared to short-term opioid users. Follow-up antihyperglycemic adherence (HR = 1.44, 95% CI = 1.25-1.64) was a significant predictor of T2DM related hospitalization when assessed as a mediator. **CONCLUSIONS:** Patients who were concomitantly prescribed long-term prescription opioids and antihyperglycemic medications were at a lower risk of T2DM related hospitalizations as compared to patients who were prescribed short-term prescription opioids. Use of prescription opioids over a longer duration did not negatively impact T2DM related hospitalizations when prescribed concomitantly in this study.

PDB7

REAL-WORLD EVIDENCE OF PREVALENCE OF CARDIOVASCULAR DISEASE AMONGST TREATED DIABETES POPULATION IN 2016

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OBJECTIVES: 2016 Canadian guidelines for the management of Type 2 Diabetes (T2D) recommend evaluation of cardiovascular comorbidities as a priority for patients not at glycemic target, and recommend preferentially using an anti-hyperglycemic agent with demonstrated cardiovascular outcome benefit for this population. The objective of this research was to determine, in the treated Type 2 Diabetes patient population, the prevalence of pre-existing cardiac comorbidities. **METHODS:** This study used PRIME, a proprietary database of chart audit abstractions collected through regular survey of primary care physicians. The data includes demographic details, risk factors, comorbidities, lab values (e.g. A1c) and pertinent details of the patients' pharmacological management for T2D including sequencing of treatments. Clinical cardiovascular disease was defined as per trials evaluating anti-hyperglycemic agents for cardiovascular outcome benefit, i.e. history of myocardial infarction, coronary artery disease, stroke, angina or peripheral artery disease. **RESULTS:** 2,039 patients treated for Type 2 Diabetes in 2016 were reviewed. Of these, 19% (95% CI 17%-20%) had clinical cardiovascular disease, as defined above. Amongst the older diabetic population, over age 65, the rate of cardiovascular disease was higher at 26% ($n=1,056$; 95% CI 23%-29%). **CONCLUSIONS:** 19% of treated Type 2 Diabetes patients have a cardiovascular comorbidity which elevates their risk of cardiac mortality. In addition, cardiac risk factors such as hypertension, high cholesterol and obesity are highly prevalent in this population. This data suggests that there is significant need for cardiovascular protection in diabetic patients.

PDB8

INDIVIDUALIZED TREATMENT GOALS FOR OPTIMAL LONG-TERM HEALTH OUTCOMES AMONG ADULT VETERANS WITH TYPE 2 DIABETES MELLITUS

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OBJECTIVES: Considerable confusions have resulted from changes of treatment goals in a number of new guidelines, based on limited and conflicting evidence that comes from randomized clinical trials. To assess the individualized treatment goals (HbA1c, blood pressure, LDL-C) for patients with type 2 diabetes mellitus (T2DM) in real-world settings. **METHODS:** US Veterans Affairs (VA) electronic medical records database was extracted between January 2005 and December 2015. Adult T2DM patients (> 18 years old) who had ≥ 2 -year enrollment and ≥ 2 HbA1c, LDL-C and BP lab tests were selected. Patients with history of complications were excluded. Second-degree polynomial and splines were applied in the longitudinal regression models to identify heterogeneity of treatment goals in their associations with risk of diabetes related complications and mortality. Demographic characteristics, medical history, and medication use patterns were controlled in the regression models. **RESULTS:** 132,994 patients were selected, with 62.68 years

old (SD=10.96) and 6.72 (SD=6.68) years of follow-up. In general population, HbA1c=6.00% (SD=0.22), LDL-C=107.85 mg/dl (SD=8.71) and BP=136.45/98.15mmHg (SD=3.03/2.43) were associated with lowest mortality risk. As of achieving lowest risk of microvascular and macrovascular complication, the optimal HbA1c were higher than the level for mortality. The optimal LDL-C levels were similar between complication and mortality risks, while lower SBP and higher DBP were associated with better outcomes. The optimal treatment goals differed between age and race subgroups. Compare with older counterparts, lower LDL-C and SBP goals were identified in younger patients. Compared with white counterparts, lower LDL-C levels were identified for lowest mortality rate among blacks and Hispanic patients. **CONCLUSIONS:** Individualized treatment goals were identified for diabetes management in the US veterans. In addition to meeting general ADA recommended goals for better quality of care and population health management, health system may identify individualized treatment goals for their own patients with T2DM.

PDB9

COMPARISON OF LONG-TERM DATA ON CARDIOVASCULAR OUTCOMES IN PATIENTS WITH TYPE 2 DIABETES RECEIVING LIRAGLUTIDE WITH ESTIMATES BASED ON RISK FACTORS

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OBJECTIVES: To compare rates of cardiovascular outcomes observed in a recent long-term study with rates expected based on subjects' demographic and risk factors. **METHODS:** The LEADER trial (Mar 2016) evaluated cardiovascular event rates in 9340 patients with Type 2 diabetes mellitus at high risk of cardiovascular disease with median follow up of 3.8 years. Patients were randomised to liraglutide 1.8mg daily or placebo in addition to standard of care (SoC). Demographic, glycaemia, lipid and blood pressure data observed in LEADER were used to predict event rates in the Core Diabetes Model (CDM) using a risk equation (UKPDS68 - Clarke 2004) commonly used to model long term outcomes in diabetes. Events predicted by the CDM were compared with events observed in LEADER. An iterative total error reduction process was used to calibrate the CDM to replicate observed event rates. Risk ratios were calculated comparing event rates observed in LEADER with those predicted by UKPDS68. **RESULTS:** Risk ratios for events observed in LEADER compared to those predicted by UKPDS68 for MI were 0.641 and 0.690 for liraglutide and SoC respectively; Stroke 1.173 and 1.190; heart failure 0.775 and 0.820; CV death 0.912 and 1.000; non-CV death 0.245 and 0.254. Values <1 indicate fewer events were observed in LEADER than predicted by UKPDS68. Smaller risk ratios for liraglutide than SoC indicate lower risk with liraglutide. Sensitivity analysis using alternative risk equations gave similar results. **CONCLUSIONS:** Rates of MI, heart failure and CV and non-CV death - though not stroke - were lower in patients receiving liraglutide in LEADER than would be expected based on published risk equations. Equivalent reductions were not observed in patients receiving SoC. Liraglutide 1.8mg prevented more cardiovascular events than can be explained by the impact of therapy on diabetes risk factors alone.

PDB10

ACHIEVEMENT OF DIABETES-RELATED QUALITY MEASURES IN PATIENTS TREATED WITH EXENATIDE ONCE-WEEKLY IN A REAL-WORLD SETTING

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OBJECTIVES: Diabetes quality measures reflect attainment of diabetes treatment goals that are associated with improved long-term outcomes. This study identified associations between exenatide once weekly (ExQW) use and common US diabetes quality measure performance in a real-world setting. **METHODS:** A historical cohort study of type 2 diabetes patients ≥ 18 years who initiated ExQW between February 1, 2012 and March 31, 2013 (index date) was conducted in a national medical record database. Patients initiating insulin therapy on index date were excluded. We identified the proportion of patients achieving quality measure targets for A1C (<7%, <8%, <9%) overall and by pre-index insulin use and BP target (<140/90 mmHg) at 12 months. **RESULTS:** This study included 792 ExQW patients. Baseline mean (SD) age was 57.2 (10.6) years, A1C was 8.3% (1.5) and 48.9% were male. Insulin was prescribed pre-index date for 334 (42.2%) patients (Pre-Ins); 458 (57.8%) had no insulin prescription before index (No-Ins). A1C quality target attainment improved significantly at follow-up vs baseline; A1C <7.0% was 31.7% vs 15.3%; A1C <8.0% was 61.4% vs 45.1%; and A1C <9.0% was 79.4% vs 71.1% (p<.001 for all). In the Pre-Ins and No-Ins groups, the proportion with A1C <7.0% at follow-up vs baseline was 20.4% vs 11.7% and 40.0% vs 17.9%; A1C <8.0% was 51.2% vs 38.6% and 68.8% vs 49.8% while A1C <9.0% was 72.7% vs 63.5% and 84.3% vs 76.6%, respectively (p<.001 for all). Overall, 76.2% had follow-up BP <140/90 mmHg vs 75.3% at baseline (p=0.544). **CONCLUSIONS:** ExQW was associated with a significant increase in the proportion of patients attaining diabetes quality measures for A1C overall and by baseline insulin use. Goal attainment was consistently lower for patients treated with insulin, possibly because they were more difficult to treat. BP goal attainment, which was high at baseline, did not change.

PDB11

REAL WORLD EFFECTIVENESS OF DULAGLUTIDE AMONG PATIENTS WITH TYPE 2 DIABETES

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OBJECTIVES: Dulaglutide is a once weekly GLP-1 receptor agonist (RA) indicated for the treatment of type 2 diabetes (T2D). The objective of this retrospective

observational study was to assess the change in HbA1c among patients with uncontrolled T2D initiating dulaglutide. **METHODS:** This analysis included adults with T2D with an initial dulaglutide prescription (index date) between November 2014 and February 2016 using data from the Practice Fusion electronic health record database, which includes >25 million patients (6.7% of US ambulatory care). Patients with ≥1 diagnosis of T2D, naive to dulaglutide with ≥1 HbA1c result in the 6-month baseline and in the 3 to <6 months post-index period were included. Uncontrolled T2D was defined as baseline HbA1c ≥7%. **RESULTS:** We identified 734 patients initiating dulaglutide, 187 (25.5%) with baseline HbA1c <7% and 547 (74.5%) with HbA1c ≥7%. At baseline, uncontrolled patients were 48% female, 51% and 49% were prescribed dulaglutide 1.5 mg and 0.75 mg, respectively, with mean±SD age 59.0±10.4 years, BMI 35.9±7.2 kg/m², and HbA1c 8.8±1.5%. During post-index period, the mean reduction in HbA1c was 0.8±1.5%; mean reductions of 0.6±1.5% and 0.9±1.4% were observed among patients with a prior prescription for GLP-1 RA versus those without, respectively (p=.017). Additionally, significant differences in mean HbA1c reduction between subgroups by age (≥65 years vs <65 years: -0.6±1.3% vs -0.8±1.5%; p=.028) and baseline HbA1c (7 to <8% vs 8 to <9% vs ≥9%: -0.1±0.9% vs -0.6±1.2% vs -1.6±1.8%; p<.001) were observed. There were no significant differences in mean HbA1c reductions between subgroups by gender, race, ethnicity, BMI, previous insulin prescription or oral antidiabetic medications, and dulaglutide dose. **CONCLUSIONS:** In real-world settings, patients with uncontrolled T2D demonstrated an improvement in their glycemic control within 6 months of initiating dulaglutide.

PDB12

EFFECTIVENESS OF A COMMUNITY-BASED TYPE 2 DIABETES SELF-MANAGEMENT EDUCATION PROGRAMME IN THE STATE OF PENANG, MALAYSIA

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OBJECTIVES: To assess the effectiveness of a structured, group-based type 2 diabetes self-management education (T2DSME) programme on participant's health outcomes. **METHODS:** A pre-post study design was employed. Adults diagnosed with Type 2 diabetes were invited to attend weekly, group-based self-management education offered in local community halls (average 2.5-hour per session for 6 consecutive weeks). The programme was developed by a multidisciplinary healthcare team (i.e. pharmacist, diabetic nurse educator, dietitian, physiotherapist and medical doctor). Empowerment philosophy and Bandura's self-efficacy theory were applied. Participant's clinical [HbA1c, fasting glucose, blood pressure, lipids, weight, body mass index (BMI) and waist circumference] and humanistic (knowledge related to diabetes management, self-care behaviours, self-efficacy and quality-of-life) outcomes were assessed at baseline, post 2-month and post 6-month of the programme. **RESULTS:** A total of 46 participants consented to the programme; 39 (84.8%) attended three or more sessions. After 2-month, participants demonstrated significant improvement in low-density lipoprotein cholesterol (p = 0.001), knowledge related to diabetes management (p = 0.025) and certain self-care behaviours including blood glucose monitoring (p < 0.001) and foot care (p = 0.024). The aforementioned outcomes were also maintained at 6-month. However, participants did not maintain the decreasing trend of HbA1c observed at 2-month with significant HbA1c increase reported at 6-month compared to 2-month (p < 0.001). At 6-month, other positive outcomes observed were improvement in high-density lipoprotein cholesterol (p = 0.029) and quality-of-life (p = 0.010). No significant differences were found in other outcomes (i.e. fasting glucose, blood pressure, triglycerides, weight, BMI, waist circumference, self-efficacy, diet, medication-taking and exercise components of self-care behaviour) between baseline, post-2 month and post-6 month of the programme. **CONCLUSIONS:** Findings suggest that short-term structured T2DSME may improve patient's clinical and psychosocial outcomes. However, self-management education should be reinforced in a continuous manner to help patients in sustaining good glycaemic control.

PDB13

A FIRST LOOK: REAL-WORLD COMPARISON OF UTILIZATION AND EFFECTIVENESS OF ALBIGLUTIDE AND LIRAGLUTIDE IN TYPE 2 DIABETES MELLITUS PATIENTS IN THE UNITED STATES

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OBJECTIVES: To compare treatment patterns and glycemic control following initiation of albiglutide versus liraglutide, among US commercially insured patients with T2DM. **METHODS:** Adult commercial health plan enrollees with T2DM with ≥ 1 pharmacy claim for albiglutide or liraglutide between 29-July-2014 and 31-December-2015 were included; the date of first fill was the index date. Patients were observed for 6 months prior to (baseline) and 6 and 12 months after the index date (follow-up). Inclusion criteria were baseline and follow-up continuous plan enrollment and evidence of T2DM. Patients with a type 1 diabetes diagnosis and ≥1 insulin prescription, gestational diabetes, or pregnancy were excluded. Patient demographic and clinical characteristics were used in 1:1 propensity score matching of albiglutide and liraglutide users. Outcomes were measured at 6 months (HbA1c, treatment patterns) and 12 months (treatment patterns). **RESULTS:** 2,213 patients were identified in each post-matched cohort with the following baseline characteristics: age 52.4±8.9 vs 52.4±9.1 years, 53.6% vs 52.8% male, Quan-Charlson score 0.61±1.0 vs 0.64±1.1, and diabetes complications severity index 0.68±1.1 vs 0.68±1.2, respectively in the albiglutide and liraglutide cohorts. At 6 months, average adherence (Proportion-of-Days-Covered) was 0.69±0.29 vs 0.64±0.29 (p<0.001), and

discontinuation was 33.2% vs 37.8% ($p=0.002$), for albiglutide and liraglutide, respectively. 11.7% of albiglutide users filled only a single index prescription vs 18.7% on liraglutide ($p < 0.001$). The HbA1c subgroup ($n=244$ each) had similar characteristics with baseline HbA1c of 8.8 ± 2.0 vs 8.6 ± 1.8 , and a decrease in HbA1c from baseline of 1.0 ± 1.7 vs 1.0 ± 1.6 ($p=0.847$) was observed for albiglutide and liraglutide, respectively. The 12-month analysis showed no significant differences in adherence or persistence. **CONCLUSIONS:** This comparative assessment of albiglutide vs liraglutide in US commercial claims shows that albiglutide patients experienced statistically significant improvements in adherence and persistence. Both groups demonstrated similar reductions in HbA1c levels 6 months after initiation of either medication.

PDB14

A RETROSPECTIVE REAL-WORLD STUDY OF DAPAGLIFLOZIN VERSUS OTHER ORAL ANTIDIABETIC (OAD) THERAPIES ADDED TO METFORMIN IN PATIENTS WITH TYPE 2 DIABETES (T2D) AND HYPERTENSION

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OBJECTIVES: Dapagliflozin is shown to be effective in improving glycemic control and blood pressure for patients with T2D and hypertension in randomized trials. This study used real-world electronic medical record (EMR) data to compare outcomes among T2D patients with hypertension treated with dapagliflozin (D) + metformin (M), with or without other OAD (D+M±OAD), versus metformin with other OAD (M±OAD). **METHODS:** Adult patients with T2D on metformin and either dapagliflozin (±OAD) or other OAD as add-on therapy from 01/01/14 to 02/28/15 were identified in a US EMR database, with the date of first prescription for D (D+M±OAD) or other OAD (M±OAD) as the index date. Patients were observed for 12 months before the index date (baseline) and 12 months after (follow-up). Patients were required to have ≥1 diagnosis for hypertension or a prescription for ACE inhibitor or ARB during baseline. Outcomes included change in A1C, systolic and diastolic blood pressure (SBP/DBP), and weight from baseline to follow-up. **RESULTS:** A total of 421 D+M±OAD patients (mean±SD age 56.5 ± 10.4 y, 46.8% women) and 469 M±OAD patients (age 57.0 ± 11.8 y, 43.9% women) were identified. Mean baseline A1C was 8.8% for D+M±OAD and 8.7% for M±OAD ($p=0.64$). DPP-4i (39% for D+M±OAD and 49% for M±OAD, $p<0.01$) and sulfonylureas (38% for D+M±OAD and 42% for M±OAD, $p=0.22$) are common OADs during baseline. Compared with M±OAD patients, D+M±OAD patients had a greater reduction in A1C (mean -1.2% vs -0.6% , $p<0.01$), SBP (-4.6 vs -1.1 mmHg, $p=0.01$) and DBP (-2.7 vs -0.6 mmHg, $p<0.01$) from baseline to follow-up. Change in weight was not significantly different (-1.6 vs -0.9 kg, $p=0.06$). **CONCLUSIONS:** In clinical practice, patients receiving D+M±OAD had greater reductions in A1C and BP versus patients on M±OAD among T2D patients with hypertension. This study supports the use of dapagliflozin as add-on therapy to metformin for such patients.

PDB16

EFFICACY AND SAFETY OF DULAGLUTIDE FOR TREATING PATIENTS WITH TYPE-2 DIABETES MELLITUS: EVIDENCE BASED SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS

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OBJECTIVES: Type 2 diabetes mellitus (T2DM) is a chronic disorder and requires lifelong treatment. It poses significant burden on healthcare costs. This study was carried out with an aim to assess the efficacy and safety of once weekly dulaglutide for patients with T2DM. **METHODS:** An extensive literature search was done in Pubmed, Cochrane central register and other databases for clinical trial (CTs) comparing the efficacy and safety of dulaglutide with other oral hypoglycaemic agents or placebo in the treatment of T2DM from inception to 14th April, 2016 by two independent reviewers. A total of 12 RCTs including total of 8870 patients comparing dulaglutide (4598 patients) to Control (4272 patients) are pooled in the present analysis. Quality of included studies was determined by Cochrane risk of bias tool. Cochrane Q ($p < 0.05$) or I2 test ($> 50\%$) was used to assess the heterogeneity. Subgroup analysis was performed. All analyses were performed using Comprehensive Meta-analysis. **RESULTS:** Fixed effect model was used for pooled analysis as no significant heterogeneity was observed. The pooled Weighted Mean Difference (WMD) = -0.40 , 95% CI -0.43 to -0.36 , $p = 0.00$ shows, dulaglutide significantly lowered HbA1c over control (placebo, metformin, and liraglutide) as well as fasting plasma glucose (FPG) and body weight (WMD = -0.18 , 95% CI -0.22 to -0.12 , and -0.24 , 95% CI -0.3 to -0.2 , $p = 0.00$, respectively). Moreover, Dulaglutide significantly increasing 55% and 33% to achieve HbA1c $< 7\%$ and $< 6.5\%$ respectively and significantly decreasing the incidence of hypoglycemia (12%) as compared to control. **CONCLUSIONS:** The finding of our study reveals the beneficial effects of dulaglutide with respect to HbA1c, FPG and weight reduction in comparison to other oral hypoglycaemic agents. Dulaglutide also demonstrate satisfactory safety profile.

PDB17

ORAL ANTI-DIABETIC DRUGS ARE NOT ASSOCIATED WITH CARDIOVASCULAR MORTALITY: A SYSTEMATIC REVIEW WITH META-ANALYSIS

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OBJECTIVES: There is a rising uncertainty related to cardiovascular safety of oral hypoglycemic agents (OHAs). Recently, the Food and Drug Administration (FDA) revised regulatory guidelines for anti-diabetic drug approval with respect to cardiovascular safety, to be within a predefined margin of statistical certainty.

Therefore, objective of the study is to conduct a systematic review with meta-analysis to assess the impact of oral anti-diabetic agents marketed post FDA regulation, on the cardiovascular safety. **METHODS:** The inclusion criteria were: (1) randomized controlled trial, (2) study participants were adult humans with type-2 diabetes mellitus (T2DM) with or without cardiovascular risk factors, (3) who are taking at least one oral anti-diabetic drug, (4) the study outcome was cardiovascular mortality, and (5) published studies in English language since March 31, 2016. PubMed, Scopus and clinical trial registries were searched based on a search criteria decided a priori. Odds ratio was calculated for each result and pooled using random-effects models. Non-overlapping 95% confidence intervals (CI) were considered statistically significant. Heterogeneity was estimated using Q and I2 with alpha values ≤ 0.10 for Q considered statistically significant. **RESULTS:** Of the 431 studies reviewed, 46,291 participants (24,439 treatment, 21,852 control) nested within 10 studies were included. Mean HbA1c in treatment group was 7.68 (SD ± 0.79) and in the control group was 7.7 (SD ± 0.83). Overall, there was no significant association between the OHAs and cardiovascular mortality (OR = 0.89, 95% CI 0.74, 1.06, Q = 21.65, $p < 0.01$, I2 = 58.43). **CONCLUSIONS:** The results of the current study suggest that OHAs are not associated with cardiovascular mortality, although, the confidence interval is very narrow and close to being significant. A network meta-analysis is needed to better understand this important issue of cardiovascular safety of oral hypoglycemic agents.

PDB18

THE IMPACT OF RAS-MODIFYING MEDICATIONS ON THE RISK OF PULMONARY INFECTIONS IN HYPERTENSIVE PATIENTS WITH TYPE 1 DIABETES

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OBJECTIVES: Patients with Type 1 Diabetes (T1D), have an immune system with a lower ability to respond to infection. Studies have shown that RAS-modifying medications (angiotensin converting enzyme [ACE] inhibitors and angiotensin receptor blockers [ARBs]) may reduce the risk for pulmonary infections. The aim of this study was to assess the impact of T1D and RAS therapy on pulmonary complications in patients with hypertension (HTN). **METHODS:** A retrospective analysis was conducted using claims data from a US commercial insurance company. The study groups consisted of patients taking either: ACE inhibitors, ARBs, or control (diuretics or calcium-channel blockers). Hazard ratios (HR) were estimated using Cox analyses to determine the impact of ACE inhibitors and ARBs on incidence of pulmonary complications controlled for diagnosis of T1D as a risk factor. The event included influenza, pneumonia, tuberculosis (TB), and Streptococcal sore throat (SSR). Initial drug model tested whether the risk of the events is impacted if the patient started with ACE inhibitors or ARBs while duration model tested whether everyday use of the medications delays the events. **RESULTS:** A total of 11,602 T1D patients and 154,083 non-diabetic patients using HTN drugs were identified. In initial drug model, T1D patients were at increased risk for influenza (HR=1.171, $p < .0001$) and pneumonia (HR=1.612, $p < .0001$). Duration model showed that T1D patients were associated with increased risk of influenza (HR=1.235, $p=0.0005$), pneumonia (HR=1.680, $p < .0001$), and SSR (HR=1.223, $p=0.0442$). Patients treated with ACE inhibitors had lower incidence of pneumonia by 17% (HR = 0.829, $p < .0001$) and TB by 30% (HR=0.698, $p=0.0343$), and ARBs exhibited a lower risk of pneumonia by 13% (HR=0.865, $p < .0001$) compared to control drugs. Duration model exhibited similar trends for each drug class. **CONCLUSIONS:** T1D was associated with increased risk of influenza and pneumonia. The use of RAS-modifying medications reduced the risk and delays onset of the diseases.

PDB19

INCREASED RISK OF AUTOIMMUNE DISEASE IN PATIENTS WITH TYPE 1 DIABETES AND THE IMPACT OF RAS THERAPY

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OBJECTIVES: Patients with type 1 diabetes (T1D) often develop other autoimmune disorders. Studies have shown that RAS-modifying medications (angiotensin converting enzyme [ACE] inhibitors and angiotensin receptor blockers [ARBs]) suppresses certain immune functions and inhibits inflammatory or autoimmune diseases. This study aims to assess the impact of T1D and hypertension (HTN) therapy on autoimmune diseases and potential benefits of using ACE inhibitors and ARBs. **METHODS:** A retrospective analysis was conducted using claims data from a US commercial insurance company (2007-2013). The study groups consisted of HTN patients taking either: ACE inhibitors, ARBs, or control (diuretics or calcium-channel blockers). Cox analyses and ordinary least squares (OLS) regression were performed to determine the impact of T1D on incidence of autoimmune diseases and estimate the extent to which an additional day of ACE inhibitors or ARBs provides additional benefit relative to a day of control drugs. Incidence and time to event were measured for multiple sclerosis [MS] (ICD-9 340.xx), systemic lupus erythematosus [SLE] (ICD-9 710.0), and rheumatoid arthritis [RA] (ICD-9 714.xx). **RESULTS:** A total of 6,276 T1D patients and 147,097 non-diabetic patients were identified. OLS regression showed that patients with T1D patients were at increased risk for all three diseases ($p < .0001$) while Cox model failed to find any effect. ARBs are calculated to be more effective at preventing onset of disease compared to control drugs. ARBs can delay disease onset by up to 12 days (MS 11.627, $p=0.0061$; SLE 11.420, $p=0.0071$; RA 11.504, $p=0.0069$) whereas ACE inhibitors reduce the time to event by 8 days (MS -8.208, $p=0.0026$; SLE -8.174, $p=0.0027$; RA -7.610, $p=0.0054$). **CONCLUSIONS:** This study showed that T1D was associated with increased risk of other autoimmune diseases. The use of ARBs delayed onset of the diseases. Further studies with improved model may identify potentially valuable role of RAS therapy.

PDB20

AUTOIMMUNE DISEASE TIME TO DIAGNOSIS REDUCED IN PATIENTS WITH TYPE 2 DIABETES AND DELAYED WITH CONTINUOUS RAS THERAPY

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OBJECTIVES: As the population of patients with type 2 diabetes (T2D) grows, it is important to look at the influence that it has on the onset of other disease. Autoimmune disease may be of particular interest because of the chronic low-grade inflammation in diabetic patients and connections to an imbalance in the Renin-Angiotensin System (RAS). This study aims to determine if RAS-modifying medications (angiotensin converting enzyme [ACE] inhibitors and angiotensin receptor blockers [ARBs]) have a beneficial impact on autoimmune disease in emerging T2D patients with hypertension (HTN) controlling for T2D and other factors. **METHODS:** A retrospective analysis was conducted using claims data from a US commercial insurance company (2007-2013). The study groups consisted of HTN patients taking either: ACE inhibitors, ARBs, or control (diuretics or calcium-channel blockers). Cox analyses were performed to determine the impact of ACE inhibitors and ARBs on incidence of autoimmune disease controlled for comorbidities, demographics, and diagnosis of T2D as a risk factor. Incidence and time to diagnosis were measured for multiple sclerosis [MS] (ICD-9 340.xx), systemic lupus erythematosus [SLE] (ICD-9 710.0), and rheumatoid arthritis [RA] (ICD-9 714.xx). **RESULTS:** A total of 28,656 new T2D patients and 147,097 non-diabetic patients were identified. Patients with emerging T2D were not at increased risk for MS (HR 1.147, $p=0.4384$) or SLE (HR 1.254, $p=0.0706$) but were for RA (HR 1.299, $p<.0001$). There was however a significantly faster progression of the disease in all three autoimmune diseases in patients with T2D. RAS-modifying anti-hypertensives did not reduce incidence of disease but did delay disease onset with continued use. **CONCLUSIONS:** T2D has been shown to impact a variety of disease in incidence, severity, and onset; autoimmune disease may soon be included on this list. ACE inhibitors and ARBs may help delay the progression of MS, SLE and RA.

PDB21

INCIDENCE OF TUBERCULOSIS AND PNEUMONIA IN A NEWLY DIAGNOSED TYPE 2 DIABETIC POPULATION AND THE IMPACT OF RAS THERAPY

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OBJECTIVES: Increased risk of tuberculosis (TB) is associated with diabetes in countries with low-income and high prevalence of both diseases. Pneumonia has also been associated with diabetes diagnosis. This study aims to investigate the impact of pulmonary complications in population with hypertension (HTN) and the possibility of using RAS-modifying medications (angiotensin converting enzyme [ACE] inhibitors and angiotensin receptor blockers [ARBs]) to delay their emergence. **METHODS:** A retrospective analysis was conducted using claims data from a US commercial insurance company. The study groups consisted of patients taking either: ACE inhibitors, ARBs, or control (diuretics or calcium-channel blockers). Hazard ratios (HR) were calculated using Cox analyses to determine the impact of ACE inhibitors and ARBs on incidence of TB and pneumonia. Initial drug model was tested to measure the extent to which the risk of the events is impacted if the patient started are ACE inhibitors or ARBs, and duration model tested whether everyday use of HTN medications delays the events. **RESULTS:** A total of 29,850 new T2D patients and 154,083 non-diabetic patients were identified. In initial drug model, emerging T2D patients were at increased risk for pneumonia (HR=1.188, $p<.0001$), but were not for TB (HR=1.425, $p=0.0745$). Patients treated with ACE inhibitors had lower incidence of pneumonia by 17% (HR=0.833, $p<.0001$) and TB by 33% (HR=0.667, $p=0.0097$), and ARBs patients exhibited a lower risk of pneumonia by 11% (HR=0.888, $p<.0001$) compared to patients treated with control drugs. In duration model, T2D patients were at increased risk for pneumonia by 12% (HR=1.124, $p<.0001$) and TB by 49% (HR=1.487, $p=0.454$). The rate at which drug therapy delays disease onset is significantly higher for ACE inhibitors and ARBs compared to control. **CONCLUSIONS:** Pneumonia and TB are part of a growing list of complications linked to emerging T2D. ACE inhibitors and ARBs may help delay the progression of pulmonary infections.

PDB22

EFFICACY AND SAFETY OF ALBIGLUTIDE IN THE TREATMENT OF TYPE II DIABETES MELLITUS: A META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS

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OBJECTIVES: This meta-analysis was carried out to assess the efficacy and safety of albiglutide (30mg subcutaneous injection administered once a week) compared to any control intervention (other anti-diabetic medication, or placebo) among patients with T2DM. **METHODS:** Literature searches were conducted in PubMed, Embase and The Cochrane library databases. In addition, Clinicaltrials.gov was also searched to obtain additional information. Studies retrieved from the databases were screened and data were extracted by single reviewer, then cross checked for accuracy by second reviewer. Randomized controlled trials assessing the efficacy and safety of albiglutide among T2DM patients with ≥ 18 years old were included in this meta-analysis. Data were pooled using random-effect model (RevMan5.3). **RESULTS:** Of the 323 studies retrieved through database search, 10 (N=5613) met the eligibility criteria. Albiglutide was found to be effective in reducing glycated hemoglobin (HbA1c) (weighted mean difference [WMD], -0.62; 95% confidence interval [CI], -0.91 to -0.32; $n=10$), and fasting blood glucose (FBG) levels (WMD, -1.51; 95% CI, -1.81 to -1.8; $n=6$) than the control intervention. No significant differences were observed in hypoglycemia (risk ratio [RR], 1.01; 95% CI, 0.73 to 1.4; $n=9$), hypertension (RR, 1.04; 95% CI, 0.68 to 1.58; $n=3$), coronary artery

disease (RR, 0.73; 95% CI, 0.33 to 1.63; $n=6$), unstable angina (RR, 0.49; 95% CI, 0.16 to 1.49; $n=4$), and any gastrointestinal (GI) events (RR, 1.10; 95% CI, 0.79 to 1.53; $n=5$) between two groups. But, there was more than two fold increased risk of developing injection site reactions in the albiglutide group when compared to the control group (RR, 2.31; 95% CI 1.13 to 4.72; $n=9$). **CONCLUSIONS:** Meta-analysis suggests that albiglutide is effective and safe among patients with T2DM. However, albiglutide appears to be associated with the risk of injection site reactions. In future more well designed randomized controlled trials with long-term follow-up are needed to establish this.

PDB23

IMPACT OF PAST COMPLIANT BEHAVIOR AND SEVERITY OF DISEASE ON THE ADHERENCE TO ANTI-DIABETIC MEDICATIONS: A RETROSPECTIVE CLAIMS DATABASE STUDY

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OBJECTIVES: Adherence to anti-diabetic medications has always been a concern due to its importance in diabetes management. Adherence to medication can depend on the patients' compliant behavior and the patients' perception of the severity of their diabetes. This study aims to assess the effect of past compliant behavior and severity of diabetes on patients' adherence to their anti-diabetic medications. **METHODS:** This is a retrospective database study of continuously enrolled (2009-2010) Texas Medicare Advantage Plan enrollees (≥ 60 years) with ICD-9 diagnosis codes for diabetic disorders. Patients were followed for one and a half year to measure their adherence to antidiabetic medication. Prescription claims for biguanides, diuretics, and sulfonylureas were utilized to determine medication adherence using medication possession ratio (MPR). The MPR 365 days following index date was used as a proxy measure of past compliance. Severity was assessed based on the presence of diabetic neuropathy (DN) in first 365 days of follow-up, with patients having DN being categorized as severe. The impact of patients' past compliant behavior and the presence of DN was assessed on the adherence during the 180 days after the compliance measurement period using multivariable logistic regression analysis. **RESULTS:** A total of 1,635 diabetic patients were identified with mean age 73.3 (± 7) years of which 58.9% were female. Almost 10% had diabetic neuropathy, and 66.5% patients were adherent to their medication in first 365 days of follow-up. Logistic regression showed that patients with DN were more likely to be adherent compared to the patients without DN (OR=3.46, 95% CI [1.91-6.26]); similarly, patients who were compliant to their medication in past were more likely to be adherent to their medications (OR=1.45, 95% CI [1.10-1.92]). **CONCLUSIONS:** Severity of diabetes (presence of DN) and previous compliant behavior is positively associated with the adherence to anti-diabetic medications.

PDB24

RISK OF HEART FAILURE HOSPITALIZATION AMONG USERS OF DIPEPTIDYL PEPTIDASE-4 INHIBITORS COMPARED TO SULFONYLUREA IN PATIENTS WITH TYPE II DIABETES

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OBJECTIVES: Recent post-secondary analysis of clinical trials suggested an increased risk of heart failure (HF) with Dipeptidyl Peptidase-4-inhibitors (DPP-4-inhibitors) but the risk remains uncertain. The aim of this study is to assess the risk of HF-hospitalization with the use of DPP-4-inhibitors vs. sulfonylurea in patients with type-II diabetes. **METHODS:** A retrospective cohort analysis using Truven Health-Commercial database was conducted among patients aged ≥ 18 years who had type-II diabetes (ICD-9: 250.x0 or 250.x2). Patients who initiated either DPP-4-inhibitors or sulfonylurea, had no prior use for at least 6 months, and had at least one additional prescription following initiation between January 2008 to December 2015 were included. Patients with a diagnosis of type-I-diabetes, gestational-diabetes, or end-stage-renal-disease prior the index-date (treatment initiation) were excluded. Follow-up continued until the occurrence of first HF-hospitalization, end of enrollment or, end of study period. Cox proportional hazards model after propensity-score matching was used to compare the risk of HF-hospitalization between patients with DPP-4-inhibitors and those with sulfonylurea. **RESULTS:** A total of 127,945 new-users of DPP-4-inhibitors [follow-up: Mean (\pm SD):110 days(\pm -121)], and 373,208 new-users of sulfonylurea [105 days (\pm -114)] were identified. Incidence rates of HF were 101 and 115 per 10,000 person-years in the DPP-4-inhibitors and the sulfonylurea groups, respectively. After matching on propensity-score ($n=127945$ each) and adjusting for risk factors, DPP-4-inhibitors group experienced 30% risk reduction in HF-hospitalization compared to the sulfonylurea group (HR: 0.70, 95%CI [0.64, 0.77]). Subgroup analysis showed a significant decrease in the risk of HF in patients without any history of cardiovascular disease (CVD) ($n=234,299$) HR: 0.63, 95%CI [0.56, 0.71]. However, there was no statistically significant difference in the risk of HF between the two groups in patients with prior CVD diagnosis ($n=21,591$) HR: 0.83, 95%CI [0.69, 1.00]. **CONCLUSIONS:** After adjusting for risk factors, the use of DPP-4-inhibitors was associated with reduced risk of HF compared to sulfonylurea.

PDB25

DIABETES PREVALENCE IN BRAZIL: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: Worldwide diabetes prevalence is around 9%, affecting approximately 415 million people. In Brazil, although there are several epidemiological studies on this subject, the prevalence of diabetes is still matter of debate. Our

objective is to investigate the prevalence of diabetes in Brazil. **METHODS:** We performed a systematic review on the prevalence of diabetes in Brazil. Potentially relevant studies were identified through an exhaustive search in MEDLINE, SciELO, LILACS, Ministry of Health and hand-search. Inclusion criteria were cross-sectional population-based, censuses, surveys or cohorts studies where diabetes diagnosis, regardless if type 1 or type 2, was self-reported (SR) or confirmed by blood glucose testes (BGT), in the Brazilian population. We conducted a meta-analysis to provide the current best prevalence estimate, using a random effects model. Descriptive analysis of studies and a comparison between self-reported and BGT studies were performed. **RESULTS:** Among the 968 located references, we included 28 studies. Thirteen were population-based studies with national representation and 15 were studies with local/regional representation. Fifteen studies were SR and 13 relied on BGT to confirm diagnosis. On SR studies, the mean prevalence was 6.25% (95% CI 5.75% - 6.74%; I2 50%) and on studies confirmed by BGT, the mean prevalence was 10.05% (95% CI 6.41% - 13.68%; I2 64%). From 24.0% to 50.4% of interviewed people were unaware of their diabetes diagnosis. **CONCLUSIONS:** Diabetes is a global health challenge. Our findings suggest that there is a difference between the prevalence reported by SR studies and those where diagnosis is confirmed by BGT. A significant number of people are unaware of their condition therefore increasing the awareness about diabetes, screening, diagnosis and care is critical. Our estimates constitute a valuable tool for policy and decision-making process, mainly in developing countries.

PDB26

PREVALENCE OF DIABETIC RETINOPATHY IN TYPE-2 DIABETES IN RELATION TO, RISK FACTORS, SEVERITY, IN THE REGION OF WARANGAL, INDIA-A HOSPITAL BASED PROSPECTIVE STUDY

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OBJECTIVES: (1) To assess prevalence of diabetic retinopathy in Diabetes Mellitus in Warangal region, (2) To assess the various risk factors in diabetic retinopathy patients, (3) To find out effect of duration of Diabetes Mellitus on severity of Diabetic Retinopathy. **METHODS:** The study was a Hospital-based, Prospective observational study. Conducted on 452 diabetic male and female volunteers that fulfilled the inclusion criteria, with their proper consent for 6 months. All are underwent detailed ophthalmoscopic examinations for Diabetic Retinopathy, out of which 223 patients developing the Diabetic Retinopathy. The International Clinical Diabetic Retinopathy and Diabetic Macula edema Disease Severity Scale was followed to categorize Retinopathy in different stages. **RESULTS:** We observed that overall, prevalence of DR in Diabetic patients of Warangal region was 49.34%. Prevalence of Non-Proliferative DR, Proliferative DR and Macular edema were 31.19%, 10.8% and 7.3% respectively. Statistically significant variables on student t-test, chi square test and Univariate analysis, associated with increased risk of diabetic retinopathy were gender men at greater risk ($P < 0.0001$), longer duration of diabetes 15 years ($P < 0.0001$), use of insulin ($P < 0.0001$), age > 60 years of DM (OR 1.83, 95% CI 1.25-2.68). Patient with age group 40-60 years are at greater risk for Macular edema showed a statistically significant (OR 1.18, 95% CI 0.18-2.01). Also Poor FBS are at greater risk (OR 0.34, 95% CI 0.15-0.77). **CONCLUSIONS:** This study concluded that prevalence of DR in DM patients of Warangal region 49.34% and that it increased with age, duration of DM and poor glycemic control and needs early detection and appropriate treatment to prevent blindness due to this condition.

PDB27

ASSOCIATIONS BETWEEN ANTIDIABETIC AGENTS AND CANCER PROMOTION: A REAL-WORLD COHORT STUDY IN SHANGHAI, CHINA

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OBJECTIVES: To evaluate the effect of metformin and sulfonylurea on the cancer promotion among naive users of anti-diabetic medications as compared to nonusers. **METHODS:** A community population based retrospective diabetes cohort was extracted from the Shanghai Community Diabetes Management System database, which is a patient registry from general practices, with which included 2353 newly onset type 2 diabetes aged ≥ 35 years during 2006-2010. Patients were grouped by the initial therapy at registry entry into no use of anti-diabetic medications ($n=722$), metformin monotherapy ($n=374$), sulfonylurea monotherapy ($n=653$), metformin and sulfonylurea combination therapy ($n=302$), and other medication therapy ($n=302$). Comparisons between monotherapy and nonuse of medication were analyzed by both intention-to-treatment and per-protocol analyses, using Cox proportional hazards models in adjusted hazard ratio (aHR) and 95% CI. **RESULTS:** A total of 94 incident cancers were diagnosed during a median follow-up time of 5 years. Compared with nonusers, sulfonylurea monotherapy was associated with significantly lower risk of cancer promotion (adjusted HR 0.53 [95%CI: 0.31-0.91]). Similar association for metformin was not statistically significant (aHR 0.57 [95%CI: 0.30-1.09]). **CONCLUSIONS:** The real-world evidence suggested that the use metformin or sulfonylurea was at least not associated with cancer promotion, in a cohort of newly onset T2DM patients.

PDB28

INCRETIN TREATMENT AND RISK OF CANCER IN PATIENTS WITH TYPE 2 DIABETES MELLITUS: SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED AND OBSERVATIONAL STUDIES

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OBJECTIVES: Increasing numbers of studies have suggested cancer risk related to the incretin treatment. This study was conducted to assess cancer risk associated with

the use of incretin-based treatment in patients with type 2 diabetes mellitus (T2DM). **METHODS:** We systematically searched MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL) and ClinicalTrials.gov for randomized controlled trials (RCTs) and observational studies comparing incretin treatment with placebo or active anti-diabetic drugs used in T2DM patients. Paired reviewers conducted the literature screening, risk of bias assessment and data extraction independently. We analyzed and reported the results separately by different study designs. **RESULTS:** 130 RCTs and 7 cohort studies were included. 130 RCTs with low to moderate risk of bias enrolled 113176 patients, of which the pooled estimates showed no statistical difference of cancer risk between incretin treatments and controls (OR: 0.99, 95%CI: 0.90-1.09). Five pre-specified subgroup analyses suggested no significant interactions. Of the 7 cohort studies included (moderate to high risk, 466693 T2DM patients), pooled estimates of the unadjusted data showed no statistical difference of cancer risk between incretin treatment and comparators (RR=0.74, 95%CI: 0.38-1.42). Subgroup differences were not detected ($P=0.75$). Pooled estimates of adjusted data showed no significant differences either (aHR=0.80, 95% CI: 0.59-1.07). **CONCLUSIONS:** Current evidence suggests that incretins, compared to other active anti-diabetic drugs, do not increase the risk of cancer in T2DM patients, but further observational studies are still warranted to confirm the findings.

PDB29

MODELING INDIVIDUAL PATIENT BLOOD GLUCOSE LEVELS AS A STOCHASTIC PROCESS: AN OBSERVATIONAL STUDY USING LABORATORY DATA FROM HOSPITALS IN JAPAN

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OBJECTIVES: Stabilizing glucose levels in patients with diabetes is important in order to prevent hypoglycemia. Studies using Real World Data exist that describe the correlation between the treatment and incidence of hypoglycemia. The incidence rate is so small that significant results could only be achieved with a large sample size; such data cannot be obtained in Japan. The objective of this study is to examine the correlation between treatment type and blood glucose level. We may find significant results because the number of data points describing blood glucose is greater than the number of data points showing complications or hypoglycemia. **METHODS:** We analyzed health insurance claims data and laboratory data provided by Medical Data Vision Co., Ltd. We selected Type 2 diabetes patients having both anti-diabetic drug claims and glucose measurements. We applied a Wiener process to each patient and estimated both drift μ and infinitesimal variance σ^2 . We then built a linear regression model with σ as the explained variable, and sex, age, and dummy variables for each anti-diabetic drug treatment or combination of treatments as explanatory variables. We compared the coefficients of the dummy variables. **RESULTS:** Data from April 2008 to September 2016 were used. 5,807 Type 2 diabetes patients were selected. The coefficient of insulin was 23.0 mg/dl (p value was < 0.0001), which was far larger than that of all the other anti-diabetics. The second largest coefficient was that of sulfonylureas, 6.5 mg/dl (p values was < 0.0001). The smallest coefficient was that of glitazone, which was -4.4 mg/dl (p value was < 0.0001). **CONCLUSIONS:** We obtained a set of significant results on the variance of the blood glucose by type of treatment. This study suggests that the patients should choose the anti-diabetic drug within the allowance of the variation of the blood glucose.

DIABETES/ENDOCRINE DISORDERS – Cost Studies

PDB30

THE ADOPTION OF IGLARLIXI FOR THE TREATMENT OF TYPE 2 DIABETES MELLITUS IN PATIENTS PREVIOUSLY EXPOSED TO INSULIN MIGHT GENERATE SAVINGS FROM THE FIRST YEAR

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OBJECTIVES: IGLarLixi 100/33 (fixed-ratio combination of insulin glargine/lisinsinamide) demonstrated that a higher proportion of IGLarLixi-treated patients achieved HbA1c targets with a beneficial effect on body weight and no additional risk of hypoglycaemia at week 30, compared to insulin glargine in clinical trials. The objective of this analysis, funded by Sanofi, was to estimate the annual budget impact of adopting IGLarLixi for the treatment of patients with T2DM uncontrolled with less than 60 IU/day of basal insulin, from a US commercial payer perspective. **METHODS:** An Excel-based budget impact model assuming 1,000,000 hypothetical US health plan members in 2017 was developed. The proportion of diagnosed T2DM eligible to receive IGLarLixi was based on published literature and market research. The comparators and market share were derived from a PharMetrics database analysis. The model assumes 0.55% IGLarLixi adoption rate from other available regimens. Drug costs were calculated using published wholesale acquisition costs. Healthcare resource use and costs were derived from a combination of published literature and national fee schedules. A one-way sensitivity analysis varying all model parameters was also conducted. **RESULTS:** The model estimates that 9,658 patients were eligible to start treatment with IGLarLixi in the first year. In the projected scenario a budget impact of -\$16,824 (-0.29%) was observed, corresponding to a cost savings of \$0.01 per member per month (PMPM). Adopting the Medicare perspective, more patients would be eligible to IGLarLixi leading to higher savings: \$0.03 PMPM, corresponding to a budget impact of -\$41,720 between the scenarios: projected and without IGLarLixi. Sensitivity analyses showed that the results are most influenced by the projected market shares of IGLarLixi and its daily cost. **CONCLUSIONS:** IGLarLixi's adoption as a treatment option for T2DM patients uncontrolled on less than 60 IU/day of basal insulin shows potential to provide budget savings in the first year.

PDB31

ECONOMIC IMPACT OF SWITCHING HIGH-DOSE INSULIN-TREATED PATIENTS WITH T2D TO HUMAN REGULAR U-500 INSULIN MONOTHERAPY WITH 3-ML PENS

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OBJECTIVES: To evaluate the pharmacy budget impact of switching severely insulin-resistant patients with type 2 diabetes (T2D) requiring >200 units of daily insulin on basal-bolus regimens or human regular U-500 insulin (U-500R) 20-ml vials to U-500R 3-mL pens from the United States (US) commercial payer and Medicare perspectives. **METHODS:** A budget impact model was used to compare pharmacy costs with and without the U-500R pen over a 3-year period. A hypothetical US commercial plan and a Medicare cohort were evaluated separately. T2D prevalence/incidence rates and historical treatment data were used to estimate the number of U-500R-eligible patients. Market share and product substitution rates were projected based on estimates from IMS Lifelink™. These projections were used to allocate the eligible population to each comparator for scenarios with and without the U-500R pen. Pharmacy costs were estimated using average total daily doses (TDDs) from published data for U-500R/comparators. Copays, coinsurance, deductible, and member distribution by cost-sharing types were considered. Extensive sensitivity analyses were performed. **RESULTS:** For the US commercial cohort (1,000,000 members), introduction of U-500R pens yielded estimated total cost savings of \$730,769 with incremental cost savings per treated member per month (PTMPM) of \$54.55 and per member per month (PMPM) of \$0.020. For the Medicare cohort, the estimated cost savings were \$54,072,594 (total), \$49.00 (PTMPM), and \$0.040 (PMPM). Although the results were sensitive to U-500R TDD relative to comparators, cost-sharing composition, and rates of uptake from U-500R vials and from comparators, sensitivity analyses showed cost savings with the U-500R pens in all cases for both cohorts. **CONCLUSIONS:** Incremental switching of high-dose insulin-treated patients with T2D to U-500R pens was estimated to reduce costs from US commercial payer and Medicare perspectives, resulting in pharmacy budget benefits across a wide range of market factors, TDD requirements, and cost-sharing schemes of insurance plans.

PDB32

BUDGET IMPACT ANALYSIS OF INSULIN DEGLUDEC COMPARED TO INSULIN GLARGINE U100 FOR TYPE 1 DIABETES MELLITUS IN THE BRAZILIAN PUBLIC HEALTHCARE SYSTEM

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OBJECTIVES: To evaluate direct and indirect costs and associated budget impact of insulin degludec (IDeg) compared to insulin glargine U100 (IGlar U100) in the treatment of Type 1 Diabetes Mellitus patients in a basal-bolus regimen (T1DM) in Brazilian Public Healthcare System. **METHODS:** A 5-year budget impact model was developed to evaluate direct and indirect costs associated with the treatment of T1DM in Brazil. Annual treatment costs for IDeg and IGlar were calculated based on basal and bolus insulin dosing, needles, hypoglycaemic events, self-monitoring blood glucose tests, routine medical appointments and productivity loss attributed to hypoglycaemia. Clinical inputs were derived mainly from meta-analyses of randomized clinical trials. Unit costs were derived from official pricing and procedures reimbursement lists in the public healthcare perspectives (i.e. CMED, BPS and SIGTAP). To estimate the budget impact, a 1,000 hypothetical cohort population with T1DM is assumed and market-share of insulins derived from market data. Currency rate is 1.00USD-3.36BRL. Univariate deterministic sensitivity analysis was performed to stress robustness of main variables. **RESULTS:** Annual treatment costs per patient with T1DM were 8,505.16BRL for IDeg and 9,011.35BRL for IGlar U100. In the baseline scenario, the treatment of T1DM with IDeg is associated with 506.19BRL of annual cost reductions per patient. Main variables driving this reduction are basal/bolus insulin dose and needles and fewer hypoglycaemic events. Overall budget impact is -101,238BRL and -506,192BRL at Year 1 and 5, respectively. During 5 years, 2,489 hypoglycaemic events can potentially be avoided. As we used a budget impact approach, HRQoL benefits were not estimated. **CONCLUSIONS:** The introduction of IDeg in the Brazilian public healthcare system is associated with potential economic savings when compared to IGlar U100 and can positively increase according to the proportion of patients treated with IDeg. Budget-holders can either save resources or treat more patients when managing T1DM.

PDB33

A COMPARISON OF TRENDS IN INSULIN PRICES AND THE GROSS DOMESTIC PRODUCT IN THE US (1983 - 2016)

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OBJECTIVES: Diabetes is one of the most prevalent chronic diseases in the United States (US). Newer analogs are generally more expensive than older insulin formulations. The increase in prices of insulin products have resulted in increased third party payer expenditures and out-of-pocket costs. This study assessed the increase in insulin prices and the gross domestic product (GDP) in the US in the period 1983-2016. **METHODS:** The average wholesale prices (AWP) of insulin were collected from the RedBook (Truven Health). The GDP per capita, a common measure of the economic growth of nation, was derived from The World Bank. Insulin products were classified according to their duration of action: ultra-short acting, short acting, intermediate acting, long acting, and premixed insulin. The

annual compound annual rate growth (CARG) for the AWP prices of insulin products were calculated and compared to the CARG of the GDP. **RESULTS:** Ultra short acting insulin products had an annual CARG price range from 14.1% to 16.5% compared with an annual CARG GDP range of 2.1% to 3.3%. For short acting insulin products, the annual CARG price range was 9.3% to 24.7% compared with an annual CARG GDP range of 2.8% to 3.8%. Intermediate acting insulin products had an annual CARG price range of 8.5% to 23.8% compared to the annual CARG GDP of 3.5% to 15.4%. Long acting insulin products had an annual CARG price range of 17.5% to 18.4% compared to an annual CARG GDP range 2.3% to 3.4%. Premixed insulin products had an annual CARG price range of 0.0% to 15.1% compared to the annual CARG GDP range of 2.9 % to 6.3%. **CONCLUSIONS:** Insulin prices increased faster than the GDP. The highest price increases were observed in ultra short acting insulin products, while the lowest price increases occurred in long acting insulin products.

PDB34

FDA APPROVAL AND PRICE ANALYSIS FOR GLUCAGON-LIKE PEPTIDE- RECEPTOR AGONIST (GLP-1 RA) FOR T2DM AND OBESITY: A DESCRIPTIVE STUDY (DURING THE PERIOD OF 2005-2016)

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OBJECTIVES: To describe trends in the Average Wholesale Price (AWP) per Define daily dose (DDD) and year of therapy at the market entry of all U.S. Food and Drug Administration (FDA)-approved GLP-1RA drugs. **METHODS:** The FDA-approved GLP-1RA drugs were collected from the Drugs@FDA database. Their DDD was extracted using the WHO anatomical therapeutic chemical classification and their AWP/unit price and market status from the RED BOOK Online(R). Descriptive statistics and liner regression were used to compare drugs' approval status, approval dates, and AWP prices/30 DDD using SAS 9.3. **RESULTS:** There were 15 dosage forms and strengths of approved GLP-1RA medications including 5 active ingredients(86.7%) and two combinations with insulin(13.3%). Exenatide(40.0%), Liraglutide(13.3%), Lixisenatide(13.3%), Albiglutide(6.7%), and Dulaglutide(13.3%) were the approved active ingredients. Exenatide was the first approved in 2005. The combination of each of Liraglutide and Lixisenatide with insulin was the last approved (late 2016). About half (53.3%) of these drugs included a box warning about thyroid C-cell tumor in animals. GLP-1RA drugs' indications were T2DM (93.3%) and chronic weight management (6.7%) for adults only. Their route of administration was subcutaneous. Their usage frequency was once daily (40.0%), twice daily (26.7%), and once weekly (33.3%). No generics were found for GLP-1RAs with 4.2% being repackaged. Their collected AWP prices ranged from \$216.35 to \$1609.71 and their effective dates ranged from 05/23/2005 to 01/01/2017. The median price/30 DDD was \$476.69 (range=\$216.35-\$1609.71). A significant direct association was found between drugs' prices/30DDD and their effective dates after inflation adjustment (slope =0.17; 95%CI=0.12-0.22). Similar associations were found for Exenatide, Liraglutide, Albiglutide, and Dulaglutide (All P-values<0.05). **CONCLUSIONS:** Five active ingredients and two combinations with insulin were approved by the USFDA. Their indications were T2DM and chronic weight management for adults only. GLP-1RAs prices/DDD were directly associated with the progress of time owing to the lack of generics.

PDB35

A STUDY ON THE VARIATION IN THE COST OF ORAL HYPOGLYCEMIC AGENTS IN INDIAN PHARMACEUTICAL MARKET

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OBJECTIVES: To analyze the variation in the cost of single drug formulations (SDFs) as well as fixed-dose combinations (FDCs) of oral hypoglycemic agents (OHAs) in Indian pharmaceutical market. **METHODS:** A screening for the SDFs as well as FDCs of OHAs was performed using online version of Current Index of Medical Specialties (CIMS) and Drug Today (Volume 2, July-September 2016). The cost of 10 units of tablets or capsules in Indian rupee (INR) of SDFs and FDCs of all brands were captured. Some FDCs of OHAs were excluded because APIs of FDCs were not available as an individual formulation in the market or costs were not available in the latest edition of Drug Today and CIMS. Percentage cost variation and average cost of SDFs and FDCs were calculated and compared. **RESULTS:** 9 single drugs in 20 different doses and 23 FDCs are available in Indian market. The variation in the cost of the SDFs is in the range of 55-1376%. Vildagliptin 50mg tablets have a least variation of 55%, while Glimiperide 2mg tablets showed highest variation of 1376%. Further, the variation in the cost of the FDCs of OHAs was in the range of 23-927%. The FDC of Glimiperide+Metformin (2+500mg) showed maximum variation of 927% while, Vildagliptin+Metformin (50+1000mg) tablets have the least variation of 23%. Out of selected 23 FDCs, 19 have lower and only 4 have higher average cost than SDFs. **CONCLUSIONS:** Compared to the SDFs, FDCs having least variation in the cost and less average cost.

PDB36

PREDICTION OF LONG TERM OUTCOMES OF TYPE 2 DIABETES IN CHILEAN POPULATION FROM THE PERSPECTIVE OF PUBLIC HEALTH SYSTEM

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OBJECTIVES: To estimate economic and health related quality of life consequences of newly diagnosed type 2 diabetes patients in Chile. **METHODS:** A Discrete Event Simulation (DES) model was built using the parametric equations of United Kingdom Prospective Diabetes Study (UKPDS) outcomes model 2. The

aim was to predict time to event from diagnosis to the occurrence of disease complications and death. Individual risk profile from newly diagnosed patients from the 2010 Chilean national health survey were used for the estimation. Health related quality of life were measured using quality adjusted life years (QALY). Costs were estimated using the normative tariff of the Chilean public payer. Cost and QALYs were discounted at an annual rate of 3%. **RESULTS:** The average expected cost of a newly diagnosed patient considering only the treatment and no complications is USD 12,300. The average expected QALYs of a newly diagnosed patient considering only the treatment and no complications is 17,08 QALY. The occurrence of a complication as heart failure is expected to rise the average expected cost of a patient without complications to USD 16,500 (increment of 34%) and to reduce the average expected QALYs to 14.85 (reduction of 13%). The occurrence of a complication as renal failure is expected to rise the average expected cost of a patient without complications to USD 99,500 (increment of 708%) and to reduce the average expected QALYs to 11.31 (reduction of 33.7%). **CONCLUSIONS:** Due to the high impact of complications on expected cost and QALYs, funding decisions for type 2 diabetes treatments should be based on the patient risk profile at the moment of diagnosis and not as a general rule.

PDB37

A REAL WORLD ANTI-DIABETES MEDICATION COST COMPARISON BETWEEN PREMIXED INSULIN ANALOGS AND LONG-ACTING INSULIN ANALOGS IN CHINESE PATIENTS WITH TYPE-2 DIABETES: A RETROSPECTIVE DATABASE STUDY

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OBJECTIVES: To assess and compare per-day anti-diabetic medication cost among Chinese type-2 diabetes mellitus (T2DM) insulin naïve patients who initiated premixed insulin analogs (premix) or long-acting insulin analogs (long-acting). **METHODS:** Data were obtained from an electronic medical record database between 2010.01.01~2015.06.30 covering medical encounter records from all general hospitals in a district from Shanghai, China. Insulin naïve T2DM patients who aged ≥ 18 years, were treated with oral anti-diabetic drug (OAD) only during baseline period (3 months prior to insulin initiation), and initiated premix or long-acting were included. Patients were followed until index insulin discontinuation or 12 months after initiation, whichever came first. T-test and generalized linear models adjusting for propensity score (PS) (including baseline demographics, number of OAD classes, comorbidities, costs, and healthcare resource utilization) were used to test the difference between two insulin groups. **RESULTS:** A total of 570 and 185 patients were identified for premix and long-acting groups, with mean (SD) age 63.0 (12.8) and 61.1(11.9) ($p=0.08$) and male 47.4% and 51.4% ($p=0.35$), respectively. During baseline, 19.3% premix users and 12.4% long-acting users had T2DM-related hospitalizations ($p=0.03$); the average number of T2DM-related outpatient visits were 0.98 and 1.23 times for premix and long-acting groups, respectively ($p=0.07$). During the follow-up period, per-day insulin dose averaged 31.7 and 15.3 international unit for premix and long-acting groups, respectively. Compared with premix users, mean per-day cost for long-acting users was 37.3% higher (15.3 vs 11.2 Chinese Yuan (CNY), mean difference (MD)[95% CI]: 4.2[3.2,5.1]) for overall anti-diabetic medication, 81.3% higher (3.3 vs 1.8 CNY, MD[95% CI]: 1.5[0.8, 2.2]) for OAD, and 28.6% higher (12.0 vs 9.3 CNY, MD[95% CI]: 2.7[2.1, 3.3]) for insulin. Results were consistent after PS was adjusted. **CONCLUSIONS:** Among Chinese T2DM insulin naïve patients, those who were initiated premix insulin had lower per-day antidiabetic medication cost than those initiated long-acting insulin.

PDB38

CHARACTERISTICS AND COSTS OF PATIENTS WITH TYPE 2 DIABETES AUGMENTING METFORMIN WITH DAPAGLIFLOZIN VERSUS GLIPIZIDE: AN ANALYSIS OF ADMINISTRATIVE CLAIMS DATA

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OBJECTIVES: To compare demographics, clinical characteristics, and health care costs among patients with type 2 diabetes (T2D) augmenting metformin monotherapy with dapagliflozin versus glipizide using a large administrative claims database. **METHODS:** Patients in the Truven MarketScan Commercial Claims and Encounters and Medicare Supplemental and Coordination of Benefits databases with a prescription for dapagliflozin or glipizide on or after January 1, 2014, were identified (date of first observed prescription termed index date). Patients were required to have metformin monotherapy for ≥ 30 days pre-index date, concomitant metformin and dapagliflozin/glipizide for ≥ 30 days post-index date, 12 months pre- and post-index date continuous health plan enrollment, ≥ 1 T2D diagnosis, and no diagnoses of gestational or type 1 diabetes. Dapagliflozin patients were matched 1:1 to glipizide patients using propensity scores. Demographics, clinical characteristics, and all-cause health care costs during the 12 months post-index date were reported. **RESULTS:** A total of 364 dapagliflozin patients were matched to 364 glipizide patients. Mean (SD) patient age and Charlson Comorbidity Index score were 53.7(8.6) years and 2.5(1.5) among dapagliflozin patients and 54.3(10.5) years and 2.6(1.6) among glipizide patients. A total of 54.4% of dapagliflozin and 62.1% of glipizide patients were women, and 27.5% of dapagliflozin and 31.6% of glipizide patients had a diagnosis of obesity at any point during the pre- or post-index date period. Mean (SD) all-cause medical (excluding pharmacy) costs during the 12-month post-index date period were \$5,278(\$11,455) among dapagliflozin patients versus \$10,013(\$34,885) among glipizide patients ($P=0.015$), while pharmacy costs were \$6,387(\$11,353) among dapagliflozin patients versus \$4,003(\$12,752) among glipizide patients ($P=0.008$). Mean (SD) total all-cause costs during the 12-month post-index date period were \$11,665(\$17,526) among dapagliflozin patients and \$14,016(\$41,597)

among glipizide patients ($P=0.322$). **CONCLUSIONS:** Despite similar demographic and clinical characteristics, dapagliflozin patients accrued statistically significantly lower medical and numerically lower total costs compared with glipizide patients.

PDB39

THE RELATIONSHIP BETWEEN HYPOGLYCEMIA SEVERITY AND WORK PRODUCTIVITY LOSS AND COSTS AMONG TYPE 2 DIABETES PATIENTS

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OBJECTIVES: Hypoglycemia can result in productivity loss and increased healthcare resource use in patients with type 2 diabetes (T2D). Previous research has focused on severe hypoglycemic events, this study sought to estimate work productivity loss and costs associated with hypoglycemic events of all levels of severity. **METHODS:** We identified adults with T2D who responded to the 2013 U.S. National Health and Wellness Survey. The study population included patients who reported a diagnosis of T2D and current treatment with an antihypoglycemic agent. Respondents were categorized into one of 3 groups based on whether an event occurred in the preceding 3 months: no hypoglycemic event (NE), non-severe event (NSE), or severe event (SE). Among those who reported hypoglycemia, SE was defined as requiring third-party assistance. Work productivity loss was measured using the Work Productivity and Activity Index. Direct costs were estimated from self-reported healthcare use. Indirect costs were calculated by combining data from the Bureau of Labor Statistics and productivity loss. Multi-variable regression models were used to adjust for baseline differences in patient characteristics. **RESULTS:** Of 3,630 respondents, 47.6% reported a NSE and 4.7% reported a SE. Increasing severity of hypoglycemia was associated with an increase in mean absenteeism (NE=5.7%, NSE=4.0%, SE=15.3%; p -trend $< .01$), presenteeism (NE=17.7%, NSE=18.7%, SE=31.1%; p -trend $< .01$), overall work impairment (NE=21.4%, NSE=20.8%, SE=37.9%; p -trend $< .01$), and activity impairment (NE=35.2%, NSE=38.6%, SE=49.9%; p -trend $< .01$). Hypoglycemia severity was also associated with higher mean indirect costs (NE=\$7,247.8, NSE=\$7,493.1, SE=\$12,166.6, p -trend=.008) and direct costs (NE=\$6,908.3, NSE=\$7,131.8, SE=\$15,410.4, p -trend $< .001$). **CONCLUSIONS:** This study suggests that hypoglycemia severity is associated with an increase in work productivity loss and higher costs. Hypoglycemia can pose a significant economic burden on patients, employers and healthcare systems and varies by the severity of hypoglycemic events.

PDB40

ASSESSING THE ECONOMIC BURDEN OF TYPE 2 DIABETES IN CHINA REFLECTING THE CURRENT STANDARD OF THE DISEASE MANAGEMENT AND FOR IMPROVED MANAGEMENT SCENARIOS USING A MODELING APPROACH

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OBJECTIVES: Recent estimates from the Diabetes-Atlas have quantified the total annual expenditures of diabetes in China between ¥354 to ¥611 Billion-Chinese-Yuan (BN-CNY) (2015). The objective of our study was to employ a modeling approach to re-estimate the annual cost burden based on the current standard of type-2-diabetes (T2D) management (status quo (SQ)) in China and a series of hypothetical improved management strategies. **METHODS:** The QuintilesIMS-CORE-Diabetes-Model (CDM) was used to evaluate the economic burden of T2D in China based on assumptions reflecting the current SQ of T2D-management and a number of step-wise-improvements. SQ was defined as a scenario in which T2D diagnosis is delayed by 4-years, treatment escalation to maintain glucose control occurs at a 9%-HbA1c-threshold, and an overall 60% adherence rate (AR). Step-wise-improvements considered immediate diagnosis, declining levels of HbA1c-escalation-thresholds to 8.0% and 7.0% and improvements in AR to 80% and 100%. The CDM was applied on per-capita level to project lifetime costs and clinical outcomes of newly diseased T2D individuals in the Chinese setting. Model outcomes were subsequently annualized and extrapolated to Chinese-national-level considering the total number of diagnosed T2D individuals in China. **RESULTS:** The total annual direct cost attributable to diagnosed T2D in China reflecting current SQ-management was estimated at 611 BN-CNY. Scenarios exploring step-wise-improvements from SQ estimated annual net-savings of ¥32, ¥33, ¥57, ¥69 and ¥73 BN-CNY for scenarios exploring immediate diagnosis, threshold reductions to 8.0% and 7.0% and AR increased to 80% and 100%, respectively. Net-savings resulted from reduced costs to treat diabetes complications (¥36, ¥63, ¥117, ¥134 and ¥154 BN-CNY) and excess treatment costs alongside step-wise-improvements (¥3, ¥30, ¥61, ¥66 and ¥81 BN-CNY). Per-capita life-expectancy was increased by 0.26, 0.69, 1.30, 1.48 and 1.68 years, respectively. **CONCLUSIONS:** Improved T2D-management-strategies can help to decrease the financial burden of the disease and increase life-expectancy of T2D individuals.

PDB41

AN ACTUARIAL ANALYSIS OF DIABETES PAYER ADDRESSABLE BURDEN

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OBJECTIVES: The goal was to describe health plan financials, from an actuarial perspective, for members with Type 1 Diabetes (T1DM) and Type 2 Diabetes (T2DM), including members with serious emergent hypoglycemic events. **METHODS:** Payer Addressable Burden (PAB) describes the cost of care curve and identifies opportunities to address those costs. Medical and prescription claims

were evaluated using Symmetry® Episode Treatment Groups®, which is an episode grouper that combines related services into medically relevant and distinct units. Claims data were taken from a proprietary database, which contained 27 million commercial and MAPD members. Three 12-month periods were assessed (April 2013 to March 2016). Three levels of costs were described: diabetes-specific (dPAB), selected comorbidities (cPAB), and total (tPAB). **RESULTS:** The average annual number of diabetes members was 1,181,848. Demographics included: female (49%), <65 yo (54%), commercial benefits (53%), T2DM (92%), ≥1 serious emergent hypoglycemic event (1.5%). High diabetes prevalence resulted in a high level of financial risk. Episodic dPAB was not remarkable compared to tPAB. Comorbidities were associated with higher dPAB, and vice versa. Pharmacy was a proportional driver of cost and trend. Members with T1DM and hypoglycemic events were associated with generally higher episodic dPAB, cPAB, and tPAB than their counterparts. Annual average dPAB and tPAB for members with hypoglycemic events was three times higher than for their non-hypoglycemic counterparts. Members with hypoglycemic events cost 4% to 5% of dPAB and tPAB PMPM for diabetes members. **CONCLUSIONS:** Actuaries prioritize the cost of the “member with diabetes” over the cost of “diabetes in the member.” Actuaries are more likely to focus on T2DM members than T1DM members, will note the larger medical cost offset opportunity with tPAB, will take interests in the interplay between diabetes and comorbidities, and will explore potentially favorable returns on investments in members at risk for hypoglycemic events.

PDB42

COST AND HEALTHCARE USE IMPLICATIONS OF BARIATRIC SURGERY VS LIFESTYLE/MEDICAL INTERVENTION FOR TYPE 2 DIABETES

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OBJECTIVES: Bariatric surgery has been shown to be more effective than intensive lifestyle and medical intervention (ILMI) for weight loss and diabetes control. We sought to compare the 2-year cost and healthcare utilization of patients with obesity and Type 2 diabetes mellitus (T2DM) randomized into either Roux-en-Y gastric bypass (RYGB) surgery or an ILMI. **METHODS:** This analysis is based on two-year follow-up of a small randomized controlled trial (RCT) with additional data from a larger cohort of patients (N=1,808). Adult patients with body mass index of 30–45 kg/m² currently on T2DM medications were recruited from Group Health Cooperative between July 2011 and June 2012. The study sample included 745 patients with non-missing outcomes during the study period. We were primarily interested in comparing the cost and healthcare utilization outcomes for patients randomized into either RYGB (N=15) or ILMI (N=17). **RESULTS:** After 2 years of follow-up in the randomized trial, there were no significant differences in health care costs for RYGB patients compared to those undergoing ILMI. There was evidence of pharmacy cost reduction for RYGB vs. ILMI patients – by about \$900 in year 2 vs. year 0; this was, however, counteracted by higher inpatient and emergency room costs for surgery patients in the two follow-up years relative to the year before surgery. Median total cost for non-randomized patients was higher by more than \$600 in year 0 and by almost \$1000 in year 2 compared to randomized patients. **CONCLUSIONS:** This study suggests bariatric surgery is not cost-saving in the short term compared to ILMI. Moreover, the costs of patients who enter into RCTs of bariatric surgery may be quite different from that of those who do not enter RCTs, suggesting that caution is needed when using data from bariatric RCTs to draw inferences about the general population of patients with obesity.

PDB43

PRESCRIPTION PATTERNS AND COSTS OF ANTIDIABETIC MEDICATIONS IN A LARGE GROUP OF PATIENTS

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OBJECTIVES: To determine the prescription patterns of antidiabetic medications and the variables associated with their use in a Colombian population. **METHODS:** A cross-sectional study using a systematized database of approximately 3.5 million affiliates of the Colombian Health System. Patients of both genders and all ages treated uninterruptedly with antidiabetic medications for three months (June–August 2015) were included. A database was designed that included sociodemographic, pharmacological, comedication, and cost variables. IBM® SPSS® Statistics software, version 23.0, was used for the data analysis. **RESULTS:** A total of 47,532 patients were identified; the mean age was 65.5 years, and 56.3% were women. Among the patients, 56.2% (n=26,691) received medication as monotherapy. The most prescribed medications were metformin, 81.3% (n=38,664), insulins, 33.3% (n=15,848), and sulfonylureas, 21.8% (n = 10,370). Insulin analogs comprised 72.3% (n=11,462) of those with insulin therapy. The mean prescribed daily dose to defined daily dose ratio was: 0.75 for metformin, 0.85 for glibenclamide and 1.30 for total insulin. Among the patients, 92.8% received comedications, including antihypertensives (79.7%), hypolipemians (65.5%), antiplatelet drugs (56.3%), analgesics (33.9%), antiulcerants (33.1%), and thyroid hormone (17.3%). The cost per 1,000 inhabitants/day was \$1.21 USD for metformin, \$3.89 USD for insulins, and \$0.02 USD for glibenclamide. The estimated annual cost of human insulin was \$198,355 USD, whereas that of the analogs was \$4,746,780 USD. The average cost per unit of insulin was \$0.002 USD and \$0.02 USD for human insulin and the insulin analogs, respectively. **CONCLUSIONS:** Generally, rational prescription habits predominated, however in some cases an overuse of comedications (such as antiulcer drugs) and a large group of patients with high cost formulations were observed. Subsequent effectiveness and cost-benefit analyzes are required.

PDB44

EFFECTIVENESS AND COST-EFFECTIVENESS OF A TWO-YEAR SHORT MESSAGING SERVICE (SMS) INTERVENTION FOR PROFESSIONAL DRIVERS WITH PRE-DIABETES

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OBJECTIVES: An observational post-randomized controlled trial (RCT) design was adopted to evaluate the long-term sustainability and maintenance of improved glycemic control, lipid profile, and reduced progression to diabetes at 3-year following a 2-year intervention of short messaging service (SMS). **METHODS:** We performed a naturalistic follow-up to the 104 participants of SMS intervention, a 2-year RCT comparing SMS to non-SMS for professional drivers with pre-diabetes (ClinicalTrials.gov Identifier: NCT01556880). Primary outcome of this post-RCT study was cumulative incidence of diabetes whereas secondary outcomes were the change in biometric data over a 5-year period. Proportional Cox regression model was constructed to estimate hazard ratio (HR) of SMS for progression to diabetes. Incremental cost-effectiveness ratio for the SMS versus non-SMS was expressed in cost (2015 price in US dollar) per quality-adjusted life-year (QALY). Uncertainty about ICER was incorporated using bootstrapping. **RESULTS:** After a mean 57-month follow-up, 19 (18.3%) were lost to follow-up after the RCT period. No significantly greater benefit of SMS over 5-year period was observed in weight, body mass index, glycemic control, and lipid profile and diabetes risk scores. Thus no significant effect of SMS on reduction in diabetes was observed in overall (HR: 1.184; 95%CI: 0.612-2.288) and pre-defined subgroups. In terms of cost-effectiveness, there were no significant differences in total costs (SMS: \$880.21; non-SMS: \$1327.51; difference: -447.30 95%CI: -447.30-488.38) and QALYs (SMS: 3.69; non-SMS: 3.68; difference: 0.01 95%CI: -0.01-0.04) between groups. Probabilities that SMS was cost-effective compared with non-SMS at a willingness-to-pay threshold of \$10,000 and \$50,000 per QALY gained were 87.3% and 87.5%, respectively. **CONCLUSIONS:** Based on post-RCT data, SMS intervention preserved the clinical benefits within the 3-year after intervention but it failed to translate from treatment efficacy to long-term effectiveness beyond 3 years. However, SMS was effective for delaying the diabetes progression, making it cost-effective over the 5-year period.

PDB45

COST-EFFECTIVENESS OF LONG-ACTING INSULIN ANALOGUES VERSUS INTERMEDIATE/LONG-ACTING HUMAN INSULIN FOR TYPE 1 DIABETES OVER 10 YEARS: A NATION-WIDE LONGITUDINAL COHORT FROM TAIWAN

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OBJECTIVES: To evaluate the cost-effectiveness of long-acting insulin therapy (LAIT) versus intermediate-acting insulin therapy (IAIT) for type 1 diabetes (T1DM) up to a follow-up of 10 years in a real-world healthcare setting. **METHODS:** This trial-based cost-effectiveness analysis was conducted in the propensity-score matched cohorts retrieved from the population-based, universal health insurance administrative database in Taiwan. Patients with T1DM who received their first basal insulin prescription within Jan 2004-Dec 2008 were identified and followed up until Dec 2013 to determine if they occurred diabetes-related complications, including cardiovascular, microvascular complications, hospitalized hyperglycemia, and outpatient or hospitalized hypoglycemia. Outcomes were measured in the number needed to treat (NNT) of each diabetes-related complication and of hyper- and hypoglycemia, total medical costs, cost per case of diabetes-related complication prevented, and cost per case of hyper- or hypoglycemia prevented. Baseline cost difference was considered. Probabilistic sensitivity analysis (PSA) was performed by nonparametric bootstrap method to consider the sampling uncertainty. **RESULTS:** Compared to IAIT, LAIT significantly reduced risks of any diabetes-related complications and hypoglycemia, and incurred the reduced total medical costs. The NNT for using LAIT versus IAIT to avoid one case having any diabetes-related complications and hypoglycemia were 10 (over 3.62 years) and 12 (over 5.84 years), respectively. The incremental medical costs for LAIT versus IAIT were -\$1,382 and -\$1,418 from a payer and a healthcare sector perspective, respectively. In the reference case analysis, IAIT is dominated by LAIT from both a payer and a healthcare sector perspective. PSA indicated that LAIT possessed a high likelihood as a cost-saving or highly cost-effective intervention. **CONCLUSIONS:** Over 10 years, the greater costs of LAIT for patients with T1DM are largely offset by savings arising from averted diabetes-related complications and hypoglycemia compared to IAIT, which suggests that use of LAIT for T1DM represents a good value for money.

PDB46

CLARIFYING CONCLUSIONS FROM A COST-EFFECTIVENESS ANALYSIS OF THE DIABETES PREVENTION PROGRAM (DPP) AND ITS OUTCOMES STUDY (DPPOS)

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OBJECTIVES: Clarify ambiguous and conflicting conclusions of a published Diabetes Prevention Program (DPP) and DPP Outcomes Study (DPPOS) cost-effectiveness study of placebo, metformin, individual and group lifestyle (ILS and GLS) interventions and indicate the degree of uncertainty around them by performing a probabilistic sensitivity analysis (PSA). **METHODS:** We took various types of cost (inside and outside DPP) and effectiveness (QALYs) numbers from the original publication and reproduced the original deterministic ICER results. We

then explored how the significant ambiguity of the original paper's conclusions could be clarified by using a net benefit (NB) formulation and the cost-effectiveness plane. We also explored uncertainty through a PSA, assigning probability distributions for costs and outcomes and doing a simulation, producing net benefit results for each set of drawn values and constructing cost-effectiveness acceptability curves and frontiers (CEAC/Fs). **RESULTS:** The NB formulation and the cost-effectiveness plane clearly indicated that GLS dominates or is cost-effective relative to the other three interventions for any likely WTP threshold (if that GLS alternative is eliminated, ILS is shown to be the cost-effective alternative, ICER= \$17,692). Metformin is only the cost-effective alternative if the WTP is quite low (less than \$1665/QALY). The PSA and CEAC/F analyses show that the GLS intervention probability of being cost-effective varies, but GLS is the clear optimal choice throughout (and beyond) a wide range of "reasonable" WTP values (\$10,000 - \$200,000/QALY). Its conditional probabilities of being cost-effective are $P(\text{CEI}WTP=\$1600) = 0.34$; $P(\text{CEI}WTP=\$100,000) = 0.66$. **CONCLUSIONS:** The original paper's ambiguous/conflicting conclusions (e.g. "policies should support the funding of intensive lifestyle and metformin interventions") obscure the simplicity of the results. The value of various depictions of deterministic and probabilistic results is shown by clarifying the original results - if these data reflect the performance of the interventions accurately, GLS is the cost-effective alternative in diabetes prevention.

PDB47

COST-EFFECTIVENESS OF TREATMENT PATHWAYS WITH DESIPRAMINE, DULOXETINE, GABAPENTIN, AND PREGABALIN FOR THE LONG-TERM TREATMENT OF PAINFUL DIABETIC NEUROPATHY

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OBJECTIVES: Patients with painful diabetic neuropathy (PDN) often do not respond to treatment and require frequent therapy switches. The objective of this study was to determine the cost-effectiveness of all possible PDN treatment pathways with desipramine (DES), duloxetine (DUL), gabapentin (GABA), and pregabalin (PRE) over a 10-year time horizon from a third-party payer perspective. **METHODS:** A micro-simulation health-state transition model was created to estimate the direct healthcare costs and quality-adjusted life-years (QALYs) in 10,000 hypothetical patients with moderate-to-severe PDN. The model compared each of the 24 possible PDN treatment pathways, which consisted of initial treatment with DES, DUL, GABA, or PRE followed by therapy switches to remaining agents after therapy failure or serious adverse events. Medication adherence values and pain relief scores were specific to each treatment and thus changed as patients progressed through each pathway. Healthcare costs and health state utilities were assigned based on pain response (i.e. moderate-to-severe vs. mild) and were derived from national sources and published estimates. **RESULTS:** Five treatment pathways were not dominated (listed in order of increasing cost): 1) DES/DUL/GABA/PRE, 2) DUL/DES/GABA/PRE, 3) DUL/GABA/DES/PRE, 4) DUL/PRE/DES/GABA and 5) DUL/PRE/GABA/DES. Mean costs ranged from \$29,200 to \$35,700. Mean QALYs ranged from 3.09 to 3.13. Using DES/DUL/GABA/PRE as the reference, DUL/DES/GABA/PRE had the lowest incremental cost-effectiveness ratio (\$1,190 per QALY gained). Deterministic sensitivity analyses showed the model was most sensitive to changes in health state utilities, medication adherence, and pain relief threshold. Probabilistic sensitivity analyses estimated that DUL/DES/GABA/PRE was cost-effective in 66% and 73% of the simulations at willingness-to-pay thresholds of \$50,000 and \$100,000 per QALY gained, respectively. **CONCLUSIONS:** Initiating treatment with DUL followed by DES, GABA, and PRE (in that order) after therapy failure appears to be the most cost-effective PDN treatment pathway. These results could help guide provider and third-party payer decisions surrounding PDN therapy management.

PDB48

ECONOMIC EVALUATION OF DIABETES EARLY TREATMENT IN CHINA

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OBJECTIVES: As of 2015, 114 million people have diabetes in China. However, only 38.6% of people with diabetes are aware that they have diabetes; merely 25.8% of people with diabetes are taking diabetes medications. Insufficient treatment and delayed insulin initiation are key challenges for diabetes management in China. This study is to evaluate the long-term impact on health outcomes and medical costs of early treatment among people with type 2 diabetes (T2DM) in China. **METHODS:** This study compares the health outcomes and medical costs between early treatment (defined as patient receiving diabetes treatment at baseline HbA1c 7.5%) versus current practice (treatment at baseline HbA1c 9.0%) over 30-year time horizon based on CORE Diabetes Model. The baseline individual characteristics, risk factors, treatment effect and medical costs are extracted from large scale studies in China. Costs and health outcomes are discounted at 3% annually. **RESULTS:** Health outcomes: early treatment is associated with less cumulative incidences of diabetes-related complications - myocardial infarction (MI), neuropathy, foot ulcer, retinopathy, congestive heart failure (CHF) reduces by 3.75%, 3.17%, 2.11%, 1.92%, 0.30%, respectively; increased expected life years by 0.371 (15.208 vs 14.837), and quality adjusted life years by 0.260 QALYs (10.855 vs 10.595). Medical costs: early treatment saves total direct medical costs, anti-diabetic medication cost, and complication cost by CNY 6,533 (201,774 vs 208,307), CNY 493 (54,911 vs 55,404), and CNY 6,986 (101,098 vs 108,084), respectively per patient. Sensitivity analysis demonstrated the robustness of the study results. **CONCLUSIONS:** Diabetes early treatment is associated with long-term improvements in health outcomes and savings in medical costs for people with T2DM in China. The new evidence suggests that early intervention is a cost-saving strategy in diabetes management in China, which will contribute in achieving the goals set in Healthy China 2030.

PDB49

PHARMACOEPIDEMOLOGICAL AND PHARMACOECONOMIC STUDY OF CO-MORBIDITIES IN DIABETES MELLITUS

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OBJECTIVES: The aim of the study was to determine in Study cost of illness and cost of utility analysis in the population. And decreasing the economic burden of the treatment by following the life style modifications. **METHODS:** study involving cohort study design. Totally of 132 diabetic patients are included. In-patients and out patients of medical and surgical department in RDT hospital, Bathalapalli - a secondary level referral hospital at rural Anantapur, AP are involved in the study period of 6 months range from August 2012 to January 2013. All in patients and out Patient who are diagnosed as Diabetic type-II, Continuing anti diabetic drugs for their diabetes management are included and Patient who are diagnosed as Diabetic type-I and pregnancy and pediatric patients were excluded. **RESULTS:** A totally of 132 diabetic patients, in which male and females are near by equal in number. Based upon the comorbidity conditions most of the subjects (69%) were suffering with diabetes+hypertension. Most of the subjects(9.9%) having comorbidity conditions of diabetes+hypertension+acute renal failureand these people are spending more money to the treatment. The average utility of drugs is more for the combination of Met+Glib+Ins than metformin+glibenlamide .Chalrson Co morbidity Index is more for the people are present in the age group of 61-70 years. cost of hospitalization with co morbidities is more(95515rs) for DM+ HTN. **CONCLUSIONS:** Finally we concluded that, anantapur is a rural area, most of people are with poor knowledge and lack of awareness. By applying all those patients in Charlson Co morbidities index we found, patient's economic status through year wise. It says many of the diabetic patients facing economic burden, especially daily wager are feeling much difficulty to face even therapy cost also. In co morbidities side we noticed most of the patients are Diabetic with hypertension, they are 55% in my study population.

PDB50

CORRELATION BETWEEN MANUFACTURING COMPANIES AND COST VARIATION OF ANTI-DIABETIC DRUGS IN UKRAINE

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OBJECTIVES: Investigate correlation between the number of manufacturing companies and the percentage of cost variation of antidiabetic drugs in Ukraine. **METHODS:** 1) retrospective analysis of 1792 inpatient's medical histories with T2DM; 2) frequency analysis of the used treatment regimens; 3) ATC/DDD-methodology. **RESULTS:** The retrospective analysis showed that monotherapy was used in 25 % of cases. Of these, 16 were treated by metformin, 5 % - glimepiride, 4% - gliclazide. So, metformin, glimepiride and gliclazide have been selected for the research. Pharmaceutical assortment of peroral antidiabetic drugs, manufacturers, minimum and maximum costs of generics in pharmaceutical market of Ukraine have been established in price list of the largest national distributor. According to the ATC/DDD-methodology DDD of metformin is 2000 mg, gliclazide - 60 mg, glimepiride - 2 mg. The investigated period was 2011-2014. As a result of ATC/DDD-analysis it has been found that the cost of DDD of monotherapy with metformin ranges from 1,28 to 1,55 UAH (in minimum costs of generics) and 3,05-5,46 UAH (in maximum costs of generics), with glimepiride - 0,66-1,06 and 1,88-3,42, respectively, with gliclazide - 0,31-1,26 and 1,62-3,97 UAH, respectively. The number of manufacturing companies of metformin was 7-9, glimepiride - 8-9, gliclazide - 3-5. Spearman rank correlation of the investigated treatment regimens indicates the weak negative association between the number of manufacturing companies and the percentage of cost variation ($p > 0.05$). **CONCLUSIONS:** Our results showed a weak negative association between the number of manufacturing companies and the percentage of cost variation of peroral hypoglycemic drugs that were selected for the investigation. Probably, it is associated with small number of manufacturers of antidiabetic drugs in the pharmaceutical market of Ukraine and, maybe, distortion of lows of the market and competition in condition of political and economic instability of the country.

PDB51

COST-EFFECTIVENESS OF GENETIC SCREENING FOR MATURITY ONSET DIABETES OF THE YOUNG (MODY)

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OBJECTIVES: Maturity onset diabetes of the young (MODY) is a genetic form of diabetes for which 13 genes are known to be responsible. Many subtypes of MODY can be treated with oral medication instead of insulin injections, which results in improved metabolic control, quality of life and cost savings. Massively parallel sequencing (MPS) enables the simultaneous sequencing of all 13 genes for a fraction of the cost of traditional Sanger sequencing. We conducted a cost utility analysis of genetic screening (targeted MPS) for MODY in a paediatric population presumed to have type 1 diabetes (T1D), where the underlying prevalence of MODY has been calculated as 2.6%. **METHODS:** A Markov decision model was developed to estimate the incremental costs and quality-adjusted life years (QALYs) of genetic screening for MODY compared with standard care over 50 years' follow up. The probabilities and quality of life weightings (utility) of long term diabetic complications were estimated from published data and population

statistics. Costs were estimated from the perspective of the Australian health care system. **RESULTS:** Genetic screening for MODY at diabetes diagnosis was more effective and less costly than standard care, with 1.39 QALYs gained and AU\$1.4 million (US\$1.05 million) saved per 1,000 patients. The costs of the screening program were fully offset within four years. A sensitivity analysis revealed that genetic screening remained dominant until the MODY prevalence fell below 0.7%. **CONCLUSIONS:** Screening for MODY in the paediatric diabetes population would reduce health system costs and improve patient quality of life. Our results were robust to assumptions around the underlying MODY prevalence and make a compelling argument for routine genetic screening in all children with presumed T1D.

PDB52

COST-UTILITY OF DAPAGLIFLOZIN VERSUS DPP4 INHIBITORS IN PATIENTS WITH TYPE 2 DIABETES MELLITUS IN COLOMBIA

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OBJECTIVES: To determine the cost-utility of dapagliflozin versus DPP4 inhibitors (DPP4i) (saxagliptin) as add on to metformin for the treatment of patients with type 2 diabetes mellitus (T2DM) who failed monotherapy. **METHODS:** A cost-effectiveness analysis was made by a discrete events model at the patient's level that simulates the incidence of the complications of the disease, and it considers a time horizon of 20 years. The model perspective is from the Colombian health system. The main outcomes are the quality-adjusted life years (QALY) and the economic results of the disease and its complications. Direct costs were updated to the year 2016 and a discount rate of 5 % was applied, both for costs and for health outcomes. The risks of developing complications were taken from the risk formulas of UKPDS68 and UKPDS66. **RESULTS:** Dapagliflozin is dominant over DPP4i in terms of QALY. The treatment with dapagliflozin generates fewer events of fatal nephropathy and amputation than DPP4i. The final stage of chronic kidney disease (CKD) and amputation generate -0.263 and -0.280, respectively, which is why dapagliflozin contributes 0.36 more discounted QALY per patient than DPP4i. Similarly, the high cost of hemodialysis in these patients means that the total treatment discounted costs with dapagliflozin are lower than those of the DPP4i strategy. In the willingness to pay curves, dapagliflozin has a probability of 71 % of being the choice strategy with any availability value to pay. **CONCLUSIONS:** From the perspective of the Colombian health system, dapagliflozin is a dominant strategy versus DPP4i in patients with T2DM who fail to control adequately with metformin monotherapy. Dapagliflozin has a great impact over CKD and QALYs.

PDB53

DAPAGLIFLOZIN VERSUS SULFONYLUREA IN PATIENTS WITH TYPE 2 DIABETES MELLITUS IN COLOMBIA: COST-EFFECTIVENESS ANALYSIS

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OBJECTIVES: To determine the cost-effectiveness of dapagliflozin versus sulfonylureas for the treatment of patients with type 2 diabetes mellitus (T2DM) who have failed metformin monotherapy. **METHODS:** A cost-effectiveness analysis was made by a discrete events model at the patient's level that simulates the incidence of the complications of the disease, and it considers a time horizon of 20 years. The model perspective is from the Colombian health system. The main outcomes are the quality-adjusted life years (QALY) and the economic results of the disease and its complications. Direct costs were updated to the year 2016 and a discount rate of 5 % was applied, both for costs and for health outcomes. The risks of developing complications were taken from the risk formulas of UKPDS68 and UKPDS66. **RESULTS:** Dapagliflozin is not inferior than sulfonylureas in terms of health outcomes of HbA1c, cholesterol and HDL. Patients with dapagliflozin lost weight (-3.22 kg) and decreased more the systolic blood pressure (-4.3 mmHg); they also had fewer hypoglycemic events (3.5 %) than patients with sulfonylureas (40.8 %), with US \$ 1,660 savings. Dapagliflozin generates more 0.41 discounted QALY than sulfonylureas and has an ICER of US \$ 6,144 per patient. In the willingness to pay curves, dapagliflozin has a 65.5 % probability of being the choice strategy with a willingness to pay value of US \$ 6,049, which is the value of a GDP per capita in Colombia. **CONCLUSIONS:** From the perspective of the Colombian health system, dapagliflozin is a cost-effective strategy versus sulfonylureas in patients with T2DM inadequately controlled with metformin monotherapy; dapagliflozin has a great impact over patient weight loss and a decreased systolic blood pressure, as well as fewer hypoglycemic events.

PDB54

COST-UTILITY OF EXENATIDE VERSUS INSULIN GLARGINE IN PATIENTS WITH TYPE 2 DIABETES MELLITUS IN COLOMBIA

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OBJECTIVES: To determine the cost-effectiveness of exenatide versus insulin glargine as adjuncts to metformin for the treatment of patients with type 2 diabetes mellitus (T2DM) who have failed monotherapy. **METHODS:** A cost-effectiveness analysis was made by a discrete events model at the patient's level that simulates the incidence of the complications of the disease, and it considers a time horizon of 20 years. The model perspective is from the Colombian health system. The main outcomes are the quality-adjusted life years (QALY) and the economic results of the disease and its complications. Direct costs were updated to the year 2016 and a discount rate of 5 % was applied, both for costs and for health outcomes. The risk to develop complications were taken from the risk

formulas of UKPDS68 and UKPDS66. **RESULTS:** Exenatide generates fewer events of congestive heart failure and deaths due to macrovascular events as well as a 4.5 kg weight loss and a decreased of 4 mmHg in systolic blood pressure versus insulin glargine. Exenatide contributes 1.24 more discounted QALY per patient compared to insulin glargine and has an ICER of US \$ 3,953 per patient, which is lesser than one per capita GDP in Colombia (US \$ 6,049). In the willingness to pay curves, exenatide has a 61 % probability of being the choice strategy with a willingness to pay of one GDP per capita in Colombia. **CONCLUSIONS:** From the perspective of the Colombian health system, exenatide is a highly cost-effective strategy versus insulin glargine in patients with T2DM who cannot be adequately controlled with metformin monotherapy, with a great impact over their weight loss and QALY.

PDB55

THE IMPACT OF GLP-1 INDUCED NAUSEA AND VOMITING ON WORK PRODUCTIVITY AND HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH T2DM

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OBJECTIVES: To assess the impact of GLP-1-induced nausea and vomiting on patients with T2DM using the 'Nausea and Vomiting Questionnaire' (NVQ) and additional questionnaires designed to gather information on health-related quality of life (HRQOL) and work productivity. **METHODS:** A non-interventional, cross-sectional survey, was administered to T2DM patients. Screened respondents provided demographics, self-reported clinical and treatment information, and nausea- and/or vomiting-related resource utilization. Inclusion required T2DM diagnosis, age 18+ years and GLP-1 agonist treatment (among other criteria). Question S14 ("In the past 7 days, have you had any nausea or vomiting after using your GLP-1 medicine?") designated eligibility for the impact survey. Enrolled participants also completed four patient-reported outcome (PRO) measures, including: NVQ, Functional Living Index-Emesis (FLIE), Work Productivity and Activity Impairment: Specific Health Problem (WPAI:SHP), and the MOS SF-12. Descriptive statistics were tabulated for all screener (eligible and ineligible responders) and survey questions (eligible only). **RESULTS:** Overall, 1,026 respondents completed screening, including 204 enrollees reporting nausea and/or vomiting in the past 7 days. Eligible patients were 66% male, white (84%), non-Hispanic (75%), average (SD) age 41(11) years, with a diagnosis of T2DM between 3 and 9 years ago (53%) and 90% were first time GLP-1 users. Respondents (>60%) reported that nausea and/or vomiting (at its worst) impacted their relationships, work productivity, eating, sleeping, and amount of energy spent during the past 7 days. Respondents indicated using prescription (32%) and over-the-counter medications (26%) to treat nausea/vomiting. The questionnaire scores were: NVQ = mean (SD) score = 52.3 (22.5), WPAI absenteeism/presenteeism/productivity loss = 22.8 (25.2) / 56.0 (27.6) / 62.2 (29.9), and SF-12 Mental / Physical = 42.7 (8.3)/ 44.6 (7.2) for the overall group. **CONCLUSIONS:** This survey study shows that although there was a significant impact of nausea and vomiting on work productivity, the impact on HRQOL was relatively modest.

DIABETES/ENDOCRINE DISORDERS - Patient-Reported Outcomes & Patient Preference Studies

PDB56

UNIVERSAL MEDICATION SCHEDULE PRESCRIBING IMPROVES ADHERENCE TO DIABETES MEDICATIONS AMONG PATIENTS WHO ARE AT RISK FOR NON-ADHERENCE

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OBJECTIVES: The Universal Medication Schedule (UMS) standardizes prescriptions by explicitly stating when to take the medicine (i.e., morning, noon, evening, bedtime). We estimated the impact of UMS prescribing on medication adherence among patients initiating oral diabetes medication. **METHODS:** This retrospective cohort study included adults with an initial fill of an oral diabetes medication at Walgreens pharmacy between January- June 2014. Adherence was measured using Proportion of Days Covered (PDC) over 12-months. Optimal adherence (OA) was determined by PDC \geq 80%. Patients received a proxy designation of low education when \geq 10% of their census tract reported <9th grade education; all others were designated as standard education. Generalized estimating equations (GEEs) were used to compare whether UMS prescriptions were associated with better adherence compared to non-UMS prescriptions. Analyses were conducted for the overall sample and subgroups of patients age 65+, multi-daily dosing, and by designated education groups. **RESULTS:** The study cohort included 484,758 patients with 559,293 medications. Patients with low education (N=119,091) were prescribed 139,979 medications; among them, 74,263 required multi-daily dosing and 22,667 were age 65+. Patients designated as standard education (N=365,667) were prescribed 419,314 medications; among them, 201,336 required multi-daily dosing, and 75,024 were age 65+. GEE models showed that low education patients who received UMS prescriptions were significantly more likely to have OA compared to low education patients who received non-UMS prescriptions (RR 1.04, 95% CI 1.02-1.07, p=0.001). The effect was largest for patients over 65 contending with multi-daily regimens (RR 1.14, 95% CI 1.07-1.21, p<0.001). Patients designated as standard education were more likely to achieve OA following UMS prescriptions (RR 1.02, 95% CI 1.01-1.03, p=0.001), but there were no significant differences among subgroups. **CONCLUSIONS:** This study demonstrated that UMS prescribing is significantly associated with higher adherence to oral diabetic medications for older adults with low education who received a multi-daily regimen.

PDB57

A QUALITATIVE STUDY OF BASAL INSULIN USE BEHAVIORS IN PATIENTS WITH TYPE 2 DIABETES

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OBJECTIVES: To better understand type 2 diabetes (T2D) patients' experiences with using basal insulin. **METHODS:** This was a qualitative focus group study among patients with T2D who were current basal insulin users. The HealthCore Integrated Research Database was used to identify currently-active, commercially-insured, survey-eligible patients based on claims from 1/1/2015-12/31/2015. Patients with Cincinnati and NYC zip codes were invited to participate in 90-minute focus groups conducted by an experienced moderator. Two focus groups (six individuals each) were conducted in Cincinnati and two in NYC. The focus group proceedings were audio and video recorded and transcribed. Patients' insights regarding basal insulin administration, prescription fill patterns, and overall basal insulin use experiences were grouped into common themes to provide a deeper understanding of the issues surrounding the use of basal insulin. **RESULTS:** Of 24 participants, 58% were female, mean age 52.1 years, and mean time since T2D diagnosis 11.9 years. The majority of participants reported that their insulin prescription fills contained more drug than needed and reported having 'left over' insulin at the end of their refill period. Nearly everyone reported using the entire amount of insulin in each vial/pen before opening a new one. This led to stockpiling of insulin over time if filled regularly; skipping a refill occasionally if they had enough supply from prior fills to cover the month; or delaying their refill until all medication was used. Missing a dose was considered a rare occurrence and was mainly due to a change in routine or environment. Adjusting their insulin dose within ± 5 units was common and typically done in response to a blood sugar reading, healthy/poor eating, exercising, or a general feeling of well-being. **CONCLUSIONS:** Insulin filling behaviors are complex and depend on multiple factors. Inconsistent filling patterns may not be a true reflection of their adherence to insulin therapy.

PDB58

A MOTIVATIONAL INTERVIEWING (MI) INTERVENTION BY PHARMACY STUDENTS TO PREVENT MEDICATION DISCONTINUATION

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OBJECTIVES: To evaluate the influence of an MI telephonic intervention by pharmacy students on discontinuation of angiotensin-converting enzyme inhibitors (ACEIs)/angiotensin receptor blockers (ARBs) among Medicare Advantage Plan (MAP) patients with diabetes mellitus (DM) hypertension (HTN). **METHODS:** A randomized trial was conducted among patients with DM and HTN enrolled in a Texas MAP. Patients who filled an ACEI/ARBs during June, 2014 and had a 6-month proportion of days covered (PDC) < 0.80 in the previous 6-months were determined non-adherent ($n=5,851$) and randomized to intervention or control groups. The intervention was a phone call by pharmacy students on rotation at the MAP followed by 5 monthly follow-up calls. Prior to implementing calls, 11 participating students attended a 3-day MI training. Patients receiving calls were randomly selected from those randomized to intervention until 250 was reached; 500 controls were randomly selected from controls. Refill data during the 6 months following initial call were evaluated to examine discontinuation defined as no record of an ACEIs/ARBs. A multivariate logistic regression model with an outcome of discontinuation vs. not was constructed to control for imbalances in baseline characteristics including age, gender, number of other medication, regimen complexity, low income subsidy (LIS) status, prescriber specialty, comorbidities, 6-month prior hospitalization, baseline 6-month PDC, and Centers for Medicare and Medicaid Services risk score. **RESULTS:** 743 patients were included in the multivariate model. Patients completing ≥ 3 calls were less likely to discontinue (OR: 0.29; 95% CI: 0.15-0.54; $p < 0.001$) and patients with higher baseline PDC were less likely to discontinue (OR: 0.34; 95% CI: 0.22-0.52; $p < 0.001$). Heart failure patients were more likely to discontinue (ORs: 2.31; 95% CI: 1.34-3.98; $p=0.002$). **CONCLUSIONS:** The MI telephone intervention was beneficial in decreasing discontinuation 6-months following initial call. Future research should examine the sustainability of intervention effect for longer periods and its influence on clinical outcomes.

PDB59

EVALUATION OF EXERCISE COMPLIANCE AND ITS CONFOUNDING FACTORS AMONG DIABETES PATIENTS IN SOUTHERN PUNJAB, PAKISTAN

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OBJECTIVES: Non pharmacological treatment play a pivotal role in the diabetes care and management thus the aim of this study was to evaluate the exercise compliance and its confounding factors among diabetes patients in southern Punjab, Pakistan. **METHODS:** A cross-sectional, descriptive study was conducted from December 2015 to March 2016. Systemic random sampling technique was used to select the diabetic patients from three government hospitals and three private clinics. At least half hour rigorous walk/day, 5 days a week was set as minimum criteria for exercise compliance. Data was summarized by descriptive statistics. Bivariate and multivariable analysis was done to assess the factors independently associated with exercise compliance. Variables with $P \leq 0.25$ in bivariate analysis were used in multivariable logistic regression. Complete analysis was done on SPSS for Windows, Version 16.0 (SPSS, Chicago, IL, USA) **RESULTS:** A total of 299 patients participated in the study. Mean age \pm SD of the respondent's was 48.8 ± 14.6 years and mean duration \pm SD of disease was 9.08 ± 6.9 years. Out of 299, 169 (56.5%) were males, 270 (90.3%) were married and 124 (41.5%) were under primary level of education. Family history of 204 (68.2%) patients was positive for diabetes. Out of total, 176 (58.8%) fulfilled the criteria for the compliance. Age (AOR=0.971 95% CI=0.951, 0.991 $p=0.006$), duration of disease more than 15

(AOR=3.418, 95% CI=1.252, 9.329 $p=0.016$) and believe that exercise will lead to weight loss (AOR=4.978, 95% CI=2.725, 9.093 $p=0.00$) were significantly associated with exercise compliance. Insignificant positive linear correlation was seen between exercise compliance and blood glucose level ($r=0.11$ $p=0.057$) **CONCLUSIONS:** Young age, more duration of disease and believe that exercise will lead to weight loss are deriving factors for the exercise compliance. Hence educating the patients on health benefits of exercise will improve compliance.

PDB60

THE ASSOCIATION BETWEEN PATIENT-PHYSICIAN COMMUNICATION AND COST-RELATED MEDICATION NON-ADHERENCE AMONG DIABETIC U.S. MEDICARE BENEFICIARIES

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OBJECTIVES: Twenty-six percent of the elderly did not take medications as prescribed due to a cost barrier. Patient-physician communication plays a critical role in managing patients with chronic conditions. There is tremendous potential to reduce cost-related medication non-adherence (CRN) by improving patient-physician communication. We aimed to evaluate the association between patient-physician communication and CRN in several relationship domains. **METHODS:** The 2012 Medicare Current Beneficiaries Survey (MCBS) was utilized, including patients who self-reported having diabetes. Those who did not have a regular healthcare provider or a clinic to go to when sick or in need of health advice were excluded. Six questions in patient-physician communications were extracted. We developed six multivariate logistic regression models with each of these communication domain questions as independent variables, CRN (yes/no if delayed in filling prescription, did not refill prescription, skipped doses, or split medications due to cost) as the dependent variable, adjusted for patient's age, gender, race, ethnicity, Medicare-Medicaid dual eligibility, and comorbid conditions. **RESULTS:** Among the 2,316 Medicare patients with diabetes, 464 (20%) reported CRN. Controlling for other covariates, patients with doctors who seemed to be in a hurry were 88% ($p < 0.01$) more likely to report CRN; patients with doctors who did not explain medical problems were 54% ($p=0.01$) more likely, while patients who had health problems that should be discussed but were not were 52% ($p < 0.01$) more likely. Patients with doctors who often acted as though she/she was doing the patient a favor by talking to the patient were 82% ($p < 0.01$) more likely to report CRN; patients with doctors they did not have confidence in were 98% ($p < 0.01$) more likely; and patients with doctors whom they could not depend on to feel better physically and emotionally were 38% ($p=0.02$) more likely to report CRN. **CONCLUSIONS:** Poor patient-physician communication is a strong risk factor for CRN.

PDB61

USING MODIFIABLE BEHAVIORAL CHARACTERISTICS TO IDENTIFY HOMOGENOUS GROUPS OF NON-ADHERENT DIABETIC PATIENTS: A CLUSTER ANALYSIS APPROACH

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OBJECTIVES: To classify non-adherent diabetic patients into homogenous clusters of similar modifiable behavioral characteristics among beneficiaries enrolled in Medicare Advantage Prescription Drug Plan (MA-PD) in southeastern Texas. **METHODS:** Pharmacy claims from year 2014 were used to identify patients using oral anti-diabetics [OADs]. Non-adherence was measured as proportion of days covered [PDC] score < 0.8 for all OADs together. A survey questionnaire to measure adherence related modifiable behavioral characteristics was developed using several validated instruments including Belief in Medicine questionnaire, Satisfaction with OAD Agents Scale, and Morisky 8-item Medication Adherence Scale. Items from the questionnaire were then reduced to five constructs (used as variables) based on prior literature: perceived necessity, perceived concerns, satisfaction, intentional non-adherence and unintentional non-adherence. The surveys were introduced via telephone to previously identified non-adherent patients in the beginning of 2015. Construct reliability was assessed using cronbach's alpha. A two-step cluster analysis was then performed to group the patients into homogenous clusters. Analysis were conducted using SAS and SPSS statistical software. **RESULTS:** A total of 160 responses were obtained. Based on construct reliability estimates, four variables (perceived necessity, perceived concerns, satisfaction, and unintentional non-adherence) were used for cluster analysis. A 5-cluster model with lowest BIC, 'good' cluster quality and cluster average silhouette (cohesion and separation) of around 0.8 was obtained. The most important variables for cluster determination was perceived concerns followed by unintentional non-adherence and satisfaction; perceived necessity was the least important variable. Based on the results, the clusters were labelled as follows: cluster 1, concerned non-adherents; cluster 2, unsatisfied non-adherents with low perceived necessity; cluster 3, forgetful non-adherents with low satisfaction; cluster 4, forgetful non-adherents; and cluster 5, mysterious non-adherents. **CONCLUSIONS:** Based on the behavioral characteristics of patients in the five distinct identified clusters, managed care organizations can design targeted interventions to address the problem of non-adherence.

PDB62

PREDICTORS OF MEDICATION ADHERENCE AMONG PATIENTS WITH TYPE II DIABETES MELLITUS IN PAKISTAN – A PILOT STUDY

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OBJECTIVES: This study aims to assess the predictors of medication adherence in Type II Diabetes Mellitus (T2DM) patients of Quetta city, Pakistan. **METHODS:** The

study was designed as a questionnaire based, cross sectional analysis. Three hundred T2DM patients attending public and private hospitals were targeted for data collection. In addition to demographic and disease related information, Drug Attitude Inventory and Michigan Diabetes Knowledge Test were used to assess medication adherence and diabetes related knowledge respectively. Treatment satisfaction was assessed by patient's experience towards health care professionals and available facilities. Descriptive statistics were used to elaborate patients' demographic and disease related characteristics. Binary logistic regression was used to predict factors independently associated with medication adherence. SPSS v. 20 was used for data analysis and $p < 0.05$ was taken as significant. **RESULTS:** Patients in the current study reported moderate adherence with mean score of 4.94 ± 2.72 . Age, gender, education, diabetes-related knowledge and treatment satisfaction were significantly associated ($p < 0.05$) with medication adherence. The created model showed a significant goodness of fit as the Omnibus Test of Model Coefficient was highly significant (Chi square = 11.342, $p = 0.001$, $df = 4$). Knowledge score had significant association (adjusted OR = 2.232, 95% CI = 1.345 - 1.766, $P < 0.001$) with medication adherence. An increase in knowledge score of one point was associated with an increase in being good adherence to a factor of 2.232 provided controlling other confounding variables. **CONCLUSIONS:** The study presents a model that is associated with medication adherence of patient with T2DM, where disease-related knowledge shaped as a predictor. The healthcare practitioners and system should formalize and acknowledge patient education as key component of therapeutic plans.

PDB63

ESTIMATING A MINIMALLY IMPORTANT DIFFERENCE OF THE EQ-5D-5L INDEX SCORE IN ADULTS WITH TYPE 2 DIABETES

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OBJECTIVES: To estimate the minimally important difference (MID) of the EQ-5D-5L index score in a population-based sample of adults with type 2 diabetes, and examine whether this estimate varies by the baseline index score and direction of change in health status. **METHODS:** Data were from baseline and one-year follow-up of an ongoing cohort of adults with type 2 diabetes in Alberta, Canada. The MID was estimated first by the instrument-defined approach, which used the difference between the baseline EQ-5D-5L index scores and the index scores of simulated single-level transitions. Then, by the anchor-based approach, which categorized one-year changes in depressive symptoms (Patient Health Questionnaire 8 items, "PHQ8"), diabetes-related distress (Problem Areas in Diabetes 5 items, "PAID5") as well as physical and mental health functioning (SF-12 physical and mental health composite scores, "PCS, MCS") into: no change ($< \frac{1}{2}$ standard deviation (SD)), small change ($\geq \frac{1}{2}$ and ≤ 1 SD), and large change (> 1 SD). The MID estimates were calculated for all change, by the direction of change (improvement versus deterioration), and for defined patient subgroups. **RESULTS:** Average age of participants ($N=1927$) was 64.5 years (SD 10.8) with 45% female. Participants had diabetes for 12.6 (10.0) years, and reported 4.2 (2.3) comorbidities. Based on the instrument-defined approach, the MID estimate was 0.043 for all change, and 0.040 and 0.045 for improvement and deterioration respectively. Using small change in anchors, the change in EQ-5D-5L was 0.042 for all change, while improving or deteriorating change scores yielded MID estimates of 0.034 and 0.049 respectively. MID estimates were consistent across subgroups; however, there is evidence of higher MID estimates for lower baseline index scores. **CONCLUSIONS:** The MID estimates of the EQ-5D-5L index score in adults with type 2 diabetes ranged between 0.03 and 0.05. These estimates were consistent across subgroups, but varied by baseline index score and the direction of change.

PDB64

HEALTH-RELATED QUALITY OF LIFE IN CHINESE WOMEN WITH GESTATIONAL DIABETES

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OBJECTIVES: The incidence of gestational diabetes (GDM) is increasing in China. Understanding the changes in the health-related quality of life (HRQOL) during pregnancy is essential to assess the efficacy of the initial GDM treatment strategy. We aimed to investigate the HRQOL in women with gestational diabetes in China and to examine which patient characteristics are associated with quality of life. **METHODS:** A cross-sectional study was conducted in a university hospital, one of the largest public healthcare provider in South China. A sample of 233 EQ-5D-5L and medical records of women at their antenatal clinic visit during August 2016 to December 2016 were recorded. Outcome measures included HRQOL and pregnancy-related complications. **RESULTS:** We collected 233 women data (Age 32.8 ± 5.55 , gestational age 34.17 ± 5.15 weeks). Of the 233 inpatient cases, 25 were diagnosed with GDM (10.7%). Mean HRQOL was 0.87 ± 0.12 in the GDM group with initial treatment and 0.83 ± 0.14 in the non-GDM group ($P=0.16$). Multipara was significantly associated with high (≥ 75 th percentile) HRQOL (OR 2.06; 95% CI 1.20-3.54). Mean HRQOL was 0.86 ± 0.14 for multipara and 0.81 ± 0.13 for primipara ($P < 0.01$). In reverse, multiple births with a lower HRQOL 0.78 ± 0.10 ($P < 0.01$). **CONCLUSIONS:** The mean HRQOL was higher in the GDM group that had undergone initial treatment than in the non-GDM group, which means the efficacy of the initial GDM treatment was high and the HRQOL outcomes even better those of the healthy pregnancy group. The lifestyle modification and diet advice could be potentially useful for pregnant women. However, we should conduct a multicenter study with a larger sample size to support the findings. Multipara was associated with a high HRQOL whereas primipara and multiple births were related to a relatively lower HRQOL in Chinese women during pregnancy.

PDB65

USING LATENT CLASS ANALYSIS TO ANALYZE HETEROGENEITY IN BARRIERS AND FACILITATORS FOR DIABETES SELF-MANAGEMENT AMONG PATIENTS WITH TYPE II DIABETES

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OBJECTIVES: The aim of this study is to analyze heterogeneity in barriers and facilitators for diabetes self-management among patients with type II diabetes. **METHODS:** A nationally representative survey was conducted among patients with type II diabetes in the US. 11 factors were selected through robust mixed-methods and represented both known barriers and facilitators of patients' diabetes management. Respondents were asked to evaluate the impact of each factor on their diabetes self-management on a five-point Likert scale ranging from "strong negative" to "strong positive". We examined the overall rating distribution for each factor and analyzed heterogeneity using latent class analysis (LCA). Sociodemographics, health status, and personality variables were included in the model to identify class characteristics. **RESULTS:** 549 respondents completed the survey. Four classes were found in LCA. Factors were most likely to be rated as "positive" among respondents in class 1 (46.4% of sample). Class 2 (24.0%) had higher probabilities to rate all factors negatively than other groups. Class 3 (18.6%) rated most factors "strong positive", and class 4 (11.1%) rated almost all factors "no impact". Patients who were older, Asian, had bachelor degree, and had hemoglobin A1c below 7% were more likely to be in class 1 ($p < 0.05$). Patients who were younger, non-Asian, disabled, had fair or poor health, had hemoglobin A1c above 7%, reported not being optimistic about future, or had not been actively improving health were more likely to be in class 2 ($p < 0.05$). Asians and those who did not actively improve health were also likely to be in class 3 ($p < 0.05$). Patients who were Asian, had low income, stated being optimistic about future, or reported not having self-control were likely to be in class 4 ($p < 0.05$). **CONCLUSIONS:** Responses to Likert scale questions are confounded by individual heuristics and personalities. Respondents tend to use part of the scale regardless of questions.

PDB66

PATIENT PERSPECTIVE ON THE IMPACT OF INSULIN RESUSPENSION ON DIABETES MANAGEMENT AND HEALTH-RELATED QUALITY OF LIFE

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OBJECTIVES: When required, adequate resuspension of insulins is important for safe and efficacious insulin administration. No published evidence of the patient perspective on insulin resuspension (IR) exists. The objectives of this study were to investigate type 2 diabetes (T2D) patients' perspectives on IR and its impact on diabetes management and health-related quality of life (HRQOL). **METHODS:** Nine semi-structured focus groups were held in the US, Mexico, Netherlands, and Turkey. Respondents were eligible if aged ≥ 18 years, had T2D, currently using modern premixed insulin for at least three months, and not taking any other injections to treat any disease, including diabetes. Transcripts were analyzed utilizing adapted grounded theory qualitative research methods. The videos of respondents' demonstrations of IR technique were reviewed and compared with the manufacturer's instructions. **RESULTS:** Sixty-four respondents participated in the focus groups. Eighty-nine percent ($n=51/57$) reported learning about IR from a healthcare provider with 55% ($n=18/33$) receiving clear instructions. Fifty-four percent ($n=21/39$) reported resuspending exactly as taught. Despite respondents receiving IR education and believing that they are resuspending as they should, 2% of respondents ($n=1/63$) demonstrated IR per the manufacturer's instructions. Twenty-six percent ($n=10/38$) reported being worried about the negative consequences of not resuspending insulin. Forty-two percent ($n=10/24$) reported being concerned about whether the insulin would be effective after missing or skipping IR. Sixty-seven percent reported believing that IR has no impact on their diabetes ($n=10/15$). Twenty-seven percent ($n=4/15$) reported experiencing negative consequences (e.g., jitteriness) due to inadequate IR. **CONCLUSIONS:** Most respondents did not resuspend per manufacturers' guidance and are unaware of their inadequate technique, which may explain the minimal impacts reported on HRQOL and diabetes management. Standard education may not be sufficient to ensure adequate IR. Thus, additional resources from healthcare professionals are required for education at treatment initiation and additional monitoring during follow-up visits.

PDB67

ASSOCIATION BETWEEN WEIGHT LOSS AND PRO AND QOL MEASURES IN PATIENTS WITH TYPE 2 DIABETES MELLITUS – A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: In most patients with type 2 diabetes mellitus (T2DM), therapy starts with adjusting lifestyle and weight control. Evidence showed that newer anti-diabetic therapy, such as incretin peptides (e.g. GLP-1 RAs), can regulate body weight. This study examined the evidence on the impact of weight loss in people with T2DM and its consequences on endpoints measured by Patient-Reported Outcomes (PROs), such as health-related quality-of-life (HRQOL). **METHODS:** A systematic literature review was carried out with two independent reviewers to collect clinical trial and real-world evidence regarding the effects of weight loss on PRO results. Data sources included Embase, Medline and Cochrane without time limitation. Additionally, conference proceedings were searched (2013-2015). **RESULTS:** The review identified 20 relevant RCTs and observational studies reporting 23 associations between weight loss and PROs. These studies described associations/correlations via Spearman or Pearson regression coefficients, logistic

regression analysis or odds ratio. Twenty-one associations described a positive correlation (implying a beneficial effect of weight loss on PRO results), on two occasions no relationship was found. Most commonly reported PRO measure was the Impact of Weight on Quality of Life(Lite) (IWQOL) with scales in physical function, self-esteem, sexual life, public distress, and work. All 7 studies showed a positive association between weight loss and IWQOL scores. For the Medical Outcomes Survey, Short Form 36 (SF-36); 5 of the 7 studies observed a beneficial association between weight loss and HRQOL. Additionally, positive associations were found between weight loss and PROs for depression (2 studies), health satisfaction (2), treatment satisfaction (1), activities of daily living or well-being (2) and diabetes specific questionnaires (2). **CONCLUSIONS:** Almost all studies observed a positive (i.e. beneficial) correlation between weight loss and PRO results in patients with T2DM. Overall, identified studies suggest that weight loss has a beneficial effect on HRQOL, depression, health satisfaction, and treatment satisfaction.

PDB68

PSYCHOMETRIC EVALUATION OF THE NV QUESTIONNAIRE IN PATIENTS WITH T2DM RECEIVING A GLP-1 AGONIST

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OBJECTIVES: To assess and provide an initial psychometric evaluation of the Nausea and Vomiting Questionnaire (NVQ) in patients with type 2 diabetes mellitus (T2DM) receiving a glucagon-like peptide-1 agonist (GLP-1) therapy. **METHODS:** Data were collected from a non-interventional, cross-sectional study via a web-based survey administered to patients self-reporting a diagnosis of T2DM, who experienced nausea and/or vomiting after initiating treatment with a GLP-1 (within prior 6 months). In addition to the NVQ, subjects also completed the Functional Living Index-Emesis (FLIE), Work Productivity and Activity Impairment (WPAI:SH) and MOS SF-12 instruments to assess convergent validity. Analyses included descriptive statistics, classical test theory psychometric analyses and exploratory factor analysis. **RESULTS:** A total of 204 subjects [mean age (SD): 41.3 (11.0), 65.7% male; 84.3% white] met eligibility criteria, for which 200 completed the survey and were included in the pre-specified analyses. Of the eligible subjects: 111 (54.4%) experienced nausea alone, and 83 (40.7%) experience both nausea and vomiting. Most subjects (86.8%) had used a GLP-1 for 3 months or less. Response distribution frequencies demonstrated endorsement of all response categories and no evidence of meaningful floor/ceiling effects. All inter-item Spearman correlation coefficients were between $r=0.30-0.76$. EFA results based on evaluation of the scree plot, factor loadings, and inter-factor correlations, recommended the use of one-factor solution, with all items' loadings ≥ 0.75 , supporting a unidimensional total impact score. Internal consistency reliability (Cronbach's alpha) for the total impact score was $\alpha=0.96$. Results from construct and known-groups validity were supportive of the pre-specified hypotheses, with most correlations moderate to strong. **CONCLUSIONS:** The results from these preliminary psychometric analyses support the use of the NVQ as a reliable and valid measure to assess the impact of nausea and vomiting among T2DM patients who have initiated GLP-1 agonist treatment. Further evaluation in a longitudinal study is needed to assess responsiveness.

PDB69

A SYSTEMATIC REVIEW OF TREATMENT SATISFACTION MEASURES: THE CASE OF TYPE 2 DIABETES TREATED WITH ORAL THERAPY

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OBJECTIVES: There has been increased interest in assessing patient satisfaction with consumers taking a more active role in the healthcare, its association with adherence, and its measurement is recommended by National Committee for Quality Assurance (NCQA). The aim of this study was to compare and contrast the psychometric properties of self-reported satisfaction measures designed for patients with type 2 diabetes treated with oral therapy. **METHODS:** Comprehensive literature review was conducted to identify self-reported instruments in English, published in peer-reviewed journals. Psychometric properties evaluated included: conceptual model, practicality (≤ 15 minutes to complete), breadth, depth (floor and ceiling effects $\leq 15\%$), reliability (internal consistency and test-retest reliability $\leq .70$), construct validity (convergent and divergent), and responsiveness. **RESULTS:** Six instruments were identified for evaluation: Diabetes Medication Satisfaction Measure (Diab-MedSat), Diabetes Medication System Rating Questionnaire (DMSRQ), Diabetes Medication System Rating Questionnaire-Short Form (DMSRQ-SF), Diabetes Treatment Satisfaction Questionnaire status version (DTSQs), Diabetes Tablet Treatment Questionnaire (DTTQ), and Perceptions About Medications for Diabetes (PAM-D). The most widely used instrument is DTSQ. All instruments except for DTTQ met conceptual model criterion, and all met the practicality criterion. Diab-MedSat, DMSRQ and DMSRQ-SF encompassed the broadest aspects of satisfaction (impact on quality of life and satisfaction with efficacy, side effects, convenience, and overall). Four of six instruments met study criterion for construct validity: Diab-MedSat, DTSQs, DMSRQ and DMSRQ-SF; with three meeting reliability criterion for group level decision making, including DMSRQ, DMSRQ-SF and PAM-D. All instruments except DTTQ met the criterion of responsiveness. **CONCLUSIONS:** Overall, no instruments showed ideal psychometric properties with DMSRQ and DMSRQ-SF fairs best, meeting almost all study criteria, followed by Diab-MedSat. In most cases, scales failing study criteria did so due to missing data. Instruments varied considerably in domains covered (breadth) and use in mixed diabetes populations (oral medication and insulin); therefore consideration of study objective is also critical in scale selection.

PDB70

PRESCRIPTION TREND FOR THE TREATMENT OF DIABETES MELLITUS AND ASSOCIATION WITH THE HEALTH RELATED QUALITY OF LIFE

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OBJECTIVES: Treatment adherence is known to be associated with the health related quality of life (HRQoL). However, little is known about the association of HRQoL and the treatment type for Type 2 Diabetes Mellitus (T2DM). So, the objectives of this study were: 1. to determine the trend in prescriptions and non pharmacological treatments for T2DM and, 2. to examine the association of HRQoL with the treatment type. **METHODS:** Cross sectional data for the years 2010 to 2014 from the Medical Expenditure Panel Survey (MEPS) were used. The study population consisted of individuals (age ≥ 12 years) with self reported non gestational T2DM (n = 9210). Non pharmacological treatment was defined as the lifestyle modification: diet changes and/or physical activity. Weighted proportion of T2DM patients prescribed particular class of medicines was calculated. Multinomial logistic regression was performed to determine the association between HRQoL and type of treatment, controlling for the disease severity, comorbidities, age, sex, race/ethnicity, employment status, insurance plan, physician specialty, socio economic status and survey year. **RESULTS:** The use of metformin and sulfonylureas decreased over the time, 38.1% and 20.3% to 33.7% and 16.3% respectively. Thiazolidinedione usage increased (8.4% - 11.2%). Insulin usage was found to be constant over the time. Overall usage of pharmacologic treatment found increased (51.2% - 70.1%) and non pharmacological treatment usage found to be decreased (31.5% - 26.9%). The odds of good QoL is 11% higher for the Sodium-glucose co transporter 2 inhibitors compared to metformin, (OR: 1.11, 95% CI = 1.07 - 1.22), and 23% higher when non pharmacologic treatment administered simultaneously with pharmacological treatment, after controlling for the mentioned covariates. **CONCLUSIONS:** This study provides current trend in the prescription pharmacologic and non pharmacologic treatments for T2DM. The decreased usage of non pharmacological treatment forms suggests need for promoting its usage in the diabetic population.

PDB71

PROFILE AND PREDICTORS OF HEALTH RELATED QUALITY OF LIFE AMONG TYPE II DIABETES MELLITUS PATIENTS IN QUETTA CITY, PAKISTAN

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OBJECTIVES: This study aims to assess the profile and predictors of Health-Related Quality of Life (HRQoL) in Type II Diabetes Mellitus (T2DM) patients of Quetta, Pakistan. **METHODS:** The study was designed as a questionnaire based, cross sectional analysis. 300 Type II diabetic patients attending public and private hospitals were targeted for data collection. In addition to demographic and disease related information, Euroqol Quality of Life was used to measure HRQoL. Moreover, Drug Attitude Inventory and Michigan Diabetes Knowledge Test were used to assess medication adherence and diabetes related knowledge respectively. Treatment satisfaction was assessed by patient's experience towards health care professionals and available facilities. Descriptive statistics were used to elaborate patients' demographic and disease related characteristics. Binary logistic regression was used to predict factors independently associated with HRQoL. SPSS v. 20 was used for data analysis and $p < 0.05$ was taken as significant. **RESULTS:** Patients in the current study reported poor HRQoL with mean score of 0.48 ± 0.36 . Age, duration of disease, number of prescribed drugs, medication adherence and treatment satisfaction were significantly associated ($p < 0.05$) with HRQoL in the cross tabulation analysis. The significant variables were entered into the model that showed significant goodness of fit with highly significant Omnibus Test of Model Coefficient (Chi-square = 12.983, $p = 0.030$, $df = 4$). Medication adherence was reported as a significant predictor of HRQoL with an increase of one adherence score was associated with improvement of HRQoL by a factor of 1.75 provided other variables remain constant. **CONCLUSIONS:** The study presents a model that is associated with HRQoL of patient with T2DM, where medication adherence shaped as a predictor of HRQoL. Healthcare professionals should pay special attention on patients' medication taking behaviour and should put their efforts in explaining the benefits of the medication adherence to the patients

PDB72

ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQOL) USING EQ-5D IN DIABETICS, PRE-DIABETICS AND GENERAL POPULATION IN CHINA

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OBJECTIVES: to assess and compare the health related quality of life (HRQoL) among diabetics, pre-diabetics and general population in China **METHODS:** Questionnaire was designed and pre-tested which included 2 parts: Sociodemographic information and EQ-5D-5L with VAS. Face-to-face survey was conducted to sampled 420 diabetes patients from tertiary hospitals in sichuan China and 420 general people from communities and parks(exclude people who claimed diabetes); telephone survey was conducted to 420 sampled people who took physical examination in tertiary hospitals in the past 2 months and found intermediate hyperglycaemia. Differences between groups were compared by chi-square test, one-way analysis of variance (ANOVA), Kruskal-Wallis test or student's t test. **RESULTS:** Effective information of 403 diabetics, 404 prediabetics and 398 general people was collected. The average age of sampled diabetics was 62.18 ± 11.3 with mean BMI 24.57 ± 4.05 kg/m², the average age of pre-diabetics was 53.29 ± 9.21 with mean BMI 23.73 ± 2.99 kg/m², and the average age of general population was 58.94 ± 12.48 with mean BMI was 23.67 ± 4.24 kg/m². EQ-5D index of diabetics, pre-diabetics and general people were 0.849, 0.911 and 0.864, and EQ-VAS scores were 68.34, 77.45 and 73.76. The percentage of self-assessed problematic mobility, self care, usual activities, pain/discomfort and anxiety/depression were 16.33%, 3.02%, 11.81%, 56.78%, and 44.72% in diabetics group. 5.94%, 0.99%, 3.47%, 37.13% and 27.97% in pre-diabetics group, and 13.15%, 2.48%, 7.94%, 51.12%, 41.94% in general group. **CONCLUSIONS:** There was a general decline trend of HRQoL

and all 5 dimensions from general people to diabetes patients, while pre-diabetics had better HRQoL than general people. The common self-assessed problematic dimensions among 3 groups were pain/discomfort and anxiety/depression, and the status of pain/discomfort was worse than anxiety/depression. Further and larger longitudinal studies are needed to confirm these findings.

DIABETES/ENDOCRINE DISORDERS – Health Care Use & Policy Studies

PDB73

EVALUATION OF BARRIERS TO EFFECTIVE INSULIN THERAPY AMONG TYPE 2 DIABETES MELLITUS PATIENTS

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OBJECTIVES: The current study aims to evaluate the hurdles responsible for delayed insulin therapy among type 2 diabetic patients in Punjab, Pakistan **METHODS:** A cross-sectional study was conducted on 250 physicians and 400 patients from hospitals and private clinics of three cities including Bahawalpur, Multan and Lahore through questionnaires designed and validated with the help of extensive literature review, expert opinions and pilot study **RESULTS:** The hurdles from physician side were due to the issues regarding patient themselves not willing to switch to insulin (72%, n=180), patient needle phobia (70.8%, n=177), unavailability of insulin in rural areas (65.2%, n=163), insulin proper storage issue is problematic (66.8%, n=167), insulin initiation requires proper education, training and counseling (70.4%, n=176) and high cost of insulin treatment (64.8%, n=162). On the other side, among patients the barriers include patient perception factors like they have updated knowledge about disease management (82%, n=328), high cost of insulin (56.6%, n=226), failed to manage disease with oral medication and lifestyle modification (52.2%, n=209) and one of their relative died of insulin (98%, n=392), administrative factor like they cannot spare enough time to perform insulin injection (56.7%, n=227) were observed **CONCLUSIONS:** Based on the findings of this study main key barriers observed were, patients' hesitation to switch from oral therapy, needle phobia, unavailability of insulin in rural areas, insulin storage issues lack of education, training and counseling to use insulin, high cost, social pressure and carrying and injecting insulin openly. On the basis of these observations, these issues and barriers can be handled by developing better strategies and measures. Government should make sure the availability of insulin in rural areas. Psychological issues should be addressed as a disease and treated accordingly. Patients should be educated about insulin proper administration and usage and newer interventions should be carried out to help them.

PDB74

ASSESSMENT OF NEW ONSET DIABETES AND STATIN MEDICATION UTILIZATION

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OBJECTIVES: This study retrospectively examines medical records of patients newly diagnosed with type 2 diabetes mellitus. We assess potential contributing factors and statin use, while evaluating patients' current diabetes control compared to national standards. **METHODS:** A United States retrospective medical chart review of 1000 randomly selected adult patients with new onset diabetes, identified from 5 Accountable Care Organizations (ACOs), was conducted. Patients had a current diagnosis of diabetes (ICD-9 codes 250.00-250.99) in the study timeframe of January 1st 2013-December 31st 2014, and had at least one recorded follow-up visit after diagnosis. Patient demographics, comorbidities, blood pressure control, LDL screening and A1c level data were collected from the medical record and analyzed using t-tests or chi-square tests where appropriate. Analyses were stratified by statin use and A1c levels. **RESULTS:** The sample was 51% male and 49% Caucasian with a mean age of 66 ± 12.7 years. A total of 501 (50.1%) diabetes patients were on a statin by the end of the study period. Patients on a statin were significantly more likely to have blood pressure below 130/80 (p=0.032) and LDL below 100 mg/dl (p=0.018) than patients not on a statin. No significant difference in age, gender or A1c level was present between statin and non-statin use patients. Out of 978 total patients that had a recorded A1c level in their medical chart, 794 (81%) patients had a recent A1c level at 8% or less. Statin usage was comparable between ≤ 8% and > 8% A1c groups of patients, with Atorvastatin and Simvastatin being the most common statins used. **CONCLUSIONS:** In this real-world observational study, only 50% of diabetes patients were on a statin. Diabetes patients taking a statin were more likely to have their blood pressure and LDL levels within national controls, compared to diabetes patients not on a statin.

PDB75

EVALUATION OF NEW ONSET DIABETES IN PRE-DIABETIC PATIENTS TAKING STATIN MEDICATION

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OBJECTIVES: This study evaluates new onset diabetes and related outcome variables over a 24 month period in pre-diabetic patients taking a statin medication. **METHODS:** A United States retrospective medical chart review of 1000 randomly selected pre-diabetic adult patients, among 5 Accountable Care Organizations (ACOs) (200 per site), was conducted. Patients were taking one of the following statins: Rosuvastatin, Atorvastatin, Simvastatin and Pitavastatin, for 12 months prior to the start of the study. Patients also had documentation of at least one of the following to confirm pre-diabetic status: metabolic syndrome, fasting blood glucose of > 100 mmol/L, A1c of > 6%, or BMI > 30 kg/m². Patient characteristics were collected over 24 months (April 1, 2014 – April 1, 2016). **RESULTS:** The sample was 51% male, and 49% white, with a mean

age of 62.3 ± 12.3 years. Of the 1000 patients initiated into the study, 146 were lost to follow up. The final cohort consisted of 854 patients with 24 months of data. BMI (p=0.033) and weight (p=0.0016) values were significantly higher among Rosuvastatin patients while fasting blood glucose levels were significantly higher among Simvastatin patients (p=0.0001). A total of 61 (7.1%) patients had a diagnosis of diabetes by the end of the study period. Most of these patients (42.6%) were taking Simvastatin before diagnosis of diabetes, and only 9 (14.7%) patients discontinued statin use, changed statin dose, or switched to a different statin after their diagnosis. **CONCLUSIONS:** In this real-world retrospective observational study, only 61 pre-diabetic patients taking a statin for at least 12 months prior to the start of the study ended up with a diagnosis of diabetes. With recent concerns regarding the link between statin use and diabetes risk, this study suggests that further research into the relationship between diabetes and statin use is necessary to improve patient health management and outcomes.

PDB76

CHOICE OF INJECTABLE THERAPY IN THE TYPE 2 DIABETES TRAJECTORY: SOCIO-DEMOGRAPHIC AND CLINICAL CHARACTERISTICS

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OBJECTIVES: Injectable therapy is required when patients with Type 2 Diabetes do not achieve glycemic control despite previous dietary and lifestyle modifications combined with oral antidiabetic therapy. The objective of this study was to compare socio-demographic and clinical characteristics of patients who initiated insulin versus glucagon like peptide-1 injectable therapy (GLP-1 RA) in a real world setting. **METHODS:** All patients who initiated insulin or GLP-1 therapy in 2010-2014 were identified in the Clalit data warehouse. Socio-demographic, clinical, and concurrent medication data were extracted in prior proximity to the time of therapy initiation (index-date). **RESULTS:** A total of 49,807 patients were identified: 41,049 receiving insulin and 8,758 GLP-1 RA. The duration of diabetes prior to injectable therapy initiation was similar (8 years). Insulin initiators, compared to GLP-1 RA initiators, were older (age 63 vs. 58); less obese [mean BMI: 29.0 (95%CI: 25.7-32.9) vs. 34.6 (95%CI: 31.6-38.4)]; had higher Charlson Comorbidity Index (47% vs. 30% index≥5) and were more likely to have HgbA1c>9.0% (50% vs. 38%), all comparisons p<.05. **CONCLUSIONS:** Clear differences were identified in the population prescribed insulin compared to that prescribed GLP-1 RA. Analyses are ongoing to further understand the impact of these characteristics on glycaemic control and other outcomes among these individuals.

PDB77

RACIAL AND REGIONAL VARIATION IN DISEASE PROGRESSION AND OUTCOMES AMONG VETERANS ADHERENT TO THEIR INITIAL ORAL ANTIDIABETIC MEDICATION

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OBJECTIVES: To investigate whether racial disparities and regional variation in outcomes and disease progression exist among veterans with incident diabetes mellitus (DM) who were initially adherent to oral antidiabetic medications (OAD). **METHODS:** The VA Corporate Data Warehouse was used to identify the first diagnosis for uncomplicated DM during 2002-2014. OAD use was assessed by proportion of days covered (PDC) for the first year of therapy using outpatient VA pharmacy records, and those with a PDC>80% were deemed adherent. Changes in clinical measures and the odds of cardiovascular outcomes, cerebrovascular events, revascularization, and microvascular complications were assessed during the first year of therapy with a focus on differences among races and geographic regions while controlling for baseline demographic and clinical characteristics. **RESULTS:** A total of 159,032 veterans were identified, and 62.5% were initially adherent to OADs. Significant improvement was observed across nearly all clinical measures, regardless of patient race or location, including an unadjusted mean reduction of 0.7% in hemoglobin A1C (p<0.0001). Less than 1% were diagnosed with a cardiovascular, cerebrovascular, or microvascular complication or required revascularization; African Americans had a lower adjusted odds of revascularization (OR: 0.59; 95% CI: 0.378-0.915) while those residing in Western states had higher odds of these procedures (OR: 1.6; 95% CI: 1.02-2.48). Microvascular complications were slightly more evident and differences in the adjusted odds of disease were observed in multiple races and regions but were again especially prominent among African Americans (neuropathy [OR: 0.92; 95%CI: 0.846-0.997], nephropathy [OR: 2.0; 95% CI: 1.825-2.262], and retinopathy [OR: 1.4; 95%CI: 1.24-1.50]) and veterans residing in Western states (neuropathy [OR: 0.83; 95%CI: 0.753-0.917] and retinopathy [OR: 1.5; 95%CI: 1.28-1.65]). **CONCLUSIONS:** Disparities in macro- and microvascular complications among patients with DM may begin to develop within the first year of OAD therapy, and additional attention may be warranted among particular sections of the population.

PDB78

A1C LEVELS AND FACTORS ASSOCIATED WITH GLYCEMIC CONTROL AMONG PATIENTS WITH DIABETES MELLITUS IN THE US

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OBJECTIVES: To investigate A1C levels among patients with diabetes mellitus (DM) in the US and understand factors associated with glycemic control. **METHODS:** This

cross-sectional analysis utilized National Health and Nutrition Examination Survey data (2011-2014) and evaluated A1C levels and factors associated with glycemic control among patients with DM via multivariate logistic regression. Chi square and t-test were used to compare patient characteristics between A1C level groups (<7% vs. ≥7%). Eligible predictors ($p < 0.2$) were included in a multivariate logistic regression model to determine the association between glycemic control and patient characteristics. **RESULTS:** Of the 1,326 patients identified with DM from 2011-2014 (mean age 61.2 years; 49.8% female), half (50.2%) achieved the American Diabetes Association (ADA) A1C target of <7%. Similarly, 60.9% and 54.3% of patients with DM achieved blood pressure (<130/80 mmHg) and lipid targets (<100mg/dL), respectively. Bivariate analysis suggested that age, gender, ethnicity, health insurance status, body mass index (BMI), and time since DM diagnosis were significantly associated with A1C level. After adjusting for covariates, patients with DM who were female, older, insured, non-Hispanic whites with a BMI from 25.0 to 29.9 and a recent DM diagnosis (<5 years) were more likely to meet the ADA A1C target of <7%. **CONCLUSIONS:** The current study highlights the importance of integrated, comprehensive DM care, given that almost half of patients with DM still do not achieve A1C, blood pressure, or lipid target levels suggested by ADA guidelines.

PDB80

INSULIN UTILIZATION PATTERN AMONG PATIENTS WITH DIABETES MELLITUS WHO INITIATED INJECTABLE GLUCAGON THERAPY

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OBJECTIVES: To describe the extent of insulin therapy use among patients with diabetes mellitus (DM) who started injectable glucagon in the United States. **METHODS:** Patients with DM (ICD-9-CM 250*) who initiated injectable glucagon therapy between 2004 and 2012 in Truven Health MarketScan® database were included in the study. Insulin treatment pattern was characterized within 12 months after glucagon initiation date (index date), and included patients who continued insulin therapy (continued); those who stopped therapy and didn't have a record of insulin prescription during the study follow up (discontinued); those who changed insulin (switched); and those who added another insulin therapy (augmented). Switched therapy defined by a gap of ≥30 days between first and second insulin with no record of first insulin after switch date, otherwise the patient is classified under augmented therapy group. **RESULTS:** A total of 164,511 patients with DM initiated injectable glucagon (median age 46 years, 52% females). About 30% (n=49,710) of patients were treated with insulin (50% females), corresponding to 77% insulin human (IH); 16% short-acting insulin (SI); 1% intermediate-acting insulin (II); and 6% long-acting insulin (LI). The majority (76%) of insulin users have augmented treatment with other insulin (n=37,821), especially among IH users (96%); 4% of SI; and <1% of II and LI users. About 19% have discontinued therapy (n=9,456), corresponding to 54% SI; 24% LI; 17% IH; and 5% II users. Approximately 4% switched insulin type (n=1,937), mostly from SI (69%); LI (17.3%); IU (9.2%); and II (4.6%). Only 1% of patients have continued insulin therapy after initiating injectable glucagon, corresponding to 56% SI; 24% LI; 16% IH; and 4% II users. **CONCLUSIONS:** Utilization of insulin varied by type, and experience with injectable glucagon appears to affect future insulin use. More research is needed to understand the drivers for insulin discontinuation and other anti-diabetes medication substitution following glucagon treatment.

PDB81

UTILIZATION PATTERN OF INJECTABLE GLUCAGON AMONG INSULIN INITIATORS WHO EXPERIENCED SEVERE HYPOGLYCEMIA

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OBJECTIVES: Injectable glucagon was approved in the United States in 1998 for the treatment of severe hypoglycemia in patients with diabetes mellitus (DM) and as a diagnostic aid in gastrointestinal radiologic examinations. This study describes the patterns of glucagon utilization in patients with DM who initiated insulin therapy in the United States. **METHODS:** Patients with DM (ICD-9-CM 250*) who initiated insulin therapy between 2004 and 2012 in Truven Health MarketScan® database were included in the study. The extent of injectable glucagon use was measured during 12 months after insulin initiation date (index date) stratified by severe hypoglycemia events that occurred any time after the index date. Severe hypoglycemia was defined as hypoglycemia events that required hospitalization or emergency room visit. Duration of glucagon use was determined by the number of days between prescription initiation and end of day supply. **RESULTS:** A total of 1,487,601 patients with DM started insulin therapy (median age 61 years, 51% females). Among them, 1.6% (n=23,191) started injectable glucagon therapy. The vast majority of glucagon users continued therapy for a median of 3 days (49% females). Among 89,059 insulin initiators with severe hypoglycemia (mean age 63 years, 56% females), only 1.7% (n=1,510) started glucagon injection. The median duration of glucagon use among those with severe hypoglycemia was 2.7 days (52% females). **CONCLUSIONS:** Utilization of injectable glucagon among insulin-treated patients who experienced severe hypoglycemia appears to be low. More research is needed to explore factors determining utilization patterns in this group of patients with DM.

PDB82

UTILIZATION AND COST OF DIABETIC MEDICATIONS AMONG US MEDICARE PART D BENEFICIARIES

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OBJECTIVES: The total cost of diabetes in the United States in 2012 has been estimated at \$245 billion. with notable expenditures for prescription medications

to treat diabetes. This study evaluates the diabetes medication prescribing patterns of US health care providers. **METHODS:** Medicare Part D 2013 Prescriber Public Use File was used for analysis. Diabetes medications were identified using drug name and the chemical ingredient information available in the data file. Diabetes-related brand/generic medication prescribing patterns were determined for providers by specialty type, diabetes drug class, and geographic region. Multivariate logistic regression model examined the association between geographic regions and generic prescribing patterns. **RESULTS:** In 2013 the total cost paid for all prescriptions in Medicare PartD program was \$80.9 billion; diabetes-related medications accounted for 11% (\$8.6 billion). Insulin products accounted for 63% of the total diabetes drug cost; other brand name hypoglycemic drugs accounted for 27% of the total diabetes drug cost and generic drugs accounted for 10% of diabetes drug cost. The most prescribed generic medication was metformin, accounting for 4% of the total diabetes drug costs. The brand drug Januvia® (sitagliptin) accounted for \$1.3 billion or 15% of diabetes drug cost. Primary care providers (e.g. family practice, pediatrics, nurse practitioner) accounted for 89% of the total diabetes drug claim counts. In the multivariate model, the odds of prescribing generic drugs was higher in the West region (adjusted odds ratio (AOR)=1.18, 95% CI=1.16-1.19), compared with the South region. Primary care providers have higher odds of prescribing generic drugs (AOR=1.50, 95%CI=1.52-1.49) compared to Specialists. **CONCLUSIONS:** Diabetes care, as evidenced by prescription medication prescribing, is largely provided by family practice physicians. Generic medications contribute only 10% of all diabetes drug costs. Insulin and brand name product prescribing have a dramatic effect on total costs of diabetes medications.

PDB83

CHARACTERISTICS ASSOCIATED WITH TYPE 2 (T2) HIGH VOLUME (HV) BASAL INSULIN DIABETES PATIENTS IN THE US

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OBJECTIVES: The aim of this study was to characterize T2 patients over 18 years of age defined by their insulin usage (Low Volume (LV) ≤80 units a day or High Volume (HV) >80 units a day). **METHODS:** Data from Truven Market Scan in 2012-2013 was applied. Truven Market Scan is a US patient level database from self-insured employers that is updated annually. Patients with ≤10 units a day or >300 units a day were excluded. All other T2 patients with at least 6 months of valid basal insulin claims were included. Descriptive statistics were performed for socio-economic characteristics such as age, gender, weight and region as well as for diabetes related outcomes such as comorbidities. **RESULTS:** Among 45785 insulin users included in the analysis, 9.54% were HV. The average DACON for the HV users was 129.6 U whereas the average DACON of LV users was 35.01 U. Of these HV users, 61.38% were male vs. the 56.87% of LV users that were male. The biggest discrepancy when comparing across regions was for the North East where 19.77% of all patients were HV users and 12.18% of all patients were LV users. HV users also tend to be more overweight or obese; (26.39% for HV users vs. 18.3% for LV users). A greater percentage of HV users had more hyperlipidemia (78.26% HV vs. 72.35% LV) as well as hypertension (83.6% HV vs. 78.16% LV). Other socio-economic factors and diabetes related co-morbidities did not exhibit any indication of possible differential trends. **CONCLUSIONS:** Initial summary evidence suggests that HV users are male, overweight/obese and experience hyperlipidemia/hypertension. Some HV patients may benefit from a pen that goes up to 160 units; which may allow for transition from BID to QD dosing.

PDB84

AN INTRODUCTIVE ANALYSIS ON THE ECONOMIC BURDEN OF DIABETES IN ITALY

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OBJECTIVES: Diabetes mellitus (DM) is the second most expensive chronic disease in Italy after cancer with total direct costs over €9 billion (2012), 70% of which attributable to hospitalizations and 30% to drug treatments. The objectives of the present study were to assess the trend in pharmaceutical and hospital expenditure of diabetes in Italy during 2013-2015. **METHODS:** Antidiabetic drugs consumption and expenditure indicators in the last available three years (2013-2015) were analyzed from the Observatory on the Use of Medicines (OSMED) published reports, to determine trends in consumption and expenditures. Data before 2013 were inconsistent and therefore excluded from the analysis. Consumption was determined according to defined daily dose (DDD)/1,000 inhabitants. Expenditure was referred to per-capita spending on territorial drugs. Data on hospital discharge for diabetes (main cause, i.e. DRGs 294-295) from the Health Ministry were matched with last published DRGs Tariffs to estimate the hospitalizations costs. **RESULTS:** In Italy, consumption of antidiabetic drugs per DDD/1,000 inhabitants was respectively, 62.8 in 2013 and 62.6 in 2015 while per-capita expenditures were €13.63 in 2013 and €14.26 in 2015. Surprisingly a slight decrease in the off-patent antidiabetic drugs consumption was observed in the period 2013 to 2015 for Italy, representing 59.5% of DDD and 20.1% of total drug expenditure in 2013 vs 59.4% DDD and 19.6% of total drug expenditure in 2015. Hospitalizations and related costs for diabetes showed a reduction in the analyzed period with 19,199 admissions (Day-hospitals 6.2%) for a cost of €27,029,044 in 2013 vs. 16,762 admissions (Day-hospitals 5.6%) equal to €23,497,024 in 2015. **CONCLUSIONS:** Despite the limitations, the data show a stable trend in diabetes expenditure with a slight increment in per-capita expenditures, probably due to introduction of new expensive drugs, and a reduction in hospital admissions leading to a decrease in hospitalization costs.

PDB85

EVALUATION OF STATIN THERAPY PRESCRIBING AMONG HOSPITALIZED PATIENTS WITH TYPE 2 DIABETES MELLITUS: FINDINGS FROM TWO MALAYSIAN TERTIARY HOSPITALS

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OBJECTIVES: The data regarding statin therapy prescribing among Malaysian patients with type 2 diabetes mellitus (T2DM) is lacking. This study was aimed to describe the prevalence of statin prescribing in Malaysian T2DM patients at two tertiary hospitals in the state of Pahang, Malaysia and to assess the appropriateness of statins prescribing according to the 2015 CPG on the treatment of T2DM. **METHODS:** A cross-sectional study was conducted between September to December 2016. The study involved hospitalized T2DM patients aged between 40 to 75 years without any contraindications to receiving statins. The study protocol obtained an ethical approval from the Malaysian National Medical Research Register. Assessment of current statin prescribing was classified as appropriate (proper statin was prescribed with no drug interactions) or inappropriate (not receiving any statins, although no contraindications) or adjustment needed (drug interactions or renal dose adjustment). **RESULTS:** A total of 393 cases were collected from the two hospitals. The prevalence of statins prescribing was about 65% (257/393). The most commonly prescribed statin was simvastatin 40 mg (53.3%) followed by simvastatin 20 mg (24.1%) and atorvastatin 40 mg (12.4%). The majority of the prescribed statins (82%) were moderate intensity ones. The evaluation of statins prescribing showed that approximately 35% of patients were not prescribed with statins contradictory to the national guidelines. About 26% of the study cases were given drugs that interact with statins. Renal dose adjustment of the given statin was detected in 5% of patients. Finally, one-third of patients were prescribed with appropriate statins. **CONCLUSIONS:** Prescribing of statins during hospitalization need to be improved to ensure eligible T2DM patients receive adequate CVD prophylaxis. Closer monitoring and/or intervention are warranted to assure that hospitalized T2DM patients are taking the proper statin dose without significant drug interactions. All initiatives to enhance statins prescribing should be considered.

PDB87

ASSOCIATION BETWEEN CARDIOVASCULAR COMORBIDITIES AND HEALTH CARE EXPENDITURES AMONG PATIENTS WITH DIABETES

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OBJECTIVES: Cardiovascular (CV) disease is two to four times more prevalent in patients with diabetes than in those without diabetes. This study sought to quantify the impact of CV comorbidities on health care expenditures among patients with diabetes. **METHODS:** A sample was drawn from 2014 Medical Expenditure Panel Survey (MEPS). Adults aged 18 years or older with self-reported diagnosis of diabetes were included. Individuals with missing data on any study covariates were excluded. Patients were classified as having cardiovascular comorbidity if they reported having ever been diagnosed with any of the following conditions: hypertension, coronary heart disease, angina or angina pectoris, heart attack or myocardial infarction, stroke, or other kind of heart disease. A generalized linear model with gamma distribution and log link were used to assess association between CV comorbidity and healthcare costs among patients with diabetes. The model adjusted for age, gender, race, education, family income, insurance coverage, self-perceived health status and duration of diabetes. The MEPS sampling weights were used to adjust for the complex survey design. **RESULTS:** A total of 2,022 individuals met study criteria, and 1,656 (81.9%) had one or more CV comorbidities. Patients with CV comorbidity were older than those without CV comorbidity (62.3 years vs. 52.2 years, $p < 0.001$). There was no significant difference in prevalence of cardiovascular comorbidity among males and females (83.6% vs. 80.6%, $p = 0.091$). Non-whites had higher prevalence of CV comorbidity than whites (85.2% vs. 80.0%, $p = 0.004$). The unadjusted cost associated with CV comorbidity was, mean (95% confidence interval, "C.I."), 7,454 (C.I.=5,541 to 9,366, $p < 0.001$) U.S. dollars (USD) per year. After adjusting for study covariates, estimated cost associated with CV comorbidity decreased to 5,287 (C.I.=2,911 to 7,663, $p < 0.001$) USD per year. **CONCLUSIONS:** Cardiovascular comorbidity is a significant contributor to healthcare expenditure in patients with diabetes with annual associated cost of 5,287 USD.

PDB88

HEALTH CARE RESOURCE UTILIZATION AND COSTS OF PATIENTS WITH TYPE 2 DIABETES TREATED WITH DULAGLUTIDE VS. EXENATIDE QW OR LIRAGLUTIDE IN THE US

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OBJECTIVES: Fernández Landó et al. [Diabetologia(2016) 59(Suppl 1):S1-S581] showed that patients with type 2 diabetes (T2D) treated with dulaglutide have higher adherence and persistence over 6 months vs. exenatide once weekly (EQW) or liraglutide patients. The objective of this secondary analysis was to describe diabetes-related resource utilization and costs over the same 6-month post-index period. **METHODS:** This analysis utilized Truven Early View data to identify patients newly initiating GLP-1 RAs between 11/2014 and 04/2015. Index treatment was identified in hierarchical order (dulaglutide, albiglutide, EQW, exenatide twice a day, and liraglutide) with no index drug claim in the pre-index period. Patients ≥ 18 years old, with ≥ 1 medical claim with T2D diagnosis and continuous enrollment for 6 months pre- and post-index were included. Diabetes-related medical, pharmacy, and total resource utilization and costs were assessed for a propensity matched sample of patients (dulaglutide vs. liraglutide, dulaglutide vs. EQW). **RESULTS:** The matched cohorts with 2,414 patients per arm for dulaglutide-EQW cohort and 2,037 for dulaglutide-liraglutide cohort were balanced in

baseline demographic and clinical characteristics. The mean \pm SD number of prescriptions for index drug in the post-index period was higher for dulaglutide vs. EQW (4.0 \pm 2.0 vs. 2.9 \pm 1.9, $p < 0.0001$) and dulaglutide vs. liraglutide (4.0 \pm 2.0 vs. 3.1 \pm 1.7, $p < 0.0001$). Dulaglutide patients had similar mean \pm SD diabetes-related medical costs (\$1,093 \pm 3,183 vs. \$1,164 \pm 3,122, $p = 0.433$) compared to EQW patients but higher pharmacy (\$4,822 \pm 2,830 vs. \$4,182 \pm 2,744, $p < 0.0001$) and total costs (\$5,914 \pm 4,378 vs. \$5,346 \pm 4,256, $p < 0.0001$), likely in part due to greater number of dulaglutide prescriptions. No significant differences existed between dulaglutide vs. liraglutide patients in diabetes-related medical (\$1,154 \pm 3,405 vs. \$1,246 \pm 3,354, $p = 0.390$), pharmacy (\$4,719 \pm 2,784 vs. \$4,551 \pm 3,091, $p = 0.069$), and total costs (\$5,873 \pm 4,529 vs. \$5,797 \pm 4,872, $p = 0.602$). **CONCLUSIONS:** Dulaglutide patients have similar diabetes-related costs vs. liraglutide, and have higher pharmacy and total costs compared to EQW in part due to higher medication use, consistent with previously demonstrated higher adherence for dulaglutide.

PDB89

INSULIN PRICE INCREASES FROM 2007-2014

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OBJECTIVES: Insulin is a life-saving drug that many patients diabetes require daily. Recent research reports that the price of insulin has soared in the previous decade. The objective of this analysis is to measure changes in the payments for insulin over time and how price is affected by market factors. **METHODS:** Data on average monthly payments for insulin was obtained the Truven Marketscan Commercial and Medicare Claims 2007-2014. The average monthly payment was calculated as expenditures per patient for a thirty-day supply of each drug in each quarter. Expenditures include payments from patients (copayments and coinsurance) and payments from the health plan. Additional data on drug characteristics and market information was also obtained from Redbook and the Food and Drug Administration (FDA) Orangebook and Drugs@FDA database. Prices for individual insulin products will depend on the quantity of prescriptions for product, quality attributes of the product, formulary tiers which vary by insurer, and market competitiveness, measured by the number and prices of competitors. Regression analysis will be used to assess the effect of market changes on insulin price including product fixed effects. **RESULTS:** On average, monthly payments for all insulins increased by 198.8 percent from the first quarter of 2007 to the last quarter of 2014. Insulin analogues accounted for over 86.5 percent of pharmaceutical claims for insulin in the Truven Marketscan Commercial and Medicare Database from 2007-2014. The majority of these price increases were absorbed by payers. Payments made by patients only increased by 36.7 percent. **CONCLUSIONS:** Insulin remains to be an incredibly cost-effective treatment to improve glycemic control among diabetic patients. However, these price increases may enhance the overall burden of illness of diabetes. As the treatment of diabetes becomes more costly, it may be important to consider the willingness of society to pay for a cure or find other treatment options.

PDB90

EFFECTS OF MULTIMORBIDITY ON HEALTH CARE UTILIZATION AND COSTS AMONG PATIENTS WITH DIABETES

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OBJECTIVES: The combination, not just the count, of comorbidities may influence diabetes care and patient outcomes. This study evaluates the effects of comorbidity clusters on health care utilization and costs among patients with diabetes. **METHODS:** Using the Optum Clinformatics database, we identified patients newly diagnosed with type 2 diabetes in 2013, excluding subjects with any diabetes diagnosis or diabetes medication use in the 12 months prior to the index date. Each patient had ≥ 12 months of continuous enrollment both pre- and post-diagnosis. We categorized patients into five mutually exclusive comorbidity groups using the widely-cited Piette and Kerr framework: none, concordant conditions only (e.g., heart disease), discordant conditions only (e.g., gastrointestinal illness), both, and dominant conditions (e.g., cancer). We compared healthcare utilization and costs in the year following a new diabetes diagnosis across different comorbidity clusters. **RESULTS:** Of the 130,193 patients with newly-diagnosed diabetes, 84% had comorbidities: 7% with concordant conditions only, 24% with dominant conditions, 25% with both concordant and discordant conditions, and 28% with discordant conditions only. Annual health care costs varied significantly by comorbidity type: dominant (\$33,152), both (\$17,928), discordant only (\$8,595), concordant only (\$8,518) and no comorbidities (\$3,183) ($p < 0.001$). Outpatient care accounted for 50%-59% of total costs among patients with any comorbidity (depending on the cluster). Patients with dominant and both concordant and discordant conditions had more inpatient, outpatient and ER visits and more prescriptions than other groups. **CONCLUSIONS:** This study is the first of which we are aware to document substantial cost variation based on the widely-used Piette and Kerr multimorbidity framework among patients with diabetes. We found that patients with dominant and both concordant and discordant comorbidities may incur significantly higher health care costs than those with other comorbidity clusters. Our results may help clinicians tailor comorbidity management plans targeting high-cost patients with diabetes.

PDB91

DELAY IN TREATMENT PROGRESSION AMONGST DIABETICS: A REAL-WORLD ASSESSMENT

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OBJECTIVES: To explore clinical inertia implications amongst Dual+ uncontrolled and basal insulin-only uncontrolled patients. **METHODS:** Data were drawn from 2016 Adelphi Diabetes Disease Specific Programme (DSP) in T2DM conducted across SEU/

USA. The Diabetes DSP is a real-world, cross-sectional survey involving completion of physician-reported forms for their next 10 consulting T2DM patients. The same patients are invited to complete a patient-reported form. Patients were classified in the following groups: [1] 2+ non-insulin regimen HbA1c <8% [2] 2+ non-insulin HbA1c \geq 8% with no therapy change \geq 4 months [3] Basal insulin-only HbA1c <8% [4] Basal insulin-only HbA1c \geq 8%. Adherence measured via the validated, patient-reported Morisky Medication Adherence Scale (MMAS-8). All results $p < 0.05$. **RESULTS:** A total of 352 specialists, 501 PCPs and 8523 patients were recruited. Of these, there were [1] 2739 Dual+ controlled; [2] 316 Dual+ uncontrolled; [3] 584 Basal controlled; [4] 391 Basal uncontrolled. Dual+ uncontrolled versus controlled patients had consulted most frequently per annum (4.96 vs 4.14), likely been hospitalized (3.5% vs 2.9%) with more frequent hospitalizations per annum (1.18 vs 1.07), physician-belief they require insulin (14.4% vs 1.3%) and are obese/severely obese (41.1% vs 31.1%) with low adherence (44.9% vs 22.9%). Basal uncontrolled versus controlled had consulted more frequently per annum (4.4 vs 4.29), been hospitalized (11.0% vs 9.3%), labelled obese/severely obese (42.1% vs 34.7%). Reasons for highest non-adherence include weight gain (15.1% vs 10.8%), injection aversion (24.0% vs. 16.2%), poor glucose monitoring (27.1% vs 16.2%) and lack of perceived need for medication (14.2% 4.6%). **CONCLUSIONS:** Despite highest healthcare provider contact, higher HbA1c non-control and low adherence, Dual+ uncontrolled patients requiring insulin therapy are not progressing in the treatment paradigm despite physician-acknowledgement this is required. For those who progress to basal insulin-only therapy, despite frequent consultations, weight concerns contribute greatly to non-adherence. Addressing both issues could improve humanistic and economic outcomes.

PDB92

ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE AMONG DIABETIC POPULATION: A CROSS-SECTIONAL STUDY

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OBJECTIVES: Objective of study is to assess present knowledge, attitudes, and practices of diabetic patients towards the management of diabetes. **METHODS:** 400 (DM) patients were enrolled in this survey based cross-sectional study and assessed through semi structured questionnaire. **RESULTS:** As 253 (63.2%) patients were from urban so they were illiterate (N=135, 33.8%) while a few were graduate (N=75, 18.8%) and only 11 (2.8%) were post-graduated and also 236 (59%) were having positive family history of disease. Majority of the participants i.e. 377 (94.2%) had poor knowledge about disease. Only 131 (32.8%) patients were having knowledge about random blood sugar level. Most of the participants (N=363, 90.7%) reported that oral hypoglycemic agents and/or insulin is necessary for management of diabetes but they were unable to differentiate their use during either type of diabetes. Majority of the patients, 377 (94.8%) agreed that controlled and planned diet should be followed to control diabetes. Only 185 (46.2%) agreed that upon control of diabetes, the medicines can be stopped immediately while other's response was neutral/disagree and p-value was 0.002. Most of the participants (N=339, 84.8%) agreed that diabetic education programs are necessary for disease management. Regardless of having sufficient knowledge about disease, patient's practice was poor as 265 (66.3%) patients were going for follow-up regularly to physician, 228 (57.0%) reported that they exercise regularly. Only 297 (74.3%) followed a controlled and planned diet while others did not. **CONCLUSIONS:** The study showed low levels of diabetes awareness but positive attitudes towards the importance of DM care and unsatisfactory diabetes practices in Pakistan. Training programs for health professionals and diabetic patients should be conducted in order to improve their management toward the disease.

PDB93

CHARACTERISTICS ASSOCIATED WITH THE CHOICE OF FIRST INJECTABLE THERAPY AMONG US PATIENTS WITH TYPE 2 DIABETES

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OBJECTIVES: The objective of this retrospective observational study was to describe and identify clinical and demographic characteristics associated with the choice of first injectable therapy (glucagon-like peptide-1 receptor agonist [GLP-1-RA] or basal insulin [BI]) among patients with type 2 diabetes (T2D). **METHODS:** This analysis included adults with T2D who initiated GLP-1-RA or BI (index date) between November 2014 and February 2016 using data from the Practice Fusion electronic health record database. Patients with ≥ 1 diagnosis of T2D, ≥ 1 office visit between 6 and 18 months prior to the index date and naive to GLP-1-RAs and BI with ≥ 1 HbA1c result in the 6-month baseline period were included. Bootstrapped logistic regression was used to identify baseline predictors. **RESULTS:** The study included 3,546 and 7,507 GLP-1-RA and BI initiators, respectively. Descriptive analyses showed that at baseline, GLP-1-RA initiators were significantly younger (mean 58 vs 63 years), had lower HbA1c (mean 8.2 vs 9.1%), lower Diabetes Complications Severity Index (DCSI) scores (mean 1.0 vs 1.7), and higher BMI (mean 36 vs 33 kg/m²) compared to BI initiators. Logistic regression showed patients that were older (odds ratio [OR] = 0.973), of black race (OR=0.579), were smokers (OR=0.713), and had higher HbA1c (OR=0.744) and DCSI scores (OR=0.868) were significantly less likely to be prescribed GLP-1 RA compared to BI. Patients with higher BMI (OR = 1.040), previous prescription of thiazolidinedione (OR=1.879) or sodium glucose cotransporter-2 inhibitor (OR=2.449), and diagnosis of obesity (OR=1.336) were significantly more likely to be prescribed GLP-1-RA. **CONCLUSIONS:** There were clinically relevant differences between the two cohorts, suggesting GLP-1 RAs and BI are prescribed to different types of patients with T2D. Key predictors that may influence the choice of a GLP-1-RA as first injectable were higher BMI and obesity; and for initiating BI were worse glycemic control, older age, and higher disease burden.

PDB94

A COMPARISON OF PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION AND HEALTH CANADA

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OBJECTIVES: The study was conducted to provide a comparative analysis of pituitary and hypothalamic hormones and analogues approved by the US Food and Drug Administration (FDA) and Health Canada (HC). **METHODS:** The World Health Organization (WHO), FDA, and HC websites were used to obtain the data of pituitary and hypothalamic hormones and analogues, approval dates, indications, contraindications, market status, dosage forms, strengths, and routes of administration. Descriptive statistics and Wilcoxon rank sum test were performed. **RESULTS:** Twenty eight drugs were identified, of which 15 were approved by the FDA and 17 were approved by HC. Among the 13 drugs marketed in both the US and Canada, two drugs were excluded due to missing information. Of the 11 remaining drugs, 9 drugs (82%) were approved by the FDA first, while only 2 drugs (18%) were approved by HC first. The average (\pm SD) number of approved indications by the FDA (1.82 \pm 0.98) was not significantly different from that approved by HC (2.45 \pm 1.75) (P-value=0.31). HC approved more indications than the FDA for 3 drugs (Somatropin, Tesamorelin, and Octreotide), and each agency approved different indications in one drug (Nafarelin). HC's average number (\pm SD) of contraindications (4.27 \pm 2.65) was not significantly different from that of the FDA's (3.36 \pm 2.10) (P-value=0.07). **CONCLUSIONS:** There were differences in the number of pituitary and hypothalamic hormones and analogues approved by both agencies. Different indications and contraindications were also found for the same drugs comparing both agencies. These differences may lead to different access to treatment options. Hence, communication between the FDA and HC on harmonizing decision-making is needed.

GASTROINTESTINAL DISORDERS – Clinical Outcomes Studies

PG11

RISK OF CLOSTRIDIUM DIFFICILE INFECTION ASSOCIATED WITH PROTON PUMP INHIBITOR USE AMONG COMMUNITY DWELLING ADULTS WITH GASTROESOPHAGEAL REFLUX DISEASE

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OBJECTIVES: There is mixed evidence regarding the risk of C. difficile infection due to use of Proton Pump Inhibitors (PPIs). This study examined the risk of C. difficile infection associated with the use of PPIs among community dwelling adults with Gastroesophageal Reflux Disease (GERD). **METHODS:** The study involved a nested case-control design using Truven Health Analytics 2003-2004 MarketScan database. Participants included adults aged more than 18 years, diagnosed with GERD anytime between January 1, 2003, and December 31, 2004 and no history of C. difficile infection between January 1, 2003 and June 30, 2003. Cases were identified as enrollees with an incident diagnosis of C. difficile infection, between July 1, 2003, and December 31, 2004 (n=97). Four age- and gender-matched controls (n=388) were identified per case using incident density sampling. A conditional logistic regression model stratified on matched case-control sets was used to evaluate the risk of C. difficile infection. **RESULTS:** The study sample consisted of 97 cases diagnosed with C. difficile infection and 388 age- and sex-matched controls. Cases had a higher Elixhauser Comorbidity Index (1.99 versus 0.34, p-value <.0001) compared to controls. The conditional logistic model revealed that the use of PPIs was not significantly associated with risk of C. difficile infection (Odds ratio (OR): 1.24, 95% Confidence Interval (CI): 0.57-2.68). Previous hospitalization (OR: 46, 95% CI: 9.26-228.59), previous antibiotic exposure (low-risk (OR: 1.07, 95% CI: 1.02-1.12), medium-risk (OR: 1.22, 95% CI: 1.09-1.37) and high-risk (OR: 1.27, 95% CI: 1.11-1.46)), abdominal pain (OR: 4.10, 95% CI: 1.73-9.69) and disease severity (OR: 1.22, 95% CI: 1.02-1.46) showed increased risk of C. difficile infection. **CONCLUSIONS:** Overall, PPIs were not associated with risk of C. difficile infection among community dwelling adults with an indication for GERD. More research is needed in other healthcare settings to understand PPIs safety profile, especially for long term use.

PG12

RISK OF PNEUMONIA ASSOCIATED WITH PROTON PUMP INHIBITOR USE AMONG COMMUNITY DWELLING ADULTS WITH GASTROESOPHAGEAL REFLUX DISEASE

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OBJECTIVES: Most of the adverse effects of Proton pump inhibitors (PPIs) were evaluated in inpatient setting and limited data exists regarding its adverse effects in community settings. This study examined the risk of pneumonia associated with the use of PPIs in community dwelling adults with Gastroesophageal Reflux Disease (GERD). **METHODS:** The study involved a retrospective cohort study design using Truven Health Analytics 2003-2004 MarketScan database. The study population included adults aged more than 18 years of age, diagnosed with GERD, identified anytime between July 1, 2003, and December 31 2003. The risk of pneumonia during the 12-month follow-up period was modeled using a time-varying Cox proportional model using monthly PPI exposure. Fractional Polynomial Cox proportional model was used to model the risk of pneumonia with cumulative duration of PPI use. Multiple sensitivity analyses were conducted to strengthen the study findings. **RESULTS:** Analysis of MarketScan database revealed that there were 89,378 patients with GERD indication and among these, 60,207 (67.36%) patients were PPI users. Patients using PPIs were older, 49.65 (\pm 10.49) years, compared to patients not using PPIs, 46.93 (\pm 11.90) years and majority of the GERD patients were females (57.4%). Results from multivariate time varying Cox regression model revealed that PPI use was associated with 53% increased

risk of pneumonia (HR, 1.53; 95% CI, 1.35–1.75). The findings were consistent across multiple sensitivity analyses. Fractional polynomial analysis revealed an initial decreased risk of pneumonia until 175 days of cumulative duration of PPI use and an increased risk after 175 days of cumulative PPI use was observed. **CONCLUSIONS:** The study found an increased risk of pneumonia associated with PPI use among community dwelling adults with GERD diagnosis. Due to increasing safety concerns there is a need to be cautious in using PPIs for extended periods.

PGI3

DIAGNOSING NONALCOHOLIC STEATOHEPATITIS (NASH) AMONG PATIENTS WITH NONALCOHOLIC FATTY LIVER DISEASE (NAFLD): FREQUENCY AND PREDICTORS OF NAFLD ACTIVITY SCORE MEASUREMENT

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OBJECTIVES: Although largely asymptomatic, nonalcoholic steatohepatitis (NASH) can lead to an increased risk of liver cirrhosis and hepatocellular carcinoma. Improved early detection of NASH can result in reducing a substantial societal burden. Current guidelines suggest the presence of NASH when the patient has a nonalcoholic fatty liver disease (NAFLD) Activity Score (NAS) of 3 or above. NAS score therefore plays an integral role in determining the size of the current NASH population. This study sought to identify the frequency and predictors of NAS measurement. **METHODS:** Data from Ipsos' NASH Therapy Monitor were analysed; the NASH Therapy Monitor is a retrospective medical chart review of NAFLD patients in the US, fielded from September to November 2016. N=174 physicians provided patient demographics, disease status, comorbidities, testing, and treatment data on their most recent 5–10 NAFLD patients. Clinical and economic outcomes were reported descriptively; logistic regression models were conducted to identify factors associated with the likelihood of a complete NAS measurement. **RESULTS:** 1396 NASH patients (57% male; mean age 51.7 years [SD = 12.0], mean BMI=35.0 [SD=9.1]) were included in our analysis. Only 52% of these patients had a complete NAFLD Activity Score (NAS), i.e. steatosis (69%), lobular inflammation (61%) and hepatocyte ballooning (61%) measured. The strongest predictors of a complete NAS measurement [at p<.05] were NAFLD fibrosis scores indicating advanced liver fibrosis (odds ratio [OR]=4.2), Medicare B insurance (OR=2.8), male (OR=2.0), lack of concomitant disorders (OR=1.7), and type 2 diabetes (OR=1.5). Obesity was not associated with a complete NAS measurement. **CONCLUSIONS:** Only half of patients had NAS measurements with elevated NAFLD scores and Medicare B insurance the strongest predictors. As NASH-specific treatment options become available, a greater focus on NAS measurement could have clinical and economic implications by allowing for earlier intervention prior to the onset of disease complications.

PGI4

COMPARATIVE EFFICACY AND SAFETY OF TOFACITINIB AND BIOLOGICS AS INDUCTION THERAPY FOR MODERATELY-TO-SEVERELY ACTIVE ULCERATIVE COLITIS: A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS

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OBJECTIVES: Tofacitinib is an oral, small molecule JAK inhibitor being investigated for moderately-to-severely active ulcerative colitis (UC). We performed a systematic literature review (SLR) and network meta-analysis (NMA) to compare the efficacy and safety of tofacitinib to available tumor necrosis factor inhibitors [TNFi] and integrin receptor antagonists for induction therapy of adults with moderately-to-severely active UC. **METHODS:** Using indexing and free-text terms, searches were conducted in EMBASE, MEDLINE, CENTRAL, DARE, and CINAHL databases to identify RCTs published as of January 2015. Proceedings of relevant conferences from 2012–2014 were also reviewed. Comparators of interest were infliximab, golimumab, adalimumab, and vedolizumab. Two reviewers independently assessed studies for inclusion, extracted and validated the study/patient data. Fixed- and random-effects Bayesian NMA were conducted to compare efficacy outcomes and rates of adverse events (AEs) at 6–12 weeks in the overall population (TNFi-naïve or exposed) and by prior TNFi exposure. **RESULTS:** Twelve induction trials were identified from the SLR (ACT I & II, EUCALYPTUS, GEMINI-I, PURSUIT SC, TOFACITINIB PHASE II, Feagan 2005, Probert 2003, UC-SUCCESS, ULTRA 1, ULTRA 2, Suzuki 2014) and included in NMA. Unpublished data from tofacitinib phase III induction trials (OCTAVE I & II) were also used in the analysis. Fixed-effects NMA showed tofacitinib 10 mg BID is associated with a higher rate of mucosal healing versus adalimumab 160/80/40mg in the overall population (OR 1.82 [95% CrI: 1.06–3.14]) and versus vedolizumab 300mg in TNFi-exposed patients (OR 3.71 [95% CrI: 1.37–10.64]). A higher rate of clinical remission was seen with tofacitinib 10mg BID versus adalimumab in TNFi-exposed (OR 11.93 [1.84–154.78]). Rates of AEs were similar between tofacitinib 10mg BID and comparators in the overall and TNFi-naïve population. **CONCLUSIONS:** This NMA suggests the novel agent tofacitinib may be more effective than adalimumab and vedolizumab as induction therapy in TNFi-exposed patients with moderately-to-severely active UC.

PGI5

IMPACT OF FOUR-FACTOR PROTHROMBIN COMPLEX CONCENTRATE WITH OR WITHOUT FIBRINOGEN CONCENTRATE ON BLOOD PRODUCT UTILIZATION IN ORTHOTOPIC LIVER TRANSPLANTATION

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OBJECTIVES: Major bleeding in orthotopic liver transplantation (OLT) is associated with significant morbidity and mortality. Limited data exists regarding comparative

effectiveness of four-factor prothrombin complex concentrate (4PCC) and fibrinogen concentrate (FC) in OLT. This study evaluated the effectiveness of 4PCC and FC on intraoperative blood product utilization during OLT. **METHODS:** A retrospective, observational, single-institution propensity score matched cohort was conducted involving OLTs utilizing 4PCC and/or FC intraoperatively from December 2013 to April 2016. Patients were included if they were greater than 18 years of age and undergoing OLT. Patients were excluded if they received simultaneous heart or lung transplantation, or did not have a documented anesthesia operative note. Greedy propensity score match technique was used to match patients unexposed to exposed patients in a 2 to 1 ratio. The authors hypothesized that intraoperative use of 4PCC with or without FC during OLT would decrease the intraoperative packed red blood cell (pRBC) unit requirements by 2 units compared to patients who did not receive drug exposure. **RESULTS:** During the study timeframe, 212 patients received OLT with 39 4PCC exposures. The matched study population included 39 patients exposed to 4PCC with or without FC, and 78 patients not exposed to 4PCC. After propensity score matching, no factors included in the model were significantly different or had standardized mean differences greater than or equal to 0.11. No statistical difference was found in pRBC or fresh frozen plasma (FFP) utilization in the exposure group compared to the unexposed group (mean pRBC unit: 12.4 ± 8.0 units versus 9.7 ± 5.6 units, p-value=0.058; mean FFP unit: 10.0 units ± 6.3 versus 12.7 ± 9.7 units, p-value=0.119, respectively). **CONCLUSIONS:** Intraoperative use of 4PCC with or without FC did not reduce intraoperative blood product requirements at a single institution.

PGI6

EVALUATION OF CONCOMITANT CORTICOSTEROID AND VEDOLIZUMAB USE IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE (IBD) IN REAL-LIFE CLINICAL PRACTICE

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OBJECTIVES: Corticosteroids (CS) are often used concomitantly with biologics in treatment of inflammatory bowel disease (IBD). However, their side-effect profile causes significant clinical and economic burden in long-term treatment. In this study, we investigated the impact of concomitant CS use on vedolizumab treatment persistence in patients with Crohn's disease (CD) and ulcerative colitis (UC). **METHODS:** This was a nationwide (Finland), retrospective, non-interventional, multi-center chart review. From 27 centers, we included adult (≥ 18 years of age) IBD patients who received at least one vedolizumab infusion since 2014. Data were collected from medical charts in a standardized case report form. The key data collection points were at baseline, week 14 and month 6 of vedolizumab treatment. **RESULTS:** 247 patients (CD 108, UC 139) were included. At baseline, 47 (43.5%) CD and 84 (60.4%) UC patients were using CS. Higher percentage of patients using CS at baseline discontinued vedolizumab during the 6-month follow-up compared to CS non-users (CD, 14/47 (29.8%) vs. 13/61 (21.3%); UC, 31/84 (36.9%) vs. 16/55 (29.1%)). Over half of the patients on CS at baseline and who persisted on vedolizumab were able to discontinue CS before 6 months timepoint (CD, 18/33 (54.5%); UC, 37/53 (69.8%)). Among CD patients, CS users had higher baseline disease activity than non-users. Such difference was not observed in UC. CS users had shorter disease duration in both CD and UC. There was no difference in the number of prior TNF-alpha inhibitors between CS users and non-users. **CONCLUSIONS:** Vedolizumab treatment persistence was lower in CS users than in non-users in both CD and UC. The majority of patients on CS at baseline who persisted on vedolizumab were steroid-free by 6 months, potentially relieving the burden of CS-induced side-effects for both patients and society.

PGI7

META-ANALYSIS AND INDIRECT COMPARISON OF MMX-BUDESONIDE AND MMX-MESALAMINE FOR THE TREATMENT OF MILD TO MODERATE ULCERATIVE COLITIS IN ADULT PATIENTS

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OBJECTIVES: To compare the efficacy of MMX-budesonide 9 mg QD (MMX-bud) and both MMX-mesalamine (MMX-5ASA) 2.4 gm and 4.8 gm QD for the treatment of active, mild-to-moderate ulcerative colitis using indirect treatment comparison. **METHODS:** A systematic review, meta-analysis and indirect treatment comparison meta-analyses using fixed effect model were conducted for the primary outcome of clinical and endoscopic remission and secondary outcomes for clinical remission, clinical improvement, and endoscopic improvement in 8 weeks. Risk Ratio (RR) estimates and associated 95% confident intervals were presented. **RESULTS:** Five eligible RCTs (3 MMX-bud and 2 MMX-5ASA studies) for the treatment of active ulcerative colitis of 8 weeks were included. At 8 weeks, the primary endpoint (clinical and endoscopic remission) showed no statistical significant difference between MMX-bud 9 mg vs. MMX-5ASA 4.8 gm (RR 1.36, 95%CI, 0.79–2.34; p = 0.49) and MMX-bud 9 mg vs. MMX-5ASA 2.4 gm (RR 1.42, 95%CI, 0.84–2.41; p = 0.41). Two of the corresponding secondary endpoints were not significant: clinical remission (RR 1.31, 95%CI, 0.78–2.17; p = 0.54 and RR 1.33, 95%CI, 0.81–2.19; p = 0.50), and clinical improvement (RR 0.90, 95%CI, 0.64–1.26; p = 0.78 and RR 0.91, 95%CI, 0.64–1.29; p = 0.81). However, MMX-bud is superior than both MMX-5ASA 2.4 gm and MMX-5ASA 4.8 gm in achieving endoscopic improvement (RR 0.62, 95%CI, 0.44–0.86; p = 0.05; RR 0.61, 95%CI, 0.44–0.86; p = 0.05). **CONCLUSIONS:** Both MMX-bud and MMX-5ASA were superior to placebo in the treatment of active, mild-to-moderate ulcerative colitis. However, for three outcomes (clinical and endoscopic remission, clinical remission, and clinical improvement), there were no statistically significant between MMX-bud 9 mg and MMX-5ASA for both 2.4 gm and 4.8 gm. Cost of medication therapy for 8

weeks (AWP: Bud-MMX 9 mg \$1600, MMX-5ASA 4.8 gm \$2117, and MMX-5ASA 2.4 gm \$1058) and rebates should be evaluated.

PGI8

IMPACT OF RIFAXIMIN AND LACTULOSE VERSUS LACTULOSE ALONE ON HOSPITALIZATION FOR ACUTE RECURRENT HEPATIC ENCEPHALOPATHY

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OBJECTIVES: Each year, approximately 110,000 hospitalizations for hepatic encephalopathy (HE) occur, totaling almost \$1 billion U.S. in health care expenses. Our purpose was to determine if there was a difference in the recurrence of overt HE in the six months following an initial HE event between patients who received preventative therapy with lactulose versus lactulose and rifaximin. **METHODS:** This was a retrospective cohort study that used a 10% random sample of medical and pharmacy claims obtained from the IMS LifeLink PharMetrics Plus database for the study period January 1, 2006 through June 30, 2015. Descriptive analyses were conducted to compare demographic and clinical characteristics between patients who received lactulose or lactulose and rifaximin. Kaplan-Meier curves and a Cox proportional hazard model, adjusting for concomitant medications, comorbidities, and diagnoses related to liver disease were estimated. **RESULTS:** Among patients in the lactulose and rifaximin group (n=169) and the lactulose group (n=437), there was no significant difference in the average age (56.9 vs. 56.0; p=0.792) or Charlson comorbidity index (6 vs. 6; p=0.246). A significantly greater proportion of patients in the lactulose and rifaximin group were on spirinolactone (73.4% vs. 61.8%, p=0.007), a proton pump inhibitor (73.4% vs. 61.8%, p=0.007), and ursodiol (16.6% vs. 8.0%; p=0.002). There was no difference in hospitalization for HE between groups (16.0% vs. 15.3%; p=0.841). After adjusting for potential confounders, there was no significant difference in risk for an event between groups (hazard ratio=1.045; 95% confidence interval 0.806-1.28). **CONCLUSIONS:** The addition of rifaximin to lactulose did not alter the proportion of patients who experienced their second overt HE event. This finding differs from previously reported results and may be the result of residual, unobserved confounding.

PGI9

GENERATION AND TESTING OF OUTCOME INDICATORS FOR NON-ALCOHOLIC STEATOHEPATITIS

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OBJECTIVES: Non-alcoholic steatohepatitis (NASH) is an emerging liver condition arising from a dismetabolic background and potentially leading to cirrhosis, end-stage complications and hepatocellular carcinoma (HCC). Despite many attempts to standardize the clinical management of NASH, international guidelines are poorly translated into clinical practice. Outcome Indicators (OIs) may optimize clinical management of NASH through the measurement, analysis and comparison of centre's results. OIs may also drive the allocation of resources, according to Value-Based Medicine. The aim of this study is to generate and test a set of OIs for NASH. **METHODS:** OIs were generated by a panel of experts via Delphi Consensus method. OIs were tested in a multi-centre, prospective clinical study. **RESULTS:** Seven OIs were generated (median vote 8-9; disagreement index near zero). Three-hundred-and-two patients were enrolled; median follow-up was 23 months. OIs generated are shown below together with the results of clinical validation: OI#1) reduction of body weight by at least 7% and successive maintenance: 14% of patients. OI#2) cardiovascular risk reduction measured by instrumental tests and risk maps: 13%. OI#3) improvement of metabolic syndrome parameters (visceral obesity, triglycerides, HDL cholesterol, blood pressure, fasting glucose levels (according to ATPIII criteria): 21%, 43%, 12.5%, 30% and 66.5%, respectively. OI#4) incidence of cardiovascular accidents: not yet validated. OI#5) survival of patients with advanced fibrosis: 97% at 2 years. OI#6) incidence of cirrhosis: 3.6%. OI#7) incidence of HCC: 2.4%. **CONCLUSIONS:** Seven OIs were generated and tested proving promising in measuring the performance of tertiary Centres dealing with NASH patients. Results obtained could serve as benchmarks for a future extension of the project to a regional/national scale. The analysis of the results also revealed consistent gaps in the current management of NASH, prompting a wide reappraisal of the processes and raising the need for dedicated care units with a multidisciplinary approach.

PGI10

ASSOCIATION OF SOCIO-DEMOGRAPHICS AND CLINICAL COMPLICATIONS WITH FUTURE MEDICAL EXPENDITURES IN DIVERTICULITIS

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OBJECTIVES: To evaluate the association of socio-demographics factors and clinical complications at presentation with future medical expenditures in diverticulitis patients. **METHODS:** Using the electronic medical records of the Kaiser Permanente Southern California Health Plan, we identified all adults (18+ years) who had acute diverticulitis (incident cases) during 01/01/2007 to 12/31/2011. Prior to diagnosis of the incident event (index date), patients were required to be a health plan member continuously enrolled for ≥ 12 months (baseline period) without evidence of diverticulitis. Through chart review, we captured the following complications during the incident presentation: abscess, intestinal obstruction, pneumoperitoneum, fistula and peritonitis. We identified medical expenditures (2016 USD) associated with inpatient (IP), emergency department (ED) and outpatient (OP) visits during the one year period after the index date. Total expenditure was the sum of IP, ED and OP expenditure. A generalized linear model with log link and gamma distribution was

specified which adjusted for the following covariates: age, race, sex, ethnicity, income, insurance type, Elixhauser comorbidity, and clinical complications. **RESULTS:** We identified 32,884 incident cases: age (mean \pm SD), 59 \pm 14 years; 58% female; 68% white. The average adjusted total expenditure was \$8,848 (95% CI \$8,703 to \$8,993). Age, race, ethnicity, income, insurance type and multimorbidity were independently associated with future total expenditure. Each identified complication was associated with significantly higher total expenditure: abscess (\$7054, (\$6171 to \$7936)), intestinal obstruction (\$4,433 (\$3235 to \$5632)), pneumoperitoneum (\$4,838 (\$4131 to \$5546)), fistula (\$7,083 (\$4359 to \$9807)) and peritonitis (\$7,324 (\$3510 to \$11137)). **CONCLUSIONS:** Presence of complicated diverticulitis was associated with significantly increased expenditure during follow-up. The magnitude of the marginal future expenditure associated with abscess, fistula and peritonitis might offset cost of elective surgical procedures, in patients presenting with such complications.

PGI11

EVALUATION OF AGE, MULTIMORBIDITY AND CLINICAL COMPLICATIONS AS RISK FACTORS FOR URGENT SURGICAL TREATMENT FOR DIVERTICULITIS

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OBJECTIVES: To evaluate the association of age, multimorbidity and clinical complications at presentation with urgent surgical management of diverticulitis. **METHODS:** We identified all adults (18+ years) who had acute diverticulitis (incident cases) during 01/01/2007 to 12/31/2011 from the Kaiser Permanente Southern California Health Plan. Prior to diagnosis of the incident event (index date), the patients were required to be health plan members continuously enrolled for ≥ 12 months (baseline period) without evidence of diverticulitis. We defined urgent surgery as a colon surgery performed within 30 days of the index date. Through chart review, we captured the following complications during the incident presentation: abscess, intestinal obstruction, pneumoperitoneum, fistula and peritonitis. A logistic regression model with robust standard errors was specified to predict the probability of receiving urgent colon surgery. The model adjusted for the following covariates: race, sex, and ethnicity with age, Elixhauser comorbidity, and clinical complications as exposures. **RESULTS:** We identified 33,445 incident cases: age (mean \pm SD), 59 \pm 14 years; 58% female; 68% white. As compared to those in the 18-35 age category, those above 65 years of age had 79% higher odds of receiving urgent surgery (Odds Ratio OR 1.8, 95% CI (1.2 to 2.6)). Compared to patients without comorbidity, those with two or more Elixhauser comorbidities had significantly higher odds of receiving surgery (OR 1.6, (1.3 to 1.9)). The odds of surgery was significantly higher when the patients presented with the following complications: abscess (OR 2.7, (2.0 to 3.7)), intestinal obstruction (OR 4.8, (3.4 to 6.7)), pneumoperitoneum (OR 2.4 (1.8 to 3.2)), and fistula or peritonitis (OR 9.1, (4.9 to 17.0)). **CONCLUSIONS:** Presence of complicated diverticulitis significantly increased the likelihood of urgent need for colon surgery. Contrary to expectation, those with multimorbidity as well as older aged patients were also at higher odds of receiving urgent surgery.

PGI12

ASSOCIATION OF CLINICAL COMPLICATIONS AND SURGERY TREATMENT ON RECURRENCE OF ACUTE DIVERTICULITIS

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OBJECTIVES: To evaluate the association of demographic factors, clinical complications and surgical management of diverticulitis with its recurrence. **METHODS:** We identified all adults (18+ years) who had acute diverticulitis (incident cases) during 01/01/2007 to 12/31/2011 from the Kaiser Permanente Southern California Health Plan. Prior to diagnosis of the incident event (index date), the patients were required to be a health plan member continuously enrolled for ≥ 12 months (baseline period) without evidence of diverticulitis. We defined recurrence as a patient meeting case definition ≥ 30 days after the index date. Through chart review, we captured the following complications during the incident presentation: abscess, intestinal obstruction, pneumoperitoneum, fistula, and peritonitis. Lastly, we identified patients who had colon surgeries within 30 days of the index event. A stratified (by sex) cox proportional model was specified with sociodemographics, Elixhauser comorbidity, clinical complications and surgical management to evaluate the hazard of diverticulitis recurrence. **RESULTS:** We identified 33,442 incident cases: 58% female; 68% white. Mean age (mean \pm SD) in females was 61 \pm 14 years while in males it was 56 \pm 15 years. During a mean (median) of 46 (49) months follow-up, 11,092 patients had a recurrence. In females, the hazard of recurrence increased with complication of abscess (Hazard ratio; (95% CI) 1.4; (1.2 to 1.7)) while surgery reduced the recurrence hazard (0.7; (0.6 to 0.8)). In males, the hazard of recurrence increased with presentation of pneumoperitoneum (1.3; (1.1 to 1.5)) and abscess (1.6; (1.3 to 1.9)) while it decreased with findings of intestinal obstruction (0.6; (0.4 to 0.9)) and with surgery (0.5; (0.4 to 0.7)). Recurrence hazard significantly increased with age in females while it significantly decreased with increasing age in males. **CONCLUSIONS:** We identified significant heterogeneity in the hazard of diverticulitis recurrence by presenting complications and by age, between the sexes.

GASTROINTESTINAL DISORDERS – Cost Studies

PGI13

COST-MINIMIZATION AND BUDGET IMPACT ANALYSIS OF CERTOLIZUMAB PEGOL FOR THE TREATMENT OF CROHN'S DISEASE FROM THE PERSPECTIVE OF THE BRAZILIAN PRIVATE HEALTHCARE SETTING

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OBJECTIVES: Despite the Brazilian constitution guaranteeing universal access to healthcare, 23% of Brazilians have a private healthcare plan. Drug coverage in the private sector is regulated by the National Agency for Supplementary Health, which in 2011 stated the mandatory cost reimbursement for immunobiologic drugs (bDMARD) for Crohn's disease (CD). Presented here is a Health Technology Assessment (HTA) approach on certolizumab pegol (CZP) for treatment of CD. **METHODS:** Data on utilization of treatment resources and disease-related costs were sourced from a private-sector survey of 36 respondents. In addition, the following DATASUS information was utilized to describe market dynamics: percentage of new patients (31%), switching (5%) and discontinuation (19%). On considering data from systematic reviews (SR), CZP was assumed to have equal efficacy to infliximab (IFX) and adalimumab (ADA); thus, a cost-minimization analysis (CMA) was conducted. For the 10-year CMA, an eight-state Markov model was developed using Microsoft Excel. The transition states were: initial treatment with bDMARD, remission, response, treatment failure, surgery, surgical remission, conventional treatment and death. The data for these states were also from SR. The budget impact analysis (BIA) had a 5-year horizon and calculated the population on immunobiologics based on historical DATASUS percentages. A probabilistic sensitivity analysis was conducted using 1,000 random simulations, with the following variables: relative remission maintenance and risk, patient weight, CZP share, withdrawal, switching and enrollment rates and costs. **RESULTS:** In the CMA, the costs calculated for 10-year treatment were: BRL 149k (IFX); BRL 118k (ADA) and BRL 83k (CZP). The probabilistic sensitivity analysis showed CZP to be less costly than comparators in all simulations. The BIA indicates that CZP provides a cost-saving of BRL 317k for the assumed 100-patient cohort over a 5-year period. **CONCLUSIONS:** CZP was shown to provide a cost-saving option over other anti-TNFs in the Brazilian private healthcare system.

PGI14 INCREMENTAL EXPENDITURES ASSOCIATED WITH RECURRENCE OF DIVERTICULITIS

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OBJECTIVES: To evaluate incremental expenditures associated with recurrence of diverticulitis and identify the primary driver of the incremental total expenditure. **METHODS:** We conducted a retrospective cohort study on the Kaiser Permanente Southern California Health Plan adults (18+ years) who had acute diverticulitis (incident cases) during 01/01/2007 to 12/31/2011. We identified medical expenditures (2016 USD) associated with inpatient (ip_exp) including emergency department, and outpatient (op_exp) visits during the one year period after the index date for patients without recurrence and one year after the recurrence date for those who had recurrence within one year of the index date. Total expenditure (tot_exp) was the sum of op_exp and ip_exp. A generalized linear model with log link and gamma distribution was specified which adjusted for socio-demographics, insurance, Elixhauser comorbidity, clinical complications at presentation and dummy variable identifying recurrence. To estimate ip_exp, we specified a two part model. **RESULTS:** We identified 30,715 incident cases of whom 14% had a recurrence within a year of their index date. The average adjusted tot_exp was \$8,325 (95% CI \$8,172 to \$8,478) for those without recurrence while it was \$11,932 (\$11,389 to \$12,474) in those who experienced a recurrence. The average adjusted op_exp was \$3,559 (\$3,516 to \$3,601) while ip_exp was \$4,776 (\$4,644 to \$4,908) amongst those without recurrence. For those with recurrence, the estimates for op_exp and ip_exp were \$4,335 (\$4,208 to \$4,463) and \$7,380 (\$6,931 to \$7,830) respectively. The incremental difference in tot_exp was \$2,911 (\$2,468 to \$3,355) higher in those who experienced a recurrence and this difference was predominantly driven by ip_exp \$2,056 (\$1,703 to \$2,409). The incremental difference in op_exp was \$685 (\$568 to \$802) higher in those who had recurrence. **CONCLUSIONS:** The recurrence of diverticulitis was associated with significantly higher total expenditure that was predominantly related to increased hospitalization and emergency department visits.

PGI15 LITERATURE REVIEW ON HOSPITAL COSTS FOR PATIENTS UNDERGOING HEPATIC RESECTIONS

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OBJECTIVES: This study aims to identify the range of direct hospital costs associated with a laparoscopic or open hepatic resections across different countries. **METHODS:** A PubMed search was performed using the keywords: hepatectomy [MeSH] and (cost OR economic OR financial) with results limited to publications of human subject studies in English from 2006 to December 2016. Studies comparing laparoscopy to open surgical techniques for hepatic resections were selected and studies of comparisons other than laparoscopy versus open procedures (e.g. robotic) were excluded. All abstracts were filtered, including meta-analysis, RCTs and observational studies excluding case studies. **RESULTS:** Eighteen of 42 studies identified were relevant for this review. The most common laparoscopic hepatic resection was wedge resection or segmentectomy as reflected that 50% of the articles included were limited to segmentectomy. Direct hospital costs varied dramatically across countries. In North America, the total direct cost (day) ranged from \$2,224-\$7,577 for open procedures and \$2,424-\$13,733 for laparoscopy. The cost of operating rooms (minute) ranged from \$16-\$183 for open procedures and \$16-\$161 for laparoscopies. The cost for hospital stay (day) ranged from \$777-\$950 regardless of procedure type. In European countries, the total direct cost (day) ranged from \$1,330-\$3,255 for open and \$1,348-\$4,807 for laparoscopy. The cost of operating rooms (minute) ranged from \$27-\$45 for open procedures and \$33-\$50 for laparoscopy. The cost for hospital stay (day) ranged from \$368-\$1,143. In Asia, the total direct cost (day) ranged from \$1,028-\$1,108 for open and \$1,566-\$1,866 for laparoscopy. The cost of operating rooms (minute) was approximately \$20 regardless of procedure type. **CONCLUSIONS:** There

are only limited cost studies published for major hepatic resections. Our results are consistent with recent systematic reviews which reported lower overall total hospital costs for laparoscopy primarily driven by shorter hospital stay.

PGI16 TRAJECTORIES OF EXPENDITURES ASSOCIATED WITH ACUTE GASTROINTESTINAL DISEASES

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OBJECTIVES: The long term economic burden of diverticular disease is poorly understood compared to other gastrointestinal (GI) diseases. We evaluated the trajectory of expenditures and incremental differences between Diverticulitis (DV), Appendicitis (AP) and Irritable Bowel Syndrome (IBS) in a managed care organization (MCO). **METHODS:** A retrospective cohort study among patients diagnosed with DV, AP or IBS, between 01/01/2002 and 12/31/2012 was conducted. Direct medical expenditures were obtained by weighting resource utilization with nationally representative reimbursement values. Prior to diagnosis of the incident event (index date), patients were required to be health plan members continuously enrolled for ≥ 12 months (baseline); and at least 60 months post index. We identified medical expenditures (2016 USD) associated with inpatient (IP), emergency department (ED) and outpatient (OP) visits during one, three and five year periods, after the index date. Total expenditure was the sum of IP, ED and OP expenditure. A generalized linear model with log link and gamma distribution was specified which adjusted for the following covariates: age, race, sex, ethnicity, insurance type, and Elixhauser comorbidity. **RESULTS:** We identified total of 38,241 patients of which 65% had IBS, 23% had DV and rest had AP. The average adjusted cumulative total expenditure per patient, in year one was \$16,502, \$13,478, \$8509; in year three was \$52,205, \$76,400, \$56,438; and in year five was \$115,754, \$195,349, and \$143,302 in AP, DV and IBS respectively. While the incremental difference between DV and AP was -\$7,436 (-\$8,043 to -\$6,830) in year one; by year three, DV patients had \$5,369 (\$2,433 to \$8,304) higher expenditure and the difference increased to \$30,670 (\$23,985 to \$37,354) by the end of fifth year. **CONCLUSIONS:** The trajectory of expenditure associated with DV suggests that it exerts significantly more economic burden on per patient basis, as compared to other well studied acute GI diseases.

PGI17 PRICE DYNAMICS OF HEPATITIS C VIRUS THERAPIES IN CROATIA

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OBJECTIVES: To investigate and explain changes of drug prices for hepatitis C virus (HCV) treatments on the Croatian market. **METHODS:** The study is a retrospective analysis, conducted using publicly available pricing lists from the Croatian National Health Insurance Fund. The encompassed period is from November 2012 to July 2016. **RESULTS:** Pegylated interferon alpha-2a (pegIFN) maintained a constant price for a longer period of time due to the lack of direct competition. Boceprevir (BOC) and telaprevir (TPV) were able to maintain a constant price since their entry on the market up until simeprevir (SIM) entered the EU5 (Germany, France, United Kingdom, Italy, and Spain) market. Consequently, prices of TPV and BOC dropped (6% and 11%, respectively) remaining at that level even after SIM entered the Croatian market. The market entry of sofosbuvir (SOF) and ombitasvir, paritaprevir, ritonavir, and dasabuvir (OBV/PTV/r/DAS) combination therapy was followed by a significant SIM's price reduction (19%) and the ultimate withdrawal of TPV. In July 2016 BOC experienced a significant drop of its price (16%) probably due to the fact that BOC is not the standard of care anymore. On the other hand, the SIM, SOF and OBV/PAR/r/DAS price drop in July 2016 was negligible (<1%). A price reductions, similar to price reductions on USA market, could not be observed on the Croatian market. **CONCLUSIONS:** HCV drug price reductions have not been under direct impact of competition on the Croatian market but they are rather a consequence of competition on the EU5 and USA markets. The Croatian market is a typical market of a small and open economy without independent price setting. The principal reason for that is the Croatian EU membership with the prohibition of price discrimination, as well as a delayed drug introduction to the Croatian market in comparison to USA and EU5 markets.

PGI18 COSTS AND RESOURCE USE ASSOCIATED WITH OPIOID-INDUCED CONSTIPATION (OIC) IN PATIENTS WITH TOTAL HIP OR TOTAL KNEE REPLACEMENT SURGERY IN THE INPATIENT SETTING

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OBJECTIVES: Constipation is a frequent side effect of opioids. Data that describe the incidence of opioid-induced constipation (OIC) and its impact on costs, resource use, and outcomes in inpatients are limited. The objective of this study was to investigate costs and resource use associated with OIC in patients undergoing total hip or total knee replacement surgery. **METHODS:** This retrospective, cohort study used a large hospital administrative database (Premier Healthcare Database) to identify adults discharged after total hip or knee replacement surgery between January 2012 and June 2015 who received an opioid during hospitalization. The OIC cohort was identified using ICD-9 codes and matched 1:1 to patients without OIC using propensity score matching. Adjusted outcomes were estimated using logistic regression analyses for categorical variables, and generalized linear models for continuous variables; $p < 0.05$

was considered significant. **RESULTS:** Of 788,488 eligible patients, 40,891 (5.2%) had OIC. Post-match OIC and non-OIC patient characteristics were well-balanced. Adjusted analyses showed that compared with patients without OIC, patients with OIC had longer hospital lengths of stay (OIC 3.6 vs. non-OIC 3.3 days, $p < 0.001$), higher costs (OIC \$17,479 vs. non-OIC \$16,265, $p < 0.001$), greater risk of ICU admission (OR = 1.12, $p = 0.028$), 30-day readmissions (OR = 1.16, $p < 0.001$), and 30-day emergency room visits (OR = 1.38, $p = 0.014$). Standard laxative use was prevalent in both cohorts (>85%), although use of newer, targeted OIC treatments (lubiprostone, methylnaltrexone, naloxegol and alvimopan) was rare (<1%). **CONCLUSIONS:** Incidence of OIC in patients undergoing total hip or knee replacement receiving opioids was 5.2% and contributed to significantly greater cost and resource utilization compared with non-OIC patients. The potential impact of OIC therapies on bowel function by measuring pre- and post-operative outcomes can be addressed in future studies.

PGI19

A LITERATURE REVIEW OF THE COST OF OPIOID-INDUCED CONSTIPATION

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OBJECTIVES: Opioid-induced constipation (OIC) is a burdensome side effect of opioid therapy that can impact the management of patients and reduce their quality of life. This literature review sought to assess the economic burden of OIC. **METHODS:** Eight databases (MEDLINE, EMBASE, CDSR, DARE, CENTRAL, HTA, NHS-EED, EconLit) were searched to identify published studies that reported the cost of OIC in patients. Recent abstract books from key pain and health outcome congresses were also interrogated. Results were assessed for relevance by two reviewers. **RESULTS:** Of 279 de-duplicated abstracts identified, a full text review found 11 studies that explored the link between OIC and cost. The USA was the country where most studies were undertaken (5 of the 11), there were two studies from Sweden and then one each from the UK, Netherlands/Belgium, Spain and Brazil. Six studies based their cost analysis on retrospective claims data, three on healthcare resource use data and two on information from healthcare professionals. Seven studies undertook cost comparisons for those with versus without OIC; the other studies estimated the direct costs of managing OIC for a specific episode or time period. Studies almost exclusively focused on healthcare costs, with only two including indirect costs; none included costs borne by patients. The cost of managing patients with OIC was consistently higher than managing those without OIC, with the highest total costs among those with severe constipation. Variation in the attributable costs of OIC and differences in study methods limited comparison between studies. **CONCLUSIONS:** The evidence suggests that OIC poses a significant economic burden that could be reduced with more effective treatment. There is a need to undertake further research across geographies to fully understand the costs incurred over time by healthcare systems, employers and patients.

PGI20

COST-EFFECTIVENESS OF VEDOLIZUMAB COMPARED WITH USTEKINUMAB AS TREATMENT FOR PATIENTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE IN THE UNITED STATES

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Biologic agents are becoming the mainstay of therapy for patients with moderately to severely active Crohn's Disease (CD). Better understanding of relative cost-effectiveness of drugs with new mechanisms of action is needed to help determine the optimal positioning of these therapies in the treatment algorithm and facilitate resource allocation decisions. **OBJECTIVES:** A cost-utility analysis was conducted to compare vedolizumab (VDZ) versus ustekinumab (UST) for treatment of patients with moderately to severely active CD from a third-party US payer perspective. **METHODS:** A model combining decision-tree and Markov structures was used to predict clinical and economic outcomes at the induction and maintenance phases of treatment. This analysis considered patients who were anti-TNF naive/non-anti-TNF refractory at the time of VDZ/UST treatment initiation within 5-year, 10-year, and lifetime horizon. Efficacy data were derived from a Bayesian network meta-analysis of VDZ and UST phase 3 trials¹; other inputs were obtained from published literature. Only direct healthcare costs were considered. Clinical outcomes were expressed as quality-adjusted life-years (QALYs). Univariate and multivariate probabilistic sensitivity analyses (PSA) were conducted to assess model robustness to parameter uncertainty. **RESULTS:** Patients treated with VDZ accrued more QALYs than patients treated with UST across all time horizons: 2.479 vs. 2.406 at 5 years, 4.308 vs. 4.220 at 10 years, 10.461 vs. 10.326 in lifetime analysis. The estimated cost difference was also in favor of VDZ: -\$51,432 at 5 years, -\$52,676 at 10 years, -\$55,523 in lifetime analysis. Univariate sensitivity analyses suggested that results are mostly sensitive to treatment response; PSA showed that VDZ is dominant in 89.6% of the simulations. **CONCLUSIONS:** The model predicted that VDZ treatment results in a higher number of QALYs gained at lower cost compared with UST in CD patients who had not failed a prior anti-TNF agent. Additional comparative effectiveness studies to confirm these findings are warranted.

PGI21

THE COST-EFFECTIVENESS OF ALBUMIN IN THE TREATMENT OF DECOMPENSATED CIRRHOSIS AND ASCITES REQUIRING LARGE VOLUME PARACENTESIS

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OBJECTIVES: Ascites is the most common complication of cirrhosis. Large volume paracentesis has become routine treatment for patients with large ascites. Plasma

expanders are recommended in large volume paracentesis to prevent circulatory dysfunction. The objective of this analysis was to evaluate the cost-effectiveness of various US plasma expanders, albumin, saline or no fluid, in patients with decompensated cirrhosis and ascites requiring large volume paracentesis. **METHODS:** A decision tree cost-effectiveness analysis was developed to evaluate the cost-effectiveness of various treatments for decompensated cirrhosis from a US hospital perspective using a 3 month time horizon. The model comparators included available US treatments: albumin, saline, and no fluid. Costs in the model included pharmacy costs and medical costs for the cirrhosis complications of hyponatremia, renal dysfunction, and hepatic encephalopathy. Effectiveness inputs were literature-based and included mortality as well as the rates of medical complications. QALYs were calculated based on health state utilities for decompensated cirrhosis and encephalopathy. The primary model results were incremental cost-effectiveness ratios (ICERs) for cost per life saved and cost per QALY. **RESULTS:** Despite albumin having higher pharmacy costs (\$261) than saline (\$6) and no treatment (\$0), the total cost per patient was lower with albumin (\$2,583) than saline (\$3,356) and no fluid (\$3,907) due to lower medical complication costs with albumin (\$2,322) compared to saline (\$3,350) and no treatment (\$3,907). The results showed that albumin had the highest survival rate (97.9%, 95.7%, and 96.2% for albumin, saline and no fluid) and gained the most QALYs (0.719, 0.698, and 0.701, respectively). In the cost per life saved and cost per QALY analyses, albumin dominated (i.e. more effective and less costly) saline and no fluid alternatives. **CONCLUSIONS:** This analysis suggests that albumin is the most cost-effective treatment for patients with decompensated cirrhosis with ascites requiring large volume paracentesis.

PGI22

THE COST-EFFECTIVENESS OF THE NEW DIRECT ACTING ANTIVIRALS IN THE TREATMENT OF CHRONIC HEPATITIS C GENOTYPE 1 AND GENOTYPE 4: A SYSTEMATIC REVIEW

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OBJECTIVES: The aim of this study is to systematically review the literature on cost-effectiveness studies conducted on the treatments of chronic hepatitis C genotype 1 and genotype 4 globally utilizing the new direct acting antivirals. **METHODS:** Online Database search was performed using PubMed, Embase and CEA Registry for all articles using the keywords "chronic hepatitis C," "cost-effectiveness," "genotype 1", and "genotype 4". That yielded 358 articles. All articles that didn't include one of the new DAA's as a comparator alone or in combination were excluded. Articles that didn't include G1, G4 or treatment-naive population were also excluded. Co-infection was not considered in this review. **RESULTS:** A total of 16 articles were included in this systematic review. Ombitasvir/ Paritaprevir/ Ritonavir/ Dasabuvir was dominant in most cases in treating CHC G1 and G4 patients with SVR above 90%. Sofosbuvir/ Ledipasvir is a competitive alternative. In one study, a head to head comparison revealed that Ombitasvir/ Paritaprevir/ Ritonavir/ Dasabuvir was cost-effective for G1. Studies in other countries (Germany, France, Portugal and UK) revealed similar results with Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir as the cost-effective option. Another study showed that Sofosbuvir and Simeprevir overcame Sofosbuvir/ Ledipasvir superiority in the base case analysis, but in further sensitivity analysis Sofosbuvir/Ledipasvir remained the cost-effective choice in 70% of cases. **CONCLUSIONS:** Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir is the most cost-effective option in the treatment of CHC G1 and G4, but with the reduction in Sofosbuvir/Ledipasvir price this might overcome the gap between those two drugs. Keeping these two options available for the public is important for financial flexibility within the population. Further studies should be conducted from a societal perspective using real-world data in order to account for the indirect costs associated with each treatment and to reflect the actual cure rate of each population according to its characteristics.

PGI23

PHARMACOECONOMICS EVALUATION OF PEGYLATED INTERFERON FOR CHRONIC HEPATITIS C OF DIFFERENT GENOTYPES—BASED ON CHINESE PATIENTS

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OBJECTIVES: This study aimed to perform a pharmacoeconomics evaluation of pegylated interferon α -2a and interferon based on Chinese chronic hepatitis C patients of different genotypes. **METHODS:** The chronic hepatitis C patients were divided into genotype 1 and non-genotype 1. Markov models were built respectively to simulate chronic hepatitis C developmental process of Chinese patients. We had evaluated the cost and utility of pegylated interferon α -2a and interferon by running 50 cycles of the models and deterministic and probabilistic sensitivity analysis were carried out. Initial age of the patients were set to be 40 according to the literature. Efficacy of these two therapies was derived from 19 Chinese randomized controlled trials by making a meta analysis. Utility of different states in the model was obtained from one survey of Chinese chronic hepatitis and the transition probability come from foreign original literature. Resource use and unit cost data were obtained from the literature and validated by Chinese clinical experts. **RESULTS:** Cost-utility analysis results showed that for genotype 1 chronic hepatitis C patients, pegylated interferon α -2a had lower cost (183631.14RMB vs 212703.42RMB) and higher utility (14.06QALY vs 12.32QALY), which proved pegylated interferon α -2a was cost-effective; with regard to non-genotype 1 patients, pegylated interferon α -2a had higher cost (112770.18RMB vs 111025.80RMB) and higher utility (15.01QALY vs 14.51QALY), and the incremental cost-utility ratio was 3488.76RMB/QALY (lower than Chinese threshold), pegylated interferon α -2a was cost-effective. In the sensitivity analysis, the results were similar with base case analysis. **CONCLUSIONS:** Pegylated interferon α -2a is cost-effective than interferon both for genotype 1 and non-genotype 1 chronic hepatitis C patients in China.

PGI24

COMPARATIVE EFFECTIVENESS OF SURGICAL MANAGEMENT OF COMPLICATED DIVERTICULITIS

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OBJECTIVES: To identify the average treatment effect (ATE) and the treatment effect in the treated (ATE_T) of surgical management of complicated diverticulitis compared to medical treatment in terms of total expenditure. **METHODS:** We designed a retrospective cohort study on the Kaiser Permanente Southern California Health Plan adults (18+ years) who had complicated diverticulitis (incident cases) during 01/01/2007 to 12/31/2011. Complicated diverticulitis was defined as presence of either of abscess, intestinal obstruction, pneumoperitoneum, fistula or peritonitis. We identified medical expenditures (2016 USD) associated with inpatient, emergency department and outpatient visits during the one year period after the diagnosis date for patients without surgery and one year after the surgery date for those who had a colon surgery within one month of the index diagnosis. Total expenditure was the summation of all expenditure categories. Using a potential outcomes framework and doubly robust inverse probability weighted regression adjustment model, we evaluated the ATE and ATE_T of surgical vs medical management of complicated diverticulitis. The covariates adjusted in the model included socio-demographics, insurance, and Elixhauser comorbidity. **RESULTS:** We identified 1320 incident cases of whom 144 had a colon surgery within one month of their index date. The average adjusted total expenditure during follow-up was \$36,706 (95% CI \$ 32,678 to \$40,734) for those with surgery while it was \$15,760 (\$14,806 to \$16,714) in those who did not undergo a colon surgery. The ATE indicated \$20,300 (\$16,173 to \$24,426) higher cost for surgical management of diverticulitis while ATE_T indicated \$19,033 (\$15,124 to \$22,943) higher cost. **CONCLUSIONS:** Under the strong ignorability assumption, we find little support for heterogeneity of treatment effects since ATE and ATE_T were nearly similar. For a randomly selected diverticulitis patient presenting with complication and treated with surgery, the expected total expenditure would be \$20,300 higher in the first year after such surgery.

PGI25

THE WORK PRODUCTIVITY BURDEN OF OPIOID-INDUCED CONSTIPATION - A LITERATURE REVIEW

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OBJECTIVES: Opioid induced constipation (OIC) can impact work productivity so that a person is unable to go to work (absenteeism), or is impaired at work (presenteeism). The objective of this literature review was to identify studies that investigated productivity burden in patients with OIC. **METHODS:** A literature review was undertaken to identify studies in patients with cancer and without cancer that quantified the work productivity burden of OIC. Searches were conducted in August 2016 in bibliographical databases: MEDLINE, EMBASE, CDSR, CENTRAL, DARE, HTA and NHSEED. Abstract books of recent congresses were also searched. Results were assessed for relevance by two reviewers and data extracted. **RESULTS:** 703 de-duplicated abstracts were identified, a full text review identified eight relevant studies. All the studies were quantitative (four included the WPAI questionnaire), most (n=6) were undertaken in the USA and three sourced data from a large international study. In studies including both cancer and non-cancer patients data were sourced from the NHWS, a GP survey, a patient survey and an observational study, all showed a negative impact on productivity in OIC patients (three of these studies reported absenteeism, one presenteeism and one overall work burden). In one, a comparative study using NHWS data, those with OIC had ~25% greater time off work, impairment working and overall work impairment than those without OIC. In the non-cancer population data came from a large international longitudinal study (two studies), the NHWS and a patient survey. Studies reported a negative impact on productivity in patients with OIC (absenteeism and presenteeism in three studies, overall productivity burden in one). **CONCLUSIONS:** This review identified a small number of studies on the productivity impact of OIC. The findings from these studies suggest that OIC has a detrimental impact on both absenteeism and presenteeism. Larger studies are however needed to confirm these findings.

PGI26

ECONOMIC BURDEN OF MAJOR COMPLICATIONS IN PATIENTS UNDERGOING LOWER ANTERIOR RESECTION SURGERY: A REAL-WORLD DATABASE STUDY

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OBJECTIVES: To estimate economic burden of three major complications: anastomotic leak (AL), bleeding and infection, in patients undergoing lower anterior resection (LAR) surgery. **METHODS:** The Premier Perspective® Database containing billing data from over 600 hospitals in the U.S was used. Included patients were > 18 years of age and had an elective LAR from 2008 to 2014. AL, bleeding and infection, were identified using ICD-9 diagnosis codes. Generalized Estimating Equations (GEE) models were used to estimate impact of each complication on length of stay (LOS), operating room time (ORT) and hospital costs (HC) after controlling for patient, procedure, and hospital factors. GEE accounted for the clustering of patients within hospitals; separate models were run for each complication. **RESULTS:** A total of 13,789 patients underwent LAR with an average age of 62.1 (range: 18-89) years. Incidence of AL, bleeding and infection was 12.7%, 9.1% and 5.6% respectively. On average, the LOS, ORT and HC of the LAR patients were 6.4 (SD: 4.8) days, 235.2 (SD: 215.9) minutes, and \$19,030 (SD: \$15,846). In the GEE models, LOS was 80.8% (95% CI: 74.2%-87.6%), ORT 9.7% (6.7%-12.8%), and HC 58.5% (51.9%-65.4%) higher in patients who had AL than those who did not have AL. Similarly, LOS, ORT and HC were 35.3% (29.3%-41.6%), 10.7% (7.7%-13.8%), and 36.7% (29.7%-44.0%) higher in patients with bleeding. Consistent results were observed for

infection with 115.3% (102.6%-128.8%), 11.0% (6.1%-16.2%), and 106.0% (91.5%-121.7%) higher LOS, ORT and HC in patients with infection compared to those who did not incur an infection. The differences of all measures between patients with a complication and those without it were statistically significant (p<0.0001). **CONCLUSIONS:** This study demonstrates that complications such as AL, bleeding and infection occur frequently in LAR and are associated with significant economic burden.

PGI27

EVIDENCE MAP OF ECONOMIC BURDEN STUDIES IN PANCREATITIS SINCE 1960

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OBJECTIVES: To create an evidence map of studies reporting the direct and indirect costs and resource use associated with different types of pancreatitis, and the geographical settings in which these studies were conducted. **METHODS:** We searched the heoro.com database (www.heoro.com) for costs and resource use studies in pancreatitis published between 1960 and 1st December 2016. We analysed the abstracts identified by the search to determine the different types of economic burden outcomes cited across the range of geographical locations, subtypes of pancreatitis and interventions. We presented the findings as an evidence map. **RESULTS:** We found a total of 197 abstracts. Of these, 180 reported resource use data from at least 32 countries, 95 reported direct costs from 19 countries and 11 reported indirect costs from 7 countries. Most studies (65) were conducted in the United States, with 21 abstracts from China, 16 from the UK, 11 from Germany, 10 from Italy, 8 from the Netherlands and 6 each from Japan and Spain. Acute severe necrotising pancreatitis was the focus of 51 studies, mainly from China and the US, chronic pancreatitis in 47 studies, mainly from the US, biliary pancreatitis in 48 studies, mainly from the US, China and Italy, and alcoholic pancreatitis in 19 studies, mainly from the US and UK. Interventions studied included surgical, endoscopic and nutritional interventions, lithotripsy and radiotherapy. Pharmaceutical interventions evaluated included octreotide, gabaxate, antibiotics and protease inhibitors. **CONCLUSIONS:** As with many diseases, there is a relative lack of published data on indirect costs of pancreatitis, and two-thirds of studies reporting direct cost data were from four jurisdictions: the US, China, the UK and the Netherlands.

PGI28

THE EFFECT OF COMORBIDITIES ON HOSPITALISATION AND MISSED WORK AMONG NON-ALCOHOLIC FATTY LIVER DISEASE (NAFLD) PATIENTS

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OBJECTIVES: Non-alcoholic fatty liver disease (NAFLD) and, more specifically, non-alcoholic steatohepatitis (NASH) are expected to become the most frequent indications of liver transplantation. The aim of this analysis was to investigate the burden of NAFLD with respect to hospitalization and work loss in the US. **METHODS:** Data from Ipsos' NASH Therapy Monitor were analysed; the NASH Therapy Monitor is a retrospective medical chart review of NAFLD patients in the US, fielded from September to November 2016. N=174 physicians provided patient demographics, disease status, comorbidities, testing, and treatment data on their most recent 5-10 NAFLD patients. Clinical and economic outcomes were reported descriptively; logistic regression models were conducted to identify factors associated with the likelihood of hospital admission and missed work (i.e., absenteeism). **RESULTS:** N= 1622 patients with NAFLD were included (59% male, mean age 52 years [SD = 8.8], mean BMI=34.8 [SD=11.8]). Of these, 53% had NASH confirmed through a NAFLD Activity Score (NAS) of 4 and above. Subanalysis of patients without missing hospitalization information (n=863) showed that 14% had spent at least one day in hospital because of NASH in the last 3 months; the median length of stay was 4.0 days. Subanalysis of employed patients without missing absenteeism data showed 16% missed work due to NASH in the last 3 months. The strongest predictors of a hospitalization were hepatitis B (odds ratio [OR]=4.9), hepatitis C (OR=4.9), and metabolic syndrome (OR= 2. 8) (all p<.05). Similar factors were associated with absenteeism: hepatitis C (OR=9.6), HIV (OR=6.1), and metabolic syndrome (OR=5.2) (all p<.05). **CONCLUSIONS:** NAFLD and NASH place a significant burden on the total healthcare system and to society. Hospital stays and loss of productivity may be reducible by prioritising treatment of patients with HCV, HBV and metabolic syndrome to prevent escalation of their condition.

GASTROINTESTINAL DISORDERS - Patient-Reported Outcomes & Patient Preference Studies

PGI29

ADHERENCE TO 5-AMINOSALICYLATES AND ITS RELATION WITH QUALITY OF LIFE AND HEALTH CARE RESOURCE UTILIZATION IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE: EVIDENCE FROM US NATIONAL SURVEY DATA

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OBJECTIVES: To evaluate adherence to 5-aminosalicylate (5-ASA) therapy and its association with health-related quality of life (HRQoL) and health care resource utilization in inflammatory bowel disease (IBD). **METHODS:** This was a retrospective study. Data were drawn from the Household Component of the Medical Expenditure Panel Survey (MEPS-HC) for 2010-2014 (178,948 yearly observations). Analysis was limited to data for adults who were identified with IBD (ICD 9 code of 555/556), received 5-ASA for IBD, and were in-scope during all rounds of MEPS-HC. Adherence was quantified as the proportion of days covered (PDC); a PDC ≥ 0.80 was classified as adherent. HRQoL was assessed with SF-12. Descriptive statistics were calculated, association were analyzed with generalized linear models. **RESULTS:** The study sample consisted of 94 yearly observations (mean±SD age: 49.72±15.79, female: 57.45%); 73.40% of observations were from nonadherent patients. Crude and age-sex

adjusted results indicated that adherence to 5-ASA had a significant association with SF-12 Mental Component Summary (CS) score (both $P < 0.01$); in age-sex adjusted analysis the mean difference was 5.81 (95% CI: 1.85-9.77) between adherent and nonadherent patients. Neither analysis found relationship between adherence and SF-12 Physical CS score. For the number of yearly emergency room (ER) visits, crude analysis showed significant association with adherence (yearly ER visit rate ratio in the adherent sample was 31.54% of the rate of the nonadherent sample; 95% CI: 0.10-1.02; $P = 0.05$); its effect was not significant after controlling for age, sex and insurance coverage. In crude and age-sex-insurance adjusted analyses adherence had a significant effect on the number of yearly hospitalizations (both $p < 0.01$); no hospitalization occurred in the adherent sample. Adherence showed no relation with yearly number of outpatient visits. **CONCLUSIONS:** Adherence to 5-ASA therapy is poor among adults with IBD. Mental component of HRQoL, and frequency of ER visits and hospitalization are strongly associated with adherence to 5-ASA in IBD.

PGI30

CORRELATES OF TWELVE WEEK TREATMENT ADHERENCE AMONG PATIENTS WITH HEPATITIS C NEWLY INITIATING DIRECT ACTING ANTIVIRAL THERAPIES INCLUDING SOFOSBUVIR CONTAINING, LEDIPASVIR/SOFOSBUVIR AND OMBITASVIR/PARITAPREVIR/RITONAVIR -DASABUVIR REGIMENS

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OBJECTIVES: To identify clinical, demographic and healthcare delivery correlates of 12 week treatment adherence among patients initiating direct acting antivirals (DAAs) including sofosbuvir-based (with ribavirin or ribavirin+peginterferon or sofosbuvir), ledipasvir/sofosbuvir -based and ombitasvir/paritaprevir/ritonavir-dasabuvir -based regimens. **METHODS:** Patients of a regional health plan in Western Massachusetts with ≥ 1 prescription claim for a DAA agent between January 1, 2014 and April 1, 2016, eligible for coverage 6 months before and after DAA initiation were included. The primary outcome was 90 day adherence defined as proportion of days covered (PDC) $\geq 90\%$. Independent variables included baseline comorbidities (HIV, opioid dependence, mental and general health comorbidities), DAA treatment modality (three broad regimens described above), type of insurance coverage (commercial vs Medicaid (MassHealth)), initial prescription cost-sharing, prescriber specialty (gastroenterology/hepatology vs other) and type of dispensing pharmacy (mail-order specialty vs hospital specialty pharmacy). The covariates included age, gender and year of therapy initiation. **RESULTS:** In total, 138 patients were included in the analyses. Overall, 70.3% of patients had PDC of $\geq 90\%$ with mean (SD) PDC of 73.7% (18.7). The multivariate logistic regression analysis showed that presence of HIV diagnosis (OR = 0.14; 95% CI, 0.02-0.91) and type of insurance coverage (OR = 7.51; 95% CI, 1.98-28.47) were significantly associated with 90-day DAA adherence. Patients with HIV and those covered by MassHealth were significantly less likely to fill 12 weeks of DAA-based therapy. Type of dispensing specialty pharmacy, prescriber specialty, opioid dependence and cost-sharing were not associated with 90-day adherence in this study ($p > 0.05$). **CONCLUSIONS:** With significant expansion of access to DAA therapy among Medicaid patients in Massachusetts in August 2016, additional adherence support is needed to ensure patients complete the course of treatment and achieve treatment response. Prescribers may also consider providing adherence support to patients with comorbid HIV diagnosis to ensure DAA treatment completion.

PGI31

PRO INSTRUMENTS USED IN STUDIES OF HEPATITIS C SINCE 1960

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OBJECTIVES: To create an evidence map of the different patient-reported outcome instruments used in studies of patients with hepatitis C infection and the geographical settings in which these studies were conducted. **METHODS:** We searched the heoro.com database (www.heoro.com) for PRO studies on hepatitis C (including chronic hepatitis C infection) published between 1960 and November 28 2016, and analysed the abstracts identified by the search to determine the different PRO instruments cited across the range of geographical locations. We presented the findings as an evidence map. **RESULTS:** We found a total of 171 abstracts that reported the use of 55 different PRO instruments. Of these 55 instruments, six were specific for liver disease or hepatitis C infection, 38 were general instruments used to evaluate quality of life, utilities or non-disease-specific symptoms such as fatigue, and 11 were specific for other conditions or diseases that were common comorbidities of people with hepatitis C infection. By far the most popular instrument was the SF-36, cited in 80 abstracts, with other tools that can be used to derive utility values, such as the EQ-5D and Health Utilities Index, also being used in several studies. Of the disease-specific instruments, the most widely used was the Chronic Liver Disease Questionnaire, cited in 12 abstracts, followed by the Hepatitis Quality of Life Questionnaire and the Liver Disease Quality of Life Questionnaire. Comorbidities assessed were generally anxiety and depression and HIV co-infection. Sixty studies were conducted in the United States, with 13 abstracts each from Germany and Australia/New Zealand, 11 from Canada and 8 from the United Kingdom. **CONCLUSIONS:** Most studies assessing patient-reported outcomes in hepatitis C have used general rather than disease-specific tools, in particular the SF-36, and were most commonly in a US population.

PGI32

PATIENTS' UNDERSTANDING OF REPORTING STOOL FREQUENCY IN CLINICAL TRIALS

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OBJECTIVES: Clinical trials for gastrointestinal (GI) tract diseases often involve patient-reported outcome (PRO) item, specifically stool frequency, as a primary

outcome measure. The aim of this study was to examine patients' understanding of how to accurately report stool count. **METHODS:** 451 participants, including 87 participants diagnosed with at least one of GI related disease (e.g., Gastroesophageal Reflux Disease, Irritable Bowel Syndrome, Ulcerative Colitis, and Crohn's disease), completed an online survey. Participants were asked "If you were participating in a clinical trial that asked you to record the number of stools you had each day and you had a stool and returned to the bathroom 5 minutes later and had a second stool, would you record this as 1 stool or 2 stools?" in a multiple choice format. Demographic information, including age, education level, and household income were also recorded. **RESULTS:** 66.3% of participants with GI related diseases provided the correct answer, 2 stools. 33.7% of participants chose the incorrect answer, where 18.2% indicated that they did not have enough information to answer the question, 9.4% stated that it depended on the amount of stool at each occurrence, and 6.1% chose 1 stool. Participants without GI related disease scored similarly with 66.4% answering correctly. The two groups did not differ in age, education, or household income. **CONCLUSIONS:** Though the majority of the participants answered the question correctly regardless of whether they were diagnosed with a GI related disease, results suggest that a third of participants were not able to determine and accurately record the stool frequency in the given scenario. These findings are consistent with regulatory guidance from the FDA (2012) on providing patients with standardized instructions and training on completing diaries for recording stool frequency.

PGI33

A SYSTEMATIC REVIEW OF THE INFLAMMATORY BOWEL DISEASE QUESTIONNAIRE FOR MEASURING HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH ULCERATIVE COLITIS

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OBJECTIVES: Ulcerative colitis (UC), an inflammatory bowel disease, substantially impacts patients' health-related quality of life (HRQL). The Inflammatory Bowel Disease Questionnaire (IBDQ) is a disease-specific measure capturing impact of UC on four domains of functioning and well-being: Bowel symptoms, Systemic symptoms, Emotional function, and Social function. Despite its frequent use in UC clinical trials, there is no recent summary of measurement properties in UC. We conducted a systematic literature review of the reliability, validity, and responsiveness of the IBDQ in UC. **METHODS:** Search strings with relevant terms were entered in PubMed, EMBASE, Cochrane CENTRAL, and BIOSIS Weekly databases. English-language articles reporting on measurement properties of the IBDQ among UC patients were reviewed. Data about specific psychometric properties were extracted and summarized across studies. **RESULTS:** Thirty-seven articles met selection criteria. The abstracted and synthesized evidence support the following conclusions about psychometric properties of the IBDQ in UC: (1) Good internal consistency (Cronbach's $\alpha \geq 0.70$) and test-retest reliability (intraclass correlations ≥ 0.70) for all IBDQ domains; (2) Good convergent validity, based on correlations between IBDQ domains and validated criterion measures of patients' functioning and well-being (mean/median $r = 0.52/0.51$, 83% of $r \geq 0.40$) and measures of disease activity (mean/median $r = 0.62/0.51$, all $r \geq 0.40$); (3) Good discriminant validity, indicated by effect sizes (Cohen's d) for standardized mean differences in IBDQ domain scores across UC patients grouped by disease activity status (mean/median $d = 1.7/1.9$, 100% of $d > 0.50$); and (4) Good sensitivity to change, based on statistically significant treatment-arm differences ($p < 0.05$) in IBDQ total scores in 72% of randomized-controlled trials (RCTs) with efficacious treatments. **CONCLUSIONS:** The IBDQ demonstrates good psychometric properties with UC patients. IBDQ domains strongly concord with measures of clinical disease activity. In RCTs, IBDQ scores reflect improvements following efficacious treatment. These results support including the IBDQ as an endpoint in RCTs to evaluate treatment effects on UC patients' HRQL.

PGI34

COMPARISON OF PARTICIPANT CHARACTERISTICS IN THE REAL-WORLD OBSERVATIONAL CONTOR STUDY WITH THOSE IN RANDOMIZED CLINICAL TRIALS (RCT): ARE REAL-WORLD PATIENTS LIKE CLINICAL TRIAL PATIENTS?

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OBJECTIVES: To compare characteristics among irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC) patients who participated in CONTOR, a real-world longitudinal research platform, with linaclotide randomized clinical trials (RCTs) to assess similarities between real-world and clinical trial patients. **METHODS:** This analysis utilized data from CONTOR compared with data pooled from four linaclotide Phase III RCTs. CONTOR included fully-insured IBS-C/CIC patients aged ≥ 18 years from a large US health plan (identification period: 12/2012-6/2015). Participants' demographics, daily abdominal symptoms (0-10 scale), work productivity (WPAI-SHP), and health status (SF-12v2 Physical/Mental Component Summary scores [PCS/MCS]) were compared between CONTOR participants at baseline (CONTOR-BL), and RCT participants at baseline (RCT-BL) and week 12 (RCT-wk12). Satisfaction with linaclotide was evaluated at CONTOR-BL and RCT-wk12. CONTOR participants were considered linaclotide-treated if they took linaclotide in the week prior to CONTOR-BL. Descriptive analyses were performed. **RESULTS:** Across 2,052 CONTOR and 2,875 RCT participants, age and gender were similar (mean age [years]:

CONTOR: 47; RCTs: 46; Female: CONTOR: 94%; RCTs: 90%). CONTOR abdominal symptoms (pain, discomfort, bloating) were less severe compared to RCTs (CONTOR-BL mean: 2.9, 3.6, 3.9; RCT-BL: 5.6, 6.1, 6.6; RCT-12wk: 3.7, 4.1, 4.7). Mean PCS was similar in CONTOR and RCT populations (CONTOR-BL: 50; RCT-BL: 47; RCT-wk12: 51). Mean CONTOR MCS was worse compared to RCTs (CONTOR-BL: 43; RCT-BL: 47; RCT-wk12: 50). CONTOR participants lost more work time than RCT participants (CONTOR-BL: 3.3%; RCT-BL: 2.3%; RCT-wk12: 1.3%). A greater number of linaclotide-treated patients from CONTOR reported satisfaction with linaclotide (CONTOR-BL (n=354):86%; RCT-wk12 (n=1,637): 67%). **CONCLUSIONS:** CONTOR participants were generally similar to RCT patients at week 12, with some differences in MCS and work productivity. Findings indicate linaclotide RCT results are likely generalizable to real-world IBS-C/CIC patients, with observed differences potentially due to differing RCT and real-world study designs.

PGI35

A LITERATURE REVIEW OF THE QUALITY OF LIFE BURDEN OF OPIOID-INDUCED CONSTIPATION

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OBJECTIVES: Opioid-induced constipation (OIC) is a side effect of opioid medication; it has been suggested that it may be more distressing than the pain of the condition itself. The objective of this literature review was to describe studies reporting the quality of life (QoL) burden of OIC. **METHODS:** A literature review was undertaken to identify studies on the QOL burden of OIC. Six electronic databases (MEDLINE, EMBASE, CDSR, DARE, CENTRAL, HTA) were searched to identify published manuscripts that reported the QOL burden of OIC. In addition, recent abstract books from key pain and health outcome meetings were interrogated to identify relevant research presented at congresses. Results were assessed for relevance by two reviewers and data extracted. **RESULTS:** 413 de-duplicated abstracts were identified and a full text review resulted in the selection of 12 manuscripts and one congress abstract (5 noncancer only, 3 cancer only, 5 combined population). Most studies were quantitative (n=12); there was one qualitative study. Five studies compared QOL in patients with OIC versus those without OIC, both generic and disease-specific measures showed QoL to be more impaired in OIC patients. A range of QoL instruments was used with the PAC-QOL (which has not been specifically validated in OIC patients) being the most common (7 studies). A number of key drivers of impaired QoL were identified including high level of constipation, dissatisfaction with laxatives, and increased laxative frequency. **CONCLUSIONS:** The existing evidence shows QoL to be impaired in patients with OIC. More effective treatment of OIC could reduce this burden. Relatively few studies were identified and further international research exploring the impact of OIC on patients over time is recommended. There is also a need to undertake studies to validate the PAC-QOL questionnaire in OIC patients.

PGI36

A REVIEW OF THE QUALITY OF LIFE BURDEN OF NON-ALCOHOLIC STEATOHEPATITIS

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OBJECTIVES: Non-alcoholic steatohepatitis (NASH) is an advanced stage of non-alcoholic fatty liver disease (NAFLD). It can lead to the development of cirrhosis, end-stage liver disease, and complications like hepatocellular carcinoma. This literature review was undertaken to understand the quality-of-life (QOL) burden of NASH. **METHODS:** We searched electronic databases (MEDLINE, EMBASE, CDSR, CENTRAL, DARE, HTA) for manuscripts on QOL and NASH published in the last 10 years as well as recent abstracts from ISPOR, ISOQOL and major liver congresses. Results were assessed by two independent reviewers and key QOL data extracted. **RESULTS:** Of 567 de-duplicated references identified, 20 manuscripts remained after review of titles/abstracts and five after full-text review; two additional manuscripts were identified through grey searching, there was one relevant congress abstract. Of the eight included studies, there were five quantitative studies, two clinical trials (herbal medical treatment, YHK and placebo; pioglitazone, vitamin E, and placebo) and one qualitative study. In the quantitative studies QOL was diminished in patients with NASH compared with an age- and sex-matched US population, and compared to those without NASH (SF-36 PCS), but not compared with other chronic liver disease. NAFLD patients with cirrhosis had lower QOL than non-cirrhotic patients. In patients with weight loss, a larger magnitude of QOL improvement was reported in those with NASH versus those without NASH. Neither clinical trial showed a significant QOL change from baseline. A conceptual framework to measure NASH-specific symptoms and impacts was developed in the qualitative study to help guide the development of a patient-reported outcome measure for NASH. **CONCLUSIONS:** NASH negatively impacts QOL, primarily impacting physical functioning and fatigue. However, the evidence base is limited; further studies are needed to understand the longitudinal QOL burden of NASH in different patient populations. There is a need to quantify the impact of future therapies on QOL.

PGI37

UNDERSTANDING THE COST OF CHRONIC IDIOPATHIC CONSTIPATION: EVIDENCE FROM THE BURDEN-CIC (BETTER UNDERSTANDING AND RECOGNITION OF THE DISCONNECTS, EXPERIENCES, AND NEEDS OF PATIENTS WITH CHRONIC IDIOPATHIC CONSTIPATION) STUDY

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OBJECTIVES: To assess the impact of chronic idiopathic constipation (CIC) on quality of life (QoL), work productivity, daily activities, and indirect costs in a sample of the US population. **METHODS:** The BURDEN-CIC study utilized the Knowledge Network Panel™ to identify CIC patients, who participated in a 45-minute, 68-question, IRB-approved online survey. Healthcare professionals (HCPs) treating CIC patients participated in a 30-minute, 32-question online survey. **RESULTS:** Over 1,100 CIC patients (mean age, 49 years; female, 70%; severe, 67%) completed the survey. Only 23% of patients felt "in control" of their symptoms, with 39% expressing "acceptance" that CIC was part of daily life. Of HCPs (n=331), 72% stated patients had high levels of frustration regarding CIC and were "stressed" (49%) or "fed up" (43%) regarding current treatments. Sixty percent of all CIC patients and 81% of severe CIC patients reported their symptoms bothersome and impacting QoL; daily activity participation was impacted 4 and 9 days/month, respectively. Most patients had used (62%) or were using (53%) OTC treatments for their CIC, with 16% currently using prescription treatment. Of current prescription therapy patients, 35% felt it was "effective," but only 14% reported "good experience/satisfied." HCPs viewed response (55%), adherence (55%), management of CIC-treatment-related diarrhea (34%), and lack of treatment options (34%) as the greatest challenges in CIC treatment. Mean monthly out-of-pocket costs to manage CIC was \$114 (all) and \$182 (severe)—ranging from \$75 for lifestyle/dietary modifications, \$123 for OTCs, and \$413 for prescriptions. Work-place productivity was impacted for 8 days/month (all) and 10 days/month (severe) with an average of 5 work days/month missed. Of all CIC patients, 15% had an emergency room visit related to CIC in the past year. **CONCLUSIONS:** CIC patients have low QoL, significant work and daily activity impairments, and high indirect costs, imposing a burden on patients and employers.

PGI38

RELATIONSHIP BETWEEN DAYS AND VOLUME OF PARENTERAL NUTRITION IN PATIENTS WITH SHORT BOWEL SYNDROME AND HEALTH-RELATED QUALITY OF LIFE - A POST HOC ANALYSIS USING SBS-QOL DATA FROM A PHASE III TRIAL

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OBJECTIVES: Short bowel syndrome (SBS) is a rare condition characterized by patient inability to maintain life with oral feeding, which often is treated with parenteral nutrition (PN). While the overall impact of PN on patient health-related quality of life (HRQL) has been reported by others, it is unknown how it varies in relation to days of PN and PN daily volume. **METHODS:** We used SBS-QOL data collected in a randomized, double-blind, placebo-controlled, phase III trial of teduglutide in adult (aged ≥ 18 years) patients with SBS and intestinal failure (STEPS: NCT00798967; EudraCT2008-006193-15), and its 2-year open-label extension study (STEPS-2: NCT00930644; EudraCT2009-011679-65), to examine the relationship between individual SBS-QOL component scores and days of PN and PN daily volume. Analyses were based on multiple assessments from 86 patients (mean observations per person = 12). **RESULTS:** Mean (SD) age of study participants was 51 (14) years and 47% were women. PN days and PN volume were significantly (P<0.05) associated with adverse impacts on everyday activities, leisure activities, social life, and diarrhea/stomal output. PN days alone was significantly (P<0.05) associated with adverse impacts on general well-being, diet, eating, and drinking habits, ability to work, physical health, emotional life, gastrointestinal symptoms, and other symptoms/discomfort. Daily PN volume alone was significantly (P<0.05) associated with adverse impacts on mobility and self-care activities, sleep, and muscle symptoms. **CONCLUSIONS:** In patients with SBS and intestinal failure, PN adversely impacts HRQL. These adverse impacts are dependent on both PN days and PN volume, and interventions that reduce one or both of these measures accordingly would be anticipated to improve HRQL.

PGI39

THE IMPACT OF PLECANATIDE ON QUALITY OF LIFE FOR PATIENTS WITH CHRONIC IDIOPATHIC CONSTIPATION (CIC): RESULTS FROM TWO PHASE 3 CLINICAL STUDIES

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OBJECTIVES: To investigate whether plecanatide, a uroganylin analog, improved health-related quality of life (HRQoL) in 2 clinical trials of patients with chronic idiopathic constipation (CIC). **METHODS:** Patients meeting modified Rome III CIC criteria were randomized to placebo, plecanatide 3mg or 6mg daily for 12 weeks. The primary endpoint was the proportion of durable overall CSBM responders (≥3 CSBMs plus increase of ≥1 CSBM over baseline in the same week) for ≥9 of 12 treatment weeks, including ≥3 of the last 4 weeks. HRQoL assessments included: Patient Assessment of Constipation-Symptoms (PAC-SYM), PAC-Quality of Life (PAC-QoL), and Treatment Satisfaction. Results are versus placebo. **RESULTS:** Patients (N=2683) had similar baseline characteristics. Pooled efficacy showed significantly greater overall durable CSBM responders with plecanatide 3mg (n=184, 20.5%) and 6mg (n=176, 19.8%) vs placebo (n=103, 11.5%; P<.001 both doses). Significant increases in CSBMs were seen during Week 1 and were maintained through Week 12. Plecanatide 3mg and 6mg significantly improved PAC-SYM at Weeks 4, 8 and 12 in both studies, with a mean change differences at Week 12 of -0.22 (P<.001) and -0.23 (P<.001) [Study 1] and -0.18 (P=.002) and -0.15 (P=.009) [Study 2]. A similar improvement in PAC-QoL was noted for both doses at Weeks 4, 8 and 12 in both studies; the mean change differences at Week 12 for plecanatide 3mg and 6mg were -0.25 (P<.001) and -0.28 (P<.001) [Study 1] and -0.20 (P<.001) and -0.19 (P=.001) [Study 2]. Plecanatide yielded significantly (P≤.001) higher mean treatment satisfaction scores at each assessment point and increased over time. **CONCLUSIONS:** Plecanatide 3mg and 6mg significantly improved bowel symptoms and HRQoL at all time points and increased the proportion of durable overall

CSBM responders. These data suggest plecanatide improves constipation and HRQoL, and therefore may offer a promising new treatment option for CIC patients.

PGI40

CLINICAL, ENDOSCOPIC, AND HISTOLOGIC ACTIVITY PREDICT HEALTH-RELATED QUALITY OF LIFE FOR PATIENTS WITH MILD-TO-MODERATE ULCERATIVE COLITIS TREATED WITH MULTIMATRIX MESALAMINE

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OBJECTIVES: Studies of patients with ulcerative colitis (UC) have established that reduction in clinical symptoms and endoscopic activity each independently predict improved health-related quality of life (HRQL). However, the combined impact of these factors on HRQL has not been examined, nor whether histologic activity predicts HRQL. The current analysis examines individual and combined associations of these 3 types of disease activity with HRQL. **METHODS:** Post hoc, exploratory analyses were conducted on data from patients with active mild-to-moderate UC in an open-label trial who received 8 weeks of treatment with 4.8 g/day of multimatrix mesalamine once daily. Outcomes assessed at baseline and final visits included clinical and endoscopic activity (UC Disease Activity Index [UC-DAI]); histologic activity index (modified Geboes' scoring); disease-specific HRQL (Short Inflammatory Bowel Disease Questionnaire [SIBDQ]); and generic HRQL (SF-12v2[®] Health Survey [SF-12v2]). The individual impact of each type of disease activity on HRQL was examined by comparing changes in SIBDQ and SF-12v2 scores between subgroups classified by disease activity status (eg, achieving clinical remission), while their combined impact was tested using multivariable regression. Hochberg adjusted P values controlled for Type I error. **RESULTS:** Improvements in SIBDQ and SF-12v2 domains were significantly larger for patients with clinically meaningful improvements in clinical and endoscopic activity (all P<0.001), patients with lower histologic activity index scores (all P<0.05), and patients in clinical and endoscopic remission compared to endoscopic remission only (all P<0.05). Findings from regression models indicated that decreased clinical and endoscopic activity, though not histologic activity, uniquely predicted improvement in SIBDQ and SF-12v2 domains. **CONCLUSIONS:** Clinical, endoscopic, and histologic activity have separable, and in some cases additive impacts on UC patients' HRQL. Treatments impacting multiple types of disease activity should result in greater improvements in patients' functioning and well-being than treatments that target clinical, endoscopic, or histologic activity alone.

GASTROINTESTINAL DISORDERS – Health Care Use & Policy Studies

PGI41

ASSESSMENT OF AWARENESS ABOUT HEPATITIS B AMONG HEALTHY POPULATION OF PUNJAB, PAKISTAN

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OBJECTIVES: The study was aimed to assess awareness about hepatitis B among residents of Punjab, Pakistan. **METHODS:** A cross sectional survey was conducted involving 616 respondents from 15th December 2015 to 15th March 2016. Respondents above 18 years of age and those domiciled in Punjab were only the target audience. Data was collected by self-distribution of pre-tested and validated questionnaire at public places like shopping malls, parks, household etc. Data was analyzed through SPSS version 20.0 by applying appropriate statistics. Initially cronbach's alpha was applied to check reliability and validity of study instrument. **RESULTS:** The mean age of the respondents was estimated to be 33.55±10.341. Less than half of participants were employed (43.2%), half (50.2%) were married, a very small proportion (5.0%) had post-graduate educational level and majority belonged to urban settings (74.2%). Both sexes equally participated in the study. Awareness was assessed by asking questions regarding general introduction to hepatitis B like signs and symptoms, infection nature, its modes of spread/transmission, treatment/prevention and disease information source. Qualification, marital status and occupation significantly influenced respondent's knowledge regarding hepatitis B (p<0.05). However, no statistically significant association was noticed regarding gender, age & residency of the study participants. Overall awareness score of respondents was estimated to be 22.28 ± 4.63. **CONCLUSIONS:** Based on findings it was concluded that majority of the participants 89.8% were aware of hepatitis B.

PGI42

FACTORS ASSOCIATED WITH TIME-TO-TREATMENT IN THE NEW DIRECT-ACTING ANTIVIRAL ERA FOR HEPATITIS C PATIENTS IN AN INTEGRATED HEALTH CARE SYSTEM

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OBJECTIVES: New treatments for Hepatitis C offer higher rates of cure with fewer side effects, yet therapy costs are high. While new direct-acting antiviral agents (DAAs) have become the standard of care, providers and payers feel pressured to prioritize treatment due to high drug costs. We aim to examine the association of patient demographic, clinical and provider characteristics associated with DAAs treatment. **METHODS:** Using electronic health record data from Kaiser Permanente Mid-Atlantic States (KPMAS), we constructed a Cox hazards model to examine the association between different patient factors on the "risk" of treatment over the study period. Our study sample included 3,017 patients with a confirmed diagnosis of Hepatitis C from the KPMAS Hepatitis C registry, as per pre-specified clinical criteria. The study period began on November 1, 2013 with the release of the initial second

generation DAAs and concluded on May 31, 2016. **RESULTS:** In a Hepatitis C panel of 3017, 995 patients (33%) initiated DAA therapy over the course of the study period. Most patients were between the ages of 61-80 (55%), Black (67%) and male (62%). About 24% of patients were censored due to death or disenrollment from the health plan prior to the end of follow-up. Log-rank tests at baseline showed differences in probability of treatment by age category, prior treatment experience and race category. A multivariable cox hazards model showed older age, between 40-80 years, so be significantly associated with increased probability of treatment. Differences in fibrosis scores did not significantly change the likelihood of treatment in our sample. **CONCLUSIONS:** While our analysis shows that age impacts time-to-treatment with a DAAs, we need to better understand the reasons for this patterns in treatment. Further research with a longer follow-up period that covers the more recently approved pan-genotypic DAAs may provide more insight into treatment decisions.

PGI43

QUALITY OF CARE IN PATIENTS WITH CIRRHOSIS AND ASCITES, HEPATIC ENCEPHALOPATHY OR SPONTANEOUS BACTERIAL PERITONITIS: A RETROSPECTIVE ANALYSIS OF ELECTRONIC MEDICAL RECORDS

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OBJECTIVES: To assess evidence-based quality metrics in patients with cirrhosis and its complications. **METHODS:** Adults with cirrhosis (ICD-9-CM 571.2 and 571.5) and complications post-diagnosis (ascites [789.59], HE [572.2] and SBP [567.23]) from 2009-2014 were identified from EMR data from an academic health system. Quality metrics for analysis were developed, including: (1) availability of MELD-Na, (2) diuretic therapy for ascites, (3) secondary prophylaxis for SBP, (4) appropriate treatment for HE, (5) SBP primary prophylaxis for qualifying patients, and (6) avoidance of non-recommended medications. Logistic regression was used to assess patient and physician-related factors that predicted achievement of parameters (2) and (4). Data analysis was conducted using SAS 9.4. **RESULTS:** A total of 4,116 patients with cirrhosis were identified: 986 (24.0%) with ascites, 665 (16.2%) with HE and 148 (3.6%) with SBP. A total of 67.54% of patients had a calculable MELD-Na. Receipt of therapy was 57.62% (diuretics) for ascites, 54.29% (secondary prophylaxis) and 60.61% (primary prophylaxis) for SBP and 49.83% for HE. A total of 68.16%, 71.45%, 72.38% of patients with ascites, HE and SBP respectively, were avoiding non-recommended medications. Regression for (2) demonstrated overweight patients (OR 0.665; 95% CI: 0.463-0.957) and non-specialists/non-primary care practitioners (OR 0.402; 95% CI: 0.208-0.775) were less likely to receive and provide quality care, respectively. Results for (4) showed that obese patients (OR 0.458; 95% CI: 0.289-0.725) were less likely to receive quality care. **CONCLUSIONS:** Quality of care was suboptimal and significant deviation in practice from evidence-based guidelines was observed.

NEUROLOGICAL DISORDERS – Clinical Outcomes Studies

PND1

PREVALENCE OF GASTROINTESTINAL EVENTS IN PATIENTS WITH ALZHEIMER'S DISEASE IN JAPAN

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OBJECTIVES: The incidence rate of dementia in Japan for people aged 65 and greater is 15%, with Alzheimer's disease (AD) being the most frequent type of dementia (65.8%). There is no epidemiological data available on the underlying rate of gastrointestinal (GI) events within a Japanese AD population. Therefore, we explored the rate of GI events amongst AD patients compared to matched elderly patients. **METHODS:** This was a retrospective analysis of electronic hospital-based database (Medical Data Vision) utilizing data from 1 August 2012 through 31 July 2015. Inclusion/exclusion criteria included: at least 2 claims for AD (ICD-10: G30.x) at least 1 month apart during the identification period (August 2013 – July 2014); ≥ 55 years old; 1 year look-back; 1 year follow-up. Non-AD elderly patients were propensity score (PS)-matched to AD patients. The PS included age, gender, region, and adjusted Charlson Comorbidity Index (removal of dementia and cerebrovascular diseases). GI events requiring hospitalization were considered severe. Cumulative incidence and 95% confidence intervals were calculated for the total number of GI events and for each event. Groups were compared with a Cox proportional hazard model. **RESULTS:** 14,091 patients were included in both the PS-matched AD and non-AD samples. The average age was 80.8 ± 6.7 and 60.3% female in both groups. PS-matched AD patients had significantly higher cumulative incidence of GI events compared to non-AD patients: all GI events: 48.73 vs 35.91 (p<0.0001), constipation: 45.90 vs 32.73 (p<0.0001), GI bleeds: 2.13 vs 1.60 (p=0.0010); acute gastric ulcer: 0.35 vs 0.18 (p=0.0038); acute peptic ulcer: 0.21 vs 0.11 (p=0.0347). The same GI events plus inflammatory bowel disease were significantly higher in AD in the severe GI sub-analysis. **CONCLUSIONS:** Patients with AD have significantly more GI events than PS-matched elderly patients. This study provides a baseline rate of GI events within an AD population in Japan.

PND2

PATTERNS AND PREDICTORS OF DEPRESSION TREATMENT AMONG ADULTS WITH MULTIPLE SCLEROSIS AND DEPRESSION IN AMBULATORY CARE SETTINGS IN THE UNITED STATES

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OBJECTIVES: The objectives of this study were to identify patterns and predictors of depression treatment in ambulatory settings in the United States (US) among adults with Multiple Sclerosis (MS) and depression. **METHODS:** A cross-sectional study was

conducted by pooling several years (2005-2011) of data from National Ambulatory Medical Care Survey and the outpatient department of the National Hospital Ambulatory Medical Care Survey. The final study sample was identified from ambulatory visits among adults (age ≥ 18 years) with MS and depression. Ambulatory visits with MS were identified by using ICD-9-CM of 340.xx, while visits with depression were identified by ICD-9-CM codes of 296.2-296.36, 300.4 or 311, or if the answer to the question "Regardless of the diagnoses written.....does the patient now have: depression?" was "yes." Dependent variable of this study was pharmacological treatment for depression with or without psychotherapy. Predictors of depression treatment were ascertained by conducting multivariate logistic regression. Complex survey designs of the datasets were adjusted to obtain national level estimates. **RESULTS:** According to the study findings, between 2005-2011 approximately 2.1 million visits involved a diagnosis of MS and depression. Depression treatment was observed in 57.25% of the study sample. Selective serotonin reuptake inhibitors were the most prescribed antidepressant class, and fluoxetine was the most prescribed individual antidepressant in the study sample. Individuals who were 40 years or older were 81% less likely (Odds Ratio=0.189, 95% CI 0.036-0.997) to receive depression treatment compared those who were in the age group of 18-39 years. With the increase in each chronic condition, the likelihood of receiving depression treatment decreased by 44% (Odds Ratio=0.554, 95% CI 0.335-0.917). **CONCLUSIONS:** Approximately six out of ten ambulatory visits involving MS and depression recorded some form of depression treatment. Future longitudinal studies should examine the clinical outcomes associated with depression treatment in this vulnerable population.

PND3

PATTERNS AND PREDICTORS OF DEPRESSION TREATMENT AMONG OLDER ADULTS WITH PARKINSON'S DISEASE AND DEPRESSION IN AMBULATORY CARE SETTINGS IN THE UNITED STATES

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OBJECTIVES: The objectives of this study were to assess the patterns and predictors of depression treatment among older adults with Parkinson's disease (PD) and depression seeking care in ambulatory settings in the United States (US). **METHODS:** We adopted a cross-sectional study design by pooling multiple-year data (2005-2011) from the National Ambulatory Medical Care Survey (NAMCS) and the outpatient department of the National Hospital Ambulatory Medical Care Survey (NHAMCS). The final study sample consisted of visits by older adults (age ≥ 65 years) with PD and depression. PD was identified by using ICD-9-CM code of 332.xx. Depression diagnosis was identified if answer to the question "Regardless of the diagnoses written.....does the patient now have: depression?" was "yes". Depression treatment, which was the dependent variable for this study, was defined as antidepressant use with or without psychotherapy. To identify the predictors of depression treatment, multivariate logistic regression analysis was conducted adjusting for predisposing, enabling, and need factors. Complex survey design of NAMCS-NHAMCS were adjusted in all analyses to obtain nationally representative estimates. **RESULTS:** According to NAMCS-NHAMCS 2005-2011, approximately 1.7 million visits recorded a concurrent PD and depression diagnosis. Depression treatment was recorded in 57.63% of the study sample visits, mainly driven by antidepressant use alone. Men were 64% less likely (Odds Ratio=0.359, 95% CI 0.139-0.932) than women to receive depression treatment. Individuals with PD and depression were 74% more likely (Odds ratio=1.743, 95% CI 1.376-2.209) and 44% less likely (Odds ratio=0.559, 95% CI 0.396-0.790) to receive depression treatment with the increase in each number of medication used and chronic condition respectively. **CONCLUSIONS:** Approximately six out of ten older adults with PD and depression received some form of depression treatment. Future real-world long-term studies should investigate health outcomes associated with depression treatment in this population.

PND4

PREVALENCE OF BEHAVIORAL DISTURBANCES AND ASSOCIATED BURDEN IN PATIENTS WITH DEMENTIA IN US CLAIMS DATA: IS THERE UNDER-REPORTING?

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OBJECTIVES: Behavioral disturbances (BD) such as agitation in patients with dementia/Alzheimer's Disease dementia are challenging to families and adversely impact direct patient care, caregiver burden, and community resources. US administrative health claims are widely available and cover a broad range of patients with detailed/comprehensive data. Yet there are few published studies evaluating BD burden. Study objective was to examine clinical characteristics of BD in patients with dementia using a large representative Medicare Supplemental sample. **METHODS:** Patients diagnosed with dementia (including dementia of the Alzheimer's type) were selected from 6.3 million Medicare beneficiaries in the Truven MarketScan Medicare Supplemental and Coordination of Benefits 2012-2015 database. BD cases were identified using ICD9 diagnosis codes 294.11 or 294.21. Patients were ≥ 65 years old, with continuous medical and pharmacy benefits for ≥ 6 months pre- and post-index date (baseline). Descriptive analyses described prevalence rates and baseline comorbidities/medications. **RESULTS:** 92,054 patients with dementia were identified, of whom 17,351 (19%) had BD. Mean age was approximately 83 years. BD patients had higher Charlson Comorbidity Index scores than non BD cases (1.83 vs 1.66 P<0.0001). During baseline, the more common comorbidities for BD vs non-BD patients were mood disorders (21.5% vs 13.2%), psychotic disorders (20.8% vs 9.6%), and urinary tract infections (20.1% versus 15.4%), respectively. More common baseline medications for BD vs non-BD included anti-dementia drugs (43.8% vs 34.8%), antidepressants (43.4% vs 33.2%), antipsychotics (25.9% vs 8.3%), and antiepileptics (28.8% vs 20.8%), respectively. **CONCLUSIONS:** Study identifies the clinical characteristics of BD in patients with dementia using one of the largest comprehensive patient sample available. While BD

is a common occurrence, the rate obtained in this study is low, potentially indicating either underreporting or lack of symptom recognition and treatment. Additional research is warranted to understand the diagnostic pathway to BD.

PND5

CLINICAL AND HUMANISTIC BURDEN AND UNMET NEEDS IN DUCHENNE MUSCULAR DYSTROPHY

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OBJECTIVES: Therapeutic landscape of Duchenne muscular dystrophy (DMD), a rare genetic disorder which causes severe and progressive muscle weakness, is rapidly changing. Our objective was to conduct a comprehensive review of global epidemiology, patient burden and unmet needs associated with DMD. **METHODS:** We conducted a targeted literature review of studies published from 2010 to 2016. Articles were retrieved for full review if the abstracts: reported prevalence/incidence or patient burden (clinical and humanistic); derived from a peer-reviewed journal; and reported in English-language. **RESULTS:** The prevalence of DMD per 100,000 males was highest in Sweden (16.8) and US (16.0) which varied with age, and the incidence was highest in Canada (27.78) and Denmark (18.80), however most estimates were over 15 years old. Common complications related to DMD included progressive cardiomyopathy, respiratory dysfunction, and orthopedic complications which affected survival. Standard of care (mostly, corticosteroids) prolonged survival but was associated with adverse events and toxicity. The quality of life (QoL) of patients with DMD was lower as compared to healthy population and QoL reduction was associated with disease progression. With a tolerable drug profile and superior efficacy, newer targeted therapies such as ataluren (approved ex-U.S. for patients with nonsense mutation DMD) and eteplirsen (approved in U.S. for DMD patients amenable to skipping Exon 51) have been recently shown to alleviate patient burden. **CONCLUSIONS:** This review highlights a significant clinical and humanistic burden among DMD patients due to lack of ambulation at an early age, short survival and lowered QoL. Epidemiological data may need updating to help accurately estimate DMD population size. With advent of new therapies targeted towards select patient subgroups in DMD, it is important to adequately understand the evolving patient characteristics, current treatment patterns and their impact on patient outcomes in the real world settings.

PND6

FACTORS ASSOCIATED WITH MISDIAGNOSIS AND UNDER-DIAGNOSIS OF ALZHEIMER'S DISEASE: A SYSTEMATIC REVIEW

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OBJECTIVES: Early screening and diagnosis of Alzheimer's disease (AD) and dementia can lead to better life planning and care. However, difficulty in diagnosis still exists and contributes to patients being misdiagnosed or under-diagnosed, resulting in a diagnosis late in the disease course. The objective of this study is to conduct a systematic review of the literature to explore the potential causes and barriers that lead to under-diagnosis and/or a misdiagnosis of AD and dementia. **METHODS:** PubMed database was searched to identify studies published from July 2008 to December 2016. The searching criteria included studies about AD and dementia completed on humans, English language, and published between 2008 and 2016. Two reviewers screened the title, abstract and full-text articles against the inclusion criteria, with two additional reviewers examining their results. Publications were excluded if they did not meet those criteria or were duplicate articles. **RESULTS:** A total of 358 articles were obtained from the literature search. Ninety-five articles were removed as duplicates. After screening, 43 articles were included and 220 original articles were excluded. Results from the articles indicate various barriers to the early diagnosis and misdiagnosis of AD and dementia including provider, caregiver, patient, health-system and diagnostic challenges. Delay or misdiagnosis could result in a poor quality of life for the patient and caregiver, contribute to financial and personal risks, and lead to the progression of the disease. **CONCLUSIONS:** Early diagnosis or detection of AD and dementia potentially reduces the social and economic burden of patients and caregivers. Additionally, it is important to diagnose patients with AD and dementia appropriately in a timely manner to ensure that treatment is initiated. With early detection of AD and dementia, risks associated with more severe cognitive impairment could be avoided. Community resources can be utilized to increase the understanding of early AD diagnosis.

PND7

IMPACT OF NON-ADHERENCE ON SEIZURE CONTROL, HEALTH-OUTCOMES AND COSTS BY ANTI-EPILEPTIC DRUG CLASS AMONG PATIENTS WITH EPILEPSY

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OBJECTIVES: To compare health outcomes and associated costs among non-adherent patients with epilepsy using different classes of AEDs. **METHODS:** Data from the 2014-2015 US National Health and Wellness Survey, a nationally representative, self-administered, internet-based survey, were analyzed. Non-adherence was assessed by the 8-item Morisky Medication Adherence Scale (non-adherence indicated by scores > 0, with 0=perfect adherence). Patients were grouped by AED class: sodium channel blocker (SCB), gamma-aminobutyric acid analog (GABA), synaptic vesicle protein 2A (SV2A), or multiple mechanism (MM). Demographic and health characteristics evaluated included age, gender, and seizure severity. Outcomes evaluated included seizure frequency, health-related quality of life (HRQoL, short-form-36 (SF-36) version 2), work productivity and activity impairment (6-item WPAI), health resource utilization (HRU), and estimated mean annual direct and indirect costs. Adjusting for patient characteristics, generalized linear models were used to compare differences in outcomes by AED group. **RESULTS:** Of 709 eligible patients, 236 (33%) were adherent and 473 (67%) were non-adherent. Adherence did not differ by AED class. Among non-adherent patients (mean age=42; 53% female), 245 (52%)

received a SCB, 25 (5%) GABA, 99 (21%) SV2A, and 104 (22%) MM. After adjusting for covariates, GABA patients had more seizures in the past 30 days vs MM, SCB, or SV2A, (19.5 vs. 2.17, 2.62, 0.53; each $p < 0.001$). Patients on SCB or SV2A vs. MM had higher mental component HRQoL scores (45.89, 45.57 vs. 40.02, both $p < 0.05$), higher health utilities (0.69, 0.68 vs. 0.63, both $p < 0.05$), less overall work impairment (11.80%, 7.09% vs. 60.68%, both $p < 0.05$), and lower total indirect costs (\$1,256, \$345 vs. \$20,783, both $p < 0.05$). No differences in HRU and direct costs were observed. **CONCLUSIONS:** In this nationally-representative survey, non-adherent patients with epilepsy treated with SCB and SV2A AEDs had fewer seizures, higher mental well-being and health utilities, decreased work impairment, and lower indirect costs versus other AED classes.

PND8

CURRENT TREATMENT PRACTICES AND THEIR EFFICACY AND SAFETY IN REFRACTORY OR SUPER-REFRACTORY STATUS EPILEPTICUS: A SYSTEMATIC REVIEW

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OBJECTIVES: To assess the efficacy and safety of treatments for refractory or super-refractory status epilepticus (RSE/SRSE). **METHODS:** The following databases were searched: Embase, Medline, Medline in-process, PsycINFO, Cochrane using keywords “status epilepticus”, “epilepsy”, “seizure”, “random”, “cohort”, “observational”. Randomized controlled trials (RCTs), non-RCTs, and observational studies were included. **RESULTS:** Database searches (August 2015) retrieved 6751 citations. Of these, 912 full-texts were screened for eligibility, after which 156 were considered as eligible. After further screening, nine RCTs, 10 non-RCTs and 120 observational studies were extracted. Super-Refractory Status Epilepticus. **CONCLUSIONS:** Findings suggest that there is no consensus for the management and definitions of RSE conditions. Agents such as valproate, propofol, midazolam and diazepam achieved good seizure control for RSE patients during continuous IV therapy but successful weaning from general anaesthetics has not been well studied. Well-designed prospective trials are needed to establish the efficacy and tolerability of RSE and SRSE treatments.

PND9

A MIXED TREATMENT COMPARISON OF DROXIDOPA AND MIDODRINE FOR THE TREATMENT OF NEUROGENIC ORTHOSTATIC HYPOTENSION

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OBJECTIVES: No head-to-head comparisons of droxidopa and midodrine for neurogenic orthostatic hypotension (nOH) have been conducted. nOH is due to underlying neurologic disorders and is characterized by ≥ 20 mm Hg decrease in systolic blood pressure (sBP) or ≥ 10 mm Hg decrease in diastolic BP within 3 minutes of standing. This research was conducted to provide a systematic indirect comparison of droxidopa and midodrine. **METHODS:** A mixed treatment comparison (MTC) was conducted using a Bayesian hierarchical model allowing for indirect comparison of the interventions. Randomized controlled trials (RCTs) for analysis inclusion were identified using a systematic literature review. RCTs were assessed for comparability based on patient population and outcome measures. Improvement in standing sBP was the efficacy outcome measured for this analysis. Supine hypertension risk was assessed as a commonly reported measure of safety. **RESULTS:** The network of 6 RCTs were included; 12 treatment arms across studies facilitated the indirect comparison of midodrine and droxidopa. There was reasonable agreement between number of unconstrained data points, residual deviance and pair-wise results, suggesting a coherent network. The fixed-effect 95% credibility intervals for sBP improvement (mm Hg) from baseline relative to placebo were (11.35, 22.95) for midodrine and (1.61, 8.90) for droxidopa, respectively (positive numbers indicate improvement over placebo). MTC estimates of 95% credibility levels for supine hypertension risk ratio (relative to placebo) were (1.2, 2.0) for midodrine and (0.72, 2.7) for droxidopa. Due to limitations of the clinical data, potential confounding factors (eg, gender and formulation differences) were not accounted for in examining treatment effects. **CONCLUSIONS:** Droxidopa and midodrine were both more effective versus placebo in increasing sBP, with a larger effect observed with midodrine treatment. However, midodrine was also associated with significantly greater risk of supine hypertension compared with placebo, while no statistically significant increased risk was observed with droxidopa.

PND10

RETROSPECTIVE ANALYSIS OF TWO CLINICAL STAGING SYSTEMS FOR AMYOTROPHIC LATERAL SCLEROSIS (ALS) USING DATA FROM A PHASE III TRIAL OF EDARAVONE

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OBJECTIVES: To evaluate the utility of the King's ALS Clinical Staging System (King's) and the Milano-Torino Staging System (MITOS) in capturing disease progression in a Phase III trial (Protocol MCI186-J19), in which edaravone was found to delay functional decline over 24 weeks, as assessed by the Revised ALS Functional Rating Scale (ALSFRS-R). **METHODS:** In MCI186-J19, patients with ALS were randomized to receive edaravone 60 mg/d (n=69) or placebo (n=68) for six 4-week cycles, after which all could receive 6 more cycles of open-label edaravone. Using patient-level data from this trial, we retrospectively mapped ALSFRS-R item scores at baseline and all follow-up assessments to King's and MITOS using published algorithms. We examined the percentage of subjects who experienced any decline in King's and MITOS, respectively, by weeks 24 and 48; we also examined the percentage of subjects who experienced a ≥ 2 -stage decline in MITOS. **RESULTS:** Eighty percent of subjects in

MCI186-J19 were King's Stage 1 or 2 at baseline; all were MITOS Stage 0. By week 24, 42.0% (95% confidence interval [CI]: 30.4%, 53.6%) of patients randomized to receive edaravone had experienced a decline in King's stage vs 55.9% (44.1%, 67.6%) of those randomized to receive placebo; corresponding figures for ≥ 1 - and ≥ 2 -stage declines in MITOS were 46.4% (34.8%, 58.0%) vs 47.1% (35.3%, 58.8%), and 2.9% (0.0%, 7.2%) vs 5.9% (1.5%, 11.8%), respectively. By week 48, 72.5% (62.3%, 82.6%) of edaravone-to-edaravone patients, and 79.4% (69.1%, 88.2%) of placebo-to-edaravone patients, had experienced a decline in King's stage; corresponding figures for ≥ 1 -stage and ≥ 2 -stage declines in MITOS were 66.7% (55.1%, 76.8%) vs 73.5% (63.2%, 83.8%), and 10.1% (4.3%, 17.4%) vs 23.5% (13.2%, 33.8%), respectively. **CONCLUSIONS:** Our retrospective study suggests that both King's and MITOS possibly may be useful in capturing differences in disease progression in clinical trials of new therapeutic agents in ALS.

PND11

FEASIBILITY OF A COMPARATIVE META-ANALYSIS OF VMAT2 INHIBITORS FOR THE TREATMENT OF TARDIVE DYSKINESIA

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OBJECTIVES: Tardive dyskinesia (TD) is a persistent and often disabling movement disorder associated with antipsychotic therapy for which there is no approved treatment. Tetrabenazine, a vesicular monoamine transporter 2 (VMAT2) inhibitor, has been studied for the treatment of TD and is listed in TD treatment guidelines. Two novel VMAT2 inhibitors have shown promising efficacy in recent clinical trials. The objective of this analysis was to assess the feasibility of conducting a meta-analysis comparing tetrabenazine versus the VMAT2 inhibitors in development. **METHODS:** A systematic literature search of clinical trials for use of selective VMAT2 inhibitors in TD was undertaken in the databases Pubmed, Embase and OVID (1980-August 2016). Data were collected for the study design, duration, size, sites, comparators, outcomes, efficacy and safety. Feasibility assessment for meta-analysis was conducted based on the potential for developing an evidence network for all selective VMAT2 inhibitors. **RESULTS:** Out of 479 references, 11 studies were relevant in 893 patients with movement disorders, including TD, for three VMAT2 inhibitors valbenazine, deutetabenazine and tetrabenazine. Two TD randomized controlled trials (RCTs) were identified for valbenazine (N=325) and one for deutetabenazine (N=117). No RCTs were identified for tetrabenazine. All studies for tetrabenazine (n=8) were case series or open-label trials, with a median sample size of 20 TD patients. 7 of 8 studies defined efficacy by a subjective assessment of “improvement”. One (single-arm) study used the AIMS. Valbenazine's KINECT2 and KINECT3, and deutetabenazine's ARM-TD were multi-site, randomized, placebo-controlled studies. Efficacy was evaluated by centralized, blinded raters using the standardized assessment (AIMS). Safety and tolerability were evaluated at every study visit. **CONCLUSIONS:** Due to a lack of controlled and blinded studies with validated primary endpoints, published evidence supporting the efficacy and safety of tetrabenazine as a treatment for TD cannot be compared to novel VMAT2 inhibitors in a meta-analysis.

PND12

REAL-WORLD EVIDENCE FOR DISEASE-MODIFYING DRUGS IN MULTIPLE SCLEROSIS: TRENDS IN THE LITERATURE

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OBJECTIVES: To summarize trends in published literature regarding real-world evidence (RWE) for disease-modifying drugs (DMDs) in patients with multiple sclerosis (MS). **METHODS:** A systematic search of peer-reviewed studies published from 2010 to 2016 using the PubMed database was conducted. Studies evaluating RWE (prospective [cohort studies, registries, case studies/series, surveys, or randomized naturalistic trials] and retrospective [administrative claims, electronic health record, and chart reviews] studies) were included. Search terms used were: multiple sclerosis AND (disease modifying OR interferon OR peginterferon OR glatiramer OR fingolimod OR teriflunomide OR dimethyl fumarate OR natalizumab OR mitoxantrone OR alemtuzumab OR daclizumab) AND (cohort OR observational OR retrospective OR database). The search was restricted to articles published in English. Publications that did not report primary data were excluded. **RESULTS:** A total of 882 articles were identified using the search strategy; 313 were excluded (69 not evaluating MS, 70 not evaluating DMDs, 45 reviews/editorials, 37 pre-clinical/clinical studies, 35 study design/methodological studies, 33 meta-analyses, and 24 models). Two-thirds (68.4%) of the studies were prospective and one-third (31.6%) were retrospective. DMD types included were: self-injectables only (36.4%); orals only (6.7%); infusion therapies only (26.4%); self-injectables and orals (1.8%); self-injectables and infusion therapies (7.4%); orals and infusion therapies (2.8%); or self-injectables, orals, and infusion therapies (18.6%). Most studies were comparative (69.1% vs 30.9% noncomparative). Outcomes evaluated included relapses (44.6%), disease/disability progression (39.7%), safety/tolerability (32.0%), biomarkers (24.8%), brain activity (21.1%), adherence (19.7%), patient-reported outcomes (17.0%), resource use (6.9%), and cost (4.6%). From 2010 to 2016, the annual number of studies increased from 47 to 130. The proportion from Europe increased from 51.1% to 60.8%, whereas the proportion from the US decreased from 38.3% to 21.5%. **CONCLUSIONS:** The prominence and types of RWE studies examining DMDs in MS is growing; additional research is needed to determine the quality of studies and the impact on decision making.

PND14

DRUG-SPECIFIC DISCONTINUATION RATES FOR AVAILABLE MULTIPLE SCLEROSIS TREATMENTS

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OBJECTIVES: To estimate drug-specific annual discontinuation rates for available disease modifying treatments of relapse remitting multiple sclerosis

(RRMS). **METHODS:** We considered the following disease modifying treatments for RRMS: teriflunomide, dimethyl fumarate, fingolimod, peginterferon B1-a, interferon B-1a (Rebif®), Avonex®, and Betaseron®), daclizumab, glatiramer acetate, natalizumab, ocrelizumab, and alemtuzumab. The discontinuation rates for each drug were derived from 26 clinical studies included in the Institute for Clinical and Economic Review-sponsored base-case network meta-analysis of multiple sclerosis; 2 studies were excluded because they did not include reasons for discontinuation. For each study, the total number of study participants, the total number of participants who discontinued, and the number who discontinued due to non-protocol related reasons were extracted. Reasons for discontinuation that were excluded from final discontinuation rates included death, refusal to sign re-consent form, withdrawing consent, protocol violation, administrative problems, or deviation from protocol. All other reasons for discontinuation were included. The percent of those discontinuing for qualified reasons out of the total number of study participants was then annualized. For each drug, an average of the annualized discontinuation percentages was taken, weighted by total study participants in each study. Results consider both proportions and their equivalent rates. **RESULTS:** Annual treatment discontinuation ranged from 1.9% to 15.5% of patients, with an average annual discontinuation of 7%. Teriflunomide (7mg, Aubagio®) and Dimethyl fumarate (Tecfidera®) had the highest discontinuation rates of available treatments with 15.5% and 13.3% annual discontinuation, respectively. Natalizumab (Tysabri®), ocrelizumab (Ocrevus®), interferon beta-1a (250 mcg, Betaseron®), and alemtuzumab (Lemtrada®) had annual discontinuation proportions below 5%. Most common reasons for treatment discontinuation included adverse events, disease progression, and loss to follow up. **CONCLUSIONS:** Disease-modifying treatments for relapse-remitting multiple sclerosis are associated with varying responses and subsequent discontinuation; providers and patients should consider likelihood of discontinuation when choosing treatment.

PND15

THE BURDEN OF ILLNESS ASSOCIATED WITH SUPER REFRACTORY STATUS EPILEPTICUS (SRSE)

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OBJECTIVES: SRSE is a life-threatening form of status epilepticus (SE) that continues or recurs despite multiple therapeutic interventions (first-, second-, and third-line agents). We set out to review information on the epidemiology, health-related quality of life (HRQoL) and economic burden associated with refractory SE (RSE) and SRSE. **METHODS:** A structured, comprehensive literature review was conducted to identify articles from literature databases, guideline databases, regulatory and health technology assessment agency websites and conference proceedings. Data were extracted from eligible articles (reporting on RSE or SRSE and providing data on at least one topic of interest). Summaries of studies meeting predefined criteria are presented. **RESULTS:** One hundred and sixty articles met the inclusion criteria. Projections or estimates of epidemiology varied by country; incidence of SRSE was 13/100,000 cases/year in the US (1 article) and 3/100,000 cases/year in Germany (1 article). Publications on humanistic burden of SRSE (8 articles) reported that patients with SRSE had a lower HRQoL compared with RSE patients. However, patients with RSE (30 articles) also experienced functional impairment and required considerable care after discharge. Caregiver burden of RSE and SRSE was sparsely reported (SRSE: n=0; RSE: n=2); however, surveys of parent views indicated that parents found it stressful when their child had a RSE episode; however, despite this, their main priority during an RSE episode was to stop their child seizing as quickly as possible. Although economic data were limited (7 articles), the cost of SRSE is considerable; in one study, total annual direct costs of cases identified using the study algorithm as SRSE, accounted for €122.8 million in Germany (2013). **CONCLUSIONS:** To our knowledge this is the first comprehensive structured literature review on the humanistic and economic burden associated with RSE and SRSE. Our review indicates that the evidence base is limited but the burden of SRSE and RSE is clearly substantial.

PND16

INCIDENCE AND PREDICTORS OF ANTIPSYCHOTICS USE AMONG PATIENTS WITH PARKINSON'S DISEASE

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OBJECTIVES: Most antipsychotics are considered potentially inappropriate in patients with Parkinson's disease (PD). Limited research exists regarding factors contributing to the use of antipsychotics in patients with PD. This study examined the incidence and predictors of antipsychotic use among patients with newly diagnosed PD. **METHODS:** This cohort study used a large administrative database from 2000 to 2015 The Medical Outcomes Research for Effectiveness and Economics Registry (MORE2 Registry®). The study sample included adult patients with PD (ICD-9-CM 332.0). Patients were followed for 3 years and Cox regression was used to examine factors associated with initiation of antipsychotics after PD diagnosis. Several demographics and clinical characteristics were included in the Cox model based on previous literature and availability in data. **RESULTS:** The study population included 1,470 patients with Parkinson's disease. The mean age of the sample was 72.06 years (SD = 9.86). The incidence of antipsychotics use was 19.25% over 3-years follow up and quetiapine was the most frequently used antipsychotic agent (44.88%) in this study. The likelihood of using antipsychotics was significantly higher for PD patients with a history of antipsychotics use (Hazard Ratio, HR=2.08, P<0.01), dementia (HR=2.02, P<0.01), depression (HR=1.91, P<0.01), and schizophrenia (HR=1.49, P=0.02). Antipsychotics were less likely to be prescribed for PD patients using levodopa (HR=0.59, P<0.01), dopamine agonists (HR=0.69, P=0.02),

catechol-O-methyl transferase inhibitors (HR=0.61, P=0.04) or other antiparkinson agents (HR=0.733, P=0.04). **CONCLUSIONS:** Antipsychotics are commonly used to control behavioral symptoms of patients with PD; however, most of these are considered potentially inappropriate in PD. Understanding the factors contributing to the use of antipsychotics can be helpful in optimizing use of these medications and improving pharmaceutical care for patients with PD.

PND17

ALLERGIES RATHER THAN ANTIBIOTICS USE ARE ASSOCIATED WITH MULTIPLE SCLEROSIS

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OBJECTIVES: The risk factors and etiology of multiple sclerosis (MS) remains unclear and controversial. Previous studies have reported contradictory associations between antibiotics use and MS, which leads more to the ongoing dispute. We hypothesized that antibiotics use might be a mediator of the association between allergies and MS. Thus, our study aimed to examine their intrinsic relationships among antibiotics use, allergy disease and MS. **METHODS:** A 1:3 matched case-control study was performed using the National Ambulatory Medical Care Survey database from 2006 to 2013 in the USA. MS cases were identified based on the ICD-9 code "340" in any diagnosis position. MS cases were matched to their controls based on year, age (difference ≤ 3 years), gender, race, payer type and region utilizing SAS 9.4. Allergy diseases and antibiotics prescriptions were extracted by ICD-9 code and drug classification code, respectively. A generalized structural equation model was built in STATA 13.1 based on our hypothesis. **RESULTS:** The weighted prevalence of MS was 133.7 per 100,000 visits. Total 829 MS patients and 2441 controls were matched. When including allergy diseases in the model, use of penicillin or other antibiotics were no longer significantly negatively associated with MS. Patients with respiratory tract allergies were more likely to use penicillin (Odds ratio [OR]=8.44, p<0.001) and other antibiotics (OR=3.93, p<0.001), but the association was not found in patients with skin allergies. Notably, both respiratory tract allergies (OR=0.26, p<0.001) and skin allergies (OR=0.38, P=0.017) were inversely associated with the risk of MS. **CONCLUSIONS:** Antibiotics use might play a mediator role between the association between allergies and MS, which has not been reported in previous studies. History of allergy diseases might be considered as a protective factor of MS, suggesting that the development of immune responses against stimulatory environmental factors could inhibit responses to auto-antigens.

PND18

MORTALITY IN ALZHEIMER'S DISEASE: A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: Mortality plays an important role in the economic evaluation of new therapies for Alzheimer's disease (AD). A systematic literature review was conducted to consolidate data on the estimates and key variables influencing economic modeling of mortality/survival in AD. **METHODS:** Relevant English-language studies were identified using a systematic literature search of Pubmed databases. Included studies (full-text) were required to report estimates for mortality/survival in AD stratified on at least one of three previously identified key variables: age, gender and AD severity. Exclusion criteria were animal studies, basic science/molecular studies, non-AD specific, lack of sound methodology, and follow-up time ≤ 2 years. **RESULTS:** A total of 12 studies were included in the final review, with 6 studies deriving estimates from newly-identified patients and 6 from presumably-prevalent patients. AD was classified using standard NINCDS-ADRDA criteria. Hazard ratios and relative risk estimates varied across the studies due to variability in the reference groups (AD vs non-AD; within-group comparisons of age/gender/AD-severity) and control variables. However, some commonalities were observed; the HR for 5-point increment in MMSE was reported by 3 studies (1 incident, 2 prevalent) and ranged from 1.11 to 1.66. Estimates for median survival [ST] were very similar among studies with incident patients, and decreased with increasing age [range = 6-7.5 years (age<75) and 3.5-4.9 years (age>85)]. The ST of AD patients was 32%-75% that of age- and gender- matched controls, with largest differences observed in patients <85. Overall, older age, male gender and greater disease severity were associated with shorter survival and increased risk of mortality in AD. **CONCLUSIONS:** Insights can be obtained from a systematic review of AD mortality data that demonstrate the increased risk of death from AD, however heterogeneity in reporting of findings impedes comprehensive meta-analysis. Future research on obtaining pooled estimates for use in economic models is warranted.

NEUROLOGICAL DISORDERS – Cost Studies

PND20

ALLOCATING PROVIDER RESOURCES TO ACCURATELY DIAGNOSE AND TREAT RESTLESS LEGS SYNDROME: A COST-EFFECTIVENESS ANALYSIS

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OBJECTIVES: Restless legs syndrome (RLS) is a neurological disorder that is frequently underdiagnosed and misdiagnosed. Patients exhibiting RLS symptoms are often initially misdiagnosed with peripheral neuropathy, anxiety, sleeping disorder, or deep venous thrombosis, resulting in delays in proper treatment. Our objective was to analyze the cost-effectiveness of training primary care physicians in early and accurate diagnosis of RLS. **METHODS:** We used a Markov model to compare two strategies: one where primary care providers receive training to

diagnose RLS (informed care) and one where primary care providers do not receive training (standard care). This analysis was conducted from the U.S. societal perspective over 1, 5, and 50 years. Costs were adjusted to 2016 US dollars. Effectiveness was measured in units of quality-adjusted-life-years (QALYs). Costs and QALYs were discounted by 3%. Cost, utilities, and probabilities for the model were obtained through a comprehensive review of literature. An incremental cost-effectiveness ratio (ICER) was calculated to interpret our findings at a willingness-to-pay threshold of \$100,000/QALY. Univariate and multivariate analyses were conducted, as was a probabilistic sensitivity analysis, to test model uncertainty. The Expected Value of Perfect Information was also calculated. **RESULTS:** In our lifetime model, providing training to primary care providers to correctly diagnose RLS was found to be cost-effective at willingness to pay (WTP) of \$100,000 with an ICER of \$4,593/QALY. The incremental cost for the informed care strategy was \$2,021 per patient and the incremental effectiveness was 0.44 QALYs per patient. The model was sensitive to the utility for treated and untreated RLS. The probabilistic sensitivity analysis revealed that at the WTP threshold of \$100,000, informed care had a 65.5% chance of being cost-effective. **CONCLUSIONS:** A program to train primary care providers to better diagnose RLS appears to be a cost-effective strategy for improving outcomes for patients suffering from RLS.

PND21

DOES THE COMMERCIAL AVAILABILITY OF CLOBAZAM AFFECT HEALTHCARE RESOURCE UTILIZATION AND COSTS AMONG PATIENTS WITH LENNOX-GASTAUT SYNDROME?

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OBJECTIVES: To compare healthcare resource utilization (HCRU) and costs on a per-patient-per-month (PPPM) basis among patients with probable Lennox-Gastaut syndrome (LGS) before and after the commercial availability of clobazam. **METHODS:** In this retrospective population study, de-identified data from MarketScan[®] Commercial and Medicare Supplemental databases (November 1, 2008 through November 2, 2014) were used to identify patients with probable LGS (≥ 2 medical claims for generalized convulsive or non-convulsive epilepsy and ≥ 1 medical claim for developmental disorder or cognitive impairment). The resulting cohort was stratified into two groups based on the commercial availability of clobazam: pre-clobazam (November 1, 2008–November 1, 2011) and post-clobazam (November 2, 2011–November 2, 2014). All-cause and seizure-related HCRU and costs for the pre-clobazam availability group were compared to those of the post-clobazam availability group. **RESULTS:** A total of 15,979 and 16,281 patients with probable LGS were identified prior to and following the commercial availability of clobazam, respectively. The post-clobazam availability group was slightly older than the pre-clobazam availability group (mean [SD]: 31.4 [24.7] vs 30.7 [25.1]; $P=0.010$); however, the gender distribution was similar. Comorbidities assessed were mostly similar between the groups with a few exceptions. There were significantly fewer seizure-related emergency department (ED; $P=0.025$), physician office ($P<0.001$), neurologist ($P<0.001$), primary care ($P=0.002$), and laboratory ($P=0.045$) visits (PPPM) among the post-clobazam availability group versus the pre-clobazam availability group. Seizure-related total ($P<0.001$), medical ($P<0.001$), physician office ($P<0.001$), neurologist ($P=0.009$), and laboratory ($P=0.020$) PPPM costs significantly decreased among the post-clobazam availability group versus the pre-clobazam availability group. No significant difference was observed when seizure-related prescription costs were compared between groups. A similar trend was observed with all-cause HCRU and costs. **CONCLUSIONS:** Patients with probable LGS experienced a reduction in all-cause and seizure-related HCRU and costs following the commercial availability of clobazam. Funding: Lundbeck

PND22

HEALTHCARE COSTS AMONG PATIENTS WITH LENNOX-GASTAUT SYNDROME TREATED WITH CLOBAZAM

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OBJECTIVES: This retrospective analysis of healthcare claims data was conducted to examine healthcare costs in patients with probable Lennox-Gastaut syndrome (LGS) treated with clobazam (CLB). **METHODS:** Patients with likely LGS were identified from epilepsy patients (≥ 2 claims for epilepsy [ICD-9-CM 345.xx] or unspecified epilepsy [ICD-9-CM 780.39]) in 6 state Medicaid databases using a random forest machine-learning algorithm. CLB users were defined as having ≥ 2 prescription claims for CLB and ≥ 1 year of continuous enrollment before CLB initiation (index date). Monthly healthcare costs were estimated for pre-CLB (1 year before index date) and post-CLB (to end of data availability) periods. Generalized estimating equations were used to characterize and predict time trends before and after CLB initiation. To estimate the impact of CLB use on healthcare costs, the slope of monthly costs before CLB initiation was extrapolated beyond the index date and compared to post-CLB costs. The difference was quantified by calculating areas under the curve (AUCs). **RESULTS:** A total of 1,301 likely LGS patients were identified. Mean (SD) duration of observation post-CLB initiation was 1.60 (0.86) years. When compared to extrapolated costs without CLB during the post-CLB period, CLB treatment was associated with significant reductions in total all-cause, total epilepsy-related, and inpatient medical costs ($P<0.05$), and a nonsignificant increase in home care costs ($P=0.45$). The difference in AUCs was equivalent to a reduction of \$1,538.89 (3.80%) in all-cause healthcare costs

in the year after CLB initiation, and reductions of \$2,236.34 (11.99%) and \$3,112.29 (26.66%) for total epilepsy-related and inpatient costs, respectively. The cost increase for home care was \$1,839.74 (11.62%). **CONCLUSIONS:** Results from this study indicate that CLB initiation in LGS patients is associated with reduced healthcare costs, mainly driven by lower inpatient costs. Funded by Lundbeck

PND23

ECONOMIC IMPLICATIONS OF REPLACING INTERFERON BETA-1A WITH OCRELIZUMAB IN RELAPSING MULTIPLE SCLEROSIS

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OBJECTIVES: Multiple sclerosis (MS) is a chronic, inflammatory disease of the central nervous system and a leading cause of disability in young adults. Ocrelizumab (OCR), a humanized monoclonal antibody that selectively targets CD20+B cells, demonstrated superior efficacy compared with subcutaneous interferon beta-1a (IFN β -1a) in reducing the number of relapses and delaying disease progression in patients with relapsing forms of MS (RMS) in two identical Phase III, randomized controlled clinical trials (OPERA I and OPERA II). We assessed the economic implications of relapses avoided with OCR compared with IFN β -1a from a US payer perspective. **METHODS:** Using the OPERA I and OPERA II efficacy data, the economic implications of relapses avoided with OCR 600 mg every 24 weeks compared with subcutaneous IFN β -1a 44 μ g three times weekly were quantified in terms of total two-year relapse costs and total cost per patient per year. Only direct costs were evaluated in 2016 US dollars. The total costs evaluated included the cost of relapse and annual treatment-related costs. **RESULTS:** In OPERA I and OPERA II, 140 fewer protocol-defined relapses were observed with OCR compared with IFN β -1a over 2 years, and the annualized relapse rate at 2 years was lower with OCR vs IFN β -1a (0.156 vs 0.291, respectively). The relapses avoided with OCR over 2 years are associated with an estimated cost offset of \$816,340 in relapse-related medical costs and with an average annual total cost offset of \$18,745 per patient. **CONCLUSIONS:** The superior clinical efficacy of OCR compared with IFN β -1a in patients with RMS in the OPERA studies is associated with cost offsets based on relapse costs over 2 years and total costs per patient per year. Funded by Genentech, Inc.

PND24

DIRECT COSTS OF CYSTIC FIBROSIS IN THE UNITED STATES: EVIDENCE FROM 2010-2014 MEDICAL EXPENDITURE PANEL SURVEY

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OBJECTIVES: The cystic fibrosis (CF) is a genetic disorder requiring medical care for whole lifespan. A previous study reported that an incremental medical care expenditure of CF was \$45,927 (2006 US dollar) per person per year based on private insurance claims database. However, the national cost burden of CF remains unknown. This study aimed to examine the nationally representative direct cost burden of CF at individual and national levels. **METHODS:** We conducted pooled cross-sectional analyses using 2010-2014 Medical Expenditure Panel Survey dataset. CF patients were identified with the ICD-9 code "277" from Medical Condition file. We employed multivariable two-part models consisting of logit and generalized linear model with log link and gamma distribution. The total expenditure was an outcome variable, summing up expenditures of office-based visit, outpatient visit, emergency department visit, inpatient visit and medication. Covariates included age, gender, race, marital status, education, family poverty level, insurance type, region and year. Adjusted incremental direct costs of CF were obtained compared to patients without CF. All costs were converted to 2014 US dollar using Medical Care components of Consumer Price Index. **RESULTS:** The unweighted (weighted) sample sizes for CF and non-CF patients were 163 (423,202) and 163,430 (313,057,747), respectively. The weighted annual prevalence of CF was 1.35 per 1,000 persons. The incremental medical expenditure of CF was \$11,283 ($p=0.003$) per person per year. The major contributor of incremental medical expenditure was medication expenditure (\$2,783, $p=0.034$) followed by inpatient expenditure (\$2,702, $p=0.123$) and office visits (\$1,153, $p=0.003$). Total national medical expenditure was \$955 million per year. **CONCLUSIONS:** The direct cost burden of CF was considerable although it was lower than the case of privately insured population. Further research on indirect costs is necessary for CF patients.

PND25

INCREMENTAL ECONOMIC BURDEN OF CARDIOMETABOLIC DISORDERS AMONG PATIENTS WITH EPILEPSY

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OBJECTIVES: Extensive evidence exists showing high prevalence and costs of psychiatric comorbidities in patients with epilepsy, but burden of non-psychiatric comorbidities in these patients has not been widely explored. Recent estimates indicate an elevated prevalence of cardiometabolic disorders (CMDs) among patients with epilepsy. This study examines the prevalence and incremental economic burden of CMDs in a US epilepsy cohort. **METHODS:** This study utilized a cross-sectional, retrospective study design using data from alternate multiple years (2008/2010/2012/2014) of the Medical Expenditure Panel Survey. Adults with epilepsy were identified using the ICD-9-CM code for epilepsy (345.xx). CMDs included diabetes, endocrine disorders, heart disease, and hypertension. Annual healthcare expenditures for hospitalizations, emergency room and outpatient visits, prescription drugs, dental care, and other services were assessed. T-tests were used to examine unadjusted differences in average annual healthcare expenditures between epilepsy patients with and without CMDs. Ordinary least squares (OLS) regression on log-transformed healthcare expenditures, adjusted for demographic, socioeconomic, and clinical characteristics, were conducted to estimate the magnitude of excess healthcare expenditures associated with CMDs.

All analyses were weighted to control for the complex sample design of MEPS. **RESULTS:** Among adults with epilepsy (unweighted $n=252$; weighted $n=2.8$ million), 37.8% had comorbid CMDs. Patients with comorbid epilepsy and CMDs had approximately three times higher total annual expenditures than patients without CMDs (\$15,359 vs \$5,314 [$P<0.001$]). Annual expenditures for prescription drugs and outpatient services were major contributors for the increased healthcare expenditures among patients with epilepsy and CMDs. OLS regression indicated that patients with comorbid CMDs had 45% ($\beta=0.372$; $\exp[\beta]=1.45$; $P<0.001$) higher expenditures than patients without CMDs. **CONCLUSIONS:** The current study highlights the high prevalence of CMDs and increased healthcare expenditures due to CMDs in patients with epilepsy. The potential burden of comorbid CMDs should be considered by providers in the management of chronic conditions in patients with epilepsy.

PND26

COST CONSEQUENCE ANALYSIS OF SC PEGINTERFERON BETA-1A EVERY 2 WEEKS VERSUS SC INTERFERON BETA-1ATIW IN PATIENTS WITH RRMS IN FIVE EUROPEAN COUNTRIES

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OBJECTIVES: To evaluate the economic and clinical impacts of treatment with subcutaneous peginterferon beta-1a (SC PEG-IFN) vs. SC interferon beta-1a (SC IFN beta-1a) for relapsing-remitting multiple sclerosis (RRMS) in five European countries (EU5): France, Germany, Italy, Spain, and UK. **METHODS:** A cost-consequence model, from the national payer perspective, was developed to compare country-specific costs of treating patients with SC PEG-IFN vs. SC IFN beta-1a. The model evaluates clinical and economic consequences of switching all patients who are currently on SC IFN beta-1a to SC PEG-IFN. A Markov model over two years with three month cycles was computed. Costs of relapse and disability status are from a cross-sectional cost of illness study (Kobelt et al. 2016). The annualized relapse rate and confirmed disability progression hazard ratios for SC PEG-IFN vs. SC IFN beta-1a were estimated using the results from Tolley et al. 2015 and Coyle et al. 2016. The RRMS populations treated with SC IFN beta-1a are from actual 2016 utilization. **RESULTS:** The number of RRMS patients treated with SC IFN beta-1a ranged from 2,810 in France to 11,699 in Germany. The use of SC PEG-IFN in place of SC IFN beta-1a reduced the number of relapses, and cost of DMT, relapse, and disability status in each country. The sum of these cost savings ranged from €9,514,404 in France to €61,955,057 in Germany, for a total savings of €178,871,314 over two years (64.2% due to drug, 27.1% to relapse, and 8.7% to disability status cost savings) across the EU5. Total savings per patient ranged from €3,460 in France to €10,865 in Spain. **CONCLUSIONS:** These results suggest that use of SC PEG-IFN compared with SC IFN beta-1a in the treatment of RRMS is a cost-saving strategy in the EU5. Additional research incorporating adherence and side effects are necessary to analyze treatment options.

PND27

COST CONSEQUENCE ANALYSIS OF SC PEGINTERFERON BETA-1A EVERY 2 WEEKS VERSUS SC INTERFERON BETA-1ATIW IN PATIENTS WITH RRMS IN THE UNITED STATES

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OBJECTIVES: To evaluate the economic and clinical impacts of treatment with subcutaneous peginterferon beta-1a (SC PEG-IFN) vs. SC interferon beta-1a (SC IFN beta-1a) for relapsing multiple sclerosis (RMS) in the United States. **METHODS:** A cost-consequence model, adopting a national perspective, was developed to compare costs of SC PEG-IFN vs. SC IFN beta-1a. The model evaluates clinical and economic consequences of switching all patients who are currently on SC IFN beta-1a to SC PEG-IFN using costs and baseline clinical characteristics specific to the US. A Markov model over two years with cycle times of three months was computed. Costs of relapse and disability status are from a cost of illness study (Kobelt et al. 2006). The hazard ratios for clinical outcomes of SC PEG-IFN vs. SC IFN beta-1a treatment were estimated using the results from Tolley et al. 2015 and Coyle et al. 2016. The RMS population treated with SC IFN beta-1a is from actual 2016 utilization. **RESULTS:** The number of RMS patients treated with SC IFN beta-1a was 19,717. The use of SC PEG-IFN in place of SC IFN beta-1a reduced the number of relapses by 10,244 and added 2,129 relapse-free years among the cohort. SC PEG-IFN also slowed disease progression (192 additional patients had an Expanded Disability Status Scale < 6.0 compared to SC IFN beta-1a), and reduced drug costs, relapse costs, and disability status costs. The sum of these cost savings for the cohort was \$217,982,252 over two years (86.4% due to drug costs, 12.1% to relapse costs, and 14.5% to disability status cost savings). Total savings per patient were \$11,056. **CONCLUSIONS:** The results of this model suggest that use of SC PEG-IFN compared with SC IFN beta-1a in the treatment of RMS in the US is a cost-saving strategy. Additional research incorporating adherence and side effects are necessary.

PND28

EXCESS COSTS ASSOCIATED WITH CENTRAL SLEEP APNEA IN THE ELDERLY

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OBJECTIVES: Central sleep apnea (CSA) occurs when the brain fails to signal the diaphragm to contract during sleep, resulting in an involuntary cessation of breathing. There are limited recent data on the economic and clinical burden of CSA among the elderly. This study evaluated the costs of this disease using data from the Medicare program. **METHODS:** Patients newly diagnosed with CSA

between January 1, 2011 and December 31, 2013 ("cases") were identified using the Medicare 5% Standard Analytical Files. Non-CSA controls were identified in the same time period and matched 1:1 to cases. All patients were required to have continuous enrollment 12 months before index and at least 30 days post-index diagnosis. Resource utilization and medical costs were evaluated from index diagnosis to end of continuous enrollment. Matching (exact) variables included: age group, sex, race, geographic region, Charlson comorbidity index group excluding congestive heart failure, index quarter, baseline presence of congestive heart failure and baseline presence of obesity. **RESULTS:** Of approximately 3.2 million patients, 1,981 cases were identified. The final analysis included 730 matched patients in both cohorts; 77.7% were male and mean age was 75 years. In the baseline period, 6.6% of patients were obese. Median follow-up duration was 32.4 months for cases and 30.8 months for controls. Compared to controls, patients with CSA had higher post-index hospitalization utilization (57.5% vs. 49.3%; $p=0.002$), higher number of visits across all settings (inpatient: 1.66 vs 1.21, $p<0.0001$; ED: 1.28 vs. 0.73, $p<0.0001$; Office: 51.95 vs. 19.23, $p<0.0001$; Outpatient: 19.94 vs. 8.55, $p<0.0001$), and higher medical costs (\$46,112 USD vs. \$28,650 USD, $p<0.0001$). **CONCLUSIONS:** Resource utilization and medical costs for elderly patients with CSA are statistically significantly higher than matched patients without CSA. These results point to the need for interventions to better manage this population.

PND29

THE ECONOMIC BURDEN OF AGITATION IN ALZHEIMER'S DISEASE: A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: To evaluate the economic burden of agitation in patients with Alzheimer's disease (AD). **METHODS:** A global systematic literature review was conducted for studies of clinical, humanistic, and economic burden of agitation in AD published in 2006-2016. References of identified papers and related literature reviews were examined. Studies meeting predetermined inclusion criteria for economic burden were summarized. **RESULTS:** Four studies from three countries (two UK, US, The Netherlands) met the inclusion criteria. Studies evaluated different economic outcomes including use of mental health services, health and social care costs, and cost of admission. In the Netherlands, agitation was associated with increased referrals to mental health services and increased economic burden. In the UK, excess cost associated with agitation was established to be £4091 a year per patient, accounting for 12% of their health and social care costs. The cost of admission for patients with behavioral symptoms was higher, but not statistically significant. In the US, a cost-benefit study of three second-generation antipsychotics and placebo reported the mean health service costs (range \$1,004-\$1,222) and adjusted total average monthly costs (range \$1,023-\$1,215) were not significantly different across groups. Two relevant literature reviews were examined, neither including papers from the current review. One included studies of economic burden of AD without focus on agitation. The second reported limited availability of studies evaluating economic burden of agitation in AD and used data collected in a systematic review of non-pharmacological interventions for agitation to model economic outcomes. Results suggested incremental increases in health care costs associated with increases in agitation symptoms. **CONCLUSIONS:** Our review has identified a gap in the existing data documenting the incremental economic burden of agitation in AD. Existing evidence suggests an increase in economic burden associated with agitation, however, additional studies are needed.

PND30

HEALTH INSURANCE COST OF HEAD TRAUMA IN HUNGARY: A COST OF ILLNESS STUDY

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OBJECTIVES: The aim of our study is to calculate the annual health insurance treatment cost of head trauma in Hungary. **METHODS:** The data derive from the financial database of the Hungarian National Health Insurance Fund Administration (NHIFA), the only health care financing agency in Hungary. We analyzed the health insurance treatment cost and the number of patients for the year 2010. The following cost categories were included into the study: out-patient care, in-patient care, CT-MRI, PET, home care, transportation, general practitioner, drugs and medical devices. Head trauma was identified with the following codes of the International Classification of Diseases 10th revision: S04-S09, S14, S18-S19, S24, S34, T36-T44, T51, T90, T96. **RESULTS:** The Hungarian National Health Insurance Fund Administration spent 3.743 billion Hungarian Forint (HUF) (17.982 million USD) for the treatment of patients with head trauma. The annual average expenditure per patient was 25556 HUF (122.8USD) while the average expenditure per one inhabitant was 374 HUF (1.8 USD). Major cost drivers were acute inpatient care (84.4 % of total health insurance costs), outpatient care (8.8%) and primary care (2.6 %). The number of patients with head trauma was 146.3 per 10000 populations. We found the highest patient number in outpatient care (146465 patients) general practitioners (43243 patients) and acute inpatient care (27861 patients). **CONCLUSIONS:** Head trauma represents a significant burden for the health insurance system. Reimbursement of inpatient and outpatient care are the major cost drivers for head trauma in Hungary.

PND31

COST-EFFECTIVENESS ANALYSIS OF ALEMTUZUMAB FOR THE TREATMENT OF MULTIPLE SCLEROSIS IN BULGARIA, 2016

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OBJECTIVES: The aim of the study is to offer pharmacotherapeutic guidelines for the treatment of relapsing-remitting multiple sclerosis (RRMS) based both on clinical data on therapeutic efficacy and economic data on comparative cost-effectiveness of potential therapeutic alternatives. **METHODS:** A systematic review of the published data on the health technology assessment of ALE for the treatment of RRMS conducted in other countries was carried out. The following databases have been used: MEDLINE, EMBASE, Web of Science, and Cochrane Library, literature from 2012 to 2016. The analysis includes assessments which are a full economic analysis of the cost/effectiveness (CEA) or cost/benefit (CUA) analysis. The benefits are expressed as final health results expressed as quality adjusted life years (QALY). The data on health benefits (Δ QALY) have been directly transferred for the needs of the economic assessment in Bulgaria. The data on drug therapy costs are based on the local reference prices in Bulgaria accessible in the Positive Drug List (PDL) as of August 2016. **RESULTS:** The outcomes of the health technology assessment of ALE for the treatment of patients with RRMS in Bulgaria are in accordance with the results from the published analogous economic analysis in other countries. ALE is a cost-effective therapy in comparison with interferon (IFN) beta-1a – ICER 7822 BGN/QALY, and in comparison with IFN beta-1b – ICER 8698 BGN/QALY. ALE dominates glatiramer acetate, fingolimod, and natalizumab. **CONCLUSIONS:** Data analysis of therapeutic efficacy, safety and pharmacoeconomic analysis leads to the conclusion that alemtuzumab can be recommended as both first and second therapeutic choice for the treatment of patients with active RRMS disease.

PND32

THE COST-EFFECTIVENESS OF CLOZAPINE VS. QUETIAPINE IN THE TREATMENT OF PARKINSON'S DISEASE PSYCHOSIS

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OBJECTIVES: Parkinson's disease psychosis (PDP) imposes a high economic burden on patients and societal resources. The prevalence of psychosis was estimated to be 25%–60% in the lifetime course of Parkinson's disease. Clozapine and quetiapine are atypical antipsychotic agents indicated for the treatment of PDP. The aim of this study was to estimate the cost-effectiveness of clozapine and quetiapine in patients with PDP. **METHODS:** This study applied decision tree approach to perform cost-effectiveness analysis, from a third party perspective. The study obtained clinical data from published clinical trials on clozapine and quetiapine in the treatment of PDP. The analysis included all adverse events reported in eligible clinical trials and categorized the subjective complains as mild adverse events. For cost data such as hospitalization, we referred to publically available information; and the Red Book was used for drugs related costs. This study used Clinical Global Impression (CGI) ratings as the measure of effectiveness. The CGI is a brief assessment of the patient's overall clinical improvement prior to and after initiating a treatment. We assumed that the CGI change was zero for patients who were excluded from clinical trials due to non-responsiveness. **RESULTS:** Over the 3-month study period, the main adverse events in clozapine group were asymptomatic leukopenia (1.84%) and leukopenia with sepsis (0.10%). The use of quetiapine was associated with confusional state (2.25%). Mild adverse events occurred in both clozapine (16.85%) and quetiapine (20.32%) groups. The Incremental Cost-Effectiveness Ratios (ICER) were calculated at \$763/55 for clozapine and \$936/42 for quetiapine. In one way sensitivity analysis, the ICER for quetiapine was consistently negative. **CONCLUSIONS:** In our study, quetiapine had higher costs and lower expected value for effectiveness than clozapine. Future studies should be performed to evaluate the cost-effectiveness of antipsychotics in long-term follow-up of patients with PDP.

PND33

COST-UTILITY OF EARLY VERSUS DELAYED TREATMENT WITH INTERFERON BETA-1B IN CLINICALLY ISOLATED SYNDROME (CIS) FROM A UNITED STATES (US) PAYER PERSPECTIVE

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OBJECTIVES: To evaluate the cost-effectiveness of early versus delayed treatment with subcutaneous interferon beta-1b in clinically isolated syndrome (CIS), a first neurologic event suggestive of multiple sclerosis (MS) that precedes the majority of MS cases. **METHODS:** We used a three-state (CIS, MS, death) Markov model, annual cycles, a US payer perspective, and a 50 year time horizon to compare early treatment with interferon beta-1b to delayed treatment upon progression to clinically definite MS (CDMS). Clinical data included transition probabilities from CIS to CDMS based on the BENEFIT trial which followed patients for up to 12 years. Data on expected costs and utilities after progression to CDMS were based on a recently published network meta-analysis and cost-effectiveness model of MS. In our model costs included drug treatment and utilization by Kurtzke Expanded Disability Status Scale (EDSS). Patients entered the model at age 30 when they had experienced a CIS suggestive of MS and had ≥ 2 clinically silent lesions on magnetic resonance imaging (MRI). We estimated costs in 2016 USD, projected life-years, and quality adjusted life years (QALYs). The primary outcome was the incremental cost-effectiveness ratio (ICER). **RESULTS:** Early treatment was more expensive (\$678K compared to \$604K for late treatment) but associated with a greater number of QALYs (8.83 compared to 8.63 for late treatment), with an ICER of \$382K per QALY. Mortality in MS and cost of treatment were the most influential

model parameters, and preliminary results from a probabilistic sensitivity analysis were consistent with the main analysis. **CONCLUSIONS:** Early treatment of CIS may not be cost-effective from the perspective of payers in the US health system, which contrasts with economic models in other countries. Importantly, all models in this area are limited by sparse CIS-specific cost and utility data.

PND34

COST-UTILITY ANALYSIS OF ALEMTUZUMAB VERSUS SUBCUTANEOUS INTERFERON BETA-1A FOR THE TREATMENT OF RELAPSING-REMITTING MULTIPLE SCLEROSIS: US PAYER PERSPECTIVE

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OBJECTIVES: To compare the cost-effectiveness of alemtuzumab versus subcutaneous interferon beta-1a in patients with relapsing-remitting multiple sclerosis (RRMS), and an inadequate response to prior treatment, in the United States from a payer perspective. **METHODS:** Utilizing a 20-year time horizon, a cost-utility analysis was conducted comparing annual intravenous (IV) infusions of alemtuzumab 12 mg (administered as 2 annual courses of 5 daily infusions at treatment initiation and 3 daily infusions at year 1) to subcutaneous interferon beta-1a 44 ug 3 times weekly. A cohort-based Markov model was developed based on the previously published School of Health and Related Research model (Chilcott 2003). Transition probabilities were based on direct clinical trial evidence of disability worsening derived from the CARE-MS II study (Coles et al 2012). **RESULTS:** The results indicate that alemtuzumab was found to be cost-effective versus SC IFNB-1a. The use of alemtuzumab was associated with slower EDSS worsening and reduced relapse burden compared with SC IFNB-1a. The quality-adjusted life-years obtained with alemtuzumab and SC IFNB-1a were 7.02 and 5.76, respectively, and total costs per patient were USD 453,031 and USD 716,627, respectively. In the base case, alemtuzumab was dominant versus SC IFNB-1a. **CONCLUSIONS:** Alemtuzumab is both cost-saving and more effective when compared with SC IFNB-1a in RRMS patients with an inadequate response to prior treatment, from a US payer perspective. **REFERENCES:** Chilcott J, et al. *BMJ* 2003;326:522; Coles AJ, Twyman CL, Arnold DL, et al. *Lancet* 2012;380:1829-39.

PND35

COST-UTILITY OF DISEASE MODIFYING THERAPIES FOR RELAPSING-REMITTING MULTIPLE SCLEROSIS

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OBJECTIVES: To assess the cost-effectiveness of disease modifying therapies (DMTs) alemtuzumab, daclizumab, dimethyl fumarate, fingolimod, glatiramer acetate (Glatopa[®], Copaxone[®] 20mg), interferon beta-1a (30mcg, 22mcg, 44mcg), interferon beta-1b (Betaseron[®], Extavia[®]), natalizumab, peginterferon beta-1a, teriflunomide (7mg, 14mg) in relapsing-remitting multiple sclerosis (RRMS) in the US. **METHODS:** We used a lifetime Markov model from a US payer perspective with health states based on Kurtzke Expanded Disability Status Scale (EDSS) in RRMS and secondary-progressive MS. RRMS patients with mean age 29 entered the model with EDSS 0-6. Relative risks of EDSS progression and rate ratios for relapses for each DMT compared to supportive care were based on a network meta-analysis of clinical trials. Safety and discontinuation data were summarized from trials. Published data was used for cost by EDSS, cost per relapse, and utilities. Discounted wholesale acquisition costs were used for DMT costs. Outcomes were projected life-years, quality-adjusted life-years (QALYs), relapses, cost per QALY (ICER), and cost per relapse-avoided. **RESULTS:** Projected life-years and QALYs ranged from 21.9 and 7.8 for teriflunomide 7mg to 23.1 and 12.6 for alemtuzumab, relapses ranged from 15.6 for interferon beta-1a (Avonex[®]) to 10.8 for alemtuzumab, and total costs ranged from \$572,000 for alemtuzumab to \$1,480,100 for daclizumab. Alemtuzumab dominated all other DMTs for both ICER and cost per relapse-avoided. In the absence of alemtuzumab, glatiramer acetate (Glatopa[®]), interferon beta-1a (Extavia[®]), peginterferon beta-1a, natalizumab, and daclizumab increased QALYs compared to supportive care, with resulting ICERs of \$194,300, \$148,300, \$11,939,400, \$284,200, and \$309,600, respectively; and glatiramer acetate (Glatopa[®]), dimethyl fumarate, fingolimod, and natalizumab decreased relapses compared to supportive care, with resulting costs per relapse-avoided of \$261,200, \$3,269,000, \$120,600, and \$119,300, respectively. **CONCLUSIONS:** Alemtuzumab provided the best health outcomes and lowest costs for patients with RRMS.

PND36

COST-UTILITY ANALYSIS OF PEGYLATED INTERFERON BETA-1A VERSUS INTERFERONS BETA-1A AND BETA-1B IN PATIENTS WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS IN COLOMBIA

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OBJECTIVES: To determine cost-utility of pegylated interferon beta-1a (PegINF β -1a) versus interferons beta-1a (INF β -1a) and beta-1b (INF β -1b) in patients with Relapsing-Remitting Multiple Sclerosis (RRMS) in Colombia. **METHODS:** The base case patient has a RRMS severity <2.5 according to Expanded Disability Status Scale, the perspective of analysis was from Colombian health system. Time horizon was 20 years; the annual discount rate was 5% for benefits and costs. Outcomes: proportion of patients without relapsing during 24 months, survival rate at 20 years, Quality-Adjusted Life Years (QALYs). Direct costs were calculated for the year 2016. A Markov decision model was constructed in a hypothetical cohort of 1000 patients, considering ten RRMS' states. The model represents the probabilities of moving from state to state, leaving the treatment and

dying. **RESULTS:** Clinical efficacies are: PegINF β -1a, 39%; INF β -1a, 23.9%; INF β -1b, 13.7%. Most common complications include depression (53%), spasticity (49%) and fatigue (70%). Total discounted costs to 20 years are: no treatment, US\$ 47,015; PegINF β -1a, US\$ 173,708; INF β -1a, US\$ 210,365; INF β -1b, US\$ 165,267. Discounted QALYs to 20 years in 1000 patients are: no treatment, 7,435; PegINF β -1a, 9,293; INF β -1a, 8,601; INF β -1b, 8,104. ICER versus no treatment are: PegINF β -1a, US\$ 68,175; INF β -1a, US\$ 140,040; INF β -1b, US\$ 176,674. Survival rates to 20 years are: no treatment, 68.3%; PegINF β -1a, 92.0%; INF β -1a, 86.9%; INF β -1b, 76.6%. To willingness to pay higher than US\$ 80,000, PegINF β -1a has a probability higher than 85% to be the chosen treatment, for lower values, the highest probability is no treatment strategy. In the univariate sensitivity analysis, PegINF β -1a is dominant over INF β -1a in all scenarios of costs, and PegINF β -1a is dominant over INF β -1b on scenario at the minimum cost of PegINF β -1a. **CONCLUSIONS:** PegINF β -1a is the most cost-effective strategy in patients with RMS, both in terms of improved survival and long term QALYs as well as in terms of lowest ICER.

PND37

DIMETHYL FUMARATE VERSUS FINGOLIMOD AND TERIFLUNOMIDE FOR THE TREATMENT OF RELAPSING-REMITTING MULTIPLE SCLEROSIS IN COLOMBIA: A COST-UTILITY ANALYSIS

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OBJECTIVES: To determine cost-utility of dimethyl fumarate versus fingolimod, teriflunomide and no treatment in patients with Relapsing-Remitting Multiple Sclerosis (RRMS) in Colombia (South America). **METHODS:** The base case patient has a RRMS severity < 2.5 according to Expanded Disability Status Scale, the perspective of analysis was from Colombian health system. Time horizon was 20 years; the annual discount rate was 5% for benefits and costs. Outcomes: proportion of patients without relapsing during 24 months, survival rate at 20 years, Quality-Adjusted Life Years (QALYs). Direct costs were calculated for the year 2017. A Markov decision model was constructed in a hypothetical cohort of 1000 patients, considering ten disease states. The model represents the probabilities of moving from state to state, leaving the treatment and dying. **RESULTS:** Clinical efficacies are: dimethyl-fumarate, 36%; fingolimod, 28%; teriflunomide, 12%. Most common complications include depression (53%), spasticity (49%) and fatigue (70%). Total discounted costs to 20 years are: no treatment, US\$ 46,113; dimethyl-fumarate, US\$ 372,421; fingolimod, US\$ 341,324; teriflunomide, US\$ 227,901. Discounted QALYs to 20 years in 1000 patients are: no treatment, 7,435; dimethyl-fumarate, 9,161; fingolimod, 8,792; teriflunomide, 8,016. ICER versus no treatment are: dimethyl-fumarate, US\$ 189,040; fingolimod, US\$ 217,426; teriflunomide, US\$ 312,647. Survival rates to 20 years are: no treatment, 68.3%; dimethyl-fumarate, 90.2%; fingolimod, 86.4%; teriflunomide, 76.5%. To willingness to pay higher than US\$ 195,000, dimethyl-fumarate has the highest probability to be the chosen treatment, for lower values, the highest probability is no treatment strategy. In the univariate sensitivity analysis, the dimethyl-fumarate case base ICER is lower than US\$ 130,000 versus fingolimod and teriflunomide, according to the value reported in the willingness to pay curves. **CONCLUSIONS:** Dimethyl fumarate is the most cost-effective strategy in patients with RMS, both in terms of improved survival and long term QALYs as well as in terms of lowest ICER.

PND38

EVIDENCE MAP OF COST-UTILITY MODELS IN MULTIPLE SCLEROSIS PUBLISHED SINCE 1960

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OBJECTIVES: To create an evidence map of studies reporting cost-utility models for multiple sclerosis, and the geographical jurisdictions for which these studies were conducted. **METHODS:** We searched the heoro.com database (www.heoro.com) for cost-utility modelling studies in multiple sclerosis (MS) that were published between 1960 and 28th December 2016. We analysed the abstracts identified by the search to determine the different types of interventions modelled across the range of geographical locations, by date and type of MS. We presented the findings as an evidence map. **RESULTS:** We found a total of 42 abstracts. Of these, 14 were on relapsing-remitting MS, six were on progressive MS and 22 were on any type of MS or did not specify. Fifteen abstracts modelled the use of interferon beta-1b, 11 interferon beta-1a and seven were on any type of interferon-beta. Fourteen abstracts modelled the cost-utility of glatiramer acetate, four natalizumab and three each fingolimod, mitoxantrone and cannabinoids. Fourteen abstracts were set in the United Kingdom, 10 in the United States, four in Sweden, three in Spain, two in Germany and seven were international literature reviews or set in multiple countries. Twenty-one of the models used a societal perspective and nine a healthcare payer perspective, with 10 abstracts not specifying this. Of the 42 abstracts, 23 were published between 2010 and 2016 and none were published before 1997. **CONCLUSIONS:** The majority of cost-utility models published for treatments of multiple sclerosis assessed interferon beta formulations or compared these treatments against newer products, and were generally relevant to the UK or US jurisdiction. The substantial impact of the disease on social and occupational functioning was reflected in the high proportion of models that were conducted from a societal perspective.

PND39

ECONOMIC BURDEN ASSOCIATED WITH THE MANAGEMENT OF EPILEPSY

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OBJECTIVES: The propose of this study was to describe the characteristics of epileptic patients and to estimate the health care resources utilization and cost

related to the management of epilepsy. **METHODS:** Patients with at least two diagnosis of epilepsy between January 2011 and December 2013 were selected from the Quebec public drug plan database (RAMQ). Only newly diagnosed epileptic patients were included, i.e. patients with no diagnosis of epilepsy in the two-year period preceding. Non-refractory epileptic patients were patients who used one or two different anti-epileptic drug (AED) and refractory patients were patients who used at least three different AED in a two-year period. A control group of patients without epilepsy matched for age group and gender was selected from a random sample in a 1:10 ratio. **RESULTS:** A total of 6,230 epileptic patients and a control group of 62,300 matched patients without epilepsy were included in this study. The average age of epileptic patients was 48.1 years (SD=24.4) and 51.0% were men. Epileptic patients had a significantly higher proportion of comorbidities such as depression, anxiety, transient ischemic attack, cerebrovascular diseases and intellectual disabilities than the matched control group without epilepsy. Epileptic patients had significantly more health care cost per year (10,290 CAN\$; SD=18,904) than the matched control group (3,516 CAN\$; SD=8,437). The primary drivers for the difference of cost were the inpatient visit and medication. The refractory epileptic patients had 1.7 times more health care resources cost per year (n=571; 17,336 CAN\$; SD=23,340) than the non-refractory patients (n=4,109; 10,263 CAN\$; SD=17,860) and 2.2 times more than the epileptic patients without treatment (n=1,550; 7,764 CAN\$; SD=19,129). **CONCLUSIONS:** The management of epilepsy is associated with a significant economic burden. Compared to non-refractory epileptic patients, refractory patients have a much higher health care resources utilisation and cost.

PND40

AN ANALYTICAL FRAMEWORK TO PROJECT THE POTENTIAL MEDICARE COST BENEFIT OF INTEPIDINE (RVT101) IN MILD-MODERATE ALZHEIMER'S DISEASE

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OBJECTIVES: The Dependence Scale (DS) captures a combination of the cognitive, functional, and psychiatric changes that occur in Alzheimer's disease (AD) and is strongly correlated with cost of patient care. As reported previously, combination therapy with donepezil and 35 mg intepirdine (RVT-101), an oral 5HT₆ antagonist in development for the treatment of mild-moderate AD, was projected based on a conversion algorithm to reduce progression in Dependence Level (DL) compared to donepezil monotherapy using data from a placebo-controlled study. Here we examine potential Medicare cost differences associated with this reduced DL progression. **METHODS:** The Alzheimer's Disease Cooperative Study - Activities of Daily Living Scale (ADCS-ADL) was measured in a 48-week study of intepirdine vs placebo on top of stable donepezil in subjects with mild-moderate AD (n=684). The ADCS-ADL was converted to DL using a published algorithm. Total costs projected to be paid by Medicare by DL were estimated from the Predictors 2 study using Medicare claims data and assigned to this study. Cost changes from baseline were compared between treatment groups. **RESULTS:** Estimated costs projected to be paid by Medicare were higher at more severe DLs, ranging from \$4,755 for DL=0/1 to \$23,311 for DL=4/5. The Medicare costs associated with the donepezil monotherapy group were projected to increase by \$595 over all visits, while the Medicare costs associated with the 35 mg intepirdine plus donepezil combination therapy group were projected to decrease by \$283. The magnitude of annualized Medicare cost benefit associated with intepirdine treatment was projected to range from \$443 to \$1,203 based on baseline DL. **CONCLUSIONS:** In this analytical framework, combination therapy with 35 mg intepirdine and donepezil was associated with projected annualized Medicare cost benefits between \$443 and \$1,203 compared to donepezil monotherapy. Intepirdine is currently being evaluated in a global Phase 3 study in mild-moderate AD with data expected in 2017.

PND41

COMPARISON OF INSTITUTIONAL PLACEMENT BETWEEN ALZHEIMER'S DISEASE (AD) PATIENTS IN MEDICAID AND TWO AD REGISTRIES

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OBJECTIVES: A significant fraction of all patients with AD receiving institutional care are covered through the Medicaid program. We sought to compare the institutional placement predicted using published equations based on DADE and CERAD studies with that in a study of the Medicaid population. **METHODS:** We simulated disease progression and the need for institutional care over 10 years in patients with AD using the AD Archimedes Condition-Event simulator (AD ACE). The AD ACE is constructed using predictive equations for change in disease biomarkers and clinical scales derived primarily from analyses of AD Neuroimaging Initiative (ADNI) data. Rates of institutional care placement were simulated based on published equations from DADE study, with a second equation based on CERAD study tested as a scenario. Patients with mild AD (mean MMSE 23) were simulated, and a more severe subset of patients (mean MMSE 21) tested as a scenario. These analyses were compared against published probabilities of institutionalization for AD patients from New Jersey Medicaid claims data. **RESULTS:** The simulated populations showed lower rates of institutional care after 3 years (10%) than the rate in Medicaid patients (23%). Over the long-term, however, the rates of institutional care in the simulated population (56%) rose to similar levels to that in the Medicaid population (52%). Simulating patients with more advanced AD had institutionalization rates similar to the base case: 10% at 3 years and 60% at 10 years. In the alternate equation scenario, rates were also similar to the base case at 3 years (10%), but even higher at 10 years (75%). **CONCLUSIONS:** Published equations for rates of institutional care may be suitable for describing the long-term need of patients with AD in a Medicaid

population, but may not adequately capture the early need, potentially underestimating the economic burden of AD in this program.

PND42

MARKET ACCESS CONSIDERATIONS IN PHARMACEUTICAL IN-LICENSING VALUATIONS

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OBJECTIVES: Valuation of assets in licensing deals is based on the asset's 'approvability', with the estimated value of the asset increasing as the likelihood of regulatory approval grows with each successful clinical development stage. This study aimed to assess the 'reimbursability' and price potential in the EU5 of a CNS asset that faces generic competition. **METHODS:** In-depth interviews with 10 former senior national and regional level payers from EU5 were conducted, along with analysis of historic EU5 at-launch prices of CNS drugs using IMS data. **RESULTS:** The asset's successful Phase III trial was 6-weeks long and conducted against placebo as the comparator. Assuming EMA approval, European payers unanimously agreed that this data would not be sufficient for negotiating premium prices in the EU5 markets. Payers requested 6 month-long direct and/or indirect comparative studies against standard of care (SoC) therapies in the EU, all of which are generic. To avoid generic price referencing, superiority in efficacy and/or safety vs SoC would have to be demonstrated. Analogue analysis of CNS drugs launched in genericised EU5 markets showed that comparative studies demonstrating non-inferiority in efficacy and superiority in safety vs generic comparators might lead to 3-4 times price premium over a generic price, while superiority in both efficacy and safety to >5 times price premium. We estimated that with the existing data the asset would be reimbursed at €1-€1.6 per day in EU5 (vs estimated \$65 per day in the US). With additional data the asset could be reimbursed at €2.5-€5 per day. **CONCLUSIONS:** Estimating the EU5 reimbursement and price potential is a crucial consideration in asset valuation process that can significantly alter the asset's NPV. Market access analysis should be carried out early in the development process to insure that the clinical development plan addresses the 'reimbursability' issues.

NEUROLOGICAL DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

PND43

QUANTIFYING THE BENEFITS OF INJECTION-RELATED PAIN REDUCTION ON PATIENT OUTCOMES

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OBJECTIVES: Evaluate patient outcomes for a new formulation of the multiple sclerosis (MS) drug glatiramer acetate (GA) associated with reduced injection-related pain. **METHODS:** This retrospective, closed-cohort study included adults from the Truven MarketScan Commercial database with: ≥2 claims with MS diagnoses, ≥6 months of continuous GA treatment before approval of the new formulation, and ≥6 months of data after the index date (earliest claim for new formulation [switchers] or GA claim closest to index date of match [non-switchers]). Non-switchers were propensity-score matched 1:1 to switchers using baseline demographics, comorbidities, resource use, and costs. Adherence (measured by proportion of days covered) and direct costs were compared for switchers and non-switchers 6 months following the index date. Difference-in-differences analysis compared outcomes 6 months before and after the index date. Wilcoxon signed-rank and McNemar's tests for matched pairs compared continuous and categorical measures, respectively. Outcomes were also assessed using multivariate regression analyses. **RESULTS:** Within 6 months of approval, approximately 42% of patients switched to the new GA formulation (switchers, n=1,362; non-switchers, n=2,093). After matching, there were no significant differences in demographics, comorbidities, or baseline costs. Following approval of the new formulation, switchers had significantly better adherence than non-switchers (90% vs 80%; p<0.0001) and total costs for switchers were \$221 less than non-switchers (p=0.01), driven by reduced medical costs of \$1,882 (p=0.17). Difference-in-differences analysis demonstrated improved adherence (+2 vs -8 percentage points; p<0.0001) and \$508 lower increase in total costs relative to baseline for switchers versus non-switchers (p=0.005). In multivariate analyses, switchers were predicted to have a 13% increase in adherence (90% vs 80%; p<0.0001) and 22% reduction in medical costs (\$8,798 vs \$11,255; p=0.002). **CONCLUSIONS:** The new formulation of GA with reduced injection-related pain improved adherence and reduced medical costs. Reformulation of other therapies that reduce injection-related pain may provide similar benefits.

PND44

ADHERENCE WITH PROPHYLACTIC MIGRAINE MEDICATIONS AMONG PATIENTS WITH AND WITHOUT PRIOR PROPHYLACTIC MEDICATION USE

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OBJECTIVES: To describe adherence and persistence with prophylactic migraine medications (PMM) among all users as well as among subgroups with (Experienced) and without (Naïve) prior PMM use. **METHODS:** This retrospective cohort study identified adult migraine patients (ICD-9 346.XX and/or migraine-specific medications) in the Truven Health MarketScan Commercial Database January 2010-June 2014. The first new PMM prescribed in the study period was the index

event; patients were stratified based on whether they had pre-index use of a different PMM (PMM Experienced) or with PMM Naïve. Patients without 12 months of enrollment pre- and post-index or with a diagnosis of HIV or malignancy were excluded. The primary study outcomes were adherence and persistence with the index PMM during the 12-month follow-up. Discontinuation was defined as a gap of ≥60 days in supply of the index PMM. **RESULTS:** 76,236 migraine patients met the inclusion criteria; 60.8% were PMM Experienced. PMM Experienced patients were older (mean age 45.0 [SD=12.3] versus 43.0 [SD=12.3]), more likely female (85.1% versus 83.3%), and had higher baseline Deyo Charlson Comorbidity Scores (0.38 [SD=0.70] versus 0.24 [SD=0.59]) than Naïve patients. Across all PMM users, mean proportion of days covered (PDC) was 0.43 (SD=0.34) and 24.0% had PDC≥0.80; PMM Experienced patients had higher PDC than Naïve patients (0.44 [SD=0.34] versus 0.40 [SD=0.33]) and were more likely to have PDC≥0.80 (25.3% versus 21.7%). Among all PMM users, 71.4% discontinued, time to discontinuation was 162.0 days (SD=142.2); PMM Experienced patients were less likely than Naïve patients to discontinue (69.5% versus 73.5%) and had a longer time to discontinuation (169.3 days [SD=143.4] versus 153.9 [SD=140.7]) (all p<0.001). **CONCLUSIONS:** Overall adherence to migraine prophylactic medication is low; PMM Experienced patients had slightly higher adherence and persistence compared to Naïve patients. Approximately one-in-four patients had PDC≥0.80 and over two-thirds discontinued their index PMM in the year after it was initiated.

PND45

PATIENT CHARACTERISTICS AND TREATMENT ADHERENCE AMONG PATIENTS TREATED WITH DELAYED-RELEASE DIMETHYL FUMARATE FOR RELAPSING REMITTING MULTIPLE SCLEROSIS IN ISRAEL

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OBJECTIVES: Few studies have relied on real-world data to describe the characteristics and treatment patterns of patients using oral disease-modifying treatments (DMTs) for relapsing remitting multiple sclerosis (RRMS) outside the US. This study reports the demographics, MS symptom burden, and treatment adherence among patients initiating treatment with a leading oral DMT – delayed-release dimethyl fumarate (DMF, also known as gastro-resistant DMF) – in Israel. **METHODS:** Patients aged ≥18 years diagnosed with MS and with ≥1 prescription for DMF were selected from de-identified electronic medical records data from a health fund in Israel (1/2013-1/2016). Patients were required to have continuous enrollment with the health fund for ≥12 months before (baseline) and ≥6 months after (follow-up) the first observed prescription (index) date. Patient characteristics during baseline and adherence during the follow-up period, as measured by medication possession ratio (MPR), were described. **RESULTS:** Of the 177 patients meeting the selection criteria (mean age: 40 years; ~30% male), 114 (64%) had previously used injectable DMTs for RRMS (primarily interferon beta). The average duration from MS diagnosis to index date was 69 months (median: 45 months). Nearly half of the patients had indications of neuropathic or musculoskeletal pain in the year before index, 26% bladder or bowel problems, 16% vision issues, 15% cognitive or psychiatric disorders, and 15% depression. The mean MPR during the 6-month follow-up period was 0.81 (median: 0.91); over two-thirds (69%) of the patients were considered adherent (MPR >0.8). **CONCLUSIONS:** Patients initiating DMF in Israel had considerable symptom burden, and many used injectable DMTs prior to treatment initiation, possibly reflecting the relatively recent approval of the medication in Israel. Most patients were adherent to treatment during the 6-month follow-up period. Further research is needed to understand long-term adherence among Israeli patients.

PND46

RETROSPECTIVE, CLAIMS-BASED ANALYSIS DEMONSTRATES LIMITED PERSISTENCE AND ADHERENCE, AND LOW DAILY DOSES OF AMANTADINE IMMEDIATE RELEASE (AMT-IR) IN PATIENTS WITH PARKINSON'S DISEASE (PD)

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OBJECTIVES: Five decades after introduction, levodopa remains the treatment of choice for PD. Chronic levodopa treatment with progressing PD contributes to levodopa-induced dyskinesia (LID), defined as involuntary, non-rhythmic, purposeless, unpredictable movements during waking hours occurring in approximately 30% of patients. LID can compromise optimal levodopa treatment. No FDA-approved drug for LID exists. AMT-IR was originally approved for influenza and later indicated in parkinsonism. It has also been evaluated in small studies for the treatment of dyskinesia. Conflicting guidelines for the use of AMT-IR in dyskinesia exist. While higher doses of AMT-IR have been shown to produce greater reductions in dyskinesia, they are associated with increased frequency of central nervous system adverse events. Real-world use, persistence, and adherence for AMT-IR has not been extensively analyzed or reported. **METHODS:** A retrospective claims-based analysis was conducted utilizing Symphony Health data to evaluate current AMT-IR utilization patterns in PD patients persistent on levodopa for at least 4 years (indicating presence of LID (Suh, 2012)). Persistence was defined as continuous therapy without refill gaps > 90 days. Adherence was defined as ≤ 5 days between expected and actual refill dates. **RESULTS:** Among 22,000 patients persistent on levodopa for 4 years, approximately 1,500 (6.8%) had taken AMT-IR. At 1 year, 39% were persistent and 7% were adherent. The average starting dose was approximately 200 mg/day amantadine HCl (equivalent to 162 mg amantadine). Only 15% of patients started at 300mg/day amantadine HCl (equivalent to 243 mg amantadine) or greater. At one year, among those initiated on ≥300mg/day (243 mg amantadine), 38% were persistent while only 4% were

adherent. **CONCLUSIONS:** This claims analysis demonstrates limited persistence and adherence at daily doses of 200-300 mg AMT-IR in PD patients. Higher dosage forms and improved delivery systems for amantadine in the treatment of LID may increase efficacy, persistence, and adherence.

PND47

LEVERAGING DISEASE MANAGEMENT & TECHNOLOGY TO HELP MULTIPLE SCLEROSIS PATIENTS ADHERE TO TREATMENT PLAN

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OBJECTIVES: Determine if patients who enroll in a CareMed Specialty Pharmacy led disease management program for the treatment of Multiple Sclerosis (MS) with SC/IM therapy are more adherent than patients who are not enrolled in such a support program. Recent MS study results show that adherence of patients on SC/IM therapy is 70.8%; these patients were not supported by any disease management programs. Further, MS patients who took their medication consistently were found to have 66% fewer emergency room (ER) visits and 23% lower medical costs than those MS patients who did not. Average MS-related medical costs for patients in the lowest medication adherence range were \$23,253, while those in the highest adherence range averaged \$17,814, resulting in an average savings over \$5,400. **METHODS:** Enroll 1,647 patients in a disease management program and track their adherence to SC/IM therapy over the course of 12 months. Develop a robust disease management program with input from physicians and patients. Construct a pharmacy based MS patient facing interactive portal. Integrate analytic and programmatic approaches to support patient adherence. Adherence metrics of this study were: 1) Number of missed doses in four weeks; 2) Reason dose was missed; 3) Perceived side effects; 4) Ease of administration; 5) Medication satisfaction. **RESULTS:** 97.4% of all SC/IM therapy doses for participating in CareMed's disease management program were administered based on physician treatment plans compared to 70.8% of all SC/IM therapy doses for patients not participating in a disease management program. **CONCLUSIONS:** Pharmacy led MS focused disease management programs can support better adherence resulting in fewer ER visits and a reduction in overall medical costs. Further study regarding disease management programs and their impact on outcomes and costs is recommended.

PND48

COMPARISON OF HEALTH UTILITY MEASURES FOR AMYOTROPHIC LATERAL SCLEROSIS IN THE GENERAL KOREAN POPULATION: STANDARD GAMBLE AND EURO QOL-5D

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OBJECTIVES: To elicit health utilities for health states of amyotrophic lateral sclerosis (ALS) in the general population of South Korea using standard gamble (SG) and Euro-quality of life five dimensions questionnaire (EQ-5D) as well as to identify the factors which cause differences in the two utility measures. **METHODS:** Four ALS health state descriptions according to disease severity were developed: mild, moderate, severe, and terminal state. Utilities of these states were measured via SG and EQ-5D from 202 respondents, who were selected using a stratified quota sampling method to represent the general Korean population. Utility values for each health state were compared using paired t-tests, and the relationships between the two utility measures and levels of disease-severity and sociodemographic factors were tested using generalized estimating equations. **RESULTS:** When disease severity increased, both SG and EQ-5D showed systematic decreases. The utility values between SG and EQ-5D for each state, excluding the mild state, were significantly different: utility value for mild 0.880 ± 0.101 vs. 0.877 ± 0.053 ($p=0.716$); moderate, 0.787 ± 0.154 vs. 0.722 ± 0.092 ($p<0.000$); severe, 0.629 ± 0.186 vs. 0.446 ± 0.186 ($p<0.000$); terminal 0.346 ± 0.206 vs. 0.014 ± 0.144 ($p<0.000$). The differences in utility values between SG and EQ-5D in health states progressively increased as patients' health states became more deteriorated. The differences in utility for moderate, severe, and terminal state were 1.06, 1.20, and 1.36 times greater, respectively, compared to that of mild state. The differences in utility were 7% higher in women than men ($p=0.02$). **CONCLUSIONS:** The study found that utility values of SG were significantly higher than those of EQ-5D. In addition, the difference between SG and EQ-5D gradually increased as patients' health became severe, implying that general population was risk averse. It is recommended that a future study be performed to find the causes of the differences between utility derived from SG and EQ-5D in the Korean population.

PND49

EFFECTS ON COMPENSATING VARIATION OF NUMBER AND KIND OF COMPETING SUBSTITUTES IN DISCRETE-CHOICE EXPERIMENTS

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OBJECTIVES: Evaluate the impact on preference estimates of changing the substitutability of treatment alternatives in DCE questions. **METHODS:** Adult members of an online panel, completed a web-enabled DCE survey (N=811). Respondents were asked to imagine they had a gene variant associated with risks of health problems. Two constructed interventions to reduce the risk of health problems were described in addition to watchful waiting: preventative surgery and medication. Using a three-alternative labeled experimental design, respondents were allowed to either choose between surgery and watchful waiting (n=193) (Group 1), medication and watchful waiting (n=217) (Group 2), and surgery or medication in addition of watchful waiting (n=401) (Group 3). A random-parameters logit (RPL) model was used to estimate separate preferences for respondents in each of the three groups. Compensating variation (CV) for the average surgery and medication were calculated for each group

to measure the expected benefit of adding each intervention to the list of alternatives to prevent future health problems. **RESULTS:** Surgery and medication CV values were similar when estimated with and without a second type of intervention in the choice questions. We found that CV varied with the likelihood and severity of future health problems. For example, among respondents who considered only the possibility of choosing medications in the choice questions, CV ranged between \$32 and \$103, based on the risk level and the severity of the health problem. In general, having only one type of intervention in the choice questions was associated with greater CV for the least valuable intervention. Only with high risk of mild health problems was surgery more desirable than medications. **CONCLUSIONS:** The study results provide some assurance that DCE models can be robust to incomplete specifications of relevant substitutes in choice questions, even in cases where clinically-relevant alternatives are imperfect substitutes.

PND50

DEVELOPING AN INSTRUMENT TO MEASURE CAREGIVER PRIORITIES FOR POTENTIAL TREATMENT FOR PRADER-WILLI SYNDROME: A COMMUNITY-CENTERED APPROACH

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OBJECTIVES: Prader-Willi syndrome (PWS) is a neurodevelopmental disorder resulting from abnormalities of genes on chromosome 15. No cure for PWS exists. Emerging treatments target hyperphagia and behavioral outbursts, the importance of which is not well documented. We developed and tested a novel stated-preference instrument to measure caregiver preferences for emerging PWS treatments. **METHODS:** We used a community-engagement approach to engage diverse stakeholders in developing and piloting the instrument. Partnering with the Prader-Willi Syndrome Clinical Trials Consortium, we assembled a community advisory board and engaged the board through interviews and meetings. The engagement influenced the design, length, wording of the survey, and the protocol for the debrief interviews. A novel best-worst scaling instrument (case 1) was designed with 13 choice tasks; caregivers were asked to determine the most and least important of the four treatment outcomes listed in each task. A score was generated where prioritized outcomes are more positively ranked. We recruited caregivers at an annual conference for the pilot of the survey and debrief interviews. Caregivers provided feedback in debrief interviews once they previewed or completed the survey. **RESULTS:** 54 caregivers completed the pilot survey (RR=50%). The majority of the PWS patients were diagnosed through genetic testing (98%). The respondents value treatments addressing hyperphagia (score = 0.77, SD: 0.44) and food-related behavior (score = 0.43, SD: 0.57). 14 caregivers completed the interviews. Interview analysis indicated clarity in the survey wording and heterogeneity in the community. **CONCLUSIONS:** We demonstrated the feasibility of conducting preference research using a community-centered approach in a broad-spectrum disease where heterogeneity is prevalent. Advocacy organizations such as Parent Project Muscular Dystrophy have been generating preference evidence to advise the Food and Drug Administration (FDA) in the patient-focused drug development. This study can inform the FDA and provides a model of engaging stakeholders for endpoint prioritization.

PND51

THE VALUE OF DIAGNOSTIC TESTING FOR PARENTS OF CHILDREN WITH RARE GENETIC DISEASES

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OBJECTIVES: Patients with rare genetic diseases traditionally experience a prolonged and expensive diagnostic odyssey culminating in a delayed diagnosis or, too frequently, no diagnosis at all. Whole-exome sequencing (WES) can now rapidly identify mutation(s) responsible for rare, single-gene diseases, and potentially reduce the diagnostic odyssey. Before WES is adopted into clinical practice, a clear estimation of the value of a WES-based diagnosis for families is critical. **METHODS:** Based on our literature review and qualitative research (focus groups, interviews with parents of children with rare genetic diseases), we developed a discrete choice experiment (DCE) survey which has been administered online to parents of children with rare genetic diseases. The DCE included 14 choice tasks with 6 attributes and 3 alternatives considering orthogonality, D-efficiency and level balance. Preferences were analyzed using conditional logit and hierarchical Bayes. **RESULTS:** Preliminary results include n=214 respondents: mean age 41 years (range: 22-65 years), female (90%), have university degrees (42%), married (72%), employed full-time (46%), identify as white (89%), and high income (\$80,000 CAD or more, 58%). Overall, 88% reported their child had genetic testing, and 64% reported their child had a diagnosis. Of those who reported no diagnosis, the mean duration spent seeking a diagnosis is 5.7 years (range: 1-25 years). The most valued attributes were time to obtain an answer from the diagnostic test (diagnosis or not), chance of obtaining a diagnosis and cost. The positive or negative impact of the results and the type of diagnostic testing were significant but not as strongly valued, with WES preferred to other testing. Parents were willing to pay approximately \$5000 CAD on average for diagnostic testing. **CONCLUSIONS:** Parents of children with rare genetic diseases place a high value on obtaining information, regardless if it is a diagnosis or not. Additionally, WES is valued over other diagnostic tests.

PND52

COMPARATIVE ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE AMONG THALASSEMIA PATIENTS WITH HEALTHY CHILDREN, A CROSS-SECTIONAL STUDY

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OBJECTIVES: The aim of this study was to assess the health-related quality of life (HRQoL) of thalassemia patients by comparing it with HRQoL of healthy persons and to evaluate the factors associated with HRQoL among thalassemia patients and level of depression of their caregivers. **METHODS:** This cross-sectional study was conducted in Thalassemia Center, Bahawal Victoria Hospital, Bahawalpur from February 2016 to March 2016 among 150 patients ranging from 2 to 18 years in age. Patient's HRQoL was measured using PedsQL (Pediatric Quality of Life) 4.0 generic scale and the depression level in their caregivers was assessed using PHQ-9 (Patient Health Questionnaire-9). HRQoL of healthy control group was also measured using same questionnaires. **RESULTS:** The mean score of psychosocial functioning was higher in control group (95.51 74.40) as compared to patients (38.5724.29). The school functioning score (26.8426.08) was lowest of psychosocial measures in thalassemia patients, followed by emotional functioning (30.2330.18) and social functioning (60.1029.87) score. The mean physical health score was found to be 49.2023.92 in patients whereas control group showed the mean score of 89.0611.91. Majority (28%) of the caregivers showed severe depression while 20.7% showed moderately severe depression and (18%) showed mild depression. **CONCLUSIONS:** In conclusion, thalassemia has substantial negative effect on HRQoL of children and their caregivers. Continuous psychological support from health authorities, improvement in policies made by government and school officials and more understanding from society can be helpful in enhancing quality of life of these patients and their caregivers.

PND53

CHOICE OF TREATMENTS AND WILLINGNESS TO PAY TO INSURE FOR MULTIPLE SCLEROSIS DISEASE MODIFYING THERAPIES

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OBJECTIVES: Prior to the approval of the first disease modifying therapy (DMT) in the mid 1990's there were limited options for treatment for Multiple Sclerosis (MS). DMTs have transformed MS by delaying its progression and reducing relapses. However, these therapies can be expensive and may have side effects. This study aimed to: 1) Characterize the preference of neurologists and the general public between the pre-DMT time period (pre-1995) and current landscape, and; 2) Assess the public's willingness to pay (WTP) for insurance to cover DMTs. **METHODS:** We conducted a national online survey. Part 1 asked neurologists and respondents from the general population to choose between pre-DMTs and current DMT regimens. In Part 2, general population respondents participated in a bidding game to determine WTP for health insurance to cover DMT costs should they develop MS. **RESULTS:** Most respondents (76% of neurologists and 65% of the general population) preferred DMTs over pre-DMT era treatments. On average, the general population had a WTP of \$22 per family member per month (PMPM) (\$16 median) for MS DMT insurance. Respondents who chose pre-DMT era treatments had a numerically lower WTP (\$19 mean, \$14 median PMPM), compared with those who preferred DMTs (\$23 mean, \$17 median PMPM). **CONCLUSIONS:** Although most respondents prefer DMTs to non-DMTs, some general population respondents and neurologists prefer pre-DMT therapies. The neurologist result is surprising given the strong physician group recommendations for use of DMTs at the earliest point possible. Ex-ante WTP for MS DMT insurance coverage is 4-5 times the current PMPM cost of MS DMTs, which was \$4.43 in 2015.

NEUROLOGICAL DISORDERS – Health Care Use & Policy Studies

PND54

DIFFERENCES IN TIMING OF MEMANTINE INITIATION IN MILD-MODERATE AND MODERATE-SEVERE ALZHEIMER'S PATIENTS IN USA VS. JAPAN

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OBJECTIVES: 1) To design and test a patient simulation platform representative of mild-moderate and moderate-severe Alzheimer's patients in the USA and Japan 2) To compare prescribing behavior between Japanese and US physicians in the treatment of Alzheimer's disease. **METHODS:** The study was comprised of two stages. First, we developed a bilingual simulation platform with 16 profiles representing a range of mild-moderate and moderate-severe patients. Various ADL measure, and patient inputs were mapped to the virtual patients' MMSE and GDS scores. After pre-testing the simulation's realism and usability, the full study was launched in September 2016. A total of 209 psychiatrists/neurologists/PCPs were surveyed (104 in Japan; 105 in the US). **RESULTS:** In general, US physicians initiated a regimen including memantine earlier than did Japanese physicians. Japanese physicians prescribed significantly less often at milder levels of severity, and their usage of memantine matched their American peers only at severe levels of impairment (MMSE score of <10). Physicians in the US also demonstrated differences in prescribing across gender, while this effect was not observed in Japan. In a post-simulation survey, physicians indicated that the simulation was realistic and that their treatment decisions within the survey reflected real-life practice. **CONCLUSIONS:** Problems with the quality and availability of prescription data necessitate the consideration of other research methods, particularly in

challenging populations (rare diseases, small subpopulations). This study demonstrated the promise of using simulation to observe prescribing behavior across different markets. Limitations of this research include significant time costs for the development of comprehensive, realistic patient profiles and currently, the inability to identify information accessed by the physician beyond categories of information viewed. Next steps include the comparison of collected data to prescribing databases and the exploration of other applications- simulating environmental changes (insurance coverage, etc.), forecasting, and message testing.

PND55

CLINICAL, DEMOGRAPHIC, TREATMENT AND COST CHARACTERISTICS OF DEMENTIA WITH LEWY BODIES FROM A LARGE US ADMINISTRATIVE CLAIMS DATABASE

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OBJECTIVES: Several analyses on treatment dynamics in Alzheimer's disease (AD) using claims data have been published, but there is little similar data available in Dementia with Lewy Bodies (DLB). This study seeks to characterize DLB treatment dynamics using data from a claims database. **METHODS:** Truven MarketScan, a US claims database with over 100 million patients, was used for this study. Two samples were identified for analysis: "cross-sectional" (Jul 2014-Jun 2015) and "longitudinal" (Jan 2010-Jun 2015). Both cohorts used similar inclusion criteria, though patients in the longitudinal cohort were tracked from their first dementia diagnosis (Dx) whereas patients in the cross-sectional cohort were identified based on a combination of ICD-9 diagnostic, confirmatory diagnostic and/or treatment (Rx) claims. **RESULTS:** For the cross-sectional analysis, 26,315 AD and 473 DLB patients were identified. The mean ages were 83 (AD) and 81 (DLB) years. AD patients were more frequently female (63% v. 52%). For the longitudinal analysis, 16,107 AD and 771 DLB patients were identified. The mean age for both AD and DLB was 81 years. AD patients were more often female than DLB patients (63% v. 53%). Despite more specialist involvement, the DLB patients were less likely to be taking dementia Rx than AD patients (69% v. 77%) and those on Rx were more likely to be on monotherapy. DLB patients had higher use of psychotropic Rx. Setting of care was similar, but the DLB group had higher annualized costs, driven by hospitalization. **CONCLUSIONS:** The gender and psychotropic use characteristics of the DLB patients identified in this analysis are consistent with the diagnosis of DLB. The results suggest that DLB patients have more annualized cost and are on more psychotropic medications than AD patients, but surprisingly are less frequently on dementia Rx.

PND56

THE USE OF ANTI-EPILEPTIC DRUGS FOR CHILDHOOD EPILEPSY IN HOSPITAL SETTINGS

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OBJECTIVES: To investigate the use of antiepileptic drugs (AEDs) for pediatric epilepsy in children's hospitals. **METHODS:** We identified the study cohort from children discharged between 10/1/2013 and 9/30/2014 in the Pediatric Health Information System (PHIS) database. Inpatient epilepsy encounters in 30 National Association of Epilepsy Center Level III or Level IV designated centers and 7 other children's hospitals were included. Inclusions were patients aged 0-17 years with ICD-9-CM diagnosis of epilepsy (345.XX). Exclusions were missing gender and charges. Simple and multivariable general-linear model with the Gamma family and log-link function were used to determine factors associated with increased AED charges for childhood epilepsy. A Multi-level model with a random-effect for each hospital was used. Analyses used SAS@ 9.4 and STATA 14.0 software. **RESULTS:** 15261 inpatient epilepsy visits were included, 30.31% with intractable epilepsy. 77.7% were under age 12. Payers included public (47.8%) and private insurers (49.1%). 13.5% patients had no AED use. 32.7% (4496 cases) were on monotherapy; among them, most commonly used AEDs were levetiracetam (LEV), oxcarbazepine (OXC), and valproic-acid-and-derivatives (VPA). Over 26% used multidrug regimens (3 to 9 AEDs) during hospitalizations. LEV shared 31% of total inpatient adjusted-AED charges (\$3,632,793USD); Clobazam and Lacosamide consisted of 24% of total adjusted-AED charges. Median inpatient adjusted-AED charge was \$284USD per inpatient, (interquartile-range (IQR) \$631; mean \$911). Factors associated increased AED charges (p-value < 0.05) include male gender (5% more charges than female), older age, Black/Hispanic (12%/10% more than White), South region (113% more than North-east), intractable epilepsy (78% more than non-intractable), and presence of complex-chronic conditions (CCC) (59% more than those without CCC). **CONCLUSIONS:** Gender, age, race, geographic practice variation, CCC, and intractable epilepsy status were significantly associated with increased adjusted-AED charges. Further study is warranted to incorporate long-term clinical outcomes into analysis models and to understand drivers of AED charges.

PND57

EXPENDITURE OF INPATIENTS WITH PARKINSON'S DISEASE IN DIFFERENT MEDICAL INSTITUTIONS IN SHANGHAI

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OBJECTIVES: There have been few studies on the expenditure of patients with Parkinson's disease (PD) in China. The aim of this study was to investigate direct cost of inpatients with PD in various medical institutions in Shanghai. **METHODS:** This study was conducted using data from the Shanghai Discharged Patients Medical Record Information Platform. The records of 2926 patients with

PD who have been discharged from all professional medical institutions in 2015 were examined. **RESULTS:** The hospitalized patients with PD were from third-grade hospitals(893), second-grade hospitals(1020), private hospitals(368), community health centers(272) and nursing homes(373). The average expenditure of all cases was RMB 27083. The average cost of patients in above-mentioned institutions were respectively RMB 37275,25782,21681,14712 and 20587. Medical consumables cost largest (45.25%) in the third-grade hospitals, while only cost less than 1.50% in other institutions. The largest part accounting for the expenses in the nursing homes, second-grade hospitals and community health centers were comprehensive medical services (including general medical services and nursing services, et al), which respectively accounted for 54.55%, 48.97% and 40.53%. The fee of drugs, not including Traditional Chinese Medicine(TCM), was more than 19.5% in each institution. The ratio of TCM expenditure in the community health centers was largest (13.29%), while the ratios in others were less than 6%. In private hospitals, the largest part of the expenditure was treatment (21.00%). **CONCLUSIONS:** PD causes significant expense for the health care system. The disparities of medical expenditure of PD in different institutions exists, illustrating the challenges for reducing the economic burden of this section of the society. This argues for more research to evaluate the rationality of some expenditure among patients in various institutions.

PND58

ALZHEIMERS DISEASE AND RELATED DEMENTIAS AND OUT-OF-POCKET HEALTHCARE SPENDING AND BURDEN

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OBJECTIVES: The objective of our study is to estimate the excess burden of annual total direct out-of-pocket spending and out-of-pocket spending on different types of healthcare services among elderly Medicare beneficiaries with Alzheimer's Disease and Related Dementias (ADRD) by comparing them to Medicare beneficiaries without ADRD. **METHODS:** We used data from 2012 Medicare Current Beneficiary Survey. The study sample comprised older adults (age >65 years), living in the community, with positive total healthcare expenditures, and enrolled in Medicare throughout the calendar year (462 with ADRD, and 7,160 without ADRD). We estimated the total out-of-pocket spending on healthcare and out-of-pocket spending by service type: inpatient, outpatient, home health, prescription drugs, and others. We measured out-of-pocket spending burden by calculating the percentage of income spent on healthcare and defined high out-of-pocket spending burden as having this percentage above 10%. Multivariable analyses included ordinary least squares regressions and logistic regressions that adjusted for predisposing, enabling, need, personal healthcare practices and external environment characteristics. **RESULTS:** The average annual per-capita out-of-pocket healthcare spending was greater among individuals with ADRD compared to those without ADRD (\$3,285 vs. \$1,895); home health and prescription drugs accounted for 52% of total out-of-pocket spending among individuals with ADRD and 34% among individuals without ADRD. Higher out-of-pocket spending burden by those with ADRD persisted even after adjustment for other factors (Beta=3.38, p=0.003). Elderly individuals with ADRD were more likely to have high out-of-pocket spending burden (AOR =1.49; 95% CI=1.13, 1.97) compared to those without ADRD. Our results showed that ADRD is associated with excess out-of-pocket healthcare spending, primarily driven by prescription drugs and home healthcare use. **CONCLUSIONS:** Medicare beneficiaries with ADRD have higher out-of-pocket expenditures as compared with Medicare beneficiaries without ADRD. The financial burden as a percent of income is higher with Medicare beneficiaries with ADRD as compared with Medicare beneficiaries without ADRD.

PND59

ALZHEIMER'S DISEASE IN CHINA: A DECISION MAKING TOOL FOR RESOURCE ALLOCATION

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OBJECTIVES: to model the future disease burden and economic impact scenarios of Dementia and Alzheimer's disease (AD) in China so as to provide a tool for health resource allocation. **METHODS:** Literature search was conducted on PubMed using pre-specified keywords. Research articles (n=50) on prevalence and cost of AD dementia in China were identified based on pre-specified criteria. Prevalence data was used against projected Chinese population in 2030 to forecast number of AD dementia cases. This data was then inputted into MS Excel based model to predict the economic cost of dementia in 2030. Finally, multiple scenarios based on prevalence and cost estimates were generated. **RESULTS:** Our model predicts by 2030 the number of people with dementia in China would grow to 7.8 Mn; a growth of over 50% compared to 2015 (5.1 Mn). This is equivalent to 20 new AD cases diagnosed hourly. Most of this growth is expected in urban China with number of AD patients growing by over 105%; female AD cases increasing more than males (108% vs 101%). The number of AD patients in rural China would only increase by 13%. China AD economic burden in base case scenario (using China prevalence rates) is expected between USD 22Bn - 93Bn (average 62Bn) in 2030. On the other hand, in Scenario 1 (using 2015 US prevalence rates) the economic burden is expected to rise to USD 178Bn (average). In Scenario 2, economic burden further increases to USD 266 Bn when aggressive Chinese AD cost estimates are utilized. **CONCLUSIONS:** Changing demographics, urban/rural shift and increased diagnosis rates are expected to lead to an epidemic of AD dementia in China in the near future. Significant investments are required immediately to reduce the huge economic impact. This research provides a

framework for future healthcare resource allocation for AD, Dementia and Mental Health investments in China.

PND60

A RETROSPECTIVE COMPARISON DESCRIBING DEMOGRAPHIC, FUNCTIONAL, AND CLINICAL DIFFERENCES OF U.S. NURSING HOME RESIDENTS WITH PARKINSON'S DISEASE WITH AND WITHOUT PSYCHOSIS

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OBJECTIVES: Describe demographic, functional, and clinical differences between nursing home residents (NHR) with Parkinson's disease (PD) and PD with psychosis (PDP). **METHODS:** A retrospective analysis was conducted using linked and de-identified Minimum Data Set (MDS) assessments and prescription claims of NHR from 10/1/2010-9/30/2012. Differences between PD (MDS item I5300, ICD9 332.0 or 332.1) and PDP (PD plus documentation of psychosis, hallucinations, or delusions) were evaluated by Chi-Square analysis. Longitudinal comparison of age- and gender-matched PD and PDP cohorts from baseline (first full MDS) to completion (last full MDS, ≥12 months apart) was by McNemar's test. **RESULTS:** Of 300,371 NHR, 6,551 PD and 1,303 PDP residents met criteria and were evaluated. More PDP residents were male (52% vs. 49%, p=0.048), had depression (67.4% vs. 50.6%; p<0.001), anxiety disorder (46.3% vs. 26.2%; p<0.001), stroke (22.4% vs. 20.0%, p=0.048), bipolar disorder (12.1% vs. 5.8%, p<0.001), and urinary tract infections (34.5% vs. 30.9%; p=0.01). More PDP residents had moderate/severe cognitive impairment (85.3% vs. 72.1%; p<0.001), frequent-always bowel or urinary incontinence (71.4% vs. 62.1% and 69.3% vs. 58.7%; p<0.001), overall behavioral symptoms (21.2% vs. 7.0%; p<0.001), rejected evaluation of care (31.2% vs. 12.8%; p<0.001), required extensive assistance/total dependence (EA/TD) (78.7% vs. 74.4%; p<0.001), and had major injuries from falls (4.8% vs. 2.6%; p=0.01). PDP residents were prescribed more antipsychotics (69.8% vs. 22.8%; p<0.001), anxiolytics/sedative-hypnotics (55.3% vs. 40.7%; p<0.001), and antidepressants (68.7% vs. 55.8%; p<0.001). Longitudinal comparison of matched cohorts (n=473 per group) showed PDP residents had greater functional deterioration requiring EA/TD (20.3% vs. 11.4%; p<0.001), and increased major injury from falls (11.4% vs. -7.1%; p=0.042). **CONCLUSIONS:** NHR with PDP had more EA/TD, major injury from falls, incontinence and antipsychotic prescriptions. A higher prevalence of these four Centers for Medicare and Medicaid Services quality measures may result in higher resource utilization.

PND61

SELF-REPORTED INSOMNIA AND SLEEP CHARACTERIZATION IN THE UNITED STATES

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OBJECTIVES: To evaluate sleep characteristics (difficulty initiating sleep [DIS], difficulty maintaining sleep [DMS], non-restorative sleep [NRS] and time slept on weekdays) in patients with self-reported insomnia. **METHODS:** Using data from a nationally representative research survey fielded in 2016, sleep characteristics, quality of life, emergency department visits and productivity loss were assessed in participants with insomnia. Standardized sleep questionnaires were used to characterize sleep complaints. Descriptive and multivariable models with US population-based weighting was used to obtain adjusted odds ratios (ORs) and 95% confidence intervals (CIs) across patient groups. **RESULTS:** Insomnia was reported in 26.8% of the US adult population. The most frequent sleep complaints reported for those with insomnia were NRS alone (30.6%), DIS, DMS and NRS (27.8%) and DMS and NRS (10.9%). Comparing patients with DIS alone or DMS alone (4.6%) and NRS alone (30.6%) weekday hours slept were 7.5, and 6.6, respectively. Days with reduced productivity in the past week were higher for those with NRS alone compared to those reporting DIS alone or DMS alone (3.43 vs. 0.42; p<0.001). Emergency department visits over the last 6 months were higher for those with DIS alone or DMS alone compared to those with NRS alone (0.91 vs. 0.38; p<0.001). Scores on the Restorative Sleep Questionnaire (v2) were lower (worse) for those with NRS alone compared to those with DIS alone or DMS alone (50.23 vs. 53.41; p<0.001). **CONCLUSIONS:** Insomnia is common complaint expressed in several ways. How patients characterize insomnia symptoms is related to health related quality of life, productivity and resource utilization.

PND62

REVIEW OF THE EPIDEMIOLOGY AND TREATMENT LANDSCAPE IN PEDIATRIC MULTIPLE SCLEROSIS IN THE UNITED STATES

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OBJECTIVES: Pediatric multiple sclerosis (MS) is a challenging condition to quantify and treat due to the evolving changes in diagnosis criteria, introduced in 2007 and revised in 2012, the limited evidence on the epidemiology of the disease and the efficacy and safety of therapies, and the lack of long-term data. No treatments have been approved for pediatric MS. This study aims to identify the epidemiological data and treatment landscape for children with MS in the US. **METHODS:** Two systematic searches were performed in MEDLINE (1946-2016) and EMBASE (1974-2016) to identify studies examining the epidemiology of pediatric MS, and any treatment guidelines or consensus statements for pediatric patients with MS in the US. Hand searches of MS societies and organizations were conducted to identify further evidence. International or regional guidelines were also considered. **RESULTS:** Of 623 references identified in the first search, 12 focused on the prevalence, incidence, or demographics of pediatric MS, 54 focused on natural history, and two considered

both. The mean age at diagnosis with MS was 15 years, and as high as two-thirds of patients were female. The prevalence of pediatric MS ranged from 0.39 to 9.70 per 100,000 children, with incidence between 0.03 and 2.3 per 100,000 children-years. Of 81 references identified in the second search, only three focused on recommendations for pharmacological treatments for children. The efficacy and safety of disease-modifying therapies suggested by consensus statements have only been reported in observational studies or small retrospective case reports and series. **CONCLUSIONS:** There is variation in the reported prevalence and incidence of pediatric MS in the US. Clinical evidence from randomized controlled trials is needed to support treatment guidelines for the pediatric MS population.

PND63

A COMPARISON OF ANTIPILEPTIC DRUGS APPROVED BY THE US FOOD AND DRUG ADMINISTRATION AND HEALTH CANADA

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OBJECTIVES: Antiepileptic drugs (AEDs) sales have been increasing globally. The US Food and Drug Administration (FDA) and Health Canada (HC) are two regulatory agencies that use different approval processes and regulatory actions to approve new drugs. The aim of this study was to conduct a comparative analysis of antiepileptic drugs (AEDs) approved in the period 1953-2016 by these two regulatory agencies. **METHODS:** In the study period, all AEDs approved by the FDA and HC were collected from the Drugs@FDA database, the Health Canada Drug Product database, and the Health Canada Notice of Compliance (NOC) database. For each AED, the following data were extracted: approval date, indications, contraindications, dosage forms, routes of administration, strengths, boxed warnings, market status and review status. Differences in these characteristics were assessed qualitatively and quantitatively. **RESULTS:** Of the 46 drugs on the WHO ATC list, 13 AEDs were never submitted to or approved by the FDA and HC; 33 AEDs were approved by either the FDA or HC. Only 19 AEDs were approved by both regulatory agencies. The mean number of AEDs' indications approved by the FDA (1.95±0.97) was higher than the HC's (1.63±0.83), though the difference was not statistically significant. The FDA approved more indications in 7 AEDs (36.8%) while HC approved more indications for only one drug. The average number of contraindications approved by HC (2.89±2.77) was higher than the average number of contraindications approved by the FDA (1.53±1.54). Other differences were identified in drug approval dates, restrictions, limitations, boxed warning, dosage forms, and strengths. **CONCLUSIONS:** There are significant differences in AEDs characteristics approved by the FDA and HC. More research may be needed to compare the clinical evidence that lead to these discrepancies between the two regulatory agencies.

PND64

GENERIC COST-EFFECTIVENESS ANALYSIS MODELS AS A PRECISION MEDICINE DECISIONMAKING TOOL: A CASE EXAMPLE

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OBJECTIVES: Economic evaluation is integral to informed healthcare decisionmaking in the rapidly growing and changing field of precision medicine, however this research is time consuming and expensive involving highly-skilled researchers. Generic models are proposed as a novel approach to address this critical evidence shortage to allow users to input local values. The purpose of this study is to develop and test a generic pharmacogenomic cost-effectiveness model. **METHODS:** A generic model was developed based on a published country-specific model to evaluate routine HLA-B*15:02 screening for new adult epilepsy patients to prevent carbamazepine-induced Stevens Johnson Syndrome and Toxic Epidermal Necrolysis (SJS/TEN) versus two strategies without screening. A country-specific model was comprehensively reviewed and modified based on evidence reviews and multi-disciplinary international team consensus to incorporate generalizable assumptions and parameter values. Input parameters requiring user-provided values were identified to reflect local conditions and reality-based sensitivity analysis. The generic model was transparently documented, tested and cross validated by comparing its incremental cost-effectiveness ratio (ICER) results using country-specific input values to results of country-specific models from Thailand, Malaysia and Singapore for the same input values. **RESULTS:** The base-case and probabilistic sensitivity analyses' results for the generic and country-specific models for all 3 countries were consistent in terms of whether HLA-B*15:02 screening was cost-effective at the country-specific cost-effectiveness threshold value. Differences between the generic and country-specific model results were largely due to differences in model structure and assumptions. **CONCLUSIONS:** A generic pharmacogenomic cost-effectiveness model is feasible and can offer an efficient and timely value-based decisionmaking tool. Developing generic models to perform cost-effectiveness analyses can provide useful evidence for decisionmaking reliably, more quickly and without staff extensively trained in decision modeling, as well as facilitate understanding about what conditions can meet cost-effectiveness thresholds.

PND65

DEMOGRAPHICS, CLINICAL CHARACTERISTICS, AND TREATMENT PATTERNS OF HUNTINGTON DISEASE PATIENTS TAKING TETRABENAZINE FOR CHOREA: FINDINGS FROM THREE DIFFERENT DATA SOURCES

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OBJECTIVES: Huntington disease (HD) is a multifaceted neurodegenerative disorder characterized by involuntary movements, specifically chorea. Tetrabenazine (TBZ),

the only FDA-approved treatment in HD, has been shown to be efficacious for chorea control; although, tolerability concerns exist. This analysis aims to examine and compare demographics, clinical characteristics, and treatment patterns of HD patients with chorea who are prescribed TBZ from three different databases. **METHODS:** Data were gathered from descriptive retrospective analyses of two large administrative claims databases, Optum and Truven, and one electronic medical record (EMR) database, IBM Explorys. Patients were identified from Optum or Truven if they had a claim of HD chorea (ICD 333.4) with continuous medical and prescription coverage pre- and post- index date (date of first TBZ claim) or from Explorys using EMRs of patients diagnosed with HD with ≥1 TBZ prescription and complete dosing information. Discontinuation was defined as having ≥90-day therapy gap in both claims analyses and either switching or stopping TBZ in the follow-up period in Explorys. **RESULTS:** 2,077 and 2,047 patients with HD-chorea were identified from Truven and IBM, respectively, and approximately 1,200 patients from Optum. Less than 15% of patients identified from all three databases had any initiation of TBZ. Of those taking TBZ, there were no gender differences. TBZ discontinuation rates were 35% and 46% in the Optum and Truven databases, respectively. In the Explorys analyses, 68% discontinued/switched from TBZ during study period. An increase in depression diagnosis after TBZ initiation was observed in all three analyses. **CONCLUSIONS:** Results were consistent in showing a low rate of treatment initiation and high rate of TBZ discontinuation in patients with HD-chorea, indicating an unmet need for an efficacious and tolerable treatment in these patients. Further research is needed to understand the reasons for low treatment initiation rates and high discontinuation rates with TBZ in the HD population.

PND66

TREATMENT PATTERNS IN TUBEROUS SCLEROSIS COMPLEX (TSC) PATIENTS WITH RENAL ANGIOMYOLIPOMA AND SUBEPENDYMAL GIANT CELL ASTROCYTOMA (SEGA)

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OBJECTIVES: TSC is a rare multi-organ disease, often with neurologic and renal complications. This study examined commercial and Medicaid insurance treatment patterns (everolimus, sirolimus, and surgeries) in TSC patients with renal angiomyolipoma or SEGA in the US. **METHODS:** Patients with ≥1 diagnosis of TSC and with renal angiomyolipoma or SEGA were extracted from the MarketScan[®] Commercial (1/1/2009-8/31/2016) and Medicaid (1/1/2009-6/30/2015) databases. Patients were followed from index date (earliest TSC, renal angiomyolipoma or SEGA diagnosis) until inpatient death or end of data. The proportion of patients treated, types of initial treatment and subsequent treatments were examined during the variable follow-up. **RESULTS:** The final sample included 1,497 TSC patients (n=896 renal angiomyolipoma only, n=411 SEGA only, and n=190 with both). Compared with commercial patients (n=984), Medicaid patients (n=513) had the same mean age (22 years), a higher proportion of males (50.3% vs. 42.9%), and a longer follow-up period (48 vs. 38 months). Treatment rates were similar between commercial and Medicaid (58.0% vs. 61.7%, p=0.182), but it took significantly more days for Medicaid patients to initiate treatment (377 vs. 516 days, p<0.001). In the commercial cohort, among the 46.4% patients starting treatment with surgery, 33.7% had repeat surgeries and 16.2% switched to drug treatment; among the 11.6% patients starting treatment with a drug, only 4.4% had subsequent surgeries. In the Medicaid cohort, among 48.0% who started treatment with surgery, 57.8% had repeat surgeries and 10.2% switched to drug treatment; among the 14.4% patients starting treatment with a drug, 16.2% had subsequent surgeries. Analysis was also conducted separately for patients with renal angiomyolipoma only, SEGA only, and both renal angiomyolipoma and SEGA. **CONCLUSIONS:** This analysis finds that only 58.0-61.7% of TSC patients with renal angiomyolipoma or SEGA received treatments and Medicaid patients had a longer time to initiate treatment than Commercial patients.

RESPIRATORY-RELATED DISORDERS – Clinical Outcomes Studies

PR51

ASSESSING THE HOSPITAL READMISSION AND MORTALITY RATES AMONG ELDERLY PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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OBJECTIVES: To evaluate the 30- and 60-day readmission and mortality rates of patients diagnosed with chronic obstructive pulmonary disease (COPD) in the US Medicare population. **METHODS:** Patients aged ≥65 years on the admission date with an inpatient stay and a primary discharge diagnosis for COPD (International Classification of Diseases 9th Revision Clinical Modification diagnosis codes: 490.xx, 491.xx, or 496.xx) were identified using Medicare data from 01JAN2010 through 31OCT2013. The discharge date was designated as the index date. Patients were required to have continuous medical and pharmacy benefits for 1 year before the admission date and 2 months after the discharge date. Patients who died within 2 months post-discharge date were also included. Demographic and clinical characteristics were examined for the 12-month pre-discharge period. The 30- and 60-day readmission and mortality rates after discharge were computed. Descriptive analysis was performed, and mean and standard deviation were provided for continuous variables as well as numbers and percentages for categorical variables. **RESULTS:** A total of 279,768 patients were identified after

applying the selection criteria. The mean age of Medicare patients with COPD was 77.8 years (standard deviation [SD]=7.7). Female (61.2%) and white (90.0%) patients were the largest demographic groups included in the study. The average Charlson comorbidity index score was 2.9 (SD=2.7). Comorbid conditions: 59.6% of patients were smokers; 45.7% had moderate or severe renal disease, 40.5% had congestive heart failure, 39.2% had diabetes, and 37.5% had any malignancy. The 30-day hospital readmission rate was 20.3%, and the mean time-to-30-day-readmission was 12.5 days. The 60-day hospital readmission rate was 29.0%, and the mean time-to-60-day-readmission was 22.4 days. The 30- and 60-day mortality rates were high: 6.5% and 9.7%, respectively. **CONCLUSIONS:** US Medicare patients diagnosed with COPD had significant hospital readmission and mortality rates in the 30 or 60 days following hospital discharge.

PRS2

COMPARATIVE ANALYSIS OF NEBULIZED ARFORMOTEROL VS INHALED LONG-ACTING BETA-AGONISTS FOR COPD: RESCUE MEDICATION USE AND MEDICAL OUTCOMES

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OBJECTIVES: Arformoterol (ARF) is a nebulized long-acting beta2-agonist for maintenance use in chronic obstructive pulmonary disease (COPD) patients. Real-world studies comparing outcomes of ARF with those of inhaled long-acting beta2-agonists (LABA) in community-based COPD patients are lacking. This study compares rescue medication use (RMU) and medical outcomes among COPD patients treated with ARF vs LABA. **METHODS:** De-identified electronic health records (EHR) of patients in the Practice Fusion EHR database between 2010 and 2016 were analyzed. Patients aged >18 years with a COPD diagnosis (ICD-9 CM: 490-492, 494-496; or ICD-10: J40-J44, J47) were included. Patients initiating ARF (index) with no prior LABA use restriction were propensity matched to LABA patients without prior ARF use. The index date for the LABA cohort was randomly assigned to correspond with the ARF index date. The proportion of patients with RMU (ie, short-acting beta agonists [SABA], short-acting muscarinic antagonists [SAMA], or combination [SABA/SAMA]), number of exacerbations, and office visits was compared 6-months pre- and post-index date. Generalized linear models were estimated as appropriate for outcome type. A p value of 0.05 was used to test statistical significance. **RESULTS:** The proportion of patients (n=3646 in each) with any RMU decreased in the post-index period for ARF and increased for LABA cohorts (odds ratios [ARF vs LABA]: 0.94, p=0.427 for SABA or SAMA and 0.68, p=0.0016 for SABA/SAMA usage). An increase in number of exacerbations and office visits was observed in the post-index period for both cohorts; increases in office visits were higher for the LABA than the ARF cohort (incidence rate ratios [ARF vs LABA]: 0.87, p=0.15 for exacerbations and 0.92, p=0.012 for office visits). **CONCLUSIONS:** ARF treatment is associated with lower SABA/SAMA use and office visits compared with inhaled LABA treatment in community-based COPD patients and may represent a potential alternative treatment choice for inhaled LABAs.

PRS3

RESULTS OBTAINED IN PATIENTS TREATED WITH OMALIZUMAB IN COSTA RICA'S SOCIAL SECURITY (CAJA COSTARRICENSE DE SEGURO SOCIAL)

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OBJECTIVES: Omalizumab is a humanized antibody IgE, used in Caja Costarricense de Seguro Social (CCSS) for the treatment of persistent severe allergic asthma with inadequate control with the available medicines, including inhaled corticosteroids. This study is aimed to assess the results obtained in patients treated with omalizumab in CCSS between 2012 and 2014. **METHODS:** Observational, retrospective study, based on the omalizumab prescriptions in the CCSS. Clinical records were reviewed to collect information on hospital admissions, emergency room (ER) visits, amount of exacerbations, day and night symptoms, forced expiratory volume (FEV) and required drugs for control. The clinical condition in the 6 months prior to treatment was considered baseline condition, and clinical response was established as the clinical condition after 6 months of treatment. **RESULTS:** We accessed information for 33 patients. Female predominated over male in a 4.5:1 ratio. Average age was 42.1 years (IC95% 35.9; 48.3). All patients were diagnosed with severe persistent asthma. The risk for hospitalization decreased 75.3% (p<0.001) with treatment. Considering the number needed to treat (NNT=2) it's required to treat 2 patients to prevent 1 hospitalization. Risk for ER visit decreased 58% (p<0.001), it's needed to treat 2 patients to prevent 1 visit to ER (NNT=2). Risk for clinical exacerbation decreased 57.6% (p<0.001), NNT=2. Risk for having day symptoms twice a week decreased 67% (p<0.001), NNT=2. Risk for having night symptoms twice a week decreased 89%. Mean FEV1 after starting treatment increased 23% (p=0.031). Risk of requiring 3 or more inhalations of rescue treatment with albuterol decreased 68% (p=0.0012). The chronic use of systemic corticosteroids decreased 64% with treatment (p<0.001). Inhaled corticosteroids requirement remains unchanged, regardless of the agent used. **CONCLUSIONS:** Giving treatment with omalizumab to patients with uncontrolled severe asthma in Costa Rica's Social Security, significantly improves their clinical condition after 6 months.

PRS4

RIOCIGUAT IN THE PHARMACOLOGICAL TREATMENT OF PULMONARY ARTERIAL HYPERTENSION: A SYSTEMATIC REVIEW

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OBJECTIVES: To perform a systematic review (SR) of the efficacy of pharmacological treatment of Pulmonary Arterial Hypertension comparing Riociguat with other

available medications or with placebo. **METHODS:** Following the steps described in the PRISMA guideline, a search for randomized controlled clinical trials was conducted in which Riociguat was used alone or in combination with other therapies, in databases MEDLINE, LILACS, Web of Science, Science Direct, Cochrane Library Wiley and in the gray literature (Google Scholar, Capes Bank of Theses and Clinical Trials). EndNote and Mendeley were used as reference managers. Outcomes analyzed were: death, 6-minutes walking distance (6MWD), WHO functional class (improvement, stabilization or worsening), hemodynamic variables (pulmonary vascular resistance, cardiac index, pulmonary-artery pressure), clinical worsening, hospitalization and quality of life. **RESULTS:** 467 articles were obtained, remaining 379 after the duplicated articles withdrawal. After exclusion by title and abstract by two independent reviewers, 47 studies remained. Through the gray literature, 6 studies were obtained, counting 53 studies for full article reading, and the eligibility criteria were verified. Five studies were selected to compose the SR. Compared with placebo, Riociguat showed improvements in 6MWD, pulmonary vascular resistance, WHO functional class and time to clinical worsening, also maintained after one year of use. Subgroup analysis was performed comparing of treatment-naive patients and patients on background PAH-targeted therapy. **CONCLUSIONS:** This work may be used as a management and decision support tool, based on the same rationality that involves a Health Technology Assessment, contributing to quality the decisions to be taken in relation to the incorporation of new technology.

PRS5

ASTHMA TREATMENT PATTERN LONGITUDINAL ANALYSIS

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OBJECTIVES: Asthma management guidelines suggest a stepwise therapeutic management strategy for asthma patients. This study aims to characterize the association between treatment step trajectories and patient characteristics. Additionally, the association between asthma health outcomes with treatment step trajectories is assessed. **METHODS:** A retrospective cohort study between Jan. 2006 through Dec. 2013 using a random sample from IMS PharMetrics Plus claims database of asthma patients in the United States aged between 6 and 64 at index. The primary outcomes of interest are treatment step (ordinal: guideline-based steps 0 (mild) to 5 (severe)) and asthma exacerbation events categorized as dichotomous and nominal (asthma-related hospitalizations, emergency room visits, and oral steroid bursts). Data was modeled using a generalized linear mixed model (GzLMM) framework for both outcomes of interests. A priori selection of covariates of interest were age, gender, Charlson Comorbidity Index (CCI), region and insurance type. **RESULTS:** There was a statistically significant association between treatment steps and time since index date, baseline age, gender, and CCI (p<0.05) under a proportional odds model. The generalized logit model indicates that treatment step 2 subjects have an overall lower odds of asthma hospitalization event compared to those on treatment steps 1,3,4 and 5 (i.e. 0.064 vs. 0.106, 0.095, 0.110, and 0.222 times lower odds of hospitalization compared to no event, respectively). Females compared to males had a higher asthma exacerbation event (1, 2, 3, and 4) odds (1.914, 1.133, 1.297, and 1.253) compared to no event. Patients with 1 unit increase in CCI value have a higher odds of event 1, 3, and 4 compared to no event. **CONCLUSIONS:** The longitudinal analysis of asthma treatment steps identified many significant associations between treatment steps and patient characteristics such as baseline age, CCI, and gender. Additionally, patients with higher CCI values and females (compared to males) had higher odds of exacerbation events.

PRS6

OPTIMIZING SURVIVAL AND COST-UTILITY IN THE TREATMENT OF BRONCHIOLITIS OBLITERANS SYNDROME: A CALIBRATED AGENT-BASED MODELING APPLICATION

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OBJECTIVES: Standard regression models for calculating cost-utility analysis often overlook outliers. In this study, our goal was to build a calibrated Agent Based Model (ABM) that could align treatments with complex and heterogeneous patient characteristics, and compare cost-utility in a more granular fashion between extracorporeal photopheresis (ECP) offered to patients at earlier versus later stages of BOS severity. **METHODS:** We calibrated an ABM that simulates survival and cost-utility. We focused on earlier access to ECP across defined scenarios and underlying disease severity. Patient characteristics such as age, gender, timing of ECP, changes from baseline in forced expiratory volume (FEV) per second, outliers at different levels of allograft rejection, and grade of BOS severity were assigned to each individual in the ABM. We then compared individual cost-utility estimates for patients receiving ECP at different stages of BOS in a manner that highlights the outlier effects, and scaled up the calibrated ABM to the U.S. transplant population using the United Network for Organ Sharing (UNOS) dataset. **RESULTS:** Our preliminary calibrated findings suggest that ECP cost-utility estimates are markedly lower when offered at earlier as compared to later stages of BOS. As such, we were able to model the value of early-intervention while illustrating outlier effects. Our findings highlight how patient-specific characteristics must be considered for maximizing survival and quality of life while minimizing cost. **CONCLUSIONS:** Using patient-level data, ABMs can illustrate survival and cost-utility in a manner that calibrates the right treatment for the right patient at the right time, such as the application of ECP to patients in various stages of BOS. In this precision medicine framework, such calibrated ABMs can be scaled and presented in a graphical way to inform policy at the population level.

PRS7

COMPLIANCE WITH A QUALITY MEASURE AND INCORPORATION OF AN EVIDENCE-BASED PRACTICE IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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OBJECTIVES: Chronic obstructive pulmonary disease (COPD) affects more than 15 million Americans and is the third leading cause of mortality in the United States. The aims of this study were to describe rate of compliance with the quality measure that patients with COPD receive an inhaled corticosteroid and inhaled bronchodilator and to assess the effect of the evidence-based practice, extended course systemic macrolide therapy, on COPD exacerbation rate. **METHODS:** Patients ≥ 18 years-of-age with a hospitalization or emergency department (ED) visit for a COPD exacerbation were identified in IMS Lifelink Plus (2006–2015). The earliest COPD exacerbation date was the index-date. Patients had continuous enrollment for 6 months before and after index-date. Patients with ≥ 1 prescription for inhaled corticosteroid and bronchodilator within 30 days from index-date were defined as standard therapy. Patients with ≥ 30 day supply of macrolide within 90 days of index-date were defined as macrolide therapy. COPD exacerbation recurrence was defined as hospitalization or ED visit in the six month post-index period. Logistic regression analysis was performed using age, sex, geographic region, and comorbidities to assess the effect of exposure to macrolide on COPD exacerbation recurrence. **RESULTS:** Of 56,055 patients who met inclusion criteria, 4,512 (8.05%) received an inhaled corticosteroid and bronchodilator, 202 (0.36%) received systemic macrolide therapy, and 41 (0.07%) received both interventions. Within six months of index-date exacerbation, 7,987 (14.25%) patients experienced another exacerbation. In unadjusted analysis, receipt of macrolide therapy was associated with lower odds of experiencing another COPD exacerbation (odds ratio 0.473, 95% confidence interval 0.319–0.701); however, after adjusting for covariates, this association no longer existed (odds ratio 0.880, 95% confidence interval 0.415–1.867). **CONCLUSIONS:** There is a low rate of compliance with the quality measure that patients with COPD receive an inhaled corticosteroid and an inhaled bronchodilator and no effect on exacerbation rate with use of systemic macrolide therapy.

PRS8

PREVALENCE AND CHARACTERISTICS OF E-CIGARETTE USERS AMONG COPD PATIENT POPULATION IN THE UNITED STATES

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OBJECTIVES: To estimate the prevalence and study e-cigarette (e-cig) user characteristics among Chronic Obstructive Pulmonary Disease (COPD) patient population in the United States. **METHODS:** The National Health Interview Survey (NHIS) 2014 data were used to generate weighted prevalence estimates among the US adult civilian noninstitutionalized population with age ≥ 18 years (Weighted N = 239,688,457). COPD individuals were those who responded yes to the question "Have you ever been told by a doctor or other health professional that you had chronic obstructive pulmonary disease, also called COPD?". Current e-cig users were the one using e-cig devices for either every day or some day while ever e-cig users were those who had ever used e-cigs even once. E-cig user characteristics among COPD subjects evaluated were age, sex, race, census region, marital status, current working status, type of employment, number of current jobs, smoking status, BMI, current use of combustible or smokeless tobacco products, and quit attempts over the past year. Chi-squared tests were used to compare the data. All our analysis employed NHIS sampling weights to generate data representative of the entire US population. **RESULTS:** Weighted prevalence estimates for current and ever e-cig users among COPD subjects were 8.64% (Weighted N = 642,848) and 24.37% (Weighted N = 1,793,828) respectively. Among current e-cig users with COPD, proportion of use were found to be higher ($P < 0.05$) for ages 45 to 64 years age (56.96%), divorced (30.75%), residents in the south region (53.88%), unemployed (87.50%), dual users of other tobacco products (68.48%), and individuals who have tried quitting tobacco use at least once in past 12 months (62.20%). **CONCLUSIONS:** Awareness and use of e-cigs have not just increased in general population, but its uptake has also increased in the COPD disease population. Usage was higher among current smokers and those who wanted to quit tobacco.

PRS9

CHARACTERISTICS ASSOCIATED WITH AWARENESS AND USE OF ELECTRONIC NICOTINE DELIVERY SYSTEM (ENDS) AMONG STUDENTS ENROLLED IN HEALTH SCIENCE PROGRAMS

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OBJECTIVES: The present study aims to assess the demographic characteristics associated with the awareness and use of electronic-cigarettes (e-cigarettes) among students enrolled in health science programs. **METHODS:** A web-based survey was conducted between July 1st and August 31st, 2016 among active undergraduate students of International Medical University (IMU) in Kuala Lumpur, Malaysia. The survey contained 31 items about sociodemographic characteristics, e-cigarette awareness, perceptions and use, as well as conventional cigarette smoking, health-risk and sensation seeking behaviours (SSB). Binary logistic regression was performed to identify factors associated with e-cigarette use. **RESULTS:** A total of 404 students were enrolled in the study. The vast majority of our cohort were aware of an e-cigarette (94.78% versus 5.22%). Out of 404, 53 (14%) students reported ever use of an e-cigarette during the past 30 days. E-cigarette use was significantly associated with nationality, gender, race, mother's and father's education. After controlling for the effects of confounders using binary logistic regression, e-cigarette users were more likely to be male, Malay, and being a child of less

educated father. Moreover, SSB total score (aOR = 1.20, $P < 0.001$), conventional cigarette use (aOR = 7.79, $P = 0.002$), hookah use (aOR = 8.51, $P < 0.001$), and cigarette smoking for parents (aOR = 0.20, $P = 0.026$) were significantly contributing to the ever use of e-cigarette. **CONCLUSIONS:** The prevalence of e-cigarette use was moderately high among students enrolled in health science program compared to the general population in Malaysia. Hence, it would be of great importance for health sciences students to explore their inner position toward e-cigarette smoking. Whether they smoke because they ignore the risk or because they deny or even seek it or do they accept the risk but procrastinate the attempt to quit.

RESPIRATORY-RELATED DISORDERS – Cost Studies

PRS10

ADDING RESLIZUMAB TO U.S. MANAGED CARE FORMULARY FOR TREATMENT OF SEVERE EOSINOPHILIC ASTHMA RESULTED IN NET TOTAL COST SAVINGS

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OBJECTIVES: Reslizumab, a humanized interleukin-5 monoclonal antibody, is a new treatment to reduce the risk of clinical asthma exacerbations (CAE) in patients with severe eosinophilic asthma. A budget impact model was developed to assess the economic impact of adding reslizumab to existing severe eosinophilic asthma treatment from the perspective of a United States (US) managed care organization (MCO). **METHODS:** A hypothetical MCO with 1,000,000 members was used in the model. The model structure was based around the current clinical pathway of patients eligible for treatment with reslizumab. Prevalence of severe eosinophilic asthma was estimated using age-specific prevalence data from the Centers for Disease Control and Prevention, US census demographic data and published literature. CAE rate, relative risk reduction of CAE associated with reslizumab, CAE costs, and drug and drug administration costs were taken from published literature. The model accommodates a 5-year time horizon. Sensitivity analyses were performed using the upper and lower limits of 95% confidence intervals for the CAE rate and relative risk reduction of CAEs. **RESULTS:** When reslizumab was included as a treatment option to a 1,000,000-member health plan, the base-case model resulted in an overall cost savings of \$862 in year 1, \$7,150 in year 2, \$12,911 in year 3, \$19,155 in year 4, and \$25,937 in year 5. Total cost savings were due to lower drug costs of reslizumab compared to omalizumab and mepolizumab and medical cost offsets from reduction of CAE. Sensitivity analyses showed that the result was most sensitive to the relative risk reduction of exacerbations associated with reslizumab. **CONCLUSIONS:** Addition of reslizumab to severe eosinophilic asthma treatment resulted in net overall cost savings to a MCO. This implies that reslizumab is a desirable treatment option among hard-to-treat patients whose cost of treatment is already high.

PRS11

COST-EFFECTIVENESS AND BUDGET IMPACT ANALYSIS OF UMEC/VI FOR THE TREATMENT OF COPD PATIENTS IN COLOMBIA

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OBJECTIVES: To evaluate the cost-effectiveness and budget impact of UMEC/VI compared with Tiotropium (TIO), Indacaterol/glicopirronio (QVA149), Indacaterol/Tiotropium (IND+TIO) and Fluticasona/Salmeterol (FCS) as maintenance bronchodilator treatment in patients aged ≥ 40 with moderate to severe COPD from the Colombian National Health System (NHS) perspective. Umeclidinium/vilanterol (UMEC/VI) is a fixed dose combination of a long-acting muscarinic receptor antagonist (LAMA) and a long-acting beta 2 receptor antagonist (LABA). **METHODS:** An analytical cost-effectiveness model (CEM) of COPD disease progression and a budget impact model (BIM) were developed from the GALAXY model. Data sources were literature reviews and governmental databases; efficacy data was derived from an indirect treatment comparison using a frequentist approach conducted by Huisman et al. The CEM used risk equations per attribute (lung function, exacerbations, symptoms, exercise capacity). Outcomes included mortality, quality of life, and resource utilization. A 20-year time horizon was used and costs and benefits were discounted at 5%. The BIM explored the inclusion of UMEC/VI in the NHS benefit plan, using a 3-year time horizon, including adverse event costs and costs of COPD-related events. **RESULTS:** TIO, IND+TIO and QVA149 were more costly and less effective than UMEC/VI and FCS. Costs per additional QALY gained/person treated with UMEC/VI compared to FCS was estimated to be COP\$1,325,903 and \$17,770,045 for 0.5 years and 20 years of treatment, respectively; indicating that UMEC/VI is cost-effective using the threshold of three times GDP/capita. Furthermore, the inclusion of UMEC/VI will allow the NHS to save COP\$16,838,928,466 in the first year (5% UMEC/VI participation rate) to COP\$19,325,269,697 in the third year (15% participation rate). **CONCLUSIONS:** UMEC/VI is less costly and more effective in this analysis, resulting in possible budget savings when included in the NHS benefit plan for patients aged ≥ 40 with moderate to severe COPD from the Colombian NHS perspective. Results are maintained in the sensitivity analysis.

PRS12

ECONOMICAL IMPACT OF TREATMENT WITH OMALIZUMAB IN COSTA RICAN SOCIAL SECURITY

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OBJECTIVES: To assess the budget impact generated by the use of Omalizumab in Caja Costarricense de Seguro Social (CCSS) and to estimate the cost effectiveness

of the intervention in Costa Rica's Social Security. **METHODS:** Based on the effectiveness study previously conducted, that demonstrated that giving treatment with omalizumab to patients with uncontrolled severe asthma in Costa Rica's Social Security, significantly improves their clinical condition after 6 months, we collected information on the amount of units of Omalizumab bought and administered to patients. Then, we constructed a model (decision tree) to evaluate the cost of clinical management of a patient with severe asthma with and without Omalizumab, using effectiveness data in clinical practice documented in CCSS. Cost data for medicines was obtained from the price paid registered in CCSS database; hospitalization cost and Emergency Room (ER) attention costs were obtained from the CCSS institutional tariff model. **RESULTS:** Between January 2012 and December 2014, a total of 33 patients received omalizumab, with a total consumption of 1.571 units and an inversion of US\$870,224,03. Last registered unit (vial with 150mg) price in December 2015 was US\$553,93. In the base case scenario modeled, that considered a 4-day hospitalization time and 7-hour ER attention, the cost of treatment per patient without Omalizumab was US\$14,526.4 and with Omalizumab it was US\$13,779.5, saving US\$747 using Omalizumab, with a cost-effectiveness ratio of US\$633 per hospitalization avoided (cost saving technology). In the most pessimistic scenario in the sensitivity analysis conducted, that considered no hospitalizations avoided neither ER attentions avoided, there was an incremental cost of US\$13,271.4, that represents about 1.31 times Costa Rica's GDI per capita (US\$10,100 in 2015). **CONCLUSIONS:** Considering effectiveness in clinical practice, omalizumab is a cost-saving technology when prescribed to patients with uncontrolled severe allergic asthma in Costa Rican Social Security.

PRS13

IMPACT OF IMPROVED STOVE ON COST OF ILLNESSES THAT ARE RELATED TO HOUSEHOLD AIR POLLUTION IN PAKISTAN

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OBJECTIVES: Use of biomass fuel for household cooking is one of the major sources of household air pollution. In low and middle income countries an improved stove has been introduced to control air pollution and reduce burden and economic burden of respiratory and other related illnesses. The objective of this paper is to estimate the cost of respiratory and other related illnesses in household that used traditional stove versus improved stove. **METHODS:** We collected data from 605 household (217 treated, 388 control) in Sindh and Punjab provinces in September 2014. We estimate cost of medical care for treatment of respiratory illnesses and eye illnesses in the women who use traditional stove (control) and improved stove (treated) group. Medical care costs include consultation charges, purchase of medicines, and laboratory/radiology charges. **RESULTS:** Yearly median medical care cost of treating respiratory illnesses and eye illnesses significantly lower in treated group (PKR 2000 and PKR 898.5 respectively) than in control groups (PKR 2027.5 and PKR 1000). In regression analysis the medical care cost of respiratory illnesses and eye illnesses were higher in the control group (PKR 446.66 (SE 5708) and PKR 965.91 (SE 2943.78) respectively) than in the treatment group. **CONCLUSIONS:** Improved stove are better in terms of fuel efficiency and in reducing the burden and economic burden of related illnesses. However we recommend further research in this area with larger sample and appropriate follow up to capture difference over time and across treated and control groups.

PRS14

DIRECT AND INDIRECT COSTS OF COPD FROM PATIENT PERSPECTIVE: 1-YEAR FOLLOW UP

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OBJECTIVES: To estimate and compare direct and indirect cost of COPD along one-year follow-up stratifying by GOLD criteria from patient perspective. **METHODS:** We conducted a prospective study during August 2013-July 2014 in a public tertiary referral hospital. We enrolled sequentially COPD patients from wards, outpatient and COPD clinics. We applied a questionnaire each visit or hospitalization during the study period to obtain sociodemographic characteristics, working days lost and out-of-pocket expenses. Patients were classified into three non-mutually exclusive groups: outpatient, inpatient and outpatient + hospitalization due to an exacerbation. In the first questionnaire we asked information for the year prior to enrollment. In the subsequent questionnaires we asked for the information between the previous consultation and the current one. In this study, we analyzed the information of follow-ups. Costs were transformed in 2014 US Dollars. **RESULTS:** We recruited 611 patients at base line; only 72% (442) had at least one follow-up. Frequencies in each group were: outpatients, 437; inpatients, 42; outpatient + hospitalization, 37. In the outpatient group, median annual direct costs ranged from \$562 to \$2,902 and were statistically different ($P < 0.001$). We observed increased cost by GOLD in the inpatient and outpatient + hospitalization groups but differences were not statistically significant. Medical cost represented a higher proportion of direct cost in the three groups of patients (53-99%). For GOLD II and IV, we found significant differences ($P < 0.05$) in direct medical cost when compare outpatient vs outpatient + hospitalization groups. Spending on drugs represented the largest amount of medical costs. The proportion on drug expenses varied 93-99% for outpatient group, 53-92% for inpatient group and 28-56% for outpatient + hospitalization group. **CONCLUSIONS:** Even when patients with COPD receive a subsidy for their medical care, they incur large out-of-pocket expenses. The biggest expense is in medicines.

PRS15

COST-EFFECTIVENESS ANALYSES OF UMECLIDINIUM BROMIDE 62.5 MCG VERSUS GLYCOPYRRONIUM 44 MCG AND UMECLIDINIUM BROMIDE 62.5 MCG VERSUS TIOTROPIUM 18 MCG IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE IN THE UK

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OBJECTIVES: Cost effectiveness of once-daily umeclidinium bromide (UMEC) 62.5 mcg was compared with once-daily glycopyrronium (GLY) 44 mcg and once-daily tiotropium (TIO) 18 mcg in patients with chronic obstructive pulmonary disease (COPD) from a UK National Health Service (NHS) perspective. **METHODS:** A linked-equation model was implemented to estimate COPD progression, associated health-service costs, exacerbation rates, survival and quality-adjusted life years (QALYs). Statistical risk equations for endpoints and resource use were derived from the ECLIPSE and TORCH studies, respectively (Briggs A, et al. Med Decis Making 2016). Treatment effects (mean [standard error]) at 12 weeks on forced expiratory volume in 1 second and St George's Respiratory Questionnaire score were obtained from two UMEC head-to-head studies: +33 mL (14.3) and -0.64 units (0.8) versus GLY (Rheault T, et al. ERJ Open Res 2016), and +53 mL (14.3) and -0.46 units (0.8) versus TIO (Feldman G, et al. Int J Chron Obstruct Pulmon Dis 2016). Treatment costs reflect UK list prices (2016) and NHS unit costs; UMEC and GLY prices being equal and less than TIO. A 5-year horizon, discounted costs and effects at 3.5% were used. **RESULTS:** Over a 5-year time-horizon, patients receiving UMEC were predicted to experience fewer annual exacerbations (-0.05), and gain life years (+0.01) and QALYs (+0.03) versus GLY. Incremental costs were £14/patient due to longer predicted survival, leading to an incremental cost-effectiveness ratio of £440/QALY. UMEC resulted in annual exacerbation reductions (-0.08) and life years gained (+0.02) versus TIO after 5 years. An incremental QALY gain (+0.03) was found against cost savings of -£355/patient. Sensitivity analyses showed that variation in the main parameters did not alter the results. **CONCLUSIONS:** Assuming the same price, UMEC may be considered a cost-effective treatment versus GLY. UMEC was dominant (less costly and more effective) over treatment with TIO. Funding: GlaxoSmithKline (study HO-14-8059).

PRS16

DIRECT AND INDIRECT COSTS OF SEVERE UNCONTROLLED ASTHMA IN THE BRAZILIAN PUBLIC PERSPECTIVE

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OBJECTIVES: The study aims to assess the direct costs of uncontrolled severe asthma from the Brazilian public payer perspective and its indirect costs from a societal perspective. **METHODS:** We used Brazilian public claim databases (DataSUS) in order to identify patients with severe uncontrolled asthma and assess their direct costs. Through a record linkage methodology, we identified patients with records in both hospital and ambulatory databases. Patients were screened according to the following criteria: long-acting beta agonist associated with high dose inhaled corticosteroids and at least two hospitalizations within a six-month period. Resource utilization was calculated and resource costs were obtained from the official Brazilian procedure table (SIGTAP). Resource utilization that could not be identified through database analysis were obtained through literature review. Total population treated by the Brazilian healthcare system was estimated based on DataSUS databases, Saúde Não Tem Preço reports (another government program for pharmaceutical assistance) and literature reporting proportion of severe uncontrolled patients within asthma population. Indirect costs were calculated using the human capital approach: data on work absenteeism was found at scientific literature and premature deaths were obtained through the Brazilian mortality information system. Per capita gross domestic product was reported by the Brazilian official statistics and demographics agency (IBGE). **RESULTS:** We screened 577 unique patients with an average daily consumption of 2,121 micrograms of budesonide and 57 micrograms of formoterol, and the hospitalization rate was 2.65 per patient-year. The calculated total direct costs incurred by the total severe uncontrolled population in Brazil was BRL 24.8 million, of which, 78% are due to hospitalizations and 17% due to drug dispensation. The calculated indirect costs were BRL 416.2 million, of which 96% are due to premature deaths. **CONCLUSIONS:** Despite relatively low direct costs, severe uncontrolled asthma is a disabling and life-threatening disease, responsible for substantial indirect costs.

PRS17

HOSPITAL COST FOR CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) FOR THE BRAZILIAN PUBLIC HEALTH SYSTEM, 2000 - 2015

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OBJECTIVES: To estimate trends in the hospitalization cost for chronic obstructive pulmonary disease (COPD) within the Brazilian Public Health System from 2000 to 2015. **METHODS:** The number of hospitalizations, total yearly cost due to COPD and mean cost per hospitalization and number of days per event were abstracted from National Health System Data (DATASUS) for the period of 2000 to 2015. Costs represent federal reimbursement values for hospitalizations (includes medical procedures, exams, medications and taxes) and were reported in Brazilian Reals (1.00BRL ≈ 0.28USD Average 2016). **RESULTS:** In Brazil, there were 2,743,061 hospitalizations due to COPD during the studied period, making a total cost of 1,530,118,424.82BRL. The average annual cost in Brazil was 102,007,894.99BRL, in

average 557,81BRL per event, with the mean length of stay of 5,87 days. The cost per hospitalization increased 100,3% during the studied period (426,49BRL to 854,42BRL). The mean annual length of stay increased by 0,5 day in 15 years. Total costs for hospitalizations for COPD among regions in Brazil increased in the North (+25,1%), Northeast (+20,8%) and Southeast (+22,2%) and decreased in the South (-31,6%) and Mid-west (-15,9%) regions. **CONCLUSIONS:** The cost of hospitalization for COPD has an important economic impact on the health-care system in Brazil. There is a trend to increase in the North, Northeast and Southeast regions, reflecting difficulties of the health system to provide adequate management of COPD. Initiatives to reduce health resource utilization and improve health status in patients with COPD should be considered in short and medium-term.

PRS18

DETERMINATION OF DIRECT COSTS OF THE PULMONARY ARTERIAL HYPERTENSION TREATMENT IN COLOMBIA

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OBJECTIVES: To develop a costing exercise that allows comparing the direct costs in each functional class (FC) I to IV, of Pulmonary Arterial Hypertension (PAH) from perspective of the third-party-payer. **METHODS:** PAH is a disease with a very low prevalence in Colombia, high rate mortality and deterioration in HRQoL, make it to be considered an orphan disease. The treatment cost of a patient with PAH varies considerably according to the disease progression, mainly influenced by the hospital and pharmacological costs that it requires. Treatment cost for patient during a year of staging in each FC of the disease were estimated, according to WHO classification, pharmacological costs for each stage were included taking into account the clinical recommendations observed in the SEPAR-ALAT2 guide. A literature review was carried out to compare information in treatment scheme necessary for the patient, including the procedures, this information was validated with experts. Costs of the resources and inputs were taken from SOAT 2001 +30 tariff, and from market drugs. **RESULTS:** Results are presented as the consolidated of direct costs that could be required by a patient over a year of treatment, these costs include outpatient, hospital management, medication support, and medical consultations required, the exercise allows to evidence a high cost in FC IV, this being US \$ 7,189 per month, while in FC-II and III costs are US \$ 2,950 and US \$ 2,918 per month respectively, a patient in FC-I would represent a cost of US \$ 294 per month. **CONCLUSIONS:** The results of the exercise demonstrate the need to concentrate the focus of patient care, to avoid its progression, since a patient progressing to FC IV represents a high considerable cost to health system. In addition to this, the progressing patient represents a higher occupation of hospital resources, which also implies a considerable deterioration in HRQoL.

PRS19

ECONOMIC IMPACT OF EXACERBATIONS DUE TO CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) PATIENTS IN THE PERSPECTIVE OF BRAZILIAN PRIVATE HEALTHCARE SYSTEM

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OBJECTIVES: To evaluate the economic burden exacerbations due to COPD in the Brazilian private healthcare system. **METHODS:** The Orizon database is an administrative database containing over 18 million lives of the Private System. Eligibility criteria were patients with ≥ 40 years with the ICD-10 codes: J41, J410, J411, J418, J42, J43, J431, J432, J438, J439, J44, J440, J441, J448, J449 from 2010 to 2015. A total of 1755 patients were identified and costs related to hospitalizations or outpatient treatment were analyzed using an exchange rate of 1 USD = 3.23 BRL. **RESULTS:** From 2010 to 2015 we observed an increasing cost per event (inpatient and outpatient), ranging from USD 4,228,10 in 2010 to USD 9,398.72 in 2015. Raising costs may be explained, at least in part, because of Brazilian annual currency inflation. The direct medical costs of hospitalized patients were much higher than outpatient treatment. The mean outpatient exacerbation treatment cost was USD 102.61 while the inpatient treatment, the mean cost was USD 9,659.05 per event. The mean yearly direct medical cost per COPD patient was USD 5,891.04 in 2010 (n = 239); USD 6,079.62 in 2011 (n = 302); USD 8,119.59 in 2012 (n = 414); USD 8,637.42 in 2013 (n = 459); USD 11,536.36 in 2014 (n = 475) and USD 13,181.13 in 2015 (n = 574). The rate of events per patient were similar among the years, ranging from 1.39 to 1.50 event/year. **CONCLUSIONS:** The treatment cost of COPD exacerbations are raising each year in the Brazilian private system. Due to high annual costs per patient, especially COPD severe cases that may require more often hospitalizations, maintaining the disease under control may save resources for health plans.

PRS20

ASSESSING THE ECONOMIC BURDEN AND 30-DAY READMISSION RATES AMONG PATIENTS WITH PNEUMONIA IN THE US VETERANS HEALTH ADMINISTRATION POPULATION

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OBJECTIVES: To assess health care costs, 30-day readmission rates, and predictors of 30-day readmission among patients with pneumonia in the US Veterans Health Administration (VHA) population (01OCT2010-30SEP2015). **METHODS:** Patients included the VHA population for diagnosed with pneumonia (International Classification of Disease, 9th Revision, Clinical Modification codes 480-486) were identified the identification period (01OCT2011-30SEPT2014). The initial diagnosis date was designated as the index date. Patients without a pneumonia diagnosis, but

with the same age, race, and gender as study pneumonia patients were identified for comparison. For control patients, the index date was randomly selected to minimize bias. Adult patients were required to have continuous medical and pharmacy benefits for 1 year pre- and post-index date. Health care costs and 30-day readmission rates during the 1-year follow-up period were compared among 1:1 matched patients with and without pneumonia. Logistic regression was used to examine the predictors of 30-day readmission. **RESULTS:** After matching, there were 165,849 patients in each group. Compared to patients without pneumonia, those with pneumonia incurred higher inpatient (\$32,134 vs \$800; $p < 0.0001$), outpatient (\$8,032 vs \$1,963; $p < 0.0001$), and total costs (\$40,167 vs \$2,764; $p < 0.0001$) as well as a higher 30-day readmission rate (33.4% vs 0.5%; $p < 0.0001$). The likelihood of 30-day readmission was lower among patients aged 18-64 years versus ≥ 65 years (odds ratio [OR]: 0.4-0.9; $p < 0.0001$) and higher among male (OR: 1.2; $p < 0.0001$), black (OR: 1.4; $p < 0.0001$), and white patients (OR: 1.3; $p < 0.0001$) compared to those of other races and those with higher Charlson comorbidity index (CCI) scores (OR: 1.1; $p < 0.0001$). **CONCLUSIONS:** Patients with pneumonia had significantly higher 30-day readmission rates and economic burden than those without pneumonia. Age, gender, race, and CCI score were significant predictors of 30-day readmission.

PRS21

MEDICAL, ABSENTEEISM, AND MORTALITY COST OF ASTHMA IN THE UNITED STATES

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OBJECTIVES: The cost of asthma is an important measure of the impact of the disease on society. Presenting the burden of the disease in monetary terms provides critical information to decision makers for better allocation of health-care resources. In this paper we provided estimates of the prevalence, medical costs, and costs of absenteeism (missed school and workdays) and mortality attributable to asthma using the most recent data available. **METHODS:** The primary source of data for this study was the 2008-2013 household component of the Medical Expenditure Panel Survey (MEPS). We used a two-part regression model to estimate annual per person medical expenditure and negative binomial models to estimate asthma-related absenteeism. We applied a human capital approach to measure the value of absenteeism and mortality. We used personal weights from MEPS to estimate national prevalence and costs of asthma. **RESULTS:** Prevalence of asthma in the United States ranged from 4.81% in 2008 to 5.16 in 2011. Over the 2008-2013 period, the incremental medical cost of asthma was \$3,081 (2015 US dollars) per person per year, with \$1,552 attributable to prescription medication, \$682 to office-based providers visits, \$161 to hospital-based outpatient visits, \$553 to hospitalizations, and \$117 to emergency rooms visits. Asthma was responsible for additional 1.78 work and 2.32 school days lost annually which represents more than 8.6 million work and more than 5.1 million school days lost nationally due to asthma, for a total loss of \$2.9 billion. The total cost of asthma was \$62.6 billion, of which \$57.9 billion was for medical expenditures and \$4.7 billion was attributed to absenteeism and mortality. **CONCLUSIONS:** The cost of asthma represents a significant economic burden in the United States. Our study results highlight the urgent need to improve and enhance strategies to prevent and control asthma, and thereby reduce its economic burden.

PRS22

PREVALENCE AND TREATMENT COST OF NON-COMMUNICABLE DISEASES RELATED TO SMOKING IN INDONESIA

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OBJECTIVES: This study aimed to estimate the current incidence and treatment cost of non-communicable diseases attributed to tobacco among Indonesian population in 2015. **METHODS:** An epidemiological study was performed. Using national universal coverage database in 2015 we calculated the incidence and treatment cost of 19 diseases. Proportion of smoking attribution toward diseases and treatment cost due to smoking were calculated using smoking attributable fraction (SAF) formula, using the prevalence of smoking and relative risk of each disease. **RESULTS:** The study revealed that the incidence of smoking related diseases accounted for 991,331 about 21.6% of total incidence of chronic diseases in Indonesia. The highest rank of diseases prevalence was hypertension, chronic obstructive pulmonary diseases (COPD) and ischemic heart disease. The treatment cost of smoking in Indonesia was conservatively estimated to be at least US\$ 2,177 million, approximately 2.5% of the 2015 gross domestic product. A majority of the cost was largely concentrated in the male population (US\$2,164 million). Treatment costs of hypertension, COPD, and ischemic heart disease had the highest cost burden. **CONCLUSIONS:** This study finding provides scientific evidence about economic burden of smoking, particularly the healthcare expenditure covered by government. Tobacco control efforts need to be prioritized in to prevent higher losses of the nation. This study's evidence is important for informing national public health policy to advocate the health promotion and prevention program.

PRS23

CALCULATION OF YEARS OF LIFE LOST (YLL) CAUSED BY TUBERCULOSIS

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OBJECTIVES: In Mongolia, tuberculosis is the sixth cause of death among all death causes, and first reason of death which caused by infectious diseases. Any research and calculation on YLL caused by tuberculosis were not

conducted. Objective of the study was to estimate YLL caused by tuberculosis among Mongolian. **METHODS:** In this analysis we used data of population illness and death rate of 2015. The YLL calculation method was the same method as which WHO uses for YLL calculation. The analysis of social and economic lost accumulated from GDP per person. In 2015, the average life expectancy of population in Mongolia was 70 years, and GDP in that year equal to \$3,943.00. **RESULTS:** In 2015, about 240 people have died due to pulmonary and extra-pulmonary tuberculosis and 177 of them were male and 63 of them female. Consequently, the YLL calculated as 6085 and 3 person per 100'000 population dies due to pulmonary and extra-pulmonary tuberculosis. Based on GDP per capita, economic cost equals to \$23,993,155.00. **CONCLUSIONS:** In 2015, preventable YLL caused by tuberculosis was equal to 6085. Furthermore, YLL high in 25-49 age group mostly among the males. Regrettably, this middle age group composes the main national human resource and it is causing great loss in our country.

PRS24

THE USE OF BEHAVIORAL ECONOMICS AND SOCIAL PSYCHOLOGY TO IMPROVE TREATMENT OF ACUTE RESPIRATORY INFECTIONS (BEARI): A COST-EFFECTIVENESS ANALYSIS

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OBJECTIVES: Based on previous research showing that three behavioral economic interventions can minimize inappropriate use of antimicrobials for upper respiratory infection (URI), we sought to determine the cost-effectiveness of these interventions: (1) Suggested Alternatives (SA), which utilizes computerized clinical decision support to suggest non-antibiotic treatment choices in lieu of antibiotics; (2) Accountable Justification (JA), which mandates free-text justification into the patient's electronic health record when antibiotics are prescribed; and (3) Peer Comparison (PC), which sends a periodic email to prescribers about his/her rate of inappropriate antibiotic prescribing relative to peers. **METHODS:** We used a 30-year Markov model from the US societal perspective to simulate the utilization of antibiotics, cost of care, and health outcomes among a cohort of 45-year-old adults presenting to a healthcare provider with URI and its potential complications. Transition probabilities between disease states, costs, and utility values were derived from the literature and available surveillance data. Discounted total costs, quality-adjusted life years, and incremental cost-effectiveness ratios of each intervention relative to no intervention were calculated, and sensitivity of these estimates assessed through a series of one-way sensitivity analyses. **RESULTS:** Relative to the status quo, each intervention is cost-effective, as ICERs indicate the dominance of each intervention over current practice (lower costs but higher QALYs). In the base case, total costs for each intervention were \$2,155, \$1,183, \$1,121, and \$1,040, and total QALYs were 28.64, 28.79, 28.81, and 28.82 for the control, SA, JA, and PC groups respectively. Dominance was driven by decreased costs for each intervention primarily due to significant decreases in healthcare utilization for antibiotic-associated ADRs. Results remained robust in one-way sensitivity analyses. Notably, the rate of bacterial resistance development did not have a substantial impact on the results. **CONCLUSIONS:** Behavioral economic interventions can be cost-effective strategies for reducing inappropriate antibiotic prescriptions by reducing healthcare resource utilization.

PRS25

COST-EFFECTIVENESS OF ROFLUMILAST AS ADD-ON TO TRIPLE INHALED THERAPY VERSUS TRIPLE INHALED THERAPY IN PATIENTS WITH SEVERE AND VERY SEVERE CHRONIC OBSTRUCTIVE PULMONARY DISEASE ASSOCIATED WITH CHRONIC BRONCHITIS IN THE UK

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OBJECTIVES: To assess the cost-effectiveness of roflumilast (ROF) added to triple inhaled therapy (ICS+LABA+LAMA) versus ICS+LABA+LAMA alone in UK patients with severe chronic obstructive pulmonary disease (COPD), chronic bronchitis and ≥ 2 moderate or severe COPD exacerbations in the past year. Data used were from the phase 3b/4 clinical trial REACT's (NCT01329029) valid cases set, as a proportion of REACT patients did not meet the licence criteria for ROF. **METHODS:** An Excel-based cohort state transition (Markov) model estimated total costs and outcomes over 40 years from a UK National Health Service and Personal Social Services perspective. The model has three GOLD-based states: severe COPD, very severe COPD, and death. All patients enter in the severe state and there is an irreversible transition from severe to very severe COPD. Background rates of moderate and severe exacerbations were estimated with negative binomial regressions adjusting for disease severity and treatment in the trial sub-population treated with triple therapy. Published health-related quality of life weights were applied to health states and exacerbations to generate quality-adjusted life years (QALYs). List prices for drugs were used. **RESULTS:** ROF reduced the annual rate of exacerbations (moderate or severe) compared with ICS+LABA+LAMA alone (rate ratio [RR]: 0.80, $p=0.0117$). There was a greater reduction in rates of severe (RR: 0.66; $p=0.003$) than moderate (RR: 0.89; $p=0.247$) exacerbations. ROF treatment resulted in the avoidance of >1 severe and 0.6 moderate exacerbations per patient. Approximate incremental gains for ROF were 0.17 QALYs at £2996 per patient (probabilistic cost per QALY: £17,855/QALY), with a 70% probability of being cost-effective at a £20,000/QALY threshold. ROF remained cost-effective under several different sensitivity analyses, and also had favorable cost-effectiveness when evaluated in patients with very severe COPD. **CONCLUSIONS:** ROF as add-on to ICS+LABA+LAMA is cost-effective for patients with severe COPD and frequent exacerbations.

PRS26

COST-EFFECTIVENESS ANALYSIS OF PORACTANT ALPHA (200MG/KG DAILY) COMPARED TO BERACTANT (100MG/KG DAILY), IN PREMATURE INFANTS WITH RESPIRATORY DISTRESS SYNDROME, FROM THE MEXICAN INSTITUTE OF SOCIAL SECURITY (IMSS) PERSPECTIVE

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OBJECTIVES: This study sought to determine the cost-effectiveness of Poractant Alpha (200mg/KG daily) in comparison to Beractant (100mg/KG daily) in the treatment of Respiratory Distress Syndrome (RDS) in premature infants from the Mexican Institute of Social Security (IMSS) perspective. **METHODS:** A systematic review of the literature was performed to identify relevant phase-III Random Controlled Trials (RCTs) and meta-analyses on the target population. Fourteen published articles were identified and a fixed-effects meta-analysis was performed using WINBUGS. A decision tree model was designed to assess the success in terms of mortality rates associated with the treatments. The costs included were cost of the drug, Intensive-Care Unit (ICU) days and adverse events. All the costs were estimated based on Diagnosis-Related Groups and Unit Costs published yearly by IMSS, except for the cost of Poractant Alpha which was obtained from other Mexican Public Health Institutions. The time horizon was 30 days, so no time discount was needed. The health outcome was the mortality rate. The perspective of the analysis was IMSS' Perspective. A probabilistic sensitivity analysis (PSA) through Monte Carlo simulations was performed. **RESULTS:** Poractant Alpha was an alternative that reduced the number of ICU days compared to Beractant in almost 3 days per patient. Also, it reduced the main adverse event associated with the treatment, the Bronchopulmonary Dysplasia, from 41.5% to 21.30%. As a result, the total cost of treatment (CoT, in USD) was \$65,385 and \$73,500, for Poractant Alpha and Beractant, respectively. Moreover, the mortality rate was 9.0% for Poractant Alpha and 16.7% for Beractant. These results were robust under uncertainty, in more than 85% of the cases. **CONCLUSIONS:** Poractant Alpha is a dominant strategy over Beractant for the treatment of the RDS in premature infants from the IMSS Perspective. These results were robust under uncertainty.

PRS28

DETERMINANTS OF TOBACCO CONSUMPTION IN POPULATION OVER 50 YEARS OLD AFFILIATED TO A COLOMBIAN GOVERNMENT SUBSIDIZED HEALTH INSURER

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OBJECTIVES: To estimate the determinants of tobacco consumption in population over 50 years old affiliated to a Colombian government subsidized health insurer. **METHODS:** A cross-sectional study based on a sample of 191,541 affiliates characterized in the individualized health risk database from a Colombian government subsidized health insurer that has approximately two million affiliates distributed in 12 departments and more than 180 municipalities. A logistic regression model was developed whose dependent variable takes value 1 if the member consumes tobacco (at least one daily in the last 30 days at the time of the survey). An adjusted analysis by age and sex was made. **RESULTS:** The smoking prevalence in people over 50 years old in 2015 was 15.1% CI (14.97% - 16.22%), in men was 21.90%, whereas in women was 9.91%. The mean of age was 61.2. In respect of determinants, education OR 0.94 CI (0.93 - 0.94), being busy OR 0.91 CI (0.89 - 0.92), good eating habits OR 0.96 CI (0.94 - 0.98) and a physical activity OR 0.98 CI (0.97 - 0.99) are protective roles in determining the consumption of tobacco. On the other hand, age OR 1.06 CI (1.06 - 1.07), alcohol consumption OR 13.82 CI (13.62 - 14.01) and living in urban areas OR 1.15 CI (1.13 - 1.17) increase the probability of consuming tobacco. Men are more likely to use tobacco than women (0.45 pp), as the income level increases, the consumption probability decreases (-0.02 pp). **CONCLUSIONS:** The smoking prevalence in the population over 50 years old is high. The present study generates evidence to review the tobacco control policy, finally, it is necessary to implement prevention programs in the insurer.

PRS29

INDIRECT COSTS ASSOCIATED WITH COPD IN BULGARIA

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OBJECTIVES: To calculate the indirect costs of Chronic Obstructive Pulmonary Disease (COPD) in Bulgaria generated from the lost productivity due to absence from work (absenteeism), due to premature retirement, and due to reduced productivity. **METHODS:** An observational study was conducted among 426 COPD patients in five main regions of Bulgaria. Information about days out of work, premature retirement and decreased productivity was collected through interview during regular patients' visits. The indirect costs were calculated using human capital approach. Average daily wage was considered in calculations of the absenteeism, minimal pension for the earlier retirement, and average wage for reduced productivity corrected with incapacity coefficient. Non-parametric method Kruskal-Wallis was applied to compare the medians of the indirect costs

for different patients group according to COPD severity. **RESULTS:** 147 (34.5%) out of all 426 enrolled COPD patients were employees and more than half of them (57%) reported absence from work. The average number of missed working hours per patient per year was 192 (24 days). The average reduced productivity was approximately 65.5% and the earlier retirement was reported by 56 patients. Indirect costs per patient generated due to reduced productivity were much higher than the indirect costs generated due to absenteeism – 3750.64 euro (SD=854.11) vs 521.45 euro (SD=380.15) per patient, respectively. The highest indirect costs per patient were associated with premature retirement – 25 353 euro (SD=19 935.50). The indirect costs are higher in the patients groups with more severe disease which is statistically significant ($p < 0.05$). **CONCLUSIONS:** COPD has significant indirect costs. With the progression of the disease the indirect costs increased and mostly that for the lost productivity.

PRS30

TAX LOSSES AND GAINS ATTRIBUTED TO SMOKING CESSATION APPLYING A TAIWAN PUBLIC ECONOMIC PERSPECTIVE

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OBJECTIVES: Conventional economic analyses excludes important economic gains attributed to smoking cessation therapy. In addition to smoking-attributable mortality and morbidity from quitting smoking, there is an established relationship between smoking and reduced productivity and wage effects. In this prototype analysis we assess how public investments in smoking cessation that changes smoking prevalence can influence future government tax revenue and social transfer costs in Taiwan. **METHODS:** A modified generational accounting framework was developed to assess relationships between smoking attributed morbidity and mortality and public economic consequences including lifetime tax revenue gains/losses and government social transfers and health spending. Based on the current prevalence of smoking in Taiwan, a cohort model was developed for smokers, former-smokers and non-smokers. The model simulated the lifetime discounted fiscal transfers for different age cohorts in five year age bands, and the benefit-cost ratio (BCR) of smoking cessation investments. Comparable models were built for males and females based on 2016 Taiwanese dollars (NTD). **RESULTS:** For different age cohorts of male smokers, those who quit smoking had an average increase in lifetime earnings of NTD127,150 ranging from NTD202,000 for those aged 25-30, and NTD28,500 for those aged 61-65. The average present value of additional lifetime tax was NTD24,350, with difference of NTD32,775 in lifetime health costs between smokers and former smokers. The average lifetime earnings loss and average tax gains in females was NTD108,680, and NTD20,810, respectively. The BCR ratio based on treatment costs ranged from 1.13 – 1.36 for male smokers. Similar BCR ratios were identified for female smokers. **CONCLUSIONS:** We demonstrate that lifetime tax revenue gains are greater from investments in smoking cessation compared with the tobacco tax revenue loss in those aged 25 – 65 in males and females. Lifetime tax revenue gains were greater in younger aged persons indicating that early intervention offers more fiscal benefits.

RESPIRATORY-RELATED DISORDERS - Patient-Reported Outcomes & Patient Preference Studies

PRS31

TARGETED LITERATURE REVIEW OF ADHERENCE TO THERAPIES IN CYSTIC FIBROSIS (CF)

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OBJECTIVES: To assess adherence to different CF therapies, association of adherence with outcomes, and factors influencing adherence. **METHODS:** A targeted literature review of studies published from 2010 to 2016. An article was retrieved for full review if the abstract met each of the following criteria: referred to adherence of any of the CF therapies, namely, inhaled treatments, oral treatments, airway clearance therapy (ACT) and other mode of treatments; published in a peer-reviewed journal and in English-language. **RESULTS:** A total of 19 studies qualified for inclusion. Overall long-term (≥ 12 months) adherence to ivacaftor is high but it is low for other CF treatments such as antibiotics, domase alfa, hypertonic saline, pancreatic enzymes (PE), airway clearance therapy (ACT) and vitamins. Patients are more adherent to inhaled therapies as compared to oral therapies such as PE and vitamins, and among inhaled treatments, more patients are adherent to tobramycin inhalations at 12 months than domase alfa or hypertonic saline. Adherence to ACT via flutter device is lower as compared to other methods, and all other inhaled/oral treatments. Adherence varied by treatment, mode of treatment administration, age, season, time and method of adherence measurement. Higher rates of exacerbations, longer length of inpatient stays as well as increase in some healthcare costs were observed among patient groups with sub-optimal adherence. Treatment-related issues (adverse effects, longer/inconvenient & frequency of administration, polypharmacy), poor patient-provider communication, lack of disease- and treatment-related knowledge and unwillingness to take medication in public were key barriers to adherence. **CONCLUSIONS:** Adherence to CF treatments was sub-optimal, varied widely and were found to influence clinical and economic burden of the disease. Identifying ways to overcome the barriers to sub-optimal adherence can positively affect outcomes associated with CF. Healthcare providers and policy makers should devise patient-centered and caregiver-enabled interventions to improve adherence.

PRS32

IMPACT ANALYSIS FOR THE LAW ON 'PROTECTION OF NON-SMOKERS, SMOKING AND DISTRIBUTION OF TOBACCO PRODUCTS' AMONG HEALTHCARE PROFESSIONAL EMPLOYEES FROM THE HEART INSTITUTE OF THE UNIVERSITY OF PÉCS

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OBJECTIVES: Smoking is one of the leading risk factors in the development of several diseases worldwide. The aim of the study was to analyse the effect of the Law amendment among healthcare professional employees from the Heart Institute of the University of Pécs, and also to measure how it affected smoking behaviour. **METHODS:** The research was based on a cross-sectional study with quantitative methods. At baseline, N=161 employees were enrolled from the Heart Institute, University of Pécs. Of these, N=125 (72.67%) could be involved into the analysis. The subjects were asked to fill in a self-made questionnaire. The questions were centred around five topics: socio-demographic characteristics, smoking behaviour, environmental tobacco smoke exposure, awareness of negative effects for health and attitude related to control policy. The analyses were made with MS Office Excel 2007/2010 and SPSS software. The analyses include t-tests, chi square tests, linear regression, and ANOVA. **RESULTS:** The main hypothesis that non-smokers give higher ratings for the effectiveness of the Law modification as opposed to smokers was proved with significant difference ($P=0,0002368$; $P < 0,05$). A marked difference was also found with respect to the rating of passive smoking among smoker, and non-smoker healthcare professionals ($P=0.01514$, $P < 0.05$). Tobacco use among smoker employees has not changed. While some of the subjects reduced the amount of cigarettes they smoked daily, others continued to go through the same amount. To summarise, no change has been recorded ($P=1$; $P < 0.05$). **CONCLUSIONS:** Smoking continues to be the main public health issue in our country, requiring continuous action in the future. Another Law amendment is going to be introduced by the government to control the packaging of the cigarette boxes. Further more extensive research should be conducted with a focus to measure the efficiency of the newer Law modifications.

PRS33

INHALER CONFIDENCE AND SATISFACTION AMONG CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) PATIENTS WITH COMORBIDITIES – A COMPARISON OF HAND-HELD VERSUS NEBULIZED MAINTENANCE BRONCHODILATORS

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OBJECTIVES: Hand-held (HH-LA) or nebulizer (Neb-LA) devices are traditionally used to deliver long-acting bronchodilators for maintenance treatment of COPD. However, a significant proportion of COPD patients with cardiovascular and neurological (CV&N) comorbidities may have low confidence in operating hand-held inhaler devices as instructed. This study compared patient-reported confidence and satisfaction with device use and their association with other PROs among COPD patients with ≥ 1 CV&N comorbidities treated with HH-LA or Neb-LA. **METHODS:** Data from 2015 Adelphi US Respiratory Disease Specific Programme, a nationally representative survey of physicians and their COPD patients were analyzed. Since HH-LA use is overrepresented in the COPD population, Neb-LA patients were oversampled ($n=204$) to augment the sample size. CV&N comorbidities included Alzheimer's, dementia, Parkinson's, cerebrovascular disease, congestive heart failure and coronary artery disease. PROs included - (i) confidence and satisfaction with inhaler device, (ii) Morisky medication adherence scale (MMAS) and (iii) COPD assessment test (CAT). Categorical and continuous outcomes variables were tested using chi-square and independent sample t-tests, respectively at $P < 0.05$. **RESULTS:** Of 909 COPD patients, 28.7% had ≥ 1 CV&N comorbidities (160/705 on HH-LA; 101/204 on Neb-LA). Baseline characteristics were comparable between patients treated with HH-LA or Neb-LA ($n=261$). A significantly higher proportion of Neb-LA than HH-LA patients in this sub-group reported being 'very' or 'completely' confident (73.7% vs. 55.2% $p=0.034$) and 'very' or 'extremely' satisfied (86.8% vs. 66.1%; $p=0.01$) with using their device. Greater confidence with use of Neb-LA in this sub-group were associated with better adherence, as reported on the MMAS ($\rho=0.30$, $p=0.02$) but not CAT (0.04, $p=0.75$) scores. **CONCLUSIONS:** In this survey of COPD patients with cardiovascular or neurological comorbidities, use of Neb-LA was associated with greater patient reported confidence and satisfaction with device use as compared to treatment with HH-LA. Greater confidence was also associated with better adherence for Neb-LA patients.

PRS34

SALFORD LUNG STUDY IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE (SLS COPD): FOLLOW-UP INTERVIEWS ON PATIENT-CENTRED OUTCOMES

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OBJECTIVES: To explore experiences of participants in SLS COPD (an open-label study comparing fluticasone furoate/vilanterol versus usual care in COPD).1 **METHODS:** Subsamples of patients completing SLS COPD were interviewed. Standard interviews (telephone/face-to-face) included closed-ended study-specific questions on: background/lifestyle, COPD symptoms/daily-life impact, environmental/temporal trigger factors, self-management/disease awareness, control, exacerbation experience/management, quality of life (QoL; specific dimensions/overall). Extended interviews (face-to-face) included the closed-ended plus additional open-ended questions. Quantitative data were analysed descriptively; qualitative data were

analysed by qualitative description approach. **RESULTS:** 400 patients were interviewed (standard, n=360/extended, n=40). Mean age (SLS COPD entry/follow-up interview=65.2/66.2 years) and gender (53.3% male) were reasonably representative of patients completing SLS COPD; 37% were current smokers. Breathlessness was the most frequently reported COPD symptom (88.5%) and the most improved/worsened (26.8%/20.9%) during SLS COPD; qualitative analysis revealed breathlessness most impacted: walking, climbing stairs, housework, self-care. Quantitative analysis revealed COPD most impacted functioning, physical activities, relationships/psychological state; qualitative analysis reinforced the broader impact of these on QoL. Strategies to prevent COPD worsening included: exercise, medication adherence, smoking reduction/cessation. 59.5% (n=238/400) described having 'quite a lot'/'very much' control over COPD; a high-risk group reported having no control (n=36[9.0%]). 66.5% (n=266/400) reported experiencing an exacerbation; severity of last exacerbation was considered (n=264/266): mild (n=21[7.9%]), moderate (n=74[27.8%]), severe (n=127[47.7%]), very severe (n=42[15.8%]); 60.5% managed this at home (resting/antibiotics and/or oral corticosteroids). Mean/total overall QoL score: 6.5/10; reported QoL changes during SLS COPD were: improvement (35.3%), no change (43.3%), deterioration (21.3%). No specific/serious adverse events were reported in interviews. **CONCLUSIONS:** Quantitative and qualitative data confirm breathlessness as the key COPD symptom, impacting most on mobility, daily activities and self-care; however, patients focused more on life-impacts of COPD than symptoms alone. This first, detailed evidence of COPD experiences over an extended period adds valuable information to the SLS COPD findings. **FUNDING:** GSK (117375). INEJM(2016) 375:1253.

PRS35

PREFERENCE FOR TASTE OF NICORETTE GUM COMPARED TO STORE BRAND NRT GUM

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OBJECTIVES: Patient adherence to nicotine replacement therapy (NRT) can affect long-term successful smoking cessation. Preference in regard to certain sensory attributes such as taste could lead to increased adherence. The goal of this study was to evaluate whether the taste of Nicorette[®] Gum is preferred over leading store brand NRT gum. **METHODS:** This three-cell, randomized, double-blind taste test was conducted among 945 adult smokers at 23 shopping malls throughout the US. Participants were randomized to one of three test cells in which they tasted two pieces of comparably flavored NRT gum (1 piece of Nicorette and 1 piece of leading store brand). Each cell represented a flavor – mint (n=319), fruit (n=314), or cinnamon (n=312). Participants were required to chew the gum for 1 minute, and “park” the gum for 1 minute before disposing. After waiting 10 minutes and cleansing their palate, participants tasted the second piece of gum in the same manner. Upon completion, subjects were asked a comparative question related to flavor preference and two questions related to whether the gum tasted refreshing and invigorating. **RESULTS:** Overall, participants significantly preferred the taste of Nicorette gum to the store brand gum, 69% to 31% (p<.0001). Smokers preferred the taste of Nicorette gum across all flavors, mint, 79% to 21% (p<.0001), fruit, 68% to 32% (p<.0001), and cinnamon, 58% to 42% (p=.003). Of all respondents, 83% and 65% claim Nicorette had a refreshing and invigorating taste, respectively, compared with their responses of 53% and 47% for the leading store brand gum, respectively. **CONCLUSIONS:** Significantly more smokers prefer the taste of Nicorette gum to the taste of the leading store brand NRT gum. The taste of nicotine gum can be an obstacle to patient adherence, and completion of recommended duration of therapy. Favorable product sensory attributes can potentially improve compliance, treatment outcomes, and quit success.

PRS36

DEPRESSION TREATMENT AND HEALTH-RELATED QUALITY OF LIFE AMONG ADULTS WITH ASTHMA

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OBJECTIVES: Depressive symptoms are common in asthma patients and depression is associated with reduction in Health-Related Quality of Life (HRQoL). We examined association between use of anti-depressants and change in HRQoL among asthma patients. **METHODS:** A retrospective longitudinal study was conducted using 2010 to 2014 Medical Expenditure Panel Survey (MEPS) data. Sample inclusion criteria were being 18 years old or older, diagnosed with asthma based on ICD code 493, and screening positive for depression based on a score of 3 or higher on the Patient Health Questionnaire (PHQ-2). MEPS Round 2 data served as baseline measures, and Round 4 data served as follow up. Separate multivariate linear regression models estimated association between anti-depressant use and change in PCS and MCS scores. The response variable was change in the PCS score in one model and change in the MCS score in the other. The predictor variable in each model was anti-depressant use, which was coded as treated or not-treated. Each model included the covariates, socio-economic status, co-morbidity, baseline MCS or PCS score, baseline PHQ-2 score, and duration of anti-depressant use. **RESULTS:** A total of 492 individuals met sample inclusion criteria. Of those, 94 (23%) used anti-depressant. A majority of the sample was female (64.2%). The mean age was 47 years (std. dev. =15.9). The baseline and follow-up MCS scores were lower among adults who were treated than those who were not treated (p=0.017). The sample mean PCS and MCS scores were 36.5 (SE=0.74) and 32.6 (SE=0.49) respectively at baseline. Individuals who used anti-depressants had positive change in the PCS score (beta= 3.27, p < .0001) and negative change in the MCS scores (beta = -5.99, p < .0001). **CONCLUSIONS:** Anti-depressant use was associated with improved the PCS scores. However, the change in the MCS score showed negative association with anti-depressant use.

RESPIRATORY-RELATED DISORDERS – Health Care Use & Policy Studies

PRS37

THE PATIENTS' COST OF THE MONTELUKAST THERAPY

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OBJECTIVES: The aim of our study is to analyze the public price of the montelukast sodium therapy in Hungary within the generic competition. **METHODS:** Data derived from the nationwide pharmaceutical database of Hungarian National Health Insurance Fund Administration. We analyze the annual turnover and price of the medicaments containing the active substance montelukast sodium from 2007 to 2015. Accordingly our indicators were: consumer price, DCT (Daily cost of Therapy), co-payment, quasi co-payment, DOT (Days of Treatment). **RESULTS:** Before the appearance of generic medicaments (October, 2011), the public price of the brand-name Singulair 10 mg tablets was 7 USD (on lifted category legal title). Due to the blind bid methods of the Hungarian National Health Insurance Fund Administration the public price of Singulair decreased to 1.5 USD in January, 2013. The public price of the generic drugs started from about 2 USD (October, 2011) and decreased to about 0.7 USD (April, 2013). Due to the increasing DOT the total amount of the public price paid by the patients had increased until 2011, it reached the amount of 1 million USD, then due to the generic competition and blind bid methods it decreased to 490.000 USD. The total amount of public price of the brand-name Singulair moved to the generics during 3 years (2011-2014). The DCT of the originator Singulair 10 mg tablets decreased from 1.1 USD to 0.34 USD, the DCT of the generic product Montelukast TEVA decreased from 0.67 USD to 0.16 USD in the period under review. **CONCLUSIONS:** Due to the generic competition the patients' access to drugs containing montelukast sodium increased significantly.

PRS38

CORRELATES OF MARIJUANA USE WITHIN THE PAST YEAR AMONG ADULTS IN THE UNITED STATES

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OBJECTIVES: To examine the correlates of marijuana use in the prior 12 months among US adults. **METHODS:** Data from 2013-2014 National Surveys on Drug Use and Health, a cross-sectional nationally representative survey, identified 64,901 adults aged 21 and above. Outcome variable was self-reported marijuana use in the past year or not. Independent variables included sociodemographic factors, cigarette smoking, and other illicit drug use. Weighted, multivariate logistic regression models were constructed to examine the association between independent variables and marijuana use. **RESULTS:** The prevalence of past-year marijuana use among respondents was approximately 12%. In the adjusted model, there was a dose response association between age and marital status and marijuana use. Respondents who were 35-49 years old (aOR = 1.37; 95% CI: 1.21 – 1.55) and 21-34 years old (aOR = 2.89; 95% CI: 2.57 – 3.26) were more likely to have used marijuana in the past year compared to those who were 50+ years as were widowed/divorced/separated (aOR = 1.27; 95% CI: 1.11 – 1.45) and never married (aOR = 2.14; 95% CI: 1.95 – 2.35) compared to married respondents. Past-year users were more likely to be male (aOR = 1.14; 95% CI: 1.04 – 1.24), and black (aOR = 1.32; 95% CI: 1.18 – 1.47) versus white. Past-year users, in addition to frequent marijuana use, also were more likely to smoke cigarettes within the past year and use other illicit drugs such as cocaine within the past year. **CONCLUSIONS:** Younger adults, men, blacks, unmarried individuals and other substance users were more likely to use marijuana. Comprehensive screening, treatment for use of multiple substances, and additional research and patient education on the possible harms of marijuana use are needed. Particularly in the age of increasing policy changes, at the state level, around the legalization of marijuana, these findings may have important public health implications.

PRS39

PREDICTORS OF NEBULIZED ARFORMOTEROL USE: A RETROSPECTIVE ANALYSIS AMONG MEDICARE BENEFICIARIES WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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OBJECTIVES: To evaluate predictors of nebulized long-acting beta2 agonist (LABA) Arformoterol (Brovana[®]) use among Medicare beneficiaries with chronic obstructive pulmonary disease (COPD). **METHODS:** This retrospective cohort study used Medicare administrative data from 2010-2014 to identify beneficiaries with ≥ 2 COPD outpatient visits 30 days apart or ≥ 1 COPD-related hospitalization(s) using ICD-9 codes (i.e., 491.xx, 492.xx, and 496). Inclusion criteria required beneficiaries to have ≥ 1 COPD medication claim(s) and continuous enrollment in Medicare parts A, B, and D. After excluding deaths, beneficiaries who initiated Brovana[®] (study group, n=11,886) were compared to those without Brovana[®] use (control group, n=450,178) to examine predictors of Brovana[®] use. Logistic regression analyses were employed to examine predictors of Brovana[®] use. Odds ratios, 95% confidence intervals, and p-values were computed. **RESULTS:** In this analysis, 91% were Caucasian (91%), 60% were female, and 36% were dual-eligibles. Mean age was similar among Brovana[®] users (72.2 ± 10.1 years) and controls (72.3 ± 10.2 years). Beneficiaries were more likely to receive Brovana[®] if they were using LAMAs (OR=1.1, 95% CI: 1.1, 1.2), inhaled SABAs (OR=1.1, 95% CI: 1.1, 1.2), systemic corticosteroids (OR=1.5, 95% CI: 1.4, 1.6), or

methylxanthines (OR=1.4, 95% CI: 1.3, 1.5). Brovana® users were more likely to have a COPD-related hospitalization (OR=1.3, 95% CI: 1.2, 1.4), an outpatient pulmonologist visit (OR=1.4, 95% CI: 1.3, 1.5), ≥1 exacerbation(s) (OR=1.3, 95% CI: 1.3, 1.4), or oxygen dependence (OR=2.0, 95% CI: 1.9, 2.1) in the year prior to initiating Brovana® (all p 's < 0.0001). **CONCLUSIONS:** In this analysis, Medicare beneficiaries who received Brovana® were more likely to be on additional COPD medications, have ≥1 exacerbation(s) and have a prior COPD-related hospitalization. These results suggest that Brovana® users may be sicker and likely to have higher COPD severity than non-Brovana® users. More work is needed to identify subgroups of patients who may benefit most from Brovana® therapy.

PRS40

PREScribing PRACTICES OF ANTIBIOTICS FOR THE TREATMENT OF RESPIRATORY TRACT INFECTIONS IN THE BAHAWAL VICTORIA HOSPITAL, BAHAWALPUR, PUNJAB, PAKISTAN

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OBJECTIVES: Estimate the prescribing practices for mild/moderate respiratory tract infections (RTIs) based on the principles established by the standard treatment guidelines. **METHODS:** Prescriptions and medication charts written during the period of November 2014 to March 2015 with the diagnosis of upper and lower RTIs were collected from ENT, Pulmonology, pediatrics 1 and pediatrics 2 wards of the Bahawal Victoria Hospital. A data collection form was designed for this study. All prescribed antibiotics and demographic information of the patients were extracted from the prescriptions. Each prescribed antibiotic was evaluated for rational prescribing based on the standard guidelines of Current Medical Diagnosis and Treatment, CDC and World Health Organization. All data was entered and analyzed by using SPSS 21.0. **RESULTS:** Among the 789 participants (56% males and 44% females), the most commonly prescribed antibiotic classes were; penicillins (47%), macrolide (35.3%), cephalosporins (33.9%) and fluoroquinolone (29.8%), respectively. The most commonly prescribed antibiotics were; erythromycin (48.7%), augmentin (36.9%) and ceftriaxone (27.7%), respectively. The overall level of inappropriate prescribing for all the patients based upon application of the standard treatment guidelines was 55.9%. The major reasons for the inappropriate prescribing were; wrong drug (29.3%), wrong dose (33.5%), wrong frequency (34.3%) and wrong duration (30.2%), respectively. **CONCLUSIONS:** The study has revealed high levels of inappropriate prescribing for the RTIs and in-addition has underlined the unavailability and inconsistency of the current treatment guidelines. The results have significant implications for the health status of patients being cured for mild/moderate RTIs and propose the need for appropriate interventions to be established and presented by authorities to address the matters raised.

PRS41

RACE AND ETHNICITY AMONG CHILDREN WITH ASTHMA IN THE UNITED STATES: ASSOCIATION WITH ASTHMA, ASTHMA CONTROL AND OUTCOMES

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OBJECTIVES: Previous studies show a high prevalence of asthma and poor control among certain subgroups of children. However, the relationship remains poorly understood. **METHODS:** This was a cross-sectional analysis of children with and without asthma (aged 6-17) in the nationally representative 2007-2013 Medical Expenditure Panel Survey. Outcomes included asthma prevalence; asthma-specific (AS) Emergency Department (ED) and inpatient (IP) visits and expenditures; and indicators of asthma control (self-reported exacerbations or use of ≥3 rescue inhaler canisters /3 months). Negative binomial regression analyses were used for ED and IP visits; Generalized Linear Models with log-link for healthcare expenditures; and logistic regression for asthma control indicators. Regressions controlled for comprehensive socio-demographics. **RESULTS:** Non-Hispanic White, Non-Hispanic Asian, Mexican and Hispanic-Central/South American children were less likely and Non-Hispanic Black, Non-Hispanic Multiple Race and Hispanic-Puerto Rican children more likely to have asthma. Among children with asthma, the following appeared to have increased ED/IP use and/or indicators of poor control: Non-Hispanic Black, Non-Hispanic Asian, Non-Hispanic Multiple Race, Hispanic-Mexican and Hispanic-Puerto Rican. For example, compared to Non-Hispanic Whites, Non-Hispanic Blacks incurred greater ED and IP visits (IRR=3.3, 34.8; p <0.05). Non-Hispanic Blacks and Non-Hispanic Asians with asthma had higher AS medical, ED and IP expenditures than Non-Hispanic Whites with asthma. The following children had greater odds of overusing rescue inhalers (compared to Non-Hispanic White): Non-Hispanic Black (2.4), Non-Hispanic Asian (7.5), Hispanic-Mexican (3.3) and Hispanic-Puerto Rican (3.2) (all p <0.05). **CONCLUSIONS:** Asthma and poor asthma control is prevalent among certain subgroups of children based on ethnicity and/or race in the U.S.

PRS42

A REAL WORLD PROFILE OF THE BASELINE CHARACTERISTICS OF ASTHMA PATIENTS NEWLY TREATED WITH OMALIZUMAB IN THE UNITED STATES

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OBJECTIVES: To assess demographics, clinical characteristics, and healthcare resource utilization (HCRU) and costs among asthma patients prior to omalizumab initiation in a real-world environment. **METHODS:** This retrospective observational cohort study utilized US claims data from the HealthCore Integrated Research Database between 01/01/2006 and 04/30/2016. The study population consisted of asthma patients newly treated with omalizumab (defined as ≥4 omalizumab claims within the first 6 months post-index period; index date=first omalizumab claim date), aged ≥6 years, and ≥12 months pre- and post-index healthcare insurance enrollment. Patient demographics, clinical characteristics, and HCRU and costs within the 12 month pre-index period (baseline) were presented using descriptive statistics. Costs were adjusted to 2016 US dollars. **RESULTS:** The study identified 768 asthma patients newly treated with omalizumab with a mean (SD) age of 45.7 (±15.90) years and 58.5% female. At baseline, 78.0% patients had ≥1 visit to an allergist/immunologist; 74.5% had allergic rhinitis; 83.2% had spirometry testing; and 81.5% had total immunoglobulin E (IgE) testing or blood/skin testing for allergen-specific IgEs. The most commonly prescribed asthma controller medications at baseline were inhaled corticosteroids (ICS)-long-acting beta agonists (LABA) combinations (including free or fixed dose combinations; 70.1%) and leukotriene modifiers (68.1%), with 73.3% of patients having ≥1 fill of medium/high dose ICS overall. In terms of HCRU, 66.8% patients had ≥1 asthma exacerbations (11.7%, 10.7%, and 58.2% inpatient, emergency room, and outpatient exacerbations [office visit and oral corticosteroid prescription], respectively; 34.4% patients with ≥2 exacerbations) at baseline. The baseline mean (SD) annual all-cause and asthma-related total healthcare costs were \$21,489 (\$27,727) and \$9,638 (\$17,546), respectively. **CONCLUSIONS:** Study results showed that the majority of asthma patients initiating omalizumab had asthma-related testing, were prescribed ICS-LABA combinations, had >1 asthma exacerbation, and significant all-cause and asthma-related costs within the 12 month pre-index period in a real-world clinical setting.

PRS43

CHARACTERISTICS OF HOSPITALIZED PATIENTS WITH COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP) AT GREATEST RISK FOR PROLONGED HOSPITAL LENGTH OF STAY IN AN INTEGRATED DELIVERY NETWORK

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OBJECTIVES: Hospitalization of patients with CABP places a major burden on the US healthcare system. There are increasing efforts to reduce length of hospital stay (LOS) among pneumonia patients. This study attempts to identify CABP patients at increased risk for prolonged LOS. **METHODS:** A retrospective study of hospitalized patients with CABP in the Geisinger IDN medical encounter 2010-2015 database was performed. Inclusion criteria: (1) age ≥ 18 years, (2) primary diagnosis for CABP, (3) >1-year enrollment before index CABP hospitalization, (4) received ceftriaxone + macrolide or a fluoroquinolone on hospitalization day 1 or 2 and continued for ≥ 2 days. The primary outcome was LOS ≥ 8 days. **RESULTS:** During the study period, 1,089 patients met study criteria. The mean (SD) age was 66.7 (16) years. The geometric mean (SD) and median LOS were 4.1 (1.8) and 4.0 days, respectively. Of the 1,089 patients, 171 (15.7%) had LOS ≥ 8 days. LOS ≥ 8 days was similar between the following groups: age ≥ 65 vs. < 65 years (14.4% vs. 16.4%), body mass index ≥ 30 vs. < 30 (12.6% vs. 17.4%), presence of COPD/bronchitis vs. absence of COPD/bronchitis (16.1% vs. 12.8%), CCI ≥ 2 vs. 0-1 (16.2% vs. 14.3%), and previous (non-CABP) hospitalization vs. no previous hospitalization (15.7% vs. 15.8%). Patients with a CURB-65 score ≥ 3 had a statistically significantly higher risk of prolonged LOS ≥ 8 days vs. those with CURB-65 score ≤ 2 (19% vs. 14%, p <0.0001). Patients with LOS ≥ 8 days had a modest elevated risk of 30-day readmissions/repeated ED visits. **CONCLUSIONS:** Patient populations with CABP thought to be at an increased risk for unfavorable health outcomes were not found to be at an increased risk for prolonged LOS. These findings highlight the need to better delineate patient populations at greatest risk for prolonged LOS.

PRS44

HOSPITAL ADMISSIONS PATTERNS IN ADULT PATIENTS WITH COMMUNITY ACQUIRED BACTERIAL PNEUMONIA (CABP): IDENTIFICATION OF POTENTIALLY AVOIDABLE HOSPITAL ADMISSIONS THROUGH A RETROSPECTIVE DATABASE ANALYSIS

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OBJECTIVES: Studies demonstrate that Community Acquired Bacterial Pneumonia (CABP) patients without major comorbidities and limited disease severity can be successfully managed in the outpatient setting. This study described hospitalization patterns among adult patients with CABP relative to disease severity using U.S. hospital data. **METHODS:** A retrospective study of hospitalized patients with a primary diagnosis for CABP in the MedAssets hospital 2012-2015 data was performed. Inclusion criteria included age ≥ 18 years, hospitalized with primary diagnosis for CABP, received ceftriaxone + macrolide or a fluoroquinolone on day 1 or 2 of hospitalization. Hospitalized CABP patients with potentially avoidable hospital admissions were categorized using the calculated Charlson Comorbidity Index (CCI) score. **RESULTS:** Among 65,347 CABP patients receiving ceftriaxone and a macrolide or a fluoroquinolone on day 1 or 2, 23,764 (36%) were hospitalized and eligible for this analysis. 78% of patients with CCI ≥ 2 were hospitalized. Among patients with CCI ≤ 1, 33% (41,583) were hospitalized. The geometric mean hospital stay was 4.1 days for patients with CCI scores ≤ 1 vs. 4.3 days for

CCI scores ≥ 2 . The 30-day in-hospital mortality rate per 1,000 was 3.4 for the hospitalized study patients: 3.7 (95% CI 2.9 - 4.6) for those with CCI ≤ 1 , and 1.9 (95% CI 0.8 - 3.9) for those with CCI ≥ 2 . **CONCLUSIONS:** More than one third of CABP patients in this study were hospitalized. Most hospitalized patients had CCI ≤ 1 . Given costs associated with managing hospitalized CABP patients, these findings highlight the need for healthcare systems to adopt well-defined criteria for hospital admission based on presence of comorbidities. These results demonstrate the need to better delineate patient populations at risk for hospitalization and in-hospital mortality, and for identifying outpatient treatments that can effectively reduce hospital admissions.

PRS45

A STUDY OF PREVALENCE, BELIEFS AND ATTITUDE AMONG HEALTHCARE PROFESSIONALS TOWARDS SMOKING AND ITS CESSATION IN SOUTH PUNJAB, PAKISTAN

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OBJECTIVES: This study aimed to investigate the Prevalence, Beliefs and Attitude of healthcare professionals towards Cigarette smoking and its cessation. **METHODS:** A cross-sectional study was carried out among health care professionals including general and family physicians, nurses and pharmacist in the southern Punjab, Pakistan. A self administered questionnaire was distributed among 200 healthcare professionals with response rate of 80%. Data was analyzed by using SPSS. Descriptive statistics was applied to evaluate the data and chi square test was used to check association between dependent and independent variables. **RESULTS:** Among total 160 respondents, 109 (68.12%) were physicians, 24(15%) were pharmacists and 27(16.8%) were nurses. Significantly greater proportion agreed that smoking was a harmful activity. Almost all of the participants considered smoking as an addictive behavior. Most non-smokers agreed that smoking cessation was the single biggest step in improving health while majority of the non-smoking professionals identified smoking as individual's life style choice. Most of the respondents had no negative beliefs and attitudes towards discussing smoking. More than half of the respondents declared that they are not appropriately trained to help patients in quitting smoking. 79% of all students believed that doctors should play a role model in smoking cessation by not smoking themselves. **CONCLUSIONS:** There is a need for an increased emphasis on inhibited smoking-related attitude development among health care professionals. Strategies should be made to encourage physicians, pharmacist and nurses to quit smoking as patients consider them as a role model and steps should be taken to train all the health care professionals regarding patient counseling for smoking cessation.

PRS46

THE INTENTION TO QUIT SMOKING AND IMPORTANCE EVALUATION ON SMOKING CESSATION APP FEATURES

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OBJECTIVES: Given that 620 million Chinese own smartphones, smartphone applications (apps) for smoking cessation are increasingly used in China to help smokers quit. We aim to analyze the intention to quit smoking among Chinese smokers with smartphones and their evaluation on the importance of smoking cessation APP features. **METHODS:** Questionnaire survey was used to collect data among smokers own smartphones during 1 May 2016 and 31 August 2016. Cumulative-odds logistic regression was used to analyze the influencing factors of intention to quit smoking. Descriptive analysis was employed to analyze demographic characteristics of smokers with smartphones and their evaluation on the importance of smoking cessation App features. **RESULTS:** The score of intention to quit smoking among 74% of smokers was ≥ 5 with a total score of 10. Only 4.4% of smokers with smartphones downloaded smoking cessation App. Intention to quit smoking was influenced by factors of the living regions (OR=1.224, 95% CI:1.03-1.46) and trying to quit smoking before (OR=3.202, 95%CI:2.08-4.93). There was no statistical significance between Intention to quit smoking and the importance score of APP features ($P > 0.05$). However, features including "clinical expert support", "will change with the follow-up needs" and "interests of smokers and allow share the process of smoking cessation with family members and friends" have higher importance score (2.78, 2.73 and 2.82 respectively). **CONCLUSIONS:** The intention to quit smoking is lower among smokers with smartphones in China. Moreover, the utilization rate of smoking cessation App is low considering the significant smoking population with smartphones. Therefore, the improvement and promotion of effectively mobile smoking cessation technology based on importance evaluation from smokers is critical to reduce the smoking and increase health.

SYSTEMIC DISORDERS/CONDITIONS – Clinical Outcomes Studies

PSY1

ASSESSMENT OF HOSPITALIZATIONS DUE TO OVERDOSE AMONG MISSISSIPPI'S DIVISION OF MEDICAID (DOM) BENEFICIARIES WITH OPIOID PRESCRIPTIONS

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OBJECTIVES: Treatment of chronic non-cancer pain with prescription opioids has increased nationally in recent years. The 2016 Centers for Disease Control guidelines for prescribing opioids for chronic pain stressed the increased risk associated with higher morphine equivalent daily doses (MEDD). Higher MEDD have been associated with increased risks of overdose and death. This study examined the

relationship between MEDD levels and hospitalization due to overdose in the Mississippi Medicaid program. **METHODS:** A retrospective observational study was conducted using Mississippi's DOM claims data. Included were beneficiaries > 18 years, continuously enrolled, and having opioid prescription claims between July 1, 2015 and June 30, 2016. Patients in long term care, in hospice care or with a cancer diagnosis were excluded. The MEDD of each opioid prescription was calculated using quantity dispensed, days supply and a conversion factor for the strength prescribed. Inpatient claims were used to identify hospitalization for overdose within 30 days of an opioid prescription. Logistic regression was conducted to determine the odds of hospitalization at MEDD levels of 50 mg and 90 mg levels compared to less than 50 MEDD. **RESULTS:** 38,262 beneficiaries were prescribed opioids during the study period and met the inclusion criteria. Of these, 19.8% had MEDD levels > 50 mg and 6.8% had daily MEDD levels > 90 . A total of 108 hospitalizations due to overdose were identified. Compared to patients with daily MEDD levels less than 50mg, patients with MEDD levels > 50 mg were 2.5 times (95% CI: 1.677-4.081) as likely to have a hospitalization for an overdose event and patients with daily MEDD levels > 90 mg were 2.6 times (95% CI: 1.680-3.721) as likely to have an overdose hospitalization. **CONCLUSIONS:** Although the percentage of beneficiaries having hospitalizations due to opioid overdose is small, the odds of an overdose is significantly increases with higher MEDD levels.

PSY2

DOES TREATMENT WITH PREGABALIN AND GABAPENTIN INCREASE THE RISK OF DEMENTIA, PNEUMONIA AND UNINTENTIONAL FALLS? A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: Pregabalin and gabapentin are the mainstay oral treatment for peripheral neuropathic pain (PNP). Iatrogenic cognitive impairment is generally considered to be reversible once consumption of central nervous system (CNS) active medications such as pregabalin and gabapentin is stopped. There is evidence to suggest the use of CNS active drugs could be associated with long-term, more detrimental adverse events including dementia, pneumonia and unintentional falls. However, it is unknown if these long-term outcomes are associated with pregabalin and gabapentin. This systematic review examined whether there is a correlation between treatment with pregabalin and gabapentin and the onset of these adverse events. **METHODS:** A systematic review was conducted using MEDLINE and EMBASE. Keywords included combinations of pregabalin, gabapentin, pneumonia, dementia and falls. The inclusion criteria for studies were: 1) written/published in English; 2) human studies; 3) publication year to reflect marketing authorization year for pregabalin (2004-present) and gabapentin (1993-present). Articles were reviewed for inclusion by an independent reviewer and 5% were cross examined by a second independent reviewer. A narrative synthesis of results using thematic content analysis was conducted. **RESULTS:** A total of eight studies reporting a correlation of adverse events and pregabalin or gabapentin were included; pneumonia (2), dementia (1) and falls (5). Study designs included case report, randomised controlled trials (RCT), pilot-RCT, retrospective toxicity and sequence symmetry analysis. Renal dysfunction and drug-drug interactions as a cause for increased risk of adverse events were two major themes identified from thematic analysis. **CONCLUSIONS:** In view of low quality and extensive heterogeneity between studies, firm conclusions could not be reached. Longitudinal database or prospective studies may help to determine the correlation between pregabalin and gabapentin and the onset of dementia, pneumonia and unintentional falls, especially in subgroups with renal dysfunction.

PSY3

EXENATIDE IN OBESE OR OVERWEIGHT PATIENTS WITHOUT DIABETES: A SYSTEMATIC REVIEW AND META-ANALYSES OF RANDOMIZED CONTROLLED TRIALS

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OBJECTIVES: Exenatide is increasingly used in obese or overweight patients with diabetes. However, its safety profile and effects on weight loss in nondiabetic obese or overweight population remain unclear. We aimed to evaluate efficacy and safety of exenatide in obese or overweight participants without diabetes. **METHODS:** We searched up to January 2016 in MEDLINE (Ovid SP), EMBASE (Ovid SP), Cochrane Central Register of Controlled Trials (CENTRAL), some Chinese databases and ClinicalTrials.gov for randomized controlled trials (RCTs) investigating exenatide in obese or overweight participants without diabetes. The primary outcomes included body weight and body mass index (BMI). We pooled data to calculate the mean differences (MDs) with their 95% confidence intervals (CIs). We assessed overall evidence quality of BMI reduction and weight loss according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. **RESULTS:** Six randomized controlled trials involving 362 patients were included in the meta-analysis. The follow-up duration ranged from 12 to 24 weeks. Compared with control group, a larger body weight loss (MD: -4.47 kg; 95%CI: -6.67 to -2.27; $P < 0.0001$), regardless of dosage and population, was achieved by the obese or overweight patients in exenatide group. Exenatide also elicited a greater reduction in BMI (MD: -0.86 kg/m²; 95% CI: -1.39 to -0.33; $P = 0.001$) and waist circumferences (MD: -1.78 cm; 95% CI: -3.13 to -0.44; $P = 0.009$) compared with the control. No significant benefits were showed in exenatide group in terms of blood pressure and lipid profiles. Gastrointestinal adverse events were mostly common during the treatment of exenatide. **CONCLUSIONS:** Exenatide could significantly reduce body weight in obese or overweight participants without diabetes, and might be a safe alternative GLP-1 receptor agonist for weight control in such patients. Larger randomized trials with longer follow-up duration are required to confirm the effectiveness and safety of exenatide.

PSY4

THE PREVALENCE OF IN-HOSPITAL FALLS IN U.S. SURGICAL ADULT PATIENTS ON PAIN MANAGEMENT IS LOWEST IN PATIENTS PRESCRIBED OPIOIDS COMPARED TO EITHER A FEMORAL NERVE BLOCK OR BUPIVACAINE LIPOSOME INJECTABLE SUSPENSION

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OBJECTIVES: For obvious reasons hospitals want to avoid a patient falling while in hospital. For patients receiving opioids, falls are considered opioid-related adverse events but recent prevalence data is unknown. The purpose of this quantitative study was to benchmark the prevalence of in-hospital falls for surgical patients on pain management (both opioid and non-opioid) in the U.S. between 2012-2015. **METHODS:** The analysis was conducted using Premier's hospital database. The cohort included adults (18+ years) undergoing major/minor surgeries with post-operative pain management between Oct, 2012 and Sep, 2015. Three major types of pain management were investigated: femoral nerve blocks (FNB), bupivacaine liposome injectable suspension and opioids. Opioid use was further broken down to oral, parenteral and Intravenous Patient Controlled Analgesics (IV PCA) sub-groups. Falls occurring during hospitalization were identified by ICD9 E-codes and/or service charges. The yearly point prevalence of falls was measured for each type of pain management and sub-groups based on the ratio of falling patients to the total surgical population of each pain therapy. **RESULTS:** The overall prevalence of inpatient falls for pain management were very low, with the highest frequency on patients receiving a FNB had (0.34%), followed by bupivacaine liposome injectable suspension group (0.28%). Opioid patients were the least likely to experience falls (0.25%). Among opioids, patients on oral opioids were prone to more hospital falls (0.27%) than parenteral (0.25%), or IV PCA opioids (0.26%). The falling rates decreased over the three years: FNB (0.43% to 0.28%), bupivacaine liposome injectable suspension (0.33% to 0.24%) and opioids (0.27% to 0.22%). **CONCLUSIONS:** The prevalence of in-hospital falls is very low. This study revealed that opioid use alone to relieve pain may not contribute to falls more than a FNB or bupivacaine liposome injectable suspension. Further studies may investigate correlation, risks and consequences related.

PSY5

ASSOCIATION BETWEEN BODY MASS INDEX CATEGORIES, OSTEOARTHRITIS PREVALENCE, & TOTAL HEALTHCARE EXPENDITURES AMONG PATIENTS WHO ARE OVERWEIGHT OR OBESE

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OBJECTIVES: To examine the association between body mass index (BMI [kg/m²]) categories, osteoarthritis prevalence, and total healthcare expenditures among patients who are overweight or obese. **METHODS:** Retrospective, observational study using U.S. electronic medical records linked to administrative claims data (Optum Integrated database). Patients selected for study were aged 18-64 years, had a recorded BMI between 25.5-80 during 2014, and were continuously enrolled in health insurance for 6 months before and after the last BMI measurement (12-month evaluation period) in 2014. Patients were classified into BMI categories using the last recorded BMI in 2014: 25-29.9 (overweight); 30-34.9 (obese/class-I [OCII]); 35-39.9 (obese/class-II [OCIII]); ≥40 (obese/class-III [OCIII]). Patients were classified as having osteoarthritis if they had ≥1 medical claim with an ICD-9-CM diagnosis code for osteoarthritis (715.xx) during the evaluation period; the remaining patients were classified into a 'reference group' without osteoarthritis. Multivariable generalized linear models, adjusting for age, sex, race/ethnicity, and geography, were used to generate adjusted estimates of osteoarthritis prevalence by BMI category and evaluation period total healthcare expenditures by BMI category/osteoarthritis through recycled prediction. **RESULTS:** A total of 155,837 patients were included for study (mean age=47 years; 50% female): 71,793 (46.1%) overweight; 45,391 (29.1%) OCI; 21,787 (14.0%) OCII; 16,866 (10.8%) OCIII. Adjusted osteoarthritis prevalence increased with each BMI category relative to the overweight category (all P<0.001): osteoarthritis prevalence in overweight=7.2%; OCI=9.1%; OCII=10.9%; OCIII=15.2%. Patients with osteoarthritis had higher expenditures than the reference group without osteoarthritis in each BMI category, and expenditures increased with BMI (all P<0.001): overweight, \$17,844 for osteoarthritis vs. \$8,830 for reference group; OCI, \$19,200 osteoarthritis vs. \$9,501 reference group; OCII, \$21,157 osteoarthritis vs. \$10,469 reference group; OCIII, \$23,857 osteoarthritis vs. \$11,805 reference group. **CONCLUSIONS:** Among patients who were overweight or obese, osteoarthritis prevalence and total healthcare expenditures increased substantially with increasing BMI category.

PSY6

BODY MASS INDEX, HBA1C CONTROL, AND HEALTHCARE EXPENDITURES AMONG PATIENTS WITH TYPE 2 DIABETES: AN ANALYSIS OF ADMINISTRATIVE CLAIMS LINKED TO ELECTRONIC MEDICAL RECORDS

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OBJECTIVES: To examine the association between body mass index (BMI) categories, poor hemoglobin A1c control (HbA1c≥7%), and healthcare expenditures among US patients with type 2 diabetes mellitus (T2DM) and BMI classified as overweight or greater (BMI ≥25). **METHODS:** Retrospective, observational study using U.S. electronic medical records linked to administrative claims data

(Optum's Integrated Claims-Clinical data). Patients selected for study were aged ≥18, had a recorded BMI between 25-80 during 2014, were continuously enrolled in health insurance for 6 months before and after the last BMI measurement (12-month evaluation period) in 2014, and had ≥1 medical claim T2DM diagnosis and ≥1 antihyperglycemic prescription claim within the evaluation period. Patients were classified into BMI categories using the last recorded BMI in 2014: 25-29.9 (overweight); 30-34.9 (obese/class-I [OCII]); 35-39.9 (obese/class-II [OCIII]); ≥40 (obese/class-III [OCIII]). Multivariable regressions adjusting for patient demographics were used to examine the associations between poor HbA1c control, BMI category, and separate outcomes of total healthcare expenditures and pharmacy expenditures measured during the evaluation period. **RESULTS:** A total of 27,117 patients were included for study (mean age=64; 52% female): Compared to patients with HbA1c<7%, those with HbA1c≥7% had 8% higher total healthcare expenditures (Cost Ratio [CR]=1.08, P=0.002, adjusted=\$22,477 vs. \$20,837) and 23% higher pharmacy expenditures (CR=1.23, P<0.001, adjusted=\$5,297 vs. \$4,297). Compared with overweight patients: OCI patients did not have significantly higher total healthcare or pharmacy expenditures; OCII patients did not have significantly higher total healthcare expenditures but did have 17% higher pharmacy expenditures (CR=1.17, P<0.001, adjusted=\$5,287 vs. \$4,527); OCIII patients had 13% higher total healthcare expenditures (CR=1.13, P=0.001, adjusted=\$24,206 vs. \$21,433) and 30% higher pharmacy expenditures (CR=1.30, P<0.001, adjusted=\$5,895 vs. \$4,527). **CONCLUSIONS:** Among patients with T2DM who are overweight or obese, poor HbA1c control and high levels of obesity are associated with higher total healthcare expenditures and pharmacy expenditures.

PSY7

DEVELOPMENT OF RECOMMENDATION FOR GESTATIONAL WEIGHT GAIN IN THE CHINESE PREGNANT WOMEN: A LONGITUDINAL STUDY

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OBJECTIVES: To develop a recommendation for gestational weight gain for the Chinese pregnant women; **METHODS:** We conducted a retrospective longitudinal study involving repeated measures of weight data at a referral medical center in China. Singleton deliveries without predefined adverse outcomes were eligible for inclusion. We used two-level linear spline model to predict weight gain by gestational age (week) according to pre-pregnancy BMI categories (Chinese population standard). We reported the recommended gestational weight gain and the rates of weight gain during pregnancy, and plotted the recommended gestational weight gain charts by week of gestation, stratified by pre-pregnancy BMI. The MLwiN 2.30 and SAS 9.4 were used for analysis; **RESULTS:** We collected data from 10,031 pregnant women with singleton and term pregnancy. After removing individuals with pre-defined adverse outcomes, 4,566 pregnant women with 50,589 repeated measurements of weight were finally included. For underweight (pre-pregnancy BMI<18.5 kg/m²), normal (18.5-23.9 kg/m²), overweight (24.0-27.9 kg/m²), and obese (≥28.0 kg/m²) pregnant women, the recommended gestational weight gains are 12.7-17.4 kg, 12.4-17.2 kg, 10.9-16.1 kg, and 9.3-14.6 kg; and the corresponding rates of weight gain are 2.40, 2.35, 2.14, and 1.95 kg/month between 14 and 36 weeks of gestation. The recommended weight gain is similar at 10th to 14th gestational week (about 0.5 kg/month) and in the last month (about 1-2 kg); **CONCLUSIONS:** The recommendation for the gestational weight gain is specifically applicable for the Chinese pregnant women, with important implications for the pregnancy weight management.

PSY8

A SYSTEMATIC LITERATURE REVIEW ON CARCINOID HEART DISEASE IN PATIENTS WITH CARCINOID SYNDROME

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OBJECTIVES: Carcinoid heart disease (CHD) is a life-threatening complication of carcinoid syndrome (CS). Our aim was to review published findings to assess epidemiology and outcomes in CS patients with CHD. **METHODS:** A systematic literature review was conducted in PubMed, Embase, Cochrane Library and ClinicalTrials.gov without date restrictions. From 380 de-duplicated records screened, 72 full-text articles were reviewed for eligibility and 39 publications were selected (EU n=21, US n=18). Data on study design, patient characteristics, CHD prevalence and outcomes were collected. **RESULTS:** No CHD-specific trials were found. Observed CHD patient sample sizes varied from 7 to 265 (median: US 65; EU 27), with study periods of 1-28 years (median: US 20y; EU 5y). Reported prevalence of CHD in CS varied from 16 to 28% but rose to 40-85% in CS patients referred for echocardiography because of suspected CHD. Urinary 5-hydroxyindoleacetic acid (u5-HIAA) levels were, on average, 2-4 fold higher in CHD patients compared to non-CHD CS. Peak 5-HIAA levels were linked to CHD progression (odds ratio, 1.08 for each increase of 25mg per 24h). CHD patients had higher mortality and morbidity vs non-CHD patients. In small intestine neuroendocrine tumours, reported 5-year overall survival was 37% for CHD patients and 71% for non-CHD patients. CHD outcomes have improved over time with greater use of somatostatin analogues, hepatic artery embolization, better perioperative management and surgery outcomes. Valvular surgery can achieve acceptable outcomes and better functional status, although perioperative mortality remains at 15-20% across studies. Tumour progression determines long-term survival after surgery. **CONCLUSIONS:** Reporting of CHD outcomes are inconsistent, and visibility is low. The understanding of epidemiology and trends remains limited due to disease rarity. Research faces limitations: lack of clinical studies, poor feasibility of randomised trials, lack of standardized criteria for quantifying CHD progression. National registries and international collaboration are needed.

PSY9

COMPARATIVE ASSESSMENT OF PREEMPTIVE POTENTIAL OF DEXMETETOMIDINE VERSUS TRAMADOL IN PERIOPERATIVE SHIVERING UNDER SPINAL ANESTHESIA: A RANDOMIZED, CONTROLLED STUDY

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OBJECTIVES: There is equivocal evidence about preemptive potential of Dexmedetomidine and Tramadol for post spinal anesthesia shivering. We evaluated safety and efficacy of Dexmedetomidine compared to Tramadol in reducing incidence of post spinal shivering with effects on haemodynamics. **METHODS:** Sixty American Society of Anesthesiologist's grade- I & II patients of either sex, aged between 18 to 60 years, scheduled for elective surgeries under spinal anesthesia were divided into two equal sized groups (n=30). After neuro-axial blockade with 3.5 ml Bupivacaine 0.5% (Heavy), patients were administered with preemptive I.V. Dexmedetomidine (1 ug/kg) or I.V. Tramadol (1 mg/kg) in random order determined by chit-pull system. Haemodynamic parameters, grade of shivering as per Wrench scale were recorded from administration of test drug till 135 minutes past administration at regular intervals and sedation score as per Filos was observed at 90 minutes past drug administration. Any adverse events during the study were also recorded. Comparability of both groups in terms of demographics was assessed using ANOVA test. Difference in incidence of perioperative shivering (Grade ≥ 2) and haemodynamic profile of both groups was evaluated using Chi-square test and unpaired t-test respectively. **RESULTS:** Dexmedetomidine group demonstrated lesser incidence of perioperative shivering under spinal anesthesia (3.33%) than that in Tramadol group (20%) (p value=0.044). A sedation score of ≥ 2 was observed in more number of patients in group D(60%) as compared to that in group T(20%)(p value=0.001). Group T presented higher occurrence of nausea (16%) compared to that in Group D (nil) (p value=0.019). However, incidence of bradycardia and hypotension were higher in group D as compared to that of group T. **CONCLUSIONS:** Dexmedetomidine was found to have higher preemptive potential for perioperative shivering over tramadol with additional benefit of sedation without respiratory depression.

PSY10

CONSISTENCY OF CLINICAL RESPONSE TO RECOMBINANT HUMAN PARATHYROID HORMONE (1-84) (RHPH[1-84]) AMONG PATIENTS WITH HYPOPARATHYROIDISM

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OBJECTIVES: Among patients with hypoparathyroidism, rhPTH(1-84) has demonstrated superior efficacy compared to placebo in achieving target serum calcium and reductions in calcium and active vitamin D supplementation. We assessed whether patient and disease characteristics might be associated with clinically-significant differences in clinical response to rhPTH(1-84). **METHODS:** Data were drawn from phase III trial (REPLACE: NCT00732615; EudraCT2008-005063-34) that randomized patients with hypoparathyroidism to receive rhPTH(1-84) (n=84) or placebo (n=40). Clinical response was defined as a composite of $\geq 50\%$ reductions in calcium and active vitamin D supplementation and achieving target serum calcium at Week 24 compared to baseline. The potential for effect modification was assessed across multiple subgroup analyses and in a multivariable analysis that combined predictors for clinical response. Potential correlates of response included demographics, vitamin D dose, calcium dose, disease duration, weight, PTH, serum calcium, serum phosphate, and renal function. **RESULTS:** Baseline characteristics of the study population were diverse. The difference in clinical response rates with rhPTH(1-84) vs. placebo was 52% (55% vs. 3%) in the overall population. Across multiple subgroup analyses, response rate difference ranged from 40% to 100%. No evidence of effect modification was detected. Four predictors of response to rhPTH(1-84) were identified in a multivariable model: shorter duration of hypoparathyroidism, lower weight, normal total serum calcium, and lower prescribed calcium dose. When patients were divided into two groups with predicted rates of response higher vs. lower than median, response rate differences were 45% in the lower group and 62% in the higher group. **CONCLUSIONS:** Across multiple studied subpopulations, including subpopulations defined by multiple markers, differences in clinical response rates range from 40% to 100% with rhPTH(1-84) vs. placebo. These results highlight the consistency of high and clinically significant response rates to rhPTH(1-84) across a broad range of hypoparathyroidism patients.

PSY11

EVALUATING THE IMPACT OF A CLINICAL DECISION SUPPORT TOOL TO REDUCE CHRONIC OPIOID DOSE AND DECREASE RISK CLASSIFICATION IN HIGH RISK VETERANS IN THE VETERANS HEALTH ADMINISTRATION

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OBJECTIVES: To determine the influence of a clinical decision support tool (CDST) in reducing morphine equivalent monthly dose (MEMD), Risk Index for Overdose or Serious Prescription Opioid-Induced Respiratory Depression (RIOSORD) score and class in veterans receiving chronic opioid therapy (COT). **METHODS:** This retrospective analysis evaluated the impact of a CDST, Chronic Opioid Therapy Clinical Reminder (COT-CR), on decreasing opioid prescribing. COT-CR correlates quality of life to current opioid regimen through a prompted pain assessment. COT veterans were identified through the VISN 21 data warehouse, an electronic health records database. Patients who received COT-CR (treatment) and did not receive COT-CR (control) were matched using propensity scoring. In the primary

analysis, we used an interrupted time series design to evaluate changes in MEMD for the intervention and control groups before and after the index date, defined as the visit date with a pain specialist or primary care provider (12 months before and 6 months after). The secondary analyses used a retrospective cohort design to evaluate changes in RIOSORD score and class from the index date to the study end. **RESULTS:** After matching, 3,801 patients were included in the intervention and control groups, respectively. For the primary analysis, there was a greater MEMD reduction rate in the post-index period for the intervention group compared to the control group (-11.6 MEMD; 95% CI: -0.97 to -22.25, P=0.032). In the secondary analyses, the intervention group had a significantly greater rate of decrease in RIOSORD score compared to the control group (-8.8% vs. -5.8%, P=0.030). Comparative changes in risk class were insignificant. **CONCLUSIONS:** A trend towards decreased MEMD, RIOSORD score and class was observed for both groups in the post-index period. Comparative reduction in MEMD and RIOSORD score was statistically significant for the intervention group. Combined with other efforts, this CDST is beneficial in minimizing opioid use and risk.

PSY12

COMPARATIVE EFFICACY OF IBRUTINIB MONOTHERAPY VERSUS OBINUTUZUMAB PLUS CHLORAMBUCIL IN THE TREATMENT OF CHRONIC LYMPHOCYTIC LEUKAEMIA (CLL): A MATCHING ADJUSTED INDIRECT COMPARISON (MAIC)

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OBJECTIVES: As there are no head-to-head trials of ibrutinib versus obinutuzumab plus chlorambucil (OBI+CHLOR) in patients with previously untreated CLL, a MAIC was performed to assess their relative effects on progression-free survival (PFS) and overall survival (OS) while adjusting for potential treatment effect modifiers. **METHODS:** Individual patient data from RESONATE-2 (ibrutinib versus CHLOR) and aggregate data from CLL11 (OBI+CHLOR versus CHLOR) were available. As per the MAIC technique, patients from RESONATE-2 not meeting the CLL11 inclusion criteria were excluded. The remaining RESONATE-2 patients were reweighted to match all relevant baseline characteristics reported for CLL11 (CIRS score, age, Binet stage, β_2 -microglobulin, del11q, ECOG status, creatinine clearance, sex and unmutated IGHV). Hazard ratios (ibrutinib vs CHLOR) for investigator assessed (INV) PFS, independent review committee (IRC) assessed PFS and OS were recalculated for the weighted population and subsequently used in a Bayesian Network Meta-Analysis to compare with OBI+CHLOR. The results were compared with those of a traditional indirect comparison (IC). **RESULTS:** The traditional IC HRs [95% credible interval (CrI), probability HR < 1 (p(HR < 1))] of ibrutinib versus OBI+CHLOR for PFS INV, PFS IRC and OS were 0.48 [CrI=0.22-1.02, p(HR < 1)=97%], 0.85 [CrI=0.44-1.63, p(HR < 1)=69%] and 0.40 [CrI=0.10-1.54, p(HR < 1)=91%], respectively. Of the total trial population of 136/133 (ibrutinib/CHLOR) participants in RESONATE-2, 95 and 96, respectively satisfied the CLL11 inclusion criteria. After matching, all available baseline characteristics were balanced across trial populations. MAIC adjusted HRs were 0.12 [CrI=0.02-0.97, p(HR < 1)=98%] (PFS INV), 0.24 [CrI=0.04-1.35, p(HR < 1)=95%] (PFS IRC) and 0.21 [CrI= < 0.01-8.89, p(HR < 1)=79%] (OS). **CONCLUSIONS:** This analysis shows that while results of a traditional IC are in favour of ibrutinib, they still represent an under-estimation of the true treatment benefit of ibrutinib on PFS and OS; namely, a 95% probability for PFS by IRC and 79% for OS of ibrutinib being better than OBI+CHLOR.

PSY13

COMPARATIVE EFFECTIVENESS OF TARGETED IMMUNOMODULATORS FOR THE TREATMENT OF MODERATE-TO-SEVERE PLAQUE PSORIASIS: A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS

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OBJECTIVES: To evaluate the comparative effectiveness of targeted immunomodulators for adults with moderate-to-severe plaque psoriasis. **METHODS:** We performed a systematic literature review of randomized controlled trials of targeted immunomodulators - TNF- α inhibitors (adalimumab, etanercept, infliximab), ustekinumab, IL-17A inhibitors (secukinumab, ixekizumab, brodalumab), and apremilast (the only oral agent) - that evaluated the comparative clinical benefits or harms relative to placebo or each another. We searched and included studies from MEDLINE, EMBASE, and Cochrane-indexed articles, as well as "grey literature" sources such as conference abstracts. The primary outcome in nearly all trials was a 75% improvement on the Psoriasis Area and Severity Index (PASI 75) during induction (10-16 weeks). To evaluate direct and indirect comparisons, we conducted a network meta-analysis (NMA) using a multinomial model within a Bayesian framework and adjusted for placebo response. **RESULTS:** We identified 36 RCTs, which included 8 direct comparisons. Across trials, the average participant was 43-46 years old and had psoriasis for 17-20 years; 22-30% had psoriatic arthritis and the baseline PASI score was 19-30. In placebo-controlled trials, patients on targeted immunomodulators had markedly higher rates of PASI 75 response (29% to 90%) than patients who received placebo (2% to 19%). In head-to-head trials, PASI 75 response rates were higher for ustekinumab (68-74%), secukinumab (77%), and ixekizumab (87-90%) versus etanercept (42-57%) and were higher for secukinumab (91%), brodalumab (85-86%), and ixekizumab (91%) versus ustekinumab (69-79%). In the NMA, the targeted immunomodulators ordered by an increasing relative risk of achieving PASI 75 during induction relative to placebo were apremilast (6.2), etanercept (9.6), adalimumab (13.0), ustekinumab (14.0), secukinumab (15.4), infliximab (16.2), brodalumab (17.3), and ixekizumab (17.9). **CONCLUSIONS:** In general, IL-17A inhibitors are more effective than ustekinumab, which are, in turn, generally more effective than etanercept, adalimumab, and apremilast.

PSY14

COST-UTILITY OF USTEKINUMAB IN THE TREATMENT OF MODERATE TO SEVERE PSORIASIS IN COLOMBIA

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OBJECTIVES: To evaluate the cost-utility of ustekinumab in moderate to severe psoriasis compared with the use of infliximab, adalimumab, etanercept and secukinumab. **METHODS:** A Markov model from a third-party payer's perspective was performed, using quality-adjusted life-years (QALYs) as the final outcome measure, which was modelled through Psoriasis Area Severity Index (PASI) 50, 75 and 90. The model timeframe was ten years with a 5% discount rate. The comparators were selected by conducting a modified Delphi panel of experts. Only direct medical costs were considered: cost of first biologic and treatment with a second biologic after failure or non-response to initial medication (failure was an absorbing state and its cost was an average of all other biologics besides the starting biologic). A probabilistic sensitivity analysis on prices and key variables of the model was also performed. **RESULTS:** The total discounted costs of treatment per patient for a 10-year period were (USD): ustekinumab \$37,682; infliximab \$49,434; adalimumab \$44,363; etanercept 50 mg \$49,017, etanercept 25mg \$48 828; and secukinumab \$52,456 (Exchange rate: 1 USD = COP \$3,000). The model estimated QALYs associated with increases in utility based on the PASI response achieved by each comparator during each weekly cycle. The accumulated QALYs after the ten year period were: 6.11, 4.20, 5.69, 5.41, 5.30 and 5.61 with ustekinumab 45mg/90mg for patients with body weight over 100 kilos, infliximab 5mg/kg, adalimumab 40mg, etanercept 50mg, etanercept 25mg and secukinumab 300mg, respectively. Shorter time on treatment with first biologic implied lower QALYs. The cost utility analysis of ustekinumab compared to all alternatives resulted in more QALYs to patients at the lowest cost. **CONCLUSIONS:** The results show that the use of ustekinumab is the alternative that added more QALYs to patients at the lowest cost in the long term in comparison to the use of any anti-TNF or anti-IL 17.

PSY15

COMPARATIVE EFFECTIVENESS OF NERVE BLOCKS VERSUS PERIARTICULAR INJECTIONS IN TOTAL KNEE ARTHROPLASTY

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OBJECTIVES: Total knee arthroplasty (TKA), one of the most painful surgical procedures, is projected to increase almost eight-fold, from 450,000 in 2005 to 3.48 million in 2030, attributable to population aging and obesity. Accordingly, advances in pain management techniques are highly relevant to orthopedic surgery. Two common pain management methods after TKA are nerve block (NB) and periarticular injection (PAI). This study explored whether either technique provided advantages in patient outcomes and satisfaction. **METHODS:** This is a retrospective study comparing adult patients who received NB (N=514) versus PAI (N=483) of ropivacaine, epinephrine, ketorolac, and morphine, for primary TKA at Mayo Clinic, Florida from 2013-2016. We compared patient outcomes including: pain scores, time after surgery to first ambulation, cumulative post-operative distance walked, postoperative length of stay, and discharge disposition. Patient satisfaction with pain control was also captured, along with resource utilization measures including emergency visits, readmissions, and revisions. **RESULTS:** Our results indicated that PAI was associated with lower pain during the 24 hours after surgery (mean score, on a 0to10 scale: NB=2.4 vs. PAI=1.7; P<0.001) compared to NB, but thereafter, until discharge, there was no difference (mean: NB=3.2 vs. PAI=3.1; P=0.370). PAI was associated with earlier knee ambulation (mean: NB=31.3 vs. PAI=22.3 hours; P<0.001), longer walking distance (mean: NB=21.4 vs. PAI=50.3 meters; P<0.001), shorter hospital stay (mean: NB=2.9 vs. PAI=2.3 days; P<0.001), more discharges to home (NB=48.3% vs. PAI=79.3%; P<0.001), and better patient satisfaction with pain control (mean score, on a 0to100 scale: NB= 88.4 vs. PAI= 92.7; P=0.006) compared to NB. Resource utilization measures (emergency visits, readmissions, and revisions) were similar between the two groups (P>0.05). **CONCLUSIONS:** With increasing demand for TKA and based on early evidence, providers and policymakers should consider PAI as an efficient pain management approach. This method has proven to provide better patient satisfaction with pain control, earlier and further mobilization, and quicker discharges, which accordingly impacts cost.

PSY16

A BAYESIAN NETWORK META-ANALYSIS (NMA) OF IBRUTINIB VS BENDAMUSTINE-RITUXIMAB FOR TREATMENT NAÏVE CHRONIC LYMPHOCYTIC LEUKAEMIA (TN-CLL) PATIENTS WITH CIRS ≤ 6 OR CLCR ≥ 60 ML/MIN

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OBJECTIVES: Ibrutinib has demonstrated superiority in terms of efficacy and tolerability to chlorambucil (Chl) for TN-CLL patients who are elderly or unfit (RESONATE-2). Within this trial there is a subgroup of less fragile patients, defined as those having a Cumulative Illness Rating Scale (CIRS) score ≤6 or Creatinine clearance (CLCr) ≥60 ml/min that could be potential candidates for bendamustine-rituximab (BR) therapy. As no head-to-head comparison exists for this relatively fit subgroup, an NMA was conducted to compare the efficacy of ibrutinib vs. BR in patients suitable for chemotherapy. **METHODS:** Out of sixteen randomized controlled trials (RCTs) in TN-CLL patients identified in a systematic literature review, four RCTs were

conducted in patients/subgroups of patients who were relatively younger or more fit (CLL8, Hallek 2010; CLL10, Eichorst 2016; LRF CLL4, Catovsky 2007; RESONATE-2, the less fragile subgroup, data at a median follow-up of 28.6 months). They are connected in a network of evidence that could inform the indirect comparison of interest. A Bayesian NMA was conducted to compare hazard ratios (HR) of overall survival (OS) and progression-free survival (PFS) of ibrutinib vs. BR, FC, FCR and Chl. A fixed effect model was used due to the limited size and structure of the network. **RESULTS:** Ibrutinib had favorable HRs and the highest pairwise probability of being the best treatment (P) in terms of PFS and OS versus BR (HR=0.36/0.55, P=100%/87%), FC (HR=0.33/0.36, P=100%/99%), FCR (HR=0.59/0.53, P=95%/92%) and Chl (HR=0.14/0.40, P=100%/99%). Ibrutinib had the highest probability of being the best treatment in the network in terms of PFS (99%) and OS (94%). **CONCLUSIONS:** This analysis suggests that ibrutinib is a more effective treatment compared to BR in terms of survival outcomes PFS and OS in TN-CLL patients who are relatively younger or more fit, defined as having a CIRS ≤6 or CLCr ≥60 ml/min.

PSY17

ROUX-IN-Y GASTRIC BYPASS IN TYPE 2 DIABETES PATIENTS WITH MILD OBESITY: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: Type 2 Diabetes (T2D) control after Roux-in-Y gastric bypass (RYGB) is a well-established outcome for obese patients. Evidence suggest that the positive metabolic benefits are independent of baseline body mass index (BMI) and surgical interventions for patients with BMI below 35 kg/m² and T2D without clinical control after optimal medical treatment are the best evidence based approach. The aim of this study was to evaluate the efficacy of RYGB for medically uncontrolled T2D in patients with mild obesity. **METHODS:** A systematic review and meta-analysis was conducted, following the respective PICOT search strategy (P: BMI <40kg/m² with inclusion of BMI <35 kg/m² and few Asiatic patients; I: RYGB; C: Clinical treatment; O: Total T2D control; partial T2D control; Glycated hemoglobin (HbA1c) variations; T: Minimum of 6 months of follow up; D: Randomized Clinical Trial (RCT) and a minimum sample size of 20 patients per arm. Researched databases included MEDLINE, Embase and Cochrane CENTRAL, with full published papers up to June 2016. The qualities of the RCTs were evaluated by risk of bias criteria and the GRADE evaluation was done by each outcome. Meta-analysis was performed with fix or random methods according to data heterogeneity. RevMan 5.0 was employed for the analysis. **RESULTS:** 5 RCTs were included in the final analysis, with follow-up times ranging from 12 to 36 months and a great proportion of patients with BMI <35kg/m². Total and partial T2D control were significantly higher within the surgical patients (RR: 20.58 [5.02; 84.35]), (RR: 20.71 [5.16; 83.12]), respectively, with a high level of recommendation. HbA1c dropped (-1.85 [-2.17; -1.53]) with a high level of recommendation. **CONCLUSIONS:** High level of evidence suggests that RYGB is the best treatment option for patients with mild obesity and uncontrolled T2D after optimal medical treatment.

PSY18

PHASE 2 OPEN-LABEL EXTENSION (OLE) STUDY OF PATISIRAN, AN INVESTIGATIONAL RNA INTERFERENCE (RNAi) THERAPEUTIC FOR THE TREATMENT OF HEREDITARY ATTR AMYLOIDOSIS WITH POLYNEUROPATHY

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OBJECTIVES: Hereditary ATTR (hATTR) amyloidosis is a rapidly progressive, life-threatening disease caused by a mutation in the transthyretin (TTR) gene, resulting in sensory, motor and autonomic neuropathies, and cardiac dysfunction. The aggressive disease course can lead to significant morbidity, disability, and mortality. The objective of this abstract is to describe the safety and efficacy of patisiran, an investigational RNAi therapeutic inhibiting hepatic TTR protein production, from its Phase 2 open-label extension (OLE, NCT01961921) study. **METHODS:** Patients with hATTR amyloidosis with polyneuropathy who previously received patisiran were eligible to continue dosing (0.3mg/kg IV) every 3 weeks for two years. In addition to long-term safety, the study assessed the difference in neuropathy impairment (mNIS+7) from baseline, and other relevant measures. mNIS+7 is a 304-point composite measure of neuropathy impairment including: neurologic exam of the limbs and cranial nerves; electrophysiologic measures of nerve fiber function; quantitative sensory testing (QST); and autonomic function. **RESULTS:** Twenty-seven patients enrolled, median age: 64 years and 74% patients with V30M mutation, the predominant mutation in this disease. Patisiran was generally well tolerated, 6 patients experienced SAEs unrelated to study drug; flushing (25.9%) and infusion-related reactions (18.5%) were the most common related AEs (all mild) and did not result in any discontinuations. Following > 24 months of patisiran, patients experienced sustained mean serum TTR lowering of ~80% (mean maximal knockdown: 93%). Preliminary 24-month data (n=24) suggests improvement in neuropathy with a mean 6.7-point decrease in mNIS+7 driven by a mean 7.7-point change in sensation (measured by QST). Overall, 17/24 patients (71%) were noted to have no change or an improvement in mNIS+7 at 24 months compared

to baseline. **CONCLUSIONS:** Preliminary 24-month data demonstrated long-term administration of patisiran was generally well-tolerated, and supports the therapeutic hypothesis that TTR knockdown can potentially halt or improve neuropathy progression in hATTR amyloidosis patients.

PSY19

COST-EFFECTIVENESS OF AZACITIDINE COMPARED WITH LOW-DOSES OF CHEMOTHERAPY (LDC) IN MYELODYSPLASTIC SYNDROME (MDS)

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OBJECTIVES: Assess, from a Mexican health care perspective, the cost-effectiveness of azacitidine compared with Low-Doses of Chemotherapy (LDC) plus best supportive care (BSC) for the treatment of adult patients with intermediate-2 and high-risk MDS, who are not eligible for haematopoietic stem cell transplantation. **METHODS:** We developed a cost-effectiveness survival analysis model of 3 stages: MDS, AML, and death. OS and costs are extrapolated beyond three-year time horizon. Discount rate of 5% was applied. To estimate the model cycle probability transition to mortality state, survival curves were constructed for each treatment arm using individual patient-level data from Study AZA-001. Unitary cost are from public price list, and profiles for the management of MDS and AML were collected separately using a structured questionnaire. Probabilistic sensitivity analyses (PSA) were conducted by simultaneous sampling from estimated probability distributions of model parameters. **RESULTS:** Overall survival was projected to increase by 72.26 weeks with azacitidine. Incremental expected total costs for azacitidine compared to LDC was MXN \$68,045. However, the cost of the drug therapy was lower with azacitidine. The ICER for azacitidine compared to LDC was MXN\$48,932 per LY. PSA showed that azacitidine was a highly cost-effective option in 96.49% of the simulated cases in MXN\$180,000/LYG willingness-to-pay. **CONCLUSIONS:** Compared with LDC, azacitidine represents a cost-effective treatment alternative in patients with MDS from a Mexican perspective.

PSY20

WHICH PAIN ETIOLOGIES ARE MOST LIKELY TO RESULT IN LONG TERM OPIOID USE? RESULTS FROM A LARGE NATIONALLY REPRESENTATIVE INCEPTION COHORT STUDY

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OBJECTIVES: This study sought to explore the relationships between pain etiologies and the probability of long term opioid use among persons newly prescribed an opioid. **METHODS:** We identified cancer-free persons with new opioid use episodes who were greater than 13 years of age without a prior history of substance abuse from a nationally representative database of commercially insured population from 2006-2015. We categorized individuals into 11 mutually exclusive pain etiology categories based on their medical claims: Trauma and Surgery, Trauma, Surgery, Burn, Delivery, Dental Procedure, Chronic pain, Non-chronic pain, Inpatient stay, Emergency department visit. Chronic pain was assessed in prior six months and all others were assessed in the week prior to receiving an opioid. Patients were followed until opioid discontinuation (a gap of at least 180 days without opioid use), eligibility loss or study end (September 2015). Cox proportional Hazards models were used to model the time to opioid discontinuation controlling for potential confounders. **RESULTS:** We identified a total of 1,386,132 patients with median time to discontinuation of 5 days. Chronic pain diagnoses (25.58%) followed by non-chronic pain (24.87%) and trauma (9.89%) were the most frequent etiologies for an opioid. Persons with chronic pain had the highest probability of continued opioid use at one year (8.91%) and dental procedures had the lowest (0.92%). Relative to surgery patients, those with a chronic pain diagnosis had the lowest likelihood of discontinuation (HR=0.73; p<0.001) followed by patients who had an inpatient stay (HR=0.76; p<0.001) or surgery and trauma (HR=0.77; p<0.001). **CONCLUSIONS:** Patients treated with opioids for chronic non cancer pain are the most likely to use opioid over long periods. Persons with surgery, trauma, non-trauma ED use, and deliveries prior to an opioid are infrequently prescribed opioids for long durations suggesting that managing acute pain with opioids seldom develops into chronic opioid use.

PSY21

ASSOCIATION BETWEEN CHRONIC HEPATITIS B AND METABOLIC SYNDROME

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OBJECTIVES: The association between chronic hepatitis B (CHB) infection and metabolic syndrome (MetS) remains inconclusive. This study examined the association between CHB infection and MetS among adults in the United States with recent data and adjustments for a comprehensive set of risk factors. **METHODS:** Adults aged 18 years or older who were clinically assessed for Hepatitis B and MetS from the National Health and Nutrition Examination Survey (NHANES) 2003-2004, 2005-2006, 2007-2008, 2009-2010, and 2011-2012 cycles were included in the study (n=29,906). MetS was defined according to the NCEP/ATP III guidelines. CHB was identified by the seropositivity of Hepatitis B surface antigen and core antibody in the absence of Hepatitis B surface antibody. Statistical analyses included chi-square tests and logistic regressions. **RESULTS:** A lower proportion of adults with CHB reported MetS as compared to adults without CHB (9.6% vs. 18.6%, p= 0.037). In adjusted analyses, adults with CHB were less likely to report MetS compared to those without CHB with an adjusted odds ratio (AOR) of 0.12 and 95% CI: (0.02-0.85). When analyzed by individual components of MetS, high waist circumference

(AOR = 0.10, 95% CI: 0.03-0.41) and dyslipidemia (AOR = 0.42, 95% CI: 0.21-0.84) were less likely among those with CHB compared to no CHB. No association between CHB and other metabolic components were found. **CONCLUSIONS:** A significantly inverse association between CHB and MetS was found in the study. Future studies need to explore the underlying mechanisms of the observed associations.

PSY22

NUMBER OF TRANSTHYRETIN FAMILIAL AMYLOID POLYNEUROPATHY CASES IN BRAZIL

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OBJECTIVES: Transthyretin familial amyloid polyneuropathy (TTR-FAP) is a rare, highly disabling, life-threatening disease characterized by progressive sensorimotor and autonomic neuropathy that presents either as sporadic cases or as familial cases, then often in geographical clusters such as Northern Portugal, Sweden, or Japan. It is irreversible and fatal within 7 to 12 years of symptom onset in the absence of therapy. Acknowledging that the epidemiological data of TTR-FAP across Brazil is inadequately understood at present, the aim of our study was to estimate the number of disease symptomatic cases in this country. **METHODS:** Analysis of the number of TTR-FAP symptomatic cases in Brazil was performed based on a published epidemiological data of TTR-FAP in Portugal, according to Parman et al., 2016, considering that the Brazil has an important Portuguese influence due to colonization. Using the Portugal epidemiological data, the TTR-FAP prevalence in Brazil was calculated considering the number of resident population in Portugal in 2016 (TTR-FAP prevalence in Portugal = [N TTR-FAP diagnosed patients] / [N resident population]). To estimate the number of Portuguese immigrants in Brazil (lusio-Brazilian population), a search of gray literature sources (secondary data) was made. The number of TTR-FAP symptomatic cases in the country was estimated by applying the TTR-FAP prevalence in Portugal to the number of lusio-Brazilian population. **RESULTS:** TTR-FAP prevalence estimate in Portugal was 1.92 (2000 symptomatic cases diagnosed / 10.4 million resident population). According to found secondary data on gray literature sources, currently 25 million lusio-Brazilians live in the country, resulting in approximately 4,800 symptomatic cases of TTR-FAP in Brazil. **CONCLUSIONS:** TTR-FAP is a rare disease and devastating. In Brazil, the number of TTR-FAP symptomatic cases was close to the number of the disease symptomatic cases observed in endemic regions, which could be associated with a burden impact to the Brazilian Public Health.

PSY23

CONCOMITANT USE OF OPIOID AND BENZODIAZEPINES AND THE RISK OF OPIOID OVERDOSE REQUIRING HOSPITALIZATIONS: A RETROSPECTIVE COHORT STUDY

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OBJECTIVES: Although opioids and benzodiazepines are now the leading cause of prescription drug poisoning and overdose deaths in the United States, their concomitant use is increasing on a yearly basis. The objective of the study was to compare the risk of an opioid overdose requiring hospitalization in patients concomitantly using opioids and benzodiazepines to patients using opioids only. **METHODS:** We identified a cohort of opioid initiators with a non-cancer pain diagnosis in a commercial claims database from 2008-14. Exposure was classified into periods of concomitant and opioid only use. For each concomitant user, we matched four control periods of opioids-only use on time since opioid initiation using an incidence density sampling approach. We estimated a propensity score on the matched sample using 86 baseline characteristics including patterns of prior opioid use. The outcome was defined as hospitalization with principal diagnosis of an opioid overdose. Using a Cox proportional hazard model with stabilized inverse probability of treatment weighting (IPTW), we calculated the hazard ratio (HR) of an opioid overdose associated with concomitant use compared to opioid only use, modelled as a time-varying covariate. **RESULTS:** We created a matched cohort of 1,114,456 opioid initiators (mean [SD] age 48[11], 64% female). The unadjusted hazard ratio (HR) for an opioid overdose was 3.08 (95% CI, 2.28-4.16). After IPTW adjustment, the HR decreased to 2.36 (95% CI, 1.86-3.03), corresponding to an absolute excess risk of 12.83 (95% CI 8.18, 19.16) overdose hospitalizations per 10,000 patient years. **CONCLUSIONS:** Compared to opioid use alone, concomitant use of opioids and benzodiazepines was associated with a significantly higher risk of opioid overdose requiring hospitalization; however the absolute risk difference was small. Further research should evaluate the mechanism of this association.

PSY24

DO PAYERS VALUE RARITY? AN ANALYSIS OF THE RELATIONSHIP BETWEEN DISEASE RARITY AND ORPHAN DRUG PRICES IN EUROPE

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OBJECTIVES: This study assessed the relationship between the prevalence of rare diseases (rarity) and the annual treatment cost of orphan drugs (price) in Europe. **METHODS:** A four step process was implemented scoping France, Germany, Italy, Norway, Spain, Sweden, UK: 1. Extraction of approved orphan drugs and disease prevalence from the European Medicines Agency website; 2. Extraction of ex-factory price from IHS POLI and country price databases; 3. Calculation of annual treatment cost per patient per drug; 4. Analysis of annual treatment costs versus disease prevalence using simple regression analysis. **RESULTS:** A total of 120 orphan drugs were analysed for indications with a prevalence ranging from 0.001 to 5 patients per 10,000 with a mean of 1.24 per 10,000 and a median of 1 per 10,000. Results show a statistically significant inverse correlation between annual treatment cost and disease prevalence in all countries,

with the treatment being more expensive the rarer the disease (France: $r=-0.370$, $p=0.002$; Germany: $r=-0.365$, $p=0.002$; Italy: $r=-0.340$, $p=0.002$; Spain: $r=-0.316$, $p=0.041$; UK: $r=-0.358$, $p=0.0004$; Sweden: $r=-0.414$, $p=0.014$; Norway: $r=-0.367$, $p=0.002$). When analysis was focused on the rarest diseases (prevalence between 0-1 per 10,000), a stronger correlation exists in all countries (France: $r=-0.525$, Germany: $r=-0.482$, Italy: $r=-0.497$, Spain: $r=-0.531$, UK: $r=-0.436$, Sweden: $r=-0.455$, Norway: $r=-0.466$; all $p<0.05$ except Sweden $p=0.077$). **CONCLUSIONS:** In all the countries in scope, this study shows an inverse correlation between annual treatment cost and disease prevalence with high statistical significance. Although pricing is a complex process where different attributes are assessed, this study supports the idea that payers in all the countries value rarity of disease in pricing decisions.

PSY25

UTILIZING AUTOMATED CLINICAL DECISION SUPPORT SYSTEMS TO REDUCE MORBIDITY, MORTALITY, AND COSTS DUE TO PRESCRIPTION OPIOID OVERDOSE – A RETROSPECTIVE STUDY

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OBJECTIVES: To estimate the risk of, and characterize risk factors associated with, serious opioid-induced respiratory depression (OIRD) among medical users of prescription opioids in two diverse patient populations and to evaluate the impact of providing automated, personalized, risk-mitigating clinical decision support on patient health outcomes and costs. **METHODS:** This retrospective characterization of risk for serious prescription OIRD in national Veterans Health Affairs (VHA) and commercially insured populations (CIP) involved administrative claims data from 1.9 million VHA and over 18 million CIP patients who were dispensed a prescription opioid. Baseline factors associated with an event of serious OIRD among 7,234 cases and 28,932 controls in CIP were identified using multivariable logistic regression. **RESULTS:** The strongest associations with serious OIRD in CIP were diagnosed substance use disorder (OR=10.20, 95% CI 9.06-11.40) and depression (OR=3.12, 95% CI, 2.84-3.42). Other strongly associated factors included other mental health disorders; impaired liver, renal, and pulmonary function; prescribed fentanyl, methadone and morphine; higher daily opioid doses; and concurrent psychoactive medications. The majority of risk factors were concordant in both populations, despite CIP being substantially younger, including more females and less chronic disease; and having greater prescribing prevalence of higher daily opioid doses. A statistically significant, monotonically increasing relationship between risk and adjusted average total monthly health care costs was observed in VHA (\$1,226 versus \$2,081, $P=0.010$, for lowest- and highest-risk patients, respectively). **CONCLUSIONS:** Risk for serious prescription OIRD among subgroups of patients with private or public health insurance is high, despite differences in demographics, clinical conditions, health care delivery systems, and clinical practices. The identification of patients at high risk for overdose through automated characterization of risk factor profiles and provision of personalized risk-mitigating measures has substantial potential to reduce the morbidity, mortality, and health care costs due to serious prescription OIRD.

PSY26

THE COURSE OF PREGNANCY AND DELIVERY OUTCOMES IN PATIENTS WITH OVERWEIGHT AFTER IN VITRO FERTILIZATION

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OBJECTIVES: To evaluate the character of pregnancy's course and delivery outcomes in patients with overweight and pregnancy induced by the program (IVF and embryo transfer) and in patients with overweight and self-pregnancy. **METHODS:** The study involved 126 patients with pregnancy (age 28 to 40 years). The first group included 67 patients with pregnancy induced by IVF and ET, and the second group included 59 patients with self-pregnancy. Statistical processing of the results obtained in the study was produced using the statistical program SPSS 21.0 (SPSS Inc., USA). For estimation of differences of quantitative indexes between groups we used Student's criterion. The differences were considered significant at $p<0.05$. **RESULTS:** In the first group 21.3% of patients were overweight while 15.1% of patients belong to class I and II obesity, according to body mass index (BMI). In the second group 9.7% of patients were overweight and 7.6% were obese. The delivery outcomes by caesarean section were observed more frequently in the patients of the first group (to 32%) compared with the second group. Among women with overweight and obese, in the first group glucose intolerance or gestational diabetes was revealed in 12.7% cases, and in the second group these diseases were revealed in 8.2% cases. In both groups, obesity and overweight were associated with age (older than 35 years, $p<0.05$), hyperglycaemia and hypertension ($p<0.001$) and macrosomia of the fetus ($p>0.05$). Macrosomia of the fetus were detected in 82.3% of patients in the first group and in the 42.6% of the cases in the second group. **CONCLUSIONS:** The patients with pregnancy induced by the IVF and ET program in comparing with women with self-pregnancy more often had overweight, which was associated with hypertension and hyperglycemia, macrosomia of the fetus.

PSY27

OPTIMIZING SURVIVAL AND COST-UTILITY IN THE TREATMENT OF ACUTE AND CHRONIC GRAFT VERSUS HOST DISEASE: A CALIBRATED SYSTEM DYNAMICS MODELING APPLICATION

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OBJECTIVES: Outliers in graft vs host disease (GvHD) can sometimes present disproportionately extreme costs and quality of life measures, which may be ignored

by regression-based estimates of cost-utility. Agent Based Models (ABMs) can capture these outlier effects, which can then be applied to patients whose characteristics match similarly. In this study, our goal was to build a calibrated ABM that could align treatments with heterogeneous patient characteristics, and compare cost-utility in a more granular fashion between extracorporeal photopheresis (ECP) offered to acute vs chronic GvHD patients. **METHODS:** Using a 20-week clinical trial panel dataset comprising 26 patients, we calibrated an ABM that simulates cost-utility for acute vs chronic GvHD patients before and after ECP. Patient characteristics such as organ involvement (skin, GI, liver, lungs, gut) and severity (II, III, IV for acute; moderate or severe for chronic) were assigned to each individual in the ABM. We scaled up the calibrated ABM to population-based estimates provided by the United Network for Organ Sharing (UNOS). **RESULTS:** Our preliminary ABM findings suggest that ECP cost-utility estimates are markedly lower in the case of chronic as compared with acute GvHD. We were able to illustrate outlier effects in both conditions. These outlier effects would not be captured in traditional regression and cost-utility analyses. Our findings highlight how patient-specific characteristics such as age, gender, and organ involvement matched to severity must be considered for maximizing survival and quality of life while minimizing cost. Simulations across the wider UNOS population confirm this effect of outliers on survivability and quality of life. **CONCLUSIONS:** Using patient-level data, ABMs can illustrate survival and cost-utility in a manner that calibrates the right treatment for the right patient at the right time, such as the application of ECP to chronic vs acute GvHD. Such calibrated ABMs may also be scalable to population-based data.

PSY28

RISK OF ACUTE LIVER INJURY ASSOCIATED WITH THE USE OF ORLISTAT: SELF-CONTROLLED CASE SERIES STUDIES USING THE MARKETSCAN® COMMERCIAL CLAIMS DATABASE

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OBJECTIVES: The objective of this study is to assess the association between the use of orlistat and the risk of acute liver injury. **METHODS:** A self-controlled case series (SCCS) study was conducted by using Truven MarketScan® Commercial Claims data (2003-2004). Patients prescribed at least one prescription of orlistat and experienced an acute liver injury during the study period were included. Conditional Poisson regression model was used to calculate the incidence rate ratios comparing the risk of acute liver injury during periods of orlistat exposure with periods of no exposure. **RESULTS:** A total of 159 patients were included in this SCCS study. With the SCCS study design to remove the effect of differences among patients, we did not detect the association between the orlistat exposure and the risk of acute liver injury. Compared to the absence of orlistat exposure period, there was no statistically significant increased risk of acute liver injury during the first 30 days treatment of orlistat (incidence rate ratio (IRR), 1.07; 95% confidence interval (CI), 0.52-2.20). The similar results were found for other time periods: 90 days before the first orlistat prescription (IRR, 1.12; 95% CI, 0.72-1.75), 31-61 days of orlistat treatment (IRR, 0.49; 95% CI, 0.12-1.99), 61-90 days of orlistat treatment (IRR, 0.54; 95% CI, 0.13-2.21), post-exposure interval (IRR, 0.88; 95% CI, 0.38-2.03), and more than 90 days orlistat use (IRR, 0.77; 95% CI, 0.38-1.56). **CONCLUSIONS:** The significant association between the orlistat exposure and the risk of acute liver injury was not detected, even though it may be due to small sample size with the low statistical power in this SCCS study. With the safety concern of acute liver injury events in patients prescribed orlistat, caution is advised for physicians in the use of orlistat. Future research is needed to guide clinical decision making.

PSY29

EVIDENCE-BASED BAYESIAN MODELING TO PREDICT SURVIVAL IN PATIENTS WITH SPORADIC INCLUSION BODY MYOSITIS (sIBM)

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OBJECTIVES: sIBM is a rare muscle disease characterized by dysphagia, atrophy and weakness of proximal and distal muscles, typically manifesting in $\geq 50s$. Limited data has been published on the disease and how mortality is associated with disease progression and severity. Our objective was to predict mortality in sIBM patients based on six disease-related outcomes that may influence patient's life span. In addition, our aim is to select the model providing best prediction of mortality against existing literature. **METHODS:** Literature review provided data on association between outcomes related to manifestation of sIBM and mortality in elderly people and patients with neurodegenerative diseases. Demographic and disease-related outcomes data from sIBM patients were collected at annual meetings of the Myositis Association. Gender- and age-adjusted survival curves from WHO served as reference survival rate. Simulation of mortality in 2000 virtual cohorts was performed using a Weibull parametric model with combinations of up to six disease-related outcomes potentially accounting for additional mortality risk in sIBM patients: 6-minute walking distance (6MWD), BMI, dysphagia, falling, aspiration pneumonia, being wheelchair-bound. Results were compared with the mortality rates observed in two published sIBM cohorts, adjusted for demographics. **RESULTS:** The simulation could exactly replicate the observed 12-year mortality rate of 72% from the multi-country study published by Cox et al., when using dysphagia and 6-minute-walking-distance as predictors. For the second publication of the sIBM cohort in France by Benveniste et al., the observed 2-year mortality rate (18%) was comparable to the % baseline mortality without any predictors. **CONCLUSIONS:** Our results suggest that long-term survival in sIBM patients can be predicted with age, gender, 6MWD and dysphagia as predictors, though with a possible country effect. Further validation of our

findings is required through natural history studies in sIBM, especially regarding the impact of the disease on the short-term survival.

PSY30

EVALUATION OF SURVIVAL OUTCOMES OF POST-FRONTLINE ANTI-MYELOMA TREATMENTS IN MULTIPLE MYELOMA PATIENTS BASED ON DATA FROM SEER-MEDICARE DATABASE

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OBJECTIVES: The regimens of lenalidomide with dexamethasone (Rd) and bortezomib with dexamethasone (Vd) are cornerstone therapies for treatment of multiple myeloma (MM), both in the frontline and subsequent lines of treatment (LOT). This study aims to characterize patients treated with these regimens for relapsed disease in a non-referral setting, and to evaluate survival outcomes with these treatments. **METHODS:** Patients with index MM diagnosis on or after January 1, 2007, and with an anti-MM treatment documented, were identified in the SEER-Medicare database. Business rules were applied to identify their LOTs. Post-frontline treatment cases that contained Rd and Vd were separately considered for analysis. Patient characterization was done of the included LOT cohorts, and survival analysis carried out. Cox regression analysis was carried out to evaluate the impact of various covariates. **RESULTS:** Of the 18,778 patients with an appropriate index MM diagnosis date, 2,725 patients had ≥ 1 relevant LOT and were included in the analysis, and yielded 12,363 LOTs. Of these, cases of ≥ 2 LOT (LOT2+) for Rd and Vd were 579 and 447, respectively. For Rd cases in LOT2+, median age was 74.2, median number of prior LOTs was 1, 65% received prior PI, 63% received prior IMiD, and 33% previously received both a PI and IMiD; the corresponding numbers for Vd cases in LOT2+ were 74.0, 1, 63%, 83%, and 47%. The median overall survival of the 2 cohorts was 32.1 and 20.7 months, median progression-free survival 13.2 and 8.3 months, and their mortality rate 0.0144 and 0.0286 per patient-month of pre-progression follow-up. **CONCLUSIONS:** Analysis of these standards of care regimens suggest worse outcomes (given the more elderly population) versus published estimates in recent clinical trials, but are consistent with outcomes based on real-world data. These results highlight the need for more efficacious treatments for relapsed/refractory MM patients.

SYSTEMIC DISORDERS/CONDITIONS – Cost Studies

PSY31

BUDGET IMPACT ANALYSIS OF 5% LIDOCAINE MEDICATED PLASTER COMPARED WITH DRY NEEDLING AND INFILTRATION OF TRIGGER POINT FOR THE TREATMENT OF MYOFASCIAL PAIN SYNDROME OF THE UPPER TRAPEZIUS UNDER THE PERSPECTIVE OF BRAZILIAN PRIVATE HEALTHCARE SYSTEM

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OBJECTIVES: Studies show that 5% lidocaine medicated plaster (LMP) has similar efficacy in the treatment of myofascial pain syndrome (MPS) of the upper trapezius in comparison with dry needling and infiltration of trigger point, and is better accepted by patients, besides being a non-invasive therapy. We aimed to simulate the financial impact of the LMP introduction in the treatment of MPS in Brazilian private healthcare system, compared with these two therapies. **METHODS:** Eligible population was calculated for 3 sizes of Health Maintenance Organizations (HMOs): big (>100,000 lives), medium (20,000-100,000 lives), and small (<20,000 lives). Data from National Regulatory Agency for Private Health Insurance and Plans were used to obtain the mean number of patients for each size of HMO and extrapolated according to growth rates to estimate future years. Prevalence rates of disabling pain, MPS and percentage of MPS with trigger points were applied to estimate the target population. Direct medical costs and resource use of intervention and comparators were estimated annually, using exchange rate of 2016. Time horizon had 5 years and 2 market share scenarios were created, one with complete uptake of 5% LMP at the first year, and another with progressive uptake, starting with 40% at the first year and increasing 15% annually. **RESULTS:** Compared with dry needling, complete uptake of 5% LMP in the first year presented cost savings of 224,785 BRL, 23,461 BRL, and 3,715 BRL after 5 years in big, medium and small HMOs, respectively. Compared with infiltration of trigger point, there were savings of 236,860 BRL, 24,721 BRL, and 3,914 BRL for big, medium and small HMOs, respectively. Scenario of progressive uptake also saved resources for all comparators and HMOs. **CONCLUSIONS:** The uptake of 5% medicated LMP for MPS treatment in the Brazilian private healthcare system has great cost saving potential.

PSY32

BUDGET IMPACT ANALYSIS OF ELIGLUSTAT FOR TREATMENT OF GAUCHER DISEASE TYPE 1 IN THE UNITED STATES

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BACKGROUND: Current therapeutic options for Gaucher disease type 1 (GD1) include intravenous enzyme replacement therapy (ERT) with imiglucerase, velaglucerase alfa, or taliglucerase alfa or oral substrate reduction therapy (SRT) with eliglustat or miglustat. Transfer of patients from ERT to SRT may present an opportunity for cost savings. **OBJECTIVES:** This study evaluated the budget impact associated with increased utilization of eliglustat for the treatment of adults with GD1. **METHODS:** A budget impact model reflecting the US payer perspective calculated the change in pharmaceutical and administration costs resulting from increasing eliglustat market share from 12% (current) to 44% (hypothetical). Eliglustat market share was drawn equally from existing shares of imiglucerase (40%) and velaglucerase alfa (40%) and

assumed to be static over the analysis period. Unit costs were obtained from Redbook (WAC), 2016. ERT WAC costs were adjusted to account for site of care-based markup and the proportion of patients receiving infusions in each site of care based on a typical large regional health plan. Administration costs were obtained from analysis of claims (DataMart Multiplan). All costs expressed in 2016 USD. **RESULTS:** In a plan with 5 million members and 25 treated patients with GD1, increased utilization of eliglustat, shifting market share evenly from all sites of care, resulted in total 3-year savings of \$4.58M (13.6%) to the plan. The corresponding per member per month (PMPM) savings were \$0.025. When all patients receiving ERT infusions in the hospital outpatient setting were shifted to eliglustat, 3-year savings increased to \$7.75M (23.0%) and PMPM savings increased to \$0.043. Results were sensitive to proportion of patients receiving infusions at each site of care. **CONCLUSIONS:** Based on these analyses, increased utilization of eliglustat resulted in meaningful cost savings to a payer's overall budget. Cost savings are highest among patients switching from ERT administered in a hospital outpatient setting.

PSY33

POTENTIAL SAVINGS FROM BIOSIMILARS IN CANADA

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OBJECTIVES: A number of biologic drugs, representing 12% of Canadian pharmaceutical sales in 2015, recently began to face, or soon will face, competition from lower-cost biosimilars. This study assesses the potential cost savings based on various assumptions of market uptake and pricing. **METHODS:** The drugs considered in the study are Avastin, Enbrel, Eprex, Gonal-F, Herceptin, Humira, Lantus, Neupogen, Remicade, Rituxan, Tysabri, and Xolair. Data from the IMS AG MIDAS™ Database, was used to forecast the Canadian utilization for each drug for three years following the expected biosimilar entry. A number of sensitivity analyses were conducted to evaluate the cost implications of different scenarios of biosimilar pricing and uptake based on Canadian and international observations. The analysis is conducted based on a number of OECD countries. The results are reported for the national market, as well as for public and private drug plans. **RESULTS:** At a drug level, the savings from biosimilar entry vary depending on the size of the market as well as assumptions of price level and potential market penetration, both of which depend on the policies governing the reimbursement of biosimilars. The findings suggest that the greatest savings could be realized by modeling similar market conditions to those prevailing in Norway and Finland. **CONCLUSIONS:** As biosimilars and originator products are not interchangeable, the market penetration and pricing of biosimilars depends on regulations and reimbursement policies. Understanding the potential savings under different scenarios of uptake and pricing provides valuable insight into the cost impact of various policy levers.

PSY34

BUDGET IMPACT ANALYSIS OF 5% LIDOCAINE MEDICATED PLASTER COMPARED WITH PREGABALIN OR GABAPENTIN MONOTHERAPY FOR THE TREATMENT OF DIABETIC POLYNEUROPATHY UNDER THE PERSPECTIVE OF BRAZILIAN PRIVATE HEALTHCARE SYSTEM

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OBJECTIVES: To estimate the financial impact of introduction of 5% lidocaine medicated plaster (LMP) monotherapy compared with pregabalin or gabapentin monotherapy, in the Brazilian private healthcare system for the treatment of diabetic polyneuropathy (DPN). **METHODS:** Eligible population was calculated for 3 sizes of Health Maintenance Organizations (HMOs): big (>100,000 lives), medium (20,000-100,000 lives), and small (<20,000 lives). Data from National Regulatory Agency for Private Health Insurance and Plans (ANS) was used to obtain the number of patients and extrapolated according to growth rates. Prevalence rates of diabetes and polyneuropathy and percentages of patients in use of antiepileptic drugs were applied to reach the final target population. Direct medical costs and resource use related to disease and adverse events management were estimated annually and based on a Markov model previously developed for cost-effectiveness analysis. Costs of drugs not used in hospitals or ambulatories weren't included once they aren't covered. Time horizon had 5 years and 2 market share scenarios were created, one with complete uptake of 5% LMP at the first year, and another with progressive uptake, starting with 40% at the first year and increasing 15% annually until reaching 100%. **RESULTS:** Compared with pregabalin, complete uptake of the plaster in one year demonstrated cost saving of 64,457 BRL, 6,727 BRL and 1,065 BRL for big, medium and small HMOs, respectively. Compared with gabapentin, cost saving increased to 1,096,971 BRL, 114,491 BRL, and 18,129 BRL for big, medium and small HMOs, respectively. Scenario of progressive uptake also showed cost saving results for all comparators and HMO sizes. **CONCLUSIONS:** The uptake of 5% LMP in Brazilian private healthcare system for DPN treatment can save costs compared with pregabalin and gabapentin. Its use associated with pregabalin also presented this potential for patients non-responders to pregabalin. Savings are attributed to lower adverse event rates.

PSY35

A BUDGET IMPACT ANALYSIS OF PARENTAL IRON TREATMENTS FOR IRON DEFICIENCY ANEMIA IN THE UK: REDUCED RESOURCE UTILIZATION WITH IRON ISOMALTOSE (MONOFER)

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OBJECTIVES: The reported prevalence of iron deficiency anemia (IDA) varies widely but estimates suggest that 3% of men and 8% of women have IDA in the UK. Parenteral iron is indicated for patients intolerant or unresponsive to oral

iron, or requiring rapid iron replenishment. This study evaluated differences in the cost of treating these patients with iron isomaltoside (Monofer; IIM) relative to other intravenous iron formulations. **METHODS:** A budget impact model was developed to evaluate the cost of using IIM relative to ferric carboxymaltose (Ferinject; FCM), low molecular weight iron dextran (Cosmofer; LMWID) and iron sucrose (Venofer; IS) in patients with IDA. To establish iron need, iron deficits were modeled using a simplified dosing table. The base case analysis was conducted over 1 year in patients with IDA with mean bodyweight of 82.4 kg (standard deviation [SD] 22.5 kg) and hemoglobin levels of 9.99 g/dL (SD 1.03 g/dL) based on an analysis of patient characteristics in IDA trials. Costs were modeled using UK healthcare resource groups. **RESULTS:** Using IIM required 1.34 infusions to correct the mean iron deficit, compared with 1.34, 1.77, and 7.74 with LMWID, FCM, and IS, respectively. Patients using IIM required multiple infusions in 34.6% of cases, compared with 34.6%, 77.2% and 99.8% of patients with LMWID, FCM and IS, respectively. Total costs were estimated to be GBP 451 per patient with IIM or LMWID, relative to GBP 594 with FCM (saving GBP 143 or 24.0% per patient) or GBP 2,600 with IS (saving GBP 2,148 or 82.6% per patient). **CONCLUSIONS:** Using IIM in place of FCM or IS resulted in a marked reduction in the number of infusions required to correct iron deficits in patients with IDA. The reduction in infusions was accompanied by substantial reductions in cost relative to FCM and IS over 1 year.

PSY36

FINANCIAL IMPACT OF THE INCORPORATION OF GOLIMUMAB AS AN ALTERNATIVE OF ANTI-TNF AGENT IN MAIN PUBLIC INSTITUTIONS IN MEXICO

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OBJECTIVES: Biologic agents are mainly used for the treatment of rheumatic diseases; particularly rheumatoid arthritis is considered one of the priority problems of public health in Mexico. This analysis aims to compare Mexican public expenditure on tumor necrosis factor inhibitors (anti-TNF) in two main health-care providers for salaried workers and to estimate the budget impact of the incorporation of golimumab as an alternative anti-TNF therapy. **METHODS:** A descriptive analysis was developed based on published data of prescribing information for each anti-TNF agent (dosage per patient for rheumatoid arthritis) and on national tenders to obtain the acquisition price for each therapy. The two institutions evaluated were the Mexican Social Security Institute (IMSS) and the Institute of Social Security and Services of State Workers (ISSSTE) covering ~50% and ~11% of Mexican population, respectively. The data obtained about the purchases of anti-TNF agents during the period 2014-2016 was used to calculate the annual number of patients in treatment. Based on these calculations, an extrapolation was performed to estimate the number of patients in treatment during 2017-2019 periods. Finally, a budget impact model was developed to analyze the impact of the penetration of golimumab in both institutions. Costs are expressed in 2016USD (\$1USD=\$20MXN). **RESULTS:** In both institutions the anti-TNF with the highest expenditure was adalimumab, followed by etanercept (25mg and 50mg) and infliximab to the last. According to total population covered, average number of patients in anti-TNF agents' treatment is 0.4% and 1.1% for IMSS and ISSSTE, respectively. With the incorporation of golimumab in 10% of patients at IMSS the total savings for 2017-2019 period would be \$2.5 million and for ISSSTE \$2.0 million. **CONCLUSIONS:** The incorporation of golimumab at IMSS and ISSSTE formularies represents potential savings that could lead to an increase in the number of patients who benefit from these anti-TNF therapies.

PSY37

BUDGET IMPACT OF LORCASERIN FOR THE TREATMENT OF OBESITY IN A MANAGED CARE ORGANIZATION

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OBJECTIVES: Lorcaserin is a 5-HT_{2C} receptor agonist indicated for chronic weight management in patients with overweight and obesity in addition to diet and exercise. Using an analytic cost model, this study examined the consequences of lorcaserin utilization in a managed care organization from a payer perspective. **METHODS:** The model generated outputs for a hypothetical one-million member health plan based on the results from BLOOM, BLOOM-DM and BLOSSOM, three Phase III clinical trials of lorcaserin 10mg BID. The population consisted of adult patients who were overweight (BMI=27-29 kg/m² with >1 obesity-related comorbidities) or obese (BMI > 30 kg/m²) with or without type 2 diabetes. Other model inputs included the proportion of patients who utilize anti-obesity medications, response to treatment, time on treatment, cost of medication, market share of lorcaserin, and potential cost savings to the health plan for weight loss. Model outputs included total costs and per-member per-month (PMPM) costs over a 3 year timeline. **RESULTS:** Among adults eligible for treatment with an anti-obesity medication (N= 350,273), the model predicted only 448 would initiate treatment on lorcaserin each year of the 3-year timeline. Among those, 43.4% without T2D and 30.4% with T2D would be expected to continue treatment for a full year. Using a wholesale acquisition price of lorcaserin of \$241.07 for a one month supply, total net cost to the health plan at one-year, including costs offsets, would be \$301,632 or 3 cents PMPM. By year 3, PMPM costs would be 6 cents. **CONCLUSIONS:** Although there is a large population eligible for anti-obesity medications, the results from this model suggest that only a small proportion of these patients will actually initiate and continue lorcaserin treatment. This resulted in relatively minimal cumulative total net costs to the health plan, less than 10 cents PMPM over a 3 year period.

PSY38

ECONOMIC EVALUATION OF DARATUMUMAB FOR THE TREATMENT OF PATIENTS WITH DOUBLE REFRACTORY MULTIPLE MYELOMA IN MEXICO

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In Mexico the Histopathological Registry of Malignant Neoplasms in 2002, reported 593 new cases of MM. Additionally the prognosis of patients with multiple myeloma is highly variable, with a median survival of 2-3 years. Daratumumab was recently approved as monotherapy for the treatment of Double Refractory Multiple Myeloma (DRMM) being the only drug approved in this indication to date in Mexico. **OBJECTIVES:** To develop an economic analysis to estimate the budgetary impact of including Daratumumab in the public sector as a treatment for patients with DRMM. **METHODS:** Currently in Mexico there's no other drug approved for the treatment of DRMM patients therefore a budget impact analysis of the use of Daratumumab in different public institutions was carried out. Regarding the current alternative treatment, two therapeutic regimens were considered: thalidomide+dexamethasone representing 43% of targeted patients; and melphalan+prednisone for the rest of patients. The time horizon was 5 years and the costs were obtained from institutional sources. Finally a deterministic sensitivity analysis was performed to test uncertainty of main variables. **RESULTS:** The estimate of DRMM patients in Mexico was 55 per year; hence the addition of daratumumab has a financial impact for the National Health System for the first year of 0.000629% of the budget, similar to budget impact in IMSS of 0.000408%, 0.000205% in ISSSTE, 0.002475% in Seguro Popular, 0.000043% in SEDENA, 0.000039% in SEMAR and 0.000006% in PEMEX. **CONCLUSIONS:** There are currently no other therapeutic options approved for the treatment of DRMM patients, in addition to the few patients who are candidates for it the addition of daratumumab to public institutions in Mexico does not generate a high budgetary impact, while providing a targeted option of treatment for them.

PSY39

ECONOMIC EVALUATION OF BENDAMUSTINE IN PATIENTS WITH RELAPSED INDOLENT NON-HODGKIN'S LYMPHOMA IN MEXICO

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Non-Hodgkin lymphoma (NHL) is a type of hematologic cancer that originates in lymphocytes T or B. Most patients with indolent NHL (iNHL) present advanced stages at the time of diagnosis and in those with early relapse (<12-24months), the disease may be resistant to drugs that have been used previously. In 2008, the estimated incidence rate of iNHL in Mexico was 3.9 and 2.9 per 100,000 per year for men and women, respectively. **OBJECTIVES:** To evaluate the cost-effectiveness and budgetary impact of bendamustine-rituximab (BR) for the treatment of iNHL that has progressed during or within six months of treatment with rituximab or a regimen containing rituximab in Mexico. **METHODS:** A cost-effectiveness analysis was performed through a Markov model to compare BR vs fludarabine-rituximab (FR) from the public healthcare perspective (main Public Institutions such as IMSS and Seguro Popular i.a.). The time horizon is lifetime, estimated at 35years, based on overall survival data from base study (NCT01456351). The costs were obtained from institutional sources and an exchange rate of \$20MXN/USD was applied. Outcomes were measured as quality-adjusted life years (QALYs), life years (LYs) and Progression-free life years gained (PFLYs). Sensitivity analyses were performed to test the robustness of the model and base case results. **RESULTS:** BR regimen is a cost-effective treatment for iNHL patients. Baseline analysis estimates that BR generates lower costs and additional efficacy of 0.936 QALYs, 1.087 LYs and 1.412 PFLYs, compared to FR. Robustness of results were confirmed by deterministic and probabilistic sensitivity analysis. Furthermore the addition of BR as a treatment option has a budget impact of 0.0000739% for IMSS, 0.0000372% for ISSSTE, 0.0000011% for PEMEX and 0.0004490% for Seguro Popular. **CONCLUSIONS:** Bendamustine-rituximab regimen is a therapeutic option for patients with iNHL, which generates greater efficiency and lower costs than FR, generating a low budgetary impact to the public institutions in Mexico.

PSY40

ANALYSIS OF COSTS MINIMIZATION OF HAEMATE-P® USE IN THE TREATMENT OF VON WILLEBRAND'S DISEASE IN COLOMBIA

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OBJECTIVES: To develop the economic evaluation of Haemate-p® use in the treatment of Von Willebrand's disease (EVW) as Gold Standard therapy versus use of coagulation factor treatments combined with different amounts of presentation from the perspective of the third-party payer. **METHODS:** It was developed the economic evaluation of Haemate-p® use against other coagulation factor treatments combined in different presentation amounts (assuming no superiority or inferiority in terms of safety and tolerance), through a cost minimization analysis in a cohort of patients, simulated at different weights in Kilograms (kg) and under the assumption of cohorts in prophylaxis and per event. The economic evaluation took into account the presentation of Haemate-p® of 1200 IU Von Willebrand Factor (vWF) + 500 IU FVIII and it was compared with presentations of Comparator 1: 375 IU vWF + 500 FVIII and Comparator 2: 1000 vWF + 0 FVIII, wherein the amounts of factor do not define the effectiveness of the therapy; analyzing cost differences in patients from 15 kg of weight to 110 kg of weight. **RESULTS:** The results are presented as the expenditure summation in use of the number of vials necessary to cover the calculated dose for each patient in a single application, in prophylaxis and per event. The use of Gold Standard therapy for VWD represents a saving of 32.81% to 74.67% in a single application of

medication, this variation depends on the combined amounts of factor used in alternative therapies. **CONCLUSIONS:** The results suggest that, in the use of coagulation factors for VWD treatment, it is necessary to recognize the effects of the different doses in the different presentations of each treatment, on the costs assumed in its application. In this sense, and as a final result, Haemate-p® is presented as the thrifty technology in the treatment of this pathology.

PSY41

MEASURING THE ECONOMIC IMPACT OF SSB TAXES IN BRAZIL: AN INPUT-OUTPUT ANALYSIS

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OBJECTIVES: This study aims to estimate the effects of the SSB tax with special focus on macroeconomic and sectoral variables, considering the productive relations and the distributional issues associated with this policy. **METHODS:** To achieve this goal, we used the Leontief price model derived from the input-output matrix for Brazil, 2009. **RESULTS:** The results show that the sugary drinks sector is weak intersectoral relations and will not appear as a key sector for the Brazilian economy. Considering these connections, simulating a tax increase of 10% on the production of sugary drinks causes a contraction of 2.84% in the gross value of production, while the economy as a whole reduced by 0.017%. Concerning to employment, the economy loses 10,020 jobs, among which 38.45% occur in the sector itself, and the remaining in sectors directly related to the SSB or sectors related to food and drinks in general. The highest deciles of income distribution are those that lose more with taxation. With the tax increase, it is estimated an increase in government revenue at R\$ 597 million. Finally, this policy would have an effect on general prices in the economy, raising the price index at 0.017%. **CONCLUSIONS:** The main conclusion of this study is that a tax increase applied to the soft drinks industry generates negative impacts on the economy, but it reaches the expected effect: reduction of household consumption for this product. Considering an additional tax of 10%, it was identified a little reduction in aggregate output given that 1) the sector has few intersectoral relations, 2) it is intended to meet final demand and 3) it has small share in the total economy. However, the increase in tax would significantly reduce the consumption of sugary drinks in the short term. These results reflect the short-term effect of rising prices on the economy.

PSY42

RELATIONSHIP BETWEEN SITE OF CARE AND INFUSIBLE BIOLOGIC MEDICATION AND ADMINISTRATION COSTS

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OBJECTIVES: To compare medication and administration costs of infused biologics for treatment of chronic inflammatory disease (Rheumatoid Arthritis (RA), Crohn's Disease (CD), or Ulcerative Colitis (UC) when administered at different sites of care. **METHODS:** Patients with RA, CD, or UC receiving an indicated infusible biologic (abatacept, infliximab, natalizumab, rituximab, or tocilizumab) were identified in Truven Commercial Claims and Encounters database (1/1/2009 to 12/31/2013) and followed for ≥ 12 months. Biologic medication and administration costs for each infusion were summarized by place of infusion: Hospital inpatient (HI); Hospital Out-Patient Department (HOPD); Physician Office (PO) or Home-based Infusion (HB); Other (O). Within each disease and site of care, administration and drug costs were compared via Kruskal-Wallis tests. **RESULTS:** Infusions from 8,307 RA, 3,530 CD and 2,148 UC patients were studied. The majority of infusions for RA occurred in PO (84%); 13% in HOPD, and 2% in HB. For CD/UC patients, 55%/59% of infusions were administered in PO, 40%/35% in HOPD; 4%/4% in HB; and <2%/≤1% were HI/O. In RA, mean drug/administration costs were similar between PO and HB; mean HB drug costs (\$3,056) were slightly higher than PO (\$2,739) and mean HB administration costs (\$201) were slightly lower than PO (\$324; N.S.). Similar trends were observed in CD/UC infusions. Highest drug/administration costs were observed in the HI and HOPD settings. **CONCLUSIONS:** Drug and administration costs differed by site of care. Total infusion costs were lowest and were similar in PO and HB although drug costs tended to be higher in HB than PO. While HI and HOPD had highest drug plus administration costs, a lower proportion of infusions were provided in these sites, particularly for RA patients. Additional studies are needed to understand patient outcomes and quality of care metrics associated with different infusion sites of care.

PSY43

IMPROVED POSTOPERATIVE CLINICAL AND DISCHARGE OUTCOMES FOR LIPOSOMAL BUPIVACAINE COMPARED TO BUPIVACAINE

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OBJECTIVES: While more than 300,000 total hip arthroplasties (THA) are performed annually in the United States, there is no gold standard for an effective post-operative THA pain strategy. The objective of this retrospective cohort study was to compare clinical, and discharge outcomes for patients utilizing an extended-release liposomal bupivacaine (LB) to a control cohort utilizing bupivacaine. **METHODS:** The LB cohort included 64 consecutive THA patients from one surgeon at a single institution between August 2013 and July 2015 and 66 consecutive THA procedures performed by the same surgeon between June 2011 and July 2013 were selected as the control cohort. Clinical (pain [VAS], distance walked, opioid use, falls) and discharge (discharge destination, length of stay[LOS], readmission rates) outcomes were compared on post-operation day (POD) 0, 1 and 2 using univariate and multivariate analyses. **RESULTS:** The LB cohort showed significantly lower AUC

VAS pain scores on POD 0, 1 and 2. Significantly fewer LB patients used rescue opioids on POD1 and POD2. LOS decreased significantly from 2.7 to 2.0 days and 30% more LB patients were discharged at POD1. After adjusting for covariates, LB patients were more likely to walk farther than controls after surgery. LB cohort had significantly fewer 30-day readmissions than the control cohort. For patients with available financial data, adjusted mean hospital charge costs were lower in the LB patients. Categorically, the LB cohort had lower costs than the control cohort for room, medical and surgical supplies, diagnostic test (including labs and operation), and physical therapy. There were no differences in falls or discharge location. **CONCLUSIONS:** This retrospective cohort study comparing LB to bupivacaine demonstrated improved perioperative pain management, less opioid use, decreased length of stay, lower costs, earlier discharge and increased physical function.

PSY44

A COMPARATIVE STUDY OF ORPHAN DRUG PRICES IN EUROPE

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OBJECTIVES: Orphan drugs have been a highlight of discussions due to its higher price than non-orphan drugs. Moreover, there is currently no European consensus on value assessment which has led to differences in price and access among countries. This study aimed to assess price differences among countries by comparing the annual treatment cost per patient of similarly available orphan drugs in France, Germany, Italy, Norway, Spain, Sweden, and the UK. **METHODS:** Orphan drugs granted market authorisation up to June 13, 2016 were extracted from the European Medicines Agency (EMA) website. The annual treatment costs per drug were calculated using ex-factory prices from IHS POLI and country price databases. The treatment cost in the comparator country was compared to the UK and ratios were analysed. Subanalyses were done on cost quartiles (most to least expensive orphan drugs in the UK) and disease areas. **RESULTS:** 120 orphan drugs were included in the analysis. Compared to the UK, the average annual costs were more expensive in France (averaged ratio 1.13), Germany (1.11), Italy (1.08), Spain (1.07), and were cheaper in Sweden (0.99) and Norway (0.88). The average ratios offered a restrictive view as the ratios were greatly heterogeneous and ranged from 0.26 to 1.92. The ratios were also heterogeneous in the different disease areas in all countries. When we divided the UK orphan drugs into 4 cost quartiles, the averaged ratios varied minimally in all countries except France which shows that the cost differences were similar for the most expensive and least expensive orphan drugs in the UK. **CONCLUSIONS:** Individual orphan drug prices can vary widely across European countries, although on average these differences are relatively minor. This study suggests that in Europe, we may not be able predict which country may have higher or lower prices for orphan drugs.

PSY45

HEALTHCARE COST COMPARISON ANALYSIS FOR MORBIDLY OBESE PATIENTS UNDERGOING BARIATRIC SURGERY WITH THOSE MANAGED BY CONVENTIONAL TREATMENT IN INDIA

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OBJECTIVES: Bariatric surgery (BS), an effective treatment for morbid obesity, is proven to reduce comorbidities. However, in absence of health economics studies in India, surgeons and patients/payers are uncertain about the long term economic implications of BS. This study aimed to evaluate and compare the cumulative healthcare cost incurred by morbidly obese patients opting for BS with those incurred by patients opting for conventional treatment over a 10-year period in India. **METHODS:** A cost comparison model was developed using a combination of a decision tree and a Markov model. Three types of surgeries common in India – laparoscopic mini gastric bypass, laparoscopic Roux-en-Y gastric bypass and laparoscopic sleeve gastrectomy, were considered in the BS arm. Transition probabilities and BS related outcomes data were sourced from published literature. The analysis considered direct medical costs including the cost of bariatric surgery and associated complications, cost of drugs, physician visits and hospitalization for managing co-morbidities, and cost of obesity management measures. All costs were discounted at 3%. The results were expressed in terms of difference in total per-patient healthcare costs incurred by patients in the two arms. **RESULTS:** For a hypothetical population with a mean age of 40 years and a mean BMI of 43 kg/m², the total per-patient cost for BS arm was ₹670,014 compared to ₹1,015,300 for the conventional arm over a period of 10 years. The per-patient co-morbidity management cost in BS arm reduced by 70% over 10 years. The current analysis estimated that initial investment in BS will be recouped within ~5.5 years post-surgery due to cost saving in co-morbidity management. **CONCLUSIONS:** The current analysis shows that although bariatric surgery requires an initial investment, it will result in lower healthcare expenses compared to conventional treatment, in a five year time period after surgery.

PSY46

ECONOMIC IMPACT OF TREATING SEVERE HEMOPHILIA A PATIENTS WITH PLASMA-DERIVED FACTOR-VIII/VWF VERSUS RECOMBINANT FACTOR-VIII IN THE UNITED STATES

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OBJECTIVES: The development of alloantibodies to factor-VIII (FVIII) therapy (inhibitors) can result in increased complications and economic burden. The Survey of Inhibitors in Plasma-Products Exposed Toddlers (SIPPET) study found higher inhibitor rates in previously-untreated patients (PUPs) treated with conventional recombinant FVIII (rFVIII) than those treated with plasma-derived FVIII

with von Willebrand factor (pdFVIII/VWF). The objective of this study was to quantify the economic impact of treating PUPs with pdFVIII/VWF versus rFVIII. **METHODS:** A 3-year time horizon Excel-based cost-analysis was developed from the perspective of a US healthcare payer. In the analysis, 1-year old PUPs initiated prophylactic or on-demand treatment with rFVIII or pdFVIII/VWF. Rates of high-titer inhibitor development were obtained from the SIPPET study (28.4% with rFVIII and 18.6% with pdFVIII/VWF). PUPs developing inhibitors received immune tolerance induction (ITI) and bypassing agents. After one year, patients successfully tolerized with ITI returned to FVIII treatment, while patients unsuccessfully tolerized received bypassing agent prophylaxis. Treatment regimens, ITI outcomes, and rates of serious bleeds were based on the literature and expert clinical opinion. All cost inputs in the analysis were identical between the two arms, except for the costs of the two antihemophilic agents which were based on WAC (Red Book). Treatment costs for rFVIII and pdFVIII/VWF patients were calculated monthly based on patient weight and total costs and then estimated on a per-patient and US population basis. **RESULTS:** Total per-patient treatment costs over 3 years were \$824,336 for rFVIII and \$540,939 for pdFVIII/VWF patients, resulting in an average annual savings of \$94,465 per patient for pdFVIII/VWF. Based on the current US population, an estimated 247 PUPs would be diagnosed annually, resulting in a cost savings of nearly \$70 million over 3 years. **CONCLUSIONS:** Treatment of severe hemophilia A in PUPs with pdFVIII/VWF has the potential to result in significant cost-savings compared to treatment with rFVIII.

PSY47

THE APPLICATION OF RECOMBINANT HUMAN THROMBOPOIETIN FOR THE EMERGENCY TREATMENT OF PRIMARY IMMUNE THROMBOCYTOPENIA

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OBJECTIVES: Recombinant Human Thrombopoietin (rhTPO) was recommended to emergency treatment in primary immune thrombocytopenia (ITP) patients in China. The application of rhTPO could potentially reduce the usage of platelet transfusion and intravenous immunoglobulin for emergency treatment of ITP patients. The study purpose is to evaluate the hypothesis in clinical practice. **METHODS:** An expert questionnaire was designed to collect relevant clinical information of emergency treatment in ITP patients. 53 hematologists completed the questionnaire who were selected from Beijing, Shanghai, Guangzhou, Jinan, Chengdu and Wuhan in China. The treatment cost of with and without rhTPO for emergency treatment in ITP patients was compared. **RESULTS:** The survey results indicate that, the rate of platelet transfusion is 50% and 85% for with rhTPO and without rhTPO respectively. The intravenous immunoglobulin in the emergency treatment of ITP patients was 30% and 50% for with rhTPO and without rhTPO respectively. And the average amount of platelet and intravenous immunoglobulin used for an ITP patient was 1.5 unit (200 ml/unit) and 5 days (400 mg/kg per day) for both groups. The treatment cost of one unit platelet transfusion conducted in our previously study was RMB 5,114. The daily treatment cost of intravenous immunoglobulin was RMB 5,000. Thus, in with rhTPO arm, the cost of platelet transfusion and intravenous immunoglobulin was RMB 3,835.5 and RMB 7,500. In without arm, the cost was RMB 6,520.35 and RMB 12,500 respectively. With rhTPO price is RMB 1,102, 7 days per an ITP patient emergency treatment. The drug price of rhTPO is RMB 7,714. So the total cost of the two arms was RMB 19,049.5 (with rhTPO) and RMB 19,020.4 (without rhTPO). The gap is only RMB 29.2. **CONCLUSIONS:** The use of rhTPO for emergency treatment in ITP patients could reduce the rate of usage of platelet transfusion and intravenous immunoglobulin without significantly increase medical cost.

PSY48

CLINICAL AND ECONOMIC BURDEN OF ACQUIRED HEMOPHILIA (AH) AMONG HOSPITALIZED PATIENTS IN THE US USING HEALTHCARE COST AND UTILIZATION PROJECT (HCUP)

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OBJECTIVES: Acquired hemophilia (AH) is a severe autoimmune disease characterized by the spontaneous development of autoantibodies against coagulation factor VIII (FVIII). The economic and clinical burden of this rare condition is poorly described. The objective of this study is to determine the clinical and economic burden of hospitalized AH patients in the US using HCUP database. **METHODS:** A retrospective cohort study using the HCUP Nationwide inpatient sample (NIS) from January 2009 to December 2013 was conducted. HCUP NIS includes discharge data on approximately 20% of all hospitalizations in the U.S. Hospital admissions for AH were identified using records with a principal diagnosis of AH (ICD-9 286.52). Total inpatient costs (converting charges to cost using cost-to-charge ratio), hospital length of stay, comorbidities and mortality during the inpatient visit were assessed. **RESULTS:** A total of 71 inpatient admissions were identified from discharges in 2009, 2012, and 2013 while no discharges for AH were found in the year 2010 and 2011. The mean age of hospitalized patients was 68.7 years (SE:1.75; median:70.7) and 57.7% admissions were male patients. Three (4.1%) deaths occurred during the inpatient stay. Mean number of chronic conditions were 7.12 (SE:0.3; median:6.6) in this cohort with hypertension being the most frequent in 72% of patients followed by deficiency anemia (38%), chronic pulmonary disease (35%), and uncomplicated diabetes (34%). Mean cost per inpatient admission was \$177,668 (SE:\$33,991; median:\$63,666) and varied widely (range: \$2,260.08-\$1,071,415). The mean length of stay was 11.8 days (SE:1.42; median:7.3). **CONCLUSIONS:** Inpatient stays to treat bleeding episodes due to AH lead to high economic and clinical burden, especially in the elderly population. Further research is required to understand treatment management and unmet needs in the hospital setting to minimize patient burden and improve outcomes.

PSY49

THE IMPACT OF RESPIRATORY DEPRESSION FOLLOWING PLANNED INPATIENT SURGERIES ON HOSPITAL RESOURCE UTILIZATION AND CHARGES ACROSS THE UNITED STATES

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OBJECTIVES: Respiratory depression (RD) is a potential adverse event after surgery partly due to the nature of the drugs used to anesthetize, sedate, and immobilize patients, as well as comorbid medical conditions and medications. To understand the impact of RD after surgery, the incidence and impact of RD on hospital charges and length of stay (LOS) were analyzed. **METHODS:** A retrospective cohort study using the QuintilesIMS Hospital Charge Data Master database was performed. Patients from over 450 hospitals across the United States were included if they were admitted for an inpatient surgery and were administered an inhaled anesthetic during the period of July 1, 2014 to June 30, 2015. To avoid clinical conditions potentially associated with RD, patients who had a procedure for the nervous, respiratory and cardiovascular systems or had an obstetrical surgery were excluded. Based on procedures and prescribed medications, seven conditions were specified as indicators of RD. To evaluate the impact of RD, patients with RD were matched to patients without RD using propensity score matching. Hospital charges and LOS were compared between matched cases and controls. **RESULTS:** 17,727 patients were included in the study cohort and 715 (4.03%) patients were identified with RD. After matching, 538 patients were included in the case and control group, respectively. Both mean and median hospital charges for cases were significantly higher than controls (Mean: \$78,190 vs. \$69,010, p=0.0026; Median: \$54,985 vs. \$49,409, p<0.0001). Average LOS was significantly longer for cases compared to controls (3.8 days vs. 3.3 days, p<0.0001). **CONCLUSIONS:** In this study, respiratory depression was found to be associated with increased hospital charges and LOS. Moreover, this study may point to the need for improving the management of respiratory depression in the perioperative setting. Applying a personalized medicine approach utilizing pharmacogenomics may help reduce the occurrence of respiratory depression.

PSY50

EPIDEMIOLOGY AND ECONOMIC BURDEN OF SYSTEMIC SCLEROSIS – A SYSTEMATIC REVIEW

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OBJECTIVES: Systemic sclerosis (SS) is a rare debilitating autoimmune disease of the connective tissue with no cure. This study aimed to assess the recent epidemiologic and economic burden of systemic sclerosis across the world. **METHODS:** Using a systematic search strategy, PubMed/MEDLINE and Embase were searched to identify relevant studies published from January 2006 to June 2016. Two independent reviewers evaluated studies for inclusion, quality, and extracted data. The review was conducted and reported according to PRISMA statement. **RESULTS:** 1,449 references were retrieved using initial searching strategy, and 22 epidemiological and 6 economic publications were selected for data extraction following inclusion/exclusion criteria. SS has a female predominance with prevalence ranging from 7-74 per 100,000 as compared to 2-15 per 100,000 in male. Incidence ranges from 1.7-3.5 per 100,000 in females as compared to 0.5-1 per 100,000 in males. Direct annual healthcare costs vary with geographic locations and health care systems, ranging from 3,300 Euros in Hungary to 17,365 USDs in the US. From a societal perspective, indirect annual healthcare costs range from 5,390 Euros in Hungary to 10,560 Euros in France. Specific cost categories were examined in detail. It's important to note that heterogeneous methodologies were used to derive these numbers so comparisons were made with caution. **CONCLUSIONS:** This review provides an updated literature review on the current estimates of disease prevalence, incidence and economic burden of systemic sclerosis in different countries. The review reports slightly higher incidence/prevalence compared to previous studies. The economic burden is high from both societal and healthcare perspectives. Different healthcare stakeholders could benefit from understanding the epidemiological and economic aspects of SS.

PSY51

RESOURCE UTILIZATION, COST, AND UNPLANNED READMISSIONS ASSOCIATED WITH HEPATORENAL SYNDROME FROM THE UNITED STATES (US) HOSPITAL PERSPECTIVE: 2009-2015

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OBJECTIVES: Hepatorenal Syndrome (HRS), the development of functional renal failure in patients with advanced chronic liver disease, is associated with high cost of patient care. The objective of this study was to examine total health care resource utilization, cost of care and outcomes, including mortality and readmission from US hospital perspective. **METHODS:** A retrospective, longitudinal analysis of the CERNER Health Facts® electronic health record (EHR) database was performed. Adult patients diagnosed with HRS based on ICD-9 code (572.4) between 2009 and 2015 were included in the analysis. Clinical data including serum creatinine were used to assess outcomes. **RESULTS:** We identified 1,571 male (62%) and 971 female (38%) patients (mean age: 57.9). The median cost for all patients was \$22,911. The highest median cost associated with HRS was in patients between 18 and 35 years old. Overall, female patients incurred higher costs than males. The highest incidence of HRS was in 2013 with ~19% of all cases from 2009 to 2015 and the highest average cost per patient was in 2009 with \$38,778. HRS mortality rate was 36.8% during initial hospitalization, and median cost of

hospitalization was higher for deceased vs. surviving patients (\$24,667 vs. \$21,360). HRS readmission rate was 17.62%, with 10.62% planned and 7.32% unplanned readmission. Unplanned readmissions were associated with higher median costs (\$31,946 vs. \$17,357). **CONCLUSIONS:** From a hospital perspective, results from this analysis of large US hospital EHR database indicate that HRS is a very severe disease with high mortality. Managing patients with HRS is associated with high burden in resource utilization, cost-of-care, and especially around the unplanned readmissions, which presents a potential opportunity for improvement.

PSY52

EXAMINING THE HEALTH CARE RESOURCE USE AND ECONOMIC COSTS ASSOCIATED WITH ACUTE MYELOID LEUKEMIA AMONG MEDICARE PATIENTS

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OBJECTIVES: To examine health care utilization and costs associated with acute myeloid leukemia (AML) among patients in the Medicare population. **METHODS:** Medicare patients aged ≥ 65 years with an AML diagnosis (International Classification of Disease, 9th Revision, Clinical Modification [ICD-9-CM] code: 205.xx) were identified from 01/01/10 to 12/31/14. The first AML treatment date within 30 days after the incident diagnosis was the index date. Patients with an ICD-9-CM code for relapse (205.02), or claims of chemotherapy after a ≥ 120 -day treatment-free gap, were considered relapse cases. Patients were required to have continuous enrollment 12 months before the initial AML diagnosis. Patients with blood cancer, chemotherapy, radiotherapy, or AML-related surgery prior to the initial diagnosis were excluded from the study. Health care costs and utilization of patients with only first-line therapy (Cohort A), and relapse patients with first- and second-line therapies (Cohort B) were examined descriptively. **RESULTS:** A total of 6,281 and 1,726 patients were included in Cohorts A and B, respectively. During the first-line therapy, the percentages of patients with ≥ 1 inpatient, emergency room (ER), and hospice visits were 89.1%, 35.6%, and 39.7% in Cohort A, respectively (mean follow-up: 247 days). During first-line therapy (mean 396 days), the percentages of patients with ≥ 1 inpatient, ER, and hospice visits were 88.9%, 42.0%, and 2.5% in Cohort B, respectively. Per patient per month (PPPM) costs for inpatient admission (\$10,451), outpatient (\$6,213), and total costs (\$17,622) were high. During second-line therapy (mean 256 days), the percentages of patients with ≥ 1 inpatient, ER, and hospice visits were 75.2%, 32.2%, and 40.9% in Cohort B, respectively. PPPM costs for inpatient admission (\$21,982), outpatient (\$6,178), and total costs (\$29,718) increased compared with the first-line period. **CONCLUSIONS:** AML patients in the Medicare population incurred significant health care utilization and costs – especially during the relapsed period.

PSY53

DIRECT AND INDIRECT COSTS OF CYSTIC FIBROSIS PATIENTS AT A UNIVERSITY HOSPITAL IN OMAN

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OBJECTIVES: This study aimed to estimate the patterns and cost burden among CF patients by focusing on annual and lifetime direct and indirect costs. **METHODS:** Data were collected by using a study with a cross sectional design in 30 patients who visited the CF clinic of the Sultan Qaboos University Hospital (SQUH) in Oman between December 2014 and February 2015. Direct health-care costs reflecting the governmental perspective were determined retrospectively by Hospital Information System (HIS) whilst indirect costs reflecting the social perspective were collected prospectively by means of a questionnaire. Most sources for unit's costs were acquired from SQUH's administrative price list of 2014. Prices of admissions, emergency, specialist and general practitioner (GP) visits were acquired from Muscat Private Hospital to reflect the actual market costs. **RESULTS:** The total annual cost per patient averaged at €27,128 \pm 42631 (year 2014 values). The majority of costs were spent on direct health costs with 91.8% (mean €25,508 \pm 43014) while indirect costs were only 8% (mean €2,275 \pm 56523). Pharmaceuticals represented 73.5% of the total costs with mean costs of €20,429 \pm 41018. Of the total costs, 7% resulted from admissions and 2.9% were from laboratory tests. Lifetime costs were averaged nearly at €543,300 \pm 763,832 (3% discount rate). **CONCLUSIONS:** CF is associated with high annual direct and indirect cost in Oman. Pharmaceuticals, productivity losses and admissions accounted for the majority of total cost. The calculated lifetime costs were 20 fold higher than total annual costs.

PSY54

THE TREATMENT OF PATIENTS WITH INJECTABLE OPIOIDS FOR UNCONTROLLED POSTOPERATIVE PAIN IN THE INPATIENT SETTING: INCIDENCE AND IMPACT ON HOSPITAL CHARGES

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OBJECTIVES: Adequate management of postoperative pain is a crucial component of patient care. Not only is pain management closely tied to patient satisfaction, but mismanaged pain can potentially negatively impact important clinical and economic outcomes. The objective of this study was to quantify the incidence of patients treated with injectable opioids for uncontrolled postoperative pain and assess how this issue impacts hospital charges. **METHODS:** A retrospective study was conducted using billing data from the QuintilesIMS Hospital Charge Data Master database. Adult patients were included if they underwent a non-emergent surgical procedure, were administered an inhaled anesthetic (sevoflurane, isoflurane or desflurane) and stayed in the hospital for >24 hours between July 1, 2014 and June 30, 2015. Patients

undergoing obstetrical surgeries or surgeries of the nervous, respiratory, or cardiovascular systems were excluded. Uncontrolled pain was defined as having received 3 or more different injectable opioids on the same day of the surgery. Patients treated for uncontrolled pain (cases) were matched to patients not treated for uncontrolled pain (controls) using propensity score matching (nearest neighbor approach). Total hospital charges were compared between cases and controls. **RESULTS:** The study cohort was comprised of 17,727 patients. Mean (SD) age was 56.3 years (15.2); Most patients were female (61.2%). One-third (33.6%, n=5,950) of patients were treated with 3 or more injectable opioids for uncontrolled pain, and propensity score matching resulted in 2,788 matched pairs. The total hospital charges for cases were significantly higher than for controls (Mean: \$64,183 vs. \$61,624, $p < 0.001$; Median: \$50,297 vs. \$48,744, $p < 0.001$). **CONCLUSIONS:** Patients treated with injectable opioids for uncontrolled pain were associated with higher hospital charges. Further research is warranted to quantify the burden of this complication and to assess potential methods for improving pain management. Applying a personalized medicine approach utilizing pharmacogenomics may help address the burden of pain in the postoperative setting.

PSY55

TRENDS IN ECONOMIC BURDEN OF CROHN'S DISEASE AND ULCERATIVE COLITIS IN THE UNITED STATES

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OBJECTIVES: Inflammatory bowel disease, which includes mainly two subtypes of the diseases: Crohn's Disease (CD) and Ulcerative Colitis (UC), is a chronic autoimmune gastrointestinal disease associated with significant economic burden. Several new biologic treatments have become available and showed effectiveness in improving patient outcomes in recent years. This study aims to estimate the trends in medical cost burden for CD and UC in a large commercial administrative claims database in US. **METHODS:** Retrospective analysis was conducted using Truven Health Market-Scan database from 2008-2014. Newly diagnosed CD and UC patients were identified using ICD-9-CM code (555.* for CD and 556.* for UC) based on a previously validated algorithm. Patient continuous eligibility at least 12 months before and after the index date (first diagnosis of CD/UC) was required. One-year medical expenditures, including inpatient admissions, outpatient visits, emergency department visits, and outpatients prescription drugs, were summarized and compared with the expenditures among comparison groups, which were established using propensity score matching method adjusting for demographics, health service utilization and comorbidities. All the cost components were inflated to year 2015 value using consumer price index and reported to describe any temporal trends. **RESULTS:** On average, annual medical expenditures were significantly higher for commercially insured CD and UC patients compared to matched patient group (\$30,392 vs \$15,099 for CD patients, \$24,981 vs \$15,678 for UC patients). From 2009 to 2013, the medical cost from CD has increased by 62.1% from \$11,724 to \$18,999 and the medical cost from UC has increased by 61.1% from \$7,848 to \$12,644. **CONCLUSIONS:** CD and UC are associated with significant economic burden. Medical costs have increased substantially in recent years for newly diagnosed patients with these conditions who are covered by commercial health plans.

PSY56

COST ASSESSMENT OF GOUT: YOUNG PATIENTS AGAINST ELDERLY

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OBJECTIVES: Gout has become is significant clinical problem in Russia, requiring costly to treat. Gout has many comorbid diseases: hypertension, chronic renal disease, coronary heart disease, heart failure, diabetes, kidney stones, which significantly increases the cost of treatment. When building a cost model based on the standards, which lists the medical intervention with the frequency of their use for diseases with high comorbidity is necessary to use the correction factor reducing margins (RM), which empirically has been calculated by RSPOR in 2007. The aim of the study was the prognostic assessment of patients with the cost of doing with gout during the year, taking into account polymorbidity and RM. **METHODS:** Were included 200 patients with gout, composed comorbid profile and matrix for all combinations of diseases, frequency combinations. Calculated the direct costs of treatment of gout and related diseases for each existing combination of comorbid pathology taking into account hospitalization rate for "young" and "old" populations and the RM (the value determined by the number of diseases, recorded in the preparation of models). **RESULTS:** In group A (age 57.9 \pm 11.3, N=150) was observed 2 comorbid disease to a patient, in the group B (age of 73.3 \pm 4.4, N=50) - 4. Elderly hospitalized significantly more often "young" - 1.2 hospitalizations per year, versus 0.7 ($p=0.001$). Direct projected costs of treating comorbid diseases 5 on 1 patient in the course of the year in the summation indices standards amounted to 21363\$, and in view of the RM-12818\$. Average direct costs for the year gout treatment in 1 patient out of a population of "young" amounted to 1315\$ per year and 7201\$ in view of comorbid diseases and the RM, in the "old" group, respectively 2033\$ and 14982\$. **CONCLUSIONS:** The marginality factor helps to make more accurate forecast of the cost of comorbid chronic diseases, the frequency of which increases significantly in older patients.

PSY57

COSTS OF HEMOPHILIA FROM A COLOMBIAN GOVERNMENT'S SUBSIDIZED HEALTH INSURER

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OBJECTIVES: To estimate the healthcare costs in patients with hemophilia in a Colombian government's subsidized health insurer in Colombia. **METHODS:** patients diagnosed with hemophilia were identified from the individual risk database of the insurer. The Individual Health Services Delivery Registry (RIPS) and the billing database were reviewed to estimate the direct medical costs between June 2015 and May 2016. The results are shown in dollar PPP. **RESULTS:** A total of 51 patients were identified with hemophilia from 1.890.000 affiliates of the public health insurer. Of these, 78% were diagnosed with Hemophilia type A (FVIII), 14% with Von Willebrand disease (EVW) and 8% with hemophilia type B (FIX). The medical cost was 8,519,020 PPP\$, of which 88.9% corresponded to medications, 6.0% to consultations, 2.0% to lab test and diagnostics images and 1.3% to hospitalization, in the year of study. The most expensive patient consumed 607,841 PPP\$ in services and 75,683 PPP\$ the less expensive. The highest annual cost per capita was caused by hemophilia Type B (238,741 PPP\$), followed by type A (173,338 PPP\$) and Von Willebrand with (90,075 PPP\$). Von Willebrand disease is the less expensive, however, medications have a high participation of total medical costs (93%). **CONCLUSIONS:** Hemophilia type B is 1.3 times more expensive than hemophilia A and 2.6 times more than Von Willebrand. The treatment of this disease is drug intensive, therefore, price regulation tends to decrease the financial risk of health systems and contributes to the efficient allocation of resources.

PSY58

A PHYSICIAN BASED ASSESSMENT OF DISEASE ACTIVITY, QUALITY OF LIFE AND COSTS OF ULCERATIVE COLITIS IN POLAND

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OBJECTIVES: The aim of this study was to assess a disease activity and quality of life reported by patients with ulcerative colitis (UC) as well as to evaluate direct and indirect costs of UC in Polish settings. **METHODS:** A questionnaire, cross-sectional study among UC patients as well as physicians involved in therapy of the patients was conducted. Clinical Activity Index (CAI) was used to assess disease activity, and the WPAI questionnaire to assess productivity loss. The quality of life was presented as utility calculated using the EQ-5D-3L questionnaire. Indirect costs included absenteeism, presenteeism and informal care were assessed with the Human Capital Approach and expressed in euros (€). The productivity loss among informal caregivers was valued with the average wage in Poland. Correlations were presented using the Spearman's coefficient, the between-group difference was assessed with Mann-Whitney U-test. **RESULTS:** 110 patients participated in the study, including 72 working persons. Mean cost of absenteeism and presenteeism was €1,737.5 (95%CI:622.9-2,852.2) and €4,059.8 (95%CI:2,545.1-5,574.6), respectively, per year per patient with a disease in remission. The mean yearly cost of productivity loss due to informal care was estimated to be €240.2 (range: 0.0-7,698.45). The corresponding values for patients with active disease were: €8,103.8 (95%CI:3,936.6-12,270.9), €4,742.0 (95%CI:1,357.6-8,126.5), and €1,296.6 (95% CI:97.3-2,495.8). The between-group difference in total indirect costs, cost of absenteeism and cost of informal care was statistically significant. The average weighted monthly costs of therapy with particular drugs categories (e.g. mesalazine or biologic drugs) differed significantly between active disease or remission patients. The difference in utility values between patients with a disease in remission (0.894, SD0.097) and patients with an active disease (0.680, SD0.262) was statistically significant. **CONCLUSIONS:** Our study revealed the social burden of UC and high dependency of direct and indirect costs as well as quality of life on the severity of UC in Poland.

PSY59

NUMBER-NEEDED-TO-TREAT (NNT) AND COST OF RESPONSES ACHIEVED IN TYROSINE KINASE INHIBITOR (TKI) TREATMENT OF REFRACTORY CHRONIC-PHASE CHRONIC MYELOID LEUKEMIA (CP-CML) IN THE UNITED STATES (US)

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OBJECTIVES: The emergence of targeted therapies with high efficacy in small patient populations such as TKI-refractory CP-CML has challenged decision-makers. We demonstrate a simple and intuitive approach to assessing the value of available TKIs (nilotinib, dasatinib, ponatinib and bosutinib) in this setting. **METHODS:** Using synthesized efficacy data from a published meta-analysis (Lipton 2014), we calculated NNT to achieve one additional response, defined as complete cytogenetic response (CCyR), for CP-CML patients treated with a TKI after failing ≥ 2 prior TKIs. NNT represents the expected number of treated patients required to achieve one additional response—i.e., the multiple of treated patients to responders. We assumed response is not evaluated prior to 3 months, per National Comprehensive Cancer Network (NCCN) guidelines. Therefore, the cost of achieving an additional response was estimated as the product of NNT and 3-month cost, based on US Wholesale Acquisition Costs (WAC) and recommended dosing for each TKI from US prescribing information (USPI). **RESULTS:** To achieve one expected response, the NNT is 1.7 (95%CrI: 1.5-1.9) patients for ponatinib, 3.8 (3.1-4.8) for nilotinib, 4.2 (2.2-11.1) for dasatinib, and 4.5 (3.4-6.7) for bosutinib (based on CCyR of 60%, 26%, 24% and 22%, respectively). With a 3-month WAC for ponatinib of \$49,683, nilotinib:\$33,892, dasatinib:\$33,897 and bosutinib:\$36,045, the estimated 3-month cost per response achieved is \$82,800 (\$73,100-\$95,500) for ponatinib, \$130,000 (\$106,000-\$161,000) for nilotinib, \$141,000 (\$75,300-\$377,000) for dasatinib, and \$164,000 (\$124,000-\$240,000) for bosutinib. **CONCLUSIONS:** Using published, synthesized efficacy estimates, the NNT to achieve response

with ponatinib in TKI-refractory CP-CML is less than with nilotinib, dasatinib or bosutinib. Despite a higher WAC, ponatinib has the lowest estimated 3-month cost per response achieved, suggesting that use of less-effective therapy in TKI-refractory CP-CML may be a poor approach to cost management. Therapy choice should, however, consider both treatment cost and the benefit-risk profile of the individual patient.

PSY60

DIRECT COSTS OF THE USE OF BIOLOGICAL THERAPIES, THE CASE OF A HEALTH MAINTENANCE ORGANIZATION IN COLOMBIA

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Biological therapies are currently used for some diseases which include: autoimmune diseases, cancer, osteoporosis among others; These treatments are long term and costly for health systems, so it is important to know the economic impact of using these medicines. **OBJECTIVES:** to estimate the direct costs associated with the use of biological therapies in the health care of patients insured with a health maintenance organization (HMO) in Colombia during the period 2014-2016. **METHODS:** A retrospective cross-sectional study was conducted in a cohort of 2597 patients distributed in 7 pathologies (rheumatoid arthritis, autoimmune diseases, cancer, osteoporosis, ophthalmologic, skin and renal pathologies) in 16 cities nationwide, affiliated with a HMO, for a period from January 2014 to August 2016. Total and average costs for the pathology, therapy, city and patient were estimated. Costs were adjusted for inflation and expressed in 2017 US dollars. **RESULTS:** The total annual cost of using biological therapies for 2014 was: \$ 10,128,248 for 2015: \$ 12,844,339 and for 2016 (until August): \$ 9,290,887. The most costly cities were Bogota with 27.7% of the total cost followed by Medellín with 15.0%. The most costly pathology was rheumatoid arthritis with 36.5% of the total cost. The average monthly cost per patient for rheumatoid arthritis was \$ 594. Cancer: \$ 1,545. Autoimmune diseases: \$ 683 and ophthalmologic pathologies: \$ 431. The therapy with the highest monthly cost was adalimumab with \$ 366,224 followed by etanercept with \$ 353,496. **CONCLUSIONS:** In general, rheumatoid arthritis is the most resource-consuming pathology, however, the average cost per patient of cancer patients is three times higher than patients with rheumatoid arthritis. In addition, although the target population has been increasing, the average costs of using biological therapies have remained stable over this period of time.

PSY61

WHAT IS THE HEALTH SYSTEM COST OF TREATING HAEMOPHILIA A IN AUSTRALIA?

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OBJECTIVES: To estimate the overall health system costs of treating haemophilia A (HA) in Australia, using recombinant factor VIII (rFVIII), ADVATE. **METHODS:** A literature-based cost study for treatment of people with severe HA in the absence of inhibitors was undertaken. ADVATE treatment was assumed to be given prophylactically to prevent bleeding episodes or "on-demand" for a bleeding episode. Utilisation data for rFVIII were derived from the Australian Bleeding Disorders Registry. Total health system costs were calculated by summing the cost of rFVIII (prophylaxis and "on-demand" use), and other direct medical costs for treating bleeding episodes and any adverse events. All costs are reported in AUD2016. **RESULTS:** Australian data were available for only five identified variables associated with treating HA: cost per international unit of rFVIII; cost of some adverse events; rFVIII usage by haemophilia severity and treatment regimen; and cost of orthopaedic surgeries. Australian data were unavailable for important variables such as hospitalisations from bleeds, home therapy, orthopaedic procedures, joint abnormalities, and median annualised bleed rates, all of which are necessary to derive costs from a health system perspective. Utilising Australian data and supplementing international data where necessary, approximate health system costs for rFVIII ADVATE patients in the absence of inhibitors receiving prophylaxis treatment was AU\$92,000 (AU\$83,000 rFVIII treatment cost) and "on-demand" was \$38,000 (AU \$31,000 rFVIII treatment cost) per severe HA patient per annum. The population cost per annum was approximately AU\$51,612,000 (AU\$45,966,000 rFVIII treatment cost) for 640 severe HA patients in Australia receiving treatment in 2014/15. **CONCLUSIONS:** Utilising Australian cost data supplemented with international data, finds the cost of rFVIII (ADVATE) is reasonable for a very effective treatment in preventing and/or treating bleeding episodes and comparable to other government funded highly specialised and/or life-saving drugs in Australia. Further research into the societal cost and benefits of treating HA in Australia is warranted.

PSY62

COST-EFFECTIVENESS ANALYSIS OF STANDARD PROPHYLAXIS VERSUS ON-DEMAND TREATMENT IN SEVERE HEMOPHILIA A IN CHINA

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OBJECTIVES: To present the first cost-effectiveness analysis comparing standard prophylaxis, i.e. prophylaxis with recombinant factor VIII from 2 to 16 years old then switching to on-demand treatment, with on-demand treatment, in treating severe hemophilia A patients in China. **METHODS:** The cost-effectiveness analysis was conducted from a societal perspective with a lifetime horizon. A Markov model was developed to reflect clinical practice in China's setting. Major events, including joint and total bleeds, major surgery, intracerebral hemorrhage, inhibitor development, outpatient visits, productivity loss and death were all considered. Clinical data and utility values were derived from multiple published studies, and resource

utilization and costs were estimated based on studies conducted in China and opinions from local experts. Analysis results were presented with incremental cost-effectiveness ratio (ICER). A threshold of 3 times local GDP per capita was applied. To test the robustness of base-case results, one-way and probabilistic sensitivity analyses were performed. Besides, scenario analyses were also undertaken to assess the impact of low-dose prophylaxis and no treatment for inhibitor. **RESULTS:** The base-case analysis favored standard prophylaxis as it is associated with lower costs (1,278,101 CNY) and higher QALYs (6.24 QALYs) per patient in lifetime. According to the one-way sensitivity analysis, this result was sensitive to the dosage of infusion in both strategies, the frequency of infusion in standard prophylaxis, and the frequency of bleeding. Probabilistic sensitivity analysis results demonstrated that over 80% simulations were lower than the cost-effectiveness threshold. Low-dose prophylaxis was also considered dominant compared with on-demand treatment. Without consideration of treatment for inhibitor, the ICER was estimated at 87,794 CNY per QALY gained, implying a cost-effective option for patients with severe hemophilia A in China. **CONCLUSIONS:** In the local context of China, standard prophylaxis for hemophilia A patients is a dominant strategy compared with standard on-demand treatment.

PSY63

COST-EFFECTIVENESS ANALYSIS OF MORPHINE MONOTHERAPY VERSUS FENTANYL MONOTHERAPY IN THE MANAGEMENT OF NEONATES UNDERGOING MECHANICAL VENTILATION IN THE INTENSIVE CARE SETTING IN QATAR

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OBJECTIVES: This study was to evaluate the clinical and economic impact of morphine monotherapy versus fentanyl monotherapy in mechanically ventilated neonates with respiratory distress syndrome in the Qatari neonatal NICU. **METHODS:** A retrospective cohort evaluation of 126 critically ill neonates on mechanical ventilation (MV) at the NICU of Hamad Medical Corporation (HMC), the main healthcare provider in Qatar, was conducted based on the medical records in within the duration from 2014 to 2016. Out of 126, 63 patients received morphine (100-200mcg/kg, followed by 15-30mcg/kg/hour continuous infusion) and 63 received fentanyl (0.5-3mcg/kg, followed by 1-5mcg/kg/hour continuous infusion). A decision analytic model followed the possible consequences of both sedatives. The primary clinical endpoint was the successful drug sedation rate, via the Premature Infant Pain Profile scoring scale. All cost data were from the perspective of HMC. Sensitivity and uncertainty analyses were conducted to enhance results robustness. **RESULTS:** Morphine achieved a successful sedation rate of 68.25%, compared to 42.85% with fentanyl. It also reduced the duration of MV and NICU stay to 5.0 days and 5.3 days, versus 10.6 days and 7.2 days with fentanyl. Also, less patients required high doses and alternative sedatives with morphine compared to fentanyl. Withdrawal symptoms nevertheless, tended to be higher in the neonates receiving morphine (0.1% versus 0%). Morphine was associated with an incremental cost-effectiveness ratio of QAR 31,847 per extra case of sedation, compared to fentanyl. Results were reported with 80% power and 0.05 significance level. **CONCLUSIONS:** This is the first cost-effectiveness evaluation of morphine versus fentanyl in NICU in literature, and is the first local clinical and/or economic evidence in relation to these in Qatar. Morphine produces significantly improved sedation and agitation levels over fentanyl. This contributes to a shorter length of stay at NICU and greater weaning from mechanical ventilation. This however comes at an increased cost.

PSY64

COST CONSEQUENCE MODEL COMPARING ELTROMBOPAG AND ROMIPLOSTIM FOR ADULT PATIENTS WITH PREVIOUSLY-TREATED CHRONIC IMMUNE THROMBOCYTOPENIA

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OBJECTIVES: This study's objective was to develop a Cost-Consequence Model comparing eltrombopag versus romiplostim for adult patients with Chronic Immune Thrombocytopenia (cITP) in the US. **METHODS:** A cost-consequence model was developed using a decision tree approach to evaluate the costs relative to treatment success of eltrombopag (ELT), romiplostim (ROM), and watch and rescue (W&R) in previously treated patients. Data on platelet count response rate, bleeding events, and adverse events were derived from all identified phase III registered clinical trials. Since none of the included treatments were compared in head-to-head trials, health outcomes were compared via indirect treatment comparison. Costs incorporated in the model included drug and administration, routine care, rescue medication, bleeding-related adverse event, other adverse event and mortality costs. **RESULTS:** In the ITT population, overall estimated cost per patient for eltrombopag was \$66,560, compared with \$92,631 for romiplostim and \$30,099 for W&R. Compared with the ITT population, this difference in cost between ELT and ROM was greater in splenectomized patients and slightly less in non-splenectomized patients, though the overall trend remained the same. When assessing cost per severe bleeding avoided in the ITT population, ELT dominated (was less expensive and more effective than) ROM. Regarding costs per responder, ROM showed an incremental benefit over ELT of 23.1%, yielding an ICER of \$113,055. Sensitivity analysis results were also consistent with the basecase findings, with results most sensitive to variations in platelet response and changes in primary therapy prices. **CONCLUSIONS:** TPO-R agonists (including eltrombopag and romiplostim) are favourable options for the treatment of adults with chronic ITP who have had an insufficient response to corticosteroids or immunoglobulins. Eltrombopag was shown to be a relatively efficient use of resources to treat chronic immune thrombocytopenia when indirectly compared to romiplostim, largely driven by its favorable severe bleeding outcomes.

PSY65

COST PER RESPONDER ANALYSIS OF USTEKINUMAB VERSUS SECUKINUMAB FOR THE TREATMENT OF MODERATE TO SEVERE PSORIASIS UNDER THE BRAZILIAN PUBLIC HEALTHCARE SYSTEM PERSPECTIVE

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OBJECTIVES: Recently, the treatment paradigm of plaque psoriasis (PsO) has evolved with the advent of biologic therapies, mainly novel interleukin inhibitors. This study aims to estimate the cost per responder of ustekinumab (UST) compared to secukinumab (SEC) in patients with moderate to severe PsO from the Brazilian public healthcare system perspective. **METHODS:** Treatment costs and cost per PASI response were calculated and compared between UST and SEC in year 1 and year 2 of treatment onwards. Annual treatment costs included only drug acquisition costs, gathered from the official price list for government purchase, and were calculated for an average patient weighting ≤ 100 kg, following dosage described in each drug label. Efficacy data on PASI responses were derived from the CLEAR study, a head-to-head 52-week trial. Cost per PASI response was calculated as the annual cost divided by the proportion of patients reaching PASI90 response at week 52. Univariate sensitivity analysis was performed to test the robustness of the model. **RESULTS:** Treatment costs were lower for UST when compared to SEC in both year 1 and year 2 of treatment onwards, resulting in savings of BRL 54,208 after 2 years of treatment. UST also presented lower cost per PASI 90 response compared to SEC in both year 1 (BRL 76,692 versus BRL 104,150) and year 2 of treatment onwards (BRL 65,955 versus 78,113). Univariate sensitivity analysis showed that, for patients weighting > 100 kg or requiring UST dose escalation, SEC presented lower cost per PASI 90 response compared to UST. **CONCLUSIONS:** From the Brazilian public healthcare system perspective, UST was estimated to present lower treatment cost and lower cost per PASI 90 response compared to SEC for the majority of patients (≤ 100 kg), still with the advantage of favorable dosing (four administrations per year).

PSY66

COST PER RESPONDER ANALYSIS OF USTEKINUMAB VERSUS SECUKINUMAB FOR THE TREATMENT OF MODERATE TO SEVERE PSORIASIS UNDER THE BRAZILIAN PRIVATE HEALTHCARE SYSTEM PERSPECTIVE

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OBJECTIVES: Recently, the treatment paradigm of plaque psoriasis (PsO) has evolved with the advent of biologic therapies, mainly novel interleukin inhibitors. This study aims to estimate the cost per responder of ustekinumab (UST) compared to secukinumab (SEC) in patients with moderate to severe PsO from the Brazilian private healthcare system perspective. **METHODS:** Treatment costs and cost per PASI response were calculated and compared between UST and SEC in year 1 and year 2 of treatment onwards. Annual treatment costs included only drug acquisition costs, gathered from the official price list, and were calculated for an average patient weighting ≤ 100 kg, following dosage described in each drug label. Efficacy data on PASI responses were derived from the CLEAR study, a head-to-head 52-week trial. Cost per PASI response was calculated as the annual cost divided by the proportion of patients reaching PASI 90 response at week 52. Univariate sensitivity analysis was performed to test the robustness of the model. **RESULTS:** Treatment costs were lower for UST when compared to SEC in both year 1 and year 2 of treatment onwards, resulting in savings of BRL 66,107 after 2 years of treatment. UST also presented lower cost per PASI 90 response compared to SEC in both year 1 (BRL 93,527 versus BRL 127,013) and year 2 of treatment onwards (BRL 80,433 versus 95,260). Univariate sensitivity analysis showed that, for patients weighting > 100 kg or requiring UST dose escalation, SEC presented lower cost per PASI 90 response compared to UST. **CONCLUSIONS:** From the Brazilian private healthcare system perspective, UST was estimated to present lower treatment cost and lower cost per PASI 90 response compared to SEC for the majority of patients (≤ 100 kg), still with the advantage of favorable dosing (four administrations per year).

PSY67

PHARMACOECONOMICS ANALYSIS OF MORPHINE MONOTHERAPY VERSUS MORPHINE PLUS MIDAZOLAM COMBINATION FOR CRITICALLY ILL NEONATES UNDERGOING MECHANICAL VENTILATION AT THE INTENSIVE CARE SETTING IN QATAR

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OBJECTIVES: No clinical or economic literature evidence of how morphine compares to its use in a combination exists. The current study was to conduct a clinical and economic analysis of morphine monotherapy versus morphine plus midazolam combination as sedatives in critically ill neonates on mechanical ventilation (MV) with respiratory distress syndrome in ICU. **METHODS:** A comparative retrospective cohort study comprised of 64 medical records of mechanically ventilated neonates in 2014-2016 at the neonatal ICU (NICU) of Hamad Medical Corporation (HMC), the main health provider in Qatar, was carried out from the hospital perspective. Sample size calculations were to achieve 80% power and 0.05 significance. Patients received either morphine (100-200mcg/kg, followed by 15-30mcg/kg/hour continuous infusion) or morphine based analgesic using midazolam (0.1-0.2mg/kg, followed by 0.01-0.06mg/kg/hour). A decision analytic model that follows the possible therapy consequences was developed. As the primary clinical endpoint, sedation success was defined as per the Premature Infant Pain Profile scoring scale. Uncertainty Monte Carlo simulation analyses were performed to confirm robustness. **RESULTS:** The base case probabilistic

analysis demonstrated that morphine monotherapy dominated the combination of morphine and midazolam, with a net cost saving of QAR 13,067 per patient and a 65.6% successful sedation rate, compared to 34.4%. The administration of morphine alone without an analgesic reduced the duration of mechanical ventilation and NICU stays to 9.5 and 7.0 days, respectively, compared to 25.1 and 34.4 days with the morphine plus midazolam combination. Add to this that neonates receiving monotherapy regimen had less administrations of higher doses and alternative sedatives (9.1% and 9.1%, versus 34.37% and 23.80%, respectively). **CONCLUSIONS:** With significantly higher clinical effectiveness and lesser cost, morphine monotherapy is superior to the morphine plus midazolam combination in the critically ill neonates who require MV. This regimen was better tolerated; allowing for more optimal pain management and improved weaning process from MV.

PSY68

COST-EFFECTIVENESS ANALYSIS OF 5% LIDOCAINE MEDICATED PLASTER MONOTHERAPY VERSUS PREGABALIN OR GABAPENTIN IN THE TREATMENT OF POST HERPETIC NEURALGIA AND DIABETIC POLYNEUROPATHY UNDER THE PERSPECTIVE OF BRAZILIAN PUBLIC HEALTHCARE SYSTEM

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OBJECTIVES: To evaluate the cost-effectiveness of the use of 5% lidocaine medicated plaster (LMP) monotherapy, compared with pregabalin and gabapentin, in the treatment of postherpetic neuralgia (PHN) and diabetic polyneuropathy (DPN) in the Brazilian public healthcare system. **METHODS:** A systematic review was performed to compare the use of LMP with placebo or active comparators on neuropathic pain management. Based on the results, disease and efficacy data were selected. PHN and DPN were the most studied neuropathic pain conditions and therefore selected. Since both diseases were evaluated together, the same structure could be used for both analyses, with minor adaptations. Two comparators were selected: pregabalin, the main comparator in clinical trials, and gabapentin, the most used drug in clinical practice. A Markov model was built based on published cost-effectiveness studies, and consisted of 6 states covering treatment, adverse events and discontinuation. The time horizon had 6 months with monthly cycles. Transition probabilities were extracted from clinical trials, head-to-head for pregabalin and placebo controlled for gabapentin. Benefits were measured in quality-adjusted life-years (QALYs), to account the improvement in adverse events. Resource use was retrieved from literature and direct medical costs were estimated based on public sources. A one-way sensitivity analysis was performed to evaluate model's robustness. Values were expressed in 2016 BRL. **RESULTS:** Incremental cost-effectiveness ratio (ICER) of LPM versus pregabalin and gabapentin were 19,256.33 BRL/QALY and 19,102.47 BRL/QALY for PHN, and 19,244.16 BRL/QALY and 23,208.75 BRL/QALY for DPN. All results from the sensitivity analysis were below the threshold recommended by WHO of 1 GDP per capita (27,229.00 BRL), and the most sensitive parameter was the mean number of plasters used. **CONCLUSIONS:** LDM monotherapy was considered highly cost-effective for the treatment of PHN and DPN compared with pregabalin or gabapentin in the Brazilian public healthcare system.

PSY69

IFABOND (VITALITEC) SURGICAL GLUE IN LAPAROSCOPIC SLEEVE GASTRECTOMY: AN INITIAL EXPERIENCE AND COST EFFECTIVENESS ANALYSIS

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OBJECTIVES: Laparoscopic sleeve gastrectomy (LSG) is one of the most common bariatric procedures. Gastric leaks and bleeding are the most frequent complications, associated with a high clinical and economic burden. The best method of staple line reinforcement in LSG is debated. Surgical glue is one of the options available. The aim of this study was to assess the safety, efficiency and relative cost-effectiveness of surgical glue used to perform laparoscopic sleeve gastrectomy in morbid obese adults as compared to standard stapling. **METHODS:** A prospective, observational and comparative before-after study was conducted. All consecutive patients undergoing LSG at Montpellier University Hospital in 2011 and 2012 were included and treated according to two groups: standard stapling (n=99, Group 1) and surgical glue reinforcement (n=94, Group 2). Clinical and economic outcomes were measured after 6 months. **RESULTS:** The duration of intervention was significantly shorter in Group 2 (68 vs. 82 minutes, p=0.001). There was no significant difference regarding complications but leaks in Group 1 were more severe. Group 2 was also associated with a reduced initial length of stay (4.8 vs. 5.2 days, p=0.01). Six-month readmissions, and total length of stay was also shorter in group 2 (5.5 vs. 6.1 days, p=0.003). Surgical glue use was associated with a significant reduction in the initial inpatient cost (5488 vs. 6152 €, p=0.005) and in the 6-month total inpatient cost including readmissions (6006 vs. 6754 €, p=0.005). The incremental cost of glue to avoid a severe complication was -5446.33 € (95CI: -8202.01; -2690.66). **CONCLUSIONS:** IFABOND® surgical glue might be a safe and cost-effective intervention in laparoscopic sleeve gastrectomy.

PSY70

COST-EFFECTIVENESS OF RITUXIMAB-BASED CHEMOTHERAPY COMBINATIONS FOR THE INITIAL THERAPY OF FOLLICULAR LYMPHOMA

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OBJECTIVES: Rituximab based chemotherapy combinations are used to treat elderly patients with follicular lymphoma (FL), but the optimal regimen is unknown. We aimed to identify the cost-effectiveness of first line rituximab-based combinations. **METHODS:** Stage II-IV grade 1-3 FL patients >65 diagnosed

between 2001-2010 who received chemotherapy within 6 months of diagnosis were identified using SEER. Healthcare costs from linked Medicare claims through 2014 were used to estimate costs using a phase of care approach and to calculate the incremental cost-effectiveness ratio (ICER). **RESULTS:** Of the 2,827 pts, 587 received rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP); 422 rituximab, cyclophosphamide, vincristine, and prednisone (R-CVP); and 576 another rituximab combination (R-other). R-CHOP was more common in pts <75 (p<0.01), males (p=0.01), less comorbid (p<0.01), advanced stage disease (p=0.05), married (p<0.01), and those treated in a big metro area (p<0.01). Propensity weighting adjusted these differences prior to the analysis. Mean overall survival was 9.19 years for pts treated with R-CHOP, which was 0.19 years longer than R-CVP and 0.87 years longer than R-other. Total cost of care was \$162,300 for R-CHOP, \$141,000 for R-CVP, and \$145,100 for R-other. The ICER for R-CHOP vs R-CVP was \$19,800/LY, while for R-CHOP vs R-other \$21,200/LY. For pts living longer than 2 years, mean monthly cost for the 1st year after diagnosis was \$1800, \$1600, & \$1600; and for the last year of life, \$5900, \$5700, & \$4700 for R-CHOP, R-CVP, and R-other, respectively. **CONCLUSIONS:** In this first real world analysis comparing rituximab based combinations in older patients with FL, the addition of an anthracycline significantly prolongs overall survival after adjusting for baseline factors and is cost-effective. Additional research is needed to compare therapy after relapse as newer agents are expensive and likely contribute to the dramatic difference in cost between the first year after diagnosis and the last year of life.

PSY71

INCREMENTAL COST-EFFECTIVENESS ANALYSIS OF BIOLOGICAL DRUG THERAPIES FOR THE TREATMENT OF ANKYLOSING SPONDYLITIS IN BULGARIA, 2016

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OBJECTIVES: Biological therapies, alone or in combination with other medications, are used as second or subsequent therapy line in the treatment of ankylosing spondylitis (AS). The biologics authorized in Bulgaria in August 2016 are etanercept (ETA), infliximab (INF), adalimumab (ADA), golimumab (GOL), certolizumab (CER), and secukinumab (SEC). The objective of the study is to assess the incremental costs (Acosts), incremental health benefits (ΔQALY) and incremental ratio (ICER) of the biological therapies for AS in Bulgaria. **METHODS:** The data on SEC efficacy have been derived from two randomized multicenter clinical trials: MEASURE-1 and MEASURE-2. Long-term data on therapeutic efficacy have been modelled using a model of RTI Health Solutions. The data on therapeutic efficacy are directly transferred in the local environment from the clinical trials and the applied model. The data on costs of the alternatives are based on the reference prices of ETA, INF, ADA, GOL, CER and SEC published in the Positive Drug List. Other direct or indirect health costs, besides the drug therapy costs, are not included in the analysis as they are considered comparable in the various therapeutic alternatives in the Bulgarian healthcare setting. **RESULTS:** The analysis of adapted data on SEC cost-effectiveness of AS in Bulgaria shows that SEC dominates CER, ETA, ADA, GOL and if we consider a cost-effectiveness threshold three times GDP per capita in Bulgaria (WTPth 36 221 BGN, 2015), is a cost-effective therapy in comparison to INF (ICER 27 552 BGN/QALY). **CONCLUSIONS:** The pharmacotherapeutic guidelines based on both clinical data on therapeutic efficacy and safety and economic data on comparative cost-effectiveness of potential biological therapeutic alternatives for the treatment of AS, recommend SEC as first choice for second line in AS treatment in Bulgaria, after failure of conventional therapy, as well as for third line after failure of anti-TNFα therapy.

PSY72

SYSTEMATIC ASSESSMENT OF DECISION ANALYTIC MODELS FOR THE COST EFFECTIVENESS OF BARIATRIC SURGERY

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OBJECTIVES: To systematically review the methodological approaches in published cost effectiveness models of bariatric surgery. **METHODS:** A systematic literature search from different databases with an end date of September 4, 2016 was done. The search was limited to English studies, cost effectiveness models comparing bariatric surgeries with non-surgical interventions and those reporting quality adjusted life years. The quality of reporting the models was performed by using CHEERS statement. **RESULTS:** The initial search for title and abstract screening resulted in 691 articles. 18 economic evaluation studies were included in the final review. The reporting quality scores of most articles were rated as acceptable, between 61% and 100%. Of the included 18 studies, 8 only were done in the USA. Most studies (89%) were modeled for adult age range between 25 and 75 years old. Half of the studies evaluated bariatric surgery versus no treatment and the other half compared bariatric surgery to medical management or conventional therapy. Sixty one percent of studies defined their health states by the existence or absence of different obesity-related comorbidities. Only 11% of studies took the societal perspective. Productivity was not captured in the societal perspective but travel time was accounted for. The time horizons varied, but 61% of studies used a lifetime horizon. Thirty nine percent of studies identified the extent of weight loss as the most sensitive and influential parameter. Seventeen percent of studies did not conduct any model validation. **CONCLUSIONS:** Cost effectiveness models of bariatric surgery had different modeling approaches and quality levels. Future cost effectiveness models should consider the adolescent population because few cost-effectiveness studies have addressed this population in which the use of bariatric surgery is rising. Also, future models should include class I obesity and overweight patients, since some studies have claimed that bariatric surgery is of benefit to lower BMI patients also.

PSY73

ECONOMIC EVALUATION OF THE USE OF IBUPROFEN AS AN NSAID WITH ANALGESIC ACTION FOR THE TREATMENT OF PATIENTS WITH ACUTE PAIN

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OBJECTIVES: To perform a complete economic evaluation of Ibuprofen as an NSAID with analgesic action for the treatment of patients with acute pain, compared to the therapeutic alternatives considered in the Basic Medication Formulary of IMSS (CBMIMSS for its acronym in Spanish). **METHODS:** A systematic review of the use of Ibuprofen as a non-steroidal anti-inflammatory with analgesic action for the treatment of acute pain was carried out. A meta-analysis was necessary to verify the therapeutic similarity of Ibuprofen vs available CBMIMSS comparators. Given the therapeutic similarity of these options, a cost minimization was the economic analysis performed, in addition to a budget impact analysis (BIA). **RESULTS:** The cost of treatment with ibuprofen represents one-third of the cost of treating patients with acute pain with the most expensive alternative (Lysine Clonixinate) \$5.88 vs \$18.53 (MXN), while the difference in cost vs Paracetamol is \$4.27 for the presentation of 200mg and \$2.93 for the presentation of 400mg. The BIA showed that the introduction of Ibuprofen would generate a saving of \$23,652.27 in the first year; on average it will have a potential saving of \$73,301.74 and an average saving percentage of 0.00015583% of the total budget. **CONCLUSIONS:** Based on the results found in the present study, it is possible to conclude that the use of Ibuprofen 400mg, is a cost-saving alternative in comparison to the therapeutic alternatives available in the CBMIMSS such as paracetamol, acetyl salicylic acid, Ketorolac, Lysine, clonixinate and metamizole.

PSY74

COST EFFECTIVENESS OF BARIATRIC SURGERY FOR MORBID OBESITY IN USA

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OBJECTIVES: To evaluate the cost-effectiveness of bariatric surgery using three different techniques – (Laparoscopic Roux-en-Y Gastric Bypass (LRYGB), Laparoscopic Adjustable Gastric Banding (LAGB) and Laparoscopic Sleeve Gastrectomy (LSG)) – as treatment for morbid obesity in USA. **METHODS:** A microsimulation model was developed over a lifetime horizon to simulate weight change, cardiometabolic comorbidities status, health consequences and costs of bariatric surgery for morbid obesity. Incremental cost-effectiveness ratios (ICERs) in terms of cost per quality-adjusted life-year (QALY) gained were used in the model. Surgical effectiveness was derived from observational studies and randomized clinical trials. Surgical complication rates, adverse events, the remission of cardiometabolic comorbidities, mortality rates, costs, utilities and other model parameters were estimated from publicly available databases and published literature. The discount rate for costs (2016 US dollars) and QALYs was 3%. **RESULTS:** Under conservative assumptions, all techniques enhanced health outcomes at lower cost (cost saving) compared to no surgery for patients with cardiometabolic comorbidities (type 2 diabetes, hypertension and/or dyslipidemia). However, bariatric surgery was not cost saving for patients without comorbidities. LRYGB is cost effective with higher QALYs (16.44) and lower cost (\$168,927) than LSG (15.74 QALY; \$187,587), LAGB (15.08 QALY; \$200,539) and no surgery (13.43 QALY; \$251,917) for patients with cardiometabolic comorbidities. In addition, LRYGB is cost effective for patients without comorbidities (17.53 QALY; \$137,879) compared with LSG (17.16 QALY; \$136,041), LAGB (16.68 QALY; \$130,971) and no surgery (15.15 QALY; \$117,367), having the maximum net monetary benefit (NMB) over a willingness to pay (WTP) range from \$0-250,000. Sensitivity analysis showed robustness to reasonable variation in overall model parameters. **CONCLUSIONS:** All types of bariatric surgeries showed significant weight loss compared to no surgery. LRYGB is the optimal bariatric technique, being cost effective compared with LSG, LAGB and no surgery options.

PSY75

COST-UTILITY ANALYSIS FOR BARIATRIC SURGERY COMPARED WITH USUAL CARE FOR THE TREATMENT OF OBESITY IN AUSTRALIA

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OBJECTIVES: To determine the cost-effectiveness of adjustable gastric banding (AGB), Roux-En-Y gastric bypass (RYGB) and sleeve gastrectomy (SG) versus usual care (UC) from the perspective of the Australian public healthcare system. **METHODS:** A Markov model was constructed to simulate the costs and outcomes for four approaches to managing obesity. The base-case was a 30-year-old Australian female with a body mass index (BMI) > 35. Subgroup analysis was conducted to account for the effect of diabetes as well as various differences in cohort characteristics. Uncertainty was characterised by one-way and probabilistic sensitivity analyses. **RESULTS:** All bariatric surgeries were effective. The incremental cost-effectiveness ratios were similar at \$24,454 for AGB, \$22,645 for RYGB and \$27,523 for SG compared to UC. At a willingness to pay threshold of \$70,000 per quality-adjusted life year (QALY), the probabilities of being cost-effective were 64%, 75% and 71% for AGB, RYGB and SG, respectively. Subgroup analysis showed that bariatric procedures are less cost-effective for older cohorts. For those with diabetes, all the procedures were dominant in comparison to UC. **CONCLUSIONS:** This model shows that all bariatric procedures are a cost-effective treatment for the management of obese patients. When given to a subgroup with diabetes, bariatric interventions become cost-saving.

PSY76

REAL-WORLD HEALTH CARE UTILIZATION COSTS IN HEMOPHILIA B PATIENTS USING STANDARD AND EXTENDED HALF-LIFE RECOMBINANT FACTOR IX PRODUCTS

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OBJECTIVES: Management of hemophilia B includes replacement of factor IX (FIX) by intravenous infusion. The recent introduction of an extended half-life (EHL) FIX product enabled comparison of health care costs and factor utilization for hemophilia B patients who switched from a standard half-life (SHL) to EHL FIX product. **METHODS:** The Truven MarketScan US claims database (January 2010–July 2016) was used to compute health care utilization costs for patients with claims data for ≥3 months prior to and after switching from SHL to EHL product. Total health care costs included FIX replacement cost (drug cost) as well as hemophilia-related inpatient and outpatient costs. Data were analyzed 12 months before and after switching FIX products. **RESULTS:** Fourteen patients with hemophilia B in Truven database switched to EHL product. Total health care utilization costs were uniformly higher in the EHL phase (post-switch) in each of the corresponding 3-month time periods examined before and after the switch. Factor replacement accounted for 96%–100% of quarterly total health care utilization costs. Median quarterly total health care costs were \$51,881, \$80,589, \$89,389, \$56,076 (SHL), and \$205,845, \$185,988, \$147,514, \$175,667 (EHL), while median quarterly factor costs were \$51,881, \$77,523, \$89,389, \$55,726 (SHL), and \$205,724, \$183,451, \$147,363, \$173,515 (EHL) in the 12–10 (n=9), 9–7 (n=10), 6–4 (n=12), 3–1 and 1–3, 4–6 (n=12), 7–9 (n=8), and 10–12 (n=7) months pre- and post-switch, respectively. Median quarterly FIX IUs were 39,000, 58,465, 68,790, 43,310 (SHL), and 74,056, 64,111, 53,083, 43,276 (EHL), respectively, in these periods. **CONCLUSIONS:** This real-world data analysis showed switching from SHL to EHL product was associated with more variable and higher health care costs in the US. Factor cost was the biggest driver of total health care costs. Further real-world analyses incorporating larger numbers of patients should be explored.

PSY77

HEALTHCARE AND MEDICAL SERVICE USE AMONG PATIENTS WITH ANGELMAN SYNDROME (AS): RESULTS FROM THE AS NATURAL HISTORY STUDY

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OBJECTIVES: Angelman syndrome (AS) is a rare neurodevelopmental genetic disorder. There are four etiologies of AS, with maternal chromosome 15q11q13 deletion accounting for most cases. This study describes healthcare resource use (HRU) and medical service use (MSU) among patients with AS and compares use by molecular subtype. **METHODS:** The AS Natural History study (NHS) is a longitudinal observational study on the development, behavior, and medical problems of individuals with AS. Caregiver-reported information collected at the baseline visit was used to assess HRU and MSU. HRU measures included hospitalization, surgery, and medication use. MSU included early childhood intervention (EI), physical therapy (PT), occupational therapy (OT), and speech therapy (ST). **RESULTS:** Data were available on 302 patients. Mean age at baseline visit was 6.0+5.9 years (range: 0.4 to 40.6) and 70% had deletion subtype. Sixty-eight percent of patients had at least one hospitalization; average number of hospitalizations was 2.3 (95% CI: 2.1-2.5) and average length of stay was 4.5 days (95% CI: 3.8-5.2). Most common reasons for hospitalization were seizures (40%), lower respiratory infection (21%), and surgery (11%). Fifty-seven percent of patients had at least one surgery, for insertion of ear tubes (34%), strabismus (30%), tonsillectomy and adenoidectomy (25%), and G-tube/fundoplication (8%). The most frequently prescribed medications were anticonvulsants (clonazepam (24%), levetiracetam (22%), valproic acid (22%), and topiramate (16%)) and gastro-esophageal reflux disease medications (ranitidine (24%) and lansoprazole (19%)). Non-prescription medication use included melatonin (42%) and various supplements (34%). Resource use was high, with participants receiving EI (95%), PT (90%), OT (88%) and ST (86%). HRU and MSU were similar when comparing patients with deletions to those with other molecular subtypes. **CONCLUSIONS:** This is the first study to evaluate HRU and MSU among AS patients. Results show high hospitalization rate and high MSU; use does not vary with molecular subtype.

PSY78

TREATMENT PATTERNS AND RESOURCE COSTS ASSOCIATED WITH THE MANAGEMENT OF PRIMARY BILIARY CIRRHOSIS

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OBJECTIVES: The purpose of this study was to describe treatment patterns, resource utilization and costs associated with the management of PBC in a real life setting. **METHODS:** This study was performed using data from the Quebec public drug plan database (RAMQ). Patients with at least two diagnoses of biliary cirrhosis and a prescription of ursodiol between January 2008 and May 2015, and with enrolment in the drug plan during the study period were selected. A control group of non-PBC patients matched for age group and gender was selected from a random sample of individuals covered by the RAMQ in a 1:10 ratio. **RESULTS:** A total of 158 PBC patients and a control group of 1,580 matched non-PBC patients were included in this study. The average age was 63.2 years (SD=12.7) and 84.2% of PBC patients were women. The treatment with ursodiol had an average duration of 4.1 years (SD=2.5) and the majority of users did not use other medications before (91.8%), during (57.0%) and after (88.6%) ursodiol treatment. Prednisone was the treatment most often used in concomitance with ursodiol (22.2%). The 1-year rate of ursodiol discontinuation was 10.8% (95% CI:5.9-15.7)

and the 4-year rate was 22.1% (95% CI:15.2-29.0). The mean total health care cost per patient per year was significantly higher among PBC patients than non-PBC patients (17,283\$CAN; SD=35,046 vs. 3,970\$CAN; SD=6,426, mean difference=13,313\$CAN). The primary driver of PBC patients' total health care cost was the hospitalization cost (8,809\$CAN) while the prescription drug cost was 5,365\$CAN and the physicians' visit and procedure cost was 2,855\$CAN. The mean number of hospitalization per year was 0.9 (mean duration=8.9 days), with 73.4% of PBC patients with at least one hospitalization. **CONCLUSIONS:** Total health care costs incurred by PBC patients in comparison with non-PBC patients confirm the significant economic burden associated with this condition.

PSY79

HOSPITAL RESOURCE UTILIZATION IN HEREDITARY AND NON-HEREDITARY HYPOGAMMAGLOBULINEMIA PATIENTS

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OBJECTIVES: Hypogammaglobulinemia (HG) is an immune disorder characterized by a lack in production of gamma globulins. Due to immune deficiencies, patients with HG often have recurrent infections. The purpose of this analysis is to examine hospital resource utilization in patients diagnosed with HG. **METHODS:** A retrospective analysis was conducted on a cross-section of HG discharges in the MedAssets health system data for October 2015 through September 2016 discharges. Between group differences were tested using Chi-Square for categorical variables and ANOVA for continuous variables. Multivariable logistic regression was used to identify significant drivers of inpatient admission. **RESULTS:** The sample population included 8670 patients treated in 283 U.S. hospitals. Only 3.1% were diagnosed with hereditary HG (HHG). Not surprisingly the HHG cohort was primarily male (72.1%) however the non-hereditary HG (NHHG) cohort had more females (59.5%). HHG patients were significantly younger (32.7 vs 59.7, $p < .0001$) and had significantly lower Charlson Comorbidity Index scores (1.1 vs 3.0, $p < .0001$). The most common comorbidities for HHG included chronic pulmonary disease (CPD, 34.6%), cancer (11.2%), and anemia (10.4%). Cancer (42.5%), CPD (37.5%), other metabolic disorders (29.1%), and anemia (25.5%) were most prevalent in NHHG. Infections were more common in the NHHG cohort (12.2% vs 6.9%, $p < .0001$). HHG patients had slightly more visits overall (4.0 vs 3.4, $p = .0308$). Inpatient utilization was higher for NHHG (9.8% vs 5.0%, $p < .0001$) with longer lengths of stay (11.5 vs 6.3 days, $p < .0001$). The greatest predictors of inpatient admission included respiratory failure (OR=17.6, $p < .0001$), infection (OR=8.6, $p < .0001$), malnutrition (OR=7.1, $p < .0001$), and epilepsy (OR=4.5, $p < .0001$). **CONCLUSIONS:** Although HHG and NHHG are both characterized by decreased production in antibodies, many differences exist in the characteristics and comorbidities between these patients. Furthermore, hospital resource utilization varies across these cohorts.

PSY80

A COMPARISON OF GDP-ADJUSTED ORPHAN DRUG PRICES IN 12 EUROPEAN COUNTRIES

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OBJECTIVES: The study compared the price differences of orphan drugs among countries by comparing the annual treatment cost per patient adjusted by nominal GDP per capita, GDP in PPP per capita, % GDP contributed by the government, government budget per inhabitant, % GDP spent on healthcare, % GDP spent on pharmaceuticals, and average annual salary of similarly available orphan drugs in low and high GDP countries in Europe: France, Germany, Italy, Norway, Spain, Sweden, UK, Greece, Poland, Bulgaria, Romania, Hungary. **METHODS:** Orphan drugs granted market authorisation up to June 13, 2016 were extracted from the European Medicines Agency (EMA) website. The annual treatment costs per drug were calculated using ex-factory prices from IHS POLI and country price databases. GDP-related figures were extracted from the OECD website. The annual treatment costs were divided by each GDP-related variable to compute for the relative costs. An international comparison of the relative costs was done and results were analysed. **RESULTS:** 120 orphan drugs were included in the analysis. The median annual costs of orphan drugs in all countries varied minimally with cost ratios ranging from 0.87 to 1.08. When the annual costs were adjusted by GDP per capita, EU-5 and the Nordics maintained the minimal differences in median cost ratios: UK 1, FR 1.26, DE 1.15, IT 1.55, ES 1.65, SE 0.91, NO 0.51. However, the lower GDP countries showed relevantly higher relative costs: GR 2.47, PL 3.44, BG 6.27, RO 4.56, HU 3.29. The same relative cost pattern was evident when adjusted with the other GDP-related variables. **CONCLUSIONS:** Individual orphan drug prices may vary widely across European countries but the median differences are relatively minor. However, when the country's ability to pay was taken into consideration using GDP indicators, lower GDP countries pay relatively higher costs for similarly available orphan drugs in Europe.

SYSTEMIC DISORDERS/CONDITIONS - Patient-Reported Outcomes & Patient Preference Studies

PSY81

ASSESSING UTILITY VALUES FOR TREATMENT-RELATED HEALTH STATES OF ACUTE MYELOID LEUKEMIA IN THE UNITED STATES

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treatment-related health states of acute myeloid leukemia (AML) and disutilities of severe adverse events (SAEs) using a sample of individuals representative of the adult general population of the United States. **METHODS:** Applying the discrete choice experiment (DCE) methodology, an online survey was designed to capture the preference responses for pairs of health state scenarios including treatment-related AML health states and key grade 3/4 AEs of chemotherapies. Treatment-related AML health states, developed based on literature review and interviews with clinicians, included complete remission (CR), no CR, relapse, stem cell transplant (SCT), and post SCT short-term recovery. Six attributes, including fever, lack of energy, problems with daily function, anxiety/depression, blood transfusions, and hospitalization, each with 2 to 4 varying levels were used to define health states. Coefficients from conditional logistic regression model with generalized estimating equations were used to generate utilities of the predefined health states and disutilities of SAEs. **RESULTS:** 300 respondents completed the survey. The distribution of respondent demographics (age, race, gender, region, and income) was within a 3% margin of the distribution reported in the 2010 US Census data. CR had the highest utility value (0.875), followed by post SCT short-term recovery (0.398), relapse (0.355), no CR (0.262), and SCT (0.158). Of the key AEs, serious infection leads to the highest decline in utility by 0.218, followed by severe diarrhea (0.176), abnormally low blood cell counts (0.100), and redness/skin peeling (0.060). **CONCLUSIONS:** AML and treatments can be associated with a reduced quality of life and impaired ability to perform daily activities. The level of impairment depends on health status, including SAEs experienced during treatment. Findings from this study supported DCE methodology as a valid approach to obtain societal preference values for treatment-related health states.

PSY82

CLINICAL CHARACTERISTICS AND HEALTH STATE UTILITIES IN PATIENTS WITH TRANSTHYRETIN FAMILIAL AMYLOID POLYNEUROPATHY IN BRAZIL

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OBJECTIVES: To obtain clinical characteristics and quality of life data using an international rare disease registry to inform development of a cost-effectiveness model for treatment of transthyretin familial amyloid polyneuropathy (TTR-FAP) in Brazil. **METHODS:** A retrospective analysis of data from the ongoing, international Transthyretin Amyloidosis Outcomes Survey (THAOS), a rare disease registry for transthyretin amyloidosis, was conducted (cut-off date: January 14, 2016). Descriptive analyses were performed on subject data collected during clinical evaluations using a variety of standard assessments, including a neurological examination that allows derivation of a Neurological Impairment Score-Lower Limb (NIS-LL), ambulatory status (for disease staging), and patient-reported health status (EQ-5D-3L). **RESULTS:** An overall total of 1,205 symptomatic subjects were included, most with the Val30Met mutation (N=970). Data were available for 93 Brazilian subjects, the majority of whom had the Val30Met mutation (N=88). Derived NIS-LL scores increased (worsened) with longer disease duration. For the transitions between the three Coutinho-based disease stages, cut-offs for the derived NIS-LL scores were established using the 25th and 75th percentiles of the second stage (46 and 63, respectively). Similar to the overall sample, Brazilian subjects with the Val30Met mutation were primarily in stage 1 (N=55, 71%) with fewer subjects in stages 2 (N=15, 19%) and 3 (N=8, 10%). EQ-5D-3L health state utilities calculated with Brazilian tariffs showed similar decrements with advancing stage in the Val30Met mutation group [mean (SD); stage 1: 0.70 (0.19), stage 2: 0.44 (0.18), and stage 3: 0.10 (0.20)] and other mutations group [stage 1: 0.68 (0.21), stage 2: 0.40 (0.16), and stage 3: 0.05 (0.11)]. **CONCLUSIONS:** Brazilian TTR-FAP subjects are similar to the overall THAOS registry cohort and exhibit lower quality of life as the disease worsens. Global disease registries such as THAOS play an important role in characterizing health status in rare diseases like TTR-FAP.

PSY83

EXPLORATION OF NURSES KNOWLEDGE REGARDING PAIN MANAGEMENT IN POST-OPERATIVE PATIENTS IN QUETTA PAKISTAN

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OBJECTIVES: The Study aimed to explore Nurses knowledge regarding pain management in post-operative patients in Quetta Pakistan. **METHODS:** A cross-sectional descriptive study was conducted in post-operative patients of various hospitals of Quetta. Data obtained from 194 STEMI patients' during August to October 2016 by using self-designed proforma which consist of vital signs, prescribed drugs, positive and negative outcomes. Statistical analysis was done by using SPSS version 20. Descriptive and inferential statistics used where applicable. **RESULTS:** Result showed that majority of nurses (n=139 (66.8%)) were staff nurse having 1-10 years of experience in hospitals. Majority of nurses 70.95% incorrectly answered regarding giving of narcotics on a continuous timetable is favored over a pro schedule for regular pain. 89.05% showed incorrect response that constant calculation of pain and medication efficiency is must for good management of the pain. 86.67% showed incorrect response that patients feeling pain can bear large doses of narcotics without respiratory depression or sedation. 88.57% nurses stated wrong response regarding she should contact the physician, if a patient still feels pain despite giving medication. **CONCLUSIONS:** Study concluded that most of the responses regarding pain management was incorrect by nurses, hence, it will be helpful to assess the efficiency of quality improvement steps such as training programs on nurses' knowledge, attitudes, and subsequent practices in pain management which ultimately results in better patient outcomes regarding pain management.

PSY84

ESTIMATING HEALTH STATE UTILITIES FOR PATIENTS WITH ACUTE MYELOID LEUKEMIA

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OBJECTIVES: To develop clinically validated health states (HS) for acute myeloid leukemia (AML) and to assign utility values based on preferences of the general UK population. **METHODS:** This study followed NICE guidance for generating HS utility values and comprised two stages: (1) AML HS were drafted based on evidence from a literature review of AML clinical and health-related quality-of-life studies (published January 2000–June 2016). A panel of UK hematologists with AML experience validated the clinical relevance and accuracy of the HS. (2) Validated HS were valued in an elicitation survey with a representative UK population sample using the time trade-off (TTO) method (the primary outcome) and also the visual analogue scale (VAS) as a secondary outcome to estimate preference values. **RESULTS:** Eight HS were developed and clinically validated: treatment with chemotherapy, consolidation therapy, transplant, graft-vs-host disease (GVHD), remission, relapse, refractory, and functionally cured. In total, 125 subjects participated (mean age, 49.6 years [range, 18–87 years], 52.8% female). Mean (95% CI) TTO preference values (n=120), ranked from lowest (worst health state) to highest (best health state) were: refractory –0.11 (–0.21 to –0.01), relapse 0.10 (0.00–0.20), transplant 0.28 (0.20–0.37), treatment with chemotherapy 0.36 (0.28–0.43), GVHD 0.43 (0.36–0.50), consolidation 0.46 (0.40–0.53), remission 0.62 (0.57–0.67), and functionally cured 0.76 (0.72–0.79). Mean (95% CI) VAS preference values followed the same rank order, ranging from 0.15 (0.13–0.17) for refractory to 0.71 (0.68–0.73) for functionally cured. **CONCLUSIONS:** To our knowledge, this is the first study to report utility values for AML from the UK societal perspective. Although utility values were quite low, subjects were able to distinguish differences in severity among AML HS and clearly recognized the seriousness of the disease. Preference values were consistent with clinical perception of HS severity.

PSY85

DETERMINANTS OF PATIENT AND PHYSICIAN TREATMENT SATISFACTION IN MODERATE TO SEVERE PSORIASIS: A MULTINATIONAL ASSESSMENT

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OBJECTIVES: To explore disease severity and Dermatology Life Quality Index (DLQI) score as determinants of patient and physician treatment satisfaction, comparing patients across treatment groups in the US and European Union Five (EU5) countries. **METHODS:** This is a retrospective study of eligible adult patients with psoriasis and their consulting Dermatologists from the 2015 Adelphi Psoriasis Disease Specific Program (DSP). Patients' self-reported responses for the DLQI, a validated questionnaire of 10 items with a composite score of 0–30, used to measure quality-of-life (QoL). Higher scores indicate more severe QoL impairment. Physicians and patients self-reported treatment satisfaction, and physicians reported severity using Body Surface Area (BSA) measurement. Study groups considered included patients receiving no therapy, topical/phototherapy, conventional systemic agents, and biologic therapies. Statistical analyses controlling for patient and physician demographics and clinical characteristics were conducted. **RESULTS:** 1,651 patients (23.9% US and 76.1% EU5) and 282 physicians completed paired responses. From the patient sample, 44.6% were female, and mean age and DLQI score were 44.6 years and 5.2, respectively. From the physician sample, 45.6% were female and median time in practice was 14 years. Median baseline BSA involvement for patient respondents was 18%. Patients satisfied with biologics showed lower DLQI scores (Mean: 3.21; 95%CI: 2.85–3.56) compared to patients not satisfied with biologics (Mean: 9.11; 95%CI: 8.29–9.93). Itching, soreness, pain, and stinging of the skin contributed most to overall DLQI score among unsatisfied patients. Comparing across treatment groups, patients not satisfied with current therapy had mean DLQI scores ranging from 8.9–13.25 after treatment. Greater proportions (75–93%) of unsatisfied patients across treatment groups had a BSA of moderate to severe psoriasis (BSA > 3%) after treatment. **CONCLUSIONS:** Patients unsatisfied with current treatment reported higher DLQI scores/worse QoL and higher BSA severity across treatment groups, which may indicate that there remains an unmet medical need for psoriasis patients.

PSY86

ASSESSING THE EXPERIENCE OF RECEIVING OBESITY MEDICATION THROUGH TELEMEDICINE: DEVELOPMENT OF A PATIENT REPORTED SURVEY

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OBJECTIVES: Telemedicine allows for a two-way, real time interactive communication between the patient and the physician at a distant site in order to diagnose conditions and prescribe treatments. Technology advancements have made telemedicine more common, particularly when addressing healthcare access issues associated with isolated populations. This study sought to develop a questionnaire to assess the overall patient experience and perceived quality of care of those seeking pharmacological obesity treatment via telemedicine vis-à-vis usual care. **METHODS:** A multi-phased study was conducted in the United States, which included concept evaluation, item generation, and cognitive interviewing. Adhering to ISPOR Good Research Practices, desk literature was reviewed and physicians (N=3) were interviewed to develop a draft survey to assess the patient experience of seeking pharmacological obesity treatment. Patients who were evaluated and diagnosed with obesity and recently received a prescription weight loss medication via enrollment in a savings card program were invited to participate in two rounds of cognitive interviews (N=10). **RESULTS:** Desk research

and physician interviews suggested concepts relating to convenience of meeting with a physician, the environment of the (physician-patient) interaction, interpersonal manner of the physician, quality of the interaction, value of the interaction, and overall satisfaction. These concepts were confirmed during the cognitive interviews with no new concepts uncovered. Respondents improved wording of items by emphasizing the importance of the physician asking "appropriate" and "non-judgmental" questions and knowing "how to consult on obesity issues" with patients, rather than just being medically knowledgeable about obesity. Patients also emphasized the importance of capturing the entire process (inclusive of obtaining the prescription itself), rather than just the physician-patient interaction. **CONCLUSIONS:** This study provided sufficient content validity for the newly developed patient experience questionnaire. Future research can implement this instrument to evaluate the patient experience of seeking pharmacological obesity treatment through telemedicine or usual care.

PSY87

ADEQUACY OF CANCER PAIN MANAGEMENT AND PAIN INTERFERENCE WITH DAILY FUNCTIONING AMONG PATIENTS VISITING ONCOLOGY WARD OF AN ETHIOPIAN UNIVERSITY

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OBJECTIVES: we aimed to assess adequacy of cancer pain treatment, its subsequent interference on functioning and the associated factors in the oncology ward of Gondar University Hospital(GUH). **METHODS:** This is a cross-sectional study conducted from February 15 to May 15, 2016 in the oncology ward of GUH. A questionnaire-based interview using Brief Pain Inventory-Short form (BPI-sf) and chart review were used as data collection procedures. **RESULTS:** Of 83 patients, 76 (91.6%) cancer patients experienced pain with varying degree of severity. Fifty four (65%) patients were receiving inadequate cancer pain treatment with negative PMI. Of 76 cancer patients with pain, 68(89.2%) experienced pain interference with their daily activities. Educational level, metastasis status, number and types of analgesics for adequacy of cancer pain management, where as stage of tumor, presence of metastasis, history of treatment modality, history of pain and pain management adequacy for pain interference on patient's daily functioning were identified as statistically significant predicting factors. **CONCLUSIONS:** It is vital to anticipate and assess pain of the cancer patients as routine clinical practice to optimize analgesic therapy through identifying and intervening barriers of adequacy of pain management, thereby improving patient health outcome and quality of life.

PSY88

VALUE OF TRANSFUSION INDEPENDENCE IN SEVERE APLASTIC ANEMIA FROM PATIENTS' PERSPECTIVES - A DISCRETE CHOICE EXPERIMENT

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OBJECTIVES: Aplastic anemia is a rare (600–900 US cases/year), serious blood disorder due to bone marrow failure to produce blood cells. Transfusions are used to reduce risk of bleeding, infection and relieve anemia symptoms. In severe patients, transfusions may be required more than once/week. The study aimed to elicit patient preferences for attributes associated with severe aplastic anemia (SAA) treatment, including transfusion independence. **METHODS:** An online discrete choice experiment (DCE) was conducted among patients with SAA who experienced insufficient response to immunosuppressive therapy (IST) and transfusion dependence for ≥3 months in the past 2 years. Recruitment occurred through an International Foundation and clinical sites. The DCE elicited preferences between hypothetical treatment pairs characterized by a common set of attributes: transfusions frequency, fatigue, risk of infection, and risk of serious bleeding. Conditional logit model with effects coding was used to estimate part-worth utilities for different attribute levels and assess the relative importance of each attribute. Predicted utility scores for transfusion frequency levels were reported. **RESULTS:** Thirty patients completed the survey. Most were age ≥40 years (73%), female (70%), and from the US (87%). 33% underwent bone marrow transplant; 37% received iron chelation therapy. Patients largely agreed that transfusion independence would bring less burden on time and costs, greater control and quality of life, less fatigue (87% noted each) and less scheduling around medical appointments (83%). The DCE found highest relative importance for risk of bleeding (0.30), followed by risk of infection (0.28), fatigue (0.23), and frequency of transfusions (0.20). More frequent transfusions resulted in lower utility, particularly increasing monthly transfusions frequency from 4 (0.57) to 8 (0.35). **CONCLUSIONS:** Among SAA patients with insufficient response to IST, estimated utility was higher with fewer transfusions. While risk of bleeding, risk of infection, and fatigue were more important for patient treatment preferences, frequency of transfusions was also important.

PSY89

PATIENT AND PHYSICIAN PREFERENCES IN SELECTING A BIOLOGIC FOR MODERATE-TO-SEVERE CROHN'S DISEASE

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OBJECTIVES: To understand the relative importance Crohn's Disease (CD) patients and gastroenterologists place on treatment-related attributes when selecting a biologic for moderate-to-severe disease. **METHODS:** Two 30-minute online surveys were designed, pre-tested and fielded with 152 moderate-to-severe CD patients and 200 gastroenterologists. Preferences were assessed via a discrete choice experiment (DCE) where respondents made twelve treatment preference choices with three hypothetical

CD treatments per choice set. Each treatment profile in the DCE varied on: efficacy in non-biologic (standard therapy) failure, efficacy in TNF- α therapy failure, active treatment remission rates, onset of induction response, reduction/elimination of corticosteroid use, route of administration, induction and maintenance dosing frequency, black box warning, and prior authorization and staff time required. Data were analyzed using conditional multinomial logit regression. Overall relative importance (RI) of attributes was the difference between the highest and lowest relative preference weights for each attribute. **RESULTS:** Among patients, 'efficacy in non-biologic failure' was the most important driver (RI: 0.75 moderate, 0.50 severe CD). 'Black box warning' was the second most important attribute for moderate CD (RI=0.51), and 'reduction/elimination of corticosteroid use' for severe CD (RI=0.39). The third most important attribute was 'reduction/elimination of corticosteroid use' for moderate CD (RI=0.43), and 'active treatment remission rates at 12 months' for severe CD (RI=0.28). Among gastroenterologists, 'efficacy in non-biologic failure patients' was the most important driver of treatment choice for moderate and severe CD (RI=0.99 and 0.97, respectively), followed by 'reduction/elimination of corticosteroid use' (RI=0.70 and 0.71, respectively), and 'black box warning' for moderate CD (RI=0.63) and 'active treatment remission rates' for severe CD (RI=0.65). **CONCLUSIONS:** Patients and gastroenterologists prefer similar attributes when making treatment decisions across severities with 'efficacy in non-biologic failure patients' the most important attribute suggesting that both prefer access to the most effective biologic after failing standard (non-biologic) therapy.

PSY90

ADVANCING THE MEASUREMENT OF TREATMENT PREFERENCES IN DUCHENNE MUSCULAR DYSTROPHY

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OBJECTIVES: Parent Project Muscular Dystrophy (PPMD) has been a leader in the measurement of treatment preferences for pediatric rare diseases by demonstrating the value of using relatively simple stated-preference methods such as best-worst scaling (BWS) and conjoint analysis. We tested the feasibility of several advanced approaches (including discrete-choice elicitation (DCE) format, incorporating treatment uncertainty, quantitative measure of risk and use of risk grids, and measurement of maximal acceptable risk) to measure the preferences of patients, caregivers, and professionals for treating Duchenne muscular dystrophy (DMD). **METHODS:** A novel DCE was developed using a vignette focused clinical-trial data and comparison to placebo. Benefits were described as (qualitative) changes in muscle strength and harm was described as the probability that the treatment would not work, risk of kidney damage, and increase risk of fracture. Respondents, recruited at PPMD's annual meeting, received 14 choice tasks identified using an orthogonal experimental design. Preferences were estimated using maximal acceptable risk estimated via the delta method in STATA. The Wald and Swait-Louviere test was used to assess differences in preferences and scale. **RESULTS:** We had 161 respondents (RR=38%) including 9 patients, 87 caregivers, and 65 professionals. Aggregate result indicated that the maximal acceptable risk for improved muscle function could be described in terms of a 21.7% increase that the drug would not work ($P < 0.001$), a 9.0% increase in the risk of kidney damage ($P < 0.001$), or a 26.0% increase in fracture risk ($P < 0.001$). Patients were the least risk tolerant ($P < 0.001$), a difference not attributable to scale ($P < 0.001$). **CONCLUSIONS:** We provide clear evidence that more advanced stated-preference methods can be applied in pediatric rare disease such as DMD. We also demonstrate that value of these methods in making move policy relevant metrics such as maximal acceptable risk and demonstrate how they can be used to explore preference heterogeneity.

PSY91

FATIGUE IN SYSTEMIC LUPUS: THE ROLE OF DISEASE ACTIVITY AND ITS MEDIATORS

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OBJECTIVES: Systemic Lupus Erythematosus (SLE) is a chronic autoimmune disease that leads to a variety of negative health outcomes resulting from inflammation in various organ systems. Though treatment continues to advance, fatigue remains one of the highest-rated, unaddressed patient complaints. Understanding the mechanisms of fatigue can help guide appropriate interventions to improve overall outcomes. The aim was to evaluate if insomnia, depression, pain, and physical functioning mediated the relationship between disease activity and resulting fatigue in individuals with SLE. **METHODS:** 110 ethnically-diverse, primarily female participants (90%) with SLE, receiving care at university medical centers, completed assessments of disease activity, psychosocial factors, and quality of life outcomes (FACIT-FT, Insomnia Severity Index, Pain Inventory, PHQ-9). All patients met ACR classification criteria for SLE. Multiple mediation analysis was conducted utilizing the INDIRECT macro for SPSS which limits parameter bias when assessing for several mediators at once (Preacher & Hayes, 2008). **RESULTS:** Mean(SD) age was 40(14.10) years; 52% reported being African American, 23% Caucasian, 13% Hispanic, and 5% Asian. A multiple mediation analysis was conducted to assess the effects of disease activity on fatigue, through the effects of depression, pain, insomnia, and physical functioning. Disease activity (SLEDAI, Mean=4.89, SD=4.43) was significantly related to fatigue symptoms (FACIT-FT, M=18.30, SD=12.25). Results indicated that depression was a significant mediator of the effects of disease activity on fatigue, [β =.219, BCa 95% CI(.013, .574), $p < 0.01$], in that adding the mediating variables to the model, the relationship between disease activity and fatigue was no longer significant, [(without mediators) $b=0.648$, $p < 0.05$; (with mediators) $b=-0.058$, $p > 0.05$]. Insomnia (M=9.26, SD=7.37, $\beta=.138$, $p > 0.05$), pain (M=5.93, SD=3.57, $\beta=.215$, $p > 0.05$), and physical functioning (M=81.40, SD=25.23, $\beta=.135$, $p > 0.05$) were not significant mediators in this relationship. **CONCLUSIONS:** Fatigue is a major issue among

individuals with SLE. Depression mediated the effects of disease activity on fatigue. Interventions aiming at depression in addition to controlling disease activity may be useful to improve fatigue and overall outcomes in individuals SLE.

PSY92

PATIENT-REPORTED OUTCOME (PRO) INSTRUMENT DEVELOPMENT FOR CONGENITAL THROMBOTIC THROMBOCYTOPENIC PURPURA (CTTP, UPSHAW-SCHULMAN SYNDROME [USS], HEREDITARY THROMBOTIC THROMBOCYTOPENIC PURPURA, hTTP)

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OBJECTIVES: Hereditary thrombotic thrombocytopenic purpura (hTTP) (severe ADAMTS13 deficiency) is characterized by microangiopathic hemolytic anemia, thrombocytopenia, and diverse clinical signs and symptoms. Prophylactic plasma infusions are typically administered every 2-3 weeks to reduce the incidence of acute events and less severe manifestations. Need exists for an hTTP-specific patient-reported outcome (PRO) tool to assess patient burden and treatment outcomes, as existing tools do not adequately capture the range of hTTP symptoms and impacts. The objective is to develop a disease-specific instrument to measure salient symptoms and impacts of hTTP. **METHODS:** A conceptual model of hTTP symptoms and impacts was developed through an iterative process of literature review and interviews with hematologists (N=5) and patients (N=11). Items in the model were compared with currently available instruments, including HIT-6, MMSE, PHQ-8 and SF-36, and scales for analogous conditions, to assist in item generation. Two rounds of cognitive debriefing patient interviews (N=10) were conducted to revise the tool. **RESULTS:** Many of the salient symptoms and impacts in the conceptual model are not captured by comparator instruments. The newly-developed instrument contains 26 items measuring the intensity of patient-reported symptoms and impacts. It includes fatigue and pain types (11-point numerical scales) over the past 24 hours; bruising (numerical scale), symptoms of cognitive impairment, vision problems, and headache (Likert scales of frequency) over the past 7 days; impacts of symptoms (daily activities, depression, anger, irritability, frustration, anxiety, mood swings; Likert scales of frequency) over the past 7 days; and treatment experiences (numerical and Likert scales) over the past 2 weeks. **CONCLUSIONS:** This is the first PRO instrument developed to assess the salient symptoms and impacts of hTTP. Cognitive debriefing interviews conducted with patients confirmed the instrument is appropriate, comprehensive, and understandable. It provides information regarding burden of disease and may be useful in assessing outcomes of treatment.

PSY93

RELIABILITY AND VALIDITY EVALUATION FOR A PATIENT-REPORTED SYNDROME SCALE: BLOOD-STASIS SYNDROME (PRS-BSS)

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OBJECTIVES: We have established a self-rating scale for a patient-reported syndrome scale: blood-stasis syndrome (PRS-BSS). This study aims to evaluate reliability, validity of PRS-BSS in order to provide a clear quantitative tool for the patients with blood stasis. **METHODS:** A cross-sectional study was conducted for data collecting. 80 participants were recruited including 50 patients with blood stasis and 30 healthy ones. 20 patients were randomly selected to fill the same scale again after 24 to 48 hours for retest reliability. The content mainly includes: the time required to complete inventory, basic demographic information such as general information. The internal consistency reliability was measured by Cronbach's coefficients. The validity of the PRS-BSS were examined by content validity, construct validity and criterion validity. The content validity was measured by completion rate, ceiling and floor effect. The construct validity was measured by factor analysis. **RESULTS:** The PRS-BSS had extremely good accepting rate and completion, 92.6% of the patients completed the questionnaire. The scale was composed of 4 dimensions (activity, sleep, mood, and aggravation), and 10 items. The retest reliabilities of summary and 4 dimensions are 0.954, 0.921, 0.877, 0.863, 0.941. The Cronbach's coefficients were 0.829, 0.813, 0.614, 0.675, respectively. The correlation coefficient of each entry and the total score were higher than 0.4. KMO test results is 0.747, Bartlett ball test shows that P is less than 0.000, comply with the requirements for factor analysis. It showed 5 factors and the contribution rate reached 80%. The results showed that the structure is clear, consistent with the theoretical framework of setting. **CONCLUSIONS:** The final PRS-BSS is from the perspective of the patient's own, and easy to accept. It is proved to have a good reliability, validity in the clinical curative effect analysis.

PSY94

INCORPORATING PATIENT INPUT IN SELECTING PATIENT REPORTED OUTCOMES INSTRUMENTS FOR CLINICAL STUDIES IN MULTIPLE MYELOMA

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OBJECTIVES: To conduct a literature review and concept elicitation interviews generating supportive evidence for multiple myeloma (MM) clinical trial PRO selection incorporating direct patient disease experience. **METHODS:** A provisional conceptual model was developed from a literature review (2005-2015) of studies which included signs, symptoms, and functional impacts of MM. Concept mapping was against EORTC QLQ-C30, EORTC QLQ-MY20, FACT-MM, FACT-Anemia, FACIT Fatigue Scale, and BFI. A qualitative, cross-sectional study confirmed key symptoms and impacts from the literature review. Concept elicitation telephone interviews were conducted with 10 US patients (4 sites) using a semi-structured discussion

guide. Thematic content analysis on interview transcripts was performed using qualitative software (ATLAS.ti). Results were incorporated into the concept mapping exercise and the conceptual model was revised. **RESULTS:** In 44 articles, 21 symptoms/signs and 23 functional impacts were identified. 13/44 studies used EORTC QLQ-C30 for symptom and functional impacts. Interview sample included newly diagnosed (5), relapsed refractory (RR; 4), and maintenance (1) non-Hispanic White patients (mean 65 years; range 52-78). Patients endorsed all 23 impacts and 22 symptoms, 16 were in the literature and 6 were new. 90% endorsed fatigue, pain; 70% endorsed bone pain, back pain, pain elsewhere, hematologic abnormalities. EORTC QLQ-C30 covered 10 symptoms/17 impacts; EORTC QLQ-MY20 an additional 7 symptoms/4 impacts. FACT-MM included comparable symptoms, and 19 impacts but no activities of daily living (ADLs or IADLs) unlike EORTC-QLQ-C30. FACT-An and FACIT Fatigue covered anemia and fatigue-related symptoms and impacts more than other instruments including BFI. **CONCLUSIONS:** EORTC QLQ-C30 generally supported the conceptual model with enhanced coverage with MY20. Endorsement of fatigue by newly diagnosed and RRMM patients indicates that this is not treatment-related alone. This population could benefit from FACT-An or FACIT Fatigue Scale in future trials to provide better coverage. Quantitative research will further enable PRO selection to fit the purpose of clinical studies.

PSY95

A QUALITATIVE ANALYSIS OF DISEASE BURDEN IN PATIENTS WITH ACUTE INTERMITTENT PORPHYRIA AND RECURRENT ATTACKS

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OBJECTIVES: Acute intermittent porphyria (AIP) is a metabolic disease characterized by acute attacks that result in nervous system dysfunction and can lead to hospitalizations and debility. The objective of this qualitative research was to elicit concepts about symptom experience and impacts from patients living with AIP who experience recurrent attacks (defined as ≥ 4 attacks per year). **METHODS:** Patients were enrolled after meeting eligibility criteria and giving informed consent. Patients completed a telephone interview in which they responded to open-ended questions about AIP, the symptoms experienced, and the impact of these symptoms and of treatment on their lives. Interviews were anonymized, transcribed and qualitatively coded. The inductive coding approach targeted textual data related to AIP symptoms, impact, and treatment. **RESULTS:** The mean age of the 19 patients interviewed was 40 years old; 15/19 were female and 11/19 used hematin prophylactically. Patients reported 0-20 attacks (mean: 9.5) in the prior 12 months. Based on patient responses, AIP attacks were defined as the rapid onset of unmanageable symptoms that prevent the performance of daily activities and may lead to hospitalization. Patients reported a total of 113 symptoms; 78 occurred during an attack and 35 between attacks (chronically). Pain was the most frequently reported symptom during attacks ($n=19$), followed by nausea ($n=16$), and vomiting ($n=15$). The majority of patients ($n=15$) reported chronic symptoms outside attacks, most commonly pain ($n=15$). All patients reported that their symptoms impacted their lives, with the greatest negative impact on sleep, work/education, personal finances, mobility and socialization. **CONCLUSIONS:** Data from these qualitative interviews highlight the high burden of disease in patients living with AIP that experience recurrent attacks. Importantly, AIP is not just an intermittent disease as its name implies, but has chronic manifestations (most commonly pain) that, along with attacks, negatively impact multiple domains of patients' lives.

PSY96

BURDEN OF DISEASE IN RETT SYNDROME: A QUALITATIVE ANALYSIS AND DEVELOPMENT OF A CONCEPTUAL MODEL

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OBJECTIVES: Rett syndrome is a rare neurological disorder, requiring lifelong 24-hour care. Beyond its clinical symptoms, it poses a significant physical, psychological, social and financial burden on individuals and their families, which can have a detrimental impact on quality of life. However, relatively few studies have examined the extent of this burden. The aim of this study is to qualitatively describe the burden of disease in individuals with Rett syndrome and their caregivers. **METHODS:** A targeted literature search was conducted to identify qualitative research examining the impact of disease on individuals and/or caregivers. Studies were reviewed to identify reported clinical symptoms and impacts, contributing to overall burden of disease. This information will be supplemented with findings from ongoing qualitative interviews with caregivers (N=15) and healthcare professionals (N=5). Due to the nature of the disease, caregivers are uniquely placed to provide an understanding of the burden of disease on individuals with Rett syndrome, and on themselves. Healthcare professionals add a clinical perspective. The interviews will be analyzed using a thematic analysis. The results of the literature review and interviews will be summarized in a conceptual model of the burden of Rett syndrome. **RESULTS:** Five qualitative papers were identified from the 383 search results. Most studies focused on one specific impact of Rett syndrome (e.g. hand movements), with

only two studies assessing the broader burden of disease. Both were limited to either patient or caregiver burden; neither examined the broader burden on both groups. The interview results are expected in spring 2017. **CONCLUSIONS:** This will be the first study to provide an overview of the factors influencing burden of disease in both individuals with Rett syndrome and their caregivers. The conceptual model will provide a useful tool to inform the development of future questionnaires, including a large-scale international burden of disease survey.

PSY97

POSTOPERATIVE PAIN PERCEPTION AFTER OPEN, LAPAROSCOPIC VS. ROBOTIC-ASSISTED INGUINAL HERNIA REPAIR

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OBJECTIVES: This study aimed to compare patients' perceived postoperative pain after robotic-assisted inguinal hernia repairs (R-IHR) vs. open IHR (O-IHR) vs. laparoscopic IHR (L-IHR). **METHODS:** A retrospective survey was conducted among patients who had O-IHR, L-IHR and R-IHR in the past 12 months. Patients were recruited from a national marketing research panel and 10 surgical practices across the United States. A questionnaire, including a 0 to 10 pain scale, was used to assess pain level perception, interruption of daily activities, and time to return to normal activity. T-tests and Z-tests were performed between R-IHR vs. L-IHR and vs. O-IHR, respectively. Sub-analyses were performed for patients age \leq / $>$ 60, having/not having previous IHRs and using/not using pre-operative pain medication. **RESULTS:** The study included 214 O-IHRs, 214 L-IHRs, and 98 R-IHRs. Of them, 35.4% had a previous IHR, and 39.2% took pain medication before surgery. R-IHRs had significantly lower perceived pain level (4.0 ± 2.9 vs. 6.5 ± 2.7 score), less perceived disruption of daily activities (6.2 ± 3.0 vs. 7.6 ± 2.0 score), less time between surgery and stopping prescription pain medication (8.9 ± 11.3 vs. 14.2 ± 18.8 days) than O-IHRs. Similar patterns were observed among patients aged $>$ 60, among those having previous IHRs and among those using pre-operative pain medications. A significantly higher proportion of R-IHR patients reported having only one follow-up visit than O-IHR patients (54% vs. 34%). Compared to L-IHR, significantly lower perceived pain (4.0 ± 2.9 vs. 4.8 ± 2.8 score) and fewer days from surgery to stopping prescription pain medication (8.9 ± 11.3 vs. 11.8 ± 13.5 days) were observed in R-IHR. For patients having previous IHRs, post-operative perceived pain level and duration of pain medications were significantly lower in R-IHR than L-IHR. All p-values were $<$ 0.1. **CONCLUSIONS:** Robotic-assisted IHR is associated with lower post-operative pain perception, less disruption of daily activities, and shorter duration of pain medicines compared to open or laparoscopic. Further prospective studies are needed to determine the long term patient benefits.

PSY98

PATIENT REPORTED OUTCOMES (PROS) ARE SUBJECT TO INTERPRETATION ERRORS: PATIENTS' UNDERSTANDING OF HOW TO REPORT PAIN SEVERITY OVER A PERIOD OF TIME

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OBJECTIVES: To determine if people understand a sample instruction from a PRO on pain severity. Patient reported outcomes (PROs) are often primary endpoints in clinical trials, serving to determine treatment safety and/or efficacy. In clinical trials for pain treatments, it is important to accurately determine pain severity to assess treatment efficacy. If data are unreliable, due to variability resulting from subject interpretation errors, results will be unreliable. **METHODS:** 485 people responded to an online survey. People were asked to select one of three answers to the following: "If you were participating in a clinical trial that asked you to report how severe your pain was on a daily basis, you should report." **RESULTS:** 436 people responded to the question. Significantly more people (66.7%) chose the wrong answer ($\chi^2=22.6$, $p<0.001$); 42.7% (186 people) selected "Average the pain you had throughout the day and report the average," while 24.1% (105 people) selected "The pain level that you are experiencing when you record the pain rating" and 33.3% (145 people) of respondents answered correctly that they should report "The pain level at its worst point." Selecting only those who reported "pain" diagnoses, 61.8% (126 of 204 people) chose the wrong answer ($\chi^2=12.8$, $p=0.002$). Results were similar for those who previously participated in clinical trials, even though 90.6% felt they understood a lot or completely understood what to do. **CONCLUSIONS:** These findings suggest that people often fail to understand instructions and concepts they are being asked to report on. When patients fail to interpret the PROs as intended and use various criteria when responding, variability is introduced impacting data quality. Failure to train subjects on instructions and concepts could lead to the erroneous assumption that data are reliable. Our findings support the need for custom training on PROs in clinical trials.

PSY99

EXPLORING THE SIGN AND SYMPTOM EXPERIENCE OF BARTH SYNDROME IN ADULT AND ADOLESCENT POPULATIONS

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OBJECTIVES: Barth Syndrome (BTHS) is a rare genetic condition with a variable expression of symptoms. This research aimed to better understand BTHS signs/symptoms in adolescent (ages 15 years and younger) and adult populations (ages 16 years and older). **METHODS:** Concept elicitation interviews (CEIs) were conducted with adolescent ($n=18$) and adult ($n=15$) patients and caregivers ($N=33$) to identify and describe the signs/symptoms that characterize the BTHS experience. In open-ended, face-to-face interviews with trained researchers, subjects discussed their condition-related experiences. Transcribed interviews were coded and analyzed and results were summarized in two BTHS conceptual models for each the adolescent and

adult populations. **RESULTS:** A total of 57 BTHS sign/symptom concepts were reported across samples (N=33) with saturation analyses confirming adequacy of sample size for each. Adolescents most frequently reported fatigue/tiredness (n=17, 94.4%), cardiomyopathy (n=14, 77.8%), muscle weakness (n=14, 77.8%), eating small quantities (n=11, 61.1%), and physical developmental delay (n=10, 55.6%). Fatigue/tiredness (n=9, 50.0%), headache (n=4, 22.2%), eating difficulty (n=3, 16.7%), and muscle weakness (n=3, 16.7%) were rated as the most bothersome symptoms. Adolescents most frequently reported muscle weakness (n=10, 88.9%) and fatigue/tiredness (n=8, 44.4%) as important to improve with treatment. Adults (n=15) most frequently reported fatigue/tiredness (n=15, 100.0%), cardiomyopathy (n=13, 86.7%), muscle weakness (n=12, 80.0%), neutropenia (n=12, 80.0%), and infection (n=9, 60.0%). Fatigue/tiredness (n=7, 46.7%), muscle weakness (n=6, 40.0%), and neutropenia (n=3, 20.0%) were rated as the most bothersome symptoms. Adults most frequently reported fatigue/tiredness (n=13, 86.7%) and muscle weakness (n=9, 60.0%) as important treatment targets. **CONCLUSIONS:** Though there were some differences, results suggest symptomatic similarities in the experience of BTHS as an adolescent and as an adult and, moreover, that both patient populations would find treatment meaningful if it targeted and reduced fatigue/tiredness and muscle weakness.

PSY100

MODELING JOINT STATUS AND OTHER FACTORS ASSOCIATED WITH PERCEPTION OF PAIN SEVERITY/INTERFERENCE AND FUNCTIONAL IMPAIRMENT IN US ADULTS WITH HEMOPHILIA: ANALYSIS OF THE PAIN, FUNCTIONAL IMPAIRMENT, AND QUALITY OF LIFE (P-FIQ) STUDY

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OBJECTIVES: To assess factors associated with pain and functional capabilities independent of hemophilia-related arthropathy. **METHODS:** US adults with hemophilia completed patient-reported outcome instruments to assess pain (Brief Pain Inventory, BPI), functional impairment (Hemophilia Activities List, HAL), and quality of life (EQ-5D-5L). Physiotherapists optionally completed joint evaluation (Hemophilia Joint Health Score, HJHS). The association of BPI scores and HAL with HJHS and other covariates was examined using simple regression models and by a multiple regression model where HJHS, age, hemophilia severity, and treatment were included with other covariates having bivariate correlations with BPI/HAL scores ($\alpha < 0.05$) using forward selection. **RESULTS:** Of 381 adults enrolled, 240 had complete HJHS scores (median age 32, 64% severe hemophilia, 9% hemophilia with inhibitors). In simple regression, higher EQ-5D-5L pain/discomfort score had strong association with worse BPI outcomes, but this association did not remain when adjusted for other covariates. For BPI pain-severity (R-squared=0.422) and BPI pain-interference (R-squared=0.386), the most consistent significant predictors of worse outcomes after adjusting for HJHS were non-employed status, use of opiates, and anxiety/use of anxiolytics. For HAL overall score (R-squared=0.700), the most significant predictors of worse outcomes after adjusting for HJHS were older age, non-employed status, more severe hemophilia (with inhibitor patients as most severe), BPI pain-severity, and higher EQ-5D-5L pain/discomfort. EQ-5D-5L anxiety/depression and use of anxiolytics/antidepressants/opiates were significant in simple regression only. Sensitivity analysis removing hemophilia severity lowered R-squared values for BPI (severity 0.38, interference 0.36) but not for HAL. **CONCLUSIONS:** Independent of joint status, employment, anxiety, and depression were associated with both pain and functional abilities; pain severity was also associated with functional abilities. The predictive power of the studied covariates was higher for functional outcomes than pain, possibly due to the closer correlation of objective joint status with reported disability, and increased day-to-day variability of pain.

PSY101

EXPLORING AND DOCUMENTING THE SIGNS, SYMPTOMS, AND IMPACTS OF PRIMARY MITOCHONDRIAL DISEASE

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OBJECTIVES: Primary mitochondrial disease (PMD) is characterized by a variety of signs/symptoms that can negatively impact patients' daily lives. This research aimed to describe the key PMD signs/symptoms and disease impacts from the perspective of PMD patients. **METHODS:** Concept elicitation interviews were conducted with PMD patients (N=20) to identify and better understand the signs/symptoms and impacts that characterize the disease experience. In open-ended, one-on-one interviews with trained researchers, subjects discussed their PMD experiences and rated the bother of their signs/symptoms. Transcribed interviews were coded and analyzed and results were summarized in a PMD conceptual model. **RESULTS:** Saturation analysis of the 47 PMD sign/symptom concepts elicited from patients confirmed the adequacy of the sample size. Mean age of participants was 42.7 years (SD=13.5), 11 were male (55.0%), and a range of PMD phenotypes were represented. The most frequently reported signs/symptoms were fatigue/tiredness (n=15, 75.0%), impaired vision (n=12, 60.0%), memory problems (n=7, 35.0%), balance problems (n=7, 35.0%), numbness (n=6, 30.0%), headache (n=6, 30.0%), muscle pain (n=6, 30.0%), and muscle weakness (n=6, 30%). Of concepts rated by at least two participants, balance problems and fatigue/tiredness had the highest mean bother ratings (8.5 and 8.09, respectively, on a 0-10 numeric rating scale). All 15 participants who reported fatigue deemed it an important symptom to improve with effective treatment. Though participants reported a variety of ways that PMD impacts their daily life (n=59), the most frequently reported were on ability to work/attend school (n=16), interact socially (n=15), exert oneself physically (n=15), and perform at work/school (n=14). **CONCLUSIONS:** Results confirmed PMD to be a symptomatically bothersome and impactful condition from the perspective of patients with the disease and, moreover, will be of immediate use to researchers and healthcare providers wishing to identify meaningful outcomes for their PMD patients.

PSY102

ACUTE PAIN AND RELATED OUTCOMES IN SURGICAL PATIENTS: RETROSPECTIVE ANALYSIS OF A LARGE US ELECTRONIC HEALTH RECORD DATABASE

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OBJECTIVES: Adequate treatment of acute pain remains lacking in the post-operative setting. The objective of the study was to examine progression in postsurgical pain and association of pain with hospital length of stay (LOS), in a large sample of US surgical patients. **METHODS:** This study examined prospectively collected data from a US electronic health record database (Cerner HealthFacts™). Adult patients who underwent a wide range of surgical procedures (identified via ICD-9 coding) between January 2000 and March 2015 were included in the analysis. Patients were required to have at least one pain score (using a 0-10 numerical pain scale) prior to and following surgery. Baseline pain was assessed as the maximum pain score within 7 days prior to surgery and was used to stratify patients into mild, moderate or severe pain category. Pain on day of surgery and postsurgical days 1-14 was defined as the maximum pain score on each day. **RESULTS:** The study identified 110,145 surgical patients. Patients with severe baseline pain experienced a decrease in pain following surgery from a mean(SD) of 8.9(1.1) pre-surgery to 6.2(3.3) on the day after. Patients with moderate baseline pain experienced minimal changes in pain, from a mean of 5.0(0.8) to 4.4(3.2) of the first day after surgery, and patients with no/mild pain experienced an increase following surgery from a mean pain of 0.7(1.2) to 3.0(3.3). There was an association between the baseline pain category and LOS such that patients with severe pain had, on average, the longest LOS (8.2 days), followed by patients with moderate pain (7.2 days), and no or mild pain (6.8 days). **CONCLUSIONS:** This analysis is suggestive of a needed improvement in management of mild-to-moderate postoperative pain and of a positive association between pre-surgical pain severity and LOS. These findings provide initial insights into potentially relevant risk factors in a broad surgical population.

PSY103

USING EXISTING DATA TO IDENTIFY CANDIDATE ITEMS TO MEASURE HEALTH-RELATED QUALITY OF LIFE IN INDIVIDUALS WITH LOW BACK PAIN

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INTRODUCTION: In low back pain (LBP), the use of health-related quality of life (HRQOL) measures is limited to generic measures; there is no availability of LBP-HRQOL measures. The generic measures may ask questions that are irrelevant for individuals with LBP, which may reduce the accuracy of patients' reports. **OBJECTIVES:** To: 1) identify items best reflecting the domains of HRQOL important to individuals with LBP, and 2) provide evidence for the discriminative capacity of the response options by mapping them onto general health perception. **METHODS:** This study is a secondary analysis of an existing dataset that consisted of 64 items relating to patients' symptoms, functional status, and general health perception. Nine important HRQOL domains were identified in previous work using individual interviews with patients, and by National Institute of Health (NIH). The 64 items were classified into different HRQOL domains by 12 participants using the Delphi method. Item response theory (IRT) was then used to estimate the properties of items for each identified domain in order to select items best reflecting each domain of HRQOL important to individuals with LBP. The best item for each domain was selected according to the distribution of the threshold values across the latent scale and the discrimination value. **RESULTS:** The LBP-HRQOL assessment tool consisted of nine items with three response levels per item. The regression coefficient was consistently decreased between response options and the linear trend test was significant for all selected items. This indicates that the response option for each item had a discriminative capacity for patients' general health perception. The LBP-HRQOL assessment tool showed a good convergent validity at both item level and total score. **CONCLUSIONS:** This study identified the items best reflecting the domains of HRQOL in LBP, forming a LBP-HRQOL assessment tool. The selected items need to be reviewed for clarity by patients and clinicians.

PSY104

HEALTH STATE UTILITY AND QUALITY OF LIFE IN FIRST REMISSION FROM DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL)

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OBJECTIVES: DLBCL is the most common form of Non-Hodgkin Lymphoma. Most DLBCL is successfully treated with immunochemotherapy resulting in long term remission. Although there is some evidence on the impact of therapy on quality of life (QoL), data are lacking on the long term impact of previous DLBCL diagnosis and treatment on QoL. The aim of this study was to describe the health state utility value and determinants of QoL in DLBCL patients in remission who are no longer receiving treatment. **METHODS:** UK patients in first remission (> 12 months) from DLBCL were recruited via a lymphoma patient organisation and a patient recruitment agency in this cross-sectional, observational, questionnaire based study [NCT02708732]. Utility scores were calculated from the EQ-5D-5L and quality of life was assessed using the FACT-Lym. Utility scores were compared to published UK population norms. **RESULTS:** 91 patients (69% female) were recruited into the study with a mean age of 50 years (range= 21-77). The mean utility for the patient population was 0.78 (range -0.01-1.00; SD 0.24). Patients most frequently reported problems in the EQ-5D Pain and Discomfort and Anxiety and Depression domains. The mean FACT-Lym score was 114 points (SD 31.37; maximum possible score 168). The items of the FACT-Lym Lymphoma-specific domain with the worst scores related to tiredness, worry and emotional distress and pain. **CONCLUSIONS:** Our study describes the real world utility values reported by DLBCL patients in first remission. People in this study report decrements in QoL. They,

although deemed to be in clinical remission, are affected by tiredness, worry and pain. Although people with DLBCL have a high chance of a full cure after treatment, this evidence that quality of life, particularly emotional functioning, is impacted during remission. Further analyses will be conducted to understand characteristics impacting responses and utility values in relation to age adjusted norms.

PSY105

DIFFERENCES IN HEALTH-RELATED QUALITY OF LIFE BASED ON ANALGESIC REGIMENS IN PATIENTS WITH CHRONIC PAIN

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OBJECTIVES: Chronic non-cancer pain can be managed with prescription drugs containing opioids or other analgesics. However, the relationship between analgesic regimens and long-term Health-Related Quality of Life (HRQoL) has not been examined. The objective of this study was to examine the association between various types of analgesic regimens and HRQoL among adults with chronic non-cancer pain. **METHODS:** We used a retrospective longitudinal design for this study with a baseline period (1 year) and follow-up period (1 year). Using the Medical Expenditures Panel Survey data for 2005-2012, patients >21 years with chronic pain conditions and without cancer were identified, and analgesic regimen were classified into: (1) opioid containing, (2) non-opioid containing, or (3) no analgesics. HRQoL was measured with the SF-12 physical component summary (PCS) scores. **RESULTS:** Overall, 26.9% of the sample (n=12,451) received an opioid-containing regimen, 16.2% non-opioid regimen, and 56.9% were not on prescription analgesics. At follow-up, compared to opioid-containing analgesic regimens, non-opioid regimens had higher PCS scores (beta=2.63, SE=0.17, p<0.0001) after controlling for HRQoL comorbidity index score. However, by controlling for baseline PCS score, the difference between opioid and non-opioid regimens in follow up PCS score was diminished (beta= 0.42, SE=0.13, p=0.001). **CONCLUSIONS:** HRQoL was higher when chronic non-cancer pain is managed with non-opioid containing analgesics. The study findings suggest that physicians may need to consider HRQoL while managing opioid therapy for non-cancer pain.

PSY106

LONGITUDINAL ASSOCIATIONS BETWEEN HEALTH-RELATED QUALITY OF LIFE AND HEALTHCARE UTILIZATION IN AL AMYLOIDOSIS

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OBJECTIVES: Light chain (AL) amyloidosis is a rare, complex disease associated with significant organ dysfunction, disability, and death. AL amyloidosis patients interact with the health care system in myriad ways; however, few studies have quantified health care utilization (HCU) in this condition. **METHODS:** A non-interventional, longitudinal online study was conducted among patients with AL amyloidosis who were recruited with assistance from patient advocacy groups. Initial (n=341) and 6-month follow-up (n=226) surveys assessed demographics, disease and treatment characteristics, and health-related quality of life (HRQoL), measured by the SF-36v2® Health Survey physical and mental component summary scores (PCS and MCS). HCU (eg, outpatient doctors' visits, emergency room [ER] visits, hospitalizations, and insurance coverage) was measured during the 6-month follow-up. The prevalence of HCU, including its bivariate associations with patient characteristics, was evaluated. Multivariable logistic regression models were used to test for associations between patient characteristics, HRQoL, and ER visit or hospitalization in the past 6 months. **RESULTS:** Overall, visits with specialists and other health care providers during the previous 6 months were nearly ubiquitous (92.0% and 94.6%, respectively). Collectively, 56.0% of patients reported ≥1 ER visit or hospitalization. ER visits and hospitalizations were not associated with number or type of organ involvement or with duration of disease. There were significant associations between PCS and ER visits (P<0.05) and between both PCS and MCS and hospitalizations (P<0.05 for all) based on multivariable analyses. **CONCLUSIONS:** There is a lack of real-world evidence regarding HCU among patients with AL amyloidosis. This research identified longitudinal associations between HRQoL and HCU, indicating there is potential for using HRQoL surveys as screening tools to predict future HCU for AL amyloidosis patients. The development of prediction models for HCU in AL amyloidosis should consider incorporating HRQoL as well as disease staging and treatment type.

PSY107

STUDY OF QUALITY OF LIFE WITH THE HELP OF IT-TECHNOLOGIES IN PATIENTS WITH HEMOPHILIA

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OBJECTIVES: Since 2007, patients with hemophilia enable treatment of blood coagulation factors in the amount of 5IU per capita, in Europe the figure is about 4, (2 to 11IU in different countries). In 2008-2011, we have examined the patients QoL with hemophilia in Russia, Ukraine and Kazakhstan. Availability of Internet allows you to implement this task with the help of software. In 2015, it was developed a program MeDiCase to assess the QoL of remote villages residents with a smartphone. **METHODS:** The questionnaire, including an assessment of the quality of life for the EQ-5D with a VAS was posted on the web-site of the Russian Society of hemophiliacs (<http://hemophilia2016.tilda.ws/>) **RESULTS:** The web-survey completed by 79 people - about 1.2% of patients receiving therapy with clotting factors on a government program (N=6793): 88%with "A" hemophilia and 12%"B". The average age - 30 years. In large cities live 67%, in small cities 17%, 16%in villages. QoL assessment on the EQ-5D questionnaire revealed that there are no problems with movement in space in 50% of people, small problems -49% extreme problems at 1%. Self-service: no

problems -79% of patients with minor problems -17% extreme problems at 4%. Daily Activity: there are no problems in 51% of patients with minor problems -45% extreme problems at 4%. Pain and discomfort: there are no problems in 25%, small problems -63% extreme problems 12%. Anxiety and depression: there are no problems in 46%, small problems -43% extreme problems -11%. Respondents rated their quality of life (VAS) as a 63(19to100). In 2008, the quality of life (VAS) was exactly 60, patients with the presence of antibodies to coagulation factors - 52. **CONCLUSIONS:** The use of IT-technologies allows patients studies via the Internet, including - with hemophilia, to assess the QoL with the EQ-5D questionnaire.

SYSTEMIC DISORDERS/CONDITIONS – Health Care Use & Policy Studies

PSY108

ALIGNMENT BETWEEN PATIENT-PRIORITIZED SYMPTOMS AND ENDPOINTS USED IN CLINICAL TRIALS: A CASE STUDY ON SICKLE CELL DISEASE

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OBJECTIVES: Recently, the US Food and Drug Administration (FDA) has hosted Patient-Focused Drug Development (PFDD) meetings with the objective of identifying symptoms/impacts on daily living most important to patients and their experiences with treatments. Voice-of-the-Patient (VoP) summary reports are published following each meeting. This pilot study examined whether symptoms prioritized by patients during the sickle cell disease (SCD) meeting (February 2014) were assessed as endpoints for indicated treatments (iTX) and treatments under study (TXus). **METHODS:** Symptoms identified by patients as "most important" were extracted from the SCD VoP report. Product labels and clinicaltrials.gov were used to identify endpoints for iTX, and Phase 2 or 3 trials for TXus over the past 5 years. Endpoints were pooled for treatments with multiple studies. To examine uptake of the SCD VoP information, a sub-analysis was performed for "post-PFDD" studies with initial clinicaltrials.gov dates later than 2015. **RESULTS:** Hydroxyurea is the only SCD iTX (N=1); ten treatments under study (TXus, N=10). VoP reported "most-important symptoms" include: acute pain crises (iTX=1/1; TXus=5/10); chronic pain (iTX=1/1; TXus=4/10); fatigue (iTX=1/10); difficulty concentrating/cognitive issues (none); intolerance to cold/weather changes (none); cardiovascular events (none specifically, adverse events generally); organ damage (TXus=1/10); Chronic leg/skin ulcers (TXus=1/10); Bone/osteopathic disorders (none); Hearing loss (none); Loss of sight/eye issues (none); Pregnancy complications (none); Complications of long-term treatment (none). Four treatments were studied post-PFDD; of these, three included VoP outcomes, including two beyond pain: organ damage (TXus 1/10) and chronic leg ulcers (TXus 1/10). **CONCLUSIONS:** This pilot study demonstrates that PFDD meetings may be having an impact on endpoint selection for trials. As patient engagement becomes more widespread, incorporation of additional patient-prioritized endpoints can be anticipated. Additionally, not all patient-prioritized symptoms are ethical for evaluation during intervention studies and may be good candidates for observational studies.

PSY109

SUGAR-SWEETENED BEVERAGES CONSUMPTION AND PRICE SENSITIVITY AMONG BRAZILIAN ADULTS: IMPLICATIONS FOR OBESITY POLICIES

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BACKGROUND: The prevalence of overweight and obesity has reached alarming rates worldwide in the past 30 years. In Brazil, specially, existing data shows that 1 in 6 Brazilian adults are obese and this number is projected to reach 33% by 2025. Concomitantly to rising obesity, Brazilian citizens have changed their patterns food consumption patterns, raising substantially raising the consumption of sugar-sweetened beverage (SSB) consumption. **OBJECTIVES:** In this context, the challenge of this essay is to estimate the price elasticity for soda and fruit drink in Brazil and the price effects on weight outcomes and obesity prevalence. **METHODS:** The elasticity was measured through a two-part model (TPM) estimated for all sample and different subgroups. The empirical model explains the quantities of SSB demanded as function of its prices and other variables. **RESULTS:** Overall, the results display a smaller prevalence and lower consumption with higher prices. The TPM model predicts a reduction of 348.3g in weekly soda consumption and 4.5g of fruit drink to each one Real increased price. For all sample estimates, price elasticity is -0.61 for soda and -1.32 for fruit drinks, suggesting that a 20% increase in price was associated with a decline of soda and fruit drink in weekly consumption by 12.2% and 26.4%, respectively. This evidence shows a higher sensitivity to price changes for juice drinks than for soda, in spite of the higher consumption of soda. **CONCLUSIONS:** Our main findings suggest that tax policy might be an effective tool to reduce the soda and juice drink consumption and body weight. We also identified that subgroups who consume higher amounts of SSB are relatively more price sensitive and in these cases pricing policies have an expressive potential in reducing SSB consumption and body weight.

PSY110

APPLICATION OF MULTIPLE CRITERIA DECISION ANALYSIS IN PROPHYLACTIC THERAPY ON HAEMOPHILIA A IN CHINA

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OBJECTIVES: Using MDCA approach to evaluate the main attributes impact on the clinical efficacy and analyzes the strengths and weakness between FVIII treatment-on-demand and prophylaxis in order to make consensus building in Chinese clinical key opinion leaders. **METHODS:** Ten attributes are selected to compare the clinical efficacy,

health utility, economic burden and treatment compliance. The weight value was investigated from 31 top hematologists. The total scores and relative ratio in each attribute are calculated by using Microsoft Office Excel software. The number of scores in each attribute is at the range from 1 to 10. **RESULTS:** The important attributes are reducing the number of bleedings, disability rate, and days of absenteeism from work/school, improve quality of life, return back to normal life, study and work (>0.10). However, the factor of reducing inhibitor development and the number of infusing per week is less importance (<0.10). The total scores in treatment on-demand is the lowest one (160.54), low-dose prophylactic therapy is in the middle (234.76), the highest score is standard prophylactic therapy (263.84). **CONCLUSIONS:** MCDA method can be used on clinical decision making on selecting haemophilia therapy. General speaking, the cost of lifelong prophylaxis is much less than that of treatment on-demand. However, in China, although the cost of FVIII treatment on-demand can be reimbursed by basic medical insurance system and catastrophic insurance scheme, it is inequity; the ratio of reimbursement and ceiling threshold various region by region. Prophylaxis therapy is a cost-effective regimen if it can be started in childhood stage. The concept of prophylactic therapy needs to be further dissemination in patients, providers and third-party policy makers.

PSY111

THE EFFECTIVENESS OF THE FDA PRIORITY REVIEW VOUCHER FOR NEGLECTED TROPICAL DISEASES AND RARE PEDIATRIC DISEASES

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OBJECTIVES: To understand how the FDA Priority Review Voucher (PRV) program has incited the development of new treatments for neglected, tropical diseases, and its effect on patient need. **METHODS:** The study employed a pragmatic literature review to determine which diseases experienced an increase in development research, as well as an analysis of the effect on treatment options and algorithms, as well as epidemiology. **RESULTS:** Between 1975 and 1999, less than 1% of newly approved drugs were for tropical diseases. Between 2007-2016, 12 PRVs were awarded; four have contributed to development programmes for tropical diseases, while the remaining eight were awarded for developments in rare pediatric diseases. The rare pediatric diseases that now have a treatment option are Morquio A syndrome, high-risk neuroblastoma, rare bile acid synthesis disorder, hereditary orotic aciduria, hypophosphatase, lysosomal acid lipase deficiency, Duchenne muscular dystrophy, and spinal muscular atrophy. The neglected tropical diseases with newly developed treatment options are malaria, tuberculosis, leishmaniasis, and cholera. Rare diseases affect about 12.5 million pediatric patients in the US, and the use of these new treatments allows for a significant increase in overall survival and quality of life. However, some critics believe this program addresses goals for neither tropical diseases, nor rare pediatric diseases. This is due to the lack of accountability with regard to development and regulatory follow-through. In support of this, manufacturers do not cite an expedited review process as a main consideration for initiating a development in neglected tropical or rare diseases. **CONCLUSIONS:** The PRV program has rewarded the development of 12 new drugs for neglected disease areas. While there are still many rare diseases that lack even one treatment option, and can thus benefit from the priority review voucher program, it is uncertain if the incentive is strong enough for manufacturers to initiate developments in these areas

PSY112

PATIENT ACTIVATION IN INFLAMMATORY BOWEL DISEASE PATIENTS

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OBJECTIVES: To describe the demographic characteristics of inflammatory bowel disease (IBD) patients in different patient activation stages. **METHODS:** A total of 50 adult patients with IBD consented to participate in this prospective study. Convenience sampling was used by the clinic staff in a gastroenterology clinic to select adult IBD patients from medical records who had scheduled office visits from April to August 2016. Selected patients were offered participation in the study. To obtain baseline activation and demographics, patients who agreed were sent an electronic or paper survey consisting of the patient activation (PAM-13) instrument and demographic questions. Responses to the PAM-13 items were converted to a PAM score using the PAM-13 score spreadsheet and the scores were then used to group each patient into one of the four progressive patient activation stages, such that patients in stage 1 generally had no knowledge/skill to manage their health while stage 4 patients were fully active in managing their health. Demographics were analyzed descriptively and compared per activation stage. **RESULTS:** The mean age of patients was 48 years (\pm 18 years) and most were Caucasian (88%), female (64%), college graduates (56%), and had Crohn's disease (59.2%). Half of the patients had an active inflammation and had been diagnosed with IBD for over 5 years. A larger percentage were highly activated with 8%, 14%, 46%, and 32% in stages 1, 2, 3, and 4, respectively. Over 50% of the higher level stage 3 and 4 patients were female, Caucasian, college graduates, and over 40 years old. Demographic and stage comparisons were not significant. **CONCLUSIONS:** Patient activation is an indicator of health behavior and health outcomes. Its routine measurement could provide useful information to healthcare providers to guide customized information exchange with individual patients. This could foster greater patient engagement in health management and enhance the patient-provider interaction.

PSY113

QUALITATIVE STUDY REGARDING THE IMPACT OF HYDROCODONE RESCHEDULING ON GERIATRIC PAIN MANAGEMENT: PRESCRIBERS' PERSPECTIVE

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OBJECTIVES: To qualitatively assess prescribers' perceptions regarding the consequences associated with hydrocodone rescheduling among geriatric patients being discharged from inpatient settings. **METHODS:** Two focus groups were conducted by a trained facilitator via a semi-structured interview in a metropolitan academic medical center in January 2016. Prescribers who manage pain for geriatric patients were recruited to explore the impact of hydrocodone rescheduling on patient care (e.g., transition of care) following discharge. Focus groups were recorded, transcribed and then analyzed using ATLAS.ti Qualitative Data Analysis software. Codes were derived from six primary research questions and results from the focus groups were summarized into key themes regarding the impact of rescheduling. **RESULTS:** Emerging themes included both positive and negative views regarding hydrocodone rescheduling. Physicians expressed concern regarding the required special serialized prescription forms needed to issue schedule II prescriptions in Texas. Issues included substituting hydrocodone with potentially less effective pain medications (e.g., tramadol) and the inability to issue refills on hydrocodone prescriptions. Attending physicians expressed ethical concerns regarding legal questions related to prescribing hydrocodone to patients not under their direct care, since most medical residents and fellows do not have the required serialized prescription forms. Additionally, rescheduling has affected the coordination of pain management care upon discharge, as patients moving to long-term care or skilled nursing facilities may not have adequate pain management when transferred. Prescribers mentioned that they review the prescription monitoring program (PMP) more often before prescribing opioids after rescheduling. **CONCLUSIONS:** A majority of physicians felt rescheduling negatively impacted both practical and ethical aspects of patient care related to pain management. Meanwhile, rescheduling has changed physicians' hydrocodone prescribing patterns, leading to more caution when prescribing hydrocodone and greater use of the PMP. Future studies should assess geriatric patients' satisfaction and quality of life regarding pain management since hydrocodone was rescheduled.

PSY114

ORPHAN DRUG PRICING: DIFFERENCES BETWEEN US AND EUROPE, INFLUENCING FACTORS AND FUTURE DIRECTIONS

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OBJECTIVES: Orphan drugs market access landscape has changed rapidly over recent years. This research aims to provide an update on OD pricing environment between US and Europe, and investigate differences, influencing factors and future trends. **METHODS:** Recent OD analogues were assessed covering different therapy areas. Market-specific pricing websites (EU5 and US) and reports from HTA bodies were analysed to understand their price level and reimbursement decisions. Payers (1-2 per market) were interviewed to validate the insights from secondary research. **RESULTS:** Price differences of ODs between US and Europe vary, depending on disease / product-related factors and market dynamics. Not all ODs have higher price in US compared to Europe. Some of the ODs (e.g. Vimizim) have similar price in Europe as US, while for other ODs, the price differences are 2-3 folds (e.g. Opsumit). Even within Europe, the price of ODs is not uniform. Several factors impact the price differences of ODs between US and Europe. For ODs with substantial benefits esp. in debilitating diseases with no/limited treatment options currently, their prices tend to be similar between US and Europe. But for ODs with no/small incremental benefits where other treatment options already exist, their prices tend to be lower in Europe vs. US. In the future, ODs will face increasing scrutiny from payers and discussions already started in Europe to re-examine the pathways for ODs. In the US, mixed messages have been given post presidential election, raising further uncertainties for OD pricing in the US. **CONCLUSIONS:** There will be increasing demand on ODs to justify their prices as healthcare systems are under increasing budget pressure. Flexible pricing with innovative contracting agreements / managed entry agreements will become increasingly important for ODs to address data uncertainties and support access in Europe and US.

PSY115

DIFFERENCES IN OPIOID UTILIZATION BETWEEN COMMERCIALLY INSURED AND TRADITIONAL MEDICAID FOR LOW INCOME ADULTS

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OBJECTIVES: Opioid-related deaths and overdoses have paralleled increases in opioid prescribing, however the influence of health payers on opioid prescribing is unclear. Under the Affordable Care Act, Arkansas expanded coverage to poor and near poor by enrolling persons into qualified health plans (QHPs) or Medicaid based on frailty level and income. This study sought to compare opioid use, chronic opioid use, and geographic variability in opioid use between individuals enrolled in Medicaid and QHPs. **METHODS:** Administrative claims data of newly enrolled subjects with at least six months of continuous coverage in 2014 were analyzed. Chronic use was defined as having at least ten opioid prescriptions over a minimum period of 90-days. A regression discontinuity design using a frailty-score which assigned subjects to Medicaid or QHPs was used to estimate the plan effect on opioid use and chronic opioid use. **RESULTS:** The final sample comprised of 151,429 individuals with a mean age of 39.78 years, 59.07% females, and 24.69% and 4.64% had a mental health and substance use disorder. There were 21,899 persons enrolled in FFS Medicaid and 129,530 in QHPs. Rates of opioid use among Medicaid and QHPs were 50.11% (49.44% - 50.77%) and 38.96% (38.69% - 39.22%) respectively. Chronic use rates among opioid user for Medicaid and QHPs were 19.97% (19.22% - 20.72%) and 13.25% (12.96% - 13.55%) respectively. Any opioid use was highest in the South-Central region (44.96%) and lowest in the North-West (36.19%). The regression discontinuity model showed that any opioid use

(OR = 0.905, $p=0.128$) and chronic opioid use (OR = 0.973, $p=0.891$) did not differ between QHPs and Medicaid. **CONCLUSIONS:** Overall, high rates of opioid use and chronic use were found, which did not differ by Medicaid or QHP enrollment. Opioid use and chronic use only showed modest variability across geographic regions in the state.

PSY116

ASSESSING THE IMPACT OF HYDROCODONE RESCHEDULING ON OPIOID PRESCRIBING USING PRESCRIPTION MONITORING PROGRAM DATA

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OBJECTIVES: Patients, healthcare providers, policymakers, and payers are intent on finding solutions to the opioid epidemic in the US. One solution enacted by the Drug Enforcement Administration in 2014 was to reschedule hydrocodone combination products (HCPs) from C-III to C-II. This change was aimed at restricting the availability of the most commonly prescribed prescription in the US. The objective of this study was to assess the immediate change in opioid utilization at the time of rescheduling, focusing on the substitution of HCPs with acetaminophen/codeine (APAP/codeine, C-III) and tramadol (C-IV), using prescription monitoring program (PMP) data. **METHODS:** An interrupted time-series design was used with data from the Texas PMP spanning June 1, 2013 to April 8, 2015. The PMP captures all controlled substance prescriptions (C-II – CV) dispensed from outpatient pharmacies. An interrupted time series design was employed to address the study objective. Opioids were grouped into four categories: 1) HCPs; 2) other C-II opioids; 3) APAP/codeine; and 4) tramadol. Each prescription was converted to daily morphine milligram equivalents (MMEs) per 100 population for analysis. **RESULTS:** The total number of prescription opioids dispensed was 30,745,113. Most were for HCPs (67.4%), followed by all other C-II opioids (12.1%), APAP/codeine (10.1%), and tramadol (10.4%). At the time of rescheduling, the mean utilization of opioids (in daily MMEs per 100 population) decreased from 67.4 to 45.2 (-32.9%) for HCPs, increased from 1.4 to 5.0 (271.5%) for APAP/codeine, and increased from 3.1 to 11.0 (256.2%) for tramadol. After rescheduling, the rate of change of APAP/codeine utilization increased by 0.06 daily MMEs per 100 population per day. **CONCLUSIONS:** Rescheduling resulted in increased use of APAP/codeine and tramadol. HCP use was restricted, as intended. The unintended consequences of increased heroin usage and potential negative impacts to patients' quality of life should also inform future policy.

PSY117

PRICE TRENDS OF ORPHAN DESIGNATED HEMOPHILIA DRUGS IN THE UNITED STATES

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OBJECTIVES: To assess price trends of hemophilia A and B drugs in the United States in the period January 1, 1992 to October 9, 2016. **METHODS:** A list of drugs approved for hemophilia A and B were obtained from the Food and Drug Administration web page from January 1, 1983 to October 9, 2016. Pricing data from January 1, 1992 to October 31, 2016, for the compiled drugs, were extracted from RedBook (Truven Health Analytics). Prices were adjusted for inflation. **RESULTS:** A total of 9 manufacturers are responsible for the commercialization of 21 proprietary drugs; 15 drugs are indicated for the treatment of hemophilia A and 6 for hemophilia B as of October 9, 2016. For hemophilia A plasma drugs, initial flat price trends upon market entry were observed with an AWP per unit range from \$0.75 to \$0.92. For hemophilia A recombinant drugs, the initial market AWP hovered below \$2.00, until 2013, when 3 new human plasma derived drugs were launched in the US drug market. Over time, these three new drugs alone, increased in price by an average of 54%. On average, recombinant drugs for hemophilia A escalated by 12% over a period of 14 years. Hemophilia B Plasma drugs entered the market in 1992 within an AWP per unit of \$0.06 and had an average cumulative price increase of 56% over 14 years. Hemophilia B recombinant drugs also increased over time at an average of 28%. **CONCLUSIONS:** The prices of hemophilia drugs at market entry increased overtime. Prices of marketed drugs increased faster than inflation. The rising price trend in hemophilia drugs may be largely due to changes in treatment regimens that support prophylactic utilization of hemophilia drugs versus on demand treatment, small number of competitors, R&D cost, and limited drug pricing regulations.

PSY118

TREATMENT COVERAGE FOR ACUTE AND CHRONIC BACK PAIN: A PILOT STUDY

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OBJECTIVES: To determine the extent of coverage for opioids and other pharmacological and nonpharmacological treatments for low back pain, we examined coverage policies for 63 pharmacologic and 12 non-pharmacologic treatments for low back pain in Medi-Cal, California's Medicaid program, Anthem, a large private insurer and CVS Caremark, a large pharmacy benefit manager. **METHODS:** We assessed the extent of and barriers to coverage using Medi-Cal's Contract Drug List, Anthem's 4-Tier National Formulary and CVS Caremark's Value Formulary for medication coverage, and provider manuals and medical policies for coverage of non-pharmacologic treatments. **RESULTS:** Of 63 prescription drug products for back pain, Medi-Cal covered 23 (37%) products, Anthem covered 52 (83%), and CVS Caremark covered 30 (48%). Medi-Cal and Anthem covered roughly the same number of opioids as non-opioids, while CVS Caremark covered twice as many non-opioids as opioids. Eighteen (29%) products were covered by all three payers and 8 (13%) were not covered by any, totaling 26 (41%) products unanimously covered or not covered across all three programs. Prior authorization was more

frequently required for Medi-Cal non-opioids (31%) and CVS opioids (50%) than for other payers and product groups. Quantity limits were very often imposed for opioids. Among non-pharmacological therapies, Medi-Cal covered occupational therapy, acupuncture and chiropractic care up to 2 visits per month. Anthem covered a modestly greater variety of non-pharmacological treatments with fewer limits on the number of visits covered. Neither Medi-Cal nor Anthem covered treatments such as biofeedback, transcranial magnetic stimulation, cognitive behavioral therapy, or yoga. **CONCLUSIONS:** Coverage is an important driver of utilization of specific healthcare services. Our analysis found substantial variability in the coverage of non-opioid pharmacologic and non-pharmacologic treatments for low back pain among these payers. Coverage restrictions may diminish the use of alternatives to opioids in settings where such alternatives have a favorable risk-benefit balance.

PSY119

PRELIMINARY REAL WORLD DATA ON SWITCHING BETWEEN ETANERCEPT AND ITS RECENTLY MARKETED BIOSIMILAR COUNTERPART

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OBJECTIVES: In February 2016, the first etanercept biosimilar (EtnBS) has been launched in Germany, which may represent a cheaper option to the original biologic agent (EtnBA). The objective of this study was to provide initial real-world data on the penetration of EtnBS within the EtnBA market by evaluating switching dynamics between the two drugs in real world clinical practice. **METHODS:** Patients receiving first EtnBS prescription, with or without previous treatment with EtnBA, were retrospectively identified using the Longitudinal Prescriptions database (QuintilesIMS® LRx) between January 2008 (beginning of database) and September 2016 (last available data). The representativeness of the database based upon current population and pharmacy coverage in 2016 is around 60% of the statutory health insurance market. For patients with prior EtnBA treatment, the mean treatment duration prior to switch was reported. In addition, the proportion of those who switched back to EtnBA and the mean time to switch were evaluated. For all patients, the drug device used was recorded. **RESULTS:** A total of 1,536 patients on EtnBS (62% using pens and 38% pre-filled syringe) were identified, of which, 813 (52%) had, on average, around 3 years of prior treatment with EtnBA. Among these, the large majority were using pre-filled syringe (70%) and kept the same kind of device when switching to EtnBS (61%). After changing to EtnBS, a total of 65 patients (8%) switched back to EtnBA after only 2 months. The 72% of the patients who switched back to EtnBA chose the same kind of device (pre-filled syringe). **CONCLUSIONS:** Despite many patients change from etanercept to its biosimilar treatment, 8% switch back to the original biologic agent in the short term. Longer term studies are required to confirm these preliminary results and investigate the reasons for changing back to the original product.

PSY120

COMPARISON OF INTRAVENOUS IRON SALES IN DIFFERENT MEASUREMENT UNITS

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OBJECTIVES: To compare drug utilization estimates by different measurement units – Eaches, Extended Units and Kilograms – using aggregated sales data for intravenous (IV) iron products. **METHODS:** We conducted a cross-sectional study using IMS Health National Sales Perspectives database (2014) to evaluate the utilization of IV iron products using three measurement units: 1) Eaches – number of vials sold, 2) Extended Units – amount of volume sold in milliliters; 3) Kilograms – amount of active ingredient sold in kilograms. The use of each IV iron product was calculated as a proportion of the number of Eaches/Extended Units/Kilograms of each IV iron product as the numerator with the total number of Eaches/Extended Units/Kilograms of all IV iron products as the denominator. **RESULTS:** The utilization patterns varied by measurement units. Irrespective of the measure used, iron sucrose and ferric gluconate were the first and second most sold products, and ferric carboxymaltose was the least sold product. The ranks of the proportion of sales of ferumoxytol and iron dextran differed by measurement unit. The ranking of sales for iron dextran and ferumoxytol remained the same (third and fourth respectively) for the Eaches and Kilogram units. However, the estimated proportion of sales of iron dextran in Extended Units (4.06%) ranked lower than the estimate for ferumoxytol in Extended Units (5.29%). The estimated proportion of sales of ferumoxytol in Eaches (1.25%) was only one fourth of the estimate in Extended Units (5.29%) and one sixth of the estimate in Kilograms (7.58%). Similarly, the estimated proportion of sales of ferric carboxymaltose in Eaches (0.31%) was approximately one fourth of the estimate in Extended Units (1.26%) and one tenth of the estimate in Kilograms (3.03%). **CONCLUSIONS:** Estimates of drug utilization using aggregated sales data largely depend on the measurement unit selection, as well as the characteristics of the product in consideration.

PSY121

REAL-WORLD DOSING AND PATIENT CHARACTERISTICS OF RECENTLY APPROVED RECOMBINANT FVIII THERAPIES IN HEMOPHILIA A PATIENTS

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OBJECTIVES: To evaluate real-world patient characteristics and treatment regimens in patients with hemophilia A using recently approved rFVIII therapies in the US, based on specialty pharmacy dispensing records. **METHODS:** A retrospective analysis

was performed using a database composed of aggregate, de-identified US Specialty Pharmacy Provider (SPP) records from July 2014 through November 2016. Patients eligible for this analysis had received ≥ 1 shipment of a recently approved rFVIII factor therapy. Recently approved factor therapies were defined as therapies approved in 2014 or later, which includes: ELOCTATE, ADYNOVATE, ALFSTYA, NUWIQ, KOVALTRY, and NOVOEIGHT. Patients were categorized based on their age, regimen and prescribed dosing frequency. Analysis of prophylactic regimens included only ELOCTATE and ADYNOVATE because of the low number of patients on other therapies. **RESULTS:** A total of 1174 patients with hemophilia A of unknown severity were included in this analysis. Forty-three percent of patients were > 18 years of age, 41% were 18-39, and 16% were > 40 ; average weights were 39kg, 84kg, and 84kg, respectively. Most patients were treated with a prophylaxis regimen (88%) with the remaining being treated on-demand (12%). ELOCTATE (71% of patients) was the most frequently dispensed therapy followed by ADYNOVATE (17%), NOVOEIGHT (8%), KOVALTRY (2%), NUWIQ (2%), ALFSTYLA (0%). The most commonly prescribed prophylactic infusion frequency was twice weekly, representing 48% of patient records. Patients on ELOCTATE (37%) were more likely to have an infusion frequency longer than twice weekly than patients treated with ADYNOVATE (13%). **CONCLUSIONS:** Recently approved rFVIII therapies have been prescribed for a large number of patients with hemophilia A in the United States. ELOCTATE is the most frequently utilized of these rFVIII therapies based on SPP dispensing records. Patients prescribed ELOCTATE and ADYNOVATE achieved extended prophylactic infusion frequencies. Those on ELOCTATE therapy were more likely to be prescribed an infusion frequency longer than twice weekly.

PSY122

LOCAL ANESTHETIC ACTIVITIES OF NEW PIPERIDINE DERIVATIVES ON THE INFILTRATION ANESTHESIA MODEL

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OBJECTIVES: Identify local anesthetic activity of new derivatives of piperidine (LAS - local anesthetic substances) - LAS-202, LAS-203 and LAS-204 - for infiltration anesthesia. **METHODS:** The studies of infiltration anesthesia were conducted on guinea pigs by methods of Byulbring and Wade in 0,25% solutions, acute toxicity was investigated on white mice. Experimentally determined the strength of action and duration of anesthesia. **RESULTS:** Most local anesthetic activity noted in LAS-202, which power of action was equal to trimecaine, significantly exceeded lidocaine by 1.4 times, and novocaine by 1.3 times. The duration of complete anesthesia of LAS-202 is equal to trimecaine, and exceeds lidocaine and novocaine. Total duration of the local anesthetic effect of LAS-202 is significantly higher than trimecaine by 1.39 times, 1.79 times that of lidocaine, and 1.83 times that of novocaine. The index of anesthesia of LAS-203 and LAS-204 approaches the corresponding parameter of trimecaine. The complete skin insensitivity of guinea pigs in the administration of compounds is few shorter than that for trimecaine, equal to lidocaine, and longer than novocaine. The total duration of the LAS-203 is 1.06 times more than trimecaine, but LAS-204 more by 1.2 times. LAS-203 and LAS-204 exceeded the corresponding index of lidocaine by 1.3 times and 1.5 times, respectively, but exceeded novocaine by 1.4 times and 1.6 times, respectively. The LD50 of tested compounds are in the range of 425 mg / kg - 472.3 mg / kg. **CONCLUSIONS:** Of greatest interest is the compound LAS-202, which in force and duration of complete anesthesia is equal to trimecaine and exceeds lidocaine and novocaine. In general duration of action, it is superior to all the reference drugs and belongs to the low-toxic group of drugs. Therefore, LAS-202 is recommended for further studies.

PSY123

PAIN MEDICATION (OPIOID AND NON-OPIOID) USE AMONG TEXAS MEDICAID ENROLLEES WITH SICKLE CELL DISEASE

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OBJECTIVES: To describe pain medication use among Texas Medicaid enrollees with sickle cell disease (SCD) and to determine the factors predicting opioid use. **METHODS:** This was a retrospective study using Texas Medicaid claims data from 9/1/11-8/31/15. Medication use of patients who were ≤ 62 years, had at least 1 hydroxyurea prescription, and had at least 1 inpatient or 2 outpatient SCD diagnoses during the study period were analyzed between 6 months before and 1 year after the first prescription of hydroxyurea. Descriptive statistics and logistic/poisson regressions were conducted to determine the prevalence of pain medication use and to identify predictors of opioid use, respectively. **RESULTS:** A total of 1,025 patients (18.0 \pm 12.6 years) met the inclusion criteria. Of these, 935 patients (91.2%) had pain medication(s) during the study period. A total of 883 patients (86.1%) had at least one opioid prescription and the mean opioid prescriptions per person was 13.0 \pm 14.0. Among opioid medications, 21.3% were among the strongest opioids such as morphine, hydromorphone and fentanyl and 78.7% were less strong opioids including codeine, hydrocodone and tramadol. NSAIDs were the most frequently prescribed non-opioid medication for pain management of SCD patients (92.4%). Poisson regression showed that the number of hydroxyurea prescriptions, female, older patients, and African American were significant positive predictors of the number of pain medication prescriptions. Logistic regression showed that adult patients (≥ 18 years) were 6.691 times more likely to have at least one opioid prescription than pediatric patients (< 18 years) while controlling for other covariates ($p < 0.001$, OR=6.691; 95% CI: 2.628-17.033). **CONCLUSIONS:** Appropriate use of pain medications is important for the management of the acute painful crisis that is a major contributor to the costs for the patients with SCD. Pediatric pain management should be addressed to assess if they receive appropriate care for their pain crises.

PSY124

ACUTE PAIN OUTCOMES FOLLOWING ORTHOPEDIC AND ABDOMINAL SURGERY

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OBJECTIVES: US national survey data indicates that acute postsurgical pain is inadequately relieved in patients and multiple studies report a high prevalence of moderate to severe pain following surgery. The objective of this study was to examine acute pain outcomes, including hospital length-of-stay (LOS), medications, and pain scores, following orthopedic and abdominal surgery using retrospective data for a large cohort of adult patients. **METHODS:** Using an electronic health record database with information from 614 hospitals across the US (Cerner Health Facts®), we evaluated trends in pain measurement, treatment, and outcomes associated with acute postsurgical pain management (n=1,581,795 adult patients from 2009-2015). The analysis included orthopedic (ICD9 codes of 76-84.X, 00.7-00.8) and abdominal surgery (ICD9 codes of 42.X-71.X) patients. Patients included in the analysis had to have at least one recorded pain score (0 to 10 scale) before and after surgery. Pain score, hospital LOS, and type of medications received were examined. **RESULTS:** Pre and post-operative pain was examined in orthopedic (n=328,893) and abdominal surgery (n=719,428) patients. Mean hospital length-of-stay was similar between the two surgery groups (4.6 and 4.7 days for abdominal and orthopedic surgery, respectively). Following surgery, 58% of patients undergoing abdominal/pelvic surgery were treated with polytherapy (more than one type of pain medication administered) for pain and 79% of orthopedic surgery patients were treated with polytherapy (vs. monotherapy). 53% of abdominal surgery patients received multimodal therapy (combination of opioid and non-opioid medications), 40% received opioid-only treatment while 7% received non-opioid only therapy. 77% of orthopedic patients received multimodal therapy while 19% received opioid only and 4% received non-opioid only therapy. **CONCLUSIONS:** Postsurgical length-of-stay is similar between orthopedic and abdominal surgery patient groups. In orthopedic patients, providers rely more heavily on polytherapy and opioid treatment methods to effectively manage pain.

PSY125

RECENT TRENDS IN EMERGENCY DEPARTMENT VISITS RESULTING FROM UNINTENTIONAL OVERDOSE OF NON-OPIOID ANALGESICS, ANTIPYRETICS, AND ANTIRHEUMATICS IN THE UNITED STATES

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OBJECTIVES: Drug-related overdoses result in > 1 million emergency department (ED) visits in the United States (US) annually. The US Food and Drug Administration (FDA) has taken significant steps in recent years to increase awareness about medication safety and reduce risks associated with unintentional drug overdoses. To assess the impact of FDA initiatives, we explored recent trends in ED visits resulting from unintentional drug overdoses, with a particular focus on non-opioid analgesic, antipyretic, and antirheumatic (NOAAA) drugs. **METHODS:** Data from the National Hospital Ambulatory Medical Care Survey (NHAMCS), a nationally representative annual sample of hospital outpatient and ED visits in the US, were analyzed for years 2002-2013. ED visits associated with overdose/poisoning of NOAAA drugs were identified using applicable ICD-9-CM diagnosis and cause of injury codes. Unintentional nature of overdose/poisoning was determined using the intent data collected in NHAMCS. Data were weighted to produce national estimates. Three-year blocks of data were combined into four observation periods (2002-2004, 2005-2007, 2008-2010, and 2011-2013). The rates of ED visits due to unintentional overdoses of NOAAA drugs were assessed per 1,000 all-cause ED visits. **RESULTS:** Total numbers of ED visits resulting from unintentional overdoses of NOAAA drugs during the observation periods 2002-2004, 2005-2007, 2008-2010, and 2011-2013 were 144,946, 146,730, 170,559, and 144,360, respectively. The rate of ED visits for unintentional overdoses of NOAAA drugs was 0.43 per 1,000 ED visits during 2002-2004, which remained fairly constant through periods 2005-2007 (0.42 per 1,000 ED visits) and 2008-2010 (0.44 per 1,000 ED visits), but decreased to 0.36 visits per 1,000 ED visits in the most recent period 2010-2013, representing a relative decrease of 18.2%. **CONCLUSIONS:** This analysis demonstrated a decline in the rate of ED visits for unintentional NOAAA drug overdoses in recent years. These findings suggest that FDA initiatives towards improving consumer awareness and medication safety may be effective.

PSY126

TREATMENT PATTERNS, TREATMENT SATISFACTION, AND TREATMENT SWITCHING IN PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

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OBJECTIVES: To describe biologic use, treatment satisfaction, and switching patterns among nr-axSpA patients. **METHODS:** Data from the 2015 SpA Disease Specific Programme, a cross-sectional, multi-national survey of patients and rheumatologists conducted in France, Germany, Italy, Spain, United Kingdom, and the United States were analyzed. Rheumatologists completed record forms containing information on current treatment therapy, reasons for switching biologics and treatment satisfaction. **RESULTS:** Data from 391 rheumatologists and 1,995 patients with nr-axSpA were included in this analysis. Of the 1,995 patients, 39% were receiving a biologic and no csDMARD, 15% biologic and a csDMARD, 14% csDMARD, 23% NSAIDs, 4% other therapy, and 5% were receiving no therapy. Patients receiving biologic therapy had significantly higher physician-reported severity immediately prior to initiation of the current treatment regimen ($p < 0.0001$) than those patients not receiving biologic therapy. Patients receiving biologic therapy also had significantly higher levels of pain immediately prior to initiation of the current treatment regimen ($p < 0.0001$). Of the 1,047 patients that received a biologic, 89.2% were receiving their first, 8.2% their second and 2.6% their third or more biologic. Of the 114 patients with known reasons

for switching from their previous biologic, 35% switched due to secondary lack of efficacy, in 33% the condition worsened, 24% switched due to poor pain control, and in 25% remission was not achieved. The proportion of patients that physicians categorized as “very satisfied” with their present regimen was significantly higher ($p < 0.0001$) for biologic patients. **CONCLUSIONS:** Biologics are reserved for the most uncontrolled patients as evidenced by severity and the intensity of pain immediately prior to initiation of current regimen. Despite this, biologic patients are associated with the highest levels of physician reported satisfaction. While there is minimal switching of biologics, when this is done, it is usually due to lack of efficacy, lack of pain relief, and effort to accomplish remission.

PSY127

CHANGES IN PRESCRIBING BEHAVIOR FOLLOWING OPIOID DOSING GUIDELINES IN A WORKERS' COMPENSATION POPULATION

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OBJECTIVES: Prescription opioid misuse has increased markedly and is associated with greater medical spending and decreased productivity. Given the association between high daily dose of prescription opioids and negative health outcomes, state workers' compensation boards have implemented policies to reduce the morphine equivalent daily dose (MEDD) prescribed. The study objective is to evaluate the impact of MEDD guidelines among workers' compensation claimants. **METHODS:** Claims data from a large, national workers' compensation insurer were utilized. The treatment group consisted of injured workers from three states with workers' compensation board guidelines implemented in 2012 recommending against prescriptions > 120 mg MEDD—Massachusetts, which developed its own guideline, and California and Utah, which adopted their guidelines from the American College of Occupational and Environmental Medicine (ACOEM). Three comparison states—Illinois, Indiana, and Pennsylvania—were selected based on having similar policy landscapes and opioid utilization trajectories, but no MEDD policy during the study period. Multivariate regression analyses used average mg MEDD post-policy implementation as the outcome. Covariates included demographics, employment status, state fixed effects, and average MEDD pre-policy implementation. Policy indicators and interaction terms between policy indicators and high dose use (> 120 mg MEDD) pre-policy were also included. **RESULTS:** Among 3,799 users, high dose prescriptions were common (12%). There was no significant reduction in daily dose in Massachusetts as compared to control states. There was a small, statistically significant reduction in ACOEM states as compared to the control states (-6.8 , $p < 0.01$). However, individuals who received doses > 120 prior to guideline adoption did not experience larger decreases in MEDD relative to those in control states. **CONCLUSIONS:** MEDD guidelines may not be sufficient to change prescribing behavior. Recent efforts by Medicaid agencies, such as implementing passive alert systems or requiring prior authorization before dispensing high dose opioids may be more effective in reducing high dose prescribing than guideline adoption and warrant further evaluation.

PSY128

DISEASE-STRATIFIED ADHERENCE TO IRON CHELATION THERAPY IN PATIENTS WHO SWITCHED FROM DEFERASIROX DISPERSIBLE TABLETS TO DEFERASIROX FILM-COATED TABLETS

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OBJECTIVES: To assess real-world adherence and persistence to iron chelation therapy (ICT) in patients switching from deferasirox (DFX) dispersible tablet (DFX-DT) to film-coated tablet (DFX-FCT), stratified by disease. **METHODS:** A retrospective pre-post cohort study was conducted in patients switching from DFX-DT to DFX-FCT using pharmacy/medical claims (06/2014 - 05/2016) from the Symphony Health Solutions' Integrated Dataverse (IDV®) database. Eligible patients were ≥ 2 years old, had a diagnosis of sickle cell disease (SCD), thalassemia, or myelodysplastic syndrome (MDS), ≥ 2 DFX-FCT claims (1st claim = index date), and ≥ 2 DFX-DT claims pre-index. Medication possession ratio (MPR) (percentage of time with access to medication) was computed for DFX-DT during the DFX-DT period (1st DFX-DT claim to index date) and for DFX-FCT during the DFX-FCT period (index date to end of observation). Proportion of days covered (PDC) and persistence (without a gap ≥ 30 , 60 days) were assessed over DFX-DT- and DFX-FCT- periods of 3 and 6 months. Comparisons between the two periods were made using Wilcoxon sign-rank tests or McNemar's tests. **RESULTS:** A total of 348, 154, and 106 patients with SCD, thalassemia, and MDS were identified, respectively. Of all patients, 55% were female and 66% aged < 35 years. Across all diseases, PDC and persistence to ICT were consistently higher during the DFX-FCT vs. DFX-DT periods, with the greatest improvement observed among MDS patients: DFX-FCT vs. DFX-DT, mean 3-month PDC: SCD 0.80 vs. 0.68, thalassemia 0.85 vs. 0.77, MDS 0.86 vs. 0.69; 3-month persistence: SCD 82.9% vs. 57.3%, thalassemia 90.3% vs. 71.8%, MDS 91.9% vs. 62.9% (all $p < 0.01$). MPR was significantly different only in MDS patients (DFX-FCT: 0.88 vs. DFX-DT: 0.82, $p = 0.05$). **CONCLUSIONS:** Adherence and persistence to ICT improved significantly after patients with SCD, thalassemia, or MDS switched from DFX-DT to DFX-FCT, with the most notable improvements seen in patients with MDS.

PSY129

A REAL-WORLD STUDY ON TREATMENT PATTERNS AND DOSE TITRATION OF PREGABALIN FOR NEUROPATHIC PAIN

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OBJECTIVES: To describe the patterns of therapy switch and discontinuation in patients receiving pregabalin for neuropathic pain (NeP), and to examine pregabalin dose titration and its impact on treatment adherence and duration. **METHODS:** MarketScan database (2009-2014) was used to extract a cohort of incident adult pregabalin users with NeP who had at least 12 months of follow-up data. Patients who had no pregabalin prescription fill within 90 days at the end of pregabalin coverage were considered to have discontinued therapy, while those with no prescription fill for pregabalin but had other NeP prescription fill were considered to have switched therapy. Adherence [measured by medication possession ratio (MPR)] and persistence (measured as the duration of continuous treatment) were compared between the cohorts with dose titration (dose augmentation within 45 days of the index date) and without dose titration. Logistic regressions and Cox proportional hazards models were used to identify the factors associated with adherence (MPR ≥ 0.8) and predictors of time to switch. **RESULTS:** Among the 5,186 patients in the analysis, approximately 75% discontinued pregabalin or switched to other NeP medication. Median time to discontinuation or switch was 6.2 months. Approximately 7% switched from pregabalin to generic gabapentin and 17% switched to other NeP medication. About half (51%) of the patients discontinued pregabalin and did not switch to other NeP medications. Approximately 18% of patients had dose titration. Patients who had dose titration were less likely to discontinue pregabalin or switch therapy (hazards ratio = 0.91, $p = 0.016$) and more likely to be adherent (MPR ≥ 0.8) (odds ratio = 2.6, $p < 0.001$) than those who did not have dose titration. **CONCLUSIONS:** Three quarters of new pregabalin users discontinued or switched therapy. Pregabalin dose titration was associated with improved adherence and longer duration of therapy.

PSY130

FACTORS INFLUENCING THE CHOICE OF BARIATRIC PROCEDURES

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OBJECTIVES: Laparoscopic roux-en-Y gastric bypass (RYGB) and laparoscopic sleeve gastrectomy (SG) are currently the two most commonly-performed bariatric surgeries. This study used a real-world dataset to examine factors that are associated with the choice between these two procedures. **METHODS:** The study was conducted using the Premier Perspective® Database, which contains a nationally representative sample of discharges from over 600 hospitals in the U.S. Included patients were > 18 years of age and underwent laparoscopic RYGB or SG between January 2014-September 2015. A multivariable logistic regression model, in which the outcome was receipt of RYGB vs. SG (reference), was built with a broad range of predictor variables: patients' demographics, body mass index (BMI), and provider/hospital information. **RESULTS:** A total of 11,948 patients underwent RYGB, and 22,670 underwent SG. Compared to SG patients, RYGB patients had higher proportion in the BMI > 50 category (29.3% vs 24.8%), but lower proportions in the BMI=35-39.9 (16.5% vs 19.2%) and BMI=40-50 (54.2% vs 56.0%) categories. In the logistic regression model, patients with BMI=40-50 and BMI > 50 were more likely to have undergone RYGB, with ORs of 1.190 (95% confidence interval: 1.090-1.298, $p < 0.0001$) and 1.417 (1.231-1.632, $p < 0.0001$), respectively, treating patients with BMI=35-39.9 as the reference group. Other factors associated with an increased odds of undergoing RYGB included female (OR=1.188, $p < 0.0001$) vs. male as reference group, comorbid conditions including diabetes (OR=1.587, $p < 0.0001$), hypertension (OR=1.133, $p = 0.0022$), and depression (OR=1.159, $p = 0.0175$). Factors associated with a decreased odds of undergoing RYGB were older age (age 65-74 [OR=0.741, $p = 0.0283$], age 75 and above [OR=0.426, $p = 0.0366$] vs. age < 45 as the reference group), and comorbid conditions including valvular disease (OR=0.779, $p = 0.0366$), and rheumatoid arthritis (OR=0.708, $p = 0.0175$). **CONCLUSIONS:** This study suggests that BMI level, age, gender, and the presence of selected comorbidities are important factors in whether patients undergo RYGB or SG.

PSY131

LONGITUDINAL ANALYSIS OF RESPONSE, COSTS AND RESOURCE USE OF PATIENTS WITH RHEUMATOID ARTHRITIS INITIATING BIOLOGIC DISEASE-MODIFYING ANTIRHEUMATIC DRUGS (bDMARDs) IN TAIWAN USING THE NATIONAL HEALTH INSURANCE RESEARCH DATABASE

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OBJECTIVES: Rheumatoid arthritis (RA) is an inflammatory disorder associated with significant physical and psychological burden. This study utilizes Taiwan's National Health Insurance Research Database (NHIRD) which is a claims-based database recording all interactions with the National Health Insurance system. This study estimated the percentage of newly treated patients with inadequate response (IR) to biologic disease-modifying antirheumatic drug (bDMARDs). **METHODS:** Data were from the catastrophic illness file within the NHIRD from 1/1/2009 to 12/31/2013. The index period spanned 2010 with 365 day pre- and post-index periods. Biologically naive patients with a healthcare event related to RA and a new claim for a bDMARD were included in this study. Patients were indexed upon their first claim for a bDMARD during the index year. A validated algorithm was used to examine the rate of inadequate response in the biologically-naïve cohort of patients. All-cause mean annual direct costs and resource use were measured in the year of follow-up. **RESULTS:** A total of 818 biologically-naïve patients initiated a bDMARD and were included in the study. At 1 year of follow-up, 66.01% ($n = 540$) were classified as bDMARD inadequate responders, 31.54% ($n = 258$) were classified as confirmed stable, and 2.44% ($n = 20$) were of unknown response status. Inadequate responders had higher mean annual resource utilization in the follow-up year with increases in hospital admissions (0.46 vs. 0.1), hospital days (3.4 vs. 0.49), outpatient visits (42.50 vs. 37.66), and emergency department visits (0.51 vs. 0.3). **CONCLUSIONS:** A significant proportion of patients with RA initiating a bDMARD for the first time showed

an IR to their treatment within a year. Patients with an IR had increased resource utilization and higher non-medication costs than those with stable disease.

PSY132

COST OF PLATELET PURCHASE AND PRODUCTION: A SURVEY OF U.S. HOSPITALS

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OBJECTIVES: Platelet transfusions are commonly utilized to treat or prevent bleeding. Costs associated with platelet production and dynamics of platelet utilization in the hospital setting, however, remain opaque. Objective of this project was to survey U.S. hospital transfusion directors to determine basic facility characteristics and quantity, type, and cost of conventionally-processed platelets (CP) purchased, produced, and/or dispensed. **METHODS:** Survey was developed with input from 2 cost researchers and 2 transfusion directors, and consisted of 29 questions (25 quantitative, 4 qualitative). Sample frame included US hospitals of varied bed size and type. Survey administration occurred by email or telephone, depending on respondent's preference. Responses were analyzed using descriptive statistics. **RESULTS:** 160 invitations were issued resulting in 27 hospital interview completions. Hospital beds ranged from 196 to 1157 (mean 638, SD 307). Nineteen (70.4%) had trauma centers, 6 (22.2%) were pediatric centers, and 6 (22.2%) had a cancer center. Sixteen (59.3%) were located in the northeast geographic census region, 6 (22.2%) in the south, 3 (11.1%) in the midwest, and 2 (7.4%) in the west. All (n=27) purchased at least some of their platelet stock from a blood supplier, with 10 (37%) collecting and manufacturing platelets on-site. Majority of platelets (74%) were transfused in inpatient setting. Mean platelet age at dispensing was 3.6 days (SD 0.6), with over half transfused at >3 days storage. Mean monthly platelets dispensed was 489.5 units (SD 535.2). Mean per-unit CP purchase cost was \$497.92 (SD \$103.29) and mean monthly CP purchase volume was 106.0 (SD 137.3). For those hospitals manufacturing platelets on-site, mean per-unit CP production cost was \$416.09 (SD \$117.08) with mean 50.5 (SD 64.1) CP units produced monthly. **CONCLUSIONS:** Results demonstrate variability in platelet utilization and associated costs among hospitals. Further study involves comparing costs of CP to platelets processed with other methodologies.

PSY133

ALL-CAUSE HEALTH CARE EXPENDITURES AMONG PERSONS WITH SICKLE CELL DISEASE

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OBJECTIVES: This study aimed to assess all-cause health care expenditures among persons with Sickle Cell Disease (SCD). **METHODS:** A retrospective cohort study was conducted using a multi-state Medicaid claims database. Inclusion criteria were being continuously enrolled in a covered health plan from January 1, 2012 through December 31, 2012 and diagnosis with SCD. SCD diagnosis was identified based on having at least one inpatient claim or at least two outpatient claims with ICD-9-CM codes for sickle cell thalassemia with or without crisis, or SCD with or without crisis. There was no explicit exclusion criterion. Mean expenditure and 95 percent confidence intervals (95% C.I.) were calculated for inpatient expenditures, outpatient expenditures, emergency room (ER) expenditures, long-term care expenditures, prescription drug expenditures, and total expenditures. Individuals with SCD and Sickle Cell Crisis (SCC) were identified based on having at least one claim with ICD-9-CM code for SCD crisis. Wilcoxon Mann-Whitney tests were used to assess difference in health care expenditures between groups. **RESULTS:** A total of 8,191 individuals met study SCD inclusion criteria, of which 4,716 (58%) had SCC. The mean (± standard deviation) age was 22.0 ± 17.1 years. A majority of the sample was female (54.4%) and most were African American (74.6%). Mean annual all-cause total health care expenditure was \$16,486 (95% C.I.=\$15,491 to \$17,482). Individuals between 15 and 34 years old tended to have higher expenditures than comparatively younger or older patients. Compared to those without SCC, individuals with SCC had significantly higher mean annual total expenditures (\$20,723 vs. \$10,737, p<0.001), which was primarily due to higher inpatient expenditures (\$11,908 vs. \$2,152, p<0.001) and ER expenditures (\$1,960 vs. \$443, p<0.001). **CONCLUSIONS:** Sickle Cell Disease is associated with high health care expenditures. Individuals with SCD and SCC had much higher health care expenditures compared to those with SCD without SCC.

PSY134

COMPARING PULMONARY ARTERIAL HYPERTENSION-RELATED HOSPITALIZATIONS BETWEEN HYPOTHETICAL COMMERCIAL AND MEDICARE PATIENTS USING A DECISION TREE MODEL

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OBJECTIVES: To compare the effects of macitentan on length of stay (LOS), and cost savings due to averted pulmonary arterial hypertension-related hospitalizations stratified by insurance type, commercial or Medicare, using a decision tree model. **METHODS:** Published references informed the incidence and prevalence of PAH. Published SERAPHIN clinical trial data informed PAH-related hospitalization and mortality rates for placebo. The inputted reduction in hospitalizations was 50% for the macitentan-treated group which is the same for those over and under 65 years of age. Costs for PAH treatments (macitentan, and background therapies sildenafil and iloprost) were inputted from Medispan 2016. Reimbursement costs for hospitalization were calculated by averaging the costs for an initial hospitalization and readmission. For the commercial cohort, the averaged reimbursement cost was \$53,679, and for the Medicare cohort, \$18,994. Average LOS in days was 14.2 for commercial versus 16.7 for Medicare. Both the mean reimbursement costs and mean LOS were obtained from a published analysis of claims data. Total length of stay includes averted hospitalizations and reductions in the LOS. The model base-case analysis assumes constant

mortality rate (2.6%) for the placebo arm. **RESULTS:** In a commercial plan of 20 million-covered lives, 1,473 PAH cases would be eligible for treatment with macitentan, leading to 143 (50% reduction) fewer hospitalizations/year, \$7,694,706 in hospital-related savings, and 3,107 days (76% reduction) in total LOS. In a Medicare plan of 20 million covered lives, 1,386 PAH cases would be eligible for treatment with macitentan, leading to 135 (50% reduction) fewer hospitalizations/year, \$2,561,392 in hospital-related savings, and 3,437 days (76% reduction) in total LOS. **CONCLUSIONS:** Both hypothetical cohorts experienced a reduction in total number and cost of hospitalizations, and length of stay. Due to differences in reimbursement, the commercial group experienced greater hospital-related savings. Further analyses will qualify the effect of macitentan on these outcomes.

PSY135

SYSTEMATIC LITERATURE REVIEW OF THE ECONOMIC BURDEN ASSOCIATED WITH DIFFUSE LARGE B CELL LYMPHOMA AND FOLLICULAR LYMPHOMA

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OBJECTIVES: To identify evidence on the disease and economic burden associated with two major sub-types of Non-Hodgkin's lymphoma: diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL). **METHODS:** Searches were conducted in Medline and Embase (Jan 2012–May 2016) and supplemented with review of conference abstracts (2015–2016). Studies of any design reporting on treatment outcomes and resource use associated with DLBCL or FL, with a sample size ≥50 patients, from the United States (US), European Union 5 (EU5), or Japan were eligible for inclusion in this review. **RESULTS:** Twenty-five studies (13 focused on DLBCL and 12 on FL) from US and EU5 met inclusion criteria, with sample sizes ranging from 50 to 6,425 patients. Patients included in FL studies were younger (median age 58–66) compared to DLBCL (median age 43–83). Hospitalization was reported in several studies (3 DLBCL and 2 FL) as an outcome, resulting mainly from febrile neutropenia in patients treated with rituximab-based immunotherapy. Hospitalization rates ranged from 14% to 32% for DLBCL and 3%–11% for FL over a median follow-up period of 26.6–57 months; in one study a subset of patients were followed for 11 years. Of evidence on costs, using individual level data from the UK's Hematological Malignancy Network, one study estimated that the total medical costs were €23,184 for DLBCL curative treatment and €2,125 for palliative management over a period of 5 years. The other used a Markov cost-effectiveness model to examine treatment strategies in DLBCL, finding sub-type based treatment most cost-effective versus R-CHOP with or without lenalidomide. **CONCLUSIONS:** There is limited evidence published on the overall disease or economic burden of DLBCL/FL, with most literature focused on hospitalization from adverse events. More comprehensive research is needed to assess the impact of DLBCL/FL on patients and healthcare systems.

PSY136

ACQUISITION AND ADMINISTRATION COSTS OF BORTEZOMIB AND CARFILZOMIB TREATMENT FOR MULTIPLE MYELOMA IN FINLAND

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OBJECTIVES: Information regarding intravenous and subcutaneous administration costs of multiple myeloma (MM) medications in Finland is scattered. Nevertheless, the need of acquisition and administration costs for health economic evaluations (HEE) of MM treatments is evident as these costs can be high. Furthermore, the first oral proteasome inhibitor (PI) treatment for MM, ixazomib, is available, potentially allowing reductions in the treatment acquisition and administration costs. We estimated the treatment acquisition and drug administration costs of infusion or subcutaneous PI treatments (carfilzomib, bortezomib) for MM in Finland. **METHODS:** Price tariffs of Finnish hospital districts are used as the basis of invoicing sent to health care service payer. Those prices were collected and analyzed to find costs for the relevant MM treatments. Furthermore, detailed inquiries were sent to all Finnish hospital districts to ensure the face validity of prices included. Two costing perspectives were applied: A) acquisition of treatment (until administered to the patient, i.e. both administration and drug cost included) and B) drug administration alone (administration included, drug costs excluded). **RESULTS:** 19 (95%) of the Finnish mainland hospital districts were included in the data collection. Relevant cost information was found from 15 (75%) districts (79% of the districts willing to participate). The mean acquisition cost was €1 923 (95%CI €1 540 – €2 305) [or \$2 035] per acquisition. The mean administration cost alone was €270 (95%CI €189 – €351) [or \$286] per administration (14% of the acquisition costs). **CONCLUSIONS:** The acquisition and administration of MM drugs given as infusions or subcutaneously in health care facilities cause significant and potentially avoidable costs. Due to the good coverage of providers' cost estimates, the present study provides useful cost estimate information for the future HEEs. Finally, novel oral medications including the first oral PI have significant potential in reducing the acquisition and administration costs.

PSY137

ORPHAN DRUGS TO TREATING RARE DISEASES: THE ITALIAN WAY FOR AN EARLY ACCESS

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OBJECTIVES: Italy has two powerful tools granting early access for patients affected by rare diseases: the Italian off-label/compassionate use procedure, regulated by Law

648/96, and the Law 326/2003 for the reimbursement of orphan and life-saving drugs waiting for the market access. The study assesses the final timeline needed to gain the reimbursed status for orphan drugs, eventually passing over the mentioned steps and describing their impact on time to market. **METHODS:** The study reviews medicinal products designated orphan drugs for rare diseases published by EMA from January 2012 to December 2016 (CHMP opinion date). These data have been interpolated with data from Italian authorization decrees Official Journal (reimbursement decrees and compassionate use decrees) and with regional access data. **RESULTS:** Out of 20 orphan drugs authorized for the first time by the CHMP in the considered timeframe, and afterward valued by AIFA, 8 (40%) obtained the reimbursement status in Italy in a medium time of 505 days. In the meantime, most of them passed over an early access granted by Italian Law 648/96 and/or by the Law 326/2003. Both these tools have guaranteed consistent savings in terms of time to patients (mean 337 days, median 168 days). Since various medicinal products have been authorized with a conditional approval, Managed entry agreement have been defined, in order to assess the real effectiveness in general population. **CONCLUSIONS:** This analysis shows the importance of the Italian structured healthcare system that permits to obtain a faster access to patients with ad hoc legislative keys and to reevaluate, at patient's level, the real effectiveness, that reflects into a calibrated mechanism of the first availability and healthcare expenditure. This process ensures an expenditure monitoring of NHS, to collect additional effectiveness clinical data and to guarantee use of the right drug for the right patient.

PSY138

ACUTE PAIN RELATED LENGTH-OF-STAY AND MEDICATION USAGE FOLLOWING CARDIAC SURGERY

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OBJECTIVES: Studies report a high prevalence of moderate to severe pain following surgery and data indicates that acute postsurgical pain is inadequately relieved in these patients. The objective of this retrospective study was to examine acute pain outcomes, particularly hospital length-of-stay (LOS) and medications administered following cardiac surgery using data from an electronic health record database. **METHODS:** Using a US electronic health record database (Cerner Health Facts®), we evaluated overall trends in pain measurement, treatment, and outcomes associated with acute postsurgical pain management of cardiac patients. Cardiac surgery (based on ICD9 code, 35.X-39.X) patients with at least one recorded pain score before and after surgery were included in the analysis. Hospital LOS and type of medications received were examined. **RESULTS:** Pre and post-operative pain was examined in cardiac surgery patients following surgery (n=367,836 from 2009-2015 for all cardiac surgery; mean age 62.8 yrs). Mean hospital postsurgical length-of-stay was 7.6 days. Following surgery, 74% of patients undergoing cardiac surgery were treated with polytherapy for pain (more than one type of pain medication administered). 71% of cardiac surgery patients received multimodal therapy (combination of opioid and non-opioid medications), 15% of patients received opioids only, and 14% received non-opioid only therapy. In the later stages of postoperative pain treatment (later stage refers to the use of treatment methods at the last time point where pain severity was assessed in the period of 14 days following surgery for each patient), 42% of patients received multimodal therapy, 25% received opioid only, and 34% received non-opioid only. **CONCLUSIONS:** Cardiac patients experience long hospital length-of-stays characterized by post-surgical pain treatment with mostly opioid-based methods. Later in the treatment period, there is a shift towards a less opioid-based pain treatment.

PSY139

BARIATRIC SURGERY – COSTS AND RESOURCES UTILIZATION IN TWO YEARS FOLLOW UP IN THE BRAZILIAN PRIVATE HEALTH CARE SYSTEM

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OBJECTIVES: Many health care systems are evolving to different payment models where they want to include the whole patient treatment in an episode payment. In order to achieve this goal, it is important to know not only procedure costs, but also patient complications and resources consumption costs in a certain period of time. Our main goal was to estimate the costs and resources utilization of bariatric surgery in the perioperative time and two years after the procedure in the Brazilian private health care system reality. **METHODS:** A longitudinal analysis was performed (2013-2015), using hospitalization records and outpatient information from private payers (Orizon). **RESULTS:** Records from 300 hundred patients were analyzed. Patients had 36 years old on average and 80% were female. The average length of stay was 2.25 days. 2.3% of the patients were readmitted in less than 30 days. 15% of the patients visited ER (1.5 visits on average) in the first 30 days post-surgery. 4% of the hospitalizations required ICU. The average patient cost of surgery plus two years follow up was USD 10,000 distributed: USD 7,541 (75%) in the perioperative time and USD 2,459 (25%) in the following two years after surgery. Variability in the post-surgery expenses ranged from USD 100 to USD 63,012. **CONCLUSIONS:** Payment models are moving towards a continuum of care payment where payers are looking for Bundle Payments. Costs variability in two years post-surgery after a bariatric procedure is huge, but on average consumes 25% of the total treatment cost. Payers and hospitals should be careful in order to consider what to include in a bundle payment to keep both financially sustainable. Studies considering more patients are needed to give a broader perspective.

PSY140

HEALTHCARE EXPENDITURES AND PATTERNS OF OPIOID USE FOR NON-CANCER PAIN

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OBJECTIVES: About 20% of the United States (US) population is affected by non-cancer pain conditions (NCPCs). While prescription opioids are used commonly for NCPCs, their use is controversial due to the issues concerning their safety. We sought to: 1) characterize opioid use in US adults with NCPCs (back/neck pain, arthritis, headache/migraine and musculoskeletal pain/neuralgia and 2) estimate direct healthcare expenditures associated with opioid use in NCPCs. **METHODS:** This retrospective cross-sectional study used data from the 2014 Medical Expenditure Panel Survey (MEPS). The study sample consisted of adults with one or more recorded observations of NCPCs (N= 7,497). Chi-square tests were used to examine unadjusted subgroup differences and a multivariable logistic regression model was used to assess the association of opioid use and the type of NCPCs. To compare average healthcare expenditures between opioid users and non-users, we matched the two groups using propensity score matching, and also used generalized linear model (GLM) to adjust for other factors. **RESULTS:** A majority of individuals with NCPC reported arthritis (N=5,266, 70.5%) and 27.4% individuals reported using prescription opioids. Individuals with musculoskeletal pain/neuralgia were more likely to use opioids than individuals with back/neck pain (OR 1.3, 95% CI 1.01-1.64). After matching, opioid users had more than twice the total average healthcare expenditures than non-users (\$13,956 vs. \$6,140). Results from the GLM model showed that the total healthcare expenditures for those using opioids were significantly higher by \$5,042 as compared to non-users (p<0.001). Further, those with arthritis and musculoskeletal pain/neuralgia had significantly higher healthcare expenditures than those with back/neck pain. **CONCLUSIONS:** The majority of opioid use was found among individuals with musculoskeletal pain/neuralgia. The total average healthcare expenditures were significantly higher among opioid users, highlighting the need to better evaluate the appropriate use of opioids for NCPCs in clinical practice.

PSY141

MAIN COMPONENTS OF PUBLIC POLICIES AND FINANCING STRATEGIES ADOPTED BY OECD COUNTRIES TO IMPROVE ACCESS TO DRUGS FOR RARE DISEASES: A SCOPING REVIEW

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BACKGROUND: Since the Orphan Drug Act in United States in 1983, several countries have been implementing courses of action to improve access to Drugs for Rare Diseases (DRD). Despite of the growing body of literature available to describe these efforts, until now, there's no systematic research in place to characterize and compare the wide range of OECD countries activities to accomplish their task. **OBJECTIVES:** Describe the main components of public policies and financing strategies adopted by OECD countries to improve access to DRD. **METHODS:** We carried out a scoping review through its five first stages. Search strategy considered different sources, as electronic databases (Medline, Embase, Cochrane, CINAHL, LILACS, ECONLIT, Web of Science), key journals (Orphanet Journal of Rare Diseases, and Value in Health), grey literature from different institutions (we consult ISPOR Health Authority by Country inventory to identify their web sites in each OECD countries), and reference lists. The search algorithm was build using the work of the ISPOR Rare Diseases Groups of Interest on terms and definitions. Categorization and result analysis were performed using the analytical-descriptive method, considering 3 conceptual frameworks: public policy definition (Subirats, 2008), financing function (Kutzin, 2000), and fourth hurdle systems (Hutton, 2006). **RESULTS:** 85 articles were included in this review, most of them referred to R+D activities in the form of incentives to preclinical and clinical research. More than 50% of the articles detailed variations in coverage decision making process, specifically quality of evidence needed to prove incremental benefits DRD. The European Union and the United States have the highest number of documents describing their policy. **CONCLUSIONS:** There is only a few of countries that actually have adopted policies to improve patients access to DRD (United States, Italy and France). Even in this group there's still work to do to influence the whole pharmaceutical system, therefore improve access.

PSY142

WHO GETS HIGH-DOSE OPIOID THERAPY FOR SICKLE CELL DISEASE RELATED PAIN?

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OBJECTIVES: To assess the prevalence of opioid therapy for pain management among commercially insured patients with sickle cell disease (SCD), and determine population-level characteristics of high-dose opioid users in United States. **METHODS:** The study was a retrospective cohort study using the Truven Health Analytics MarketScan® database. Eligible SCD patients (n=7,561) were identified between 2009 and 2013. Opioid use was determined based on the outpatient pharmacy dispensing records and opioid analgesic doses were converted to oral morphine equivalents (OME). A follow-up period of 24 months after the index SCD diagnosis was studied. **RESULTS:** 2,753 (36.4%) of patients received opioid therapy. The highest prevalence of opioid use was observed in the 20-29 years age group (48.5%). Oxycodone- and hydrocodone-containing medications were the most commonly used opioids. Seventy-five percentage of the pediatric patients (n=821) on opioid medications used 0-2 mg OME per day. In contrast, 32% of the adult patients (n=1,932) had daily requirements above 10 mg OME. In multivariate analyses, hydroxyurea use (OR 7.3, 95% CI 5.0-10.5), NSAID use (OR 5.3, 95% CI 3.9-7.1), and prior history of opioid use (OR 47.3, 95% CI 30.3-74.0) were significantly associated with high-dose opioid use. Patients aged 50 years and older had higher odds of being high-dose opioid users (OR 2.7, 95% CI 1.9-4.0) versus younger patient aged 18-29 years. Venous occlusive crisis (OR 2.5, 95% CI 1.8-3.5) and avascular necrosis (OR 2.5, 95% CI 1.7-3.5) associated with high-dose opioid use. Additionally, 3+ annual emergency department visits (OR 2.7, 95% CI

1.8-4.1), and 2+ annual hospitalizations (OR 2.5, 95% CI 1.6-4.0) were also associated with high-dose opioid use. **CONCLUSIONS:** The high-dose opioid users among adult SCD patients represents a cluster of patients with severe disease requiring more healthcare resources. Optimization of care for this subset of patients with SCD may have the potential to reduce healthcare costs.

PSY143

RARE OR NEXT COMPETITIVE LANDSCAPE

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OBJECTIVES: More than 500 orphan products are in the pipeline. These include precision therapies, novel therapies and gene therapies representing the hope of first time treatments and potential cures. We sought to understand approval success rates and failure reasons that may lead to opportunities for HEOR evidence. **METHODS:** We conducted a targeted review of peer reviewed and grey literature to identify studies to evaluate trends in orphan drug designations, FDA approvals and Complete Response Letters (CRL). **RESULTS:** Since inception of the Orphan Drug Act of 1983, FDA approved 500 products to treat rare conditions. Over 200 orphan drugs were approved in the past decade. In 2015, 50% of new molecular entities (NME) were for rare diseases. This same year, Office of Orphan Product Development received 440 orphan status applications, granted 355, designated 20% as breakthrough status, granted 34% fast track status, and approved 21 NMEs. Not all orphan drug applications are approved despite recognition of unmet medical need in conditions such as, Idiopathic Pulmonary Fibrosis, Huntington's disease, and Fabry disease. CPLs denote product approval and designate failures. In the latter, clear descriptions of evidence required to adequately demonstrate patient benefit is provided. Our study identified the following evidence shortcomings: need for additional efficacy/safety data requiring new phase 3 trials; lack of response reliability; lack of evidence demonstrating patient benefits; inability to achieve sustained thresholds of clinical benefit, and failure to demonstrate expected outcomes. Products utilizing biomarkers and surrogate endpoints not well characterized or linked to clinical response also failed. **CONCLUSIONS:** Outcomes Researchers are well poised to develop much needed RWE that considers the heterogeneity in rare conditions to demonstrate patient benefit. Analyzing PROs by individual domains may provide a clearer picture of initial and durable patient response. Modeling and simulation may accommodate for limited patient populations and augment evidence.

PSY144

ESTIMATING THE BURDEN OF DISEASE OF OBESITY AND ITS MAIN CONSEQUENCES IN COLOMBIA

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OBJECTIVES: High body mass index (BMI) has been associated with 5.47% of global Disability Adjusted Life Years (DALYs). High income countries tend to concentrate this burden (11.35% of total DALYs in USA) but even middle income countries like Colombia have above average overweight-associated DALYs (7.1%). Obesity represents the highest end of the spectrum in this disorder Burden of disease methodology allows the estimation of the impact of diseases on a population using a single and comparable measure: DALY. The purpose of this study was to evaluate the burden of obesity in Colombia. **METHODS:** Burden of disease was evaluated according to the WHO guidelines. A literature review was conducted in electronic databases (SCIELO, BVS, LILACS, MEDLINE) to search data on incidence, prevalence, complications and/or DALYs. Official sources (MoH, DANE) and international databases (IHME, GBD) were reviewed for epidemiological information regarding obesity and its main consequences. DALYs estimation used the methodology proposed in GBD 2010. **RESULTS:** Main diseases associated with obesity as a risk factor were type 2 diabetes mellitus (DM2), hypertension, dyslipidemia, cardiovascular disease, sleep apnea, osteoarthritis, cancer and depression. We estimated the relative risk (RR) of developing these conditions by each BMI 1-unit increment. For example, 30-44 years-old population's RR was 1.36 for DM2, 1.04 for osteoarthritis, 1.10 for endometrial cancer, and 0.89 for cardiovascular diseases (reducing 1 BMI unit). Comorbidities that generate more DALYs were: hypertension, back pain, DM2 and cardiovascular disease. Total burden in DALYs was 1 772 522; 36.4 DALYs per 1000 population (30.4 for males and 42.2 for females). **CONCLUSIONS:** Study shows the high burden of obesity in Colombia. Many non-pharmacological, pharmacological or surgical alternatives, ranging from public health policies to bariatric surgery, are available for obesity treatment. Cultural and system-level barriers, however, may limit interventions.

PSY145

EXAMINING UNCERTAINTY AROUND THE AMERICAN COLLEGE OF MEDICAL GENETICS (ACMG) RECOMMENDATIONS FOR NEWBORN SCREENING (NBS) FOR DEFECTS OF BIOPTERIN COFACTOR BIOSYNTHESIS (BIOPT BS) USING MANSKI BOUNDS AND BOOTSTRAPPING

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OBJECTIVES: In 2006 the ACMG made recommendations for NBS based on an entry point to an algorithm (EPA) it designed, determined by scoring a survey about attributes of various conditions. The EPA determined a set of follow up questions that led to final recommendations. This study examined one of these conditions - BIOPT BS - and assessed if the influence of uncertainty related to the missing survey responses and/or sampling variation for this condition might change scoring sufficiently to modify the EPA and the recommendation. **METHODS:** This research explored the uncertainty relating to the missing data by using a boundary estimate

(Manski, 1989), sampling variation uncertainty by bootstrapping, and their joint influence. We examined two questions of BIOPT BS (score, 1174) that ACMG reported data for: simplicity of therapy (SIMPLICITY) and confirmation of diagnosis (CONF). Total scores > 1200 indicate a new EPA and potentially a different NBS recommendation. **RESULTS:** The EPA did not change when estimating Manski bounds for SIMPLICITY (+/- = 5.1/1.6) and CONF had no missing values, so could not change. When bootstrapping the original data, and around the upper boundary SIMPLICITY estimate, the bootstrapped means implied that the EPA changed not at all or in only a very small percentage of cases (0). **CONCLUSIONS:** The score change from examining the uncertainty relating to missing data and sampling variation for the two questions ACMG reported for BIOPT BS condition is not sufficient to alter the EPA and potentially alter the recommendation. Further exploration of missing data for other questions is needed to fully assess the robustness of the ACMG recommendation.

PSY146

EFFECTIVENESS OF A SCHOOL-BASED PROGRAM IN PREVENTION OF OBESITY AMONG PRESCHOOL CHILDREN IN EGYPT

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OBJECTIVES: To assess the effectiveness of a school-based program in improving knowledge and practices of kindergarten children towards healthy diet and physical activity. **METHODS:** A Quasi-experimental Comparison-group Pre-Post program evaluation study was conducted at kindergartens at Port-Fouad city, in North-East Egypt. At baseline, a total of 1215 preschool children (634 intervention and 581 control) were surveyed for dietary and physical activity knowledge using picture scale activity. Anthropometric measurements were performed to assess body mass index percentiles (age-and-sex-specific). Besides, parents had filled in a self-administered questionnaire about family demographics as well as preschoolers' dietary and physical activity practices. A 4-month educational program; based on the social cognitive theory constructs, was implemented and included 16 class-room activities as well as family involvement activities. At 4-month follow-up, children's dietary and physical activity knowledge and practices were evaluated and compared to baseline evaluation. **RESULTS:** The mean age of children in this study was 5.2±0.6 years. On the age-and-sex-specific BMI percentiles, 12.5% were overweight, while 15.9% were obese. The mean change in overall knowledge level was significantly higher in the intervention than control groups (19.4% vs 6.3%). Practice level in the intervention group had significantly increased at 4-month follow-up assessment, while insignificant change was reported for control group (7.37% vs 0.17%). BMI percentiles had been changed variably among overweight and obese children in both groups. Overweight children had got 0.47 less percentiles in the intervention group compared to 0.33 in the control group, however, obese children had much decrease in BMI percentiles (0.51 vs 0.49, respectively). **CONCLUSIONS:** This 4-month school-based program had effectively improved children's knowledge and practices towards healthy diet and physical activity. This program could be integrated in regular kindergarten's curricula as a contribution to the prevention of obesity among preschool children.

PSY147

VALUE ASSESSMENT CRITERIA FOR ORPHAN DRUGS ACROSS EIGHT EUROPEAN COUNTRIES: HTA AND BEYOND

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OBJECTIVES: We explore the criteria informing coverage decisions of orphan drugs across different diagnostic conditions to understand if different HTA processes result in preferential assessments, conflicting recommendations, and inequitable access to innovative treatment for rare diseases. **METHODS:** Countries included were England, France, Germany, Italy, Poland, Scotland, Spain, and Sweden. Through a selection of orphan drug appraisals between 2006 and 2012, twenty orphan (including ultra-orphan) drug-indication pairs were identified and selected. The sample was split equally between oncology and non-oncology indications. Submitted clinical and economic evidence was identified, collected and analysed systematically and on a case-by-case basis, and following a validated methodological framework. Coverage and funding options based on HTA recommendations as well as on criteria or policies other than HTA were also considered. **RESULTS:** There is huge heterogeneity in coverage recommendations depending on setting. In general, there seems to be a higher willingness to pay for orphan drugs, either through a higher ICER threshold, or only when costs are not exceeding the budget. Additional criteria related to the rarity of diseases or special considerations, particularly centered on unmet need and severity, seem to play an important and increasing role beyond strict cost-effectiveness criteria. Decisions about purchasing may be influenced by factors beyond HTA (e.g. early access schemes), which may be relevant to orphan drugs. Little uniformity exists in the time taken to assess a drug following marketing authorisation, leading to inequities in access. **CONCLUSIONS:** Despite the extensive and ever increasing use of HTA for orphan drugs, the variations in HTA recommendation outcomes across jurisdictions and the -often- very significant time lapses between the date of marketing authorisation, the final HTA recommendation and the eventual funding decision, imply variations in access and highlight the importance of establishing specific policies for orphan drugs to ensure fair assessment and equitable access to treatment for rare diseases.

PSY148

DRUG PROFILE REVIEW OF THE FDA U.S. ORPHAN DRUG ACT APPROVALS (2006-2016)

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OBJECTIVES: As of mid-2016, the 1983 U.S. Orphan Drug Act (ODA) has facilitated the approval of more than 400 innovative medicines for the treatment of small patient

groups with high unmet need. This pathway has been suggested as being a new industry product strategy to capitalize on regulatory and pricing benefits. In order to understand the actual level of innovation and therapeutic value present amongst orphan drug FDA approvals, a comprehensive review of novel orphan designated therapies in the past decade was conducted. **METHODS:** A review of all orphan-designated drug approvals spanning the period 2006–2016 in the FDA's Orphan Drug Product designation database identified 294 orphan designation approvals. A comprehensive data compilation of NDA and BLA approvals granted by CDER and CBER for the same period was then conducted, yielding 1,118 and 174 marketing approvals, respectively. Following data cleanup, 136 orphan designations were identified as being associated with CDER (112/1,118, or 10%) and CBER (24/174, or 14%) NME approvals. **RESULTS:** While the majority of approvals were associated with high therapeutic utility, 18 approvals (13%) for arguably less innovative products, such as ancillary treatments, radiopharmaceutical agents, and diagnostic assays. Excluding these products from the final sample (N=118), less than half of novel orphan designated approvals had been for biologics (41%). Oncology was the top therapeutic area (42%), with the majority of therapies targeting hematologic malignancies (58%), melanoma (14%), and NSCLC (12%). Despite the growing discussion over gene therapies and targeted treatments, only 7% of all agents mentioned the use of diagnostic testing or specific mutations in their labels. **CONCLUSIONS:** The analysis identified only a minority "non-innovative" products suggesting that the ODA pathway is supporting overall the launch of products with the intended profile targeting rare diseases with high unmet need.

PSY149

ASSESSMENT OF DISEASE STATE KNOWLEDGE AND AWARENESS AMONG THE GUARDIANS OF THALASSEMIA PATIENTS ATTENDING DIFFERENT HEALTH FACILITIES IN QUETTA, PAKISTAN

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OBJECTIVES: The current study was aimed to assess knowledge and awareness about thalassemia among the guardians of thalassemia patients of Quetta, Pakistan. **METHODS:** The cross-sectional descriptive study was undertaken by using structured questionnaire in different Thalassemia Centers of Hospitals of Quetta, Pakistan from March to July 2016. Convenient sampling was adopted for data collection. A total of 327 Patients diagnosed with thalassemia major were included for study while patients taking oral Iron overload treatment were excluded. Descriptive and inferential statistics (Mann Whitney U test and Kruskal Wallis tests, $p < 0.05$) were used to assess the significance among study variables. Analysis was performed using IBM SPSS v.20. **RESULTS:** The result showed that mean age of the respondents were 35.5 ± 15.45 years and 154 (60.6%) were males. Majority of the respondents ($n=97$, 38.2%) had primary level of education and belonged to urban area ($n=174$, 78.55%). The results also showed majority ($n=242$, 96.9%) of respondents had adequate knowledge regarding thalassemia. Health care providers were reported as major source of thalassemia information by more than 75% of the study participants. Comparison of mean score showed that education level, occupation, area of residence had significant ($p < 0.05$) associated with the knowledge score. **CONCLUSIONS:** The study concluded that the guardians of the thalassemia patients had better understanding regarding their child diseases and this could be beneficial in better care of child.

RESEARCH POSTER PRESENTATIONS – SESSION IV

HEALTH CARE TREATMENT STUDIES

MEDICAL DEVICES/DIAGNOSTICS – Clinical Outcomes Studies

PMD1

ADVERSE EVENTS AND DEVICE MALFUNCTIONS ASSOCIATED WITH INTRAVENOUS PATIENT-CONTROLLED ANALGESIA: A RETROSPECTIVE ANALYSIS OF 2011-2016 MAUDE DATABASE

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OBJECTIVES: To determine the magnitude and characteristics of adverse events and device malfunctions associated with intravenous (IV) patient controlled-analgesia (PCA) occurring in inpatient hospital settings. **METHODS:** IV PCA device-related events, occurring in inpatient settings were extracted from reports submitted to the FDA Manufacturer and User Facility Device Experience (MAUDE) database during January 1st, 2011 through September 12th, 2016. Descriptive analyses and qualitative review of text narratives were performed to characterize IV PCA errors. **RESULTS:** A total of 1430 IV PCA device-related events were included in this analysis. Approximately, 11% ($n=157$) of these events were associated with unfavorable outcomes including worsening of pain ($n=62$), death ($n=20$), therapy interruption ($n=13$), and hospitalization ($n=13$). Device safety issues were the leading cause of errors accounting for 93% of the 1430 events; other causes included operator errors (2.6%), patient errors (1%), and indeterminate (3.4%). Common factors contributing to device-related events included leak in systems (27%), defective equipment (22%), failure to deliver drug (14%), distal occlusion (10%), overdose (6%), under-dose (3.3%), faulty alarm system (19%) and pump programming issues (0.6%). Opioid-related adverse drug reactions (ADR) were observed in 5.5% ($n=78$) events; of which respiratory depression ($n=40$) and sedation ($n=17$) were the two most common ADRs reported. To prevent further occurrences of harm, IV PCA devices were recalled and replaced in a majority (58%) of the reported 1430 events, and emergent clinical interventions (such as administration of narcotic antagonist, intubation, transfer to intensive care unit) were necessary in 2.7% of these events. **CONCLUSIONS:** Despite the benefits of IV PCA, a substantial number of device malfunctions and adverse events associated with IV PCA devices were identified. Additional safety measures including training and novel PCA systems that could

potentially circumvent some of these harmful events while still retaining the advantages associated with PCA in pain management are needed.

PMD2

A SYSTEMATIC LITERATURE REVIEW ON THE USE OF LOCKING COMPRESSION PLATE (LCP™) TECHNOLOGY FOR PROXIMAL AND DISTAL HUMERUS FRACTURE TREATMENT

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OBJECTIVES: Proximal & distal humerus fractures are common injuries in elderly population and usually associated with osteoporosis. Fracture reduction through surgical approach implies the use of plates & screws, such as commercially-available LCP™ (Locking Compression Plate) system, its branded Philos™ plate for proximal humerus, and DCP™ (Dynamic Compression Plate) technology; comparative clinical evidence on their utilization could support technology choice. This study's objective was to perform a systematic literature review to assess clinical outcomes derived from the use of LCP™, Philos™ & DCP™ technology for the treatment of proximal and distal humerus fractures. **METHODS:** A systematic search of PubMed, Cochrane Library and Medigraphic for published literature on the use of the former technologies was conducted; considered key words included "locking compression plate", "dynamic compression plate", "humerus fractures", "proximal/distal humerus", "distal humerus plate", "Philos plate", "meta-analysis", "clinical trial" and "systematic review". Inclusion criteria included RCTs, case reports, revisions/meta-analysis, as well as studies in English or Spanish and publications in indexed journals; exclusion criteria included clinical studies in experimental models and other treatment alternatives for proximal and distal humerus fractures. **RESULTS:** 1,064 studies were initially identified; duplicated articles and inclusion/exclusion criteria yielded 62 articles on LCP™ and DCP™ use, with 6 studies directly comparing LCP™ and DCP™ systems, 55 studies describing LCP™ outcomes and 1 case report on DCP™ use. Further analysis revealed no comparative evidence nor publications on DCP™ use on proximal or distal humerus fractures. Comparative studies focused on other non-humerus fractures, with no statistically-significant differences in terms of functionality, fixation & bone bonding time, complications and operating time between technologies. Positive outcomes favoring LCP™ in terms of pseudoarthrosis, 1-month consolidation rate and greater bone fixation rigidity were found. **CONCLUSIONS:** LCP™ technology seems a safe and effective treatment for proximal and distal humerus fractures, while DCP™ has no published evidence on such injuries.

PMD3

HEALTH OUTCOMES FOLLOWING UPPER GASTROINTESTINAL ENDOSCOPY PROCEDURES: AN UPDATED SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: Upper gastrointestinal (GI) endoscopy procedures are considered fairly routine in the United States and are one of the most common interventional procedures done globally. Patient safety during these procedures is paramount as there are multiple methods available for anesthesia, sedation and airway maintenance affecting morbidity and mortality. The purpose of this review is to specifically evaluate endotracheal intubation (ETT) and laryngeal mask airway (LMA) management options for patients undergoing upper GI procedures. **METHODS:** A Boolean search strategy was employed to identify manuscripts from the peer-reviewed literature published from 1996-2016 that reported results from upper GI endoscopy procedures and patient health outcomes. The search terms "upper GI endoscopy" AND "complications" OR "failures" OR "adverse events" were used to identify the scientific research papers that examined different airway management methods as well as clinical, humanistic and economic outcomes. **RESULTS:** A total of 247 abstracts were reviewed for content validity and the ability to compare health outcomes, including complications, of LMA and ETT used for upper GI endoscopy. The literature summary determined that when an ETT was used to protect the airway, a statistically significant greater incidence of laryngospasm, hoarse voice, coughing and sore throat was found compared with procedures that used an LMA to protect the airway. The differences in the risk of regurgitation, vomiting, nausea and the success of insertion on the first attempt were not statistically significant between the two airway management methods. **CONCLUSIONS:** Based on this comprehensive systematic literature review covering twenty years of clinical research it is clear that airway management techniques during out- and in-patient upper GI procedures are a key element affecting patient health outcomes. Morbidity and mortality rates can be greatly improved with successful airway management. Further head to head comparative clinical research is needed to identify the best methodologies for airway management during these common procedures.

PMD4

DIFFERENTIATING VALUE OF SHEAR WAVE ELASTOGRAPHY IN BREAST ULTRASOUND: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: To conduct a systematic review and meta-analysis to evaluate the effectiveness of Shear Wave Elastography (SWE) combined with Ultrasound (US), for the differential diagnosis of breast lesions. **METHODS:** The literature searches were conducted using KoreaMed, Ovid-MEDLINE, Ovid-EMBASE, and Cochrane Library on December 28, 2015. The studies that were excluded: animal experiments, preclinical experiments, abstracts, reviews, articles not published in Korean or in English, grey literature, case studies, and not breast tumors. Two authors independently selected articles and evaluated the articles quality using Scottish

Intercollegiate Guidelines Network (SIGN). The assessment was based on the following factors: biopsy reduction rate (change in the level of Breast Imaging Reporting and Data System, BI-RADS), and diagnostic performance. **RESULTS:** A total of 23 articles were included in the final assessment. The diagnostic cut-off value of the SWE varied: Emax (16 articles, cut-off 30~108.5 kPa), Emean (1 article, cut-off 41.6 kPa), qualitative index (5 articles), and qualitative and quantitative index (3 articles). In the 8 articles, when adding SWE to US, the level of BI-RADS changed from IV to III in 12.8~89% of cases with 0~3.8% false negative rate, and 27.1~73.7% rate of decrease in biopsy for patients who received US. Meta-analysis was performed on 21 articles (4,558 breast masses). The diagnostic performance of SWE + US vs. US were: pooled sensitivity was 0.94 (95% confidence interval [CI] 0.93~0.95, I2=79.0%) vs. 0.94 (95% CI 0.92~0.95, I2=83.3%), pooled specificity was 0.75 (95% CI 0.73~0.76, I2=96.4%) vs. 0.55 (95% CI 0.53~0.57, I2=98.6%). **CONCLUSIONS:** SWE is an effective test for discriminating benign and malignant tumors in patients suspected of breast cancer, which prevents unnecessary biopsy when used alongside the breast US.

PMD5

DEMOGRAPHIC TRENDS IN ADHD DIAGNOSIS IN U.S. CHILDREN USING NHANES DATA BETWEEN 2004 AND 2012

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OBJECTIVES: To characterize changes in the demographic distribution of attention-deficit hyperactivity disorder (ADHD) diagnosis from 2004 to 2012 in the United States. **METHODS:** ADHD diagnosis data was extracted from the National Health and Nutrition Examination Survey (NHANES) Summary Health Statistics for U.S. Children, a source of nationally representative data on children in the United States. The ADHD cases were identified based on ICD9-CM diagnosis codes. Chi square tests were used to investigate differences in ADHD diagnosis rates by demographic characteristics (age, race, and gender) within each year and simple linear regression was applied to determine the extent of change over time. All statistical analyses were performed using SAS 9.2 (SAS Institute, Cary, NC) at a priori significance level of 0.05. **RESULTS:** The ADHD diagnosis rate was higher among males, Whites, and school aged children and adolescents (vs. preschoolers aged 3-4) in each year examined. The total number of ADHD cases as well as all demographic groups with the exception of African Americans and preschoolers aged 3-4 exhibited an increasing trend between 2004 and 2012. **CONCLUSIONS:** ADHD diagnosis among youth showed a significant increase in the U.S. between 2004 and 2012. Notable increases and group differences were also observed among demographic subgroups. These findings indicate a need for future research in reasons for such group differences as well as treatment differences.

PMD6

ROLE OF SERUM CYSTATIN C AND CREATININE IN IDENTIFYING STAGING OF ELDERLY CHRONIC KIDNEY DISEASE PATIENTS

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OBJECTIVES: To identify and compare the chronic kidney disease (CKD) staging by cystatin C and creatinine based estimated glomerular filtration rate (eGFR) equations among elderly CKD patients in later stages of CKD. **METHODS:** A total of 300 elderly Malay participants were included in the study aged ≥ 65 years at the Hospital University Sains Malaysia (HUSM), Kelantan Malaysia. Demographic data and past history were recorded. Serum creatinine was assayed by Chemistry Analyzer Model Architect-C8000 (Jaffe Method). While serum cystatin C was examined by Human cystatin C ELISA kit (SIGMA-ALDRICH) using Thermo Scientific VARIOSKAN Flash ELISA reader. CKD-EPIcr-cysequation was used as a reference equation to compare the eGFR equations result of other equations. In order to evaluate the agreement between various eGFR equations in staging CKD, Cohen kappa (κ) analysis was used. **RESULTS:** Altogether 300 patients were recruited of which majority were female (n=169, 56.3%). Mean age of the study participants were 67.6 + 6.7 years. Overall majority of the male (64.4%) and (35.4%) female patients were aged 70-79 years. Cohen kappa (κ) value of 0.01-0.2 was considered as negligible, 0.21-0.4 as fair, 0.41- 0.6 as moderate, 0.61-0.8 as substantial, and 0.81-1 as almost perfect agreement. The result of cystatin C based eGFR equation i.e. CKD-EPIcr was more efficient as compared to creatinine based eGFR equations i.e. MDRD and CKD-EPIcr with $p < 0.05$. **CONCLUSIONS:** The cystatin based eGFR equation was more accurate in identifying the correct staging of elderly CKD patients as compared to creatinine based eGFR equations. Cystatin C can possibly be used as alternative to creatinine as endogenous biomarker.

PMD7

EFFECT OF BMI ON ENDOGENOUS BIOMARKERS (SERUM CYSTATIN C AND CREATININE) AMONG ELDERLY CHRONIC KIDNEY DISEASE PATIENTS

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OBJECTIVES: To identify the effect of BMI on endogenous biomarkers i.e. cystatin C and creatinine among elderly CKD patients. **METHODS:** Four groups of participants were selected for this purpose on the basis of Body mass index (Normal, overweight, obese and underweight). Serum cystatin C and creatinine was determined by ELIZA and Jaffe Method respectively. A validated data collection form was developed to record patient demographics and relevant clinical data. Statistical analysis was performed via SPSS version 22. **RESULTS:** A total of 300 participants were included in the study at the Hospital University Sains Malaysia (HUSM), Kelantan Malaysia, in which majority of the study subjects were females 169 (56.3%). Mean age of patients was 67.6 + 6.7 years. Most of the male (64.6%)

(35.4%) female patients were aged 70-79 years. Mean body mass index (BMI) of the patients was 26 + 5.7 kg/m². Fifty four (53.4%) male and 47 (46.6%) female patients were overweight whereas 27 (47.3%) male and 30 (52.7%) female patients were obese. The one-way ANOVA result reported significant difference for serum creatinine with $p < 0.05$ for all the four groups on the basis of BMI. While for serum cystatin C the result was non-significant with $p > 0.05$. **CONCLUSIONS:** Cystatin C can be used in place of creatinine to correctly identify the staging of elderly CKD patients as it is not affected by BMI level as compared to creatinine.

PMD8

EXAMINING UNCERTAINTY AROUND AMERICAN COLLEGE OF MEDICAL GENETICS (ACMG) RECOMMENDATIONS FOR NEWBORN SCREENING (NBS) FOR HYPERMETHIONINEMIA (MET)

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OBJECTIVES: In a 2006 ACMG report, MET was recommended as a secondary NBS target based on an algorithm whereby survey scoring determined an entry point to the algorithm (EPA) containing follow up questions, leading to a final recommendation. ACMG ignored any uncertainty regarding its scoring. We examined the potential impact of missing data in the classification of MET as a secondary target by the ACMG by first assessing whether missing data uncertainty could lead to a different EPA. **METHODS:** In survey scoring for MET, two questions out of 18 have individual responses reported by ACMG; the first question, "Burden If Untreated" (BURDEN), had 6 missing responses and the second, "availability of treatment" (AVAIL), had 5 missing responses. The total MET score was 1121; the cut off values for the EPA were at 1200 and at 1000. We assessed the potential impact of missing data to call into question the confidence in the original EPA by using boundary estimates (Manski 1989). **RESULTS:** The original score based on responders was 29 for BURDEN and 70 for AVAIL. Lower/upper boundary estimates were, respectively, (25/38) and (62/73). Neither of these changes, alone or combined, was sufficient to alter the EPA and the recommendation for MET. **CONCLUSIONS:** Scoring for MET is affected by uncertainty due to missing data. However, examining the uncertainty for only these 2 questions was not sufficient to change the EPA or the NBS recommendation. Additional examination of the potential influence of missing data for other survey questions and examining the influence of other sources of scoring uncertainty (e.g. sampling variation) is needed in order to confirm the robustness of the ACMG recommendation for MET.

PMD9

COMPARATIVE EFFECTIVENESS OF MRI VERSUS MAMMOGRAPHY FOR POST-TREATMENT SURVEILLANCE IN PATIENTS UNDERGOING BREAST-CONSERVING THERAPY FOR BREAST CANCER

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OBJECTIVES: Magnetic resonance imaging (MRI) is a sensitive method of breast imaging. The goal was to compare the effectiveness of MRI vs. mammography for post-treatment surveillance in patients undergoing breast-conserving therapy for breast cancer. **METHODS:** This cohort study used the Texas Cancer Registry linked Medicare claims data from 2004-2012. The study cohort included older women (age > 65 years) diagnosed with ductal carcinoma in situ or SEER Historic stage 0, 1 and 2 breast adenocarcinoma who underwent breast-conserving surgery+radiation therapy. The primary independent variable was use of MRI +/- mammography vs. mammography alone after definitive therapy. Outcomes included time to local recurrence, number of total biopsies, and number of negative biopsies defined as biopsy not followed by breast cancer diagnosis and treatment. Independent variables included patient demographics, comorbidities and clinical characteristics such as cancer stage and tumor size. Unadjusted and adjusted Cox proportional hazards regression models were constructed to evaluate the comparative effectiveness of MRI versus mammography on time to detection of recurrence. Unadjusted and adjusted zero-inflated Poisson regressions were constructed to compare the incidence of total and negative biopsies with MRI vs. mammography. **RESULTS:** Of 7,693 patients, 6,360 (82.7%) used mammography only, 483 (6.3%) used MRI and mammography and 850 (11.1%) had no post-treatment surveillance breast imaging. The use of MRI increased over time from 0.5% in 2004 to 17.7% in 2012 ($p < 0.001$). In adjusted analysis, MRI was associated with higher detection of recurrence (HR 1.56; 95% CI, 1.15-2.13), but also associated with higher number of total biopsies ($\beta = 0.95[0.08]$) and negative biopsies ($\beta = 1.01[0.09]$). **CONCLUSIONS:** MRI use for post-treatment surveillance increased in Texas in the last decade. The use of MRI resulted in greater detection of recurrence. Use of MRI was also associated with an increased number of total and false positive biopsies; follow-up was not long enough to evaluate if the early detection improved survival.

PMD10

COMPARISON OF DELIRIUM DETECTION RATES IN DEMENTIA AND NON-DEMENTIA ELDERLY POPULATION BY FAMILY CAREGIVERS USING FAMILY CONFUSION ASSESSMENT METHODS (FAM-CAM) IN THE EMERGENCY DEPARTMENT - AN OBSERVATIONAL STUDY

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OBJECTIVES: The Family Confusion Assessment Method (FAM-CAM) has been validated in outpatient populations but has not been tested in populations with dementia or in hospitalized patients. This study compared delirium detection rates using the Family Confusion Assessment Methods (FAM-CAM) in caregivers of dementia

patients versus those of non-dementia patients against a gold standard interviewer rating, Confusion Assessment Methods (CAM). **METHODS:** This observational study enrolled 108 elderly patient/family member dyads who presented to Emergency Department at the University campus of UMass Memorial Health Care. Upon admission, the research staffs used the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) to assess dementia in the patients. Two interviews were conducted to assess delirium in the patients as follows: each patient was interviewed by a trained rater using the CAM, and each family caregiver was guided through the FAM-CAM questionnaires. **RESULTS:** The average age of enrolled patients was 81 years old. IQCODE identified 51% of patients as having dementia. The prevalence of delirium was 28% according to both the CAM and the FAM-CAM. The sensitivity of the FAM-CAM was 60.8% (CI= 41-81%) in patients with dementia and 42.8% (CI=6-80%) in patients without dementia. The specificity of the FAM-CAM was 74.3% (CI=59-88%) in patients with dementia and 90.1% (CI=82-99%) in patients without dementia. **CONCLUSIONS:** The sensitivity was 20% higher in dementia patients, which shows that FAM-CAM performs better than CAM at recognizing delirium in dementia patients and supports validation of its use in high-risk patient population with Delirium Superimposed on Dementia (DSD). The FAM-CAM offers critical knowledge of family caregivers on patient's baseline cognitive and physical function, therefore has great potential to help health care clinicians identify delirium during their patient assessment. Future studies with a larger sample size of different races and with education of caregivers on delirium-associated symptoms are encouraged.

PMD11

REAL-WORLD CLINICAL BENEFITS ASSOCIATED WITH FLOWABLE GELATIN HEMOSTATIC MATRIX FOR LUMBAR SURGERY IN CHINESE PATIENTS

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OBJECTIVES: To assess real-world clinical benefits associated with flowable gelatin hemostatic matrix (SURGIFLOTM) for hemostasis in a pilot cohort of Chinese patients who underwent cervical vertebrae surgery (CVS). **METHODS:** A pilot cohort was created by randomly selecting 10% of patients who received CVS for cervical spondylosis in 2014 and 2015 in a tier III hospital in Beijing, China. The medical records related to CVS for the included patients were reviewed to extract patient baseline characteristics, surgery procedures, utilization of SURGIFLOTM, and selected outcome measures during and after the operation. Multiple regression analyses with adjustment assessed the impact of the utilization of SURGIFLOTM as hemostatic agent on measured outcomes during and after CVS. **RESULTS:** The created pilot cohort included 70 patients (24 with utilizing SURGIFLOTM and 46 without utilizing SURGIFLOTM). The utilization of SURGIFLOTM was associated with significantly higher proportion of urban worker insurance plan (75.0% vs. 43.5%, $p=0.022$) and higher proportion of cerebral infarction history (20.8% vs. 0%, $p=0.004$) at baseline. Significant association was only observed between the utilization of SURGIFLOTM and body temperature normalization three days after surgery [odds ratio (OR) 0.01, $p=0.025$]. Additionally, the utilization of SURGIFLOTM was strongly associated with lower bleeding volume during operation, shorter hospital stay length after operation, and less utilization of drainage catheter after operation. However, the sample size of this pilot cohort was not large enough to detect the statistical significance for these observed associations. **CONCLUSIONS:** Utilizing SURGIFLOTM for hemostasis in CVS led to significantly more patients with normalized body temperature three days after surgery. The potential clinical benefits associated with the utilization of SURGIFLOTM for CVS warrant confirmation by future studies with sufficient power.

PMD12

CAN CLOSED INCISION NEGATIVE PRESSURE THERAPY IMPACT POST OPERATIVE OUTCOMES IN BREAST RECONSTRUCTION?

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OBJECTIVES: Evidence suggests that incision management with negative-pressure therapy (ciNPT) may provide clinical benefit in various surgical applications such as orthopedic, sternotomy, abdominal wall repairs, colorectal procedures by protecting surgical incisions and removing fluid and infectious materials. This study compares post-operative outcomes including complication rates and drain use among patients using ciNPT* versus standard of care (SOC) after breast reconstruction. **METHODS:** This single-site, retrospective cohort study included data for breast reconstruction procedures from October 1, 2013 - March 31, 2016. Data collected included demographics, chemotherapy/radiation exposure, surgical technique, ciNPT use, number of drains, total drain duration, and 90 day post-operative complication rates. Two-sided T-test and Chi-square or Fisher's Exact tests were performed at $\alpha=0.05$. **RESULTS:** The study included data on 155 patients (ciNPT=64, SOC=91) and 294 breasts (ciNPT=125, SOC=169). There were no significant differences in patient characteristics between the two groups except for prior breast surgery, radiation and chemotherapy exposure. More patients in the ciNPT group underwent a pre-pectoral technique of breast reconstruction compared to the control group. At the breast level, the overall complication rate was 7 (5.6%) in the ciNPT group compared to 24 (14.2%) in the SOC group ($p=0.0176$). There were significant differences in infection rates [0(0%) v. 10(5.9%)], dehiscence [0(0%) v. 11 (6.5%)], necrosis [1(0.8%) v. 16(9.5%)] when comparing the ciNPT and SOC groups respectively. All patients in the ciNPT group had 2 drains compared to 81.7% of the SOC group ($p<0.0001$). The ciNPT group had significantly lower mean drain days

per-drain (6.1 vs. 9, $p<0.0001$) and total drain days (12.2 vs. 18.1, $p<0.0001$) compared to SOC group. **CONCLUSIONS:** Our study demonstrated significantly lower complication rates and drain duration among the ciNPT group. These results may translate to improved patient outcomes and efficient use of resources in a hospital setting. Further studies are needed to corroborate the findings in our study.

PMD13

MEASURING ADALIMUMAB DRUG LEVELS BY ELISA TO DETECT TREATMENT RESPONSE IN RHEUMATOID ARTHRITIS: A SYSTEMATIC REVIEW AND BIVARIATE META-ANALYSIS

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OBJECTIVES: In patients with rheumatoid arthritis (RA) receiving the anti-TNF therapy adalimumab, circulating drug levels are associated with treatment response. Commercial tests (using a method called ELISA) can monitor anti-TNF drug levels in routine practice but the accuracy of this approach is uncertain. This study aimed to synthesise all published evidence on the accuracy of adalimumab drug level measurement by ELISA to detect treatment response in RA. **METHODS:** A systematic review identified all published receiver operating characteristic (ROC) curve analyses that measured adalimumab drug levels by ELISA tests to detect treatment response in RA. Medline and Embase were searched electronically (from inception to August 2016). Two researchers identified studies using pre-defined inclusion criteria. Test outcomes were classified as positive if drug levels exceeded the study-specific cut-point. Data on study design characteristics, sample characteristics, and test outcomes from 2x2 tables (true-positive; false-positive; true-negative; false-negative) were extracted. QUADAS-2 was used to assess study quality. A hierarchical bivariate meta-analysis synthesised findings to account for between-study heterogeneity and correlation between sensitivity and specificity. **RESULTS:** 4,006 abstracts were identified and four studies met the review inclusion criteria. In all studies, patients received 40mg adalimumab every two weeks. Studies varied in their design and sample characteristics. Studies had low risk of bias and low concern of applicability to the research objective. The hierarchical bivariate meta-analysis estimated an average test sensitivity of 0.95 (95% CI: 0.85-0.98) and specificity of 0.68 (95% CI: 0.28-0.92). **CONCLUSIONS:** Measuring high adalimumab drug levels by ELISA testing appeared to be predictive of treatment response in RA. Low drug levels were less predictive of no treatment response. In practice, drug level measurement may be used in conjunction with anti-drug antibody testing to improve accuracy. The relative cost-effectiveness of using ELISA tests, and the implications of imperfect test accuracy, should be evaluated before being recommended in routine practice.

PMD14

COMPARISON OF ECONOMIC AND CLINICAL OUTCOMES BETWEEN STRATAFIX™ KNOTLESS TISSUE CONTROL DEVICES AND CONVENTIONAL SUTURES IN PATIENTS UNDERGOING KNEE REPLACEMENT FOR OSTEOARTHRITIS IN REAL WORLD CLINICAL PRACTICE

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OBJECTIVES: To compare economic and clinical outcomes between patients undergoing knee replacement for osteoarthritis with use of STRATAFIX™ Knotless Tissue Control Devices (SFX KTCD) vs. conventional sutures alone. **METHODS:** Retrospective, observational study using the Premier Hospital Database. Patients (aged ≥ 18 years) selected for study had an elective hospital admission, with discharge occurring between 1/1/2010-9/1/2015, carrying primary ICD-9-CM procedure and diagnosis codes for knee replacement and osteoarthritis (first qualifying=index admission). Patients with any billing record for use of SFX KTCD during the index admission were classified into the 'SFX KTCD group'; those with billing records only for conventional sutures were classified into the 'conventional group'. Primary outcomes were index admission's length of stay (LOS), total hospital costs, and discharge status (skilled nursing facility [SNF]/other vs. home/home health care); exploratory outcomes included surgical site infection (SSI) and operating room time (ORT) during index admission. The SFX KTCD and conventional groups were propensity score matched (1:1/nearest neighbor/caliper=0.10) on patient, hospital, and provider characteristics. Generalized estimating equations accounting for hospital-level clustering after matching were used to compare outcomes between study groups. **RESULTS:** Each group comprised 7,264 patients (14,528 total patients; mean age=66.5y; % females=61.8%). The groups were generally well-balanced on matching covariates: mean standardized difference calculated across 52 covariates=0.02. Compared to the conventional group, the SFX KTCD group had statistically significant: shorter LOS (2.7d vs. 2.9d, $P=0.0059$), lower probability of discharge to SNF/other vs. home/home healthcare (25.7% vs. 28.7%, $P=0.0126$), and shorter ORT (183min vs. 190min, $P=0.0235$). Total hospital costs and SSI rates were lower for the SFX KTCD vs. conventional group; however, these differences were not statistically significant. **CONCLUSIONS:** Among patients undergoing knee replacement for osteoarthritis in real world clinical practice, use of SFX KTCD vs. conventional sutures alone was associated with shorter LOS, shorter ORT, and less resource intensive discharge status.

PMD15

PHYSICIAN INSIGHT OF HEALTH ECONOMIC BENEFIT OF RHYTHMIA THREE - DIMENSIONAL MAPPING SYSTEM FOR RADIOFREQUENCY ABLATION PROCEDURES

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OBJECTIVES: To explore and demonstrate the clinical/economic benefits associated with Rhythmia, a three-dimensional mapping system for radiofrequency ablation

procedures. **METHODS:** Rhythmia Mapping System was approved by China CFDA in 2015. Its clinical benefits include less mapping time, high precision and high degree of automation, however, no study has been conducted to explore and evaluate its potential health economic benefits. In this study, a KOL survey was conducted to explore such benefits. A questionnaire was designed to collect data associated with potential benefits of Rhythmia Mapping System such as the clinical advantages, the comparison with other mapping system, and the usage experience of Rhythmia system. Thirty-five clinicians who had Rhythmia experience from 11 cities (Shanghai, Beijing, Guangzhou, etc.) in China completed the questionnaire. This survey population accounted for 70% of the physicians who had experience with Rhythmia Mapping System in China. **RESULTS:** The survey demonstrated the following health economic benefits: 94.3% of physicians believe that the Rhythmia system can improve the ablation efficacy of patients with complex arrhythmia. Compared with other mapping systems, Rhythmia system can reduce the median operation time by 30 minutes. The Atrial Fibrillation (AF) recurrence ratio of Rhythmia system versus other systems were 5% and 20%, and recurrence frequency were 1.5 and 2 respectively. With current cost of radiofrequency ablation averaging 73,873.68 Chinese Yuan (CNY) and the number of patients requiring radiofrequency ablation in China being 31.36 million, the application of Rhythmia system (used only for 0.5% of all radiofrequency ablation operation) could result potential saving of 55 million CNY. Assuming the utilization of Rhythmia system comes up to 10%, the saving would be up to 1.1 billion CNY. **CONCLUSIONS:** Rhythmia three-dimensional Mapping System can improve the mapping accuracy and the efficacy of patients with complex arrhythmia. Substantial cost could be saved due to the application of Rhythmia system.

PMD16

REAL-WORLD CLINICAL BENEFITS ASSOCIATED WITH THE UTILIZATION OF FLOWABLE GELATIN HEMOSTATIC MATRIX FOR CERVICAL VERTEBRAE SURGERY IN CHINESE PATIENTS

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OBJECTIVES: To assess real-world clinical benefits associated with flowable gelatin hemostatic matrix (SURGIFLOTM) for hemostasis in a pilot cohort of Chinese patients who underwent cervical vertebrae surgery (CVS). **METHODS:** A pilot cohort was created by randomly selecting 10% of patients who received CVS for cervical spondylosis in 2014 and 2015 in a tier III hospital in Beijing, China. The medical records related to CVS for the included patients were reviewed to extract patient baseline characteristics, surgery procedures, utilization of SURGIFLOTM, and selected outcome measures during and after the operation. Multiple regression analyses with adjustment assessed the impact of the utilization of SURGIFLOTM as hemostatic agent on measured outcomes during and after CVS. **RESULTS:** The created pilot cohort included 70 patients (24 with utilizing SURGIFLOTM and 46 without utilizing SURGIFLOTM). The utilization of SURGIFLOTM was associated with significantly higher proportion of urban worker insurance plan (75.0% vs. 43.5%, $p=0.022$) and higher proportion of cerebral infarction history (20.8% vs. 0%, $p=0.004$) at baseline. Significant association was only observed between the utilization of SURGIFLOTM and body temperature normalization three days after surgery [odds ratio (OR) 0.01, $p=0.025$]. Additionally, the utilization of SURGIFLOTM was strongly associated with lower bleeding volume during operation, shorter hospital stay length after operation, and less utilization of drainage catheter after operation. However, the sample size of this pilot cohort was not large enough to detect the statistical significance for these observed associations. **CONCLUSIONS:** Utilizing SURGIFLOTM for hemostasis in CVS led to significantly more patients with normalized body temperature three days after surgery. The potential clinical benefits associated with the utilization of SURGIFLOTM for CVS warrant confirmation by future studies with sufficient power.

PMD17

ASSOCIATION BETWEEN RECOMBINANT HUMAN BONE MORPHOGENETIC PROTEINS AND POST-OPERATIVE OPIOID USE IN LUMBAR FUSION PROCEDURE PATIENTS: A PROPENSITY-SCORE MATCHED ANALYSIS

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OBJECTIVES: To investigate the association between Recombinant human Bone Morphogenetic Protein-2 (rhBMP-2) use during lumbar fusion procedures and the demand for opioid analgesics in the first post-surgical year. **METHODS:** We conducted retrospective study using the Multi-Payer sClaims Database (MPCD) 2007-2010. Patients aged > 20, who received a Degenerative Disc Disease-indicated lumbar fusion procedure and had at least one opioid prescription filled in the three months prior to surgery, were identified. Propensity score matching (1:1) of rhBMP-exposed and unexposed patients was used to mitigate the effects of confounding. Outcomes of interest were opioid independence and decreases in opioid doses as measured in morphine equivalents assessed at 3-6 and 9-12 months post-procedure. Logistic regression and Analysis of Covariance models were used to examine the association between rhBMP-use and post-operative opioid use patterns. **RESULTS:** A total of 318 patients were included in the propensity score matched cohort; most were female (61%) and under 65 years old (68%). Few patients achieved opioid independence at either the 3-6 ($n=71$, 22.3%) or 9-12 months ($n=115$, 36.2%) post-surgical windows. During the 3-6 months window, patients who received rhBMPs reduced their opioid use rates (Estimated Mean Difference: -28.4 vs. -19.5, p value= 0.69) and achieved opioid independence (21.4% vs. 23.3%, OR=0.92, 95% CI, 0.54-1.56, p value = 0.74) at rates that were statistically comparable to their matched comparators. Similar

patterns were observed during the 9-12 months window. **CONCLUSIONS:** We found no evidence to suggest that rhBMP use during spinal fusion procedures is associated with either the discontinuation or decrease of opioid analgesic therapy. Given the significant morbidity associated with prolonged opioid therapy, the high prevalence of continued opioid use after surgery warrants further study.

PMD18

SOCIOECONOMIC INEQUALITIES IN QUALITY-OF-CARE AND OUTCOMES AMONG PATIENTS UNDERGOING PERCUTANEOUS CORONARY INTERVENTION IN HONG KONG

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OBJECTIVES: Socioeconomic status has been associated with adverse cardiovascular outcomes. We aim to evaluate the impact of socioeconomic status on characteristics and outcomes of patients undergoing percutaneous coronary intervention (PCI) in Hong Kong. **METHODS:** We retrospectively analyzed 3300 patients undergoing PCIs between Sep 2009 and Dec 2013 at a tertiary academic institution. Low socioeconomic status (LSES) was defined by recipient of the Comprehensive Social Security Assistance (CSSA) Scheme which provides a safety net for those who cannot support themselves financially based on total household income and asset tests. Baseline characteristics and 12 month clinical outcomes including death, myocardial infarction (MI), target vessel revascularization (TVR) and composite major adverse cardiac events (MACE, composite of death, MI and TVR) were compared between LSES and non-LSES patients. Independent predictors of 12 month MACE were identified using multivariate analysis. **RESULTS:** Of 3,300 patients, 19.2% ($n=635$) were of LSES with mean age of 64 ± 10.9 years and 75.6% male. LSES patients had high rates of co-morbidities including smoking, renal failure, history of MI, heart failure, previous PCI compared to non-LSES patients (all $p < 0.01$). LSES patients had higher rates of death (5.1% vs. 3.2%), MI (2.2% vs. 0.6%), TVR (2.2% vs. 1.1%) and MACE (9.8% vs. 4.8%, all $p < 0.01$) at 12 months. LSES was an independent predictor of 12-month MACE (Odds Ratio [OR] 1.45, 95% confidence interval [CI] 0.99-2.12, $p=0.05$). The use of drug-eluting stents (DES) was the only independent predictor of freedom-from-MACE at 12 months (OR 0.48, 95%CI 0.35-0.66, $p < 0.01$). However, DES is only used in 20.6% of LSES patients compared to 80.7% of non-LSES patients ($p < 0.01$). **CONCLUSIONS:** Among patients undergoing PCI, a low socioeconomic status is associated with a higher prevalence of cardiovascular risk factors and adverse outcomes but less effective therapy such as bare-metal stents.

PMD19

A GLOBAL EPIDEMIOLOGICAL FORECAST OF HOSPITAL-TREATED INFECTION EVENTS AND INFECTION TYPES

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OBJECTIVES: To estimate the global burden of Hospital-Treated Infection Events (HTIs) and HTI subtypes in 2016, and forecast the number of HTI events through 2026 using country-specific hospital discharge databases and literature review. **METHODS:** Hospital-treated infections are classified into community-acquired, healthcare-associated, and hospital-acquired infections. Six types of infections: urinary tract infections, respiratory, surgical site, bloodstream, intra-abdominal, and skin structure infections affect millions of patients every year placing a huge burden on low-and middle-income countries. We estimated the number of HTI events for each infection type by analyzing large hospital discharge databases and reviewing country-specific literature. We forecast changes in the number of events through 2026 based on economic development and changes in country-specific demographics. **RESULTS:** We estimate that pneumonias are the predominant infection types among European countries at 13 per 1,000 individuals, while urinary tract infections are predominant in the Americas at 16 per 1,000 individuals, a rate 3.6 times higher than urinary tract infections among European countries. Bloodstream event rates across Middle East and African countries are about 2.8 times higher than European countries, reflecting poor infection control measures. We predict a 34.8% increase in surgical-site infection events in Middle Eastern and African countries over the forecast period. **CONCLUSIONS:** We observed heterogeneity in the rates of hospital-treated infection types among regions of the world. We predict increases in hospital-treated infection events across different regions due to demographic trends.

PMD20

FRAMINGHAM RISK SCORE PREDICTING MAJOR ADVERSE CARDIAC EVENTS IN POST CORONARY ANGIOPLASTY PATIENTS: A RIDDLE, MYSTERY AND ENIGMA

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OBJECTIVES: Framingham risk score (FRS) predicts the incidence of coronary atherosclerotic disease (CAD) but the same prediction in cardiovascular (CV) events after coronary angioplasty is questionable. **METHODS:** In this prospective study 1001 patients who underwent percutaneous transluminal coronary angioplasty (PTCA) from 1/6/2015 to 30/6/2016 were recruited and followed up for a period of 6 months. The clinical, anthropometric and other biochemical CVD risk factors of the study participants were done at the baseline. The univariate and multivariate cox proportional hazard regression analyses were performed to evaluate the relation between the cardiovascular risk factors and major adverse cardiac events (MACE) at one month. **RESULTS:** At 6 Months, MACE was observed in 83 (8.3%) subjects who underwent PTCA. The area under the curve (Hazards Ratio/HR) for FRS and NT Pro

BNP in predicting MACE was found to be 0.81 (95% CI: 0.73-0.88) and 0.89 (95% CI: 0.82-0.96) respectively. In type 2 diabetic patients, after adjustment for potential confounders baseline FRS > 20 and baseline NT ProBNP > 500 was significantly associated with MACE [adjusted hazard ratio (HR): 3.03, 95% CI: 1.41-6.54, $p = 0.005$]. In nondiabetic patients, NT ProBNP (> 500) was significantly associated with MACE [adjusted hazard ratio (HR): 2.08, 95% CI: 1.61-5.54, $p = 0.002$]. FRS under predicted MACE in non-diabetic subjects. **CONCLUSIONS:** FRS and NT ProBNP > 500 predicted MACE in Diabetic subjects, but FRS underpredicts MACE in Non-diabetic, where other risk factors anticipated it. It appears that FRS beyond threshold appears to predict MACE in diabetic subjects.

MEDICAL DEVICES/DIAGNOSTICS – Cost Studies

PMD21

BUDGET IMPACT ANALYSIS OF THE CELL CYCLE PROGRESSION TEST IN LOW AND INTERMEDIATE RISK, LOCALIZED PROSTATE CANCER

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OBJECTIVES: Clinical risk stratification of localized prostate cancer (PCa) guides treatment decisions. However, residual uncertainty and inaccurate classification could yield over- or under-treatment of patients considered for interventional treatment or active surveillance. The cell cycle progression (CCP) test, a genomic assay that estimates PCa aggressiveness, could improve accuracy of risk assessment and treatment choice for low- or intermediate-risk patients. This study estimated the five-year budget impact of CCP from an Ontario public payer perspective. **METHODS:** A budget impact analysis was conducted by comparing costs between a reference scenario without CCP and a new scenario with CCP. Since no studies have shown CCP's effect on clinical outcomes, we assumed that CCP would only change the distribution of initial treatments, not progression or survival. Each year an estimated 6,196 men are newly diagnosed with low- or intermediate-risk PCa. Treatment patterns for these groups of patients were obtained from the literature, and the expected uptake of CCP was estimated using expert opinion. The effect of CCP on treatment decisions was based on two clinical utility studies. **RESULTS:** We estimated the costs associated with the CCP test itself to be \$47.9 million, the costs associated with additional physician visits required to interpret the test result to be \$0.7 million, and the savings due to treatment change (increased use of active surveillance and decreased use of interventional treatment) to be -\$7.3 million. As a result, publicly funding the CCP test would result in a net budget impact of \$41.3 million in the first five years. Results were most sensitive to assumptions regarding the uptake and the extent that CCP altered current treatment. **CONCLUSIONS:** Publicly funding the CCP test would result in a large incremental cost to the provincial budget.

PMD22

ECONOMIC IMPACT ANALYSIS OF BRCA1 AND BRCA2 GENETIC TESTS IN WOMEN WITH ADVANCED STAGE OVARIAN CANCER IN THE COLOMBIAN CONTEXT

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OBJECTIVES: To develop an economic impact of BRCA1 and BRCA2 genetic tests in women with advanced stage ovarian cancer in the Colombian context. **METHODS:** Using the decision tree model, in a lifetime horizon, we analyzed the application of BRCA1 and 2 genetic tests in a hypothetical cohort of 100 patients diagnosed with this disease, taking into account the probability of positive or negative result according to the scientific evidence. At the same time, the prevalence and incidence of this disease was taken in order to find the probability of development or non-development of ovarian cancer in the relatives of these patients, for each patient with this disease, a family member at risk of developing ovarian cancer was associated according to the national household survey of the National Administrative Department of Statistics in Colombia, given the indication of the tests (Adelaida criteria). Drug costs (per minimum unit of presentation) and procedures were taken from databases of the Colombian health system, according to the management in clinical practice guidelines, which were corroborated by clinical experts. The cost of the tests was provided by the funder. A sensitivity analysis was performed based on the size change of the hypothetical cohort of the relatives. **RESULTS:** For a cohort of 100 patients the cost of applying the tests is USD \$4,536,728 and not to do so is USD \$4,587,387, with savings of USD \$50,659 (USD \$ 507 per patient) for its implementation. As the hypothetical cohort of relatives increased in the sensitivity analysis to 2 and 3, the savings per patient are USD \$3,636 and USD \$6,765 respectively. **CONCLUSIONS:** Given the savings in costs showed, it is concluded that it is important to implement the use of genetic tests in order to save costs of treatment of ovarian cancer and to prevent the late diagnosis of the disease.

PMD23

BUDGET IMPACT OF NEXT GENERATION SEQUENCING FOR MOLECULAR ASSESSMENT OF ADVANCED NON-SMALL CELL LUNG CANCER

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OBJECTIVES: Evaluate the budget impact of next-generation sequencing (NGS) instead of single-gene testing for tissue-based molecular assessment of non-squamous, advanced non-small cell lung cancer (aNSCLC) from the United States healthcare payer perspective. **METHODS:** A Markov model was developed to evaluate an annual cohort of newly-diagnosed, non-squamous aNSCLC patients in a

hypothetical million-member plan followed for 5 years. aNSCLC epidemiology data were from published literature. Mutation prevalence and testing rates for activating mutations were considered for current and emerging gene targets (EGFR, ALK, ROS-1, BRAF, MET, HER2, RET), and sourced from literature. Rates of successful test completion were informed by literature and clinical expert opinion. Patients identified as EGFR+ and ALK+ were assumed to be treated with erlotinib and crizotinib, respectively; clinical trial enrollment was an option for patients with other mutations. Adverse events, progression, and survival rates with targeted therapy or chemotherapy were from randomized clinical trials. Costs of testing and first-line and maintenance therapies were based on Medicare 2016 reimbursement values; adverse event and post-progression costs were from literature. **RESULTS:** Of 1-million plan members, 312 patients were expected to be newly-diagnosed with non-squamous aNSCLC and 177 were tested. Of the 57 tested patients expected to have activating mutations, single-gene testing identified 39 patients and NGS identified 56. Testing-related costs decreased \$45,326 with NGS instead of single-gene testing. First-line and maintenance treatment costs increased \$264,185, offset by \$79,612 of savings in post-progression-related costs. Total budget impact over 5 years for this cohort assessed with NGS instead of single-gene testing was \$139,247 (\$0.0023 per-member per-month). **CONCLUSIONS:** NGS is expected to improve identification of activating mutations and enable improved patient selection for targeted therapy and/or clinical trial enrollment. The impact to payer costs is expected to be breakeven or minimally cost-additive.

PMD24

BUDGET IMPACT ANALYSIS OF REMOTE MONITORING OF CRT/ICD THERAPY IN PATIENTS WITH HEART FAILURE IN BRAZIL: A PROBABILISTIC APPROACH

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OBJECTIVES: To estimate the budget impact of incorporating Remote Monitoring (Home Monitoring™) of Cardiac Resynchronization Therapy (CRT) and Implantable Cardioverter-Defibrillator (ICD) in Brazilian Public Healthcare System (SUS). **METHODS:** We undertake a budget impact analysis by means of cost calculator approach. Eligible population consisted of patients with CRT/ICD therapy in SUS diagnosed with heart failure (ICD-10 I50). Retrospective (2010-2016) number of patients with those characteristics was obtained through Health Informatics Department of the Brazilian Ministry of Health (DATASUS). Ordinary least square method was used to predict eligible population over the next five years. One scenario was built taking into account current and new intervention costs (BRL, Brazilian currency), whereas a second also included costs related to heart failure. Uptake of new intervention in SUS and its effect in current environment was estimated taking the private market and its differences with SUS in mind. Probabilistic sensitivity analysis was performed in order to explore parametric uncertainties. For the sake of clarity k means thousand. **RESULTS:** Deterministic results pointed out a budget impact of BRL 102k, BRL 427k, BRL 617k, BRL 879k and BRL 1,161k over the next five years. When opportunity costs are taken into account the budget impact drops to BRL 102k, BRL 1,2k, BRL 19k, BRL 72k and BRL 172k, respectively. Although uncertainties in BIA are not fully quantified, in view of our model, there is 95% of probability that budget impact will be less than BRL 155k, BRL 670k, BRL 1,200k, BRL 1,950k and BRL 2,950k over the next five years, respectively. **CONCLUSIONS:** Forecasting expenses with technology acquisition over the following five years lead to costs around BRL 102k to BRL 1,161k, favouring about 1,706 patients. Opportunity costs of new technology are capable to decrease dramatically budget impact, although meaningfully uncertainties may not be quantified in this model.

PMD25

BUDGET IMPACT ANALYSIS OF CAPSULE ENDOSCOPY FOR SCHEDULED MONITORING IN CROHN'S DISEASE

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OBJECTIVES: Crohn's disease, a chronic inflammatory condition of the gastrointestinal tract, is associated with substantial healthcare costs. Endoscopic inspection is considered essential for monitoring and optimizing treatment. Ileocolonoscopy visualizes the colon and terminal ileum but additional imaging is required to evaluate the entire bowel. Small bowel and colon capsule endoscopy (SBC-CE) evaluates the entire small bowel and colon in a single assessment. This analysis considers whether use of SBC-CE could reduce costs. **METHODS:** A patient-level, discrete-event simulation evaluated care and costs (in 2016 USD) in 1,000 patients (representing 140,184 patients in the health plan) over 5 years. During each cycle, patients were exposed to the risk of disease progression, adverse events, surgery, and death. Disease state changes used underlying Markov models for development of ulcers, stricturing, rectal disease, and anatomic involvement. Treatment decisions were reviewed every 3 months using patient-reported information and marker assessment or results from endoscopic monitoring. Monitoring was performed every 3, 6, or 12 months for patients starting treatment, presenting with symptoms, or in remission, respectively. **RESULTS:** SBC-CE resulted in a lower total cost of care (-1.1%, -\$169.2 million). Monitoring costs (-8.3%), adverse events costs (-2.6%), and treatment costs (-0.4%) were reduced with SBC-CE compared with ileocolonoscopy. SBC-CE identified more patients with non-symptomatic disease, moving them to treatment more efficiently. Sensitivity analyses demonstrated that model results were robust to sampled changes in input parameters, with SBC-CE resulting in a reduced total cost of care in 84.6% of simulations and a median cost saving of \$3,760 per patient. **CONCLUSIONS:** Use of SBC-CE for monitoring of Crohn's disease can result in reduced healthcare costs. Savings are generally realized in the cost of monitoring and avoidance of adverse events associated with ileocolonoscopy.

PMD26

A BUDGET IMPACT ANALYSIS OF TOTAL DISC REPLACEMENT (TDR) FOR SINGLE-LEVEL LUMBAR DEGENERATIVE DISC DISEASE (LDDD): A U.S. PRIVATE HEALTH INSURER PERSPECTIVE

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OBJECTIVES: Concerns regarding the budget impact of lumbar total disc replacement (TDR) surgery for patients with lumbar degenerative disk disease (LDDD) may underlie delayed coverage by US Private health insurers, despite mounting evidence on the favorable efficacy, safety and cost-effectiveness of TDR relative to lumbar fusion (LF). The objective of this study was to estimate the budget impact of single-level lumbar TDR coverage for LDDD for a typical US private health plan. **METHODS:** An economic model (one-year time horizon) was developed for an insurance plan of one million privately insured patients, evaluating LDDD prevalence, failure rates to conservative care, current fusion adoption rates and probable TDR substitution patterns. Cost components include surgical costs (device costs, operating room time, hospitalization and surgeon's fees), reoperations and community-based care. Published U.S. epidemiological data underlies the prevalence of LDDD, conservative care failure rate and number of current lumbar fusions performed. Procedure costs of TDR and fusion were informed by Medicare 2016 DRG payment rates. **RESULTS:** In the absence of TDR coverage, the model predicts that the target insurance plan to incur annual costs of \$18.56 million for LDDD patients who fail conservative care. If TDR is restricted to on-label use, and the patients who access TDR are those who would have fusion had TDR not been available, then the budget impact is predicted to fall to \$18.39 million, leading to a cost savings of \$170,000 with coverage of TDR. In a separate threshold analysis, TDR is predicted to remain budget neutral as long as 57% or more of TDR-treated patients are those who would have had a fusion surgery in the absence of TDR coverage. **CONCLUSIONS:** Based on the available evidence, TDR is expected to be less costly than surgical fusion and result in minimal to no budget impact when coverage is aligned with well-studied patient populations.

PMD27

ECONOMIC IMPACT OF THE USE OF THE PHARMACOGENETIC TEST OBTAINED FROM A SALIVA SAMPLE IN COLOMBIAN PATIENTS WITH MAJOR DEPRESSION ROMERO PRADA ME¹, ALBANES BELTRAN JP², ROA CARDENAS NC¹, VASQUEZ MELO EC¹¹Salutia Foundation - Research center in economy, management and health technologies, Bogota, Colombia, ²Universidad Nacional de Colombia, Bogotá, Colombia

OBJECTIVES: To determine the economic impact of the use of the pharmacogenetic test obtained from a saliva sample, compared with standard care, in patients diagnosed with major depression in the Colombian context. **METHODS:** The model is a decision tree to simulate the natural history of the disease in two study arms; the use of a pharmacogenetic test in the treatment, according to the genetic profile, versus the standard care, evaluating the stabilization or non-stabilization of the symptoms in response to the treatment, based on the probabilities taken from the scientific evidence, and from real data took from a Colombian over a 12 month period. **RESULTS:** The total cost of treatment of a patient with major depression using the pharmacogenetic test and the standard care is USD \$ 3,224.75 and USD \$ 2,990.89, respectively. The difference of USD \$ 233.86, is mainly associated with the cost of implementing the genetic test. However, the analysis showed that the costs of drugs have a reduction of 47% and a saving in the cost of hospitalizations of USD \$ 793.14 in patients who undergo the genetic test compared to those following the standard care. In addition, the use of pharmacogenetics generates a saving of USD \$ 496.56 in costs derived from disabilities compared with those following standard care. **CONCLUSIONS:** The use of pharmacogenetic testing in the treatment of patients with major depression generates savings in the cost of disability, in addition to reducing drug costs and hospitalization compared to standard care.

PMD28

ECONOMIC ANALYSIS OF QUANTAFLU COMPARED WITH DOPPLER ABI, FOR DETECTION OF PERIPHERAL ARTERY DISEASE: A U.S. HOSPITAL PERSPECTIVE

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OBJECTIVES: The prevalence of peripheral artery disease (PAD) is high, however physician awareness and involvement in diagnosis can be low. An in-office, automated, and quick measurement system, Quantaflu, has been shown to help detect PAD in patients where it was previously unrecognized. An economic analysis was conducted to compare the Quantaflu PAD test with Doppler Ankle Brachial Index (ABI) from the U.S. provider perspective in patients with suspected PAD. **METHODS:** The analysis was based on 96 (Doppler) and 128 (Quantaflu) patients tested per month for PAD at a single healthcare facility. Testing time per patient was assumed to be 20 minutes with Doppler and 5 minutes with Quantaflu. Prospective, multi-center study results reported Device sensitivity/specificity values of: 54.7%/94.3% and 89.5%/90.0% for Doppler and Quantaflu respectively. Cost parameters included device rental (Quantaflu) or capital costs amortized over useful life (Doppler), maintenance or accessory costs, labor testing costs. Results were expressed over one month for the total population as well as per patient. One-way sensitivity analyses were completed on core model parameters. **RESULTS:** In the model simulation, Quantaflu was predicted to yield cost savings per test compared with Doppler (i.e., \$5.15 vs. \$6.16 per test). In total, the model predicted that Quantaflu would result in 32 additional patients being tested per month, and 6 additional potential PAD patients identified based on overall time savings. The average cost per test, as a proportion of reimbursement, was predicted to be 3.7% with Quantaflu and 4.4% with Doppler. Cost saving results remained robust across various sensitivity analyses. **CONCLUSIONS:** The Quantaflu PAD test was predicted to provide cost savings on a per test basis for U.S. providers primarily due to time saved on test administration, while

potentially increasing the detection of PAD patients. Future study should involve further real-world analysis of potential cost-efficiencies with this product.

PMD30

INVESTIGATION OF THE COST-EFFECTIVENESS OF FENO MEASUREMENT AS A SCREENING TOOL TO DETECT OMALIZUMAB RESPONSIVENESS IN DIFFICULT-TO-TREAT ASTHMA PATIENTS

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OBJECTIVES: Describe the cost-effectiveness of fractional exhaled nitric oxide (FeNO) in identifying omalizumab responders in comparison to an alternative traditional strategy. **INTRODUCTION:** According to the CDC, in 2014 there were 17.7 million (7.4%) adults and 6.3 million (8.6%) children living with asthma in the US. Of all asthmatics, 5-10% have a difficult-to-treat form of the disease, and are responsible for almost 50% of the total costs of asthma therapy nationwide. When management of asthma with traditional therapies including inhaled corticosteroids fails, allergic asthmatics are often considered for treatment with omalizumab, a monoclonal anti-IgE antibody. However, since not all patients respond to omalizumab, healthcare payers often require an omalizumab trial to assess responsiveness before approving a longer-term prescription. **METHODS:** Using a decision analysis, cost-effectiveness for two alternatives for predicting omalizumab responsiveness was compared: utilization of FeNO measurement prior to initiation of omalizumab trial (FeNO + omalizumab trial) and the current standard of care, initiation of omalizumab trial only. Model assumptions were drawn from the most recent literature pertaining to the sensitivity and specificity of the alternative strategies in identifying omalizumab responders, the typical duration of payer-required omalizumab trials, and omalizumab treatment costs. To demonstrate the robustness of the results, one-way and multi-way sensitivity analyses were performed. **RESULTS:** Per-patient costs for omalizumab during the trial period and initial treatment period totaled \$10,943 for the FeNO + omalizumab trial, and \$13,703 for the omalizumab trial alone. The expected cost per omalizumab responder identified was \$4,328 for those in the FeNO + omalizumab group, and \$7,786 for those in the omalizumab trial only group. FeNO + omalizumab trial remained the more cost-effective alternative through all one-way and multi-way sensitivity analyses performed. **CONCLUSIONS:** The implementation of FeNO measurement prior to initiating an omalizumab trial is cost-effective and has widespread policy implications for healthcare payers.

PMD31

EVALUATION OF REAL WORLD CLINICAL AND PHARMACY BUDGET OUTCOMES WHEN SWITCHING TO A WEARABLE INSULIN DELIVERY DEVICE FOR INSULIN ADMINISTRATION IN PATIENTS WITH SUBOPTIMALLY CONTROLLED DIABETES- A RETROSPECTIVE STUDY

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OBJECTIVES: To evaluate the clinical and budgetary impact of continuous use of a 24-hour wearable basal-bolus insulin delivery device (IDD) in patients with suboptimally controlled diabetes previously administering multiple daily injections (MDI) of insulin. **METHODS:** An electronic medical records database was queried to identify patients exceeding glycemic targets (A1C >7.0%) switched to V-Go IDD from MDI. Evaluated variables were extracted at baseline and up to 3 follow-up visits, post IDD initiation. Clinical and pharmacy budget comparisons to baseline were evaluated in patients with ≥ 5 months of continuous IDD use during the observation period. Impact to pharmacy budget per patient was derived by applying average unit pricing from market leaders for both basal and prandial insulins as well as pricing for insulin delivery via pen needles/syringes and V-Go IDD for prescribed insulin therapy. All costs were based on a normalized 30-day supply and published wholesale acquisition costs (WAC) in 2016 U.S. dollars as of December 31, 2016. **RESULTS:** Evaluated patients (N=86) had a mean baseline A1C of 9.2 ± 1.4%, duration of diabetes 15 ± 9 years, weight 98 ± 19 kg, and insulin total daily dose (TDD) 108 ± 48 units/day with an associated insulin therapy direct pharmacy cost of \$924.80 ± \$392.90 per patient/month. After a mean duration of 29 ± 5 weeks of administering insulin with an IDD, A1C was reduced by 1.2 ± 1.4%, p<0.0001, TDD decreased by 44% to 61 ± 19 units/day, p<0.0001 and direct insulin therapy costs were reduced to \$778.80 ± \$154.20, p=0.001 for a savings of \$146.00 ± \$378.60 per patient/month. Weight and patient reported hypoglycemia remained similar to baseline. **CONCLUSIONS:** Switching from MDI to basal-bolus therapy delivered with V-Go IDD was associated with significant reductions in A1C and insulin requirements and resulted in significant savings to the pharmacy budget.

PMD32

COST-EFFECTIVENESS OF USING FENO IN THE MANAGEMENT OF ASTHMA

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OBJECTIVES: Describe the cost-effectiveness of utilizing fractional exhaled nitric oxide (FeNO) to inform asthma management in comparison to the standard of care. **INTRODUCTION:** According to the CDC, in 2014 there were 17.7 million (7.4%) adults and 6.3 million (8.6%) children living with asthma in the US. Asthma guidelines recommend periodic assessment and management of symptoms to prevent exacerbations, the most severe of which can lead to hospitalization, increased healthcare utilization and cost. Some asthmatics have difficulty with achieving disease control, and despite treatment with effective controller agents including inhaled corticosteroids, and sometimes biologics for severe asthma patients, these patients experience an average of 2 exacerbations annually. In addition, according to recent data from Petsky et al. (Cochrane Reviews 2016), when FeNO is incorporated into asthma management, the risk of asthma exacerbations is reduced by 40-50%. **METHODS:** Using a decision analysis, the short-term

cost-effectiveness of two alternatives to asthma management was compared: FeNO measurement in addition to standard of care management and the current standard of care without FeNO measurement. Model assumptions were drawn from the most recent literature pertaining to exacerbation frequency and severity as well as to medication and other medical resource utilization associated with the two asthma management strategies. **RESULTS:** Annual expected per-patient asthma management costs totaled \$2,013 for FeNO plus standard of care, and \$2,637 for standard of care alone. The use of FeNO to guide asthma management is expected to result in 0.077 additional QALYs per patient per year, rendering FeNO measurement as an adjunct to standard of care the dominant asthma management strategy. **CONCLUSIONS:** This cost-effectiveness assessment suggests that widespread inclusion of FeNO measurement for guidance of asthma management would result in reduced risk for exacerbations and overall healthcare cost savings.

PMD33

BUDGET IMPACT MODEL APP ESTIMATING COST SAVINGS AND CLINICAL OUTCOMES OF THE HEART FAILURE PREVENTION PROGRAM. EXAMPLE FROM THE UK

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OBJECTIVES: Develop a budget model app estimating financial impact of introduction of heart failure diagnostics program. Present economic model as communication app to inform regional healthcare budgeting and decision making for patients with heart failure disease. **METHODS:** The model was originally developed in MS Excel and transformed into HTML5 app format for delivery purposes. The model utilizes UK hospital episode statistics as a primary data source. Future healthcare budget projections and extent of savings from introduction of heart failure prevention program are estimated from a payer perspective. Model simulation time horizon is 5 years. Efficacy data was informed from published clinical study demonstrating high accuracy of early testing results of a diagnostic campaign. Sensitivity analysis was conducted to estimate parametric uncertainty around model outcomes. **RESULTS:** Direct medical cost savings following an introduction of a heart failure prevention program are estimated to be GBP 2,320 per patient. Cost savings in outpatient and inpatient settings were GBP 1,673 and 647 respectively. Sensitivity analyses indicated that efficacy and price of a prevention program had the strongest magnitude of impact on model base case results. **CONCLUSIONS:** Model estimated that diagnostic heart failure prevention program is a cost-saving intervention. A budget impact model app may effectively inform decision making and regional budget planning as it provides technical ability to modify model inputs during presentation to healthcare payers. An economic model powered with web capabilities and dedicated data visualization libraries provide effective means to convey detailed economic data to healthcare payers and providers.

PMD34

LITERATURE REVIEW: HEALTH ECONOMIC MODELING OF COMPANION DIAGNOSTICS FOR TARGETED CANCER THERAPY

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OBJECTIVES: Health economic (HE) modeling of companion diagnostics (CDx) shares certain principles with pharmacoeconomic modeling, however it does have underlying challenges. The aim of this study is to review methodologies used in the HE modeling of CDx for targeted cancer therapy. **METHODS:** A literature search was conducted in EMBASE[®] to identify HE studies on CDx for targeted cancer therapy. Full journal articles were selected following the PRISMA statement and the modeling methodologies were reviewed. **RESULTS:** A total of 367 abstracts were identified and 40 studies on CDx HE modeling were selected for review. The number of HE studies on CDx increased from 1 in 2003 to 8 in 2016, including lung cancer (21), breast cancer (8), colorectal cancer (7), melanoma (1), ovarian cancer (1), gastric cancer (1) and chronic myeloid leukemia (1). 36 studies were cost-effectiveness (or cost-utility) analysis and 4 other studies reported only economic outcomes. 29 of the 36 studies compared with vs. without CDx to guide the targeted therapy, and 16 compared different CDx strategies. Cost-effectiveness analysis was conducted with a time horizon ranging from 1 year to lifetime, and markov model or decision-tree was commonly used with 5 using both models. All studies included CDx and treatment costs from a payer or health system's perspective and 5 were conducted from a societal perspective. 7 studies specified the selection of CDx diagnostic performance, and only 2 considered impacts of false positive/negative results. The majority of studies concluded that using CDx to guide targeted therapy could improve health outcomes with additional costs, and it was stated that cost-effectiveness of a CDx is sensitivity to treatment costs of a targeted therapy. **CONCLUSIONS:** With the increased adoption of targeted cancer therapy with CDx, best practice in HE modeling of CDx will be critical to assist the economic evaluation of both CDx and targeted therapies.

PMD35

COST-EFFECTIVENESS OF FIBERGLASS TOTAL CONTACT CASTING, IRREMOVABLE CAST WALKERS AND REMOVABLE CAST WALKERS IN THE TREATMENT OF PATIENTS WITH DIABETIC FOOT ULCERS IN ONTARIO, CANADA

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OBJECTIVES: Diabetic foot ulcers (DFU) cause substantial morbidity and are a risk factor for lower limb amputation. We assessed economic implications of off-loading devices including fiberglass total contact casting (TCC), irremovable cast walker (iTCC) and removable cast walker (RCW) in the treatment of DFU patients

in Ontario, Canada. **METHODS:** We developed a decision analytic model to determine the cost-effectiveness of TCC, iTCC and RCW compared with each other and with therapeutic shoes (TS) from the Ontario public payer perspective. Clinical model parameters (effectiveness and safety) of offloading devices were obtained from our systematic clinical evidence review. Costs of offloading devices and adverse events were taken from literature and expert opinions. Main outcomes of the model were incremental cost per healed ulcer, quality-adjusted life-years (QALYs) and the incremental cost-effectiveness ratio (ICER). We conducted sensitivity analyses to explore the robustness of our findings. All costs were expressed in 2016 Canadian Dollars. **RESULTS:** RCW and TS were dominated by TCC and iTCC in both cost effectiveness and cost-utility analyses. In the cost-utility analysis, TCC was associated with 0.002 QALYs gained at an additional cost of \$428 compared to iTCC over the 6-month time horizon. This translated into an ICER of \$258,000 per QALY gained. The model was sensitive to time-to-healing using TCC, iTCC and healing probability of TCC and iTCC. Increased accessibility to an offloading device among DFU patients by 25% reduces the amputation cost by \$16 million per year. **CONCLUSIONS:** RCW or TS was more expensive and less effective than TCC or iTCC in the treatment of DFU. iTCC is as effective as TCC in the treatment of patients with DFU and associated with fewer costs. iTCC should likely be the preferred option when acceptable to patients and clinicians. In situations where it cannot be used, TCC may be a reasonable alternative.

PMD36

THE ECONOMIC IMPACT FOR SELF-INSURED EMPLOYERS IN THE USA FROM EARLY DIAGNOSIS OF DIARRHEA DOMINATED OR MIXED IRRITABLE BOWEL SYNDROME (IBS-D/M) USING A NOVEL IBS DIAGNOSTIC BLOOD PANEL

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OBJECTIVES: The average time from first symptoms to diagnosis of IBS-D/M is 6.1 years. During the pre-treatment symptomatic period patients' work ability is reduced through increased absenteeism and presenteeism. This analysis assesses the economic impact of using a novel IBS diagnostic blood panel for the presence of two biomarkers associated with IBS-D as early diagnosis of IBS-D/M for self-insured employers in the USA. **METHODS:** Three integrated models were constructed: (1) Diagnostic cost-minimization (C-M) decision model comparing (a) exclusionary diagnostic pathway (standard of care) with (b) a diagnostic strategy using the IBS diagnostic blood panel. (2) The C-M model formed the basis for a diagnostic budget-impact analysis (BIA), which compared the annual cost of the two diagnostic strategies. (3) Work impact model to calculate the total diagnostic cost of the IBS-D diagnostic panel strategy, derived from the C-M model, the cost of treatment with rifaximin and the cost impact of reduced absenteeism and presenteeism for true positive IBS-D/M diagnosed and successfully treated patients. **RESULTS:** The C-M estimated the per patient total diagnostic cost was \$4,303 for the exclusionary pathway and \$2,555 for the IBS-D diagnostic panel strategy. The BIA estimated the annual potential diagnostic cost savings for a 10,000 employee organization would be \$92,498 or \$0.77 per member per month (PMPM). For the same organization the estimated number of work days gained from reduced absenteeism and presenteeism from true positive and successfully rifaximin treated IBS-D/M patients was 270 days. This translated into an annual net cost saving of \$34,918, or a PMPM saving of \$0.29. **CONCLUSIONS:** This economic evaluation, using the three integrated models, indicate that introducing a novel IBS diagnostic blood panel could lead to cost savings for self-insured corporations in the USA. Incorporating pro-active IBS diagnosis into corporate benefit or wellness programs could be an efficient strategy.

PMD38

COST EFFECTIVENESS OF VAB (VACUUM ASSISTED BIOPSY) VERSUS SURGERY IN THE REMOVAL OF FIBROADENOMAS

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OBJECTIVES: Fibroadenoma of the breast is most common in young women in their 20s and 30s, but can be found in women of any age. Fibroadenomas can cause physical deformity, discomfort and emotional distress, and as a result, are often removed. Two of the most common approaches to removing Fibroadenomas are surgical excision and percutaneous excision via Vacuum Assisted Biopsy (VAB). While open surgical excision is effective, it can be very costly due to operating room charges. Additionally, it can also lead to negative outcomes such as bruising, swelling, scarring and possibly infection. VAB has been shown to be safe and highly effective at removing Fibroadenomas. It offers significant advantages to the patient including minimal morbidity, scarring, reduced re-biopsy rates and cost. **METHODS:** A retrospective analysis of both Surgical Excision and VAB procedures from the Premier Hospital Database was conducted. The economic outcomes of patients whose discharge data included CPT codes for VABB procedures 19083 and surgical excision procedures 19101, 19120, 19125 were evaluated in the outpatient setting. Adult patients (>18) with a procedure between 1/2014-12/2014 were evaluated. Total costs for the procedure, re-operations and clinical complications were collected. **RESULTS:** The analysis produced cohorts of 24,479 for Surgical Excision and 30,067 for VAB. Average age for Surgical Excision was 51.50, SD 17.03 and for VAB was 54.44, SD 15.29. Cost of VAB was associated with a lower all-cause cost of \$1,755.77 (\$1,152, SD \$4,102.01 VAB vs \$2,908.66, SD \$2,110.33 Surgery); readmission rates for Surgical Excision was 11-17% of cases while for VAB was 4-9%. **CONCLUSIONS:** Lower healthcare utilization and outpatient hospital cost was found to be associated with the use of VAB compared to Surgical Excision. The research shows that VAB can be cost saving and have better patient outcomes compared with Surgical Excision for Fibroadenomas of the breast.

PMD39

A PROSPECTIVE PRAGMATIC CLINICAL TRIAL TO COMPARE THE REAL-WORLD USE OF A WEARABLE INSULIN DELIVERY DEVICE TO STANDARD TREATMENT OPTIMIZATION IN TYPE 2 DIABETES PATIENTS WITH POOR GLYCEMIC CONTROL USING MULTIPLE DAILY INSULIN INJECTIONS

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OBJECTIVES: This prospective pragmatic clinical trial (PCT) evaluated a wearable insulin delivery device (V-Go) compared to a standard treatment optimization control (STO) in a community-based practice setting. The primary outcome was the change in A1C from baseline to end of study (EOS). Treatment cost and effectiveness analyses in patients receiving multiple daily insulin injections (MDI) were conducted. **METHODS:** This cluster randomized trial, where study sites rather than individual patients, were randomized to initiate V-Go and stop other insulin therapy or to continue diabetes treatments. Patients taking insulin were enrolled in both groups and treated according to routine practice for up to 4 months. All treatments and medications were obtained by usual care utilizing patient health insurance. **RESULTS:** The analysis population included 52 sites in the United States with 246 STO and 169 V-Go patients. Baseline A1C ranged from 7.9 to 14.2% and was higher for V-Go vs. STO (9.88% vs. 9.34%; $p < 0.001$) indicating a selection bias to initiate V-Go in more advanced diabetes patients. Significant A1C decreases from baseline to EOS with V-Go (-0.95%, $p < 0.001$) and STO (-0.46%, $p < 0.001$) and for V-Go vs. STO ($p < 0.002$) were observed. To control for the baseline and treatment imbalance of the overall cohort, cost and efficacy analyses in patients utilizing comparable baseline diabetes treatment, basal bolus insulin injections, were performed. V-Go ($n=95$) had higher mean baseline A1C than STO ($n=113$), 9.895% vs 9.374%, and a larger change from baseline of -1.015% vs -0.377%; $p < 0.01$. The mean per patient per day (PPPD) cost of diabetes treatment, using Wholesale Acquisition Cost (WAC) and including all concomitant diabetes medications and devices, was \$32.60 for STO compared to \$30.59 for V-Go patients. **CONCLUSIONS:** This PCT demonstrated improved diabetes treatment outcomes and total diabetes treatment cost in patients with poor diabetes control initiating a wearable insulin delivery device in a real-world setting.

PMD40

COST-EFFECTIVENESS OF NEXT GENERATION SEQUENCING FOR DETECTION OF LOWER RESPIRATORY TRACT INFECTIONS IN IMMUNOCOMPROMISED PATIENTS

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OBJECTIVES: Lower respiratory tract infections (LRTIs) are a significant cause of mortality in immunocompromised patients. Next generation sequencing methods may improve diagnostic performance relative to a panel of targeted molecular diagnostic tests and cultures (PANEL) for detection of microorganisms from bronchoalveolar lavage (BAL); however, the relative cost-effectiveness is unknown. The objective of this study was to determine the cost effectiveness of NGS relative to PANEL for detection of respiratory infections in BAL specimens. **METHODS:** We built a decision tree to assess 30-day costs and mortality per patient tested in a population of hospitalized immunocompromised patients with suspected LRTI. Outcomes were compared in BAL specimens tested with NGS and PANEL. Inputs were identified from literature sources or expert opinion. Probabilistic sensitivity analysis was performed using the 20 variables that had greatest influence from a one-way sensitivity analysis. We tested two scenarios: 1) a base case in which we assumed the costs of the tests were the same 2) a test case in which we determined the cost difference at which NGS testing would be acceptable at a willingness-to-pay threshold of \$50,000 per life saved. **RESULTS:** The base case analysis (assuming testing costs of NGS and PANEL were the same) showed that NGS had lower costs with no mortality difference compared to the PANEL over the 30 days (\$19,460 and 88.99% survival vs. \$19,551 and 88.86% survival per patient tested, respectively). The incremental cost-effectiveness ratio (ICER) for the NGS vs. PANEL reached \$50,000 per life saved when the cost of the NGS test was \$154 greater than PANEL, or if the specificity of NGS was 1% lower than PANEL. NGS achieved 66 and 75% likelihoods of being cost-effective at willingness to pay thresholds of \$0 and 50,000, respectively. **CONCLUSIONS:** NGS-based testing is most likely cost-effective compared to PANEL for testing immunocompromised patients with symptoms of LRTI.

PMD41

COST-EFFECTIVENESS OF REVISION HIP ARTHROPLASTY IN TYPE IIIB ACETABULUM DEFECTS WITH USING A CUSTOM POROUS THREE-FLANGED ACETABULAR IMPLANT

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OBJECTIVES: Total hip arthroplasty (THA) is a common, cost-effective operation for patients suffering from coxarthrosis. Unfortunately, revisions are relatively frequent and their incidence is correlated to the size of the acetabular defect. The aim of this study is to analyse the cost-effectiveness of a new type of porous three-flanged implant (PTFI) targeting revision surgery of Paprosky type IIIB acetabular defects compared to the most common alternative for these serious acetabular defect, being a (non-porous) Custom Three-flanged Acetabular Component (CTAC). **METHODS:** CTAC were compared to the new PTFI by means of a Markov model with four states (successful, re-revision, resection and dead). The cycle length was set at 6 months with a 10 year time horizon. Implant survival, transition probabilities and quality of life measures were obtained through systematic literature search and data obtained from the manufacturers. Costs from the health care payer's perspective were calculated based on data from the literature, obtained from manufacturers and from social security agencies. Discount rates were used on cost (3%) and QALY (1.5%)

estimates. **RESULTS:** Based on the outcomes of our model, the new PTFI provides good value for money. For the basecase of a 65 year old man, a QALY gain of 0.296 and cost reduction of 390€ is obtained. In all age and gender groups the use of the new PTFI is dominant. The price of the implant has the highest impact on cost side while the utility for successful surgery has the biggest influence on the QALY. Probabilistic analysis resulted in 33.4% of the cases being dominant. **CONCLUSIONS:** Based on the findings of this model, the new PTFI has the potential to provide excellent value for money when used in revision arthroplasty of Paprosky type 3B acetabular defects. This was mainly due to lower revision and complication rates.

PMD42

COST-EFFECTIVENESS OF ORBITAL COMPARED TO ROTATIONAL ATHERECTOMY OF SEVERELY CALCIFIED CORONARY ARTERY LESIONS IN JAPAN

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OBJECTIVES: Percutaneous treatment of severely calcified coronary artery lesions is associated with lower procedural success and higher complication rates compared to non-calcified lesions, and continues to present a clinical and economic challenge. Compared to rotational atherectomy (RA), orbital atherectomy (OA) has been shown to decrease procedure failure and reintervention rates. Our objective was to explore the cost-effectiveness of OA compared to RA in the Japanese healthcare system. **METHODS:** A decision-analytic model calculated reintervention rates and consequent total one-year costs. Effectiveness inputs were therapy-specific target lesion revascularization (TLR) rates and all-cause mortality, pooled from identified clinical studies. Index and reintervention costs were determined via claims data analysis of $n=33,628$ subjects treated in Japan between April 2014 and March 2016. We computed incremental cost-effectiveness in ¥ per life year (LY) gained based on differences in one-year cost and projected long-term survival. In the absence of a final reimbursement amount, we assumed an OA device cost of ¥500,000, and tested a range of ¥350,000 to ¥650,000. **RESULTS:** Total one-year costs were ¥75,478 higher with OA compared to RA (¥2,765,239 vs. ¥2,689,761). Higher index procedure device and accessory costs for OA (¥567,800 vs. ¥365,850) were largely reclaimed at 1-year follow-up, because of lower 12-month target lesion revascularization rates (5.0 vs. 15.7%). Based on one-year mortalities of 5.5% and 6.8% for OA and RA, projected mean survival was 8.34 and 8.16 LYs respectively (+0.17), resulting in an ICER of ¥439,214. OA was the dominant strategy for device cost less than ¥465,000, and reached a maximum ICER of ¥1,079,314 at device cost of ¥650,000. Findings were robust across a wide range of clinical and utilization assumptions. **CONCLUSIONS:** Orbital atherectomy for the treatment of severely calcified coronary artery lesions is a cost-effective and potentially cost-saving treatment approach in the Japanese healthcare system. Future confirmatory analyses are warranted.

PMD43

DIRECT COST ANALYSIS OF PERIPHERALLY INSERTED CENTRAL LINE CATHETERS AND DEEP VEIN THROMBOSIS EPISODES

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OBJECTIVES: Catheter-related thrombosis is associated with significant morbidity and economic burden. Recent studies have identified an association between the risk of deep vein thrombosis (DVT) and peripherally inserted central catheters (PICC) diameter size. One of the most commonly recommended strategies to minimize the risk of DVT is the use of the smallest PICC diameter appropriate for therapy. This economic analysis estimates a range of DVT-related costs that may be averted when shifting current utilization to smaller diameter PICCs where clinically indicated. **METHODS:** The model assumed an average number of 1,000 PICCs being inserted annually per hypothetical US hospital as the base case. The analysis compared annual DVT costs in a current treatment mix (i.e., 25% 4 Fr, 60% 5 Fr, and 15% 6 Fr PICCs) versus a future treatment mix (i.e., 65% 4 Fr, 30% 5 Fr, and 5% 6 Fr PICCs). The average cost to treat a DVT episode was \$15,973 based on public literature for PICC-related DVT reported by Evans (2013). DVT rates were also derived from Evans (2013) (i.e., 0.77% 4 Fr, 2.78% 5 Fr, and 7.55% 6 Fr). Sensitivity analyses were conducted examining alternate PICC utilization, DVT rates, and DVT costs. **RESULTS:** The analysis predicted that increased use of smaller diameter PICCs in the future treatment mix may potentially avoid approximately \$204,614 when compared with the current mix due to reduced DVT-related costs. Sensitivity analyses estimated cost savings with the future practice mix ranging from \$12,362 to \$849,920. **CONCLUSIONS:** Increasing the use of smaller diameter PICCs has the potential to provide cost savings due to potentially avoided DVT episodes. It is important to consider that the causes of DVTs are multifactorial, with PICC diameter only being one factor of several that may affect potential DVT episodes.

PMD44

UTILIZATION AND COSTS OF DIGITAL BREAST TOMOSYNTHESIS OR BREAST ULTRASOUND IN CONJUNCTION WITH FULL-FIELD DIGITAL MAMMOGRAPHY

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OBJECTIVES: Digital breast tomosynthesis (DBT) and breast ultrasound (US) are increasingly used for breast cancer screening. The objective was to describe utilization trends and health plan costs of these tests compared to the use of traditional full-field digital mammography alone (FFDM). **METHODS:** The Truven Health MarketScan Commercial Database was used to identify women aged 40-64 years undergoing screening mammography in 2005-2015. Women were required to have 12 months

pre- and 6 months post-index continuous enrollment. For each screening scenario (FFDM alone, FFDM+DBT, and FFDM+US), an annual screening rate was estimated and the average annual cost was determined. Also, the rate of diagnostic mammography performed within 180 days for 2015 was estimated. **RESULTS:** Approximately 5,000,000 women met the inclusion criteria in each year for the trend analysis. Screening mammogram rates rose from 38.9% in 2005 to 45.8% in 2009, but have remained relatively stable recently (2011-2015 range: 42.8%-43.6%). The percentage of screened women who received US+FFDM on the same day increased from 0.7% in 2005 to 3.8% in 2015. In 2015, the year in which a DBT code became available, 9.5% of screened women received FFDM+DBT and 0.4% received FFDM, DBT and US on the same day. Diagnostic mammography rates following a screening exam were 8.9% for FFDM alone, 7.3% for FFDM+DBT, and 14.0% for FFDM+US. Average screening regimen costs were \$178.93 for FFDM, \$242.55 for FFDM+DBT and \$420.20 for FFDM+US. **CONCLUSIONS:** While FFDM+US is less common than FFDM+DBT, utilization of FFDM+US is growing and average costs are higher for FFDM+US than FFDM+DBT. Diagnostic mammography is more commonly performed after FFDM+US than after FFDM+DBT or FFDM alone. Additional research should be conducted to understand factors contributing to this difference.

PMD45

DIRECT MEDICAL COSTS TO MEDICARE OF IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR COMPLICATIONS THAT REQUIRED LEAD REOPERATION

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OBJECTIVES: The epidemiology of complications associated with implantable cardioverter defibrillators (ICD) has been well-studied. However, economic data are needed to understand the overall impact of lead-related complications and the cost effectiveness of alternative treatment strategies. The objective of this study was to estimate the direct medical cost to Medicare of transvenous (TV) lead complications that required reoperation. **METHODS:** Using Medicare enrollment and claims data from 1/1/2010 through 12/31/2014, we identified 1,691 patients (cases), age \geq 65, who underwent reoperation (repositioning, repair, or removal) of TV leads between 1/1/2011 and 12/31/2013. For comparison, we identified a pool of candidate controls who underwent initial ICD implantation between 1/1/2010 and 12/31/2010, but who did not undergo lead reoperation thereafter. From these, two controls were selected for each case ($n=3,382$) matched on age, sex, and geographic region. All patients were followed from six months before, to up to six months after, their index date, which was defined as the date of reoperation in cases and 1/1/2013 in controls. We calculated the cumulative direct medical cost to Medicare (Medicare allowed charges) of all services related to ICD complications during the observation period, and compared costs between cases and controls. **RESULTS:** The mean age was 78, 40% were female, 92% were white, and 72% had a Charlson Comorbidity score \geq 2. Among cases, 63% were hospitalized for lead reoperation and 65% underwent removal. Overall, the average cumulative cost of TV lead complications requiring reoperation was \$47,548 and \$3,956 among controls (difference \$43,592; 95% confidence interval \$41,726-\$45,459; $p < 0.001$). The average cumulative cost of TV lead complications among those requiring lead reoperation in the presence of infection (21% of cases) was \$86,745. **CONCLUSIONS:** The economic consequences of TV lead complications requiring reoperation are substantial. Effective approaches to reducing lead reoperations are likely to result in significant cost-offsets.

PMD46

SPINAL CORD STIMULATION INFECTION RATE AND INCREMENTAL ANNUAL EXPENDITURES: RESULTS FROM A US PAYER DATABASE

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OBJECTIVES: To estimate the infection rate and the annual health expenditures associated with spinal cord stimulation (SCS)-related infection. **METHODS:** Data from the Truven MarketScan[®] Commercial Claims and Medicare Supplemental databases were used to identify patients with a SCS neurostimulator generator implant during the calendar years 2009-2014. Patients were continuously enrolled for at least 12 months before and after implant. The patients were further divided into initial group or replacement group. Annual expenditures were estimated for patients who experienced a device-related infection versus those without infection since SCS generator implant. The generalized linear model was conducted to estimate annual expenditures, utilizing a gamma distribution and a log link function. All multivariable expenditure models were conducted separately for patients in the initial group and the replacement group. All models were controlled for presence of infection before generator implant, Charlson comorbidity index score, as well as patient demographics. **RESULTS:** The study included 6,615 patients; 5,563 patients were identified as the initial group, and 1,052 patients were identified as the replacement group. The overall SCS-related infection rate within 12-months post-implant was 3.11%. The infection rates for the initial group (3.09%) and replacement group (3.23%) were not significantly different ($p=0.8104$). The multivariable expenditure models revealed that patients with infection had higher annual expenditures than patients without infection in both initial implant and replacement implant groups. Estimated incremental annual healthcare expenditures for patients with an infection were \$59,716 (95% CI: \$48,965-\$69,480) for initial implanted patients and \$64,833 (95% CI: \$37,377 - 86,519) for replacement patients. **CONCLUSIONS:** The approximate 3% infection rate within 12-months of SCS implant determined from a large administrative database further emphasizes the need for improvement in SCS infection control practices. The result shows the expenditure burden associated with SCS-related infection is substantial, and the management of SCS-related infection is important from both clinical and economic standpoints.

PMD47

IMPACT OF THE ADOPTION OF MICROPLEGIA DELIVERY SYSTEM: CLINICAL AND ECONOMIC ANALYSIS USING THE PREMIER DATABASE

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OBJECTIVES: This study examined the clinical and economic impact of adoption of microplegia delivery system compared to traditional cardioplegia from the hospital perspective. **METHODS:** This retrospective cohort study used Premier Hospital data (January 2009 to March 2015) for patients undergoing one of the following primary procedures: coronary artery bypass graft (CABG), aortic valve replacement (AVR), or mitral valve replacement (MVR). The first three months of data after a hospital adopted the microplegia delivery system (MDS2) system was excluded. Outcomes for this analysis included: a composite adverse event endpoint, total visit cost, medication cost, length of stay (LOS) and ICU days. The composite adverse event included: major cardiac (acute myocardial infarction, angina, stent occlusion/thrombosis, stroke/TIA) or renal (acute kidney injury with and without dialysis) events, sepsis or other infection, wound, abdominal or pulmonary complications, cardiogenic shock, bleeding or death. A multivariable difference-in-differences (DID) analysis using fixed effects was performed for each outcome. All models were adjusted for patient demographics, surgical characteristics and comorbid conditions. **RESULTS:** A total of 256,814 visits met the inclusion criteria. After controlling for within hospital variation and all covariates, there was a 2.25% absolute risk reduction in the composite of adverse events with MDS2 compared to traditional cardioplegia, which equates to a relative risk reduction of 5.25%. There were significant reductions in LOS and ICU days at the 0.1 alpha level. A per case reduction of \$1,231 in total visit costs and a \$192 in medication costs was found in MDS2 hospitals. This equates to a 2.5% reduction in total cost and a 5% reduction in medication costs. **CONCLUSIONS:** For hospitals performing CABG, AVR and MVR surgeries with second generation microplegia delivery systems, significant reductions were seen in adverse events, LOS, and ICU days, which lead to reductions in total visit costs and medication costs.

PMD48

COST ANALYSIS FOR MEDICAL DEVICES FOR RARE DISEASES IN BULGARIA - A CASE WITH EPIDERMOLYSIS BULLOSA

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OBJECTIVES: To define the financial burden of medical devices for rare disease epidermolysis for the Bulgarian healthcare system and to predict their budget impact in the next 3 years. **METHODS:** Prospective, observational study of the direct cost of reimbursed medical devices for health insured patients with epidermolysis bullosa during 2014 - 2016 was performed. Budget impact was extrapolated for the next 3 years applying linear function and considering the impact of the severity of the disease on the cost. **RESULTS:** The medical devices reimbursed for patients with epidermolysis bullosa are non-stick transferring or absorbent pads for disease' dystrophic, simplex and lethal forms (ICD codes Q81.0, Q81.1, Q81.2). Number of registered patients with lethal form of the disease is 1, 11 are with dystrophic form, and 3 with simplex. The total reimbursed cost for 2016 were 103 000 euros (0.3% of budget for medical devices) for patients with epidermolysis bullosa dystrophic (approximately 9 000 Euro per patient per year), followed by epidermolysis bullosa simplex - 16 000 euros (0.04% of budget for medical devices and approximately 5 000 Euro per patient per year). Cost per patient per year differs statistically significant with the increase in case of more severe form. The expected cost changes for the next 3 years follow a linear trend of increase with the severity of the disease and account for up to 300 000 Euro on total. **CONCLUSIONS:** The public funds reimbursed medical devices only for patients with epidermolysis bullosa. The direct costs are significantly low for the Bulgarian healthcare system and the expectations are for slightly increasing in the near future which logically depends on the number of cases and severity of the disease.

PMD49

ECONOMIC EVALUATION OF EMERGING DIAGNOSTIC TEST FOR CORONARY ARTERY DISEASE

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OBJECTIVES: A number of diagnostic tests are available for patients with suspected coronary artery disease. It is widely known, however, that the poor accuracy of the existing tests results in poor diagnoses, unnecessary invasive procedures, and high healthcare costs. An emerging technology, the HeartFlow Analysis, utilizes data from Coronary CT Angiography to determine what patients need a cardiac intervention. Clinical studies have demonstrated that the test is safe and effective. Using clinical data, our objective is to evaluate the cost consequences of incorporating a HeartFlow analysis in the patient pathway. **METHODS:** Using data gathered from the Planned Invasive Cohort ($n=380$) in the PLATFORM (Prospective Longitudinal Trial of FFRCT: Outcome and Resource Impacts) trial (Douglas 2015) we calculated the number of patients needed to treat (NNT) with a HeartFlow Analysis in order to avoid a negative outcome. In this analysis a negative outcome was defined as an invasive interventional coronary angiography (ICA) where the patient did not have obstructive disease. We then applied cost weights based on Medicare reimbursement rates (national average of technical and professional fees) and an assumed HeartFlow price of \$1,500, to estimate the costs required to avoid an invasive angiography. **RESULTS:** It was determined that for this population 1.64 patients must have access to a diagnostic pathway with HeartFlow in order to avoid an unnecessary angiography. The average weighted cost of diagnosing a patient using this pathway was \$1,210. With an NNT of 1.64, we see a cost of \$1,984 to avoid the cost of an invasive angiography (\$2,838). The cost savings of \$834 represents a 30% reduction from the cost of sending a patient to angiography. **CONCLUSIONS:** Incorporating a HeartFlow Analysis into a patient's diagnostic pathway has the potential to significantly reduce the cost of care.

PMD51

COST-BENEFIT ANALYSIS OF DENTAL CROWNS IN UKRAINE: METALCERAMIC VS. ALL-CERAMIC CROWNS

Got S, Zaliskyy O, Zaliska O

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OBJECTIVES: Metal ceramic (MC) crowns have been considered the gold standard for the repair of damaged teeth. However, the esthetic of MC crowns is limited by the metal framework and the layer of opaque porcelain needed for masking the underlying metal grayish shade. All-ceramic crowns have been used over the last four decades as an alternative for MC crowns to overcome their esthetic limitations. Although, the price of all-ceramic crowns is much higher. Policy makers require information on the relative benefits and costs associated with different types of crown materials in order to support reimbursement decisions. The objective of this study was to evaluate the cost-benefit ratio of dental metal ceramic and all-ceramic crowns. **METHODS:** three hundred ninety four patients participated in the study. They were included into two treatment groups and were followed up for two years and three months at Lviv National Medical University. People were selected among the patients who only needed crown restorations. Direct and indirect costs of the treatments were paid out of the pocket by patients. **RESULTS:** Total costs for the group (#1) with metal ceramic crowns were 21630\$ and for the group (#2) with all-ceramic crowns were 26700\$. The analyses yields a cost-benefit ratio of 291,8 for group #1 and 168,1 for the group #2. **CONCLUSIONS:** Metal ceramic crowns provide a positive cost-benefit ratio compared with the all-ceramic crowns. Metal ceramic dental restorations fulfill the treatment needs and continue to be the widely recommended treatment for the patients with extensively decayed teeth.

PMD53

EVALUATING THE COST-EFFECTIVENESS RESULTS OF DIAGNOSTIC STRATEGIES FOR HEPATOCELLULAR CARCINOMA IN JAPAN

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OBJECTIVES: To evaluate cost-effectiveness estimates through model validation and characterization of uncertainty in a cost-effectiveness analysis comparing gadoteric acid-enhanced magnetic resonance imaging (EOB-MRI) with extracellular contrast-media-enhanced MRI (ECCM-MRI) and contrast-media-enhanced computed tomography (CE-CT) for diagnosis of hepatocellular carcinoma (HCC) in Japan with a focus on local versus foreign inputs. **METHODS:** Nearly all input parameter values were from local Japanese sources. Model inputs and structure were validated by a Delphi panel of clinical experts. Uncertainty in model inputs was addressed using probabilistic sensitivity analysis. Scenario analyses were also conducted using values derived from previously conducted non-Japanese studies, including diagnostic sensitivity and specificity values reported according to tumor size and utility values used in previous economic evaluations. Probabilistic and sensitivity analyses were conducted based on a 6-stage Markov model constructed to estimate lifetime direct costs and clinical outcomes associated with HCC diagnosis using EOB-MRI, ECCM-MRI and CE-CT. **RESULTS:** For the per patient probabilistic results for a hypothetical cohort of 100,000 patients over a lifetime horizon, EOB-MRI was associated with lower direct costs (1,485,875JPY) and generated a greater number of QALYs (10.158) than either ECCM-MRI (1,750,167JPY, 9.865 QALYs) or CE-CT (1,907,129JPY, 9.724 QALYs). Under the scenario analysis by tumor size, EOB-MRI was found to be dominant, resulting in a larger incremental difference in costs than was found in the base case versus other diagnostic strategies. In the scenario analysis for the utility values, EOB-MRI remained dominant despite smaller incremental differences compared to the base case. **CONCLUSIONS:** Both probabilistic and scenario based results closely matched the base case results, providing preliminary validation of the model and supporting the finding that EOB-MRI is a cost-effective option over ECCM-MRI and CE-CT.

PMD54

A COST-EFFECTIVENESS ANALYSIS OF CONTINUOUS SUBCUTANEOUS INSULIN INFUSION VERSUS MULTIPLE DAILY INSULIN INJECTIONS IN INDIAN PATIENTS WITH TYPE 1 DIABETES

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OBJECTIVES: Incidence of type 1 diabetes mellitus (T1DM) is increasing at a rate of 3%-5% annually in India. Multiple Daily Insulin (MDI) injections and Continuous Subcutaneous Insulin Infusion (CSII) are effective modes of intensive therapy in patients with T1DM. CSII offers better glycemic control but incurs a higher cost as compared to MDI. This is the first-ever cost-effectiveness analysis to compare CSII against MDI in Indian healthcare setting. **METHODS:** India specific data were extracted from published literature (MEDLINE, Embase, Cochrane Library). If unavailable, data were adapted or assumed as per the standard guidelines. Analysis was conducted using a Markov simulation model with a time horizon of 8 years. Costs and quality-adjusted life years (QALYs) were discounted at a rate of 3.5% annually. Model outcomes were reported as incremental cost-effectiveness ratio (ICERs) and net benefit. Probabilistic sensitivity analysis was performed using Monte Carlo simulation. **RESULTS:** Cost and QALYs gained were higher with CSII (cost INR 9,34,430.89; QALY 2.498) versus MDI (cost INR 1,00,263.73; QALY 1.256) with a net benefit of INR 41,47,638.13. Compared to MDI, an additional cost of INR 6,71,534.69 was accrued with CSII for one year of perfect life gained. The ICER was greater than three times India's Gross Domestic Product (GDP) per capita (INR 1,10,368.91). **CONCLUSIONS:** Compared to MDI, CSII has higher cost but better outcome. Considering greater QALYs gained with CSII, patients can be offered with some measures to reduce the out-of-pocket expense on therapy.

PMD55

COST EFFECTIVENESS ANALYSIS OF A FLASH CONTINUOUS GLUCOSE MONITORING SYSTEM FOR TYPE 1 DIABETES (T1DM) PATIENTS RECEIVING INTENSIVE INSULIN TREATMENT IN THE UK

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OBJECTIVES: Regular glucose monitoring is important for T1DM patients receiving intensive insulin. A novel, factory-calibrated flash continuous glucose monitoring system (the FreeStyle Libre™ system) continuously measures glucose levels from interstitial fluid. Data transfers to a handheld reader from a wearable arm sensor without requiring routine self-monitoring of blood glucose (SMBG). The IMPACT RCT (Bolinder 2016) showed reduced time spent in hypoglycemia in T1DM for the flash monitoring system compared to SMBG, while decreasing the number of blood glucose tests by 91%. A time trade-off study demonstrated a utility benefit with the flash monitoring system compared with SMBG (Matza 2015). This analysis assesses the cost-effectiveness of the flash monitoring system versus SMBG in T1DM patients receiving intensive insulin from a UK NHS perspective. **METHODS:** The IMS Core Diabetes Model was run over a 50-year lifetime horizon, modelling a population reflecting the IMPACT study. Intervention effects included study-based reductions in hypoglycemic events (glucose <70mg/dL; 25.5% fewer daytime events, 33.2% fewer nocturnal events), and the utility benefit (0.03; Matza 2015). Costs are reported in 2015 GBP. Incremental cost-effectiveness ratios (ICERs) were calculated, with sensitivity analyses conducted for key inputs. **RESULTS:** The base case ICER was £25,045 and cost per hypoglycemia event averted was £27. For the scenario analyses, ICERs ranged from £7,643 to £30,811. **CONCLUSIONS:** Improved hypoglycemia and a health utility benefit translate to a base case ICER under the NICE threshold for cost-effectiveness for medical devices of up to £30,000 per QALY. This result was confirmed across a range of scenario analyses. The flash monitoring system may be considered cost effective for use in the UK NHS for T1DM patients receiving intensive insulin.

PMD56

ADAMTS13 TEST AND/OR PLASMIC CLINICAL SCORE IN MANAGEMENT OF ACQUIRED THROMBOTIC THROMBOCYTOPENIC PURPURA (TTP) - A COST-EFFECTIVE ANALYSIS (CEA)

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OBJECTIVES: Reduced ADAMTS13 activity distinguishes potentially fatal TTP from other thrombotic microangiopathies (TMA). The PLASMIC score helps determine the pretest probability of severe ADAMTS13 deficiency. Due to potential adverse effects of therapeutic plasma exchange (TPE) while awaiting the activity level, we performed a CEA by investigating the benefits of incorporating in-hospital ADAMTS13 assays and/or PLASMIC scores into clinical practice. **METHODS:** A 3-day CEA model was created comparing 4 scenarios in a patient with TMA: 1) Send-out ADAMTS13 with 3-day TPE performed in the meantime; 2) In-hospital ADAMTS13 test with TPE initiated if ADAMTS13 activity was <10%; 3) Perform the first option if the PLASMIC score showed intermediate-high risk; 4) Utilize the second option if the PLASMIC score was at intermediate-high risk. Model parameters were based on medical literature (sensitivities/specificities, incidence of TTP in TMA, TTP and/or TMA mortality with or without TPE, TPE adverse events, and costs for TPE and adverse effects adjusted for inflation). ADAMTS13 assay-costs were derived institutionally. **RESULTS:** If only cost was considered, option 4 is the cheapest (\$4,732/patient) followed by 2, 3, and 1. If only effectiveness was evaluated, option 1 has the highest life-year saving (LYS) at 0.98 LYS/patient followed by 3, 2, and 4. Therefore, for cost/LYS per patient, option 4 (\$5,207/LYS) < 2 (\$5,414/LYS) < 3 (\$9,847/LYS) < 1 (\$15,838/LYS). The incremental cost effectiveness ratios for option 2, 3, and 1 compared to 4 are \$49,643, \$97,444, and \$152,127, respectively. **CONCLUSIONS:** In patients with clinical presentations of TMA, having an in-hospital ADAMTS13 test to establish the prompt diagnosis of TTP appears to be cost-effective. Utilizing the PLASMIC score increases the cost-effectiveness of the test. Initiating TPE on all TMA patients while waiting for send-out ADAMTS13 results is not cost-effective. Our findings support the need for establishing a rapid and reliable in-house ADAMTS13 test.

PMD57

COST-EFFECTIVENESS OF G5 MOBILE CONTINUOUS GLUCOSE MONITORING (CGM) COMPARED TO SELF MONITORING BLOOD GLUCOSE (SMBG) ALONE FOR TYPE 1 DIABETES (T1DM) IN THE US

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OBJECTIVES: To explore the cost-effectiveness of real-time G5 Mobile CGM compared to SMBG alone in Multiple Daily Injection (MDI) using T1DM patients in the US. **METHODS:** The IMS CORE Diabetes Model (CDM) (v. 9.0) was used to assess the long-term (50 year) cost-effectiveness of CGM (G5-Mobile) compared to SMBG alone for a T1DM cohort. Treatment effects and base-line characteristics of patients were sourced from the DIAMOND randomized controlled trial (RCT) while all other assumptions and costs were sourced from published research. The accuracy and clinical effectiveness of G5 Mobile CGM is the same as G4 Platinum CGM used in DIAMOND RCT. Base case (BC) assumptions included a) starting HbA1c 8.6%; b) change in HbA1c -1.1% for CGM group, -0.5% for SMBG alone; c) 50% reduction in severe hypoglycemic events (SHEs) and 26% conservative reduction in non-severe hypoglycemic events (NSHEs) for CGM

group; d) dis-utilities of -0.0142 for NSHEs and SHEs not requiring medical intervention, and -0.047 for SHEs requiring medical resources. Treatment costs and outcomes were discounted at 3%. **RESULTS:** The incremental cost-effectiveness ratio (ICER) for base-case G5 Mobile vs. SMBG was \$25,435/QALY. Sensitivity analyses showed that base-case results were sensitive to changes in percent reduction in hypoglycemic events and to changes in disutilities associated with these events. A 50% reduction in non-severe hypoglycemic events for CGM resulted in an ICER of \$14,469/QALY. The base-case results were minimally impacted by changes in starting HbA1c levels, incorporation of indirect costs and changes in discount rate. **CONCLUSIONS:** The results of this analyses show that G5 Mobile CGM is cost effective within the T1DM population using MDI, assuming a US willingness-to-pay threshold of \$100,000 per Quality-Adjusted Life Year (QALY). Thus, CGM should be used "first" before more expensive treatments such as sensor augmented pumps are used in Type 1 diabetes patients on multiple daily injections.

PMD59

PROJECTED COST-EFFECTIVENESS FOR TWO GENE-DRUG PAIRS USING A MULTI-GENE PANEL FOR PATIENTS UNDERGOING PERCUTANEOUS CORONARY INTERVENTION

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OBJECTIVES: For patients undergoing percutaneous coronary intervention (PCI), gene-drug associations exist relevant to first-line treatment options—antiplatelet agent, clopidogrel, and pain medication, tramadol. Knowledge of genotype information allows for avoidance of adverse drug events (ADEs) during critical clinical windows. This evaluation estimated cost-effectiveness associated with a multi-gene panel, providing CYP2C19 genotype-guided strategy for antiplatelet therapy, with CYP2D6 genotype-guided pain management, compared to single gene test for CYP2C19 with random assignment for pain treatment, and to standard treatment (no testing, clopidogrel with random assignment for pain treatment). **METHODS:** Decision analysis modeling was used to project costs from a US payer perspective and patient quality-adjusted life years (QALYs) for the three strategies over a 15-month time horizon. The model captured composite risks of major adverse cardiovascular events and pain therapy-related ADEs and associated utility estimates. Costs were expressed in 2016 US dollars and estimated using Medicare reimbursement rates when available. A 3% annual discount rate was applied to costs and QALYs. **RESULTS:** Over 15 months, multi-gene testing was least costly and yielded more QALYs compared to both single gene and no testing; total incremental costs were \$2,265 lower with incremental gains of 0.0318 QALYs for multi-gene compared with single gene and \$7,398 lower with 0.190 QALY gains compared to no test. Base case analyses revealed multi-gene was dominant compared to both single gene and no test. It demonstrated cost savings with increased QALYs. Net monetary benefit for multi-gene based on a \$150,000/QALY willingness-to-pay threshold was \$5,441 and \$26,378 compared to single gene testing and no testing, respectively. **CONCLUSIONS:** For these patients, a multi-gene-guided strategy yields a favorable incremental cost-effectiveness ratio compared to the other two treatment strategies. Pre-emptively ascertaining additional gene-drug pair information can inform clinical and economic decision-making at point of care. Future work includes validating these preliminary results.

PMD60

COST EFFECTIVENESS ANALYSIS OF A FLASH CONTINUOUS GLUCOSE MONITORING SYSTEM FOR TYPE 2 DIABETES (T2DM) PATIENTS RECEIVING INTENSIVE INSULIN TREATMENT IN THE UK

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OBJECTIVES: Regular glucose monitoring is important for T2DM patients receiving intensive insulin. A novel, factory-calibrated flash continuous glucose monitoring system (the FreeStyle Libre™ system) continuously measures glucose levels from interstitial fluid. Data transfers to a handheld reader from a wearable arm sensor without requiring routine self-monitoring of blood glucose (SMBG). The REPLACE RCT showed a reduced time spent in hypoglycemia in T2DM patients receiving intensive insulin for the flash monitoring system compared to SMBG, while decreasing the number of blood glucose tests by 92%. A time trade-off study demonstrated a utility benefit with the flash monitoring system compared with SMBG (Matza 2015). This analysis assesses the cost-effectiveness of the flash monitoring system versus SMBG in T2DM patients receiving intensive insulin from a UK NHS perspective. **METHODS:** The IMS Core Diabetes Model was run over a 40-year lifetime horizon, modelling a population reflecting the REPLACE study. Intervention effects included study-based reductions in hypoglycemic events (27.7% reduction in glucose <70 mg/dL) and the utility benefit (0.03; Matza 2015). Costs were reported in 2015 GBP. Incremental cost-effectiveness ratios (ICERs) were calculated, with sensitivity analyses conducted for key inputs. **RESULTS:** The base case ICER was £23,842 and cost per hypoglycemia event averted was £93. For the scenario analyses, ICERs ranged from £6,555 to £29,517. **CONCLUSIONS:** Improved hypoglycemia and a health utility benefit translate to a base case ICER under the NICE threshold for cost-effectiveness for medical devices of up to £30,000 per QALY. This result was confirmed across a range of scenario analyses. The flash monitoring system may be considered cost effective for use in the UK NHS for T2DM patients receiving intensive insulin.

PMD61

ECONOMIC EVALUATION OF REMOTE MONITORING OF CRT/ICD THERAPY IN HEART FAILURE PATIENTS

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OBJECTIVES: To estimate efficiency of Remote Monitoring (Home Monitoring/TM, HM) of Cardiac Resynchronisation Therapy (CRT) and Implantable Cardioverter-Defibrillator (ICD) in Brazilian Public Healthcare System (SUS). **METHODS:** In patients with CRT/ICD therapy to treat heart failure (ICD-10 I50), continuous follow-up is based on outpatient visits (Conventional Follow-Up, CFU). HM is a new alternative which transmits real-time data to a central and then, to patient's cardiologists. By means of a health-state transition model, incremental costs (in Brazilian currency, BRL) and efficacy (in life-years gained, LYG) were estimated in a time horizon of 10 years. Costs related to SUS were retrieved through Health Informatics Department of the Brazilian Ministry of Health (DATASUS). From patient-level data of IN-TIME study, a survival analysis (Exponential distribution) was run in order to predict risk of death across the years between CFU and HM groups. Probabilistic sensitivity analysis (PSA) and alternative scenarios were carried out to assess parametric and structural uncertainties. **RESULTS:** Base-case showed an incremental cost-effectiveness ratio (ICER) of BRL 2,599 per incremental LYG when HM and CFU are compared. PSA pointed out similar central point and indicates that thresholds over BRL 2,450 favours HM as the technology most efficient. As an alternative scenario, mortality was assumed to be the same for both groups. In this case, HM promotes an incremental cost of BRL 3,839 on average. Other alternative scenarios brought similar results. **CONCLUSIONS:** Discussing threshold in Brazil remains a controversial subject. Irrespective of this issue, economic evaluations are still useful to bring about additional information. In this view, HM is likely to promote additional direct costs and LYG. Compared to drugs, the cost of each additional benefit is much cheaper. In addition, this model is not sensitive to opportunity costs as less demand for cardiology outpatient clinics.

PMD62

ECONOMIC EVALUATION OF THE THINPREP PAP TEST FOR THE DETECTION OF ABNORMAL CELLS, CERVICAL CANCER AND/OR PRECURSOR LESIONS

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OBJECTIVES: Carry out an economic evaluation of the ThinPrep Pap test through the evaluation of sensitivity and specificity for the detection of abnormal cells, cervical cancer and/or precursor lesions. **METHODS:** A cost-effectiveness study was conducted, through a decision tree comparing ThinPrep Pap test vs conventional cytology for the detection of abnormal cells, cervical cancer and/or precursor lesions. The outcomes are expressed as number of detected cases, calculating the total and incremental effectiveness, the total and incremental costs and the Incremental Cost Effectiveness Ratio (ICER). The time horizon was instantaneous, i.e., the duration of a test. It was considered an institutional perspective. A deterministic and probabilistic sensitivity analysis was conducted, in order to analyze the uncertainty. **RESULTS:** ThinPrep Pap test in comparison with the conventional cytology demonstrated a major effectiveness expressed as number of detected cases. Assuming a 1,000 patient cohort, the additional detected cases using ThinPrep Pap test was of 26 cases. The use of ThinPrep Pap test generated an incremental cost of \$18.20 USD per patient, the ICER was \$701.50 USD. ThinPrep Pap test is a cost-effective option for the detection of abnormal cells, cervical cancer and/or precursor lesions. **CONCLUSIONS:** Based on the obtained results, ThinPrep Pap test is a diagnostic test that allows the detection of precursor lesions and inflammatory processes of the cervix, which allows an early diagnostic to prevent cervical cancer in the Mexican population. Furthermore, it was demonstrated that ThinPrep Pap test is a cost-effective option for the Mexico's National Healthcare System.

PMD63

ECONOMIC EVALUATION OF TOPICAL ADMINISTRATION OF GEL WITH PIRFENIDONE (KITOSCELL Q®) AS AN ADJUVANT IN THE TREATMENT OF PATIENTS WITH DIABETIC FOOT ULCERS

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OBJECTIVES: To evaluate the cost-effectiveness of the gel with Pirfenidone treatment as an adjuvant in patients with diabetic foot ulcers (DFU), compared to the alternatives available in the National Formulary (NF). **METHODS:** A decision-tree model was implemented to compare the costs and effectiveness of Pirfenidone versus the alternatives available in the NF (gauze, hydrocolloids and antimicrobials dressings) for the treatment of DFU. The clinical outcome was defined as full epithelialization and the time horizon was 8-weeks. Local costs of the resources were obtained from those published by the Mexican Institute of Social Security (IMSS), and the price of the Pirfenidone was provided by Grupo Medifarma. Univariate and probabilistic sensitivity analysis were performed to confirm the robustness of the model findings. The time horizon was 8-week. The analysis was done from public perspective. **RESULTS:** The use of Pirfenidone as adjuvant in the treatment of patients with DFU in a cohort of 100 patients is a cost-saving alternative, demonstrating an increase of 38.1% completely re-epithelialized ulcers in contrast to other dressings, for \$44,318.43. **CONCLUSIONS:** Pirfenidone, is an alternative that provides health benefits use ad adjuvant in the treatment of patients with DFU; and in addition, represents savings to the public health system.

PMD64

COST-EFFECTIVENESS ANALYSIS OF RADIOFREQUENCY CATHETER ABLATION WITH SMARTTOUCH® VERSUS FIRST-GENERATION CRYOBALLOON ABLATION ON THE TREATMENT OF PAROXYSMAL ATRIAL FIBRILLATION PATIENTS IN CHINA

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OBJECTIVES: Clinical guidelines recommend pulmonary-vein isolation by means of radiofrequency catheter ablation (RFCA) or cryoballoon ablation (CB) as treatment for paroxysmal atrial fibrillation (PAF). While RFCA with SmartTouch® Catheter (ST) and the first-generation CB (CB-1) are widely-used in China, studies examining the cost-effectiveness of the two technologies are rare. This study was to determine the cost-effectiveness of ST vs. CB-1 in Chinese PAF patients from a payer's perspective. **METHODS:** A two-part model was developed to estimate the cost-effectiveness of the two technologies. The short-term part was a decision-tree that included surgery-related complications within the first 18 months from discharge. The long-term (up to 20 years) part was a Markov chain including the health states of normal sinus rhythms, AF recurrence, stroke, post stroke, intracranial hemorrhages (ICH), post ICH, and gastrointestinal bleeding. Clinical and utility data were obtained from published literature. Cost data were collected from Chinese leading hospitals. The model calculated quality-adjusted life years (QALYs) and total costs per patient. Costs and QALYs were discounted by 3.5% annually. A one-way sensitivity analysis was conducted for all parameters. **RESULTS:** Captured by the 5-year, 10-year, and 20-year Markov model plus 18-month decision tree model, the total costs per patient for the ST vs. CB-1 groups were \$14,717.17 vs. \$16,662.94, \$16,988.95 vs. \$19,485.67 and \$19,591.78 vs. \$22,570.62, respectively; 5-year, 10-year, and 20-year QALYs for the ST vs. CB-1 groups were 4.23 vs. 4.22, 6.43 vs. 6.38 and 8.64 vs. 8.53, respectively. The result suggests dominant ICERs across all scenarios, indicating that ST, compared with CB-1, has better efficacy and lower overall costs. The one-way sensitivity analysis did not change the conclusion, indicating the robustness of the result. **CONCLUSIONS:** RFCA with ST is a dominant treatment of PAF in China compared to CB-1. This evidence supports the broad clinical application of RFCA with ST over CB-1.

PMD65

TREATMENT SEQUENCE IN INTERMEDIATE STAGE HEPATOCELLULAR CARCINOMA: A COST-EFFECTIVENESS ANALYSIS OF TWO APPROACHES WITH TRANS-ARTERIAL RADIOEMBOLIZATION

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OBJECTIVES: Hepatocellular carcinoma (HCC) is a major health problem worldwide. Trans-arterial radioembolization (TARE) is a relatively new option for the management of non-resectable HCC, although not explicitly recommended in clinical guidelines. Other approaches include systemic chemotherapy (i.e. sorafenib) or trans-arterial chemoembolization (TACE). Few studies have shown the favourable cost-effectiveness profile of TARE versus sorafenib, however scant evidence exists about which treatment sequence is best. In this study we evaluated two treatment sequences, TARE followed by TACE and eventually sorafenib (=TTS) and TARE followed by sorafenib alone (=TS) in intermediate stage patients, to identify the most cost-effective pathway from the Italian healthcare system perspective. **METHODS:** Starting from patient level data collected at three oncology centers in Italy, a Markov model was developed to project costs and health outcomes (life years and QALYs) associated with intermediate stage HCC patients for TTS and TS cohorts over a lifetime horizon (yearly discount rate 3.5%). Healthcare resource utilization was derived from standard management protocols for TARE, TACE and sorafenib. Costs were obtained from DRGs reimbursement rates and official tariffs. **RESULTS:** Considering 16 patients for TTS (47% with sorafenib administration) and 22 patients for TS treatments, the model estimated an average lifetime cost per patient of 36,509€ and 42,812€, respectively, and 3.494 years (1.385 QALYs) for TTS and 2.361 years (0.937 QALYs) for TS, in terms of health outcomes. TTS sequence resulted as dominant strategy. **CONCLUSIONS:** The cost-effectiveness of TARE versus sorafenib for the treatment of intermediate-advanced HCC has been previously stated. Our study, performed on a subset of patients with intermediate stage HCC, revealed that TARE followed by TACE plus eventually sorafenib may be a dominant strategy compared to TARE followed by sorafenib alone. Further RCTs and real world data are needed to better characterize the treatment pathways and confirm these conclusions in different settings and jurisdictions.

PMD66

COST-EFFECTIVENESS ANALYSIS OF EGFR MUTATION TEST FOR NON-SMALL CELL LUNG CANCER IN CHINA

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OBJECTIVES: To examine the cost-effectiveness of EGFR mutation testing in China, and make recommendations on whether 'EGFR testing strategy' is more appropriate than 'no EGFR-testing strategy'. **METHODS:** A five-year Markov model was constructed to predict expected costs and outcomes for each strategy, in which three states including progression-free survival, progressive survival and death were taken into account. The percentages of patients with or without EGFR testing using traditional chemotherapy or molecular targeting therapy were based on Chinese literatures and expert interviews. Likely, the probabilities of transition from one state to another were also based on literatures and expert interviews, and

the quality-adjusted life-years (QALYs) of different states were from literatures. We only included direct medical costs from the healthcare payer's perspective. The incremental cost-effectiveness ratio (ICER) was calculated using QALYs gained. Sensitivity analyses were conducted. **RESULTS:** The incremental cost and effectiveness of the 'EGFR testing strategy' compared to the 'no EGFR-testing strategy' was estimated to be approximately 32,383.83 yuan and 0.294 QALY per patient. The ICER was then calculated to be around 110,219.90 yuan per QALY gained. These results suggest that the 'EGFR testing strategy' is more cost-effective compared with the 'no EGFR-testing strategy' when 15,4098 yuan per QALY based on GDP in 2015 was considered an acceptable threshold. These results were supported by the sensitivity analyses. **CONCLUSIONS:** From the perspective of healthcare payer, the ICER of the 'EGFR-testing strategy' can be considered as a cost-effective therapy compared with the 'no EGFR-testing strategy' by the threshold of 154,098 yuan.

PMD67

ECONOMIC EVALUATION OF ULTRASONOGRAPHY AND MAMMOGRAPHY FOR BREAST CANCER SCREENING AMONG WOMEN IN CHINA

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OBJECTIVES: This study aimed to analyze the cost-effectiveness and cost-utility of annual ultrasonography screening, annual mammography screening and no screening for breast cancer among Chinese women, so as to provide evidence for the choice of breast cancer screening methods in China. **METHODS:** A Markov model was developed from a societal perspective among asymptomatic Chinese women over 40 years at risk for breast cancer over a lifetime horizon. The decision model was populated with data derived from China. According to the simulation results, we obtained the discounted lifetime costs, discounted quality-adjusted life years (QALYs) gained, and the number of detected breast cancer cases. Then we compared the incremental cost-effectiveness ratio. Parameter uncertainty was explored using one-way sensitivity analysis and probabilistic sensitivity analysis. Subgroup analysis was conducted based on different city levels and geographical areas in China. **RESULTS:** 54 breast cancer cases were estimated to occur among every 1000 women over their lifetime, with 27 detected by ultrasonography and 33 detected by mammography. Compared to no screening, the incremental cost-utility ratio (ICUR) of ultrasonography screening was ¥102653/QALY and the ICUR of mammography screening was ¥201309/QALY. In probabilistic sensitivity analyses, the probabilities of the ICUR being a threshold of ¥100000/QALY were 54.5% for annual ultrasonography and 26.2% for annual mammography. The sub-group analysis showed that compared to no screening, ultrasonography screening for breast cancer was cost-utility in all levels of cities and all geographic areas in China. The ICUR of mammography screening compared to no screening was very close to the threshold in eastern China. **CONCLUSIONS:** Compared to no screening, annual ultrasonography screening for women aged 40 was cost-utility and could be used as the primary method for breast cancer screening in China. Mammography screening was not cost-utility in central and western China, and could be used in eastern economically developed areas.

PMD68

COST-EFFECTIVENESS OF A BRONCHIAL GENOMIC CLASSIFIER FOR THE DIAGNOSTIC EVALUATION OF LUNG CANCER

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OBJECTIVES: A bronchial genomic classifier had been prospectively validated to improve diagnostic accuracy of bronchoscopy for suspected lung cancer in order to identify patients at low probability who may be more suitable for active surveillance as opposed to a biopsy via an invasive procedure. Our objectives were to assess the frequency of invasive procedures and the cost-effectiveness of bronchoscopy plus genomic classifier versus bronchoscopy alone in diagnostic work-up of patients at intermediate risk for lung cancer in the United States. **METHODS:** A decision-analytic Markov model was developed to project the costs and effects of the two competing strategies, using test performance from the AEGIS-1 and AEGIS-2 studies. Diagnostic accuracy of non-invasive and invasive follow-up, as well as associated adverse event rates were derived from published literature. Procedure costs were based on claims data and 2016 inpatient and outpatient reimbursement amounts. The model projected the number of invasive follow-up procedures, two-year costs and quality-adjusted life years, by strategy, and the resulting incremental cost-effectiveness ratio (ICER), discounted at 3% per annum. **RESULTS:** Use of invasive procedures were reduced by 28% at one month and 18% at two years, respectively. Total costs and QALY gain were similar with classifier use (\$27,221 vs. \$27,183, and 1.512 vs. 1.509 QALYs, respectively), resulting in an ICER of \$15,052 per QALY. **CONCLUSIONS:** The use of a genomic classifier for inconclusive bronchoscopies is associated with meaningful reductions in invasive follow-up procedures at about equal costs and is therefore a high-value strategy in the diagnostic work-up of patients at intermediate risk of lung cancer.

PMD69

COMPARISON OF MAGNETIC RESONANCE IMAGING FOLLOWED BY MAGNETIC RESONANCE-GUIDED TARGETED BIOPSY VERSUS SYSTEMATIC TRANSRECTAL ULTRASOUND-GUIDED BIOPSY IN DIAGNOSING PROSTATE CANCER: A COST-EFFECTIVENESS ANALYSIS IN THE US POPULATION

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OBJECTIVES: Systematic transrectal ultrasound-guided biopsy (TRUSGB) has raised concerns regarding the overdiagnosis of prostate cancer (Pca). Magnetic

resonance imaging followed by magnetic resonance-guided targeted biopsy (MRI-MRGB) is gaining more popularity. Evaluation that simultaneously considers cancer outcomes, healthcare costs and quality-of-life is needed to further inform decision making in the US population. **METHODS:** A decision-analytic Markov model with a lifetime horizon of 10 years was developed to evaluate diagnostic accuracy, long-term health outcomes, costs, and quality-of-life of the two strategies (i.e., MRI-MRGB versus TRUSGB) in men with elevated prostate-specific antigen (>4 ng/ml). Probabilities of clinical events were obtained from published literature. Direct medical costs included diagnostic and treatment-related healthcare costs. Costs were inflated to 2015 US dollars and discounted at an annual rate of 3%. Quality-adjusted life years (QALYs) were derived from published literature and expert opinions. We calculated the incremental cost-effectiveness ratio (ICER), which was equal to the difference in costs of two interventions divided by the difference in QALYs. Sensitivity analyses were performed to assess uncertainty. **RESULTS:** The MRI-MRGB strategy yielded lower total costs (US 5,358 versus 6,372) and higher total QALYs (7.21 versus 7.19) than TRUSGB. Therefore, TRUSGB was dominated by the MRI-MRGB strategy. The results were robust with the sensitivity analyses. **CONCLUSIONS:** The MRI-MRGB strategy generated lower total costs but higher QALYs than the TRUSGB strategy. Therefore, MRI-MRGB was the optimal choice that provided the greatest health benefits for the diagnosis of men with suspected PCa in the US population.

PMD70

ECONOMIC EVALUATION OF AN ENDOSCOPIC SYSTEM (DA VINCI® ROBOTIC SURGICAL SYSTEM) FOR PATIENTS WITH LUNG CANCER

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OBJECTIVES: To perform an economic evaluation study of the endoscopic system (Da Vinci®) as treatment for patients with lung cancer in Mexico. **METHODS:** Justified by the results from a systematic review of the clinical literature previously developed, that conclude that the health benefits in terms of decrease in mortality and surgical complications were similar, a cost minimization analysis was developed in comparison with Video-assisted thoracoscopic lobectomy (VATL). The analysis was performed from the National Health System perspective. This evaluation also considered only direct medical costs took from institutional sources. The temporal horizon was determined immediate, i.e., the duration of time of the surgical interventions in comparison, it was not included a social discount rate. The analysis also included the equivalent annual cost through the calculation of the annuity factor. With the purpose of analyze uncertainty, a univariate deterministic sensitivity analysis was done, it contemplated variation in the cost of the surgical system Da Vinci, cost of consumables used and the number of annual surgeries done by the public health services from Mexico. **RESULTS:** The use of Da Vinci surgical system in the treatment of lung cancer generates a cost per surgical intervention of \$4,367,6642 USD, and \$6,041,9646 USD in the case of VATL, the use of Da Vinci surgical system generates a save per intervention of \$1,674,3004 USD. **CONCLUSIONS:** The use of Da Vinci surgical system in the treatment of lung cancer is an equally safe and efficacious strategy than the one available nowadays in the National Health System, but with less cost per surgical intervention. From an institutional perspective, the use of Da Vinci surgical system is a cost saving strategy.

PMD71

COST-EFFECTIVENESS OF PERCUTANEOUS VENTRICULAR ASSIST DEVICES FOR HIGH-RISK PCI PATIENTS IN ONTARIO, CANADA

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OBJECTIVES: The newly introduced percutaneous Ventricular Assist Devices (pVAD) have been shown to provide better hemodynamic support but there is no evidence that they improve clinical outcomes in high-risk percutaneous coronary intervention (PCI) compared with the intra-aortic balloon pump (IABP), the current standard of care. We aim to evaluate the cost-effectiveness of pVAD compared with IABP in patients undergoing high-risk PCI in Ontario. **METHODS:** A cost-utility analysis was conducted from the Ontario public payer perspective using a 10-year time horizon. A Markov cohort model was developed to simulate the process of patients going through PCI treatment. Patients in the post-PCI state (no complication) may either stay in this health state or transition to death or develop Major Adverse Cardiac Events (MACE), specifically "acute myocardial infarction", "stroke" and "repeat revascularization". Transition probabilities and mortality rates were calculated using data from the PROTECT II study, a randomized controlled trial comparing pVAD and IABP. Costs were reported in 2016 Canadian dollars and obtained from the Ontario Case Costing Initiative, the CCN Cardiac Registry and the published literature. Utilities were obtained from various Quality of Life studies. Probabilistic sensitivity analyses were used to assess parameter uncertainties. **RESULTS:** High-risk PCI supported by pVAD resulted in a loss of 0.109 QALYs with an additional cost of \$24,260 per patient, compared to IABP. As such, pVAD was dominated (more costly and less effective). Even in scenarios that favoured pVAD (such as setting the long-term MACE probabilities between treatments to be the same at 90 days and using the same mortality rate for both arms), it was still not cost-effective compared with IABP. **CONCLUSIONS:** Our economic evaluation showed that the pVAD was not an economically attractive alternative to IABP in high-risk PCI patients in Ontario. Further research will be needed to identify a population in which pVAD is clinically and economically attractive.

PMD72

COST-EFFECTIVENESS OF TRANSCATHETER AORTIC VALVE IMPLANTATION COMPARED WITH SURGICAL AORTIC VALVE IMPLANTATION IN HIGH SURGICAL RISK PATIENTS WITH SEVERE AORTIC STENOSIS IN ONTARIO, CANADA

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OBJECTIVES: Severe aortic stenosis (AS) refers to pathological, clinical and pathophysiological changes associated with decreased aortic valve area, as a consequence of calcification. Transcatheter aortic valve implantation (TAVI) is a treatment option for severe AS patients, who are at high risk or ineligible for surgical treatment. We assessed economic implications of TAVI compared with surgical aortic valve replacement (SAVR) for high-risk patients with severe AS in Ontario, Canada. **METHODS:** We developed a Markov model with monthly cycles to determine the cost-effectiveness of TAVI compared with SAVR from the Ontario public payer perspective. The model had a 5-year time horizon. Clinical model parameters (effectiveness and safety) of TAVI and SAVR were obtained from a systematic clinical evidence review. Costs of procedures, procedure-related adverse events were collected from an Ontario costing study. The main outcomes of the model were costs, quality-adjusted life-years (QALYs) and the incremental cost-effectiveness ratio (ICER). We conducted univariate and probabilistic sensitivity analyses to explore the robustness of the findings. Costs were expressed in 2016 Canadian Dollars and discounted at 5% per annum. **RESULTS:** The base-case analysis showed that TAVI was associated with 0.181 QALYs gained at an additional cost of \$9,412 compared to SAVR over the 5-year time horizon. This translated into an ICER of \$51,988 per QALY gained. Univariate sensitivity analyses showed that the model was most sensitive to care costs of both TAVI and SAVR, and monthly follow-up costs of major stroke in the first and second years. Probabilistic sensitivity analyses showed that at the willingness-to-pay of \$50,000 and \$100,000 per QALY, the probability that TAVI would be cost-effective was 47% and 92%, respectively. **CONCLUSIONS:** The use of TAVI for patients at high surgical risk and severe aortic stenosis is cost-effective in Ontario. TAVI is a reasonable alternative for severe AS patients with high surgical risk.

PMD73

COST-EFFECTIVENESS OF ARGUS II RETINAL PROSTHESIS SYSTEM FOR ADVANCED RETINITIS PIGMENTOSA

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OBJECTIVES: Retinitis pigmentosa (RP) causes progressive retinal degeneration and blindness. The Argus II retinal prosthesis system can improve visual function in blind patients with advanced RP. We assessed economic implications of the Argus II system for advanced RP in Ontario, Canada. **METHODS:** We developed a Markov model to determine the cost-effectiveness of the Argus II system compared with standard care in RP patients from the Ontario public payer perspective. The main outcomes of the model were costs, quality-adjusted life-years (QALYs) and the incremental cost-effectiveness ratio (ICER). The model had a 10-year time horizon. Clinical model parameters (effectiveness and safety) of the Argus II system were obtained from the literature. Cost components (Argus II devices, surgery, maintenance of devices and treatment of adverse events were included). We conducted univariate and probabilistic sensitivity analyses to explore the robustness of the model. Costs were expressed in 2015 Canadian Dollars and discounted at 5% annually. **RESULTS:** In the base-case analysis, compared with standard care, Argus II system resulted in a gain of 1.13 QALYs (3.12 QALYs with Argus II versus 2.08 QALYs with standard care) with an additional cost of \$234,606 (CDN) (\$361,034 with Argus II versus \$126,428 with standard care) over a 10-year time horizon. This translated into an ICER of \$207,616 per QALY gained. Univariate sensitivity analyses showed that the model was most sensitive to health-related utility of RP patients, and the cost of implantation and device parameters. Probabilistic sensitivity analyses showed that at the willingness-to-pay amounts of \$100,000 and \$200,000 per QALY, the probability that Argus II would be cost-effective was 21% and 45%, respectively. **CONCLUSIONS:** The Argus II system improved the quality of life of RP patients but at a very high incremental cost. Its cost effectiveness would not typically be considered attractive given the incremental cost effectiveness ratio.

PMD74

COST-EFFECTIVENESS OF PET-CT VERSUS ADRENAL VEIN SAMPLING FOR THE DIAGNOSIS OF HYPERTENSION CAUSED BY PRIMARY ALDOSTERONISM

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OBJECTIVES: Primary aldosteronism (PA) is caused by a benign adrenal gland tumour and leads to the development of hypertension (high blood pressure). PA is the cause of 11% of all hypertension cases. It can be cured by surgical removal of the affected gland (if unilateral), but is not always diagnosed as the current technique (adrenal vein sampling [AVS]) has a high failure rate and is unpleasant for patients. The aim was to compare the cost-effectiveness of PET-CT with AVS for the identification of PA patients suitable for surgery. **METHODS:** A discrete event simulation was developed. Anonymised individual patient data from Addenbrooke's hospital (Cambridge, UK) were used to inform the patient characteristics of those screened. Sensitivity and specificity of the diagnostics were taken from the literature and the outcomes of surgery on hypertension were modelled. The model captured the impact of hypertension on the risk of cardiovascular events and death. The model used a UK NHS perspective, a lifetime time horizon and a 3.5% annual discount rate. NHS reference costs were

used and utilities were taken from the literature. **RESULTS:** PET-CT resulted in 0.04 additional QALYs (11.340 vs 11.299 for PET-CT vs AVS, respectively) and £64.43 fewer costs (£8,571.93 vs £8,636.36 for PET-CT vs AVS, respectively), meaning that PET-CT dominated AVS. PET-CT remained dominant across the majority of one-way sensitivity analyses, with positive ICERs under £10,000/QALY only for the upper bound of PET-CT cost (£6,997/QALY), upper bound of cost of laparoscopic adrenalectomy (£246/QALY) and lower bound of AVS cost (£7,702/QALY). **CONCLUSIONS:** Despite being a more costly procedure, PET-CT was overall a cost saving alternative to AVS for the diagnosis of unilateral PA, due to the greater number of successful surgeries and hence better long-term outcomes. This could change the way that PA is diagnosed in clinical practice, providing a less traumatic method for patients.

PMD75

COST UTILITY ANALYSIS OF DEEP BRAIN STIMULATION VS. BEST MEDICAL TREATMENT IN THE MANAGEMENT OF PARKINSON DISEASE WITH EARLY MOTOR COMPLICATIONS IN COLOMBIA

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OBJECTIVES: Deep Brain Stimulation (DBS), has shown motor symptoms and quality of life improvement in advance Parkinson Disease (PD). There is evidence that DBS could also be effective in PD with early motor complications, which must be reflected in longer time horizon to offset the initial costs and better quality adjusted life years (QALYs). We did a cost-utility analysis of DBS vs. Best Medical Treatment (BMT) in the management of PD patients with early motor complications in Colombia. **METHODS:** After transferability analysis, adaptation of previously developed Markov model for cost-utility analysis was done. The Unified Parkinson's Disease Rating Scale measured "on_meds" was used to model disease progression and treatment effectiveness. Data was taken from the prospective EarlyStim-PD CT, including patient's characteristics, effectiveness and adverse events (AE). Data was used for fall probability, utility values, BMT withdrawal. The 15-years rechargeable DBS device was assumed. Resource use and costs were gathered from official prices and KOL. Colombian Mortality rates, a 15 years horizon, 3.5% discount rate and payer perspective was assumed. All costs were converted to USDollars to allow international comparison. Univariate and probabilistic sensitivity analysis were done. **RESULTS:** To 15 years, total discounted cost for DBS was estimated in USD\$85,198 vs. USD\$103,560 for BMT, (- USD \$18,362). DBS yield 5,15 discounted QALYs compared to 4,10 for BMT, configuring dominance over BMT and not requiring to do incremental analysis. The main difference was obtained in medication costs, offsetting the DBS implantation costs. There were also savings in AE, follow up, falls, and other hospital costs. The univariate analysis showed the results were especially sensible to horizon. In the probabilistic analysis, 99.4% of iterations fall in the SE quadrant. **CONCLUSIONS:** Compared to BMT, DBS yielded a higher total Quality of life to a lower total cost, generating costs savings in a 15 years horizon.

PMD76

A COST-EFFECTIVENESS ANALYSIS BETWEEN RADIOFREQUENCY CATHETER ABLATION (RFCA) AND ANTI-ARRHYTHMIC DRUG IN THE TREATMENT OF CHINESE PATIENTS WITH ATRIAL FIBRILLATION (AF)

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OBJECTIVES: Catheter ablation (RFCA) procedure for AF has been widely applied in China, however, no published study has examined the cost effectiveness of catheter ablation in the Chinese setting. To determine the cost effectiveness of RFCA vs. anti-arrhythmic drugs in the treatment of Chinese AF patients from third-party payer perspective. **METHODS:** The cost effectiveness of RFCA was evaluated in comparison with anti-arrhythmic drugs (AADs). Outcomes in the model were captured as quality-adjusted life years (QALYs). A decision analytical model was constructed to evaluate the short-term and long-term cost effectiveness. The cost data were from a micro cost study based on real world Chinese hospital costs. Clinical effectiveness data were obtained from a prospective, non-randomized, single center study in China as well as literature review and the physician survey. **RESULTS:** In the short term and long term time horizons, the RFCA treatment arm incurred more costs than the AADs arm but also had more QALY improvement than the AADs arm. When compared RFCA with AADs, the ICERs were ¥66,763.91, ¥36,279.52 and ¥29,359.32 per QALY for 8, 15, and 20-year time horizons respectively. The sensitivity analyses demonstrated that the results were most sensitive to the changes in RFCA cost and CHADS2score among the variables tested. **CONCLUSIONS:** The present study provides the first cost-effectiveness analysis comparing these two most popular treatment strategies currently practiced in China. The study results support that RFCA is a cost effective therapy, when compared with anti-arrhythmic drugs, in the treatment of Chinese AF patients with ICERs lower than three times of per capita GDP in China. The results also demonstrated that the RFCA procedure is more cost effective in the longer time horizons.

PMD77

COST-UTILITY ANALYSIS OF THE PROLARIS TEST FOR PROSTATE CANCER IN PATIENTS WITH A POSITIVE BIOPSY

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OBJECTIVES: Improving the accuracy of risk stratification at diagnosis is an important goal in prostate cancer (PCa) research. This study aims to assess the

cost-utility of Prolaris, a biopsy tissue-based cell cycle progression (CCP) assay, in the risk assessment of PCa patients with a positive biopsy, from the Canadian healthcare system perspective. **METHODS:** A Markov model was used to estimate the quality adjusted life years gained (QALYs) and costs for three strategies (standard 12-core TRUSGB, MRI-guided biopsy (MRGB) and standard TRUSGB plus Prolaris) over 5, 10, 15 and 20 years. The model takes into account the accuracy of diagnostic tests and the probability of assignment to various treatment options. We assumed that patients re-categorized with Prolaris to very low risk PCa will be placed on active surveillance. Direct medical costs based on the Quebec healthcare system's perspective were included. **RESULTS:** The difference in QALYs between TRUSGB + Prolaris and TRUSGB ranged from 0.01 to 0.11, with the highest difference observed over the 20-year time horizon. The corresponding values of the cost difference ranged from 1,900CAD and 1,000CAD. In addition, no benefit in QALY was observed between the TRUSGB + Prolaris strategy and the MRGB strategy. However, a higher cost was observed in the TRUSGB + Prolaris strategy (between 2,300CAD at 5 years and 4,300CAD at 20 years). The cost-utility analysis revealed an incremental cost-utility ratio (ICUR) as high as 190,000CAD/QALY at 5 years and as low as 9,200CAD/QALY at 20 years. **CONCLUSIONS:** Our preliminary results suggest that the incorporation of Prolaris in PCa diagnosis represents a cost-effective measure over a 10-, 15- and 20-year time horizon compared TRUSGB alone, with an ICUR below the threshold of 50,000CAD. However, the TRUSGB + Prolaris strategy was costlier and less effective than the MRTB strategy.

PMD78

ECONOMIC EVALUATION OF CONTINUOUS AMBULATORY PERITONEAL DIALYSIS (CAPD) AND HEMODIALYSIS (HD) FOR END-STAGE RENAL DISEASE (ESRD) PATIENTS IN INDONESIA

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OBJECTIVES: To determine costs of Continuous Ambulatory Peritoneal Dialysis (CAPD) and Hemodialysis (HD) treatment, as well as to assess cost-effectiveness between CAPD and HD modality in treating patients with End-Stage Renal Disease (ESRD) in Indonesia using societal perspective. **METHODS:** Patients with End-Stage Renal Diseases, aged >50 undergoing PD and HD were observed retrospectively. Clinical records were taken during the observation, as well as questionnaire used to gather cost during PD and HD procedures. A Cost Utility Analysis with Markov Model was developed applying 50 cycles, representing the switching between two modalities. Potential deterministic scenario and probabilistic sensitivity were performed. **RESULTS:** Using societal perspective, we calculated CAPD with incremental cost is CAPD is IDR 7,533,209 (US\$ 562) lower than HD. The QALY of HD is 3.51 and CAPD is 3.66. After ICER estimation PD potentially cost saving IDR 48,850,332 (US\$ 3,645) per QALY gained. We also conducted scenario with considering plausible values in parameters and explore the change in ICER and QALY values. **CONCLUSIONS:** Although the average direct medical costs of PD is higher than HD, in terms of cost-effectiveness, the results suggest that PD as an initial treatment is better in terms of cost and outcome rather than offering HD for ESRD patients.

PMD80

MEDICAL RESOURCE USE AND COST CONSEQUENCES OF HOSPITALIZATION FOR REPOSITIONING, REPAIR, OR REMOVAL OF IMPLANTABLE CARDIOVERTER DEFIBRILLATOR TRANSCUTANEOUS LEADS

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OBJECTIVES: Rates of implantable cardioverter-defibrillator (ICD) complications requiring transcutaneous (TV) lead reoperation have been documented. However, the resource use and costs of these complications are less understood. The objectives of this study were to estimate the Medicare costs and hospital length of stay (LOS) for ICD complications that required inpatient admission for repositioning, repair, or removal (reoperation) of TV leads. **METHODS:** Using Medicare administrative and claims data, we identified 1,068 patients, age ≥ 65, who were hospitalized for reoperation of ICD TV leads between 1/1/2011 and 12/31/2013. We calculated the total cost to Medicare of each admission, including inpatient facility and professional costs, and performed unadjusted and adjusted analyses to identify factors associated with variation in the total costs and LOS for these admissions. **RESULTS:** The mean age was 78, 61% were female, 92% were white, and 27% had a Charlson Comorbidity score ≥ 5. A majority of patients (70%) underwent lead removal, 26% underwent repositioning, and the remainder underwent repair. Mean LOS was statistically significantly longer for patients who underwent lead removal (12.3 days; 95% Confidence interval [CI]=11.4-13.2) than for those who underwent lead repair (6.4 days; 95% CI=2.8-10.0), or repositioning (7.0 days; 95% CI=5.5-8.5). Mean total cost also was significantly higher for patients who underwent lead removal (\$45,838; 95% CI=\$42,967-\$48,708), than for repair (\$32,767; 95% CI=\$21,574-\$43,960), or repositioning (\$28,347 days; 95% CI=\$23,614-\$33,081). Among those who underwent removal, infection was associated with significantly longer LOS (+10.3 days; 95% CI 8.2-12.3) and higher total cost (+\$11,690; 95%CI \$5,143-\$18,237). **CONCLUSIONS:** The economic consequences of ICD complications that require inpatient admission for reoperation of TV leads are substantial, especially in those who require lead removal in the presence of infection. Understanding the economic consequences of TV lead complications is essential to estimating the potential cost offsets associated with reducing these rates.

MEDICAL DEVICES/DIAGNOSTICS – Patient-Reported Outcomes & Patient Preference Studies

PMD81

PEN NEEDLE REUSE IN CHINESE DIABETES PATIENTS: A LITERATURE REVIEW

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OBJECTIVES: The purpose of this study is to analyze the current situation of pen needle (PN) reuse and replacement frequency in Chinese diabetes patients. **METHODS:** A systematic review of the literatures in Chinese and English was performed by using data from CNKI, VIP, WANFANG DATA, CBM, PUBMED, SCIENCE DIRECT, SCOPUS, WEB OF SCIENCE, COCHRANE LIBRARY, EMBASE. The search terms used were “diabetes”, “PN”, “China”, “Chinese”. Systematic review were excluded. **RESULTS:** 79 articles were included, of which 4 were in English and 75 were in Chinese; 11 were multi-center study, 59 were single-center study, and 9 were unspecified. The collected sample were 18,063. About 88.02% patients reused PN. By ranking from highest to lowest, the reuse rate of PN in regions of China were, Northwest China (97.35%), Southern China (88.48%), Central China (88.27%), North China (87.95%), Southwest China (87.59%), Northeast China (78.39%), and East China (72.7%). 85.47% patients reused PN in areas with pen needle reimbursement (PNR) (Tianjin, Jiangsu, Zhejiang and Guangdong), lower than that without PNR (92.03%). One PN was used about 12.83 times on average. For replacement frequency, most patients reused the PN for more than 6 times, and some of them replaced PN when one insulin was used up, or when PN was broken. This phenomenon was more serious in rural areas: 22.5% patients replaced PN per week, 44.2% replaced PN half a month and 33.2% longer than half a month. Increases in PN's reuse frequency would lead to skin problems, injuries, increased pain, inaccurate dose et al. However, only 49.87% patients knew it. **CONCLUSIONS:** PN reuse was common among diabetes patients in China. PN reuse rate is different by regions. PNR policy may have impact on PN reuse. The awareness of harm of PN reuse was relatively low. All the data from literatures, which may lead to bias.

PMD82

CAN A NEW FLASH CONTINUOUS GLUCOSE MONITORING SYSTEM IMPROVE PATIENT ADHERENCE TO GLUCOSE MONITORING AND GENERATE DATA TO SUPPORT THERAPEUTIC DECISION MAKING?

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OBJECTIVES: In a multi-center patient and physician survey conducted at 17 diabetes clinics in Germany, researchers identified that 20.6% of patients did not submit any blood glucose information during visits. Furthermore 29.3% of surveyed doctors rated available data as flawed or inappropriate for therapy adjustment. This lack of actionable glycemic information may prevent optimal therapeutic management. In a 2014 publication, Koster et al. reported in 2010, incremental medical costs attributed to diabetes were €2391 per patient in Germany. Of that amount, 26.5% was spent on managing hyperglycemia and 73.5% on complications. **METHODS:** Review of 2 recent RCTs in patients on intensive insulin, using a novel, sensor-based, factory-calibrated flash continuous glucose monitoring system (FreeStyle Libre™ system) to evaluate patients' monitoring behavior and to determine if the new system had any impact on this behavior. This review also looked at the amount and quality of data generated by subjects using the system. **RESULTS:** At the end of each 6 month study, patients were scanning their glucose sensor on average 8.3 times/day (T2DM) and 15.1 times/day (T1DM), compared to 3.8 finger sticks (T2DM) and 5.5 finger sticks (T1DM) at baseline. In both studies, the sensors collected over 88% of available glucose data. 95% or more of HCPs strongly agreed that data from the system will support them to make informed therapy decisions and help them to positively engage patients in the process. **CONCLUSIONS:** For patients with diabetes receiving intensive insulin, the flash continuous glucose monitoring system has been shown to improve adherence to glucose monitoring and to capture actionable data to guide appropriate therapy decisions. The major portion of costs associated with diabetes come from managing short and long term complications which result from inadequate management of the disease

PMD83

METHODS FOR DEVELOPING A PREFERENCE AND USABILITY SURVEY FOR DEVICES: A CASE STUDY IN DIABETES

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OBJECTIVES: Research has indicated that aligning prescribed treatments with patient preferences can maximize adherence and clinical outcomes. Herein we describe the development of a usability/preference survey for the purpose of evaluating insulin pens. **METHODS:** A multi-phased study was conducted in the United States, United Kingdom, and Canada. Adhering to ISPOR Good Research Practices, desk literature was reviewed and certified diabetes educators (CDEs) were interviewed by a trained moderator to develop a draft survey to assess preferences and usability of insulin pens. Two rounds of qualitative interviews were then conducted with CDEs and patients with diabetes. Each interview served a dual purpose of both concept elicitation and cognitive debriefing, with the survey being administered on a study-provided electronic tablet. No further feedback was given after these two rounds and the survey was then considered final. **RESULTS:** The structured interviews (N=3; 1 per country) with CDEs provided the initial language for the survey items (e.g., rating how “smooth”, “easy to learn”, “easy to inject” each pen was). Interviews with both CDEs and

patients in the first round of cognitive debriefing (N=3 CDEs and N=6 patients, with representation from each country) introduced minor changes to the wording of the instructions and the addition of the item “ability to reach the injection button” based on patients who had finger dexterity limitations. The final round of cognitive debriefing (N=3 CDEs and N=6 patients) confirmed the acceptance of the changes and tablet presentation, with nearly all respondents reporting using the tablet was “very easy”. **CONCLUSIONS:** The multi-phased approach helped to develop a preference and usability survey with content validity in the populations of interest. Future insulin pen studies can utilize this survey to comprehensively capture the patient/CDE perspective.

PMD84

DEVELOPMENT AND CONTENT VALIDITY OF THE PATIENT-REPORTED INTRAOCULAR LENS QUESTIONNAIRE (PR-ILQ)

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OBJECTIVES: The Food and Drug Administration's (FDA) Office of Device Evaluation and Center for Devices and Radiological Health and the American Academy of Ophthalmology (AAO) published recommendations on the development and use of patient-reported endpoints. The objective of this study was to develop a PRO instrument to assess outcomes associated with intraocular lens (IOL) surgery in ways consistent with FDA and AAO recommendations. **METHODS:** Concepts relevant to patients with cataracts and IOL surgery were identified via concept elicitation interviews (CEIs) with therapeutic experts (N=10) and with patients both pre- (n=10) and post-IOL implantation (n=34) of various lens types. Data saturation from the patient interviews was evaluated to ensure that the sample was large enough and that all relevant concepts had been elucidated. Following its construction, the questionnaire's content was evaluated via two rounds of cognitive debriefing interviews (CDIs) with post-cataract surgery patients (N=32). All interviews were audio-recorded, transcribed verbatim and analyzed using qualitative data software. **RESULTS:** The CEIs identified concepts of measurement related to physical symptoms, visual disturbances, vision quality and vision correction for near, intermediate, and far distances. This resulted in the creation of the Patient-Reported Intraocular Lens Questionnaire (PR-ILQ), with three distinct scales: the Spectacle Independence Scale (SIS), the Vision Disturbance Scale (VDS), and the IOL Replacement Satisfaction Scale (IOL RSS). Some modifications to the scales were made following the first round of CDIs in order to increase patient understanding. The final PR-ILQ was found to be well understood by patients and relevant to their condition and its treatment. **CONCLUSIONS:** The PR-ILQ is a novel questionnaire comprised of three scales to assess the pre- and post-IOL experience among patients with cataracts. This study supports the content validity of the PR-ILQ and its alignment with published recommendations by the FDA and AAO.

PMD85

A SYSTEMATIC REVIEW OF ACTIGRAPH USE TO MONITOR SLEEP IN PEDIATRIC CHILDREN

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OBJECTIVES: To identify studies that use actigraphs, or similar devices, in monitoring sleep in pediatric children. **METHODS:** An electronic literature search was conducted on three databases (PubMed, EMBASE, PsycINFO) using the EBSCOhost platform, along with citation searches, from inception to October 2016. Key search terms included “actigraph”, “children”, and “insomnia” or “sleep”. English, peer-reviewed studies that used actigraphs, or similar monitoring devices, for assessing sleep in a cohort of pediatric children (aged 4 to 12 years only) were included. **RESULTS:** A total of 927 articles resulted from the initial search. After title screening occurred, 102 articles remained for abstract review. Sixty articles were identified for full-text review, with 25 as the final number of studies included for this review. Studies were most commonly conducted in the United States (n=14). All studies used actigraphs or similar devices with placement on either the wrist (n=20), waist/hip, (n=5), or shoulder (n=1) to assess sleep quality. The most common actigraph brands were Actiwatch AW's (n=5) and Actigraph GT3X+ (n=4). Seven studies used a sleep diary/log that was completed by a parent as a secondary measure to monitor sleep in children. Outcomes that were most commonly measured in the studies included sleep start time/sleep onset (n=20), sleep duration period (n=25), sleep efficiency (n=17), and nighttime wake frequency/duration (n=17). **CONCLUSIONS:** Researchers should be aware of the considerations when using actigraphs in a population of children, including the use of a secondary measure (e.g., sleep diary) when collecting actigraphy data as studies in this review indicated the benefit of using such type of measure to support actigraphy data. But overall, the use of actigraphs is common and beneficial when needed to monitor sleep quality as an outcome in a pediatric population.

PMD86

ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE (HRQL) AND EFFECT OF DEMOGRAPHICS ON HAEMODIALYSIS PATIENTS IN QUETTA, PAKISTAN

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OBJECTIVES: This study aimed to assess health-related quality of life and effect of demographics on haemodialysis patients in Quetta, Pakistan. **METHODS:** Prospective observational study was conducted to assess HRQL of haemodialysis patients. Study was conducted in the Sandeman provincial hospital Quetta (SPH) and

Baluchistan institute of nephrology and urology Quetta (BINUQ), data was collected from March - May 2016. A self-design questionnaire was used to measure demographics, disease condition and co morbidities of haemodialysis patients and EQ-5D EuroQol UK (English) questionnaire has been used in this study to measure HRQoL. The statistical analysis was performed by using SPSS v 20. **RESULTS:** One hundred eighty-five (185) patients were included in the study which was the total available patients at time of study. EQ-5D index score was 0.46 and visual analog scale (VAS) was 0.45 which reveals poor HRQOL in haemodialysis patients. Regression model reported Gender, Marital Status, Education, occupation and Monthly Income Locality were not significantly associated with HRQOL ($p > 0.05$) except Age group. Keeping Age group 18-28 year as reference, only two sub age groups were significantly associated and Odd Ratio (OR) showed that 38% HRQOL decrease with increasing age. However, HRQOL among male is 4% better than female **CONCLUSIONS:** In present study, the respondents showed poor HRQOL it is concluded if we increase the haemodialysis sessions from two to three sessions per week it may improve the HRQOL of the patients.

PMD87

UNWISE CHOICE OF PATIENTS UNDERGOING PERCUTANEOUS CORONARY INTERVENTION IN HONG KONG WHERE STENT CHOICE IS BASED ON PATIENTS' WILLINGNESS-TO-PAY

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OBJECTIVES: Percutaneous coronary intervention (PCI) in Hong Kong is self-financed (SF) and the choice between drug-eluting (DES) and bare-metal stents (BMS) is dependent on patient's willingness-to-pay. We aimed to evaluate the outcomes and factors associated with patient's choice of stents. **METHODS:** We retrospectively analyzed 2330 consecutive patients who underwent PCI between Sep 2009 and Dec 2013 at a tertiary academic institution. Baseline characteristics and 12-month outcomes including death, myocardial infarction (MI), target-vessel revascularization (TVR) and composite major adverse cardiac events (MACE) were evaluated among 2 groups of patients who chose DES (SF-DES) and BMS (SF-BMS). Independent predictors of DES use and MACE were identified using multivariate analysis. **RESULTS:** DES were used in 1,835 (78.8%) of SF-PCI. Patients who chose DES were less likely to have a history of stroke, MI, renal failure, heart failure and present with acute coronary syndrome and cardiogenic shock (all $p < 0.01$). There was no significant difference in income and education level between SF-DES and SF-BMS subgroups. Number of treated lesions (Odds Ratio [OR] 1.29, 95% confidence interval [CI] 1.10-1.51) was an independent predictor of DES use. Patients with a history of MI, stroke, acute ST-elevation MI, current smoker and renal failure were more likely to choose BMS. There were significantly higher 12-month mortality (5.1% vs 2.6%), TVR (2.4% vs 0.8%), and MACE (8.5% vs 3.8%) in SFI-BMS compared to SFI-DES patients (all $p < 0.01$). The use of DES was the only independent predictor of freedom-from-MACE at 12 month (OR 0.50, 95%CI 0.33-0.76, $p < 0.01$). **CONCLUSIONS:** In a healthcare system where choice of stents is largely dependent on the patient's willingness-to-pay instead of clinical criteria, the less expensive and effective bare-metal stents remained to be used in some high risk patients and was associated with worse outcomes.

MEDICAL DEVICES/DIAGNOSTICS - Health Care Use & Policy Studies

PMD88

F-CALPROTECTIN USE IN INFLAMMATORY BOWEL DISEASE (IBD) IS CHARACTERIZED BY IMPROVED DIAGNOSTIC ACCURACY, LESS PATIENT HARM AND DECREASED COSTS, COMPARED WITH CONVENTIONAL SEROLOGICAL MARKERS AND COLONOSCOPY - THE US PERSPECTIVE

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OBJECTIVES: Gastrointestinal disorders may exhibit overlapping symptoms making diagnosis difficult in primary care. Inflammatory bowel disease (IBD - prevalence $< 0.5\%$) is a chronic inflammation of the gastrointestinal tract. Irritable bowel syndrome (IBS) is a functional disorder without gastrointestinal inflammation (prevalence of 10-20%). Endoscopy is the gold standard to diagnose IBD vs. IBS, but due to IBD's low prevalence is negative in most of cases. Furthermore, colonoscopy is invasive, expensive, and uncomfortable for the patient and not without risks. F-Calprotectin (FC) is a fecal marker of intestinal inflammation. IBD patients exhibit FC levels significantly higher than the general population whereas IBS patients have FC levels higher than healthy controls, but significantly lower than IBD patients. Therefore, FC can be used as a pre-endoscopic test to differentiate between IBD and IBS. The present study evaluates the cost-effectiveness of a) FC compared to b) CRP+ESR, and c) colonoscopy to distinguish IBD from IBS in the US. **METHODS:** A Markov model was developed for each diagnostic strategy; using data from the published literature, 1.6% of the colonoscopies brought about complications, resulting in Emergency Room visits/surgery. Inadequate colon preparation (23%) and consequent repeated colonoscopies (30.3%) were also considered. Outcomes include cost savings, cost-per-corrected-IBD diagnosed, and colonoscopy reduction. Uncertainty was addressed with sensitivity analysis. **RESULTS:** FC results in a lower price (average cost/patient: FC = \$426.4; CRP+ESR = \$579.4; Colonoscopy = \$771.5), and it reduces the number of unnecessary endoscopies (FC = 736 colonoscopies avoided; CRP+ESR = 722) and reduces the associated complication costs (FC = \$1558, CRP+ESR = \$1787, Colonoscopy = \$4975), increasing the number of correctly diagnosed IBD (N=63) and IBS (N=26) patients. **CONCLUSIONS:** Results show that the usage of FC as pre-endoscopic diagnostic tool is associated with fewer colonoscopies and correctly identifies more disease while decreasing costs compared to

the alternatives. Consequently, FC demonstrates superior value both from patient and payer perspective, while simultaneously increasing diagnostic efficacy.

PMD89

PREVENTIVE CARE SCREENING PATTERNS AMONG WOMEN WITH MEDICAID OR COMMERCIAL INSURANCE, 2010-2015

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OBJECTIVES: To describe the prevalence of breast, cervical and colorectal cancer screening among women with Medicaid or Commercial insurance from 2010-2015. **METHODS:** The Truven Health Analytics MarketScan Commercial and Medicaid Multi-State Databases were used to identify women aged 30-59 with continuous enrolment in either database from 2010 through 2015. The primary analysis outcome was the prevalence and frequency of mammography (age 40+), Pap (age 30+), HPV, and colonoscopy (age 50+); results were reported overall and by 5-year age strata. **RESULTS:** A total of 2,042,752 women with commercial insurance and 127,076 women with Medicaid were included in the analysis. Most commercially-insured women (82.0%) received at least one mammogram during the 6-year study period and 54.7% received at least three. One-third (35.3%) of commercially-insured women had a gap between mammograms of at least three years. The majority (78.8%) of commercially-insured women had a Pap test during the study period, though 42.1% had a gap of more than three years between Pap tests. Approximately one-half (45.1%) of commercially-insured women received at least one HPV co-test during the study period. Colorectal screening was more common among commercially-insured women ages 55-59 (63.6%) than 50-54 (28.5%). Two-thirds (61.7%) of Medicaid-insured women received at least one mammogram and one-fourth (23.7%) received at least three. Two-thirds (69.8%) of Medicaid-insured women had a gap between mammograms of at least three years. The majority (58.3%) of Medicaid-insured women had a Pap test during the study period, though 69.8% had a gap of more than three years between Pap tests. Approximately one-quarter (25.9%) of Medicaid-insured women received at least one HPV co-test. Approximately one-half (47.2%) of Medicaid-insured women ages 50-59 underwent colorectal screening during the study period. **CONCLUSIONS:** Patterns of preventive screening utilization vary by type of insurance coverage. Many women fail to access any screening services while others experience large gaps between exams.

PMD90

USE OF SCREENING TOOLS AND PATTERNS OF HEALTHCARE UTILIZATION AMONG PREGNANT WOMEN DIAGNOSED WITH PRETERM LABOR IN THE U.S. EMERGENCY DEPARTMENT SETTING

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OBJECTIVES: Fetal fibronectin (fFN) testing and transvaginal ultrasound (TVUS) are tools used to assess risk of preterm delivery among women with symptoms of preterm labor (PTL). Objectives were to assess patterns of care and timing of delivery among a cohort of pregnant women with symptomatic PTL; evaluate use of fFN testing and TVUS during the 5-months prior to delivery; and identify patient characteristics associated with utilization of fFN testing. **METHODS:** Retrospective cohort study using the MORE2Registry®, a nationwide multi-payer claims database covering 139 million lives. Study cohort included women who presented at the emergency department (ED) and were diagnosed with PTL from 6/1/2012-11/30/2015. Exclusion criteria: premature rupture of membranes, pre-eclampsia, viral infection, no record of infant delivery, and < 5 months insurance coverage. Patient characteristics associated with use of fFN testing were identified using logistic regression modeling. **RESULTS:** 23,062 patients were included in study, of which 17,512 (75.9%) were discharged home following the ED encounter (20.1% delivered ≤ 3 days); the remaining 5,550 (24.1%) women were admitted to the hospital (91.3% delivered within that stay). Among those discharged home, 9.2% received fFN testing only, 16.4% received TVUS only and 5.0% received both tests during the 5 months prior to delivery. Among women who received fFN testing alone and were discharged home, 6.6% delivered within 3 days versus 21.6% of women who received only TVUS. Further, among women who were discharged home from the ED and had both fFN testing and TVUS during the five months prior to delivery, 4.7% delivered within 3 days. Key predictors of fFN testing included more frequent physician office visits and receipt of TVUS. **CONCLUSIONS:** Utilization of either TVUS or fFN for patients at risk of preterm delivery was low. Clinicians may consider fFN testing alone or in conjunction with TVUS to assist with evaluation and management of PTL patients.

PMD91

THE DETERMINANTS OF ADOPTION AND DIFFUSION OF INNOVATIVE NON-PHARMACEUTICAL TECHNOLOGIES ACROSS LIFE CYCLE: A SYSTEMATIC REVIEW OF QUANTITATIVE STUDIES

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OBJECTIVES: The proliferation and uneven diffusion of new medical technologies in recent years has been raising concerns on affordability and equity of care, inspiring the publication of scientific papers on the determinants of their adoption. The knowledge of the determinants spurring adoption and diffusion of innovative medical technologies is relevant for policymakers because it helps them implementing evidence-based health policies aimed at influencing the adoption of innovation, thus reducing inequities in uptake rates across areas and populations. We identified the empirical literature investigating the determinants of adoption and diffusion of innovative health technologies. Our goal is to discuss the existence of consensus on the direction and significance of the factors that influence their

adoption in each phase of technologies life cycle (i.e., early adoption, adoption, diffusion). **METHODS:** We performed a systematic review of quantitative empirical literature. **RESULTS:** We identified a total of 33 studies, published between 1977 and 2014. We conclude that early adoption of innovative technologies is positively affected by physicians' characteristics (e.g., experience with new technology by himself or by other physicians in the same hospital) and fee-for-service reimbursement scheme. The probability of adoption is mainly driven by provider's characteristics (e.g., size, importance of being perceived as technology leaders, previous adoption of similar/substitute technologies, strong medical staff involvement in acquisition decisions), by physicians' experience with the technology and by the new technology's expected impact on hospitals and physicians revenues. Socio-economic determinants (e.g., health expenditure), hospitals and physicians reimbursement schemes, market structure (e.g., number of providers, number of substitute procedures), providers' features (e.g., size, quality of care, reputation), and physicians' characteristics (e.g., experience with technology, innovator status of the team) significantly increase the extent of diffusion. **CONCLUSIONS:** Our results can be used as a guide by policymakers who wish to influence the adoption of new medical technologies with evidence-based decisions.

PMD92

NEW EUROPEAN MEDICAL DEVICE DIRECTIVE AND THE POTENTIAL CONSEQUENCES FOR US AND EUROPEAN MANUFACTURERS

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OBJECTIVES: Medical devices (MDs) must comply with the EU directives and be CE marked before entering the European market. Despite these high requirements, several serious health risks have been observed during the past years, which were initiated by implanted MDs. These incidents have caused the European Commission to revise the Medical Device Directives (MDD). The implementation of the new MDD will affect the stakeholders like manufacturers, regulatory bodies, physicians, and patients in Europe as well as in the US. Aim of this work was to assess the consequences of the new MDD with regard to the stakeholders and to estimate their potential occurrence rate. **METHODS:** A SWOT analysis has been performed to identify the strengths, weaknesses, opportunities and threats of the new MDD followed by a risk analysis. **RESULTS:** The SWOT analysis revealed two types of consequences of the new MDD: Immediate consequences that are associated with a high probability of occurrence like an increased workload and higher product development costs for manufactures, improved product safety for patients, enhanced pool of medical evidence for regulatory bodies and physicians. Potential indirect consequences of the new MDD, which are less likely or even unlikely, are consequences regarding a delayed market access of new products, a higher co-payment for patients using MDs, a discrimination of diseases with a low prevalence as well as a negative impact on the development of innovative products. **CONCLUSIONS:** For US and European stakeholders the implementation of the new MDD will result in a benefit, especially for patients and regulatory bodies. Nevertheless, an extended regulation may also cause unfavorable consequences. Therefore, and even though the implementation of the new rule will take a few years, it is important that manufacturer anticipate hidden consequences as early as possible. Therefore, the findings of the SWOT analysis are the basis for the development of strategic scenarios.

PMD93

ASSESSMENT OF NEW MEDICAL DEVICES WITH ADMINISTRATIVE DATABASES: THE NEED FOR TRACEABILITY

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OBJECTIVES: Administrative data (e.g., hospital discharge databases HDDs) can be used as a real world source of clinical and economic evidence for assessing new medical devices (MDs), providing that their use can be identified in the data. In absence of updated classification systems for procedures and diagnoses, which allow to identify the use of new technologies in the data, traceability can still be achieved thanks to authorities' coding guidelines (i.e., indication on how to combine the existing codes for procedures and/or diagnoses when new technologies are used). In 2009 Italy adopted version 2007 of the ICD-9-CM classification system and version 24 of DRGs, which are still in use. The rapid pace of innovation characterizing MDs poses a serious problem of traceability of their use in administrative data. The aim of this work was to investigate the capacity of the classification system currently used in Italy to identify innovative MDs. **METHODS:** We searched all the national and regional coding guidelines published from 2009 (i.e., the year of introduction of the new classification systems) to 2015. We extracted from each document the list of technologies for which the Ministry of Health and/or the Regional Authorities provided with coding indications. **RESULTS:** Our results show that only few recent technological innovations can be identified in the Italian HDDs. This reduces the possibility for Decision Makers to measure new technologies' outcomes and costs in the real world clinical practice. **CONCLUSIONS:** A better traceability of new MDs would provide a valuable support to the new Italian Health Technology Assessment Programme. Indeed, having the possibility to identify their use in HDDs would real-world assessment and re-assessment of MDs 2-3 years after their introduction.

PMD94

CHARACTERISTICS ASSOCIATED WITH HAVING A BREAST CANCER SCREENING TEST AMONG WOMEN 50 TO 74 YEARS OLD IN THE UNITED STATES

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OBJECTIVES: The U.S. Preventive Services Task Force recommends that women 50 to 74 years old with average risk for breast cancer have a mammogram every

2 years. This study assessed characteristics associated with having a mammogram. **METHODS:** A sample was drawn from 2014 Medical Expenditure Panel Survey (MEPS) data. Inclusion criteria were being female and 50 to 74 years of age. Exclusion criteria were a self-reported diagnosis of breast cancer or missing data on any study variables. Receipt of a mammogram was captured in the MEPS through a question that asked respondents how long it had been since their last mammogram. A binary variable was created to indicate whether each respondent had a mammogram within the past 2 years, it was the response variable in analysis. Association with having a mammogram in the past 2 years was assessed for the variables age, race, educational level, marital status, and insurance coverage. Multivariate logistic regression was used to assess association between selected characteristics and having a mammogram. The MEPS sampling weights adjusted for the complex survey design. **RESULTS:** A sample of 4,070 women met study criteria. Mean (\pm standard deviation) age was 59.9 ± 6.7 years. The sample was predominately white (66.8%). The prevalence of having a mammogram within the past 2 years was 77.4 percent (95% CI=76.1 to 78.7 percent). Women with a college degree (Odds Ratio=1.57, $p<0.001$), married women (Odds Ratio=1.47, $p<0.001$), and those with insurance coverage (Odds Ratio=3.82, $p<0.001$) had higher likelihood of having a mammogram in the past 2 years. No significant association was found between age, race, and use of mammogram. **CONCLUSIONS:** Over three-quarters of women met the breast cancer screening recommendation for mammograms. Having a college degree, being married, and having insurance coverage were associated with higher likelihood of using the mammogram test.

PMD95

U.S. PAYER ASSESSMENT OF LATE STAGE CLINICAL TRIALS INVOLVING DIGITAL HEALTH TECHNOLOGIES AND PHARMACEUTICAL MANUFACTURERS

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OBJECTIVES: We investigated US payer perceptions of collaborations between digital health technologies (DHTs) and pharmaceutical manufacturers (PMs) currently undergoing late-stage FDA trials. Our aim was to determine reimbursement implications based on an assessment of trial design and stated health outcomes. **METHODS:** A 5-part analysis was administered to members of Xcenda's Managed Care Network. Respondents were asked to evaluate 4 clinical trials, each including a DHT/PM intervention, across 4 disease categories: age-related macular degeneration, type 1 diabetes, atrial fibrillation, and human immunodeficiency virus. For each study, respondents were given a summary trial report and asked to assess study parameters using a 5-point Likert scale. Responses were tallied for each parameter, and scores were assessed based on ratings of ≥ 4 on the Likert scale (top-2-box method). Respondents were also asked to rate research activities that would add value to payer appraisals for each technology. Finally, a willingness-to-pay score was derived based on the technologies meeting their stated clinical endpoints. **RESULTS:** 43 respondents completed the assessment, representing 168 million covered lives in the US. All participants were active members of their organization's pharmacy & therapeutics committee. The atrial fibrillation, mobile monitoring study was rated the highest top-box score in terms of "willingness-to-pay" (44%) and "overall study quality assessment" (37%). While "appropriateness of study population" was rated highly across all studies (65% average), "demonstration of improved patient outcomes" was rated as the lowest parameter in quality (32%). The top 3 supplemental research activities recommended overall were the addition of a claims-based analysis (49%), long-term follow-up (47%), and development of a cost-effectiveness model (41%). **CONCLUSIONS:** This study has yielded insight for how DHT/PM partnerships can best convey the value of their technologies to US payers. Obtaining additional evidence generation via real-world analysis and demonstrating improvements in patient outcomes may represent viable opportunities for technologies to obtain favorable coverage decisions.

PMD96

SURGICAL AORTIC VALVE REPLACEMENT 90-DAY EPISODE OF CARE ANALYSIS

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OBJECTIVES: The CMS Innovation Center (CMMI) has a growing number of models that test payment and service delivery to achieve better care for patients at lower cost. Among these are episode-based payment models (i.e. bundled models) where participants are accountable for the cost and quality of care provided to Medicare fee-for-service beneficiaries during the inpatient stay and 90-days after discharge. The objective of this analysis was to determine average Medicare expenditures from index hospitalization through 90 days for surgical aortic valve replacements (SAVR) compared to existing mandatory orthopedic and cardiovascular episode of care models from CMMI. **METHODS:** Utilizing the 100% SAF Medicare file we identified index hospitalizations anchored by MS-DRGs that align with the episodes of interest. Medicare expenditures for the index hospitalization, readmissions, post-acute care, outpatient care, and physician services occurring within 90 days of discharge were analyzed. Descriptive statistics were used to compare and contrast the spending across each episodes of care. **RESULTS:** 90-day episode of care average spending for SAVR [\$62,912] was higher than current CMMI orthopedic and cardiovascular [CABG \$46,510, AMI PCI \$25,976, AMI Medical \$27,536] episodes of care. Considerable variation across procedures existed with the most striking difference occurring in the index hospitalization. For SAVR procedures, 78% of spending is concentrated in the index hospitalization versus current CMMI cardiovascular and orthopedic models [range from 45% to 75%] where the distribution of spending is more evenly dispersed across other settings-of-care. For SAVR, post-acute care represented 6% while readmissions accounted

for 7% of the 90-day expenditures. **CONCLUSIONS:** The high percentage of spending on SAVR in the inpatient setting (78%) may create a challenge for a bundled payment model. Conditions with high post-acute care and readmission rates could be better targets for testing bundled payments and offer providers more opportunities to improve care and lower Medicare spending.

PMD97

BUDGET IMPACT ANALYSIS OF P4HB VS PERMANENT SYNTHETIC MESHES IN COMPLEX ABDOMINAL WALL REPAIR IN AUSTRIA, GERMANY, UK, SPAIN AND SWITZERLAND IN THE HOSPITAL SETTING

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OBJECTIVES: Despite advances in surgical technique and prosthetic technologies, the risks for recurrence and infection are high following the repair of incisional ventral hernias. The current standard for reinforced hernia repair is synthetic mesh, which may reduce the risk for recurrence in many patients. Patients with comorbidities, contaminated wounds or previous wound infections experience higher rates of surgical site occurrences/infections (SSO/SSI). Mesh choice in Complex Abdominal Wall Repair (CAWR) may have an impact on short and long-term patient outcomes. The aim of this study was to analyze the economic consequences of P4HB Mesh use versus Permanent Synthetic Meshes in CAWR, under the perspective of the Austrian, German, UK, Spanish and Swiss National Health Systems. **METHODS:** A dynamic excel-based decision-analytic model was developed to assess the Budget Impact of P4HB Mesh in Complex Abdominal Wall Repair. For each Synthetic Mesh comparator, variables on efficiency were set as Hernia Recurrence, Infected Mesh Implantation, Wound Infection and Seroma. The analysis covered an 18 month time horizon and assumed 100% use for each technology. Public databases, as well as published and grey literature were used to estimate model input data. In the base case, a price difference of +1,700€ for P4HB mesh was considered. A tornado analysis was conducted for verification. **RESULTS:** Compared to Permanent Synthetic meshes, use of P4HB mesh in CAWR resulted in cost savings of 1,596€/1,514€/1,476€/1,376€/2,408€ per procedure in Austria/Germany/UK/Spain/Switzerland, respectively. The sensitivity analysis showed robust results for P4HB mesh, even in the most complex scenarios. **CONCLUSIONS:** Compared to Permanent Synthetic meshes, use of P4HB mesh may lead to potential cost savings in CAWR. Further research is needed in order to better assess rates of clinical complications, as well as the appropriate patient groups where P4HB technology would be most beneficial for patients and health systems

PMD98

COST SAVING ANALYSIS FOR A BIPOLAR SEALER (BS) DEVICE DURING HEPATIC AND SPINE SURGERY COMPARED TO STANDARD MONOPOLAR ELECTROSURGERY IN COLOMBIA

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OBJECTIVES: Perioperative blood loss and transfusion are important concerns in complex surgeries. Blood loss is associated with higher incidence of complications, transfusion rates, longer Length of Stay (LOS) and operating room time. The BS claims reduced intraoperative bleeding, lower transfusion rates and faster recovery times. This work estimates cost savings in spine fusion and hepatic surgeries using a low temperature RF Bipolar sealer versus standard monopolar electrosurgery (SME) from a Colombian provider perspective. **METHODS:** An Excel cost-saving model was developed to assess the differential cost of using BS during spine fusion and hepatic surgeries, compared to SME. Variables included were transfusion rate, transfusion rate LOS, comparators related LOS, operating room time, direct costs of technologies, opportunity costs for operating room, hospital bed, and blood units. Clinical inputs were populated via a systematic literature search. Opportunity costs were estimated with hospital administrator, KOL input and the official Colombian tariff manual. **RESULTS:** One partial hepatectomy and four spine surgery reference clinical publications were reviewed for this analysis. Spine procedures included Lumbar posterolateral, posterior spinal-fusion for degenerative lumbar scoliosis, posterior spinal-fusion for adolescent idiopathic scoliosis, and multilevel spinal-fusion surgery. For hepatectomy cases, there were cost savings in all cost categories, cost technology difference, blood bank, operating room and LOS, with USD\$ 2,138 total saving per procedure. For spine-fusion surgeries, costs were higher (USD\$ 255,2) for BS in cost technology difference, however they were offset by the lower costs in the blood bank, operating room and LOS. Dependent upon the type of spine surgery, total savings ranged from USD\$ 78 to USD\$ 2,327 per procedure. In all reviewed clinical works, lower blood loss was reported (-19% to -55%), compared to SME. **CONCLUSIONS:** The use of BS during Hepatectomy and fusion-spine surgeries could represent important savings from the Hospital perspective compared to SME.

PMD99

OVERSUPPLY OF CT AND MRI EQUIPMENT, BUT UNDERSUPPLY OF MAMMOGRAPHY EQUIPMENT IN JAPAN

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OBJECTIVES: The OECD has reported an oversupply of CT and MRI equipment in Japan compared with other developed countries. We investigated current situation of CT and MRI equipment compared with that of mammography equipment in Japan. **METHODS:** We compared the 1) trend in the total numbers of CT and MRI equipment and examinations with the total numbers of mammography equipment

and examinations using data from the Medical Institution Survey in Japan, and 2) the total numbers of CT, MRI, and mammography examinations per 100,000 individuals (women for mammography). **RESULTS:** The total numbers of CT and MRI equipment and examinations have increased over the last decade. Compared with the total numbers in 1996, the numbers of CT and MRI equipment have increased 1.4 and 2.5 times, respectively. The total numbers of examinations was 5.8 times for CT and 10.3 times for MRI. From 2008 to 2011, the total numbers of mammography equipment and examinations increased by 10% (the national data before 2005 could not be obtained). The national average number of equipment per 100,000 individuals was 6.2 for mammography, 10.2 for CT, and 4.7 for MRI. The national average number of examinations per 100,000 individuals was 7,983 for mammography, 22,464 for CT, and 10,627 for MRI. In all the 46 prefectures (excluding Fukushima), the numbers of equipment and examinations per 100,000 individuals were always higher for CT than for mammography. The number of MRI equipment per 100,000 individuals was higher than that of mammography equipment in 9 prefectures. The number of MRI examinations per 100,000 individuals was lower in 9 prefectures than that of mammography examinations. **CONCLUSIONS:** CT and MRI examinations have increasingly been performed in Japan compared with mammography examinations. Notably, the supply of mammography equipment has not markedly increased compared with the supply of CT and MRI equipment.

PMD100

A U.S. HOSPITAL BUDGET IMPACT ANALYSIS OF A SKIN CLOSURE SYSTEM COMPARED WITH STANDARD OF CARE IN HIP AND KNEE ARTHROPLASTY

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OBJECTIVES: CMS' mandatory bundle for hip and knee arthroplasty necessitates provider accountability for quality and cost of care to 90-days. Wound closure is a key area to consider within hip and knee arthroplasty. The DERMABOND® PRINEO® Skin Closure System combines a topical skin adhesive with a self-adhering mesh without the need for dressing changes or suture or staple removal. This study estimated the budget impact of DERMABOND PRINEO System compared to other wound closure methods for hip and knee arthroplasty. **METHODS:** A 90-day economic model was developed assuming 500 annual hip/knee arthroplasties for a typical U.S. hospital setting. In current practice, wound closure methods for the final skin layer was set to 50% sutures and 50% staples. In future practice, this distribution shifted to 20% sutures, 20% staples, and 60% DERMABOND PRINEO System. Healthcare resources included materials (eg, staplers, steri-strips, and traditional/barbed sutures), standard or premium dressings, outpatient visits, and home care visits. An Expert Panel, comprised of 3 orthopedic physician assistants, two orthopedic surgeons, and a home health representative, was used to inform several model parameters. Other inputs were informed by national data or literature. Unit costs were based on list prices in 2016 USD. **RESULTS:** The analysis predicted that use of DERMABOND PRINEO System could achieve cost savings of \$56.70 to \$79.62 per patient, when standard or premium wound dressings are used, respectively, with sutures or staples. This translated to an annual hospital budgetary savings ranging from \$28,349 to \$39,809 when assuming 500 arthroplasties. Dressing materials and post-operative healthcare visits were key drivers of the results. **CONCLUSIONS:** Based on the results of this analysis, it is anticipated that the DERMABOND PRINEO System may provide cost savings within hip and knee arthroplasties due to decreases in resource utilization in the post-acute care setting.

PMD101

COST-EFFECTIVENESS ANALYSIS OF THE DIAGNOSIS OF MUCOSAL LEISHMANIASIS IN COLOMBIA

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OBJECTIVES: To estimate the cost-effectiveness of available diagnosis alternatives for Mucosal Leishmaniasis (ML) in suspected patients. **METHODS:** A simulation model of the disease's natural history was built with a decision tree and Markov Model. The model's parameters were identified by systematic review and validated by expert consensus. A bottom-up costing analysis to estimate the costs of diagnostic strategies was performed reviewing 48 clinical records of patients diagnosed with ML. The diagnostic strategies compared were: 1) no diagnose; 2) Parasite culture, biopsy, indirect immunofluorescence (IFI) and Montenegro in parallel; 3) Parasite culture, biopsy, IFI in parallel; 4) PCR-miniexon and 5) PCR-kDNA. Three scenarios were modeled in people with clinical suspicion, according of ML prevalence: high, medium and low. For each alternative, the costs and results were estimated. The time horizon was the life expectancy, taking as average age of diagnosis 31 years. Incremental cost-effectiveness ratio (ICER) was calculated per DALY avoided, and sensitivity analyzes were performed. It was considered a threshold of three GDP per capita and all costs were reported in American dollars of 2015 **RESULTS:** The PCR-miniexon was the most cost-effective alternative in the level low clinical suspicion, with an ICER of US\$ 3,380.88. At medium and high clinical suspicion levels, the most cost-effective strategy per additional DALY was the PCR-kDNA with ICERs of US\$ 2,915.04 and US\$ 3,210.28, respectively. **CONCLUSIONS:** Diagnostic tests for ML based on PCR are cost-effective strategies at a willingness to pay of three GDP per capita for DALY avoided, regardless level of

clinical suspicion. The PCR-kDNA was the most cost-effective strategy in the competitive scenario, with the parameters included in the present model.

PMD102

FACTORS INFLUENCING ATTITUDES TO BREAST CANCER SCREENING

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OBJECTIVES: The purpose of our research was to reveal the motivational and restraining factors that prevail on screening participation and to examine the knowledge of the respondents on breast cancer, breast cancer screening among women attending screenings. **METHODS:** Quantitative cross-sectional study was carried out in 2016 at the Breast Centre of the Radiology Clinic, University of Pécs, among women between 45-65 years, who attended on mammography with an invitation letter or medical referral. Patients with a diagnosis of breast cancer or other malignant diseases were excluded (n=333). The question groups of the questionnaire were: sociodemographic data, reasons for examination, attitude, knowledge about breast cancer and breast screening. Besides descriptive statistical analysis χ^2 -test, ANOVA, Kruskal Wallis, Mann-Whitney test, logistic regression were applied ($p < 0.05$) with SPSS 20.0 program. **RESULTS:** Most respondents (73%) were influenced by their environment to participate on breast screening. However, they are more afraid of finding some kind of lesion compared to other patients without complaints ($p=0.002$). Those living in a relationship are more likely to participate on mammography within two years ($\beta=-0.649$, $p=0.041$; OR=1.91, 95%CI [1.02; 3.57]. The unpleasantness of the test was considered as the most important among the restraining factors. 283 women (85%) failed to recognize the symptoms of breast cancer. The knowledge of breast cancer symptoms is a protective factor for screening regarding absence ($\beta = 1.225$, $p=0.029$; OR=0.29, 95%CI [0.09, 0.88]. Risk factors of breast cancer were completely listed only by a few patients from the sample, 6.3%. The main source of information was the gynecologist (33.7%). **CONCLUSIONS:** The current value of breast cancer screening appearance is around 50%, still below the expected level (70%). The expansion of population knowledge, efforts to decrease the negative experience about the examination, the organization of fast and flexible screening service can support the achievement of this goal.

PMD103

STUDY ON THE EFFECT OF COMBINED USE OF A REMOTE MONITORING PILLBOX, MULTI-DOSE BLISTER PACKAGING, AND AUTOMATED REMINDERS ON MEDICATION ADHERENCE IN PATIENTS ON LIPID LOWERING, ANTIHYPERTENSIVE, OR ORAL DIABETES THERAPIES

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OBJECTIVES: To assess the efficacy of a multi-modal, remote monitoring intervention on medication adherence of patients previously nonadherent to therapy (proportion of days covered (PDC) $< 80\%$) according to Independence Blue Cross claims data. **METHODS:** Patients with ongoing care at Penn Medicine, taking 4+ chronic oral medications, and established nonadherence to lipid lowering, anti-hypertensive, or oral diabetes therapies were invited to participate in the randomized controlled trial. Consenting patients were randomized to treatment or control arms and observed for 6 months. Patients in the treatment group received a commercially available service that includes 1) aligning the patient's medication regimen into weekly multi-dose blister packages that insert into 2) a remote monitoring pillbox that alerts the patient with lights, sounds, phone, or text message reminders when a dose is missed and 3) relays adherence information to study staff for outreach if $< 80\%$ of doses are taken for three consecutive days. Patients in the control group received usual care without reminders or outreach. **RESULTS:** Treatment (N=17) and control (N=33) groups were well-matched for demographics and adherence prior to randomization. In the 12 months prior to index date, the treatment group had an average PDC of 70.4% vs. 69.5% for the control group. All patients in the treatment group moved from non-adherent (PDC $< 80\%$) in the prior period to adherent in the treatment period across all drug classes of interest with number of on-time refills moving to 98%. At 6 months, treatment patients had higher rates of therapy persistence at 91.3% remaining persistent at 6 months vs 61.8% for control (Log-rank $p < 0.05$). Potential covariates age, gender, education level, and race were not statistically significant in predicting early therapy termination. **CONCLUSIONS:** Patients on the intervention demonstrated significant and sustained improvements in medication adherence. Further testing should be done to determine the effectiveness of the approach on clinical outcomes and cost related measures.

PMD104

TOPICAL HEMOSTAT TRENDS AND FACTORS ASSOCIATED WITH UTILIZATION IN KNEE AND HIP ARTHROPLASTY

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OBJECTIVES: Examine trends in topical hemostat utilization and factors associated with use in knee and hip arthroplasty. **METHODS:** The Premier Perspective® Database containing billing data from over 700 hospitals in the U.S. was analyzed. Patients age 21 or older who underwent an inpatient total knee or hip (total or partial) arthroplasty or revision surgery, from 2009 to 2014 were identified. Topical hemostat utilization was identified searching the free text fields of the hospital billing record. Categories of hemostats included: fibrin sealant, flowable, synthetic sealant, thrombin, Oxidized Regenerated Cellulose (ORC), gelatin or plant based, and patients with a combination of hemostats. Patient, provider, and procedure factors associated with use of any topical

hemostat were explored in a multivariable model. All statistical analysis accounted for clustering of patients within hospital; p-values < 0.05 were considered significant. **RESULTS:** 932,243 patients were identified. A majority were knee procedures (60.1%), almost a fifth of hip procedures were partials (19.5%), and revision procedures account for a similar percent in both groups (knees 8.2%, hips 9.7%). The majority of patients were female (60.9%), had an elective procedure (86.1%), and were seen at an urban hospital (90.0%). Ten percent of patients received a topical hemostat, with the top three being thrombin (52.8%), fibrin sealant (19.5%), and flowable (18.8%). Usage of topical hemostats was relatively stable over the study period. Factors associated with hemostat usage included: diagnosis of a bleeding disorder (OR=1.3[95% CI(1.1-1.6)]), having a transfusion prior to surgery (OR=1.3 [1.2-1.4]), undergoing an elective surgery (OR=1.2[1.1-1.2]), ischemic heart disease (OR=1.2[1.0-1.3]), peripheral vascular disorders (OR=1.2[1.1-1.2]), and arthritis (OR=1.1[1.0-1.1]). **CONCLUSIONS:** Topical hemostat usage has been stable between 2009 and 2014. Elective surgeries, transfusions prior to surgery, ischemic heart disease, peripheral vascular disorders, and arthritis were associated with receiving a topical hemostat. Further research is warranted on the impact of topical hemostats in these procedures.

PMD105

THE EFFECTS OF VARIOUS BLOOD SAMPLING TECHNIQUES AND EQUIPMENTS ON BLOOD TEST

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OBJECTIVES: In laboratory diagnostics, 70% of errors occur in the preanalytical phase. Our purpose was to identify factors that increase hemolysis in blood samples collected from intravenous catheters and to examine whether incorrect order of draw results in biased test results. **METHODS:** This quantitative, cross-sectional study was carried out in Karolina Hospital, Mosonmagyaróvár, Hungary between September 1. and November 30, 2016. Volunteers were selected by non-randomized purposive sampling. Blood was collected from 120 volunteers using intravenous catheters of various sizes (18, 20, 22 and 24G). During phlebotomy the following parameters were recorded: catheter size, tourniquet time, difficulty of phlebotomy, blood flow through the cannula, site of cannula insertion. Data were analyzed using descriptive (absolute and relative frequency, median, interquartile range - IQR) and mathematical (χ^2 -test, Mann-Whitney U tests, linear and logistic regressions) statistical analyses ($p < 0.05$). **RESULTS:** The rate of hemolyzed samples was 13.3% (16/120). Hemolysis was significantly increased by the use of intravenous cannula 22-24G (OR: 3.638, 95% CI: 1.101-12.027, $p < 0.05$), tourniquet time over one minute (OR: 4.256, 95% CI: 1.286-14.087, $p < 0.05$) and site of blood draw distal to the antecubital fossa (OR: 6.143, 95% CI: 2.023-18.653, $p < 0.05$). Increased tourniquet time resulted in increased LDH ($r=0.226$, $p=0.013$) and CK ($r=0.248$, $p=0.006$) levels. **CONCLUSIONS:** Using cannula $> 20G$, tourniquet time longer than 1 minute and drawing blood from sites other than the antecubital fossa result in increased risk of hemolysis. Increased toniquet time also resulted in the increase of certain analytes.

PMD106

DIAGNOSTIC DELAY IN PATIENTS DIAGNOSED WITH COLORECTAL CANCER

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OBJECTIVES: In developed countries, colorectal cancer is the second most common cause of cancer death involving both genders. The research aims to reveal that at which stage, with which symptoms patients with colon tumors are detected, and to estimate the duration of patient delay and its role in the prognosis of the disease. **METHODS:** A quantitative, retrospective document analysis was carried out, where patients diagnosed with colorectal cancer were analysed between 2012 and 2016 in Komárom-Esztergom County (n=518). Collected data were: gender, age, histological type, stage, metastasis, symptoms, patient delay. Data were processed by SPSS 20.0 programme, applying descriptive statistical analysis, χ^2 -test, Mann-Whitney and Kruskal-Wallis test ($p < 0.05$). **RESULTS:** 89% of the patients are treated because of the malignant tumor of the rectum (adenocarcinoma). 63,9% of the patients are male ($p=0,016$). The average age is 64,8 years. 53,7% of the patients are diagnosed at stage III, when lymph node involvement also exists, and this rate is significantly higher in the 60-70 age group ($p=0,016$). The most frequent symptoms are blood in the stool (65,5%), weight loss (29,5%), diarrhea (19,7%) and pain (17,8%). In case of patients at stage III, the occurrence of bloody stool ($p=0,006$), weight loss ($p < 0,001$), and pain ($p=0,015$) is significantly higher. 36,1% of the patients visit the doctor with their symptoms after 3-6 months. 13,5% after more than a year. Regarding patients with stage IV, delay significantly ($p=0,004$) was longer. The delay was significantly longer in case of weight loss ($p < 0,001$) and diarrhea ($p < 0,001$), while the blood in the stool ($p < 0,001$) the delay was shorter. **CONCLUSIONS:** The majority of patients are diagnosed with advanced tumors, which is clearly linked to the patient delay. Knowledge development of lifestyle influencing factors, awareness raising symptoms, and general medical oncology alertness may be an important moment of delay reduction.

PMD107

MHEALTH: HOW TO IMPROVE EFFECTIVENESS AND EFFICIENCY OF CANCER MANAGEMENT

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OBJECTIVES: The continuous booming of mHealth allows the development of new models of care, and might revolutionize the overall delivery of care. However, evidence on the potential effects of mHealth is still scant and current literature

mostly focuses on chronic diseases. To address this research gap, we researched mHealth current utilization in cancer care and aimed at assessing the perceived impact of mHealth on clinicians and patients by comparing the opinions of those who use it with those of individuals that still do not use mHealth. **METHODS:** We carried out a survey on 1,033 cancer patients and 1,116 oncologists in 5 European countries (France, Germany, Italy, Spain and the UK) and the United States. The objective of the questionnaire was to assess the current State of the Art of mHealth in cancer care (how many use it and for which purposes) and the perceived mHealth performance with respect to several different dimensions: efficiency, clinical effectiveness, and quality of life. **RESULTS:** The proportion of Users among clinicians is higher than the one observed in the patient group (77% vs 28%). This gap takes place in all geographic areas. As to the impact of mHealth on clinicians' activities and on patients' overall quality of life, Users express a higher degree of agreement with the mHealth potential. Among Users, those who use mHealth more frequently and for symptom management and compliance enhancement express higher levels of perceived improvement. **CONCLUSIONS:** mHealth can provide a more accurate way of managing cancer care. Although evidence is not definitive on actual benefits, Users perceive higher levels of satisfaction with respect to efficiency, effectiveness and impact on overall quality of life. However, the actual spread of such technologies is still scarce, especially among patients, with very limited utilization for activities related to treatment and follow-up and with several barriers to be tackled, ranging from financial management to privacy concerns.

PMD108

DO HIGH-VOLUME ORTHOPEDIC SURGEONS HAVE LOWER REVISION RATE THAN LOW-VOLUME SURGEONS? A MEDICARE DATABASE ANALYSIS

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OBJECTIVES: Surgical outcomes are thought to be superior for high- versus low-volume surgeons. This study was designed to evaluate whether an association exists between a surgeon's own surgical volume and revision rate. **METHODS:** Patients within Medicare's Standard Analytic File (SAF) Limited Data Sets who underwent total hip arthroplasty (THA) or total knee arthroplasty (TKA) from 2012 to 2014 were identified using Diagnosis-related Groups (DRGs) 469-470 and International Classification of Disease 9th edition procedure codes (ICD-9-PCS) 81.51 or 81.52 for THA and 81.54 for TKA. Patients who died within 12 months of index were excluded. Revisions within the 12-month follow-up were identified (THA revision: ICD-9-PC 81.53, 00.70, 00.71, 00.72, 00.73, and TKA procedure: 00.80, 00.81, 00.83, 00.84, 81.55). Two-year surgery volume and average revision rate per surgeon were calculated. Surgeons with < 10 procedures were excluded. Surgeons were grouped based on revision rates and volume of surgery (surgical volume decile: D_SV, revision rate decile: D_RR). Logistic regression was used to calculate odds of having a High_RR surgeon (top decile RR) as a function of procedure volume. **RESULTS:** A total of 9,446 and 9,507 TKA and THA surgeons were included. The one-year incidence of revision was 2.51% and 1.77% after THA and TKA, respectively. High_RR surgeons had revision rates \geq 5.00% and 4.61% for THA and TKA, respectively. The proportion of High_RR in each D_SV decreased significantly as D_SV increased. From the lowest to the highest D_SV, the proportion of High_RR surgeons decreased from 25.3% to 1.81% for hips, and 20.72% to 0.11% for knees. The OR of having a High_RR surgeon in the lowest D_SV versus the highest was 5.50 (95%CI: 4.04-7.63) for hips and 40.92 (95%CI: 18.07-92.67) for knees. **CONCLUSIONS:** The proportion of surgeons with high revision rates was significantly greater in the lower surgery volume decile vs higher decile.

PMD109

PARTICIPATION ON ORGANIZED BREAST CANCER SCREENING PROGRAM AT THE MAMMOGRAPHY CENTER OF THE CLINICAL CENTER IN PÉCS (2011-2015)

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OBJECTIVES: Our research aims to examine the participation rates of the invitees for breast screening and to reveal changes in the rate of participants on breast imaging tests in a five years (2011-2015) interval by data review, and to analyze ratio and changes in breast imaging examinations. **METHODS:** A quantitative retrospective research was carried out at the Mammography Center at the Clinical Center at the University of Pécs between 01.01.2011-31.12.2015 based on the documents of patient performance data reported monthly to the National Health Fund. We recorded the screening-, and other diagnostic imaging tests (ultrasound, invasive), the total of 177 575 investigations were analyzed. Descriptive statistical analyzes (absolute and relative frequency, distribution ratios) with Excel programme. **RESULTS:** During the five years a total of 84 474 persons appeared in radiological imaging examinations, the average age was 55.1 years. Participation rate of women who received invitation on mammographic screening was 23.7% in 2011, 17.7% in 2012, and 20.4% in 2013, in the year of the invitation or within two years. In 2015 performance relative to the patient population increased, as a result of the introduction of an extra shift per week. Under 34 years of age ultrasonography, over 66 years mostly diagnostic mammographic images are applied. The breast screening code reported cases in 2015 showed a decrease of 0.45%, diagnostic breast examination shows 4.72% increase compared to the previous quarter. Within the five-year average 45.09% of the examinations were reported as diagnostic tests, mammography screening represent 54.91%. **CONCLUSIONS:** The participation rates are below the known international screening programs and reference values. The target group following the invitation will appear in the test mainly for diagnostic purposes. More than 40% of women did not participate in mammography screening following the invitation.

PMD110

THE NEED FOR PAYER COVERAGE OF LARGE NEXT GENERATION SEQUENCING PANEL TESTING IN EPILEPSY: POTENTIAL FOR MISSED DIAGNOSES USING A SMALL GENE PANEL APPROACH

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OBJECTIVES: Clinical guidelines and expert consensus agree on the importance of a molecular diagnosis that identifies the underlying genetic etiology of epilepsy. While close to 1000 genes have been linked to epilepsy (Wang et al. Seizure. 2016), payer coverage policies support testing only a small number of epilepsy genes. To evaluate the potential for missing the underlying molecular diagnosis in patients affected with epilepsy, we reviewed positive results from patients tested with large next generation sequencing (NGS) panels. Our goal was to identify diagnoses that would have been missed if only epilepsy genes supported by payer coverage policies had been tested. **METHODS:** We evaluated pathogenic variants in genes identified in 714 epilepsy patients tested in our lab with consent using comprehensive epilepsy gene panels ranging from 471 to 1000 genes. Pathogenic variants were classified according to ACMG guidelines (Richards et al., 2015). The cohort included patients with phenotypes ranging from simple epilepsy to complex epilepsy syndromes. We compared pathogenic genes identified in the cohort against a set of 35 epilepsy genes identified as covered in a review of published US payer policies. Deletion and duplication variants were not analyzed in this study. **RESULTS:** Eighty-eight patients who tested positive using comprehensive panels had variants identified in 41 different genes. Fifty-five percent (48 of 88) had variants in genes with established drug and dietary treatments, or avoidance (Hani and Mikati, 2016; Pearl, 2016; Balestrini and Sisodiya, 2017). When compared with the set of payer-covered epilepsy genes, diagnoses would have been missed in 35% of patients (31 of 88). Furthermore, 6% of these patients (2 of 31) had variants in genes with established treatments options. **CONCLUSIONS:** Our data suggest clinical utility associated with testing epilepsy patients using a large gene panel approach, and support the extension of payer coverage to many more epilepsy-associated genes.

PMD111

IDENTIFYING ATTRIBUTES OF PROSTHETIC DEVICES FOR USE IN A BENEFIT-RISK STUDY

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OBJECTIVES: Through significant investment in novel technologies, upper-limb prostheses are rapidly increasing in functionality. These more advanced prostheses are expected to be submitted to the United States Food and Drug Administration (FDA) for regulatory review soon. Given recent guidance released by FDA, the benefit and risk tradeoffs patients are willing to make might be considered in regulatory review. We aim to demonstrate an approach for the identification of patient preference attributes for upper-limb prosthetic devices. **METHODS:** We engaged in evidence synthesis, expert consultation, and community engagement. To identify attributes, we conducted a targeted literature review and interviews with experts (n=10), and reviewed interviews with upper-limb amputees (n=7). We conducted a prioritization exercise through two focus groups with upper-limb amputees, end-users, and regulators and through a paper-based survey administered during a public meeting. Results from the exercise were analyzed using Best-Worst Scoring and rescaled on a 100 point scale. **RESULTS:** We identified 62 unique benefits, risks, and convenience attributes of upper-limb prosthetic devices. Based on expert input, we selected 16 risk items to be included in the prioritization exercise. 13 people participated in the focus groups and 34 people completed the prioritization survey. The four most influential risks were reliability (BWS score: 67.38, SE: 1.78), pain (65.78, SE: 1.62), infection (62.58, SE 1.55), and malfunction (62.41, SE: 1.70). The four least influential risks were MRI compatibility (32.09, SE: 1.68), time until use (31.38, SE: 1.80), training (30.85, SE 3.79), and outdated device (BWS: 29.96, SE: 1.78). **CONCLUSIONS:** This study documents rigorous development work for a stated-preference study in accordance with FDA's patient preference information guidance. It provides an approach that can be used by FDA reviewers to evaluate preference study design. Future studies will identify upper-limb amputees' willingness to trade between the benefit, risks, and practical aspects of prosthetic devices.

PMD112

TECHNOLOGICAL INNOVATION AND THE RATE OF CONCOMITANT CARDIAC PROCEDURES: THE CASE OF SURGICAL AORTIC VALVE REPLACEMENTS (SAVRs)

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OBJECTIVES: Technological advancement in diagnosis and therapy has led to an increase in number of patients undergoing surgery for valvular heart disease. This has also increased the number of concomitant procedures. Patients commonly undergo coronary artery bypass grafting, mitral repair or replacement, tricuspid repair and arrhythmia ablation as part of their cardiac surgery. The purpose of this research is to use real world evidence from hospitals across the United States to summarize the procedural mix, patient demographics and comorbid conditions for patients having SAVR. **METHODS:** Hospital visits from the MedAssets database from 2010-2014 with a record of SAVR were included in this analysis. Differentiation between isolated SAVR versus concomitant procedures were determined via ICD-9 coding. Rates of isolated versus concomitant procedures were calculated across hospitals. Descriptive statistics for patient demographics and comorbid

conditions were generated for patients having isolated SAVRs versus concomitant procedures. **RESULTS:** A total of 42,049 SAVRs across 199 hospitals met the inclusion criteria. Over half 23,367 [56%] of all SAVRs were performed as a concomitant procedure. Average age for concomitant procedures were slightly higher than isolated [67.5 versus 66.9] with the majority [67%] of concomitant SAVR patients being 65 years of age or older. When examining the procedure mix within each age group, a slightly lower percentage of concomitant SAVRs are being performed in patients under the age of 65 vs. patients ages 65+ [53% versus 57%]. Patients with concomitant procedures are sicker with an average Charlson comorbidity index of 2.18 versus isolated SAVR patients' average score of 1.95. **CONCLUSIONS:** The majority of SAVRs being performed are concomitant procedures for both patients <65 and 65+ years of age, and concomitant patients are sicker than those having isolated SAVR. As surgical technological advancements continue, the fact that SAVR patients across ages are typically not having these procedures in isolation should be considered.

PMD113

THE CHOICE BETWEEN HIP PROSTHETIC BEARING SURFACES IN TOTAL HIP REPLACEMENT: COST-EFFECTIVENESS ANALYSES USING UK AND SWEDISH HIP JOINT REGISTRIES DATA

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OBJECTIVES: Hip prosthetic implants used in primary total hip replacements (THR) have a range of bearing surface combinations (metal-on-polyethylene, ceramic-on-polyethylene, ceramic-on-ceramic, metal-on-metal); head sizes (small <36mm, large 36mm+); and fixation techniques (cemented, uncemented, hybrid, reverse hybrid), which influence prosthesis survival, quality of life, and healthcare costs. This study compares the lifetime cost-effectiveness of prosthetic implants to determine the optimal choice for patients of different age and gender profiles. **METHODS:** We developed a tunnel-state Markov model to compare implant combinations. Hip joint registries in the UK and Sweden were used to estimate the probability that patients require revision surgeries after primary THR across three time periods (0-2, 2-10, and 10+ years), for males and females aged <55, 55-64, 65-74, 75-84, and 85+ years. Implant, revision, and follow-up care costs were estimated from hospital procurement prices, national tariffs, and published studies. Quality-adjusted life years (QALYs) were calculated using utility estimates, taken from published studies. We calculated incremental net monetary benefits and generated cost-effectiveness acceptability curves. **RESULTS:** QALY benefits were similar between implants; rates of revision drove differences in cost and overall findings. Optimal choices varied mainly between traditionally used cemented metal-on-polyethylene and hybrid ceramic-on-polyethylene implants. Small head cemented metal-on-polyethylene implants were optimal for males 85+ and females 65 through to 84 years; large head cemented metal-on-polyethylene implants for females 85+; all with over 75% probability of being most cost-effective. Hybrid ceramic-on-polyethylene large implants were optimal for under 55s, with 54 and 25% probability of being most cost-effective for males and females, respectively. **CONCLUSIONS:** Our findings suggest that traditional implants are optimal for patients above 55, but the choice is considerably more uncertain for younger adults. Implant failure is a key cost driver. Further research into implant revision risks is recommended to reduce decision uncertainty.

PMD114

TRENDS IN DIAPYPSIS MODALITY FOR PATIENTS WITH END-STAGE RENAL DISEASE (ESRD) IN KOREA: 2003-2015

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OBJECTIVES: To assess trends in peritoneal dialysis (PD) and hemodialysis (HD) for patients with end-stage renal disease in Korea for the past thirteen years. **METHODS:** National administrative healthcare database in Korea from January 1, 2003 to December 31, 2015 was used. Patients who received dialysis for at least three months at that year were included as prevalence cases. Incidence cases were defined as patients who maintained the same modality for at least three months after starting PD or HD at that year. Trends in the number of patients, and medical cost in each year were assessed by dialysis modality. Age-adjusted rate per 100,000 of patients with PD or HD per year were also calculated based on 2015 Korea standard population. **RESULTS:** Regarding prevalence, while the number of HD was highly increased from 12,415 in 2003 to 46,233 in 2015, PD was slightly increased from 6,519 in 2003 to 8,962 in 2015; the rate of increase was 280.4% versus 37.5%. The rate of increase in total cost of HD in 2015 compared with 2003 was approximately four times higher than that of PD (426.7% versus 114.6%). In incidence cases, the number of HD increased by 84.3% in 2015 compared to 2003, but PD decreased by 27.1%. While total cost of HD increased by 270.6% in 2015 compared to 2003, those who received PD decreased by 4.0%. **CONCLUSIONS:** For the latest decade, HD was highly increased compared with PD in Korea, and medical cost of HD also increased dramatically. Therefore, further research is needed in order to investigate effective allocation of national healthcare resources on ESRD patients received dialysis.

PMD115

TECHNOLOGY ASSESSMENT OF THE EFFECTIVENESS AND CONVENIENCE OF SMART PUMPS IN NON CRITICAL HOSPITALARY SETTINGS

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OBJECTIVES: To assess the effectiveness and staff convenience of Smart Pumps in comparison with Standard Pumps for intravenous drug administration in

non-critical hospitalary settings. **METHODS:** A systematic literature search was conducted following IETS recommendations, by using Medline, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects and LILACS. The search was restricted for Spanish, English or Portuguese, including indexed journal, humans, and preference for original studies. Titles and abstract were reviewed for first screening by one reviewer. Pre-selected full text articles had a second level screening by two additional reviewers. Relevant information was gathered in a predefined template. Because heterogeneity and qualitative nature of the information, results were presented in a narrative form. **RESULTS:** Six observational studies were found to fully met inclusion criteria and research question. Smart Pumps showed heterogeneous and different degrees of benefits in terms of the following outcomes: medication error avoidance, reduction in adverse events, improvements in medication adherence and better convenience for nursing staff. **CONCLUSIONS:** This technology assessment suggests that the usage of Smart Pumps, for intravenous drug administration in non-critical settings, could be an effective technology to improve medication errors, adverse events and adherence, while enhancing nursing staff convenience.

PMD116

STUDYING THE STATUS OF LUNG FUNCTION OF CARPENTERS IN QUETTA DISTRICT, PAKISTAN

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OBJECTIVES: The study was designed to assess the effect of wood dust on pulmonary system of carpenters. **METHODS:** The total number of 100 male carpenters age ranging from 18-50 years, more than one year work experience selected randomly from the wood industries in Quetta district, Pakistan. Data was collected by using self-questionnaire based on interview and Spirometric tests were carried out. Forced vital capacity (FVC), Forced expiratory volume over the first second (FEV1) and FEV1/FCV ratio were observed and analyzed. To find statistically significant difference between the mean of groups by ANOVA test ($P < 0.05$) was observed on post hoc analysis (Tukey's multiple comparison analysis) by using SPSS 22. **RESULTS:** The total 100 carpenters were selected and divided in to four categories of age groups; out of which age group 18-27 years were 55 (55.0%), followed by age group 28-37 years 19 (19.0%), age group 38-47 years 15 (15%) and age group 48 years > 11 (11.0%). The mean of percentage predicted for (FVC) the group exposed to wood dust for less than 5 years was 57.8, exposure group 5-15 years the value was 63.63 and in exposure group 15 years & > 59.12. The mean of percentage predicted for (FEV1) in less than 5 years exposure group was 58.77, in exposure group 5-15 years was 67.29 and in exposure group 15 years & > was 67.15. The mean of percentage predicted for FEV1/FVC in exposure group < 5 years was 94.04, in exposure group 5-15 years was 94.23 and in the exposure group 15 years & > was 89.74%. **CONCLUSIONS:** The finding of this study determined that the wood dust adversely affect the Pulmonary System and this damage is linked with the duration of exposure to wood dust. The study population related to the wood industries workers affected with the restrictive lung disease.

PMD117

EXAMINING UNCERTAINTY AROUND THE AMERICAN COLLEGE OF MEDICAL GENETICS (ACMG) RECOMMENDATIONS FOR NEWBORN SCREENING (NBS) FOR MEDIUM/SHORT CHAIN L-3-OH ACYL-COA DH DEFICIENCY (M/SCHAD)

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OBJECTIVES: In 2006, ACMG published NBS recommendations. This research examines its reliance on expert survey scores about disease attributes. Scores determined an entry point to an algorithm (EPA) leading to recommendations; different EPAs led to different algorithm questions. **METHODS:** ACMG did not acknowledge uncertainty RE: scoring. We examine sampling uncertainty and uncertainty associated with missing responses, individually and jointly. We examine one condition, M/SCHAD (score, 1223), recommended as a Secondary Target. We use two questions with reported data: sensitivity/specificity of the test (SCREEN) and need for specialists in confirming diagnosis (CONF_DIAG). Missing data uncertainty uses boundary estimates based on potential scores for missing values; sampling uncertainty uses bootstrapping. Total scores < 1200 imply a new EPA and potentially a different recommendation. **RESULTS:** For CONF_DIAG alone, the EPA did not change due to any of the uncertainty assessments. When bootstrapping around the mean of the original data for SCREEN and around the lower boundary estimate, the EPA changes for 12.3% and 42.7% of the bootstrap cases, respectively. Because of the unique importance of SCREEN in the algorithm, the same percentages of cases implied that the recommendation would change to "not recommended". Combining both questions, resulted in similar percentages leading to a new EPA with potential changes in recommendations. **CONCLUSIONS:** The ACMG algorithm advantaged conditions with multiplex screening, so a new EPA generally did not matter - regardless of the total score, M/SCHAD would always be a secondary target recommendation. The notable exception is when the SCREEN score was < 100 where M/SCHAD would then be "not recommended." This result casts doubt on the recommendation for M/SCHAD but also on the entire ACMG process, highly insensitive to its survey results for all other questions.

PMD118

SMALL AND MEDIUM-SIZED ENTERPRISES: HOW DO THEY FARE IN THE UK MEDICAL TECHNOLOGIES EVALUATION PROGRAMME (MTEP)?

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OBJECTIVES: Health technology assessment (HTA) of medical devices is rarer than pharmaceuticals, due to limited clinical evidence, shorter lifespan and variable

pricing. In contrast to pharmaceuticals, the majority of medical device manufacturers (MDMs) are small and medium-sized enterprises (SMEs). The Medical Technologies Evaluation Programme (MTEP), developed in 2010 by the UK National Institute for Health and Care Excellence (NICE), promotes development and market access of new medical technologies. However, barriers for SMEs include costs and high clinical evidence requirements. In this study, we assess how well the MTEP provides a route to market for SMEs. **METHODS:** We extracted data from the 36 published/draft medical technology guidances (MTGs), identified the size of manufacturers and analysed how SMEs (defined as MDMs with <500 employees) compare to larger MDMs in terms of guidance output, recommendation status and time to publication. **RESULTS:** Whilst 98% of UK MDMs are SMEs, we show that only 63% of MTG sponsors are SMEs. The annual number of MTGs fluctuates, but overall presents a cumulative annual increase of 0.2 MTGs. However, there is an annual decrease of 0.1 MTGs for SMEs. For large MDMs, 100% of MTGs published were positive, compared to 71% for SMEs. Finally, SMEs experience a longer mean time to publication (15.9 vs. 12.8 months, $p=0.27$) and a much wider range in publication time (23 vs. 8 months), driven by a considerably higher maximum time to publication. **CONCLUSIONS:** The MTEP is an important step towards improving HTA for medical devices. However, much remains to be done to improve participation by SMEs. SMEs appear less likely to submit applications, and receive fewer positive recommendations. A lack of clinical evidence was cited in every case of non-recommendation; suggesting SME's struggle to meet NICE's evidence requirements. Therefore, we present considerations for NICE to improve SME participation in the MTEP.

PMD119

ECONOMIC EVALUATION OF LUNG CANCER SCREENING WITH LOW-DOSE COMPUTERIZED TOMOGRAPHY (LDCT) FOR SMOKING GROUPS IN TAIWAN

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OBJECTIVES: Lung cancer is the leading cause of death worldwide. Patients with lung cancer were often diagnosed at late stage. If patients can be diagnosed and treated earlier, the survival rate is above 60%. One large trial by the National Lung Screening Trial (NLST) in the United States found that compared to chest X-ray, low-dose computed tomography (LDCT) screening can reduce 20% death due to lung cancer. However, there were lack of localized clinical or economical evidences regarding the implementation of population-based LDCT lung cancer screening among high-risk smoking groups, in particular for those countries without trial-based evidences. This study used Taiwanese epidemiological local data to conduct an economic evaluation of implementing LDCT screening among high-risk groups. **METHODS:** This study conducted 1st order Markov simulation models to analyze the life-time cost-effectiveness of LDCT screening. Quality-adjusted life years (QALYs) and costs were calculated among high-risk groups between screening and no screening population. Through literature review, database analysis and expert opinions, base parameters were generated. 10,000 hypothetical individuals were simulated. **RESULTS:** Compared to those without receiving LDCT screening, our results suggested that screening group tended to have better QALYs. The incremental QALYs was 0.16 and ICERs was NT\$303,748 per QALY gained. Regarding the results from one-way sensitivity analyses, the ICER between male and female was only slightly different; the trend of ICER value started to be lower when the starting screening age 55 to 75 was the lowest point and then went up. Compared to no smoke group, smoke group tended to have higher incremental QALYs. Former smoker (quick smoke <15 years or current smoker with 20-30, >=30 pack year tended to have higher QALYs and ICERs. **CONCLUSIONS:** Consistently with existing studies, this study provided evidences that LDCT screening policy might be cost-effectiveness for providing to age 55 to 75 and heavy smokers.

PMD120

INCORPORATING ECONOMIC EVIDENCE INTO COCHRANE REVIEWS: AN UPDATED METHODS FRAMEWORK AND A WORKED EXAMPLE IN A REVIEW OF INTERVENTIONS FOR INCREASING UPTAKE OF DIABETIC RETINOPATHY SCREENING

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OBJECTIVES: Health care decisions are made in the context of constrained budgets. Thus, evidence on the health effects of interventions is often not sufficient for decision-making as it also requires evidence on resource use, costs, and their cost-effectiveness. Extending the scope of Cochrane Intervention Reviews (CIRs) to incorporate economic evidence can increase their usefulness in decision-making. We developed a methods framework for conducting a full systematic review of economic evidence which was piloted in a new Cochrane review of interventions for increasing the uptake of Diabetic Retinopathy Screening (DRS). The framework focused on helping end-users help understand key economic trade-offs between alternatives. **METHODS:** Following the framework, searches were conducted to identify full economic evaluations, cost analyses, or comparative resource utilization studies conducted alongside eligible randomised controlled trials (RCTs). These studies were next classified according to the type of economic evaluation and analytic framework used. Characteristics of included studies and their results were extracted. Risk of bias and overall methodological quality were assessed using the Cochrane Risk of Bias Tool v.1.0 and the CHEERS statement plus CHEC criteria. **RESULTS:** 76% of included economic studies were conducted in the USA and the remainder in Europe. Two of the thirteen included economic studies were full economic evaluations. Proximity to screening venue, reminders through personal telephone and diabetic self-education management with the use of non-physicians (personally trained on diabetes management)

were evaluated in individual studies, reporting increasing screening attendance by 14-18% (similar to the range seen in the whole CIR) at additional costs which varied depending on the intervention. Higher cost interventions were not obviously more effective. Applicability to harder to reach groups is limited. **CONCLUSIONS:** The economic perspective raises questions about the value of more costly interventions but more full economic evaluations focusing on hard to reach populations are needed.

PMD121

HTA OF INTENSIVE CARE VENTILATORS FOR PEDIATRIC PATIENTS

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OBJECTIVES: The purpose of the study was to evaluate different type and manufacturers of intensive care ventilators in order to support the health care decision-making process about the choice to adopt the best available technology for ventilation of pediatric patient in intensive care units at Bambino Gesù Children's Hospital. **METHODS:** The technology assessment process was developed by using a new methodology, the Decision-oriented HTA (DoHTA), a new implementation of the EUnetHTA CoreModel, integrating the Analytic Hierarchy Process. A literature review was carried out to gather evidence on safety and overall effectiveness of different kind of intensive care ventilators, with several ventilation modalities and strategies. The synthesis of scientific evidences, and results of the specific context analysis resulted in the definition of components of the decisional hierarchy structure, consisting in detailed characteristics of the technology's performances covering the aspects on feasibility, safety, efficacy, costs, and organizational and technical characteristics of the technology. A subgroup of these indicators has been included in a checklist form for the evaluation of different type and manufacturers of intensive care ventilators, each of which was tested in three independent runs performed in three different department. In addition, an economic evaluation was also carried out. **RESULTS:** Preliminary DoHTA results showed that the domains with the highest impacts within the evaluation are safety and clinical effectiveness (34.77% and 25.69%, respectively) followed by organizational aspects, technical characteristics of technology and costs and economic evaluation. The final objective is to define the alternatives' ranking through a comparison between alternative technologies' performances. **CONCLUSIONS:** The technology assessment project allowed to identify strengths and limits of the most recent intensive care ventilator' models in the specific contexts of use by involving all health professionals interested, and eventually identify the best option for the hospital.

PMD122

MACHINE LEARNING AS A DIAGNOSTIC TOOL FOR VALIDATION OF SENSITIVITY

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OBJECTIVES: Using Machine-Learning, this research identifies key diagnostic reading levels that lead to prediction of diabetes among readmitted patients, and provides analysis as to why this is the case. **METHODS:** Gathered by researchers at the University of California Irvine, the dataset encompasses 10 years (1999-2008) of clinical care at 130 US hospitals and integrated delivery networks. It includes over 50 features representing patient and hospital outcomes. The dataset includes information concerning demographics, diagnostics, prescriptions, existence of diabetes and readmission. I used the Complex Tree method for analysis, using readmission as the independent variable, with the thresholds of diagnostic readings from A1C test selected for their sensitivity and specificity. **RESULTS:** Roc curve with Area Under Curve 67.8% and False positive class 64% True positive Rate (TPR) of current classifier and positive class 83.3%. Positive class determined >8 and negative classes >7 and normal readings of A1C diagnostic test. **CONCLUSIONS:** A1C test and more specific the higher threshold is more prominent to show high sensitivity and true positive between the predictive and the true value. Given te independent variables readmission rate.

PMD123

QUALITY OF MANDATORY REPORTING OF ADVERSE EVENTS ASSOCIATED WITH INTRAVENOUS PATIENT-CONTROLLED ANALGESIA DEVICES

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OBJECTIVES: To assess the quality of mandatory reporting of adverse events associated with intravenous (IV) patient-controlled analgesia (PCA) devices in the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database. **METHODS:** We analyzed IV PCA device-related events, occurring in inpatient settings, reported to the MAUDE database from January 1st, 2011 through September 12th, 2016. The FDA requires all medical device manufacturers and user facilities to report any device-related adverse events that may have caused or contributed to death or serious injury within 30 calendar days and 10 calendar days to manufacturers respectively. We assessed timeliness of mandatory reporting (difference between date of report and date of event) using a 40-day and 10-day maximum reporting time criteria for manufacturers and user facilities, respectively. **RESULTS:** Of the 1430 IV PCA device-related events submitted to MAUDE, a total of 92 AEs including deaths (n=13) were present in structured AE data fields. Upon qualitative review of the text narratives, 7 additional cases of death absent in the structured AE field were identified. Several reports had missing information on location of event, personnel involved with event, and specific opioid involved. The average reporting time for AEs was 42 days (n: 92, S.D: 108 days, range: 0-801 days). The mean reporting time for a manufacturer-submitted event was 48 days (n: 65, SD: 116 days, range: 0-801 days); 22% of these events were submitted outside the 40-day maximum reporting

time. Similarly, the mean reporting time by user facilities was 9 days (n:5, SD:2 days, range: 5-11 days). However, 3 of these events were reported outside the 10-day maximum reporting time. **CONCLUSIONS:** Despite regulatory requirements, our findings suggest variance in the reporting of mandatory IV PCA device-related events. Additional training and outreach programs are needed to improve the current quality of reporting of AEs associated with IV PCA devices.

PMD124

EXAMINING UNCERTAINTY AROUND AMERICAN COLLEGE OF MEDICAL GENETICS (ACMG) RECOMMENDATIONS FOR NEWBORN SCREENING (NBS) FOR CYSTIC FIBROSIS (CF)

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OBJECTIVES: CF was recommended by the ACMG for NBS, based on an algorithm whereby survey scores determined an entry point to an algorithm (EPA) with EPA-specific follow up questions, determining final recommendations. No uncertainty RE: survey scoring was acknowledged by ACMG. The objective of this research is to identify, from unreported survey responses, potential numbers of missing responses (M) to certain questions and estimate the influence of uncertainty due to missing data and sampling variation on the confidence in the total score reported and recommendation made. In CF a loss in score of > 1 point will result in a change in EPA and final recommendation. **METHODS:** Estimates of missing responses consistent with question total scores were made. The influence of missing data was estimated through boundary estimates (Manski, 1989); bootstrapping estimated the influence of sampling variation. Their joint influence was also examined. **RESULTS:** The score (48) for one question implied a range of possible missing observations (2, 3, 6 or 7 of 65 expected responses). Using the conservative M=2, a lower bound (LB) of 46.15 (1.85 points below the original mean) implied a possible influence of missing data on the EPA and recommendation. Bootstrapping around the LB indicated 56.4% of means to be lower than the critical value for an EPA and recommendation change. **CONCLUSIONS:** Even with a conservative estimate of missing responses (2) to this one question, missing data could influence the EPA and final recommendations. Adding the influence of sampling variation implies even less confidence around the scoring and recommendation since any decrease > 1 point in the scoring changes the recommendation to "not recommended".

PMD125

NATIONAL TRENDS OF LAPAROSCOPIC SURGERY IN KOREA: RESULTS FROM THE HEALTH INSURANCE REVIEW AND ASSESSMENT SERVICE-NATIONAL INPATIENT SAMPLE

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OBJECTIVES: Over the past decade, laparoscopy has gained wide acceptance as a curative surgical procedure in various body organs. However, it is not known whether laparoscopic surgery is increasingly being adopted in Korea. The purpose of this study was to evaluate national trends regarding the utilization of laparoscopy for the surgical treatment in Korea. **METHODS:** All laparoscopic surgeries are recorded nationwide by HIRA using the related procedure code and the code for laparoscopic devices. Using the Health Insurance Review and Assessment Service-National Inpatients Sample (HIRA-NIS), which was a stratified sampling from the entire population under the Korea national health insurance system (Year 2010, 2011, 2012, 2013, 2014), descriptive statistics for the patterns of laparoscopic surgery in various organs were performed. To identify laparoscopic surgery, we selected medical device codes of all Trocar (Blade, Bladeless, Blunt, Ballon type, etc.). The procedure codes were grouped as colorectal, esophagus, hepato-pancreatic-biliary, stomach, thoracic based on the target organs. **RESULTS:** The number of laparoscopic surgery increased more than 30% over the study period, from 12,312 to 17,694. The most of cases were performed in colorectal and stomach cancer. In colorectal cancer, 4726 cases in 2010, 4960 cases in 2011, 5306 cases in 2012, 5071 cases in 2013, 5985 cases in 2014. In stomach cancer, 4004 cases in 2010, 4822 cases in 2011, 4783 cases in 2012, 4540 cases in 2013, 5457 cases in 2014. Furthermore, laparoscopy was increasing utilized in colorectal or stomach cancer related procedures; Subtotal Gastrectomy-Distal(code Q0252), Rectal and Sigmoid Resection-Anterior resection(code QA921), Rectal and Sigmoid Resection-Low anterior resection(code QA922). **CONCLUSIONS:** The present study shows a significant increase in the number of laparoscopy performed in various organs as the surgical treatment in Korea from 2010 to 2014, which is in-line with recent findings of increased utilization with the rest of the world.

DISEASE-SPECIFIC STUDIES

CARDIOVASCULAR DISORDERS – Clinical Outcomes Studies

PCV1

A CROSS SECTION STUDY ON PHARMACOVIGILANCE IN POST STROKE PATIENTS

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OBJECTIVES: To determine the prevalence of neuropsychiatric disorders and to assess the adverse reactions and cost effects in stroke management. **METHODS:** The patients diagnosed as stroke and wished to participate were identified from Neurology Department of Tertiary care teaching hospital and consent was obtained. Cross-sectional study for six-month duration after getting clearance from the Human Ethical Committee (order no: IEC no.07/22/2011/MCT). All the subjects were evaluated for adverse drug reactions through telephonic or face to face interview. Data processing tabulation of descriptive statistics did on statistical software. **RESULTS:** Out

of 52 patients 71.15% were males and 28.84% females. The mean age of the patients was 63.21 (±10.19) years and the median was 65. 85% stroke patients were non-vegetarian. 61% patients had Blood Pressure, followed by 55% Dyslipidemia, 42% Diabetes Mellitus. Depression (46.15%) was observed high in percentage of domain present, subsequently Aggregation (30.77%), Anxiety (26.92%). A total of 38 incidences of ADRs were observed, The highest reported ADR was GI bleeding (17.3%). According to Naranjos algorithm majority of ADRs found to have probable 74%, possible 23.6% and definite 2.6% and no doubtful categories. Medical cost for drug varies from Rs.300 to 800. The medicines were supplied by Govt. according to the availability had great relief for poor socio economic groups. **CONCLUSIONS:** The incidence of ADRs were more for males compared to females. Majority of the patients seems to have mistaken the symptoms of ADR to be due to the disease being treated and old age.

PCV2

REGIONAL DIFFERENCES IN THE ECONOMIC BURDEN OF HEART FAILURE: EVIDENCE FROM THE HEALTHCARE COST AND UTILIZATION PROJECT (HCUP) DATABASE

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OBJECTIVES: The aim of this study is to examine regional differences in hospital cost, healthcare utilization, and mortality for Medicare patients with heart failure (HF). **METHODS:** The study is a retrospective observational design using visit-level de-identified hospital records from the Healthcare Cost and Utilization Project database for the year 2013. Visits with a primary diagnosis of HF, Medicare insurance, age of 18 or older, and with the hospital region recorded were eligible for inclusion. Descriptive statistics were generated for patient demographics, comorbidities, and hospital characteristics by region (Northeast, Midwest, South, West). Primary outcomes included cost, length of stay, and mortality. **RESULTS:** A total of 143,732 visits met the inclusion criteria, 2.02% of the annual visits. The distribution of visits by region was: South (40%), Midwest (24%), Northeast (21%), and West (15%). Across all regions, HF patients had high rates of hypertension (>70%), renal failure (>45%), atrial fibrillation (>40%), and chronic pulmonary disease (>35%); with the South having the highest percentage of people with diabetes (47.28%). Across all regions, most patients were Caucasian, while Black patients had the most visits among minorities in all regions except the West where Hispanics (13%) had the most visits and were emergently admitted. The West was the only region with a percent of coronary artery disease below 50% (48.14%) and had the lowest average length of stay (4.72 ± 5.46 days) but the highest average cost per visit (\$13,878 ± 28,381). The Northeast had the highest mortality rate (3.68%), with the Midwest having the lowest (2.97%). **CONCLUSIONS:** This study found differences in cost, healthcare utilization, and mortality between regions with the most significant differences occurring in the West, with the highest average cost per visit and a high mortality rate, yet the shortest average length of stay.

PCV3

ASSESSMENT OF TREATMENT & OUTCOMES OF ST SEGMENT ELEVATION MYOCARDIAL INFARCTION (STEMI) IN SANDEMAN PROVINCIAL HOSPITAL QUETTA, PAKISTAN

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OBJECTIVES: Study aimed to assess treatment & outcomes of STEMI in Sandeman Provincial Hospital Quetta. **METHODS:** A cross-sectional descriptive study was conducted in cardiac patients of STEMI as the principal diagnosis registered in Sandeman provincial hospital Quetta. Data obtained from 194 STEMI patients' during May to August 2016 by using self-designed proforma which consist of vital signs, prescribed drugs, positive and negative outcomes. Statistical analysis was done by using SPSS version 20. Descriptive and inferential statistics used where applicable. **RESULTS:** Result showed that majority of STEMI patients (n=145 (74.7%) were male. Most of the patients (n=64 (33.0%) having age ranges between 59-68 years. Majority of the patients (n=71 (36.6%) were diagnosed with Anterior wall MI. Ninety-three patients (47.9%) were prescribed with four drugs for STEMI and most of patients (n=120 (61.9%) were using Streptokinase. In majority of patients (n=139 (71.6%) recovery is achieved, (n=163 (84.0%) patients Cure is partially achieved, BP maintenance is achieved in (n=101(52.1%) patients. Normal heart rate was achieved in (n=127 (65.5%) patients. One-hundred and ten (56.7%) achieved normal ECG, Maximum Patients (n=139 (69.6%) achieved stability. In-hospital mortality was occurred in (n=18 (9.3%) patients. ADRs and Drug interactions were not reported in majority of the patients. **CONCLUSIONS:** Study concluded that majority patients were male diagnosed with STEMI therefore, consideration of healthcare providers should be driven towards this alarming condition to reduce its occurrence to improve health facility in order to improve health of such patients.

PCV4

THE EFFECT OF SHORT-ACTING B2-AGONISTS ON ARRHYTHMIA FOR PEDIATRIC PATIENTS WITH BRONCHOPULMONARY DYSPLASIA AND CONGENITAL HEART DISEASE USING TEXAS MEDICAID DATABASE

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OBJECTIVES: Congenital heart disease (CHD) is known to be associated with congenital and acquired airway disorders such as bronchopulmonary dysplasia (BPD). Short-acting β2-agonists (SABA) are highly effective in the treatment of BPD. However, β-adrenoceptor agonists have inotropic and chronotropic effects that can increase arrhythmias or tachycardia. To our knowledge, among pediatric patients with CHD, the association of SABAs therapy with arrhythmia in pediatric patients with BPD have not been evaluated before. The focus of this study was to compare the occurrence of arrhythmia between SABA users and non-users among

pediatric patients with BPD and CHD. **METHODS:** Texas Medicaid database from 2008–2014 was used to conduct the retrospective cohort study. Patients aged ≤ 12 years who had a diagnosis of CHD (ICD-9-CM 745–747.xx, V151) and BPD (ICD-9-CM 770.7) were included in this study. SABAs included albuterol, ipratropium, levalbuterol, and tiotropium. Covariates adjusted for were demographic factors (age, gender, and race) and clinical factors (respiratory distress syndrome, asthma, cardiovascular condition, and use of anti-arrhythmia drugs). Propensity score matching, logistic regression, Cox proportional hazard regression model, and Kaplan–Meier plots were used to compare the occurrence of arrhythmia between the control and the test groups. **RESULTS:** After 1:1 matching, 2,882 patients were identified. Logistic regression showed that SABA users were more likely to have arrhythmia compared to non-users (OR=2.17 (95% CI: 1.56–3.02), $p < .0001$). For individuals on SABA therapy, the number of supply days of SABA was significantly associated with the occurrence of arrhythmia ($p < .001$). A Cox proportional hazard model showed that the risk of arrhythmia for SABA users were significantly higher than non-users (HR=2.10 (95% CI: 1.53–2.90), $p < .0001$). **CONCLUSIONS:** Our analysis showed that SABA use in pediatric patients with BPD and CHD may be associated with higher risk of arrhythmia. Physicians should monitor patients for long-term SABA therapy to avoid potential risk of arrhythmia.

PCV5

PATTERNS AND PREDICTORS OF DEPRESSION TREATMENT AMONG STROKE SURVIVORS WITH DEPRESSION IN AMBULATORY SETTINGS IN THE UNITED STATES

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OBJECTIVES: Objectives of this study were to examine the depression treatment patterns and predictors among stroke survivors with comorbid depression seeking care in ambulatory settings in the United States (US). **METHODS:** We used a cross-sectional study design by pooling multiple-year data (2005–2011) from the National Ambulatory Medical Care Survey and the outpatient department of the National Hospital Ambulatory Medical Care Survey. Older adults (age ≥ 50 years) with stroke and depression comprised the final study sample. Ambulatory visits that involved stroke diagnosis were identified by using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) of 430.xx–438.xx. Depression was identified in visits where the answer to the question “Regardless of the diagnoses written.....does the patient now have: depression?” was “yes.” Depression treatment defined as antidepressant use with or without psychotherapy comprised the dependent variable in this study. Multivariate logistic regression analysis was conducted to ascertain the predictors of depression treatment. All analyses were adjusted for the complex survey design of the datasets to obtain nationally representative estimates. **RESULTS:** During 2005–2011 timeframe, approximately 3.96 million ambulatory care visits recorded a stroke and depression diagnosis. Overall depression treatment was observed in 47.32% of the study sample, mainly driven by antidepressant use alone. An overwhelming majority used selective serotonin reuptake inhibitors (77% of overall antidepressant use), and sertraline was the most prescribed antidepressant (30.5% of overall antidepressant use). Sex, race/ethnicity, region of residence, number of medications recorded at the sampled visit, and number of chronic conditions were significantly associated with depression treatment. For example, men were approximately three-times more likely (Odds Ratio=2.772; 95% CI, 1.127–6.819, $P=0.027$) than women to receive depression treatment. **CONCLUSIONS:** According to this nationally representative sample, depression treatment is low among stroke survivors in ambulatory care settings in the US. Appropriate interventions should be developed to optimize post-stroke depression treatment.

PCV6

PATTERNS AND PREDICTORS OF DEPRESSION TREATMENT AMONG COMMUNITY-DWELLING OLDER ADULTS WITH STROKE AND DEPRESSION IN THE UNITED STATES

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OBJECTIVES: The objectives of this study were to examine national-level patterns and predictors of depression treatment among community-dwelling stroke survivors with comorbid depression. **METHODS:** This study adopted a retrospective, cross-sectional study design using multiple alternate years of Medical Expenditure Panel Survey (MEPS) [2002, 2004, 2006, 2008, 2010, 2012] data. The study sample consisted of older adults (age ≥ 50 years) who were stroke (ICD-9-CM codes of 430.xx–438.xx) survivors with comorbid depression (ICD-9-CM code of 296.xx, or 311.xx) and did not die during the calendar year. Depression treatment, identified by antidepressant medication use with or without psychotherapy, was the dependent variable of this study. Multinomial logistic regression analysis was conducted to examine the association of factors with depression treatment in the study sample. Depression treatment categories included antidepressant use only; combination therapy of antidepressant and psychotherapy; and no depression treatment. **RESULTS:** An overwhelming majority (87.6%) of the study sample (unweighted N=370) reported some form of depression treatment. Antidepressants only and combination therapy were reported by 74.8% and 12.8% of study sample respectively. Selective serotonin reuptake inhibitor (61%) was the most commonly reported antidepressant class, while sertraline (15.8%) was the highest reported individual antidepressant. Depression treatment was associated with age, education, poverty status, perceived mental health status, functional disability, presence of other chronic conditions, body mass index, smoking, metro status, and region. For example, among stroke survivors with comorbid depression, those who were 65 years and older were nearly six times more likely (Odds Ratio=5.80, 95% CI 2.48–13.5) to report use of antidepressants only compared to those who were 50–64 years old. **CONCLUSIONS:** The majority of the study sample received some form of

depression treatment and several individual-level factors were associated with the receipt of depression treatment. Future studies should assess outcomes associated with depression treatment in this vulnerable population.

PCV7

A LITERATURE REVIEW OF CRITICAL LIMB ISCHEMIA IN JAPAN REVEALS AN AMPUTATION PREVENTION STANDARD OF CARE, BUT NEED FOR IMPROVED ENDOVASCULAR TECHNOLOGIES

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OBJECTIVES: To review the current epidemiology, treatment patterns, and outcomes of critical limb ischemia (CLI) in Japan. **METHODS:** Clinical literature review of Japanese CLI (2007–2017; English; PubMed) was completed to identify the risk factors and the current clinical outcomes of treating CLI with revascularization and/or primary amputation. **RESULTS:** The incidence of CLI in Japan is 100 to 200/million/year and the main risk factors identified are older age, diabetes, kidney disease, and smoking—similar to what is seen worldwide. Japanese citizens with these risk factors; however, is steadily increasing. Japan has the highest proportion of elderly citizens in the world (38% will be >65 by 2050), a rapidly increasing prevalence of diabetes (13.5%), a higher proportion of hemodialysis patients, and a high number of smokers (19.7%). Patients that progress to CLI in Japan; however, experience very low rates of primary amputation—5% (2006–2011), 2% (2013) and 1% (2014). There is also a high utilization of revascularization procedures in Japan (43% surgical and 51% endovascular or hybrid) to treat CLI patients. The amputation and mortality rates are similar between the two treatment modalities, but endovascular treatments in Japan result in higher revascularization rates than surgical treatment. **CONCLUSIONS:** The changing Japanese lifestyle is increasing the number of people suffering from diabetes, kidney disease, hypertension, and dyslipidemia—thus, CLI is expected to rise and impact the Japanese healthcare system. The extremely low rate of primary amputation in Japan to treat CLI; however, suggests a Japanese standard of care with an emphasis on amputation prevention which has been shown in other studies to reduce costs and improve quality of life. One area of improvement revealed by this review is the need for better endovascular treatment technologies that lead to lower revascularization rates—another way to contain medical costs in a society with a growing prevalence of CLI.

PCV8

CHARACTERISTICS OF EARLY SACUBITRIL/VALSARTAN USERS IN A MANAGED CARE POPULATION WITH HEART FAILURE TO INFORM FUTURE OUTCOMES STUDIES

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OBJECTIVES: Sacubitril/valsartan was approved by the FDA in July 2015 for treating heart failure (HF). We aimed to examine the baseline characteristics of patients who started sacubitril/valsartan from July 2015 to September 2016. **METHODS:** This was an observational study using medical and pharmacy administrative claims from the HealthCore Integrated Research Database. Patients with any pharmacy claim for sacubitril/valsartan between 7/1/2015 and 09/30/2016 were identified. The first claim date for sacubitril/valsartan was assigned as the index date. Patients included in the analysis were ≥ 18 years and with continuous health plan enrollment during the 12 months pre-index ($n=874$). **RESULTS:** Cardiologists represented the majority of prescribers (84%) for sacubitril/valsartan index prescriptions. Commercial coverage was predominant in our sample (65%), followed by Medicare Advantage (19%) and Medicare Supplemental (16%). Most of the patients were male (74%) and above 60 years (62%), with an average age of 62 years. Common comorbidities included hypertension (85%), peripheral vascular disease (54%), atrial fibrillation (43%), and diabetes (41%). The most commonly used pre-index HF medications were beta-blockers (93%), ACE inhibitors/ARBs (86%), loop diuretics (72%), and mineralocorticoid receptor antagonists (MRA) (51%). Of these drug classes, the majority of patients received three (36%) or all four classes (37%) before initiating sacubitril/valsartan, with 5% on only one or none of these. Approximately half (52%) of patients had a hospitalization in the 12 months pre-index, with an average length of stay of 8.9 days. Of patients with any hospitalization, 23% had re-admission within 30 days of discharge. The majority of the hospitalizations were for HF (87%; mean length of stay: 8.9 days). **CONCLUSIONS:** The results help to characterize the complexity of the patient population receiving sacubitril/valsartan for treating heart failure. Future studies that evaluate real world outcomes should understand the characteristics of the sacubitril/valsartan users to determine the most appropriate comparator population.

PCV9

THE COST-EFFECTIVENESS OF STATINS FOR SECONDARY PREVENTION OF CARDIOVASCULAR DISEASE: OBSERVATIONAL STUDY USING DATA FROM ROUTINE ELECTRONIC MEDICAL RECORDS

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OBJECTIVES: To evaluate the cost-effectiveness of statins for secondary prevention of cardiovascular disease in routine practice from the perspective of the English NHS. **METHODS:** Electronic English NHS health records of 6,078 previously untreated patients of age 60+ receiving statins following the occurrence of a myocardial infarction (MI) and a one-to-one propensity score matched control of untreated patients after a MI, resulted in $n=12,156$ patients. Costs of primary care service use and referrals were calculated from CPRD data and inpatient hospitalisations from HES and HRG codes. QALYs were calculated from ONS mortality records and utilities from the literature applied to MI or ischemic stroke events recorded in HES. Inverse probability of censoring weights (IPCW) were used to estimate counterfactual outcomes in the absence of treatment cross-over in the

control arm. **RESULTS:** The distribution of baseline characteristics was balanced across the two treatment groups, and 43% initially untreated patients crossed-over to statins treatment. For 60-74 year olds, we found an increase in QALY with statins of 0.66 (95% CI: 0.44-0.87) and, in the 75+ group, a gain of 0.81 (95% CI: 0.72-0.88) per patient. Excluding the CV-unrelated costs of inpatient hospitalisations, the total incremental costs were respectively £1,616 (95% CI: 1347-2095) and £2,644 (95% CI: 2034-2963) per patient. Statins had an ICER of £2456 (95% CI: 1814, 2759) in the younger patient group and of £3250 (95% CI: 2843, 3531) in the older group. In contrast, when inpatient hospitalisation costs ICD-10 codes for non-CV events were included, statins resulted in cost savings (95% CI: -1165, 2782), and was consequently dominant, in the younger group, and had incremental costs of £5562 (95% CI: 4356, 6436) for an ICER of £7200 (6221, 8587) in patients aged 75+. **CONCLUSIONS:** Quasi-experimental evaluation using data from electronic medical records of patients treated in routine practice is feasible. CEA based on decision models may underestimate the cost-effectiveness of statins, due to their omission of hospitalisation costs associated with non-CVD outcomes.

PCV10

HEALTHCARE UTILIZATION AND COSTS IN PULMONARY ARTERIAL HYPERTENSION (PAH) PATIENTS TREATED WITH ENDOTHELIN RECEPTOR ANTAGONISTS (ERAs) OR PHOSPHODIESTERASE TYPE 5 INHIBITORS (PDE5IS)

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OBJECTIVES: Pulmonary arterial hypertension (PAH) is a rare, progressive disease characterized by increasing pulmonary vascular resistance and pressure. There are 13 approved PAH-specific medications in the USA targeting three distinct pathways. Without head- to-head comparative effectiveness trials, stakeholders may assume that ERAs and PDE5is produce similar health outcomes. The study evaluated all-cause healthcare utilization, all-cause hospitalization, costs and adherence in PAH patients treated with ERAs or PDE5is. **METHODS:** Using the PharMetrics Plus claims database, the most recent PAH therapy for all patients was identified between 1/1/2009-6/30/2015 (first Rx claim = index date). Therapies included the ERAs: ambrisentan, bosentan, and macitentan and the PDE5is: sildenafil and tadalafil (PDE5i erectile dysfunction drugs were excluded). Patients had continuous healthplan enrollment ≥ 3 months pre- and ≥ 6 months post-index. All-cause healthcare utilization, costs and proportion of days covered (PDC) were compared between ERA and PDE5i. Multivariable generalized linear models were used to assess all-cause hospitalization costs. **RESULTS:** A total of 805 ERA and 1,818 PDE5i patients were analyzed over 6 months post index. The mean age of the ERA cohort was lower (51.9 vs. 53.0, $p=0.011$) and included more females (74.5% vs. 61.5%, $p<.0001$). Post-index, ERA patients had more PAH prescriptions (mean 6.6 vs. 5.0, $p<.0001$), had fewer outpatient visits (mean 12.6 vs. 16.0, $p<.0001$) and fewer hospitalizations (29.4% vs. 36.5%, $p<.0001$). PDC was higher in ERA patients (mean 0.85 vs. 0.78, $p<.0001$). Mean unadjusted hospitalization costs for all patients were lower in the ERA cohort (\$20,017 vs. \$37,570, $p=0.007$). Adjusted hospitalization costs for patients with a hospitalization were 19% lower in ERA patients ($p=0.048$). **CONCLUSIONS:** PAH patients treated with ERA were younger, with higher adherence to therapy, lower resource use, fewer hospitalizations, and lower hospitalization costs than PDE5i treated patients. These results provide real-world evidence suggesting PAH therapies with different treatment pathways produce different clinical and economic outcomes.

PCV11

COMPARISON OF AMLODIPINE VERSUS OTHER CALCIUM CHANNEL BLOCKERS ON BLOOD PRESSURE VARIABILITY IN HYPERTENSIVE PATIENTS IN CHINA: A RETROSPECTIVE PROPENSITY SCORE-MATCHED ANALYSIS

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OBJECTIVES: Calcium channel blockers (CCBs) was associated with lower blood pressure variability (BPV) than other classes of antihypertensive drugs. Nonetheless, the correlation within CCBs group is unclear. This study aimed to assess the effect of Amlodipine versus other CCBs on BPV. **METHODS:** A retrospective propensity score-matched analysis was conducted, which retrieved 6,995 hypertensive inpatients encounter data (with median age at 69 years old, 52% was female, diastolic blood pressure (DBP) ≥ 40 mmHg and < 150 mmHg; systolic blood pressure (SBP) ≥ 70 mmHg and < 260 mmHg), who took at least one antihypertensive agent and completed at least three SBP measurements during the visit. International Classification of Diseases (ICD-10) was used to identify the hypertensive patients. BPV was calculated with standard deviation of SBP during a single inpatient visit. The Propensity Score Matching (PSM) was used to balance the cohort of patients prescribed Amlodipine or other CCBs. Series of appropriate statistical tests were applied to the propensity score-matched sample to examine the different effects on BPV. Additionally, the hypertensive patients with comorbidity i.e. Coronary Artery Disease (CAD), Diabetes Mellitus (DM), Myocardial Infarction (MI), Heart Failure (HF) and Chronic Kidney Disease (CKD) were analysed. **RESULTS:** For the hypertensive patients ($n=2004$, for each cohort), patients prescribed Amlodipine had lower BPV than patients prescribed other CCBs (12.7 mm Hg vs. 13.6 mm Hg, $p<.05$). For the hypertensive patients with comorbidity ($n=1242$, for each cohort), patients prescribed Amlodipine had lower BPV than patients prescribed other CCBs as well (13 mm Hg vs. 13.7 mm Hg, $p<.05$). **CONCLUSIONS:** Amlodipine was associated with lower BPV than other CCBs for both hypertensive patients and hypertensive patients with comorbidity.

PCV12

THE READMISSIONS, HEMORRHAGIC EVENTS AND ANNUAL MEDICAL COSTS OF THREE ANTI-PLATELET STRATEGIES IN SECONDARY PREVENTION AMONG NON-CARDIOEMBOLIC ISCHEMIC STROKE PATIENTS: A REAL WORLD STUDY

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OBJECTIVES: The objective of this research was to compare effects, adverse drug events, economic burden of Aspirin, Clopidogrel, combined Aspirin and Clopidogrel in secondary prevention of non-cardioembolic ischemic stroke. **METHODS:** New onset IS patients with hospitalizations during Jan, 2012 to Dec, 2012 were identified by their diagnosis from Beijing medical insurance database, then followed up their records until Sep,2013. Prescription records of patients were separated into three groups, patients with Aspirin records only, patients with Clopidogrel records only, and patients with both Aspirin and Clopidogrel simultaneously for some time. Recurrence and incidence of hemorrhagic events were calculated in each group and compared with others. Logistic regression was used to control relevant factors of recurrence. Generalized linear model (GLM) was performed to identify factors which affected annual medical costs. **RESULTS:** The readmissions of aspirin group, clopidogrel group and combined group were 42.5%, 71.1%, 47.2% separately and the incidence of hemorrhagic events were 4.0%, 2.2%, 4.2% separately. Different antiplatelet strategies showed significant difference in recurrence by logistic regression. Medical costs of patients in aspirin group was the lowest among three groups and readmission, age, index hospitalization stays, levels of index hospitalization had significant effects on annual medical costs. **CONCLUSIONS:** Aspirin is the most effective and cost-effective anti-platelet strategy to prevent recurrence in non-cardioembolic ischemic stroke patients. But limitations of Beijing medical insurance database and relevant bias should be taken into account when interpret the results.

PCV13

EFFECTIVENESS OF A COMMUNITY-BASED HYPERTENSION SELF-MANAGEMENT EDUCATION (HSME) PROGRAMME IN THE STATE OF PENANG, MALAYSIA

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OBJECTIVES: To evaluate the impact of a structured, group-based Hypertension Self-management Education (HSME) programme on participant's clinical and psychosocial outcomes. **METHODS:** A pre-post study design was employed. With the help of community leaders from non-governmental organisations in the state of Penang, adults diagnosed with hypertension and treated with anti-hypertensive(s) were recruited to participate in the study. Participants attended a total of 4-weekly (2-hour each session) of HSME programme. The programme was developed locally based on Bandura's self-efficacy theory. Participant's clinical (i.e. blood pressure, lipids, weight, body mass index, waist circumference, percentage body fat and percentage skeletal muscle) and psychosocial (medication adherence, hypertension self-care behaviour, self-care motivation, self-efficacy and quality-of-life) outcomes were assessed at baseline, post 1-week and post 2-month of HSME programme. **RESULTS:** A total of 45 participants consented to join the programme, with 36 (80.0%) attended two or more sessions. Most participants (68.9%) were female with a mean age 60 ± 7.72 years old. Post 1-week of intervention, participants were found to have significant improvement in high-density lipoprotein (HDL) cholesterol ($p = 0.001$), day spent on vigorous physical activity ($p = 0.007$), self-care motivation ($p = 0.001$) and self-efficacy ($p = 0.005$). At 2-month, participants sustained some of the aforementioned positive outcomes include HDL cholesterol, self-care motivation and self-efficacy with other significant improvement reported in medication adherence ($p = 0.005$) and hypertension self-care behaviour ($p = 0.002$). However, a significant decrease in percentage skeletal muscle ($p = 0.002$) was found between post-1 week and post-2 month. No significant differences were found in other outcomes between baseline, post 1-week and post 2-month of HSME programme. **CONCLUSIONS:** This short term HSME though had limited impact on participants' blood pressure but was found to improve other clinical and psychosocial outcomes. Therefore, a well-structured educational programme should be in place to support hypertensive patient in sustaining daily self-care activities.

PCV14

SYSTEMATIC LITERATURE REVIEW (SLR) OF EFFICACY OF STATIN AND NONSTATIN LIPID LOWERING THERAPIES FOR CARDIOVASCULAR EVENT REDUCTION

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OBJECTIVES: The objective of this SLR was to characterize the evidence supporting the efficacy of pharmacologic LDL-C-lowering therapies for reducing the incidence of major cardiovascular events and mortality. A network meta-analysis (NMA) is planned to compare the efficacy of agents added to statins (PCSK9 inhibitors [e.g. evolocumab], CETP inhibitors, ezetimibe). **METHODS:** A broad SLR using standard methods (eg, Cochrane) was conducted using databases, clinical trial registries, and congress abstracts (through 01/2016). Studies reporting time to a major vascular events or incidence of major vascular events were selected. Possible networks of trial evidence were formed for each outcome to explore the feasibility of performing NMA. **RESULTS:** There were 42,502 records. 390 full papers were screened, of which 208 were relevant. Overall, 66 completed

or ongoing trials were identified: 43 trials focused on statin therapy, 7 trials on monotherapy of nonstatin agents and 16 trials on addition of agents to statins (e.g. PCSK9 inhibitors, CETP inhibitors, ezetimibe, fibrates). There were 8 trials reporting cardiovascular outcomes and evaluating agents added to statins (evolocumab N=3; alirocumab N=2; ezetimibe N=1; anacetrapib N=2) that could inform a NMA, 3 of which were ongoing. Of the 8 trials, 5 were secondary prevention, of which 4 were cardiovascular outcomes trials; 3 were in mixed/primary prevention populations with exploratory cardiovascular outcomes. Secondary prevention trials differed in inclusion criteria regarding type and timing of prior events. Primary endpoints were most often composites generally including death, myocardial infarction, stroke, and hospitalization for unstable angina. Four studies also include revascularization within the composite endpoint. **CONCLUSIONS:** This SLR summarizes the current state of evidence for reduction of cardiovascular events with lipid-lowering therapies. In the absence of head-to-head trials, the SLR will support an NMA that will assess the relative effectiveness of therapies that are added to statins (initially evolocumab vs ezetimibe).

PCV15

COMPARISON OF CALCIUM CHANNEL BLOCKERS VERSUS OTHER CLASSES OF ANTIHYPERTENSIVE DRUGS ON BLOOD PRESSURE VARIABILITY IN HYPERTENSIVE PATIENTS IN CHINA: A RETROSPECTIVE PROPENSITY SCORE-MATCHED ANALYSIS

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OBJECTIVES: Previous studies suggested that blood pressure variability (BPV) was an important risk factor for stroke, coronary heart disease and all-cause mortality. This study aimed to assess the effect of calcium channel blockers (CCBs) versus other classes of antihypertensive drugs on BPV, including angiotensin-1 receptor blockers (ARBs), angiotensin-converting-enzyme inhibitors (ACEIs), beta blockers (BB) and diuretic (DI). **METHODS:** A retrospective propensity score-matched (PSM) analysis was conducted, which retrieved 5,627 hypertensive inpatients encounter data (with median age at 69 years old, 51% was female, diastolic blood pressure (DBP) ≥ 40 mmHg and < 150 mmHg, systolic blood pressure (SBP) ≥ 70 mmHg and < 260 mmHg), who took at least one antihypertensive agent and completed at least three SBP measurements during the visit. International Classification of Diseases (ICD-10) was used to identify the hypertensive patients. BPV was calculated with standard deviation of SBP during a single inpatient visit. The PSM was used to balance the cohort of patients prescribed CCBs or other classes of antihypertensive drugs. Series of appropriate statistical tests were applied to the PSM sample to examine the different effects on BPV. Additionally, the hypertensive patients with comorbidity i.e. Coronary Artery Disease (CAD), Diabetes Mellitus (DM), Myocardial Infarction (MI), Heart Failure (HF) and Chronic Kidney Disease (CKD) were analysed. **RESULTS:** For the hypertensive patients (n=1889, for each cohort), patients prescribed CCBs had lower BPV than patients prescribed other classes of antihypertensive drugs (12.3 mm Hg vs. 12.8 mm Hg, $p < 0.05$). For the hypertensive patients with comorbidity (n=737, for each cohort), patients prescribed CCBs had even lower BPV than patients prescribed other classes of antihypertensive drugs (11.9 mm Hg vs. 12.9 mmHg, $p < 0.05$). **CONCLUSIONS:** CCBs was associated with lower BPV than other classes of antihypertensive drugs for the hypertensive patients, and much lower BPV was associated for the hypertensive patients with comorbidity.

PCV16

FONDAPARINUX SODIUM COMPARED WITH LOW MOLECULAR WEIGHT HEPARINS FOR THROMBOPROPHYLAXIS AMONG PATIENTS AT RISK AS PER VIRCHOW'S TRIAD: A SYSTEMATIC REVIEW AND META ANALYSIS

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OBJECTIVES: The objective of this meta-analysis was to systematically review the randomized clinical trials (RCTs) of Fondaparinux sodium 2.5 mg once daily versus low molecular weight heparins (LMWH) at the titrated dose for the prophylaxis of venous thromboembolism (VTE) among the patients who are at risk as per Virchow's triad. **METHODS:** Systematic search in the database e.g. EMBASE, MEDLINE, Cochrane Library, ProQuest, Science Direct, Google Scholar and clinicaltrials.gov was done to identify RCTs evaluating both treatments for the prophylaxis of VTE among patients at risk published in English language from the year 2000 to 2016. A web-based systematic review tool "Covidence" was used to systematically screen the studies of interest. Analysis in "RevMan" was performed with the relative odds based on the random effect model. Results were presented as odds ratios (OR) with their 95% confidence intervals. The assessment of study quality and risk of bias among the included studies was performed as per Cochrane collaboration. **RESULTS:** After screening 10, 506 articles, 4,676 were selected for review. Thirteen RCTs were included in the final analysis after reviewing these 4,676 articles. Pooled analyses showed a significant 54% reduction for VTE (OR=0.46 [0.36, 0.60]) and 11% reduction in mortality (OR=0.89 [0.63, 1.25]) with Fondaparinux compared to LMWH. Contrarily, there was a significant 47% increase in the risk for the major bleeding (OR=1.47 [1.14, 1.89]) and 16% increase in minor bleeding (OR=1.16 [0.90, 1.49]) with Fondaparinux compared to LMWH. Quality assessment results identified four studies with high risk in the "blinding of participants and personnel" domain. **CONCLUSIONS:** This meta analysis concluded that Fondaparinux showed a superior efficacy in terms of reduction of VTE and mortality. However, it also increased the risk for major bleeding. Thus, observation is warranted to prevent the adverse effects post Fondaparinux administration.

PCV17

NET BENEFIT OF ANTICOAGULATION IN ATRIAL FIBRILLATION CHANGES MARKEDLY WITH VARIATION IN POPULATION STROKE RATES

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OBJECTIVES: U.S. guidelines recommend anticoagulating patients with atrial fibrillation (AF) and CHA2DS2-VASc score of 2 or greater. This recommendation relies on stroke risk from the SPORTIF trials; a score of 2 represents 2.2% annual incidence of stroke. New evidence from multiple AF cohorts indicates the risk of stroke off anticoagulants may vary considerably. This variation in stroke risk may substantially impact the net benefit of anticoagulation. We used stroke rates from SPORTIF and the larger U.S. community-based ATRIA cohort to address this question. For given CHA2DS2-VASc scores, stroke rates in ATRIA are, on average, 2% lower than in SPORTIF. **METHODS:** We conducted a simulation study of 33,436 patients with incident AF within the ATRIA-CVRN Kaiser California cohort. We determined the gain in quality-adjusted life years (QALYs) associated with anticoagulation compared with no thromboprophylaxis, using a previously published Markov state transition decision model incorporating patient-specific stroke and hemorrhage risk factors. We performed two simulations using stroke rates reported in (1) SPORTIF and (2) ATRIA. We report the number of patients expected to benefit from anticoagulation (gain ≥ 0.1 QALYs). We also determined population and mean gain in QALYs/patient through guideline-based anticoagulation. **RESULTS:** Simulations using SPORTIF rates lead to expected net benefit for 74.6% (24,960) of the cohort while simulations using ATRIA rates lead to expected net benefit for 26.4% (8,817). Using SPORTIF rates, guideline-based anticoagulation (i.e., CHA2DS2-VASc 2+), would lead to a gain of 12,716 QALYs (mean, 0.47/per patient receiving anticoagulation therapy). By contrast, using ATRIA rates, guideline-based anticoagulation would lead to a gain of 966 QALYs (mean, 0.04/patient receiving anticoagulant therapy). **CONCLUSIONS:** The net benefit of anticoagulation for AF is highly sensitive to variation in baseline stroke rates. Future work is needed to reconcile the observed variation in baseline stroke risk so that the benefit of anticoagulation can be accurately determined.

PCV18

INCIDENCE OF CARDIOVASCULAR EVENTS AMONG SECONDARY PREVENTION PATIENTS TREATED WITH STATINS OR EZETIMIBE IN JAPAN

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OBJECTIVES: To estimate the incidence of cardiovascular events (CVE) among secondary prevention patients in Japan **METHODS:** A retrospective cohort study examined adults initiating either a statin or ezetimibe from 1/1/2006-5/31/2014 in the Japan Medical Data Center database (2005-2015). The first observed statin or ezetimibe prescription defined the index date. Patients had ≥ 12 months of pre- and post-index date plan enrollment. Patients with atherosclerotic cardiovascular disease (ASCVD) during the pre-index period were identified, including the subgroup of patients with $\geq 25\%$ statin up-titration in the follow-up period. Incidence of CVE, defined as a new inpatient claim for myocardial infarction (MI), unstable angina, stroke, coronary revascularization procedure, heart failure (HF), transient ischemic attack, or peripheral artery disease was reported. **RESULTS:** 5,302 patients with previous ASCVD were included (mean [SD] age: 55.7 [9.5] years, 63.8% males). Diabetes (59.6%) and hypertension (59.5%) were the most prevalent comorbidities, pre-index. 69.8% of patients received moderate intensity statins and 0.8% received both statins and ezetimibe. Post-index date, 8.1% had any new CVE over a mean follow-up of 2.8 years; stroke (2.4%), MI (2.2%) and HF (1.5%) were the most common events; incident rates of these events per 1000 person-years of follow-up were 8.6 (stroke), 7.9 (MI) and 5.5 (HF). Among ASCVD patients who up titrated statin (N=385), 8.6% had a new CVE after statin up titration over a mean follow-up of 2.7 years; MI (2.9%), stroke (2.3%) and HF (1.6%) were the most common CVEs. Incidence rates of these events per 1000 person-years in patients with ASCVD and statin up-titration were 10.6 (MI), 8.7 (stroke) and 5.8 (HF). **CONCLUSIONS:** In a real world Japanese cohort with ASCVD, many patients still had recurrent CVEs despite receiving statins and/or ezetimibe. These findings highlight a continued unmet medical need in the area of secondary CVE prevention in Japanese patients.

PCV19

IMPACT OF RENAL FUNCTION ON CLINICAL OUTCOMES AMONG NONVALVULAR ATRIAL FIBRILLATION PATIENTS TREATED WITH WARFARIN OR RIVAROXABAN

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OBJECTIVES: Renal functional impairment is linked to increased risk of thromboembolic and bleeding events in patients with nonvalvular atrial fibrillation (NVAF) treated with warfarin or rivaroxaban. This cohort study assesses the impact of renal function on ischemic stroke and major bleeding rates in NVAF patients in the real-world setting. **METHODS:** Patients with first dispensing of warfarin or rivaroxaban after 11/2011 from the IMS Health Real-World Data Adjudicated Claims and Optum's Integrated Claims-Clinical de-identified data were included. Outcomes were stratified by estimated creatinine clearance (eCrCl from Cockcroft-Gault formula) for ischemic stroke, major bleeding, and a composite measure

(ischemic stroke, myocardial infarction (MI) or venous thromboembolism (VTE)) and analyzed using hazard ratios. Patients were stratified by those with eCrCl < 60 mL/min and eCrCl \geq 60 mL/min. Confounding adjustments were made with inverse probability of treatment weights. **RESULTS:** Analyses included 874 rivaroxaban and 1,069 warfarin users in IMS data and 1,269 rivaroxaban and 2,256 warfarin users in Optum data. Baseline characteristics for weighted cohorts were similar. In Optum data, the risk of ischemic stroke was significantly lower for patients treated with rivaroxaban (HR = 0.31 [0.17-0.59], $p=0.0003$) as well as for patients with eCrCl < 60 mL/min (HR = 0.19 [0.05-0.68], $p=0.0105$). In IMS data, the risk of ischemic stroke was not statistically different between cohorts overall or between subgroups. In both databases, the risk of major bleeding events was not statistically different between study groups and the risk for the composite measure was significantly lower for rivaroxaban-treated NVAf patients with eCrCl \geq 60 mL/min. **CONCLUSIONS:** Across IMS and Optum databases, ischemic stroke rates were either significantly lower for rivaroxaban-treated NVAf patients (overall and for patients with eCrCl < 60 mL/min) or not statistically different between cohorts. The risk of bleeding was not statistically different between cohorts for any subgroups across databases.

PCV20

THE IMPACT OF LOW-DENSITY LIPOPROTEIN CHOLESTEROL GOAL ATTAINMENTS ON CARDIOVASCULAR OUTCOMES: A RETROSPECTIVE COHORT STUDY IN CHINESE ACUTE CORONARY SYNDROME PATIENTS

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OBJECTIVES: This study aimed to assess the effect of low-density lipoprotein cholesterol (LDL-C) goal attainments (of <2.6mmol/L, <1.8mmol/L, and \geq 50% reduction) on first major adverse cardiovascular events (MACEs) for acute coronary syndrome (ACS) patients who underwent percutaneous coronary intervention (PCI). **METHODS:** A retrospective cohort study was conducted using case reviews of post-PCI ACS patients at an acute public hospital in Hong Kong between January 2009 and August 2015. Patients were followed from the date of PCI procedure until the first event of MACE (including all-cause death, myocardial infarction, heart failure, documented unstable angina, revascularization, and stroke) or to the end of the first year. Kaplan-Meier estimates were used to evaluate the impact of LDL-C goal attainment prior to the event on event-free time (time from the latest lipid goal attainment to the first occurrence of MACE). **RESULTS:** A total of 1684 patients were identified. Mean age was 68.7 years (78.8% males). At one-year endpoint, 658 (39.1%) attained the LDL-C goal of <1.8mmol/L, 727 (43.2%) had LDL-C between 1.8 mmol/L and 2.6mmol/L, and 299 (17.8%) had LDL-C \geq 2.6mmol/L. About 10% experienced a MACE within one year. The attainment of LDL-C level <2.6mmol/L was significantly associated with lower rates of MACEs during the one-year follow-up, and a further lowering of LDL-C level to 1.8 mmol/L did not lead to any incremental clinical benefits. Statin therapy was highly associated with LDL-C goal attainments but high-intensity statin therapy itself was not associated with a reduced rate of MACEs. Obtaining a \geq 50% reduction in LDL-C was associated with a significant reduction in MACEs. **CONCLUSIONS:** The clinical benefits of achieving an LDL-C goal of <2.6mmol/L or obtaining a \geq 50% reduction were reconfirmed, whereas achieving a <1.8mmol/L goal was not.

PCV21

LIPID TARGET ACHIEVEMENTS AMONG HIGH AND VERY HIGH RISK PATIENTS IN OMAN: FINDINGS FROM THE CEPHEUS STUDY

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OBJECTIVES: To determine lipid target achievements among Omanis with high and very high risk status from the Centralized Pan-Middle East Survey on the under-treatment of hypercholesterolemia (CEPHEUS) according to the recent recommendations from the National Lipid Association. **METHODS:** The Omani CEPHEUS study included 399 high and very high atherosclerotic cardiovascular disease (ASCVD) risk patients (\geq 18 years) on lipid lowering drugs (LLDs). The lipid fractions included high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), non-high density lipoprotein cholesterol (non-HDL-C) and apolipoprotein B (Apo B). **RESULTS:** The overall mean age of the cohort was 58 \pm 12 years, 48% (n=192) were female and 79% (n=316) had very high ASCVD risk status. Lipid target attainments for HDL-C, LDL-C, non HDL-C and Apo B were 41%, 26%, 35% and 35%, respectively. Very high ASCVD risk patients were less likely to attain lipid goal attainments compared to those with high ASCVD risk status (LDL-C (21 vs. 45%; $p<0.001$), non-HDL-C (30 vs. 55%; $p<0.001$) and Apo B (33 vs. 45%; $p=0.048$). Lipid goal attainment was significantly lower in those with higher triglyceride levels ($p<0.001$ for HDL-C, non-HDL-C and Apo B goal achievements). Females were also less likely to make lipid goals ($p<0.001$ for HDL-C, LDL-C and Apo B goal achievements). **CONCLUSIONS:** Despite being on LLDs, a large proportion of patients in Oman, especially those with very high ASCVD risk status, those with high triglyceride levels as well as females, are not at recommended lipid targets and remain at a substantial residual risk for cardiovascular diseases.

PCV22

EXAMINATION OF CARDIO-VASCULAR RISK FACTORS IN THE PRIORITY OF ATRIAL FIBRILLATION

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OBJECTIVES: Stroke-prophylaxis is the most massive subject of interest of atrial fibrillation, which is highly influenced by presence of risk factors toward for

arrhythmia. Our goal was to examine risk factors, successfulness of frequency control, effectiveness of anticoagulant therapy. **METHODS:** The study was a retrospective, quantitative cross-sectional study with non-randomized sampling method. Target group was patients treated with anticoagulant therapy. Enrollment criteria: atrial fibrillation, age 20-90 years, NYHA II. stage. Excursion criteria: patients having elective intervention that influence INR rates. The study was carried out at the University of Pécs Clinical Centre, Cardiology Clinic in 01.01.2012-31.12.2012. Data collecting was done by patients records analysis. Statistical analysis included linear regression, T-test, Chi square test, variance analysis (ANOVA) withy SPSS 20.0. **RESULTS:** We found significant correlation between BMI values-, systolic blood pressure-, modified medication and its effect on frequency control-, correct anticoagulant therapy- and the INR parameters, and the increased risk of thrombo-embolia in patients with atrial fibrillation. ($p<0.05$) **CONCLUSIONS:** International publications prove increasing incidence of atrial fibrillation. (Schnabel, 2012) Based upon clinical protocols and our study we emphasize importance of stratification of risk factors, individual optimization of the anticoagulant therapy in the interest of effective stroke prevention (Járai, 2008) and increased chance of survival (Matos, 2009).

PCV23

INCIDENT CANCER AND ADHERENCE TO STATINS AND ANTIHYPERTENSIVE MEDICATIONS FOR CORONARY ARTERY DISEASE AMONG ELDERLY MEDICARE BENEFICIARIES

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OBJECTIVES: To examine the relationship between incident cancer and adherence to statins and angiotensin-converting enzyme inhibitors (ACEIs), angiotensin II receptor blockers (ARBs), or beta-blockers among elderly individuals with CAD. **METHODS:** A retrospective observational longitudinal study assessing elderly Medicare fee-for-service beneficiaries with pre-existing CAD and incident breast (BC), colorectal (CC), or prostate (PC) cancer (N=12,096) and those with no cancer (NC) (N=34,257). Adherence to pharmacotherapy was measured during one-year pre- and post-index period at 120-day intervals. Key independent variable was grouped by cancer type and sex. Medication adherence was categorized into mutually exclusive groups. The adjusted relationship between incident cancer and medication adherence was analyzed using the generalized estimating equation. Inverse probability treatment weights were used to account for observed group differences between cancer and non-cancer groups. **RESULTS:** Only 29.1% of the elderly with CAD were adherent to both statins and ACEIs/ARBs/beta-blockers. In adjusted analyses, women [AOR=0.70; 95%CI=0.58,0.81; $P<0.0001$] and men [AOR=0.62; 95%CI=0.49,0.74; $P<0.0001$] with CC and men with PC [AOR=0.90; 95%CI=0.83,0.98; $P=0.022$] were significantly less likely to be adherent to both medication classes compared to their NC counterparts. No significant differences in adherence were observed for BC compared to those with NC. Even among those using single medication class, women [AOR=0.65; 95% CI=0.51,0.80; $P<0.0001$] and men with CC [AOR=0.59; 95%CI=0.42,0.76; $P<0.0001$] were significantly less likely to be adherent to that medication class compared to women and men with NC. **CONCLUSIONS:** Adherence to evidence-based medications for CAD varied by cancer types. Elderly Medicare beneficiaries with CC or PC were less likely to be adherent to evidence-based medications for CAD. Future research needs to explore the effect of non-adherence to concomitant medications on health outcomes such as survival among patients with incident CC and PC.

PCV24

HYPERLIPIDEMIA DRUG UTILISATION PATTERN IN PATIENTS WITH HYPERLIPIDEMIA BASED ON CLAIMS DATABASE OF HOSPITALS IN JAPAN

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OBJECTIVES: The aim of this study was to describe real-world prescription patterns, adherence and persistence of hyperlipidaemia (HLD) drugs for patients with HLD in Japan. **METHODS:** This study was a retrospective analysis using a hospital-based claims database provided by Medical Data Vision (MDV). Adult patients with HLD (ICD10: E78) initiating an HLD drug class between 01 January 2014 and 31 December 2014 were evaluated. Individuals were categorized as previously untreated (UT) or previously treated (PT), depending on the prescription of HLD drugs within the 12-month look-back period, and they were followed for at least 12 months. Adherence was measured using the medication possession ratio (MPR) and patients were defined as adherent when MPR \geq 80%. Persistence was defined as no discontinuation of initial HLD drugs during 12 months after the drug initiation. Standard descriptive and survival analysis methods were used to evaluate persistence and adherence. **RESULTS:** The analysis included 19,589 patients (UT: 13,185, PT: 6,404). Mean age was 66.6 years (UT: 67.1, PT: 65.7). The proportion of patients treated with one single drug class varied between the UT (98.3%) and PT cohorts (48.9%). The most frequently prescribed drug class was moderate statin. Among patients treated with several concomitant HLD drug classes, the most frequently prescribed combinations were moderate statin plus polyunsaturated fatty acids. Mean MPRs of single drug class therapy were over 95% across all HLD classes in UT and PT cohorts. The 12 months persistence rate of moderate statin was 62.1% and 68.4% in UT and PT cohorts, respectively. **CONCLUSIONS:** Moderate statin was the most frequent choice when initiating a first HLD drug therapy and a combination treatment was preferred for more experienced patients. The study showed patients with HLD are mostly adherence to drug therapies.

PCV25

BASILINE CHARACTERISTICS OF A RETROSPECTIVE CLAIMS ANALYSIS OF CARDIOVASCULAR OUTCOMES AND HEALTH CARE RESOURCE UTILIZATION AND COSTS IN HIGH-RISK STATIN-TREATED PATIENTS WITH HYPERTRIGLYCERIDEMIA

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OBJECTIVES: The ongoing REDUCE-IT study is investigating the effects of the prescription omega-3 fatty acid icosapent ethyl as add-on therapy to statins on long-term cardiovascular (CV) events in high-risk patients with hyperlipidemia. The objective of this study was to examine real-world evidence on CV outcomes and health care resource utilization and costs in a patient population similar to REDUCE-IT. **METHODS:** This was a retrospective administrative claims analysis using the Optum Research Database of medical and pharmacy claims data, enrollment information, laboratory results, and mortality data. Patients ≥ 45 years with documented diabetes and/or atherosclerotic CV disease (ASCVD), baseline statin usage, baseline triglycerides ≥ 150 mg/dL, and up to 5 years of available data for follow-up were included. Patients had continuous enrollment with medical and pharmacy coverage for 6 months of baseline and ≥ 6 months of follow-up. Evaluation parameters included use of fibrates and prescription omega-3 fatty acid products, statin titration patterns, rates of occurrence of first and subsequent major CV events, new chronic heart failure, transient ischemic attack, coronary revascularization, and quantification of health care costs and resource utilization. **RESULTS:** This report describes the baseline characteristics of the study population: 27,471 patients were included and had these characteristics: mean (SD) age, 61.6 (9.6) years; 46.7% female; 41.2 months mean follow-up; 69.3% commercial insurance enrollees, 30.7% Medicare; 83.7% on statins only, 13.4% on statin+fibrate, 1.9% on statin+omega-3, 1.0% on statin+fibrate+omega-3. Most (85.0%) patients had diabetes, 29.1% had ASCVD, 2.1% had prior myocardial infarction, and 3.1% had prior stroke. **CONCLUSIONS:** This real-world evidence study of patients with characteristics similar to those in REDUCE-IT identified more than 27,000 patients for an analysis that is well positioned to provide robust insight into medication patterns, CV events, health care costs and resource utilization, and the potential impact of icosapent ethyl therapy, based on the forthcoming REDUCE-IT results.

PCV26

FREQUENCY, PROGNOSIS AND RISK FACTORS AMONG CONGESTIVE HEART FAILURE IN DIALYSIS PATIENTS ATTENDING PUBLIC HOSPITALS OF QUETTA CITY, PAKISTAN

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OBJECTIVES: The current research was conducted to evaluate Congestive Heart Failure (CHF) in dialysis patients; its frequency, prognosis, and risk factors among patients attending public healthcare institutes of Quetta city, Pakistan. **METHODS:** This is a multicenter cohort study conducted at two public healthcare institutes of Quetta city, Pakistan. Data of 117 patients for one year was screened from the official records and evaluated retrospectively to identify variables of interest. Data was collected through a validated information sheet. SPSS v.20 was used for data analysis and data was described descriptively. **RESULTS:** All patients had End-Stage Renal Disease (ESRD) and were on regular maintenance hemodialysis therapy. Out of all selected patients, 7.7% patients had Non-Insulin Dependent Diabetes Mellitus, 4.3% patients had Ischemic Heart Disease, 78.6% had Left Ventricular Hypertrophy and 80.34% had Cardiomyopathy. Forty five patients (38.46%) were confirmed with CHF. Thirty seven (31.6%) of those had systolic dysfunction, 8 (6.8%) had diastolic dysfunction and 4 (3.4%) had both systolic and diastolic dysfunction. In the subjects with systolic dysfunction, 2.6% measured ejection fraction (E.F) of $\leq 20\%$, 13.7% measured 21-30% and 15.4% measured 3-40%. Additionally, 13 (28.9%) patients developed de novo CHF. Recurrence of CHF was observed in 26 patients (57.7%) whereas among the CHF group, ten patients died during the study period presenting a mortality rate of 24% in CHF group. **CONCLUSIONS:** The incidence of CHF was relatively high in our study population of ESRD. It was also observed that risk factors of both the disease conditions collaboratively exacerbated each other, resulting in worsening of patients' condition. Frequent recurrence of the disease, re-hospitalization and enhanced mortality in our study population is evident of adverse prognosis of CHF in ESRD population.

PCV27

BLEEDING-RELATED HOSPITAL ADMISSIONS AND 30-DAY RE-ADMISSIONS WITH DABIGATRAN VERSUS WARFARIN IN PATIENTS WITH NONVALVULAR ATRIAL FIBRILLATION

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OBJECTIVES: To compare the incidence of bleeding-related hospital admissions and 30-day re-admissions with dabigatran versus warfarin in patients with nonvalvular atrial fibrillation (NVAF). **METHODS:** Retrospective cohort study using a population-wide database managed by the Hong Kong Hospital Authority. Patients newly diagnosed with NVAF from 2010 through 2014 and prescribed dabigatran or warfarin were 1:1 matched by propensity score. The incidence rate of hospital admission with bleeding (a composite of gastrointestinal bleeding, intracranial hemorrhage, and bleeding at other sites) was assessed by zero-inflated negative binomial regression. Among patients who were continuously prescribed with their initial anticoagulants upon discharge, we assessed the risk

of 30-day re-admission with bleeding using a Cox proportional hazard regression model, with adjustment for length of stay and type of bleeding in the initial bleeding episode. **RESULTS:** Preliminary results indicated that among the 51946 patients with NVAF, 8309 users of dabigatran or warfarin were identified, with 5160 patients matched by propensity score. Of these, 151 (5.9%) dabigatran users and 172 (6.7%) warfarin users were hospitalized with bleeding during follow-up. The incidence of first hospitalized bleeding did not differ significantly between groups (incidence rate ratio [IRR]: 0.92; 95% confidence interval [CI]: 0.66-1.28). Cox regression analysis indicated that dabigatran use was associated with a higher risk of 30-day re-admission with bleeding over warfarin (adjusted hazard ratio [HR]: 2.87; 95%CI: 1.10-7.43). The difference became statistically non-significant when the observation period was extended to 60 days of discharge (HR: 1.89; 95%CI: 0.89-4.04). **CONCLUSIONS:** When compared to warfarin, dabigatran was associated with a comparable incidence of hospital admission but a higher risk of 30-day re-admission with respect to bleeding. Given that dabigatran achieves full anticoagulation more quickly than warfarin, close early monitoring of patients initiated on dabigatran following hospital discharge for bleeding is warranted.

PCV28

PREVALENCE AND INCIDENCE OF CLINICAL ATHEROSCLEROTIC CARDIOVASCULAR DISEASE (ASCVD) IN TAIWAN

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OBJECTIVES: To estimate the annual prevalence and incidence of clinical atherosclerotic cardiovascular disease (ASCVD) in Taiwan. **METHODS:** We conducted a cross-sectional study using Taiwan's 2005-2013 National Health Insurance Research Database (NHIRD). Patients with clinical ASCVD, defined as patients with coronary artery disease (acute coronary syndrome, coronary revascularization, myocardial infarction and stable or unstable angina), ischemic stroke or transient ischemic attack (TIA), peripheral arterial disease or peripheral artery revascularization according to ACC/AHA 2013 guidelines, were identified. Annual prevalence and incidence were reported per 100,000 individuals and further stratified by age and gender. **RESULTS:** Among Taiwanese adults aged more than 20 years, the overall prevalence of clinical ASCVD per 100,000 persons was 2,318 in 2006 and increased to 3,305 in 2013. Incidence of clinical ASCVD (1,263 in 2006 and 1,126 in 2013 per 100,000 persons) remained constant during the study period. The overall prevalence/incidence trends among patients with clinical ASCVD was similar between men and women. The prevalence and incidence increased with age until 84 years of age. **CONCLUSIONS:** The prevalence of ASCVD increased over time during 2006 to 2013 among Taiwanese population. Stable incidence of clinical ASCVD was observed during the study period.

PCV29

PROTECTING THE GAINS: WHAT CHANGES ARE NEEDED TO PREVENT A REVERSAL OF THE DOWNWARD CVD MORTALITY TREND?

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OBJECTIVES: Cardiovascular disease (CVD) mortality has decreased by $>60\%$ over the past 50 years, partially due to development of preventive therapeutics (e.g., statins, antihypertensive agents) and acute interventions, however progress is slowing. With an aging US population, an expected rise in obesity and diabetes, and competing needs for limited resources, future patterns of CVD are uncertain. **METHODS:** We developed a Microsoft® Excel-based model to project trends in CVD mortality. National Health and Nutrition Examination Survey (NHANES) data was used to estimate population-level trends in CVD-related risk factors (e.g., smoking, diabetes, cholesterol, blood pressure). Cohorts of 1,000,000 individuals were generated and assigned characteristics based on risk factor projections. Microsimulations were performed to estimate the 10-year CVD risk for individuals using the Framingham Risk Score. Risk scores, calculated separately for men and women, were used to predict future CVD prevalence and mortality. Scenarios, differing by uptake of current therapies, pharmaceutical innovations with efficacy exceeding available alternatives, and risk factor prevalence, were assessed to estimate the annual mortality rate from 2017-2040 given uncertainty. **RESULTS:** When incorporating a demographic shift, but assuming constant risk factors, current treatment utilization, and no major innovations, we predicted the CVD mortality rate would increase by 12% by 2040. In order to decrease CVD mortality by 15% given projected changes in risk factors, innovative therapies that can provide incremental benefits equal to or greater than the those associated with the introduction of statins will need to be identified and widely utilized. **CONCLUSIONS:** Although CVD is the leading area of direct healthcare costs with $< \$230$ billion spent in 2013, further investment is necessary to continue reducing the CVD burden. Increasing access and adherence to current preventative therapeutics could slow the increase in mortality, but innovative therapies may be needed to maintain the downward trend in CVD deaths.

PCV30

EVALUATION OF PATIENTS' KNOWLEDGE ON WARFARIN AND INR GOAL ATTAINMENT IN AN OUTPATIENT CLINIC OF A TERTIARY HOSPITAL IN NIGERIA

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OBJECTIVES: To assess the knowledge of patients receiving warfarin therapy in outpatient cardiology clinic using a validated and adapted Anticoagulation

Knowledge Assessment (AKA) questionnaire and examine the relationship between patients' anticoagulation knowledge and INR control. **METHODS:** The study was a cross-sectional survey. Patients (n=70) on warfarin who visited the outpatient clinic of the cardiology unit from July 2016- September 2016 were enrolled and asked to complete the AKA questionnaire upon voluntary consent. Demographic and clinical data such as INR goal range, and 5 INR values preceding the date of consent were manually extracted from patients' record data. Passing score was defined as at least 12 correct responses out of 23- INR relevant AKA questions (52%). INR control was defined by 3 outcome measures: number of INR values within goal range, time in therapeutic range (TTR), and standard deviation (SD) of INR values. **RESULTS:** Of the 70 patients enrolled, 60 patients consented to participate (85.7%; females 45%; mean age± SD 60.07±7.75; % with post-secondary education 28.3%). Most patients (n=52) had goal INR ranges of 2.0 to 3.0 (86.6%). Of the 60 patients who completed the questionnaire, 26 (43.3%) achieved the passing score (52%). There was no significant relationship between number of correct INR-relevant responses and INR control as defined by any of the 3 measures (count of INR values within range rho = 0.070, P = 0.595; TTR rho = 0.092, P = 0.595; and SD rho = 0.118, P = 0.371). **CONCLUSIONS:** Although 43.3% (n= 26) achieved the passing score of 52%, there was no significant relationship between patients' knowledge of warfarin and INR control. Establishment of educational programs for patients on anticoagulation drugs are recommended for future studies.

PCV31

PREVALENCE AND INCIDENCE OF ATHEROSCLEROTIC CARDIOVASCULAR DISEASE AND CARDIOVASCULAR RISK FACTORS IN SOUTH KOREA: A POPULATION-BASED STUDY

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OBJECTIVES: To estimate the prevalence and incidence of patients with atherosclerotic cardiovascular disease (ASCVD) or at high risk for ASCVD in Korea using national claims data. **METHODS:** We identified patients aged ≥18 years with ASCVD or with risk factors for ASCVD during 2013-2015 using the national claims data of Health Insurance Review and Assessment Service. ASCVD was defined as myocardial infarction (MI), angina (stable and unstable), coronary revascularization, peripheral artery disease (PAD), ischemic stroke, and transient ischemic attack (TIA). Cardiovascular risk factors, namely hypertension and diabetes mellitus, were also examined. Prevalence and cumulative incidence of ASCVD were reported per 1000 persons and further stratified by age and gender. Incident patients were those without history of or risk factors for ASCVD in the year prior to the first occurrence of ASCVD or any risk factor. **RESULTS:** Among South Korean adult patients, the overall prevalence of ASCVD per 1000 persons was 98 in 2014 and 101 in 2015. The prevalence of diabetes mellitus and hypertension was 113 and 206 per 1000 persons in 2015, respectively. Cumulative incidence of ASCVD per 1000 persons was 55 in 2014 and 60 in 2015. Cumulative incidence of diabetes mellitus and hypertension in 2015 was 34 and 27 per 1000 persons, respectively. Overall prevalence and cumulative incidence of ASCVD per 1000 persons was higher in women than in men (105.62 and 64.58 in women v. 96.52 and 56.41 in men, respectively). The prevalence and incidence of ASCVD increased with age until the age of 79 years. **CONCLUSIONS:** This national population-based study confirmed a high prevalence and incidence of ASCVD and cardiovascular risk factors in the adult population of South Korea.

PCV32

PREDICTORS OF STATIN UTILIZATION IN US PATIENTS WITH NON-FATAL MAJOR ADVERSE CARDIOVASCULAR EVENTS

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OBJECTIVES: To estimate the prevalence of statin utilization, as well as identify the predictors of statin use in US patients with non-fatal major adverse cardiovascular disease (MACE). **METHODS:** The study was a retrospective analysis using data from Premier hospital database. Patients aged 18 to 89 diagnosed in 2010 with primary non-fatal MACE were identified and followed for 5 years. Two groups of participants were studied: Statin users and non-statin users at index hospitalization and by each year after the index event. Statistical modeling was used to examine the associations between cardiovascular risk factors and statin utilization, as well as the prevalence of statin utilization. Statistical analysis was performed using SAS 9.3 software. **RESULTS:** 420,866 patients met the inclusion criteria (44%) coronary artery disease, ischemic stroke (21%), myocardial infarction (18%), peripheral artery disease (13%), and unstable angina (4%). The mean age was 66.8 years (SD=12.6), 61.3% and 71.1% were men and white, respectively. The prevalence of statin utilization ranged from 43% during the index event and increased from 71.2% to 72% from 2011 to 2015. After adjusting for baseline, clinical, and hospital characteristics, female gender was associated with an 18.4% increase (OR=1.18, 95% CI: 1.15-1.25) in the odds of statin utilization compared to males one year after the index event. The model predicted a lower probability of statin use one year after the index event at 0.76 (95% CI: 0.72-0.79) for individuals with diabetes compared to those without diabetes, after adjusting for other covariates. **CONCLUSIONS:** Findings provide insights on the prevalence and predictors of statin utilization. Gender and diabetes are significant factors that had consistent impact on statin use during the five years. These factors may be useful guides for targeting interventions to increase statin use in patients with cardiovascular events.

PCV33

LEVERAGING OPEN DATA TO CREATE NEW INSIGHTS IN CARDIOVASCULAR EPIDEMIOLOGY

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OBJECTIVES: The study sought to pool and harmonize patient-level data from open source databases to evaluate: 1) how associations between modifiable risk factors and coronary heart disease (CHD) changed over time; and 2) if the population attributable fractions (PAF) of CHD due to modifiable risk factors changed post year 2000. **METHODS:** The study pooled individual patient-level data (n=28,081) from 5 observational cohort studies available in the NHLBI Biological Specimen and Data Repository Information Coordinating Center (BioLINCC). Data were harmonized to allow for examination of four modifiable risk factors: 1) systolic blood pressure (SBP), 2) diabetes, 3) smoking, and 4) total to high-density lipoprotein cholesterol ratio (total:HDL-C) in an older (1983-2000, "pre-2000") and more contemporary (1998-2010, "post-2000") era. Matched pairs of participants free from cardiovascular disease (n=14,009) were selected and followed for up to 12 years for new-onset CHD. **RESULTS:** Pooling data from multiple studies afforded sample size sufficient for necessary precision and generalizability of estimates that could not have been achieved with a single cohort. The rate of CHD declined from pre-2000 to post-2000 by 17% (p-value<0.001). Reductions in PAFs between periods were not statistically significant for SBP and total:HDL-C and exceeded 25% and 15%, respectively, post-2000. Compared with pre-2000, PAF of diabetes post-2000 declined from 10% to 5% (p-value=0.004). **CONCLUSIONS:** Open source cohort data from multiple government funded registries proved to be a vital resource in studying the time course of risk factors and CHD. Analysis of pooled data revealed that although CHD risk declined with time, the proportion of CHD still attributable to modifiable risk factors remained high. After considerable effort to pool and harmonize data, the scientific value of these cohort studies can be exploited further through subsequent analyses to address other pressing questions in cardiovascular epidemiology.

PCV34

PATIENT ADHERENCE TO NOVEL ORAL ANTICOAGULANTS (NOACs) FOR THE TREATMENT OF ATRIAL FIBRILLATION AND OCCURRENCE OF ASSOCIATED BLEEDING EVENTS: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: We sought to review the available published literature on adherence to NOACs and associated bleeding events, among patients with AF. **METHODS:** Observational studies assessing patient adherence to NOACs conducted on AF patients between September 2010 and June 2016 were identified by systematic searching of PubMed, Scopus and Google Scholar, using MeSH keywords to locate eligible studies, in accordance with Cochrane guidelines. Papers from included studies were quality assessed in duplicate, and data extracted according to a range of pre-defined criteria and outcomes. Meta-analysis was performed using a Random effects model with DerSimonian-Laird weighting to obtain pooled effect sizes. **RESULTS:** From 185 potentially relevant citations, six studies, comprising 1.6 million AF patients, met the eligibility criteria and were included in the review and meta-analysis. Among these, successful adherence to NOACs occurred in some 75.6%. Adherence levels were higher in patients treated with dabigatran (72.7%) compared with those treated with apixaban (59.9%) or rivoraxaban (59.3%). However, the level of adherence was still suboptimal than expected 80% rate. Bleeding events in non-adherent patients were found to be 7.5%. **CONCLUSIONS:** Suboptimal adherence to NOACs among AF patients was highlighted as a significant risk factor that may affect clinical outcomes, with a higher percentage of non-adherent patients having bleeding events. There is an urgent need for research on the effects of specific interventions to improve patient adherence to NOACs and to assess the related outcome factors that may be associated with adherence.

PCV35

REDUCTION OF TOTAL MORTALITY AND CARDIOVASCULAR MORBIDITY WITH FIXED-DOSED COMBINATIONS OF ANGIOTENSIN RECEPTOR BLOCKERS COMPARED TO EXTEMPORANEOUS COMBINATIONS

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OBJECTIVES: Control of hypertension (HTN) remains unsatisfactory in the majority of cases. The improvement of HTN control is the target of introducing multidrug, fixed-dosed combinations (FDC) of complementary drugs. The aim of this study is to compare the efficacy of FDC versus extemporaneous combinations (EXT) on total mortality and cardiovascular morbidity in a real-life setting. **METHODS:** Longitudinal, retrospective, post-observational study in a Primary Care setting of the Comunidad Valenciana in Spain, that included 116,937 hypertensive patients treated with angiotensin 2 receptor blockers (ARB) and at least calcium channel blockers (CCB) or one diuretic (D), either on EXT or FDC, during the years 2012 and 2013. **RESULTS:** The proportion of female gender was 53.2 %, mean age was 66.3 ± 13.2 years. 35% of patients kept FDC throughout the study, 34% maintained EXT, 4% added, 3% switched to FDC, 7% switched to EXT, 4% added EXT, 13% kept both. Both strategies reduced BP, but systolic and diastolic reductions were significantly larger in the FDC group (4.3 vs. 3.5 mmHg y 2.2 vs. 1.8 mmHg, p<0.0001), respectively, as was the proportion of controlled patients at follow-up (55.7 % vs. 55.3 %, p<0.001).

Treatment with FDC was associated with a reduced total mortality (5.3 % vs. 8.4 %, OR: 0.88; CI 0.87/0.89; $p < 0.0001$), a reduced incidence of stroke (3.8 % vs. 4.5 %, OR: 0.83; CI 0.79/0.87; $p < 0.0001$) and of ischemic heart disease (4.9 % vs. 7.9 %, OR: 0.60; CI 0.58/0.63; $p < 0.0001$) compared to extemporaneous treatment, not only in patients maintaining FDC during the whole study, but also in those who switched to or added FDC. **CONCLUSIONS:** Higher reductions of BP, a higher proportion of controlled patients and a lower total mortality and cardiovascular morbidity are achieved with ARB in fixed-dosed combination with diuretics or calcium channel blockers in comparison with extemporaneous combinations.

PCV36

DEVELOPMENT AND VALIDATION OF A PREDICTION MODEL FOR RECURRENT CARDIOVASCULAR EVENTS AMONG PATIENTS WITH ASCVD IN THE US

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OBJECTIVES: Survival of patients with atherosclerotic cardiovascular disease (ASCVD) has increased; understanding the burden of subsequent events is important. Research is lacking regarding predictors of recurrent coronary risk. Our objective was to develop and validate a prediction model for recurrent CV events among patients with established ASCVD. **METHODS:** We conducted a retrospective cohort study using data from Truven Health MarketScan® Commercial Claims and Encounters. Adults (≥ 18 years) diagnosed with ASCVD in 2012 (index date) with at least one LDL-C measurement in the 12 months prior to the index date were included. Patients were followed for the occurrence of a subsequent CV event (myocardial infarction, stroke, hospitalization for unstable angina, stroke, or coronary revascularization), the end of enrollment, or the end of 12-months follow up. We used Cox proportional hazards regression to evaluate the predictive ability of clinical and laboratory risk factors and selected the model with the highest discriminatory ability. Temporal validation was performed using two cohorts of patients in 2011 and 2013. We assessed discrimination and calibration in all three cohorts. **RESULTS:** A total of 49,651 patients met our inclusion criteria. Strong predictors of a subsequent CV events included older age (≥ 66 years), male gender, geographical location, LDL-C above 100 mg/dL, history of cancer, chronic kidney disease, and a major cardiovascular event. High potency statin treatment (HR 0.75; 95% CI 0.67-0.84) and moderate potency statin treatment (HR 0.85; 95% CI 0.77-0.94) were significantly associated with reduced risk of recurrent CV events. The prediction model showed a reasonable C-statistic (0.70, 95% CI 0.66-0.74) and had an acceptable discrimination in the two validation cohorts (0.58, 95% CI 0.53-0.52; and 0.53, 95% CI 0.49-0.57, respectively). **CONCLUSIONS:** This risk prediction model of recurrent CV events may be informative in evaluating short-term prognosis and treatment decisions among patients with ASCVD in real-world clinical settings.

CARDIOVASCULAR DISORDERS – Cost Studies

PCV37

BUDGET IMPACT ANALYSIS OF DUAL ANTIPLATELET THERAPY WITH COMBINATION OF TICAGRELOR AND ACETYLSALICYLIC ACID IN COMPARISON WITH COMBINATION OF CLOPIDOGREL AND ACETYLSALICYLIC ACID IN PATIENTS WITH ACUTE CORONARY SYNDROME MANAGED WITH CORONARY ARTERY BYPASS GRAFTING IN CONDITIONS OF RUSSIAN HEALTH CARE SYSTEM

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OBJECTIVES: To assess the budget impact of the use of ticagrelor combined with acetylsalicylic acid (ASA) in comparison with clopidogrel plus ASA in patients with acute coronary syndrome (ACS) managed with coronary artery bypass grafting (CABG) from societal perspective in Russia. **METHODS:** Clinical effectiveness of the therapeutic alternatives under evaluation was compared by subanalysis, which includes ACS patients, managed with CABG, from randomized controlled trial PLATO. Direct medical expenses on antiplatelet therapy with ticagrelor plus ASA and original clopidogrel plus ASA during one year and management of patients dying from cardiovascular and other causes, as well as indirect expenses due to gross domestic product loss in case of premature death were included in the analysis. In budget impact model only for indirect cost discount rate 3% was applied. **RESULTS:** Both cost of one-year antiplatelet therapy (39 145 rubles per patient for ticagrelor plus ASA vs. 29 193 rubles for clopidogrel plus ASA) and direct medical expenses (40 624 rubles per patient for ticagrelor plus ASA vs. 32 088 rubles for clopidogrel plus ASA) were higher in case of therapy with ticagrelor plus ASA. Meantime, due to markedly lower total mortality (5.1% for ticagrelor plus ASA vs. 9.9% for clopidogrel plus ASA) indirect expenses (100 810 rubles per patient for ticagrelor plus ASA vs. 208 584 rubles for clopidogrel plus ASA) and total expenses (141 434 rubles per patient for ticagrelor plus ASA vs. 240 672 rubles for clopidogrel plus ASA) were lower for therapy with ticagrelor plus ASA. **CONCLUSIONS:** Despite higher medical expenses total cost of care for ACS patient managed with CABG in conditions of Russian health care system is lower in case of therapy with ticagrelor combined with ASA as compared to clopidogrel combined with ASA.

PCV38

BUDGET IMPACT ANALYSIS OF RIVAROXABAN IN CHINA

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OBJECTIVES: Rivaroxaban is the only new oral anticoagulant with three indications approved in China to reduce the risk of stroke among people with

non-valvular atrial fibrillation (NVAF), treat deep vein thrombosis (DVT), and prevent Venous thromboembolism (VTE) after total knee or hip replacement surgery (TKR & THR). The objective of this study was to evaluate the budget impact of introducing rivaroxaban in the management of AF, DVT, TKR and THR patients from payers' perspective. **METHODS:** An Excel-based budget impact model was developed. Model inputs included the prevalence of AF patients, the incidence of DVT, TKR and THR patients, the proportion of target patients receiving rivaroxaban, the efficacy and safety of treatment choices, cost data, and resultant health care utilization. Most of the variables were from literature, including the epidemiology data, efficacy, safety and costs. Two different scenarios were applied according to the setting of the threshold of willingness to pay, i.e. 2-3 times GDP per capita in the top 100 cities in China. Costs and cost savings were reported as year-2016 CNY. **RESULTS:** The largest cost savings associated was observed in TKR and THR patients to prevent DVT and PE (CNY 163.7 million and CNY 221.4 million in two scenarios). In DVT populations, the cost savings were also observed with CNY 47.9 million and CNY 63.7 million in two scenarios. While for AF populations, the budget would increase due to the pharmacy costs with additional CNY 74.0 million to CNY 149.0 million. The main drivers for cost saving include the avoided event costs, administration costs in AF and DVT population and the overall costs in TKR and THR patients. **CONCLUSIONS:** The introduction of rivaroxaban as a treatment option for patients with AF, DVT, TKR, and THR could achieve substantial cost savings for payers. The total combined savings ranged from CNY 62.7 million to CNY 211.1 million.

PCV39

BUDGET IMPACT ANALYSIS OF ACETYLSALICYLIC ACID 100MG, SIMVASTATIN 40 MG AND RAMIPRIL 5-10 MG (SINCRONIUM®) FOR THE SECONDARY PREVENTION OF CARDIOVASCULAR EVENTS IN MEXICO

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OBJECTIVES: To assess the financial impact of the introduction of AAS 100 mg, simvastatin 40 mg and ramipril 5-10 mg (Sincronium®) in the secondary prevention of cardiovascular events in adult patients with a recent or not recent history of acute myocardial infarction (MI), from the perspective of the Mexican Healthcare System. **METHODS:** Two scenarios were used, the current one, a reference scenario with the single-components (AAS 100 mg, simvastatin 40 mg and ramipril 5-10 mg) was compared against future scenario, using polypill (Sincronium®), assuming an initial penetration rate of 5% and annual increases of 10%, considering a time horizon of 5 years (2016 to 2020). Direct medical costs, as they are drugs administration, acute event and chronic events were considered. The target population was calculated based on the incidence of acute myocardial infarction in persons 40 years old and over, as well as the mortality of this event. The costs and results are presented in United States Dollar (USD, 2016) the epidemiological data and unit costs were obtained from country's institutional sources (Mexico) and the literature. **RESULTS:** The average annual cost per patient was \$845.84 USD for treatment with the single-component and treatment with the polypill (Sincronium®) was \$851.00 USD. Based on the penetration rate, the time horizon and the estimated population (101,347 in 2016, 180,220 in 2017, 242,212 in 2018, 291,509 in 2019 and 331,237 in 2020) there is an additional average consumption of \$355,172.95 USD which represents 0.0107% of the total budget allocated to medicines. **CONCLUSIONS:** The introduction of the polypill in the public health sector does not represent a significant financial impact on the Mexican healthcare system's budget.

PCV40

BUDGET IMPACT ANALYSIS OF THE USE OF CONTACT FORCE CATHETER IN ATRIAL FIBRILLATION ABLATIONS IN THE BRAZILIAN HEALTH CARE SYSTEM

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OBJECTIVES: Cardiac ablation has been increasingly used to treat complex arrhythmias, once the success rate of the procedure reaches 86% while drug treatment reaches only 22% success rate. Studies demonstrate that, by using the Contact Force catheter it is possible to increase the success rate of the procedure, reduce complications and reduce the need of additional ablation procedures. It is estimated that in Brazil there are 940,000 people with Atrial Fibrillation and 44,000 would be eligible for ablation treatment in the private health care system (HCS). Our main objective in this study was to evaluate whether or not the adoption of Contact Force Catheter in a radiofrequency ablation can reduce costs in the Brazilian private HCS. **METHODS:** A budget impact model of the use of the contact force catheter technology was elaborated comparing it to catheter without contact force for AF ablation. One-year follow-up was considered. The success rates found in the literature were :92% for ablation using a contact force catheter, and 74% for non-contact force catheter ablation. Also there were developed two scenarios for the contact force technology adoption (70% and 100% adoption). Data were collected from a database that has 18 million lives. Total number and average reimbursement of procedures were included. **RESULTS:** The initial investment in catheter adoption in the private HCS would be USD\$ 685,358 and USD\$1.4 million, considering 70% and 100% conversion scenario, respectively. However, considering the total cost of treatment in one year, the HCS would have a cost reduction of USD\$ 2.3 million and USD\$ 4.8 million, considering the scenarios of 70% and 100% of conversion, respectively. **CONCLUSIONS:** The adoption of the Contact Force Catheter in ablations by the Brazilian private HCS could improve patients' clinical outcomes, and potentially reduces the total costs of treatment, bringing economic and financial sustainability to HCS.

PCV41

COSTS AND CONSEQUENCES OF LACK OF ADHERENCE TO PRESCRIBING GUIDELINES FOR STATINS IN THE UK: A VALUE OF IMPLEMENTATION ANALYSIS

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OBJECTIVES: To assess the health consequences and costs of lack of adherence to National Institute for Health and Care Excellence (NICE) guidelines on the prescribing of statins for the primary prevention of cardiovascular disease in the United Kingdom. **METHODS:** Value of implementation methods are applied to consider Quality adjusted life years (QALYs) lost and net monetary benefit lost due to the lack of adherence to NICE guidelines using data on current prescribing patterns of statins in the UK and data on the size of the total population currently recommended to receive statins by NICE guidelines. The study considers the value of improving implementation of statins in patients recommended to receive statins and the costs of over prescribing statins to patients currently not recommended to receive statins by current guidelines. **RESULTS:** The under prescribing of statins in patients recommended to receive statins with substantial consequences in terms of QALYs. The net momentary value of these lost QALYs is in excess of 1 billion per year. Equally there is currently wide scale overprescribing of statins in patients who are not currently recommended to receive by statins. The total costs to the NHS of this over prescribing are between £101 million and £128 million per annum, with uncertain benefits in terms of cardiovascular events prevented and uncertain cost-effectiveness. **CONCLUSIONS:** Lack of adherence to NICE guidelines on the prescribing of statins for the primary prevention of cardiovascular disease has significant consequences both in terms of health and NHS budgets. There is considerable value to be had from programs aimed at encouraging greater adherence to NICE guidelines on the prescribing of statins.

PCV42

THE HOSPITAL BURDEN OF MAJOR AMPUTATION DUE TO PERIPHERAL ARTERY DISEASE IN THE UNITED STATES

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OBJECTIVES: This study uses data from hospitals across the United States to estimate the prevalence of peripheral artery disease (PAD) among inpatient hospitalizations and to explore the clinical and economic burden to the hospital when treating patients with advanced PAD with either revascularization or amputation. **METHODS:** Data was derived from the MedAssets health system database of more than 400 hospitals across 42 states for the years 2010-2014. To be eligible for inclusion, inpatient hospitalizations required a diagnosis of PAD and a record of an intervention (revascularization or major/minor amputation). Adverse event rates, length of stay (LOS), and average reimbursement per diem were calculated by intervention for all PAD patients and a subset of patients with a primary PAD diagnosis. **RESULTS:** Of the over 17 million inpatient hospitalizations in the database, 616,401 (3.5%) have a diagnosis of PAD, with 95,561 (15.5%) having a record of an intervention. Of these visits, 48,072 (50.3%) had a primary diagnosis of PAD with 35,220 (73.3%) having a revascularization alone, 8,955 (18.6%) having a major/minor amputation alone and 3,897 (8.1%) having both. Rates of sepsis or other infection (5.8% vs 1.6%) and pulmonary complications (10.6% vs 5.3%) are higher for patients having a major amputation alone versus revascularization alone. Average hospital reimbursement per diem estimates were significantly lower for the major amputation cohort versus the revascularization cohort (\$2,383 vs \$4,399). This is driven by LOS which is almost 2X higher for major amputation versus revascularization (11.0 vs 5.9 days). **CONCLUSIONS:** PAD affects a significant number of inpatient admissions with a substantial hospital burden due to complications and long lengths of stays. Hospital limb salvage programs that include revascularization procedures/algorithms may reduce this burden while providing cost savings to the hospital.

PCV43

RISK OF MAJOR AMPUTATION OR DEATH AMONG PERIPHERAL ARTERY DISEASE PATIENTS WITH CRITICAL LIMB ISCHEMIA ACROSS TREATMENT PATHWAYS

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OBJECTIVES: The most advanced form of peripheral artery disease (PAD) is critical limb ischemia (CLI), defined as chronic ischemic rest pain, ulcers, or gangrene attributable to arterial occlusive disease. This research estimates the risk of major amputation or inpatient death by treatment pathway for patients with CLI. For those patients having a major amputation the incremental expenditures per member per month (PMPM) were estimated. **METHODS:** Data from MarketScan Commercial and Medicare Supplemental Databases from January 2006-December 2014 was utilized. Eligible patients required at least 2 visits—one with an ICD-9 diagnosis of PAD and another of CLI, as well as 6 months of continuous enrollment prior to diagnosis of CLI. Cohorts were developed based on patients' treatment pathway: endovascular revascularization (EVAS), surgical revascularization (SVAS), minor amputation without revascularization (MinAMP), or no intervention (NONE). The odds of major amputation or inpatient death for each cohort were estimated using the Cox proportional hazards model. Total expenditures PMPM (inpatient and outpatient) were estimated using a gamma log-link model. All models were adjusted for patient demographics and comorbidities. **RESULTS:** Patients who met inclusion criteria (N=52,527), were subset into treatment pathway cohorts: EVAS (N=29,798), SVAS (N=10,683), MinAMP

(N=5,126), NONE (N=6,920). Patients without an intervention had significantly higher odds of major amputation or inpatient death compared to patients who had MinAMP (1.59 times), EVAS (2.08 times), or SVAS (2.12 times). Patients having a minor amputation had higher odds of major amputation or inpatient death compared to EVAS (1.31 times) and SVAS (1.33 times). The estimated incremental expenditures PMPM for patients with a major amputation was \$5,165. **CONCLUSIONS:** This study of a national payer database found that revascularization reduces the risk of a major amputation or inpatient death for patients with CLI. Also, expenditures are higher when a major amputation occurs, costing the payer approximately \$5,000 per member per month.

PCV44

EVALUATION OF HEALTHCARE COSTS OF ELDERLY NONVALVULAR ATRIAL FIBRILLATION PATIENTS TREATED WITH APIXABAN VS. RIVAROXABAN AND DABIGATRAN

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OBJECTIVES: The burden of nonvalvular atrial fibrillation (NVAF) is expected to double in the near future, with significant increases in hospitalizations and healthcare costs. We evaluated healthcare costs among elderly NVAF patients after initiating treatment with apixaban vs. rivaroxaban and dabigatran. **METHODS:** Patients with Medicare coverage initiating apixaban, rivaroxaban or dabigatran (index event) were identified from the Humana database (1/1/2013-9/30/2015). Patients were required to be ≥65 years and have an NVAF diagnosis and 12 months of continuous health plan enrollment prior to the index event date. NVAF patients were grouped into cohorts depending on the drug initiated. Patient characteristics were evaluated during the baseline period. Propensity score matching (PSM) was conducted to control for differences in patient characteristics of study cohorts. All-cause and major bleeding (MB)-related healthcare costs during the follow-up periods were evaluated and compared between cohorts. **RESULTS:** After PSM, 13,620 patients treated with apixaban and rivaroxaban were matched with 6,810 in each cohort. During the follow-up, apixaban vs. rivaroxaban treatment was associated with lower all-cause total healthcare costs (inpatient+outpatient+prescription: \$22,146 vs. \$26,803 per-patient-per-year (PPPY), p<0.001), total medical costs (inpatient+outpatient: \$17,021 vs. \$22,145 PPPY, p<0.001), and MB-related total medical costs (\$2,030 vs. \$3,422 PPPY, p<0.001). After PSM, 4,654 patients treated with apixaban and dabigatran were matched with 2,327 in each cohort. During the follow-up, among patients treated with apixaban vs. dabigatran all-cause total healthcare costs (\$21,616 vs. \$23,758, p=0.12) were not significantly different, but all-cause total medical costs (\$16,413 vs. \$19,218 PPPY, p=0.04) were significantly lower for patients treated with apixaban vs. dabigatran. **CONCLUSIONS:** In the real-world setting after initiating treatment, healthcare costs for all causes and those that are MB-related were lower for elderly NVAF patients who received apixaban vs. rivaroxaban. Medical costs for all causes were also lower for patients who received apixaban vs. dabigatran.

PCV45

AN INCREMENTAL COST ANALYSIS OF ORBITAL ATHERECTOMY PLUS ANGIOPLASTY COMPARED TO ANGIOPLASTY ALONE FOR THE TREATMENT OF CRITICAL LIMB ISCHEMIA

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OBJECTIVES: To perform an incremental cost analysis of Diamondback 360 peripheral orbital atherectomy system (OAS) in conjunction with balloon angioplasty (BA) compared to BA alone for the treatment of critical limb ischemia (CLI) in peripheral artery disease (PAD) patients from a US hospital perspective. **METHODS:** A deterministic decision tree simulation model was constructed for a hypothetical cohort of 100 PAD-CLI patients with moderate-to-severely calcified below-the-knee lesions undergoing an endovascular revascularization. Clinical (peri-operative and one-year complications) and healthcare utilization (OAS device, balloon(s), and bailout bare metal stenting) data were obtained primarily from the CALCIUM 360[®] trial and supplemented with a best evidence review of the published literature (BA arm only). Eligible studies were pooled and parameters weighted by sample size. Cost data (2016 dollars) were obtained from 2014 HCUP and published evidence. Incremental cost to the hospital for performing OAS+BA vs. BA was computed by summing cost differences corresponding to differential utilization during the procedure and treating peri- and post-operative complications. One-way, scenario (a composite one-year major adverse event) and probabilistic sensitivity analyses (SA) were performed to gauge the model robustness. **RESULTS:** For every 100 revascularizations, the incremental costs to the hospital at one-year were \$467,355 lower with OAS+BA compared to BA alone. These savings reflected a reduced need for revascularization in the target lesion (TLR) and/or vessel (TVR) and, amputation, and lower end-of-life care costs, despite higher technology costs upfront. One-way SA demonstrated that the model was most sensitive to: amputation rates and its costs, OAS device cost, TLR/TVR frequency and its costs, and one-year mortality and end-of-life care cost. **CONCLUSIONS:** Compared to stand-alone BA, OAS+BA appears to be associated with cost savings of \$4,674 per-patient-per-year to a hospital/health system. SA determined that the superior economic value of OAS+BA was robust to the specified parameter value ranges.

PCV46

COMPARISON OF ALL-CAUSE HEALTHCARE RESOURCE UTILIZATION (HCRU) AND COSTS AMONG PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION (NVAF), NEWLY TREATED WITH NEW ORAL ANTI-COAGULANTS (NOACS)Gilligan AM¹, Franchino-Elder J², Song X³, Wang C⁴, Henriques C¹, Sainski-Nguyen A¹, Wilson K⁵, Smith DM⁶, Sander S²¹Truven Health Analytics, Ann Arbor, MI, USA, ²Boehringer Ingelheim, Ridgefield, CT, USA, ³Truven Health Analytics, Shrewsbury, MA, USA, ⁴Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA, ⁵Truven Health Analytics, Bethesda, MD, USA, ⁶Truven Health Analytics, Ann Arbor, MI, USA

OBJECTIVES: Among NVAF patients, compare all-cause cost and healthcare resource utilization (HCRU) between dabigatran and apixaban, and dabigatran and rivaroxaban. **METHODS:** Adult NVAF patients newly diagnosed and treated with dabigatran, apixaban or rivaroxaban during 10/01/2010-12/31/2014 were identified using MarketScan claims databases. Patients were continuously enrolled for 12-months prior to index date (first NOAC claim) and were followed from index until medication switch, discontinuation, inpatient death or end of continuous enrollment or study period. Dabigatran patients were matched to apixaban and rivaroxaban patients and two 1:1 propensity score matched groups were created. Per-patient-per-month (ppm) HCRU and costs were reported. Generalized linear models compared total, inpatient, outpatient, and pharmacy costs within each group. **RESULTS:** A total of 26,646 and 8,857 dabigatran patients were matched to rivaroxaban and apixaban patients, respectively (mean age 68 years; 37% female in each matched group). Compared with rivaroxaban, dabigatran patients had significantly lower mean all-cause, ppm total healthcare, inpatient, and pharmacy costs (\$4,147 vs. \$4,559; \$1,484 vs. \$1,812; and \$630 vs. \$644, respectively, all $P < 0.05$) and significantly fewer hospitalizations (0.06 vs. 0.07), outpatient visits (4.81 vs. 4.95), and pharmacy claims (4.77 vs. 4.91) (all $P < 0.01$). Compared with apixaban, dabigatran patients had similar mean, all-cause, ppm total healthcare, inpatient, outpatient, and pharmacy costs (\$3,849 vs. \$3,807; \$1,225 vs. \$1,198; \$1,953 vs. \$1,930 and \$671 vs. \$678, respectively, all $P > 0.05$) and, similar hospitalizations (0.05 vs. 0.05, $p = 0.097$) but significantly higher outpatient visits (4.68 vs. 4.24) and pharmacy claims (4.79 vs. 4.57), (both $P < 0.01$). Multivariate analyses demonstrated dabigatran had significantly lower total, inpatient, and outpatient costs than rivaroxaban and similar costs (across all categories) as apixaban patients. **CONCLUSIONS:** Dabigatran had significantly lower total costs and HCRU than rivaroxaban patients. Total costs were similar between dabigatran and apixaban. Dabigatran had more outpatient and pharmacy HCRU than apixaban but similar hospitalizations, the main driver of costs.

PCV47

PREVALENCE OF PATIENTS WITH PERIPHERAL AND CORONARY ARTERY DISEASEGunnarsson C¹, Lee MS², Ryan MP¹, Kotlarz H³, Martinsen BJ³¹CTI Clinical Trial and Consulting Services, Cincinnati, OH, USA, ²UCLA Medical Center, Los Angeles, CA, USA, ³Cardiovascular Systems, Inc., St. Paul, MN, USA

OBJECTIVES: Peripheral artery disease (PAD) is similar to coronary artery disease (CAD) in that they are both caused by atherosclerosis that narrows and blocks arteries in various critical regions of the body. An advanced form of PAD and CAD is the development of calcified lesions which are typically seen in the critical limb ischemia (CLI) and in complex CAD. This research uses real-world payer data to understand the prevalence of CLI and coronary artery calcification (CAC) in both the PAD and CAD populations. **METHODS:** Data for this study were derived from the MarketScan Commercial Database and the Medicare Supplemental and Coordination of Benefits Database from January 2006 - December 2014. Patients were eligible if they had a diagnosis of either PAD or CAD. Patients were categorized into the following cohorts based on their treatment pathway: [1] PAD only (with and without CLI), [2] CAD only (with and without CAC), or [3] PAD and CAD (with CLI only, with CAC only, with both, with none). **RESULTS:** A total of 6,981,758 patients met the inclusion criteria: 1,375,601 (20%) had PAD only, 4,429,217 (63%) had CAD only, and 1,176,940 (17%) had both PAD and CAD. Of the PAD only patients, 130,938 (10%) had a diagnosis of CLI. Of the CAD only patients, 180,740 (4%) had a diagnosis of CAC. For patients with both PAD and CAD, 881,626 (75%) had no record of calcification, 134,585 (11%) had CLI only, 126,716 (11%) had CAC only, and 34,013 (3%) had both CLI and CAC. **CONCLUSIONS:** This study found that a significant number of patients have PAD and CAD. Calcification in these patients is also a significant occurrence; therefore, testing for CLI and CAC should be performed.

PCV48

ATHERECTOMY UTILIZATION SHOWS LOWER ODDS OF ADVERSE EVENTS DURING OUTPATIENT PERCUTANEOUS CORONARY INTERVENTIONS COMPARED TO ANGIOPLASTY ALONEGunnarsson C¹, Chambers JW², Ryan MP¹, Baker ER¹, Kotlarz H³, Martinsen BJ³¹CTI Clinical Trial and Consulting Services, Cincinnati, OH, USA, ²Metropolitan Heart and Vascular Institute, The Heart Center, Mercy Hospital, Minneapolis, MN, USA, ³Cardiovascular Systems, Inc., St. Paul, MN, USA

OBJECTIVES: An indicator of advanced coronary artery disease (CAD) is the presence of coronary artery calcification (CAC). Current treatment for CAC is revascularization via percutaneous coronary intervention (PCI). However, PCI in severely calcified lesions is associated with higher angiographic complications and major adverse cardiac event (MACE) rates, as well as lower procedural success in placing a stent when compared to non-calcified lesions. **METHODS:** Data were derived from the MarketScan Commercial and Medicare Supplemental Databases

from October 2011 - December 2014. Eligible patients had a record of an outpatient PCI and at least one claim with an ICD-9 diagnosis of CAC or a record of the following three risk factors [Diabetes, Renal insufficiency or Failure, and ≥ 70 of age] along with their diagnosis code of CAD. Patients with evidence of multiple PCI procedures were excluded. Comparisons were made between patients having outpatient angioplasty compared to atherectomy alone. Patients were followed for 90-days with adverse events and total expenditures tracked. Multivariable models were adjusted for differences in patient demographics and comorbid conditions. **RESULTS:** 1,358 patients met all inclusion criteria [angioplasty alone (N=1,009) and atherectomy (N=349)]. Patients treated with outpatient angioplasty alone had a 1.69 [CI: 1.26, 2.27] higher odds of having an adverse event within 90-days compared to patients treated with atherectomy for vessel preparation. After model adjustments, no statistically significant differences in 'all cause' expenditures at 90 days were found. **CONCLUSIONS:** This study of a national payer database found that CAC patients treated with angioplasty alone have a higher risk for an adverse event during outpatient PCI compared to those with atherectomy treatment prior to angioplasty and stent placement. Furthermore, despite the additional added device for vessel preparation, expenditures were no different at 90 days post procedure.

PCV49

ECONOMIC BURDEN OF HOSPITALIZATION FOR CONGESTIVE HEART FAILURE AMONG ADULTS AGED > 19 YEARS OLD IN THE PHILIPPINESTumanan-Mendoza BA¹, Mendoza VL², Punzalan FE³, Pestano NS⁴, Bermudez-De los Santos AA⁴, Natividad RB⁴, Macabeo R⁴, Shiu LA⁴¹Manila Doctors Hospital; University of the Philippines College of Medicine, Manila, Philippines, ²De La Salle Health Sciences Institute, Dasmariñas, Cavite, Philippines, ³Manila Doctors Hospital; University of the Philippines College of Medicine & Philippine General Hospital, Manila, Philippines, ⁴Manila Doctors Hospital, Manila, Philippines

OBJECTIVES: 1) To determine the hospitalization costs (healthcare and non-healthcare costs) for congestive heart failure (CHF) using the societal perspective; 2) To compare the healthcare-related hospitalization cost using the societal perspective with the payer's perspective - PhilHealth's case rate payment for CHF; 3) To determine the total economic burden of CHF hospitalization in the Philippines in 2014. **METHODS:** This is a cost of illness study. The hospitalization cost (usually incurred through out-of-pocket expenses in the Philippines) included cost of diagnostic procedures, treatment, professional fees and hospital charges. The non-healthcare costs included production losses as well as transportation and food expenses incurred by the patient or his caretaker during confinement or both. **RESULTS:** The overall mean healthcare-related cost for CHF hospitalization in government hospitals in the Philippines in 2014 was PHP19,340 - 28,220 (US\$436 - 636). In private hospitals, the cost ranged from PHP28,370 - 41,800 (US\$639 - 941). In comparison, PhilHealth's case rate payment for CHF is PHP15,700 (US\$354). The mean non-healthcare cost, on the other hand, was PHP10,700 - PHP14,600 (US\$241 - 329). Using PhilHealth's case rate payment and the total number of CHF cases in 2014, the total economic burden was PHP691,522,200 (US\$15,574,824). In contrast, calculation using the study results on healthcare-related cost only showed that the total economic burden for CHF hospitalization would be PHP851,850,000 - 1,841,563,000 (US\$19,185,811 - 41,476,644). **CONCLUSIONS:** Using the societal perspective, the mean healthcare-related hospitalization cost for CHF in the Philippines in 2014 was about 23% - 80% more than the PhilHealth's case rate payment if one was confined in a government hospital. However, this cost was underestimated since government hospitals defray some of the hospitalization cost, exemplified by the low charges (or nil) for room/ward accommodations. Confinement in a private hospital resulted to 1.8 - 2.7 times higher hospitalization cost than the case rate payment.

PCV50

COMPARISON OF THE REVENUE AND HEALTH OUTCOME BENEFITS OF TWO TYPES OF HEARTWORM PREVENTATIVES IN DOGS: LONG-LASTING MOXIDECTIN INJECTABLE VERSUS MONTHLY ORAL PREVENTIONMwacalimba KK¹, Amodie D², Pavlock AM²¹Zoetis, Indianapolis, IN, USA, ²Zoetis, Greeley, CO, USA, ³AMP Research Solutions, Parker Ford, PA, USA

OBJECTIVES: The objective of this study was to compare revenue and health outcome benefits associated with two canine heartworm prevention (HWP) modalities: long-acting moxidectin (LAM) injection and oral monthly HWP. LAM is given in the veterinary clinic every 6 months, while oral monthly HWP is purchased by the pet owner from the clinic and given at home each month. **METHODS:** In 2014, a retrospective 5 year (2009-2014) records analysis was conducted at 18 veterinary practices to determine the health and revenue benefits of the second LAM injection (which occurs 5-7 months after the annual wellness visit). One thousand six hundred twenty-six invoices for 918 dogs met the study review criteria. In 2016, we conducted a similar analysis at 9 of the 18 practices for dogs on oral monthly HWP. In this study, 1,177 invoices for 396 dogs met the review criteria. **RESULTS:** The second LAM visit allowed the veterinarian to evaluate dog health for a second time in a single year. This resulted in identification of more health issues (22%) than those diagnosed at the annual wellness visit (10%) or the monthly HWP return visit (4%) 5-7 months later. Practice revenue was higher for the second LAM visit than for monthly HWP, with an average invoice of \$121.13 for LAM compared with \$56.41 for monthly HWP. Finally, the average cost of LAM (\$45.96) was less than the average cost of 6 months' worth of monthly HWP (\$54.06). **CONCLUSIONS:** The second LAM visit identified more health issues than the comparable return visit for dogs on monthly HWP and delivered nearly 65

more clinic revenue. Economic projections for an average veterinary clinic with 3,000 - 5,000 dogs showed that if 25% received LAM for HWP, the clinic would generate \$48,750 - \$81,250 additional revenue per year.

PCV51

EFFECTIVENESS AND ECONOMIC EFFICIENCY OF THE TREATMENT OF CORONARY HEART DISEASE WITH SALVIANOLATE INJECTION: A RETROSPECTIVE COHORT STUDY

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OBJECTIVES: To examine the effectiveness and economic efficiency of the treatment of coronary heart disease with salvianolate injection. **METHODS:** We retrospectively studied hospitalized patients with coronary heart disease from August 2011 to December 2015 by using electronic medical record database. Patients who received salvianolate injection combined with conventional treatment were selected as exposed group, while those who received conventional treatment alone were selected as unexposed group. Propensity score matching (PSM) analysis was used to balance the characteristics of patients. Then we evaluated hospital stay, nitrates use, total medical costs and subcategories costs of both groups. **RESULTS:** In all, 2250 patients were included. And 401 patients in each group were analyzed after PSM. A significant decrease was found in hospital stay ($P < 0.05$) and nitrates use ($P < 0.05$) in exposed group. Total medical costs per patient had no significant difference between two groups. Subcategories costs comparison showed that the Chinese patent medicine costs of exposed group were significantly higher, and other subcategories costs of exposed group were lower or not significantly different from unexposed group. **CONCLUSIONS:** Patients who receive salvianolate injection combined with conventional treatment have shorter hospital stay and less nitrates use than who receive conventional treatment alone. But there is no significant difference between two groups in total medical costs.

PCV52

COMPARISON OF COSTS AND HEALTHCARE UTILIZATION BETWEEN PATIENTS USING NOVEL ORAL ANTICOAGULANTS (DABIGATRAN & RIVAROXABAN) VERSUS WARFARIN

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OBJECTIVES: Dabigatran and Rivaroxaban are Novel Oral Anticoagulants (NOACs) which have shown better or similar efficacy compared to warfarin in clinical trials. The objective of the study was to compare annual all-cause costs for NOACs vs warfarin and to identify the major cost drivers based on the clinical subgroups. **METHODS:** A retrospective cohort study utilized de-identified data from Optum[®] Clinformatics[™] Data Mart (Optum Insight, Eden Prairie, MN) (Jan 1, 2010 and Dec 31, 2012). Adult patients with ≥ 1 diagnosis of atrial fibrillation or flutter (ICD-9 427.31/32), > 1 prescription of NOACs or warfarin, 6-months pre-index continuous enrollment and CHA2DS2VASC score > 1 were included. Post-index costs and Healthcare Resource Utilization (HCRU) was calculated using GLM model with gamma distribution. The total cost, sum of medical (inpatient + outpatient) and drug cost was adjusted for inflation to 2016. Unadjusted costs were analyzed by subgroups (Gender, Region, Age, Insurance Type, CHA2DS2-VASC Score, and Charlson's Co-morbidity Index [CCI]). **RESULTS:** A total of 3287 and 1770 patients were included for warfarin and NOAC cohort respectively. The NOAC users were slightly older (66 vs 65 years) and more severe based on the CHA2DS2VASC and CCI. The annual drug cost for NOAC was greater (\$4998 vs \$331, $P < 0.05$), but was offset by lower medical cost (\$22,134 vs \$31,400, $P < 0.05$). The total annual cost for NOACs (\$26,803 vs \$32,157) was significantly lower than warfarin ($P > 0.05$). The frequency of ER visits was similar (14 vs 13) but office visits (76 vs 49) were significantly higher for warfarin vs NOACs ($P < 0.05$). Based on subgroup analysis, CCI and age < 65 were major cost drivers of medical cost while Northeast region and CHA2DS2VASC score > 2 were major drivers of the drug costs. **CONCLUSIONS:** Annual total cost and HCRU for patients prescribed the NOACs was lower compared to warfarin.

PCV53

THE INPATIENT BURDEN OF MEDICARE PATIENTS WITH HEART FAILURE, CHRONIC KIDNEY DISEASE AND A HISTORY OF STROKE: A RETROSPECTIVE DATABASE ANALYSIS

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OBJECTIVES: The aim of this study is to evaluate the effect of having chronic kidney disease (CKD) and a history of stroke along with heart failure (HF) on hospital cost, healthcare utilization, and mortality for hospitalized Medicare patients. **METHODS:** A retrospective observational study utilizing 2013 data from the Healthcare Cost and Utilization Project (HCUP) database. Inpatient visits were eligible for inclusion if there was a primary diagnosis of HF, primary payer of Medicare and age 18+. Descriptive statistics were produced for patient characteristics and comorbidities by cohort - those with and without CKD and a history of stroke. Outcomes included cost, length of stay (LOS), and mortality. **RESULTS:** A total of 61,719 inpatient visits met inclusion criteria: 56,209 with HF only and 5,510 with HF, CKD and a history of stroke. Mean age was similar for both cohorts (76.3 vs 76.9). Inpatient visits with HF, CKD and a history of stroke had a higher proportion of males (50.7 vs 43.4%) with more minority representation (33.1 vs 26.1%). These patients also had more chronic conditions (4.53 ± 1.57 vs 2.89 ± 1.55) with higher

rates of both uncomplicated (38 vs 33.1%) and complicated diabetes (16.1 vs 5.3%), hypertension (81.3 vs 68.2%), deficiency anemias (44.1 vs 22%) and peripheral vascular disorders (20 vs 10.5%). Both cohorts experienced the same average LOS (4.43 days) with average costs (\$8,727 vs \$9,488) and mortality rates (1.9% vs 2.1%) being slightly lower for those patients with HF, CKD, and history of stroke. **CONCLUSIONS:** Inpatient admissions for HF patients with CKD and history of stroke have higher rates of comorbidities and more chronic conditions than those with HF only; however, despite this LOS is the same and mortality/costs appear lower. This data will be further explored with multivariable analysis.

PCV54

INDIRECT, DIRECT NON-MEDICAL COST AND QOL BY NEW YORK HEART ASSOCIATION (NYHA) CLASSIFICATION IN CHINESE HEART FAILURE PATIENTS

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OBJECTIVES: Heart failure (HF) is a disease with high morbidity and mortality that leads to loss of productivity, caregiver burden and negative impact on patients' quality of life. There is very limited data to examine the burden other than direct medical cost of HF in China. This study aims to evaluate the indirect cost, direct non-medical cost and quality of life by NYHA classification in Chinese HF population by with real-world data from societal perspective. **METHODS:** This study was conducted via patient surveys collected from the cardiology/cardiac surgery departments of 8 tier III hospitals in four major cities in China. Adult patients diagnosed with heart failure more than one year and had NYHA classification information were selected to interview. Indirect cost examines the patients and their caregivers' salary loss due to work absence and cessation, and reduced productivity due to HF; direct non-medical cost examines transportation, accommodation and meals associated with HF treatment. Patient quality of life was examined using health utility value measured by EQ-5D-5L. **RESULTS:** A total of 150 HF patients were interviewed. The mean \pm SD age was 66.60 ± 14.14 years. The annual mean indirect cost and annual direct non-medical cost was at 24,783CNY and 2,454CNY respectively, with no significant difference between NYHA classes (ANOVA test: $P > 0.05$). The mean health utility value for Chinese HF patients was estimated at 0.725 by EQ-5D-5L, and significant difference were observed by NYHA classification of I, II, II-III, III, III-IV and IV at 0.732, 0.78, 0.78, 0.715, 0.636, 0.66 (ANOVA test: $P > 0.05$), respectively. **CONCLUSIONS:** Both indirect cost and direct non-medical cost impose extra economic burden on top of significant direct medical costs in Chinese HF patients. HF patients' quality of life is significantly lower than that of elder Chinese population over 60 years with a minimum health utility 0.79 and a maximum health utility 0.89 by EQ-5D-5L.

PCV55

COMORBIDITY STATUS AND MEDICAL EXPENDITURES IN U.S. HYPERTENSIVE ADULTS

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OBJECTIVES: To investigate comorbidity status and its impact on medical expenditures in U.S. hypertensive adults. **METHODS:** We pooled the 2011-2014 Medical Expenditure Panel Survey data for this analysis. Patients were included if they: 1) had a diagnosis code for hypertension; 2) were aged ≥ 18 years; and 3) were not pregnant during the study period ($N=26,049$). We modified the Elixhauser Comorbidity Index (EI) to better analyze the impact of hypertension-related comorbidities on medical expenditures. The dependent variable was total annual medical expenditures paid by all payers. Generalized linear model with a log link and gamma distribution were used for the estimations. All costs were adjusted to the 2014 U.S. dollars. **RESULTS:** Based on the modified EI, 14.7% of patients did not have any comorbid condition, 24.2% had 1 comorbid condition, 24.5% had 2 conditions, and 36.6% had ≥ 3 conditions. The 10 most frequent comorbidities were hyperlipidemia (55.9%), diabetes (27.3%), rheumatoid arthritis (26.8%), depression (24.9%), chronic pulmonary disease (CPD) (16.9%), coronary heart disease (CHD) (16.7%), hypothyroidism (12.5%), solid tumor (6.1%), heart rhythm disorders (6.0%), and stroke (4.7%). Medical expenditures were \$4,236 (95% confidence interval, \$3,788-\$4,684) for those without any comorbid condition, \$6,361 (\$5,927-\$6,794) for those with 1, \$8,815 (\$8,276-\$9,355) for those with 2, and \$14,601 (\$13,781-\$15,420) for those with ≥ 3 . Of the 10 most frequent comorbidities, the condition with the largest impact on medical expenditures was stroke (\$6,474), while rheumatoid arthritis (\$4,079) had the smallest impact. Hyperlipidemia, diabetes, depression, CPD, CHD, and heart rhythm disorders increased expenditures by \$5,079, \$5,288, \$5,175, \$6,461, and \$5,447, respectively. **CONCLUSIONS:** Comorbidities were highly prevalent among hypertensive adults and each successive comorbidity significantly increased the medical expenditures. These findings illustrate the importance of looking at the impact of comorbid conditions and can be used to help develop and evaluate interventions for hypertension prevention and control.

PCV56

FACTORS IMPACTING HOSPITALIZATION EXPENDITURE OF MYOCARDIAL INFARCTION PATIENTS IN BEIJING, CHINA

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OBJECTIVES: To identify factors impacting the hospitalization expenditure of myocardial infarction (MI) patients in Beijing, China from January 2012 to September 2013. **METHODS:** The Beijing Medical Insurance Database has

maintained reimbursement activities of about 13.5 million urban residents in Beijing. Using patient medical records from the database, 10% of the MI patients were randomly selected as study subjects. Variables such as hospitalization expenditure, patients' demographic characteristics, length of stay at first hospital admission, whether having rehospitalization due to MI (yes/no), comorbidities, and hospital type at first hospital admission (tertiary vs. non-tertiary hospitals) were collected. An ordinary least squares regression analysis was conducted, in which the dependent variable was the logarithm of annualized hospitalization expenditure and independent variables were the other variables. **RESULTS:** A total of 1,235 MI patients (mean age 65.78 ± 15.36 years) were randomly selected from the database. The incidence of MI-associated hospitalization was dominant among males (n=935, 75.31%). The regression model was significant (P<0.05, R square = 13%). The significant positive predictors of hospitalization expenditures were male patients, age (≥45 years old), length of stay at first hospital admission, rehospitalization due to MI, comorbidity (heart failure and diabetes), and being admitted by tertiary hospitals at first hospital admission. **CONCLUSIONS:** Male MI patients 45 years old or greater, with heart failure and diabetes, are likely to incur higher hospitalization expenditure. To lower hospitalization expenditure of MI patients in Beijing, effective measures could include reducing the length of hospital stay and controlling spending at tertiary hospitals.

PCV57

COST OF HEART FAILURE IN ARGENTINA: A CROSS SECTIONAL STUDY

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OBJECTIVES: Costs of a large series of HF patients of a hospital utilization and cost study (Value in Health 2013;16:A70), were analyzed, stratified by age, sex, multimorbidity (MM), and for inflation and monetary units conversions (2015). Inflation and monetary units distort cost and transferability in Argentina. **METHODS:** In a multicentric 3 hospital Health Care Cost and Utilization Study, a cross sectional (1 year output), selected HF patients with Clinical Classification Software adaptation for Argentina (CCS #108) in 2008, in first (1Dx) or secondary (2Dx) diagnosis. HF prevalence, stratified by age, sex, multimorbidity (MM), measured with the Chronic Condition Indicator (CCI), mortality, HF in 2Dx, and <30 day readmissions (<30 d ReH). Total costs (TC\$), per discharge costs (mean, median), were analyzed. Current monetary values used ACECRA/CEDIM, SHIDP, 2015 medical costs study (up to 2015). International Dollar (\$) conversion PPP, used QUANDL \$ PPP (conversion rate to \$ PPP is 6,604, year 2015). Mean 95% CI were estimated with bootstrapping. **RESULTS:** 1187 HF CCS #108 in 1Dx discharges is a TC\$ of \$38 272 825 \$ (1.57% of TC\$), 69.05 % occurs among pts. age >65 yrs old (and 24.56 % >85yrs old). Mean cost per discharge was 32 243 \$ PPP (95%CI 27 524, 37 347) and median cost 7 829 \$PPP for HF in 1Dx (6,60 times 2008 value). Mean cost decreases with increased age strata (p trend<0,01) (stratified data not presented here). 969 HF CCS 108 in 2Dx a TC\$ 61 410 345 \$ PPP. While 213 discharges with <30 d ReH among HF 1 Dx represent TC\$ 8 459 432 \$ PPP (22% of HF TC\$). **CONCLUSIONS:** Total HF costs increase with age and male sex, while per discharge cost is reduced by age strata. ACECRA/CEDIM,SHIDP cost study permitted to obtain costs with inflation adjustment and monetary conversion to \$ PPP.

PCV58

MEASURING INDIRECT COSTS (PRODUCTIVITY AND CAREGIVER BURDEN) IN THE ACC/AHA GUIDELINE STATIN BENEFIT GROUPS

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OBJECTIVES: Productivity loss associated with morbidity and mortality from heart disease and stroke totaled \$99 billion in 2010 in the US. We estimated the annual costs of productivity loss and caregiver burden (CB) for three statin benefit groups (SBG) defined by ACC/AHA guidelines, including patients with atherosclerotic cardiovascular disease (ASCVD) (SBG1), patients with LDL-C > 190 mg/dL (SBG2), and patients with diabetes and LDL-C 70-189mg/dL (SBG3). **METHODS:** We used the 2011–2012 National Health and Nutrition Examination Survey to classify individuals into SBGs and derive employment status, hours worked, and work limitations. Among those employed, productivity loss was estimated as the difference in hours worked between individuals with and without work limitations. Having any condition (not heart disease specific) that limits ability to work proxied for caregiving need. For CB, we combined the proportion requiring caregiving with time spent providing care, caregiver employment status, and reduction in hours worked for caregivers, from data from Caregiving, 2015 survey. We stratified by age and monetized productivity and CB using median annual US salary (\$48,320). **RESULTS:** Annual productivity losses among those employed were \$12,727 for SBG1, \$0 for SBG2, and \$11,226 for SBG3. The proportion requiring caregiving was highest for SBG1 (32% for <65 years; 35% for ≥65), with up to \$13,234 in CB. Proportion requiring caregiving for SBG2 and SBG3 increased with age (9% (28%) for <65 years vs. 22% (45%) for ≥65 for SBG2 (SBG3), with up to \$8,992 and \$15,874 in CB, respectively. Approximately 13.8 million patients in SBG1, 2, and 3 have work limitations, amounting to \$150 billion in productivity losses; CB is \$465 billion. **CONCLUSIONS:** Productivity losses and CB are substantial in the top three SBG when compared to direct medical costs associated with heart disease and stroke (\$63 billion), and highlight the importance of indirect costs in economic modeling.

PCV59

THE ECONOMIC IMPACT OF MYOCARDIAL REVASCLARIZATION: TREATMENT COSTS FROM THE PERSPECTIVE OF THE PUBLIC HEALTH SYSTEM

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OBJECTIVES: The objective of the study is to describe the economic impact analysis of the procedure's costs for myocardial revascularization and their variations among CURITIBA'S CITY hospitals accredited by Brazilian Government Health Care System (BGHS). Currently in Brazil there are no studies comparing the costs of different types of treatment for ACS in BGHS. Background: Prevalence data in Brazil estimate that 5% to 8% of adults older than 40 years old have acute coronary syndrome (ACS). The disease is the leading cause of mortality in Brazil. Thus, coronary heart disease is the leading cause of death worldwide, making it one of the diseases with the highest clinical and financial impact. **METHODS:** From January to December 2015, the frequency, length of stay, number of deaths and total cost of the procedure were evaluated through data registered on DATASUS/TABWIN from BGHS were collected. Days in hospital and angiographic and revascularization procedures were counted in the groups of patients and total cost of care for 12 months was calculated using current billing levels. **RESULTS:** A total amount of R\$ 4.778.548,39 (USD 1.592.849,46 at rate 1:3) were spend for 368 procedures divided by 5 hospitals. A 3.733 inpatient days were counted during all time procedures (ICU care = 1.744 days). 26 deaths were noticed (17,96%) during the same period. Differences in total and daily costs of ICU, in the rates of permanence and mortality were detected among the five stakeholders health care providers. **CONCLUSIONS:** The difference in hospitalization costs for the Myocardial Revascularization procedures, within the Public Unified System of Curitiba, was shown to be a cost-effectiveness variable that may affect the managers' decisions regarding use and allocation.

PCV60

PCSK9 INHIBITORS SHOW VALUE FOR PATIENTS AND THE U.S. HEALTHCARE SYSTEM

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OBJECTIVES: Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors were approved by the U.S. Food and Drug Administration (FDA) as cholesterol-lowering therapies for persons with familial hypercholesterolemia or atherosclerotic cardiovascular disease. However, the long-term cost-effectiveness of PCSK9 inhibitors is not clear. This study was designed to estimate the long-term health impact and economic value of PCSK9 inhibitors for older Americans (aged 51 and older). **METHODS:** We conducted simulations using the Future Elderly Model (FEM), an established dynamic microsimulation model, to project the lifetime outcomes for the population aged 51+ in the United States. Health effects estimates and confidence intervals from published meta-analysis studies were used to project changes in life expectancy, quality-adjusted life-years, incidence of heart disease and lifetime medical spending resulting from use of PCSK9 inhibitors. We consider two treatment-eligibility criteria: 1) current FDA eligibility; and 2) an extended eligibility criterion that considers PCSK9 inhibitor use for persons with no pre-existing cardiovascular disease (CVD) but with high-CVD risks. **RESULTS:** Utilization of PCSK9 inhibitors by individuals covered by the current FDA approval would extend life-expectancy at age 51 by an estimated 1.2 years and would yield a lifetime net value of \$11,100 per capita. We also estimate that PCSK9 inhibitors would generate a lifetime net benefit of \$21,000 per capita if utilization were extended to those with high-CVD risk. Looking only at the population covered by current FDA approval over the next 20 years, PCSK9 inhibitors would generate cumulative net value of \$0.96 trillion. **CONCLUSIONS:** Our study suggests that PCSK9 inhibitors would offer positive long-term net value for patients and the U.S. healthcare system. In addition to current FDA-approved indications, our study also suggests greater value if more people gain access to this new class of drugs.

PCV61

COST-EFFECTIVENESS ANALYSIS OF DABIGATRAN VERSUS RIVAROXABAN FOR NON-VALVULAR ATRIAL FIBRILLATION USING REAL-WORLD EVIDENCE IN MEDICARE BENEFICIARIES

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OBJECTIVES: To assess the cost-effectiveness of dabigatran 150 mg twice-daily versus rivaroxaban 20 mg once-daily for the treatment of patients with non-valvular atrial fibrillation (NVAF) based on real-world evidence in the United States Medicare population. **METHODS:** A previously published Markov model, which followed patients with NVAF at risk of thromboembolic stroke, intracranial hemorrhage, major extracranial bleeding, and acute myocardial infarction through the natural course of the disease, was adapted to enable cost-effectiveness evaluation of dabigatran versus rivaroxaban from a US payer perspective. Risks of events were estimated based on a study in Medicare beneficiaries which demonstrated significantly fewer bleeding events associated with dabigatran compared to rivaroxaban. In the base-case, treatment persistence was based on a published US study in a population with commercial insurance. Given differences in the populations considered, a scenario analysis examined effects of equal persistence. Utility and cost inputs were extracted from published literature or estimated from nationally representative data (REDBOOK, CMS

costing files, and AHRQ-MEPS). All costs were adjusted to 2016 US dollars. Outcomes were discounted at 3%. Scenario and probabilistic sensitivity analyses (PSA) were conducted to test the robustness of the results. **RESULTS:** Over a five-year time horizon, dabigatran incurred \$18,848 in total costs and 3.343 quality-adjusted life-years (QALYs)/patient compared to rivaroxaban with \$22,382 total costs and 3.339 QALYs/patient; dabigatran dominated rivaroxaban (less costly and more effective). PSA demonstrated that at a threshold of \$50,000/QALY, dabigatran was dominant in 98% of cases. The results remained robust in the scenario analyses assuming same treatment persistence, demonstrating dabigatran was the dominant option with \$1,642 cost savings and 0.07 incremental QALYs. **CONCLUSIONS:** Over a five-year time horizon, the analyses demonstrated that dabigatran in Medicare patients with NVAF was a dominant option compared to rivaroxaban and was likely to remain cost-effective relative to rivaroxaban in PSA and scenario analyses.

PCV62

COST-EFFECTIVENESS OF THROMBOPROPHYLAXIS WITH ENOXAPARIN FOR GENERAL SURGERY PATIENTS IN CHINA

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OBJECTIVES: Premature death due to pulmonary embolism is a short-term complication of venous thromboembolism (VTE). The long-term clinical course after VTE can be further complicated by excess mortality, recurrent VTE, Chronic thromboembolic pulmonary hypertension (CTEPH) and the post-thrombotic syndrome (PTS), all of which may produce sizable long-term economic burdens. The cost-effectiveness of thromboprophylaxis with enoxaparin versus no prophylaxis has been established in other countries. The aim of this study was to evaluate the cost-effectiveness of enoxaparin in Chinese patients after general surgery with comparison of no prophylaxis. **METHODS:** A decision model, which included both the acute VTE (represented as a decision tree) and the long-term complications (represented as a Markov model), was developed to assess economic outcomes of the two strategies for Chinese patients after general surgery. Transition probabilities related to VTE, categorized by Caprini score (the VTE risk assessment model which is well accepted by international and Chinese clinical guideline), were derived from published literature. Costs and utilities were derived from published literature and local healthcare settings. One-way and probabilistic sensitivity analyses were performed to test the uncertainty concerning the model parameters. Quality-adjusted life year (QALY) and direct medical costs were measured over a five-year horizon. Incremental cost-effectiveness ratios (ICERs) were calculated. **RESULTS:** Comparing with no prophylaxis, thromboprophylaxis with enoxaparin gained additional 0.010, 0.014, 0.030 and 0.072 QALYs in patients with Caprini score 3-4, 5-6, 7-8 and ≥ 9 , respectively. In Caprini score 3-4 and 5-6, the ICER of enoxaparin versus no prophylaxis was ¥9,834 and ¥2,190 per QALY gained when enoxaparin used for 7 days. In Caprini score 7-8 and ≥ 9 , thromboprophylaxis with enoxaparin was dominant. Sensitivity analyses confirmed the results. **CONCLUSIONS:** The study suggests that thromboprophylaxis with enoxaparin is a cost-effective intervention for all VTE risk levels in patients undergoing general surgery in China.

PCV63

COST-EFFECTIVENESS OF EVOLOCUMAB IN TREATMENT OF HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLAEMIA IN BULGARIA: MEASURING HEALTH BENEFIT BY EFFECTIVELY TREATED PATIENT-YEARS (ETPY)

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OBJECTIVES: An elevated level of low-density lipoprotein cholesterol (LDL-C) constitutes an important modifiable risk factor for cardiovascular disease (CVD). Individuals with heterozygous familial hypercholesterolaemia (HeFH) are particularly vulnerable to CVD events and often do not achieve adequate reduction of LDL-C with standard of care (SoC). The objective of this analysis was to demonstrate the clinical and economic value of LDL-C lowering with evolocumab in HeFH patients from the Bulgarian public health care perspective. **METHODS:** A disease-specific measure of health benefit was devised: Effectively treated patient-years (ETPYs) combine length of life with the likelihood of attaining best-practice recommendations on LDL-C lowering aimed at reducing CVD events. 'Effective treatment' was defined as a reduction in LDL-C levels of $\geq 50\%$. Considering a life-long treatment duration, a Markov model was adapted to compare the addition of evolocumab to SoC (high-intensity statins) versus SoC alone. Demographics, baseline characteristics and efficacy were taken from pertinent trial data. The model uses the relationship between LDL-C lowering and reduced CVD event rates observed in the Cholesterol Treatment Trialists' Collaboration (CTTC) meta-analyses. **RESULTS:** The total incremental costs of evolocumab added to SoC versus SoC alone are BGN120,111 while adding 9.35 ETPYs over lifetime. These results imply an incremental cost per ETPY of BGN12,846 (US\$7,258; €6,559). The use of evolocumab is associated with a relative reduction in the CVD event rate by 46% (22% per 1 mmol/L), consistent with CTTC. **CONCLUSIONS:** The addition of evolocumab to SoC may be considered cost-effective in light of an additional expense per patient-year gained in which individuals with HeFH receive effective treatment under the terms of international prevention guidelines. ETPYs are an intuitive and clinically meaningful

measure of patient benefit that, in relation to costs, can support healthcare decision-making not subject to the cost-per-QALY paradigm, and that recognises and considers process-oriented factors of value, specifically quality of care.

PCV64

MODELING THE IMPACT OF ALIROCUMAB TREATMENT DELAY ON 3-YEAR CARDIOVASCULAR EVENT RISK

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OBJECTIVES: Patients with atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) on statin remain at high risk for cardiovascular (CV) events and may benefit from additional lipid-lowering therapy (LLT), such as PCSK9 inhibitors (PCSK9i). Yet patients and physicians are required to fulfill several steps before reimbursement, with up to 75% prescription denials. This analysis modeled the effects of delaying treatment with alirocumab (a PCSK9i) on CV event risk. **METHODS:** A Markov cohort model with annual cycles was developed to estimate the long-term rate of CV events for patients with clinical ASCVD or HeFH on statins and high low-density lipoprotein cholesterol (LDL-C). CV events included acute coronary syndrome (ACS), revascularization, ischemic stroke, and CV death. The model estimated 3-year CV event risk when patients received add-on alirocumab at the start of the simulation or after 1- or 2-year delays. Baseline characteristics, annual CV risk and transition probabilities among ASCVD patients were estimated using real world data (with published literature for HeFH patients). CV risk reduction was based on Cholesterol Treatment Trialists' (CTT) meta-analysis. Four high CV risk cohorts were modeled: 1) HeFH with ASCVD and LDL-C > 130 mg/dL; 2) recent ACS (0-1 year) with LDL-C > 70 mg/dL; 3) ASCVD with LDL-C > 100 mg/dL; and 4) ASCVD with LDL-C > 70 mg/dL. **RESULTS:** For each aforementioned cohort, the model analyzed the 3-year CV risks when patients received add-on alirocumab at the simulation start or after 1- and 2-year delays: 1) 18.7%, 23.2%, and 27.5%; 2) 20.7%, 24.4%, and 26.2%; 3) 13.9%, 15.9%, and 17.7%; and 4) 13.5%, 15.0%, and 16.4%. Overall, 3-year CV event risk increased by an absolute +1.5% to +8.8%, or a relative increase of 11% to 47%. **CONCLUSIONS:** Delaying treatment access to alirocumab was associated with a proportional increase in CV events of 11% to 47%.

PCV65

UTILIZING CLINICAL DECISION SUPPORT SYSTEMS TO ALIGN CLINICAL AND VALUE-BASED REIMBURSEMENT INITIATIVES

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OBJECTIVES: To estimate the potential impact of personalized clinical decision support (CDS) of statin therapy on achieving goal LDL-cholesterol (LDL-C) levels and the effect on atherosclerotic cardiovascular events (CVEs) and healthcare costs. **METHODS:** A retrospective analysis of EHR data for 2.673 million commercially insured patients with elevated LDL-C who met AHA/ACC criteria for and were treated with statins. Evidence-based CDS recommended most effective/least effective statin drug-dose combinations to reach goal LDL-C for each individual. Likelihood of subsequent CVE for patients receiving recommended most effective/least effective drug-dose combinations were based on observed LDL-C and published medical research. Agent-based and Monte Carlo simulation were used to extrapolate CVEs and subsequent cost of care over a ten-year period for 20,000 treated patients. For 10,000 simulation runs, costs were calculated for payers and patients based on national averages for provider reimbursement and patient copayments and deductibles. **RESULTS:** Wide variance in the efficacy of statin therapy strategies was observed. The proportion of patients achieving goal LDL-C levels ranged from 14% to 42%, median 31%, across 26 typical statin therapy drug-dose combinations. The reduction of LDL-C ranged from 59mg/dL (37%) to 12mg/dL (9%), median 23mg/dL (17%). Simulations of the most effective/least effective statin drug-dose combinations showed significant differences in ten year expected (a) number of CVEs (509 vs. 813), (b) total cost of care (\$83 M vs. \$99 M), and (c) patient out-of-pocket expenses (\$26 M vs. \$33 M). **CONCLUSIONS:** Approaches to statin therapy are highly variable and associated with significant differences in outcomes and cost of care. Cardiovascular disease remains the single most common cause of morbidity and mortality in the U.S., and lower LDL-C levels are associated with reduced numbers of CVEs. Personalized, evidence-based clinical support guidelines can help practitioners identify the most clinically- and cost-effective pharmacological interventions.

PCV66

PHARMACOECONOMIC STUDY OF ROSUVASTATIN AGAINST ATORVASTATIN IN CARDIOVASCULAR DISEASES AND STROKE IN TELANGANA REGION OF INDIA: A COST EFFECTIVENESS ANALYSIS

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OBJECTIVES: The main objective of the current study is to assess the costeffectiveness of Rosuvastatin and Atorvastatin in cardiovascular diseases and stroke conditions. Statins being dyslipidemic agents are successfully used as a standard therapy for both primary and secondary prevention of cardiovascular diseases and stroke. **METHODS:** This pharmacoeconomic study is a cross sectional ambispective study. A total of 300 patients were screened from which 150 are eligible for primary prevention group and 108 for secondary prevention group. Drug costs, number of events avoided and lipid profiles were recorded, cost

effectiveness ratios were determined. Decision tree model was used and statistical comparisons are done using Microsoft Excel 2007. **RESULTS:** This study revealed that Rosuvastatin was more effective in preventing recurrence of events i.e., events avoided by Rosuvastatin was 86.37% when compared to Atorvastatin of 64.07%. Rosuvastatin costs an incremental cost of \$136.5 per lipid profile maintenance and \$82.82 per event avoided in primary and secondary prevention groups respectively. When calculated in terms of lipid level maintenance Rosuvastatin showed a significant reduction in serum cholesterol (Sr.Ch) of 182.97 ± 30.4 mg/dl, High density lipoproteins (HDL) of 42 ± 2.8 mg/dl, Triglycerides (TG) of 148.5 ± 79 mg/dl, Low density lipoproteins (LDL) of 108.9 ± 29 mg/dl were as Atorvastatin showed Sr.Ch of 180.26 ± 35.4 mg/dl, HDL of 40 ± 15.4 mg/dl, TG of 155.8 ± 93.8 mg/dl, LDL of 115.4 ± 30 mg/dl. **CONCLUSIONS:** The above results revealed that Rosuvastatin is more cost effective drug in spite of its high unit cost when compared with Atorvastatin. The additional effectiveness gained by Rosuvastatin is worth its additional cost.

PCV67

LIFETIME BENEFITS OF IMPROVED HEART FAILURE TREATMENT AMONG OLDER AMERICANS

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OBJECTIVES: Lifetime Benefits of Improved Heart Failure Treatment Among Older Americans **METHODS:** We adapted an established economic-demographic micro-simulation to estimate scenarios in which a hypothetical "cure" eliminates the incidence of CHF and, separately, six other diseases in patients aged 50 in 2016. We followed this cohort until death and estimated the total life years and disability-free life years with and without a cure, for the population as a whole and for race- and gender-defined subpopulations. **RESULTS:** We estimate an increase in CHF prevalence from 4.29% in 2012 to 8.08% in 2030, generally higher than previous estimates. Diagnosis with CHF coincides with significant increase in disability and medical expenditures, particularly among blacks compared with whites. A CHF "cure" among those aged 50 in 2016 would generate nearly 2.7 million additional life years, and over 1.1 million disability-free life years, worth \$200 to \$400 billion. These gains are generally greater among blacks than whites, thereby reducing disparities. **CONCLUSIONS:** Improved treatment for CHF could generate significant social value, and reduce existing health disparities.

PCV68

A PHARMACEUTIC ECONOMICS ANALYSIS OF A GOVERNMENT INITIATIVE OF DYSLIPIDEMIA IN CHINA DEVELOPED COMMUNITY CLINICAL PRACTICE

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OBJECTIVES: China Adult Dyslipidemia Management Program (CADMP) is a government initiative aiming to provide practical evidence of comprehensive management of cardiovascular disease for China national basic public health service policy by integrating lipid management with the existing hypertension and diabetes management. Shenzhen pilot is one of the three pilots among 5 subprojects of CADMP. The study is intended to assess the cost effectiveness of lipid management in CADMP Shenzhen. **METHODS:** 15738 participants with high risk of cardiovascular disease were recruited from 6 districts 52 primary care practices (17.6% were simple dyslipidemia, 57.2% with both dyslipidemia and hypertension, and 14.33% were dyslipidemia with hypertension and diabetes) We conducted a randomized, controlled trial to examine the effects of CADMP interventions in 404 participants from 26 community practices. 204 participants were randomly selected receiving a set of interventions, including integrating dyslipidemia into performance assessment policy, physician trainings, and patient education, while 200 participants received regular treatment. **RESULTS:** CADMP was cost-effective (defined as <\$24,112 per QALY, KEEP's ICER was \$9484 per QALY) for adults older than age 20. For every 1% reduction in control rate of LDL-C, the intervention group even saves \$ 9.53 than the control group and the institutional cost is \$7.07. The mean concentrations of LDL-c in interventional group before and after therapy decreased significantly from 3.26 to 3.02 (mmol/L, $P < 0.05$), and rate of treatment increased from 29.94% to 33.37% ($P < 0.05$). The reduction of LDL-c and TC in intervention group were significantly higher than the control group (TC -0.43 vs -0.1; LDL-c -0.42 vs 0.06 mmol/L, $P < 0.05$). **CONCLUSIONS:** Dyslipidemia management in community hospitals with a multilevel approach that integrates policy actions, physician trainings, and health education is cost effective. The study provides scientific evidence for future policy of dyslipidemia in China contributing to prevent increasing cardiovascular disease mortality.

PCV69

ASSESSING THE COST-EFFECTIVENESS OF PATIROMER PLUS SPIRONOLACTONE THERAPY IN HEART FAILURE PATIENTS WITH HYPERKALEMIA

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OBJECTIVES: Although spironolactone therapy has been shown to significantly improve survival in heart failure (HF), many patients are unable to tolerate spironolactone due to hyperkalemia. Our objective was to estimate the cost-effectiveness of patiromer, a newly approved drug for the treatment of

hyperkalemia, plus spironolactone (PS) in patients with NYHA III-IV HF receiving a renin-angiotensin-aldosterone system inhibitor (RAASi, ACE inhibitor or angiotensin receptor blocker) and otherwise unable to tolerate spironolactone due to hyperkalemia. **METHODS:** We conducted a cost-utility analysis using a Markov model to evaluate the incremental cost-effectiveness ratio (ICER) for PS with RAASi versus RAASi only in patients with HF and hyperkalemia from the US payer perspective. We enhanced a previous version of the model by considering treatment discontinuation. Clinical parameters were derived primarily from the RALES spironolactone RCT, the OPAL patiromer study, and recent cohort studies of patients with HF. Wholesale acquisition costs were used for drugs and hospitalization costs were derived from HCUP data. Quality of life estimates were based on a prospective study on patients with HF using the EQ-5D. Total direct healthcare costs, quality-adjusted life years (QALYs), and ICER were estimated using a 10-year time horizon and a 3% discount rate. One-way sensitivity analyses were conducted to assess model uncertainty. **RESULTS:** The average increase in QALYs with addition of patiromer plus spironolactone was 0.27, accompanied by an increase in cost of \$15,600, giving an ICER of approximately \$57,800/QALY. These findings were driven by the decreased risk of mortality and hospitalization with spironolactone therapy. A limitation is our assumption that the RALES study findings apply to the modeled population, but study findings were robust to sensitivity analyses. **CONCLUSIONS:** Based on our modeling analysis, use of patiromer to enable spironolactone therapy in NYHA III-IV HF patients may provide a clinical benefit and good economic value.

PCV70

COST-UTILITY ANALYSIS OF THREE NEW ORAL ANTICOAGULANTS IN THE PREVENTION OF THROMBO-EMBOLIC EVENTS VERSUS WARFARIN IN PATIENTS WITH ATRIAL FIBRILLATION IN THE COLOMBIAN CONTEXT

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OBJECTIVES: To estimate the cost-effectiveness ratios of the use of rivaroxaban, dabigatran and apixaban versus warfarin for the prevention of thrombo-embolic events in patients with non-valvular atrial fibrillation in Colombia. **METHODS:** Development of Markov chain model with quarterly cycles and lifetime horizon. Cerebral vascular accidents, bleeding and myocardial infarctions are estimated, with the main outcomes being the years of life saved (LYS) and quality-adjusted life years QALYs from the perspective of the third payer. In base case, the risk of patient was 0% low risk, 13% moderate risk and 87% high risk under CHA2DS classification. Costs are source Local data base for technologies and insurance costs for events. **RESULTS:** The mean QALYs and total health care cost with lifetime horizon, of patients treated with warfarin was 6.75 QALYs/ USD 6,208, with rivaroxaban was 7.07 QALYs/ USD 7,597, with dabigatran was 7.02 QALYs/ USD 8,207, and with apixaban was 6.80 QALYs / USD 8,525. Thus, an incremental cost-effectiveness ratio compared to warfarin was estimated in USD \$4,340 for rivaroxaban, USD \$7,410 for dabigatran and USD \$46,348 for apixaban. **CONCLUSIONS:** Oral anticoagulants in general, shows results superior to those estimated for warfarin in the analyzed patients, highlighting decrease in stroke and bleeding. While rivaroxaban is estimated to be a cost-effective technology for Colombia, dabigatran is identified as potentially cost effective, while apixaban would not be cost effective for being above Colombia's cost-effectiveness threshold. Among the oral anticoagulants, rivaroxaban is estimated as a cost-saving technology versus dabigatran and apixaban, mainly due to the reduction of events, stroke and better patient adherence.

PCV71

MEDICARE PATIENTS WITH CONGESTIVE HEART FAILURE: A COMPARATIVE ANALYSIS OF RESOURCE UTILIZATION BY REASON FOR ADMISSION (CARDIAC, PULMONARY, OR VASCULAR)

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OBJECTIVES: To estimate the differences in the cost of care to the hospital, length of stay, and mortality rates for Medicare patients with congestive heart failure having an inpatient admission for one of the following three reasons: cardiac, pulmonary or vascular. **METHODS:** This study was a retrospective observational analysis, conducted using the 2013 HCUP NIS database. Inpatient admissions (n=230,868) were included in this analysis if Medicare was the primary payer and if the patient had a ICD-9 diagnosis code of congestive heart failure. Hospitalizations meeting the inclusion criteria were categorized and subsequently analyzed by the congestive heart failure patient's primary diagnosis or reason for admission as follows: cardiac (n=185,619), pulmonary (n=40,844), and vascular (n=4,365). **RESULTS:** There were significant differences across the three groups (cardiac, pulmonary, vascular) with inpatient vascular admissions having the highest rate of diagnoses on record. Patients with vascular admissions were more likely to be male, African American, and coming from teaching hospitals located in urban areas. Vascular inpatient admissions had significantly higher total costs (mean of \$25,927, SD \$27,499) than cardiac (mean of \$14,674, SD \$20,581) and pulmonary (mean of \$9,837, SD \$20,980). Length of stay was significantly longer as well: vascular group (mean of 7.74 days, SD 8.84) compared to either cardiac (mean of 5.53 days, SD 5.33) or pulmonary (mean of 5.11 days, SD 4.33). Mortality rates were higher for vascular 5.18% versus 3.58% for cardiac and 2.44% for pulmonary. **CONCLUSIONS:** Whether a congestive heart failure patient is admitted to the hospital for cardiac, pulmonary, or vascular reasons can significantly impact the burden of illness to the hospital for their inpatient stay.

CARDIOVASCULAR DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

PCV72

THE EFFECT OF GAPS IN ADHERENCE TO ANTIHYPERTENSIVE MEDICATION ON FALLS RISK IN OLDER ADULTS

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OBJECTIVES: There is an on-going debate as to whether antihypertensive medications are associated with an increased falls risk in older adults. Patients initiating antihypertensive medication have been observed to have an increased falls risk attributed to initial hypotensive effects. In contrast studies of long-term users of antihypertensive medication have reported conflicting findings. However few studies examining this association have assessed medication adherence - non-adherent patients may experience hypotensive symptoms due to blood pressure fluctuations. Our objective was to investigate the relationship between poor adherence to antihypertensive medication and falls in older (>65 years) long-term antihypertensive users. **METHODS:** We recruited community dwelling older adults (N=1592) from 106 community pharmacies in the Republic of Ireland between March and May 2014 and administered a baseline structured telephone interview. A follow-up structured telephone interview was conducted at 12 months. Each interview was linked to dispensing records for the previous 12 months. To assess the longitudinal association between adherence to antihypertensive medication and falls, adherence was estimated as the number of five day gaps in medication supply from linked dispensing records for the 12 months prior to the baseline interview. Falls were assessed via questionnaire at 12 month follow-up interview. For our binary outcomes, any fall and any injurious fall during follow-up, relative risks were estimated using modified Poisson regression models with robust standard errors. **RESULTS:** Adjusting for fall risk factors, increasing number of five day gaps in adherence to antihypertensive medication was associated with an increased risk of falls (aRR 1.11, 95% CI 1.03-1.19, p=0.005) and injurious falls (aRR 1.19, 95% CI 1.06-1.33, p=0.003) during follow-up (n=1084). **CONCLUSIONS:** Poor adherence to antihypertensive medication was observed to increase falls risk in older adults which may relate to fluctuations in blood pressure secondary to non-adherence. However further studies examining the timing of the falls in relation to non-adherence are required.

PCV73

TREATMENT PATTERNS AND MEDICATION ADHERENCE AND PERSISTENCE AMONG PATIENTS WITH PULMONARY ARTERIAL HYPERTENSION IN REAL-WORLD DATABASE REPRESENTING A LARGE US HEALTH PLAN

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OBJECTIVES: Pulmonary arterial hypertension (PAH) is a chronic and progressive disease characterized by high pressure in the pulmonary arterioles, with increased pulmonary vascular resistance that can result in right heart failure and premature mortality. With several new PAH medications available since 2013, more information is needed regarding treatment patterns, persistence, and adherence. **METHODS:** Patients with a diagnosis code for pulmonary hypertension and treated with an approved medication for PAH (ERAs, PDE-5is, prostacyclins, sGCs) identified by pharmacy claims between January 2010 and March 2015 were included. Patients were ≥18 years old with continuous enrollment in a large US health plan with medical and pharmacy coverage for 6 months before (with no PAH medication claim) and ≥1 year after initiating a PAH-related medication. Patients were followed until disenrollment from the plan or end of study (March 2016). Initial and subsequent treatment regimens were examined. Persistence was measured as months to discontinuation or modification, and adherence was measured as proportion of days covered (PDC). **RESULTS:** The study included 1637 patients. Most patients initiated treatment with a monotherapy (93.8%). PDE-5is and ERAs were used in 70.0% and 26.8%, respectively, of initial treatment regimens. Of patients who discontinued (n=443) or modified (n=581) their initial regimen, 78.9% did so within one year (mean ± SD 7.6 ± 9.0 months, median 4.0). Combination therapies comprised 42.7% (248/581) of second regimens. Patients initiating combination therapy usually did so within six months (55.4%). ERAs were associated with higher PDC (0.8 ± 0.4 vs. 0.6 ± 0.4, p < 0.001) and persistence (9.5 ± 10.8 vs. 7.5 ± 8.6 months, p < 0.01) than PDE-5is. Combination therapies were associated with greater persistence than monotherapies (11.7 ± 11.1 vs. 7.4 ± 8.8 months, p < 0.01). **CONCLUSIONS:** Patients with PAH most often initiated treatment with monotherapies, commonly PDE-5is in spite of lower adherence and persistence than ERAs. Most patients remained treated with monotherapies. Therapy adjustments to initial regimens occurred early and in the majority of patients.

PCV74

PRESCRIPTION TREND AND DRUG ADHERENCE OF NON-VITAMIN K ANTAGONIST ORAL ANTICOAGULANTS IN ELDERLY PATIENTS WITH ATRIAL FIBRILLATION

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OBJECTIVES: To examine monthly prescription trend and drug adherence of non-vitamin K antagonist oral anticoagulants (NOACs) including apixaban, dabigatran, and rivaroxaban in elderly patients with atrial fibrillation (AF). **METHODS:** We used nationally representative data named Health Insurance Review and Assessment Service-Aged Patient Sample 2014 that contained medical and pharmacy claims of approximately 1 million elderly patients aged 65 or older. We included patients who had at least one diagnosis of AF (ICD-10 code I48.0) and at least one prescription of NOAC between January 1, 2014 and December 31, 2014 to assess monthly prescription trend. To assess adherence, we included patients who had at least one diagnosis of AF and at least two prescriptions of NOACs. The adherence to NOACs was assessed by calculating the medication possession ratio (MPR). If calculated MPR was ≥0.80, it was

considered as adherent case. **RESULTS:** Among 40,473 elderly patients with AF, 1,234 patients were eligible for prescription trend analysis and 921 patients were eligible for adherence analysis. In 2014, Dabigatran was the most prescribed NOAC in Korea (47.2-61.7%). The number of patients prescribed rivaroxaban was slightly smaller than dabigatran (35.5-41.6%). Only a small fraction of AF patients were prescribed apixaban (2.4-12.8%). The mean MPR was 0.95, 0.93, and 0.91 for apixaban, dabigatran, and rivaroxaban, respectively (P < 0.023). Non-adherence (MPR < 0.80) was observed in 16.2% of rivaroxaban users, 11.6% of dabigatran users and 8.3% of apixaban users. **CONCLUSIONS:** In 2014, 921 elderly AF patients using NOACs had generally high drug adherence. However, adherence to apixaban was significantly better than the adherence of dabigatran and rivaroxaban. The little differences in mean MPR between 3 NOACs may be explained by differences in dosing regimen and adverse reactions profile. Further research is warranted to explore the reason of different drug adherence between NOACs and the impact of adherence on outcomes.

PCV75

THE EFFECT OF A REGULATORY FIT INTERVENTION ON STATIN MEDICATION ADHERENCE

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OBJECTIVES: To design and test the effect of a regulatory fit intervention on the behavior of statin medication adherence. **METHODS:** Patients taking a statin medication participated in a randomized, prospective field experiment. Patients completed two online questionnaires designed to capture patient variables and deliver the intervention, and two weeks later to assess subsequent behavior. The intervention consisted of manipulations priming patients with framed messages that created a Fit or Non-fit between patients' regulatory orientation and implementation intentions. The three study groups were: Fit, Non-Fit and Control. ANOVA pairwise comparisons were run to determine whether significant differences between groups exist. **RESULTS:** Patients in the regulatory Fit group experienced greater statin medication adherence levels compared to the patients in the Non-Fit and Control groups. When patients' motivational intensity, behavioral intentions, self-efficacy, or outcome expectancies were strong - there was no difference in statin medication adherence levels between the Fit, Non-Fit, and Control groups. A statistically significant difference in adherence was detected between the Fit and Non-Fit and between the Fit and Control groups for the weak condition for both intention and motivation. A difference between the Fit and Non-Fit groups was seen when patients' outcome expectancies were weak. Regardless of the strength of self-efficacy, there was no difference found between any of the groups in statin medication adherence levels. **CONCLUSIONS:** The regulatory Fit intervention revealed that statin medication adherence levels are highest in the Fit condition, regardless of the strength of behavioral intention, motivational intensity, self-efficacy, or outcome expectancies. When these patient-related factors are weak, there is an opportunity to improve the behavior of statin medication adherence with a Fit Intervention as there was a significant difference found between the Fit and Non-Fit/Control groups.

PCV76

ASSESSMENT OF MEDICATION ADHERENCE IN HYPERTENSIVE PATIENTS OF QUETTA USING MMAS AND HILL BONE COMPLIANCE SCALE

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OBJECTIVES: This study aimed to assess the level of adherence of hypertensive patients in Quetta, by using MMAS-8 and Hill Bone Compliance Scale. **METHODS:** A Cross-sectional descriptive study was conducted in Sandeman Provincial Hospital and Bolan Medical Complex to assess the adherence among hypertensive patients of Quetta, Pakistan. Study has been conducted from March to October 2016. Convenience sampling technique was used to collect data. Those patients who were willing to participate and were suffering with hypertension and receiving medication treatment are included in study. MMAS-8 Urdu version and Hill bone compliance scale was used to assess the level of medication adherence. SPSS V 20 used for descriptive and inferential statistics. **RESULTS:** Respondents mean age was 45.1 years. Majority 223 (55.6%) were. Marital status showed that maximum respondents 361 (90.0%) were married. Majority of respondents 108 (26.9%) were uneducated. Majority 178 (44.4%) were housewives. And Ethnic group showed that maximum respondents 132 (32.9 %) were Pashtun. The MMAS-8 mean score of adherence in hypertensive patients was 3.55. Among 401 majority of patients 306 (76.6%) were poorly adhered to medications. Ninety-four (23.4%) had moderate adherence. While only (0.2%) had good adherence. The mean score of hill bone compliance Scale in hypertensive patients was 24.16, 83.4% (n=336) had imperfect adherence and 16.2% (n=65) have perfect adherence. **CONCLUSIONS:** It is concluded, patients with hypertension were non-adherence to treatment regimen by using both the questionnaire and both MMAS-8 and Hill Bone Compliance Scale give similar results.

PCV77

NOVEL ORAL ANTICOAGULANTS (NOACs) ADHERENCE AND BLEEDING EVENTS IN ATRIAL FIBRILLATION PATIENTS: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: Non-adherence and discontinuation of anticoagulant therapy leads to increased ischemic stroke risk and contributes to suboptimal outcomes of the anticoagulant treatment. In fact, there is rising concern regarding poor adherence with these newer anticoagulant agents. This systematic review and meta-analysis was aimed to investigate the adherence to NOACs and adverse events in patients

with AF. **METHODS:** Original research articles conducted on patients with AF and using any NOACs (dabigatran, rivaroxaban and apixaban) reporting adherence for at least 35 days were included. Scientific databases including PubMed, Web of Science, and Google Scholar were searched using MeSH keywords to obtaining literatures researched between 2008 to till June, 2016. Study characteristics, patient's sociodemographic and clinical characteristics, medication adherence levels and bleeding events reported were recorded. **RESULTS:** The overall sample size of the six studies is 1,640,157, with CHADS2 scores <2 in 551 patients, CHADS2-VASc ≥ 2 in 62,232 AF patients. Three-fourth [75.6% (95%CI= 66.5-84.8), $p < 0.001$] are adherent to NOACs. However, a higher rate [72.7% (62.5-82.9), $p < 0.001$] of adherence was observed with Dabigatran than Apixaban [59.9% (3.2-123.1), $p = 0.063$] and Rivaroxaban [59.3% (38.7-80.0), $p < 0.001$]. Sub-group analysis revealed that nearly 57% of the AF patients on NOACs have CHADS2 scores <2 and 20% of these patients were non-adherent to NOACs. Overall bleeding events rate associated with NOACs non-adherent AF patients was found to be 7.5% (0.2-14.8), $p = 0.045$. However, nearly 11.2% of AF patients experienced bleeding events were non-adherent to NOAC medications. A higher proportion of bleeding events were noticed with Dabigatran (14.7%). **CONCLUSIONS:** Adherence rates, while uniformly suboptimal, nevertheless varied considerably, lowest at 59.3% for rivaroxaban and 59.9% for apixaban, followed by dabigatran (75.6%). Overall bleeding events associated with NOACs rates were 7.5% However, lower adherence to NOACs was associated with worse outcomes.

PCV78

PATIENT PREFERENCES FOR ORAL ANTICOAGULATION THERAPY IN ATRIAL FIBRILLATION: A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: The objective of this study was to systematically analyze the scientific literature assessing atrial fibrillation (AF) patients' preferences with regard to long-term oral anticoagulation (OAC) treatment. **METHODS:** We searched Medline, Scopus, Embase (1980-2015) and added records from reference lists of publications found. Outcomes of interest included any quantitative information about AF patient opinions or preferences towards OAC treatment. **RESULTS:** We included 27 publications describing results of studies conducted in 12 different countries. Among these, 16 studies analyzed patient preferences towards OAC in general. These studies predominantly assessed which benefits (mainly, lower stroke risk) AF patients would require to tolerate harms (mainly, higher bleeding risk) associated with an OAC. Most studies showed that patients were willing to accept higher bleeding risks if a stroke risk reduction is reached (2-4 major bleeds for 1 prevented stroke accepted). Most of the publications additionally showed that AF patient preferences towards OAC may differ from the perspective of clinical guidelines or the perspective of physicians. The remaining 11 included studies assessed AF patient preferences towards specific OAC medication options, namely NOACs versus VKAs. Here, our review showed that AF patients prefer easy-to-administer treatments, such as treatments that are applied once daily without any food/drug interactions and without a need for bridging and frequent blood controls. **CONCLUSIONS:** Stroke risk reduction and a moderate bleeding risk increase are the most important attributes for an AF patient's decision for or against OAC treatment. If different anticoagulation options have similar clinical characteristics, convenience attributes matter to patients. Here, AF patients favour attribute levels that describe NOAC treatment.

PCV79

CORONARY DISEASE PREFERENCES: A SYSTEMATIC REVIEW

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OBJECTIVES: In clinical scenarios on which exists more than one clinically appropriate intervention strategy, patients preferences should inform decision-making. Preferences for different treatments may be particularly relevant for approximately 12% of patients with coronary artery disease (CAD) who are eligible for either angioplasty or surgery. While cardiologists debate on optimal revascularization method, little is understood about the patient viewpoint. This study aims to systematically identify published healthcare preference studies related to CAD. **METHODS:** Data sources Medline, EMBASE and Lilacs were searched on 10 December 2016. Two researchers independently reviewed titles. Disagreements were resolved by consensus. Study eligibility criteria involved preference studies related to CAD. **RESULTS:** Of the 1,001 citations, 11 met the inclusion criteria. Total sample size was 3,499 patients and 177 physicians. Studies were conducted in the USA (7) and Europe (4). The studies used conjoint analysis (1), standard gamble (1), rating (3), ranking (1), and willingness to pay (1). Importantly, many outcomes not used in clinical trials were valued as more important than repeat revascularization, a very usual outcome. Physicians chose angioplasty over surgery significantly less than the patients when risk of death was quoted as 4% and 6%. Overall, by respondents preferred angioplasty to surgery, even when the hypothetical risk of repeat procedure was three times the risk observed in surgery. Patients weighted stroke more significantly than clinicians did; they also considered stroke worse than death. **CONCLUSIONS:** This study is the first systematic review of the methods used to explore patient's preferences between angioplasty and surgery. We considered the data scarce and identified some methodological challenges. Trials should include outcomes that are more important than repeat angioplasty and improve physician communication: neither the information given to patients nor the methods of presentation have been standardised. Compared to physicians, patients appear willing to accept considerable risk with angioplasty to avoid surgery.

PCV80

QUALITATIVE STUDY TO IDENTIFY PATIENT PERCEIVED SYMPTOMS OF STATIN INTOLERANCE

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OBJECTIVES: Patient perceptions of symptoms related to statin intolerance are not well understood. This study describes patient perceived difficulties with statins and identifies key symptoms to assess when evaluating statin intolerance. **METHODS:** Adults with dyslipidemia and history of physician-reported statin intolerance to ≥ 2 statins within the past 6-months were recruited from three lipid clinics in the US. Qualitative interviews were conducted to understand patients' experiences with statins and describe adverse events they attributed to statins. Interview sessions were audio recorded, transcribed and coded for qualitative content analysis. Coded concepts were grouped by similar content for analysis. **RESULTS:** Twenty patients were interviewed, mean age 65 (range 48-83), 65% male. Sixty percent had tried ≥ 4 statins and tried lower doses, non-daily doses, pain relievers, and other supplements to reduce symptoms. There were 486 distinct patient expressions of symptoms related to statin intolerance in the transcript database. Symptoms most frequently described were muscle related pain/discomfort (35%) including aching, cramps, pain, soreness and general discomfort. Other muscle symptoms (9%) included muscle fatigue, heaviness, stiffness, tightness and weakness. Non-muscle-related pain symptoms were also reported (16% of symptom expressions) including bone and joint pain and pain in the chest, neck and back. Fatigue, exhaustion, tiredness and low energy made up 15% of all symptom expressions. Cognitive issues (memory and concentration) comprised 8% of the difficulties reported. Other patient symptom expressions included mood changes (e.g., irritability), gastrointestinal problems, and generally feeling ill. Across all reported symptoms, severity ratings (11 point scale) ranged from 2.0-10.0 (mean 7.2, sd 2.2). **CONCLUSIONS:** We identified a broad range of symptoms experienced by patients with statin intolerance. Levels of symptom severity are also important and both should be considered when evaluating statin intolerance. More research is needed to identify symptoms and severity that relate to patient's decision to withdraw from statins.

PCV81

LINGUISTIC VALIDATION OF MALAYSIAN VERSION OF HYPERTENSION SELF-CARE PROFILE (HBP-SCP) TOOL

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OBJECTIVES: To translate and provide a Malaysian version of HBP-SCP that was conceptually equivalent to the original English version for use in the Malaysian setting. **METHODS:** The linguistic validation of HBP-SCP was conducted according to the principles of good practice for translation and cultural adaptation process for patient-reported outcomes measures, delineated by the International Society for Pharmacoeconomics and Outcomes Research task force. These steps included preparation, forward translation, reconciliation, back translation, back translation review, harmonisation, cognitive debriefing, review of cognitive debriefing and finalisation. **RESULTS:** Some words were replaced during the initial translation process to ensure the meanings of the original items were culturally acceptable in Malaysian setting. For instance, the word "lard" was replaced by "margarine" (item 6 and 8) and the phrase "Oodles of Noodles" was replaced by "Instant Noodles" (item 3). In addition, the word "eat" in the sentence "Eat less than 1 teaspoon of table salt per day (6 grams)?" in item 5 (behaviour scale) and item 6 (motivation and self-efficacy scales) was literally translated as "menggambil (take)" instead of "makan (eat)" which culturally acceptable equivalents to original English version. Following the cognitive debriefing, the word "sodium" was not intuitively understood by 5 out of 7 hypertensive patients. Hence, an additional word "gram (salt)" was added to provide an easily comprehensible version. The item "Forget to take your blood pressure medicine" was initially translated to "Terlupa mengambil ubat darah tinggi" in item 15 (behaviour scale) and item 16 (motivation and self-efficacy scales). However, some patients misunderstood the meaning of "menggambil" as taking blood pressure medication from the pharmacy counter and thus, the word "menggambil" was changed to "makan". **CONCLUSIONS:** The translated Malaysian version of HBP-SCP tool was conceptually equivalent and culturally acceptable for use in Malaysia. Future psychometric validation is anticipated.

PCV82

PSYCHOMETRIC EVALUATION OF CONDITION SPECIFIC HEALTH RELATED QUALITY OF LIFE MEASURES AND RELATED CONSTRUCTS USED IN PERSONS WITH APHASIA

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OBJECTIVES: Aphasia is a neurologically based language disorder caused by damage to the left hemisphere of the brain. Aphasia affects approximately one third of stroke survivors and has a significant impact on their health related quality of life (HRQL). The objective of this study was to compare and contrast the psychometric properties of condition specific HRQL measures and related constructs used in persons with aphasia (PWA). **METHODS:** Instruments were identified by conducting a comprehensive literature review of condition specific, self-report measures of HRQL in English used in persons with aphasia. Evaluation

of eight instruments was based on the following criteria: conceptual model, versatility (eg varying severity of aphasia), practicality (≤ 15 minutes to complete), depth (floor and ceiling effects), breadth (physical, mental, role, social and communicative functioning), reliability (internal consistency and test-retest), construct validity, and responsiveness. **RESULTS:** The most widely used scales were Stroke and Aphasia Quality of Life (SAQOL-39g), Burden of Stroke Scale (BOSS) and Assessment of Living with Aphasia (ALA). SAQOL-39g and BOSS met most study criteria but neither met the practicality criterion nor did they use pictures to enable nonverbal responses. Breadth criterion was met by SAQOL-39g, BOSS, Communication Disability Profile (CDP), ALA and Quality of Communication Life Scale (QCL). Construct validity criterion was only met for SAQOL-39g. Reliability criterion was met for SAQOL-39g, BOSS, Community Integration Questionnaire modified for PWA (CIQ), ALA, CDP and Communication Outcome after Stroke (COAST). In most cases unmet criteria was due to unreported data. **CONCLUSIONS:** Key consideration in instrument selection is validation in the target population: aphasia severity, type, setting and other stroke sequelae; and desired construct of measurement. Overall, although BOSS and SAQOL-39g scored highly, lack of visual prompts and length, limits their suitability in PWA. Only CDP provided breadth including communication functioning, aphasia type, and reliability for domain scores.

PCV83

PATIENT PREFERENCES FOR CHOLESTEROL TREATMENT OPTIONS: A DISCRETE CHOICE EXPERIMENT (DCE)

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OBJECTIVES: With the recent approval of PCSK9 inhibitors, patients with cardiovascular disease (CVD) and their clinicians face a choice between a statin and this potentially more effective but very costly medication class. We conducted a DCE to understand what trade-offs patients are willing to make among the benefits, risks, and costs of these two medication classes. **METHODS:** We selected a sample of patients with self-reported CVD from an online national panel. Respondents completed a web-based questionnaire that presented a hypothetical clinical scenario and 12 choice questions, each containing 2 treatment options. Patients were asked to select their preferred treatment by comparing their attributes. Using conditional logistic regression, we estimated relative preferences, maximum acceptable risk, and willingness to pay. **RESULTS:** Among the 689 patients who met inclusion criteria, 521 (76%) completed the questionnaire. The average age was 62 years. The odds of choosing a drug requiring an injection every two weeks compared to a daily pill was 0.57 (95% CI 0.54-0.61). In order to accept the need to inject, patients would expect a 17% reduced risk of non-fatal CVD events, 11% reduced risk of fatal CVD events, 60% reduced risk of muscle symptoms, or 16% reduced risk of memory loss over a 10-year period. Patients on average were willing to pay \$51/month out of pocket, or to have their insurance pay up to \$1670/month for a daily pill rather than a bimonthly injection. **CONCLUSIONS:** With all other attributes being equal, monthly treatment cost and the need for injection were major drivers of patient preferences for choice of treatment. The smaller positive impact of expected benefits of PCSK9 inhibitors compared to statins in terms of reducing risk of CVD events are unlikely to offset these negative impacts on patient preferences unless outcome studies demonstrate significantly higher benefit than currently anticipated.

PCV84

HEALTH RELATED QUALITY OF LIFE AMONG SURVIVORS OF MYOCARDIAL INFARCTION IN THE UNITED STATES: A PROPENSITY SCORE MATCHED ANALYSIS

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OBJECTIVES: To identify differences in health-related quality of life (HRQoL) domains between survivors of myocardial infarction (MI) and propensity score matched controls. **METHODS:** This retrospective, cross-sectional study examined HRQoL differences between survivors of MI and propensity score matched controls using data from the 2013 Behavioral Risk Factor Surveillance System (BRFSS) survey. The study sample consisted of adults aged 50 or older who: (i) completed the BRFSS survey, and (ii) reported data on HRQoL. Adults that reported they had ever been told they had an MI formed the case group and those who did not formed the control group. Propensity scores were generated using logistic regression based on gender, race/ethnicity, age, smoking status, and body mass index (BMI). Each case was matched to three controls (1:3) to increase the power of the analyses. Univariate analyses were conducted using chi-square tests before and after propensity score matching. Multivariable analyses were conducted to identify HRQoL differences between groups. Life satisfaction, sleep quality, and activity limitations were estimated using binary logistic regression. Social support, general health, physical health, and mental health were estimated using multinomial logistic regression. Significance was set at $p < 0.05$. **RESULTS:** The final sample consisted of 23,282 survivors of MI matched to 69,846 controls ($n=93,128$). Compared to controls, survivors were 3 times more likely to report fair/poor general health (Adjusted Odds Ratios (AOR)) = 3.06, 95% CI:2.769-3.396) and 1.7 times more likely to report daily activity limitations (AOR = 1.69, 95% CI:1.56-1.84). Survivors reported poorer physical health (AOR = 2.07, 95% CI:1.88-2.28) and poorer mental health (AOR = 1.56, 95% CI:1.35-1.80). There was no difference between groups in level of emotional support, sleep quality, or life satisfaction. **CONCLUSIONS:** Survivors of MI experienced lower HRQoL on domains of general health, physical health, and mental health compared to propensity score matched controls.

PCV85

DETERMINATION OF HEALTH RELATED QUALITY OF LIFE IN CORONARY HEART DISEASE (CHD) PATIENTS ATTENDING DIFFERENT HOSPITALS IN QUETTA, PAKISTAN

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OBJECTIVES: This study was conducted to determine the health related quality of life in Coronary heart disease (CHD) patients attending different hospitals in Quetta, Pakistan. **METHODS:** This cross sectional study was undertaken in different hospitals of Quetta, Pakistan from January to October 2016 and recruiting patients with coronary heart disease attending the hospital for follow ups the data was obtained by using EQ-5D-3L questionnaire to evaluate health related quality of life (HRQOL) descriptive statistics were used to present result and united kingdom general population survey were used to evaluate EQ-5D scoring and analysis were performed using IBM SPSS v.20. **RESULTS:** Three hundred and fifty-three CHD patients were enrolled in study, majority were belonging to age group 56 - 65 years ($n=126$, 35.5%) with male dominance ($n=269$, 75.8%). The mean EQ-5D descriptive score and EQ-VAS score were 0.54536 ± 0.304 and 67.15 ± 15.99 . Demographic characteristics; number of medicines, gender, ethnicity, occupation, education and income were associated with the mean EQ5D and VAS and lower health related quality of life scores in patients with CHD. **CONCLUSIONS:** The present study showed that quality of life was low in those suffering from CHD. CHD had an adverse impact on all aspects of life such as physical and psychological functioning and general wellbeing.

PCV86

EVALUATION OF HEALTH-RELATED QOL IN HYPERTENSIVE PATIENTS USING EQ-5D IN SOUTHWEST CHINA

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OBJECTIVES: To assess the health-related QoL of hypertensive patients in southwest China and compare it with other area in China, and identify the factors that influence the QoL of hypertensive patients. **METHODS:** Face to face survey was conducted to 600 samples of hypertensive patients who were recruited from tertiary hospitals in Chengdu, the biggest southwest city in China. Sociodemographic of patients were collected through questionnaires, and health-related quality of life were measured using the EQ-5D-5L scale. Chi-square test, one-way analysis of variance (ANOVA) and student's t test were employed to estimate the differences between various sociodemographic conditions. **RESULTS:** 562 effective responded hypertensive patients were involved in this study. The mean of EQ-VAS score of hypertensive patients was 73.42 ± 13.93 while the mean of EQ-5D index of the sample was 0.835 ± 0.133 . EQ-5D index of men (0.862) was higher than women (0.814) (chi-square = 4.311, $P < 0.001$). Patients who had exercise habits (0.845) gained higher EQ-5D index than those without exercise habits (0.816) ($P = 0.013$). Patients with complications (0.819) had lower EQ-5D index than those without complications (0.855) ($P = 0.002$). EQ-5D index increased gradually with the increase of reimbursement ratio ($P = 0.033$). EQ-5D index of patients with annual household income of less than 30,000 yuan (≈ 4348 US\$) was 0.809, while the EQ-5D index of patients with annual household income of 300,000 to 1,000,000 yuan (≈ 144927 US\$) was 0.869, and there were statistical difference between this two income groups. The EQ-5D index of patients who smoking or drinking were higher than those who did not smoke or drink, and the difference was statistically significant ($P < 0.001$). **CONCLUSIONS:** The EQ-5D index of hypertensive patients in southwest China fell in literature reported 0.78-0.93, but the EQ-VAS score was lower than it in Peking urban hypertensive patients (77.39 ± 14.41). Gender, exercise habits, complications, reimbursement ratio, and household income are the main factors influenced the QoL of hypertensive patients.

PCV87

HEALTH RELATED QUALITY OF LIFE ASSESSMENT WITH MEDICAL OUTCOMES STUDY THE 12-ITEM SHORT- FORM HEALTH SURVEY (MOS SF 12) AND THE 14-ITEM SHORT-FORM HEALTH SURVEY FOR CHRONIC VENOUS INSUFFICIENCY (MOS CIVIQ 14) THAI VERSIONS

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OBJECTIVES: High incidence of Chronic venous disease (CVD) was noted meanwhile patients did not seek treatment at an early stage. Relevance leg symptoms spotted for primary screening remains clinical challenges. **METHODS:** The medical outcomes study (MOS) with health-related quality of life, a 12-Item Short-Form Health Survey (SF-12) and a 14-Item Health Short-Form Health Survey for Chronic Venous Insufficiency (CIVIQ-14) were employed in hospital-setting together with physical examinations for an interventional study. A cross-sectional analysis was performed to assess reliability and correlation of the questionnaires with specific implication of leg symptoms. **RESULTS:** 120 patients were screened, 48 patients clinically diagnosed with CVD. For the inter-scale correlation and internal consistency reliability interpreting with Cronbach's alpha coefficients, CIVIQ-14 Thai version were reliable with Cronbach's alpha coefficient of 0.914 (for 14-item global score), 0.867 (for 7-item physical and pain score) and 0.787 (for 7-item psychological score), whereas SF-12 were reliable, with the same of 0.810 (for 12-item for global score), 0.939 (for 7-item physical and pain score) and 0.661 (for 5-item mental score). These two questionnaires were well correlated for physical score, interpreting with bivariate Pearson correlation coefficient, with a 95% CI of 0.713 (0.663 to 0.790), $p < 0.001$ and for global score, 0.745 (0.640 to 0.819),

$p < 0.001$. No significant correlation of psychological score of $-0.062(-0.197$ to $0.091)$, $p = 0.501$. The major leg symptoms significantly have rendered impacts on the raw score for physical components score and for global score but not for mental components of both SF-12 and CIVIQ-14. Patients with CIVIQ-14 score lower than 75.7 were more likely to have been diagnosed CVD. **CONCLUSIONS:** Both the CIVIQ-14 and the SF-12 were highly correlated for scoring on physical function, useful for primary screening of chronic venous disease. Though majority of leg symptoms and adjustment of appropriate threshold scores were suggested to be a useful tool for screening CVD. This CIVIQ-14 Thai version was useful but larger heterogeneous patient exploration confirmation suggested.

CARDIOVASCULAR DISORDERS – Health Care Use & Policy Studies

PCV88

EFFECT OF DIRECT-TO-CONSUMER ADVERTISING (DTCA) ON STATIN USE IN THE UNITED STATES

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OBJECTIVES: The value of direct-to-consumer advertising (DTCA) of prescription drugs is widely debated, as is the effect of DTCA on prescription sales and health care utilization. We examined the association between DTCA intensity for statin medications and prescription sales and cholesterol-related health care utilization. **METHODS:** We conducted an ecological study for 75 designated US market areas (DMAs) from 2005 to 2009 using linked data regarding: (1) televised DTCA volume for rosuvastatin and atorvastatin derived from Nielsen television ratings; (2) non-DTCA marketing and promotion derived from IMS Health Integrated Promotion Services; (3) retail, mail order and long-term care prescription drug sales derived from IMS Health Xponent; (4) prescription drug and ambulatory care health care utilization derived from Truven MarketScan; (5) contextual factors such as health care density and socioeconomic status derived from the Area Resource File. We derived information for each month at each DMA and used multi-level negative binomial regression to account for nesting of individuals. Main outcomes and measures were: (1) Volume of total, new and refilled prescription sales; (2) number of statin prescriptions dispensed; (3) high cholesterol-related outpatient visits. **RESULTS:** The average intensity of statin ad exposures per household varied substantially across DMAs. After adjustment for socioeconomic, demographic and clinical characteristics, each 100-unit increase in advertisement viewership was associated with a 2.22% (95% confidence interval [CI] 0.30 to 4.19%) increase in statin sales. Similar patterns were observed between DTCA and statin dispensing among the commercially insured. DTCA was associated with increases in high cholesterol-related outpatient visits among adults 18-45 years of age (3.15% increase in visits per 100-unit increase in viewership, 95% CI: 0.98 to 5.37%) but not among those 46-65 years (0.51%, 95% CI: -1.49 to 2.55%). **CONCLUSIONS:** DTCA for statins is associated with increases in statin utilization and hyperlipidemia-related outpatient visits, especially for young adults.

PCV89

A NOVEL VENTRICLE RESTRAINT DEVICE (ASD) REPETITIVELY DELIVER SALVIA MILTIORRHIZA TO EPICARDIUM HAVE A GOOD CURATIVE EFFECTS IN HEART FAILURE MANAGEMENT

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OBJECTIVES: Passive ventricular restraint is non-transplant surgical option for the management of end stage dilated heart failure (HF). The objective of this work is to expand the therapeutic techniques of current medicine, for this purpose we design a novel ventricle restraint device (ASD) which has ability to deliver a therapeutic drug directly to the heart. In this study we deliver a Traditional Chinese Medicine (TCM) Salvia Miltiorrhiza (Danshen Zhusheyue, SM) through active hydraulic ventricles support drug delivery system (ASD) and we hypothesize that it will have better result in heart failure management than the restraint device and drug alone. **METHODS:** Sprague Dawley (SD) rats were selected and divided into five groups (n=6), Normal, HF, HF+SM (IV), HF+ASD, HF+ASD+SM groups respectively. Prior to surgery ECG were performed which showed a normal heart function in all groups. **RESULTS:** The HF+ASD-SM group showed a significant therapeutic improvement with respect to other treatment groups. Masson-Trichrome staining was used to study histopathology of cardiac myocytes, large blue fibrotic area was observed in HF, HF+ASD and HF+SM (IV) groups while HF+ASD+SM showed negligible fibrotic myocytes in histological examination at the end of study period (30 day). The diastolic and systolic parameter (LVEDP and LVSP) were brought to normal when treated with HF+ASD+SM and show significant (P value < 0.05) over individual ASD and SM therapy. Blood Brain Natriuretic Peptide (BNP) significantly declines in HF+ASD+SM group animals compared with HF and HF+SM (IV) groups respectively. **CONCLUSIONS:** It is concluded that novel ASD device augment the therapeutic effect of drug and can deliver Salvia miltiorrhiza to the cardiomyocytes significantly as well as provide additional support to the dilated ventricles by the result of heart failure.

PCV90

RISK FOR CARDIOVASCULAR ADMISSIONS IN SGLT2 AND DPP4 THERAPIES

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OBJECTIVES: The Food and Drug Administration (FDA) approved formal indication for an antidiabetic drug for preventing cardiovascular deaths compared to placebo. It is not clear if cardiovascular hospitalizations are lower for sodium glucose transporter 2 inhibitors (SGLT2) compared to dipeptidyl peptidase 4 inhibitors (DPP4). Second, it is uncertain if any benefit occurs in heart failure. Recognizing both needs, we assessed the association between initial dispensing of either class with cardiovascular hospitalizations in general and heart failure in particular. **METHODS:** The new user study design was applied to type 2 diabetic patients initiating SGLT2 versus DPP4 medications from April 2013 to December 2014 and followed through June 2015. We analyzed time to first cardiovascular (myocardial infarction, stroke or angina) and heart failure admissions after initiating therapy (index date). We adjusted for post-index time-varying covariates and baseline characteristics. Continuous enrollment for 6 months pre-index was required to assess baseline factors. We conducted a marginal structural model (MSM) analyses to estimate Cox proportional hazards. **RESULTS:** Patients initiating SGLT2 (N=5,484) were younger (mean 55 years) compared to 59 years for DPP4 (N=32,113). Overall, 2.6% and 6.0% patients had cardiovascular admissions after initiating therapy for SGLT2 (n=142) and DPP4 (n=1,928) cohorts respectively. About 0.9% and 3.6% patients had heart failure admissions after initiating therapy for SGLT2 (n=50) and DPP4 (n=1,151) cohorts respectively. Using DPP4 as a reference, the Cox MSM adjusted risk for heart failure admissions was significantly lower for patients on SGLT2 (HR = 0.64, 95% CI 0.48 - 0.85, p = 0.002). There was no difference in cardiovascular admissions (HR=0.86, 95% CI 0.72 - 1.03, p = 0.10). **CONCLUSIONS:** This study found a significantly lower risk in heart failure but not cardiovascular admissions for SGLT2 users. Clinical studies are needed to provide evidence on each SGLT2 agent's impact on heart failure exacerbations.

PCV91

DRG BASED PERFORMANCE INDICATORS OF ANGIOLOGICAL ACTIVE INPATIENT CARE

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OBJECTIVES: Angiological active inpatient care has been a field with a separate professional entity and code since 2012. Our study aimed at analysing the performance indicators of angiological active inpatient care. **METHODS:** Data analysed were taken from the DRG-based financial database of the National Health Insurance Fund Administration and the year examined was 2015. In our study, we determined average nursing times, the case-mix index (CMI), case numbers and cost weight for activities listed under professional code '0101 Angiology, phlebology, lymphology'. **RESULTS:** In the year 2015, 13 health care institutions out of 7 counties reported having provided angiological care with a separate professional code to the National Health Insurance Fund Administration in Hungary. The national annual angiological active inpatient volume amounted to 12,076 cases and 101,546 nursing days which was financed by the National Health Insurance Fund Administration with a DRG cost weight of 13.573. The market share of angiological care was 0.54% of the total active inpatient care based on case numbers, 0.57% based on cost weight, 0.80% based on number of active beds and 0.83% when calculated according to nursing days. The national average case-mix index for all medical specialist fields was 1.15249, while the average number of nursing days was 5.3 days/case. The national case-index of angiology (1.17373) was the highest in university clinics (1.39419) and the lowest in hospitals in the capital (1.02154). The national average length of stay was (8.1 days/case) was longer than the national professional average and was the shortest in town hospitals (7.6 days/case) and the longest in special hospitals (9.8 days/case). **CONCLUSIONS:** Performance indicators of angiological care suggest that the its case-mix index is higher than the national professional average, whereas nursing times are somewhat longer. Performance indicators of different types of institutions (universities, town and county hospitals, Budapest hospitals) show significant differences.

PCV92

A FEASIBILITY STUDY ON 10-YEAR CVD RISK ASSESSMENT AS A PRIMARY PREVENTION TOOL FOR CARDIOVASCULAR DISEASE

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OBJECTIVES: China National Center for Cardiovascular Disease launched a guideline-based 10-year risk assessment of cardiovascular disease (CVD) phone APP, and created a heart age index to visualize the CVD risk to public. This is the first time using totally Chinese local database which includes 40,000 people following up 10-15 years to assess CVD incidence risk. We assessed the self-test effect of the app in China and the feasibility of promoting the app as a secondary prevention tool for CVD by government. **METHODS:** Media and government projects encouraged people spontaneously using the app and answering 8 CVD risk factor's questions. We analyzed the current status of cardiovascular risk in Chinese residents, the prevalence of hypertension, hyperlipidemia, diabetes, the distribution of heart-age and so on by SPSS. **RESULTS:** During 5 months, 18,214 people (39.7% of men, 60.3% of women) used the app around the whole country. The mean age was 55.9 years, the mean heart-age was 64.8 years, and the mean 10-year CVD risk was 4.1%. For hypertension, hyperlipidemia and diabetes patients, the mean 10-year CVD risks were 8.7%, 7.1%, and 9.5% respectively. Prevalence of hypertension (SBP ≥ 140 mmHg or DBP ≥ 90 mmHg), hyperlipidemia (total cholesterol > 6.2mmol/L) and diabetes mellitus were 15.8%, 14.4% and 8.5%,

respectively. Among hypertensive patients, 33.4% had hyperlipidemia at the same time, and 10.5% of diabetes patients had hyperlipidemia. The correlation coefficient between hypertension and hyperlipidemia was 0.101 ($P < 0.001$), between hyperlipidemia and diabetes was 0.022 ($P = 0.003$), and between hypertension and diabetes was 0.038 ($P < 0.001$). **CONCLUSIONS:** The 10 years CVD risk evaluation app can be a primary prevention tool for CVD in China. For Chinese population, heart-age is 10 years older than actual age. Hyperlipidemia is highly associated with hypertension and diabetes, so it's necessary for Chinese government to include blood lipid management in its national policy.

PCV93

SIMULTANEOUS ENDOVASCULAR ANEURYSM REPAIR AND CORONARY ARTERY BYPASS GRAFTING

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OBJECTIVES: Simultaneous endovascular aneurysm repair (EVAR) and coronary artery bypass grafting (CABG) includes two different surgical operations doing by two teams of operating surgeons during one anaesthetic support. Patients with concomitant aortic aneurysmal disease and coronary artery disease stay in group of high risk of perioperative aortic aneurysm rupture and myocardial infarction. Therefore, simultaneous EVAR/CABG can reduce the incidence of late aortic aneurysm rupture and myocardial infarction and can improve survival in the short and long-term period. This research aim is to evaluate clinical effectiveness, safety and economic effectiveness of simultaneous EVAR/CABG compared with conducting these surgical operations separately. **METHODS:** For opportunity to evaluate clinical effectiveness, safety and economic effectiveness of simultaneous EVAR/CABG the systematic literature search was conducted in databases of evidence-based medicine named MEDLINE, EMBASE, Tripdatabase, Clinical Trials. Publication date: no later than 10 years (since 2007). **RESULTS:** As a result of systematic search we found 12 articles; all of these articles confirmed clinical effectiveness and safety of simultaneous EVAR/CABG in patients with large and/or symptomatic aortic aneurysm and severe coronary artery disease. Simultaneous EVAR/CABG can be viable procedure with low operative mortality and acceptable rate of perioperative complications. From the side of economic effectiveness conducting simultaneous EVAR/CABG can reduce costs for 1 patient treatment by a mean of 7.5% (1 120 USD) due to 1) reducing duration of hospital stay and postoperative rehabilitation; 2) no need for additional anaesthetic support; 3) decreasing in incidence of post-operative aortic aneurysm ruptures and myocardial infarctions in patients with concomitant aortic aneurysmal and coronary artery diseases. **CONCLUSIONS:** Simultaneous endovascular aneurysm repair and coronary artery bypass grafting can be viable procedure for patients with concomitant large and/or symptomatic aortic aneurysm and severe coronary artery disease with low operative mortality, acceptable rate of perioperative complications and has some economic advantages over conducting these surgical operations separately.

PCV94

MEN ARE PREDICTABLE: MODELING CARDIOVASCULAR DISEASE PREVALENCE FROM POPULATION SURVEY DATA

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OBJECTIVES: Calculating the economic burden of disease requires data regarding disease prevalence. National estimates can be derived from surveys of the general population, which may also access individuals not actively participating in the healthcare system. The Behavioral Risk Factor Surveillance System (BRFSS) is the largest annual country-wide population sampling of health and risk factors. The fidelity of these data, however, may be questionable, relying on accurate self reporting. Cardiovascular disease (CVD) prevalence was examined by gender to assess the feasibility of predicting future trends. **METHODS:** BRFSS data were trimmed to complete cases for 9 CVD risk factors: gender, age, race, overweight, physical activity, diabetes, high blood pressure, smoking and alcohol consumption. Data from 2011 and 2013 were used to train Bayesian and tree-based algorithms to evaluate predictor performance on unseen data from subsequent years (2013 and 2015) by comparing predicted with reported prevalence. **RESULTS:** For algorithms used, predictions of future prevalence were significantly better for males than females ($p < 0.001$, Šidák multiple testing correction). In the best performing algorithm (Naïve Bayes), the mean percent difference from the actual prevalence for males was $3.8 \pm 2.5\%$ and females $15.1 \pm 6.2\%$ ($p < 0.05$, two-tailed t-test). Data from 2013 yielded better 2-year predictions (2015) for women than the same time span with 2011 data (2011 to 2013, $p < 0.05$, two-tailed t-test), while for men, there was no significant difference ($p = 0.54$, two-tailed t-test). Models trained on the genders combined resulted in underestimates of prevalence ($p < 0.001$, Z-test). **CONCLUSIONS:** Patient-reported survey data can be used to predict cardiovascular disease prevalence. Accuracy of estimation is better in males versus females. Given that BRFSS data are retrospective, our findings may reflect more substantial lifestyle changes in females or suggest discussion on changes in how survey data from female respondents are collected.

PCV95

PROJECTED IMPACT OF ADOPTING A MULTIPLEXED PREEMPTIVE GENOTYPING INTERVENTION IN CARDIAC CATHETERIZATION LABORATORY PATIENTS

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OBJECTIVES: To estimate the impact of preemptive genotyping in cardiac catheterization laboratory patients based on the number of clopidogrel, warfarin, and simvastatin prescribing changes recommended by the Clinical Pharmacogenetics

Implementation Consortium (CPIC). **METHODS:** A retrospective analysis was conducted in a cohort of patients referred for coronary angiography at UNC Hospitals from 2012 to 2014 who consented to participate in a single-center study with medication data available at discharge and follow-up ($n=122$). Patient DNA samples were sequenced using a custom pull-down method for library preparation and next-generation sequencing using the Illumina HiSeq platform. Bioinformatic tools (i.e. Burrows-Wheeler aligner, FreeBayes) were used for the genetic analysis, and a minimum sequencing depth of 20x was required for genotype and haplotype calling. Pharmacogenetic-guided drugs and genes included in the analysis were: clopidogrel (CYP2C19 *1, *2, *3, *17), simvastatin (SLCO1B1 rs4149056), and warfarin (CYP2C9 *1, *2, *3; VKORC1 rs9923231). **RESULTS:** Prescription data for warfarin, clopidogrel, and simvastatin were available for all patients. Haplotype calling was successful in 118 patients (96.7%) for CYP2C19, 112 patients (91.8%) for CYP2C9/VKORC1, and 122 patients (100%) for SLCO1B1. A total of 87 prescriptions were given for clopidogrel, warfarin, and simvastatin. Based on the CPIC guidelines, 17 of these prescriptions (19.5%) were eligible for a change in dose or drug. According to the presence of an at-risk genotype, the number of CPIC recommended prescribing changes included: 10 (16.9%) out of 59 patients on clopidogrel, 2 (18.2%) out of 11 patients on warfarin, and 5 (29.4%) out of 17 patients on simvastatin. **CONCLUSIONS:** Adopting a preemptive genotyping intervention that multiplexes CYP2C19, CYP2C9/VKORC1, and SLCO1B1 would be relevant for approximately 1 out of 5 cardiac catheterization laboratory patients. Additional studies in larger cohorts are needed to confirm the generalizability of these findings.

PCV96

PLACEMENT OF NEW FDA-APPROVED DRUGS IN MEDICARE PART D FORMULARIES, 2009-2014

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OBJECTIVES: To assess time-to-formulary-placement (TFP) of selected drugs post-FDA approval among Medicare Part D plans. **METHODS:** Data obtained from CMS public use files. TFP was calculated for 34 drugs in 8 therapeutic classes (anti-hyperglycemics, anticoagulants, antiplatelets, MS agents, DMARDs, COPD drugs, antiepileptics, and antipsychotics) as the difference in months between first observed formulary placement among all Part D plans and plan-specific formulary placement dates for a sample of 863 plans with continuous CMS contracts, 2009 to 2014. A 2-part multivariable model estimated the impact of drug characteristics (new chemical entity, line extension, combination product, number of competing products in class) and Part D plan characteristics (basic vs enhanced benefits, PDP vs MAPD, Star rating), on the probability of adoption of each drug (part 1) and TFP (part 2). **RESULTS:** First Part D formulary placements varied from 3 to 9 months post-FDA approval with longest delays for rivaroxaban, ticagrelor, and indacaterol. On average, 58.5% of plans placed each drug within 6 months, and 65.9% within one year of first formulary placement. Mean TFP was 4.3 months across all drugs with the most rapid adoption for antipsychotics (2.7 months) and antiepileptics (3.3 months). The longest TFP (6.5 months) was for COPD drugs and antiplatelets. In adjusted analyses, enhanced benefit plans and higher Star ratings increased odds of formulary placement (ORs=1.38 and 1.36, respectively, $p < .0001$) whereas being a benchmark plan lowered odds of placement (OR=0.78, $p=.03$). Line extensions and combination products had very low odds of placement (OR=0.10 and 0.22, respectively, $p < .0001$). There were no significant differences in TFP between PDPs and MAPDs. Follow-on products in the same pharmacological class were placed significantly more often than first-in-class products, but TFP was slower. **CONCLUSIONS:** There is significant heterogeneity in probability of placement and TFP on new drug introductions in the Part D marketplace.

PCV97

USE OF SECONDARY PREVENTION MEDICATIONS AMONG PATIENTS WITH ACUTE CORONARY SYNDROMES IN TIANJIN, CHINA

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OBJECTIVES: To examine the use of secondary prevention medications including antiplatelets, beta-blockers, ACEIs/ARBs, and statins among patients with acute coronary syndromes (ACS) in Tianjin, China. **METHODS:** Data were obtained from Tianjin Urban Employee Basic Medical Insurance database (2011-2014). Patients with primary discharge diagnosis of ACS during 2012.01.01-2013.12.31, and who were under the insurance cover for a minimum 12months before (baseline) and after (follow-up) index hospitalization were included. Patients were divided into two groups according to percutaneous coronary intervention (PCI) during index hospitalization. The use of secondary prevention medications was measured during index hospitalization and follow-up (0-3, 4-6, 7-9,10-12 months after discharge) for both total cohort and subgroups. Optimal medical therapy (OMT) was defined as receiving antiplatelet drug, statins, ACEIs/ARBs and beta-blockers during the specific study period. **RESULTS:** In total, 14,358 patients (64.7 \pm 10.7 years; 54.6% male) with ACS were identified. Of these 22.1% ($N=3,172$) had PCI. They were significantly younger (62.3 ± 10.0 vs. 65.4 ± 10.8 years, $P < 0.001$) and more were males (73.3% vs. 49.3%, $P < 0.001$) compared with non-PCI group. Of total patients, 81.0% had ≥ 1 prescriptions of antiplatelet during index hospitalization, followed by statins (79.7%), ACEIs/ARBs (59.8%) and beta-blockers (57.2%). The use of each medication class decreased gradually during follow-up. Only 31.5% of them were prescribed with OMT during index hospitalization, which decreased to 22.6% at 0-3 months, 12.9% at 4-6 months, 10.3% at 7-9 months and 10.6% at 10-12 months. Compared with non-PCI group, PCI group had more patients with OMT at index hospitalization (53.9% vs. 25.2%, $P < 0.001$), but it also decreased during

follow-up (46.2%, 26.7%, 19.8% and 20.6%, respectively). **CONCLUSIONS:** The use of secondary prevention medications and OMT were suboptimal and decreased over follow-up among Chinese ACS patients, including those with PCI procedure. Further strategies to promote the optimal medical care of ACS are needed.

PCV98

UTILIZATION PATTERNS OF NON-VITAMIN K ANTAGONIST ORAL ANTICOAGULANTS IN ELDERLY PATIENTS WITH ATRIAL FIBRILLATION WHO FAILED WARFARIN THERAPY

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OBJECTIVES: To assess drug utilization pattern of non-vitamin K antagonist oral anticoagulants (NOACs), including potentially inappropriate dosing, switching, and concomitant use of contraindicated drugs. **METHODS:** We used nationally representative data named Health Insurance Review and Assessment Service-Aged Patient Sample 2014 that contained medical and pharmacy claims of approximately 1 million elderly patients aged 65 or older. We included patients who had at least one diagnosis of atrial fibrillation (AF) and had at least one prescription of NOACs (apixaban, dabigatran, or rivaroxaban) between January 1, 2014 and December 31, 2014. Switching was defined as initiating another NOAC and using it \geq 8 days. Contraindicated drugs were defined according to package insert of each NOAC. Logistic regression model was used to assess factors associated with concomitant use of contraindicated drug. **RESULTS:** We identified 1,234 elderly patients with AF treated with apixaban (n=106), dabigatran (n=593), and rivaroxaban (n=535). The proportion of potentially inappropriate dosing was the highest in rivaroxaban users (16.9%), followed by dabigatran and apixaban users (9.3% and 0.9%, respectively). Switching occurred in 5.4%, 2.6%, and 0.9% of patients treated with dabigatran, rivaroxaban, and apixaban, respectively. Among 1,234 patients, 236 patients (19.1%) were prescribed contraindicated drugs. The concomitant use of other oral anticoagulants was relatively frequent. Clinic-hospital compared with tertiary hospital (odds ratio (OR): 2.434; 95% confidence interval (CI): 1.215-4.876) and outpatient setting compared with inpatient setting (OR: 4.718; 95% CI: 3.692-6.028) were significantly associated with concomitant use of contraindicated drugs. **CONCLUSIONS:** Among 1,234 elderly AF patients using NOACs in 2014, 11.8% were not treated with appropriate dosing and 19.1% were prescribed contraindicated drugs that could affect bleeding risk and treatment effectiveness. Furthermore, NOACs use in clinic-hospital or in outpatient setting was significantly associated with concomitant use of contraindicated drugs. Therefore, careful monitoring is warranted for these patients.

PCV99

COMBINATION THERAPY VERSUS INTENSIFICATION OF STATIN MONOTHERAPY FOR THE PREVENTION OF CORONARY HEART DISEASE: AN ADAPTED REPORT TO THE TUNISIAN CONTEXT

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OBJECTIVES: Coronary heart disease (CHD) is the most common cause of mortality worldwide. The burden of CHD causes 27,14 % of total mortality in Tunisia. Statins are the leading molecules in CHD prevention. The national insurance fund paid 9% of its total drug expenditures in 2015 in statins. INASanté has launched an HTA study aiming to compare the intensification of statin monotherapy versus a combination therapy for the prevention of CHD in patients with moderate to high cardiovascular risk. This study aims to reduce prescription variability and not justified therapies. **METHODS:** Research was carried out on the basis of HTA on the net from 2006 to 2016. Title, abstract and full text screening, was performed by two independent reviewers, using prespecified eligibility criteria. A critical appraisal was performed using INAHTA, PRISMA checklists, FLC 2.0 and EUnetHTA adaptation toolkit. One review from Agency for Healthcare Research and quality (AHRQ) elaborated in 2014 was retained. An adaptation process has been started. We gathered lipid lowering agents' consumption data from key institutions and we started a qualitative study through interviews with cardiologists and general practitioners from public and private sector and representatives from scientific societies. Interviews will be computerized and analyzed using NVIVO. After discussing the results with the working group the report will be synthesized and validated. **RESULTS:** According to AHRQ report, all evidence for clinical outcomes were graded insufficient when comparing the therapies. Effect on lowering LDL-C depends on the combination agent. In Tunisia, according to the first interviews, the only combination reported is with fibrates, in case of associated hypertriglyceridemia. BAS are no more prescribed; Ezetimibe has not yet obtained the marketing authorization. **CONCLUSIONS:** There are significant differences among practitioners in prescription habits. This can be related to the populations' characteristics, availability of molecules and lack of common guidelines.

PCV100

USING GROUP BASED TRAJECTORY MODELS TO CHARACTERIZE STATIN MEDICATION ADHERENCE PATTERNS AMONG PATIENTS ENROLLED IN A MEDICARE ADVANTAGE PLAN (MAP)

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OBJECTIVES: Despite the well-documented efficacy of statins in primary and secondary prevention of cardiovascular disease, adherence to statins remains

suboptimal, compromising potential effectiveness. The Centers for Medicare and Medicaid Services (CMS) utilizes the proportion of days covered (PDC) as a measure for medication adherence, with a PDC > 80% considered optimal. PDC provides a single value to represent a follow-up period but cannot fully capture variations in adherence behavior patterns. These patterns should be considered when designing interventions, as they may influence prognosis. Our objective was to characterize different adherence patterns using group-based trajectory models among statin users in a MAP. **METHODS:** This project utilized data from a Texas MAP. Patients enrolled from January 2013 to June 2016 with prescription claims were included. The index date was defined as the first statin prescription between January to June 2015, and baseline characteristics were determined from the period 2 years prior to index. Patient adherence was assessed for 1 year after. Monthly PDCs were calculated during the follow-up and dichotomized as adherent (PDC >0.8) or not. Twelve monthly PDC values were then modeled as a longitudinal response in logistic group-based trajectory models. Patients were assigned to a trajectory based on those models. We estimated between 2 to 6 groups for evaluation. **RESULTS:** 7,850 patients were included in the trajectory modeling. The model with 4 groups was determined the most clinically relevant for the development of tailored interventions. Trajectory groups included: (1) high or nearly perfect adherence; (2) rapid decline or discontinuation; (3) gradual decline; and (4) a gap or declining adherence that improved later. **CONCLUSIONS:** Trajectory models can depict varying patient adherence patterns and facilitate the development of tailored interventions. Future research will focus on identifying predictors associated with the identified trajectories and developing trajectory customized interventions to enhance adherence.

PCV101

GEOGRAPHIC VARIATION IN ORAL ANTICOAGULANT PRESCRIBING PATTERNS AMONG US VETERANS

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OBJECTIVES: The objectives of this study are to describe (1) recent trends in TSOAC prescriptions, (2) the source of financing for OACs prescriptions, and (3) geographic variation of provider prescribing patterns for TSOACs among VHA and Medicare dual enrollees. **METHODS:** We identified patients with a first diagnosis of AF (ICD-9-CM code 427.31 and ICD-10 codes I48.X) in the VHA Corporate Data Warehouse (CDW) between 2012 and 2016. We linked the prescriptions for OACs these patients had in the VHA and in Medicare Part D between 2012 and 2013. **RESULTS:** We identified 64,763 patients diagnosed with AF who were prescribed OACs during 2012 and 2013. There were 300,659 VHA prescriptions and 106,102 Part D prescriptions during the study period. The proportion of Medicare prescriptions increased from 23.2% in 2012 to 28.0% in 2013. Among the 18 Veterans Integrated Service Networks (VISNs), the proportion of Medicare prescriptions varied between 16.4% (VISN 12, Name) and 46.3% (VISN 4) (median=25.1%). The proportion of TSOACs increased from 18.0% in 2012 (range 11.5%–32.0% across VISNs) to 25.0% in 2013 (range 16.3%–39.0%). Dabigatran was the most prescribed TSOAC, accounting for 14.8% of all prescriptions in 2012 and 13.2% in 2013. VISN 4 had the highest rate of TSOAC adoption in 2013, with 20.0% of prescriptions for Dabigatran and 16.6% prescriptions for Rivaroxaban. Medicare prescriptions were more likely to be for TSOACs than for warfarin compared to prescriptions within the VHA system. TSOAC prescriptions increased substantially across all VISNs during the study period. **CONCLUSIONS:** There is substantial geographic variation in TSOAC prescriptions in the VHA. Dual VHA and Medicare use accounts for a significant and increasing proportion of veterans diagnosed with AF. Our results also show significant geographic variation in the adoption of novel anticoagulants within the VHA. Reliance on Medicare Part D has increased during the study period.

PCV102

UTILIZATION AND EFFECTIVENESS OF PCSK9 INHIBITORS IN IMPROVING LIPID PROFILE IN ROUTINE CLINICAL PRACTICE

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OBJECTIVES: Proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9-I) are a new class of drugs that have been shown to further reduce low-density lipoprotein cholesterol (LDL-C) by 50-70% against various background lipid-lowering therapies. We aimed to assess the use of two PCSK9-I, alirocumab and evolocumab, and compare their effectiveness in improving lipid profile to statins in routine practice. **METHODS:** Using a large U.S. administrative database, OptumLabs Data Warehouse, with linked laboratory data, we identified 798 patients who initiated PCSK9-I between 8/1/2015-7/31/2016. Among patients with lipid measurements at both baseline and follow up, we propensity score matched patients treated with PCSK9-I (alone or with statins) to those treated with statins (alone or with other non-PCSK9-I lipid lowering drugs). Patients were balanced on 40 baseline characteristics, including socio-demographics, lipid levels, comorbidities, prior lipid lowering treatment and other medication use. We used linear regression to compare the absolute change and percentage change of lipid levels. **RESULTS:** The mean LDL-C of PCSK9-I users was 122.2 mg/dL prior to the initiation of PCSK9-I, similar to those observed in the Phase III trials. However, over one third of the patients had LDL-C <100 mg/dL. Most users (72%) used non-PCSK9-I cholesterol lowering drugs (mostly statins) at baseline. In the matched cohort (N=166), over an average of 10 weeks, PCSK9-I were associated with a greater reduction in LDL-C (-14.0 mg/dL, p=0.02; -12%, p=0.01) and non-high-density lipoprotein cholesterol (-15.3 mg/dL, p=0.03; -9.4%, p=0.01) in comparison to statins. Neither drugs significantly reduced LDL-C in patients with LDL-C <100 mg/dL. **CONCLUSIONS:** PCSK9-I were commonly prescribed for patients who

either had low LDL-C or already achieved low LDL-C on statins, which is a group largely excluded from clinical trials. Consistent with trials, PCSK9- demonstrated a greater reduction in LDL-C than statins in routine clinical practice, but this benefit was not seen in patients with low LDL-C.

PCV103

ANALYSIS OF SECONDARY PREVENTION MEDICATION USE AMONG PATIENTS WITH NON-CARDIOEMBOLIC ISCHEMIC STROKE IN BEIJING

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OBJECTIVES: To describe the secondary prevention medication use of patients with non-cardioembolic ischemic stroke in Beijing, China. **METHODS:** This was a retrospective cohort study using Beijing Urban Employee Basic Medical Insurance database. Patients (≥ 18 years old) hospitalized with a primary diagnosis of non-cardioembolic ischemic stroke (index event) between Oct.01 2012 and Dec.31 2014 were included. High-risk patients were further identified by Essen Score ≥ 3 , with absence of smoking information in the database. The period from 2 years prior to index date to Dec 31 2015 or death (whichever comes first) was observed to analyse baseline characteristics and secondary prevention medication usage. **RESULTS:** In total 33,730 patients were included in the study, with mean age of 67.1 years and 68.7% male. Among which, 59.1% were high-risk patients. During the index hospitalization, 85.4% of the total patients received antiplatelet medication, 83.7% of patients combined with hyperlipidaemia received lipid-lowering medication, 78.2% of those with hypertensive received antihypertensive medication, and 70.1% of those with diabetic patients received antidiabetic medication. The percentages decreased to 43.1%, 44.1%, 50.6% and 43.4% during 10-12 month after index hospitalization, respectively. Similar trend was found among the high-risk patients: 84.3% with antiplatelet medication, 81.8% with lipid-lowering medication, 79.6% with antihypertensive and 68.6% with antidiabetic medication at index hospitalization; but decreased to 42.7%, 41.7%, 49.0% and 41.2% during 10-12 month after index hospitalization, respectively. Among the patients treated with antiplatelet therapy at index hospitalization, 50.1% used aspirin, 23% clopidogrel and aspirin, and 19.2% clopidogrel. 39.9% of those patients experienced antiplatelet therapy modification during follow-up period. **CONCLUSIONS:** More than half of the included stroke patients were high-risk patients. The secondary prevention medication usage was suboptimal in the clinical practice even for high-risk patients. Efficient intervention is needed to improve the adherence to guideline.

PCV104

PRESCRIPTION PATTERNS OF ANTIHYPERTENSIVE MEDICINES IN CHINA: A DESCRIPTIVE ANALYSIS IN REAL-WORLD CONDITIONS

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OBJECTIVES: Hypertension is one of the key risk factors for cardiovascular disease, stroke and renal failure. Limited data is available on prescription patterns of the antihypertension in China in recent years. The objective of this study was to assess the prescription patterns of antihypertensive medicines for outpatients in the real-world conditions in China. **METHODS:** A cross-sectional study was conducted to describe the current prescribing practices for outpatients diagnosed with hypertension, from May 2011 to May 2015. Prescribing patterns of antihypertensive medicines were analysed, including monotherapy, two-drug combination therapy and three-drug combination therapy. For each pattern, prescriptions of different classes of medicines were studied. In addition, different drugs in each class were described for monotherapy. **RESULTS:** A total of 18,562 outpatients were included in the study, 51% was female, age ranged from 14 to 107 years old. The prescription analysis indicated that monotherapy pattern was the most frequently prescribed (55.6%), followed by two-drug combination (30.9%) and three-drug combination (13.5%). Calcium channel blockers (CCBs) ranked the highest as monotherapy (55.0%). The combination of CCBs and angiotensin-I receptor blockers (ARBs) or CCBs and angiotensin-converting-enzyme inhibitors (ACEIs) accounted for the highest proportion in two-drug therapy (39.3%). The combination of CCBs, ARBs/ACEIs and beta blockers (BB) was the most frequently prescribed in three-drug therapy (37.7%). Additionally, in monotherapy, Amlodipine was the most prescribed agent in CCBs class (56.5%). In the other classes, Valsartan in ARB or ACEI class (35.0%), Indapamide in DI class (41.1%), Bisoprolol Fumarate in BB class (42.2%), and Terazosin Hydrochloride in the others (57.5%). **CONCLUSIONS:** The result observed that majority of outpatients in this study were prescribed monotherapy, followed by two drugs, a few required three of drugs. It is found that the most frequently used class of antihypertensive drug was CCBs, of which Amlodipine was the most frequently prescribed drug.

PCV105

ANALYSIS OF STATIN PRESCRIPTION FOR DYSLIPIDEMIA WITH THE NATION-WIDE HEALTH INSURANCE CLAIMS DATA IN JAPAN: A REPEATED CROSS-SECTIONAL STUDY

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OBJECTIVES: Although statin therapy for dyslipidemia is recommended widely in the world, the age ranges recommended by clinical guidelines differ among countries. In Japan, there is great interest in how statin is prescribed specially for very elderly population because of facing an unprecedented aging society. However, little is known about how statins are used in the real world. This study aimed to exam the state of statin prescription in Japan. **METHODS:** The prevalence of statin prescription for dyslipidemia in Octobers between 2011 and 2014 was measured with randomly sampled outpatient data from the national claims database that

covered over 90% of the domestic patients. The rate of sampling was 1%. We analyzed the prevalence stratified by age and sex to adjust the covariates. **RESULTS:** Of 136613 patients with dyslipidemia in 2011, 49.8% was used statins. After the year, the prevalence was increased (52.4% n=145215, in 2012; 56.6% n=150428, in 2013; 56.7% n=155999, in 2014; p for trend <0.001). In 2014, the prevalence was higher in women than men (68.7% vs 59.2%, p<0.001) and differed among age groups of 64-year-old and younger, 65 to 74, 75 to 84 and 85-year-old and older (51.4%, 75.7%, 69.4% and 73.4%, respectively, p<0.001). **CONCLUSIONS:** In Japan, the prevalence of statin prescription for dyslipidemia has increased recently. Most of very elderly patients with dyslipidemia used statins. Further study is needed to evaluate the cost-effectiveness of statin use in very elderly patients.

PCV106

ASSOCIATION BETWEEN PRIMARY CARE ACCESS AND ACUTE CARE UTILIZATION FOR HYPERTENSION: A SYSTEMATIC REVIEW

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OBJECTIVES: Conditions for which hospitalizations can be avoided through timely and effective outpatient care are often referred to as ambulatory care sensitive conditions (ACSC). These conditions can generally be managed effectively in a primary health care setting however the expected inverse association between primary health care access and ACSC hospitalizations is not strongly supported in the medical literature. We conducted a systematic review to assess the association between primary care access and hospitalizations and/or emergency department visits for hypertension, an ambulatory care sensitive condition. **METHODS:** We searched electronic databases (Medline and Embase) from inception to October 2015 to identify all observational studies evaluating the association between primary care access and hospitalizations and/or emergency department visits for patients diagnosed with hypertension. Study quality was assessed using components of the Newcastle Ottawa Scale and the Downs and Black Checklist. **RESULTS:** Our search strategy yielded 4170 articles and of the 42 potentially relevant articles, three met criteria for inclusion within our review. Results and metrics used to assess this association varied substantially across the three studies. Two studies found a positive correlation between the number of primary care visits or general practitioner density and hospitalization rates for hypertension, while one study found increases in general practitioner density resulted in a reduction in hospitalization rates for hypertension. Study quality also varied with few studies adjusting for key patient- and system-level factors and severity of hypertension. **CONCLUSIONS:** There is limited and inconclusive evidence on the relationship between access to primary care and acute care utilization for hypertension. Further research adjusting for disease severity and key confounders is required to elucidate this relationship.

PCV108

CHOLESTEROL MANAGEMENT BY US HEALTH PLANS

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OBJECTIVES: Many of the agents to treat hypercholesterolemia have become generically available. In recent years, newer targeted therapies have become available with different targets, higher prices and requiring clinician-administration. To understand how US managed care (MC) plans were using the various tools available to manage their formularies and members with hypercholesterolemia, hyperlipidemia and high triglycerides. **METHODS:** Managed care medical directors and pharmacy directors completed an online interactive survey. Topics included: advisor and plan information, copays and drug/treatment usage of different classes for cholesterol management (classifying as: Unrestricted, 1st tier, 2nd tier, 3rd tier, or requiring prior authorization [PA]). **RESULTS:** There were 54 responses () between December-16 and January-2017. Fifty-nine percent of respondents were Medical Directors, with the remainder comprised mostly of pharmacists who mostly worked for a health plan (62.3%). The health plans were 41.1% national, 30.4% regional, and 28.6% local. Plans could cover multiple types of members and 79.6% covered commercial lives, 61.1% Medicaid; 68.5% Medicare. Responses identified the highest PA rates were for: Proprotein Convertase Subtilisin/Kexin type 9 (PSC9s) inhibitors (alirocumab and evolocumab)=84.62%, lomitapide=71.1%. The PSC9s are injected, require self-administration training, and will likely be subject to a specialty copay. Classes with generic options were often first tier and included statins=47.2%, triglycerides management products=33.3%; and fibrates=29.4%. Combination cholesterol agents=44.2% and cholesterol/cardiovascular combinations=43.1% and were mostly in tier 2. While over the counter fish-oil products and supplements were generally unrestricted in Medicaid plans, not covered by Commercial or Medicare plans; the prescription therapy icosapent was PA restricted by 17.3% of plans. The most common tier 2 products included ezetimibe (40.4%) followed by the bile-acid sequestrants (32.7%). **CONCLUSIONS:** As new products enter the cholesterol management market, health plans will likely impose restrictions and plan designs on new classes favoring less expensive generically available agents until real world effectiveness data becomes available.

PCV109

NON-ADHERENCE TO STATINS AND ANTIHYPERTENSIVE MEDICATIONS AND HOSPITALIZATIONS AMONG ELDERLY FEE-FOR-SERVICE MEDICARE BENEFICIARIES WITH PRE-EXISTING CORONARY ARTERY DISEASE AND INCIDENT CANCER

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OBJECTIVES: To examine the relationship between adherence to both statins and ACEIs/ARBs/beta-blockers and coronary artery disease (CAD)-related

hospitalizations. **METHODS:** A retrospective observational longitudinal study was conducted using SEER-Medicare data. Elderly Medicare fee-for-service beneficiaries with pre-existing CAD and incident breast, colorectal, or prostate cancer (N = 12,096) were observed for a period of 12 months before and 12 months after cancer diagnosis. Hospitalizations measured every 120-days were categorized into three groups: (1) any CAD-related hospitalization; (2) other hospitalizations; or (3) no hospitalization. Medication adherence was categorized into five mutually exclusive groups: (1) adherent to both statins and ACEIs/ARBs/beta-blockers (reference group); (2) not adherent to both statins and ACEIs/ARBs/beta-blockers; (3) adherent to either statins or ACEIs/ARBs/beta-blockers; (4) use of one medication class and adherent to that class; or (5) use of one medication class and not adherent to that medication class. The unadjusted and adjusted relationship between medication adherence and hospitalization was analyzed using repeated measures multinomial logistic regressions. Inverse probability treatment weights were used to control for observed group differences among medication adherence categories. **RESULTS:** Adherence to both statins and ACEIs/ARBs/beta-blockers was estimated at 31.2% during the 120-day period immediately after cancer diagnosis; 13.7% were not adherent to both medication classes during the same period; 27.4% had CAD-related hospitalizations immediately after cancer diagnosis and this percentage declined to 10.6% during the last four months of the post-cancer period. In the adjusted analyses, those not adherent to both statins and ACEIs/ARBs/beta-blockers were more likely to have CAD-related hospitalization compared to those who were adherent to both medication classes [AOR = 1.82; 95% CI = 1.72, 1.92; P < 0.0001]. **CONCLUSIONS:** Given the complexity of interaction between CAD and cancer, it is important to routinely monitor medication adherence in general clinical practice and provide linkages to support services that can increase medication adherence.

PCV110

CLINICAL AND ECONOMIC BURDEN OF TRANSFUSION IN CARDIAC SURGERY: A SYSTEMATIC REVIEW

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OBJECTIVES: We conducted a systematic review to identify published evidence from observational studies on the clinical and economic burden of transfusion in cardiac surgery. **METHODS:** We searched Embase, Pubmed and the Centre for Reviews and Dissemination (CRD) suite of databases for English language articles and analyzed these qualitatively. The search was limited to evidence published in the last 10 years (2006-2016). **RESULTS:** The review identified 16 publications and 15 were observational study design. Majority of the studies examined patients undergoing coronary artery bypass graft (CABG) and aortic valve replacement (AVR). The rate of transfusion ranged from 15% to 84% in those patients who experienced excessive bleeding after cardiac surgery. A significant reduction in transfusion rates and red blood cell (RBC) usage was observed with patients who did not experience bleeding, use blood conservation strategies and less invasive surgical techniques (n=6). Platelet use ranged from 9.8% to 84% and was significantly higher in patients who experienced bleeding or underwent re-exploration (n=5). Fresh Frozen Plasma (FFP) use ranged from 2.4% to 63% (n=5) and there was a significant difference in units of FFP transfused in patients with post-operative bleeding and re-exploration (n=2). Transfused cardiac surgery patients had significantly longer hospital stays, were more frequently hospitalized and utilized more ICU services. Total costs of blood and transfusions were highest in the United States and correlated significantly with transfusion rate. Mortality data (n=5) showed that patients who received transfusion had higher in-hospital (1.7%-3.07%) and long-term (5.8%-6.4%) mortality and a dose-dependent relationship between unit of packed RBC and higher odds for post-operative mortality. **CONCLUSIONS:** Transfusion of blood products and the resultant higher resource utilization in cardiac surgery patients pose substantial clinical burden to the patient and economic consequences to the hospital/health system. Reducing both factors has the potential to reduce patient morbidity and healthcare cost.

PCV111

CLINICAL AND ECONOMIC BURDEN OF BLEEDING IN CARDIAC SURGERY: A SYSTEMATIC REVIEW

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OBJECTIVES: We conducted a systematic review to identify published evidence from observational studies on the clinical and economic burden of bleeding in cardiac surgery. **METHODS:** We searched Embase, Pubmed and the Centre for Reviews and Dissemination (CRD) suite of databases for English language articles and analyzed these qualitatively. The search was limited to evidence published in the last 10 years (2006-2016). Relevant studies were identified using a priori defined inclusion and exclusion criteria relating to the burden of bleed in a mixed cardiac surgery population. **RESULTS:** The review identified 13 publications all based on observational study design. Majority of the studies examined patients undergoing coronary artery bypass graft (CABG) (n=6) and aortic valve replacement (AVR) (n=3). The rate of bleeding ranged from 94.2% in those requiring re-exploration and 4.94% in those with more than one complication. On average (n=6), bleeding and complications lead to significantly higher rates of re-exploration (1.2% to 50%) compared to patients without bleeding events or complications. The length of intensive care unit (ICU) (n=3) and hospital (n=4) stay was significantly shorter in those with no/minor bleeding compared to those

who experienced major bleeding. Post-operative ventilator use (n=6) ranged from 8.8% to 35.5% in those who experienced bleeding. Mortality increased for patients who underwent re-exploration or experienced uncontrolled bleeding; 1.9% to 21.1% operative death and 3.1% to 22.4% 30-day mortality. Eleven publications found significant higher average cost of cardiac surgery for those who experienced peri-operative bleeding and re-operation due to bleeding. **CONCLUSIONS:** Bleeding related complications and higher resource utilization in cardiac surgery patients who experience uncontrolled surgical bleeding pose substantial clinical burden to the patient and economic consequence to the hospital/health system.

PCV112

ESTIMATED ANNUAL NUMBER OF US ACUTE-CARE HOSPITAL INPATIENTS MEETING ACCP CRITERIA FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS

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OBJECTIVES: To use the most recent available data (Y2014) to estimate the annual number of US acute-care hospital inpatients who could benefit from venous thromboembolism (VTE) prophylaxis. **METHODS:** We applied the 2012 American College of Chest Physicians (ACCP) Consensus VTE prophylaxis guideline to hospitalized patients based on the Clinical Classification System (CCS) codes for major surgery and acute medical illnesses available from the National Inpatient Sample (NIS), a nationwide acute-care hospital database sponsored by the US Agency for Health Care Quality and Research. **RESULTS:** Of a total of 35.4 million inpatients discharged from US acute-care hospitals in Y2014, 11.6 million (33%) matched the ACCP risk criteria for VTE prophylaxis. When ACCP surgical risk criteria were applied to 7.5 million patients who had a procedure in an operating room, 4.4 million (59%) were found to be at VTE risk; and, among 20.8 million evaluable medical patients, 7.1 million (34%) met ACCP criteria for VTE prophylaxis based on non-surgical VTE risk factors. **CONCLUSIONS:** Approximately one-third of all patients hospitalized in the US meet ACCP criteria for VTE prophylaxis due to risk factors associated with surgery and/or an acute medical illness. Given that approximately 60% of all VTE events occurring in the community are related to recent acute-care hospitalization, providing universal, safe and effective VTE prophylaxis to this population affords an important opportunity to significantly reduce the incidence of VTE and to reduce the rate of hospital readmissions. These data provide support for developing and monitoring compliance with hospital-wide guidelines for VTE prevention. In addition, these data can support the estimation of costs and benefits of providing VTE prophylaxis to at risk US hospitalized patients.

PCV113

CARDIOVASCULAR DISEASE PATTERN IN OUTPATIENT DEPARTMENT OF GONDAR UNIVERSITY REFERRAL HOSPITAL: A 6 YEAR RETROSPECTIVE CROSS SECTIONAL STUDY

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OBJECTIVES: The aim of this study is to assess the pattern of cardiovascular diseases and associated factors in outpatient department of cardiac clinic of Gondar university referral hospital. **METHODS:** A retrospective cross-sectional study was employed to describe pattern of cardiovascular diseases among patients registered and started follow-up at the outpatient chronic illness clinic of Gondar University Referral Hospital during the period from October, 2010 – October, 2015. The data was collected from August, 2015 till December, 2015. The collected data were cleaned, entered and analyzed in SPSS for Windows version 20.0. Chi square and binary logistic regression was performed to test significant difference among predictive variables and cardiovascular diseases. **RESULTS:** Out of 1105 patient medical records 862 fulfilled the inclusion criteria. Majority of the patients were females (65%) and living in urban (62.7%). Two third (65.2) of cardiovascular patients were above 50 years old and a quarter of CVD patients were in age range of 50-59. In 37.7% of patients headache was the reason for first time visit to hospital and to be diagnosed for CVDs. Hypertension accounts for the majority (62.3%) of cardiovascular patients followed by heart failure (23.9%). Dyslipidemia (86.2%), Hypertension (72.8%) and Ischemic heart diseases (73.2%) were associated with urban residency (p<0.01). Patients from rural (COR=1.306 (1.026-2.166), AOR=1.272(1.017-2.030)) and patients with additional illnesses (COR= 1.813(1.279-2.782), AOR =1.551(1.177- 2.705)) were more likely to poor cardiovascular disease outcome by the physician assessment on their last follow up (p<0.05, CI- 95%). **CONCLUSIONS:** Hypertension was found to be the most frequent cardiovascular disease followed by heart failure; and hypertensive heart disease was the leading cause of cardiac diseases. Most of the patients had improved assessment by their physician on their last follow up, but patients from rural and with Comorbidity conditions were risks to increase poor cardiovascular outcome.

PCV114

CHRONIC HEART FAILURE TREATMENT IN THE US: CHALLENGING ENVIRONMENT FOR NEW BRANDED AGENTS IN GENERICIZED MARKET

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OBJECTIVES: In chronic heart failure (CHF) the standard of care is comprised of inexpensive evidence-based generic agents. Novel CHF therapies sacubitril/valsartan and ivabradine offer improvements in clinical outcomes and are attractive treatment options for patients who continue to suffer from high mortality and

morbidity rates. However, in a highly-genericized CHF market, prescribing of these therapies could result in significantly increased expenditures in an environment of tightening healthcare budgets for U.S. insurers. This research explores how payers and physicians interact and how reimbursement decisions impact the prescribing of novel CHF therapies. **METHODS:** In September 2016, 72 cardiologists and 71 primary care physicians across the U.S. were surveyed regarding their current prescribing of sacubitril/valsartan and ivabradine. Thirty U.S. managed care organization pharmacy and medical directors were also surveyed. **RESULTS:** Despite being viewed as more efficacious than standard of care CHF therapies by surveyed cardiologists, sacubitril/valsartan is being prescribed to only a fraction of CHF patients. Cost-related issues, unfavorable payer coverage, and restrictions set by payers are major barriers to prescribing of sacubitril/valsartan and ivabradine by surveyed physicians. For 35-45% of physicians, payer-imposed restrictions have contributed to them not prescribing these drugs to eligible patients. Meanwhile, cost drives formulary inclusion decisions for 47% of surveyed payers, who impose significant access and reimbursement restrictions on sacubitril/valsartan and ivabradine. Prior authorization is the main cost-containment strategy, employed by over 50% of surveyed payers. One strategy being explored to overcome the barriers to drug access is engagement in outcomes-based contracts, whereby payers reward good outcomes through improved formulary placement of the drug or a credit toward rebates given. **CONCLUSIONS:** In a highly-genericized CHF market, health plans provide less-favorable coverage and reimbursement for the premium-priced therapies. Engaging in OBC may be one way forward for manufacturers to get better coverage of their drugs and demonstrate their cost-effectiveness.

PCV115

PCSK-9 INHIBITORS – COVERAGE AND COST-SHARING FOR MEDICARE PART D BENEFICIARIES NATIONWIDE

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OBJECTIVES: PCSK9 inhibitors are effective in reducing low-density lipoprotein cholesterol (LDL-C) among persons with familial hypercholesterolemia or pre-existing cardiovascular disease (CVD) whose LDL-C levels remain high on maximally tolerated statin therapy. However, the expense of PCSK9 inhibitors (> \$14,000/year versus < \$120 for generic statins) can pose substantial burden on patients' out-of-pocket costs and on insurers' drug expenditures. This is of particular concern for Medicare given the high prevalence of CVD (27% ischemic heart disease) and hyperlipidemia (45%) among Medicare beneficiaries. We examined coverage and cost-sharing for PCSK9 inhibitors (alirocumab and evolocumab) in Medicare Part D plans. **METHODS:** Data came from the June 2016 Centers for Medicare and Medicaid Services Prescription Drug Plan Formulary, Pharmacy Network, and Pricing Information Files for Part D plans. We determined: 1) the proportion of plans providing coverage, 2) monthly and annual out-of-pocket cost, and 3) total drug cost (plans' 30-day retail cost), averaged across 2,575 Part D plans in 50 states and the District of Columbia. We projected beneficiaries' annual out-of-pocket costs under a standard 2016 Part D benefit with a \$360 deductible and a coverage gap, where cost-sharing increased when beneficiaries' total drug expenditures exceeded the \$3310 threshold set for 2016. **RESULTS:** As of June 2016, alicumab and evolocumab were covered by 87% and 42% of plans, respectively. Required mean monthly out-of-pocket costs were high for both drugs: \$336 for alicumab and \$321 for evolocumab. Beneficiaries would have entered the coverage gap in March even without filling any other prescriptions, with projected annual cost-sharing of \$4988 for alicumab and \$4958 for evolocumab. This represented 35% of the annual total drug costs (\$14814 for alicumab and \$13596 for evolocumab). **CONCLUSIONS:** The substantial cost-sharing required for PCSK9 inhibitors for Medicare beneficiaries covered by Part D may adversely affect their real-world access and adherence.

PCV116

EVALUATION OF AWARENESS REGARDING HYPERTENSION AMONG HYPERTENSIVE PATIENTS OF PUNJAB, PAKISTAN

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OBJECTIVES: The present study aimed to evaluate the knowledge among hypertensive patients. **METHODS:** A questionnaire based descriptive, cross-sectional study was conducted in the outpatient setting of Benazir Bhutto hospital Rawalpindi, Sir Ganga Ram hospital Lahore, Nishtar hospital Multan and Bahawal Victoria hospital in Bahawalpur, Pakistan. Knowledge regarding hypertension was assessed by using Hypertension Fact Questionnaire. Statistical package for social sciences (SPSS) version 20.0 was used to analyze data. Descriptive statistics was used to summarize data and chi square test was used to assess the association between categorical and dependent variable. Non parametric tests (Mann Whitney U test and Kruskal Wallis test) were used to find statistical difference in the scores based on categorical variable. **RESULTS:** Among the 340 participants, mean age (SD) was 50.25 (11.49), with 60.6% of females dominating the entire cohort. Majority of the participants (73.6%) belonged to urban area. About 35.6% had HTN for more than 5 years, 53.5% had family history of hypertension and 53.2% had hypertension along with co-morbidity. The mean score of hypertension knowledge was 8.43±3.44. The result of the study demonstrated that hypertensive patients have average knowledge. **CONCLUSIONS:** The current study findings revealed the importance of educational programs to increase the awareness of the patients regarding the importance of lifestyle modifications and medication for control of disease.

PCV117

POSSIBILITIES OF INCORRECT BLOOD PRESSURE MEASURING – COMPARISON TRIAL OF VALUES MEASURED WITH DIFFERENT TOOLS

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OBJECTIVES: Hypertension is endemic in Hungary today. Incorrect measuring tool of blood pressure can be responsible for hypertension diagnosed improperly. Our goal was to examine differences between values measured with different tools. **METHODS:** Our survey was a quantitative, cross-sectional study in the Kaposi Mór Teaching Hospital Outpatient care unit, Somogy County, Hungary in 2016. Non-randomized, purposive sampling was used to enroll patients between 18-85 years of age. (N=201). Exclusion criteria were: pregnancy, injured, amputated, paralyzed, fractured arm, having lymphoedema, contracture, chimino fistule, midline iv. catheter or other that can hinder correct measuring on the upper arm. We used mercurial, aneroid, oscillometric, patient-monitor attached blood pressure meters. Descriptive and mathematical statistics (t-test, chi-square test, ANOVA) were made on MS Excel software (p<0.05) **RESULTS:** ANOVA statistics approved significant difference between systolic and diastolic parameters measured by different tools. (p<0.05) Post-hoc analysis showed significant difference between systolic values measured by mercurial and monitor-attached, and aneroid and monitor-attached oscillometric measuring (p<0.05). From the aspect of the diastolic values, we found significant differences between mercurial and monitor/oscillometric device. There is also a significant difference between the aneroid and monitor/oscillometric measuring. (p<0.05) **CONCLUSIONS:** We can consider mercurial and aneroid blood pressure meters accurate, the monitor- and oscillometric devices recorded higher blood pressure rates. It is important – especially in patients with hypertension – to control the blood pressure with validated measurement tools in the everyday practice.

PCV119

CLINICAL CHARACTERISTICS AND PROGNOSIS OF HEART FAILURE PATIENT'S WITH REDUCED AND PRESERVED EJECTION FRACTION ADMITTED TO UNIVERSITY OF GONDAR REFERRAL HOSPITAL, NORTH WEST ETHIOPIA: A RETROSPECTIVE COHORT STUDY

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OBJECTIVES: The aim of this study is to outline the clinical characteristics and medication profile, assess the survival status and prognostic factors of Ethiopian HF patients with HFrEF and HFpEF. **METHODS:** A retrospective cohort study was carried out and we employed medical records of patient's, admitted as a result of HF to the University of Gondar Referral Hospital in the period between December 02, 2010 and December 01, 2015 due to HF. **RESULTS:** Of the 850 patients who were admitted due to HF, 311 patients met the inclusion criteria. Majority of the patients had HFpEF (52.73%) and tend to be women (76.22%) . They predominantly had etiologies of valvular and hypertensive heart diseases, and took calcium channel blockers and anticoagulants. Conversely, patients with HFrEF had etiologies of ischemic heart disease and dilated cardiomyopathy and were prescribed angiotensin converting inhibitors (ACEI) and beta blockers. Kaplan Meier curves and Log rank test (p= 0.807) showed that there was no statistically significant difference in the mortality difference among patients with HFpEF and HFrEF. On the other hand, Cox regression analysis showed advanced age, lower sodium level, higher creatinine level and absence of medications like ACEI, spironolactone and statins independently predicted mortality in all HF patients. **CONCLUSIONS:** Different clinical characteristics were found in both groups of HF patients. There was no difference in survival outcome between patients with HFrEF and HFpEF. A retrospective cohort study was carried out and we employed medical records of patient's, admitted as a result of HF to the University of Gondar Referral Hospital in the period between December 02, 2010 and December 01, 2015 due to HF. Kaplan Meier curve was used to analyze the survival status and log rank test was used to compare the curves. Cox regression was used to analyze independent predictors of mortality in all HF patients.

PCV120

TREND IN 30-DAY READMISSION RATES AMONG PATIENTS WITH ACUTE MYOCARDIAL INFARCTION: RESULTS FROM A LARGE, SINGLE HEALTHCARE ORGANIZATION

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OBJECTIVES: Hospital readmissions can be proxy of poor health and quality. Reducing readmission rates has been a priority for healthcare providers and payers. We examined the trend over time in 30-day all-cause readmission rates among patients with AMI in a large, single healthcare network of 11 hospitals in the Chicagoland area. **METHODS:** AMI patients admitted from 2008 to 2016 who were 18 years or older, discharged to home self-care, home health, or home infusion were included in the analysis. Adjusted logistic regression with Generalized Estimating Equations was used to account for clustering of multiple admissions within patients. Additionally, the model adjusted for age, gender, race, insurance, length of hospital stay, and discharge disposition. **RESULTS:** Records of 15,243 patients were analyzed and it was determined that 10% of these patients were readmitted within 30 days. The Majority of the patients in the sample were males (62%), primarily White (60%), and were discharged to home (76%). The Average age of the sample was 65 years (±13.7) and more than half (55%) had public insurance (i.e., Medicare & Medicaid). Patients who were readmitted were slightly older (67 vs 65 years) and had longer length of stay (5 vs 4.1 days). Females, patients with public

insurance, and those who were discharged to home health were more likely to be readmitted. A significant downward trend over time was observed in 30-day readmission rates in the fully adjusted model (OR=0.96; CI=0.94-0.97). **CONCLUSIONS:** We found a significant reduction in 30-day readmission rates over time between the years 2008 and 2016. This reduction is substantial as it reduces both physical and economic burden of readmissions on our patients and healthcare system and remains a significant quality measure closely linked to incentives and penalties for care providers by the private and public payers.

PCV121

THE EFFECT OF PATIENT EDUCATION PROGRAM ON HYPERTENSION-RELATED KNOWLEDGE AMONG USERS OF COMPLEMENTARY AND ALTERNATIVE MEDICINES

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OBJECTIVES: To assess hypertension-related knowledge among patients pursuing complementary and alternative medicines (CAM) as a way of self-care; and find the differences in patient's knowledge following educational intervention. **METHODS:** The study was conducted between May to December 2015 among hypertensive patients attending two major teaching hospitals in Baghdad, Iraq. A cross-sectional design was adopted; and a convenience sampling technique was used for patients' recruitment. Data collection based on the use of standard validated questionnaire for patient assessment on enrollment and follow-up clinical visit thereafter. Patients were engaged in two separate CAM education sessions and a four-page booklet was used for the purpose of education. **RESULTS:** Inadequate knowledge towards hypertension (mean=6.94±3.2) was prevalent among the respondents. A significant difference in hypertension-related knowledge was seen among CAM users and non-users (P=0.007). Where, CAM users were less (mean=6.69±3.3) in their level of hypertension-related knowledge than CAM non-users (mean=7.64±3.4). This was affected by demographic characteristics like gender (P=0.004), education (P<0.001), monthly income (P=0.002), and marital status (P=0.003). However, a significant improvement in patients' knowledge was detected following the enrollment in the education program (P<0.001). **CONCLUSIONS:** Hypertension-related knowledge was inadequate among Iraqi hypertensive patients pursuing CAM as a way of self-care. This poor knowledge among CAM users was affected by diverse patient's characteristics like gender, education, monthly income, and marital status. A significant improvement in hypertension-related knowledge was seen following the educative information. The education program was effective and provide reliable information for the purpose of patient's education in the context of CAM.

PCV122

DELAYING TREATMENT WITH CHOLESTEROL-LOWERING MEDICATIONS IN PATIENTS MEETING NEW TREATMENT GUIDELINES: A RETROSPECTIVE COHORT ANALYSIS

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OBJECTIVES: The 2013 American College of Cardiology/American Heart Association (ACC/AHA) guidelines may expand eligibility for cholesterol-lowering therapy to a large number of new users. The objective of this paper is to document the potential for this expansion in to improve clinical outcomes and reduce cost. **METHODS:** Patients meeting 2013 guideline classification criteria were identified using Humana data [2007-2013] and divided into three groups: elevated LDL [identified in earlier guidelines], selected diabetes patients and patients with atherosclerotic cardiovascular diseases [ASCVD]. Patients with no pre-classification cholesterol treatment were then selected and divided in two treatment groups: early [before any CVD event] and late/never treated. The clinical outcomes were the time to four separate events [AMI, stroke, coronary stenting, coronary artery bypass graft surgery (CABG)]. Costs were measured over the first year following a risk classification. Clinical outcomes were analyzed using Cox proportional hazards models. Costs were analyzed using generalized linear models [GLM] and the RAND two-step model for hospital costs. **RESULTS:** 237,856 people were classified according to ACC/AHA guideline criteria and met study inclusion/exclusion criteria. Only 3.5% of study patients fell into the elevated LDL risk group identified under previous guidelines and 65% of these patients were treated 'early.' Early treatment rates were lower for ASCVD patients [37%] and diabetes patients [46%]. Early treatment significantly reduced event risks [H.R 0.26 to 0.34, p<0.0001] across the 4 events and reduced cost over the first year -\$3,607 [p<0.001]. Early treatment was most effective in the 'new' ASCVD risk group which was the largest, at highest risk, and most expensive to treat of the 3 ACC/AHA risk group. **CONCLUSIONS:** The 2013 treatment guidelines for cholesterol-lowering therapy will significantly increase the number of patients eligible for treatment. However, all eligible patients must receive 'Early' treatment to experience reduced CVD event risk and lower health care.

INDIVIDUAL'S HEALTH – Clinical Outcomes Studies

PIH1

ASSOCIATION OF SEDATIVE HYPNOTICS AND FALL RISK IN COMMUNITY-DWELLING OLDER ADULTS WITH CHRONIC CONDITIONS: A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: Degree of fall risk attributed to sedative hypnotics in older adults is unclear when complicated by chronic conditions with underlying fall

risk. Accordingly, the objective of this review was to assess the risk of falling, fall-related fractures, and fall-related hospital admissions in community-dwelling older adults with chronic conditions who are prescribed sedative hypnotics. **METHODS:** PubMed, PsychInfo, CINAHL, and ClinicalTrials.gov were searched using keywords such as "sedative hypnotic," "fall-risk," and "older adult." Criteria for article inclusion were: 1) English-language; 2) peer-reviewed; 3) published between 1980-2016; 4) experimental or quasi-experimental study designs; 5) adults > 65 years of age; 6) adults with a chronic condition that increases baseline risk of falling (diabetes, heart disease, atrial fibrillation, hypertension, osteoporosis, depression, cancer); 7) adults with a fall from the same level in the community setting; and 8) adults prescribed 1 or more benzodiazepine(s) or z-hypnotic(s) indicated for insomnia (triazolam, temazepam, flurazepam, zolpidem, (es)zopiclone, zaleplon). Exclusions were verified by a second independent investigator. Quality assessment utilized the Mixed Methods Appraisal Tool (MMAT). **RESULTS:** After full-text review, 5 articles were retained. Studies used cross-sectional or single-group longitudinal designs, with MMAT quality scores of 50%-75% and sample sizes ranging from 124-1,062. Only one study assessed fracture risk and no studies assessed healthcare utilization. The risk of falls was inconsistent across studies and population subgroups. For example, benzodiazepines increased the odds of falling by 18 times (OR: 18.22, 95% CI 2.71-122.38) in older adults with atrial fibrillation. However, sedative hypnotics did not statistically significantly increase odds of falling in older adults with stroke (OR: 2.3, 95% CI 0.76-6.76). **CONCLUSIONS:** Increased risk of falling attributable to use of sedative hypnotics in older adults may vary based on underlying chronic conditions. Further studies should investigate contributors to fall risk in older adults with specific types of chronic conditions.

PIH2

ASSESSMENT OF THE SAFETY AND EFFICACY OF LONG-TERM ACTING REVERSIBLE CONTRACEPTIVE METHODS (LARC) COMPARED TO CONVENTIONAL METHODS (NON-LARC) IN ADOLESCENTS: A META-ANALYSIS

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OBJECTIVES: The aim of this study was to analyze the efficacy and safety of long-acting reversible contraceptive methods (LARC) compared to conventional contraceptive methods in adolescents. **METHODS:** We performed a systematic search in Medline, Embase, Lilacs and the Cochrane Database from inception to May 2016, for observational studies and randomised controlled trials comparing the use of LARC versus non-LARC in adolescents. Two reviewers independently selected studies, assessed quality, and extracted data. Discrepancies were resolved through consensus. The outcomes were adherence, pregnancy rate, adverse events, abortion rates, and adolescent's contraception choice. We used the RevMan 5.0 to combine results across studies. We derived risk ratios (RRs) and mean differences with 95% CIs using a random-effects meta-analytic model. **RESULTS:** Nine relevant studies were included. LARC's 12 months adherence is better than non-LARC (RR 1.38 [95% CI 1.01 - 1.87]); analyzing only more recent studies, those since 1999, an even better 12 months adherence (RR 1.53 [95% CI 1.05 - 2.23]) was observed. There was no difference between LARC and non-LARC concerning the pregnancy rate (RR 0.46 [95% CI 0.09 - 2.52]). Also, there was no difference between the methods in relation to adverse events (RR 0.78 [95% CI 0.59 - 1.03]), abortion rates (RR 1.88 [95% CI 0.07 - 47.60]). Adolescent's contraception choice favored non-LARC (RR 0.63 [95% CI 0.33 - 1.19]). **CONCLUSIONS:** LARC presents better adherence with no difference in relation to the pregnancy and abortion rates. Also, there is no difference concerning adverse events between LARC and non-LARC. Notwithstanding, non-LARC is still preferred by the adolescents, although without statistical significance. We conclude that LARC has potential benefits on preventing unplanned pregnancy among adolescents. However, it is noteworthy that most of the included studies are from the 1970's and the absence of more recent studies comparing new available technologies may impact our results.

PIH3

POTENTIAL DRUG-DRUG INTERACTIONS IN PEDIATRIC WARDS OF GONDAR UNIVERSITY HOSPITAL, ETHIOPIA: A CROSS SECTIONAL STUDY

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OBJECTIVES: To determine the prevalence, level of severity of potential drug-drug interactions (PDDIs) and the associated factors for PDDIs in hospitalized pediatric patients of Gondar University Hospital. **METHODS:** A retrospective cross-sectional study was conducted for a period of 3 months from March to May 2014 in pediatric wards of Gondar University Hospital. Systematic random sampling technique was used to select charts from all pediatric patients' charts with every 7th interval to get sample size of 384. Univariate and multivariate analysis were performed to compute crude odds ratio and adjusted odds ratio respectively. Statistical significance was set at P value < 0.05. **RESULTS:** A total of 176 (45.8%) patients had at least one PDDI. A total of 393 PDDIs, which were comprised of 283 types of interacting combinations, were identified. Of the total of 393 PDDIs, most were of moderate severity [201 (51%)] followed by minor [152 (39%)] and major severity [40 (10%)]. The most common interacting pairs of major severity were gentamicin + furosemide (6), cotrimoxazole + methotrexate (4) and phenytoin + artemether (4). The occurrence of PDDIs was significantly associated with age and polypharmacy. **CONCLUSIONS:** The study showed that most of the interactions had moderate severity followed by minor severity. Age and polypharmacy were found to show statistically significant association with the occurrence of PDDIs. Due to sensitive nature of pediatric population, close monitoring is recommended for the detection and management of PDDIs to prevent its negative consequences.

PIH4

READMISSIONS TO HOSPITAL DUE TO ADVERSE DRUG REACTIONS IN ELDERLY AUSTRALIANS

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OBJECTIVES: To investigate the rate of adverse drug reaction (ADR)-related hospital readmissions in elderly patients previously hospitalized due to an ADR, and identify predictors of ADR-related readmission. **METHODS:** This retrospective study was conducted at the Royal Hobart Hospital, Tasmania, Australia. Data were collected from the digital medical records of 768 elderly patients in the PADR-EC (Prediction of Hospitalization due to Adverse Drug Reactions in Elderly Community-Dwelling Patients) study. The PADR-EC score is the sum of points assigned to five significant predictors of ADR-related hospitalization - antihypertensive use (3 or 5 points if 1-2 or ≥ 3 antihypertensives, respectively), renal failure (eGFR < 60mL/min/1.73m²), dementia, anticholinergic use and drug changes in the preceding 3 months (2 points each). Causality, preventability and severity of each ADR admission were assessed using the Naranjo algorithm, Schumock and Thornton criteria and Hartwig's criteria, respectively. **RESULTS:** ADR-related readmissions occurred after 20% (n=31) of 153 ADR-related index admissions. Patients readmitted with ADRs had significantly higher PADR-EC scores at discharge of their index admission (median PADR-EC score 7, interquartile range 5-9) than patients who were not readmitted with ADRs (6, 5-7, P=0.012). Most (80%) ADR-related readmissions were considered 'preventable'. ADR severity was 'moderate' in 97% and 'severe' in 3% of admissions. Renal disorders (27%) represented the most common ADRs, followed by cardiovascular (22%) and endocrine/metabolic disorders (16%). The most frequently implicated drug classes were diuretics (26%) and agents acting on the renin-angiotensin system (23%). Using the Naranjo algorithm 84% of ADRs were probable and 16% were possible. For most admissions (94%) the ADR resolved and the patient recovered. **CONCLUSIONS:** One in five elderly patients hospitalized due to an ADR were readmitted with an ADR within 12 months of discharge. The PADR-EC score could potentially be used at hospital discharge to prioritize patients for interventions to prevent subsequent ADR-related hospital admission.

PIH5

ERECTILE DYSFUNCTION SEVERITY, RISK FACTORS, AND HEALTH OUTCOMES AMONG 40-70 YEAR-OLD MEN ACROSS EIGHT COUNTRIES

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OBJECTIVES: Erectile dysfunction (ED) prevalence and burden of illness can vary according to geography, time, and methodologies. The current study examined health-related quality of life (HRQoL) and productivity impairments associated with varying ED severity and associated risk factors. **METHODS:** Data on adult men (40-70 years old) were analyzed from the 2016 National Health and Wellness Survey in Brazil, China, France, Germany, Italy, Spain, United Kingdom, and United States. Men with ED were selected on the basis of self-reporting any difficulty achieving/maintaining an erection in the past six months, and this measure was also used to define four levels of ED severity (mild, moderate, moderate/severe, and severe). Men with benign prostatic hyperplasia (BPH) were excluded. HRQoL measures included Mental and Physical Component Summary scores (MCS and PCS, respectively) derived from the SF-36v2, as well as SF-6D health utility scores. Work Productivity and Activity Impairment questionnaire-based measures were also included. Generalized linear models analyzed each outcome as a function of ED severity and risk factors, controlling for country, demographics, health characteristics and behaviors, and Charlson comorbidity index scores. **RESULTS:** Among 24,100 men with ED, moderate, moderate/severe, and severe ED were associated with significantly more negative MCS (-1.86, -3.67, and -4.38, respectively), PCS (-1.42, -2.94, and -4.45), and health utilities (-0.023, -0.049, and -0.064), and higher absenteeism (1.38, 2.16, and 2.53 times the rate, respectively), presenteeism (1.33, 1.84, and 1.94), overall work impairment (1.32, 1.85, and 1.94), and activity impairment (1.29, 1.66, and 1.75) than those with mild ED (all p < .001). The presence vs. absence of other comorbid conditions (depression, diabetes, obesity, smoking, and hypertension) was also associated with poorer outcomes; statistical significance varied by condition. **CONCLUSIONS:** Among 40-70 year-old men with ED, severity and comorbidities such as smoking, depression, and hypertension were associated with poorer health outcomes globally.

PIH6

IDENTIFICATION AND EVALUATION OF CLINICAL AND ECONOMIC IMPACT OF POTENTIAL DRUG RELATED PROBLEMS IN THE ELDERLY

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OBJECTIVES: To evaluate pattern and predictors of potential DRPs among elderly inpatients and its consequential clinical and economic impact. **METHODS:** Prospective interventional study was performed for a period of 18 months among the internal medicine department inpatients. Potential DRPs were determined and grouped into categories. Clinical impact of pharmacist-initiated drug therapy changes were evaluated by the research pharmacist and an independent clinical panel for any possible impact on the readmission probability, length of hospital stay, treatment failure, etc. To analyse the economic impact of pharmacist interventions, the impact of cost savings on the length of stay, readmission probability, medical procedures and drug cost were considered. **RESULTS:** Among the 863 admitted patients, 728 DRPs (84%) were identified from 661 patients (1.10 DRPs/person). Most frequent DRPs were those involving drug selection/administration (35%) and the commonly implicated drug category was drugs used for

alimentary tract and metabolism (N=318). Major clinical pharmacist intervention was deletion of the drug (29%) and in 55% cases the intervention was accepted and the treatment was changed. The total cost of DRPs were estimated to be approximately USD 5,818.96, out of which approximately USD 4,887.93 could have been preventable as 84% of the potential DRPs were of preventable nature. According to the clinical panel, 28% of the pharmacist interventions had possibly important clinical relevance. Pharmacist interventions reduced the length of hospitalization, disease relapse and treatment failure in 41%, 19% and 16% cases respectively. The total cost saving from interventions was estimated to be USD 3,816.49. Regarding the predictors of DRP, incidence of DRPs was significantly higher among females, middle aged elderly, patients with polypharmacy, multiple diseases, longer duration of hospitalisation and lower survival rate. **CONCLUSIONS:** Many DRPs in elderly are preventable with structured patient care. Geriatric pharmacotherapy services by clinical pharmacist can contribute to minimize DRPs in elderly.

PIH7

TRENDS OF OPIOID UTILIZATION DURING PREGNANCY AND INCIDENCE OF NEONATAL ABSTINENCE SYNDROME

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OBJECTIVES: An increase in opioid utilization during pregnancy in recent years has contributed to a surge in the incidence of Neonatal Abstinence Syndrome (NAS). The objective of the study was to compare the pattern and intensity of opioid utilization during pregnancy in deliveries with and without NAS. **METHODS:** We examined women in a commercial claims database for years 2011-14 who filled an opioid prescription during pregnancy for a non-cancer indication. Pregnancies were stratified into pre-term and full-term. NAS was identified using ICD-9 code 779.5. For each prescription, the morphine equivalent dose (MED) was calculated, and the average daily MED was estimated on a bi-weekly basis for each patient during the gestation period. We matched one NAS delivery to one non-NAS delivery on eight risk factors—including cumulative opioid use in the first two trimesters—to create a matched set that theoretically differed in its risk for NAS through a difference in opioid utilization in the last trimester. **RESULTS:** We found 314 cases of NAS in 61,568 pregnancies (5.10 cases per 1,000 deliveries). In the unmatched analysis, we found that compared to non-NAS pregnancies, NAS pregnancies had a significantly higher average daily MED during the gestation period (+36 mg MED, p<0.01). In NAS pregnancies, we noted a decrease in the average daily MED following the onset of pregnancy, which remained stable up until the third trimester where it subsequently increased. In the matched analysis, the mean MED in the third trimester was higher in the NAS group compared to the non-NAS group (+2.41 mg MED). Our findings in the pre-term pregnancy group were similar. **CONCLUSIONS:** While opioid exposed patients who developed NAS made a concerted effort to decrease their opioid utilization following the onset of pregnancy, opioid utilization remained high throughout the gestation period. Near-term opioid use was associated with NAS.

PIH8

CLAIMS-BASED IDENTIFICATION OF PEDIATRIC HYPONATREMIA PATIENTS IN THE UNITED STATES

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OBJECTIVES: Retrospective database analyses can be used to conduct feasibility of clinical studies by estimating potential cases of interest in real-world settings. The objective of this study was to identify potential cases of pediatric patients with hyponatremia using three large patient databases in the United States. **METHODS:** Analyses of two administrative claims databases - Optum Clinformatics data (1/1/2014-12/31/2014) and the Truven MarketScan Commercial Claims data (1/1/2014 - 12/31/2014) and one electronic health records database - Humedica data (1/1/2013 - 12/31/2013) was conducted. For the Optum and Truven databases, patients with ICD-9 codes for 276.1x (hyponatremia, hyposmolality) either in the inpatient or outpatient setting and <17 years of age (pediatric hyponatremia) were identified; results were expressed as the number of potential pediatric cases per all health plan members covered. For the Humedica database, occurrence of at least two serum sodium values <130 mmol/L was used as a confirmatory criteria for hyponatremia among patients with ICD-9 codes for 276.1x and results were expressed as the number of pediatric cases with serum sodium <130 mmol/L per all patients with ICD-9 codes for 276.1x. **RESULTS:** In the Optum database, there were 22,373 cases of hyponatremia out of approximately 12.3 million members of which 1,004 were <17 years of age. This resulted in a rate of 1 patient with pediatric hyponatremia per 12,334 members covered. Similarly, analysis of the Truven database resulted in a rate of 1 patient with pediatric hyponatremia per 15,374 members. Results of the Humedica database indicated a rate of 1 pediatric hyponatremia patient with at least two labs for serum sodium <130 mmol/L per 318 patients with hyponatremia. **CONCLUSIONS:** A rare occurrence of potential cases of pediatric hyponatremia in the real-world setting may present challenges for clinical trial recruitment in this patient population.

PIH9

ASSESSMENT OF THE CHILDREN CHARACTERISTICS DIAGNOSED WITH MALNUTRITION IN DIFFERENT HOSPITALS OF QUETTA, PAKISTAN

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OBJECTIVES: The present study is done to assess the characteristics of children who are diagnosed with malnutrition in different hospitals of Quetta, Pakistan. **METHODS:** A cross-sectional study conducted in private and government

hospitals of Quetta from February to August 2016. Children aged from 2 months to 12 years were included in the study. Data was collected using a special Performa made for this particular study WHO guideline was used to developed. The Performa include information regarding clinical appearances, current complain, measurements of weight, Height, Mid-Upper Arm Circumference (MUAC) circumference of head (COH). As per WHO guideline the Z-score were calculated and standard scoring (Standard Deviation (SD)) was used to identified malnutrition status. The patients were categorized as 0 to-1 SD mild, -1 to -2 SD moderate and ≤ -2 SD severe malnutrition categories. **RESULTS:** A total of 344 patients were included in the study. Out of which 52% (n=177) were male. According to the Z-score the patients were categorized to malnutrition status as; mild (n=38, 11.3%), moderate (n=72, 21.5%), severe 157 (46.9%). Most of the patients (n=140, 41.8%) come with the malnutrition as their current complain. Result shows that malnutrition was more prevalent in children age less than 2 years (n=185, 55.2%) with majority 43.6 % had improper breast feeding and (n=168,49%) had improper weaning. Majority of the patients (n=209, 60%) have no records of their vaccination. Most of the parents of the patients (n=160,47%) are uneducated. **CONCLUSIONS:** The present study concluded that most of the children diagnosed with malnutrition were categorized as severally mal-nutrient, the malnutrition in children was most prevalent in early ages and improper breast feeding and weaning were the main cause of malnutrition, which may be because of the reason that majority of the parents of the children diagnosed with malnutrition were uneducated.

PIH10

PREDICTORS OF ANAEMIA AMONG ANTENATAL CLINIC REGISTRANTS IN URBAN GHANA: AN ANALYTIC CROSS-SECTIONAL STUDY 2016

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OBJECTIVES: Anaemia in pregnancy remains disease of Public Health Concerns in Ghana, however limited intervention exists for its prevention during preconception period. This study aimed at determining prevalence and factors associated with it at ANC registration at District Health facility to inform policy. **METHODS:** We conducted analytic cross-sectional study. A total of 232 ANC registrants aged 15-45 years were randomly selected between February -July 2016. We interviewed participants on socio-demographic, past medical, obstetrics, diet, medications using interviewer administered structured questionnaires, and routinely requested Hemoglobin and malaria parasitaemia data were analyzed. Data abstracted was managed in EPI info 7 and Stata 13.0. Univariate and Multiple logistic regression analysis were done at 95% confidence level. **RESULTS:** Prevalence of anaemia among participants was 31.0%. While 44% of participants aged 25-29, 25% aged 30-34 years. Fifty two percent had primary education, 30.2 and 11.6 percent had secondary and tertiary respectively. While 72.8 percent registered in 2nd and 3rd trimesters, only 27.2% registered in the 1st trimester. Logistic regression analysis (95% confidence level) showed low monthly income < 25.00 USD [APOR= 2.33; Pvalue 0.05], Sickle Cell Disease [APOR= 3.41; Pvalue 0.01], eating fish [APOR= 0.29; Pvalue 0.01], and eating of fruits [APOR= 0.24; Pvalue 0.00] were significantly associated with developing anaemia in pregnancy at registration. However, only bivariate analysis showed preconception haematecnic intake [POR= 1.20; CI 0.51-2.79], having some formal education [POR=0.56; CI 0.20-1.52], eating cereal/grain [POR=2.34; CI 1.07-5.12] and tubers [POR=0.62; CI 0.35-1.10] to be associated with the disease. **CONCLUSIONS:** Undoubtedly, there is high prevalence of anaemia in pregnancy particularly among low income earning women with majority of registrants presenting late. Preconception sickle cell disease screen coupled with comprehensive dietary counseling and support among prospective pregnant women has the potential to prevent anaemia in pregnancy.

PIH11

CORRELATES FOR HEALTH-RELATED QUALITY OF LIFE AMONG PREGNANT WOMEN IN CHENGDU OF CHINA: RESULTS FROM A HOSPITAL BASED SURVEY

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OBJECTIVES: Health-related quality of life (HRQOL) is a patient-reported outcome among pregnant women that is often neglected in clinical practice. We conducted a cross-sectional survey to examine the status of HRQOL among pregnant women and its correlates in Chengdu of China. **METHODS:** We enrolled women during the third trimester of pregnancy at antenatal clinics of West China Second Hospital from October 30, 2013 to February 28, 2014. Participants completed the Chinese version of Short Form 36 Health Survey (SF-36) to assess the HRQOL. Social demographics, pregnancy history, and personal characteristics were also collected during the survey. **RESULTS:** A total of 2244 pregnant women aged 30.0 (standard deviation: 4.0 years) were recruited. The overall score for SF-36 was 66.91 (standard deviation: 11.6), and scores for eight domains ranged from 51.30 (standard deviation: 24.7) for role physical to 78.2 (standard deviation: 12.6) for mental health. Univariate analyses showed age, education level, occupation, living condition, age of first pregnancy, and relationship with mother-in-law were associated with all or most domains of SF-36 (all $P < 0.05$). Multiple linear regression demonstrated that education level, living condition, and relationship with mother-in-law remained statistically significant after controlling for age, occupation, annual household income per capita, age of first pregnancy, and other potential confounders. The SF-36 score for the general health domain increased with increasing level of satisfaction with living condition (β coefficient -3.67, $P < 0.001$ for dissatisfactory and 2.96,

$P = 0.003$ for fully satisfactory versus the satisfactory). Pregnant women who had good relationship with mother-in-law reported higher score for the mental health domain than those who did not (β coefficient 1.76, $P < 0.001$). **CONCLUSIONS:** Our findings indicate that personal characteristics may affect HRQOL among pregnant women, and deserve particular attention to improve HRQOL in clinical practice.

PIH12

NUTRITIONAL AND SOCIO ECONOMIC DETERMINANTS OF HEMOGLOBIN LEVEL IN CHILDREN AGED 12-24 MONTHS

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OBJECTIVES: Anemia is multifactorial in etiology. Preventative efforts, predominantly focused on increasing iron intake between the period of conception and 24 months of age as this duration is sensitive to nutrient effects on child growth, cognition, and school attainment. However, Data on association of various factors on hemoglobin level are limited. Hence the objective was to determine biological, nutritional and socioeconomic factors associated with hemoglobin level in Indian children aged 0-24 months. **METHODS:** A cross sectional Pilot study was conducted over a period of 4 months (Nov 2015 - Feb 2016) in three pediatric outpatient clinics of New Delhi, India. A predesigned questionnaire was used to record data by the pediatrician from 66 mother and child pair. Socio-demographic profile, birth weight, anthropometric, feeding pattern and consumption of iron fortified cereals was collected. Hemoglobin estimation was done as a part of normal examination by the pediatrician. A child was considered to be on iron fortified cereal if a minimum 1-2 serving/day was feed along with homemade foods. **RESULTS:** The prevalence of anemia (hb <11 g/dl) in study sample was 42.4%. The mean age with hemoglobin of <11g/dl and >11g/dl was 13.7+3.7 months and 12+1.0 months respectively. Similarly for these two group mean birthweight and BMI was 2.6+0.6 kg, 2.9+0.3kg and 14.6+1.14 kg/m², 16.1+1.01 kg/m² respectively. The results of multiple linear regression showed that Hemoglobin was significantly associated with birth weight ($p = 0.0001$) and consumption of iron fortified cereals ($p = 0.001$) whereas age of mother ($p = 0.145$), parity ($p = 0.08$) and maternal education ($p = 0.09$) were not significant. **CONCLUSIONS:** Consumption of iron fortification cereals was significantly associate with hemoglobin level. Given the negative impact of anemia on the development of children in future, there is an urgent need for effective remedial public health interventions. Due to limited geographic location and small sample size, further larger and controlled studies are needed.

PIH13

PREVALENCE AND ASSOCIATED FACTORS OF HERBAL MEDICINE USE AMONG PREGNANT WOMEN ON ANC FOLLOW-UP AT GONDAR UNIVERSITY REFERRAL HOSPITAL, ETHIOPIA: A CROSS-SECTIONAL STUDY

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OBJECTIVES: The present study aimed at assessing the prevalence and correlates of herbal medicine use among pregnant women on ANC follow-up at Gondar university referral hospital, Ethiopia. **METHODS:** An institutional-based cross sectional study was employed on 364 pregnant women attending ANC clinic from March to May 2016 at Gondar university referral hospital, northwest Ethiopia. Data on socio-demography, pregnancy related information as well as herbal medicine use was collected through an interviewer-administered questionnaire. Descriptive statistics, univariate and multivariate logistic regression tools were used to analyze with the prevalence and correlates of herbal medicine use. **RESULTS:** From 364 respondents, 48.6% of them used herbal medicine during current pregnancy. Ginger (40.7%) and Garlic (19%) were the two most commonly used herbs in pregnancy. Common cold (65%), constipation (14.7%) and inflammation (13%) were the most common reasons for herbal use. Majority of herbal medicine users (89.8%) have not consulted their doctors about their herbal medicine use. Average monthly income less than 100 USD (AOR: 3.079 95 % CI: 1.221-7.767) were found to be strong predictors of herbal medicine use. **CONCLUSIONS:** The use of herbal medicine during pregnancy is a common practice and associated with being rural residency, illiteracy and low average monthly income. Given the high frequency of herbal medicine and a very low disclosure rate, health care providers should be open to discuss the use of herbal medicines with their pregnant women as it will lead to better health outcome.

INDIVIDUAL'S HEALTH - Cost Studies

PIH14

A FIVE-YEAR BUDGET IMPACT ANALYSIS OF THE INCLUSION OF ETONOGESTREL IMPLANT FROM THE PRIVATE HEALTH SECTOR PERSPECTIVE IN BRAZIL

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OBJECTIVES: Oral contraceptives are effective in the prevention of unplanned pregnancy, but are associated with low adherence and may result in contraceptive failure. Long acting reversible contraceptive methods combine reversibility with high effectiveness. This analysis aimed to estimate the projection of costs using the etonogestrel implant and the levonorgestrel intrauterine system for five years, from the private health perspective of Brazil. **METHODS:** The eligible population was female beneficiaries in September 2016, aged 19 to 48 years. Cost and market-share of contraceptives data were obtained from local sources. The prices for etonogestrel implant and levonorgestrel intrauterine system were 902.85 BRL and 760.33 BRL, in addition to 173.5 BRL and 236.52 BRL, respectively, as reimbursement by procedure. For levonorgestrel intrauterine system, it was also considered a hysteroscopy or

surgical curettage in 25% of cases in the base case and 75% in the alternative scenario. **RESULTS:** In five years, the budget impact in the base case was 1,583,792,751 BRL and 1,560,566,016 BRL without and with the inclusion of etonogestrel implant, respectively, resulting in savings of 23,226,735 BRL. In the alternative scenario, savings with the inclusion of etonogestrel implant would be of 106,230,590 BRL. **CONCLUSIONS:** The inclusion of the etonogestrel implant in private health sector in Brazil could save from 23.2 to 106.2 million reais, depending on the rate of hysteroscopy, supplementing the contraceptive options for Brazilian women, also having fewer clinical restrictions compared to use of the levonorgestrel intrauterine system.

PIH15

NUMETA BUDGET-IMPACT MODEL FOR PEDIATRIC PARENTERAL NUTRITION

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OBJECTIVES: To estimate the budget impact of NUMETA for neonatal and pediatric patients who are unable to tolerate oral or enteral feeding, requiring parenteral nutrition from the health care provider perspective. **METHODS:** A budget impact model was adapted from a global version in order to capture, from the hospital perspective, all resource such as ingredients, consumables, installations and device costs and staff-time of the whole production chain of preparing parenteral nutrition. In addition, costs due to medication errors and complications were included as well. Patients can switch from in-hospital compounded products (manual or automated) or externally produced products to NUMETA and the budget impact of these switches are calculated for a three year time horizon. Model inputs were collected from different sources such as: secondary data review, twelve expert interviews and four administrative data bases from health care providers, compounding center and benefit plan manager. Local currency, Colombian Pesos COP. **RESULTS:** Baseline scenario cost of standard of care COP 77,199,921,044. Cumulative budget impact in conservative forecast (5.6% of Numeta adoption in 3 years): 1st year COP -50,467,362; 2nd year COP -334,598,067 and 3rd year COP -993,123,652. Cumulative budget impact in high adoption scenario (15.4% of Numeta adoption in 3 years): 1st year COP -216,231,139; 2nd year COP -1,429,679,947 and 3rd year COP -3,198,051,979. **CONCLUSIONS:** Based on the assumed perspective and inputs, Numeta is not expected to impact negatively the pediatric parenteral nutrition budget in Colombia.

PIH16

COST COMPARISON OF SHORT PROTOCOL OF STIMULATION AND JAPANESE PROTOCOL (TERAMOTO'S PROTOCOL) OF ART IN UKRAINE

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OBJECTIVES: In Ukraine state funding of ART was launched on the Orders of MoH №579 from 24.11.2004. During the recent times, there is a tendency for protocols with minimal stimulation and minimal hormonal load which aim at obtaining not the largest number of ova, but more high-quality ova. Japanese protocol of IVF is the most physiological and contains minimal hormonal interventions during couple of cycles. In short protocol used drugs Elonva 150, Orgalutran, Pregnil 5000, Progesterone. In average a general cost per 1 cycle is 24 261 UAH. It is 842,10\$ (1 \$=28,81 UAH). In Japanese protocol used drugs Clomifenum 500, Menopur 75 ME, Orgalutran and Pregnil 5000. The total value of the 1 cycle is 14 864UAH. It is 515,93\$ (1 \$=28,81 UAH). worth noting that Teramoto's protocol does not foresee supporting therapy with progesterone drugs. Peculiarity of the short protocol is work on the woman's natural hormonal background with using drugs that prevent early maturation of the ovule. **METHODS:** We compared the average price for each medical guideline. We used actual prices taken from database MORION (Kyiv) on 1.11.2016. **RESULTS:** We have conducted comparison characteristics of the price of short protocol and Teramoto's protocol. Having analyzed average dosage of medical means (13) it was found out that the use of medical means by Teramoto's protocol is for 38,73% cheaper in comparison with medical means of extracorporeal fertilization short protocol. Additionally supporting therapy with vitamins is prescribed which is individually for every woman and is determined by doctor. **CONCLUSIONS:** Teramoto's protocol treatment will be by one third cheaper in comparison with short stimulation. Also specific feature is usage of small dose of medication which allows to avoid numerous complication of hormonal therapy. Great advantage of Japanese protocol is absence of painful sensations by woman.

PIH17

POTENTIAL OUT-OF-POCKET SAVINGS FOR DUAL-ELIGIBLE BENEFICIARIES WITH DEVELOPMENTAL DISABILITIES AFTER MEDICARE PART D PLAN OPTIMIZATION

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OBJECTIVES: Approximately 7% of dual-eligible (Medicare/Medicaid) beneficiaries suffer from Developmental Disability (DD). They often have a high medication burden and thus may be prone to higher than necessary out-of-pocket (OOP) drug costs under the Medicare prescription drug benefit (Part D). **METHODS:** Community clinics were conducted by University of the Pacific pharmacy students during the fall 2016 Medicare open enrollment period. Beneficiaries were provided Part D plan assistance by trained student pharmacists. Demographic, drug, subsidy, plan and cost data were collected during each intervention; the latter items were retrieved from the online Medicare Plan Finder Tool (www.medicare.gov). Formulary coverage and potential OOP cost-savings by optimizing a beneficiary's drug plan were recorded/calculated. **RESULTS:** In total, 106 dual-eligible beneficiaries (51 with DD) were assisted. Beneficiaries with DD took on average 7 prescription medications/month, whereas those without DD took 8 prescription medications/month. Approximately 88% of those with DD could have achieved lower OOP drug costs; on average they could have saved \$2,133 by switching Part D plans in the upcoming year. Similarly, 84% of

non-DD beneficiaries could have minimized their OOP costs, with average savings of \$1,988 by switching to a new 2017 Part D plan. However, the average potential annual opportunity cost saving from switching to the lowest cost PDP was \$2133 among Duals with DD, which was \$145 higher than Duals without DD on average. **CONCLUSIONS:** Part D plans change formulary and cost-structure each year. It is imperative that all beneficiaries reevaluate Part D plan offerings during Medicare open enrollment. PDP optimization can play a vital role decreasing OOP costs. Beneficiaries with developmental disabilities may lack the resources necessary to effectively navigate the benefit. Partnerships between organizations/agencies that serve those with DD and trained pharmacy students can prove fruitful and beneficial to all involved.

PIH18

THE IMPACT OF MALNUTRITION ON HOSPITAL OUTPATIENT COST AMONG COMMUNITY-DWELLING OLDER CHINESE ADULTS

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OBJECTIVES: Malnutrition and its associated outpatient costs are of concern among older adults in general. The association of malnutrition and outpatient costs however is of particular interest in China, which has the largest elderly population in the world. This paper aims to study the association between nutrition status, number of outpatient visits, and outpatient cost per month among community-dwelling Chinese elderly. **METHODS:** We used 2013 China Health and Retirement Longitudinal Study (CHARLS) survey data, which included a nationally representative sample of 7,768 community-dwelling Chinese elderly. Measures of hand grip strength, Body Mass Index, and weight loss were used as indicators of malnutrition status. We excluded regular physical examinations and immunization to focus on the outpatient visits requiring treatment of illness. We employed multivariate regressions to analyze the impact of malnutrition on the number of outpatient visits and costs per month. We also control for socio-demographics, health status, health insurance and quality of health care and in our regressions. **RESULTS:** We found that malnutrition increased both the number of outpatient visits per month and the cost associated with each individual outpatient visit. Specifically, malnutrition was associated with 17% more outpatient visits (0.54 vs. 0.46; $p < 0.01$), and 9% higher outpatient costs per month (¥195.27 vs ¥178.42; $p < 0.01$). In total, malnutrition was associated with ¥4.45 billion additional outpatient costs for older adults in China every year. **CONCLUSIONS:** Malnutrition was associated with significantly higher hospital outpatient visits and associated costs. These results suggest that malnutrition is an independent predictor of outpatient cost, thus highlighting the importance of malnutrition screening, identification, and treatment for Chinese elderly (age ≥ 60 years old) living in the community. Improving nutrition requires relatively inexpensive clinical and educational interventions and could potentially be cost-effective methods to reduce health care costs of malnourished older Chinese adults.

PIH19

THE PUBLIC HEALTH AND ECONOMIC IMPACT OF PNEUMONIA IN THE ELDERLY POPULATION IN BRAZIL

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OBJECTIVES: In the elderly population, acute respiratory infections are an important cause of morbidity and mortality, especially with the rapid changes in demographic structure in Brazil. Streptococcus pneumoniae is a major cause of illness and death worldwide. Current Immunization Program in Brazil includes pneumococcal vaccination in high risk groups (e.g. diabetic patients, immunosuppressed, with pulmonary disease, among others). This study evaluated the burden of pneumonia among elderly in Brazil from the public healthcare perspective. **METHODS:** A retrospective analysis of Brazil public hospital admissions for pneumonia was developed according to ICD-10 classification (Pneumonia J12-J18) in elderly (aged ≥ 60 years), as reported in Brazilian Hospital Information System (SIH/DATASUS) database from January 2014 to December 2015. **RESULTS:** In this population, respiratory infections were the leading cause of mortality, and pneumonia was responsible for more than 60% of it. Hospital admissions by pneumonia were 231,921 and 242,465 in 2014 and 2015, respectively, and deaths were 39,807 and 43,112 for the same period. Mean length of stay was 7 days for the analyzed period. The total admissions cost was 256,638,420 BRL and 267,012,950 BRL in 2014 and 2015 respectively, which represents 51.4% of total respiratory diseases costs. Mean cost per admission was 1,103.85 BRL over the two year period. **CONCLUSIONS:** The costs associated with hospitalizations for pneumonia in the elderly from the public healthcare perspective can be substantial in Brazil. Despite the existence of an Immunization Program for high risk groups, the number of admissions for pneumonia remains high. A universal vaccination program for the elderly population could bring a higher benefit in the current vaccination program.

PIH20

THE ASSOCIATION BETWEEN MALNUTRITION AND HOSPITAL INPATIENT COST AMONG COMMUNITY-DWELLING OLDER CHINESE ADULTS

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OBJECTIVES: China has a large and growing elderly population. In 2012, 171 million Chinese residents were over 60 years old, and this segment of the population is expected to grow to 487 million by 2050. Malnutrition is widespread among older Chinese adults, with estimates of prevalence in the literature ranging

from 5.3% to 37.5%. However, there is little research on the impact of malnutrition on hospital costs for older Chinese adults. This study aims to investigate the association between malnutrition and hospital inpatient cost in community-dwelling elderly Chinese. **METHODS:** We use 2013 China Health and Retirement Longitudinal Study (CHALRS) data, which consists of nationally representative socio-demographic, economic and health information of community-dwelling adults aged 45 years or older (our sample is limited to those age 60 and older). Measures of hand grip strength, Body Mass Index (BMI), and weight loss were used as indicators of malnutrition status. Multivariate regressions were used to explore the effect of malnutrition on respondent's number of hospital admissions and total inpatient cost in the past year. In addition, we controlled for socio-demographics, health status, and quality of health care in the regression tests. **RESULTS:** Malnutrition was associated with more hospital admissions and higher inpatient costs (both p values < 0.01). Specifically, an average malnourished older Chinese adult has 32% more hospital admissions (0.29 vs. 0.22; $p < 0.01$), and 31% higher costs for all inpatient services in the past year compared to a well-nourished senior (¥2,066 vs. ¥1,580; $p < 0.01$). In total, malnutrition increased hospital inpatient cost by ¥10.69 billion. **CONCLUSIONS:** Malnutrition was associated with more hospital admissions and higher inpatient costs among community-dwelling older Chinese adults. Therefore, inexpensive efforts to address malnutrition including malnutrition screening and oral nutrition supplements could be effective in reducing hospital cost for the Chinese elderly.

PIH21

ECONOMIC BURDEN ASSOCIATED WITH PEDIATRIC OPIOID POISONINGS

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OBJECTIVES: The main objectives of this study were to: 1) Estimate the economic costs associated with opioid poisonings and 2) Examine the characteristics associated with opioid poisoning-related costs in children. **METHODS:** Economic costs were estimated using the 2012 Nationwide Emergency Department Sample, Kids' Inpatient Database, Multiple Cause-of-Death file and other published sources, applying a societal perspective. Direct costs included costs associated with emergency department (ED) visits, hospitalizations and ambulance transports. Indirect costs included productivity costs due to caregivers' absenteeism and premature mortality among children. Markov chain Monte Carlo analysis was used to impute missing costs and sensitivity analyses were performed. A generalized linear model with a log-normal distribution was used to estimate the association of sociodemographic, clinical, payer and hospital characteristics with ED and inpatient costs. **RESULTS:** Total economic costs of pediatric opioid poisonings in the United States were calculated at \$230.8 million in 2012. Total direct costs were estimated to be \$21.1 million. Total productivity costs were calculated at \$209.7 million, and 98.6% of these costs were attributed to opioid poisoning-related mortality. There were a total of 4,584 ED visits, 1,877 hospitalizations and 123 deaths related to opioid poisonings in children. Mean costs for pediatric opioid poisoning-related ED visits and hospitalizations were estimated at \$1,289 (SE = 54) and \$6,633 (SE = 630), respectively. Teenagers had 1.39 (95% CI: 1.15-1.68) times higher ED costs compared to ≤ 6 year olds. Inpatient costs were significantly higher among children with higher median household income, moderate-to-extreme loss of function, post-discharge transfer, and private insurance. **CONCLUSIONS:** Opioid poisonings in children resulted in direct and indirect costs of \$230.8 million in 2012. Quantified healthcare costs associated with pediatric opioid poisonings can help decision-makers understand the economic trade-offs in planning interventions.

PIH22

ESTIMATION OF BREAST CANCER INCIDENT CASES AND MEDICAL CARE COSTS ATTRIBUTABLE TO ALCOHOL CONSUMPTION AMONG INSURED WOMEN UNDER AGE 45 YEARS IN THE UNITED STATES

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OBJECTIVES: To estimate the percent of breast cancer cases, total number of incident breast cancer cases, and the total annual medical care costs attributable to alcohol consumption among insured younger women by type of insurance (Medicaid, private, and both groups) and by stage at diagnosis. **METHODS:** We used data from the 2012-2013 National Survey on Drug Use and Health, the Centers for Disease Control and Prevention's National Program of Cancer Registries, the National Cancer Institute's Surveillance, Epidemiology, and End Results Program, and published literature to estimate: 1) the alcohol-attributable fraction of breast cancer cases among younger women aged 18-44 years by type of insurance; 2) the total number of breast cancer incident cases attributable to alcohol consumption by stage at diagnosis and insurance status; and 3) the total annual medical care costs of treating breast cancer incident cases attributable to alcohol consumption. All costs were expressed in 2013 US dollars. **RESULTS:** Among younger women enrolled in Medicaid, private insurance, and both groups, we estimated that 8.7%, (95% confidence interval [CI]:7.4-10.0%), 13.8% (95% CI:13.3-14.4%), and 12.3% (95% CI:11.4-13.1%) or 1-in-12, 1-in-7, and 1-in-8 of all breast cancer cases were attributable to alcohol consumption. Across both insurance groups, the largest proportion of estimated attributable incident cases were in localized stage. The estimated total number of breast cancer incident cases attributable to alcohol consumption was 2,212 (95% CI: 2,125-2,303). These breast cancer incident cases accounted for estimated total annual medical care costs of \$201.7 million (95% CI: \$191.1-\$212.2 million). **CONCLUSIONS:** Alcohol use in younger women is a modifiable risk factor for breast cancer. We estimate that breast cancer attributable to alcohol has medical care costs in excess of \$200 million per year. Thus the findings from this study could be used to support evidence-based interventions to reduce alcohol consumption in younger women.

PIH23

ABSENTEEISM AND INDIRECT ECONOMIC BURDEN ASSOCIATED WITH PRIMARY AND SECONDARY HYPOGONADISM: A RETROSPECTIVE MATCHED COHORT ANALYSIS OF EMPLOYED COMMERCIALY-INSURED PATIENTS IN THE US

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OBJECTIVES: To characterize the indirect economic burden associated with primary and secondary hypogonadism (PSHG) in the United States. **METHODS:** Using the MarketScan[®] Health and Productivity Management Database, patients who had ≥ 1 medical claim with a diagnosis related to PSHG (initial claim=index date) and had evidence of testosterone therapy (TTh) within 12 months of index between 1/1/2010 and 12/31/2014 were identified (cases). Included cases were ≥ 18 years and had ≥ 12 months of continuous enrollment with absenteeism eligibility and medical and pharmacy benefits before and after (follow-up) index. Controls with no diagnoses related to PSHG and no evidence of TTh were matched 3:1 to PSHG cases based on patient characteristics (age, region, insurance type, index year) and absenteeism eligibility. Overall and non-recreational absenteeism hours missed from work and associated productivity costs were measured during the 12 month follow-up period. Non-PSHG controls and PSHG cases were compared using descriptive statistics (chi-square tests for categorical variables and t-tests for continuous variables). Associated productivity cost was calculated by multiplying missed work-hours by an average hourly wage constant of \$25.14/hour based on the US Bureau of Labor Statistics 2015 report. **RESULTS:** The study identified 2,300 PSHG cases and 6,899 non-PSHG controls (mean age 49 [SD=8] years), of which 84.6% and 81.2% had ≥ 1 absenteeism claim and 74.5% and 67.9% had ≥ 1 non-recreational absenteeism claim, respectively. PSHG cases missed an average 251.7 (SD=207.9) work-hours overall including 85.6 (SD=167.9) non-recreational hours. Non-PSHG controls missed an average 202.4 (SD=154.3) work-hours overall including 46.6 (SD=97.9) non-recreational hours. PSHG was associated with significantly higher overall and non-recreational missed work-hours (49.3 and 39.0 respectively; both $p < 0.001$). The additional hours missed from work translated to overall productivity cost of \$1,240, of which \$979 was non-recreational (both $p < 0.001$). **CONCLUSIONS:** PSHG is associated with significantly higher absenteeism compared to non-PSHG controls which translates to significantly increased indirect economic burden.

PIH24

HOUSEHOLD COST OF INJURIES IN CHILDREN UNDER FIVE YEARS IN THE EJISU-JUABENG MUNICIPALITY OF THE ASHANTI REGION, GHANA: A CROSS SECTIONAL STUDY

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OBJECTIVES: To estimate the household cost and assess the burden of injury in children less than five years on household in an urban setting in Ghana. **METHODS:** A multistage sampling was used to select 600 households in Ejisu in the Ejisu-Juabeng Municipality of Ashanti Region. Structured questionnaire was used in the data collection. The data were analysed into descriptive statistics in STATA version 13.0 to estimate the direct, indirect and total cost of injury. Sensitivity analysis was run on the cost estimates for a period of 5-10 years. **RESULTS:** The educational level 2.2[95% CI: 1.6, 3.0], living room 0.6 [95% CI:0.4, 0.7]) and household size 0.7[95% CI: 0.6, 0.9] were statistically significant risk factors of injury in children under five years. The total sum of GHC 3,922.60 (US\$ 1,028.20) averaging GHC6.67 (US\$ 1.83) was incurred on injury per household. An indirect cost of over four million Ghana Cedis (GHC4, 808,938) US\$ 1,260,534.81 was lost averaging GHC814.89 (US\$ 213.60) per household. The time value lost was 10,690 cumulative working days with a monetary equivalence of GHC 4,754,320 (US\$1,246,217.56) averaging GHC17, 873 (US \$ 4,684.92) per household. In 20.0% of respondents, the burden was in the form of disabilities; amputation 24.2%, and visual disabilities 8.3%. Physical and educational developments of the children were also affected. **CONCLUSIONS:** The study revealed high household cost and varying burden of injury in children under five years. The findings are significant for policy update, design and implementation of safety and preventive interventions for injury control.

PIH25

COST EFFECTIVENESS ANALYSIS OF THE USE OF IUS-LNG AGAINST ORAL CONTRACEPTIVES AND NSAIDS, FOR THE TREATMENT OF HEAVY MENSTRUAL BLEEDING IN COLOMBIA

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OBJECTIVES: To estimate the cost-effectiveness ratios for the use of IUS-LNG versus the use of oral contraceptives and three NSAIDs (mefenamic acid, tranexamic acid and naproxen) for the treatment of heavy menstrual bleeding in Colombia. **METHODS:** A Markov model was developed to estimate the rate of bleeding control evaluating frequency of hysterectomies as the main clinical outcome and the total healthcare costs. The base case is patients with excessive loss of menstrual blood that affect quality of life related to health. It uses a 12-month horizon, with monthly cycles. The chances of menstrual bleeding control were estimated from clinical trials. It includes the costs of the technologies extracted from local data base and the events from insurance costs. Healthcare costs included: hysterectomies with their complications and ablation. **RESULTS:** IUS-LNG was found as the technology that prevents the largest number of hysterectomies in one year: 72% of patients treated with the IUS-LNG did not arrive to hysterectomy, compared to 45% of patients under oral contraceptives and 41% under NSAIDs. In terms of average costs, patients treated with IUS-LNG, ACOs and NSAIDs are estimated at USD \$438, USD \$507 and USD \$751,

respectively. Thus, IUS-LNG is considered a dominant technology in the control of heavy menstrual bleeding. **CONCLUSIONS:** IUS-LNG is a dominant first line alternative compared to other technologies covered by the Colombian health care system reducing between 13,5% and 41,5% of costs and avoiding between 49,0% and 53,3% hysterectomies versus other non-surgical options as NSAIDs and ACOs, respectively.

PIH26

COST-EFFECTIVENESS ANALYSIS OF ETONOGESTREL IMPLANT VERSUS LEVONORGESTREL INTRAUTERINE SYSTEM FROM THE PRIVATE HEALTH SECTOR PERSPECTIVE IN BRAZIL

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OBJECTIVES: An unplanned pregnancy can have profound consequences, e.g., unsafe abortion, which is a public health problem in Brazil. Ensure access to highly efficient contraceptive may impact in reducing unplanned pregnancies. Therefore, this analysis aimed to evaluate the cost-effectiveness of long acting reversible contraceptives (etonogestrel implant versus levonorgestrel intrauterine system), from the Brazilian private health perspective. **METHODS:** The eligible population was private insurance beneficiaries in September 2016 that were current users of levonorgestrel intrauterine system, aged 19 to 48 years. Efficacy, cost and market-share of contraceptives data were obtained from local sources. Annual discontinuation and failure rates of each method were considered. Average cost of an unplanned pregnancy was 3,181.33 BRL. The prices for etonogestrel implant and levonorgestrel intrauterine system were 902.85 BRL and 760.33 BRL, in addition to 173.5 BRL and 236.52 BRL, respectively, as reimbursement by procedure. For levonorgestrel intrauterine system, it was also considered a hysteroscopy in 25% of cases in the base case and 75% in the alternative scenario. Time horizon was 15 years, with yearly cycles. Costs and benefits were discounted by 5% per year. **RESULTS:** In an initial population of 213,714 women, etonogestrel implant avoided 395 unplanned pregnancies after 15 years, with savings in device costs and unplanned pregnancies costs, therefore being cost-saving, in both scenarios. The reduction in total costs was of 27.117.307 BRL for the base case and 159.161.722 BRL for the alternative scenario. **CONCLUSIONS:** Compared to levonorgestrel intrauterine system, etonogestrel implant was cost-saving, with a reduction of unplanned pregnancies and costs. Given its high efficacy and cost-effectiveness, etonogestrel implant should be included as an option for women in the private health sector of Brazil.

INDIVIDUAL'S HEALTH – Patient-Reported Outcomes & Patient Preference Studies

PIH27

KNOWLEDGE, ATTITUDE AND PRACTICE (KAP) TOWARDS VACCINATION: A CROSS SECTIONAL STUDY AMONG THE PARENTS IN URBAN REGION OF MALAYSIA

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OBJECTIVES: To evaluate parent's knowledge attitude and practice (KAP) on vaccination and also to assess factors associated with low adherence to vaccination due to pharmacoeconomic factors in urban region of Malaysia. **METHODS:** Pre-validated questionnaire was used to obtain response from 200 parents from different communities with different educational and socioeconomic status. Proper adherence and appropriate knowledge was noted on the basis of selected socioeconomic parameters. **RESULTS:** One hundred and fifty five (77.6%) parents were having appropriate knowledge with mean score of $\pm 62\%$. A p-value < 0.05 was considered significant. There was statistically significant association observed between educational level and adherence to vaccination schedule ($\Phi = 0.583$, $p < 0.021$). Low socioeconomic status directly influenced adherence and practice related to vaccination schedule ($p < 0.001$, $\Phi = 0.753$) provided by ministry of health, Malaysia. No statistically significance was seen between any other variable and vaccination schedule provided by ministry of health, Malaysia. **CONCLUSIONS:** Female participants had good knowledge and practice in comparison to male participants. All the participants rejected the involvement of religious beliefs in their decisions for vaccinating their children. There is a good knowledge, attitude and practice towards vaccination in all three communities i.e. Malay, Indian and Chinese. There is some gap in attitude about vaccination which should be discussed and resolved.

PIH28

ASSESSING MOTIVATIONS FOR CHOOSING THE PLACE TO GIVE BIRTH AMONG PREGNANT WOMEN

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OBJECTIVES: A government decree legalized home birth under strict conditions since May 2013 in Hungary. In our study we examined women's opinion about such topics as pregnancy and giving birth, what choice do they make in order to take an active part of the whole process of pregnancy. **METHODS:** A cross-sectional, quantitative study with non-probability, targeted sampling was performed between 2014. 12. 01. – 2015. 02. 15. Our sample consists of pregnant women (N=163). Results were calculated with SPSS 22.0. Besides descriptive statistics we calculated χ^2 -test

and independent samples t-test ($p < 0.05$). **RESULTS:** There is a significant connection between frequent prenatal care attendance and choosing home birth ($p < 0.05$). However it does not show correlation with socio-demographic data nor parity ($p > 0.05$). There is also a significant connection between concerning for the newborn baby and choosing place to give birth ($p < 0.05$), and women concerning for their own health and choosing place to give birth ($p < 0.05$). **CONCLUSIONS:** Our survey could give an insight into the current situation, when home birth is legally approved. Regarding the importance of this topic we find it necessary to make further research. Women have an increasing need to give birth in a pleasant, relaxing, loving, homely atmosphere. It is important to give scope to alternative care in hospitals, allow the presence of family, doulas and midwives to help pregnant women with their combined force.

PIH29

ASSESSING THE NUTRITIONAL STATUS OF THE ELDERLY LIVING AT ELDERLY NURSING HOMES

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OBJECTIVES: Malnutrition has a negative affection for elderly people's health and quality of life, yet it is not an uncommon phenomenon in elderly homes. The aim of our study was to assess the nutritional status and factors affecting their nutrition of elderly people living in homes in Kalocsa, Hungary. We were also assessing the connection between nutritional status of the elderly, their mental health and other diseases. **METHODS:** A longitudinal, quantitative study was carried out with non-probability, targeted sampling at the elderly nursing home in Kalocsa, Hungary between 2015. 08. 04. and 2015. 12. 12. Our sample consists of people above 60 years (N=100). Data collection was made with a self-made questionnaire, document analysis, anthropometric measurements and standard questionnaires (MUST, MNA-SF, MNA, SNAQ65+, MMSE). SPSS 22.0 was used for calculating descriptive statistics, χ^2 -test, paired samples t-test and ANOVA ($p < 0.05$). **RESULTS:** Mean age of responders is 81.24 ± 8.758 years. Prevalence of malnutrition in the sample: MNA3=8%; MNA-SF3=11%; MUST3=13%; SNAQ65+3=14%. Nutritional status of elderly people decreased significantly according to MUST and MNA-SF ($p < 0.05$). There is a strong connection between the presence of dementia and malnutrition according to MNA ($p=0.018$). Nutritional status is influenced by hypertension ($p < 0.05$), gastrointestinalitis ($p=0.008$), psychiatric condition ($p=0.037$), bone and muscle disorders ($p=0.008$), appetite ($p < .001$) ability to swallow ($p < 0.05$) and self-sufficiency ($p < 0.001$). **CONCLUSIONS:** Nearly one quarter of elderly living in homes suffers from malnutrition. Malnutrition or the risk of it occurs more frequently in people with dementia – this result is similar to the findings of Malara et. al in 2010.

PIH30

RURAL-URBAN MIGRATION AND THE HEALTH OF ELDERLY PARENTS IN CHINA

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OBJECTIVES: Large-scale rural-urban labour migration and rapid population ageing are two important demographic developments in China. Both result in a growing number of left-behind rural elderly. The paper investigates the effects of adult children's rural-urban migration on the health of their left-behind elderly parents in China. **METHODS:** We use a panel data set constructed from the 2011 and 2013 waves of the China Health and Retirement Longitudinal Study (CHARLS). We employ an instrumental variables (IV) strategy to account for the endogeneity of children's migration decision. We use village level sent-down youth (SDY) numbers as an exogenous source of variation in the likelihood of adult children's migration. To improve the measure we calculate an interaction effect between the SDY number and the GDP growth in the cities where SDY originally came from. **RESULTS:** A strong first stage result is confirmed in our research for the effect of SDY on individuals' migration decisions. The preliminary second stage result shows that children's migration has a positive effect on the left-behind parents' health outcomes. We argue that the income effect from remittances is the most likely transmission channel of children's migration on elderly left-behind parents' health. This explanation is confirmed by studying how the effects differ across socio-demographic sub-groups. We also compare different dimensions of elderly health to provide a detailed picture of the health effects of rural-urban migration in China. **CONCLUSIONS:** This paper contributes new findings for China to the growing international literature analysing the effects of rural-urban migration on the health of elderly left-behind family members, controlling for self-selection of the migration-decision making. We also provide new evidence on the changing mechanisms of intergenerational support in the context of rapid urbanisation and population ageing in China.

PIH31

CRITICAL NEED FOR A NEW PATIENT-RELATED OUTCOMES (PRO) MEASURE IN CLINICAL PRACTICE AND RESEARCH FOR PATIENTS WITH VULVODYNIA

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OBJECTIVES: To appraise existing PRO measures used in clinical practice and research for vulvodynia. **METHODS:** The study employed a literature review followed by interviews with clinicians and payers to appraise PRO measures in vulvodynia. Exhaustive review of literature, and review of trials from ClinicalTrials.gov were carried out, accompanied by structured interviews of 27 clinicians and payers from France, Germany, Spain, Great Britain, Italy, and the USA. Strengths, weaknesses, and unmet needs associated with existing PRO measures

were identified in the context of evidence development as well as importance of PRO-generated data on future access to treatments for patients with vulvodynia. **RESULTS:** Nine PROs were identified through secondary research, five were generic measures including Numerical Rating Scale (NRS), Visual Analog Scale (VAS), Short Form-McGill Pain (SF-MPQ), Brief Pain Inventory (BPI), and SF-36. Four disease-specific measures were identified including Female Sexual Functioning Index (FSFI), Female Sexual Distress Scale (FSDS), Marinoff Dyspareunia Scale (MDS), and Vulvovaginal Symptoms Questionnaire (VSQ). Pain and sexual functioning were important attributes captured in these measures. Stakeholders were satisfied with the NRS and VAS for measuring pain, while clinicians were somewhat satisfied with the FSFI and SF-36 to capture the impact on daily life. Critical gaps identified in existing PROs included their relevance to patients' daily lives, such as ability to wear tight pants, use tampons, or ride a bike without pain. Payers in Spain and Germany identified the need for such specificity in order to understand the impact of new treatments, and to provide broader access. **CONCLUSIONS:** Pain intensity and sexual quality of life were adequately captured, however, existing PROs did not capture all aspects of the patient experience with vulvodynia, as communicated by both clinicians and payers across six countries. Therefore, there is a critical need for a robust disease-specific PRO for clinical practice and research.

PIH32

PREDICTORS OF ANXIETY AND DEPRESSION AMONG PREGNANT WOMEN ATTENDING A TERTIARY HEALTHCARE INSTITUTE IN QUETTA CITY, PAKISTAN

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OBJECTIVES: Anxiety and depression (A&D) are commonly reported among pregnant women; however, there is paucity of information from developing countries. The current study therefore aims to evaluate the frequency of A&D and to highlight the predictors among pregnant women attending a tertiary healthcare institute in Quetta city, Pakistan. **METHODS:** A questionnaire based, cross-sectional survey was conducted. The pre-validated Hospital Anxiety and Depression Scale (HADS) was used to assess the frequency of A&D among study respondents. Anxiety and depression scores were calculated via standard scoring procedures while logistic regression was used to identify the predictors of A&D. SPSS v. 20 was used for data analysis and $p < 0.05$ was taken as significant. **RESULTS:** Seven hundred and fifty pregnant women responded to the survey. Majority of the respondents belonged to age group of 26-35 year (424, 56.4%) and had no formal education (283, 37.6%). Furthermore, 612 (81.4%) of the respondents were unemployed and had urban residencies (651, 86.6%). Mean anxiety score was 10.08 ± 2.52 ; mean depression score was 9.51 ± 2.55 and total HADS score was 19.23 ± 3.91 indicating moderate A&D among the current cohort. Logistic regression analysis reported significant goodness of fit (Chi square = 17.63, $p = 0.030$, $df = 3$), indicating that the model was advisable. Among all variables, age had a significant association when compared with HADS scores (adjusted OR=1.23, 95% CI = 1.13 - 1.62, $p < 0.001$). **CONCLUSIONS:** Moderate A&D was reported among the study respondents. Furthermore, age was highlighted as a predictor of A&D. The evidence from this and other studies provide an impetus for support programs for anxious and depressed pregnant women. The benefits of implementing good mental health in antenatal care have long lasting benefits for both mother and infant. Therefore, there is a need to incorporate A&D screening in the existing antenatal programs.

PIH33

LONGITUDINAL ASSESSMENT OF USING COMMON BENZODIAZEPINE/NON-BENZODIAZEPINE HYPNOTICS AMONG THE ELDERLY

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OBJECTIVES: Concerning that elderly should avoid to use benzodiazepine (BZD) and non-BZD hypnotics for long-term, this study aimed to observe elderly patients' disease statuses, efficacy outcomes, and safety concerns of using BZD/Z-drugs longitudinally. **METHODS:** We enrolled elderly patients who regularly visited a 2000-bed medical center and were prescribed with listed BZD/Z-drugs for more than 1 week in study group and those who had not taken these medications in control group. Those elderly who ever had severe neuropsychiatric disorders, active cancer, received organ transplantations, or couldn't cooperate with interview were excluded. All enrolled patients were interviewed for the following measures every three month and up to one year: changes in insomnia quality, functional statuses, Mini-Mental State Examination, fall experience, depression scale, occurrence of adverse drug reactions (ADRs), Morisky Medication Adherence Scale 8-item, EuroQol EQ-5D-5L, and health utilizations. **RESULTS:** Up to January 19, 2017, 239, 160, 114, 64 and 17 patients, respectively, completed the first, second, third, fourth and fifth visit assessments. 53.2% of 239 elderly patients were enrolled in the study group. Comparing to that in control group, elderly patients in study group tended to: have poor EQ-5D-5L scores, have more cognitive impairment, and have poor medication adherence in first visit. More elderly in study group ever experienced falls and 42 encountered BZD/Z-drug ADRs. Of 17 patients completed 1-year follow-up, 9 patients in the study group tended to have less diseases, visited less outpatient units, spent less outpatient expenses, had better sleep quality, but had more complex medication regimens and encountered more BZD/Z-drug ADRs across times, comparing to 8 patients in control group. **CONCLUSIONS:** Those elderly patients taking BZD/Z-drugs had poor clinical and humanistic outcomes, poor medication adherence, and more complex medication regimens and encountered more BZD/Z-drugs related ADRs across time than those patients not taking these medications.

PIH34

MALNUTRITION ASSOCIATION WITH FUNCTIONAL STATUS AND HEALTH OUTCOMES AMONG COMMUNITY-DWELLING OLDER CHINESE ADULTS

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OBJECTIVES: Malnutrition is associated with multiple adverse outcomes among both hospitalized and community-dwelling older adults. Although China has the largest elderly population in the world, limited research assessing the impact malnutrition has on the physical health of Chinese older adults exists. We investigated the association between malnutrition, functional status, health outcomes, and healthcare costs among community-dwelling older Chinese adults. **METHODS:** A national sample of adults aged 60 years or older collected as part of the Wave II-2013 China Health and Retirement Longitudinal Study (CHARLS) survey were included in the analysis. Measures of hand grip strength, body mass index, and weight loss were used as indicators of malnutrition status. Functional status was assessed via adapted versions of the Katz Index of independence in basic activities of daily living (ADLs) and the Lawton-Brody Index of independence in instrumental ADLs (IADLs). Health outcomes included self-reported health status and probability of having one of the 14 assessed comorbid conditions (e.g., stroke, chronic stomach disease, hypertension, etc.). Multivariate regressions were used to analyze the associations. **RESULTS:** Malnutrition was associated with lower but insignificant basic ADLs ($p > 0.1$), but significantly lower instrumental ADLs, poorer health status, higher probability of having stroke and chronic stomach disease (all p values < 0.1). As a significant contributor of poorer health status, malnutrition, increased hospital cost by ¥214 (14% increase, $p < 0.01$) per person per year. Although malnutrition contributed to lower functional independence (IADLs), higher probability of having stroke and chronic stomach disease, no significant increase in hospital costs was observed. **CONCLUSIONS:** Malnutrition was associated with poorer functional, health status, and cost outcomes among community-dwelling older Chinese adults. Therefore, malnutrition screening and treatment with oral nutritional supplements are essential in improving the health of older Chinese adults living in the community, and potentially lowering the costs of healthcare.

PIH35

HEALTH-RELATED QUALITY OF LIFE OF PREGNANT WOMEN ATTENDING THE TERTIARY CARE HOSPITAL QUETTA, PAKISTAN

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OBJECTIVES: The study aimed to evaluate Health Related Quality of Life (HRQoL) in pregnant women attending the teaching hospital of Quetta, Pakistan. **METHODS:** A cross sectional study was conducted from February to September 2016 to evaluate the HRQoL in pregnant women attending Bolan medical Complex Hospital. The data was collected by using WHOQOL-BREF questionnaire developed by WHO. Descriptive analysis was used for elaborating patients' demographic characteristics. All analyses were performed using SPSS 22.0. **RESULTS:** A total of 387 pregnant women were included in the study. Majority of the respondent were between the age group of 26-35 years, majority were housewives ($n=280$, 72.2%). Most of the respondents were surveyed in third trimester ($n=163$, 42%). The overall WHOQOL-BREF mean score was 49.16 and the mean score for each domain were: Physical domain; 12.58, psychological domain; 11.47, social domain; 13.50 and environmental domain; 11.61. **CONCLUSIONS:** The results of the study showed that Health Related Quality of life in pregnant ladies are adversely affected. The pregnancy affect all the aspects of life of the women this may cause physiological and psychological issues to the pregnant ladies during or after the termination of the pregnancy. Focusing on the quality of life during pregnancy can be beneficial for health of women as well as the child.

INDIVIDUAL'S HEALTH - Health Care Use & Policy Studies

PIH36

IMPACT OF ICD-10 ON CODING OF HYSTERECTOMY PROCEDURES

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OBJECTIVES: Beginning on October 1, 2015, International Statistical Classification of Diseases, or ICD-10 coding was implemented in the US healthcare system. Number of procedure codes increased from 3,882 to 71,974 in ICD-10. The change has implications of coding infrastructure and potentially reimbursement. Goal of the study was to describe how commonly performed surgeries are coded using ICD-10. **METHODS:** We used Premier hospital inpatient database for Q4,2015 (first full quarter with ICD-10 data). We identified discharges with a primary diagnosis and relevant Medicare Severity-Diagnosis Related Group (MS-DRGs) for hysterectomy (734-743). Descriptive analysis was conducted to report the top ICD-10 procedure codes. **RESULTS:** 8,975 discharges were identified for hysterectomy, with MS DRGs 734-743 and relevant primary diagnoses codes, the top three including: 1) D259: Leiomyoma of Uterus, Unspecified, with 2,201 discharges; 2) D251: Intramural Leiomyoma of Uterus, with 760 discharges and; 3) C541: Malignant Neoplasm of Endometrium with 625 discharges. Top primary procedures included: 1) OUT90ZZ: Resection of Uterus, Open Approach, with 4,211 or 46.92% of discharges; 2) OUT94ZZ: Resection of Uterus, Percutaneous Endoscopic Approach (PEA), with 872 (9.72%); 3) OUT9FZZ: Resection of Uterus, Via Natural or Artificial Opening, with PEA, with 646 (7.2%); 4) OUB90ZZ: Excision of Uterus, Open Approach, with 561 (6.25%) and; 5) OUT97ZZ: Resection of Uterus, Via Natural or Artificial Opening, with 547 (6.1%). **CONCLUSIONS:** We report the first, real-world experience of ICD-10 coding. Code for open abdominal hysterectomy was reported in nearly half of hysterectomy procedures and was the single most commonly used procedure code.

PIH37

MEASURING THE IMPACT OF GERIATRIC CARE AMONG MEDICARE BENEFICIARIES

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OBJECTIVES: To measure the impact of geriatric care on patient outcomes using Medicare claims data **METHODS:** A matched cohort analysis was performed, comparing patient outcomes among those with and without geriatric care. The study cohorts were created from claims spanning 2010-2014, representing a random 5% sample of Medicare FFS beneficiaries that were aged 65+ in 2010. Patients with at least one geriatric care claim between (but not before) 2011-2014 were propensity score matched to those without any geriatric care claims from 2010-2014. Survival rates, healthcare resource utilization (HCRU) and costs were compared between matched cohorts. **RESULTS:** 118,382 patients receiving geriatric care were identified, along with a random sample of 535,526 patients not receiving geriatric care. Samples of the cohorts were taken and propensity score matching was performed to create 10,000 matched pairs. Kaplan-Meier plots comparing the two matched cohorts indicated that, overall, the geriatric care group had shorter survival times than their counterparts. Among sicker patients, however, the analysis suggested that survival times were relatively longer in the geriatric care group. In terms of HCRU, patients receiving geriatric care were, on average, likely to have more inpatient, outpatient and physician office claims (62%, 18% and 49% more, respectively). Mean monthly costs were comparable in the two matched cohorts (p=0.53). **CONCLUSIONS:** Geriatric care has the potential to improve the longevity of those afflicted by multiple chronic conditions. Geriatricians' focus on coordination of care increases the amount of healthcare resource utilization but costs are on par with patients not receiving geriatric care, possibly the result of support that is more efficient and preventative in nature. While only a small proportion of elderly patients receive geriatric care, this study suggests that more patients and the healthcare system at large could benefit from promoting the involvement of and increasing access to geriatricians.

PIH38

17-ALPHA-HYDROXYPROGESTERONE ADMINISTRATION TO HIGH-RISK PREGNANT MOTHERS RESULTS IN SIGNIFICANT GAINS IN PREGNANCY-RELATED OUTCOMES IN GEOGRAPHICALLY DIVERSE MEDICAID POPULATIONS

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OBJECTIVES: Administration of weekly 17-alpha-hydroxyprogesterone caproate (17P) injections in high-risk pregnancy from 16-24 weeks until delivery reduces pre-term birth (PTB) rates by up to 30%. This retrospective cohort analysis investigated the impact of 17P on gestational age and neonatal intensive care unit (NICU) utilization in 17P-treated versus untreated cohorts. **METHODS:** The study cohort consisted of Medicaid members (ages 16-45 years) from six geographically diverse managed care organizations with ≥1 estimated gestational live birth registered in our claims database who were administered 17P from 2014-2015 (N=382). The comparator cohort consisted of members with the same high-risk characteristics in the Medicaid population who were not administered 17P, delivering babies from 2013-2015 (N=7,918). Intra-cohort comparisons (pre- versus post-gestational weeks within cohorts) and inter-cohort comparisons (difference-in-differences [DID] estimation between cohorts) for primary outcome measures were calculated using two tailed t-tests and unadjusted generalized least square regression models, respectively. **RESULTS:** 17P-users averaged two years older than non-users, with higher rates of comorbidities, healthcare and pharmacy utilization, acute hospitalization, and gestational risk (56% versus 28%). With 17P administration, the average gain in gestational age was 1.4 weeks (p<0.001); 35.6 to 37.0 weeks pre- to post-17P versus -0.2 weeks (p<0.0001); 38.7 to 38.5 weeks pre- to post-delivery for comparator). DID analysis between pre- and post-periods of the 17P cohort revealed a statistically significant gain of 1.6 weeks (p<0.0001). The average reduction in NICU rate was -5% (p=0.1); 26% to 21% pre- to post-17P versus -0.3% (p=0.695); 7.8% to 7.5% pre- to post-delivery for comparator). DID analysis revealed a statistically significant gain of +4.7% (p=0.013). Total medical cost savings were projected at >\$12 million USD. **CONCLUSIONS:** 17P is an effective treatment for Medicaid members in managed care with a history of PTB in increasing gestational age, decreasing NICU utilization, and reducing health care costs.

PIH39

COST BURDEN OF SARCOPENIA ASSOCIATED HOSPITALIZATION IN ADULTS BY AGE AND RACE/ETHNICITY

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OBJECTIVES: Estimate the cost of increased hospitalizations associated with sarcopenia within age and race subpopulations. **METHODS:** Sarcopenia was defined as having a low appendicular lean body mass index (less than 0.789 for males and 0.512 for females) and functional limitation. We examined age related sarcopenia in older adults (age≥65), and non-age related sarcopenia in the middle-aged (age 40-64). The prevalence of sarcopenia and associated hospitalizations were estimated using the National Health and Nutrition Examination Survey (NHANES) for 1999-2004. The cost of increased hospitalizations is estimated for age and race/ethnicity subpopulations using the 2014 Healthcare Utilization Project National Inpatient Sample (HCUP NIS). The subpopulation burden is calculated using the size of the subpopulation (U.S. Census), subpopulation prevalence, subpopulation increased hospitalizations and the subpopulation average cost per hospitalization. Confidence intervals were estimated by simulation. **RESULTS:** Individuals with sarcopenia incur \$2263 (2014 USD, CI: \$947, \$3778) more hospital costs per year than individuals without sarcopenia. The average cost per subpopulation member (total cost divided by subpopulation size) varies by

race/ethnicity: \$238 (CI: \$96, \$417) for Whites; \$45 (CI: \$16, \$87) for Blacks; \$451 (CI: \$191, \$814) for Hispanics and \$379 (CI: \$95, \$900) for Others (p<0.05). The overall cost of increased hospitalizations associated with sarcopenia was \$39.5 billion (CI: 16.2B, 67.4B), or \$254 (CI: \$193, \$433) per individual. Whites accounted for the largest portion of this cost (age 40-64: \$12.9B; age ≥65: \$12.7B; Total: \$25.6B), followed by Hispanics (age 40-64: \$5.9B; age ≥65 : \$3.1B; Total: \$9.0B), Others (age 40-64: \$2.1B; age ≥65 : \$2.0B; Total: \$4.1B) and Blacks (age 40-64: \$0.1B; age ≥65 : \$0.6B; Total: \$0.8B). **CONCLUSIONS:** Sarcopenia is a costly condition across age and race/ethnicity subpopulations. Hispanics bear the highest per capita cost, followed by Others, Whites and Blacks. Further study is needed to understand the differential impact of sarcopenia on these groups.

PIH40

EXTENDED-SPECTRUM-B-LACTAMASE PRODUCING ENTEROBACTERIACEAE IN GESTATIONAL URINE CULTURES: PREVALENCE AND RISK FACTORS

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OBJECTIVES: Extended-spectrum-β-lactamase producing Enterobacteriaceae (ESBL-PE), once prevalent only in the hospital setting, are becoming major pathogens of obstetric and neonatal infections. A better understanding of ESBL-PE epidemiology in pregnant women may help guide better screening policies and appropriate empirical antibiotic treatment. The study was aimed to analyze the prevalence of ESBL-PE in gestational urine cultures and the risk factors associated with ESBL-PE growth in gestational urine cultures. **METHODS:** A retrospective cohort study was conducted with electronic health records (EHR) from the centralized Clalit Health Services (CHS) database. The study population included pregnant members who delivered in one of the CHS hospitals between 2009-2013 who provided at least one urine culture during the pregnancy. **RESULTS:** The study population included 134,152 women (95% of total CHS deliveries). 15,282 (11.4%) of the cultures yielded Enterobacteriaceae growth, with 603 (3.9%) ESBL-PE positive results. The proportion of ESBL-PE in gestational urinary cultures increased from 2.8% in 2009 to 6.4% in 2013. In the multivariate logistic regression model, Arab ethnicity (OR=1.33 CI95% 1.11-1.58), assisted fertilization procedures (AFP) (OR=1.48 CI95% 1.09-2.02), and the use of antibiotics (especially penicillins OR 1.36 CI95% 1.32-1.65 and quinolones OR 1.71 CI95% 1.28-2.27) were found to be associated with ESBL-PE growth in gestational urine cultures. **CONCLUSIONS:** The prevalence of ESBL-PE in gestational urine cultures in this large epidemiological study was increasing at an alarming rate. In this, usually healthy, population the most important risk factors are related to multiple encounters with health-providers and those connected to previous antibiotic treatment. The risk factors can be implicated in screening and cohorting strategies. The policy to prevent ESBL-PE outbreaks in neonatal units should include maternal and neonatal screening, cohorting and notifying the medical staff when ESBL-PE positive women and their neonates are admitted.

PIH41

LONGITUDINAL CHANGES IN HEALTH CARE UTILIZATION AND RELATED COST AMONG ELDERLY WITH DIFFERENT FRAILTY LEVEL IN TAIWAN

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OBJECTIVES: To longitudinally evaluate the impact of frailty on health care utilization and corresponding expenditure in a nationally-representative elderly cohort. **METHODS:** We conducted a retrospective cohort study using the 2005-2013 Taiwan's Longitudinal Health Insurance Database. The study cohort consisted of 86,133 subjects aged between 65 and 100 years in 2005. Using cumulative deficit approach, we constructed the frailty index (FI), which included deficits from outpatient and inpatient diagnosis during 2005. Further, we categorized study population into 4 groups according to the FI: fit (FI=0-0.0625), mild frailty (FI=0.0625-0.125), moderate frailty (FI=0.125-0.1875) and severe frailty (FI>0.1875). Health care utilizations (including outpatient, emergency department and inpatient visits) and corresponding direct medical costs for 4 groups were estimated annually during the 8-year follow-up period (2006-2013). **RESULTS:** Overall, 2.9% (n=2,498) subjects were classified as severe frailty, 5.5% (n=4,741) as moderate frailty, 16.54% (n=14,244) as mild frailty and 75.06% (n=64,650) as fit. We found that frailer elderly would have more outpatient visits (during 1st year of the follow-up period, severe frailty: 57.36, moderate frailty: 48.02, mild frailty: 39.16 and fit: 21.54 visits/person-year). The annual numbers of emergency department visits and hospital admissions were also increased with frailty during the 8-year follow-up period. Mean direct medical cost during follow-up period was highest for severe frailty group (\$5,026/person-year), followed by moderate frailty (\$3,835/person-year), mild frailty (\$2,966/person-year) and fit groups (\$1,766/person-year). For severe frailty group, the direct medical cost associated with hospital admissions (during 1st year of the follow-up period, \$3,433/person-year) was higher than the cost associated with outpatient visits (\$2,415/person-year). However, the direct medical cost associated with outpatient visits was higher than the cost associated with hospital admissions among other 3 groups. **CONCLUSIONS:** We provided the important real-world data for patient-level longitudinal changes in health care utilization and direct medical costs among older population categorized by frailty.

PIH42

VARICELLA-RELATED HEALTH CARE RESOURCE UTILIZATION IN PERU

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OBJECTIVES: Varicella-zoster virus (VZV) is a serious health concern that results in considerable burden to public health systems, with a minimal estimate of

375,000 cases per year in children under 15 in Peru. Since the introduction of safe and effective varicella vaccines, several countries have implemented routine childhood varicella immunization programs that have drastically reduced associated morbidity and mortality. Peru currently does not include the varicella vaccine in their public childhood immunization schedule. The purpose of this study was to evaluate the burden of illness associated with varicella in Peru. **METHODS:** This was a multicenter, retrospective chart review study of patients aged 1-12 years with a primary varicella diagnosis between 2011 and 2016 in Peru. Clinical complications due to varicella, along with associated healthcare resource utilization (HCRU) were assessed in both the inpatient and outpatient settings using summary statistics. **RESULTS:** A total of 179 children with varicella (101 outpatients, 78 inpatients) from 9 centers (6 public, 3 private), were included in the study, with a mean age of 3.3 (SD: 3.3) and 2.4 (SD: 3.4) years, respectively. Among outpatients, 5.9% experienced at least one complication, specifically skin and soft tissue infections (100% of those experiencing complications), compared with 96.2% of inpatients, among which the most common complications included skin and soft tissue infections (75.3%), pneumonia (6.2%), and encephalitis (3.7%). HCRU estimates included use of over-the-counter (OTC) medications (72.3% outpatients, 89.7% inpatients), prescription medications (30.7% outpatients, 94.9% inpatients), tests/procedures (0.0% outpatients, 80.8% inpatients), and consultation with allied health professionals (0.0% outpatients, 39.7% inpatients). The average duration of hospital stay was 6.8 (95% CI: 5.8, 8.0) days for inpatients. **CONCLUSIONS:** Varicella is associated with substantial clinical complications and healthcare resource utilization in Peru, subsequently indicating a significant health and economic burden, which supports the need for the implementation of a routine childhood varicella vaccination plan.

PIH43

PRESCRIPTION DRUG USE AND COST ASSOCIATED WITH A PEDIATRICIAN-LED CARE MODEL SERVING CHILDREN WITH SPECIAL HEALTHCARE NEEDS (CSHCN) WITH COMPLEX CHRONIC CONDITIONS (CCC)

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OBJECTIVES: Care for children with medical complexities represents a significant challenge for health care systems and has emerged as an increasingly important component of pediatric practice. A pediatrician-led care coordination may increase the quality of care for medically complex children. We examined the prescription utilization and cost patterns of children with special healthcare needs having complex chronic conditions. **METHODS:** This was a retrospective secondary analysis of prescription utilization and costs using Texas Medicaid administrative claims data for patients with complex chronic conditions (N=229) who were enrolled in the Specially for Children pilot study and patients with complex chronic conditions not enrolled in the Specially for Children pilot study. Daily dispense cost was determined by dividing amount paid for a claim by its corresponding days supply. Descriptive statistics were used for determining the costliest and most frequently paid drug claims. **RESULTS:** A total of 229 patients with 24,478 drug claims were included in the study. The average cost per prescription was \$443. The costliest drug claim had a daily dispense cost of \$5,706 (HP Acthar Gel 80 unit/ml) with the top ten ranging from \$5,706 to \$1,454. Average daily dispense cost of the ten most frequent drug claims ranged from \$0.57 to \$10.30. The AHFS category with the highest attributed cost was for hemostatic agents (\$2,085,711, N=55 prescriptions). The most frequent paid drug claim was levetiracetam 100mg/ml solution (N=715). Additionally, AHFS category anticonvulsants, miscellaneous accounted for the most drug claims (N=846). Of the ten costliest AHFS categories, enzymes had the highest average cost per claim (\$41,358, N=18). **CONCLUSIONS:** We found the ten most expensive drugs to all exceed a daily dispense cost of \$1,450. The next step is to compare differences in prescribing trends and costs between the pediatrician-led model and usual care model.

PIH44

CHANGES IN HEALTHCARE SPENDING AFTER DIAGNOSIS OF COMORBIDITIES AMONG ENDOMETRIOSIS PATIENTS

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OBJECTIVES: To characterize health care spending associated with endometriosis-related comorbidities. **METHODS:** Women aged 18-49 with endometriosis (N=128,088) were extracted from 2006-2015 de-identified ClinformaticsTM DataMart (Optum Insight, Eden Prairie, MN) claims data. Endometriosis was identified by ICD-9 diagnosis code 617.x on ≥1 inpatient or emergency room claim or ≥2 outpatient claims. For 22 comorbidities, comorbidity patients (first diagnosis after initial endometriosis diagnosis) and controls (no comorbidity diagnosis) were identified. Controls were matched 1:1 to comorbidity patients using geographic region, insurance plan type, age and baseline healthcare spending. Index date was defined as first comorbidity diagnosis date for comorbidity patients, and equal number of days after earliest endometriosis claim for controls. Total medical and pharmacy spending was measured during 12 months before and after the index date. Pre-post differences for comorbidity patients and controls were compared using difference-in-differences linear regression. **RESULTS:** The number of patients with each of the 22 comorbidities varied between 121 and 16,177. Mean age was 37 years. Spending was significantly higher after onset of 8 comorbidities: breast cancer (+\$54,453), ovarian cancer (+\$19,881), pregnancy complications (+\$7,728), systemic lupus erythematosus/rheumatoid arthritis/Sjogren's/multiple sclerosis (+\$5,073), infertility (+\$4,630), uterine fibroids (+\$4,007), ovarian cyst (+\$3,866) and headache (+\$373) (p<0.001 except for headache [p=0.045]). Spending was significantly lower for fatigue (-\$385), cystitis/UTI (-\$1,312) and eczema (-\$1,626) (p<0.001 except for fatigue [p=0.048]). Spending was not different for endometrial

cancer, interstitial cystitis, stress, pelvic inflammatory disorder, mood disorders, constipation, fibromyalgia, depression, sprue, hypothyroidism, and irritable bowel syndrome. Difference-in-differences estimates were significantly higher for comorbidity patients for all comorbidities except eczema (p≤0.003). **CONCLUSIONS:** For 8 comorbidities associated with endometriosis, there were significant absolute increases in health care spending after onset; for another 13, there were significant relative increases in spending. Whether these relationships reflect the diagnosis or extent of endometriosis or the pathophysiology of the disease requires further investigation.

PIH45

SURGICAL TREATMENT PATTERNS AND RELATED COSTS FOR WOMEN WITH NEWLY DIAGNOSED UTERINE FIBROIDS

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OBJECTIVES: This study had two objectives: 1) Describe surgical treatment patterns among women with newly diagnosed uterine fibroids (UF), and 2) Estimate the medical costs associated with these surgical interventions. **METHODS:** The Truven Health Analytics MarketScan Commercial and Medicare Supplemental Databases were used to identify women aged ≥30 years with continuous enrollment for at least 12 months before and after the new diagnosis of UF (ICD-9-CM code 218.x) during 2010-2014. Patients with prior UF surgeries or evidence of large uterus or gynecological cancer during the study period were excluded. Receipt of hysterectomy, hysteroscopic myomectomy or uterine artery embolization (UAE) were primary outcomes. Healthcare resource utilization and costs were estimated for gynecologic-related costs (GYN) among women with at least 12 months of continuous enrollment following one of these surgical procedures. **RESULTS:** A total of 292,318 women with newly diagnosed UF met the selection criteria. Overall, 33.1% of patients underwent a surgical procedure for fibroids within 1 year of diagnosis. 21.9% of women underwent hysterectomy within 1 year of diagnosis, decreasing from 24.0% in 2010 to 19.3% in 2014 (p<0.001). Yearly rates of hysteroscopic myomectomy were relatively stable (range 4.8% to 5.4%). 86,767 patients met the selection criteria for the cost analysis, consisting of 72,448 hysterectomy, 10,544 hysteroscopic myomectomy, and 3,775 UAE patients. In the first month post-surgery, GYN-related costs for hysteroscopic myomectomy patients (\$6,113) were approximately one-half those of hysterectomy (\$13,370) or UAE (\$11,237). Total annual GYN-related costs were highest for hysterectomy (\$14,662) followed by UAE (\$13,540), and hysteroscopic myomectomy (\$9,492). **CONCLUSIONS:** Hysterectomy was the most common UF surgical intervention and represented the greatest healthcare costs following surgery compared to minimally invasive approaches like hysteroscopic myomectomy. These results can help inform future quality and cost-effective decisions about UF surgical treatment choices.

PIH46

CENTENARIANS IN COLOMBIA: AN ANALYSIS OF THREE DATABASES

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OBJECTIVES: To estimate the number and geographical distribution of centenarians in Colombia. **METHODS:** The study was a retrospective analysis, based on three different databases: the Colombian 2005 census, death certificates from 2010 to 2013, and Individual Registry of Health Services (RIPS), the official database of the Ministry of Health, for the year 2014. **RESULTS:** In the census, 3,165 centenarians (1,972 women, 62.3%) were identified, the highest rates of individuals over a hundred years of age (centenarian) were then in La Guajira (2.23 x 10,000), Chocó (1.90) and Sucre (1.61), all of them located in the Caribbean region, and with some of the highest poverty indicators including child mortality. In the four years analyzed, 3,611 centenarians died, with the highest proportions (per thousand deaths) in Chocó (10.4), La Guajira (9.4) and Sucre (6.5). The RIPS identified 3,390 centenarians in 2014, with the highest rates in Sucre (2.17 per 10,000), Chocó (1.29) and Córdoba (1.11). **CONCLUSIONS:** Although the results are consistent in terms of the number and geographical distribution of centenarians, there could have been errors in the record of the date of birth, which is the basic information used to estimate age in all the three sources analyzed. Another explanation may involve higher physical activity, traditional family and community support, low levels of stress, and healthy diet in these regions; these factors have been also associated with longevity in the denominated as "blue zones" (areas of the world with centenarian population rates 10 times higher than in the US). More studies are required to assess geographical distribution of elderly in Colombia and to evaluate factors that could be associated with certain specific geographical distribution.

PIH47

TRENDS IN EXTERNAL CAUSES OF CHILD MORTALITY IN COLOMBIA

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OBJECTIVES: Infant mortality figures have been improving worldwide. We analyzed official figures for Colombia, with emphasis on "external" causes of death (particularly drowning, traffic accidents, homicides, poisoning and burns). These causes, in general, have been neglected compared with communicable, perinatal, maternal and nutritional (Group 1 diseases in WHO classification). **METHODS:** The National Administrative Department of Statistics (DANE) and the Ministry of Health information system (SISPRO) publish periodic reports from all deaths certificates in Colombia by age, gender, cause of death and geographic location. We analyzed the information from January 2005 through

December 2013. **RESULTS:** During this nine-year period, 106 339 infants (children under 5 years of age) died in Colombia; 85 897 of them (81%) in the first year of life; 4 043 (3.8%) from the five external causes analyzed (males 59%). There was a decrease in the overall number of deaths over the period, from 14 266 in 2005, to 9 499 in 2013. Among external causes of death, the first one was drowning, responsible for 1 749 deaths (around 4 each week), followed by traffic accidents, with 1 282. Homicides were responsible for 692 deaths, and burns for 199. In all the cases analyzed there was a decrease in overall causes of death during the decade, highest (up to 62% reduction) in the Central Andean regions, and lower (on average 22%) in the Caribbean region. Three Colombian departments in the Amazonian region, bordering Brazil (Amazonas, Guainía and Vaupés) did not show any change at all. **CONCLUSIONS:** Despite large regional inequalities, Colombia is achieving the fourth United Nations' Millennium Development Goal: reducing the mortality of children less than 5 years of age. Some progress has been made in deaths from external causes, but there is still a way to go, since these causes of death are, in principle, all preventable.

PIH48

IMPACT OF CLINICAL PHARMACIST INTERVENTION ON THE KNOWLEDGE OF IMMUNIZATION IN PARENTS OF PEDIATRICS IN TERTIARY CARE HOSPITAL

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INTRODUCTIONS: Childhood mortality and morbidity is high due to infectious diseases. The burden of infectious diseases in pediatrics has been reduced primarily due to immunization. Studies show evidence regarding misconceptions on parents' knowledge and negative attitudes towards childhood immunization. This study aims at promoting childhood immunization by improving the parent's knowledge on immunization. **OBJECTIVES:** The objectives were to understand the knowledge level of parents on immunization, educate them regarding the same and post-counseling, assess the impact of education on immunization. **METHODS:** The study was divided into pre and post-intervention phases. In the pre-intervention phase, the parent completed a quantifiable pre-validated questionnaire after which the parent about importance of immunization and also by providing patient information leaflet. In the post-intervention phase, parents completed the post-intervention questionnaire and both pre and post intervention questionnaires were quantified and interpreted. **RESULTS:** 150 children were enrolled in the study, of whom 81(54%) were female babies. 115 mothers and 35 fathers attended the counseling session. 78 (52%) were working, 50 (33.3%) non-working and 22 (14.7%) did not reveal their working status. The commonly observed ADRs were fever alone (33%) and fever with swelling (17.2%). In most children (62 of 150 [41%]) no ADRs were observed. Most of the parents in pre-intervention phase, got the score of 3-6 (which is considered as low knowledge as per the questionnaire scoring and in the post-intervention phase, 9-10 (which is considered good knowledge). Comparison of pre and post-intervention scores showed that parents' knowledge got improved after counseling by the clinical pharmacist. **CONCLUSIONS:** From our study, a significant difference was observed in the pre and post-intervention scores. This study recommends the inclusion of clinical pharmacist in the national immunization program as counselor who certainly will be helpful in imparting education on immunization to parents which improves the national immunization rates. **Key words:** Counseling, Immunization, Pediatrics, Vaccination

PIH49

QUALITY OF LIFE OF GYNECOLOGIC CANCER PATIENTS

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OBJECTIVES: Mortality from cancer covers 25% of all mortality from diseases in Hungary. Cancers are more and more unsparing and getting more younger victims every year. The aim of our study was to analyze the quality of life (QoL) of patients suffering from breast or cervical cancer, and to assess the factors influencing QoL. **METHODS:** We carried out a quantitative, cross-sectional study with non-probability, targeted sampling between 2015.10.01-2015.12.22. Our sample consists of patients who have histologically confirmed diagnosis of breast cancer (n=29) or cervical cancer (n=43). A self-made questionnaire and standard questionnaires (EORTC-QLQ C30, QLQ-BR23, EORTC QLQ-CX24) were used as well. SPSS 22.0 was used to calculate descriptive statistics and t-test (p<0.05). **RESULTS:** Mean age of responders is 43.2 (SD: 9.02) years. Socio-demographic data and QoL have a significant connection (p<0.05). Age correlates with exacting physical activity; fulfilling family's needs; longer, strenuous walks; enjoyment of life in cervical cancer patients (p<0.05). There is no connection between age and any of the assessed QoL related factors (p>0.05) in breast cancer patients. We also found significant connection between age and sexual activity, enjoyment of coitus, level of interest in coitus and fear of pain in our population (p<0.05). **CONCLUSIONS:** Based on our results we can conclude that several socio-demographic data affect QoL in cancer patients, which are considered as supporting factors of successful coping. We found many similarities with other studies according to our results.

PIH50

QUALITY OF LIFE OF PATIENTS WITH ENDOMETRIOSIS

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OBJECTIVES: Clinically the deeply infiltrating endometriosis regarded as the most severe form of the disease and 20-35% of patients are affected. The organ

involvement causes a variety of symptoms and complaints and it has an unfavorable effect on the quality of life. This study aimed: to investigate the perioperative changes of the deeply infiltrating endometriosis disease impacts of the quality of life and sexuality. To examine and compare the possibilities of the surgical techniques in the context of the complications. **METHODS:** A retrospective, partly longitudinal research, following surgery document analysis (n = 61) and we made a processing of the individually structured questionnaire with standard elements. We used 15D to measure the quality of life and MFSQ standard questionnaire to measure the sexuality (n=44). We calculated relative and absolute frequency, mean, standard deviation, paired t-test, χ^2 -test, correlation and one way analysis of variance (p<0.05) with the help of the SPSS 22. program. **RESULTS:** The average age was 34.73 years (SD=5.12). 73.8% of the patients had at least 3 organ with endometriosis involvement and 82.5% were removed by laparoscopic surgery. The length of stay showed an upward turn tendency in the context of the complications (p<0.05). The sample vitality and sexual relations 40.9% were characterized by no complaint and between sexual partners and satisfaction (r = 0.44, p<0.05) and between orgasm and sexual partners (r = 0.52, p<0.05) medium correlation were detected. **CONCLUSIONS:** The surgery was efficient in the treatment of the DIE. Moreover the surgery significantly improve the work, physical activity, leisure activities, social relationships and the individual emotional function. The social relationships and emotional state stable, but correlation is not detectable by the positive perception of sexual satisfaction unlike Kössi and mtrai's study described (2012).

PIH51

SOCIOECONOMIC DETERMINANTS OF UNDERNUTRITION AMONG UNDER-FIVES IN LA GUAJIRA, COLOMBIA

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OBJECTIVES: Worldwide childhood undernutrition is a major risk factor for death and disability. La Guajira (Colombia) is a mostly rural state, with the highest proportion of indigenous population. The aim of this study was to estimate the factors related to undernutrition in under-five population (U5P) in one of the regions with the highest burden of disease due to undernutrition in Colombia. **METHODS:** We designed a cross-sectional study with data from the National Survey of the Nutritional Situation in Colombia (ENSIN, 2010), to identify the undernutrition associated factors in U5P. The outcome variable was undernutrition, defined as weight-for-age lesser or equal than 2 standard deviation (SD). Odds Ratios (OR) adjusted by taking into account the muestral design were calculated to assess the risk of each group compared to a reference group. Statistical analyzes were performed in STATA 12. **RESULTS:** A total of 622 children under-five were analyzed. The prevalence of undernutrition was 11.2%, 58.3% were male, 79.1% lived in rural areas, 36.2% do not have health insurance, and 73.1% were indigenous. According to the birth order, 13% were the first, 26% were the 2-3, 25% the 4-5 and 36% the 6 or more. In the logistic model, children living in houses with sewage had a lower risk of acute undernutrition (OR, 0.16; 95% CI, 0.05-0.57), while being the sixth child or later increases the risk of undernutrition (OR, 4.07; 95% CI, 1.50-10.99). **CONCLUSIONS:** Community-based interventions are needed to reduce the high prevalence of undernutrition in La Guajira, Colombia. Priority should be given to nutritional and other socioeconomic interventions for large families. Being able to identify high risk households will increase the efficiency of the policies to prevent and control undernutrition in La Guajira.

PIH52

REMOVAL OF ENDOMETRIAL POLYPS USING HYSTEROSCOPIC MORCELLATION: A SYSTEMATIC REVIEW

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OBJECTIVES: Hysteroscopic morcellation (HM) is a technique for removing endometrial polyps using the rotational mechanical energy of the morcellator. The objective of this review is to pool the result of HM for removal of endometrial polyps in terms of the safety and effectiveness. **METHODS:** Two reviewers independently selected the articles using 8 Korean databases, MEDLINE, EMBASE, and Cochrane Library and collected data regarding the safety outcomes based on complication rate and fluid deficit, and for the effectiveness outcomes based on success rate, surgical usability (operating time, resection time, installation time, and the number of insertions of instrument), and pain. **RESULTS:** Out of 270 articles searched, a total of 9 articles including 5 comparative studies compared HM with hysteroscopic resection (HR) and 4 single arm studies were finally included in this review. The results of our meta-analysis indicated that complication rate was not significantly different in between the 2 groups (RR=0.67, 95% CI: 0.43~1.03, p=0.07, I2=0.0%), whereas success rate was significantly higher in the HM group than in the HR group (RR=1.13, 95% CI: 1.02~1.26, p=0.02, I2=60.0%). Fluid deficit was significantly less in HM group than in the HR group in 1 comparative study while the other study presented no significant difference in between two groups. Four comparative studies reported significantly better surgical usability and pain in the HM group compared to the HR group, or similar results in between the 2 groups without significant difference. **CONCLUSIONS:** On the basis of current data, HM is a safe and effective technique for removing endometrial polyps compared with HR since there was no significant difference in complications and fluid deficit between the two groups and besides better results on success rate, surgical usability, and pain in the HM group than in the HR group.

PIH53

KNOWLEDGE AND AWARENESS REGARDING CERVICAL CANCER AND ITS PREVENTION AMONG NURSES WORKING IN DIFFERENT HOSPITALS OF QUETTA, PAKISTAN

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OBJECTIVES: This study aimed to assess the knowledge and awareness regarding cervical cancer and its prevention among nurses working in different hospitals of Quetta, Pakistan. **METHODS:** The cross sectional, descriptive study was conducted by using structured questionnaire in different hospitals of Quetta from January to September 2016. Convenient sampling technique was applied by targeting all the nurses working in different hospitals of Quetta city. Study questionnaire was developed and tested for validity and reliability. Descriptive and inferential statistics (Mann Whitney U test and Kruskal Wallis tests, $p < 0.05$) were used to assess the significance among study variables and were performed by using IBM SPSS v.20. **RESULTS:** Out of 415 distributed questionnaires 324 were returned (response rate of 78%). The mean Age of respondents were 28.18 ± 9.5 years. Majority ($n=127$, 43.3%) of participants were interns and had no or less than one year of experience ($n=128$, 43.7%) with negative family history of any cancer ($n=275$, 93.9%). Mean knowledge score was 18.52 ± 4.84 with majority ($n=258$, 88.1%) had adequate knowledge regarding cervical cancer. Respondents age, current area of practice, qualification, Institute of degree and past family history were contributing factors ($p > 0.05$) in adequate knowledge in this study. The results also revealed that not only 68.3% ($n=200$) and 65.5% ($n=192$) respondents knew that cervical cancer is vaccine preventable and availability of the vaccine for it. **CONCLUSIONS:** Nurses working in different hospitals of Quetta city had better understanding of the disease cervical cancer and its prevention. Yet many of the respondent are not aware of it vaccine and its availability.

PIH54

ASSESSMENT OF KNOWLEDGE AND AWARENESS REGARDING POSTMENOPAUSAL SYNDROME AMONG FEMALES IN QUETTA, PAKISTAN

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OBJECTIVES: The present study was conducted to evaluate knowledge and awareness regarding postmenopausal syndrome (PMS) among the females in Quetta, Pakistan. **METHODS:** A cross-sectional study was conducted among the females aged 30 years and above from January to September 2016. Knowledge regarding postmenopausal syndrome was assessed by a self-administered structured questionnaire contain different questions related to PMS. Descriptive analysis was used to demonstrate the characteristics of the study population. Inferential statistics (Kruskal Wallis tests, $p < 0.05$) were used to assess the significance among study variables. **RESULTS:** A total of 550 distributed questionnaires, 447 were returned (with response rate of 81%). Mean age of the respondents was 38.06 ± 6.194 years. Mean of the total knowledge score was 12.77 ± 3.910 . Fifty-three percent had adequate knowledge regarding postmenopausal syndrome and 47.0% had poor knowledge regarding postmenopausal syndrome. 73.5% of the respondents were aware about the age of menopause. None of the demographic characteristics has statistical significant association with the mean knowledge scores of the study participants. **CONCLUSIONS:** The study respondents had poor level of knowledge about postmenopausal syndrome. Healthcare professionals should give information to females about postmenopausal syndrome so that, the knowledge could be improved.

MENTAL HEALTH – Clinical Outcomes Studies

PMH1

ASSOCIATION BETWEEN DEMENTIA, DISCHARGE DIAGNOSIS, AND 30-DAY READMISSION

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OBJECTIVES: Study aims were to (1) determine the association of dementia with 30-day readmission, and (2) determine if this association varies by most common primary discharge diagnosis at the index hospitalization. **METHODS:** This retrospective cohort study used data from the 2013 Nationwide Readmission Database. The cohort included 265,466 patients aged 65 and older. A 1:1 matching procedure by age, gender, discharge disposition, and emergency department use was used to match 132,733 patients with dementia to patients with no dementia. Descriptive statistics was used to determine top five primary diagnoses for patients with a 30-day readmission. **RESULTS:** 30-day readmission rates were higher among dementia patients (17.2%) compared to non-dementia patients (14.9%) ($p < 0.01$). In adjusted analysis, dementia was associated with 1.15 (95% CI=1.13-1.18) higher likelihood for 30-day readmission. The top five primary discharge diagnoses among patients with a 30-day readmission were septicemia, congestive heart failure, urinary tract infection, pneumonia, and hip fracture. Dementia was associated with higher odds for 30-day readmissions for patients with a primary discharge diagnosis of septicemia (OR=1.34, 95% CI=1.12-1.61) and pneumonia (OR=1.40, 95% CI=1.04-1.90), but not congestive heart failure (OR=1.29, 95% CI=0.96-1.75), urinary tract infection (OR=1.02, 95% CI=0.76-1.38) or hip fracture (OR=0.99, 95% CI=0.77-1.27). **CONCLUSIONS:** Dementia is associated with higher odds for 30-day readmissions regardless of their primary reason for admission. The risk of 30-day readmission is greater for patients with a primary diagnosis of septicemia or pneumonia at the index hospitalization. Care plans for specific conditions may reduce the risk for readmission associated with dementia.

PMH2

CONCOMITANT PSYCHOTROPIC USE AND RISK OF HOSPITALIZATION IN ELDERLY MEDICARE BENEFICIARIES

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OBJECTIVES: The objective of this study was to assess the prevalence of concomitant psychotropic use and its association with all cause-hospitalization among Medicare beneficiaries. **METHODS:** In this longitudinal study, the Medicare Current Beneficiary Survey (MCBS) was used to identify beneficiaries who were psychotropic drug users between 2007 and 2012, ≥ 65 years old, community dwelling and continuously enrolled in parts A, B and D for ≥ 2 consecutive years. Each year, beneficiaries were characterized as single users, short-term concomitant users (≤ 90 days overlap of 2+ drugs), or long-term concomitant users (> 90 days overlap of 2+ drugs). Hospitalization for any cause was measured yearly. In this repeated measures design, we assessed psychotropic use in the year prior to hospitalizations to address temporality. Generalized estimating equations (GEE) in multivariable logit models were used to estimate the odds of hospitalizations adjusted for demographic covariates, smoking, reported health status, total activities of daily living, instrumental activities of daily living and number of chronic conditions. **RESULTS:** Of the 1,612 beneficiaries identified as psychotropic drug users, 64% were single users, 9% were short-term concomitant users and 28% were long term concomitant users at baseline. 24% were hospitalized during follow up. From 2007 to 2012, concomitant psychotropic use consistently ranged from 36% to 38%, with the exception of 2008, when concomitant use increased to 40%. Long-term concomitant use was more prevalent than short-term use, ranging from 27% to 31% vs. 6% to 9%. Short-term concomitant use decreased from 9% in 2007 to 7% in 2012. Compared to single users, short-term concomitant users and long-term users had 45% (95% CI: 1.07-1.95) and 30% (95% CI: 1.07-1.57) increased odds of hospitalization. **CONCLUSIONS:** Among older Medicare beneficiaries, short and long-term concomitant psychotropic use is associated with all-cause hospitalizations. Providers should exercise caution when prescribing psychotropic drugs concomitantly in this patient population.

PMH3

RISKS ASSOCIATED WITH CONTINUED USE OF RISPERIDONE FOR DEMENTIA IN THE ELDERLY LONG-TERM CARE POPULATION

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OBJECTIVES: To evaluate the relative likelihood of adverse events, including relapse of psychosis, stroke and death, associated with continued "off-label" use of risperidone in elderly patients with dementia compared to those who discontinued use of the drug after four months. **METHODS:** This population-based cohort study analyzed long-term care (LTC) patients in a large nationally representative and statistically de-identified administrative claims database. The sample consisted of dementia patients aged 65+ treated with risperidone between 2008 and 2011. Patients were identified by the existence of a new prescription fill for risperidone (treatment naïve) and a diagnosis for dementia (without bipolar or schizoprenia) within one year prior to the index fill. Patients were followed from 30 days up to 24 months after four consecutive months of risperidone use to assess the relative risk of death, stroke and time to relapse of psychosis. **RESULTS:** The study population included 4,672 patients with dementia that were prescribed risperidone between 2008 and 2011 (female = 65.3%, mean age = 82.3 ± 5.6). Findings reveal significantly higher incidence of psychosis in patients with continued use compared to those who discontinued use of risperidone (22.0% vs. 12.0%, $p < 0.01$), which contradicts clinical trials. **CONCLUSIONS:** Contrary to existing literature, this study found that elderly LTC dementia residents who discontinued use of risperidone after four months had a lower risk of psychosis as compared to those who continued use of the drug. This large claims-based analysis demonstrates the value of validating clinical trial outcomes in real-world settings. Additional research is needed to further investigate the safety of long-term "off-label" use of risperidone in elderly LTC patients with dementia.

PMH4

IMPACT OF PRENATAL EXPOSURE TO ANTIDEPRESSANTS ON ADVERSE BIRTH OUTCOMES

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OBJECTIVES: There has been an increase in the diagnosis of depression and the use of antidepressants, especially in women of childbearing age, in the past decade. This has drawn attention to the potential impact of depression and antidepressants on pregnancy and fetal development. To determine the impact of prenatal exposure to antidepressant on the risk of adverse birth outcomes. **METHODS:** The study was conducted using a population-based cohort including all singletons deliveries in years 2008 to 2014 in SC Medicaid population. Information on antidepressant medication and diagnosis of depression and birth outcomes were obtained from South Carolina Medicaid database and birth certificates. The exposed group comprised children of mothers who had a diagnosis of depression and used antidepressants at any time during their pregnancy. The reference group comprised children of mothers who had a diagnosis of depression but did not use any antidepressants during pregnancy. We estimated the association using Marginal Structural Models. **RESULTS:** Approximately 107, 683 women had a diagnosis of depression in the SC Medicaid population. After applying the study inclusion and exclusion criteria, we got the study sample of 4,450 women. And approximately 36% women received antidepressants during pregnancy. In our study we found that the odds of preterm delivery were 1.72 times (95% CI: 1.63 - 1.79) in the group that received antidepressants during pregnancy as compared to those who did not.

Prenatal exposure to antidepressants also increased the odd of having low birth weight/small for gestational age 1.63 times (95%CI: 1.53 – 1.73) and the increased odds of NICU admission by 1.66 times (95% CI: 1.58 – 1.73). **CONCLUSIONS:** In conclusion we found that prenatal exposure to antidepressants is significantly associated with a higher risk of adverse birth outcomes such as preterm delivery, low birth weight/small for gestational age, and NICU admissions.

PMH5

NATIONAL ESTIMATES OF POTENTIAL DRUG-DRUG INTERACTIONS OF ANTI-DEPRESSANTS IN THE UNITED STATES: AN ANALYSIS OF THE NATIONAL AMBULATORY MEDICAL CARE SURVEY DATA

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OBJECTIVES: Antidepressants are among the most common prescription drugs taken by Americans. However, some antidepressants can cause clinically significant drug-drug interactions. The study aims to examine the prevalence and factors associated with potential drug-drug interactions of antidepressants in U.S. outpatient settings. **METHODS:** This project proposed a secondary data analysis using the 2012 National Ambulatory Medical Care Survey (NAMCS) conducted by the National Center for Health Statistics. All patient visits with at least one antidepressant prescription were included. Drug-drug interaction was defined according to Drug Interaction Facts. A series of weighted descriptive analyses were performed to evaluate the prevalence of potential drug interactions. A multivariate logistic regression was developed to examine how patient characteristics impact the presence of drug interactions. Receiver operating characteristic (ROC) curve was used for assessing the discrimination in the proposed logistic regression model. **RESULTS:** Approximately 93.7 million antidepressants were prescribed in US outpatient settings including selective serotonin re-uptake inhibitors (SSRI) (63.2 million), atypical antidepressants (20.4 million), tricyclic antidepressants (TCA) (10.1 million), etc. Among these, 6.9% of them had at least one potential major or moderate drug interaction. The most frequent drugs interacting with antidepressants were: sertraline, fluoxetine, venlafaxine, oxycodone, citalopram, etc. The results of multivariate logistic regression showed that there was a significantly increased likelihood of encountering drug interactions in relationship with patient's age, race, and number of medication used ($P < 0.001$). The area under the ROC curve was computed as 0.61, corresponding to the logistic regression model with moderate discrimination. **CONCLUSIONS:** Unfortunately, drug-drug interaction can be difficult to remember and are commonly missed. However, its adverse effects can lead to morbidity or even mortality if appropriate clinical actions are not taken. As with all perspectives in pharmacovigilance, when determining the relevance and significance of the choice of drugs, considering patient's individual characteristics is of the utmost importance.

PMH6

UNDERSTANDING OPIOID OVERDOSE RISK IN A COMMERCIALY INSURED POPULATION

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OBJECTIVES: To determine important risk factors for opioid overdose in a commercially insured population using integrated medical and pharmacy claims data, as well as publically available data published by the CDC and CMS. **METHODS:** Patients with at least one prescription opioid claim during January 2014 – August 2016 ($n = 2,443,769$) were selected from an administrative claims database of commercially insured members. Patients were followed on a monthly basis until the conclusion of the study period or until a lapse in eligibility. Patient characteristics including medical diagnosis groups, medical and utilization as well as use of multiple prescribers, and family member opioid use were captured. A binary logistic regression analysis was performed on a stratified random sample to estimate likelihood of overdose in the following month ($n=60,867$). Recognizing that integrated medical and pharmacy data may not be available, an additional binary logistic regression model was created without medical data. **RESULTS:** The model using integrated medical and pharmacy data included 16 variables, with prior opioid overdose, substance use and mental health related diagnosis, and utilization of drugs associated with overdose. History of prior opioid overdose (ICD9 965.X and ICD10 T40X) showed the strongest ability to predict overdose, with 25.1% of those overdosing having a prior overdose (OR 16.0 95% CI 8.8 – 28.9). Age was also a strong predictor, with 33.6% of those overdosing in the 15-25 age range (OR 2.5 95% CI 1.9 – 3.3). The model had a c-stat of 0.850 on the training data and 0.881 for the validation data. The model which was restricted to pharmaceutical data had a lower c-stat, with 0.817 for the training data and .839 for the validation data. **CONCLUSIONS:** Medical and pharmacy utilization patterns can identify members with a history of opioid use at an elevated risk of overdose and thus inform targeted behavioral health interventions.

PMH7

PATTERNS AND PREDICTORS OF DEPRESSION TREATMENT AMONG COMMUNITY-DWELLING ELDERLY INDIVIDUALS WITH DEMENTIA AND DEPRESSION IN THE UNITED STATES

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OBJECTIVES: This study examined the patterns and predictors of depression treatment among community-dwelling elderly individuals with comorbid dementia and depression using a nationally representative sample in United States. **METHODS:** A retrospective, cross-sectional study was conducted using multiple years of Medical Expenditure Panel Survey (MEPS) [2002, 2004, 2006, 2008,

2010, and 2012] data. The study sample consisted of elderly (age ≥ 65 years) individuals with dementia, depression and alive during the calendar year. Elderly individuals with dementia were identified by ICD-9-CM code of 290.XX or 294.XX or 331.XX or if they reported use of cholinesterase inhibitors or memantine. Depression was identified by ICD-9-CM code of 296.xx, or 311.xx. The dependent variable of this study was depression treatment, defined as antidepressant medication use with or without psychotherapy. Multinomial logistic regression was conducted to identify factors associated with depression treatment in the study sample. All analyses adjusted for the complex survey design of MEPS to obtain national-level estimates. **RESULTS:** An overwhelming majority (nearly 88%) of the study sample (unweighted $N=173$) reported receipt of depression treatment. Antidepressants only and combination therapy (antidepressant with psychotherapy) was reported by 75% and 13% respectively of the study sample. Selective serotonin reuptake inhibitors (65%) and escitalopram (17.38%) were the most prescribed antidepressant class and individual agent respectively. Age, race/ethnicity, marital status, limitations of instrumental activities of daily living, perceived mental health status, and pain were significantly associated with the reporting of receipt of depression treatment. For example, Whites were approximately three (Odds Ratio=3.10, 95% CI: 1.23-7.82) and five (Odds Ratio=4.93, 95% CI: 2.30-10.5) times more likely to report use of antidepressant alone and combination therapy respectively compared with other race/ethnicities. **CONCLUSIONS:** Almost 90% of individuals with comorbid dementia and depression received depression treatment and several subgroup differences existed in terms of reporting the use of depression treatment.

PMH8

APPLICATION OF ANALYTICAL HIERARCHY PROCESS FOR COMPARING VORTIOXETINE TO AGOMELATINE AND VENLAFAXINE XR IN MAJOR DEPRESSIVE DISORDER

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OBJECTIVES: To assess the overall performance priority of three antidepressants: vortioxetine, agomelatine and venlafaxine XR in major depressive disorder using the Analytical Hierarchy Process (AHP), a Multi-Criteria Decision Analysis approach. **METHODS:** An AHP decision model, combining outcomes of efficacy, tolerability and quality of life was developed on Excel[®]. Weights for each outcome were extracted from a publication reporting patients' and professionals' relative preference. Two head-to-head randomised clinical studies were the main sources of inputs of the AHP decision model: SOLUTION (NCT01571453) and REVIVE (NCT01488071). SOLUTION was an 8-week double-blind, randomized, fixed dose study comparing vortioxetine (10mg) to venlafaxine XR (150 mg) in MDD patients in Asia. REVIVE was a 12-week double-blind, randomized, flexible dose study comparing vortioxetine (10-20 mg) to agomelatine (25-50 mg) in patients who switched due to an inadequate response to previous antidepressant treatment. The performance priorities of the antidepressants on each outcome were measured in terms of odds-ratio or mean differences within each study. The overall performance priority of an antidepressant (range [0-1]) is the sum of the performance priority regarding each outcome measure multiplied by the weight of this outcome measure. **RESULTS:** With SOLUTION inputs, the overall performance priority was higher for vortioxetine versus venlafaxine XR from the patients' (0.56 vs. 0.44) and professionals' (0.54 vs. 0.46) perspective. Similar findings were obtained with REVIVE inputs for vortioxetine versus agomelatine from the patients' (0.61 vs. 0.39) and professionals' (0.60 vs. 0.40) perspective. **CONCLUSIONS:** The AHP is a useful decision-making tool combining multiple criteria into an overall score translating the treatment performance into a treatment preference as defined by patients or professionals. The results show greater preference for vortioxetine versus venlafaxine XR and agomelatine due to its good combined effect on efficacy, tolerability and quality of life.

PMH9

COMPARATIVE EFFECTIVENESS OF OPIOID ABUSE TREATMENTS: A SYSTEMATIC REVIEW

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OBJECTIVES: Opioid abuse and overdose is a major public health issue in the United States. Accordingly, the purpose of this review is to compare the impact of opioid abuse treatments (methadone, buprenorphine, buprenorphine-naloxone, naloxone, and naltrexone) on mortality and healthcare utilization. **METHODS:** A systematic literature review was performed in Fall 2016 using PubMed, PsycINFO, IPA, and CINAHL according to PRISMA guidelines. Outcomes of interest included opioid overdose mortality and healthcare utilization rates. Study eligibility was determined by two reviewers in an un-blinded and standardized manner. English-language studies utilizing a quasi-experimental or experimental design in a sample of U.S. adults at least 18 years of age were eligible for review. Additional inclusion criteria consisted of: prescription or nonprescription opioid use in the study sample; provision of methadone, buprenorphine, buprenorphine-naloxone, naloxone, or naltrexone; and a measure of suspected opioid overdose death or healthcare utilization rates. **RESULTS:** Eleven eligible full-text articles were identified over the period of 1998 to 2016. Sample sizes varied from 25 to over 8,000, with 5 observational and 6 experimental study designs. Five articles addressed opioid overdose mortality only, 5 examined healthcare utilization rates only, and one assessed both overdose mortality and healthcare utilization. Only one study directly compared two opioid dependence medications (buprenorphine-containing products versus methadone); 10 studies used counseling or no treatment (usual care) as the comparator. Buprenorphine and buprenorphine-naloxone resulted in a lower number of ambulatory care visits at 6 months compared to methadone

(mean difference=-71, $p < 0.0001$). Overdose mortality and healthcare utilization rates were lower across all treatments compared to usual care. No appreciable risks of bias were found. **CONCLUSIONS:** All treatments illustrated benefits in terms of overdose mortality and healthcare utilization rates, but buprenorphine-containing treatments may be associated with lower healthcare utilization rates compared to methadone. Additional comparative studies are needed.

PMH10

REAL LIFE ASSESSMENT OF ABILIFY MAINTENA (RELIAM): INTERIM ANALYSIS FROM A CANADIAN NATURALISTIC STUDY OF ARIPIPRAZOLE LONG-ACTING INJECTABLE IN PATIENTS WITH SCHIZOPHRENIA

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OBJECTIVES: In patients with schizophrenia, non-adherence to treatment with oral antipsychotics contributes to suboptimal management of the disorder through increased rates of relapse, reduced time in remission, and eventually poor functional outcomes. With the objective of increasing the utility of findings from controlled clinical trials to real-life clinical settings, ReLIAM (Real Life Assessment of Abilify Maintena) was designed as a naturalistic, prospective, non-interventional, Canadian study, with functioning and illness severity as the main outcomes, for patients with schizophrenia treated with aripiprazole once-monthly 400 mg (AOM) in routine clinical environments. **METHODS:** Canadian patients with schizophrenia, prescribed AOM prior to screening, were initiated for treatment with once-monthly AOM and followed for 24 months. Study assessments were recommended, but not imposed for the purpose of the study, to occur every 3 months. The primary endpoint is functional status, assessed by the Global Assessment of Functioning (GAF) Scale at 12 months. Additional measures include changes in illness severity, social and occupational functioning, productivity loss, caregiver burden, and safety and tolerability. **RESULTS:** As of November 2016, 192 eligible patients at 18 sites in Canada were enrolled, with 158 patients (79.8%) having at least one post-baseline assessment. Patients were classified as early psychosis (≤ 5 years from original diagnosis; 65.2%, $n = 103$) or later (> 5 years; 32.9%, $n = 52$). Interim analysis at 12 months showed mean increase in GAF score from baseline of 10.6 ($n = 100$; 95% CI 7.63, 13.65; $p < 0.001$), and mean change in Clinical Global Impression - Severity (CGI-S) of illness score from baseline of -0.9 ($n = 90$; 95% CI -1.09, -0.64; $p < 0.001$). Safety and tolerability were consistent with the Canadian Product Monograph of AOM. **CONCLUSIONS:** In this first report of naturalistic data for AOM in Canadian patients with schizophrenia, significant improvements in overall patient functioning and illness severity were observed over 12 months of treatment.

PMH11

ASSESSMENT IN WORK PRODUCTIVITY AND THE RELATIONSHIP WITH COGNITIVE SYMPTOMS (ATWORC): PRIMARY ANALYSIS FROM A CANADIAN OPEN-LABEL STUDY OF VORTIOXETINE IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER (MDD)

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OBJECTIVES: Cognitive dysfunction is an important dimension of Major Depressive Disorder (MDD). However, few studies have assessed the relationship between cognitive dysfunction and workplace productivity. AtWoRC (Assessment in Work productivity and the Relationship with Cognitive symptoms in patients with MDD taking vortioxetine; NCT02332954) is an interventional, open-label, Canadian study designed to assess the association between cognitive symptoms and work productivity in gainfully employed patients with MDD receiving vortioxetine. **METHODS:** Patients diagnosed with MDD were prescribed vortioxetine and assessed over a total of 52 weeks at routine care visits that emulated a real-life setting. Patients were classified as having not been treated with another antidepressant (first treatment) or having inadequate response to a previous antidepressant (switch). The primary endpoint is partial correlation between changes in patient-reported cognitive symptoms (20-item Perceived Deficits Questionnaire; PDQ-D-20) scores and self-reported work productivity loss (Work Limitations Questionnaire; WLQ) scores over 12 weeks of vortioxetine treatment. Additional assessments include changes in symptom and disease severity, functioning, pharmacoeconomics, and safety and tolerability. Data presented here is from the primary analysis at Week 12; the study is currently ongoing. **RESULTS:** As of November 2016, 196 eligible patients (97 first treatment, 99 switch) at 26 sites were enrolled, received at least one treatment dose, and attended at least one post-baseline study visit. Primary analysis at Week 12 indicated a significant correlation between PDQ-D-20 and WLQ scores ($r = 0.633$; $p < 0.001$). The correlation between PDQ-D-20 and WLQ scores was comparable and significant in both first treatment ($r = 0.671$; $p < 0.001$) and switch patients ($r = 0.584$; $p < 0.001$). Safety and tolerability were consistent with the Canadian Product Monograph for vortioxetine. **CONCLUSIONS:** After 12 weeks of treatment with vortioxetine, improvements in self-reported cognitive dysfunction were significantly associated with improvements in self-reported workplace productivity in Canadian patients with MDD.

PMH12

CLAIMS-BASED ASSESSMENT OF MEDICAL AND DRUG TREATMENT FOR POST-PARTUM DEPRESSION DURING THE FIRST YEAR AFTER DELIVERY

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OBJECTIVES: Postpartum depression (PPD) is a serious affective disorder, estimated to occur in 10-20% of postpartum women and characterized by depressed mood, insomnia, anxiety, and in some cases, suicidal ideation and thoughts of harming

the baby. First line-treatments for PPD include psychosocial interventions, psychotherapy, and antidepressants. Inpatient (IP) and emergent care may be needed for some women who do not respond adequately to these treatments. The objective of this study was to assess PPD treatment patterns during the 12 months after delivery among women who were covered by U.S. private payers. **METHODS:** This retrospective study using the OptumHealth Care Solutions, Inc. claims database (January 2010-September 2015) identified PPD cases based on diagnoses for PPD or depression 12 months postpartum on at least one IP or emergency department (ED) visit, or two outpatient (OP) visits, or one OP visit and an antidepressant or anti-anxiety prescription drug fill. **RESULTS:** Among 163,565 deliveries, 11,514 PPD cases were identified. Nearly all (93%) received some form of treatment; the first observed treatment or claim with a diagnosis was on average 17 weeks postpartum. Pharmacotherapy (antidepressant or anti-anxiety) was most common (78%), with an average of 5.2 fills. Almost half (45%) received psychotherapy, primarily OP (99%), with an average of 9.2 visits. Few had IP residential psychotherapy ($N=27$; average length of stay (ALOS), 9 days) or partial hospital psychotherapy ($N=17$). Most with PPD-related IP (7%, ALOS 15 days) or ED care (4%) had pharmacotherapy (65%) or psychotherapy (73%) after delivery but prior to care in IP or ED settings. **CONCLUSIONS:** Pharmacotherapy and psychotherapy were the most common treatments for PPD; but treatment in an ED or IP setting was required for some despite prior pharmacotherapy. New treatments that can effectively and quickly treat PPD are needed to limit risk for more intensive and costly treatment.

PMH13

COMPLEX PHARMACOTHERAPY USE AND RESPONSE PREDICTORS IN BIPOLAR DISORDER

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OBJECTIVES: Medications are frequently used in combination to treat bipolar disorder (BP), although there is limited evidence on the effects of complex pharmacotherapy (CP) on outcomes. We examined demographic and clinical characteristics and response in relationship to CP. **METHODS:** The Bipolar CHOICE study compared the effectiveness of lithium + adjunctive personalized therapy (APT) versus quetiapine + APT over 6 months in 482 adult BP patients. We defined CP use as taking for $\geq 50\%$ of visits ≥ 3 of the following BP drug treatments: lithium, antipsychotics, antidepressants, lamotrigine, divalproex, carbamazepine, other anticonvulsants, and anxiolytics. We used multivariate logistic regression to assess associations between CP use and demographic and clinical characteristics and, among those with CP use, the characteristics associated with clinical response (≥ 0.50 Clinical Global Impression-Severity for BP (CGI-S-BP) score decrease (range: 1-7)) or remission (CGI-S-BP ≤ 2 for ≥ 8 weeks). **RESULTS:** Overall, mean age was 39 years, 68% had bipolar I, mean baseline CGI-S-BP was 4.5, and the mean number of BP medications was 2.5, with 45% having CP. Patients age 35-44 (vs. < 25), with prior psychiatric hospitalization and higher BISS depression scores were more likely to have CP, while those with Black (vs. White) race and prior suicide attempt were less likely to have CP. Among patients with versus without CP, 47% vs. 62% responded. Among patients with CP, having comorbid social or generalized anxiety disorder (OR=0.23, 95% CI [0.07-0.74]) and higher BISS mania score (OR=0.31 [0.13-0.73]) were associated with lower likelihood of clinical response. **CONCLUSIONS:** Nearly half of patients had CP; among these fewer than half responded and comorbid anxiety disorder and worse manic symptoms were associated with non-response. More studies are needed to assess other outcomes (e.g., adherence and side effects) associated with CP.

PMH14

PROMINENT NEGATIVE SYMPTOMS IN PATIENTS WITH SCHIZOPHRENIA: FINDINGS FROM THE EUROSC STUDY

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OBJECTIVES: Negative symptoms in schizophrenia are characterised by a reduction or removal of normal processes, and may include loss of emotional responsiveness or motivation and poverty of speech. The aim of the present study is to describe the impact of negative symptoms on patients' clinical characteristics, quality of life and healthcare resource utilisation, using a 2-year cohort study. **METHODS:** We analysed data from EuroSC, a 2-year European cohort study conducted in France, Germany and UK, including a total of 1,208 patients. Patients were classed as presenting with prominent negative symptoms if they scored ≥ 4 on at least three negative items or ≥ 5 on at least two negative items of PANSS. Numerous clinical characteristics, including presence of depression, functioning, quality of life, medication and resource utilization, were assessed at baseline and compared between patients with and without prominent negative symptoms. **RESULTS:** Prominent negative symptoms affected 20.5% of patients, and were associated with a higher depression score (CDSS, 4.23 vs 2.57, $p < 0.0001$), more abnormal involuntary movements (AIMS, 3.74 vs 1.96, $p < 0.0001$), worse functioning (GAF, 39.52 vs 54.52, $p < 0.0001$), reduced quality of life (physical dimension of SF36, 46.92 vs 48.33, $p = 0.048$) and utility (EQ5D, 0.68 vs 0.75, $p = 0.002$), higher caregiver burden (IEQ, 0.93 vs 0.73, $p = 0.01$), and increased risk of relapse at 12 months (47.7% vs 31.2%, $p < 0.0001$). In addition, these patients were found to receive multiple antipsychotics (1.48 vs 1.28, $p = 0.001$), and were more likely to switch treatment after 24 months (21.7% vs 17.9%, $p = 0.01$). Finally,

they required longer hospitalisation over a 6-month prospective follow-up period (11.48days vs. 7.13days, $p=0.04$). **CONCLUSIONS:** Our results showed that patients with prominent negative symptoms experience significant burden in terms of clinical characteristics, but also require more intense healthcare management. This stresses the need for new treatments targeting negative symptoms.

PMH15

USE OF ANTIDEPRESSANT DRUGS IN ADOLESCENTS OF COLOMBIA: A PRESCRIPTION-INDICATION STUDY

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OBJECTIVES: Determine the indications for use of antidepressants medications in adolescent's population (14- 19 years) of Colombia. **METHODS:** Cross-sectional study, including adolescent patients of either sex who were receiving an antidepressant between January 2015 and June 2016, in general and psychiatric medical consultations of the health system in a follow-up period 18 months. The medical records were reviewed to assess sociodemographic, pharmacological and clinical variables, including diagnosis, approved or not indication and comedication. Multivariate analyzes were performed. The study received bioethical approval. **RESULTS:** A total of 350 adolescents treated with antidepressants were evaluated, with a mean age of 16.3 ± 1.4 years, with slight female predominance (59.7%). Most prescriptions were made by general practitioner ($n=258$; 73.7%). The most commonly used antidepressants were fluoxetine ($n=130$; 37.1%), sertraline ($n=56$; 16.0%) and trazodone ($n=47$; 13.4%). The main indications for use were depression ($n=92$; 26.3%), anxiety ($n=53$; 15.1%), migraine ($n=48$; 13.7%), control abuse of psychoactive substance use ($n=34$; 9.7%), and insomnia ($n=20$; 5.7%). Only 150 (42.9%) prescriptions were performed according to approval by regulatory agencies. Multivariate analysis of the prescription unapproved indications showed that having depression (OR:0.004; 95%CI:0.001-0.018), anxiety (OR:0.028; 95%CI:0.010-0.076) or bipolar affective disorder (OR:0.071; IC95%:0.011-0.461) were associated with lower likelihood that its use was outside the approved. **CONCLUSIONS:** The prescription of antidepressant drugs in Colombian adolescent patients is being done especially with fluoxetine, sertraline and trazodone, mainly for unapproved indications according to FDA and INVIMA. There are no guidelines for clinical practice in the country for the use of these drugs in the adolescent population. It is necessary to know more about this topic of interest because of the high frequency of use and the general lack of knowledge about effectiveness, safety and use of these drugs in the adolescent population

PMH16

NATIONAL TREND AND PREDICTORS OF ANTIPSYCHOTIC MEDICATION USE IN U.S. ADULTS WITH SCHIZOPHRENIA: ANALYSIS OF DATA FROM THE 2008-2013 MEPS

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OBJECTIVES: To examine the national trends and predictors associated with antipsychotic use among individuals with schizophrenia. **METHODS:** A retrospective cross-sectional study were conducted using 2008-2013 Medical Expenditure Panel Survey (MEPS) data. Descriptive and Chi-square tests were used to describe patterns of antipsychotic use. Multivariate logistic regression analyses were conducted to explore the relationship between the different variables in the study with antipsychotic use. **RESULTS:** Overall, antipsychotic-medication users decreased from 582,581 in 2008 to 478,553 in 2013, a 17% decrease. The multivariate analyses revealed that no antipsychotic use was associated with patients who were older than 59 [OR=0.28, 95% CI= 0.08, 0.94], female [OR=0.44, 95% CI= 0.26, 0.74], non-white [OR=0.34, 95% CI= 0.19, 0.62], previously or never married [OR=7.88, 95% CI= 3.13, 19.84], or who had prescription coverage by Medicare, Medicaid or other [OR=3.38, 95% CI= 1.38, 8.29], [OR=3.89, 95% CI= 1.74, 8.72], or [OR=7.29, 95% CI= 2.25, 23.66], respectively. Respondents who perceived themselves as having good general health were negatively associated with not receiving antipsychotic medication [OR=0.42, 95% CI= 0.23, 0.76]. **CONCLUSIONS:** During the study period, antipsychotic medication use declined for patients with schizophrenia. This finding suggests targeting subgroups for specific improvement strategies to protect high-risk patients with schizophrenia.

PMH17

THE PREVALENCE, PREDICTORS, AND ECONOMIC IMPACT OF DRUG-DRUG INTERACTION INVOLVING ANTIPSYCHOTIC MEDICATIONS IN UNITED STATES

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OBJECTIVES: To estimate the national prevalence, socio-demographic and health characteristics, and direct incremental expenditures of drug-drug interactions (DDIs) involving antipsychotics among adult in united states. **METHODS:** A retrospective database analysis was conducted and individuals who were exposed to any DDI were identified from the 2010-2014 Medical Expenditure Panel Survey. The prevalence of DDI was evaluated by four international drug interaction compendia. The predictors and expenditures were estimated by employing multiple regression models and the propensity score method. **RESULTS:** From 2010 to 2014, the national prevalence of DDIs was 4.7 million (36%) with incremental costs of \$4,563 per person annually. Adults exposed to DDIs cost 55% more annual total health care expenditures than those are not exposed (RR = 1.55, 95% CI [1.25, 1.92]). Likewise, cost of office-based (RR = 1.78, 95% CI [1.34, 2.38]), and prescription drugs (RR = 2.08, 95% CI [1.55, 2.78]) were significantly associated with exposure to DDIs. Factors associated with greater odds of DDIs

exposure were age, sex, race, type of health insurance, general health, and polypharmacy. **CONCLUSIONS:** The prevalence of DDIs is substantially high among adults using antipsychotics. A significant relationship between the exposure to the DDI and higher total health care expenditures were found. This finding can help policy makers in implement intervention strategies that are effective in lowering the DDI incidence and in reducing the overall cost of care.

PMH18

PSYCHOTROPIC POLYPHARMACY IN THE TREATMENT OF CHILDREN AND ADOLESCENTS WITH MENTAL DISORDERS: PREVALENCE AND DETERMINANTS

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OBJECTIVES: To evaluate the prevalence and determinants of long-term multiclass psychotropic polypharmacy (PP) among children and adolescents with mental disorders. **METHODS:** A retrospective cross-sectional study was conducted using the 2013-2015 administrative claims data from Texas Children's Health Plan. PP was defined as the receipt of ≥ 2 psychotropic medications from different drug classes concurrently for 60 days or more. Based on the number of prescribers involved in the treatment, the patients were categorized into two groups: a) single prescriber (SP) and b) multiple prescribers (MP). Logistic regression models and the Farlie decomposition method (extension of Blinder-Oaxaca [BO] decomposition) were conducted to assess the relative importance of determinants of PP based on the Andersen Behavioral Model. **RESULTS:** A total of 24,147 children and adolescents with a diagnosis of mental disorder and prescription of psychotropic medication were identified. The prevalence of PP was 20.09%. Logistic regression analyses revealed that patients with specialist involvement (enabling factor) had 5.3 and 3.6 times higher likelihood of receiving PP in the SP (OR=5.32; 95% CI 4.62-6.14) and MP (OR=3.57; 95% CI 3.20-3.99) groups, respectively. Other significant factors associated with PP were patient race (predisposing factor) and diagnosis of bipolar disorders and depression, as well as the number of mental disorders diagnosed (need factor) and number of prescribers involved in treatment (MP group only). The Farlie decomposition analysis estimated that the observed need factors explained only 25% of the difference in the receipt of PP between patients seen by PCPs and specialists within both SP and MP groups. **CONCLUSIONS:** The most prominent enabling factor associated with PP was involvement of a specialist in the treatment of mental disorders. Only one-fourth of the difference between PCPs and specialists' prescribing of PP was explained by observable need factors, underscoring the importance of evaluating different prescribing practices by PCPs and specialists.

PMH19

PREVALENCE AND PREDICTORS OF POTENTIALLY INAPPROPRIATE MEDICATIONS IN DEMENTIA PATIENTS

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OBJECTIVES: Potentially inappropriate medication (PIM) use contributes to increased morbidity and mortality in dementia patients. Prior studies have focused on specific classes of PIMs (e.g. strong anticholinergics) or on nursing home dementia patients. No study has comprehensively evaluated PIM use in community-dwelling dementia patients. The current study thus used Medicare database to examine the prevalence and predictors of PIMs in elderly dementia patients. **METHODS:** This retrospective cohort study used the 5% national Medicare data from 2011-2012. The cohort included elderly patients diagnosed with dementia in the baseline year, i.e. 2011. PIMs were defined in the follow-up year, i.e. 2012, using the American Geriatric Society Beers criteria for PIM use due to drug-disease interactions. Predictors were identified in the baseline year based on the Andersen Behavioral Model, and included predisposing (sociodemographic), enabling (dual eligibility) and need factors (Elixhauser comorbidities, medication use and healthcare utilization). Descriptive statistics was used to determine the prevalence of PIMs. Multivariable logistic regression analysis was used to determine predictors of PIMs in dementia patients. **RESULTS:** The cohort included 57,469 elderly dementia patients. The mean age was 85 ± 8 years, and most patients were females (77%) and non-Hispanic whites (82%). Overall, 53.1% of dementia patients received PIMs. The prevalence of different classes were as follows: antipsychotics (31.3%), H2-receptor antagonists (11.3%), antihistamines (10.3%), antimuscarinic urinary incontinence (9.1%), antiemetics (6.7%), nonbenzodiazepine receptor agonist hypnotics (6.1%), tricyclic antidepressants (5.7%), antispasmodic (3.3%), skeletal muscle relaxants (1.6%), antiparkinsons (1.5%), benzodiazepines (1.1%). Multivariable logistic regression found that females (odds ratio [OR], 1.16), Blacks (OR, 1.18), patients with Elixhauser comorbidities (twelve conditions), emergency room visit (OR, 1.1) and more than five prescription medications (OR, 3.0) were associated with higher likelihood of receiving PIMs. **CONCLUSIONS:** One out of two dementia patients received at least one PIMs. Predictors identified in the study can be targeted to reduce PIM use in dementia patients.

PMH20

EPIDEMIOLOGY OF BIPOLAR DISORDER TYPE I (BD-I) IN THE UNITED STATES: A SYSTEMATIC REVIEW OF THE LITERATURE

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OBJECTIVES: To perform a systematic literature review (SR) of studies in peer reviewed journals on 10 epidemiologic aspects of BD-I in the US: its annual

incidence, prevalence and respective trends; mortality rates and trends; associated comorbid disorders; stages, severity levels and its natural progression. **METHODS:** A literature search was performed using relevant search terms to identify articles published between 2006 and 2016. Studies were identified through electronic Embase, MEDLINE, and PubMed databases. Manual review of bibliographies allowed for the detection of complementary studies. **RESULTS:** Eleven SR and five complementary studies addressed the incidence and prevalence of BD-I. US National Institute of Mental Health (NIMH) estimated the prevalence of BD-I as 1% (lifetime) and 0.6% (12-month). Mean age of disease onset was 20 years, with over 70% of cases diagnosed at the age of 30. Available data was inconclusive for trends on prevalence and there was no incidence data available for US population. Fourteen SR and eight primary studies addressed comorbid disorders. Substance use disorder was highly prevalent with alcohol abuse over 40% and drug dependence between 18% and 30.4%. Borderline personality disorders (12.5%) and anxiety disorders (65% to 86.7%), including generalized anxiety disorder (14.4% to 38.7%) and obsessive-compulsive disorders (10.7% to 24.6%) were highly prevalent and have a negative impact over the course of BD-I. We retrieved 9 SR and one primary study regarding BD-I's staging and natural progression. Staging models identified several features in common: an earlier phase, prodromal phase, initial phase, relapsing phase and end-stage. **CONCLUSIONS:** BD is a chronic and disabling disease with onset in early adulthood. Knowledge on epidemiologic features may help increase awareness and early diagnosis, although there is a gap in our understanding of prevalence rates over time. Also, physicians must be attentive of the high comorbidity rates associated with BD-I.

PMH21

ROUTINE ELECTROLYTE MANAGEMENT AMONG ALCOHOLIC WITHDRAWAL IN HOSPITALIZED SETTING ALCOHOLIC DEPENDENT PATIENTS: ANTICIPATING A FINDING FOR BENEFITS IN CLINICAL MANAGEMENT

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OBJECTIVES: This study aimed to investigate if there is possible association of both hypomagnesemia and hypokalemia with the severity of alcohol withdrawal syndrome. **METHODS:** A prospective cohort study was conducted in alcohol dependence male patients with age > 18 years, admitted in Suanprung Psychiatric Hospital, Chiang Mai Thailand during May to October, 2014. The severity of alcohol withdrawal syndrome was assessed using criteria for Clinical Institute Withdrawal for Alcohol Revised (CIWA-Ar) score which divided into mild, moderate, severe, and very severe. Hypokalemia grade was defined as serum potassium < 3.5 mEq/L meanwhile the Hypomagnesemia grade was serum magnesium < 1.4 mEq/L. The multivariable ordinal logistic regression was performed for data analysis. **RESULTS:** A total of 172 male patients, average aged of 44.3 ± 10.1 years. The hypokalemia was found in 71 patients (42.0%) whereas only 38 patients (22.5%) had hypomagnesemia. However, further analysis with controlled for potential confounders, surprisingly hypomagnesemic patients had more severity of alcohol withdrawal as compared with a non-hypomagnesemia (adj. OR 3.49; 95%CI 1.20-10.11, p=0.02). Similarly, patients with hypokalemia showed higher severity of alcohol withdrawal compared to those with non-hypokalemia (adj. OR 2.89; 95%CI 1.05-7.99, p=0.04). **CONCLUSIONS:** Both hypomagnesemia and hypokalemia were strongly associated with severity of alcohol withdrawal syndrome. Suggesting that the plasma Magnesium level determination should be also placed in a routine laboratory test. As such clinicians should be well aware and provide magnesium sulfate sufficiently to prevent severe alcohol withdrawal syndrome.

MENTAL HEALTH – Cost Studies

PMH22

A BUDGET IMPACT ANALYSIS OF ABUSE DETERRENT OPIOID FORMULATION

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OBJECTIVES: To model the economic impact associated with increased use of abuse-deterrent formulations of prescription opioids. **METHODS:** A budget impact model was conducted from the payers' perspective considering a population of 1,000,000 lives, using a 3-year timeframe. Utilization of prescription opioids was determined using data from a state Prescription Drug Monitoring Program for the year 2015, focusing on the long-acting opioids fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and oxymorphone. Hospital cost associated with prescription opioid overdose was derived from the Healthcare Cost and Utilization Project. The base case assumed a 5%, 7%, and 10% increase in the use of abuse-deterrent opioid products in each of the three years respectively. We estimated that this would equate to approximately 194 additional patients per year, with a corresponding average annual reduction of 14 emergency department visits and 16 hospital discharges for prescription opioid overdose. A sensitivity analysis accounted for the uncertainty of model parameters on overall and per-member-per-month costs. **RESULTS:** The costs associated with the utilization of long-acting prescription opioids increased from \$11,446,622.38 in the base year to \$12,736,268 in year 1, \$13,252,126 in year 2, and \$14,025,914 in year 3 corresponding to a per-member-per-month cost of \$1.06 in year 1, \$1.10 in year 2, and \$1.17 in year 3. We estimated the total cost of overdose of the 3-year period to be \$5,428,061.20 (\$ 1,854,913.00 in year 1, \$1,815,862.20 in year 2, and \$1,757,286.00 in year 3). **CONCLUSIONS:** Increased use of abuse-deterrent opioid formulations was associated with an increase in total cost of \$5,674,441 and an average increase of \$0.16 in per-member-per-month spending as compared with the current mix of long-acting prescription opioids. Reduction in prescription opioid overdoses

resulting from the increased use of abuse-deterrent opioid formulations yielded savings of \$429,558.80.

PMH23

ECONOMIC BURDEN OF BIPOLAR DISORDER IN THE UNITED STATES: A SYSTEMATIC REVIEW OF THE LITERATURE

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OBJECTIVES: Bipolar disorder (BD) is one of the leading causes of disability secondary to mental/behavior disorders worldwide. We aimed to evaluate the economic burden imposed by BD over employability; work performance and health related quality-of-life (HRQoL) of patients in the United States (US). **METHODS:** We conducted a comprehensive search in Medline and EMBASE from 2006 to 2016 for studies addressing the following aspects: cost-of-illness (direct and indirect costs and impact of specific pharmacological treatments), impact over employability and work productivity, HRQoL (over course of illness and during specific pharmacological treatments). **RESULTS:** We included 26 studies evaluating cost-of-illness. Annual societal costs per BD patient varied from \$1,904 to \$33,090, with production losses making up to 20%-94% of costs. Overall direct healthcare costs ranged from \$8,000-\$14,000 purchasing power parities. Total annual health care costs were higher for BD patients than for those without (\$12,764 vs \$3,140). Improved adherence to medication was related to lower medical costs in BD (1-point increment in MPR reduced \$123-\$439 mental health expenditures in manic/mixed symptoms patients receiving antipsychotics). Fifteen studies addressed impact of BD over employability and work productivity. Around 40%-60% of BD patients were employed, with higher employment rates during early phases of disease compared to later stages. Mean annual absence costs (sick leave, short/long-term disability, and workers' compensation) were significantly higher for BD employers when compared with those without the disease (\$1,995 vs \$885). Results from 11 studies showed that HRQoL is impaired in BD patients compared with healthy individuals and with patients diagnosed with other chronic psychiatric and medical conditions. BD pharmacological and non-pharmacological treatments have a positive effect on HRQoL. **CONCLUSIONS:** When compared with other populations, BD patients imposed higher medical costs for payers; however, treatment adherence was associated with reduced health expenditures. Both employability and work productivity were negatively affected by the disease, as was HRQoL.

PMH24

ECONOMIC BURDEN OF UNCONTROLLED ATTENTION DEFICIT HYPERACTIVITY DISORDER IN THE US: A RETROSPECTIVE ANALYSIS OF DATABASE CLAIMS FROM A COMMERCIALY INSURED POPULATION

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OBJECTIVES: Despite availability of several treatment options, adequate symptom control remains a major concern in attention-deficit/hyperactivity disorder (ADHD). Lack of symptom control may impose a significant economic burden, yet few studies have quantified the frequency of uncontrolled symptoms and its relation to costs. This retrospective claims database analysis assessed the impact of ADHD symptom control on health care costs. **METHODS:** MarketScan® Commercial Database claims between January 1, 2010 and June 30, 2015 were used to identify pediatric (age 6-12), adolescent (13-17), and adult (18+) patients with ≥ 2 ADHD diagnoses (ICD-9 314.0x), ≥ 1 newly-started ADHD medication pharmacy claim, and continuous enrollment 6 months before and 12 months following ADHD medication initiation ("index"). Symptom control cohorts were defined from 6-month post-index treatment changes: (i) "well controlled"—without dose increase or treatment switching/augmentation; (ii) "partially controlled"—dose increase; and (iii) "poorly controlled"—dose increase and/or treatment switching/augmentation. Annual adjusted cost differences were estimated using generalized linear models. **RESULTS:** The ADHD patient sample (97,230 pediatric; 58,641 adolescent; 135,177 adults) was 69.7%, 65.0%, and 48.7% male, respectively. Mean (SD) age was 8.9 (1.9), 15.0 (1.4), and 31.2 (12.1) years for the pediatric, adolescent, and adult groups, with percent well- (62.1%, 73.7%, 73.0%), partially- (8.8%, 6.4%, 6.1%), and poorly-controlled (29.1%, 19.9%, 20.9%), respectively. Well-controlled pediatric patients had lower annual mean total costs (\$3,709) than partially- (\$4,269) and poorly-controlled patients (\$5,127) (all p-values < 0.001). Annual mean medical and pharmacy costs were also lower among well-controlled patients (\$2,180, \$1,572, respectively) than partially- (\$2,163, \$2,123) and poorly-controlled (\$2,776, \$2,363) patients. Similar cost trends were observed for adolescent and adult populations. **CONCLUSIONS:** Our findings suggest that, after one year of treatment, 20.9% - 29.1% of ADHD patients were poorly controlled, and incurred 20.7% - 38.2% greater costs than well-controlled patients, suggesting better symptom control may have economic benefits.

PMH25

HEALTH CARE COSTS OF TREATMENT-RESISTANT DEPRESSION IN A MEDICAID POPULATION

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OBJECTIVES: Among adults in the Medicaid program who were initiating anti-depressant medications for depression, we compared the health care economic

burden of patients who did and did not develop treatment-resistant depression (TRD). **METHODS:** A retrospective longitudinal cohort analysis was performed of the Truven Market Scan Medicaid database (2008-2014). We selected non-elderly adults (18-63 years) with continuous pharmacy and service coverage during a study period spanning 12 months before and after an index antidepressant prescription. Eligible patients had 1) an antidepressant fill after ≥ 6 months without antidepressant possession, 2) a depression diagnosis within 30-days of the index antidepressant fill; and 3) no claims for schizophrenia, bipolar disorder, or dementia and no Medicare coverage during the study period. TRD was defined as initiation of a third treatment course (antidepressants or augmentation therapy) after 2 treatment courses at an adequate dosage and duration (≥ 6 weeks) during the study period. We compared the health care costs of TRD and non-TRD patients during the 12-months following antidepressant initiation. Costs were compared using ordinary least squares (p-value obtained using a nonparametric bootstrap). **RESULTS:** Approximately 25.1% (2,733 of 10,872) of the cohort met criteria for TRD. Patients with TRD had significantly higher mean (SD) total health care costs than patients without TRD \$17,590 (\$42,768) vs. \$9,138 (\$23,885). This difference included higher inpatient \$5,776 (\$36,277) vs. \$2,578 (\$19,348), outpatient \$6,315 (\$9,968) vs. \$4,091 (\$8,111), emergency department \$522 (\$1,857) vs. \$284 (\$1,080), prescription pharmacy \$4,225 (\$11,582) vs. \$1,740 (\$4,984), and other medical care \$752 (\$4,520) vs. \$446 (\$2,887) costs. All group comparisons had a $p < 0.0001$. **CONCLUSIONS:** Within the Medicaid program, approximately one-quarter of adults initiating antidepressant treatment for depression develop treatment-resistant depression during the subsequent year. In relation to depressed patients without treatment-resistance, TRD patients have substantially higher health care costs across every major cost category.

PMH26

HEALTHCARE RESOURCE USE IN SCHIZOPHRENIA SUFFERERS - FINDINGS FROM THE EUROSC COHORT

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OBJECTIVES: Schizophrenia is associated with extensive healthcare resource use which may relate to symptom type and severity. This study aims to quantify healthcare resource utilisation associated with different profiles of schizophrenia symptoms, based on data from the European Schizophrenia Cohort - a naturalistic two-year follow-up of 1,208 patients. **METHODS:** At each of the five semi-annual follow-up visits, patients were classed into eight health states based on the Lenet classification, accounting for symptom type (positive/negative/cognitive) and severity (mild/moderate/severe). We estimated consultations with general practitioner (GP), psychologist, psychiatrist and other specialists, day-clinic visits and the length of inpatient stay over six months preceding each visit, using a two-part statistical model based on two generalised mixed models. **RESULTS:** GP visits over 6 months ranged from 1.15 to 2.08, with highest burden linked to moderate positive and negative symptoms. Psychologist visits were the least frequently utilised resource type; highest use was estimated in patients who experienced moderate (0.50) or severe (0.44) predominantly negative symptoms, or severe positive and cognitive symptoms (0.51). All patients frequently visited their psychiatrist - with those experiencing mild symptoms requiring fewest visits (3.01) - but were far less likely to visit other specialists (probability 10-20%), with an average number of visits below 1.0 for all health states. Day clinic use varied widely between health states, both in terms of probability (2-14%) and the number of visits amongst those who did attend (7.9-91.7). Between 11% and 35% of patients required hospital admission, with patients experiencing extremely severe symptoms at highest risk. However, amongst those admitted, hospitalisation was generally prolonged regardless of health state (39-57 days). **CONCLUSIONS:** We quantified the substantial healthcare requirements of schizophrenia patients with different symptom characteristics, which is likely to assist future understanding of differences in resource utilisation of treatments along different health states in this disease.

PMH27

HEALTHCARE RESOURCE UTILIZATION AND COSTS AMONG ADULT SCHIZOPHRENIA PATIENTS USING ONCE-MONTHLY VERSUS TWICE-MONTHLY LONG-ACTING ANTIPSYCHOTICS

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OBJECTIVES: To compare real-world healthcare resource utilization (HRU) and costs between schizophrenia patients stabilized on once-monthly (OM) second generation long-acting injectable antipsychotic (LAI) versus twice-monthly (TM) second generation LAI. **METHODS:** Medicaid data from 6 states were used to identify adults with schizophrenia. Patients with ≥ 2 consecutive claims of the same OM LAI (paliperidone palmitate or aripiprazole) or TM LAI (risperidone) within 45 days with the same dosage and days supplied were selected. Patients needed ≥ 6 months of eligibility prior to LAI initiation and were observed from the second consecutive claim (index date) to the end of data availability. Outcomes were measured for 12 months after the index date. HRU was compared using incidence rate ratios (IRRs) and 95% confidence intervals (95% CIs) from multivariate generalized linear regression models with a negative binomial distribution. Costs were compared using linear regressions, with p-values estimated using bootstrap techniques with re-sampling (B=499). **RESULTS:** A total of 785 OM patients and 625 TM patients met all study criteria. Patients in the OM cohort were younger (40 vs. 42 years, $p=0.022$) and were more likely to be men (68% vs. 63%, $p=0.043$) than in the TM cohort. After adjustment for potential confounders,

patients in the OM cohort had fewer outpatient visits (IRR: 0.89, 95%CI: 0.79; 1.00), inpatient visits (IRR: 0.73, 95%CI: 0.58; 0.92), and long-term care visits (IRR: 0.58, 95%CI: 0.35; 0.94). There was no significant difference in total healthcare costs (mean difference: -\$146, $p=0.228$) between OM and TM patients. OM patients had significantly higher pharmacy costs (mean difference: \$313, $p < 0.001$) and significantly lower medical costs (mean difference: -\$460, $p < 0.001$) compared to TM patients. **CONCLUSIONS:** Patients stabilized on an OM LAI had lower frequency of HRU and lower medical costs, which offset the higher pharmacy costs compared to patients stabilized on a TM LAI.

PMH28

ANALYSIS OF THE MEDICAL SERVICE UTILIZATION AND EXPENSES OF THE HOSPITALIZED PATIENTS WITH ALZHEIMER'S DISEASE IN SHANGHAI

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OBJECTIVES: To investigate the medical service utilization and the economic burden of the hospitalized patients with Alzheimer's disease in Shanghai. **METHODS:** We collected the homepage information of the discharged Alzheimer's disease patients in various medical institutions in Shanghai at various levels in 2015, and conducted statistical analysis on the sex, age, medical payment approach, length of stay, and hospitalization expenses of the patients. **RESULTS:** There were 940 discharged Alzheimer disease patients in Shanghai in 2015, among whom 342 were male, 124 were aged 60-69 years old, 182 were aged 70-79, 468 were aged 80-89 and 131 were aged over 90. Nursing homes and community health centers constituted the major part of the primary medical institutions. In the nursing homes, there were 271 patients; the per capita hospitalization expense was 30415 Yuan. The largest parts accounting for the hospitalization expenses were general medical services (43.62%). In the community health centers, there were 116 patients; the per capita hospitalization expense was 18065 Yuan. The largest parts accounting for the most of hospitalization expenses were general medical services (40.93%). General hospitals and psychiatric hospitals constituted the major part of the tertiary medical institutions. In the general hospitals, there were 146 patients; the per capita hospitalization expense was 24359 Yuan. The largest parts accounting for the most of hospitalization expenses were western pharmaceutical (32.39%). In the psychiatric hospitals, there were 175 patients; the per capita hospitalization expense was 54189 Yuan. The largest parts accounting for the most of hospitalization expenses were general medical services (25.90%). **CONCLUSIONS:** The results show that the economic burden of patients with Alzheimer's disease in Shanghai is relatively high. At the institutional level, the tertiary medical institution undertakes most of diagnostic service, but the primary medical institutions which should assume the primary nursing and rehabilitation function have not demonstrated the advantages.

PMH29

PRICE ANALYSIS OF ANTIDEPRESSANT MEDICATIONS MARKETED IN U.S

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OBJECTIVES: Antidepressants is one of the most prescribed class of drugs in the US. The AWP does not represent the drug acquisition cost, but it is one of the most commonly used benchmarks for drug reimbursement. This study assessed the trends in average wholesale prices (AWP) at market entry of antidepressant drugs approved by the FDA and marketed in the US as of October 31, 2016. **METHODS:** Regulatory information was derived from the FDA website. Average wholesale prices (AWP) per unit at market entry were derived from the RedBook (Truven Health Analytics, Inc.). The AWP history was collected from approval to October 31, 2016. The FDA daily-defined dosage (DDD) for adult patients was obtained from FDA-approved labels. The AWP per DDD, 30 DDD and year were calculated. Prices were adjusted for inflation using the consumer price index (CPI). Descriptive statistics were performed in the study. **RESULTS:** FDA listed 56 approved antidepressant drugs as of October 2016. There were 20 antidepressant drugs approved by FDA in 1980s, 15 in 1990s, 14 in the 2000s, and 7 in the period 2010-2016. The median AWP per DDD at market entry was \$4.02 (range=\$0.28 - \$58.27) in the 1980s, \$10.75 (range=\$1.04 - \$37.35) in the 1990s, \$24.96 (range=\$4.54 - \$84.39) in the 2000s, and \$25.38 (range=\$8.67 - \$149.33) in the period 2010-2016. The median CPI-adjusted AWP per DDD of antidepressant drugs at market increased in average \$0.7 per year. **CONCLUSIONS:** The pharmaceutical companies' inflation-adjusted listed prices at market entry increased 6.6 times over the period of analysis. Prices of marketed antidepressant drugs also increased faster than the inflation.

PMH30

THE IMPACT OF LONG ACTING INJECTABLE ANTIPSYCHOTICS ON THE HEALTH AND ECONOMIC OUTCOMES OF SCHIZOPHRENIA PATIENTS

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OBJECTIVES: To investigate the health and economic impact of long acting injectable (LAI) antipsychotics on schizophrenia patients. Schizophrenia is a chronic severe and disabling mental disorder typically onset in early adulthood. Treatment persistence with the traditional daily oral antipsychotics has been suboptimal. LAIs reduce the administration frequency to biweekly, monthly or quarterly, and have been shown to improve treatment persistence. **METHODS:** A health economic model was developed to compare the health and cost outcomes of patients treated with commonly prescribed antipsychotics in France as

maintenance therapy from the patient perspective to put it in context of self-pay economics. The LAI comparators included paliperidone, aripiprazole and risperidone, along with commonly used oral treatments. The model tracked treatment persistence, relapse, key adverse events and direct and indirect costs (associated with unemployment, care giving, loss in productivity and mortality). Clinical inputs were based on mixed treatment comparisons of pivotal phase III clinical trials, while cost inputs were based on published literature. **RESULTS:** Over a 1-year period, schizophrenia patients without treatment on average had 0.57 relapses and incur €6,092 direct medical costs and €31,187 total costs (direct and indirect). Patients on LAIs experienced fewer relapses (0.20~0.25) than those on oral (0.29~0.43) or no treatment. Paliperidone palmitate 3-month dosing (PP3M), LAI with the lowest administration frequency, had the lowest number of relapses (0.20) due to improved treatment persistence and better efficacy. Receiving either LAIs (€4,959~€5,719) or oral treatment (€3,711~€4,975) reduced direct medical costs compared to no treatment. When indirect costs were included, patients receiving LAIs had lower costs than those receiving oral or no treatment, with cost being the lowest for PP3M. **CONCLUSIONS:** Schizophrenia imposes significant health and cost burden on patients and families. LAIs provided a better alternative to orals in reducing relapses and total costs, with PP3M delivering the best outcome.

PMH31

POSTPARTUM DEPRESSION SCREENING IN ALBERTA, CANADA: A COST EFFECTIVENESS ANALYSIS USING ADMINISTRATIVE DATA

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INTRODUCTION: Postpartum depression (PPD) is a debilitating disease that affects women's quality of life, social functioning and productivity. In Canada, the prevalence of PPD is estimated to be between 10-15%. Left untreated, PPD can lead to significant consequences for the mother, father and child. **OBJECTIVES:** To examine the cost effectiveness of screening versus not screening for PPD in Alberta using the Edinburgh Postnatal Depression Scale (EPDS) with a cut point of 12/13 within the first year postpartum. **METHODS:** A decision analytic model was created to determine the incremental cost per quality adjusted life-year (QALY) of PPD screening over one year postpartum using a public payer perspective. The majority of model inputs were derived using an Alberta-based research cohort linked to administrative data. Costs are reported in 2016 Canadian dollars. Sensitivity and scenario analyses were completed to test the uncertainty surrounding varying model inputs. **RESULTS:** Screening for PPD using the EPDS at a cut point of 12/13 appears to be more costly (\$66) and more effective (0.0021 QALYs) compared to not screening, with an incremental cost effectiveness ratio (ICER) of \$30,822 per QALY. The base case inputs were chosen to be conservative, the ICER for all other scenarios ranged from \$13,382-\$30,077 per QALY. Sensitivity analyses indicated that the utilities of having and not having PPD were important drivers of the model. **CONCLUSIONS:** Following extensive scenario and sensitivity analyses, it appears that the ICERs for PPD screening falls within the acceptable threshold range (\$50,000 per QALY) for health programs and services in Canada. We therefore recommend screening for PPD using the EPDS with a cut point of 12/13 in Alberta.

PMH32

PHARMACOECONOMIC ANALYSIS OF AGOMELATINE FOR THE TREATMENT OF MAJOR DEPRESSIVE DISORDER IN KAZAKHSTAN

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OBJECTIVES: The aim of this study is to conduct an economic evaluation of agomelatine compared with venlafaxine and its most common alternative in routine clinical practice for the treatment of patients with major depressive disorder (MDD) in Kazakhstan. **METHODS:** Markov's model was developed to assess the 2-year efficiency of agomelatine relative to the antidepressant analog (venlafaxine) in the treatment of patients with MDD in Kazakhstan. The analysis was conducted from the perspective of the Ministry of Health and Social Development of the Republic of Kazakhstan. Costs are expressed in US dollars (USD) at the exchange rate of 2015 (185.05 KZT = 1 USD), the health benefits were counted in QALYs. Costs and results that occur outside of one year were discounted at an annual rate of 3%. **RESULTS:** Cumulative costs for patients with MDD during the biennium amounted to 220.17 USD and 329.57 USD in the case of treatment with venlafaxine and agomelatine, respectively. Agomelatine therapy predicts 0.466 QALY per patient, whereas treatment for venlafaxine the figure is 0.386 QALY. Thus, CER 706.64 USD/QALY vs 571.06 USD/QALY, respectively. The indicator of the incremental cost-effectiveness of ICER is 1677.05, which is "very cost-effective," according to WHO recommendations (less than 1 per capita GDP). **CONCLUSIONS:** Pharmacoeconomic analysis showed that the use of agomelatine in the "standard treatment strategies of MDD," proved to be more cost-effective than conducting a standard therapy with venlafaxine for ICER indicators.

PMH33

COST-OFFSET ANALYSIS OF SOCIAL AND EMOTIONAL LEARNING PROGRAMS FOR THE PREVENTION OF EXTERNALIZING BEHAVIOR PROBLEMS: AN ECONOMIC MODELING STUDY

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OBJECTIVES: Externalizing behavior problems are common among children, and place a high disease and financial burden on individuals and society. Social and

Emotional Learning (SEL) programs are commonly used to prevent such problems, but little is known about their possible longer-term cost-offsets. This study estimates the costs and longer term savings of the two evidence based SEL programs currently available in Sweden, Good Behavior Game and Second Step, for the reduction of externalizing behavior problems in children. **METHODS:** A population-based Markov model was developed to estimate the cost-savings of the two SEL programs compared to a no intervention scenario, achieved by a reduction in clinical cases of attention-deficit/hyperactivity disorder (ADHD), Conduct disorder (CD) and comorbid ADHD/CD. Epidemiological data were collected from the 2015 Global Burden of Disease Study. Intervention effectiveness parameters were estimated from a meta-analysis of relevant studies, where effects assumed to reduce to zero after one year. This study adopted a limited societal perspective including costs accruing to the health care and education sectors while intervention costs were based on intervention descriptions. The target population was a cohort of 8-10-year-old healthy children in the 2015 Swedish population followed through to the age of 15 years, assuming 100% intervention coverage. Multivariate probabilistic and univariate sensitivity analyses were conducted to test model assumptions. **RESULTS:** Intervention cost per child amounted to 70 USD and total cost-savings per child over the modeling period were estimated at 330 USD. The cost-offset relationship for prevention was 1.49, implying that for 1 USD invested, 1.49 USD can be gained over the modeling period. **CONCLUSIONS:** Our results suggest that these two evidence based SEL programs are likely to yield cost-savings to society. Further research is needed to investigate cost-savings accruing to other sectors of the society, as well as the cost-effectiveness of such interventions.

PMH34

COST-EFFECTIVENESS EVALUATION, INCLUDING COGNITIVE OUTCOMES, OF VORTIOXETINE IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER SWITCHING FROM FIRST ANTIDEPRESSANT THERAPY IN THE UNITED STATES

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OBJECTIVES: A US-setting, cost-effectiveness evaluation was performed comparing vortioxetine versus levomilnacipran and vilazodone for the treatment of major depressive disorder (MDD) after a switch due to first antidepressant inadequate response. **METHODS:** A decision tree, supplemented with a 2-month cycle Markov model of additional antidepressant switches, was built (1-year time horizon). Published data were used for comparative efficacy (remission, recovery, and relapse), tolerability (withdrawal due to adverse events [AEs]), health state-associated utilities, and short- and long-term AE-related disutilities. Cognition-related inputs (cognition rates, disutilities, and costs) were based on analyses of clinical trial results (published and unpublished). Using a societal perspective, direct healthcare costs and indirect costs from absenteeism were considered (2015 US dollars). The main outcome was the incremental cost-effectiveness ratio (ICER). Sensitivity analyses, including burden of cognition, were conducted. **RESULTS:** The total costs and initial treatment-line recovery rates were \$6615 and 34.1% for vortioxetine, \$6763 and 28.3% for levomilnacipran, and \$6294 and 28.8% for vilazodone. Vortioxetine was associated with a greater quality-adjusted life year (QALY) versus levomilnacipran (0.0070) or vilazodone (0.0083); was dominant versus levomilnacipran, and cost-effective versus vilazodone (ICER, \$38,608/QALY); and had a 75% probability of being cost-effective at a \$50,000 willingness-to-pay threshold (recommended US-based lower limit). In sensitivity analyses using residual cognition rates of 49.3% for vortioxetine, 58.0% for levomilnacipran, and 63.7% for vilazodone, vortioxetine was associated with an additional QALY versus levomilnacipran (0.0085) or vilazodone (0.0109), and was dominant versus levomilnacipran and cost-effective versus vilazodone (ICER, \$27,633/QALY). Similar results (base and cognition scenarios) were found taking into account only direct costs (>60% of total costs). **CONCLUSIONS:** In this analysis of MDD treatment after first antidepressant switch, vortioxetine showed higher QALYs and lower costs than levomilnacipran, and was cost-effective versus vilazodone; an ICER reduction was found after cognition outcomes inclusion (28% versus base). These data suggest potential benefits of switching to vortioxetine.

PMH35

ECONOMIC EVALUATION OF PALIPERIDONE PALMITATE FOR TREATING CHRONIC SCHIZOPHRENIA PATIENTS IN THE UAE

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OBJECTIVES: Schizophrenia is a long-term mental disorder that affects how a person thinks feels and behaves. Management of these patients is both clinically and financially challenging. In the United Arab Emirates (UAE), standard of care (SoC) is daily oral antipsychotics which have adherence concerns. Paliperidone palmitate (PP-LAI) has recently been approved for chronic schizophrenia and is administered monthly. This is an economic evaluation of PP-LAI in the UAE. **METHODS:** A cost-utility analysis was conducted using a previously validated 1 year decision tree model reflecting the treatment pathways, costs and outcomes of three treatment options; PP-LAI monotherapy, SoC or PP-LAI plus SoC. Direct costs, inflated to 2016 where applicable, and treatment effects were obtained from literature and standard price lists. Where these were not available, data were collected from a local panel of experts who also validated the treatment pathways. The primary outcome was the cost per quality-adjusted life-year

(QALY) gained **RESULTS:** The average PP-LAI patient in the base case with or without SoC experienced 0.840 QALYs while the SoC patient experienced 0.812 QALY. Since the PP-LAI plus SoC group cost more than the PP-LAI monotherapy without additional QALY gains, PP-LAI plus SoC was discarded from further analysis. PP-LAI monotherapy resulted in incremental cost savings of AED 831 (USD 226) when compared to SoC. PP-LAI monotherapy is therefore projected to be an economically dominant treatment option. Dominance drivers were greater remission days and lower hospitalization and ER visits for PP-LAI vs SoC. The model was sensitive to a wide range of published SoC adherence rates. In scenario analyses, the conclusions were between increased economic dominance and highly cost-effective when PP-LAI monotherapy was compared to SoC. **CONCLUSIONS:** PP-LAI is projected to save costs and improve patient outcomes in the UAE and should be considered a viable treatment alternative by payers and prescribers alike.

PMH36

A SYSTEMATIC REVIEW OF HEALTH ECONOMIC STUDIES ON BIPOLAR DISORDER TYPE I IN THE UNITED STATES

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OBJECTIVES: Bipolar disorder (BD) is a chronic disease associated with several medical and psychiatric comorbidities that can have serious economic impact. We aimed to identify, describe and critically assess health economic studies in BD-I in the US during the last ten years and provide recommendations for future researchers. **METHODS:** We searched MEDLINE, EMBASE, NHS EED and ISPOR's database to identify articles/posters with economic evaluations (cost-effectiveness-CEA, cost-utility-CUA, cost-minimization-CMA, cost-benefit-CBA and budget impact analysis-BIA) performed on BD-I patients. We collected information on: population, intervention/comparator, setting, modeling, data quality, clinical/economic outcomes and uncertainty analysis. For quality assessment, two checklists (Drummond/Philips) recommended by the Cochrane Collaboration were applied. **RESULTS:** Six studies were included (4 articles, 1 poster, 1 budget impact model-BIM) covering various medications alone or combined (lamotrigine, lithium, olanzapine, quetiapine, aripiprazole, lurasidone and risperidone) in several disease settings (overall maintenance, maintenance after stabilization or with recent manic episodes, acute depression or hospitalization following acute mania). Regarding study types (type of modeling) we found 4 CEA/CUA (Markov model), 1 CEA (decision tree) and 1 BIA (discrete event simulation). Measures of benefit included: number of acute episodes, euthymic days, QALY, remission rate and utilities. Four CEAs used ICER as economic outcome and one used Net Benefit Analysis (NBA). Quality assessment showed medium-to-high risk of bias, and very weak clinical bases supporting analyses. **CONCLUSIONS:** Further economic studies on BD-I should take into consideration the main comparators used in real-life. When no head-to-head comparison exists, researchers should perform systematic review and possibly network meta-analysis. Since BD-I is a chronic disease, a lifetime framework should be considered for time horizon. Parameters from previous publications should be used carefully, since many of them may be invalid. Economic analyses could be developed further to include other treatment options and Markov model should cover subsequent treatment lines.

PMH37

THE ECONOMIC BURDEN OF OPIOID USE DISORDER (OUD): RESULTS OF A STRUCTURED LITERATURE REVIEW

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OBJECTIVES: Opioid use disorder (OUD) is a chronic and relapsing medical illness associated with a high cost to individuals, families and society. We evaluated the current literature to identify evidence gaps and summarise published data on economic costs associated with OUD. **METHODS:** A structured, comprehensive literature review was conducted to identify articles describing the burden and treatment landscape of OUD including: risk factors, patient characteristics and comorbidities, epidemiology, humanistic and economic burden, employment and crime, treatment options and current clinical guidelines. Global literature databases, guideline databases, regulatory and health technology assessment agency websites and relevant society guidelines were searched for data published between 2000-2015. Articles were not restricted by language. Eligible articles were those reporting on OUD (including opioid dependence and abuse) and providing data on ≥ 1 topic of interest. **RESULTS:** A total of 2,234 records were screened; 202 articles met the selection criteria and were included in this literature review, 31 of which reported on economic burden. From these 31 articles, only one reported total economic burden associated with untreated opioid dependence as CAD\$5,086 million/year (cost year: 1996). The remaining articles (Australia [7], UK [1], Canada [2], US [20]) focused on specific elements of economic burden, including costs of treatment programmes, criminal justice and use of prescription opioids. Of these, studies looking specifically at prescription opioid abuse, dependence and misuse, reported that the total societal cost was US\$55.7 billion (2007) and US\$78.5 billion (2013). **CONCLUSIONS:** The literature reports a substantial economic burden associated with OUD. However, the majority of the evidence is from studies reporting on specific elements of cost, with limited direct and indirect cost data. Furthermore, the latest comprehensive data were reported approximately 20 years ago. Thus, the lack of recent global data is likely to result in underestimation of the current economic burden associated with OUD.

MENTAL HEALTH – Patient-Reported Outcomes & Patient Preference Studies

PMH38

TREATMENT PATTERNS, ADHERENCE AND CLINICAL OUTCOMES IN BIPOLAR DISORDER TYPE I: A SYSTEMATIC REVIEW OF OBSERVATIONAL STUDIES

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OBJECTIVES: To perform a systematic review of literature on real-world data from observational studies on bipolar disorder (BD) treatment regarding patterns-of-care, adherence, and clinical outcomes of second-generation atypical antipsychotics (SGA). **METHODS:** A literature search was performed on Medline and Embase to identify articles on BD addressing patterns-of-care, adherence and clinical outcomes of SGA therapy from 2006 to 2016. **RESULTS:** Fifty-three studies were included for analysis. Regarding patterns of drug utilization, SGA monotherapy are prescribed for about 45% of patients as first antimanic therapy (quetiapine in 39.5% and aripiprazole in 37.2% of cases). Overall, prescriptions for BD patients include mainly SGA monotherapy or in combination (45-50%) and mood stabilizers (e.g. lithium, anticonvulsants) for 65-80% of cases. During follow-up, combination therapy (SGA+mood stabilizers) is prescribed to 50-70% of patients. Adherence to clinical guidelines prescription recommendations range from 50%-83%. Adherence to medication was measured by medication possession ratio (MPR), with an MPR $\geq 80\%$ considered as appropriate adherence to therapy. Some studies reported very poor adherence rates (MPR: 15-25% and MPR $\geq 80\%$ for only 6-10% of patients receiving SGA), but the majority reported MPRs ranging from 40-75%. Mean duration of SGA use was 175 to 290 days over a 12-month period, but persistence was described as around 100 days. Reasons for non-adherence were: younger age; baseline substance use disorder; higher disease burden, with a greater number symptoms; side effects as a cause for frustration; comorbid anxiety and obsessive-compulsive disorder. **CONCLUSIONS:** Observations from real-world evidence are essential components in economic models development and decision-making process. This review showed which patterns-of-care are adopted in real practice for the treatment of BD patients. SGA monotherapy is used for 45% of patients during first antimanic episode, almost 50% of cases receive SGA (monotherapy or combination) overall and up to 70% are treated with SGA plus mood stabilizers during follow-up.

PMH39

EVALUATION OF DEPRESSION PREVALENCE AND ASSOCIATED DEMOGRAPHIC RISK FACTORS AMONG STUDENTS OF A PUBLIC SECTOR UNIVERSITY: A CROSS-SECTIONAL STUDY

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OBJECTIVES: To obtain the prevalence of depression and whether the socio-demographic variables were associated with depression in professional university students. **METHODS:** A cross-sectional study was carried out on students of ages between 18-25 years in faculty of pharmacy and alternative medicine in The Islamia University of Bahawalpur, Pakistan. Data was collected by self-administered questionnaire on socio-demographic variables. Depression was evaluated by Beck depression inventory (BDI). BDI scores of 17 or more than 17 are considered depressive. SPSS version 20.0 was used for data analysis. Mann-Whitney U test and Kruskal-Wallis analysis of variance were applied for continuous data analysis. **RESULTS:** Out of all respondents, 40% students suffered from depression and had BDI scores of 17 or above of it. The prevalence of depression among 2nd year students is 43.2%, 52.3% in students with poor study performance, 56.2% in students residing in urban areas, 50% in students of 20 years older or less, and 68.2% in students with poor socio-economic status. Depression was significantly associated with poor socio-economic status, study year and study performance showing p value > 0.001 for all variables while depression levels were insignificantly high among females and urban residents showing p values 0.479 and 0.193 respectively. **CONCLUSIONS:** Professional Students of a public sector university of Pakistan have high prevalence of depression. Considering high prevalence of depression among university students, a student counseling service should be arranged to help the students with poor study performance and poor financial back ground.

PMH40

INCORPORATING PATIENT PERCEPTIONS ABOUT TREATMENT IN COST-EFFECTIVENESS ANALYSIS

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OBJECTIVES: ACUDep, a randomized pragmatic trial, compared acupuncture, counselling, and usual care for relieving depression. Patient perceptions about the effectiveness of treatments may affect costs and health outcomes through compliance or a placebo effect. The objective of this study was to assess the cost-effectiveness for patient subgroups with different perceptions about treatment effect. **METHODS:** ACUDep reported outcomes on costs and EQ-5D for up to 12 months for 755 patients. Patient perceptions about the effectiveness of each treatment was measured on a five-level likert scale. A binary variable was generated indicating if a patient had a positive opinion about the treatment, i.e. they thought the treatment would be fairly effective or very effective. A seemingly unrelated regression was used to estimate costs and QALYs with coefficients for treatment received, positive perception of each treatment and an interaction term between all coefficients. **RESULTS:** Most patients did not have a positive perception of any of the treatments, 31.3% responded very ineffective, fairly ineffective or can't decide for their perception of effectiveness of all treatments. 5.7% of patients had a positive perception of all treatments. Using a threshold of £20,000

per QALY the cost-effective treatment varied depending on the expectation of treatment effectiveness. Acupuncture was the cost-effective treatment for patients that were not optimistic about any or all of the treatments. Counselling was the cost-effective treatment in the subgroups that thought only counselling would be effective, only acupuncture would be effective or either of them would be effective. Usual care was cost-effective in the patient populations that thought that only usual care would be effective or usual care and either acupuncture or counselling would be effective. **CONCLUSIONS:** In this analysis patient perception does affect observed treatment outcomes and alters which treatment is cost-effective. Further consideration should be given to assessment of patient perceptions and their use in reimbursement decisions.

PMH41

PRO INSTRUMENTS USED IN STUDIES OF BIPOLAR DISORDER SINCE 1960

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OBJECTIVES: To create an evidence map of the different patient-reported outcome instruments used in studies of patients with bipolar disorder, the geographical settings in which these studies were conducted and the interventions assessed. **METHODS:** We searched the heero.com database (www.heero.com) for PRO studies on bipolar disorder published between 1960 and December 16 2016, and analysed the abstracts identified by the search to determine the different PRO instruments cited across the range of geographical locations and interventions. We presented the findings as an evidence map. **RESULTS:** We found a total of 127 abstracts that reported the use of 85 different PRO instruments. Of these 85 instruments, 19 were specific for bipolar disorder, depression or mania, 45 were general instruments used to evaluate quality of life, functioning or utilities, nine assessed other conditions or diseases that were common comorbidities of people with bipolar disorder, including anxiety, eight assessed treatments or adherence, three evaluated the impact of the disease on work productivity and one assessed caregiver burden. The most frequently used tool was the SF-36, cited in 26 abstracts, followed by the Young Mania Rating Scale (18 abstracts), Q-LES-Q (17 abstracts), Hamilton Depression scale (15), MADRS (13) and SF-12 and WHOQOL-BREF (10 each). The United States was the most common setting, with 56 abstracts, followed by the United Kingdom (8 abstracts), Canada and Italy (7 abstracts each), then Australia, Brazil and Spain (6 abstracts each). Drug interventions were assessed in 28 abstracts, and psychological interventions in 15. **CONCLUSIONS:** A wide range of PRO tools have been used in studies of bipolar disorder, but only ten tools were cited in more than five abstracts each. Research into the quality of life in bipolar disorder has generally been assessed from a US perspective.

PMH42

PAIN ASSESSMENT AMONGST PATIENTS WITH DEMENTIA

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OBJECTIVES: The aim of our study was to examine the possibilities of the assessment of pain in people with dementia and assess the clinical applicability of these scales in the nursing practice. **METHODS:** The study was a cross-sectional, descriptive, quantitative analysis. By purposive sampling we enrolled patients with dementia at the age of 60 or older (N=101). Exclusion criteria included not having any other mental or acute somatic disease and not being in terminal condition. The study was carried out at the facility of the Hungarian Baptist Aid in Pécs between 01.12.2015 and 31.01.2016. The analysis was done with Microsoft Office Excel software including descriptive statistics (absolute frequency, relative frequency, mean, standard deviation, confidence interval) and mathematical statistics (Chi2-test, T-test ANOVA) at $p < 0.05$. We used five different assessment scales. The NRS (numeric rating scale) is a general one, while the other four scales, PAINAD (Pain Assessment in Advanced Dementia Scale), FLACC (Face, Legs, Activity, Cry, Consolability scale), Doloplus 2 and PACSLAC (Pain Assessment Checklist for Seniors with Limited Ability to Communicate) are special scales made to assess behavior in people with dementia who do not communicate. **RESULTS:** We found that the NRS scale indicates excessive sensitivity in people with mild dementia ($p=0.03$), while in people with severe dementia, the NRS scale did not assess pain so accurately compared to the findings of the other four scales. PAINAD, FLACC, and Doloplus 2 proved to be more reliable. PACSLAC was the most considerable, but its clinical usability seems to be limited due to long and complex evaluation. **CONCLUSIONS:** Considering all, we can state that the four dementia-specific scales which rely on patients' behavior are more reliable in terms of means than the NRS. Using these was more beneficial in our clinical practice.

PMH43

DEPRESSION ASSESSMENT IN PATIENTS DIAGNOSED WITH PARKINSON'S DISEASE FOR CLINICAL PRACTICE

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OBJECTIVES: To show the complexity of patients with Parkinson's disease (PD) by illustrating an accurate profile based on the prevalence of depression and other complications and differences observed among patients from UK and USA, for further good practices recommendations. **METHODS:** A cross sectional descriptive study was conducted using an electronic survey among patients from UK and USA diagnosed with PD. Patients ($n=104$) were screened for depression by using the Zung Self-Rating Depression Scale (SDS). Prevalence of movement and nervous system symptoms was assessed by using multiple choice questions and the

distress of each category was scored from 0 to 3 (0=no, 1=mild, 2=moderate, 3=severe) where a higher score indicates greater distress. Cronbach's alpha (α) was calculated to confirm the reliability of the SDS and distress questionnaire. Comparisons between patient groups were made with ANOVA and two-tailed t-test, correlations were interpreted based on calculations of Pearson's R and descriptive statistics summarized the features of the sample. **RESULTS:** Most of the patients were from UK (65.38%), 50.96% were female and 54.81% showed depression according to SDS ($\alpha=0.78$). Comparisons between UK and USA patient groups disclosed no significant differences (all $p > 0.05$). Patients aged 40-50 showed a higher incidence of depression ($p=0.025 < 0.05$) with a more severe stage of depression ($p=0.0042 < 0.05$). Prevalence of movement and nervous system symptoms as well as the distress of these symptoms ($\alpha=0.75$) are up to two times higher in patients with depression than in those without ($p < 0.05$). In patients with depression according to SDS, 51.80% consider themselves not being depressed and in those that do not have depression according to SDS, 15.20% consider themselves depressed. **CONCLUSIONS:** All patients with PD revealed a complex profile and require good management of frequent comorbidities. Prevalence of depression calls for medical professionals to be vigilant in the screening process.

PMH44

ASSOCIATION BETWEEN MALNUTRITION AND DEPRESSION AMONG COMMUNITY-DWELLING OLDER CHINESE ADULTS

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OBJECTIVES: Malnutrition and depression are of important concern among older adults. Assessment of the two and their association is of particular interest in China, which has the largest elderly population in the world. We investigated the association between malnutrition and depression among community-dwelling older Chinese adults, and how their association impacts healthcare costs. **METHODS:** Data from 4,916 adults aged 60 years or older collected as part of the Wave II-2013 China Health and Retirement Longitudinal Study (CHARLS) survey were analyzed. Measures of hand grip strength, body mass index, and weight loss were used as indicators of malnutrition status. Subjects were categorized into "depressed" and "non-depressed" groups based on the Center for Epidemiological Studies Depression Scale (CES-D) scores. Logistic regression was used to analyze the association between malnutrition and depression after controlling for confounding factors including socio-demographics, health status, and functional independence. **RESULTS:** Of the adults studied, 23% were depressed, of whom 30% were malnourished. In the non-depressed group, only 21% of the adults were malnourished. Regression results indicated that malnourished individuals were 51% more likely to be depressed than their non-malnourished counterparts ($OR=1.513$, $p < 0.001$). Hospital related service cost was ¥3,160 per person per year for malnourished and depressed adults compared to ¥1,824 for malnourished and non-depressed adults (73% decrease, $p < 0.01$), and ¥1,902 for non-malnourished and depressed adults (66% decrease, $p < 0.01$). **CONCLUSIONS:** Depression prevalence was significantly higher among malnourished older Chinese adults. These results suggest that depression is a common mental disorder among community-dwelling older adults and that malnutrition could induce depression as a result of the psychological vulnerability of this population. The incidence of depression coupled with malnutrition is associated with a significant increase in hospital related costs; thus highlighting the importance of both malnutrition and depression screening and treatment for older Chinese adults living in the community.

PMH45

FIT FOR PURPOSE REVIEW OF MEASURE OF DEPRESSION SYMPTOMS TO OBTAIN FDA PRO LABEL CLAIMS

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OBJECTIVES: A primary use for patient reported outcomes (PROs) is to measure latent states which are otherwise unmeasurable. As such the CNS field offers a potpourri of disorders where the core of the disease must be measured via PRO. Depressive disorders are a quintessential CNS area where a number of PROs exist. However, since the 2006 draft guidance for PRO label claims was published, only two depressive disorders have obtained PRO label claims and neither of these were based on a measure of depression. The current study reviews the readiness of several commonly used depression measures to obtain a PRO-based label claim. **METHODS:** Commonly used fit-for-purpose review tables were used to evaluate qualitative and quantitative readiness of the following PROs, which are either exclusively depression scales or include a subscale for depression: Beck Depression Inventory II (BDI-II), Quick Inventory of Depressive Symptomatology—Self Report (QIDS-SR), Outcome Questionnaire (OQ-45), Clinically Useful Depression Outcome Scale (CUDOS), Center for Epidemiologic Studies Depression Scale (CES-D), Patient Health Questionnaire (PHQ-9), Patient-Reported Outcomes Measurement Information System Depression Scale (PROMIS). **RESULTS:** Although each of these scales has been used in medical and clinical research, virtually all of these scales have published qualitative research findings; many were developed before qualitative development approaches with patients were accepted practice. PROMIS Depression PRO meets most of the criteria but is strongest when used as an adaptive PRO, something the FDA has not yet endorsed. **CONCLUSIONS:** Work needs to be done to come out with a multidimensional depression PRO that can be used for PRO-based label claims. The FDA PRO Consortium is developing a tool for this purpose. However, if pharmaceutical companies wish to obtain differentiated messages then additional PRO depression measures are likely to be required, such as one sees in rheumatic disorders.

PMH46

A REVIEW OF HEALTH-RELATED QUALITY OF LIFE MEASUREMENT IN DUAL DIAGNOSIS POPULATION

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OBJECTIVES: A literature review was conducted (1) to identify studies that utilized health-related quality of life (HRQoL) instruments in patients with dual diagnosis of mental illness and substance use disorder, and (2) to document the psychometric properties of the HRQoL instruments. **METHODS:** The literature review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The search was conducted in PubMed electronic database up to November, 2016. Selected MeSH terms included “Mental Disorder,” “Quality of Life,” and “Substance-Related Disorders.” Bibliographies of articles were screened for additional citations. The exclusion criteria included reviews, RCTs without HRQoL data, grey literature, and non-English articles. **RESULTS:** A total of 35 articles were included in the qualitative synthesis of the review. From the 35 studies, 19 different instruments that assessed HRQoL in the dual diagnosis population were reported. The most commonly used measurement was the Quality of Life Interview (QOLI), which was utilized in 7 (20%) studies. All but 3 measures (MQoL, EuroQoL-5D, Cantril’s Ladder Scale) were previously tested for reliability, of which the Social Adjustment Scale Self-Report (SAS-SR) was not found to be reliable. Only SAS-SR was not previously tested for validity and 8 (42%) instruments were previously assessed for responsiveness. One measurement (MQoL) assessed all four main domains of HRQoL (physical, psychological, social, and spiritual). The amount of items each instrument contained varied from 1 (Cantril’s Ladder and SOFAS) to 143 (QOLI). **CONCLUSIONS:** There are currently no instruments that are specifically designed to measure HRQoL in dual diagnosis population. The high variability of the number of instruments used in the studies demonstrate a need for a robust instrument in this vulnerable population. Since the dual diagnosis population requires specific tailoring due to their unique disease, future research could focus on creating a valid and reliable HRQoL measure.

PMH47

ANALYSIS OF HUMANISTIC BURDEN REVEALS A NEED FOR OPIOID USE DISORDER (OUD) DISEASE-SPECIFIC HRQL INSTRUMENTS

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OBJECTIVES: Opioid use disorder (OUD) is characterised by repeated, compulsive seeking or use of an opioid, despite adverse social, psychological and/or physical consequences. Patients with OUD have a variety of symptoms and a reduced health-related quality-of-life (HRQoL). We performed a comprehensive literature review that included an evaluation of the types of instruments used to assess severity of patient symptoms and the impact of OUD on HRQoL. **METHODS:** A structured, comprehensive literature review was conducted to identify articles describing the humanistic (symptoms/caregiver) burden of OUD. Global literature databases, guideline databases, regulatory and health technology assessment agency websites, and relevant society guidelines were searched. Searches were conducted for articles published between 2000–2015. Articles were not restricted by language. Eligible articles were those reporting on OUD (including opioid abuse and dependence) and providing data on at least one topic of interest. **RESULTS:** A total of 2,234 records were screened, of which 202 articles met the selection criteria and were included in this literature review. Of these, 45 articles reported on a humanistic burden of OUD, within which 54 instruments were identified. These included: general HRQoL instruments (17), instruments for mental health assessment (9), specific instruments for drug abuse (13) and questionnaires on relationships and social support (15). Most instruments were reported only once, with 5 instruments (WHOQOL-BREF, SF-36, SF-12, Opiate Treatment Index and Addiction Severity Index) reported in ≥4 articles each. None of the instruments were specifically developed for OUD. **CONCLUSIONS:** Our review indicates a wide range of instruments are used to assess the humanistic burden in OUD. However, compared with patient symptoms, HRQoL was assessed less often and only using general instruments. Our findings suggest an unmet need for the development of OUD disease-specific HRQoL instruments that can effectively assess the different dimensions of the humanistic burden associated with this chronic relapsing disease.

PMH48

HRQOL IN NEGATIVE SYMPTOMS OF SCHIZOPHRENIA

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OBJECTIVES: Schizophrenia negative symptoms (SNS) represent the major contributor to poor functional outcomes, loss in productivity and poor quality of life (QoL) of schizophrenic patients. It is unclear which instruments may be used for assessing QoL of such patients. SNS are characterized by severe withdrawal and paucity of speech, and communication making patients elicitation of perception difficult. The aims of this study were to identify the health related quality of life (HRQoL) instruments used in patients suffering from schizophrenia with predominant negative symptoms (NS) or mixed NS and to assess the level of validation of the instruments used to assess QoL of patient with SNS. **METHODS:** A systematic literature review was performed using the Medline database via PubMed. Studies with a QoL measure in schizophrenic patients published between 1989 and March 2016 were identified. The studies involving SNS patients were included, then, the instrument used was reported and a targeted research was

performed to identify if a conceptual framework was performed, the instrument, psychometric proprieties were identified as well as the pivotal and successive validation if available. **RESULTS:** Seventeen HRQoL instruments used in SNS patients were identified including 3 generic questionnaires, 8 for nonspecific mental health questionnaires, and 6 specific for schizophrenia. Conceptual frameworks were identified for 4 instruments, reported as performed but not described for 3 and for 10 instruments they were no mentions of conceptual framework. No HRQoL specific to SNS population was identified. No data are reported for those SNS patients specifically. **CONCLUSIONS:** No QoL instrument has been validated in SNS patients and it is even unclear for all of them if they are conceived for capturing HRQoL in SNS patients. SNS are widely prevalent in schizophrenic patients but their impact on QoL remains unknown. This requires further research.

MENTAL HEALTH – Health Care Use & Policy Studies

PMH49

ATYPICAL ANTIPSYCHOTIC USE IN ELDERLY PATIENTS WITH DEPRESSION

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OBJECTIVES: Although atypical antipsychotics are indicated for management of late-life depression, little is known about their use in the elderly. The objective of this study was to determine the prevalence and predictors of atypical antipsychotics and augmentation therapy in elderly patients with depression. **METHODS:** This study utilized the 2010 and 2011 National Ambulatory Medical Care Survey and outpatient department component of the National Hospital Ambulatory Medical Care Survey data. The study included elderly patients (age ≥65years) diagnosed with depression. Atypical antipsychotics and antidepressants were identified using American Hospital Formulary Service classification and Multum lexicon codes. Descriptive weighted analysis was performed to determine the prevalence of atypical antipsychotic use and multivariable logistic regression analyses were performed to determine the factors associated with the prescription of atypical antipsychotics and augmentation therapy. **RESULTS:** According to the national surveys, there were about 22 million ambulatory visits for depression during the study period; atypical antipsychotics were prescribed in 3.53% (95% CI, 2.02-5.04) of the visits. Among depression patients who were using antidepressants, 4.86% (95% CI, 3.07-6.04) used as an augmentation therapy. Multivariable regression analysis revealed that hispanics (odds ratio [OR] = 0.33; 95% CI, 0.12-0.90) was associated with decreased likelihood of antipsychotic prescription, whereas personality disorder and obsessive compulsive disorder (OR = 10.23; 95% CI, 2.80-37.40) were associated with increased likelihood of prescribing antipsychotics. For augmentation therapy, hispanics (OR = 0.06; 95% CI, 0.02-0.24) and primary physicians (OR = 0.24; 95% CI, 0.09-0.69) were associated with decreased likelihood; and obsessive compulsive disorder and personality disorder (OR = 7.56; 95% CI, 1.75-32.69) were associated with increased likelihood of antipsychotic prescription. **CONCLUSIONS:** Several clinical and demographic factors contribute to atypical antipsychotics use in the elderly. With the increased safety concerns, there is a need to monitor treatment related adverse effects in the elderly.

PMH50

ANTIDEPRESSANT MEDICATION USE AMONG ELDERLY PATIENTS WITH DEPRESSION

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OBJECTIVES: This study examined the prevalence and predictors of antidepressant medication use among elderly patients with depression in ambulatory settings. **METHODS:** This retrospective cross-sectional study utilized 2011 National Ambulatory Medical Care Survey (NAMCS) data. The study included patients aged 65 years or older diagnosed with depression. Antidepressant medications were operationally defined using the American Hospital Formulary Service Pharmacologic-Therapeutic classification and identified using Multum lexicon codes. Antidepressant medication classes included were Tricyclic antidepressants (TCAs), Selective Serotonin Reuptake Inhibitors (SSRIs), Monoamine oxidase inhibitors (MAOIs), Tetracyclic antidepressants, Selective Serotonin Nor-epinephrine Reuptake Inhibitors (SSNRIs), Phenylpiperazines and miscellaneous antidepressants. Descriptive weighted analysis was used to examine prevalence of antidepressant medications prescription. Independent variables included patient characteristics such as sex, age, race, ethnicity, region, and payment sources; and provider characteristics like physician medical degree, specialty type, office setting type, metropolitan statistical area, solo practice, primary physician and whether the patient was seen before. Multivariable logistic regression was used to assess the predictors of antidepressant therapy. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated using an a priori alpha level of 0.05. **RESULTS:** In 2011, a national estimate of 26.51 (95% CI, 21.70-31.32) million office visits were made by elderly patients with depression in the United States. Of these 11.82 (95% CI, 9.22-14.43, 44.59%) million involved prescribing of antidepressants. The most commonly prescribed antidepressants were SSRIs (31.16%), followed by SSNRIs (8.07%) and Phenylpiperazines (4.03%). Multivariable analysis revealed that compared to other payment sources, patients with Medicare (OR, 0.348; 95% CI, 0.17-0.71) and private insurance (OR, 0.37, 95% CI, 0.21-0.67) were less likely to receive antidepressant medication therapy. **CONCLUSIONS:** The study found that 45% of the elderly depression visits involved prescription of antidepressant medications. SSRIs were the most commonly prescribed antidepressants. Payment source was a significant predictor of antidepressant drug prescription.

PMH51

LAW ENFORCEMENT OFFICERS' READINESS TO PROVIDE NALOXONE IN AN EMERGENCY SITUATION IN THE COMMUNITIES OF WEST VIRGINIA

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OBJECTIVES: Communities in West Virginia (WV) have been disproportionately impacted by the opioid epidemic with 35.5 drug-overdose deaths per 100,000 persons in 2015. Law enforcement officers (LEOs) have the legal authority to stock, carry, and use naloxone, but the real-world use and availability through LEOs in WV is unknown. The objective of our study was to assess the readiness of LEOs in WV to provide emergency naloxone in the communities they serve. **METHODS:** A prospective cross-sectional study was conducted using a self-administered questionnaire between September and December 2016. The questionnaire consists of demographic information, current experiences with naloxone, prior experience with opioid overdose situations, perceived barriers to carrying and administering naloxone, the level of knowledge of opioid overdose management, and attitudes towards managing an opioid overdose. **RESULTS:** The survey was completed by 149 active, non-retired WV officers who had an average age of 45.6(±11.4) years and 13.8(±10.0) years of experience at their department. The results indicated that the use of naloxone was rare, only 12.7% of respondents said that naloxone was available for use, 72.7% of LEOs reported being at the scene of an opioid overdose in the past 12 months, and the majority (58.6%) reported being at the scene before EMS. Half of the respondents were not interested in receiving training to administer naloxone, and of those individuals, 53.5% were serving counties with elevated prescription drug death rates (≥20 per 100,000). Knowledge scores were higher for officers who had completed training on naloxone than those who did not or were not interested (t=2.27, p=0.02). Barriers to naloxone use identified by the LEOs included lack of training, time, safety, cost, storage, and liability. **CONCLUSIONS:** We conclude that willing officers should continue to be trained, but for officers in counties where death rates are the highest, new strategies to increase buy-in are still needed.

PMH52

EFFICACY, SAFETY AND COST-EFFECTIVENESS OF ARIPIPRAZOLE COMPARED TO OLANZAPINE FOR SCHIZOPHRENIA: SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: Aripiprazole is a dopamine-serotonin system stabilizer not included in the standard treatment of schizophrenia in Brazil's universal health system. It has been the reason of many court orders demanding its supply. This study proposes a systematic review with meta-analysis of the efficacy, safety and cost-effectiveness of aripiprazole compared to olanzapine, a standard drug for schizophrenia in Brazil, to evaluate the rationality of its use for the treatment of schizophrenia. **METHODS:** A systematic review was conducted in accordance to the Cochrane Handbook guidelines, including RCTs and complete economic evaluations. A electronic search in the databases of Medline, The Cochrane Library and Lilacs and a complementary search in theses and dissertations databases, scientific journals, and abstracts of international meetings were conducted. Results of independent studies were combined via meta-analysis. **RESULTS:** Six RCTs and ten economic evaluations were included. None of the studies showed efficacy results that significantly favored aripiprazole and two studies significantly favored olanzapine. Most studies did not show difference between olanzapine and aripiprazole regarding neurological adverse effects. One paper reported a better neurological adverse effects profile for olanzapine. All six studies found worse metabolic profile for olanzapine. The meta-analysis of aripiprazole in comparison with olanzapine showed that patients in use of aripiprazole are more likely to discontinue treatment (RR[IC95%]=1.15[1.06-1.24]; I2=0%; p-value<0.0009) and less likely to have weight gain >7% (RR[IC95%]=0.44[0.25-0.55]; I2=0%; p-value<0.00001). Olanzapine was found dominant in seven economic evaluation studies and aripiprazole was dominant in two. In one study, aripiprazole was less expensive and less effective than olanzapine (RCEI of 3,951.72 €/remission). **CONCLUSIONS:** Aripiprazole was not found to be a better therapeutic alternative than olanzapine. But, despite of being less efficacious and show worse cost-effectiveness profile, aripiprazole might be useful for patients that were considered irresponsive or intolerant to olanzapine.

PMH53

IMPACT OF USING AFFILIATE IDS ON PQA'S OPIOID MULTIPLE PROVIDER MEASURE AMONG MEDICAID BENEFICIARIES

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OBJECTIVES: Computing the Pharmacy Quality Alliance (PQA) measure for obtaining opioids from multiple prescribers and pharmacies relies on the use of provider identifiers to distinguish different providers. However, prescriptions from different providers in the same facility are not reflective of "doctor shopping" and filling prescriptions from chain pharmacies in the same community are not reflective of "pharmacy shopping". This study examined the effect of using affiliate practice IDs compared to individual provider IDs when computing PQA's provider shopping measure. **METHODS:** Mississippi Medicaid claims for 2015-16 were used to identify beneficiaries ≥18 years of age, continuously enrolled, without a cancer diagnosis and ≥2 prescription claims for opioids. The proportion of beneficiaries receiving opioids from 4 or more prescribers AND 4 or more pharmacies were classified as provider shopping. The provider shopping measure was computed using the individual provider and pharmacy identifiers reported on the claims and using affiliate identifiers that grouped prescribers in the same

facility and chain pharmacies in the same zip code. **RESULTS:** A total number of 30,494 beneficiaries were included. They were mostly female(72.79%), African American(50.63%), aged 18-44 years(50.22%) and enrolled in Medicaid managed care plans(90.79%). When using affiliate IDs, the number of beneficiaries identified as using 4+ prescribers dropped from 7,276 to 5,674 (22.02% reduction, p<0.0001) and the number identified as using 4+ pharmacies dropped from 2,446 to 2,079 (15.13% reduction, p<0.0001). The percentage of beneficiaries classified as "provider shopping" dropped from 5.21% to 4.01% (p<0.0001). **CONCLUSIONS:** The significant reduction in PQA's measure shows that failing to account for affiliates within the same practice may lead to an overestimation in the number of opioid misusers. Opioid misuse is a sensitive public health issue and affiliate IDs should be used, if possible, when identifying beneficiaries as potential misuse cases.

PMH54

MEDICATION ADHERENCE AND DISCONTINUATION IN PATIENTS WITH BIPOLAR DISORDERS WHO INITIATED A LONG ACTING INJECTABLE ANTIPSYCHOTIC VERSUS THOSE WHO CHANGED ORAL ANTIPSYCHOTICS

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OBJECTIVES: To examine medication adherence and discontinuation in patients with bipolar disorder (BP) initiating a long acting injectable antipsychotic (LAI) versus those who changed to a different oral antipsychotic. **METHODS:** This retrospective cohort analysis used Truven Health Analytics MarketScan® Commercial and Medicaid claims databases. Of the adult patients (≥18 years) diagnosed with BP, two mutually exclusive cohorts were created: LAI cohort, defined as initiating an LAI (no prior LAI therapy) between 01/01/2013 and 06/30/2014; and oral cohort, defined as patients who changed to a different oral antipsychotic (mono-therapy) during the same period. The first day of initiating an LAI or changing oral antipsychotic was the index date. Linear and Cox regression models were conducted to estimate medication adherence (proportion of days covered (PDC)) and time to medication discontinuation (continuous medication gap ≥ 60 days), respectively. Models adjusted for patient demographic and clinical characteristics, baseline medication use, and baseline ED or hospitalizations. **RESULTS:** The final sample consisted of 1,672 (14.7%) LAI initiators and 9,672 (85.3%) oral antipsychotic users. Compared with the oral cohort, LAI initiators had better medication adherence (PDC≥0.8: 30.9% vs. 21.5%, p<0.001; unadjusted mean: 0.51 vs.0.45; p<0.001). Controlling for covariates, the adjusted mean of PDC remained higher in the LAI initiators than in the oral cohort (0.50 vs. 0.45; p<0.001). Additionally, LAI initiators had a lower discontinuation rate (76.5% vs. 82.4%; p<0.001) and a significantly longer time to medication discontinuation than the oral cohort. The median time to discontinue index LAI was 149 days, compared with 99 days for oral monotherapy (p<0.001). The oral cohort had a higher hazard than the LAI cohort for discontinuing their index treatments (hazard ratio: 1.19; p<0.001). **CONCLUSIONS:** This real-world study suggests that patients with BP initiating LAIs had better medication adherence and lower discontinuation risk than those who changed to different oral antipsychotic monotherapy.

PMH55

ADHERENCE AND TREATMENT PATTERNS OF EARLY ADOPTERS OF BREXPPIPRAZOLE THERAPY WITH SCHIZOPHRENIA - RESULTS FROM A RETROSPECTIVE ANALYSIS OF LONGITUDINAL PRESCRIPTION DATA

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OBJECTIVES: Brexpiprazole, a serotonin-dopamine activity modulator, was approved in the United States for the treatment of schizophrenia on 10-Jul-2015. This is the first opportunity to examine the characteristics, treatment patterns and adherence in schizophrenia patients treated with brexpiprazole, compared to other atypical antipsychotics (AAPs). **METHODS:** The study utilized longitudinal pharmacy prescription and outpatient medical claims databases. Patients were ≥18 years old, diagnosed with schizophrenia, and newly initiated on brexpiprazole or other AAPs (olanzapine, quetiapine, ziprasidone, risperidone, aripiprazole, or lurasidone) between 10-Jul-2015 and 31-Mar-2016. Patient characteristics and treatment history were measured in the 12 months before therapy initiation. Treatment adherence was measured as a variable medication possession ratio (MPRv) among patients with ≥2 fills. **RESULTS:** 225 patients on brexpiprazole and 30,808 patients on other AAPs (6,112 olanzapine; 7,419 quetiapine; 2,085 ziprasidone; 7,841 risperidone; 3,956 aripiprazole; 1,671 lurasidone) were identified. Brexpiprazole patients were younger (41±15.4 years) than those on other AAPs (p<0.0001 for all); 50±15.9 for olanzapine, 50±14.8 for quetiapine, 48±14.0 for ziprasidone, 51±15.2 for risperidone, 48±14.9 for aripiprazole, 46±14.3 for lurasidone). 95% of brexpiprazole patients and 37-63% of other AAP patients had used ≥1 antipsychotic before initiating treatment. Psychiatrists/psychologists more frequently prescribed brexpiprazole (77%) compared to other AAPs (51-68%). Mean MPRv was 92% in brexpiprazole, 90% in olanzapine, 88% in quetiapine and risperidone, 91% in ziprasidone, 87% in aripiprazole, and 88% in lurasidone. Fewer patients treated with brexpiprazole (64%) used ≥1 concomitant psychotropic medication compared to other AAPs (67-75%). **CONCLUSIONS:** This is the first study to describe brexpiprazole utilization in schizophrenia patients in the real-world setting. Patients treated with brexpiprazole were different from those treated with AAPs in terms of age, treatment history, prescribing physician specialty, and concomitant medication use. Patients treated with brexpiprazole and other AAPs had comparable therapy adherence. Brexpiprazole was prescribed more often by specialists than other AAPs.

PMH56

COMPARISONS OF 30-DAY RE-HOSPITALIZATION RATES IN PATIENTS WITH SCHIZOPHRENIA RECEIVING LONG-ACTING INJECTABLE ANTIPSYCHOTICS DURING HOSPITALIZATION

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OBJECTIVES: To examine 30-day hospital readmission rates in patients with schizophrenia treated with different long-acting injectable antipsychotics (LAIs) during their index hospitalization. **METHODS:** Inpatient claims from Premier Perspective Database™ were used to identify adult patients (age ≥ 18 years) hospitalized with a primary diagnosis of schizophrenia (ICD-9-CM diagnosis code 295.XX) between 01/01/2013 and 06/30/2015 who received an LAI and were discharged home or to a home care program during the first (index) hospitalization. Five mutually exclusive LAI cohorts were included: aripiprazole, fluphenazine, haloperidol, paliperidone, or risperidone. All-cause and psychiatric-related 30-day re-hospitalization rates were calculated across different LAIs. Logistic regression models controlling for patient demographic and clinical characteristics were constructed to estimate associations between different LAIs and 30-day hospital readmissions. **RESULTS:** Of the 73,222 hospitalized adult patients with schizophrenia, 15,286 (20.9%) were treated with LAIs: aripiprazole (206), fluphenazine (2,052), haloperidol (7,088), paliperidone (2,767), or risperidone (3,173). Compared with those in other LAI cohorts, patients in the aripiprazole cohort were younger (mean (SD) age: 37.3 (14.4)); a higher percentage of them were white (48.1%) and married (11.2%). The aripiprazole cohort had the lowest Charlson comorbidity score (mean (SD): 0.35 (0.68)), but the highest percentages of depression (12.1%) and anxiety (18.5%). The 30-day readmission rates were lowest in the aripiprazole cohort (all-cause: 9.7%; psychiatric-related: 8.7%), followed by haloperidol (10.0%; 9.5%), paliperidone (10.8%; 10.2%), risperidone (10.9%; 10.5%), and fluphenazine (11.0%; 10.4%). However, the differences were not statistically significant with and without adjusting for patient demographic and clinical characteristics. **CONCLUSIONS:** This real-world study is, to our knowledge, the first to examine 30-day re-hospitalization rates among schizophrenia patients treated with different LAIs. Our findings suggest that 30-day re-hospitalization rates were lowest in the aripiprazole cohort but relatively low across the different LAIs.

PMH57

COMPARISONS OF RE-HOSPITALIZATION RATES IN PATIENTS WITH BIPOLAR DISORDER RECEIVING LONG-ACTING INJECTABLE ANTIPSYCHOTICS DURING HOSPITALIZATION

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OBJECTIVES: To examine hospital readmission rates in patients with bipolar disorder (BD) treated with different long-acting injectable antipsychotics (LAIs) during their index hospitalization. **METHODS:** Inpatient claims from Premier Perspective Database™ were used to identify adult patients (age ≥ 18 years) hospitalized with a primary diagnosis of bipolar disorder between 01/01/2013 and 06/30/2015 who received an LAI and were discharged home or to a home care program during the first (index) hospitalization. Five mutually exclusive LAI cohorts were included: aripiprazole, fluphenazine, haloperidol, paliperidone, or risperidone. All-cause and psychiatric-related 60-, 90-, and 180-day re-hospitalization rates were calculated across different LAIs. Logistic regression models controlling for patient demographic and clinical characteristics were conducted to estimate associations between different LAIs and hospital readmissions. **RESULTS:** Of the hospitalized BD patients, 2,414 were treated with LAIs: aripiprazole (76), fluphenazine (261), haloperidol (839), paliperidone (538), or risperidone (700). Compared with those in other LAI cohorts, patients in the aripiprazole cohort were younger (mean (SD) age: 38.7 (15.3)). The 60-, 90-, and 180-day readmission rates were lowest in the aripiprazole cohort (all-cause 14.5% (60-day), 17.1% (90-day), 23.7% (180-day); psychiatric-related 14.5%, 17.1%, 22.4%), followed by fluphenazine (16.5%, 20.3%, 26.1%; 14.9%, 18.8%, 23.8%), risperidone (17.4%, 20.6%, 28.1%; 16.4%, 19.3%, 26.6%), paliperidone (17.4%, 21.4%, 27.5%; 16.2%, 19.9%, 25.3%), and haloperidol (18.5%, 20.5%, 25.5%; 18.0%, 19.9%, 24.4%). However, none of these differences were statistically significant with and without adjusting for patient demographic and clinical characteristics. **CONCLUSIONS:** This real-world study is, to our knowledge, the first to examine 60-, 90-, and 180-day readmission rates among hospitalized BD patients treated with different LAIs. Only a small number of patients received aripiprazole LAI. While there were no statistically significant differences across the various LAIs, the aripiprazole cohort showed lower hospital readmission rates compared to the other cohorts.

PMH58

MEDICATION ADHERENCE AND DISCONTINUATION IN MEDICAID PATIENTS WITH SCHIZOPHRENIA INITIATING A LONG ACTING INJECTABLE ANTIPSYCHOTIC VERSUS THOSE WHO CHANGE TO A DIFFERENT ORAL ANTIPSYCHOTIC

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OBJECTIVES: To compare medication adherence and discontinuation in patients with schizophrenia who initiate a long acting injectable antipsychotic (LAI) to

those who change to a different oral antipsychotic. **METHODS:** This retrospective cohort analysis used the Truven Health Analytics MarketScan® Medicaid claims database. Of the identified adult patients (≥ 18 years) diagnosed with schizophrenia, two mutually exclusive cohorts were created: LAI cohort, or patients initiating LAI therapy between 01/01/2013 and 06/30/2014 (the identification (ID) period); and oral cohort, or patients who changed to a different oral antipsychotic mono therapy during the ID period. The first day of initiating an LAI or changing oral therapy was the index date. Primary outcome measures were medication adherence (proportion of days covered) during the 1-year post-index period and medication discontinuation (continuous medication gap ≥ 60 days) of the index LAIs or orals during the entire follow-up period. General linear Cox regression models were used to estimate medication adherence and time to medication discontinuation. Models adjusted for patient demographic and clinical characteristics, baseline medication, and baseline emergency department visits or hospitalizations. **RESULTS:** The study sample consisted of 2,861 (50.7%) LAI initiators and 2,777 (49.3%) oral monotherapy users. Compared with the oral cohort, LAI initiators had better medication adherence (adjusted mean: 0.55 vs. 0.50, p < 0.001). LAI initiators also had a lower discontinuation rate (72.5% vs. 77.2%; p < 0.001) and a significantly longer time to medication discontinuation than the oral cohort. The median time to discontinue index LAI was 196 days, compared with 123 days for the oral cohort (p < 0.001). The oral cohort discontinued their index treatment at a higher rate than the LAI cohort (hazard ratio: 1.20; p < 0.001). **CONCLUSIONS:** This real-world study suggests that patients with schizophrenia initiating LAIs had better medication adherence and lower discontinuation risk than patients who changed to different oral antipsychotic monotherapy.

PMH59

BREXPIPRAZOLE USE IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER: RESULTS FROM A RETROSPECTIVE ANALYSIS OF LONGITUDINAL PRESCRIPTION DATA

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OBJECTIVES: Brexpiprazole, a serotonin-dopamine activity modulator, was approved in 2015 in the United States for the treatment of schizophrenia and for use as an adjunctive treatment for major depressive disorder (MDD). The aim of the study was to describe patient characteristics, treatment history before adjunctive atypical antipsychotic (AAP) initiation, and adherence to brexpiprazole and older AAPs indicated for MDD (quetiapine, aripiprazole, and lurasidone). **METHODS:** Prescription and medical history were obtained from longitudinal prescription and medical claims databases. Patients selected were ≥ 18 years of age with a diagnosis of MDD who initiated adjunctive brexpiprazole or other AAPs between 10-Jul-2015 and 31-Mar-2016. Patient characteristics and antidepressant use were measured in the 12 months before therapy initiation. Adherence was measured by variable medication possession ratio (MPRv) during a 3 month follow up period in patients with ≥ 2 fills. **RESULTS:** 4,265 brexpiprazole, 88,063 quetiapine, 63,004 aripiprazole, and 11,462 lurasidone patients were identified. Mean age of brexpiprazole patients was 49 ± 14.4 years (quetiapine: 54 ± 16.7 years, aripiprazole: 49 ± 15.7 years, lurasidone: 44 ± 14.3 years). 55% of brexpiprazole patients had prior use of a selective serotonin reuptake inhibitor (quetiapine: 59%, aripiprazole: 58%, lurasidone: 54%), and 48% of brexpiprazole patients had prior use of a serotonin and norepinephrine reuptake inhibitor (SNRI) (quetiapine: 30%, aripiprazole: 38%, lurasidone: 33%) in the previous year. Among patients newly diagnosed with MDD, 19% of brexpiprazole, 11% of quetiapine, 12% of aripiprazole, and 12% of lurasidone patients had used ≥ 3 antidepressants prior to current therapy. Mean MPRv was 90% in brexpiprazole, 89% in quetiapine, and 88% in aripiprazole and lurasidone. **CONCLUSIONS:** Brexpiprazole patients were more often treated with a prior SNRI compared to other AAP patients. Brexpiprazole patients had used ≥ 3 prior antidepressants. Adherence to brexpiprazole was similar to that of other AAPs.

PMH60

NON-BUPRENORPHINE OPIOID UTILIZATION AMONG PATIENTS USING BUPRENORPHINE/NALOXONE (SUBOXONE)

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OBJECTIVES: Buprenorphine/naloxone is commonly used to treat opioid dependence, however, non-buprenorphine prescription opioid utilization among these patients has not been well defined. We sought to characterize patterns of opioid utilization among incident buprenorphine/naloxone (Suboxone) users in eleven states. **METHODS:** We used IMS Health anonymized, individual-level, all-payer pharmacy claims to identify incident users of buprenorphine/naloxone between January 2010 and August 2013. We focused on patients 18 years of age and defined each patient's first treatment episode as the length of time from the patient's incident prescription for buprenorphine/naloxone (index fill) until the first day of a gap where the patient had no buprenorphine/naloxone on-hand for 90 or more days. We calculated measures of non-buprenorphine opioid utilization during the first treatment episode as well as during 12-month periods prior to and following this episode. **RESULTS:** Of the 22655 individuals meeting inclusion criteria, 49% were female and 50% were between 25 and 46 years of age. The median length of the first treatment episode was 79 days (interquartile range [IQR], 30 to 226 days). More than half (58%) of buprenorphine/naloxone recipients filled prescriptions for other opioids following buprenorphine/naloxone treatment and 30% filled at least

one opioid prescription during their treatment episode. The median total of morphine milligram equivalents (MME) 12 months prior to treatment was 250 mg/per month (IQR 38 to 1347) then declined to 221 mg/per month (IQR 39 to 1034) and 175 mg/per month (IQR 25 to 1106) during and following the treatment episode, respectively. The median MME per opioid day supplied prior to, during and following the first treatment episode remained constant at 40 mg per day. **CONCLUSIONS:** Treatment with buprenorphine/naloxone is associated with reduced non-buprenorphine opioid use. However, a substantial proportion of patients fill prescriptions for non-buprenorphine opioids during and following such treatment.

PMH61

ADHERENCE AND TREATMENT PATTERNS IN BREXPIPRAZOLE THERAPY IN LONG-TERM CARE PATIENTS WITH SCHIZOPHRENIA: RESULTS FROM A RETROSPECTIVE ANALYSIS OF LONG-TERM CARE DATA

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OBJECTIVES: Brexpiprazole, a serotonin-dopamine activity modulator, was approved in 2015 in the United States for the treatment of schizophrenia. This is the first opportunity to examine real-world adherence and treatment patterns in patients with schizophrenia treated with brexpiprazole and atypical antipsychotics (AAPs) in the long-term care (LTC) setting. **METHODS:** Longitudinal LTC pharmacy and outpatient medical claims data from 10-Jul-2015 to 03-Mar-2016 were used. Patients were included if they had a diagnosis for schizophrenia, were ≥ 18 years old, and newly initiated brexpiprazole or other AAPs (olanzapine, quetiapine, ziprasidone, risperidone, aripiprazole, or lurasidone). The index date was the date of first AAP fill. Patient characteristics and treatment history were measured in the 12 months pre-index. Post-index adherence was measured as variable medication possession ratio (MPRV) among patients with ≥ 2 fills of the index medication. **RESULTS:** 77 patients on brexpiprazole and 21,403 patients on other AAPs (5,018 olanzapine; 4,638 quetiapine; 932 ziprasidone; 5,884 risperidone; 2,117 aripiprazole; 693 lurasidone) were identified. Mean ages (years \pm standard deviation) were 48 \pm 15.2 for brexpiprazole, 54 \pm 15.5 for aripiprazole, 50 \pm 14.2 for lurasidone, 56 \pm 15.6 for olanzapine, 56 \pm 15.4 for quetiapine, 57 \pm 14.8 for risperidone, and 52 \pm 14.4 for ziprasidone. Brexpiprazole was prescribed mainly by psychiatrists/psychologists (68%) while other AAPs, except lurasidone, were prescribed more by PCPs (olanzapine: 52%, quetiapine: 54%, ziprasidone: 50%, risperidone: 56%, aripiprazole: 49%, lurasidone: 41%). 96% of brexpiprazole patients were previously treated with ≥ 1 AAP compared to other AAPs (olanzapine: 56%, quetiapine: 65%, ziprasidone: 64%, risperidone: 49%, aripiprazole: 59%, and lurasidone: 72%). Mean MPRV values were 94% in brexpiprazole, 93% in aripiprazole, and 95% in all other AAPs. **CONCLUSIONS:** This is the first study to describe the use of brexpiprazole for schizophrenia in the LTC setting. Brexpiprazole was prescribed mainly by specialists, and most brexpiprazole patients were previously treated with AAPs. Adherence to brexpiprazole was similar to other AAPs.

PMH62

BREXPIPRAZOLE USE IN LONG-TERM CARE PATIENTS WITH MAJOR DEPRESSIVE DISORDER: RESULTS FROM A RETROSPECTIVE ANALYSIS OF LONG-TERM CARE DATA

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OBJECTIVES: Brexpiprazole, a serotonin-dopamine activity modulator, was approved in 2015 in the United States for the treatment of schizophrenia and for use as adjunctive therapy in major depressive disorder (MDD). Characteristics of patients with MDD and their treatment adherence to brexpiprazole have not been previously studied in the long term care setting. **METHODS:** The study used data from longitudinal long-term care pharmacy and outpatient medical databases. Patients aged ≥ 18 years, with a diagnosis of MDD, and who initiated brexpiprazole or an older atypical antipsychotic (AAPs; quetiapine, aripiprazole, or lurasidone) between 10-Jul-2015 and 3-Mar-2016 were included. Patient characteristics and prior use of antidepressants were measured in the 12 months prior to therapy initiation. Treatment adherence was measured by variable medication possession ratio (MPRV) over a 3 month follow up among patients with ≥ 2 fills. **RESULTS:** 177 brexpiprazole, 14,261 quetiapine, 5,376 aripiprazole, and 1,244 lurasidone patients were identified. Mean age of brexpiprazole patients was 49 \pm 15.4 years (quetiapine: 64 \pm 18.8 years, aripiprazole: 57 \pm 18.4 years, lurasidone: 48 \pm 16.4 years). Anxiety was observed in 54% of brexpiprazole patients. 52% of brexpiprazole patients received their prescriptions from psychiatrists/psychologists compared to other AAPs (25% of quetiapine, 35% of aripiprazole, 45% of lurasidone). More brexpiprazole patients were previously treated with a selective serotonin reuptake inhibitor, and fewer were treated with a selective norepinephrine reuptake inhibitor compared to other AAPs. Mean MPRV values were 94% in brexpiprazole, 94% in quetiapine, 93% in aripiprazole, and 92% in lurasidone. **CONCLUSIONS:** This is the first study to describe the use of brexpiprazole for MDD in the long-term care setting. Patients treated with brexpiprazole were more often treated with a prior selective serotonin reuptake inhibitor and were more often treated by a specialist compared to patients on other AAPs. Adherence to brexpiprazole was similar to that of other AAPs.

PMH63

USE OF ANTIPSYCHOTICS AMONG SENIORS LIVING IN LONG-TERM CARE FACILITIES, 2014

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OBJECTIVES: This analysis examines the use of antipsychotics among seniors living in long-term care (LTC) facilities, and the concurrent use of antipsychotics with other psychotropic drugs, which further increases risk of side effects. It also looks at the characteristics of residents treated with antipsychotics, including diagnoses, behaviours and other functional measures. **METHODS:** Drug claims data from the National Prescription Drug Utilization Information System (NPDUIS) Database, housed at the Canadian Institute for Health Information (CIHI), provide detailed information about antipsychotic use. LTC resident assessment data from CIHI's Continuing Care Reporting System (CCRS) provide detailed resident information. **RESULTS:** Residents with severe cognitive impairment and those exhibiting highly aggressive behaviour were more likely to have used an antipsychotic. However, a large proportion of seniors exhibiting severe aggression were not treated with antipsychotics, suggesting that non-drug alternatives were often considered. Quetiapine was the most commonly used antipsychotic (19.2% of LTC residents), followed by risperidone (14.1%). Among seniors who were chronic users of an antipsychotic, nearly two-thirds (64.3%) were also chronic users of an antidepressant, while roughly 1 in 6 (15.0%) were also chronic users of a benzodiazepine. In Manitoba, antipsychotic use decreased from 38.2% in 2006 to 31.5% in 2014. This was due in part to initiatives implemented by the Winnipeg Regional Health Authority, to reduce inappropriate antipsychotic use in LTC facilities. **CONCLUSIONS:** In September 2014, The Canadian Foundation for Healthcare Improvement began supporting several health care organizations across Canada to adopt initiatives to reduce inappropriate antipsychotic use in LTC facilities. As more facilities start implementing similar strategies, the overall rate of antipsychotics use in LTC facilities may decrease.

PMH64

RETROSPECTIVE STUDY OF ANTIPSYCHOTICS UTILIZATION IN RUSSIAN FEDERATION

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OBJECTIVES: This study aims to analyze the evolution of the consumption pattern of the antipsychotic drugs (APs) in Russian Federation. **METHODS:** The sales data of the antipsychotic drugs in Russian Federation during the period 2010-2015 was retrieved from the DSM-group marketing database and subsequently analyzed. The drugs have been classified into typical antipsychotics (TA), atypical antipsychotics (AA) and sustained-action APs. Consumption data have been expressed in daily-defined dose (DDD) per 1,000 inhabitants per day of treatment (DDD/1000/day) total for hospital, retail and reimbursable pharmaceuticals. The total number of DDD/1000/day was calculated for Russian Federation on the whole, as well as for each federal district, region and republic of the Russian Federation, by adding up the DDD/1000/day for the individual antidepressants. **RESULTS:** Antipsychotic consumption decreased from 3.80 in 2010 to 3.59 DDD/1000/day in 2015 (Δ -5.5%). TA consumption decreased (from 61% in 2010 to 55% in 2015) and that of the AA and sustained-action APs ones increased (from 17% (2010) to 19% (2015) and from 22% (2010) to 26% (2015) respectively). In 2010, the most consumed drug was haloperidol oral (0.99 DDD/1000/day). However, during the period 2010-2015 utilization of haloperidol oral decreased by 23%, but it remains the most consumed APs (0.76 DDD/1000/day) in 2015. The drug with the largest increase in consumption was olanzapine oral. Its consumption increased in three times in the period 2010 - 2015 (from 0.027 to 0.080 DDD/1000/day). **CONCLUSIONS:** It was found that the APs consumption in Russian Federation during the period 2010-2015 has not changed significantly (Δ -5.5%). At the same time TA (1-st generation drugs) consumption decreased and that of the AA and sustained-action APs ones increased. Therefore, the level of consumption of TA in Russian Federation remains high (over 50% of the total APs consumption).

PMH65

EFFECT OF ATYPICAL ANTIPSYCHOTIC PRIOR AUTHORIZATION IMPLEMENTATION ON PATIENT OUTCOMES AMONG OHIO MEDICAID BENEFICIARIES

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OBJECTIVES: A major concern regarding prior authorization (PA) policies for atypical antipsychotics (AAs) is that they produce undue burden on an already vulnerable population which may worsen outcomes. In October 2008 Ohio Medicaid implemented a PA-policy that contained a unique stipulation exempting psychiatrists. The objective of this study was to determine the impact of this PA-policy on healthcare utilization and cost for patients newly prescribed AAs. **METHODS:** Patient-level data analyzed came from Ohio Medicaid fee-for-service claims files June/2007-September/2009. A difference-in-differences regression approach was used to compare outcomes in the PA-active year to the year pre-implementation between patients treated by psychiatrists and those treated by nonpsychiatrists. Patients were stratified based on index-AA prescribing-physician type, and those treated by PA-exempt psychiatrists served as the control. Patients were included if they were ≥ 18 , had an AA claim following 120-days of washout, and had 180 days of post-index healthcare utilization data. Patients with any gap in coverage and those dual-eligible for Medicare were excluded. Logistic regression was used to estimate the policy-attributable effect on all-cause and psychiatric-related hospitalizations, emergency department visits, outpatient visits, and physician office visits. Policy-attributable changes in all-cause and psychiatric-related expenditures were assessed using a generalized linear model with a log-link function and gamma distribution. All regressions included the following covariates to control for confounding: age, sex, race, diagnosis, comorbidities, previous healthcare utilization, index-AA type, and AA-adherence. **RESULTS:** 1,129

patients from the pre-PA-period (psychiatrist-treated=400; nonpsychiatrist-treated=729) and 2,032 patients from the PA-period (psychiatrist-treated=955; nonpsychiatrist-treated=1,072) were included in the difference-in-differences analysis. No statistically-significant policy-attributable effect was found except for all-cause hospitalizations, which decreased substantially with an OR=0.54 (95%CI: 0.33-0.88, $p=0.014$). **CONCLUSIONS:** Implementation of the PA-policy did not negatively affect patient outcomes, and was shown to reduce the odds of hospitalization. The psychiatrist-exemption implemented by Ohio may represent a PA-design that reduces medication costs while preserving patient quality-of-care.

PMH66

COSTS OF ALCOHOL USE DISORDER AND RECOMMENDATIONS FROM AN EXPERT PANEL TO REDUCE COSTS OF RECIDIVISM

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OBJECTIVES: The United States Surgeon General Report on alcohol, drugs, and health addresses one of the largest health crises we face in America and proposes changes to the way we approach and care for substance use disorders. This research sought to quantify and validate healthcare utilization and costs for patients diagnosed with alcohol use disorder (AUD) using a US health insurance claims database. **METHODS:** We identified AUD patients from Truven Health Analytics' MarketScan® Research Databases. Patients included had 12 months of continuous coverage in a health plan from January 1 - December 31, 2013. Data analyzed included demographics, resource utilization and costs from acute inpatient stays with the diagnoses of interest. Additional information from outpatient claims and electronic medical records (EMR) are reported. These data were reviewed by an expert panel of 10 clinicians and researchers who subsequently suggested solutions for reducing recidivism and costs. **RESULTS:** There were 51,889 patients aged 10 - 59 years with a diagnosis of alcoholism, of which 26,978 patients were admitted to a hospital for treatment. The average number of hospital visits was 3.1 per patient for the year with most returning to hospitalization within 45 days. The average cost of admission was more than \$14,000 for males and slightly lower for females. The panel of clinicians validated these findings and suggested clinical monitoring to augment current treatments. **CONCLUSIONS:** As shown in this claims analysis, annual costs of AUD and recidivism in this population have substantial economic consequences. Proactive clinical monitoring and disease management, already used within general health care settings to address other potentially progressive illnesses, could be applied in emerging cases of substance misuse. Use of clinical monitoring and treatment management should be accompanied by informed clinical protocols to reduce the frequency and amount of substance use along with family education to support lifestyle changes.

PMH67

COST-EFFECTIVENESS OF LONG ACTING INJECTABLE BUPRENORPHINE VERSUS SUBLINGUAL BUPRENORPHINE TO TREAT OPIOID USE DISORDER IN SWEDEN AND THE UNITED KINGDOM

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OBJECTIVES: There is growing concern in Europe over heroin and prescription opioid abuse. Opioid-related overdose deaths have peaked historically at 7000 annually. Associated healthcare utilization, productivity loss, criminal justice and social welfare expenditures place a considerable burden on publicly-funded European systems. Medication assisted therapy (MAT) is effective, but limited by abuse/diversion, non-adherence, accidental poisoning and administrative burdens like supervised dosing. There has been an emphasis on introducing long-acting, abuse-deterrent MATs. Long-acting, injectable buprenorphine (LA-BPN) has demonstrated benefits versus sublingual buprenorphine (SL-BPN) in a 24-week Phase 3 clinical trial for opioid-dependent patients. This analysis sought to determine whether LA-BPN is cost-effective versus SL-BPN in Sweden and the UK. **METHODS:** We developed a Markov model to assess the cost of LA-BPN per QALY-gained versus SL-BPN. Cohorts were cycled weekly for 52 weeks among 5 states: on treatment (1) without or (2) with illicit opioid use, off treatment (3) without or (4) with illicit opioid use, and (5) death. Transitions were derived from the clinical trial. Event probabilities, costs, and utilities were literature-based and included diversion/misuse, infection, hospital/rehabilitation utilization, productivity loss, pediatric poisoning, and criminal justice. Separate Swedish and UK scenarios accommodated local costs and utilities. Uncertainty was assessed by univariate and probabilistic sensitivity analysis. **RESULTS:** The SL-BPN cohort encountered more relapses, 3% higher rates of serious adverse events, and approximately 400% greater risk of non-fatal overdose, which is consistent with trial outcomes. LA-BPN was associated with lower healthcare utilization, criminal justice, and lost productivity costs and more QALYs. These relationships were consistent in Sweden and the UK and demonstrates that under certain conditions LA-BPN is a dominant strategy. **CONCLUSIONS:** These estimates support LA-BPN as a cost-effective alternative to SL-BPN from Swedish and UK perspectives. Findings should be interpreted carefully as they are not based on direct observation in a real-world setting.

PMH68

TWO-YEAR HEALTHCARE UTILIZATION AND COST AMONG A MEDICAID SCHIZOPHRENIA POPULATION AT HIGHER RISK OF HOSPITALIZATION

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OBJECTIVES: The Quality Improvement and Risk Evaluation (QI-RE) model predicts 12-month risk of hospitalization for schizophrenia patients based on 12

months of medical and pharmacy data. We describe cost and utilization over 24 months for Medicaid patients with schizophrenia with higher risk (HR) of hospitalization (>50% predicted 12-month QI-RE risk of hospitalization). **METHODS:** Adult patients with schizophrenia (ICD-9 295.xx) and ≥2 claims for the same antipsychotic were selected from the Truven Health MarketScan Medicaid database, with the date of 2ndantipsychotic claim as index. Continuous enrollment in Medicaid for ≥12 months prior to and ≥24 months after the index date were required, as well as ≥1 pre-index claim for an antipsychotic other than the index drug. We evaluated annual and two-year healthcare resource utilization and reimbursed costs. We calculated means and standard deviations (SD) for continuous variables and frequencies for categorical variables. **RESULTS:** Of 7,430 study-qualified patients, 44.6% (n=3,317) were HR. The mean (SD) age of HR patients was 38.9 years (13.0), with 53.6% female. The most common comorbidities were depressive disorders (55.1%), lung disease (49.5%), hypertension (46.5%), and substance abuse (43.1%). In the two years post-index, 69.7% of HR patients had ≥1 hospitalization (57.1% in Year 1, 46.3% in Year 2). In Year 1, HR patients accounted for 74.3% of inpatient admissions and 63.1% of emergency department visits; in Year 2, those proportions were 71.5% and 63.3%, respectively. With mean annual healthcare costs per patient of \$47,372 for Year 1 and \$41,674 for Year 2, HR patients represented 54.4% of total healthcare costs for Year 1 and 53.6% for Year 2. **CONCLUSIONS:** Higher QI-RE risk is associated with a disproportionate share of inpatient utilization and total costs not only in the first year post-index, but also in the second year.

PMH69

STRESS PREDICTION MODEL OF UNDERGRADUATE BURAPHA UNIVERSITY STUDENT 2016

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OBJECTIVES: 1. To evaluate stress level of Undergraduate Burapha University Student (UBUS). 2. To establish UBUS Stress Model. **METHODS:** Cross-sectional survey study was performed to investigate stress. Stress is operationalized into 6 dimensions namely: education, friendship, environment, activities, health, and expectation from the family. Population was all Burapha students in 2016. Sample was calculated according to Yamane 1973. It generated n=448. A non-probability quota sampling was performed. **RESULTS:** A 100% data collection was gathered. Burapha students were in the middle stress level. We found no significantly different of the stress means between students in 3 groups -pure sciences, health science and social sciences- ($p<0.05$ ANOVA). Hierarchical stepwise multiple regression generated stress equation prediction as: Stress = 14.834+ 1.733 Education*+ 1.710 Friendship*-0.707 Family Expectation*-0.109 Health+0.292 Activity -0.291 Environment **CONCLUSIONS:** Three significant stress predictors were education, friendship and family expectation. No significance differences stress among different major groups of student.

PMH70

NURSING HOME ANTIPSYCHOTIC PRESCRIBING PRACTICES AND RISK OF HOSPITALIZATION AND MORTALITY IN DEMENTIA PATIENTS

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OBJECTIVES: Antipsychotic drug use in dementia patients is considered suboptimal care. Nursing home level antipsychotic rate, a measure of nursing home quality of care, may lead to adverse outcomes. The study evaluated the association of nursing home level initiation of antipsychotics with 30-day all-cause hospitalization and mortality. **METHODS:** This retrospective cohort study used Medicare claims data, Minimum Data Set, and the Online Survey, Certification, and Reporting data from 2007-2009. The cohort included short-stay (nursing home stay ≤ 100 days) elderly nursing home residents with dementia. The outcome measures were 30-day all-cause hospitalization and mortality. Multilevel Andersen Behavioral model was used to select patient and contextual level predisposing, enabling and need factors. Contextual level nursing home antipsychotic initiation rate was categorized into tertiles (low, medium, or high) based on proportion of dementia residents newly started on antipsychotics during the baseline period. Hierarchical logistic regression models were used to determine the association of nursing home antipsychotic rate with 30-day hospitalization and mortality, while controlling for patient and contextual level covariates. **RESULTS:** The cohort included 9,611 patients from 2,548 nursing homes. In the hierarchical logistic regression models, nursing home level antipsychotic rate was not associated with 30-day hospitalization (low, OR 1.01, 95% CI 0.89-1.15; medium, OR 0.97, 95% CI, 0.84-1.13; high, OR 1.11, 95% CI 0.97-1.28) or 30-day mortality (low, OR 0.98, 95% CI 0.79-1.23; medium, OR 0.87, 95% CI, 0.66-1.14; high, OR 0.90, 95% CI 0.70-1.16); compared to 0% initiation rate. Patient level antipsychotic use was associated with increased risk of 30-day hospitalization (OR 1.18, 95% CI 1.01-1.37) but not with 30-day mortality (OR 0.96, 95% CI 0.73-1.26). **CONCLUSIONS:** Nursing home level antipsychotic prescribing practices was not associated with short-term all-cause hospitalization or mortality. However, patient-level antipsychotic was associated with higher risk of 30-day hospitalization.

PMH71

PREDICTORS OF ANTIPSYCHOTIC INITIATION AMONG SHORT-STAY NURSING HOME DEMENTIA PATIENTS

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OBJECTIVES: Antipsychotic drugs are used to treat behavioral and psychological symptoms of dementia despite of their significant safety concerns. This study

examined patient and contextual factors associated with initiation of antipsychotics among nursing home residents with dementia. **METHODS:** This retrospective cohort study used Medicare claims, Minimum Data Set, and the Online Survey, Certification, and Reporting data from 2007-2009. The study sample consisted of short-stay (nursing home stay ≤ 100 days) elderly nursing home residents with dementia. Patient level antipsychotic initiation was the outcome measure. Multi-level Andersen Behavioral model was used to select patient and contextual level predisposing, enabling and need factors. Contextual level nursing home antipsychotic initiation rate was categorized into tertiles (low, medium, or high) based on proportion of dementia residents newly started on antipsychotics during the baseline period. The association of predisposing, enabling and need factors with initiation of antipsychotics was evaluated using hierarchical logistic regression model. **RESULTS:** A total of 9,611 patients was identified residing in 2,548 nursing homes. Overall antipsychotic initiation rate was 11.2%; nursing home level initiation rate was 0% in 890, <12.6% in 659 (low), 12.6%-16.7% in 465 (medium) and 16.8%-70% in 534 (high) nursing homes. Nursing home level antipsychotic initiation rate was associated with patient's increased likelihood of initiating antipsychotic (Medium: OR 1.36, 95% CI 1.09-1.71, High: OR 1.48, 95% CI 1.20-1.82). Among patient level factors, predisposing (female), enabling (dementia unit, mood indicators, mild and moderate/severe behavior, moderate and severe cognitive performance), and need (drug abuse, psychosis, anti-anxiety medication use) were associated with higher likelihood of antipsychotic initiation. **CONCLUSIONS:** Both patient and contextual level predisposing, enabling and need factors influenced initiation of antipsychotics among nursing home residents with dementia. The study revealed that antipsychotic prescribing practices play an important role in the use of antipsychotics in nursing home residents with dementia.

PMH72

A COMPARISON OF ANTIPSYCHOTIC DRUGS APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION AND HEALTH CANADA (1950-2015)

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OBJECTIVES: The use of antipsychotic drugs has been significantly increasing in the US and Canada, both agencies evaluate drug in similar ways. However, differences in approval processes and outcomes such as approved indication, contraindication, and limitation of use exist with other classes of drugs. The objective of this study was to provide a comprehensive and comparative analysis of antipsychotic drugs approved by the U.S. Food and Drug Administration (FDA) and Health Canada (HC). **METHODS:** A list of all antipsychotic drugs approved by both agencies from 1950 to 2015 was gathered. For each drug, the following data were extracted: indications, contraindications, dosage forms, routes of administration, strengths, market statuses and review statuses. Differences were identified and compared qualitatively and quantitatively. **RESULTS:** Out of the 68 antipsychotic drugs on the WHO ATC list, 29 had never been approved by or submitted to the FDA and HC. Of the 39 drugs that were approved by both agencies, 20 are currently on the market in both countries. For these 20 drugs, the average number of approved indications by FDA (2.85 ± 1.96) was higher than HC (2.20 ± 0.81), though not statistically significant. Qualitative analysis revealed differences in approved indication in 80% of the drugs. HC approved more contraindications than the FDA (6.25 ± 4.96 vs. 3.90 ± 3.18 ; p-value < 0.05). Moreover, differences were identified in limitation of use, restriction of indications, approval dates between the two agencies. **CONCLUSIONS:** There are significant differences in the antipsychotic drugs approved by both agencies. Additionally, differences in indications, contraindications, and other characteristics of drugs were identified. Harmonization of the drug regulatory process may help in decreasing these differences.

PMH73

SUICIDE IN LATIN AMERICAN INDIGENOUS POPULATION: A SYSTEMATIC REVIEW

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OBJECTIVES: High rates of suicide have been reported in different ethnic minorities. Some researchers suggest this sociological, anthropological and medical phenomenon is a major public health issue in Latin America. **METHODS:** We performed a systematic review of the literature in PubMed, Scopus, PsycNET and Scielo (the Latin American database). An additional search for "grey literature" was done in Scholar Google using suicide (and Spanish or Portuguese equivalents) associated with each Latin American country. The reference lists of all included articles were reviewed for any additional studies. Searches were carried out on March 2016. Articles were reviewed in full text. No language or publication date limits were applied. Only articles centered on or considering indigenous population were used for data extraction. Meta-analysis was not attempted due to heterogeneity of study characteristics, including study populations, study designs, and research methodology. Narrative synthesis was therefore used to analyze the extracted data. **RESULTS:** Initial searches identified 1862 potential references, of which 75 were selected for full-text review, 2 of which were not available. Data was extracted from 41 articles published between 1980 and 2015; 21 of them referred to Brazil, 13 to Colombia, 2 to Chile, 1 to Peru, while 4 additional articles included data from several Latin American countries. **CONCLUSIONS:** Suicide rates are high and have been apparently increasing over time, despite high underreporting and scarce scientific interest on the issue. Suicide mostly occurs in middle aged men, using hanging as most frequent method. Alcohol consumption is widely associated. Changes in lifestyles influenced by industrialization, environmental degradation, and cultural and religious invasion have affected indigenous groups, making them

experience what has been described as "cultural death". Mental health disorders in Latin American indigenous groups have not been studied in depth. Interventions have to incorporate their own traditions and beliefs.

PMH74

TREATMENT PATTERNS AND CHARACTERISTICS OF ADULT PATIENTS WITH ATTENTION DEFICIT/HYPERACTIVITY DISORDER RECEIVING ATOMOXETINE IN JAPAN

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OBJECTIVES: To describe the characteristics and medication treatment patterns of adult patients with attention-deficit/hyperactivity disorder (ADHD) prescribed atomoxetine in Japan. **METHODS:** A retrospective analysis of insurance claims data was conducted using the Japan Medical Data Center database. Adults (≥ 18 years) with ADHD who had ≥ 1 atomoxetine claim from 1 January 2013, to 31 December 2014, and ≥ 180 days of follow-up were included. First atomoxetine claim defined the index date. Patient characteristics included age, gender, and comorbid conditions. Treatment patterns assessed included rates of atomoxetine discontinuation, switching, persistence, adherence (assessed via the medication possession ratio), and use of concomitant medications. **RESULTS:** A total of 457 adults met all inclusion criteria; mean (SD) age was 32.7 (10.4) years, and 61% of patients were male. Nearly 72% of the patients had at least one comorbid mental health condition in the baseline period; depression (43.8%) and insomnia (40.7%) were the most common mental comorbidities. Most common physical comorbidities were chronic obstructive pulmonary disease (14.4%) and diabetes (12.9%). Psychotropics were received by 59.7% of patients during baseline period and by 66.0% during follow-up period; however, only 6.6% received psychotropics concomitantly with atomoxetine. Overall, 40.0% of adults discontinued atomoxetine and 65.9% were persistent with atomoxetine therapy at 3 months post-index date. Mean (SD) atomoxetine medication possession ratio was 0.57 (0.25), and 25.4% switched to an alternative ADHD therapy; methylphenidate (22.4%) and psychotropics (77.6%) were the most common medications to switch to. Nearly 8% augmented atomoxetine with an alternative ADHD therapy. **CONCLUSIONS:** In this observational study, a majority of adults with ADHD treated with atomoxetine were still persistent with therapy at 3 months post-index date, with one-quarter switching to alternative ADHD therapy. Higher proportions of both mental and physical comorbidities, along with greater use of psychotropic medications in the baseline period, were observed among patients with ADHD prescribed atomoxetine.

PMH75

A SYSTEMATIC LITERATURE REVIEW OF CLINICAL PRACTICE GUIDELINES FOR THE TREATMENT OF BIPOLAR DISORDER TYPE I (BD-I)

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OBJECTIVES: To perform a systematic review (SR) of literature and present the most current and up-to-date treatment recommendations issued by clinical practice guidelines (CPG) around the world, as well as those from SR of randomized controlled clinical trials (RCT) regarding BD-I therapy strategies. **METHODS:** A set of questions was formulated on BD-I regarding current treatment options (and their efficacy and safety), non-pharmaceutical options, which guidelines are available and what strategies are recommended. A search string was formulated to retrieve CPGs and another to identify SR of Randomized Controlled Clinical Trials (RCT). We focused on therapies recommended by those CPG for treating manic or mixed episodes or for prevention of manic episodes in BD-I. We searched MEDLINE, EMBASE, CRD Database and National Guidelines Clearinghouse. **RESULTS:** We retrieved ten CPG from several countries and three SR of interest. Guidelines issued recommendations on indications for psychiatric admission, pharmacological interventions for the management of acute mania, acute depression, maintenance and long-term care and psychosocial and non-pharmacological interventions. The SR for treatment of acute mania included sixty-eight trials with 16,073 patients assigned to 14 different treatments. Most trials (79%) comprised two study groups, the mean duration was 3.4 weeks, and the mean sample size was 105.7 patients per group. The second SR was an update of the first, with 57 studies involving 95 comparisons with 14,256 patients. Treatments were found to be superior to placebo with small differences in efficacy. The last SR (33 trials with 6,846 patients) analyzed drugs for long-term/maintenance treatment. Most drugs were better than placebo for any mood episode relapse or recurrence. **CONCLUSIONS:** Good quality evidences about treatment options are available for almost every aspect of bipolar disorder. Detailed publications can help clinicians find the therapy that best suits each patient during mania, depression and for maintenance treatment.

URINARY/KIDNEY DISORDERS – Clinical Outcomes Studies

PUK1

EFFECT OF ALLOPURINOL IN THE ESTIMATED GLOMERULAR FILTRATION RATE IN PATIENTS OVER 50 YEARS

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OBJECTIVES: To estimate the effect of allopurinol on hyperuricemia and estimated glomerular filtration rate (eGFR). **METHODS:** An observational non-concurrent prospective cohort study. Patients older than 50 years with hyperuricemia were included. All patients received allopurinol 100-300 mg day for 12 months. The levels of uric acid (UA) were determined and the glomerular filtration rate (GFR) was

estimated at baseline. Changes in AU and in GFR were observed after treatment. **RESULTS:** 50 patients diagnosed with hyperuricemia on treatment with allopurinol were eligible with a mean age of 71.6 ± 11.1 years. 58% of the patients were male and 46% had diabetes mellitus. UA levels decreased significantly from 7.1 ± 1.1 mg/dl to 5.5 ± 1.2 mg/dl ($p < 0.001$). The GFR increased from 46.3 ± 19.1 ml/min/1.73 m² to 49.0 ± 20.6 ml/min/1.73 m² but this increase was not significant ($p = 0.14$). There were no reports of adverse reactions to allopurinol. **CONCLUSIONS:** In this study, allopurinol was effective and safe in the treatment of hyperuricemia but did not significantly increase GFR in patients older than 50 years.

PUK2

IMPACT OF INDIVIDUAL DIAGNOSIS CODES ON DATABASE ESTIMATES OF OVERACTIVE BLADDER

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OBJECTIVES: To assess the effect of individual International Classification of Disease, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes on database estimates of overactive bladder (OAB) in the absence of a specific OAB ICD-9-CM code. **METHODS:** ICD-9-CM codes used to define OAB were identified from a review of published claims database studies. OAB prevalence and patient characteristics were evaluated for each code using 2015 OptumHealth claims data. Prevalence was calculated among all subjects in the data with insurance eligibility. The share of patients with a medical claim for each code was counted overall, and compared between visits to urologists and all other healthcare providers. Patient clinical and demographic characteristics and oral OAB pharmacologic treatment rates were measured for each sample. **RESULTS:** Fourteen studies were reviewed, yielding 27 distinct ICD-9-CM codes used to identify OAB patients. A total of 206,527 patients had ≥ 1 claim with any of these codes (1.57% of all enrollees). The most commonly used ICD-9-CM code (788.31 - urge incontinence), identified only 12,472 patients (0.09%), while ICD-9-CM 788.41 (urinary frequency) accounted for the most patients (N=111,374, 0.84%) but was only used in 8 of 14 studies. Only 19% of patients with ICD-9-CM 788.41 were seen by urologists compared with 25% of all OAB patients identified. Relative to all other OAB patients identified, those with ICD-9-CM 788.41 had lower mean age (42.7 years vs. 45.9 years; $p < 0.0001$), fewer males (33% vs. 46%; $p < 0.0001$), and lower rate of oral pharmacologic treatment (3% vs. 6%; $p < 0.0001$). Patients with ICD-9-CM 596.51 (hypertonicity of bladder) were most likely to receive treatment (21%). **CONCLUSIONS:** Due to the lack of a specific ICD-9-CM code for OAB, numerous combinations of codes have been used to identify OAB patients. This analysis shows the codes chosen have a significant impact on the patient population and treatment pattern estimates.

PUK3

EFFECTIVENESS OF LOSARTAN 50MG IN THE MANAGEMENT OF POST DIALYSIS EUVOLEMIC HYPERTENSION: A SINGLE BLINDED RANDOMIZED CONTROL TRIAL Aftab RA

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OBJECTIVES: To assess the effectiveness of losartan 50 mg on Post dialysis euvolemic hypertensive patients against standard antihypertensive pharmacotherapy. **METHODS:** A multicentre, prospective, randomised, single blind trial was conducted at hospital university sains Malaysia, Kelantan Malaysia, to assess the effect of losartan 50mg once daily (OD) among post dialysis euvolemic hypertensive patients. Covariate Adaptive Randomization was used for allocation of participant to standard or treatment arm, and were followed up for eight weeks. Pre, intra and post dialysis session blood pressure measurements were recorded along with any adverse events. Wilcoxon statistical test was performed to note the difference in blood pressure from baseline. **RESULTS:** A total of 70 patients were randomised into standard (n=35) and treatment arm (n=35) and were followed for a period of 8 weeks. The mean baseline post dialysis systolic blood pressure of standard arm was 156.1(±14.3) mmHg as compared to treatment arm 157.7(±13.3) mmHg. In the standard group, the mean post dialysis blood pressure dropped by 0.5 mmHg by the end of 4th week but increased by 0.5 mmHg by the next four weeks. However the treatment arm reported a drop of 2.8 mmHg of BP drop during 8 week trial period. Analysis suggests that there was a significant difference in blood pressure readings at the end of 8 weeks among patients treated with losartan ($P < 0.001$) however no such statistical association was observed in standard arm ($P = 0.17$). **CONCLUSIONS:** A slow, steady significant decline in post dialysis BP was observed among euvolemic hypertensive patients that were treated with losartan 50mg.

PUK4

COMPARATIVE EFFECTIVENESS OF PERITONEAL DIALYSIS VERSUS HEMODIALYSIS FOR END-STAGE-RENAL DISEASE

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OBJECTIVES: To assess comparative effectiveness of peritoneal dialysis (PD) and hemodialysis (HD) in end-stage renal disease (ESRD) patients initiating dialysis therapy. **METHODS:** We constructed retrospective cohort with national administrative healthcare databases. The study population comprised patients with ESRD in Korea who newly treated kidney dialysis such as hemodialysis and peritoneal dialysis between January 1, 2004 and December 31, 2015. We excluded patients who received kidney transplant; lost follow-up; death; stop dialysis within three months from the initiation date. The primary outcome was all cause mortality, and the secondary outcome was incidence of major adverse cardiac and cerebrovascular events (MACCE). We analyzed that the comparative risks of

primary and secondary outcomes were determined with the use of Cox regression. Propensity-score matching was used to assemble patient cohorts with similar baseline characteristics. **RESULTS:** A total of 96,626 eligible patients with ESRD were composed of 18,216 treated with PD, 78,410 treated with HD. The crude mortality rates were 95.0 per 1000 patient-years (PY) in PD and 96.5/1000PY in HD. Compared with HD, PD was associated with increased risks of mortality (adjusted hazard ratio: 1.27, 95% CI: 1.24-1.31, p -value < 0.0001) and MACCE rate (CVD, HR: 1.11, 95% CI: 1.06-1.16, p -value < 0.0001). The results were similar in analysis of matching patients. However, in subgroup analysis, there was no statistical significant difference between HD and PD, especially in non-diabetic patients less than age 65. **CONCLUSIONS:** The results from this study show that patient treated with PD was associated with a high risk of mortality and MACCE. However, there was no statistical significant difference in group of non-diabetic patients less than age 65. Although we could not assess cost effectiveness, considering cost and time to spend dialysis, appropriate selection of dialysis modality according to baseline characteristics is needed.

PUK5

EFFECTIVENESS OF ANGIOTENSIN CONVERTING ENZYME INHIBITORS VERSUS ANGIOTENSIN RECEPTOR BLOCKERS AMONG CHRONIC KIDNEY DISEASE PATIENTS

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OBJECTIVES: Meta-analyses of randomized controlled trials suggest angiotensin-converting enzyme inhibitors (ACEIs) may reduce the rate of kidney failure compared to angiotensin II receptor blockers (ARBs) among patients with chronic kidney disease (CKD). However, controlled trials have not enrolled enough patients to permit precise inferences for this important population. We examined the comparative effects of ACEIs and ARBs on renal and cardiovascular outcomes among CKD patients using insurance claims data. **METHODS:** We conducted a retrospective new-user cohort study using national U.S. data from OptumLabs on privately insured individuals and Medicare Advantage enrollees. We identified individuals ≥ 18 years old with CKD who initiated therapy with an ACEI or ARB between 2005 and 2015 after ≥ 6 months of nonuse. We used Cox proportional hazards models to estimate hazard ratios (HRs) and 95% confidence intervals (CIs) by inverse probability of treatment weighting to compare ACEIs versus ARBs for progression to end-stage renal disease (ESRD), myocardial infarction (MI), and ischemic stroke. **RESULTS:** The study cohort comprised 48,489 patients, with a total of 3,148 ESRD progression, 1,011 MI, and 741 stroke events. Mean follow-up was 2.2 years. Inverse probability weighting resulted in well-balanced treatment groups. HRs comparing patients treated with ACEIs to those treated with ARBs were 0.87 (95% CI, 0.80-0.94) for ESRD, 1.08 (95% CI, 0.93-1.25) for MI, 1.10 (95% CI 0.93-1.30) for stroke, and 1.10 (95% CI 0.98-1.23) for the composite of stroke or MI. Results were consistent across stability analyses using different outcome definitions, treatment washout periods, and continuous enrollment periods. **CONCLUSIONS:** Use of ACEIs among CKD patients was associated with a lower rate of ESRD and similar rates of cardiovascular outcomes compared with use of ARBs. Our results are consistent with the results of meta-analyses of CKD clinical trials, but are more precise, and suggest that ACEIs may be the preferred treatment to slow CKD progression.

PUK6

REAL WORLD CARDIOVASCULAR (CV) RISK PROFILE IN INDIVIDUALS TREATED FOR OVERACTIVE BLADDER (OAB)

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OBJECTIVES: Antimuscarinic (AM) and β₃ adrenergic receptor agonist medications (mirabegron) are commonly used to treat symptoms associated with OAB. Mirabegron is typically prescribed as a second line agent to AMs. The objective was to describe baseline characteristics including CV risk in OAB patients initiating treatment with either mirabegron or an AM, or those who were untreated. **METHODS:** Integrated claims and electronic health records (EHR) of patients with OAB were examined. Index was the first date of treatment for AM or mirabegron between October 2012 and December 2014. Patients with 12 months pre-index data, baseline blood pressure (BP) measurements, and no CV events within 30 days pre index were included. Untreated OAB cohort included patients without recorded OAB treatment. Index for untreated patients was the earliest date with their OAB related diagnosis within the same identification period. Unadjusted demographic and clinical characteristics, including CV risk factors, were compared across groups at index. **RESULTS:** The study groups included 54,187 untreated patients, 10,311 AM patients, and 408 mirabegron patients. Compared to AM and untreated patients, mirabegron patients were older (mean age 70 years vs. 67 years AM and 60 years untreated). Males comprised 33.6% of mirabegron patients, 26.8% of AM patients, and 39.6% of untreated patients. Mirabegron patients were more likely to have had prior CV events > 30 days pre index (17.2% vs. 14.3% for AM and 12.3% for untreated), and were more likely to have diabetes mellitus (42.2% vs. 34.8% for AM and 26.3% for untreated). Baseline BP and cholesterol were similar across groups. Concomitant medication use was highest in AM patients. **CONCLUSIONS:** In a real world analysis, baseline CV risk differs between OAB patients receiving mirabegron versus antimuscarinics. Analysis using integrated claims and EHR data therefore require adequate bias reduction techniques for assessing CV risk in OAB populations.

PUK7

THE PREVALENCE, TREATMENT AND CHARACTERISTICS OF OVERACTIVE BLADDER PATIENTS IN THE MEDICARE FEE-FOR-SERVICE (FFS) POPULATION

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OBJECTIVES: To estimate the prevalence of Medicare FFS patients 65+ years receiving treatment in 2013 for OAB and to determine what patient characteristics were associated with higher prevalence. **METHODS:** The 2013 Medicare Beneficiary Part B Carrier Claims File (Carrier), the Part D Drug Event File (PDE), and the Medicare Beneficiary Annual Summary File (BASF) for patients over 65 years were used to calculate prevalence of OAB and the number of patients with OAB among the Medicare FFS population. OAB was defined as having an OAB related diagnosis and/or a Part D claim for an antimuscarinic or mirabegron and/or a CPT code (52287) for onabotulinumtoxinA injection of the bladder. The BASF was linked to the Carrier and PDE Files to determine patient age, gender, and race/ethnicity. **RESULTS:** The national prevalence rate of OAB among Medicare FFS patients was 7.17% (N=2,278,865); the rate was 7.72% among males and 6.74% among females. By race/ethnicity subgroups, the prevalence rate was lower in Blacks (5.8%) and Hispanics (5.86%) compared with Whites (7.43%). Patients 75+ years have a significantly higher OAB prevalence rate of 9.32% (p<0.01) than those 65-74 years (5.44%). Nationally the prevalence of OAB in rural zip codes was 6.01% vs 7.49% in urban zip codes. Among OAB patients only 21.4% were being treated with mirabegron or an antimuscarinic. Treatment rates are higher in females (29% vs 13% in males), Hispanics (29.5% vs 22% and 21% in Blacks and Whites, respectively) and older populations (23% in ≥75 years vs 19% in 65-74 years). **CONCLUSIONS:** The prevalence rates are similar to older estimates of Medicare data but are much lower than studies based on self-reporting. However, overall treatment rates of only 21% is in line with findings from other studies. These results also show substantial differences in OAB prevalence rates in particular patient demographics.

PUK8

DIFFERENTIAL PRESCRIBING OF ANTIMUSCARINIC AGENTS IN OLDER ADULTS WITH COGNITIVE IMPAIRMENT

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OBJECTIVES: To evaluate differential prescribing of newer vs. older antimuscarinics in older adults and determine if appropriate prescribing of a newer over an older antimuscarinic occurred in persons with preexisting cognitive impairment. **METHODS:** We performed a population-based retrospective analysis using the 5% random sample Medicare claims data linked with Part D data from 2007 to 2012. We identified new-users of older (e.g., oxybutynin) and newer (e.g., tolterodine, trospium, solifenacin, darifenacin, fesoterodine) antimuscarinic in adults aged 65.5 years and older, and conditions potentially associated with differential utilization of newer vs. older antimuscarinics in the 6 months prior to the first prescription using ICD-9-CM diagnosis and procedure codes and medication claims. Conditions analyzed included indicators of cognitive impairment (mild cognitive impairment, dementia, or anticholinergic medication), comorbid conditions (defined by Elixhauser), and other conditions common in the elderly. We used multivariate logistic regression with backward selection to assess the selection of newer vs. older antimuscarinics after adjusting for comorbid conditions. **RESULTS:** Of the 55,405 older adults with a new prescription for an antimuscarinic, 68% received a newer antimuscarinic as initial therapy. Overall, 7,314 patients were diagnosed or treated for dementia prior to initial therapy. Older adults diagnosed or treated for dementia were more likely (OR 1.14, 95% CI 1.07-1.20) to receive a newer compared to an older antimuscarinic. When diagnosis and treatment were considered separately in the multivariate analyses, patients treated for dementia were more likely to receive a newer antimuscarinic (OR 1.23, 95% CI 1.15-1.31). However, 29% of patients previously diagnosed or treated for dementia were initiated on an older antimuscarinic. Increased age, osteoporosis, and vertigo were associated prescription of a newer antimuscarinic. **CONCLUSIONS:** Older adults treated with anti-dementia medication(s) were appropriately treated with a newer antimuscarinic. Our results suggest there is still a need to improve the appropriateness of antimuscarinic prescribing.

URINARY/KIDNEY DISORDERS – Cost Studies

PUK9

A BUDGET IMPACT ANALYSIS OF INCREASING PERITONEAL DIALYSIS (PD) IN JAPAN

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OBJECTIVES: This study investigates the 5-year healthcare budget impact of variable distribution of adult patients treated with peritoneal dialysis (PD) and in-center hemodialysis (ICHD) in Japan. **METHODS:** An Excel-based budget impact model was constructed to assess dialysis-associated costs when changing dialysis modalities between PD and ICHD from the Japan payer perspective. The model incorporates the current modality distribution of PD (3%), ICHD (83%) and hemodiafiltration (14%) as per the Japanese Society of Dialysis Therapy (JSDT) registry data at the end of 2015. Epidemiological data including dialysis prevalence, incidence, and mortality from the JSDT registry reports were used to estimate the dialysis patient population for the next 5 years. Costs were estimated from claims of patient data collected by Medical

Data Vision (MDV) Ltd, a well-established data source for epidemiological and pharmacoeconomic studies from Japan. Alternative scenarios included the prevalence of PD increasing by 5%, 7.5%, and decreasing 0.5% yearly over 5 years. All 3 scenarios were accompanied with commensurate changes in ICHD. **RESULTS:** An increase in the prevalent PD population from 3% in 2016 to 23%, or 33% in 2020 is predicted to result in 5-year cumulative savings of ¥160,888,039,711, and ¥241,332,059,567, respectively, for the Japanese government. If the prevalent PD population were to decrease from 3% in 2016 to 1% by 2020, the total expenditure for dialysis treatments would increase by ¥16,088,803,971 over the next 5 years. **CONCLUSIONS:** This analysis shows that increasing the uptake of peritoneal dialysis regimen could potentially reduce dialysis-associated costs in Japan.

PUK11

ASSESSMENT OF CLINICAL EFFICACY AND COST COMPARISON OF ERYTHROPOIETIN ALPHA AND DARBEPOETIN ALPHA IN HEMODIALYSIS PATIENTS

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OBJECTIVES: Administration of erythropoiesis stimulating agent (Epoetin alpha or Darbepoetin alpha) is the standard of care for treatment of anemia in hemodialysis (CKD5D) patients. The Pharmacoeconomics of this therapy is important in developing countries since most of the patients are on self-funding for medications. This study was conducted to compare cost per patient and clinical efficacy of these agents in CKD5D patients. **METHODS:** A retrospective study was conducted for a period of one year (January – December 2016) on stable CKD5D patients receiving regular erythropoietin treatment (Epoetin alpha or Darbepoetin alpha) at a tertiary care hemodialysis center in India. Patients with gastrointestinal bleeding, cancer, iron deficiency, pure red aplasia, hemolytic anemias and non-compliant were excluded. The baseline characteristics were compared between the Erythropoietin alpha (E) and Darbepoietin (D) groups. The E group received 4000 Units subcutaneous (S.C) Epoetin alpha and the (D) group received Darbepoietin 40 units S.C once weekly. The maintenance dose and intravenous iron were continued as per clinician discretion. At the end of one year the mean hemoglobin levels (Hgb) and cost per patient for drug were compared between the groups. The statistical analysis was done using SPSS version 15. **RESULTS:** There were 29 patients in E group and 23 in D group. The baseline characteristics were comparable. The average Hgb level over one year was the 9.71 ± 1.43 g/dl in E group and 9.73 ± 0.98 g/dl in D group (p=0.942) suggestive of similar efficacy. There was a significant difference in the mean costs per patient per year for Erythropoietin alpha (30075.86 ± 2392.04 INR) and Darbepoietin (69843.47 ± 6660.31 INR) (p=0.001). **CONCLUSIONS:** Epoetin alpha has a better pharmacoeconomic value compared to Darbepoietin in maintaining Hemoglobin levels in CKD5D patients with similar clinical efficacy. It needs large prospective randomized trials to obtain more definitive data.

PUK12

ASSESSING THE ECONOMIC BURDEN AND 30-DAY READMISSION RATES AMONG PATIENTS WITH URINARY TRACT INFECTION IN THE US VETERANS HEALTH ADMINISTRATION POPULATION

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OBJECTIVES: To assess the health care costs, 30-day readmission rates, and predictors of 30-day readmission among patients with urinary tract infection (UTI) in the US Veterans Health Administration (VHA) population (01OCT2010-30SEP2015). **METHODS:** Patients diagnosed with UTI (International Classification of Disease, 9th Revision, Clinical Modification codes 590, 595, 597, and 599) were identified from the VHA dataset for the identification period (01OCT2011-30SEP2014). The initial diagnosis date was designated as the index date. Patients with the same age, race, and sex as the study UTI patients, but without a UTI diagnosis, were identified for comparison. An index date was selected randomly to minimize bias. Adult patients were required to have continuous medical and pharmacy benefits for 1 year pre- and post-index date. Health care costs and 30-day readmission rates were compared among 1:1 matched patients with and without UTI during the follow-up period. Logistic regression was used to examine the predictors of 30-day readmission. **RESULTS:** After matching, 468,883 patients were included in each group. Compared to patients without UTI, those with UTI incurred significantly higher inpatient (\$13,240 vs \$682; p<0.0001), outpatient (\$6,019 vs \$1,786; p<0.0001), and total costs (\$19,260 vs \$2,469; p<0.0001) as well as a higher 30-day readmission rate (9.3% vs 0.5%; p<0.0001). The likelihood of 30-day readmission was lower among patients aged 18-64 years versus ≥65 years (odds ratio [OR]: 0.4-0.9; p<0.0001) and higher among male (OR: 1.3; p<0.0001), black (OR: 1.2; p<0.0001), and white patients (OR: 1.1; p<0.0001) compared to those of other races and those with higher Charlson comorbidity index (CCI) scores (OR: 1.2; p<0.0001). **CONCLUSIONS:** Patients diagnosed with UTI had significantly higher 30-day readmission rates and economic burden than those without UTI. Age, gender, race, and CCI score were significant predictors of 30-day readmission.

PUK13

OPTIMIZING SURVIVAL AND QUALITY OF LIFE USING BAYESIAN NETWORK MODELING IN KIDNEY TRANSPLANTATION

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OBJECTIVES: Existing solid organ transplant models are based upon organ availability, donor compatibility and general measures of severity but they lack the ability to fully capture the personalized context of treatments that certain instances can avoid the need for transplantation and re-transplantation. In this study, we propose supervised and unsupervised Bayesian Network Models to predict the most personalized pathways that minimize the disease progression conditional upon patient needs and access to the most suitable technology. Furthermore, in addition to prediction, we will also test how well patients would perform if given access to technology that can slow the progression of illness and assess the impact of these interventions on likely rate of transplant and downstream costs. **METHODS:** Using the United Network for Organ Sharing (UNOS) National Organ Procurement and Transplantation Network (OPTN) dataset from 2000-2015, we developed a Bayesian Network Model to estimate the joint probability distribution bilaterally, between donor and recipient, to predict transplant survival rates conditional upon defined biological, clinical and treatment variables. **RESULTS:** Preliminary results in kidney transplantation show that increases in survival rates are correlated not only with host characteristics or donor characteristics, but also treatment characteristics. A k-fold validation of the Bayesian Network Model shows more than 60% predictive power for survival rates. Such models can be made available graphically to transplant teams to assist in optimizing donor characteristics and treatments to the precise needs of kidney patients. **CONCLUSIONS:** The precision medicine movement of today not only requires access to life saving technologies, but also access to pre-emptive information on donors, hosts and treatment options that can be personalized to unique biological and behavioral variables.

PUK14

COST-EFFECTIVENESS OF ANGIOTENSIN-CONVERTING ENZYME INHIBITORS VS. ANGIOTENSIN II RECEPTOR BLOCKERS AS FIRST-LINE TREATMENT IN AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE

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OBJECTIVES: ADPKD is a rare monogenic renal disorder impacting approximately 1:2500 individuals among the general US population. Cardiovascular Disease is the most common cause of mortality among ADPKD patients. Hypertension has been documented as a predictor of disease progression and severity. Few intervention studies have examined the role of antihypertensive therapies in ADPKD and therefore a need to synthesize the literature exists. The objective is to determine if novel Angiotensin II Receptor Blockers (ARBs) are more cost-effective than Angiotensin-Converting Enzymes (ACE) Inhibitors as first line treatment in ADPKD. **METHODS:** A Markov-state decision model was constructed for estimation of cost and outcome benefits in hypertensive ADPKD patients. Transition probabilities were extrapolated from a retrospective cohort study comparing Chronic Kidney Disease (CKD) stage transitions in ADPKD patients. Annual pharmaceutical costs pending average daily dose per CKD stage was extracted from a large US healthcare claims database. Median total health care costs per CKD stage or transplant were extracted from published data. Time horizon was set to 30 years with 1-year duration to cycle shift. Cost-effectiveness analysis was conducted to estimate the incremental cost-effectiveness ratio (ICER) of ACE-I vs. ARB per additional year of prevented transplant and/or death. Sensitivity analysis was conducted using a one-way probabilistic analysis with 10% variation in transition/mortality probabilities and cost. **RESULTS:** Total annual health care costs accrued after 30 years among ADPKD patients taking ACE-I was estimated to be approximately \$3,505,028.41 compared to ARB at \$3,644,327.65. Life expectancy was increased by 1.39 years among patients taking ACE-I. Approximate 10-year survival in patients taking ACE-I was 47% compared to ARB at 34%. **CONCLUSIONS:** ACE-I dominated ARB and displayed greater cost-effectiveness due to lower cost and increased capacity to prolong years of life without transplant or death among hypertensive ADPKD patients. This model validates the use of ACE-I as first line treatment for hypertension management in ADPKD patients.

PUK15

COST-EFFECTIVENESS OF TWO PREVENTIVE STRATEGIES FOR CYTOMEGALOVIRUS INFECTION IN INTERMEDIATE RISK COLOMBIAN RENAL TRANSPLANT PATIENTS

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OBJECTIVES: Our objective was to compare the cost-effectiveness of the two most used valganciclovir-based cytomegalovirus (CMV) prophylaxis strategies, in intermediate risk renal transplant patients in Colombia. The two alternatives are "universal prophylaxis" strategy, which uses valganciclovir for the first 90 days post-transplantation, and "anticipated therapy", which requires weekly viral load surveillance, warranting therapy only when positive. **METHODS:** We designed a TreeAge-based third party payer perspective (Colombian healthcare system) decision tree, considering only direct medical costs, in 2014 Colombian pesos (1 USD = 2000 COP) and a time horizon of one year. Target population was intermediate CMV risk patients (positive receptor). Transition probabilities were extracted from clinical studies, validated with a Delphi expert panel method; procedural costs were obtained from the official tariff manual (ISS 2001) with a 33% adjustment based on the health component of the Colombian Consumer Price Index for the year 2014. Medication costs were obtained from the official Ministry of Health information system (SISMED). **RESULTS:** Universal prophylaxis with valganciclovir was dominant, with lower costs and less probability of infection. The average cost of the first year in anticipated therapy would be US\$ 15,481, whereas in the case of universal therapy the cost would be slightly lower

US\$ 14,984 (incremental cost of US\$ 497). Results did not change significantly with deterministic and probabilistic sensitivity analyses. **CONCLUSIONS:** For Colombian renal transplant patients with an intermediate risk of CMV infections, universal prophylaxis strategy should be the best option.

PUK16

COST-EFFECTIVENESS OF THYMOGLOBULINE VS. ATG-FRESENIUS FOR INDUCTION IMMUNOSUPPRESSION IN KIDNEY TRANSPLANTATION IN CHINA

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OBJECTIVES: Induction immunosuppression therapy is used to support optimal outcomes in kidney transplantation. This study was to assess the cost-effectiveness of Thymoglobuline (Rabbit Anti-human Thymocyte Immunoglobulin) versus ATG-Fresenius (Anti-T lymphocyte globulin) in kidney transplantation in the Chinese setting. **METHODS:** A two-part survival model was developed consisting of a "short-term" part and a "long-term" part. The "short-term" part analyzed the first-year using decision tree and consisted of the "functioning transplant", "acute rejection (AR)", "delayed graft function (DGF)", "dialysis", and "death" health states. The "long-term" part analyzed the two to five-year using Markov model and consisted of the "functioning transplant", "chronic dysfunction", "recurring primary disease", "dialysis", and "death" health states, with capture of the association between DGF and graft loss. Costs including drug acquisition and other direct medical costs were derived from GBI SOURCE CHINA database, chart review and expert panels. Clinical outcomes and utility were retrieved from published literature. The model calculated quality-adjusted life years (QALYs) and total costs per patient. Costs and QALYs were discounted at an annual rate of 3.5%. Sensitivity analyses will be conducted in this ongoing study. **RESULTS:** Patients receiving Thymoglobuline observed more clinical effectiveness than patients receiving ATG-Fresenius mainly due to less AR, DGF and dialysis. The incremental QALY was 0.0297 over a 1-year horizon and 0.0392 over a 5-year horizon. Thymoglobuline and ATG-Fresenius drug cost were ¥15,602 and ¥11,580, respectively. However, the total treatment costs of the Thymoglobuline arm were lower than the ATG-Fresenius arm due to lower costs related to DGF, AR, dialysis and adverse events. In total, Thymoglobuline saves ¥4,407 and ¥11,490 over the 1-year and 5-year horizon, respectively. Thymoglobuline was dominant compared with ATG-Fresenius. **CONCLUSIONS:** Despite higher drug acquisition costs, thymoglobuline-treated patients achieve better short and long term outcomes, resulting in cost savings by avoidance of graft failure and long-term dialysis costs.

PUK17

CHANGES IN EFFICIENCY OF U.S. DIALYSIS CENTERS AMID REGULATORY AND PAYMENT REFORM

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OBJECTIVES: To evaluate the impact of a new prospective payment system (PPS) on the relative efficiency of U.S. Medicare-certified dialysis providers after implementation of this major payment reform in 2011. **METHODS:** In a longitudinal, facility-level retrospective analysis using national data from Medicare Renal Facility Cost Reports, a data envelopment analysis (DEA) was performed to model the technical efficiency of free-standing dialysis centers for the years 2010-2012. DEA uses a linear programming technique to convert multiple inputs (costs, staffing levels) and an output measure (number of dialysis sessions) to a relative efficiency score between 0 and 1, where scores are proportional to the efficiency frontier (score of 1.0). The DEA-based Malmquist Productivity Index was used to assess dynamic efficiency year over year. Results were stratified by industry segment and geographic and environmental covariates. **RESULTS:** 4234 free-standing dialysis centers with data from all three years were included in the analysis. About 33% of facilities were functioning efficiently (efficiency scores $\geq .90$) in 2010, dropping to only 26% in 2011 and 23% in 2012. Overall technical efficiency declined by 3.2% from 2010 to 2011 and by 7.7% from 2011 to 2012. Modest efficiency gains in 2011 but not in 2012 were seen in facilities that were members of medium-sized or non-profit chains. Sub-analyses showed that efficiency gains in drug-related costs were offset by less efficient clinical staffing after 2010. **CONCLUSIONS:** Contrary to expectations, the US dialysis industry did not appear to realize any short-term gains in technical efficiency in response to the 2011 Medicare payment reforms, as compared to the period just prior to reform. Some facilities may have anticipated PPS reforms by implementing efficiency measures prior to 2011. Our future work in this field will incorporate quality of care dimensions and case-mix adjustment in the measurement of efficiency over a longer timeframe.

PUK18

ADHERENCE AND DE NOVO DONOR-SPECIFIC ANTIBODY FORMATION IN RENAL TRANSPLANT RECIPIENTS: IMPLICATIONS FOR CLINICAL AND ECONOMIC OUTCOMES ASSOCIATED WITH PROLONGED-RELEASE AND IMMEDIATE-RELEASE TACROLIMUS IN CANADA

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OBJECTIVES: While advances in immunosuppression have resulted in substantial improvements in short-term renal allograft survival, improvements in longer-

term graft survival rates have been less marked. This may be due, in part, to antibody-mediated rejection driven by formation of de novo donor-specific antibodies (dnDSA). Because of its association with non-adherence, dnDSA has emerged as an important factor in longer-term graft loss. Long-term data on adherence, dnDSA formation, and graft failure were used to model clinical outcomes and costs associated with prolonged-release (PR) versus immediate-release (IR) tacrolimus (TAC) in renal transplant recipients in Canada. **METHODS:** A decision tree developed to capture differences in adherence between IR-TAC and PR-TAC was combined with a five-state Markov model of dnDSA formation, graft failure, and patient survival. Transition probabilities were determined by a series of Weibull, logistic, and least squares regression models. Adherence, quality of life, patient and graft survival, and drug costs were derived from Canada-specific sources. Analyses were run over a 25-year time horizon. Costs were reported in 2016 Canadian dollars, inflated where necessary. **RESULTS:** The proportion of patients experiencing dnDSA was reduced from 22.1% with IR-TAC to 20.5% with PR-TAC, reflecting a 7.2% relative reduction in dnDSA, and a number needed to treat of 63 to avoid dnDSA onset. In patients experiencing dnDSA, mean time to onset increased by 0.24 years to 7.9 years with PR-TAC relative to IR-TAC. At a willingness-to-pay threshold of CAD 50,000 per quality-adjusted life year gained, PR-TAC would be considered cost-effective at a price 13.5% higher than that of IR-TAC. **CONCLUSIONS:** Based on modern clinical data on the incidence of dnDSA in adherent versus non-adherent patients, improved adherence associated with PR-TAC would delay the onset and reduce the incidence of dnDSA, and PR-TAC would remain cost-effective at a 13.5% higher per-milligram price when compared to IR-TAC in Canada.

PUK19

HEALTH ECONOMIC ASSESSMENT OF TREATMENT SEQUENCES FOR THE MANAGEMENT OF PATIENTS WITH METASTATIC RENAL CELL CARCINOMA IN THE UNITED STATES

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OBJECTIVES: Estimate the overall cost and health outcomes associated with commonly used treatment sequences in patients with metastatic renal cell carcinoma in the United States. **METHODS:** A patient-level simulation using discretely integrated condition event modeling method was developed to estimate the survival and costs accrued on treatment sequences. The model assessed sequences that started with either pazopanib or sunitinib, which are commonly used first-line agents, followed by nivolumab, cabozantinib, axitinib, everolimus, or lenvatinib+everolimus as second-line agents. Patients received best subsequent care after the second line of treatment, with the assumption that it did not impact estimated survival. Efficacy data for pazopanib and sunitinib were obtained from published literature. For nivolumab and everolimus, underlying risk equations for disease progression, treatment discontinuation, and survival were developed using patient-level data from the CheckMate 025 trial. The equations accounted for the baseline patient characteristics (Memorial Sloan Kettering Cancer Center score) and key predictive clinical events, such as response achievement and duration of response, with each individual treatments. Efficacy of cabozantinib, axitinib, and lenvatinib+everolimus was incorporated based on a network meta-analysis. Adverse event rates were obtained from published literature for all therapies. Treatment, administration, adverse event management, and monitoring costs were obtained from published literature and publicly available sources. **RESULTS:** The model-estimated cost/life-years gained were \$314,914/4.2 years for nivolumab, \$324,251/4.0 years for cabozantinib, \$264,776/3.2 years for axitinib, \$270,726/2.8 years for everolimus, and \$684,626/5.1 years for lenvatinib+everolimus-containing sequences. The model suggested that treatment sequences with nivolumab as the second-line therapy had the lowest cost per life-year gained (\$74,589/life-year) versus treatment algorithms with other targeted agents as second-line therapy (range, \$81,378–\$134,496/life-years). **CONCLUSIONS:** Treatment sequences that utilize sequential therapy with sunitinib or pazopanib followed by nivolumab may offer improved life expectancy at a lower cost versus the sequences that utilize second-line agents other than nivolumab.

URINARY/KIDNEY DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

PUK20

QUALITY OF LIFE IN END STAGE RENAL DISEASE PATIENTS

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OBJECTIVES: To evaluate health-related quality of life (HRQoL) in patients in vintages of end stage renal disease (ESRD). **METHODS:** The health states related with dialysis intervention was surveyed by face-to-face interview. We assessed HRQoL in terms of the state of health after dialysis. The HRQoL of 301 patients was measured mainly using EQ-5D. HRQoL was assessed using Korean version of the EQ-5D health questionnaire. We defined 3 vintages by treatment: Group 1: from diagnosis to 1 year, Group 2: from 1 year to 5 year, Group 3: 5 year over. **RESULTS:** According to a study that analyzed a target of 154 peritoneal dialysis (PD) and 147 hemodialysis (HD) for the survey, the utility values are as follows. First, HRQoL showed that the mean value reduced greatly in patients who PD than HD. PD value is 0.86, HD value is 0.80. Second, the mean values were arranged in order from Group 1 to Group 3; PD Group 1 0.88, Group 2 0.87, Group 3 0.82; HD Group 1 0.82, Group 2 0.79, Group 3 0.80. **CONCLUSIONS:** The results

shown that HRQoL has improved with peritoneal dialysis as compared to hemodialysis treatment. The treatment vintage has a negative impact on HRQoL. HRQoL in end stage renal disease patients is an important outcome measure. Culture and disease specific QOL instruments that assess patients' objective and subjective experiences covering most aspects of QOL are urgently needed.

PUK21

“FEELING IT THE NEXT DAY”: A QUALITATIVE STUDY OF PATIENTS' LIVED EXPERIENCES OF NOCTURIA BEYOND THE NIGHT

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OBJECTIVES: Nocturia, waking to urinate ≥ 2 times during the night, is a chronic condition typically present in $>50\%$ of men and women over 60 years old and associated with significant patient burden due to sleep disruption. This study explored the lived experiences of patients with nocturia including disruptions to their lives during the night and day. **METHODS:** We interviewed patients diagnosed with nocturia who had experienced symptoms in the past two weeks. Open-ended questions and follow-up probes were employed to explore patient experiences at all times of the day. Qualitative analysis of patients' narratives formed a summary of their experiences, including any apparent contrasts between patients. **RESULTS:** Twenty patients were interviewed (n=10 male, n=10 female), with a mean age of 64 (range 39–80) and an average time since diagnosis of 26 months (range 7 – 69 months). Most patients reported 3 nightly voids; the frequency of voids influenced nocturia's impact on sleep quality and quantity. In addition to night-time phenomena, patients faced difficulties 'the next day'. These included day-time tiredness and lack of energy, and concerns related to emotional wellbeing (e.g. feeling irritable), social functioning (e.g. avoidance of sleeping away from home) and cognitive functioning (e.g. concentration); all of these limited patients' capacity to work, perform daily activities or fulfil role responsibilities. Experiences were largely dictated by patients' lifestyles; younger patients in employment more readily emphasised the day-time physical and psychosocial burdens. Patients attempted to lessen the severity of nocturia and its impact, through coping behaviours which were physician-led (e.g. avoidance of caffeine) or self-taught (e.g. daytime napping). **CONCLUSIONS:** While the symptom of nocturia only occurs during the night, the impact on patients is longer lasting, affecting functioning and wellbeing throughout the following day. Patients' circumstances can affect the extent of their burden; recognising this can help improve effective management and patient-centred care.

URINARY/KIDNEY DISORDERS – Health Care Use & Policy Studies

PUK22

NEW APPROACHES FOR ENHANCING QUALITY OF LIFE AND RESOURCE UTILIZATION FOR CKD PATIENTS

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OBJECTIVES: Chronic kidney disease (CKD) and its complications is one of the biggest challenges facing public health care sector in Egypt. Anemia is one of the major complications of (CKD) it was recognized as dominant factors for mortality and morbidity rates in cardio vascular disease (CVD). It's prevalence among pre end stage renal disease patients. (52% males, age mean \pm SD 51 \pm 14 years), 67.8% were anemic. Which lead to increase economic burden for public payer. The objective of this study to evaluate impact of new treatment strategies using Erythropoietin on quality of life and resources utilization. **METHODS:** QOL Survey conducted for 600 patients on dialyses at 8 centers for 8 governorates. Pre end stage renal disease patients were selected. (SF-36) questionnaire used history of anemia was collected and included. NKF-KDQOI guidelines used for Anemia definition as Hb level low (9-10 g/dl), intermediate (11-12 g/dl), high <13.5 g/dl among males and <12 g/dl among females. Among females. Maintenance, early detecting & prevention for anemia was included for patient's criteria. Results were in terms of QALY total costs of management of anemia & complications were local one. **RESULTS:** For 600 patients Quality of life increased by 70% for CKD anemia patients who early detected or prevented than patients corrected. For Hb level low (9-10 g/dl) QALY gained was 1.1 QALY versus (.6) for not treated. Level high (<13.5 g/dl) QALY gained was 1.9 QALY versus (.5) for not treated with EPO. Median medical cost for anemia and complications reduced by 58%. **CONCLUSIONS:** Early detection and using EPO as a line of treatment for CKD Patients might have a positive impact on patient's quality of and cost saving. It should thus be considered in the treatment guidelines.

PUK23

VALIDATION OF THE ADPKD OUTCOMES MODEL TO A SPANISH SETTING AND AN EVALUATION OF THE IMPACT OF TREATMENT ON THE BURDEN OF ESRD

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OBJECTIVES: Autosomal dominant polycystic kidney disease (ADPKD) affects 3.96/10,000 population in Europe and is the leading inheritable cause of end-stage renal disease (ESRD). Robust models of ADPKD progression, characterised by increased total kidney volume (TKV) and declining renal function, are important to inform patient management and treatment decisions. This study aimed to assess the validity of the ADPKD Outcomes Model (ADPKD-OM) from a Spanish perspective and evaluate the impact of slowing disease progression via treatment in terms of ESRD incidence and renal replacement therapy (RRT) requirements. **METHODS:** The ADPKD-OM is a patient-level lifetime simulation relating baseline and time-

dependent age, TKV and estimated glomerular filtration rate to ESRD. The model's clinical face and operational validity were assessed by external Spanish experts (clinical/modelling). Life expectancy, ESRD incidence and time on RRT were predicted for patients with/without tolvaptan therapy. Published Spanish data informed ESRD model inputs; patient characteristics and treatment effect on renal function decline (31.6% reduction) were taken from the TEMPO3:4 study. **RESULTS:** The validation exercise concluded the model adequately estimated ADPKD disease progression and further highlighted the historically limited availability of TKV in clinical practice and differences in patterns of organ availability and dialysis in Spain. The model estimated 95% of TEMPO3:4 patients reached ESRD at mean age 53 years and spent six years on dialysis, with one transplant performed for every 2-3 patients. Treatment was estimated to prevent 4% of ESRD cases, delay mean time to ESRD by 4.5 years, avoid 5% of transplants, and reduce dialysis time by five months per patient. **CONCLUSIONS:** The validation of the ADPKD-OM supports the model's use to inform health outcomes decision-making in Spain. This study indicates that treatment that slows ADPKD progression may alleviate the burden of ESRD for patients and offer meaningful reductions in healthcare resource use, with positive implications for service delivery in Spain.

PUK24

IMPACT OF FDA SAFETY WARNINGS ON ERYTHROPOIESIS STIMULATING AGENTS (ESA) PRESCRIBING AMONG NON-DIALYSIS CHRONIC KIDNEY DISEASE PATIENTS

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OBJECTIVES: In June 2011, the US FDA issued modified recommendations for more conservative dosing of erythropoiesis-stimulating agents (ESA) in patients with chronic kidney disease (CKD). To evaluate the effect of FDA safety warnings on anemia treatment in non-dialysis CKD patients. **METHODS:** A retrospective analysis (2008-2014) of Truven MarketScan Commercial and Medicare administrative claims data was conducted for patients with CKD stages 3-5. Monthly rates of anemia treatment including ESA, intravenous iron, and blood transfusions were estimated for years after the FDA safety warnings (Jun2011- Dec2014), compared with rates from pre-FDA warnings (Jan2009 - May 2011). An interrupted time series analysis and generalized estimating equations were used to quantify the impact of the safety warnings. **RESULTS:** We identified 24970 patients during the pre-warnings and 29465 patients during the post-warnings. Among Medicare patients, ESA prescribing rates decreased steadily from 2009 to 2011, followed by slower decreases from 2011 to 2014. Overall ESA prescribing prevalence was 90.7 per 1,000 patients in 2009, and decreased at a rate of 1.2 prescriptions per 1000 patients per month until the end of the pre-warning period. During the post-warning period, ESA prescribing continuously decreased by 0.5 prescriptions per 1000 patients per month. After adjusting for covariates, the probability of prescribing ESAs was 28% lower (relative risk (RR),0.72; 95% confidence interval (CI),0.70-0.74) but the probability of prescribing intravenous iron and blood transfusions were 20% (RR,1.20; 95% CI,1.12-1.29) and 34% (RR,1.34; 95% CI,1.21-1.48) higher, respectively, during the post- compared to pre-warning period. Similar trends of outcomes were observed in commercially insured CKD patients. Characteristics associated with increased ESA prescribing included CKD stage 4 (RR,2.05), CKD stage 5 (RR,2.90), female (RR,1.19), and involvement of a nephrologist (RR,1.18). **CONCLUSIONS:** The FDA safety warnings were associated with steady decreases in ESA prescribing but increases in intravenous iron and blood transfusions in CKD patients.

PUK25

HOW CAN A LOW COST ECONOMIC PERSPECTIVE BE INCLUDED TO A SYSTEMATIC REVIEW: A CASE STUDY OF SYSTEMATIC REVIEW OF SURGICAL TREATMENTS FOR WOMEN WITH STRESS URINARY INCONTINENCE

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OBJECTIVES: Extending the scope of Cochrane Intervention Reviews (CIRs) to incorporate economic evidence, alongside evidence for health effects, can increase their usefulness for decision-making. However, the primary methodology for incorporating economic evidence into a CIR - an integrated full systematic review of economic evidence - is time consuming and requires specialist input from a health economist. The Brief Economic Commentary (BEC) methodology is especially designed to support inclusion of economic evidence in CIRs, without placing large additional workload on review teams or requiring specialist input. We demonstrated this framework by applying it in Cochrane reviews investigating the effectiveness and cost-effectiveness of surgical treatments for women with stress urinary incontinence. **METHODS:** NHS Economic Evaluation Database and MEDLINE were searched to identify eligible cost-of-illness and economic evaluation studies conducted between 1994 and 2016. A short description of the economic burden of the health condition was developed based on the findings of selected cost-of-illness studies and integrated into the background section of the CIR. Basic details of the characteristics and principal findings of included economic evaluations were extracted and summarised in the discussion section. **RESULTS:** Eligible economic evaluations studies included a systematic review covering various countries and three primary studies from the UK, Finland and Spain. Of the surgeries considered, all of these studies found Tension-free Vaginal Tape (TVT) to be more cost-effective compared with Laparoscopic mesh colposuspension and open colposuspension. However, two studies reported Mid-Urethral Sling procedure (MUS), a much recent surgery, to be less costly and as effective as TVT. **CONCLUSIONS:** This work confirmed that BECs can summarise relevant economic information for decision-makers without large additional workload. Development of BECs represents a low

cost method for inclusion of economic evidence in systematic reviews when a full integrated systematic review of economic evidence, or modelling economic evidence is beyond scope.

RESEARCH POSTER PRESENTATIONS - SESSION V

RESEARCH ON METHODS STUDIES

RESEARCH ON METHODS - Clinical Outcomes Methods

PRM1

EVALUATING PARTITIONED SURVIVAL MODEL AND MARKOV DECISION-ANALYTIC MODEL APPROACHES FOR USE IN COST-EFFECTIVENESS ANALYSIS: ESTIMATING AND VALIDATING SURVIVAL OUTCOMES

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OBJECTIVES: To assess long-term survival outcomes for nivolumab in renal cell carcinoma (RCC) predicted by three model structures: a partitioned survival model (PSM) and two variations of a semi-Markov model (SMM). **METHODS:** Three economic model structures were developed and populated using parametric curves fit to patient-level data from the CheckMate 025 trial, a phase 3 study comparing nivolumab with everolimus in previously treated patients with RCC. All models consisted of three health states: progression-free survival (PFS), progressed disease, and death. The PSM estimates stated occupancy using an "area under the curve" approach from overall survival (OS) and PFS curves, whereas the SMMs explicitly derived transition probabilities to calculate patient flow between health states. One SMM assumed that post-progression survival (PPS) was independent of PFS duration (PPS-Markov); the second SMM assumed differences in PPS based on PFS duration (PPS-PPS-Markov). **RESULTS:** In CheckMate 025, the 2-year OS rate was 51.7%; the PSM, PPS-Markov, and PPS-PPS-Markov predicted 2-year OS rates of 52.9%, 55.0%, and 54.2%, respectively. OS curves derived in the PSM provided the closest fit to the trial data. The five year survival, conditional upon surviving one year, was 18.2%, 10.0%, and 22.1% for the PSM, PPS-Markov, and PPS-PPS-Markov, respectively. The mean OS for nivolumab estimated by the PSM, PPS-Markov, and PPS-PPS-Markov was 41.1, 36.2, and 45.2 months, respectively. **CONCLUSIONS:** All three model structures provided a good fit to the trial data, but different long-term survival was predicted by each model. This would likely lead to differences in estimated cost-effectiveness results if used in economic evaluations, which has particular implications for health technology assessment bodies. In the absence of long-term survival follow-up data, the use of external datasets and clinical opinion to validate survival predictions become important to justify choice of model structure.

PRM2

EFFECT OF ICD-10 TRANSITION ON PATIENT IDENTIFICATION AFTER ONE YEAR IN A US MANAGED CARE DATABASE

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OBJECTIVES: The transition from ICD-9-CM to ICD-10-CM in October 2015 raised potential concerns due to differences in diagnosis code specificity across some conditions. Counts and percentages of patients with each of nine conditions in September 2015, October 2015, and October 2016 were compared in a large US managed care database. **METHODS:** This retrospective analysis used medical claims data for commercial and Medicare Advantage enrollees in September 2015, October 2015, and October 2016. Patients with > 1 medical claim for type 2 diabetes mellitus (T2DM), depression, lung cancer, rheumatoid arthritis (RA), atherosclerotic cardiovascular disease (ASCVD), chronic obstructive pulmonary disease (COPD), hepatitis C, asthma, or heart failure were retained. ICD-9-CM and ICD-10-CM code lists were constructed by an MD coding specialist. Monthly patient counts for each condition were determined and the percentage of patients with each condition was calculated relative to the entire database. **RESULTS:** In 2015 and 2016, data were available for 12.45 million and 13.84 million patients, respectively. For 6 of the 9 conditions, the absolute percentage of patients increased after one year (September 2015, October 2015, October 2016): T2DM, 3.15%, 3.11%, 3.47%; depression, 2.00%, 1.86%, 1.89%; lung cancer, 0.11%, 0.11%, 0.12%; RA, 0.26%, 0.26%, 0.27%; ASCVD, 1.18%, 1.68%, 1.84%; COPD, 1.13%, 1.15%, 1.30%; hepatitis C, 0.08%, 0.08%, 0.07%; asthma, 0.87%, 0.82%, 0.85%; heart failure, 0.57%, 0.58%, 0.66%. Possible reasons for these variations included differences in code representations and the use of generalized codes early in the transition. **CONCLUSIONS:** In this large US managed care database analysis, the transition from ICD-9-CM to ICD-10-CM codes was associated with absolute percentage increases in 6 of 9 conditions after one year, requiring further analysis of the reasons for these increases. These findings indicate the importance of careful review of code lists for analyses bridging the transition period and the need for investigation of the reasons for inconsistencies.

PRM3

A METHODOLOGY FOR EVALUATING PRIMARY NONADHERENCE USING ANNO-NOMIZED RETROSPECTIVE ELECTRONIC MEDICAL RECORDS AND PRESCRIPTION CLAIMS DATABASES

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OBJECTIVES: Primary medication nonadherence (PMN) occurs when a medication is prescribed but the patient fails to obtain the medication. A challenge in measuring PMN is linking written prescriptions to prescription claims. We

describe a method for measuring PMN by linking an electronic medical record (EMR) database to a longitudinal prescription claims database (LRx). **METHODS:** Patients with new prescription orders (180 days washout) for statins, ezetimibe, or statin combinations were identified in a large US EMR database between 7/1/2013–7/31/2015 (first order date was index). These patients were linked deterministically to LRx. Patients were required to have ≥ 180 days of stability in both databases pre and post-index and ≥ 1 low-density lipoprotein cholesterol (LDL-C) value in the 180 days pre-index. PMN was determined by the proportion of patients with a new EMR prescription order for a therapy of interest and no claim for that therapy in LRx by 30–180 days post-index. Demographic and clinical characteristics of the adherent and PMN populations were compared using descriptive statistics. **RESULTS:** Of the patients indexed in EMR, 90.6% linked to LRx. A total of 69,227 patients met study criteria. PMN was observed in 38.6% of the population at 30 days, and in 34.3% at 180 days. Significant age and gender differences were found between adherent and PMN patients. Patients with PMN had a higher prevalence of diabetes (28.4% vs 25.7%), and hypertension (56.0% vs 50.0%), and had a lower mean LDL-C level (101.3 vs 137.2). **CONCLUSIONS:** This study demonstrates an ability to link a large EMR population to a prescription database to evaluate PMN. The finding suggest that if a prescription fill is not seen by day 30 it is likely abandoned, making PMN an important consideration in adherence assessments. This research forms a strong basis for evaluating the predictors of PMN, such as LDL-C level.

PRM4

EVALUATION OF A CUSTOMIZED COMPLIANCE PROGRAM FOR ORAL ONCOLYTIC THERAPY FOR LEUKEMIA

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OBJECTIVES: The pursuit of precision medicine and development of targeted therapies has led to a rapid increase in oral oncolytics. Self-administration can pose compliance challenges for drugs with narrow toxic/therapeutic ratios resulting in lower treatment efficacy and increased adverse events. The purpose of the study was to evaluate a medication therapy management (MTM) program with drug- and disease-specific customized clinical services. **METHODS:** The MTM program was designed and developed for patients with chronic myeloid leukemia (CML) and Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), taking an oral tyrosine kinase inhibitor TKI. MTM was administered by nurse specialists who provided education, referrals to agencies to assist with housing, food, transportation, and housekeeping costs, as well as coping strategies for both patients and their caregivers. Program effectiveness was assessed by medication possession ratio MPR defined as the sum of the days' supply of the drug during a defined period of time divided by the number of days elapsed during the period. The MPR difference between program participants and non-participants was tested using Chi square tests with $\alpha=0.05$. **RESULTS:** A total of 201 patients were analyzed to assess the impact of the MTM initiative, 144 patients who participated in the program and 57 who did not. All patients had MPRs $>40\%$. MPRs $>90\%$ were calculated for 46% of MTM patients versus 28% of non-MTM patients ($P=0.0209$). MPRs above the customary target of 80% were found calculated for 62% ($n=89$) of MTM patients versus 42% ($n=24$) of Non-MTM patients ($P=0.0112$). **CONCLUSIONS:** Costly and potentially toxic oral treatments of life threatening illnesses pose problems for patients, their providers and payers. Optimizing compliance and persistence can maximize the clinical outcomes and cost effectiveness of intervention. Novel programs that directly engage patients may be one solution.

PRM5

REAL-WORLD EVALUATION SCREENING STUDY AND REGISTRY OF DYSKINESIA IN PATIENTS TAKING ANTIPSYCHOTIC AGENTS: THE RE-KINECT STUDY

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OBJECTIVES: Tardive dyskinesia (TD) is an involuntary movement disorder that is associated with exposure to antipsychotic medications. Scant evidence exists regarding the burden of TD symptoms and even less has been published, recently, regarding the role of TD in the overall health status of patients. A prospective registry study, RE-KINECT, was designed to document the presence and impact of abnormal, involuntary movements (possible TD) in a real-world cohort of outpatients taking antipsychotics. **METHODS:** Approximately 1000 adults from 70 outpatient US psychiatry practices will be included. Patients with ≥ 3 months lifetime exposure to antipsychotic(s) and ≥ 1 psychiatric disorder will be eligible for screening. TD symptom estimation involves a two-tiered approach: (1) visual observation of involuntary movements by an intake staff member (2) independent clinician assessment and confirmation of possible TD symptoms in general body regions (head/face, neck/trunk, upper/lower limbs). Assignment to Cohort 1 or 2 (without or with visible signs of involuntary movements, respectively) is based on clinician assessment. To measure the possible impact of psychiatric illness (both Cohorts), baseline data include: clinician assessment, patient HRQOL and burden/disability questionnaires; and 12-month retrospective chart review (medical and treatment history). Cohort 2 will participate in a 12-month longitudinal evaluation period with baseline caregiver questionnaire (optional); clinician assessments of significant recent changes in TD symptoms or psychiatric condition and patient-reported outcomes (e.g., overall health status, awareness of involuntary movements, disease burden, health related quality of life [EQ5D], functional impact/disability [Sheehan Disability Scale]) at each visit; and final retrospective chart review. **RESULTS:** Recruitment is ongoing; interim baseline data will be presented at meeting. **CONCLUSIONS:** This novel registry aims to evaluate the real world

potential impact/burden of TD compared to similar patients (with psychiatric illness) without TD. Prevalence of possible TD based on non-clinician and clinician screening and functional impacts of the condition will be described.

PRM6

ESTIMATION OF SURVIVAL OUTCOMES FOR USE IN ONCOLOGY VALUE FRAMEWORKS

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OBJECTIVES: Hazard ratios (HRs) are commonly preferred as inputs to calculate clinical benefit across oncology value frameworks. However, these data are not consistently reported in publications, and individual patient data are not readily available. Therefore, we present a practical method for estimating the HR of survival data. **METHODS:** We selected a published phase 3, multicenter trial (NCT00482833) in which investigators compared all-trans retinoic acid (ATRA) plus chemotherapy with ATRA plus arsenic trioxide (ATO) in the treatment of patients with low-to-intermediate risk acute promyelocytic leukemia (APL). The median follow-up was 34.4 months. At the time of the study publication, only 2-year overall survival (OS) and event free survival (EFS) were reported; HRs for both OS and EFS were not reported, and median OS and EFS had not been reached. To derive the HRs, we first obtained the number of patients at risk for each time point (12-month intervals until 48 months). Then, using a graphic tool, we extracted survival probabilities from the published Kaplan-Meier (K-M) curves for each treatment arm. Patient counts with censoring at each time point were not reported; thus we assumed a constant censoring rate within each 12-month interval. **RESULTS:** Using the K-M curve from the published trial, the calculated HRs of OS and EFS were 0.21 and 0.23, respectively, suggesting patients with ATRA combined with ATO and chemotherapy had better survival outcomes compared with patients receiving ATRA plus chemotherapy. This result is consistent with reported outcomes from a recent meta-analysis, estimating the HRs of OS and EFS to be 0.44 and 0.38, which included data from the same published trial. **CONCLUSIONS:** Despite potential biases associated with relying on published data to derive median survival, the present analysis presents a practical method to estimate key survival inputs for application in oncology value frameworks.

PRM7

INSULIN IS MOST APPROPRIATE COMPARATOR TO GLP-1 RECEPTOR AGONISTS AND DPP-4 INHIBITORS IN REAL-WORLD CARDIOVASCULAR OUTCOME STUDIES

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OBJECTIVES: To illustrate selection bias when choosing inappropriate anti-diabetes medications (ADM) as comparison to incretin enhancers in cardiovascular outcome studies using real-world data. **METHODS:** Adults with type 2 diabetes (T2D) who initiated ADM between 2006 and 2012 and enrolled in Humedica HER database were included in this retrospective cohort study. Initiators of incretin enhancers were compared to initiators of insulin, metformin, sulfonylureas, and thiazolidinediones (TZD). Incretin enhancers included glucagon-like peptide-1-receptor agonists (GLP-1-RA) and dipeptidyl peptidase-4-inhibitors (DPP-4-I). In order to describe the effect of T2D severity progression on future treatment choices, study follow-up was divided into two 12-month periods prior to ADM initiation date (index date), outcome period (12 months closest to index date), and baseline period (12 months farthest from index date). T2D severity and complications were measured during the baseline period, and incident hospital-related myocardial infarction (MI) events were measured during the outcome period. Stepwise proportional hazards regression was used to estimate the pre-exposure risk of MI between ADM groups, with 95%CI upper limit ≥ 1.0 as selection bias indicator. **RESULTS:** 61,262 GLP-1-RA/DPP-4-I enhancer initiators were compared to 80,465 insulin; 184,655 metformin; 104,905 sulfonylureas; and 47,812 TZD initiators. On average, initiators of GLP-1-RA/DPP-4-I had T2D severity and complication history comparable to insulin initiators, but significantly different from other ADM initiators (poorly controlled T2D—HbA1c $>7.5\%$ and microvascular complications, respectively: GLP-1-RA/DPP-4-I, 11.2% and 6.2%; insulin, 10.8% and 7.9%; metformin, 2.6% and 1.8%; sulfonylureas, 5.3% and 3.4%; and TZD, 5.9% and 3.0%). Unlike other ADM, compared to insulin initiators, GLP-1-RA/DPP-4-I initiators didn't have pre-exposure risk of MI (95%CI upper limit <1.0): insulin HR=0.5, 95%CI=0.42-0.6; metformin HR=0.97, 95%CI=0.81-1.16; sulfonylureas HR=1.24, 95%CI=1.03-1.5; and TZD HR=0.76, 95%CI=0.56-1.04. **CONCLUSIONS:** To minimize selection bias in real-world cardiovascular outcome studies, GLP-1-RA and DPP-4-I should be compared to insulin rather than to other ADM.

PRM8

AN INDIRECT TREATMENT COMPARISON OF UNAPPROVED TREATMENT OPTIONS OF ALZHEIMER'S DISEASE FOR RESEARCH PRIORITIZATION

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OBJECTIVES: There are several potential investigational therapies for Alzheimer's disease with inconclusive evidence of efficacy. This network meta-analysis was conducted to compare these treatments indirectly and prioritize future research directions. **METHODS:** Indirect comparison of MMSE scores was conducted using STATA-13. The probability of each treatment for being most efficacious regimen was calculated using the difference against placebo, and counting the proportion of iterations of the Markov chain. **RESULTS:** A total of twenty-two studies were included. Overall 2,974 individuals were randomized to vitamins (cyanocobalamin, folic-acid, tocopherol), NSAIDs (indomethacin, piroxicam, ibuprofen, diclofenac+misoprostol), statins (atorvastatin, pravastatin, simvastatin), omega-3 fatty acids, sertraline, PBT2, xanthenes derivatives (denbutylline, propentofylline) or

placebo. Results showed that simvastatin was the most efficacious regimen with a difference (95% prediction interval) of 0.91 (-3.26, 5.09) against denbufylline; 2.44 (-1.69, 6.57) against omega-3 fatty acid; 1.21 (-4.13, 6.55) against PBT2; 1.71 (-2.44, 5.86) against propentofylline; 0.58 (-3.82, 4.98) against atorvastatin; 2.76 (-1.27, 6.79) against cyanocobalamin; 3.48 (-1.31, 8.28) against diclofenac-misoprostol; 2.30 (-1.48, 6.08) against folic acid; 2.81 (-1.20, 6.82) against ibuprofen; 4.83 (-0.53, 10.20) against indomethacin; 2.21 (-0.98, 5.40) against placebo; 2.71 (-2.02, 7.44) against sertraline; and 2.61 (-0.89, 6.12) against tocopherol. The cumulative probabilities for being the best treatment were: simvastatin (39.4%), atorvastatin (23.0%), PBT2 (17.2%), denbufylline (12.9%), propentofylline (3.5%) sertraline (1.6%), other treatments (<1%). **CONCLUSIONS:** Of all the unapproved potential treatments of Alzheimer's, statins and PBT2 showed a superior efficacy. Therefore, future further clinical investigations should consider statins and PBT2 as preferred candidates.

PRM9

THE POTENTIAL OF ELECTRONIC HEALTH RECORD DATA TO OPTIMIZE RECRUITMENT EFFICIENCY IN CARDIOVASCULAR OUTCOME TRIALS

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OBJECTIVES: To demonstrate the potential value of electronic health records (EHR) from an integrated healthcare system in the USA to enroll research subjects by simulating the inclusion/exclusion criteria of an ongoing cardiovascular (CV) outcomes trial with high dose eicosapentaenoic acid (EPA), a prescription omega-3 fatty acid. **METHODS:** Reduction of Cardiovascular Events with EPA - Intervention Trial (REDUCE-IT) is a Phase III trial evaluating the safety and efficacy of 4 grams daily of high dose EPA (Vascepa®) in reducing first major CV events in a high-risk patient population. Enrolled adults have LDLc levels 40-100 mg/dL on statin therapy and high triglyceride (TG) levels (150-499 mg/dL). Inclusion criteria included established atherosclerotic CV disease (ASCVD) (risk group 1; RG1) and treated diabetes plus one or more ASCVD risk factors (risk group 2; RG2). We used the comprehensive EHR from the Northwest and Southern California regions of Kaiser Permanente to identify patients who met inclusion criteria for RG1 and RG2. We applied exclusion criteria from REDUCE-IT (heart failure, malignant cancer, surgery, and liver, kidney, or thyroid function abnormalities) to better identify a target population. **RESULTS:** Of 25,432 subjects who met inclusion criteria, 12,097 were assigned to RG1 and 13,335 to RG2. A total of 57.8% (n=6,996) and 45.2% (n=6,030) in RG1 and RG2 met at least one exclusion criterion. The most common exclusion criteria for RG1 included: heart failure (28%), cancer (25%), and planned surgery (15%); and for RG2: low renal function (16%) and cancer (15%). **CONCLUSIONS:** Our results demonstrate that EHRs from large integrated healthcare systems may be an efficient tool to screen and enroll populations of interest in a CV outcome trial. Pre-screening with EHR data has the potential for substantive reductions in clinical trial recruitment time and cost by pre-excluding subjects that will not qualify.

PRM10

USE OF INTERMEDIATE CLINICAL ENDPOINTS (ICE) AS A PRIMARY EFFICACY ENDPOINT IN MALIGNANT MELANOMA

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OBJECTIVES: To assess the use of intermediate clinical endpoints (ICE) as the primary endpoint(s) to demonstrate efficacy of therapies targeting for non-metastatic/early stage malignant melanoma. **METHODS:** A systematic review was conducted in PubMed to identify clinical trials using ICE as a primary endpoint in early stage (non-metastatic, stage I or II) malignant melanoma (to assess ICE use today). An additional search was conducted in clinicaltrials.gov to identify the use of ICE as a primary endpoint in on-going malignant melanoma trials (to assess future ICE reporting). Searches were limited to studies in the English language, and restricted to between November 2011 and October 2016. Studies reporting only overall survival (OS) as the primary endpoint, or studies that were not clinical trials were excluded. **RESULTS:** Of 226 titles and abstracts screened from PubMed, seven trials were included in the analysis. Of 440 records screened from www.clinicaltrials.gov, one was included in the analysis, resulting in an inclusion of eight studies. All were randomized phase 3 trials. Relapse-free survival (RFS) and disease-free survival (DFS) were reported in 3 trials each, representing the most frequently reported ICE as a primary endpoint (38% each). RFS/DFS is defined as the time from randomization to recurrence of disease or death, and combined, encompass 75% of reported ICE. Other reported ICE were distant metastasis free interval (DMFI, 1 trial) and lymphnode field relapse (1 trial). One trial reported OS as a co-primary endpoint. **CONCLUSIONS:** The definitions of the most observed ICE in malignant melanoma, namely, RFS and DFS, appear to overlap, warranting better delineation of definition for future standardization of endpoints. However, the overall literature indicates a growing body of clinical evidence in malignant melanoma that report ICE as a primary endpoint, bringing focus to prevention or delay of disease progression to alleviate patient burden.

PRM11

EFFECT OF EDUCATIONAL INTERVENTION TOOL IN KAP SCORE DIFFERENCES AMONG ADULT RESPONDENTS AT THREE TIME POINTS

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OBJECTIVES: Healthcare provider recommendation is critical to increase the human papillomavirus (HPV) vaccine uptake among the un-vaccinated adult

population aged 18 to 26 years. Our aim was to estimate the effect of educational intervention tool in KAP score differences among adult respondents at three time points. **METHODS:** The educational intervention consisted of an educational pamphlet or Fact sheet which contained information regarding HPV infection and HPV vaccination. The knowledge gained was assessed at baseline and post one to three weeks, whereas knowledge retained was assessed between baseline and post 3 to six months. McNemar test was used to compare knowledge scores between pre-test and post-test, and the proportion of correct responses for each question, respectively based on binomial distribution and Wilcoxon signed ranks test was used to estimate the precise differences in KAP scores between the three time points. **RESULTS:** A total of 942 participants, responded to all the three phases of the study conducted in rural and urban areas. The pre-test and post-test KAP score differences shows a statistically significant difference in KAP scores ($p < .001$) for all the 16 knowledge based items. Participants who received the educational intervention had a significantly higher knowledge about HPV infection and HPV vaccination ($p < .001$). **CONCLUSIONS:** Educational intervention promotes an increase in knowledge about HPV and HPV vaccination. Further investigation should be conducted to determine if this intervention can be sustained beyond the short term and influence vaccination and pap screening behavior in women. Key: HPV infection, Knowledge, Attitude, Perception, Practice, HPV Vaccine, Educational intervention

PRM12

INSULIN SHOULD BE COMPARED TO INCRETIN ENHANCERS INSTEAD OF OTHER ANTI-DIABETES MEDICATIONS IN SAFETY AND OUTCOMES STUDIES

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OBJECTIVES: To describe prognostic characteristics of patients with type-2-diabetes (T2D) prior to initiating anti-diabetes medications (ADM). **METHODS:** Humedica EHR database was used to describe characteristics of adult ADM initiators between 2006 and 2012. ADM classes included metformin, sulfonylureas, thiazolidinediones (TZD), incretin enhancers (incretins), and insulin. Study follow-up was divided into two 12-month periods prior to ADM initiation date (index date). T2D characteristics were measured during the 12-month period farthest from index date to reflect disease progression latency and impact on future treatment choices. T2D severity and complications included diabetes duration, HbA1c, micro/macrovacular complications, and healthcare utilization indices. **RESULTS:** 479,099 ADM initiators were studied (mean age 58 years, SD=12; mean T2D duration 2.7 years, SD=1.5), corresponding to 38% metformin; 22% sulfonylureas; 10% TZD; 13% incretins; and 17% insulin initiators. There were significant differences between ADM groups ($p \text{ value} \leq 0.001$). Initiators of incretins and insulin had worse T2D compared to other ADM initiators. Mean HbA1c (SD) for incretins and insulin users were 6.7% (1.8) and 6.6% (2.4), respectively; compared to metformin 6.4% (1.6) and other ADM users 6.6% (2.0). 11% of incretins and insulin users had poorly controlled diabetes, compared to 3% metformin, 5% sulfonylureas, and 6% TZD users. Micro/macrovacular complications were more in incretins and insulin initiators (retinopathy, 1.7% and 2.4%; neuropathy, 2.7% and 3%; nephropathy, 1.9% and 2.4%; heart failure, 2% and 2.8%; coronary artery disease, 2.5% and 2.4%) than other ADM initiators, e.g. metformin (0.6%; 0.8%; 0.4%; 0.9%; and 1.4%, respectively). General and diabetes-related healthcare utilization was higher in incretins and insulin users. **CONCLUSIONS:** History of diabetes severity and complications should be taken into account when selecting comparison groups. Comparing insulin to incretins is more appropriate than to other ADM.

PRM13

BURDEN OF ANEMIA AMONG EVER-MARRIED WOMEN IN BANGLADESH: DOES HOUSEHOLD ECONOMIC INEQUALITY MATTER? HOW DEMOGRAPHICS, DIABETES, MATERNITY AND BMI DECOMPOSE ON THE ANXIETY?

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OBJECTIVES: The purpose of this study was to explore the strength and form of association between household economic inequalities, along with other confounders' inference prevalence of anemia among ever married women in Bangladesh. **METHODS:** Data from a 2011 Bangladesh Demographic Health Survey (BDHS) were used for this study. The ordered logistic regression or proportional odds model was used to test the association between anemia and explanatory variables in the form of four models: Model 1: household economic status, Model 2: Model 1 plus sociodemographic factors, Model 3: Model 2 plus diabetes & maternity factors; Model 4: Model 3 plus nutritional status or BMI. **RESULTS:** It was revealed that respondents in the low socioeconomic status (SES) group were around two times more likely to suffer from anemia as compared to the respondents in the richest SES group ($p < 0.01$; model 1). Respondents who had completed secondary or higher education were better equipped to protect themselves from anemia as compared to those who were illiterate ($p < 0.01$; model 2). Model 3 and 4 revealed that individuals suffering from diabetes appeared to be around two times more affected by anemia (OR: 1.67 & 1.74; $p < 0.05$ respectively) as compared to individuals having a normal fasting blood plasma glucose level. Women who were neither lactating nor pregnant were at lesser risk for developing anemia as compared to those that were. In addition, it was seen that BMI appears to function as a protective factor for controlling anemia in the full model (Model 4). **CONCLUSIONS:** BMI, maternity status, and diabetes mellitus were observed significantly associated with anemia and reducing the significance of the SES, thus it may be claimed that standard of SES is inferring these variables, which in turn affects the benchmark hemoglobin level in women.

PRM14

USING ITERATIVE USER EXPERIENCE DESIGN TO IMPROVE ELECTRONIC CLINICAL OUTCOMES ASSESSMENT DATA QUALITY

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OBJECTIVES: Electronic Clinical Outcome Assessments (eCOA) are increasingly utilized for clinician-rated outcomes in clinical trials. Obstacles to effective implementation of eClinRO include poorly functioning electronic tools and interfaces. In earlier research, we described a method for incorporating User Experience design in the development of an eCOA tool. This new research examines the impact of this design process on COA data quality in ongoing trials. **METHODS:** Based on the User Experience review, enhancements to the eCOA tools were made. These included employing internal logic, automated scoring, standardized instructions and scoring conventions. The user interface was modified to better accommodate a clinical setting. These enhancements were intended to decrease error rates. An older version of the tool, "Version 1", was utilized in a global RCT. Following the design process, the tool was revised and "Version 2" was utilized in a subsequent RCT that used the same clinical outcomes, the ADAS-Cog and the MMSE. The clinicians who utilized the system in trials had their data evaluated by a clinical reviewer at the Screening visit. **RESULTS:** Of the 475 ADAS-Cog administrations using Version 2 reviewed at Screening, 34 (7.2%), required a contact with the clinician due to an error in scoring. This represents a significant reduction ($p < 0.05$) in error rates compared to the previously reported 11.3% with version 1 of the ADAS-Cog eCOA tool. Similarly, 558 new versions of the MMSE were reviewed at screening of which 35 (6.3%) required a contact with the rater. Compared to the 10.8% error rate previously reported utilizing Version 1 of the eMMSE, a significant reduction ($p < 0.01$) in error rates was observed. **CONCLUSIONS:** Compared to the original version, the improvements made in the COA's implemented in the electronic system significantly improved data quality by reducing error and ensuring standardized administration and scoring.

PRM15

ASSESSMENT OF REAL-WORLD DATA SURROGATE FOR THE RESPONSE EVALUATION CRITERIA IN SOLID TUMORS (RECIST)

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OBJECTIVES: The 21st Century Cures Act calls for the incorporation of real-world evidence (RWE) into the drug labeling process. Critics cite deficiencies of RWE as compared to randomized controlled trials (RCT). We aimed to assess whether subjectively reported best response to treatment differed from responses based on radiographic measurements of target lesions. **METHODS:** Electronic case report forms (eCRF) were fielded to assess clinical response to systemic therapy in a rare malignancy. A comparison of subjectively reported best response with radiographic measurements of target lesions was performed to assess responses. **RESULTS:** Fifteen physicians with experience treating this malignancy participated in a CRF-based analysis of patterns of care. Treatment response for each line of therapy was collected for each of the 59 patients via CRF. For 9 patients (15%) with reported partial remission (PR), CRFs were augmented with bidimensional measurements of sentinel tumors from pre-treatment and best response radiographs (reports). Treatment response was calculated using sum of diameters according to RECIST and compared to the corresponding physician-reported response. Measurement-based response revealed 4 PR, 2 stable disease, and 3 progressive disease, and a concordance of 44.4% (95% CI: 15.3%, 77.4%) between response assessment methods. Reasons cited for variance include availability of previous scans for comparison, inconsistency in target lesions imaged, bone metastases difficult to follow, and use of diameter vs SUV (standardized uptake value) on positron emission topography (PET) scans. **CONCLUSIONS:** Subjective assessments of response collected via manual chart extraction, electronic medical record (EMR) review via natural language processing, or CRF may be problematic and limit the potential role of RWE in drug label expansion. The collection of target lesion measurements by CRF presents an attractive alternative to elevate the quality and accuracy of clinical response assessment in oncologic patients, but limitations exist.

PRM16

ESTIMATING COSTS ASSOCIATED WITH EXACERBATIONS OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) – A RANGE OF ALGORITHMS

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OBJECTIVES: To examine various algorithms for estimating costs from claims data associated with chronic obstructive pulmonary disease (COPD) exacerbations. **METHODS:** The sample included COPD patients aged ≥ 40 years from a large US claims database who initiated long-acting bronchodilator monotherapy between 1/1/2008 and 1/31/2015. COPD exacerbations, associated costs, and all-cause costs (2015 consumer price index-adjusted) were ascertained in the one year prior to treatment initiation. Exacerbation events were defined as a COPD-related inpatient stay; emergency department (ED) visit; or an ambulatory visit followed by systemic corticosteroid or antibiotic use within 10 days. Exacerbation episodes consisted of multiple events, and continued until 14 days without an event. Exacerbation costs were defined by four algorithms: 1) COPD-related costs between episode start and end dates; 2) including COPD-related costs within 7 days following the end date; 3) including COPD-related costs within 14 days following the end date; 4) algorithm 3 plus costs for diagnostic work-up procedures (e.g. pulmonary imaging, spirometry) and breathing assistance (e.g., oxygen, ventilation). **RESULTS:** The analysis included 27,394 patients; mean \pm SD age 68 ± 10 years; 50% female; and 60% on Medicare. During the observation period, 43% of patients experienced ≥ 1 exacerbation and 15%

had ≥ 1 exacerbation leading to an inpatient stay. All-cause and COPD-related mean \pm SD monthly costs were \$1543 \pm \$2695 and \$592 \pm \$1831, respectively. Mean \pm SD monthly COPD-exacerbation costs according to each algorithm were: 1) \$190 \pm \$735; 2) \$207 \pm \$800; 3) \$216 \pm \$828; 4) \$245 \pm \$1116. Mean \pm SD monthly severe-exacerbation (inpatient or ED) costs were: 1) \$151 \pm \$703; 2) \$157 \pm \$725; 3) \$162 \pm \$745; 4) \$187 \pm \$1040. **CONCLUSIONS:** Depending on the algorithm, COPD exacerbations accounted for 32% to 41% of COPD-related costs and 12% to 16% of all-cause costs. COPD-related exacerbation costs were estimated to be nearly 30% higher with the broadest algorithm compared with the most conservative algorithm. Severe exacerbations accounted for 75% to 80% of COPD-related exacerbation costs.

PRM17

ESTIMATING GLOMERULAR FILTRATION RATE IN PRIMARY CARE ELECTRONIC MEDICAL RECORD DATABASES IN EUROPE

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OBJECTIVES: Chronic kidney disease (CKD) prevalence is increasing, partially as a consequence of the increasing diabetes prevalence, and is rightly increasingly watched by health authorities. The estimated glomerular filtration rate (eGFR) is used to monitor kidney status. It is a calculation based on the results of a blood creatinine test along with other variables such as age, sex, and race, depending on the equation used. The aim of this study was to compare eGFR values calculated with the use of Cockcroft & Gault formula (CG) and Simplified Modification of Diet in Renal Diseases (sMDRD) in European electronic medical record (EMR)-databases. **METHODS:** This study used data from QuintilesIMS EMR-databases which are EMR and prescribing databases of primary care physicians in community-based, fee-for-service practices in the UK and Germany. Frequency of renal impairment based on eGFR was estimated using both CG and sMDRD equations on a cohort patients with type 2 diabetes (T2D) receiving a glifozin treatment. Diagnoses for renal failure were also retrieved. **RESULTS:** A cohort of over 8000 and 1700 of glifozin-treated T2D patients in the UK and Germany respectively were assessed for kidney status. Creatinine serum test were available for 95% and 75% of patients in the UK and Germany respectively. eGFR with CG formula could be calculated for 90% and 30% of patients in the UK and Germany respectively, while it was available for 95% (UK) and 75% (Germany) of patients using sMDRD. The eGFR values varied depending on the formula used. A higher proportion of patients with moderate and severe renal impairment were retrieved using sMDRD. **CONCLUSIONS:** In agreement with previous works we found that CG formula tends to overestimate eGFR value. We recommend the use of sMDRD in European EMR-databases for calculation of eGFR.

PRM18

TOWARDS OPTIMIZED ONCOLOGY CLINICAL TRIAL DESIGN: A PLATFORM TO ASSESS THE SENSITIVITY OF CLINICAL ENDPOINTS TO MAXIMIZE DRUG VALUE

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OBJECTIVES: Recent value-based frameworks, such as ASCO, provide algorithms to compute the relative value of oncology therapies. Such algorithms are typically based on a weighted combination of endpoint scores that provide an avenue to optimize the value outcome. As such, this study aims to: 1) propose a platform to incorporate ASCO's evolved methodology to compute net health benefit (NHB), 2) assess sensitivity of underlying clinical endpoints, and 3) provide real world examples of how the platform may be employed. **METHODS:** A Monte Carlo simulation-based platform was developed to compute a baseline distribution of NHB scores of the advanced disease setting, and conduct sensitivity analysis of endpoints. The endpoints spanned three key drug attributes: Clinical Benefits including Hazard Ratio (HR), median Overall Survival (mOS), HR for Disease Progression (HR DP), median Progression-free Survival (mPFS), Response Rate (RR), Drug Toxicity (T), and bonus attributes including Tail of the curve (ToC), Palliation (P), QoL (Q), and Treatment-free Interval (TFI). Further for each endpoint combinations, associated clinical trial costs were estimated. NHB scores were then compared against those costs to determine optimal endpoint combinations for clinical trials of three example oncology drugs. **RESULTS:** While the NHB scores trace a bell curve with a maximum score of 140, the median scores across all endpoints were in the 17-70 range. The levers with the highest sensitivity were HR and mOS. Most importantly, holding clinical benefit score constant, Toxicity has higher sensitivity vs Palliation or Treatment-free Interval. **CONCLUSIONS:** While clinical benefit is the primary driver for the NHB score, multiple combinations of clinical endpoints were possible to achieve the same NHB score, suggesting that if the criteria of success includes optimizing NHB, certain clinical endpoints may be prioritized to achieve relatively lower oncology trial costs. This platform may be extended to additional value-based frameworks such as ICER in future studies.

PRM19

QUANTIFYING THE HEALTH OUTCOMES OF MARKET ACCESS POLICIES – USING SIMULATION MODELING TO COMPARE ACCESS TO CANCER MEDICINES ACROSS GLOBAL MARKETS

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OBJECTIVES: To design a simulation model that can quantitatively project and compare the health outcomes of varying market access policies on cancer medicines across global markets. **METHODS:** Using Non-Small Cell Lung Cancer (NSCLC) as an example, we conducted a literature review on health economics and market access models in the therapeutic area. Though the cost effectiveness of cancer medicines among various patient subpopulations has been well studied, research on how market access policies can lead to differential health outcomes has been primarily qualitative. We designed a de novo simulation model with 4 submodules – epidemiology,

medicine, access policy, and disease pathway - to quantify the health outcomes of access policies. The model base case simulated the access landscape to NSCLC medicines in the United States (US) with 6 additional scenarios that replaced the US access policy with that of Australia, Canada, France, Germany, South Korea, and United Kingdom. **RESULTS:** The epidemiology module generated NSCLC patients based on real world 2006-2016 statistics on stage, genetic mutation, subtypes, and performance status. The medicine module includes chemotherapy, medicines targeting tumor blood vessel growth and various genetic mutations, and immunotherapies. The access policy module introduced the aforementioned medicines to patients per each country's unique access landscape, such as dates of market authorization, reimbursement status, market share, indication expansion, early access schemes, dedicated cancer drug fund, and accounted for prescribing outside of the approved indication. Based on the efficacy of each drug and patient access status, the disease pathway module then projected overall survival, progression free survival, and mortality. The difference in health outcomes between the scenarios quantified how market access policies can impact the collective health outcomes of NSCLC patients in the US. **CONCLUSIONS:** Simulation models can provide quantitative evidence to evaluate the impact of country-level market access policies on patient health outcomes.

PRM20

TO RE-CENSOR, OR NOT TO RE-CENSOR, THAT IS THE QUESTION: CRITICAL CONSIDERATIONS WHEN APPLYING STATISTICAL METHODS TO ADJUST FOR TREATMENT SWITCHING IN CLINICAL TRIALS

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OBJECTIVES: To determine when re-censoring should be incorporated in statistical analyses undertaken to adjust for treatment switching in randomised controlled trials, and to demonstrate the utility of inverse probability weighting (IPW) as an alternative to re-censoring. Treatment switching often has a crucial impact on estimates of the effectiveness and cost-effectiveness of new oncology treatments. Switching adjustment methods such as rank preserving structural failure time models (RPSFTM) and two-stage estimation estimate 'counterfactual' (i.e. in the absence of switching) survival times and incorporate re-censoring to guard against informative censoring in the counterfactual dataset. However, re-censoring often involves a loss of longer term survival information which is problematic when estimates of long-term survival effects are required. **METHODS:** A simulation study was conducted, testing RPSFTM and two-stage adjustment methods with and without re-censoring, and with IPW in place of re-censoring, across scenarios with various switch proportions and sizes and time dependencies of the treatment effect. Methods were assessed according to their estimation of true restricted mean survival (in the absence of switching) at the end of trial follow-up. **RESULTS:** RPSFTM analyses that incorporated re-censoring were prone to bias when the treatment effect decreased over time - over-estimating the treatment effect by approximately 3-11% in these scenarios, compared to bias of approximately 0-2% for RPSFTM and two-stage analyses that did not incorporate re-censoring. Two-stage analyses usually over-estimated the treatment effect when re-censoring was incorporated and consistently under-estimated the treatment effect when re-censoring was not incorporated. Using IPW in place of re-censoring resulted in low levels of bias when the censoring proportion and switching proportion were relatively low (both approximately 25%). **CONCLUSIONS:** Re-censoring should not always be incorporated in adjustment analyses when the objective is to estimate the long-term treatment effect. Conducting analyses with and without re-censoring may provide useful information on the size of the true treatment effect.

PRM21

OPTIMAL DESIGN OF PRE-AUTHORIZATION TRIALS FOR EFFECTIVENESS EVALUATION IN SCHIZOPHRENIA

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OBJECTIVES: Randomized-controlled trials (RCT) often use strict eligibility criteria on patient characteristics, thereby weakening generalizability of results in the real world (RW). This study aimed at analyzing the differences between RW and typical schizophrenia Phase 3 RCT populations and predicting the impact of relaxing exclusion criteria on estimates of antipsychotic drug effect. **METHODS:** The data source was the observational SOHO cohort, which included 10,218 schizophrenia patients (characteristics and symptom evolution measured by the Clinical Global Impression-Severity score, CGI-S, at 3 months after antipsychotic drug switch). The cohort was assumed to represent RW schizophrenia patients. The "RCT population" was defined as a cohort subgroup after applying typical RCT exclusion criteria. The impact of re-including each of the following excluded patients was simulated: (1) disease chronicity (1-3 years), (2) history of suicide attempt, (3) alcohol abuse, (4) substance abuse, and (5) care only in private practices. Patients with one or two of these characteristics were re-included by replacement into the "RCT population" to define "enriched RCT populations", while keeping the sample size identical. Ordered probit regression models were built to predict the effect (change in CGI-S score) of the two most prevalent antipsychotic drugs based on different "enriched RCT populations", and compared with drug effects in the RW population. **RESULTS:** RCTs with enriched populations enabled a more accurate prediction of the effect observed in the RW population than RCTs designed with typical Phase 3 exclusion criteria. The impact of enrichment differed depending on which exclusion criterion was relaxed, and the simulations provided a guide to rationally open schizophrenia trials to certain types of RW patients. **CONCLUSIONS:** Simulating the inclusion of "RW patients" before running a Phase 3 RCT may help designing the trial so as to select the most relevant exclusion criteria to be relaxed, and in turn, allow a better prediction of RW drug effectiveness.

PRM22

APPLICABILITY OF APPLE RESEARCH KIT TO DELIVER COGNITIVE TESTING IN CLINICAL TRIALS: RESULTS OF A PILOT STUDY

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OBJECTIVES: To evaluate the use of Apple Research Kit (ARK) to deliver a Paced Visual Serial Addition Test (PVSAT) in a controlled environment and provide preliminary acceptability evidence for this approach. **METHODS:** Subjects with chronic pain conditions completed the PVSAT, a measure of attention and visual processing speed in which subjects are asked to add consecutive digits. The test was developed using ARK and deployed on an iPad Mini. Subjects provided written informed consent, and ethical approval was obtained. Associations between PVSAT performance and participant characteristics were assessed (ANOVA). **RESULTS:** 124 subjects (57 male, 67 female) aged 19-69 years (mean 48.3 ± 13.0) entered the single-center study. Correct additions ranged from 3 to 59 out of a possible 60 (mean: 40.6 ± 16.3); number of dyads (sequences of correct answers) ranged from 2 to 29 (mean 9.2 ± 6.4); and maximum dyad length ranged from 1 to 57 responses (mean: 18.2 ± 15.4). Response speed (correct additions) was normally distributed, ranging from 1.32 to 3.36 s (mean: 2.12 ± 0.43). There was no evidence of gender or age effects, but PVSAT performance was related to education level. The number correct and maximum dyad length were significantly lower among those with a bachelor's degree or less versus those with a master's/doctoral degree (p=0.030 and p=0.029, respectively). **CONCLUSIONS:** The PASAT has been used to study working memory and attention in indications including traumatic brain injury and multiple sclerosis, and to provide a means of introducing stress while studying other constructs. Studies have shown performance to be related to intellect and mathematical ability which may be related to education as identified in our study. ARK provided a straightforward approach to app development, resulting in a solution with good participant acceptance. ARK shows promise to enable cognitive testing on mobile devices in clinical trials.

PRM23

PATIENT ATTITUDES AND ACCEPTABILITY TOWARDS USING THEIR OWN MOBILE DEVICE TO RECORD PATIENT REPORTED OUTCOMES DATA IN CLINICAL TRIALS

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OBJECTIVES: To evaluate patient attitudes towards the use of "bring your own device" (BYOD) to record patient reported outcomes (PRO) data in clinical trials. **METHODS:** Subjects entering a health questionnaire study using BYOD and a provisioned device were asked to complete a questionnaire assessing their attitudes towards BYOD use in clinical trials. **RESULTS:** 155 subjects (72 male, 83 female) aged 19-69 years (mean 48.6 ± 13.1) suffering from a range of conditions resulting in chronic pain entered the single-center study. 149/155 (96%) were familiar with downloading and using apps on their mobile device, and 92% (142/155) felt that they could definitely or probably download the study app without assistance. Ninety-four percent (146/155) stated they would definitely or probably be willing to download an app on their own mobile device for a forthcoming clinical trial; and 135 (87%) reported no concerns doing so. Common concerns volunteered included uncertainties on the use of personal data (7/20) and the effect on available device storage capacity (4/20). When considering BYOD, 115 subjects (74%) identified reimbursement for data charges as important, very important or essential; with 78%, 90% and 97% reporting ensuring data privacy, ease of installation and use, and no interference with other device functions as important or greater respectively. Forty-five percent of subjects felt using their own device would be more convenient compared to 15% preferring a provisioned device (40% had no preference). **CONCLUSIONS:** Amongst the sample in this study there was good acceptance for the use of BYOD in clinical trials. Some concerns could be mitigated by training, information and appropriate app design. This study required subjects to use their own mobile device and the authors acknowledge that attitudes in the wider population may differ. However, this study provides a favorable indication that BYOD may be acceptable to participants in clinical trials.

PRM24

REAL WORLD EVIDENCE AND NETWORK META-ANALYSES: A SYSTEMATIC LITERATURE REVIEW OF EVIDENCE SYNTHESIS METHODS COMBINING DIFFERENT STUDY DESIGNS

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OBJECTIVES: Bayesian network meta-analysis (NMA) has become standard practice in evidence synthesis. NMAs typically only include randomized clinical trials (RCT) based on the hierarchy of evidence. Real world evidence (RWE) is increasingly used in health economics and outcomes research. The objective of this research was to review methods combining different levels of evidence and to compare their benefits and drawbacks. **METHODS:** A systematic literature review was conducted to identify methodological papers and published NMAs combining different study designs. Searches were conducted in PubMed and Embase. Extensive hand searches were also conducted and consisted of reviewing citations found in included publications and searching conference proceedings, health technology agencies' websites, and methodological guidelines. **RESULTS:** Four main methods for combining evidence from different study designs were identified: naïve pooling of all types of evidence, conducting a design-adjusted analysis, using non-randomized evidence as prior information, and running a three level hierarchical model. These methods were

associated with advantages such as optimizing precision and network connection through the inclusion of more evidence, modelling bias directly by accounting for between-study type variability, understanding the bias non-randomized data may introduce into the analysis, and generating more generalizable NMA outputs. These methods were also associated with the following drawbacks: introduction of bias by including non-randomized trials, challenges associated with evaluating the bias associated with RWE studies. **CONCLUSIONS:** Given the lack of published guidance in this research area, the methods reviewed are considered exploratory and their perception by health technology assessment agencies is uncertain. While the three level hierarchical modelling approach seems to best allow for bias adjustment, further research remains to be conducted to address the bias inherent to pooling data from different sources. Refining these methods would help develop tools for a more generalizable comparative effectiveness assessment of health technologies.

PRM25

SURVIVAL TREND AND IMPACT OF ADVERSE DRUG REACTIONS DURING HAART ON SURVIVAL FUNCTION IN HIV/AIDS PATIENTS

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OBJECTIVES: Current study is aimed to observe survival trend in HIV/AIDS patients and to explore the impact of ADRs experienced during HAART on survival trends of the patients. **METHODS:** An observational retrospective study of all patients diagnosed of HIV infection and on HAART therapy from Jan 2007 to Dec 2012 was conducted at infectious disease department of Hospital Pulau Pinang, Malaysia. The survival function was observed on Kaplan-Meier survival analysis and Cox-regression for survival function. Data was descriptively analyzed by using statistical package for social sciences (SPSS 20). **RESULTS:** Out of 792 patients that underwent HAART therapy, 607 (76.6%) were male and 185 (23.3%) were female patients. The probability of 6 years survival was compared where the overall median follow up time of all patients was 36 months or 3 years (inter-quartile range 33.5-38.4). On Kaplan-Meier survival function analysis, better survival probability were observed among non-smokers (p 0.194), non-alcoholics (p 0.002), and non-drug abusers (p <0.001). Overall 338 (42.6%) patients had experienced adverse drug reactions where a total number of 449 (56.7%) adverse drug reactions were reported among which 329 (73.2%) occurred in males and 120 (26.8%) in female patients. The survival probability with significant association (p <0.001) among patients with absence of ADR were reported higher on Kaplan-Meier survival. On Cox-regression survival analysis, Alcoholic patients (HR 1.14, p 0.02), drug abusers (HR 1.38, p 0.01) and patients with ADRs (HR 0.65, p <0.001) shows a higher risk for death with higher Hazard ratio. **CONCLUSIONS:** The study indicates that a patient's life-style and occurrence of ADRs has a direct impact on survival probability in HIV/AIDS patients which shows a greater risk to death and poor survival. However, a multicenter study with a large sample size may provide us with better understanding of this relationship.

PRM26

EVALUATION OF PHARMACIST'S EDUCATIONAL AND COUNSELING IMPACT ON PATIENTS' CLINICAL OUTCOMES IN A DIABETIC SETTING

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OBJECTIVES: The study aimed to evaluate pharmacist's educational and counseling impact including adherence to instructions of diabetic patients' outcomes in the endocrinology clinic of Olabisi Onabanjo University Teaching Hospital, Sagamu, Ogun State, Nigeria **METHODS:** This was a 6 Month randomized controlled study involving 150 consented elderly type 2 diabetic patients. Patients who met the inclusion criteria were randomly assigned into both control and intervention groups (75 patients each). The 75 patients on our intervention group were educated by the Pharmacist on diabetes and hypertension, their complications, risks, preventive measures and management. This was done at least six times during the study period unlike the control group who received no such education. In particular, they were counseled on the need for medication and treatment adherence such as clinic visits, and life style modifications including diet and exercise. Outcome measure included changes in fasting blood sugar (FBS), blood pressure (BP), body mass index (BMI) and adherence to instructions. **RESULTS:** There were no statistical differences between the baseline and 6 months data of the control group as mean fasting blood sugar were 162.2 ± 69.1 and 159.9 ± 57.2 (P= 0.825) and mean systolic blood pressure of 144.7 ± 23.8 and 145.5 ± 18.6 (P= 0.819) respectively. The intervention group had mean fasting blood sugar of 156.7 ± 30.5 and 131.8 ± 40.4 (P < 0.001) and mean systolic blood pressure of 146.4 ± 13.9 and 133.8 ± 18.5 (P < 0.001) respectively. Adherence levels to medication taking in the groups were 42.7% : 94.7% respectively (P=0.001). **CONCLUSIONS:** In diabetes management, patient education and counseling have become key tools in achieving both glycaemic and blood pressure control.

PRM27

DEVELOPING AN ICD-10-CM VERSION OF CHARLSON COMORBIDITIES FOR UNITED STATES REAL-WORLD HEALTHCARE DATA

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OBJECTIVES: Charlson comorbidities are frequently used to describe populations and for risk adjustment in observational studies and are often identified using

International Classification of Diseases, Clinical Modification (ICD-9/10-CM) codes. To date, no ICD-10-CM Charlson code list has been published for United States (US) healthcare data, although a code list was published for the Canadian adaptation of ICD-10 (Quan et al. *Med Care* 2005;43:1130-9). The objective was to develop a code list for the US. **METHODS:** ICD-9/10-CM crosswalks (CMS GEMs, Optum360® Encoder Pro) were used to identify ICD-10-CM codes (effective 01-Oct-2015 through 30-Sep-2016) for Charlson enhanced ICD-9-CM codes in Quan et al. Coding experts also conducted 'native searches,' but medical experts used the concepts from Quan et al. to determine a code/concept's relevance for inclusion. The Deyo ICD-9-CM code list was also considered. **RESULTS:** Comparison with Quan et al., ICD-9/10-CM crosswalks, and expert review identified ICD-9-CM deletions/additions (4/29 unique codes/ranges) and ICD-10-CM deletions/additions (30/73 codes/ranges). The most common reason for deletions was a code existed in Canada but not US. The most common reason for additions is unknown; the added codes/ranges may not exist in Canadian ICD-10 but a list of all codes was unavailable. Comorbidities with the most code deletions/additions were mild (30) and moderate or severe liver disease (22) and renal disease (30). Additionally, 13 codes/ranges were re-categorized between mild versus moderate or severe liver disease and 6 codes/ranges between diabetes with versus without chronic complications. **CONCLUSIONS:** We developed an ICD-9/10-CM code list for Charlson comorbidities for the US. The differences between US and Canadian codes highlight the importance of considering cross-country ICD differences when adapting code lists. Additionally, using ICD-9/10-CM mapping tools alone was not sufficient; native code searching and expert review were critical inputs. Codes should be revised with future ICD-10-CM changes and validated in real-world datasets.

RESEARCH ON METHODS – Cost Methods

PRM28

THE APPLICATION OF RECOMBINANT HUMAN THROMBOPOIETIN (RH TPO) IN SECONDARY PREVENTION OF CHEMOTHERAPY INDUCED THROMBOCYTOPENIA PATIENTS IN CHINA

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OBJECTIVES: Chemotherapy induced thrombocytopenia (CIT) is a common symptom in patients after various cycle of chemotherapy. Recombinant human thrombopoietin was approved in China Food and Drug Administration for CIT treatment. Secondary prevention for patients experienced CIT for the subsequent chemotherapy cycles are important considerations in clinical practice. In this study, we aim to investigate the fact of the usage of pre-dosing of rhTPO in secondary prevention of CIT through a physician insight survey. **METHODS:** An expert questionnaire was designed to collect information of rhTPO in pre-dosing of CIT patients. Major questions include tumor types of pre-dosing application and the rate of pre-dosing in CIT patients. 51 oncologists from 21 tertiary 3 hospitals in Beijing, Shanghai, Guangzhou, Jinan, Chengdu, Wuhan completed the questionnaire. **RESULTS:** 32 of 51 (62.75%) clinicians who completed the questionnaire. 16 kinds of cancer were mentioned in the questionnaire. The most frequent cancer of clinicians referred is lung cancer mentioned by 15 physicians. The overall rate of pre-dosing of rhTPO is 15.7%; the pre-dosing rate in CIT patients with ovarian cancer, breast cancer and esophageal cancer is 11.3%, 12.5% and 12.5% respectively. 6 clinicians reported used rhTPO of pre-dosing in ovarian cancer, breast cancer and esophageal cancer in real world. **CONCLUSIONS:** Clinically, the different proportion of pre-dosing of rhTPO was used in CIT patients in different tumors. The overall application rate is still relatively low and the potential clinical and economic benefit of rhTPO in secondary prevention of CIT is not fully realized. Further study to fully explore rhTPO clinical and economic benefits is needed to identify the criterion of pre-dosing of rhTPO.

PRM29

A METHOD FOR IDENTIFYING LONG-TERM CARE USE IN CLAIMS DATA

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OBJECTIVES: Medicare and commercial insurance plans provide limited long-term care (LTC) coverage, resulting in potential underestimation of total care costs when using insurance claims. The objective of this study was to test a method using place-of-services codes (POS) to identify and categorize LTC transitions for a cohort of dementia patients. **METHODS:** Analyses used de-identified administrative claims (2011 to 2015) from the OptumLabs™ Data Warehouse, a database which includes retrospective administrative claims data on more than 150M U.S. commercially-insured and Medicare Advantage enrollees. Using diagnosis codes and prescription claims, a dementia cohort was created with 36 months continuous coverage pre and 6 months post diagnosis. Hospice patients were excluded. POS codes were used to identify LTC use for nursing (31, 32, 33, 54), intermediate-care (55, 56, 61) and assisted-living (13) facilities. Current Procedural Terminology (CPT) codes (99304-99310, 99315-99318, 99324-99340) also indicated LTC use. Each month for each individual was coded as LTC or community (1/0). Hospitalization during any <3-month LTC-stay gap was coded an LTC month. To categorize community-LTC transitions, a 12-month rolling average of LTC-months was calculated. Months with an average >=0.5, received an LTC code. Based on monthly indicators, individuals were categorized into six care-transition groups: (1) Continuously community; (2) Community to LTC; (3) Continuously LTC; (4) LTC to community; (5) Community to mixed months of LTC; (6) LTC to mixed months of community. **RESULTS:** Out of 41,179 dementia cohort beneficiaries, 16,862 (41%) had a LTC use. Of those, 10,641 (63.1%) were categorized as continuously community; 3,754 (22.3%) transitioned,

community to LTC; 1,671 (9.9%) were continuously LTC; 53 (0.3%) transitioned LTC to community; 499 (3.0%) transitioned community to mixed LTC; and 244 (1.4%) transitioned LTC to mixed community. **CONCLUSIONS:** Use of POS and CPT codes related to claims is a viable method to identify LTC use and care transitions using claims data.

PRM30

CONSIDERATIONS IN THE ECONOMIC EVALUATION OF NURSE PRACTITIONERS AND CLINICAL NURSE SPECIALISTS ROLES

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OBJECTIVES: Advanced practice nurses (nurse practitioners (NPs) and clinical nurse specialists (CNSs)) have been introduced internationally to increase access to high quality care and to tackle increasing health care expenditures. The poor quality of economic evaluations (EEs) of advanced practice nursing roles to date raises the question of whether current EE guidelines are adequate when examining their cost-effectiveness of such a complex intervention as advanced practice nursing roles. **METHODS:** Our assessment of appropriateness of current EE guidelines for evaluations of NP&CNS roles was informed by a qualitative synthesis of: 1) narrative review of discussion papers on EE of advanced practice nursing roles; 2) quality assessment of EE of NP&CNS roles alongside randomised controlled trials; 3) review of guidelines for EE; and, 4) input from an expert panel. **RESULTS:** The narrative review revealed several challenges in EEs of advanced practice nursing roles (e.g., complexity of the roles, variability in models and practice settings where the roles are implemented, and impact on outcomes that are difficult to measure). The quality assessment of EEs of NP&CNS roles identified methodological limitations of these studies. When we applied the Guidelines for the EE of Health Technologies: Canada to the identified challenges and limitations, discussed those with experts and qualitatively synthesized all findings we concluded that standard guidelines for EE are generally appropriate for evaluation of NP&CNS roles and should be followed routinely. However, seven out of 15 current guideline sections (describing a decision problem, choosing type of EE, selecting comparators, determining the study perspective, estimating effectiveness, measuring and valuing health, and assessing resource use and costs) may require additional role-specific considerations to fully capture costs and effects of these roles. **CONCLUSIONS:** The proposed role-specific considerations, which clarify application of standard guidelines sections to EE of NP&CNS roles, may strengthen the quality and comprehensiveness of future EEs of these roles.

PRM31

THE IMPACT OF NON-DIVISIBILITY, DIMINISHING MARGINAL RETURNS TO SCALE AND NON-MARGINAL BUDGET IMPACT ON THE COST-EFFECTIVENESS THRESHOLD

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OBJECTIVES: The optimal cost-effectiveness threshold has been subject to much debate. In the standard model, technologies are assumed to be divisible and exhibit constant returns to scale. The threshold is plotted as a linear function through the origin of the cost-effectiveness (CE) plane. We consider the implications of departures from these assumptions, including the possibility of technologies. **METHODS:** We conducted simulations using a model of a hypothetical health care system comprising three stages: allocation of an initial budget among a pool of initial technologies, consideration of a new technology, and reallocation of resources if the new technology is adopted. The optimal threshold ensures that new technologies are adopted only if the net incremental benefit of adoption and reallocation is positive. Three scenarios were considered: divisible technologies exhibiting constant returns; divisible technologies exhibiting diminishing returns; and non-divisible technologies. For each scenario we estimated the optimal thresholds for net investments and net disinvestments across a range of possible budget impacts and different initial budgets. **RESULTS:** The standard exposition of the threshold holds if: (a) technologies are divisible and exhibit constant returns to scale; (b) one technology remains partially adopted following initial allocation; and (c) the budget impact of each new technology is sufficiently small that reallocation involves expanding or contracting only the partially adopted technology. In all other cases, the threshold depends upon whether the new technology is a net investment or net disinvestment and the magnitude of the budget impact. The threshold curve is a piecewise linear function under divisibility and constant returns, a concave function under divisibility and diminishing returns, or a step function under non-divisibility. **CONCLUSIONS:** The standard exposition of the threshold is a special case that holds only under specific conditions. Under other conditions, threshold curves take a different functional form that reduces the scope for new technologies to appear cost-effective.

PRM32

A STATISTICAL ANALYSIS PLAN TO UNDERSTAND OSTEOARTHRITIS PATIENT JOURNEY BY LINKING MEDICARE CLAIMS ACROSS CARE DELIVERY SETTINGS

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OBJECTIVES: To design a statistical approach to understand the journey of knee osteoarthritis (OA) patients through different care delivery settings, how resource use patterns shift over time, and key drivers of disease burden. **METHODS:** We

conducted extensive literature research on relevant health economics and cost publications. Most studies were conducted cross-sectionally under one specific care delivery setting. Complete patient journey and associated resource use across different settings such as primary care and outpatient remain unclear. Medicare Limited Data Sets (LDS) included deidentified patient-level claims data. We reviewed data dictionaries of LDS and designed a statistical analysis plan to derive resource utilization of knee OA patients in primary care, home health, inpatient, outpatient, and skilled nursing facility settings. **RESULTS:** All LDS files share the same patient ID that can be used to pool all claims data into a master resource use dataset. Knee OA patients are identified through relevant ICD-9 codes in diagnosis records. A control population with comparable demographics to the OA population is generated through propensity matching algorithm. Resource utilization is estimated on both claim level and patient level. On the claim level, the analysis derives hospital charge amount, reimbursed amount, length of stay, surgeries, referrals, and diagnosis-related group information. On the patient level, the resource use by the OA population when compared to the control group is calculated. A regression analysis uses demographics, comorbidities, provider, and treatment as independent variables and disease burden as the dependent variable. The aforementioned analyses is to be conducted on 2 sets of data files that are 5 years apart to account for any shifts in care delivery patterns over time. **CONCLUSIONS:** Assessing linked Medicare claims across delivery settings can help produce quantitative evidence for payers to better understand, prepare for and manage the journey in knee OA treatment among Medicare beneficiaries.

PRM33

COST SAVINGS FROM REDUCED PROLONGED AIR LEAK DUE TO THE APPLICATION OF POWERED ENDOCUTTERS IN VIDEO-ASSISTED THORACOSCOPIC LUNG RESECTION PROCEDURES: A REAL-WORLD EVIDENCE STUDY IN CHINA

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OBJECTIVES: To evaluate the impact of powered endocutters on the overall hospitalization costs in video-assisted thoracoscopic surgery (VATS) in China. **METHODS:** Powered staplers reduce the occurrence of Prolonged Air Leak (PAL) in VATS, which is a common complication associated with increased Length Of Stay (LOS) and hospitalization costs. A decision tree was built simulating health state transitions after VATS, in order to estimate and compare the total hospitalization costs per patient between powered and manual endocutter groups. PAL rates associated with powered stapler and manual endocutter were collected from a clinical trial conducted in China (NCT02338583) in 2015 and the published literature. The average index hospitalization costs, re-hospitalization costs, and health state transition rates were sourced from the China Health Insurance Research Association(CHIRA) whose original data source was China National Insurance Claim Database. Patients with PAL were defined as those experiencing continuous air leak for more than 5 days from post-op tube drawing. **RESULTS:** Although powered staplers command a price premium upfront (Average price difference, 1,670.5 RMB), they significantly reduce PAL occurrence compared with manual staplers (Powered: 1.1%, Manual: 16.8%, p<0.05), while each PAL contributes to significantly higher index hospitalization costs (PAL: 61,442 RMB; No PAL: 50,949.8 RMB, p<0.05), longer LOS (PAL: 23.2 days, No PAL: 15 days, p<0.05), higher re-hospitalization rates (PAL: 0.55, No PAL: 0.374, p<0.05), and higher re-hospitalization costs per patient (PAL: 25,097.3 RMB, No PAL: 12,445.1 RMB, p<0.05). Consequently, the overall hospitalization costs per patient were lower for powered stapler patients relative to manual staplers (Powered: 57,487.2 RMB, Manual: 58,900.9 RMB). **CONCLUSIONS:** Based on study outcomes, we conclude that the application of powered staplers is associated with overall cost savings in addition to numerous clinical benefits. It can be recommended in clinical use. *6.283119 Chinese Yuan Renminbi per 1 US Dollar - 2015 Yearly Average based on x-rates data, <http://www.x-rates.com/average/?from=USD&to=CNY&amount=1&year=2015>, Accessed on January 16th, 2017

PRM34

ECONOMIC VALUATION OF AVOIDABLE MORTALITY IN THE CARIBBEAN REGION OF COLOMBIA

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OBJECTIVES: to value the economic cost of losing human capital induced by preventable causes of death in the Caribbean Region of Colombia in the period 1999-2013 **METHODS:** two methods were applied. First, life tables were constructed by performing hypothetical scenarios of elimination of death causes for five-years, five-year periods and for each department. Allowing to know the impact of different avoidable causes of death on the mortality patterns of this population (probability of death, survival and life expectancy). The second method was the human capital valuation model, which consists in estimating the economic value of Years of Potential Life Lost (YPLL) and Years of Productive Potential Life Lost (YPPPL). **RESULTS:** if deaths from external and circulatory system causes were avoided in the period of study, the probability of dying in men would decrease by 37,2% and 15,8%, and the life expectancy would increase by 5 and 7,8 years respectively. In women case, these odds would decrease by 19,7% and 10,4% if deaths from circulatory and respiratory systems causes were avoided, and the life expectancy would increase by 10 and 4,3 years respectively. The economic value generated of losing human capital by preventable causes of

death, adjusted for unemployment was US\$13,48 billion (PPP), of which 72.4% is due to avoidable deaths in men and 27.6% in women. This amount corresponds to 15.7% of Caribbean Region production, to 9.31% of Bogota GDP and to 2.3% of the national production for 2013. **CONCLUSIONS:** the economic burden of loss of human capital from preventable causes of death is significant and represent an important part of the region's economic resources. Furthermore, these causes of death could be avoided by public policies of prevention and promotion of low-budget, contributing to the economic growth and development of this Region.

PRM35

MODELING COMPETING RISKS IN DISCRETE EVENT SIMULATION MODELS: ILLUSTRATING AND COMPARING DIFFERENT APPROACHES

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OBJECTIVES: To close the guidance-gap on modeling competing risks in discrete event simulation, by illustrating suitable approaches and comparing their impact on time-to-event and health economic outcomes and the uncertainty surrounding these outcomes. **METHODS:** Based on the ISPOR Good Modeling Practices Guidelines, three approaches were applied in a simulation study and a case study: (1) select the time-to-event first and the event second, (2) select the event first and the time-to-event second, and (3) select the event first to occur. The approaches were compared based on how well time-to-event data and cost-effectiveness outcomes were replicated, in terms of the prevalence of events, time-to-event distributions, cost-effectiveness point-estimates, and uncertainty surrounding these point-estimates. To assess sample size impact on the approaches' performance, sample size was varied in the simulation study and subgroup analyses were performed for the case study. **RESULTS:** In both the simulation and case study, the second approach represented the original data better in terms of the event prevalence and time-to-event distributions. For the case study, this difference in performance did not result in substantial differences between the approaches regarding the cost-effectiveness point-estimates and uncertainty surrounding them. However, the simulation study did show substantial differences in health economic outcomes, e.g. for one of the hypothetical trials the probability of being cost-effective was 74%, 93%, and 81%, for the first, second, and third approach, respectively. **CONCLUSIONS:** The illustrated approaches perform differently with regard to the simulated time-to-event outcomes. Although the magnitude of this difference and the extent to which it impacts cost-effectiveness point-estimates and their uncertainty depends on the data's and models' structures, these health economic outcomes may be impacted and thereby potentially influence resource allocation decisions. Based on the results of this study, the second approach selecting the event first and the time until this event second, seems to be preferred.

PRM36

UNCERTAINTY IN TIME-TO-EVENT DISTRIBUTIONS' PARAMETERS ESTIMATES IN DISCRETE EVENT SIMULATION MODELS

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OBJECTIVES: Patient-level simulation models, e.g. discrete event simulations, are increasingly being used to describe variation (first-order uncertainty) in time-to-event data using statistical distributions. However, the uncertainty in these distributions' parameter estimates (second-order uncertainty) is typically being ignored in probabilistic sensitivity analyses. To highlight the need for incorporating the uncertainty in estimated parameters of distributions used to describe patient-level variation, different approaches are illustrated and compared. **METHODS:** Two approaches, (1) based on bootstrapping and (2) using multivariate Normal distributions, were applied in a simulation study and a case study. The approaches were compared regarding time-to-event outcomes and health economic outcomes, such as parameter point-estimates, time-to-event distributions, cost-effectiveness point-estimates, and the uncertainty surrounding them. To assess sample size impact on the uncertainty in distributions' parameter estimates, sample size was varied in the simulation study and subgroup analyses were performed for the case study. **RESULTS:** Incorporating uncertainty in time-to-event distributions' parameter estimates resulted in a substantial amount of additional uncertainty surrounding the health economic outcomes, illustrated by larger 95%-confidence ellipses surrounding the Incremental Cost-Effectiveness Ratio and different Cost-Effectiveness Acceptability Curves. Both approaches performed similar for large sample sizes (e.g. n=500). However, the approach using multivariate Normal distributions was more sensitive to extreme values for small sample sizes (e.g. n=25), resulting in unrealistic health economic outcomes. **CONCLUSIONS:** It is important to account for uncertainty in time-to-event distributions' parameter estimates to avoid underestimation of the total uncertainty surrounding health economic outcomes, and subsequent sub-optimal resource allocation decisions. To do so, the bootstrap-based approach is preferable, as no assumptions about underlying distributions are required, the correlation in the complete dataset is maintained, and this approach is less sensitive to extreme values. This study is particularly relevant to the field of personalized medicine, which is characterized by large uncertainty induced by evidence gaps or subgroup stratification.

PRM37

COMPARISON OF PREDICTIVE MODELING OF COST AND HCU BY CROSS-VALIDATION

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OBJECTIVES: Many important variables in health economic studies are usually heavily skewed or with many zeros. Therefore validity of ordinary least squares (OLS) model is of concern for some analysts. To address the concern, alternative methods are

proposed to analyze these data. In this study, we applied several methods to a sample data to evaluate the performances of these methods for the analysis of cost data or length of stay (LOS) data. **METHODS:** The sample data was from a study to assess the health economic burden of patients with treatment resistant depression (TRD) in comparison to non-TRD patients among major depressive disorder (MDD) patients. Patient's demographic information, payment type, and other baseline characteristics were accessed. By using OLS, generalized linear models with different distributional assumptions (Gamma, Poisson or negative binomial (NB), etc.) in one or two-part models, the differences of mean of medical cost or LOS from two subgroups were estimated and compared. Simulations were also conducted to compare the performance of different statistical models. **RESULTS:** Among 57090 patients in the cohort, there were 5824 TRD vs. 51266 non TRD patients. Cost variables were heavily right skewed. For instance, the skewness for medical cost was 20.93. The results showed the differences of mean medical cost estimation were \$4948.00 by OLS, \$5809.34 by Gamma regression with LOG link function and \$1884.03 by LOG transformed OLS model. Another outcome LOS, which contained 89.6% observations with zeros, was also tested. The results indicated that difference of mean LOS estimation were 1.93 days by OLS, 1.86 days by NB regression and 1.76 days by Poisson regression. **CONCLUSIONS:** When dealing with cost or LOS, different statistic models or methods could have big impact on the results or interpretation. Carefully selecting models that reflect or better fit the possible data distribution may be more appropriate practice.

PRM39

INCLUSION OF LEARNING CURVE EFFECTS IN ECONOMIC EVALUATIONS OF MEDICAL DEVICES: EMPIRICAL EVIDENCE FOR HTA

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OBJECTIVES: To empirically assess the consequences of the inclusion of the learning curve (LC) in the HTA of medical devices by evaluating its potential impact on i) the evaluation of procedural outcomes of medical devices (MD), ii) the evaluation of rising and avoided costs; iii) the estimation of ICER; iv) the interpretation of economic evaluations in the light of planning the delivery of specific services. **METHODS:** A systematic review was conducted to identify the current state of knowledge about the LC in the economic evaluation of MDs and its inclusion in HTA processes. Based on the findings, the authors empirically estimated the LC for three MDs using real world data. Multivariate trend analysis assuming different parametric models both at the operator and institutional level was applied. Economic evaluation was performed with the inclusion of the LC to compare the effects. Additional analyses: comparison of LC parameters across different MDs; test of the persistence of the LC from procedural outcomes to final endpoint. **RESULTS:** LC effects are particularly evident for devices with high degree of complexity of use and high discontinuity with the previous technology. The learning effects are more evident on procedural outcomes and tend to gradually lose significance once final endpoints are considered. As a consequence, the LC has a more measurable impact on costs, even though in some cases also effectiveness is impacted. **CONCLUSIONS:** The inclusion of an observed LC could be extremely useful for HTA bodies. First, the initial "inefficiencies" could be identified, assessed, and considered as costs for the system. Second, the ICER evaluated after the learning plateau is reached could be different from the one including the learning phase, but both are needed for a fully informed HTA and for an optimal planning aimed at balancing local access and minimization of learning phase-related costs.

PRM40

IMPACT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) CODING DIFFERENCES ON HEALTH CARE UTILIZATION AND COST OUTCOMES FOR RESEARCH SPANNING THE ICD-9 TO ICD-10 TRANSITION

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OBJECTIVES: Generally, coding specificity increased with International Classification of Diseases, 10th Edition (ICD-10). However, for chronic obstructive pulmonary disease (COPD), the opposite is true. COPD is no longer easily differentiated from chronic obstructive asthma (COA), which is now included within the COPD ICD-10 code range (J41-J44). This analysis examined the impact of this coding difference on COPD-related healthcare utilization (HCU) and costs measurement, and determined appropriate ICD-9 codes to ensure consistency in COPD studies spanning the ICD-9/10 transition. **METHODS:** The sample included COPD patients aged ≥ 40 years from a large US claims database who initiated long-acting bronchodilator monotherapy between 1/1/2008 and 1/31/2015. Patients had ≥ 1 year of continuous enrollment pre- and post-treatment initiation. Monthly COPD-related HCU and costs (2015 consumer price index-adjusted) were ascertained while patients remained on long-acting bronchodilator monotherapy. Claims were considered COPD-related if there was a COPD diagnosis in any position according to two different coding definitions: 1) COPD (ICD-9 [491.xx, 492.x, or 496] or ICD-10 [J410, J411, J418, J42, J430, J431, J432, J438, J439, J440, J441, J449]); and 2) COPD+COA (ICD-9 493.2x). **RESULTS:** Analysis included 27,394 patients; mean \pm SD age 68 \pm 10 years; 50% female; and 60% on Medicare. During a mean \pm SD post-index period of 192.7 \pm 308.0 days, 69.0%, 9.3%, and 12.0% of patients had ≥ 1 COPD-related ambulatory visit, emergency department visit, or inpatient admission, respectively, according to definition 1; and 69.6%, 9.5%, and 12.2% per definition 2. Mean \pm SD monthly COPD-related costs were \$1,205.5 \pm \$4,063.1 and \$1,222.0 \pm \$4,093.0, according to definitions 1 and 2, respectively. **CONCLUSIONS:** Among COPD patients initiating long-acting bronchodilator monotherapy, the impact of including ICD-9 codes for COA when ascertaining COPD-related HCU and costs was minimal. Therefore, inclusion of ICD-9 codes for COA is unnecessary to maintain coding consistency in studies spanning the ICD-9/10 transition. This analysis should be replicated in other COPD populations to confirm these findings.

PRM41

PAYING FOR YEARS OF LIFE LOST: A PROPOSAL TO ESTIMATE TOBACCO TAXATION IN COLOMBIA

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OBJECTIVES: Taxes are the most effective way to reduce tobacco consumption, but always meet with resistance, and are difficult to justify. We propose a new method to estimate tobacco taxation based on the economic value of the years of life lost due to smoking. **METHODS:** We performed a literature review to estimate the reduction of life expectancy of a smoker, and adjusted it based on the average cigarette consumption of a smoker in Colombia. The threshold value of life used in cost-effectiveness studies, i.e. three times the per capita gross domestic product (GDP), which was \$16.6 million Colombian pesos (COP) in 2015, equivalent to USD 6,056, (exchange rate 1 USD = 2,743 COP), was applied to each year of life lost. Based on the average years of cigarette smoking and the number of packs consumed during that life span, the tax that each cigarette pack should have been calculated so that, with a 3% interest annual rate, the smoker would have paid the amount corresponding to the years of life lost by the time of his or her death. **RESULTS:** Given an estimated (conservative) 6 years life expectancy reduction, each smoker should contribute to the health system COP 299 million (USD 109,008). Assuming an average consumption of 166 annual packs of cigarettes for 50 years, COP 2.7 million (USD 969) should be raised every year, and each pack should have a tax of COP 16,022 (USD 5.84). **CONCLUSIONS:** The three times per capita GDP threshold has been used to approve new interventions that gain healthy years of life. We believe it could also be applied to products that are associated with health decrements.

RESEARCH ON METHODS – Databases & Management Methods

PRM42

COMPARISON OF THE CMS CHRONIC CONDITIONS DATA WAREHOUSE (CCW) ALGORITHMS AND THE CONDITION-BASED AND PRESCRIPTION-BASED COMORBIDITY SCORES AS PREDICTORS OF AMBULATORY HEALTHCARE UTILIZATION

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OBJECTIVES: It is a common practice in observational studies using administrative claims data to control for confounding using comorbidity scores. The Charlson Comorbidity Index (CCI) is perhaps one of the most widely used measures. However, the CCI was developed for predicting inpatient deaths. The Centers for Medicare and Medicaid Services Chronic Condition Warehouse (CCW) algorithms for identifying 27 chronic conditions and the RxRisk prescription-based comorbidity score offer alternative measures that may be more suitable for studies of outpatient utilization. This study examined the ability of all three comorbidity measures to predict outpatient healthcare utilization. **METHODS:** A retrospective analysis was conducted using Mississippi Medicaid administrative claims data for all beneficiaries continuously enrolled from January 1, 2014 to December 31, 2016. For each beneficiary, the first outpatient visit in 2015 was considered as the index date. CCI, RxRisk, and CCW scores were calculated for each beneficiary from medical and pharmacy data for the 12-month period prior to the index date. Outpatient healthcare utilization was calculated as the number of outpatient care visits occurring during the 12 months post index date. Three separate prediction models were run for each of the three comorbidity scoring techniques. All three models had gender, age, and race as covariates. Model performance was assessed using the R2 for the models. **RESULTS:** The model with using CMS CCW measure had an R2 of 17.6% when predicting outpatient healthcare utilization. This model had better predictive power than the CCI model (R2 = 14.6%) and the RxRisk model (R2 = 15.6%). **CONCLUSIONS:** Both the CMS CCW and the RxRisk comorbidity measures were better at predicting outpatient healthcare utilization. When conducting observational studies on outpatient healthcare events researchers should consider using comorbidity measures that better capture chronic conditions that predict outpatient healthcare utilization rather than the CCI measure.

PRM43

PATIENT-LEVEL SIMULATION-BASED SENSITIVITY ANALYSIS TO EVALUATE THE IMPACT OF UNDER-RECORDING OF UNDERLYING COMORBIDITIES IN A RETROSPECTIVE CLAIMS DATABASE ANALYSIS

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OBJECTIVES: To evaluate the impact of under-recording of comorbidities in a retrospective claims database analysis of patients with claims for neovascular age-related macular degeneration (nAMD) treated with ranibizumab or unlicensed bevacizumab. **METHODS:** A retrospective analysis was conducted in the QuintilesIMS Integrated Data Warehouse (IDW) database to compare reported incidence of stroke between ranibizumab (n=44949) and unlicensed bevacizumab (n=131718). Event rates were compared using rate ratios (RR) within a multivariate Poisson regression, adjusted for baseline demographics and comorbidities. Frequencies of reported comorbidities were much lower than those reported in similar studies of nAMD populations (Curtis 2010; Gower 2011), potentially due to the open nature of the IDW database, which may not integrate all patient-level medical encounters. Over 40% of patients did not have any comorbidity recorded. This finding was unexpected owing to the typical age profile of nAMD patients. A patient-level sensitivity analysis was conducted to adjust for under-recording of medical history in the IDW database. Comorbidity records from the patients with at least one recorded comorbidity were

randomly sampled with replacement and used to substitute records for the patients without recorded comorbidities, stratified by index drug, age group, gender and stroke event. **RESULTS:** The adjusted RR for the reported rate of prevalent stroke for ranibizumab was comparable with unlicensed bevacizumab (0.993 (95% CI: 0.961, 1.025)). Following the simulation-based sensitivity analysis, the adjusted RR for the reported rate of prevalent stroke was 0.964 (95% CI: 0.932, 0.997). A similar effect was observed for incident stroke. **CONCLUSIONS:** Under-recording of potential confounding factors may lead to biased estimates even if non-differential between groups. With large sample size resulting in narrow confidence intervals, even small magnitude of resulting bias may affect the statistical interpretation of the study results. Therefore, it is important to utilize appropriate statistical methods to detect and correct for comorbidity under-recording.

PRM44

CORE CLINICAL DATA ELEMENTS FOR CANCER GENOMIC REPOSITORIES: A MULTI-STAKEHOLDER CONSENSUS

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OBJECTIVES: A 2016 report from the Institute of Medicine concluded that one of the barriers to achieving the full potential of precision medicine was the inability to track outcomes for patients treated with molecularly targeted therapies. This inability was due both to the lack of critical information in health records and databases as well as the lack of data structure that would allow integration of data from diverse sources. CMTP and MED-C undertook this project to identify a core set of data elements and values essential to understanding the clinical utility of molecularly targeted therapies in oncology. **METHODS:** A diverse group of more than 50 experts and stakeholders, including researchers, clinicians, patients, medical societies, life sciences companies, public and private payers, and regulators was engaged over 9-10 months. Seven organizations with prominent existing or planned oncology databases (AACR, ASCO, EORTC, Genentech, Genomics England, NCI, ORIEN) shared their cancer and genomic data dictionaries. A master file of data elements was developed and categorized along with a proposed set of core data elements. The draft set was discussed in depth at an in-person stakeholder conference on April 27, 2016 in Baltimore, MD. Based on that discussion, the set was revised and provided electronically to conference participants for final comment. **RESULTS:** A consensus set of 49 data elements with value domain types and specific values was developed. Data element categories included demographics (6 data elements), medical history (6), physical examination at diagnosis (6), initial diagnosis (16), treatment episode(s) (6), and outcomes (9). Drop-down menus of values were utilized wherever possible to avoid referencing external coding systems and provide ease of use. A manuscript for publication submission is being finalized. **CONCLUSIONS:** Cancer genomic repositories' adoption of these core clinical data elements will facilitate achieving the potential of precision medicine.

PRM45

BIG DATA ANALYTICS FOR EARLY DIAGNOSIS OF AMYOTROPHIC LATERAL SCLEROSIS (ALS)

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OBJECTIVES: Analyze a large claims database to explore if early predictors of ALS can be identified and potentially shorten the diagnosis timeline. The average delay in ALS diagnosis is one year after the appearance of first symptom, which can be detrimental as it delays initiating approved treatments and may preclude patients from enrolling in clinical trials. **METHODS:** The Truven MarketScan® database, containing patient-level claims for 170+ million patients, was used without any code pre-selection for this analysis. A mutual information (MI) measure was used to quantify the statistical relevance of every code in MarketScan to a future ALS diagnosis in four US states. Codes included: diagnosis codes, procedure codes, medications, provider types, and care facility types. An ensemble of classifiers developed employing machine learning techniques was applied to optimize the selection and ranking of ALS diagnosis predictors. We looked for predictors within the following time brackets: 3,6,9,12,18,24,36,48, and 60 months before the initial ALS diagnosis. **RESULTS:** The ALS ICD-9 diagnosis code identified 12,332 ALS patients with an average of 4.4 years of claims history. ALS patients: average age 60 years ± 14 years; 58% male, and 25% had a prescription claim for riluzole. The top differentiating diagnoses more common in ALS group compared to overall population were: non-traumatic joint disorders (-60 months), connective tissue diseases (-60 months), skin disorders (-48 months), fatigue (-36 months), lower respiratory diseases (-24 months), gastrointestinal disorders (-18 months) and other nervous system disorders (-12 months). **CONCLUSIONS:** This study suggests 5 years before ALS diagnosis, patients may be presenting with symptoms suggestive of connective tissue disorders, skin disorders, and nonspecific neurological complaints. Next steps of this project are to validate these findings in national dataset, optimize the algorithm differentiating ALS patients prior to diagnosis, and further characterize early predictors of ALS.

PRM46

SIMILARITIES AND DIFFERENCES BETWEEN REAL WORLD PATIENT DATA SOURCES: A GLOBAL CASE STUDY

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OBJECTIVES: To assess and highlight variations in patients' demographic and clinical characteristics, disease management and healthcare utilization across geographies and data sources using patients with gout as an example. **METHODS:** A cross-sectional study of gout patients ages 18+ years was conducted using electronic health records (EHRs) from US (a healthcare system from the Anolinx eResearch Network, Anolinx, and Kantar Health Ambulatory EHR, KH) and Israel (Clalit Health Services, CHS); healthcare claims from Germany (BKK) and South Korea (Health Insurance Review & Assessment, HIRA); and patient-reported survey data from the National Health and Wellness Survey (NHWS) from US, Japan, and from five European Union (EU) countries (France, Germany, Italy, Spain, and UK). Gout patients were identified as having at least one gout diagnosis or healthcare encounter for a single year for each data source, during 2014-2016. Patients from EHR data were required to have an additional diagnosis or gout medication purchase to insure an 'active' (non-historic) gout patient. Demographics, clinical characteristics, disease management and healthcare resource utilization data were examined. **RESULTS:** 109,975 adult gout patients were identified using EHR (Anolinx n=2148; KH n=51,722; CHS n=10,234), claims (BKK n=31,162; HIRA n=7696), and patient-reported survey data (NHWS-US n=3457; NHWS-Japan n=1172; NHWS-EU5 n=2384). Patient characteristics and healthcare use varied by data source and geography. For example, the proportion of patients 65+ years was similar between EHR datasets (Anolinx=53.9%; KH=51.7%; CHS=51.9%), but varied by data source and geography for claims (BKK=65.1%; HIRA=24.6%) and patient-reported survey data (NHWS-US=42.9%; NHWS-Japan=61.2%; NHWS-EU5=54.2%). Allopurinol use (≥ 1 prescription/purchase during the study year) was higher in EHR (KH and CHS~66%) compared to patient-reported survey (NHWS-Japan and EU5 ~22%) cohorts. **CONCLUSIONS:** Collecting and analyzing data from diverse patient populations across geographies, healthcare systems, data sources, and cultures is essential for providing informative real-world evidence of disease management and progression and health outcomes.

PRM47

VALIDATION OF A WEIGHTED HEALTH STATE INDEX FOR DEPRESSED PATIENTS IN HEALTHCARE DATABASES: A SURVEY OF UK GENERAL PRACTITIONERS AND PSYCHIATRISTS

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OBJECTIVES: A health state index (HSI) was developed to reflect the health state of depressed patients initiating antidepressants in a UK medical records database. The HSI includes 29 weighted parameters available in the database, considered relevant to depression by a group of experts. Polarity of weights are positive if parameters indicate better health status and negative if they indicate worse health status; weight values range from 1 to 9. Here we present an online survey aiming to confirm the weighting (polarity and value) of HSI parameters by a sample of UK physicians. **METHODS:** The survey was launched in 2015 aiming to recruit 100 GPs and psychiatrists. Participants were presented with the list of HSI parameters and asked for each to indicate whether it would have a positive or negative impact on a depressed patient's health state. Participants were then required to rate each parameter from 1 to 9: 1 for lowest impact on the patient's health state, 9 for highest impact. **RESULTS:** A total of 42 GPs and 32 psychiatrists participated. Among the 10 parameters with positive HSI weights, 8 were rated positive by >75% of physicians. Average differences between values of positive HSI weights and physician-rated weights ranged from 2.0 to 6.3 (median=3.6). All 19 negative HSI parameters were rated negative by >75% of physicians. Average differences between values of negative HSI weights and physician-rated weights ranged from 1.0 to 5.6 (median=1.8). Differences between HSI and physician-rated weights were larger for smallest values of HSI weights. **CONCLUSIONS:** While physicians agreed on the polarity of most parameters included in the HSI, agreement on weight values was poor. Results tend to indicate the HSI should only take into account direction of the parameters' impact (positive, negative) and not intensity (weight value): a new index based on these findings should be tested.

PRM48

USING REAL-WORLD DATA TO SUPPORT PROTOCOL OPTIMIZATION: A MULTI-COUNTRY APPROACH IN ULCERATIVE COLITIS

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OBJECTIVES: Real-world data are increasingly used to support innovative study designs. In addition to supplementing or replacing primary data collection, EMR and claims can be used to assess feasibility of patient selection criteria. By supporting improved study design, analysis of these data may reduce likelihood of protocol amendments and accelerate recruitment. The objective of this study was to assess the ability of EMR and claims from 11 countries to support evaluation of patient selection criteria. **METHODS:** Real-world data sources in 11 countries were used to assess patient selection criteria for an ulcerative colitis (UC) case study. Patient selection criteria included diagnosis of UC, UC severity (defined as prescription for biologic or corticosteroid), and absence of exclusionary diagnoses including Crohn's disease and megacolon. Attrition tables were created for each country based on application of selection criteria. **RESULTS:** The data asset best suited to support protocol feasibility greatly depends on the underlying healthcare delivery system, database characteristics, and data use restrictions within each

country. In the UC case study, linked EMR and claims data were used in the US and provided the most robust assessment, with 24% of adult UC patients meeting applied criteria. General Practitioner (GP) EMR data were used in Canada, the UK, Spain, Germany, and Italy, while hospital claims were used in France and Japan to better capture the target patient population. Application of criteria in GP EMR identified 3.4-37% of UC patients as potentially eligible; 9-46% of UC patients met applied criteria in hospital claims. Differences were a combination of country-specific practice patterns and source of data which impacts the generalizability of the data. **CONCLUSIONS:** Real-world data provide a rich resource within which to assess the impact of patient selection criteria on protocol feasibility. Local knowledge and data expertise are critical to correctly analyze and interpret country-level results for global study planning.

PRM49

CASE STUDIES ON THE IMPACT OF ICD-9-CM TO ICD-10-CM CODING TRANSITION ON STUDIES USING REAL-WORLD DATA IN THE UNITED STATES

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OBJECTIVES: On October 1, 2015 payers in US required all medical claims to be submitted using ICD-10-CM instead of ICD-9-CM. Increased quantity and specificity of codes in ICD-10-CM will likely enhance misclassification in claims data during transition. This study describes real-world ICD-10-CM coding patterns for several diseases during ICD-10-CM transition. **METHODS:** Adjudicated claims in Truven Health MarketScan® Commercial and Medicare Supplemental databases for adult patients were used. Patients with ICD-9-CM and ICD-10-CM codes spanning the transition through January 31, 2016 were selected for: lung cancer (LC), pleural mesothelioma (PM), Alzheimer's disease (AD), and diabetes mellitus (DM). LC was identified using ICD-9-CM=162.2-162.9 and ICD-10-CM=C34.*; PM using ICD-9-CM=163.* and ICD-10-CM=C45.0; AD using ICD-9-CM=331.0 and ICD-10-CM=G30.0, G30.1, G30.8, and G30.9; and DM using ICD-9-CM=250.* and ICD-10-CM=E10.*-E14.*. **RESULTS:** Clinically relevant ICD-10-CM associated with ICD-9-CM LC (in $\geq 1\%$ of ICD-9-CM cohort and rate ratio $\geq 2x$ versus matched other cancer controls) were C34.*. Clinically relevant ICD-10-CM associated with ICD-9-CM PM were C34.*, C38.4, C45.0, C45.7, C45.9, C76.1, C80.0, and C80.1. Of patients receiving an AD ICD-9-CM 331.0, 66% received one of the 4 G30.* ICD-10-CM, other clinically relevant codes observed at a frequency of at $\geq 10\%$ included dementia and altered mental status (F03.90, F02.80, F02.81, and R41.82). Depending on DM type, ICD-10-CM yielded high sensitivity (97.6%-100%) for type 2 diabetes (T2D), when additional age restriction and treatment criteria were used. Corresponding values for type 1 diabetes (T1D) were 77.4%-86.8%. Clinically relevant ICD-10-CM associated with ICD-9-CM codes were E10.9 and E10.65 for T1D, and E11.9 and E11.65 for T2D. **CONCLUSIONS:** We were able to identify real-world coding patterns in claims data during the transition. As providers gain greater familiarity with ICD-10-CM, coding practice will likely evolve over time. Researchers should continue to look for similar descriptive or validation studies of cohort algorithms relevant to the study period.

PRM50

CHALLENGES OF IDENTIFYING TREATMENT PATTERNS OF PATIENTS WITH ADVANCED SOFT TISSUE SARCOMA USING CLAIMS DATA IN THE UNITED STATES

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OBJECTIVES: Soft tissue sarcoma (STS) is a heterogeneous group of rare solid tumors that arise from soft tissues, such as muscle, fat, nerves and blood vessels. The objective of this study is to describe the treatment patterns among patients diagnosed with advanced STS. **METHODS:** Newly diagnosed STS patients with at least two ICD-9-CM codes of 171.x on two different days between July 1, 2004 and March 30, 2014 were identified from the Truven MarketScan claims database. The first ICD-9 code was considered the index diagnosis. Due to the absence of disease stage and other clinical variables, patients were assumed to have advanced disease if they had no claims for excision or resection surgery from 30 days prior to the index diagnosis through the end of first-line chemotherapy. **RESULTS:** Of 17,009 patients eligible for the study, 4159 (24.5%) received first-line chemotherapy, of whom 1589 (38.2%) patients were advanced STS patients (mean age of 57.9, SD=14.5), 47.8% male and a mean Charlson Comorbidity Score (excluding cancer codes) of 0.6 (SD=1.2). Although there are a limited number of regimens for STS in treatment guidelines, 214 unique first-line treatment regimens were identified in claims data. The most frequently used regimen included unclassified drugs (211(13.3%)). Despite being the standard of care, only 47(2.96%) patients had claims for doxorubicin monotherapy and 99 (6.23%) had claims for doxorubicin combination therapy; 118 (7.43%) patients had claims for docetaxel+gemcitabine and 32(2.01%) for gemcitabine monotherapy. **CONCLUSIONS:** The chemotherapy regimens used to treat STS patients were heterogeneous and not consistent with prior research. The proportion of patients who received standard-of-care doxorubicin was considerably lower than anticipated. These findings are likely due to the high number of unclassified drug codes and lack of specific ICD-9 codes for STS. These limitations should be considered prior to using claims alone to identify or study STS patients.

PRM51

USABILITY EVALUATION OF CLINICAL AND OPERATIONAL POPULATION MANAGEMENT TOOLS IN VISN 21

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OBJECTIVES: Veteran Integrated Service Network (VISN) 21 Pharmacy Benefits Management (PBM) pharmacists utilize electronic health record data to create and

maintain over 300 real-time clinical and operational population management dashboards and reports. These tools allow for a comprehensive and interactive view and analysis of pharmacotherapeutic and performance data. Clinicians and managers use this data to more efficiently monitor patient populations and staff for quality, safety, and value. While anecdotal feedback has been solicited and use of these tools has been widely adopted in VISN 21, utility has never been formally assessed. This project will evaluate the current usability of these tools. **METHODS:** A survey based on the validated System Usability Scale (SUS) to objectively measure usability was developed. The instrument gathers demographic and use information from current users, opinions on data accuracy, ease, and applicability of the current tools and was sent to staff that had accessed a dashboard in the prior year. Following this survey, an in-depth heuristic evaluation will be done by external dashboard developers. Changes will be made to dashboards based on feedback and the SUS survey instrument re-sent to assess any change in usability. **RESULTS:** For the first SUS survey we received 207 responses out of 1653 surveyed (12.5% response rate), with 73 pharmacists (35%), 72 nurses (35%), and 26 physicians (13%), 36 others (17%) responding. SUS average scores for the 5 most used dashboards were 61.1 ± 14.84 ($N=151$). On a scale of 1-5, with 1 being strongly disagree and 5 being strongly agree, user confidence that data matches the medical record was 3.43 ± 1.00 , accurate and correct 2.62 ± 1.15 , and most current 3.71 ± 1.07 . **CONCLUSIONS:** Respondents considered dashboard usability marginally acceptable by SUS grading scale. Users agreed that the dashboard and report data matches the medical record and is up-to-date. Next steps are to complete the heuristic evaluation, make changes, and re-survey.

PRM52

DEVELOPMENT OF EPISODE-BASED PAYMENT MODELS FOR CHRONIC MYELOGENOUS LEUKEMIA (CML), LUNG CANCER, MELANOMA, AND BREAST CANCER

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OBJECTIVES: Innovative healthcare reimbursement models are gaining attention and have been implemented by several payers, including the Centers for Medicare & Medicaid Services (CMS) Innovation Center with the Oncology Care model (OCM). A common alternative payment model is the episode-based payment. This study aimed to develop an episode-based payment model for a commercial insurance plan for various types of cancer. **METHODS:** Administrative claims databases from 3 regional commercial health plans were used to identify continually eligible patients (Age ≥ 18) with various cancer diagnoses. Episode triggers were identified using CMS' OCM methodology. In calculating the episode based payments, we found many adjustments to the OCM methodology were necessary to implement the methodology in a commercial population. For example, OCM uses generalized linear model based on national Medicare data to calculate adjustment factors. This isn't applicable to regional commercial health plans, so instead a model using age, gender, and comorbidity burden data was used. **RESULTS:** The adapted OCM model was applied to data from 5,764 patients, representing 9,511 episodes, meeting the analysis criteria. Actual expenditures for these patients were found to be \$435M, while the episode-eligible calculated target amount for the same population was \$251M. **CONCLUSIONS:** This exercise led to several learnings that may be of interest to commercial payers looking to implement an oncology payment model based on OCM. Many adjustments must be made to the OCM methodology to be applicable to populations beyond Medicare. Care must be taken to ensure adjustments are made in an actuarially sound way. Not all oncology expenditures are eligible for inclusion in this episode-based model. Episodes are triggered for patients undergoing active chemotherapy meeting other inclusion criteria. Some patients, i.e. those in remission, may be utilizing oncology services for monitoring and follow-up, but these services are not eligible for inclusion in OCM episodes.

PRM53

THE IMPACT OF CARE DISCONTINUITY ON RECORDING PATIENT CHARACTERISTICS CRITICAL FOR COMPARATIVE EFFECTIVENESS AND SAFETY RESEARCH WHEN USING ELECTRONIC HEALTH RECORDS

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OBJECTIVES: Electronic health records (EHR) have been increasingly used for comparative effectiveness research. It is unclear how care-discontinuity, defined as receiving care outside of an EHR system, may affect data completeness and study validity using EHR. We aimed to quantify care-continuity of an EHR system and compare the misclassification of key variables in patients with high vs. low care-continuity. **METHODS:** Study cohort comprised all patients ≥ 65 in EHR from two large US provider networks linked with Medicare insurance claims data from 2007/1/1 to 2014/12/31. By comparing EHR and claims data, we quantified care-continuity by the Mean Proportion of Encounters Captured (MPEC) by the EHR system. Within levels of care-continuity, we quantified misclassification by Mean Standardized Differences between the proportions of 40 key variables based on EHR alone vs. linked claims-EHR data (MSD_40_variables, <0.1 was used to indicate satisfactory variable classification). We compared patient characteristics in those with high vs. low EHR continuity. **RESULTS:** Based on 104,403 patients in EHR system 1 and 79,336 in EHR system 2, the mean capture proportions of all records were 24% and 18% in system 1 and 2, respectively. The misclassification of key variables (MSD_40_variables) based on EHR alone was 11.5-19.6 fold greater in those with lowest level of care-continuity (MPEC $< 10\%$) than that in those with highest level of care-continuity (MPEC $\geq 80\%$), across EHR systems and years during follow-up. In both systems, capturing at least 60% of the encounters in an EHR was required to have satisfactory variable classification. The patient characteristics in those with high and low care-continuity were found to be

comparable. **CONCLUSIONS:** Care-discontinuity may lead to substantial misclassification in key variables. Researchers may consider restriction to those with high care-continuity to improve study validity when relying exclusively on EHR data.

PRM54

INTEREST IN REAL-WORLD RESEARCH AMONG PHYSICIANS IN SMALL PRACTICE SETTINGS ACCESSED VIA AN ELECTRONIC MEDICAL RECORDS SYSTEM

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OBJECTIVES: Although a great deal of real-world physician-patient interaction occurs in small practice settings, not a great deal of real-world research has been performed in these settings. Use of EMR systems facilitates outreach to small practice settings—the objective of this study was to assess interest in participating in real-world research among physicians in these settings. **METHODS:** We fielded a 15-item survey to physicians from small practice settings, with items devoted to professional characteristics, interests in particular research methodologies and therapeutic areas, as well as motivations to get involved in research and concerns that might limit involvement. Likert scales ranging from 1 (“not at all”) to 7 (“extremely”) were used in all ratings. Physicians from small practice settings across all fifty states were accessed through their EMR system. **RESULTS:** A total of 264 physicians completed the survey, of whom 73.4% were sole practitioners and 87.9% in a 1-2 physician practice. Approximately three-quarters (72.3%) were male and on average they were in practice for two decades (21.6 years); fewer than one-half (46.2%) had ever functioned as a clinical investigator. Highest levels of interest were expressed in physician and patient surveys (4.57 and 4.02 average ratings) and phase IV real-world clinical trials (4.17), and lowest interest levels in phase II-III trials (3.41). Preferences for research in specific therapeutic areas did not differ markedly (3.40-3.95), except for oncology (2.60). Highest ranking motivations for participating in research were to help their patients (5.63) and advance science/medicine (4.82). Highest ranking concerns included devoting time to research and allowing data collection instruments into the EMR (both at 4.27). Three in five physicians (60.5%) indicated interest in being contacted for future research projects. **CONCLUSIONS:** Physicians in small practice settings are interested in participating in real-world research. EMR systems can be used to access these physicians and, by extension, the patients they treat.

PRM55

PHARMACEUTICAL STRATEGIC PRICING: AN ANALYSIS OF GLOBAL CROSS-SKU PRICING APPROACHES

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OBJECTIVES: To evaluate the pricing approach of all oncology products that have received FDA and EMA approval between 2011-2016 to understand the existence of flat, curvilinear, and linear pricing in the USA, EU5 (Germany, France, Italy, Spain, Great Britain), Canada, Australia, and Japan. **METHODS:** Oncology drugs approved by the FDA and EMA between 12/01/2011 and 12/01/2016 were obtained from the official regulatory websites. Topical and transdermal preparations were excluded from the analysis. The ex-manufacturer prices for individual SKUs of each of these drugs were sourced from the IHS PharmaOnline International database. Pricing linearity was assessed by two methods. (1) B. Jönsson methodology which analyzed the highest and lowest SKU prices, strengths and prices/milligram. This method, however, was found to have deficiencies in recognition of curvilinear pricing strategies, therefore, a novel (2) CBPartners methodology was devised to analyze the price of all available SKUs, apply strict category definitions of “flat”, “linear”, and “curvilinear” pricing and utilize a process of elimination to ensure accurate categorization. **RESULTS:** Between 12/01/2011 and 12/01/2016 84 oncology products received FDA or EMA licenses. Of these, 70 products (83%) qualified for further analysis as per exclusion criteria. A total of 39 (56%) oral and 31 (44%) injectable drugs remained for analysis. Of the injectable products, only one product exhibited flat pricing and none had curvilinear pricing, resulting in linear pricing being almost exclusively employed. Oral products presented much more variance. Flat pricing was used in at least one market by 16 products, linear by 14 and curvilinear by 5. **CONCLUSIONS:** There is a clear difference in how different SKUs of oral and IV oncology products are priced, with IV products almost always pursuing a linear pricing strategy and orals varying between flat and linear pricing. Pricing trends demonstrate the existence of region-specific strategies employed and devised by manufacturers.

PRM56

THE VALUE OF REAL-WORLD DATABASES IN RARE DISEASES: UTILITY AND APPLICATIONS IN FABRY DISEASE

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OBJECTIVES: Rare diseases research presents with many challenges. Real-world databases have been increasingly utilized in rare diseases, to understand diseases and evaluate treatment impacts. A review of published database studies in Fabry disease has been performed, to assess the landscape, utility and application of different types of databases in various regions and countries. **METHODS:** A targeted literature review was conducted in PubMed and Embase for years 1980-2016, to identify studies utilizing data from various real-world databases, including medical, claims, pharmacy, hospital and other sources; registry studies were not included. **RESULTS:** The search yielded a total of 42 studies conducted in various regions globally. The majority of the studies were published after 2007. A larger proportion was based on health care databases in Europe ($n=33$). Germany represented the country with the largest number of publications ($n=9$). Among the types of the data collection methods used, the majority were medical chart or EMR reviews ($n=40$). Most often these studies were done in specialized Fabry referral centers located in tertiary care hospitals. The

majority were single center studies (n=27), while others were multi-center, and one of the studies was based on a home infusion database. The research questions evaluated ranged from understating disease manifestations and natural history, to assessing disease management and treatment impact. Many studies (62%) included long-term follow-up period, to understand natural history and/or long-term treatment outcomes. **CONCLUSIONS:** During the last decade there has been an increasing use of real-world databases in rare diseases, including Fabry disease. The review of Fabry database studies showed the value of these approaches. Many studies included relatively large number of patients and long-term follow-ups, and richness of data that are otherwise hard and time consuming to achieve with other research approaches. Real-world databases offer an opportunity of providing needed data and answering research questions in rare diseases space.

PRM57

BRAZILIAN HEALTHCARE RECORD LINKAGE (BRHC-RLK) – A RECORD LINKAGE METHODOLOGY FOR BRAZILIAN MEDICAL CLAIMS DATASETS (DATASUS)

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OBJECTIVES: Develop a reliable methodology to correlate records from medical claims databases within the Brazilian public health care system (SUS). **METHODS:** Two medical claim databases from the Brazilian Ministry of Health information system (DataSUS) were considered for this study: Ambulatory (SIA) and Hospital (SIH) - both databases are made publicly available in separate without deterministic record keys for record linkage. A record linkage algorithm was developed to craft a broad real world longitudinal patient dataset. A set of parameters such as patient ZIP code, municipality, age or birth date, race, nationality, gender, and ICD were assessed to create a de-identified patient key, as well as to link SIA and SIH datasets. The record linkage methodology consists of a set of eighteen steps based on deterministic and probabilistic connections between de-identified patient keys from both databases; variables are banded into different combinations at each step to maximize the number of connections. Results are considered valid only if no inconsistencies of birth date and gender are found for the same de-identified patient key. Finally, additional variables available were set aside from validation due to reporting inconsistencies and volatility. **RESULTS:** Linkage outcomes vary depending on disease and health care setting dynamics (e.g. in or out patient) as well as epidemiologic characteristics (e.g. prevalence and age group concentration). As an illustration, within a hepatocellular carcinoma cohort, 1,189 patients were independently found at SIA and 5,140 at SIH as well. Finally, 2,763 patients were linked over the intersection, resulting in a total cohort of 9,092 patients in 2015. **CONCLUSIONS:** Both cohort size and the distribution between hospital and ambulatory setting are aligned to published literature providing initial evidences on the potential of the methodology. Such approach promises advances in the development of analysis such as health care resource utilization, hospital admissions, diagnosis and treatment dynamics based on patient-centric real world evidence.

PRM58

CLINICAL EFFICACY AND COST EFFICIENCY ASSESSMENT OF CADAVERIC ALLOGRAFT SKIN GRAFTING IN THE MANAGEMENT OF EXTENSIVE BURNS AND SEVERE WOUNDS

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OBJECTIVES: The problem of treatment of extensive burns remains one of acute problem of medicine. In the Republic of Kazakhstan burns are between 3.5% and 5% of all injuries. When wound is too deep the extensive wound surface becomes a cause of metabolic imbalance and homeostasis. Because of short of donor resources long-term existence of burn surface leads to consumption, multiple organ dysfunction syndrome and to fatality that brings significant economic losses to society. Despite existing of various types of synthetic and biological coatings the allogeneic skin up to date is "gold standard" in management of extensive burn wounds. The best way to solve problem of shortage of allogeneic skin is development of cadaveric donation. Objective: authors evaluated clinical efficacy and cost efficiency of cadaveric allograft skin grafting in management of extensive burns according to data of researches available in database of evidence-based medicine. **METHODS:** Review of literature was conducted on safety and efficacy of cadaveric allograft skin grafting in databases PubMed, Cochrane Library, NICE, Clinical Trials, TripDatabase etc. according to research issues (PICOs) and key words. **RESULTS:** After literature review of 17928 sources, relevant for criteria PICOS reports were selected for study, 19 of which were taken for final analysis. The remaining publications were excluded due to noncompliance with criteria of research questions. **CONCLUSIONS:** Results of 19 studies demonstrate clinical efficacy and cost efficiency of technology. Main way of cadaveric allograft skin application is temporary wounds closure after necrectomy when own donor resources is not available. According to foreign burn centers data cadaver skin application after escharotomy in management of extensive burns can reduce mortality rate and hospital stay duration. Compared with currently available synthetically temporary provisional bandages cadaveric allograft skin is more cost-effective. Recommendations based on this study to establish skin bank for cadaveric donation development were given to health policy makers.

PRM59

EVALUATING THE EFFECT OF PRESCRIPTION MONITORING PROGRAM CASH PRESCRIPTIONS ON THE PQA MEASURE: USE OF OPIOIDS FROM MULTIPLE PROVIDERS IN PERSONS WITHOUT CANCER

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OBJECTIVES: Prescription Drug Monitoring Programs (PDMPs) are state-run electronic databases used to track the prescribing and dispensing of controlled prescription drugs to patients. The PDMP is accessible to providers and pharmacies across the state as a measure to combat abuse of controlled substances such as prescription opioids. Mississippi's Division of Medicaid (DOM) and the State Pharmacy Board implemented an agreement to receive PMP data for all beneficiaries. The objectives of this project were to conduct a descriptive review of cash payments for controlled substances and to assess how cash paid for opioid prescriptions impact performance on the Pharmacy Quality Alliance (PQA) quality measure: Use of opioids from multiple providers in persons without cancer. **METHODS:** A retrospective analysis was conducted using DOM's pharmacy claims linked with PMP data for the period July 1, 2015-June 30, 2016. The PQA measure was calculated according to the measure specifications with and without the inclusion of cash prescription data from the PMP. **RESULTS:** 13,574 Mississippi DOM beneficiaries were present in the PMP data accounting for approximately 76,000 prescriptions for cash-paid controlled substances. The most commonly prescribed cash-paid prescriptions included acetaminophen-hydrocodone, alprazolam, tramadol, and oxycodone. The total number of individuals flagged by the Provider Shopping measure increased slightly from 3,033 (8.95%) to 3,071 (9.05%) upon inclusion of cash prescriptions (p < 0.001). Similarly, the average number of unique pharmacies and physicians visited by Medicaid beneficiaries increased slightly from 5.36 to 5.43 (p < 0.001) upon inclusion of cash prescriptions. **CONCLUSIONS:** Inclusion of cash prescriptions resulted in a slight increase in cases identified as "provider shopping". Although the difference was statistically significant, the increased percentage and actual number of beneficiaries may not be meaningful from a quality measure perspective. However, identifying beneficiaries using cash to pay for narcotics should improve efforts to identify beneficiaries at high risk of abuse or diversion.

PRM60

MACHINE LEARNING INTEGRATION WITH MOLECULAR DIAGNOSTICS: PROGRESS AND POTENTIAL PITFALLS

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OBJECTIVES: The use of machine learning interfaces that sift through massive and sometimes unrelated data to identify trends and provide insight for healthcare decision-making is relatively new. One promising application is clarifying the link between individual patient diagnostic test results, treatments, and outcomes, along with longitudinal and population data sources and peer-reviewed literature. Early machine learning approaches have the potential to leverage scenario learning to more accurately inform business and health care decisions. In this study, we aim to survey the current applications of machine learning to optimize the intersection between test use and treatment selection, patient management, and outcomes to understand implications for the future of health economics and outcomes research. **METHODS:** We conducted a targeted review of the peer reviewed and grey literature to identify studies describing machine learning applications in healthcare diagnostics, with a special emphasis on integration with molecular diagnostic testing that informs treatment selection and care management decisions. This review included both academic healthcare and commercial research, and academic/commercial collaborations. **RESULTS:** The application of machine learning to medical imaging is well-described in the literature. By contrast, fewer than 50 published reports of machine learning interfaces with molecular diagnostics, mostly in infectious diseases and oncology, were identified. Results are considered in the context of disease and health decision focus, level of maturity and acceptance, linkage with patient management and health outcomes, and implications for evidence-based health decision making. **CONCLUSIONS:** As our knowledge of biomarker configurations evolves along with machine learning approaches, we have the potential to alter patient management approaches, as well as our conventional definitions of evidence-based medicine. While in its infancy, the implications of machine learning for health decision making, including in areas like precision medicine and in vivo imaging are discussed, as well as considerations for HEOR best practices leveraging these applications.

PRM61

CREATING A LARGE-SCALE PHYSICALLY INTEGRATED ELECTRONIC HEALTH RECORD DATA SYSTEM TO SUPPORT A LEARNING HEALTHCARE SYSTEM

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OBJECTIVES: The promise of electronic health records (EHR) for population health analytics has not been fulfilled in the US partially due to a lack of interoperability across different systems. Distributed data networks (DDN) represent one approach to addressing this limitation, but require complex governance and coordination among participants. We describe an alternative based on a large-scale, centralized, and physically-integrated EHR data. **METHODS:** Patient-level data from multiple different electronic medical records systems were staged and standardized within multiple health systems to create Optum's EHR Database, (Optum, Eden Prairie, MN). Patient identifiers were de-duplicated and clinical data mapped across information systems before being de-identified. We assessed completeness of select variables among 3 groups: (1) All adults (≥ 18 years), (2) Adults with a chronic disease diagnosis, and (3) Adults who have ≥ 12 months of data preceding index diagnosis that includes at least one prescription order, one laboratory result, and one encounter with a general practitioner. **RESULTS:** From 2007-2016, there were data relating to 69 million patients (58% women) from 52 health systems. There were, on average, 3.2 record identifiers from different data sources within or across health systems for each unique patient. There were 4 million

adults in Group 1 (36% 18–39 years, 34% 40–59 years, and 30% 60+ years). There were 1.9 million patients in Group 2, and 670,926 in Group 3. The median follow-up span was respectively 26, 48, and 56 months. The median number of medical encounters was 2 in Group 1 and 10 in Group 3. In Group 3, BMI, blood pressure, complete blood count, and basic metabolic panel information was available for $\geq 95\%$ of patients. **CONCLUSIONS:** A physically integrated EHR system that spans multiple healthcare systems feasibly overcomes issues of interoperability. Advantages for linkage to claims and mining of free-text notes will be discussed.

PRM62

A FITRADEOFF APPROACH FOR ASSESSMENT AND UNDERSTANDING OF PATIENT ADHERENCE BEHAVIOR

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OBJECTIVES: Pharmaceutical industry faces a mighty challenge of low Patient adherence to their drugs which effect their economic prosperity and peace. Patient as Decision Maker intrinsically decides to carry forward with a treatment scope based on multiple attributes associated with that treatment. These attributes can be ranging from his experience to actual benefit from treatment. We present a methodology that complies with following objectives: Extracting intrinsic information from Patient as a Decision Maker Presenting a framework for evaluation of different treatment scopes for understanding Adherence behaviour **METHODS:** We present a framework of Flexible and Interactive Tradeoff (FITradeoff) approach that helps to extract partial information from patient based on a set of alternatives as per the additive model of Multi-Attribute Value Theory (MAVT). This gives an overall value to each treatment plan as assessed by a Patient as a Decision Maker. This value will be an approximation to their adherence behaviour as well. **RESULTS:** We tested our method on Data with patient treatment alternatives. Results generated provided an assessment and understanding mechanism for patient adherence behaviour. **CONCLUSIONS:** This method provides a unique decision support system which involves interaction with patients to better understand their adherence behaviour. A further extension to this work can be optimizing the sets of questions that has to be asked to the Decision Maker.

PRM63

USING PROPENSITY MATCHING AND IMPUTATION METHODS TO INTEGRATE PATIENT-REPORTED SURVEY DATA WITH ELECTRONIC HEALTH RECORDS IN TYPE 2 DIABETES

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OBJECTIVES: Electronic Health Records (EHR) data and patient-reported survey data have their own strengths and limitations. This study aimed to develop a method to integrate disparate datasets—patient-reported survey data with EHR data—to provide a more complete view of disease characteristics and health outcomes among patients with type 2 diabetes (T2D). **METHODS:** The two sets of data sources included: 1) data (2012 to current) from a large nationally representative US ambulatory EHR database and 2) data from the 2016 US National Health and Wellness Survey (NHWS), a nationally representative, self-administered, internet-based survey of adults (≥ 18 years). T2D patients were identified from NHWS if they self-reported a physician diagnosis of T2D. Adult T2D patients were identified in the EHR using diagnosis codes (ICD-9, ICD-10 and SNOMED codes), or text strings indicating T2D in the diagnosis field, or patients who had two or more prescriptions of oral antidiabetic medications or GLP-1 injections. Common variables between the two data sources included demographics (e.g., age, gender, ethnicity) and comorbidities (e.g., Charlson Comorbidity Index). A matching algorithm based on propensity to be in the NHWS data set was used to match patients from NHWS to those in the EHR, where predictors were the common variables. With the matched dataset, imputation was utilized to impute values of interest (e.g., HbA1c, health-related quality of life) where missing. **RESULTS:** A total of 3,347,750 patients with T2D were identified in the EHR and 4,113 patients with T2D were identified in NHWS. The mean age of the EHR sample was 64 years old and 58 years for the NHWS sample. The final matched sample included 12,399 patients with T2D (1:2 match). **CONCLUSIONS:** Using propensity matching and imputation methods, disparate datasets could be combined to provide a more informative dataset of patient and disease characteristics.

PRM64

EARLY ANALYSES OF NEWLY APPROVED DRUGS MAY PRODUCE BIASED CONCLUSIONS

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OBJECTIVES: Real-world health care data are increasingly used to study the effectiveness of interventions in large, heterogeneous patient populations. It is important to understand what biases could arise in the analysis of real-world data collected shortly after a new treatment is introduced, especially in the design of comparative effectiveness research. **METHODS:** This retrospective cohort study used pharmacy and medical claims from the HealthCore Integrated Research Database. Eligible patients were age 18 years or older with a diagnosis of gastric or gastroesophageal junction cancer (GC) (ICD-9-CM code 151.xx) who received trastuzumab between January 1, 2010 and March 31, 2014. Patients were followed until censoring, death, or end of the data stream (July 31, 2014). Descriptive statistics were used to summarize trastuzumab use. Differences by year were evaluated using F-tests for continuous variables and χ^2 tests for categorical variables. **RESULTS:** The 188 eligible patients had a mean age of 60 years; 81%

were male; 52% received radiation therapy, and 34% had a resection or gastrectomy. These factors were not significantly different by year of trastuzumab initiation. However, there were statistically significant differences ($p < 0.05$) in time between GC diagnosis and initiation of trastuzumab [e.g. mean (SD) 2010: 174 (128.2) days vs. 2013: 91 (96.4)] and trastuzumab line of treatment [e.g. n (%) first-line 2010: 10 (44%) vs. 2013: 45 (83%)]. **CONCLUSIONS:** Over time, trastuzumab, which was approved in 2010 for previously untreated HER2+ GC, migrated from later to earlier lines of therapy despite consistent patient demographic characteristics. Since treatment effectiveness may change across lines of treatment, bias may arise when comparing treatments used in a specific line of therapy. This potential bias associated with introductory clinical use in GC should be addressed via appropriate study design, statistical adjustments and careful interpretation of results.

RESEARCH ON METHODS – Modeling Methods

PRM65

USING RANDOM FOREST FOR RISK PREDICTION MODEL OF HOSPITALIZATION ASSOCIATED WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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OBJECTIVES: Chronic obstructive pulmonary disease (COPD) is a progressive disease negatively impacting quality of life. It is highly associated with increased risk of hospitalization; however, this risk has not been extensively studied. This study proposes a model to predict risk of hospitalization and identifies important factors contributing to hospitalizations for COPD. **METHODS:** This study used a longitudinal retrospective cohort. Health care claims from a single, large self-insured employer group was used. The database included claims for more than 10,000 employees and their dependents from January, 2010 through December, 2012. Insured persons with COPD were identified using ICD-9 diagnosis codes defined by the Center for Disease Control and Prevention (CDC). Hospitalized patients were matched by gender with non-hospitalized patients at a ratio of 1:3. Classification Random Forest (RF), a machine learning technique, was used to predict risk of COPD hospitalization and determine associated risk factors. The RF model was run 10 times (total of 10,000 trees) with 31 variables identified from literature. **RESULTS:** 252 persons ≥ 18 years of age were identified with COPD. For the final RF analysis, 48 COPD patients with hospitalizations and 144 without hospitalizations were included. There were 100 (52.1%) men; average age was 46.9 years (SD=12.4); average Charlson comorbidity score was 2.5 (SD=1.4). The analytic group was randomly divided into training (80%) and validating (20%) data set. Probability of hospitalization was 0.26003. The mean AUC was 0.94, sensitivity of 0.73, and specificity of 0.96. Kappa statistic was 0.73. Outpatient visit, comorbidity status, age, and number of prescription claims were important factors for risk of hospitalization. **CONCLUSIONS:** This study used an innovative technique to identify risk factors associated with hospitalization for COPD. These findings suggest the use of early intervention and goal-directed therapy to improve patient outcome and patient management by reducing potentially preventable hospitalizations.

PRM66

META-ANALYZING TIME-SPECIFIC EVENTS USING COMPOUND POISSON PROCESS: THE CASE FOR POST-STROKE SEIZURES

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OBJECTIVES: When number of events are reported over varying duration of times, meta-analyzing these data using a compound Poisson process can help generate a survival curve for these events with time-varying hazard. We identify the structural assumptions underlying these methods, determine the number of knots possible given the data, where hazard changes, and apply these methods to group-level data from the literature on incident seizures following stroke. **METHODS:** We searched PubMed and EMBASE for observational studies of post-stroke seizures from 1997 to 2016. We built a likelihood function based on a compound Poisson process that used different Poisson distribution across multiple overlapping intervals to model the counts of events. We divided 5 years into 3 intervals: within 7 days, from 8 days to 1 year, and from 1 year to 5 years after stroke. We compare this time classification to alternatives, which also include a constant hazard model over time using a single Poisson process or an exponential parametric model. Goodness-of-fit was demonstrated using AIC and BIC criteria. **RESULTS:** Our preliminary results, based on 12 studies published in the past 20 years suggest that the compound Poisson process with time varying hazard is the best model based on the lowest AIC and BIC, and the Poisson process with constant hazard is also better fitting than using a parametric survival approach. We found that hazard rate of seizures is 0.014, 0.023, and 0.173 for 3 intervals respectively: first 7 days, from 8 days to 1 year, and from 1 year to 5 years after stroke, indicating that the risk of seizure after stroke changes over time. **CONCLUSIONS:** The compound Poisson process could be a better way to meta-analyze count-data over different exposure periods, present the summary as survival curves that are readily interpretable by applied researcher and clinicians, and can spur meaningful clinical action.

PRM67

AN ACTIVE LEARNING ALGORITHM FOR EFFICIENT DEVELOPMENT OF EMULATORS OF COMPLEX MODELS, WITH AN APPLICATION IN PROSTATE CANCER SCREENING

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OBJECTIVES: Emulators are fast-to-evaluate statistical approximations of (typically computationally expensive) mathematical models (simulators). Using

emulators in lieu of simulators can speed up computationally expensive analyses. Emulators are developed using the output of simulators at specified input parameter values (design points). Developing well-performing emulators can require many design points, which becomes computationally expensive. We describe an iterative active learning (AL) algorithm to efficiently develop emulators. We explicate by developing emulators for a prostate cancer screening simulator (PSAPC). **METHODS:** The AL algorithm starts with a seeding set of design points and sequentially chooses additional design points in regions where (1) the simulator output is fast-changing and (2) the emulator predictions' variance is maximized. We developed one- and two-dimensional Gaussian Process-based emulators of the PSAPC using the AL algorithm versus using current standards (Latin Hypercube Sampling [LHS]). The simulator output was mean life-years saved with prostate-specific antigen based screening versus no screening. We compared the accuracy of emulators' predictions by calculating the maximum difference between the emulator prediction and the PSAPC (lower is better) and the emulator's 95% prediction volume (lower is better). **RESULTS:** The median maximum deviation in life-days saved between emulator predictions and the PSAPC were comparable between the AL emulators (one dimension: 0.008 [range: 0.006-0.024]; two dimensions: 0.217 [range: 0.171-0.234]) and LHS emulators (0.012 [range: 0.002-0.038], 0.201 [range: 0.079-0.441], respectively). Compared with LHS, performance results with AL had smaller variance. Furthermore, the AL algorithm improved the emulators' accuracy 25% faster per additional design point. Results were comparable with the other metric. **CONCLUSIONS:** In the example, compared with emulators trained with LHS, emulators trained with AL (1) attain comparable accuracy; (2) have smaller variance in their performance; (3) improve their performance faster per additional design point. Efficiency gains may be greater in (well-behaved) larger-dimensional problems.

PRM68

VALIDATION OF A TYPE 2 DIABETES MONTE CARLO MICRO-SIMULATION MODEL USING REAL-WORLD DATA

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OBJECTIVES: To validate the Treatment Transitions Model (TTM) using real-world data **METHODS:** Patients with at least one medical claim for type 2 diabetes mellitus (T2DM) and one pharmacy claim for a non-insulin antidiabetic medication during the index period (January 2008 - August 2013) were identified from a large health plan claims database. The first claim for T2DM was set as the index date. Patients enrolled a year prior to the index date, and at least two years post-index, were included in this study. Based on treatment guidelines recommended by American Diabetes Association and European Association for the Study of Diabetes, four treatment escalation pathways were chosen. Baseline population characteristics including demographics and complication history were collected from the database retrospectively. These characteristics and trial-based treatment efficacies were used by the TTM to predict the incidence of diabetes-related complications during the post-index period, which was then compared to the incidence in claims data. **RESULTS:** Only one pathway - patients starting on one oral antidiabetic medication and escalating to three oral antidiabetic medications had a sufficient base sample size (n=296) to include in the analysis. Comparing the 2-year prevalence of diabetes-related complications predicted by TTM to those observed in the claims database revealed (respectively): retinopathy (11.5% vs. 18.9%), microalbuminuria (5.6% vs. 21.6%), peripheral neuropathy (33.4% vs. 38.5%), angina (20.0% vs. 36.8%), and stroke (13.8% vs. 19.3%). **CONCLUSIONS:** A key finding was that the treatment pathways recommended by the guidelines were not observed in real-world settings. The higher prevalence of complications in claims data than what was predicted by the model may indicate issues in interpreting diagnosis codes, or underlying issues in the population not originally observed in the baseline characteristics. Work is ongoing to refine the model and investigate gaps between real-world data and model predictions.

PRM69

APPROACHES TO STANDARDISING CARDIOVASCULAR RISK EQUATION ENDPOINTS IN ORDER TO FACILITATE THEIR INCLUSION WITHIN A TYPE 2 DIABETES MODEL

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OBJECTIVES: There are a number of published cardiovascular (CV) risk equations (RE) suitable for use in type 2 diabetes mellitus (T2DM) cost effectiveness (CE) models. Their inclusion is complicated due to the inconsistency of CV endpoints for which risk is estimated. The QuintilesIMS CORE Diabetes Model (CDM) applies a United Kingdom Prospective Diabetes Study (UKPDS) weighting algorithm to five CV risk equations to enable consistency in modelled CV events. The objective of this study was to describe the impact of the weighting algorithm on predicted total and incremental CV risk for a number of CV RE. **METHODS:** This study used the T2DM CV risk equations available in the CDM to estimate five-year risk of myocardial infarction (MI), stroke, ischemic heart disease (IHD) and congestive heart failure (CHF). The following risk equations were included: Swedish-National Diabetes Registry (S-NDR); ADVANCE (Global); FREMANTLE (Australian); ARIC (US) and PROCAM (Germany). A dynamic risk factor related weighting algorithm based on the five-year risk of MI, stroke, IHD and CHF derived from the UKPDS 68 RE was applied to standardize endpoints. Results were illustrated using a UKPDS baseline cohort profile. **RESULTS:** Predicted five-year cumulative CV risk using UKPDS 68 RE was 0.075 (52.3% of this risk was attributable to MI; 5.8% to stroke; 39.1% to IHD and 2.8% to CHF). Five-year CV risk for S-NDR was 0.038; ADVANCE 0.028; FREMANTLE 0.071; ARIC 0.212 and PROCAM 0.08. A 1% increase in HbA1c was associated with an increase in cumulative CV risk of 12.8% (UKPDS 68); 11.6%

(S-NDR); 10.8% (ADVANCE); 12.3% (FREMANTLE); 0.5% (ARIC) and 0.5% (PROCAM). **CONCLUSIONS:** Approaches to standardizing endpoints predicted across CV RE facilitates their inclusion within T2DM economic models. This is particularly relevant given the appetite amongst health technology assessment groups to evaluate the sensitivity of predicted CE output to choice of RE.

PRM70

CAN IRELAND'S COLORECTAL SCREENING PROGRAMME SAVE MORE LIVES, SAVE MONEY AND LIVE WITHIN EXISTING COLONOSCOPY CAPACITY LIMITS?

FINDINGS FROM THE MISCAN MICROSIMULATION MODEL

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OBJECTIVES: Ireland's colorectal cancer screening programme, BowelScreen, offers biennial faecal immunochemical testing (FIT) for 60-69 year-olds. Screening sensitivity and specificity of FIT are adjusted by varying the test positivity threshold. BowelScreen uses a FIT cut-off of 225ng/ml of haemoglobin. Existing literature indicates that a lower cut-off of 50ng/ml would cost less and be more effective, but require more colonoscopies for positive screen findings, which is a key capacity constraint. The objective of this study was to determine if a more effective, less costly screening strategy exists within BowelScreen's current colonoscopy capacity requirements. **METHODS:** The MISCAN cancer screening model was used to simulate 144 strategies of varying screening intervals, age ranges and FIT cut-offs. Outputs estimated were net costs, quality-adjusted life-years (QALYs) and number of colonoscopies required. **RESULTS:** A combination of a reduction in the FIT cut-off to 50ng/ml, an extended screening interval of 3 years and a reduced screening start age of 55 saves 20% more QALYs, reduces costs by 7%, and yields a 17% reduction in colonoscopy requirements. **CONCLUSIONS:** Simple changes to BowelScreen could save lives, reduce costs and relieve pressure on colonoscopy capacity.

PRM71

DEVELOPMENT OF A DEPENDENCE SCALE-BASED COST-EFFECTIVENESS

FRAMEWORK TO ASSESS THE VALUE OF ALZHEIMER'S DISEASE TREATMENTS

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OBJECTIVES: Healthcare payers must compare the value of alternative Alzheimer's Disease (AD) treatments, but existing modeling frameworks are limited and focus primarily on delay to institutionalization. The Dependence Scale (DS) reflects the level of assistance AD patients require and is associated with AD progression (across cognitive, functional and behavioral domains), health-related quality of life (HRQOL), and direct medical and non-medical expenditures. Nonetheless, there are no established DS-based cost-effectiveness analysis (CEA) frameworks. We endeavored to fill this gap. **METHODS:** We developed a probabilistic state-transition simulation model that projects long-term cost-effectiveness based on DS changes. The model relates DS to HRQOL and cost using findings from Guo (2014) and Zhu (2015), respectively. The relationship between DS and mortality can be toggled, facilitating analysis of indirect treatment effects on survival. Outcomes include AD progression, life years, quality-adjusted life years (QALYs), and costs related to medication, inpatient and outpatient care, and informal caregiver time. To illustrate a model application, we evaluated a hypothetical oral agent for mild AD (baseline DS=3) that halves the DS progression rate while taken, is discontinued at a DS ≥ 10, costs \$500/month, and doesn't impact mortality. Additional scenarios will be explored. **RESULTS:** Over a lifetime, monthly AD progression averaged 0.022 DS points (new treatment) and 0.045 DS points (standard care). The new treatment added 0.25 QALYs and increased costs by \$19,200. Most of this cost increase reflects the new drug (\$36,400); the biggest cost offsets were reduced caregiver time (-\$12,300) and inpatient care (-\$2,900). The hypothetical treatment was cost-effective in 14%, 52%, and 83% of simulation runs at willingness-to-pay thresholds of \$50,000, \$75,000, and \$100,000 per QALY gained. **CONCLUSIONS:** Our DS-based modeling framework provides a new approach to evaluate the long-term comparative-effectiveness and cost-effectiveness of alternative AD strategies using an increasingly common trial endpoint associated with HRQOL and cost.

PRM72

COMPARISON OF COST-EFFECTIVENESS ACCEPTABILITY CURVES (CEAC) IN MODELED ANALYSES WITH AND WITHOUT ESTABLISHED HETEROGENEITY OF PATIENT CHARACTERISTICS

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OBJECTIVES: The analysis of cost-effectiveness acceptability curves (CEAC) represents a method to describe the uncertainty around incremental cost-effectiveness ratios (ICERs) in cost effectiveness analyses (CEA). CEAC are derived from the distribution of simulated incremental cost and effect pairs on the ICER plane (scatter plot). Modeled CEA are commonly conducted by projecting mean patient profiles. However, real life populations are heterogeneous which should be reflected in the modeling. This is especially relevant since patient heterogeneity considerably impacts on the distribution of cost effectiveness pairs in the ICER scatter plot and consequently on CEAC predictions. The objective of our study was to quantify differences in CEAC predictions with and without established patient heterogeneity within a hypothetical CE scenario. **METHODS:** Lifetime analyses comparing the CE of metformin+sulphonylurea (M+S) versus metformin + DPP-4 (M+D) was undertaken using the QuintilesIMS-CORE-Diabetes-Model (CDM). Patient baseline characteristics were obtained from NHANES and applied in the model in terms of mean inputs (ignoring heterogeneity) (A), random sampling of baseline characteristics (B) and via projection of individual NHANES patient level

data (PLD) profiles (C). Efficacy data for dual therapy was sourced from a published mixed treatment comparison; HbA1c and BMI change of -0.8% and 0.199kg/m² (M+D) and -0.79% and 0.707kg/m² (M+S), respectively, were applied. Discounting was applied at 3.0%. **RESULTS:** CEAC from mean projections (A) demonstrated an 8.2%, 26.2%, 37.4% and 42.4% cost-effectiveness likelihood for M+D vs. M+S for willingness-to-pay thresholds of \$25,000, \$50,000, \$75,000 and \$100,000 USD, respectively. This compared to 18.7%, 26.8%, 33.2% and 38.4% in analyses that applied random sampling of patient baseline characteristics (B) and 9.3%, 14.3%, 21.1% and 26.6% in analyses that projected individual PLD profiles (C). **CONCLUSIONS:** Failure to accommodate patient heterogeneity in CEA can significantly distort CEAC and may lead to erroneous interpretations of cost effectiveness.

PRM73

PREDICTION OF HYPOGLYCEMIA RISK AMONG PATIENTS WITH TYPE 2 DIABETES (T2D) USING AN ENSEMBLE-BASED, HYPOTHESIS-FREE PROCEDURE

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OBJECTIVES: To develop and validate a predictive model for 12-month hypoglycemia risk in adults with T2D using an ensemble-based, hypothesis-free, predictive-modeling approach. **METHODS:** Data were collected retrospectively for the period January 2008–December 2013 from the Truven Health MarketScan[®] Commercial, Medicare Supplemental, and Laboratory databases. Eligible participants were ≥18 years with T2D, and had a first pharmacy claim for an antidiabetes medication (index date) and continuous 18-month enrollment (6 months pre- and 12 months post-index). Baseline patient characteristics were collected during the pre-index period. Hypoglycemia events in the post-index period were identified via ICD-9 diagnosis codes or a blood glucose measure ≤70 mg/dL (Level 1 hypoglycemia according to 2016 ADA/EASD guidelines). Bayesian model averaging was via Markov Chain Monte Carlo sampling across the posterior distribution of model probabilities. This results in an ensemble of predictive models to examine the association of patients' baseline characteristics and hypoglycemia risk. **RESULTS:** An ensemble of 128 predictive models for 12-month hypoglycemia risk was sampled from the posterior distribution of model probabilities based on data from 558,963 eligible participants. Overall, 5,823 patients (1.0%) had ≥1 hypoglycemia event captured during 12-months' follow-up. The most probable predictors of hypoglycemia included prior hypoglycemia, older age (≥75 years), insulin use, sulfonylurea use, mood disorders, and high baseline healthcare utilization and costs. C-statistics were used to select the most accurate logistic regression model in a validation dataset (C-statistic=0.73). In a held-out sample that was used to test the likely accuracy of the model, participants were classified into two annual hypoglycemia-risk groups: ≤5.0% or >5.0%. The mean estimated hypoglycemia risk of the ≤5.0% group was 1.3% (95% CI 1.2–1.4%); the mean risk estimate of the >5.0% group was 14.0% (95% CI 12.5–15.6%). **CONCLUSIONS:** Predictive modeling was successfully used to identify 12-month hypoglycemia risk and predictors of hypoglycemia in adults with T2D.

PRM74

EFFECT OF DURATION OF FOLLOW-UP ON CALCULATING MULTIPLE MYELOMA TREATMENT PROBABILITIES USING INCIDENCE DENSITY RATIOS

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OBJECTIVES: To evaluate how variation in duration of follow-up affects the predicted probability of initiating multiple myeloma (MM) lines of therapy (LOTs) when using incidence density ratios (IDRs). **METHODS:** A U.S. administrative claims database was used to identify adult patients with ≥2 MM diagnoses who received ≥1 MM treatment ≤90 days of their MM diagnosis (first MM treatment = index) with insurance eligibility 24-months pre-and ≥3-months post-index. Patients were excluded if they had MM treatment pre-index, non-MM chemotherapy, pregnancy-related codes or an HIV diagnosis. LOTs were defined as each occurrence of: stem cell transplant, a ≥60-day gap in treatment, retreatment, or change in MM therapy. Generalized linear Poisson models were used to estimate IDRs (per person-year of observation), predicting the percentage of patients with 2, 3 and 4 LOTs at 6-month observation intervals for 5 years. **RESULTS:** A total of 4,987 MM patients were included in this analysis. At six months of observation, the estimated percentage of patients (i.e. the IDRs) with 2, 3 and 4 LOTs per person-year of observation was 40.4%, 4.6% and 0.5%, respectively. At five years of observation, the IDRs for patients with 2, 3 and 4 LOTs per person-year of observation were 19.9%, 9.4% and 4.5%, respectively. If only 6-months of observation is used to calculate IDRs, the probability of having a second LOT is 203% (40.4%/19.9%) greater than calculation using 5-years of observation. Stability of estimates did not occur until approximately 3.5 years after initiation of LOT 1. **CONCLUSIONS:** Economic models using treatment probabilities based on IDRs should be evaluated to ensure the duration of time over which the values are calculated is consistent with the characteristics of the disease and population being modeled. Failure to utilize an appropriate length of follow-up may result in significant estimation error.

PRM75

USE OF RELATIVE RISK RATIOS TO PRESENT UNCERTAINTY IN MICROSIMULATION MODELS WITH MULTIPLE COMPARATORS: AN APPLICATION TO BREAST CANCER SCREENING STRATEGIES

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OBJECTIVES: Microsimulation is the preferred modeling approach to assess comparative effectiveness and cost-effectiveness of cancer screening strategies.

These models often involve multiple comparators from strategies formed by a combination of initiation/cessation age and screening intervals. Using probabilistic analysis to present findings in models with multiple comparators is challenging because the probability of cost-effectiveness not only depends on the relative costs and screening effectiveness among alternative strategies but also is sensitive to the number of comparators in the model. **METHODS:** We developed a microsimulation model to compare the cost-effectiveness mammography screening strategies for average-risk women. Scenario A includes 10 strategies covering guidelines from three professional societies with three cessation ages (75/80/none), plus the no-screening option. Scenario B expands to 28 strategies by varying initiation (40/45/50), cessation (75/80/none) age, screening intervals (annual/biennial), and hybrid strategies that transition from annual to biennial. We obtained clinical parameters from the literature or statistical modeling (e.g., age-dependent sojourn time) and cost inputs from Medicare fee schedule and analyzing SEER-Medicare data. To address uncertainties, we ran 100 repetitions of the model, each simulating individual woman's lifetime natural history for a birth cohort of 100,000. Simulation results were converted to relative risk ratios (RRR) using multinomial logistic regressions. **RESULTS:** At \$100,000/QALY willingness-to-pay, Scenario A showed the most cost-effective strategy (annual 45-54, biennial 55-75) had 31% chance to yield the highest net benefit, whereas the probability reduced to 19% for the most cost-effective strategy (biennial 40-75) in Scenario B. Using the next-best strategy as the base category, multinomial model showed that the most cost-effective strategy was 1.15 and 1.36 times more likely to yield the highest net benefit in Scenario A and B, respectively. **CONCLUSIONS:** Presenting uncertainty in RRR can mitigate trends toward a lower probability for the most cost-effective strategy in models with a larger number of comparators.

PRM76

PREDICTING THE RISK OF DIABETIC RETINOPATHY USING ARTIFICIAL NEURAL NETWORK AND BIG DATA IN HEALTHCARE

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OBJECTIVES: In this study, we used artificial neural network—a popular data mining tool, to build a predictive model for risk of diabetic retinopathy. We compared its performance with Logistic regression in terms of their discrimination capacity. **METHODS:** National Health and Nutrition Examination Survey (NHANES) data was used in this study. Participants with a diabetes diagnosis and a known retinopathy status (yes/no) were included. Two models were built using training sample: artificial neural network and logistic regression. We used these two models to predict the risk of diabetic retinopathy in the testing sample. Receiver operating characteristic (ROC) were calculated and compared for these two models for their discrimination capability. **RESULTS:** A total of 757 patients were recruited and 21.5% had retinopathy. A random sample of 400 was chosen as the testing sample and the rest was used as the training sample. The Area Under the Curve (AUC) is about 0.75 for training sample according to above logistic regression, meaning that a randomly selected individual from the positive group has a test value larger than that for a randomly chosen individual from the negative group 75 percent of the time. After logistic regression and network analysis were conducted in the training sample, we used the outputs from both models to predict the likelihood in the testing sample (N=400). The areas under the receiver operating characteristic curves were 0.72 and 0.73 for the logistic model and the neural network, respectively. There were no significant differences in predictive ability between the approaches. **CONCLUSIONS:** This study suggests that it is possible to develop a reproducible and transportable predictive instrument for diabetes patients with retinopathy complication. In our research, both logistic regression and neural network models did a good job of predicting the risk for retinopathy complication.

PRM77

FORECASTING DRUG DIFFUSION IN THE US COMMERCIAL INSURANCE MARKET

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OBJECTIVES: The aim of this research was to develop a model that accurately predicts diffusion patterns for oral prescription drugs used to treat cardiovascular conditions. **METHODS:** This study used 2007-2014 the MarketScan Commercial Claims and Encounters Database, which includes claims from privately insured individuals. Additional information related to characteristics of eight drugs with indications for either hyperlipidemia, diabetes mellitus, type 2, hypertension or DVT/pulmonary embolism treatment was collected from the U.S. Food and Drug Administration (FDA) and the Pharmsprojects Citeline Database. The analysis was restricted to new molecular entities that were launched during the study period of 2008-2013 and patients over the age of 18 who were prescribed at least one of these medications. Limited dependent variable regressions were used to model the diffusion of selected drugs with cardiovascular indications as measured by patient utilization over time. Drug-related covariates and patient-level demographic characteristics were used to estimate the number of patients who receive a drug. Covariates included measures related to the strength of clinical evidence and risk/benefit recommendation for a treatment, the number of competitors at launch, and how innovative a drug was at launch. **RESULTS:** Findings suggest that the number of patients with an indicated diagnosis is the most significant overall predictor of diffusion in a commercially insured population regardless of therapy. However, models predicting diffusion at different points in time show that some factors are more significant than others depending on whether diffusion is forecasted from launch or at six, 12, or 24 months. **CONCLUSIONS:** Demand-based forecasting of the expected market share for new products is a common internal practice within the pharmaceutical industry. However, little information is publicly available about the models used to estimate diffusion. Understanding the rate at which drugs diffuse could help to inform healthcare budgets.

PRM78

NON-PROPORTIONAL HAZARDS. EXTRAPOLATING RELATIVE TREATMENT EFFECTS BEYOND OBSERVED DATA WITH CANCER IMMUNOTHERAPIES

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OBJECTIVES: The use of extrapolation in cost-effectiveness analysis (CEA) is essential to estimate costs and benefits of treatments over a lifetime. Typically, parametric equations are used to extrapolate a 'baseline' comparator with relative treatment effects applied to obtain absolute values for all interventions. An assumption of proportional hazards (PH) is common in oncology, but may fail with cancer immunotherapies. **METHODS:** We conducted a systematic literature review and a fractional polynomial (FP) network meta-analysis (NMA) of second-line metastatic non-small cell lung cancer randomised controlled trials. We used a log-logistic distribution to model atezolizumab overall survival data and applied time varying hazard ratios (HR) from the FP NMA. While FPs can be estimated over an observed period, polynomials may not extrapolate well. Naïve extrapolation to a lifetime horizon could be difficult to justify without clinical evidence. We explored the effects on five comparators; nivolumab (3mg/kg), pembrolizumab (2mg/kg), atezolizumab (1,200mg), docetaxel and nintedanib plus docetaxel with three scenarios: increasing HRs without capping, capping HRs at 12 months and using the PH NMA HR estimate from 12 months onwards. **RESULTS:** A first order FP model with P1=0 (Weibull) was selected. The HRs for docetaxel and nintedanib plus docetaxel versus atezolizumab increased over the time scale of one week to 12 months; 0.81 to 1.57 and 0.79 to 1.44, respectively. Nivolumab and pembrolizumab did not show evidence to dismiss a PH model over time compared to atezolizumab. The mean overall survival for docetaxel was 1.24, 1.36 and 1.48 years for the increasing HR, capped at 12 months and using the PH NMA estimate (1.39) from 12 months, respectively. **CONCLUSIONS:** Incorporating time varying HRs into a CEA needs care and involves considerations beyond simple statistical measures of fit. This example demonstrates using PH HRs over extrapolated data may not be reasonable between immunotherapies and chemotherapies.

PRM79

EVIDENCE SYNTHESIS FOR DIAGNOSTIC TESTS WITH PARTIALLY ORDERED PERFORMANCE AND NO REFERENCE TEST

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OBJECTIVES: We develop evidence synthesis models for obtaining sensitivity and specificity of diagnostic tests from independent studies, when the true disease status is unknown. To explicate, we estimate the performance of tuberculin skin test (TST) and interferon-gamma release assays (IGRA) to diagnose Latent Tuberculosis Infection (LTBI) for a cost-effectiveness analysis of screening of immigrants for LTBI. **METHODS:** We develop a Bayesian hierarchical random effects model that (1) treats the unobserved disease status (LTBI) as a latent variable; (2) allows for between-study heterogeneity in disease prevalence and in the sensitivities and specificities of tests (TST, IGRA); (3) accounts for threshold effects across studies; (4) accommodates covariates; (5) allows test results to be correlated conditional on disease status. The model also (6) allows for partial ordering of test performance, because information elicited from nine context experts, suggests that IGRA cannot have worse specificity than TST. While for each study the model has more parameters than independent data points, identification is attained and estimation becomes possible through "borrowing of strength" across studies, and from the expert-provided ordering of the specificities. **RESULTS:** We obtain estimates for LTBI prevalence and the sensitivities and specificities of TST and IGRA for 12 scenarios defined by whether immigrants come from a country with high tuberculosis incidence; have had BCG vaccination; have chronic diseases; have HIV infection; or are 30 versus 50 years old. For an example scenario of 30-year-old immigrants not from a high-incidence country, without history of BCG vaccination, without TB case contact, or diseases, the median of the posterior densities for the sensitivities of TST and IGRA are 0.75 and 0.85, respectively. **CONCLUSIONS:** We developed a meta-analysis model that estimates test performance measures in the absence of a gold standard, which is a very common situation in decision and economic analyses of test-and-treat strategies.

PRM80

MODELING THE IMPACT OF EXOGENOUS BOOSTING ON HERPES ZOSTER: AN UPDATED METHODOLOGICAL REVIEW OF THE VARICELLA ZOSTER VIRUS LITERATURE

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OBJECTIVES: Historically, mathematical models of the impact of universal childhood varicella vaccination (UVV) have used limited data to capture effects of exogenous boosting (EB). EB posits that cell-mediated immunity (CMI) is boosted for individuals re-exposed to varicella zoster virus (VZV), leading models to often conclude that UVV will cause a temporary herpes zoster (HZ) increase. Our objective was to update a previous literature review (Ogunjimi et al., 2013) to summarize any new evidence from observational or modeling studies related to EB and its parameterization. **METHODS:** Electronic searches of two databases and seven congresses were performed using the previous review's published search strategies. Identified studies were screened to determine inclusion eligibility and to identify additional sources. Data on observational study designs and mathematical model structures, EB frameworks, and HZ-related parameter values were abstracted, with results synthesized. **RESULTS:** The updated review identified 29 additional studies. Among 17 observational studies, 8 analyses included both

pre- and post-UVV data in 4 countries. Most analyses (n=6) reported pre-UVV increases in HZ incidence, making it difficult to attribute post-UVV increases to UVV versus other causes. Among 12 modeling studies, various EB frameworks were considered, ranging from no EB to full permanent immunity; the progressive immunity framework (i.e., CMI increases for a proportion of VZV exposures and accumulates after each exposure) best captured EB based on statistical fit to real-world pre-UVV data. HZ-related parameter values varied widely by study/country, even for biologically-based parameters (e.g., CMI duration); assumed HZ-related parameter values for vaccinated individuals were similar. Other key factors affecting post-UVV HZ incidence included population contact patterns, demographic changes over time, and pre-UVV HZ incidence. **CONCLUSIONS:** New methods for incorporating EB into mathematical models may better capture EB than previous approaches, although further research on the biological processes and resulting effects of EB on HZ incidence is needed.

PRM81

ESTIMATION OF INJECTABLE DRUG STRENGTH FROM INSURANCE CLAIMS DATABASE

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OBJECTIVES: Drug strength for injectable drugs is not commonly captured in Medical or Pharmacy claims database but an important factor for understanding drug compliance, persistency and length of therapy. This study is to build a model to estimate the injectable drug strength from Insurance Claims Database. **METHODS:** Total ~700k Lupron scripts from 6117 Prostate Cancer patients from the Truven MarketScan Commercial Claims and Encounters (CCAE) and Medicare Claims (MDCR) from 2000 to 2016 were used in the analysis. 35,058 scripts with drug strength information are used to build the prediction model. Both Logistic Regression and General Linear Regression model were tested. Physician specialty, type of benefit plan, geographic region of employee residence and employment status and employee classification, total drug cost and treated year are evaluated in the model. Model performance is evaluated by error rate from 10-fold cross validation. The predicted Lupron strength was also compared with the simple imputation based on total drug cost in the context of compliance rate and length of therapy. **RESULTS:** Among 6117 patients treated with Lupron, 22.5mg regimen is most scripted. General Linear Regression model perform better with an error rate of 0.09. By comparing the results from no imputation, simple imputation and model based imputation, the results revealed that simple imputation is over estimating in drug strength and model based imputation is close to the actual observed data. Calculated mean of compliance rate and length of therapy for non-imputation, simple imputation and model based imputation is 89% and 18.59 months, 94% and 20.17 months, 86% and 18.38 months, respectively. **CONCLUSIONS:** Many injectable scripts are missing drug strength information from Insurance Claims database, using model-based prediction, drug strength can be estimated more accurately using factor such as drug total cost, treated year and other associated factors.

PRM82

ESTIMATING THE IMPACT OF CHANNELING BIAS ON REAL-WORLD SURVIVAL IN ADVANCED CANCER

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OBJECTIVES: To estimate the comparative effectiveness in terms of overall survival (OS) of an advanced cancer treatment (immuno-therapy A) against established comparators B and C. Medical experts expected a channeling bias for product A at launch, towards patients with the worst OS prognostics. **METHODS:** Phase 3 clinical trials reported OS hazard ratio (HR) of 1.6 [1.4, 1.9] for A vs B and 2.1 [1.9, 3.2] for A vs C. The distributions of OS prognostic in the real-world population at treatment initiation for the active comparators, and how they would differ for product A at launch, were elicited from experts as proportions of patients with favorable, intermediate or unfavorable prognostic. A Bayesian model was built in HOPE, a new tool for predicting real-life comparative effectiveness. The model was based on patient-level Phase 3 clinical results on OS and trial patient characteristics, including their survival prognostic at treatment initiation. It accounted for competing risks of biological progression and toxicity events on the risk of death over time. Two scenarios, with and without channeling effect, were simulated. **RESULTS:** The model with channeling bias returned mean estimates of median survivals that were almost equal: 15.7, 15.0, 15.6 months for treatments A, B and C, respectively, whereas the medians in the absence of channeling were 16.8, 14.6 and 13.4 months, respectively. The impact of channeling at launch of A for the three products was estimated as the difference between these means. **CONCLUSIONS:** The HOPE software allowed for rapid prediction and visualisation of real-life survival outcomes by automatically combining clinical trial data and expert opinions on patient distributions in a single model. The simulation allowed for estimating the magnitude of post-launch channeling effects of a new cancer treatment.

PRM83

A CRITICAL APPRAISAL OF THE USE OF MARKOV MODELLING APPROACHES IN ECONOMIC MODELS OF ANXIETY

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OBJECTIVES: To assess the strengths and limitations of Markov modelling approaches for assessing the cost-effectiveness of treatments for anxiety based

on a review of the published literature. Anxiety disorders have a high rate of chronicity with a recurrence rate of almost 23.5% in patients who have remitted. The effectiveness of treatment is highly dependent on patients' previous history and characteristics. Even though Markov models are among the most established and accepted approaches for decision modelling in Health Technology Assessments (HTAs), it is unclear whether they are adequate for modelling the complexities of anxiety disorders. **METHODS:** We performed a targeted literature search for published Markov models designed to assess the cost-effectiveness of treatments for anxiety disorders in the following databases: NHS Economic Evaluations Database, Medline and Medline In-process and Embase. One reviewer assessed articles for eligibility and included only studies that reported results for Markov models developed for adults with anxiety disorders. Anxiety disorders were defined using DSM-V criteria. Models were critically appraised according to standard checklists and de novo criteria developed to assess their applicability to anxiety. **RESULTS:** Our searches retrieved 164 hits. 23 articles were reviewed at full-text and four articles met the inclusion and exclusion criteria. The models assessed the cost-effectiveness of specific drugs (two studies), psychotherapy (one study) or combinations of both (one study) in generalized anxiety disorders, panic disorder and social anxiety disorder. The results of the quality assessment were mixed. Most of the identified Markov models did not adequately reflect the increased risk of recurrence based on patients' history of prior relapse and sociodemographic characteristics. **CONCLUSIONS:** Most of the identified Markov models for anxiety disorders have a limited ability to capture the increased risk of recurrence associated with previous anxiety experience.

PRM84

HERPES ZOSTER VACCINE EFFECTIVENESS AND WANING OF EFFECTIVENESS

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OBJECTIVES: Synthesize all available clinical data on the herpes zoster (HZ) vaccine, and determine the best model from which to predict the vaccine effectiveness and waning of effectiveness for the HZ vaccine based on age and time since vaccination. **METHODS:** A targeted search of PubMed and Google was performed. The search was limited to literature between January 2006 and December 2016. Literature eligible for inclusion were peer-reviewed papers in scientific journals, conference abstracts and posters. **RESULTS:** Six models for the HZ vaccine were produced to estimate the waning of effectiveness. All studies used HZ incidence among vaccinated vs. unvaccinated populations as measures of effectiveness. Four are based on the models presented in Li et al. (2015) clinical study data. One is based on the Long-Term Persistence Study (LTPS) clinical data in Morrison et al. (2015) as modeled by Le and Rothberg (2015). The sixth model is based on the findings of Baxter et al. (2015), real world data from Kaiser Permanente Northern California. These data represent up to 8 years of patient follow up and includes over 400,000 vaccinated patients. One model from Li et al. predicted a drop in effectiveness in year 2 but with slower waning in subsequent years. A second model from Li et al. predicted that vaccine effectiveness over time is similar in all 60+ age groups. Both of these models are consistent with the model based on data from Baxter et al. **CONCLUSIONS:** Cost-effectiveness results for herpes zoster prevention is highly dependent on age at vaccination and the waning of effectiveness for the HZ vaccine. Based on the evidence for real world effectiveness against zoster for the HZ vaccine, we recommend utilizing the data from Baxter et al. to predict effectiveness and waning for individuals being vaccinated with the HZ vaccine.

PRM85

USE OF MUTUAL INFORMATION THEORY IN BUILDING A PREDICTIVE MODEL FOR ANKYLOSING SPONDYLITIS DIAGNOSIS

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OBJECTIVES: Mutual Information (MI) metrics can be utilized to identify predictive patterns obscured by the volume of data in claims databases. MI measures shared content between two data samples and quantifies the relevance of each predictor to a diagnosis. Predictors are classified by predictive ability and reliability, and analysis repeated. Each iteration eliminates predictors and changes ranking. Iterative optimization eventually defines the most effective predictive model. Many US patients with ankylosing spondylitis (AS) experience a 7 to 13-year delay before correct diagnosis. Delayed diagnosis and treatment contribute to considerable economic, physical, and psychological burdens on patients, caregivers, physicians, and society. Thus, we aim to develop a predictive model for AS based on sequence and timing of diagnostic, procedure, prescription, and provider (DPPP) codes observed in histories of patients with AS diagnosis to aid in earlier identification of AS patients. **METHODS:** Data for this retrospective cohort study were extracted from de-identified US claims from over 182 million people from January 1, 2006 through September, 2015. Study population comprised patients with AS diagnosis (ICD-9-CM 720.0). For each AS patient, a minimum of 10 patients without AS matched by age, gender, enrollment period, and geographic region were randomly selected from the same database. MI was applied to identify DPPP codes that differentiate AS from the matched-control population. Combinations of DPPP codes were ranked by MI value (high MI indicates higher relevance to AS diagnosis) to determine predictors. **RESULTS:** Claims histories of 12,162 AS diagnosed patients and 121,620 matched-controls were analyzed to build a proof of concept predictive risk model that separates AS patients from matched-controls. A total of 12,678 features were analyzed and 150 classifiers were built (with 3-fold cross-validation). **CONCLUSIONS:** Additional modifications and vigorous validation of the proof

of concept predictive model will be made to enhance clinical relevance and practicality.

PRM86

RATIONAL COMPUTER ASSISTED DESIGN FOR THE STUDY OF ACUTE TOXICITY OF LOCAL ANESTHETICS

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OBJECTIVES: Comparing study of acute toxicity of new synthesized piperidine derivative after a single dose and by the use of Computer Assisted Design. Nowadays the use of traditional methods of study of acute toxicity is severely limited, according to the humanization of experimental studies. In these conditions, Computer Assisted Design/CAD is more applicable, when computer recreates the structure of the chemical in a three-dimensional image. **METHODS:** in the Institute of Chemical Sciences synthesized new derivatives of piperidine under laboratory code MAB118, MAB121, MAB124, MAB129, MAB130, MAB131, MAB134. Acute toxicity was studied by traditional methods: intraperitoneal, subcutaneous injection of 4% water solutions of local anesthetics to white mice of both sexes where used. Toxicity assessment was carried out on the base of LD50 rate. The calculation of quantum chemical parameters was carried out by semiempirical Hartree-Fock method with the assistance of a calculation program MOPAC 6. **RESULTS:** The results of the calculations of LD50 allow to select group of low toxicity (MAV 121, 129 MAV, MAV, 130, MAB134) and moderate toxicity (MAV 118, MAV, 124, MAB131) compounds. Analysis of the relation between the toxicity and quantum-chemical characteristics was performed using Computer Assisted Design. Low-toxic compounds were characterized by: high level of stability in the form of neutral molecules, due to the negative values of heat of formation and full of energy, combined with a relatively low reactivity, evidenced by the positive dipole moment. Compound with moderate toxicity form a neutral molecule and H-cation, with H-cation significantly less stable than H-cation of low-toxicity compounds, as well as lower dipole moment. Compound with moderate toxicity are less reactive than low toxicity ones. **CONCLUSIONS:** The results indicate the possibility of applying the parameters of quantum chemistry and molecular mechanics to predict the toxicity of derivatives of piperidine and optimization of primary screening

PRM87

EXPLORING PYTHON FOR USE IN MODELING: DECREASING RUN-TIMES FOR PROBABILISTIC SENSITIVITY ANALYSIS

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OBJECTIVES: Python was released in 1991 as a general-purpose programming language. Its use for scientific computing in industry and academic research has increased significantly in recent years. We discuss using Python in health economic modelling and, in particular, the advantages associated with its powerful multi-dimensional array object through various practical examples including a probabilistic sensitivity analysis (PSA). **METHODS:** A fictional model was explored comparing two drugs for prevention of moderate and severe manifestations of a hypothetical disease. The model and PSA were implemented in NumPy, a fundamental package which extends the Python core language for scientific computing. The algorithm stores data in a 3-dimensional (d) array with the first two axes corresponding to model health states and cycles, respectively. The third axis represents a unique simulation where input parameters are varied randomly according to appropriate probability distributions. The 3-d nature of the array allows for simultaneous calculation and storage of many different versions of the model. **RESULTS:** In this fictional model with 5 disease states and 40 cycles, a PSA with 1,000 simulations in Python has a run-time of 50 milliseconds and 450 milliseconds for a PSA with 10,000 simulations. The PSA was much slower in Excel with run-times of approximately 45 seconds and 8 minutes for 1,000 and 10,000 simulations, respectively. **CONCLUSIONS:** The implementation of the PSA using NumPy were many orders of magnitude faster compared to Excel. Faster execution, especially with complex models, improves the feasibility to explore many scenarios and test structural validity. There is recognition that the complexity of many diseases are not accurately captured in Excel cohort models; thus there is a shift towards more sophisticated modeling such as individual simulation. Coupled with the requirement for PSA, the adoption of software platforms that can manage computationally expensive algorithms will become increasingly more important.

PRM88

HEALTH STATES UTILITY VALUES IN NICE MULTIPLE TECHNOLOGY APPRAISALS: ADHERENCE TO THE NICE REFERENCE CASE IN THE AREA OF CANCER

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OBJECTIVES: The National Institute of Health and Care Excellence (NICE), routinely considers evidence on the cost-effectiveness of health technologies in formulating its recommendations on treatments for use in the English National Health Service. NICE periodically publishes methodological guidelines, known as the 'reference case', to ensure technology appraisals meet good quality standards. In spite of this, previous reviews of NICE appraisals have shown high levels of heterogeneity in the methods used to obtain health state utility values for decision analytical models. The aim of this paper was to investigate the level of adherence to the 2013 NICE reference case with respect to the health state utility values employed in recent Multiple Technology Appraisals (MTAs) in the area of cancer. **METHODS:** The level of adherence to the reference case in all MTAs conducted by Assessment Groups between 2008 and 2016 was assessed using a checklist that aims to evaluate the extent of decision uncertainty originating from

evidence on utility values. **RESULTS:** Thirty-five technology appraisals in the area of cancer were reviewed. Adherence heterogeneity to the NICE reference case was identified mainly due to unsystematic search for evidence on utility values, lack of utility values derived from the EQ-5D, and limited amount of data on generic and disease specific patient-reported Health-Related Quality of Life (HRQoL) outcomes. **CONCLUSIONS:** Adherence to the NICE reference case may be increased by stricter requirements for the systematic identification, validation and reporting of evidence on health states utility values used in economic evaluation and the development of mapping algorithms suitable to synthesise summary data from disease specific or generic HRQoL tools commonly reported in cancer trials.

PRM89

MODELING WITH VERY BIG DATA: A PILOT STUDY USING LARGE-SCALE MACHINE LEARNING IN A CLUSTER COMPUTING FRAMEWORK TO PREDICT EMERGENCY ROOM (ER) VISITS

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OBJECTIVES: To develop and demonstrate the feasibility and limitations of predictive modeling methods adapted for a very large and heterogeneous dataset containing longitudinal data spanning up to 10 years for more than 50 million unique patients. **METHODS:** We retrospectively studied predictive factors associated with ER visits using an EHR-based database (IBM Explorys) containing broader clinical information for a larger patient population than earlier research on this topic. After filtering to exclude inactive patients, the remainder were counted as positive for the primary outcome if they had visited the ER between January 2014 and December 2015, with risk factor data extracted from January 2004 forward. In the initial exploratory phase, we calculated odds ratios for 543 factors from major categories including demographics/socioeconomic status (n=5), health-care utilization and drug usage (n=9), past diagnoses (n=285), and past procedures (n=244). For modeling, the filtered dataset was randomly divided 80%/20% into training and testing subsets. Declarative large-scale machine learning software (SystemML) was used to train a logistic regression model with L2-regulation on a 6-node computing cluster. **RESULTS:** After filtering, the study population consisted of 35 million active patients, with 11% visiting the ER during the reference period. Training was completed in 1.3 hours, generating a model that achieved an AUC of 83.27% on the testing subset. Strong predictors identified by the model included poverty (percentage of families below poverty level within a zip code), race, history of substance abuse and mental illness, sprains and strains, and abdominal pain. **CONCLUSIONS:** This pilot confirms the feasibility of and provides a roadmap for predictive modeling with very large datasets containing a rich spectrum of clinical data, with the potential to uncover previously unknown risk factors. Improved models might be generated by using more granular diagnostic groupings and detailed drug information, and including more interactions between variables.

PRM90

THE PATIENT VOICE INCLUDES EMOJIS: A CASE STUDY IN THE USE OF PROBABILISTIC TOPIC MODELING TO CHARACTERIZE PATIENT CONVERSATIONS IN AN ONLINE COMMUNITY OF PTSD PATIENTS

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OBJECTIVES: To identify and respond to patient-defined priorities in care delivery and drug development, it is important to understand what is important to patients. Increasingly, patients share large volumes of free-text data over social media and within online communities. The text generated in these ways is often too massive to allow for complete human review and summarization, making approaches using natural language processing particularly valuable. This case study demonstrates the use of probabilistic topic modeling, with attention to the preservation of emojis, to characterize over 200,000 free-text posts from post-traumatic stress disorder (PTSD) patients in the online patient community PatientsLikeMe (PLM). **METHODS:** Approximately 54% of PLM patients contribute free-text posts to the platform through user bios, forum conversations, or as annotations associated with structured data. Posts contributed by PTSD patients were pre-processed to remove html and stopwords, and to map emojis to text-based descriptions. Latent Dirichlet allocation (LDA), a form of probabilistic topic modeling, was performed to identify topics discussed among patients. Model parameters were selected on the basis of perplexity as measured on a 10% holdout group. **RESULTS:** A total of 224,997 free-text posts were contributed by 8,518 unique PTSD patients between 3/1/2012 and 3/1/2016. Fifty topics were identified, including topics related to quality of life (family, religion, music, literature, pets/service animals), exposure to trauma (military combat, abuse), symptoms (pain, depression, anxiety, insomnia, anger), and treatments (medical marijuana, supplements, side effects). **CONCLUSIONS:** Computational methods to summarize large volumes of free-text data are a valuable tool for characterizing the patient experience. One such method, LDA, can be used to provide a high-level overview of topics discussed by patients. In combination with structured data sources, patient generated free-text data may provide insight into the ways in which patients live with their condition and take steps to maximize their quality of life.

PRM91

LONGITUDINAL DETERMINANTS OF DYNAMIC STATIN ADHERENCE: A RETROSPECTIVE COHORT STUDY

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OBJECTIVES: To model the baseline and time-varying determinants of longitudinal statin adherence, and to identify and characterize the heterogeneity in statin

adherence patterns over time. **METHODS:** We used MarketScan commercial claims data from 2008-2013. Adults newly initiating a statin, with at least 3 years of continuous eligibility after statin initiation were included. The 3 year follow-up period was divided into 12 periods of 90 days; a period was considered an adherent one if the patient was exposed to statins for 80% of the days. Baseline covariates included age, sex, and history of congestive heart failure (CHF), hypertension (HTN), stroke, asthma, chronic obstructive pulmonary disease (COPD), depression, and diabetes (DM). Time varying covariates included new onset of clinical conditions (same conditions as baseline plus liver dysfunction and myopathy) and average non-statin daily pill burden in a period (<1, 1-2, or >2 pills/day). Generalized estimating equations (GEE) were used as primary analysis. We estimated Group Based Trajectory Models (GBTM) while adjusting for all baseline and time-varying covariates as secondary analysis. **RESULTS:** 252,272 patients met the inclusion criteria. For the GEE analysis, patients having a history of COPD (odds ratio [OR] 0.88, p<0.05) or new onset of depression (OR 0.78, p<0.05) were most likely to be non-adherent to statin therapy. For GBTM analysis, the 5 group model was identified as the best model. We found significant interactions between the covariates and the identified subgroups of adherence in the GBTM. For instance, in the highest adherence subgroup, new onset of myopathy was associated with highest decrease in adherence (OR 0.73, p<0.05), while for the non-adherent groups, new onset of stroke was associated with highest increase in adherence (OR 2.25, p<0.05). **CONCLUSIONS:** Compared to baseline covariates, time varying covariates had greater magnitudes of effect and therefore may be more important in determining longitudinal medication adherence.

PRM92

ASSESSMENT OF PROPORTIONAL HAZARDS IN NICE SUBMISSIONS: A REVIEW OF RECENT NICE APPRAISALS IN CANCER

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OBJECTIVES: Conducting a network meta-analysis (NMA) of hazard ratios (HRs) for time-to-event outcomes, when the proportional hazards (PH) assumption is violated, could lead to biased treatment effect estimates. Published algorithms exist to reconstruct individual patient data from digitised plots making formal testing of PHs possible. In the UK, NICE has stressed the importance of using an appropriate scale, thus Health Technology Assessment (HTA) groups may expect justification for the choice of scale in reimbursement submissions given the accessibility of formal diagnostic testing techniques. Taking the UK as a case study we aimed to identify whether this was the case in recent NICE appraisals. **METHODS:** We searched the NICE website for Technology Appraisal (TA) guidance documents in cancer published in the last three years. Searches were run in December 2016. We reviewed the TAs to identify whether manufacturers had assessed the PH assumption and justified the choice of scale when synthesising time-to-event endpoints for a NMA. HTA groups' comments on these assessments were also identified. **RESULTS:** A total of 45 TA submissions in oncology were identified. 27 included an NMA of survival endpoints, of which only 6 manufacturers assessed PHs using established methods on trials included in the NMA. In an additional 10 submissions the HTA group noted that PHs does not hold in one or more of included trials and should have been considered in determining the analysis methods. Methods used to address non-proportional hazards included; independent modelling of treatment arms, fractional polynomial models, and piecewise modelling. **CONCLUSIONS:** Choice of scale is important to avoid bias in an NMA. HTA groups have criticised submissions that have not justified or formally tested the PHs assumption for NMAs synthesising HRs. Manufacturers should justify choice of scale used in NMAs for reimbursement submissions and conduct formal assessment of PHs when synthesising HRs for time-to-event outcomes.

PRM93

WHEN DOUBLY ROBUST IS NOT ROBUST ENOUGH: NONPARAMETRIC MATCHING METHODS UNDER TREATMENT HETEROGENEITY

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OBJECTIVES: Recent technological advances have increased the ability to deliver precision-targeted individualized treatment plans. This approach concentrates treatments among patients most likely to benefit from a particular therapy. This presents methodological challenges for evaluators as the average treatment on the treated (ATT) is likely to be substantially larger than the average treatment effect (ATE) considered across the entire population. This study aimed to explore the most accurate non-parametric matching methods for estimating the ATT among a population with treatment heterogeneity. **METHODS:** Both Monte Carlo simulation and semi-simulation using actual data from the Medical Expenditure Panel Survey (MEPS) 2012 were conducted. We simulated three propensity score distributions each with three treatment heterogeneity correlations. Within each of these nine scenarios, we created 1000 datasets each with 500 patients. Mean squared predicted error for OLS, one-to-one matching, k-nearest-neighbor matching, propensity score weighting, kernel matching, and local linear matching were calculated and compared to known truth. For each matching estimator, the ATT was estimated with both direct mean comparison and weighted OLS using the propensity scores in a weighting function. **RESULTS:** All matching methods showed improvement (14%~69%) compared to using an estimator based on OLS alone. Kernel matching provided the best theoretical improvement over OLS (69%). Because the efficiency of kernel matching relies on the choice of bandwidth, we applied leaving-one-out algorithm to identify the bandwidth. Kernel matching with optimized bandwidth yielded a 61% improvement over OLS, and outperformed the other matching methods. In addition, our simulated results suggested that applying OLS after matching yielded worse results than a direct mean comparison after matching. **CONCLUSIONS:** Kernel matching was identified as the most accurate methods in estimating ATT, and the leaving-one-out algorithm

was a reliable method in selecting bandwidth. Matching provides improvement over OLS, but caution should be exercised when combining matching with regression techniques.

PRM94

SIMULATING MULTIVARIATE DISTRIBUTIONS WITH ARBITRARY MARGINAL DISTRIBUTIONS AND DEPENDENCE STRUCTURES

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OBJECTIVES: Researchers often need to generate random samples from multivariate distributions (MVDs) with specific univariate marginal distributions (MDs) and dependence structure. Applications include propagating uncertainty via forward-Monte-Carlo simulation for a set of variables in a mathematical model, or creating synthetic datasets that are “similar” to a target population. Typically, information exists about (1) the form, mean, and variance of the marginal distribution (MD) for each dimension, and (2) the empirical correlation matrix. **METHODS:** We propose to approximate MVDs using Gaussian copulas, which factor an MVD into a product of arbitrary MDs times a dependence structure. For the MDs, we select from common distributional forms (e.g., normal, beta, Bernoulli) and specify their parameters with moment matching. For the dependence structure, which is parameterized by a correlation matrix, we use an empirical correlation matrix. As an example, we create a synthetic cohort that is “similar” to a target cohort of patients with coronary artery disease from the American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR). We use a parametric survival model and compare the predicted survival curves in the synthetic population and in the original cohort. **RESULTS:** We approximate the MVD of 13 continuous variables (e.g., age, heart rate) and 20 categorical variables, some of which are dichotomous (e.g., sex) or ordinal (e.g., number of disease vessels), using the Gaussian copula and demonstrate that multivariate random sampled preserve the first-order (means) and second-order moments (variances and covariances) of the MVD and the MDs of all variables. Predicted survival curves agreed well between the synthetic data and the original data. **CONCLUSIONS:** In the application, the synthetic sample appears to emulate the original data in terms of model predictions. More generally, this approach can serve as a flexible and robust approach for approximating an MVD using only estimates of first and second moments

PRM95

EVALUATING THREE MARKOV MATRIX SOFTWARE MODELS FOR HIV TREATMENT COST EFFECTIVENESS ANALYSIS

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OBJECTIVES: Three decision models were to compare that calculate the cost-effectiveness of HIV treatment options using Markov multi-state, transition probabilities, along with corresponding transition state costs and utilities. The first HIV calculator was a, publicly available, spreadsheet model described in the textbook “Decision Modeling for Health Economic Evaluation” edited by Briggs et al. A second basic freeware Markov cost-effectiveness calculator is available online through www.healthstrategy.com. The third program is a recently developed health economic evaluation modeling package, Heemod that has been made available for free on cran.r-project.org, the open-source R repository. The objective of our study was to evaluate the results from these three HIV model approaches. **METHODS:** For this evaluation, we modified the original Excel HIV spreadsheet structure and data using mono therapy versus combo therapy for all cycles. Using two treatment option matrices, the variable inputs that can be modified in these applications include state transition probabilities, number of cycles, cost per state, and utility per state. **RESULTS:** We considered four transition states for each therapy option, and 20 cycles with no discounting. The MS Excel spreadsheet model versus the online JavaScript software versus the Heemod R model compared very well with results respectively as follows: average incremental costs in British pounds: (67701 vs 67853 vs 66977), average incremental utility: (5.89 vs 5.90 vs 5.74) and average incremental cost-effectiveness ratio: (11500 vs 11494 vs 11678). **CONCLUSIONS:** The browser-based, online calculator has potential benefit as a basic educational tool for students and health professionals interested in exploring these analytical approaches. The Heemod package requires R software installation but has many positive features, and is likely to be expanded in capabilities and treatment model examples in the future.

PRM96

CAUSALITY WITH REAL WORLD EVIDENCE: BURDEN OF PROOF, PROOF OF PRINCIPLE

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OBJECTIVES: To establish and evaluate whether replicating and reconciling surrogate markers in epidemiological studies can establish causal relationships. **METHODS:** Multiple longitudinal and panel data sources from different countries quantify the conditional probabilities of surrogate endpoints (e.g., heart rate, treatment(s), etc.) and established biological outcomes (e.g., all-cause mortality, HbA1c and diabetic complications, etc.). Therapeutic or biological models consist of all-cause mortality and heart rate; diabetic-complications/ HbA1c and treatment; adverse events and pain management; and mortality and HDL-C. Countries include the UK, Germany, U.S., Canada and Australia. Estimation methods include survival analyses and generalized estimating equations (GEE). Pairwise results from those analyses were compared (reconciled) to all previous RCTs and epidemiological studies identified by comprehensive and systematic reviews of published studies where odds-ratios served as measures in common. **RESULTS:** Heart rate predicted mortality twice with survival and/or GEE analyses, 0.00694 ($P < 0.001$) in Canada, 0.00683 ($P < 0.001$) in

Copenhagen panel data (1981-1983) and 0.00717 (1991-1993) with the Weibull. With GEE, the coefficients were 0.0268 ($P=0.006$) in Australia, 0.0249 ($P=0.008$) in the meta-regression of 16 controlled clinical trials. All three reproduced clinical trials with odds-ratios within 1/100ths. In diabetes, longitudinal analyses of treatment trice reproduced HbA1c reductions by 0.99% (UK), 0.92% (Germany) and 0.89% (US) with complication risks reduced by 0.388%, 0.414% and 0.436% per 1% HbA1c reduction. In pain management, 9 of 10 adverse events are statistically the same in two datasets. GEE analyses from Australia data reproduced 25 epidemiological studies for mortality and HDL-C. **CONCLUSIONS:** Precise reproductions of conditional probabilities across multiple datasets and their numeric reconciliations with other established clinical and epidemiological evidence establish causality. Real World epidemiological studies support clinicaql findings in larger, more general populations and when replicated and reconciled among one provide proof of principle for casual inferences.

PRM97

IDENTIFYING ADMISSION CHARACTERISTICS THAT ARE CORRELATED WITH THE COST OF A COPD-RELATED HOSPITALIZATION – A REGRESSION ANALYSIS OF THE 2012 HCUP-NIS SURVEY DATA SET

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OBJECTIVES: To quantify the association between hospital admission characteristics and cost of a chronic obstructive pulmonary disease (COPD)-related hospitalization to understand which admission factors have the greatest impact on costs of a COPD hospitalization. **METHODS:** A regression analysis was adapted to the 2012 HCUP National Inpatient Survey database (nT = 7,161,567 total admissions, nC = 71,410 COPD-related) to determine if there was an association between admission characteristics and the cost of a COPD hospitalization. After flagging each COPD-related hospitalization based on the reported diagnosis related group (DRG), a multiple linear regression model was implemented to investigate the extent to which the inputs follow the assumptions of linear regression. This led to the log-normal transformation of the dependent variable and exclusion of non-significant inputs. The statistically significant variables were then incorporated into a complex regression model taking into consideration the sample-survey design which included stratification, unequal weighting, and domain subgrouping of the DRGs identified as COPD-related. Estimates for the regression coefficients were computed in SAS 9.3 and included the following variables: length of stay, number of chronic diagnoses at admission, age at discharge, gender, death during hospitalization, elective admission, major OR procedure, and admission during weekends. **RESULTS:** The final model identified the presence of a major OR procedure (Estimated Reg. Coeff. = 0.4965) and the length of stay (Estimated Reg. Coeff. = 0.1505) as the variables that had the greatest impact on cost (log-cost) of a COPD admission. However, the regression calculated a line of best fit that approximated only half of the variance within the observed admission costs ($R\text{-Square} = 0.5217$). **CONCLUSIONS:** Further investigation is needed to identify other factors that impact the correlation between the cost of a COPD hospital stay and admission characteristics.

PRM98

WHY ISN'T IT THE NORM TO USE NORMAL IN PSA?

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OBJECTIVES: Probabilistic Sensitivity Analysis (PSA) investigates the impact of uncertainty around parameter estimates on model results. Many health economics models wrongly use the distribution of the underlying parameters to model the mean estimates in PSA, such as gamma for costs, log-normal for rates and beta for probabilities. However the appropriate distribution to sample mean values is independent of the type of parameter and is always the normal distribution given sufficient sample size. We advocate modeling guidelines should recommend the use of normal distribution when sampling means, when the sample size is large enough. We demonstrate how the PSA results change when the underlying distribution is used rather than the normal distribution. **METHODS:** We used simulation methods to produce several histograms of means, each calculated from samples of increasing size, and compared the distribution of these means against the distributions that are frequently used instead of the normal distribution. We then proceeded to assess the impact of the choice of distribution on the cost-effectiveness results when the means are sampled with a normal distribution vs. the underlying distribution. **RESULTS:** Histograms show that as the sample size increases, the distribution of means calculated using the underlying distribution deviates more from the distribution of the sampled means, which converge in distribution to normal. The model results suggest that using normal distribution instead of the underlying distribution changes the probability of being cost effective. **CONCLUSIONS:** Sampling means from a normal distribution is a more accurate way of representing uncertainty around mean estimates. The use of the underlying distribution to sample from the means leads to inaccurate PSA results. Given the importance of PSA results in making reimbursement recommendations, researchers should be careful to use the appropriate distribution to simulate the means, which is the normal distribution.

PRM99

BAYESIAN ANALYSIS OF FLEXIBLE PARAMETRIC FRAILTY MODELS FOR THE EVALUATION OF REPEAT TREATMENT IN PATIENTS WITH INTERVAL CENSORED DATA: APPLICATION TO A LARGE RANDOMISED CONTROLLED TRIAL IN OVER-ACTIVE BLADDER SYNDROME

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OBJECTIVES: Recurrent events are common in clinical trials of chronic diseases. Due to the ongoing nature of chronic conditions, and consequently clinical trials,

patient follow-up can be intermittent and information regarding the time of symptom development is often unreported or poorly reported. Motivated by a large randomised trial in overactive bladder (OAB) syndrome, interest lies in evaluating the duration of treatment effect defined as the time to patient-reported return of symptoms following repeat injection of botulinum toxin in patients with interval censored data. **METHODS:** Poly-Weibull models were fitted in a Bayesian framework in order to obtain posterior predictive distributions from which to sample unreported event times for interval censored data. To further account for the correlation between repeated events within the same individual, we incorporate a shared frailty term. We applied this methodology to a clinical trial of patients receiving a maximum of 3 repeated injections of botulinum toxin for OAB over a 5 year follow-up period. To compare repeated injection, restricted mean survival time (RMST) was calculated. Performance of Bayesian prediction models were assessed for varying proportions of missing data, and misspecification of distributional form using simulation studies. **RESULTS:** Bayesian flexible parametric frailty models found that there may be a small cumulative effect of botulinum toxin in patients with OAB (RMST1: 0.93, 95%CrI: 0.81,1.05; RMST2: 0.97, 95%CrI: 0.83,1.13; and RMST3: 0.98, 95%CrI: 0.75, 1.24 for active injection 1, 2 and 3 respectively) but this difference was not of clinical or patient importance. Simulation studies found that Bayesian prediction models generally perform well with up to 50% of interval censored data, but care should be taken when selecting distributional form. **CONCLUSIONS:** With an increasing need to assess the time to symptom recurrence in chronic conditions, and the difficulties faced with intermittent follow-up, the use of a flexible Bayesian framework would appear to be advantageous.

PRM100

MODELING MIGRAINE DAY FREQUENCY USING THE BETA-BINOMIAL DISTRIBUTION: A CASE STUDY OF ERENUMAB AS MIGRAINE PROPHYLAXIS

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OBJECTIVES: Current measures of clinical effectiveness of migraine prophylaxis are predominantly based on the reduction in frequency of migraine days (MDs) per 28 days. It is therefore important to accurately link economic and quality of life outcomes to reductions in MD frequency to model the cost-effectiveness of migraine prophylactics. Traditionally, headache day frequency has been characterized by Poisson, binomial and negative binomial distributions, and zero-inflated variants of these. All of these distributions are associated with theoretical and practical limitations. The beta-binomial distribution has been applied in other fields to model this type of count data. This analysis aims to compare the beta-binomial distribution to Poisson, binomial, negative binomial and zero-inflated negative binomial distributions in modeling MD frequency, using data from a phase II study of erenumab (NCT01952574). **METHODS:** The study compared erenumab 70mg against placebo in patients with episodic migraine. Data on the frequency of MDs per 28 days were used to fit Poisson, binomial, negative binomial, zero-inflated negative binomial and beta-binomial distributions. The average root mean squared errors (RMSE) across all 28-day observation periods was used to quantify the deviation of each distribution from the trial observations. **RESULTS:** Data from 257 patients were available from the study, with a maximum follow-up of 64 weeks. The average RMSEs were 0.239, 0.257, 0.104, 0.081 and 0.098 for the Poisson, binomial, negative binomial, zero-inflated negative binomial and beta-binomial distributions, respectively, for the erenumab group, and 0.201, 0.221, 0.089, 0.081 and 0.089 for the placebo group. **CONCLUSIONS:** Based on the RMSE estimates, the negative binomial, zero-inflated negative binomial and beta-binomial provide comparable fits to the trial observations, and fit better than the Poisson and binomial fits. This was observed in both the erenumab and placebo groups. The results suggest that the beta-binomial may be an alternative choice of distribution for modeling MD frequency in migraine populations.

PRM101

PERFORMANCE OF MACHINE LEARNING ALGORITHMS IN PREDICTING 30 DAY HEART FAILURE READMISSIONS RISK USING AN ADMINISTRATIVE CLAIMS DATABASE

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OBJECTIVES: To evaluate machine learning algorithms in modelling the risk of 30-day heart failure (HF) readmissions in a cohort of commercially insured patients in the US. **METHODS:** We used MarketScan commercial claims data (2012-14) to identify a cohort of patients ≥ 18 years admitted with a primary diagnosis of heart failure. Heart failure index admissions and 30 day readmissions were defined using the Centers for Medicare and Medicaid Services (CMS) definitions. Using a combination of CMS defined predictors and empirical analysis, we identified 146 predictors of hospital readmission. Predictors were assessed in the one year period prior to the index heart failure hospitalization. Study data were split into the training set (75%) and the test set (25%). We compared four commonly used machine learning algorithms for binary classification: elastic net regularized generalized linear models, random forests, gradient boosted machines, and support vector machines. We employed 10 fold cross validation on the training set to train each algorithm; predictive performance for each algorithm was assessed using the c-statistic [AUC] on the test set. **RESULTS:** In a cohort of 17,631 patients with a qualifying index admission for heart failure, 2,830 patients had a readmission within 30 days. The mean age of the patients in the cohort was 55 years, and 60.2% were males. Based on the c-statistic on the test set, gradient boosted machines performed the best (AUC 0.66), followed by elastic net

regularized logistic regression (AUC 0.65), random forests (AUC 0.65), and support vector machines (AUC 0.63). **CONCLUSIONS:** Compared to previous models which report an AUC of 0.60, we were able to increase the AUC by 0.06, representing a 12% increase in predictive ability. However, this increase in AUC was largely driven by an increase in the number of predictors rather than any differences in performance between the machine learning algorithms themselves.

PRM102

CALIBRATION OF DISEASE MODELS FOR HEALTH SYSTEMS EVALUATION

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OBJECTIVES: This project examines approaches to the calibration of natural history models from a Bayesian perspective. The result of the calibration is a joint probability distribution of parameters which can be used in a probabilistic analysis (PSA) using a predictive model to compare different interventions. Two diseases are examined. The two models have important differences in terms of the calibration strategies that are employed. The interventions considered for each disease are different too; this affects the choice of model structure. The first disease is HPV, which uses a patient level simulation to account for the transmission dynamic nature of the disease, which is important in considering the impact of herd immunity from vaccination. The second is Hepatitis C, and the purpose of this model is to examine progression of disease and the impact of different strategies for the screen-detected and symptomatic populations. **METHODS:** Markov Chain Monte Carlo (MCMC) sampling was used to obtain samples from the joint distribution for the unobservable parameters and compared with Monte Carlo approach. **RESULTS:** The biggest challenge with HPV model calibration was the extensive unparallelisable computational time (20 days of computing time per chain per processor) that was significantly slowing down the calibration process. The non-identifiability of the parameter space had also a great impact on convergence of chains. A solution to the problem was to impose a structural prior on the joint parameter space. The Hepatitis C model calibration was an easier problem. The convergence was quicker, computational time was acceptable and some sensible predictions were achieved. Adaptive MCMC was used for calibrating this model. **CONCLUSIONS:** Advantages of MCMC: for HPV — a better fit comparing to simple Monte Carlo method; for Hepatitis C — good exploration of the parameter space. Disadvantages of MCMC: poor mixing and convergence for HPV model; additional computational time for Hepatitis C model.

PRM103

MODELING LONGITUDINAL CHANGE IN PATIENT REPORTED OUTCOMES USING LATENT CURVE MODELS

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OBJECTIVES: Latent curve models (LCMs) offer a flexible method for analyzing change over time in patient reported outcomes (PROs). In this presentation, we demonstrate how LCMs can be used to understand within- and between-patient variability and to test a wide array of PRO-focused research hypotheses. **METHODS:** The current study used a simulated data example consistent with data obtained in PRO research to illustrate how a series of LCMs can be applied and interpreted in practice. The outcomes were based on PRO domains of fatigue and physical functioning. We begin by describing independent univariate LCMs for fatigue and physical functioning and then expand these models to the bivariate case (i.e., modeling the longitudinal relationship between fatigue and physical functioning simultaneously). **RESULTS:** The univariate fatigue and physical functioning LCMs showed that patients varied in their baseline levels and rates of change over time in both PRO domains. On average, fatigue increased through the course of the study whereas physical functioning decreased over time. The bivariate LCM, which jointly modeled fatigue and physical functioning, showed that patients with more fatigue at baseline tended to have decreased physical functioning at baseline and patients with greater increases in fatigue over time had faster declines in physical functioning. Further, there was evidence of a negative within-person autoregressive effect of fatigue on physical functioning. More precisely, when a patient was more fatigued than usual on a given day, they had worse physical functioning than usual on the following assessment day. **CONCLUSIONS:** Researchers are often interested in assessing hypotheses concerning longitudinal change in PROs over time. While many traditional statistical methods for repeated measures have limitations (e.g., highly restrictive, no insights on individual differences, disconnect from theoretical models), LCMs offer a dynamic framework for testing many hypotheses relating to between- and within-person change in one or more constructs over time.

PRM104

HOPE, "HEALTH OUTCOMES PERFORMANCE ESTIMATOR": A NEW TOOL TO PREDICT REAL-LIFE OUTCOMES

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OBJECTIVES: A growing number of decision makers are embracing performance-based contracts as the avenue to shift the pharmaceutical business paradigm from selling drugs to selling outcomes. Meaningful performance-based contracts require anticipating clinical outcomes under usual circumstances of care at a time when little evidence exists outside of clinical trials for the new intervention. A novel tool based on bridging-to-effectiveness modeling was developed to anticipate the real-world performance of new drugs. **METHODS:** The tool was built as an R/Shiny-based web interface. The user selects a therapeutic area with a set of outcomes, interventions and real-world practice scenarios to be evaluated. Data

on key patient and drug usage characteristics (effectiveness drivers) and drug efficacy can then be entered either as patient-level datasets or via summary statistics. Real-world outcomes for the selected interventions are predicted over time using a longitudinal Bayesian model with default prior parameter distributions. The tool then jointly simulates the dynamics of outcomes, exposure and effectiveness drivers for any user-defined virtual cohort. Results in terms of comparative effectiveness are displayed along with confidence intervals. **RESULTS:** Two case examples were run with the tool to predict real-world outcomes under various scenarios: prediction of survival in renal-cell carcinoma patients and of hospitalization rates in schizophrenic patients with an exposure first channeled to most severe patients after launch [1]. **CONCLUSIONS:** The tool allows for rapid prediction and visualisation of real-life outcomes with confidence intervals, accounting for all evidence available to the user. This tool could save months of modeling time, e.g., in the context of fast-paced performance-based contract negotiations. 1. Schneeweiss S et al. *Clin Pharmacol Ther.* 2011 Dec;90(6):777-90. <https://www.ncbi.nlm.nih.gov/pubmed/22048230>

PRM105

VALIDATION OF HOSPITAL MANAGEMENT EVALUATING METHODS IN CHINA

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OBJECTIVES: Little is known about the current management practices of the hospitals in China. To address this gap, we developed a comprehensive survey instrument of Chinese Hospital Management Survey (CHMS) following the well-adapted methodology of World Management Survey (WMS). **METHODS:** The Chinese version of CHMS includes questions on 20 management practices covering four major management domains: operation, monitoring, targeting, and incentives. Based on the CHMS setting, four-dimension and twenty-item management models are analyzed with construct validity test, which is performed by confirmatory factor analysis (CFA). **RESULTS:** 810 middle level managers (department directors and head nurses) were recruited from over 400 nationally representative Chinese hospitals and interviewed for the CFA test. The chi-square statistic for the model is 396 with 164 degrees of freedom (p value = 0.000) while CMIN/DF: 2.4, RMSEA: 0.042, indicating a good model fitting. The further indications of model fit, NFI, RFI, IFI, and CFI are all above 0.9 which is the typical benchmark for model acceptance. Our research provides evidence for correspondence between conceptual and empirical hospital management and the insight of model fitting on the current data. **CONCLUSIONS:** Our results conclude that CHMS has satisfied validation in Chinese hospital management practices, providing efficient methods of survey to assess hospital management in China.

PRM106

A META-EPIDEMIOLOGICAL SURVEY OF THE REPORTING OF EFFECT MODIFICATION IN NETWORK META-ANALYSES

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OBJECTIVES: To evaluate the current state of reporting and handling of effect modification in network meta-analyses (NMAs), as well as perform exploratory analyses to identify factors that are potentially associated with incomplete reporting of effect modifiers in NMAs. **METHODS:** We conducted a meta-epidemiological survey utilizing a systematic review of NMAs published in 2013 and identified through MEDLINE and Embase databases. We extracted information and reported descriptive statistics on effect modifiers analyzed, adjustment methods used, study outcomes, and potential independent factors for incomplete reporting. We evaluated three study outcomes: the reported statistical analysis plan, the reported analyses results, and complete reporting (i.e. reporting of both plan and analyses results). We performed univariate logistic regression analyses exploring potential associations between factors and outcomes. **RESULTS:** The review identified 77 NMAs. The most common effect modifier explored was study design (15.4% or 30/195), and most common adjustment method used was sensitivity analysis (40.3% or 31/77). Over 45% (35/77) of studies did not describe a plan, nearly 40% (30/77) did not report the results of analyses, and approximately 47% (36/77) of studies had incomplete reporting. Exploratory univariate regression analyses yielded a statistically significant association for the factors of journal impact factor, ratio of randomized controlled trials to number of comparisons, and total number of randomized controlled trials. **CONCLUSIONS:** Current reporting practices are largely deficient, given that almost half of identified published NMAs do not explore or report effect modification. Journal impact factor and amount of available information in a network were associated with completeness of reporting. This study highlights the need for readers to be aware of whether statistical analysis plans include steps that report and address potential effect modifiers due to the impact they may have on analyses.

RESEARCH ON METHODS – Patient-Reported Outcomes Studies

PRM107

STATISTICAL MAPPING OF UTILITY SCORES FROM THE REVISED FIBROMYALGIA IMPACT QUESTIONNAIRE

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OBJECTIVES: To perform an economic evaluation, mapping from a disease specific measure onto a generic preference-based measure is essential when utility values of health states are not available in the same sample. In fibromyalgia (FM), no

mapping studies have estimated the EQ-5D-3L from the Revised Fibromyalgia Impact Questionnaire (FIQR). This study aimed to predict an EQ-5D-3L utility score from the FIQR. **METHODS:** Data for 160 Spanish adults with confirmed FM according to the American College of Rheumatology 1990 criteria were used. Econometric models investigated were ordinary least square (OLS), censored least absolute deviations (CLAD) and multinomial logistic (MNL) models in ten alternative specifications. Choice of model was based on the 'Best' performance which was defined as: the lowest absolute difference (AD), mean absolute error (MAE), and root mean squared error (RMSE), and the highest R2 statistics. **RESULTS:** The majority of the sample were females ($n=156$, 97.5%), with mean (SD) age of 57.3 (8.8) years. Patients had a mean (SD) FIQR total score of 68.9 (18.87) and a mean (SD) EQ-5D-3L utility value of 0.47 (0.22). The predicted mean utilities in all OLS models were identical (up to four decimals) to the observed means. The OLS model performed best compared with CLAD and MNL with the lowest error statistics (AD = 0.0000; MAE = 0.1279; MSE = 0.1576; R2 = 0.4675). The best performing mapping function, defined by the OLS, is able to predict the EQ-5D-3L tariff score using the 21 FIQR collapsed items in a discrete form, age and educational level. **CONCLUSIONS:** It was feasible to map from the FIQR to the EQ-5D-3L. Over the ten model approaches tested, the OLS was the best performing model which predicted the tariff score of the EQ-5D-3L. Further research is required to verify the mapping function between these two measures.

PRM109

MEASUREMENT PROPERTIES OF THE RASCH-BUILT OVERALL DISABILITY SCALE IN PATIENTS WITH HEREDITARY ATTR AMYLOIDOSIS WITH POLYNEUROPATHY

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OBJECTIVES: The Rasch-built Overall Disability Scale (R-ODS) was initially designed and validated to measure activity and social participation limitations in patients with immune-mediated peripheral neuropathy. The objective of this research was to generate evidence on the measurement properties of the R-ODS in patients with symptomatic hereditary ATTR amyloidosis (hATTR amyloidosis) with polyneuropathy. **METHODS:** Assessments ($n=359$) of the 24 R-ODS items were collected in the patisiran phase 2 open-label extension (OLE, NCT01961921) and the APOLLO phase 3 placebo-controlled trials (NCT01960348). Trial participants were symptomatic hATTR patients with polyneuropathy, including a broad range of disease severity as measured by mobility impairment and broad range of underlying genetic mutations. The data underwent a comprehensive psychometric analysis based on Rasch Measurement Theory. **RESULTS:** R-ODS items covered a wide spectrum of activity and social participation limitations that essentially captured the significant breadth of limitations observed in the patient sample (96% of the range covered). However, the coverage of the part of the continuum corresponding to the lowest levels of limitation (i.e. the most "difficult" activities) could be improved. The 3-point response scale of the R-ODS was appropriate, as all response options for all items were correctly ordered. Most items showed acceptable fit to the Rasch model. The reliability of the R-ODS measure was good (Person Separation Index: 0.95). Item responses were stable between subgroups (age, gender, global region, genotype), with a very small number of items showing Differential Item Functioning, mostly between global regions. **CONCLUSIONS:** Overall, the R-ODS is an appropriate measure of activity and social participation limitations in hATTR patients with polyneuropathy. Further research is needed to understand and assess the tool's sensitivity to detect changes in these limitations over time.

PRM110

AN EVALUATION OF THE PSYCHOMETRIC PROPERTIES OF THE SF-12V2 HEALTH SURVEY AMONG ADULTS WITH HEMOPHILIA IN THE UNITED STATES

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OBJECTIVES: This study examined the psychometric properties of version 2 of the SF-12 Health Survey (SF-12v2) among adults with hemophilia in the United States. **METHODS:** A cross-sectional design using web-based and paper-based self-administered surveys was utilized. Patients were recruited using an online panel, a Facebook community of hemophilia patients, and a hemophilia treatment clinic. The psychometric properties of the SF-12v2 were assessed for construct validity, internal consistency reliability, and presence of floor and ceiling effects. **RESULTS:** A total of 218 respondents completed the survey, with most recruited via the online panel ($n = 197$). Confirmatory factor analysis using the WLSMV estimator in Mplus supported a two-factor model for the SF-12v2 where the physical functioning, role physical, bodily pain, and general health items loaded onto a latent physical factor (LPF) while the role emotional, mental health, social functioning, and vitality items loaded onto a latent mental factor (LMF). Correlated residuals for items belonging to similar domains were estimated and there was a significant correlation between LPF and LMF. All standardized factor loadings were strong and statistically significant, indicating adequate convergent validity. Item-to-other scale correlations were lower than item-to-hypothesized scale correlations and model testing revealed that LPF and LMF were not perfectly correlated, suggesting good item and construct discriminant validity. Significant decreases in physical component summary (PCS) and mental component summary (MCS) scores were associated with increasing symptom severity, supporting known-groups validity. Internal consistency reliability was satisfactory, with Cronbach's alpha of 0.848 for the LPF and 0.785 for the LMF items. None of the participants received the least or maximum possible PCS or MCS score,

indicating the absence of floor and ceiling effects. **CONCLUSIONS:** Overall, the SF-12v2 was found to be psychometrically valid. These results provide a basis for its use in future studies designed to measure the health-related quality of life of adults with hemophilia.

PRM111

QUALITATIVE RESEARCH TO EXPLORE THE PATIENT EXPERIENCE OF X-LINKED HYPOPHOSPHATAEMIA (XLH) AND TO EVALUATE THE CONTENT VALIDITY OF THE BPI-SF AND WOMAC® FOR USE AS CLINICAL TRIAL ENDPOINTS

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OBJECTIVES: XLH is a rare genetic disorder in which low serum phosphorus levels lead to defective bone mineralization and consequently to rickets in children and osteomalacia in adults. Research concerning the patient experience of XLH is lacking. This qualitative interview study was conducted to address this gap in published literature and to evaluate the face and content validity of the Western Ontario McMaster Universities Osteoarthritis Inventory (WOMAC®) and Brief Pain Inventory-Short Form (BPI-SF) for use as endpoints in adult XLH clinical trials. **METHODS:** Face-to-face, semi-structured interviews were conducted with 18 adults with XLH in the US. Open-ended questioning was used to elicit spontaneous concepts relevant to the patient experience of XLH, focusing on the symptoms and functional limitations associated with the disease. Cognitive debriefing of the WOMAC® and BPI-SF was also conducted to assess the relevance of items and patient understanding of item wording, recall period, and response options. **RESULTS:** Thirty-two distinct symptom concepts were elicited including pain symptoms, systemic symptoms, sensory symptoms, tiredness/fatigue symptoms, and musculoskeletal symptoms. Participants reported experiencing significant bone and joint pain, stiffness, mobility limitations, and an impact on their ability to work due to symptoms. A conceptual mapping exercise indicated that the key symptom and impact concepts reported by patients are assessed by the BPI-SF and WOMAC®, confirming their relevance to XLH patients. This was supported by the cognitive interviewing which found both instruments to be relevant and well understood by the majority of patients. **CONCLUSIONS:** These interviews generated rich, qualitative insight into the patient experience of XLH. There was strong support for the face and content validity of the BPI-SF and WOMAC®, suggesting both instruments are suitable as XLH clinical trial endpoints with respect to these aspects of validity. Psychometric evaluation is recommended to establish the reliability, validity, and ability to detect change of these instruments.

PRM112

CONTENT VALIDITY OF QUESTIONNAIRES ASSESSING INJECTION REGIMEN BURDEN IN GROWTH HORMONE DEFICIENT (GHD) ADULTS AND CHILDREN TREATED WITH GROWTH HORMONE

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OBJECTIVES: To understand the burden of GHD injection regimen and evaluate patient understanding of and ability to respond to newly developed questionnaires assessing human growth hormone (hGH) injection regimen burden. **METHODS:** A review of the empirical literature identified concepts relevant to hGH injection burden, with a focus on treatment regimen. Results informed the conceptual framework and two questionnaire batteries were designed to assess aspects of the treatment burden relating to using hGH injection in adult and pediatric patients. Expert advice meetings were conducted to confirm key measurement concepts and gather feedback on the questionnaires. Individual hybrid concept elicitation (CE) and cognitive debriefing (CD) interviews were conducted with patients (and caregivers of pediatric patients) to explore and confirm injection treatment burden concepts important to patients and caregivers, and to evaluate comprehensiveness of the questionnaires and respondents' ability to understand and respond to the questionnaire instructions and items. **RESULTS:** Results from the literature review (N=30 articles) and input from US (n=3) and European (n=3) experts facilitated the generation of questionnaire content assessing: (1) pen ease of use; (2) regimen convenience; (3) patient, caregiver, and family life interference due to regimen; (4) benefit/satisfaction/willingness to continue treatment; (5) regimen choice/preference; (6) intent to comply with regimen; (7) injection-related signs/symptoms; and (8) reasons for missed injections. Hybrid interviews with 21 patients (adults [n=6] and child/parent dyads [n=15]) confirmed that the questionnaires comprehensively capture their hGH injection-related treatment regimen experience (including key concepts), and are easily understood. Minor wording revisions improved question clarity and understanding of the concept. **CONCLUSIONS:** Findings from this research support the content validity of the questionnaires; resulting in new clinical outcome assessment measures to assess hGH injection regimen burden for adults, children and their caregivers.

PRM113

PREDICTORS OF UTILITY OVER TIME AMONG PATIENTS WITH TREATMENT-NAIVE ADVANCED MELANOMA FROM THE PHASE 3 CHECKMATE 067 TRIAL: 28-MONTH UPDATE

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OBJECTIVES: The aim was to update previous analyses of predictors of health-related quality of life over time to estimate utilities for patients with treatment-naive advanced melanoma using the 28-month data cut from the randomized

CheckMate 067 trial comparing nivolumab + ipilimumab, nivolumab monotherapy, and ipilimumab monotherapy for use in a cost-effectiveness model (CEM). **METHODS:** The EQ-5D was administered at baseline and every 6 weeks in CheckMate 067 and was used to generate index utility scores using the UK time trade-off method. Covariates were based on a combination of prior analyses of large trial data sets, including patient demographic and clinical characteristics, quantitative metrics of fit, qualitative/clinical plausibility, and relevance to the CEM. Several longitudinal mixed linear models were explored using different covariate sets. **RESULTS:** This analysis included 916 patients and 7735 visits where the EQ-5D was administered. Mean baseline utility score was 0.774 for nivolumab + ipilimumab patients, 0.779 for nivolumab patients, 0.773 for ipilimumab patients, and 0.775 across all patients. The final model selected included baseline utility (to adjust for imbalance between treatment arms), progression status (pre/post), and treatment arm. Parameter estimates in the model were 0.418 for baseline utility ($p < 0.001$), -0.035 for progression status ($p < 0.001$), and -0.028 ($p = 0.042$) and -0.026 ($p = 0.064$) for ipilimumab and nivolumab + ipilimumab (vs. nivolumab), respectively. Additional models including time before death or end of follow-up were tested, but the selected model was found to be a better fit to the data. When implemented in the CEM, the utility estimates for the preprogression and postprogression states were 0.792 and 0.758, respectively (applying nivolumab as the reference treatment arm). **CONCLUSIONS:** Results showed that baseline utility, progression, and treatment were predictors of utility over time, which is consistent with prior analyses of this trial as well as other nivolumab monotherapy and ipilimumab monotherapy trials.

PRM114

EQ-5D-3L UTILITIES TARIFFS: DIFFERENCES IN GERMAN AND UK UTILITIES AND QALYS IN PATIENTS WITH MODERATE TO SEVERE PSORIASIS

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OBJECTIVES: Health utilities needed for quality-adjusted life-years (QALYs) are often measured by instruments such as the EQ-5D-3L, with utility weights calculated by country-specific algorithms. This analysis explored the differences in utilities and QALYs when applying two different national EQ-5D-3L algorithms. **METHODS:** EQ-5D-3L data came from CLEAR, a phase 3b, 52-week, head-to-head study comparing the efficacy and safety of secukinumab versus ustekinumab in adults with moderate to severe plaque psoriasis. EQ-5D-3L was assessed at baseline and weeks 4, 8, 12, 16, 28, 48, and 52. Utilities were calculated from observed data, using algorithms from Germany and the United Kingdom (UK). Treatment response was defined as Psoriasis Area Severity Index (PASI) reduction of < 50% (i.e., PASI 50), 50-74, 75-89, and 90-100. A linear mixed model evaluated the relationship between EQ-5D-3L utility score and PASI, with the baseline utility score used as a covariate. QALYs were calculated in an existing cost-effectiveness Markov model evaluating biologic psoriasis treatments over 10 years. **RESULTS:** Utility estimates derived from the German algorithm were higher than those derived from the UK algorithm. Differences decreased with higher PASI response. The mean baseline utility scores (0.8039 and 0.6812 for Germany and UK, respectively) were included in the Markov model to estimate the utility scores by PASI response. Estimated utility weights using German and UK algorithms were 0.888 and 0.801 for PASI 50; 0.924 and 0.850 for PASI 50-74; 0.937 and 0.880 for PASI 75-89; 0.951 and 0.908 for PASI 90-100, respectively. This resulted in lower incremental QALYs with German utilities than with UK utilities (0.068 vs. 0.095, respectively). **CONCLUSIONS:** Applying different country-specific utility algorithms to EQ-5D-3L clinical trial data provided substantially different utility weights, affecting incremental QALY estimates in moderate to severe psoriasis. This variance should be considered when interpreting the results of cost-effectiveness analyses.

PRM115

ARE PATIENT'S RESPONSES TO FIVE POINT VERBAL DESCRIPTOR SCALES AND VISUAL ANALOGUE SCALES REPLICATE MEASURES? AN EXPERIMENTAL MANIPULATION

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OBJECTIVES: To determine if verbal descriptor scale (VDS) categories are equidistant from each other, represent unique response choices in patient-reported outcome measures and are equivalent to visual analogue scales. **METHODS:** 400 subjects were sampled 1:1:1:1 across four disease areas: type-2 diabetes, chronic obstructive pulmonary disease (COPD), depression, and osteoarthritis. Recruitment employed population sampling methods in Boston, MA. Enrolled subjects participated in an experimental design assessing general health rating styles. Subjects mapped VDS categories (none, very mild, moderate, severe, and very severe; the mild category was omitted by design) to the corresponding locations on a vertically-oriented VAS (unanchored and scored 0-100 in ascending order from bottom to top of VAS) The association between VAS score and VDS was examined. **RESULTS:** 419 subjects were enrolled from each of the four disease areas, with n=104 for all except depression (n=107). Four VAS responder-profiles were detected: ascending, descending, mis-ordered, and missing data. Ascending subjects (n=55) mapped the VDS ratings from the bottom to top of the VAS (none=0 : very severe=100). Descending subjects (n=187) ordered VDS ratings from top to bottom of the VAS (none=100 : very severe=0). Mis-ordered subjects (n=75) mirrored descending subjects without monotonic ordering. Missing subjects (n=102) were missing at least one VDS rating, and generally mirrored the descending pattern. Whether subjects employed an ascending or descending VAS response-profile, average VAS scores corresponding to each VDS category were proportionately ordered. **CONCLUSIONS:** Comparing VAS

and VDS response-profiles, subjects inconsistently interpreted the unanchored VAS. In spite of interpretation heterogeneity, when VDS ratings were mapped to a VAS, average VAS scores were approximately equidistant and ordered monotonically. Therefore, the expected VDS scores appear to satisfy the proportional odds assumption for the VAS.

PRM116

MODE COMPARISON IN ELICITING PREFERENCES FOR CARE-RELATED QUALITY OF LIFE: EVIDENCE FROM ENGLAND USING THE ASCOT SERVICE USER MEASURE

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OBJECTIVES: Traditionally, researchers relied on eliciting preferences through face-to-face interviews. Recently, there has been a shift towards using alternative modes, such as the internet, to gather such data. These different modes may be a source of variation in the results. In health services research, preferences are important as they provide an estimate of the value of each quality of life state, and can be used as weights to reflect the differential utility of each state. In this study, we compare the preferences elicited from two modes of administration (internet versus face-to-face) for the best-worst scaling (BWS) technique using the Adult Social Care Outcomes Toolkit service user measure (ASCOT-S). **METHODS:** Data were collected from a representative sample of the general population in England. The respondents (face-to-face: n=500; online: n=1,001) completed a survey which included the BWS experiment involving the ASCOT-S, consisted of 32 tasks which were blocked into 4 segments. Multinomial logistic regressions were undertaken to analyse the data. To allow for direct comparisons between the modes, model coefficients were standardised. **RESULTS:** Respondents in the face-to-face survey placed lower value on the lower levels of all ASCOT-S domains, except social participation, than those in the internet survey. The highest point difference of 0.12 was observed in Level 2 of the occupation domain. For the highest level of all ASCOT-S domains, except social participation, preference weights were higher in the face-to-face survey than the internet with point differences of up to 0.10. **CONCLUSIONS:** This study compared utility weights obtained from a BWS exercise using two modes of administration for the ASCOT-S. The findings showed variation of responses between the two modes. Most differences were not significant and were low in absolute value. This suggests that preference weights are similar across the different modes of administration. We reflect on the implications of these findings for cost-effectiveness research.

PRM117

PSYCHOMETRIC VALIDATION OF THE ATOPIC DERMATITIS IMPACT QUESTIONNAIRE (ADIQ)

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OBJECTIVES: Atopic dermatitis (AD) is associated with substantial impairment of patients' health-related quality of life (HRQoL). A new instrument, the AD Impact Questionnaire (ADIQ), was developed following FDA PRO Guidance (2009) to assess impact of AD on patients' lives. The ADIQ was included in a Ph2 clinical trial and data from that trial was used to assess measurement properties. **METHODS:** In a Ph2 clinical trial 209 patients aged 18-75y with moderate-to-severe AD (after initial screening and a 2-week topical corticosteroid [TCS] run-in period), were randomized to receive lebrikizumab 125mg Q4W, 250mg single dose (SD), 125mg SD, or placebo (PBO) plus twice-daily medium-potency TCS to all lesional skin for 12 weeks. Secondary analyses of screening, run-in, and Week 12 data, were used to evaluate item-level statistics, scaling structure, reliability and validity. Data from all arms were pooled to assess measurement properties of the ADIQ. Data from patients with stable disease, i.e. less than a meaningful change (6.6pts) on the Eczema Disease Severity Index (EASI), was used for analyses with multiple time-points, e.g. test-retest. **RESULTS:** 203 (97%) patients completed the ADIQ at screening. It showed evidence of adequate reliability ($\alpha=0.76$); reproducibility (ICC = 0.95); and validity, with the latter including moderate correlations with the Dermatology Life Quality Index (DLQI; $r=0.84$), and patient-reported components of SCORing Atopic Dermatitis [SCORAD; $r=0.41$ (pruritus) and 0.46 (sleep loss)] at screening. Concurrent correlation between the ADIQ and indices of disease severity, [overall SCORAD, EASI and Investigator Global Assessment (IGA)] was relatively low. However, change in ADIQ from screening to Week 12 readily detected minimal important differences in disease severity over the same time period, with SCORAD, EASI and IGA concordance indices ranging from 0.76 to 0.81. **CONCLUSIONS:** Results suggest the ADIQ is a reliable and valid measure to assess treatment benefit on AD patients and can complement disease severity assessments.

PRM118

A SYSTEMATIC REVIEW OF QUALITY OF LIFE DOMAINS AND ITEMS RELEVANT TO QUALITY OF LIFE TO PATIENTS WITH SPONDYLOARTHRITIS

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OBJECTIVES: To summarize, from the literature, Quality of Life (QoL) domains and items relevant to patients with Spondyloarthritis (SpA), and to determine if commonly used SpA Patient-Reported Outcome (PRO) instruments include the identified domains. **METHODS:** We used PRISMA criteria for systematic review and searched Medline® Embase® and PsycInfo® using relevant keywords. In addition, hand searches of references of the included articles were conducted. All articles were reviewed for inclusion by 2 independent reviewers. Articles were included if they contained information on domains and/or items of relevance to QoL of patients with SpA derived from patients' own perceptions or reports. QoL domains

and items relevant to patients with axial or peripheral SpA were extracted and presented using the adapted World Health Organization Quality of Life (WHOQOL) domain framework. SpA PROs were assessed to determine if they included the domains identified. **RESULTS:** We retrieved 14,343 articles, of which 34 articles fulfilled inclusion criteria for review. 25 articles were conducted in the European population. Domains such as negative feelings and activities of daily living were found to be present in 28 and 27 articles respectively. SpA impacted QoL in all domains of the adapted WHOQOL framework. Domains that differed between types of SpA were financial resources, general levels of independence and medication side effects. Embarrassment, self-image and premature ageing were items that differed by geographical setting. PROs to capture domains for peripheral SpA were similar for axial SpA. **CONCLUSIONS:** We found that a wide range of domains and items of QoL were relevant to patients with SpA with minimal differences between patients with axial and peripheral SpA. Clinicians may consider using peripheral SpA PROs to measure QoL of patients with axial SpA.

PRM119

LINGUISTIC VALIDATION OF THE NEUROGENIC BOWEL DYSFUNCTION SCORE IN JAPANESE

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OBJECTIVES: The Neurogenic Bowel Dysfunction score (NBD score) is a self-reported symptom-based score for neurogenic bowel dysfunction that takes into account both constipation and fecal incontinence, and weighs each symptom of NBD according to its impact on self-reported quality of life (QoL). It is used for the clinical assessment of colorectal and anal dysfunction in persons with spinal cord injury (SCI). Our objective was to perform a cultural adaption/linguistic validation of the questionnaire into Japanese for use in Japan by following FDA PRO Guidance- and ISPOR-compliant methodology. **METHODS:** The NBD Score was translated into Japanese utilizing the following process: two forward translations, reconciliation of the forward translations, back translation, and resolution of the back translation with the forward translation. The project team reviewed the translated version before the instrument was evaluated in cognitive interviews (CIs) with a sample of five Japanese individuals with neurogenic bowel dysfunction. **RESULTS:** Conceptual issues related to the English source text were identified by the Sponsor during review of the final, validated translation. For example, the first item does not include "once a week" as a response option. While this was noted by the respondents during cognitive interviewing, it did not impact their comprehension of the question or the instrument. Any update to the Japanese translation to include this response choice would require an amendment to the original English text. **CONCLUSIONS:** Through the rigorous translation/adaptation and review process, as well as verification through cognitive interviews, the translation of the NBD score questionnaire into Japanese is considered to be conceptually equivalent and culturally appropriate for the target population. The Japanese version is now linguistically validated for use in clinical trials.

PRM120

DERIVING MAPPED HEALTH STATE UTILITY VALUES FOR ECONOMIC EVALUATION USING SUMMARY HEALTH RELATED QUALITY OF LIFE MEASURES AS SUFFICIENT STATISTICS

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OBJECTIVES: Health state utility values (HSUV) required for pharmacoeconomic evaluations are often unavailable from randomised controlled trials (RCTs). Instead some RCTs collect health related quality of life (HRQoL) data and mapping methods have been developed to derive utilities from such data for pharmacoeconomic evaluations. Published mapping algorithms are either linear functions of detailed HRQoL item level data or nonlinear functions of domain scores, which require individual patient data as inputs. Researchers often do not have access to item scores or individual patient data, but are more likely to have summary domain score data available to them. The objective of this study was to propose methods to obtain HSUV from nonlinear mapping algorithms using summary HRQoL domain scores. **METHODS:** We used a linear Taylor approximation to a nonlinear mapping algorithmic function of summary HRQoL domain scores centred at the midpoint of a clinically important difference. We illustrate this for estimating utility values before and after disease progression, using summary domain scores of the FACT-G from an RCT of a targeted therapy for advanced cancer, as inputs to the response mapping algorithm estimated by Longworth. We compare our results with mapped utilities obtained from the best fitting (linear) item-level algorithm using individual patient data. **RESULTS:** We found that the utility of stable disease was 0.783 with the linearised algorithm and 0.779 (95% CI: 0.763 - 0.796) with the best-fitting algorithm using IPD; utility post-progression was 0.747 and 0.725 (95% CI: 0.706 - 0.744), respectively. **CONCLUSIONS:** Linearisation of existing non-linear mapping algorithms may be used to obtain reliable HSUV for informing healthcare decisions, in the common situations where only summary HRQoL domain score data are available for research.

PRM121

PSYCHOMETRIC EVALUATION OF THE BRIEF PAIN INVENTORY - SHORT FORM (BPI-SF) AND WESTERN ONTARIO AND MCMASTER UNIVERSITIES OSTEOARTHRITIS INDEX (WOMAC®) FOR USE IN X-LINKED HYPOPHOSPHATAEMIA (XLH), A RARE GENETIC DISORDER

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OBJECTIVES: XLH is a rare genetic disorder in which adults typically experience significant symptoms including skeletal pain, stiffness, and impaired mobility. To

date, no validated measures exist to quantify these symptoms from the patient's perspective. The current study evaluated the psychometric properties of the BPI-SF and WOMAC® to assess their suitability for use as clinical trial endpoints to measure pain, stiffness, and physical functioning in adults with XLH. **METHODS:** Data from an online burden of illness (BOI) study (n=201) and data from an open-label phase 2b clinical trial (n=20) were used to evaluate the psychometric properties of the BPI-SF and WOMAC in adult patients with XLH. Psychometric analyses included construct validity (confirmatory factor analysis, known groups method, convergent and discriminant validity), reliability (inter-rater, test-retest reliability) and ability to detect change. Exploratory analyses were also conducted to define meaningful change on the BPI-SF and WOMAC. **RESULTS:** Confirmatory Factor Analysis demonstrated appropriate item-score groupings for both the BPI-SF and WOMAC with the majority of model fit statistics surpassing a-priori thresholds. BPI-SF and WOMAC scores were able to significantly differentiate between groups of patients defined according to a range of clinical and demographic characteristics. BPI-SF and WOMAC scores were positively and strongly correlated with measures of similar concepts in the BOI sample. Strong reliability (internal consistency ($\alpha = 0.81-0.96$), test-retest ($= 0.43-0.82$)) was also established for both instruments. The responsiveness analysis was limited due to the small sample size in the trial population. MID values (anchor and distribution-based) were most consistent for the BPI-SF pain severity (0.91-1.62), BPI-SF pain interference (0.59-1.86), and WOMAC Pain scores (7.24-11.28). **CONCLUSIONS:** These findings provide evidence that the BPI-SF and WOMAC are valid and reliable measures of pain, stiffness, and physical functioning impairments in XLH.

PRM122

HOW WELL DOES THE EQ-5D-5L SCREEN FOR MENTAL HEALTH COMPARED TO THE SF-12?

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OBJECTIVES: To examine the performance of EQ-5D-5L (index score; anxiety/depression dimension), and the SF-12 version 2 (feeling downhearted/depressed item, mental health (MH) domain, and the Mental Composite Summary (MCS) score) in identifying individuals with depressive symptoms. **METHODS:** Baseline data from a cohort study of adults with type 2 diabetes in Alberta, Canada were used. The EQ-5D-5L index score and MCS were categorized into quintiles, and the MH domain into quartiles. Both EQ-5D-5L anxiety/depression dimension and SF-12 feeling downhearted/ depressed item have five levels. Depressive symptoms "DS" (using the Patient Health Questionnaire 8 items, PHQ) were categorized into two severity levels: any DS (PHQ \geq 10) vs. absent DS (PHQ<10); moderate-severe DS (PHQ \geq 15) vs. absent moderate-severe DS (PHQ<15). We calculated sensitivity (Sn), specificity (Sp), and area under receiver operator curve (AUROC) for each of the measures' elements for each DS level. **RESULTS:** For any level of DS: optimal performance was at quintile 4 for EQ-5D-5L index score (Sn=83%; Sp=69%; AUROC=0.76), level 2 for anxiety/depression dimension (Sn=92%; Sp=64%; AUROC=0.78), level 3 for feeling downhearted/depressed item (Sn=72%; Sp=81%; AUROC=0.76), quartile 3 for MH domain (Sn=85%; Sp=71%; AUROC=0.78), and quintile 4 for MCS (Sn=90%; Sp=72%; AUROC=0.81). Overall AUROC were highest for MCS (0.90) and EQ-5D-5L anxiety/ depression (0.87). For moderate-severe DS: optimal performance was at quintile 4 for EQ-5D-5L index score (Sn=93%; Sp=64%; AUROC=0.79), level 3 for anxiety/depression dimension (Sn=77%; Sp=89%; AUROC=0.83), level 3 for feeling downhearted/depressed item (Sn=84%; Sp=76%; AUROC=0.80), quartile 3 for MH domain (Sn=96%; Sp=65%; AUROC=0.80), and quintile 5 for MCS (Sn=88%; Sp=86%; AUROC=0.87). Overall AUROC were highest for MCS (0.90) and EQ-5D-5L anxiety/depression (0.90). **CONCLUSIONS:** The EQ-5D-5L performed very well as a screen for mental health in this population. The anxiety/depression dimension performed similarly to the SF-12 MCS and slightly better than the SF-12 MH domain in identifying depressive symptoms.

PRM123

A TALE OF TWO SURVEYS: PATIENT SURVEY RECRUITMENT VIA EMAILS AND LETTERS

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OBJECTIVES: To compare and contrast patient survey recruitment via pre-notification emails and mailed letters. **METHODS:** Patients were recruited for two survey studies using pre-notification emails and mailed letters. Study A's target population consisted of survey-eligible, commercially-insured patients with cardiac arrhythmia and Study B consisted of survey-eligible, commercially-insured type-2 diabetic insulin users. Patients for both studies were identified from administrative claims in the HealthCore Integrated Research Database. Study participation consisted of completing a one-time survey either via the internet or over the telephone. The protocols and all survey materials were approved by the New England Institutional Review Board. The recruitment pre-notification e-mails and letters contained information regarding the purpose of the survey, who was conducting the survey, participation criteria, a link to complete the survey via the internet and a phone number to complete the survey over the telephone. Patients who did not respond to the e-mails or letters were contacted by telephone and consenting patients completed the survey over the telephone. Summary sample dispositions, survey metrics and rates were calculated by study and type of recruitment and a descriptive analysis was conducted. **RESULTS:** Of Study A's 2,657 emails, 353 responded, 118 consented, 91 qualified and 80 completed the survey; of Study A's 3,638 letters, 447 responded, 268 consented, 230 qualified, and 224 completed the survey. Study A's email and letter list completion rates were 3.0% and 6.2%; cooperation rates were 24.5% and 54.8%. Of Study B's 4,624 emails, 376 responded, 251 consented, 207 qualified and

164 completed the survey; of Study B's 5,132 letters, 419 responded, 298 consented, 253 qualified, and 236 completed the survey. Study B's email and letter list completion rates were 3.5% and 4.6%; cooperation rates were 49.4% and 63.1%. **CONCLUSIONS:** More research is necessary to determine the impact of these recruitment methods in other therapeutic areas and study designs.

PRM124

ADAPTING THE MEDICATION ADHERENCE REASONS SCALE (MAR-SCALE) FOR ONLINE ADMINISTRATION ACROSS MULTIPLE COMORBID CONDITIONS, MODES OF ADMINISTRATION, AND FREQUENCIES OF USE

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OBJECTIVES: Medication non-adherence can limit the full realization of treatment benefits for patients. Numerous factors account for non-adherence, including various reasons reported by patients via the Medication Adherence Reasons Scale (MAR-Scale). The current objective was to revise the MAR-Scale to extend its scope to various comorbid conditions across modes and frequencies of administration. **METHODS:** The MAR-Scale items and presentation were adapted in collaboration with input from patients, healthcare professionals, researchers, and survey programmers, to accommodate different modes and frequencies of administration and up to 17 comorbid condition groups (including arthritis, diabetes, and pain). The presentation and programming were modified with the intention of engaging respondents and minimizing fatigue/burden, while encompassing the broader scope. **RESULTS:** The original MAR-Scale was reorganized into an online grid format where each item is answered across conditions (adjacent columns). Respondents enter a number within a valid range for each item within a condition, instead of selecting among predetermined response option boxes. Respondents are asked about any prescription medication(s) taken per condition, albeit broken out by administration mode (oral, topical, self-injection) and frequency (daily, weekly). MAR-Scale items were revised to accommodate the different modes; similarly, response options were adapted with respect to past 0-7 days for daily use (as per the original) or 0-4 weeks for weekly use. Mode (3) by Frequency (2) combinations result in up to six MAR-Scale grids completed separately. Introductory instructions were modified to highlight the focus of each version. The modified MAR-Scale will be administered to approximately 20,000 participants for further testing, revision, and validation. **CONCLUSIONS:** The original, treatment-specific MAR-Scale was adapted to provide real-world data across various conditions and modes and frequencies of administration (for each patient). This revised measure allows for a broader assessment of patients' treatment experiences and challenges, thereby helping inform more programmatic interventions intended to improve adherence within and across conditions.

PRM125

INVESTIGATING THE RELATIVE VALUE OF HEALTH AND SOCIAL CARE RELATED QUALITY OF LIFE USING DISCRETE CHOICE

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OBJECTIVES: A key outcome in the economic evaluation of health interventions is the Quality Adjusted Life Year (QALY). The quality of life (QoL) weights used to estimate QALYs are generally provided by preference-based measures of health such as the EQ-5D. However, interventions can also result in improvements in non-health related QoL (e.g. social care), but currently these effects are only partially captured. The aim was to investigate the feasibility of using Discrete Choice Experiment (DCE) methods to understand the relative relationship between, and derive preferences for, health and social determinants of QoL (described using EQ-5D-5L and ASCOT). **METHODS:** An online DCE was carried out in Australia. Respondents were presented with choice sets including two profiles with attributes from both the EQ-5D-5L and ASCOT. Each respondent completed 15 tasks from an underlying design of 300 choice sets. Analysis used standard approaches to analyzing DCE data, employing conditional logit modelling to estimate coefficient decrements for each level of each attribute to examine the relative importance of each. **RESULTS:** The results suggest that the levels of the majority of the dimensions are monotonic. There is clear trading between health and social care, indicated by differences in the magnitude of the coefficients across the different aspects of QoL included in the DCE tasks. Respondents reported being able to conceptualise the states presented and complete the tasks, but there was some incomplete surveys. **CONCLUSIONS:** We have tested a possible choice based approach that will allow us to make inferences about QoL based on data obtained from different preference based instruments. DCE is a feasible method to improve our understanding of how aspects of health related and social care related QoL are traded against other, and the relative importance of each. The data also provide a basis for stimulating further research in this area.

PRM126

PAIN ASSESSMENT: A MYRIAD OF TECHNIQUES TO MEASURE PAIN SEVERITY – DOES IT MATTER WHICH ONE IS USED?

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OBJECTIVES: A variety of methods have been developed to assess pain severity. This study was conducted to determine if there are meaningful differences in responses across the different techniques. **METHODS:** 400 subjects were sampled 1:1:1:1 across four disease areas: Type-2 Diabetes, Chronic Obstructive Pulmonary Disease, Depression, and osteoarthritis. Recruitment employed free-media-advertising-based population sampling methods in Boston, MA. Eligible adult

subjects were screened to confirm diagnosis and disease severity. As part of a larger study, enrolled subjects completed multiple single-item pain assessments: a horizontal and vertical polar-anchored visual analog scale (VAS; scored 0-100), two 11-point numerical rating scales (NRS; polar-anchored and box-plot), and a single six-point verbal descriptor scale (VDS; no, mild, moderate, intense, very intense, and excruciating pain). Responses on all pain items were compared to determine subject consistency in response across modes of assessment. **RESULTS:** 419 subjects were enrolled from each of the four disease areas, with n=104 for all except Depression (n=107). Vertical and horizontal VAS scores were not perfectly correlated, but nearly ($r=0.9$). VAS scores correlated strongly with both NRS and the VDS item: $r=0.9$, $r=0.9$, and $r=0.8$, respectively. Average VAS scores were monotonically and proportionately ordered across VDS levels: 5.9, 23.4, 49.4, 68.9, 77.1, and 94.2, respectively. However, substantial heterogeneity was noted for each VDS level: range of 0-63, 3-93, 10-88, 0-97, 10-100, and 81-99, respectively. N=159 (39%) subjects preferred the polar-anchored NRS to other methods of assessment. The main reason for preferring the polar-anchored NRS was ease of use. The second most preferred method was the six-point VDS, preferred by n=143 (35%). **CONCLUSIONS:** Single-item pain assessments are myriad. Subjects do not respond identically across administration forms. However, forms are strongly correlated. Within a given VDS rating substantial variance in VAS scores is observed. Subjects prefer the ease of use of the polar-anchored NRS.

PRM127

COMPARING HEALTH-RELATED QUALITY OF LIFE OF SCHIZOPHRENIA PATIENTS WITH PREDOMINANT NEGATIVE SYMPTOMS TREATED WITH CARIPRAZINE AND RISPERIDONE

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OBJECTIVES: Our study aimed at assessing the health-related quality of life gain with the drug cariprazine in the treatment of schizophrenia for patients with predominant negative symptoms (PNS) compared to risperidone. **METHODS:** We conducted a data analysis on individual patient level data derived from the RGH-188-005 clinical trial. The 30 items of the Positive and Negative Syndrome Scale (PANSS) were used to categorize patients into 8 different health states defined according to the approach of Mohr and Lenert published in 2004 and 2005. Utilities were assigned to Mohr-Lenert health states in accordance with the 2004 publication by Lenert et al. A Bayesian polytomous state transition model with an uninformative prior was constructed with the software WinBUGS with the involvement of three psychiatrists. This was linked to a Markov model with 8 health states based on the 8 Mohr-Lenert health states to estimate the potential gains in quality-adjusted life years (QALYs) of patients. Therapy switch as an option was built into the model, linked to lack of efficacy and adverse events to reflect real-life treatment patterns. **RESULTS:** Based on the transition relative frequency matrices, patients had a higher probability of reaching better health states on the cariprazine arm of the RGH-188-005 clinical trial compared to the risperidone arm. In the Markov model, this resulted in an estimated QALY gain of 0.02922 per patient when therapy switch was not considered, comparing cariprazine to risperidone after one year of treatment. The model showed an estimated QALY gain of 0.02530 per patient when therapy switch was considered, comparing cariprazine to risperidone after one year of treatment. **CONCLUSIONS:** Cariprazine can provide additional health-related quality of life gain in the treatment of schizophrenia for patients with predominant negative symptoms compared to risperidone.

PRM128

IS THE SF-6D DAILY SENSITIVE TO CAPTURE QALY-VARIATION ON REACTOGENICITY OF INJECTABLE VACCINES?

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OBJECTIVES: Injectable adjuvanted vaccines cause local reactogenicity which may temporarily impact the Quality of Life (QoL) of vaccinated individuals. Variation in QoL-change expressed as quality-adjusted life year (QALY)-scores can be assessed with validated questionnaires used at regular time points capturing the health states of vaccinees. **METHODS:** Adult subjects (N=50) received a 2-dose vaccination schedule of an AS03-adjuvanted H5N1 pandemic influenza vaccine. At Day0 (just before the injection) and during the next 6 days (post-injection) subjects completed the SF-36 questionnaire with a 24 hours recall period (ClinicalTrials.gov Identifier: NCT01788228). Data were analyzed to obtain a daily QALY-score using the same algorithm as for the transformation of the SF-36 weekly questionnaire into a SF-6D being considered an appropriate QALY-score measure. During the same period, local and general symptoms were evaluated for each participant on a daily basis. It was hypothesized that the daily QALY-scores and the symptom scores were to correlate, if the former instrument was able to capture appropriately QALY-variation. **RESULTS:** Questionnaires were filled in with an average rate of compliance of 98%. The daily sum of local (pain, redness, swelling) and general (fatigue, gastrointestinal symptoms, headache, arthralgia, myalgia, chill, sweating, fever) symptoms scores were 90 (Day0), 127 (Day1), 99 (Day2), 41 (Day3), 28 (Day4), 12 (Day5), and 4 (Day6). The average daily QALY-scores were 0.885 (Day0), 0.860 (Day1), 0.874 (Day2), 0.887 (Day3), 0.893 (Day4), 0.901 (Day5), and 0.902 (Day6). The correlation coefficient between the two scores was -0.952 ($p < 0.001$). **CONCLUSIONS:** We observed that symptom scores slightly increased for the first 2 days post-vaccination, and daily QALY-scores reflect and are able to capture that change. Noteworthy is that the QALY-loss on reactogenicity of the

adjuvanted vaccine was marginal in time and score (-0.020/day during 2 days) which supports the tolerability of the H5N1 AS03-adjuvanted vaccine

PRM129

LET THERE BE LITE

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OBJECTIVES: Health status measures vary widely in size and complexity, defining from 2 to 12 million unique states. The simplest system comprises two states – alive and dead; the standard 3-level version of EQ-5D defines 243 health states. This paper examines a theoretical precursor version of EQ-5D based on 2 response levels per dimension. **METHODS:** National population surveys for England and Wales were pooled to create a single dataset of EQ-5D-3L self-reported health status for more than 38,000 individuals. Responses were recoded so that no problem = 0 and ANY problem = 1. Values for the resulting classification of 32 health states were estimated using the 0-100 VAS ratings as the dependent variable in an OLS model. The "lite" index was then applied in two further datasets (in lung cancer and back-pain patients) which also included standard clinical measures of severity. **RESULTS:** When used as a state measure or in valuing changes in health status, the "lite" index demonstrated statistically significant results consistent with the clinical parameters designate as primary markers in the two clinical studies – the Lung Cancer Symptom Scale and Roland/Morris Disability Questionnaire. For the purposes of identifying change in health status over time, the "lite" index performs satisfactorily, distinguishing groups of patients who improve/deteriorate following treatment. The "lite" index values show only small differences when compared with corresponding scores based on the conventional EQ-5D-3L. **CONCLUSIONS:** For mild to moderate disease/conditions a 2-level descriptive classification and an associated weighting system (in this case based on the 3-level version of EQ-5D) functions as well as more complex health status measurement systems. A small, compact descriptive system has the merit of requiring much simpler valuation methods than more complex systems. It is worth noting that the first index system in common usage by UK health economists was based on a 28 health state classification.

PRM130

EQUIVALENCE OF TELEPHONE AND FACE-TO-FACE PATIENT-REPORTED OUTCOME INTERVIEWS: LITERATURE REVIEW AND IMPLICATIONS FOR THE NEI VFQ-25

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OBJECTIVES: The NEI VFQ-25, a patient-reported outcome (PRO) measure of vision-related quality of life, is often administered by telephone or face-to-face interview, given the difficulties of self-administration in patients with low vision. To evaluate whether available evidence informs the equivalence of these two modes of administering the NEI VFQ-25, we conducted a literature review to identify: 1) studies on equivalence of telephone and face-to-face administration of any PRO instrument, and 2) studies with mixed-mode NEI VFQ-25 administration. **METHODS:** A systematic literature review was conducted for each objective. Medline was searched using keywords for English articles published after 1980 for objective 1 (equivalence review) and after 1997 for objective 2 (research review). Bibliographies of published articles were also reviewed. Studies on food frequency, mental illness, drug/alcohol use, or sexual behavior were excluded. **RESULTS:** The equivalence review identified 11 publications comparing face-to-face and telephone PRO interviews, all of which supported equivalence of the two modes. However, no equivalence study comparing the two modes of administration specifically for the NEI VFQ-25 was identified. In 8 out of the 9 studies in adults using other PROs, equivalence was assessed by comparing mean scores of the two interview modes administered successively to the same population. In 7 of these 9 studies, interviews were conducted within 2 weeks. The research review identified 6 instances in which NEI VFQ-25 data were obtained by a mix of face-to-face and telephone interviews. These 6 studies (3 interventional, 3 observational) were conducted across conditions including age-related macular degeneration, diabetic macular edema, and retinal vein occlusion. **CONCLUSIONS:** The literature review shows that it is common to use mixed-mode telephone and face-to-face interviews for administering the NEI VFQ-25. Equivalence studies of face-to-face and telephone interviews of PROs across a wide range of instruments, diseases, and ages support this method of combined analysis.

PRM131

TRANSLATION OF THE ZARIT BURDEN INTERVIEW 22 ITEMS (ZBI-22) INTO 95 LANGUAGES: CHALLENGES AND IMPORTANCE OF THE CONCEPTUAL DEFINITION OF THE ORIGINAL VERSION

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OBJECTIVES: The Zarit Burden Interview (ZBI) is a caregiver self-report measure, developed in US English, specially designed to reflect the stresses experienced by caregivers of dementia patients. Caregivers are asked to respond to a series of 22 questions about the impact of the patient's disabilities on their life. For each item, caregivers are asked to indicate how often they felt that way (never, rarely, sometimes, quite frequently, or nearly always). The objectives of this study were to present the challenges of the translation of the ZBI-22 into 95 languages and the importance of developing a conceptual definition for each item. **METHODS:** In most

languages, the standard translation process consisted of: 1) Concept definition with the developer 2) Forward/backward translation step including a review of the backtranslation by Prof. Zarit; 3) Clinician review; and 4) Cognitive interviews with five caregivers. **RESULTS:** No cultural issues were identified during the process. Most of the challenges were semantic. One of the greatest challenges was in finding the most appropriate words for the description of the feelings of the caregivers (i.e., do you feel stressed, embarrassed, angry, uncomfortable, afraid); each word representing a specific concept needing a clear differentiation. Items 7 and 13 raised queries given their idiomatic nature (7. Are you afraid of what the future holds for your relative?; 13. Do you feel uncomfortable about having friends over?). The interventions of Prof. Zarit helped the teams in finding appropriate translations. Examples of solutions found are presented. **CONCLUSIONS:** The input of the developer in providing conceptual definitions and clarifications during the process was key in developing translations of the ZBI-22 conceptually equivalent to the original.

PRM132

LINGUISTIC VALIDATION OF AN INSTRUMENT TO EVALUATE HEALTH-RELATED QUALITY OF LIFE IN PEDIATRIC PATIENTS WITH GROWTH HORMONE INSUFFICIENCY IN 7 LANGUAGES FOR 5 COUNTRIES

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OBJECTIVES: To translate and linguistically validate a pediatric HRQOL instrument for paper administration in 7 languages for 5 countries, intended for use by children with growth hormone insufficiency or idiopathic short stature. Pediatric instruments are often intended for respondents with a wide range of developmental abilities, demanding varied approaches to cognitive testing. To enrich our understanding of pediatric populations, we seek a cognitive interview approach with the goal of consistently yielding more robust qualitative data. **METHODS:** Corporate Translations translated, harmonized, and back translated the instrument into 7 languages for 5 countries, with an emphasis on age-appropriate terminology. The harmonizations were subjected to in-person cognitive debriefing interviews with children. Informed by the Report of the ISPOR PRO Good Research Practices for the Assessment of Children and Adolescents Task Force (Matza, et al., 2013), age-based interview criteria were developed for subjects aged 3-12 years. Subjects aged 3-6 years completed the instrument via interviewer administration, with follow-up questions targeting difficulty in comprehension. Subjects 7-12 years self-completed the instrument, with probes targeting difficulty in comprehension and the impact of short stature on QOL. A caregiver was present at all interviews. Item and probe responses, suggestions for translation revisions, and additional substantive comments were recorded and analyzed. **RESULTS:** Cognitive debriefing was successfully completed with 35 subjects, 15 children aged 3-6 years and 19 children aged 7-12 years. Both groups provided substantive comments to confirm understanding. As a result, revisions were made to the questionnaire translations in favor of age-appropriate language and improved conceptual clarity. **CONCLUSIONS:** Cognitive interviews were conducted successfully with pediatric patients with shorter stature. This approach provided evidence that a single instrument can be accessible for a wide age range, given that interviewer- and self-administered options are available. This instrument is considered linguistically validated for use in 7 languages for 5 countries.

PRM133

ADAPTATION AND ASSESSMENTS OF THE CHINESE VERSION OF THE ICECAP-A MEASUREMENT

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OBJECTIVES: To adapt and assess the ICECAP-A measurement for estimating the general quality of life (QoL) in China. **METHODS:** Both qualitative and quantitative analysis were conducted to validate the translated ICECAP-A well-being measurements. After a focus group discussion regarding the appropriateness and wording of ICECAP attributes in Chinese, we conducted an online survey in China with 1000 randomly selected adults aged over 18 years. We conducted psychometric tests and compared factors influencing the ICECAP-A with those influencing EQ-5D-3L. **RESULTS:** In general, discussion group members agreed that the 5 attributes content is sufficient to evaluate wellbeing in China. To adapt to Chinese culture, the direct translation of “being settled” and “friendship” are reworded to direct translations of “stability” and “kindness”. Our results show that the Chinese version of ICECAP-A has good internal consistency with an overall Cronbach's Alpha coefficient of 0.7999. The concurrent validity indicates that ICECAP-A is only weakly correlated with EQ-5D-3L ($r < 0.4$). Although both ICECAP-A and EQ-5D-3L are highly correlated with happiness, they may reflect different perspectives of wellbeing measurements. **CONCLUSIONS:** ICECAP-A can be adapted for a wellbeing measurement in China but it requires cultural changes to the wording. It is a valid measurement and can complement the EQ-5D in measuring general QoL. However, further work is still needed to value and test the sensitivity of the ICECAP-A in relation to public health and social care interventions for patients.

PRM134

THE NECESSITY OF A VISUAL CONCEPT ELABORATION WHEN TRANSLATING STANDARD ANATOMICAL TERMS FOR CLINICAL OUTCOMES ASSESSMENTS (COAS) IN NON-LATIN LANGUAGES

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OBJECTIVES: COAs often contain questions pertaining to distinct body parts of the subject. This is troublesome as some cultures refer to multiple body parts as one entity, for example, ‘upper arm’ and ‘shoulder’ referred to as ‘arm’. The aim of this study is to investigate how much linguistic validation methods such as visual

concept elaborations guarantee accuracy when translating human anatomy. The study focuses on 3 non-Latin languages, Russian, Urdu and Arabic, as these languages have previously produced difficulties when translating COAs. **METHODS:** Linguists were asked to provide literal translations of 17 commonly-used terms for human anatomy with no visual concept elaboration for context. A selection of anatomical terms was used to establish whether they have a direct translation or need to use multiple terms or descriptions. Linguists were then provided with a visual concept elaboration consisting of an image with arrows illustrating the intended anatomical location. This was followed by a review of the translation alongside the visual image whereby linguists gave their feedback regarding the changes needed for anatomical accuracy. Based on this data, an evaluation on the effectiveness of a visual concept elaboration was determined. **RESULTS:** An overall percentage for changes needed for accuracy was given across all languages. A percentage of words changed per language was also calculated and then a sample of 3 terms were cross-referenced to analyse the proportion of changes needed within the languages in the study. Out of the 17 body parts, edits to the translation were necessary for 55% overall across the 3 non-Latin languages. The general trend was that extremities produced the most issues in translation, for example, differentiations between ‘forearm’ and ‘upper arm’ were only discerned through using the visual concept elaboration. **CONCLUSIONS:** To obtain anatomical accuracy in translation for each language, a visual concept elaboration was proven to be an essential tool.

PRM135

CONTENT VALIDITY OF THE PRESCRIPTION OPIOID MISUSE AND ABUSE QUESTIONNAIRE (POMAQ) AMONG CHRONIC PAIN PATIENTS

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OBJECTIVES: To assess the content validity and patient interpretation of the Prescription Opioid Misuse and Abuse Questionnaire (POMAQ), a questionnaire to evaluate potential prescription opioid misuse and abuse behaviors among patients with chronic pain prescribed long-term opioid therapy, as part of FDA PMR Study 3033-3. **METHODS:** A cross-sectional, qualitative study was conducted in patients with chronic pain, most currently on prescription opioids. Four patient groups were recruited from 6 clinical sites (Known Opioid Abusers; Known Abusers of Other Substances; Non-opioid Abusers; and Non-opioid Users) to participate in a one-on-one cognitive interview. Patients completed the POMAQ via web-administration and participated in an in-depth semi-structured interview to assess the patient's understanding of the questionnaire. Descriptive statistics and content analysis were performed. **RESULTS:** 54 patients were interviewed. Mean age was 48.7 ± 12.3 years; 57.1% female; 78.6% Caucasian; mean duration of chronic pain was 11.2 ± 8.2 years with lower back pain at 74.5%. Overall, the POMAQ was well-understood, received positive feedback, and all but one participant stated they were comfortable completing the questionnaire. A few ($n=6$, 11%) expressed concerns about completing the POMAQ using a secure internet site as they were not computer savvy ($n=3$, 5.4%) or were concerned about internet security ($n=3$, 5.4%). All participants stated they were honest when completing the POMAQ, but 51% ($n=18/35$) did not think others would be honest when completing the POMAQ. Minor wording modifications were made to the POMAQ to address concerns or issues noted by the participants and to enhance clarity and understanding of the POMAQ. **CONCLUSIONS:** The POMAQ has demonstrated acceptability and content validity among patients with chronic pain. The POMAQ is currently undergoing quantitative validation among a larger cohort of chronic pain patients on prescription opioids.

PRM136

COGNITIVE DEBRIEFING OF THE ADVANCED SYSTEMIC MASTOCYTOSIS SYMPTOM ASSESSMENT FORM (ADVSM-SAF)

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OBJECTIVES: Advanced forms of systematic mastocytosis (advSM) are rare diseases characterized by neoplastic mast cell infiltration of tissues, resulting in a variety of disease-related signs and symptoms. Informed by results from the literature, expert advice meetings, and patient concept elicitation interviews, the advSM Symptom Assessment Form (advSM-SAF) was developed to evaluate treatment efficacy in regulated clinical trials. Before implementation in clinical studies, the advSM-SAF was subject to cognitive debriefing interviews (CDIs) to understand and document the extent to which the tool was understandable to patients with advSM and the extent to which they could provide meaningful responses to the questionnaire. **METHODS:** The advSM-SAF is a 10-item electronic diary assessing eight advSM symptoms using a 24-hour recall period and a 0-10 numeric response scale. CDIs were conducted with patients with advSM to evaluate the advSM-SAF for readability, relevance, and comprehensiveness, and to test the usability of the electronic patient-reported outcome (ePRO) device. Subjects were asked to complete the advSM-SAF and provide feedback on the instructions, items, and response options. **RESULTS:** CDIs were conducted with 13 subjects with advSM. At least 78%, 89%, and 92% of subjects interpreted each of the response options, instructions, and items, respectively, as intended by the instrument developers. Based on subject feedback, one text deletion and one revision, a reordering of items on sign/symptom severity to follow those on sign/symptom frequency, were made to the advSM-SAF. Subjects reported no issues with ePRO device usability. **CONCLUSIONS:** The CDI results indicate that the

advSM-SAF is understandable to patients with advSM and that it can provide scores that accurately reflect their health status. These results, along with those from previously collected information from the literature, therapeutic area experts, and patients provide support for the ADVSM-SAF as a content valid questionnaire ready for implementation into clinical trial settings.

PRM137

CHALLENGES IN TRANSLATING THE NEUROPSYCHIATRIC INVENTORY (NPI) INTO 74 LANGUAGES

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OBJECTIVES: The Neuropsychiatric Inventory (NPI) was developed in US English to assess, through interviews with caregivers, ten behavioral disturbances occurring in dementia patients: A. Delusions, B. Hallucinations, C. Agitation/Aggression, D. Depression/Dysphoria, E. Anxiety, F. Elation/Euphoria, G. Apathy/Indifference, H. Disinhibition, I. Irritability/Lability, and J. Aberrant Motor Behavior. Two neurovegetative areas were added afterwards: K. Sleep, and L. Appetite and Eating Disorders. Screening questions assess the presence or absence of changes in behaviors in the patient. If the behavioral change is present, then, subquestions (n=7 to 9) are asked to evaluate behaviors in terms of frequency, severity, and distress. The objective of this study was to present the challenges faced during the translation of the NPI-12 into 74 different languages representing ten language families. **METHODS:** The NPI was translated in most languages with a process including: 1) Concept definition with the developer 2) Forward/backward translation step; 3) Final reconciliation; 5) Clinician review; and 6) Proof-readings. **RESULTS:** The translation process did not reveal any cultural issues since most of the concepts assessed were cross-culturally relevant. The psychiatric terms (e.g., delusions, euphoria, etc.) were carefully translated with the clinician input in each country. When a literal translation was impossible, synonyms or periphrases were used. Most of the challenges identified were linked to the use of idiomatic/colloquial content, such as the use of “talk big” in subquestion 6 (Does the patient “talk big”) in section F, or the use of “flying off the handle” in subquestion 1 (Does the patient have a bad temper, flying “off the handle”...) in section I. In some languages, idiomatic expressions were available to express the same notions. However, in many languages either a synonym or a circumlocution was needed. Examples are presented. **CONCLUSIONS:** A rigorous methodology was essential in producing NPI translations conceptually equivalent to the US English original.

PRM138

SATURATION OF SIGN AND SYMPTOM CONCEPTS IN CONCEPT ELICITATION STUDIES WITH RARE DISEASE AND VULNERABLE PATIENT POPULATIONS

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OBJECTIVES: In qualitative research, saturation reflects the point at which little or no new novel data can be elicited from an interview sample. Research suggests that saturation in symptom-focused concept elicitation (CE) studies can be demonstrated in samples with as few as 10 subjects. The objective of this study was to examine the applicability of these results to patient populations that are difficult to recruit and/or interview. **METHODS:** A retrospective analysis of results from n=10 CE studies completed between 2014 and 2016 was conducted. Saturation was assessed by dividing each sample into chronological groups and comparing the number of unique concepts spontaneously elicited in the earlier groups to those emerging in the final group. **RESULTS:** A total of 140 participants across 10 studies were included in this analysis with sample sizes ranging from N=8 to N=20 (M=14). Average age of participants was 40.8 years (SD=23.0) and sixty-seven (48%) were female. Therapeutic areas included rare genetic disorders (n=4), rare and advanced stage cancer (n=5), and a dermatological condition in adolescents (n=1). A total of 341 sign/symptom concepts were elicited across all studies with an average of 34 (SD=16.50, range=13 to 57 concepts) concepts per study. An average of 91.5% (range = 75.4% to 100%) of concepts across studies emerged within the first 75% of interviews. **CONCLUSIONS:** Results from the present analysis are consistent with previous studies, can inform sample size decisions in qualitative research, and provide researchers working in rare disease or with vulnerable populations confidence that, if rigorously designed and conducted, their concept elicitation studies can be successful with sample sizes of 10 to 15 participants.

PRM139

SLEEP TRACKING AND EXERCISE IN DIABETES PATIENTS (STEP-D): A PILOT STUDY TESTING THE CONCURRENT VALIDITY OF FITBIT HR DATA WITH SELF-REPORT DATA

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OBJECTIVES: Determine the direction and magnitude of the associations between Fitbit data and self-report data for sleep and exercise data collected from active users with type 2 diabetes (T2D). **METHODS:** STEP-D is a longitudinal, pilot study composed of individuals (n=86) diagnosed with T2D. Participants wore a Fitbit for 14 consecutive days and completed four Internet surveys taken at three time points: Day 1 (baseline), Day 7 (interim) and Day 14 (closing). The Fitbit tracked minutes asleep and number of steps taken. The questionnaire included items gauging the number of days exercised in a typical week, gym membership, number of nights in a typical week having trouble sleeping and the number of nights having sleep problems. Means and standard deviation were used to report all data and Pearson correlations were used to test the association between the Fitbit and self-report data. **RESULTS:** Participants, on average took 4,955.0 steps/day and slept 6.7 hours/day. They also self-reported an

average of 2.0 days of exercise and 2.3 nights having trouble falling asleep in a typical week. The association between self-reported days exercised in a typical week and the correlation for mean steps was strong for Fitbit (r=0.60; p<0.01). Self-reports of sleep issues were moderately correlated with sleep variability. Self-reported nights having trouble falling asleep in a typical week was associated with more time spent in bed based on the Fitbit (r=0.28, p= <0.05). **CONCLUSIONS:** Findings indicate that Fitbit and self-report data are positively associated for sleep and exercise, but physical activity is more closely aligned than sleep-related information. This may indicate that Fitbit is more valid for measuring certain behaviours. If these findings are replicated in T2D, then large-scale collection of certain objective HRQoL measures is possible, but data limitations will need to be acknowledged.

PRM140

IMPACT OF THE AGE OF THE TARGET AUDIENCE ON TRANSLATION DECISIONS

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OBJECTIVES: The aim of this study is to assess how the age of the target audience in patient questionnaires impacts on translation decisions using, as an example, the linguistic validation of the Child Behavior Checklist (CBCL) aimed at preschool children aged from 1½ to 5. **METHODS:** We assessed the list of children's commonly used terms from the CBCL for any potential linguistic difficulties. We thereby ascertained that some terms would need to be adapted from Modern Standard Arabic (MSA) into Lebanese Dialect, as the children would not understand MSA. We compared this approach to the translation process for Korean and Japanese. **RESULTS:** The word list was reviewed by the lead linguist, and we ascertained that a number of the MSA terms would be unfamiliar to a child. We decided to substitute terms where necessary, in order to provide terms in a dialect familiar to the child, as well as culturally appropriate for the age group concerned. Out of the 310 terms, 19 were also localized. We compared this to the approach taken in both Korean and Japanese where there was little need to adapt the translation to a local dialect. There was also little need to alter the source terms for localization purposes. **CONCLUSIONS:** To enable understanding, it was sometimes essential to either change the dialect or localize the source terms to ones that would be familiar to the target audience. In the case of Arabic for Lebanon, the decision to replace some of the original MSA terms demonstrates that in order to achieve comprehension, particularly for a young age group, country- and age-specific adaptation is sometimes a vital component of the translation process.

PRM141

A HEARING BOLT-ON ITEM CAN INCREASE THE SENSITIVITY OF THE EQ-5D-5L INDEX SCORE TO HEARING IMPAIRMENT

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OBJECTIVES: To investigate the effect of adding a hearing bolt-on item to the EQ-5D-5L on the sensitivity of the utility-based index score. **METHODS:** Cross-sectional data on the EQ-5D-5L questionnaire with the addition of a hearing bolt-on item, namely, ‘I have no/slight/moderate/severe/extreme problems hearing’, was collected through face-to-face interviews with 428 participants of a community-based hearing impairment screening program in Singapore. We calculated the standard EQ-5D-5L index score using the Singaporean value set. By assuming that the multiplicative model used to predict the Singaporean EQ-5D-5L values applies to the hearing bolt-on system, we calculated the bolt-on index score using a series of hypothetical disutility values for hearing loss. In order to achieve comparability, the range of the bolt-on index score was adjusted to equate that of the EQ-5D-5L index score. We compared the mean EQ-5D-5L and bolt-on index scores of individuals with differing levels of hearing impairment and their ability to discriminate between different levels of hearing impairment using the F-statistic from the ANOVA test and the area under the curve (AUC) from the receiver operating characteristic (ROC) analysis. **RESULTS:** In all the comparisons of individuals with different levels of hearing impairment, the absolute mean difference in the bolt-on index score was larger than that in the standard EQ-5D-5L index score, and the bolt-on index score showed larger F-statistic and AUC values than did the standard EQ-5D-5L index score. The absolute mean difference, F-statistic, and AUC values increased with increasing disutility assumed for hearing loss. **CONCLUSIONS:** The hearing bolt-on EQ-5D-5L can be more sensitive than the standard EQ-5D-5L in discriminating between different levels of hearing impairment. The increased sensitivity increases with the disutility of hearing loss.

PRM142

LINGUISTIC VALIDATION OF THE RESPIRATORY SYNCYTIAL VIRUS NETWORK (RESVINET) PARENT AND CLINICIAN-FACING QUESTIONNAIRES IN ENGLISH AND SPANISH FOR THE UNITED STATES

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OBJECTIVES: The ReSVinet parent and clinician-facing Clinical Outcomes Assessments (COAs) are questionnaires intended to assess the condition of children with Respiratory Syncytial Virus. The original questionnaires were developed in Spain Spanish and required translation and linguistic validation into English and Spanish for the United States. The impact of using non-English source files on the application of the ISPOR Principles of Good Practice (PGP) was reviewed. **METHODS:** The PGP outline the steps for Linguistic Validation projects but were designed for an English source COA and, consequently, adjustments were required for the following steps: Preparation (reduced scope for COA analysis; no concept elaboration development); Back Translation and Cognitive Debriefing Reviews (reduced scope for project manager involvement in discussions). Once the US English files were finalised, the Spanish for the US could begin following

the PGP. This paper compares the changes made in the editing and back translation review steps of the translation process. **RESULTS:** When editing the English translation, 15% of items required updates to the parent COA, and 17% of the clinician COA items. Of these, 14% were stylistic, 77% were translation errors; and 9% were formatting updates. The Spanish translation required 28% and 12% of items to be updated respectively. Of these, 37% were translation errors; 50% were formatting issues; 9% were to improve consistency; and 4% were to correct an error in the source. During back translation review of the English, 5% and 11% of items were edited respectively (50% were misunderstandings of the source, and 50% were a wrong translation). In the Spanish, these figures were 0% and 1% respectively (25% were to improve consistency, 25% were to correct translation errors while 50% were misunderstandings of original). **CONCLUSIONS:** This analysis demonstrates the necessity for full preparation and concept elaboration, ensuring accurate linguistic validation and a reduced need for edits.

PRM143

"AM I BOTHERED?" INVESTIGATING THE POTENTIAL PROBLEMS WITH THE WORD "BOTHER" IN THE LINGUISTIC VALIDATION OF QUALITY OF LIFE QUESTIONNAIRES

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OBJECTIVES: QoL questionnaires often contain items that enquire how bothered a patient is by their condition. Corpus-based studies concluded that three meanings could be defined for "bother"; relating to "pain", "annoyance" or "hassle" (Glynn, 2010). This evidently poses a challenge for translators in faithfully conveying the meaning for accurate data collection. This study investigates the extent to which this is an issue in linguistic validation projects. **METHODS:** A selection of experienced translators was contacted covering 20 languages. The linguists were asked whether "bother" posed problems in their translations of PRO instruments. They were then asked whether it was possible to find a "direct equivalent" in their language which could be used to convey the intended meaning without affecting patient understanding. Their answers were collated into two categories; one where a direct equivalent could be easily identified, and a second where a direct equivalent could not be found, and translation would require further clarification in order to truly reflect the source. **RESULTS:** 35% of linguists confirmed there was not a direct equivalent in their language which could cover all intended meanings. The French translator advised that, depending on context, several potential words could be implemented with additional adverbs to further explain the meaning. In Dutch several terms exist which convey a part of the meaning, but there is no single term, and it may be necessary to select one "most appropriate" term. **CONCLUSIONS:** A significant proportion of languages studied have difficulty finding an exact equivalent for the range of meanings that "bother" conveys. To produce a translation that accurately conveys the intended aim of the question and therefore gather accurate data, context should be taken into consideration, and the possibility of using a more restricted or descriptive text should be considered. Developers may also consider whether a more specific term is advisable.

PRM144

PLACEMENT OF RECALL PERIOD IN PATIENT-REPORTED OUTCOME QUESTIONNAIRE ITEMS: DOES IT MATTER?

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OBJECTIVES: Questionnaire developers lack evidence to inform basic item construction activities, including the appropriate placement of a recall period. This study evaluated whether participants interpreted items in three English language patient-reported outcome (PRO) questionnaires consistently, regardless of whether the recall period was placed at the beginning or end of the item. **METHODS:** In three separate studies, cognitive interview participants were assigned to one of two groups. Group A completed an item with the recall period at the end followed by the completion of an alternative version of the item identical in content but with the recall period at the beginning. Group B completed the items in the reverse order. In both groups, participants were asked to provide their interpretations of both versions. An example of a tested item pair is as follows: "Over the past 24 hours, rate your worst stomach pain" and "Rate your worst stomach pain over the past 24 hours." All interviews were audio-recorded, transcribed, and the qualitative data were entered into ATLAS.TI for analysis. **RESULTS:** Of the 97 total participants, 69.1% were female and the mean age was 43.9 years. Eighty-eight participants contributed to the analysis with all participants in Group A (n=8) having a gastrointestinal condition and, in Group B (n=80), 44 participants had a gastrointestinal condition and 36 participants had a dermatological condition. In Group A, 100.0% of participants interpreted the items consistently (i.e., stated that the items were the same). In Group B, 79 of the 80 participants (98.8%) interpreted the items consistently. **CONCLUSIONS:** This study provided evidence that placement of the recall period at either the beginning or end of PRO questionnaire items does not impact the interpretation of the item content. Additional research will be needed to confirm these findings in other cultures/languages and content areas.

PRM145

PREVALENCE OF CVD AMONG TYPE 2 DM PATIENTS

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OBJECTIVES: The study was designed to assess the proportion of CVD among type 2 DM patients, to assess the risk factors for developing CVD among type 2 DM

patients and to assess the CVD risk factor for the next 10 years by using JBS3 scale. **METHODS:** A hospital-based study was carried out at St. Philomena's hospital. Subjects were recruited based on inclusion and exclusion criteria and the data collected were pooled and analyzed. **RESULTS:** Among 106 patients' recruited 72 patients were diabetics and 34 patients were Non-diabetics. Majority was in the age group of 51-60 years in both the groups. The BMI value was found to be abnormal in diabetic patients. Majority of the DM patients had HTN than the Non-DM group. It was also observed that the prevalence of CVD was higher among the DM patients than Non-DM patients. Hypothyroidism was found to be a common co-morbidity among both the groups. It was found that there were elevated biochemistry values and abnormal ECG and ECHO readings in DM patients than Non-DM patients. By using JBS3 scale, it was found that DM patients had more risk for developing CVD than Non-DM patients. **CONCLUSIONS:** The study was concluded that type 2 DM patients were more prone to develop CVD than the Non-Diabetics.

PRM146

AN ALTERNATIVE WEIGHT ELICITATION METHOD FOR USE IN MULTI-CRITERIA DECISION ANALYSIS FOR HEALTHCARE

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OBJECTIVES: The aim of this study was to develop and illustrate the use of an alternative weight elicitation method for use in multi-criteria decision analysis for healthcare, in the context of imprecision and uncertainty. **METHODS:** The proposed method consists of two steps: 1) the rank ordering of evaluation criteria based on decision-makers' (DMs) preferences using the principle component analysis and 2) the estimation of the criteria weights using the variable inter-dependent analysis and the Monte Carlo simulation. The method was applied to a hypothetical case study involving the elicitation of DMs' preferences for five criteria, cost, sensor size, zoom, weight and optical image stabilizer, used to select the best device for eye surgery. **RESULTS:** The criteria were ranked from 1-5, based on a strict preference relationship established by the DMs. For each criterion, the deterministic weight was estimated as well as the standard deviation and 95% credibility interval. **CONCLUSIONS:** The proposed method is appropriate in situations where only ordinal DMs' preferences are available to elicit decision criteria weights.

PRM147

AN INNOVATIVE APPROACH TO MIXED-MODE LONGITUDINAL DATA COLLECTION: METHODS AND RESPONSE RATES FROM THE CHRONIC CONSTIPATION & IBS -C TREATMENT AND OUTCOMES REAL WORLD RESEARCH PLATFORM (CONTOR)

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OBJECTIVES: CONTOR is a novel, mixed-mode longitudinal research platform combining administrative medical and pharmacy claims and patient-reported data to examine associations between symptoms, treatment use and experience, and patient-reported outcomes among patients with chronic idiopathic constipation and irritable bowel syndrome with constipation. The objective of this abstract is to describe methods and response rates for CONTOR participants. **METHODS:** Fully-insured patients ≥ 18 years old were identified in two waves from a large, geographically-diverse US health plan using medical and pharmacy claims. Patients were invited by mail to participate and complete a self-administered paper survey at baseline, a 7-day daily diary at baseline and month 12, and monthly and quarterly online surveys over 12 months. Outcomes assessed include medication use, quality of life, symptoms, treatment satisfaction, and demographics. Eligible participants at baseline were invited to continue participation throughout the study period regardless of response to each monthly/quarterly survey. Patients were compensated for participation via pre- and post-paid incentives. Survey responses were linked to administrative claims data. **RESULTS:** Of 18,590 patients invited to participate, 2,693 responded to the baseline survey (16.8% of eligible mailed invitees). In addition, 1,725 daily diaries were returned at baseline (11.3% of eligible mailed invitees) and 1,177 at 12 months (64.4% of enrolled participants). Response rates for enrolled participants averaged 70.5% (range 66.9-74.6) for monthly surveys and 70.8% (range 65.2-74.2) for quarterly surveys. **CONCLUSIONS:** CONTOR study response rates highlight the success of innovative approaches to real-world data collection by combining mixed-mode surveys and pre- and post-paid incentives to effectively engage participants in a longitudinal observational study. The initial response rate of <20% reflects the length and complexity of the baseline survey and the year-long study commitment. Once participants were enrolled, response rates over the 12-month period were higher than anticipated and remained steady throughout data collection for both samples.

PRM148

VALIDATING SELF-REPORTED PATIENT SURVEY DATA ON DIABETES SELF-MANAGEMENT USING PATIENT ELECTRONIC MEDICAL RECORDS

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OBJECTIVES: To validate self-reported patient survey data on diabetes self-management using patient's electronic medical records (EMR). **METHODS:** The cross-sectional study included patients (age ≥ 18 years) diagnosed with type 2 diabetes mellitus (T2DM) (ICD-9 code: 250.xx) and had ≥ 2 physician visits. The

sample was identified from a physician group's EMR database. A mail-based survey assessing diabetes self-management practices was administered to a random sample of 2,100 patients, stratified into three groups based on HbA1c level: <7, 7-9, and >9. Patient survey responses were then linked to their EMR data using unique patient codes. A 'concurrent triangulation design' was then employed to validate and substantiate patient survey responses with the EMR database for variables that were common in the two databases such as demographics, comorbidities, HbA1c, year since diagnosis, and diabetes medications. Descriptive, comparative and correlational analyses were conducted using IBM SPSS Statistics 24.0. **RESULTS:** A total of 210 responses were received (10% response rate). Self-reported age (mean: 63.7±11.7 years) and age from EMR (mean: 64.5±12.2 years) were strongly correlated ($r=0.94$, $p<0.001$). Marital status ($\rho=0.72$, $p<0.001$), race ($\rho=0.69$, $p<0.001$), and gender ($\rho=0.99$, $p<0.001$) showed strong significant correlation as well. Moderate correlation ($r=0.63$, $p<0.001$) was observed between self-reported HbA1c (mean: 7.8±1.7) and HbA1c from EMR (mean: 7.9±1.7). Additionally, important clinical variable such as HbA1c in the EMR data had fewer missing values ($n=7$) compared to self-report data ($n=59$). **CONCLUSIONS:** Since the patient groups were based on HbA1c, it was an extremely important variable and yet, HbA1c data was missing for 28.1% of survey respondents. Supplementing EMR data not only validated the survey responses, but also enabled substitution of survey reported HbA1c with HbA1c from EMR. The use of mixed-method research offers an in-depth understanding of the data and overcomes the limitations of a single method.

PRM149

RECRUITMENT STRATEGIES AND GEOGRAPHIC REPRESENTATIVENESS FOR PATIENT SURVEYS IN RARE DISEASES

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OBJECTIVES: Describe patient recruitment strategies and assess geographic representativeness of the sample in a survey of US patients with myeloproliferative neoplasms (MPNs), a group of rare blood cancers. **METHODS:** The Living with MPNs survey was a 20-minute online questionnaire administered to patients between the ages of 18-70 who had MPNs. The survey assessed the impact of MPNs on employment, work productivity, and activities of daily living. Survey data were collected between April and November 2016. An optional \$25 incentive was offered to respondents who completed the survey. Survey recruitment strategies included posts on MPN-focused social media (e.g., patient group Facebook pages), emails and/or post cards sent by MPN groups, posts on patient advocacy websites, banner ads at selected medical websites, text or banner ads through Google or Facebook, and postcards sent to hematologist/oncologist offices for distribution. Geographic representativeness was assessed by number of respondents per 10 million residents of each US state. **RESULTS:** 904 eligible MPN patients completed the survey. Largest recruitment was through survey ads posted on MPN-focused social media groups (47.6%), followed by emails (35.1%) and postcards (13.9%) sent by MPN groups, and other communication channels (3.4%). 779 patients (86.2%) opted to receive the incentive. CA, TX, and NY had the highest number of respondents (89, 65, and 51, respectively). Four states (DE, HI, MT, and VT) had no respondents. After adjusting for state population, 17 states had ≥ 25 patients per 10 million residents. **CONCLUSIONS:** Recruitment through patient groups and advocacy organizations using social media was an effective approach in obtaining a geographically representative sample of patients with rare diseases.

RESEARCH ON METHODS – Statistical Methods

PRM150

USING AGGREGATE DATA TO PROXY INDIVIDUAL-LEVEL CHARACTERISTICS IN HEALTH SERVICES RESEARCH: THE IMPACT OF GRANULARITY

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OBJECTIVES: To examine the impact of systematically varying the size of the neighborhood from which aggregate proxies for individual-level characteristics are calculated. Health services researchers commonly employ aggregate proxies for individual-level data when the latter is not available. Socioeconomic characteristics of residential areas (e.g. counties) from census data frequently augment outcomes studies. Extant studies on biases introduced by aggregate proxies yield inconsistent results, and may suffer from confounds due to differences between aggregate vs. individual data collection methods. This study explored the impact of systematically varying the granularity of the aggregate proxies, i.e., the size of the geographic neighborhood used to calculate the individual proxy characteristics, while holding the underlying data collection methodology constant. **METHODS:** Data were taken from a commercial market research database of the entire US population aggregated at the 9-digit zipcode level (>30MM groups). The socio-demographic variables age, ethnicity, education, marital status, home ownership, and mean net worth were extracted to be used as predictor variables. Four different granularities were calculated: the original zip+4 level, followed by successive aggregations to the block group, census tract and county levels. The response variable selected was mean household income. This variable, which simulates an individual-level response variable was maintained at the zip+4 level, but successively matched to predictors on the basis of zip+4, block group, census tract and county. Means, standard deviations (SD) and zero-order correlation coefficients between the predictor variables and the response variable were calculated at the four granularity levels. **RESULTS:** As neighborhood size increased, predictor variable means remained relatively stable, SDs consistently decreased, and correlations with the response increased, except for county, which showed the lowest correlations of all four granularities. **CONCLUSIONS:** When other sources of bias, such as methodological differences, are controlled for, the use of aggregate

proxy data may overestimate the true relationship with a response variable, up to county level, which may be too large to be a valid proxy.

PRM151

MATCHING-ADJUSTED INDIRECT COMPARISONS IN ANKYLOSING SPONDYLITIS, PSORIATIC-ARTHRITIS AND PSORIASIS: HOW DO THEY ALIGN WITH NICE DSU RECOMMENDATIONS?

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OBJECTIVES: Matching-Adjusted Indirect Comparison (MAIC) in comparative effectiveness research is increasingly used and complements traditional approaches. The NICE Decision Support Unit (DSU) recently published a Technical Support Document (TSD) on population-adjusted indirect comparisons, including recommendations for the application and reporting of MAICs. The objective was to review MAICs in Ankylosing Spondylitis (AS) Psoriatic-Arthritis (PsA) and psoriasis in the context of these recommendations. **METHODS:** A systematic literature review (2010-2016) and a targeted search in congress proceedings in AS, PsA and psoriasis was conducted to identify published MAICs. We developed a checklist based on the NICE DSU recommendations to assess alignment. This included amongst other criteria if the target population had been clearly stated, evidence of imbalance or heterogeneity between source trials was provided, if all matching variables and effective sample size (ESS) post matching were reported or whether evidence was considered that matched variables included effect modifiers or prognostic variables. **RESULTS:** 19 MAIC publications were identified: AS (4), PsA (7), psoriasis (8). All were published prior to NICE DSU and included only biologic treatments. Results of the assessment with developed checklist revealed that many publications failed to fully report all items recommended by NICE DSU. Almost all MAICs ($n=18$) reported baseline variables used for matching. Only 11 reported the ESS and same number of MAICs did not report any measure of uncertainty. A large variability was observed among other criteria such as the rationale for selecting the matching variables, or evidence of imbalance pre matching. **CONCLUSIONS:** This review of MAICs in AS, PsA and psoriasis showed low compliance to recent NICE DSU TSD recommendations. This research raises important issues to be addressed in each MAIC and can inform future MAIC guidelines. 1Phillippo, D.M., Ades, A.E., Dias, S., Palmer, S., Abrams, K.R., Welton, N.J. NICE DSU Technical Support Document 18: Methods for population-adjusted indirect comparisons in submission to NICE. 2016. Available from <http://www.nicedsu.org.uk>

PRM152

IRT IN ACTION: A DEMONSTRATION OF THE EQUIVALENCE OF IRT-BASED SCORING WHEN USING ITEM SUBSETS

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OBJECTIVES: In our role as psychometricians, concerns have been raised to us by researchers less familiar with the technical mechanics of item response theory (IRT)-based scoring that the items or item subsets used to score individuals could negatively influence the accuracy and resulting conclusions made from estimated IRT scores. Our objective is to provide an accessible demonstration that, when using items from a common, previously calibrated item bank, regardless of the items seen by individual patients or groups, the obtained IRT-based scores from a patient reported outcome are unbiased, precise, and equivalent. **METHODS:** Data were simulated using item parameters from an existing item bank, which includes several subsets of items of relevance to the domain (such as Social quality of life (QoL) within a general QoL scale; somatic symptoms within depression; End of Day Comfort within overall contact lens comfort). Scores were obtained for these simulated observations using a variety of subsets of items, including the use of computerized adaptive testing as well as items from only specific substantive subsets. Estimated scores were then compared to the known generating values to examine accuracy, as assessed by bias, root mean squared error, correlation of estimated scores to true scores, and group descriptive (mean, SD) comparisons to the generating distribution. **RESULTS:** Known associations (such as more answered items lead to more accurate scores) were reflected in the findings. Further, regardless of the specific items used, the estimated scores were generally unbiased, adequately precise, and the distributional summaries of the estimated scores mirrored those of the generating distribution well. **CONCLUSIONS:** Regardless of the content of items seen by individuals, up to presenting only items with content from a specific substantive subset of items, the statistical mechanics underlying IRT-based scoring provide for equivalent scores that accurately reflect true values.

PRM153

STATISTICAL EFFICIENCY AND BIAS OF DIFFERENCE IN DIFFERENCE DESIGN VERSUS NON-EQUIVALENT CONTROL GROUP ANALYSIS METHODS

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OBJECTIVES: Multiple analysis methods exist for various research designs. Testing the efficiency of these methods is important to prevent Type I and Type II errors from entering the data interpretation. These efficiency studies are more important when non-randomized studies are used, such as the Non-equivalent Control Group (NECQ) design, because the researcher cannot rely on adverse effects from being equally distributed between groups. **METHODS:** Two simulated data sets ($N=100,000$) were constructed for Control 'patients' with no treatment effect for pre-posttest values. (Normal Distribution with mean=0, Standard Deviation=1 N(0,1)). Three groups were simulated for Treatment groups each ($N=100,000$) reflecting increasing treatment effects with N(0,1) at baseline, and N(-0.5,1), N(-1.0,1), and N(-1.5,0.1) for increasing treatment effect posttest values. Two analysis

methods for NECQ were tested. 1. Standard Difference in Difference (DnD) statistics - group t-tests on (Post-Pre) data. 2. Paired t-tests within groups and group t-test for posttest values (G/PTT). Samples were extracted for analysis if there was a difference between baseline mean values. For each of the three conditions 1,000 replications were performed. **RESULTS:** Statistical differences at Baseline were present in 6.9% (approximately what would be expected under the null), of all aggregated comparisons. When these samples from the simulation were extracted, successful treatment effects by DnD were present in 12%, 30% and 46% of trials whereas using G/PTT found significant treatment effects in 9%, 24% and 38% of the N(-0.5,1), N(-1.0,1), and N(-1.50,1) combinations respectively. **CONCLUSIONS:** Different results were found between identical samples depending on which statistical method was used. It is unclear if the difference is due to selection bias, regression artifact or some other bias. DnD analysis may over-estimate the effectiveness of treatments when baseline bias is present (Type I error), or G/PTT methods may underestimate treatment effects (Type II error). Clearly in non-randomized studies baseline tests of equivalence need to be performed.

PRM154

USING LATENT CLASS ANALYSIS TO MODEL PREFERENCE HETEROGENEITY IN HEALTH: A SYSTEMATIC REVIEW

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OBJECTIVES: We sought to document the applications of LCA in the stated-preference literature focusing on health and to inform future studies by identifying current norms in published applications. **METHODS:** We conducted a systematic review of the MEDLINE, Embase, EconLit, Web of Science, and PsycINFO databases. We included English-language stated-preference studies that used LCA to explore preference heterogeneity in healthcare or public health. Two reviewers independently reviewed titles, abstracts, and texts. Key outcomes extracted included segmentation methods, preference elicitation methods, number of attributes and levels, sample size, model selection criteria, number of classes reported, and hypotheses tests. Study data quality was assessed using the PREFS quality checklist. **RESULTS:** 78 met the inclusion criteria. 84% were published between 2011 and 2016. Preferences were assessed on a wide variety of topics. Most focused on the preference of patients (32.9%) and the general population (29.1%). Nearly 80% were discrete choice experiments. The number of attributes ranged from three to twenty, with over half of the studies (57.7%) having four to six attributes. Sample size in LCAs ranged from 47 to 2,005, with a mean of 480 and a median of 300. BIC (55.9%) and AIC (52.5%) were commonly used for model selection. 80% of studies reported two to three classes. The number of classes was associated with sample size, country of origin, stated-preference methods, segmentation methods, and criteria used for model selection. While 45% of studies discussed clinical implications, LCA has been increasingly used to inform policy since 2010. **CONCLUSIONS:** LCA has been increasingly used to study preference heterogeneity in health and support decision-making. As its application in health is relatively new, there is little consensus on some modeling issues. More guidance is needed to improve the quality of LCA studies in health to meet increasing demand to study patient preference heterogeneity.

PRM155

SELECTING THE BEST PERFORMING METHODS TO CONTROL FOR BIAS IN COMPARATIVE EFFECTIVENESS RESEARCH USING REAL WORLD DATA

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OBJECTIVES: To assess the performance of five commonly used methods to reduce confounding bias in Comparative Effectiveness Research using Real World Data. **METHODS:** Using two hypothetical interventions in simulated cohorts, with different sample sizes, (n= 200, 500, 1000, 2000,5000), we examined the effect in the estimation of the treatment effect, using: 1) Multivariate regression (MR), 2) propensity score matching (PSM), 3) propensity score stratification (PSS), 4) doubly robust estimation (DR), and 5) inverse probability treatment weighting with regression model (IPTW). **RESULTS:** For each model, we assessed the true positive rate for correctness of statistical significance and the root mean square error. Our results showed that if model is specified correctly and the sample size is large (> 1000), the results of the models do not show differences regardless of random noise levels. More specifically, if covariates are correlated with each other or with the interventions, MR does not perform well unless the sample size is large. For small sample sizes, IPTW is often the best performing model, even for misspecified postulated propensity score and regression models. PSM should be considered under low noise levels and larger sample sizes. DR does not perform well when model is corrected. DR does not show good performance even when both postulated propensity score and regression models were misspecified. **CONCLUSIONS:** The selection of the method to control for bias in CER using RWD, should consider the specification of the models, sample size, and the correlation of the variables included. IPTW, for most scenarios, is the best choice and PSM should be used with care especially under high noise levels and small sample sizes.

PRM157

TWO-STAGE PIECEWISE LINEAR MODEL FOR INVESTING DOSE-RESPONSE RELATIONSHIP IN META-ANALYSIS: METHODOLOGY, EXAMPLES, AND COMPARISON

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OBJECTIVES: Dose-response meta-analysis (DRMA) is widely employed to establish potential dose-response relationship between exposure and disease outcome. However, no method is readily available for exploring relation between

discrete exposure and a binary or continuous outcome. **METHODS:** We proposed a piecewise linear (PL) DRMA model which provide a solution to this issue. We used parity and sleep data to illustrate how to apply PL model in DRMA for assessing relation between discrete or continuous exposure with outcome. We also empirically compared PL model with nonlinear spline model. **RESULTS:** PL model fitted well in our two examples. For parity and risk of rheumatoid arthritis (discrete exposure): among women with 3 or less birth, the RR was 0.88 (95%CI: 0.77, 1.00) for every 1-birth increment; otherwise (3 or more births), the RR was 1.10 (95%CI: 0.99, 1.23) for every 1-birth increment. For sleep duration data: RR of all-cause mortality was 1.31 (95%CI: 1.25, 1.39) for every 1-hour reduction of sleep duration among people who slept less than 7 hours; and was 1.15 (95%CI: 1.07, 1.24) for every 1-hour increase among people who slept more than 7 hours. For continuous exposure, the results of PL model were less precise and flexible compared to higher order function. **CONCLUSIONS:** Piecewise linear function is a simple and valid method for DRMA and can be used for discrete exposure. It also represents an alternative to non-linear model DRMA.

PRM158

POPULATION-ADJUSTED TREATMENT COMPARISONS: ESTIMATES BASED ON MAIC (MATCHING-ADJUSTED INDIRECT COMPARISONS) AND STC (SIMULATED TREATMENT COMPARISONS)

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OBJECTIVES: To review the properties and assumptions of methods for population-adjusted treatment comparison, including Matching-Adjusted Indirect Comparison (MAIC) and Simulated Treatment Comparison (STC), and to provide guidance on their use in health technology appraisal. **METHODS:** Standard methods for indirect comparisons and network meta-analysis are based on aggregate data, with the key assumption that there is no difference between trials in the distribution of effect-modifying variables. Two methods which relax this assumption, MAIC and STC, are becoming increasingly common in industry-sponsored treatment comparisons, where a company has access to individual patient data (IPD) from its own trials but only aggregate information from competitor trials. Both methods use IPD to adjust for between-trial differences in covariate distributions. We review the properties of these methods in light of the wider literature on standardisation and calibration based on propensity score reweighting and covariate adjustment, which are the foundation for MAIC and STC respectively, and identify the key assumptions in the context of indirect comparisons. **RESULTS:** There is a lack of clarity about how and when the methods should be applied in practice, and both MAIC and STC as currently applied can only produce population-adjusted estimates that are valid for the populations in the competitor trials, rather than the target population for the decision. In addition, the fundamental distinction between "anchored" and "unanchored" forms of indirect comparison – where a common comparator arm is or is not utilised to control for between-trial differences in prognostic variables – is under-emphasised, with the unanchored comparison making assumptions that are infeasibly strong. **CONCLUSIONS:** We provide recommendations on how and when population adjustment methods of this type should be used in order to provide statistically valid, clinically meaningful, transparent and consistent results for any given target population, and set out the additional analyses that should be presented to support their use.

PRM159

MATCHING-ADJUSTED INDIRECT COMPARISONS TO ASSESS COMPARATIVE EFFECTIVENESS: A SYSTEMATIC REVIEW OF APPLICATION IN SCIENTIFIC LITERATURE AND HEALTH TECHNOLOGY APPRAISALS

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OBJECTIVES: In the absence of head-to-head studies, indirect comparisons are being recommended and widely used to estimate comparative effectiveness. Matching-Adjusted Indirect Comparison (MAIC) re-weights Individual Patient Data from one study to match the distribution of baseline characteristics of another, reducing heterogeneity due to observed trial differences compared with conventional meta-analytic methods. The objective of this study was to review the application of MAIC in the scientific literature and in Health Technology Assessments (HTA). **METHODS:** A systematic literature review was conducted using Ovid (Medline, Cochrane Library) and Embase (Embase, Medline) platforms from years 2010 through October 2016. In addition, assessment documents from key HTA bodies (England, Scotland, Canada and Australia) were reviewed. Publications from conferences where the authors of this study have been involved were also targeted for evidence. **RESULTS:** A total of 61 publications (manuscripts, posters or abstracts) reported the use of MAIC across different therapeutic areas: auto-immune and rheumatology(23), oncology(22), infectious diseases(7), neuroscience(4), hematology(2), metabolic diseases(1), respiratory(1) and unspecified disease(1). An increasing trend in MAIC publications was observed as 29 publications were released alone in 2016, compared to 6 in 2010. Differences were observed in the methodologies employed regarding placebo effects and variable matching between publications. The MAIC methodology was part of 21 HTA submissions with the first submission in 2012. Comments on MAICs were inconsistent across HTA bodies, with some requesting MAIC analyses, others questioning them. This diversity in quality and acceptability is likely explained by unclear standards of application, reporting and interpretation of the MAIC analyses. **CONCLUSIONS:** The current study found that the use of MAIC has been increasing across different therapeutic areas, and so has its acceptability by HTA

bodies even though many MAICs have not been reported adequately. If applied, reported and interpreted correctly, MAIC can be a valid technique for comparative effectiveness research.

PRM160

AN OUTCOMES REGRESSION APPROACH FOR INDIRECT COMPARISONS OF SURVIVAL OUTCOMES WHEN STANDARD NETWORK META-ANALYSIS IS NOT FEASIBLE

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OBJECTIVES: In many cases the relevant evidence base of competing interventions cannot be reflected with one connected evidence network of randomized controlled trials (RCTs) to perform standard network meta-analysis. We present an outcomes regression method to perform indirect comparisons regarding time-to-event outcomes when the evidence bases consist of disconnected RCTs and/or single-arm trials. **METHODS:** This method requires access to individual patient data for at least one index interventions from which a set of bootstrap samples are obtained with replacement. For each bootstrap sample multiple competing multivariable survival models are estimated that describe the log-hazard over time as a function of prognostic factors and effect-modifiers. Their predictive performance is assessed based on the “out-of-bag” samples. Next, for each trial for which only summary data is available and not connected to other trials, a large number of hypothetical individuals are simulated based on the reported marginal distributions of the covariates of interest and their assumed correlation. For each of these populations the average log-hazards over time with the index intervention is predicted based on the model with best predictive performance for each of the bootstraps. Their summary distribution by trial effectively represents the outcome with an index intervention-based control group for each of these trials, which in turn allows all trials of relevance to be connected and to proceed with between-trial comparisons using standard network meta-analysis models. **RESULTS:** The method is illustrated with an indirect comparison of interventions for advanced melanoma. **CONCLUSIONS:** The proposed outcomes regression method uses cross-validated models, ensures that the prediction of outcomes and indirect comparisons are performed on the same (transformed) scale, and uncertainty associated with estimation of the outcome model parameters is propagated through the indirect comparison. It can be considered a useful addition to previously proposed methods for indirect comparisons in the presence of disconnected networks.

PRM161

OPTIMIZING SYSTEMATIC LITERATURE REVIEWS FOR THE CONDUCT OF NETWORK META-ANALYSES: SUGGESTIONS FOR GOOD PRACTICES

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OBJECTIVES: Network meta-analysis (NMA) is recommended by most HTA guidelines to assess the relative effect of interventions. Guidelines recommend collecting data using systematic literature reviews (SLR). However, adherence to SLR guidelines is generally insufficient to optimize NMA feasibility and reduce the risk of producing incorrect results. Our aim was to review common issues faced when collecting data for NMAs and propose approaches to avoid them. **METHODS:** Specific challenges to collect data for NMAs were identified based on our experience of NMAs for HTA submissions: (1) Definition of study question to optimize NMA feasibility, (2) Transparency on study selection, (3) High level of missing data due to publications reporting incomplete data (4) Risk of double-counting patients. Examples are given for each challenge and recommendations for good practices are suggested. **RESULTS:** Common challenges related to the definition of the study question include the specificity of the study population and the inclusion of comparators not relevant to the study question to connect the network of studies. The study selection process generally lacks transparency due to NMA-specific exclusion criteria (e.g. non-availability of data in a format suitable for NMAs, studies that are disconnected from the network due to the absence of common comparator). Missing data or data reported in graphs only are frequent and may lead to the exclusion of trials from NMAs. Finally, SLRs generally capture several publications from the same trial, which may result in double-counting patients in NMAs. To overcome these common issues, we propose a template of flow chart to document the NMA study selection process, and a list of secondary sources to be searched to avoid missing data. **CONCLUSIONS:** The SLR process is of utmost importance to optimize NMA feasibility. While we suggest recommendations to ensure the quality of this process, further research is needed to reach a consensus on good practices for NMA data collection.

RESEARCH ON METHODS – Study Design

PRM162

MEANINGFUL MENTORSHIP ASSOCIATED WITH REWARDING SHORT-TERM RESEARCH: RESULTS FROM AN EVALUATION OF ISPOR STUDENT EXPERIENCES

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OBJECTIVES: Results from the 2013 International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Student Member Internship Survey suggested that many students felt unprepared to manage multiple projects and present to leadership. This study, conducted by the 2016-2017 ISPOR Student Network Survey Committee, aimed to describe recent internship experiences and identify key facilitators for

success. **METHODS:** An online, mixed-methods survey was developed and distributed to student members with the goal of evaluating internship/short-term research experiences. The survey collected data between October 2016 and December 2016. Logistic regression models evaluated associations between student and internship attributes and satisfaction outcomes. Two committee members independently identified themes in qualitative responses. **RESULTS:** Thirty-two ISPOR student members completed the survey (48% female, ages range: 22-40 years); PhD (71%), masters (13%), and PharmD students (10%). Most experiences were in the US (81%) and lasted 13 weeks on average (range: 4-52 weeks). The most common employer settings were pharmaceutical industry (45.5%), consulting (23%), and non-profit companies (18%). Scope of responsibilities included market access (14%), pre-market research (14%), post-market research (18%), and policy research (23%). Two major facilitating themes emerged from the qualitative responses: mentorship and networking. Meaningfully mentored students were 3.5 times more likely to have a personally rewarding experience (OR =3; p<0.01) and twice as likely to “strongly agree” their skills were challenged and strengthened (OR=8; p<0.05). Too short of duration was described as a barrier; however longer internships were not associated with contribution to a publication (p=0.2). Employer type, scope of responsibility, gender, or degree program were not associated with a personally rewarding internship. **CONCLUSIONS:** Meaningful mentoring was the most important factor contributing to a personally rewarding internship that challenged and strengthened skills. The results of this study can assist employers understand the range of opportunities available to ISPOR students and the factors that cultivate a positive experience.

PRM163

QUALITY OF REPORTING IN SURGICAL RANDOMIZED CLINICAL TRIALS

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OBJECTIVES: Randomized controlled trials testing surgical interventions have drawn increasing attention. The adequate reporting of surgical trials represents one of important issues. We conducted a cross-sectional survey to assess the reporting quality of surgical trials and explored associated factors. **METHODS:** We searched PubMed for 2-arm parallel randomized trials assessing surgical interventions published in 2003 or 2013. Quality of reporting was evaluated against the CONSORT checklist containing 29 items (standard CONSORT plus CONSORT Extension for Nonpharmacological Treatments). Univariate and multivariate linear regression was undertaken to explore factors associated with quality of reporting measured with CONSORT scores. **RESULTS:** Some 120 trials were identified and included. The mean (s.d.) CONSORT score was 12.7 (4.0). Trials published in 2013 achieved a higher CONSORT score than those in 2003 (mean 14.5 (3.8) versus 10.8 (3.4) respectively, P<0.001). The extent to which those trials met the requirement for CONSORT reporting differed substantially across items: four of 29 items were adequately reported across trials, and seven were reported adequately in less than 20% of trials. Less than 40% of the trials described the details on surgical interventions and care providers (such as nursing care and anesthetics management). In multivariate regression analysis, trials published in 2013 (coefficient 3.0, 95%CI, 1.9 to 4.2) and multicenter studies (coefficient 2.1, 95%CI, 0.8 to 3.4) were associated with statistically higher quality of reporting. **CONCLUSIONS:** The quality of reporting in surgical trials improved in the past decade. Overall quality, however, remains suboptimal, particularly in those important details regarding surgical interventions and management. Journal editors and trials investigators should consider more rigorous standards in the reporting of surgical trials.

PRM164

A METHOD FOR IDENTIFYING PERIPHERAL INTRAVENOUS (PIV) CATHETER-RELATED COMPLICATIONS IN A U.S. HOSPITAL DISCHARGE DATABASE

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OBJECTIVES: To evaluate the feasibility of identifying patients with peripheral intravenous lines (PIV) in real world data and, if possible, estimate rate of PIV-related complications. **METHODS:** We studied hospital admissions (7/1/2013-6/30/2015) in the Premier Perspective Database® of US hospital discharge records. We first identified PIV with dedicated procedure codes, but found significant under-reporting. Therefore, based on interviews with expert clinicians, we identified conditions that were unlikely to cause a complication themselves that would be mistaken as PIV-related (i.e., blood stream infections [BSI], cellulitis, phlebitis, infections not elsewhere classified [NEC], and extravasation), but in which PIV use could be assumed. The selected conditions were pneumonia, chronic obstructive pulmonary disease (COPD), myocardial infarction, congestive heart failure, chronic kidney disease, diabetes with complications, and major trauma (hip, spinal, and cranial fractures). Admissions with potential non-PIV causes of complications such as dialysis, surgery, and central line use excluded. We reported number of patients with each condition and proportion with each complication (number of patients with complication/number of patients in condition cohort). **RESULTS:** We identified 588,375 qualifying admissions (N=15,637–187,904 depending on condition): mean (SD) age 66.1 years (20.6), 52.4% female, 71.2% white, and mainly non-elective admission (95.2% in urban hospital setting (83.5%). Medicare was primary payment source (66.2%). There were 10,354 patients (1.8%) with at least one complication. Complication rates varied by cohort: from 0.98% of COPD cohort to 2.67% of pneumonia cohort. Overall, BSI accounted for 82.2% of complications, cellulitis for 13.9%, phlebitis for 4.6%, infections for 0.8%, and extravasation for 0.1%. **CONCLUSIONS:** Using a methodology based on clinical expert input, PIV-related complications were uncovered in hospital data at rates consistent with clinical research on PIV

complications. Future analyses will explore the clinical and economic impact of these complications in each of the conditions studied.

PRM165

RELATIVE EFFICACY AND SAFETY OF LACOSAMIDE AS MONOTHERAPY FOR ADULTS WITH NEWLY DIAGNOSED FOCAL SEIZURES: A NETWORK META-ANALYSIS OF RANDOMIZED CLINICAL TRIALS

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OBJECTIVES: Lacosamide was recently approved as monotherapy for adults with focal seizures in the European Union (already approved in USA). Comparative data are needed to inform clinical decision-making. This network meta-analysis (NMA) compared lacosamide with other antiepileptic drugs (AEDs). **METHODS:** Randomized, controlled trials of AED monotherapy in newly-diagnosed patients (aged ≥ 16 years) were identified via systematic literature review. NMA was performed to obtain relative estimates for efficacy (6 and 12-month seizure-freedom) and safety (discontinuations due to adverse events [AEs], serious treatment-emergent-AEs [TEAEs], serious drug-related-AEs [DRAEs]) for the overall population and elderly subpopulation. Efficacy analyses used pooled data for immediate-release and controlled-release (CR) carbamazepine. **RESULTS:** Data from twelve trials evaluating ten AEDs were analyzed. For 6-month seizure-freedom, lacosamide showed similar efficacy to carbamazepine (odds ratio [OR]: 1.23 [95% Credible Interval: 0.91-1.63]) and levetiracetam (1.25 [0.77-1.91]), with numerically better efficacy versus other AEDs (lamotrigine: 1.39 [0.62-2.70]; zonisamide: 1.63 [0.99-2.52], phenytoin: 1.92 [0.66-4.46]). Comparison with valproate showed large uncertainty (0.70 [0.08-2.59]). Lacosamide showed similar efficacy to carbamazepine for 12-month seizure-freedom (1.02 [0.77-1.32]), with OR versus other AEDs ranging from 1.18 (levetiracetam) to 1.66 (lamotrigine). Lacosamide tended towards numerical advantages versus levetiracetam, carbamazepine-CR, and zonisamide for discontinuations due to AEs (OR range: 0.48-0.74) and for risk of serious TEAEs versus carbamazepine-CR and zonisamide (range: 0.78-0.90). Risk of serious DRAEs for lacosamide (0.38 [0.10-0.90]) and levetiracetam (0.33 [0.06-0.95]) was similar versus carbamazepine-CR. Similarly, elderly subpopulation analyses showed similarities between lacosamide, lamotrigine, and levetiracetam when compared to each other and versus carbamazepine-CR (with some numerical advantages) on seizure-freedom, and serious DRAEs. **CONCLUSIONS:** Numerical benefits versus other AEDs indicate lacosamide is a valuable addition to the armamentarium of focal seizure monotherapies. However, the available evidence was insufficient to demonstrate meaningful differences between AEDs for efficacy outcomes, as reflected by the wide Credible Intervals. **STUDY SUPPORT:** UCB Pharma-sponsored.

PRM166

ASSESSING TRENDS OF DEVELOPING STUDENT INTERESTS WITHIN THE ISPOR STUDENT NETWORK, 2011 TO 2016

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OBJECTIVES: Each year, the International Society of Pharmacoeconomic and Outcomes Research (ISPOR) Student Network administers a "Student Interest Survey" to identify student member interests in the field. This study aims to evaluate changes in student interests. **METHODS:** Survey data was available for years from 2011 to 2016. Each year, the online survey was posted on ISPOR website and Student Network's Facebook Page. Additionally, email reminders were sent to registered ISPOR members via the ISPOR Student Network and Student Chapter Presidents. To improve the response rate, incentives were offered. Responses were evaluated according to its availability in each year. **RESULTS:** The survey was distributed to approximately 900 student members each year. The response rate ranged from 18%-24% (total number 141-218 each year) during the study period. Most respondents lived in North America (mean \pm SD:57 \pm 12.24%) and were enrolled in a PhD program (mean \pm SD:52 \pm 2.9%). The interest in attending the next Annual International meeting averaged 51% over the years. The level of interest in the Student Research Showcase and Mock Interviews significantly increased over the past five years (51% in 2013-14 to 81% in 2015-16) while interest for Student T-shirt Competition dipped (52% in 2012-13 to 30% in 2015-16). Most students were interested in guest speakers from government/policy makers (mean \pm SD:77 \pm 4.4%), academia (mean \pm SD:77 \pm 6.4%), pharmaceutical industry (mean \pm SD:73 \pm 6.5%), and consulting (mean \pm SD:71 \pm 4.7%) at student forums and educational webinars. Shifting interest in research topics for student forums and educational webinars changed from general health outcomes overview (91% in 2012) to specific HEOR areas such as economic evaluation, comparative effectiveness, and patient-reported outcomes (80%, 82%, 70% respectively in 2016). Students preferred specific topics presented as case studies at educational webinars. **CONCLUSIONS:** As the field of HEOR keeps evolving, students interest are becoming more specific. The trends of student interest over the past 5 years highlight avenues to enhance student engagement and knowledge.

PRM167

MEASURING THE VALIDITY AND RELIABILITY OF VALUE ASSESSMENT FRAMEWORKS FOR CANCER DRUGS: AN EVALUATION METHOD

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OBJECTIVES: We aimed to develop a methodology for evaluating convergent validity and inter-rater reliability of value assessment frameworks. **METHODS:** Framework convergent validity, defined as the correlation among drug rankings across frameworks, can be assessed using Kendall's W coefficient. Framework reliability is evaluated using intraclass correlation coefficients (ICC), which measure the stability of outcomes across users. Drugs can be assessed by independent physician and non-physician evaluators, who can use published drug trial data and instructions provided by framework developers to assign each drug a numeric or letter score. Mean scores for drugs within pre-defined categories (e.g., condition; indication) are rank-ordered to estimate Kendall's W. Multiple scores for the same drug are compared using ICC. To evaluate stability of results, W and ICC are assessed with varying numbers of evaluators and frameworks. The method was applied here by 8 evaluators, who assessed 15 oncology drugs and completed a survey on their experiences. **RESULTS:** Excluding review of drug trial data, each assessment took on average 25 minutes for ASCO, 21 for ICER, 14 for ESMO, and 8 for NCCN. Mean time to review each drug's data was 20 minutes. Kendall's W was 0.560 (p=0.010), 0.562 (p=0.010), and 0.920 (p<0.001) for drugs assessed in breast, lung, and prostate cancers, respectively. ICC (95% CI) for ASCO, ESMO, ICER, and NCCN were: 0.800 (0.660-0.913), 0.818 (0.686-0.921), 0.652 (0.466-0.834), and 0.153 (0.0045-0.371), respectively. Evaluators considered framework usability reasonable with this method. **CONCLUSIONS:** This novel method allows quantitative analyses of value assessment frameworks' convergent validity and inter-rater reliability. Although the approach can be used to determine the reproducibility of value assessments produced by these frameworks, the true test of their contribution to value-based decision-making will be how they influence decisions made by clinicians and patients when used in clinical practice settings.

PRM168

RELEVANCE OF INDIRECT COMPARISON IN HAS ASSESSMENT

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OBJECTIVES: "Head-to-head" trial or direct comparison is the classical approach considered as gold standard to compare the efficacy, safety and additional overall benefit of 2 treatments. Indirect comparison may in some cases be the only option to compare interventions. Although, in theory, French health authority (HAS) accepts the indirect comparisons and a guideline for indirect comparison is published, it is not clear if they are accepted in practice. The aim of this study is to identify the number of indirect comparisons in oncology as well as their acceptability by HAS. **METHODS:** HAS reports published between 01/01/2012 and 31/12/2016 for oncology products were extracted from HAS website. Only initial submission reports were included in this study. Generics and biosimilar products assessments were excluded. Then, indirect comparisons were identified in each report as well as the opinion of HAS on these comparisons when available. **RESULTS:** 292 reports for oncology products were extracted among which 67 were included in this study. Indirect comparisons were submitted only for 8 of the 67 products in addition to the head-to-head randomized clinical trials. HAS considered that indirect comparisons have a minor impact and they were not considered actually in the final assessment. Consistently, HAS questioned the value of these indirect comparisons because they were thought to have limitations due to period differences, potential heterogeneity of studies (population and patients' management etc) as well as potential population selection that may be very different even though those heterogeneity criticisms were not robustly documented. **CONCLUSIONS:** The use of indirect comparison is becoming unavoidable as it is almost impossible to generate comparative head-to-head data for all relevant interventions. Despite some products indirect comparisons availability for other HTA agencies, they are not filed to HAS. When filed they happen to have very little impact on the HAS assessment.

PRM169

PREFERRED INFORMATION SOURCES AND NEEDS OF CANCER PATIENTS ON DISEASE SYMPTOMS AND MANAGEMENT: A CROSS-SECTIONAL STUDY

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OBJECTIVES: This study aimed at identifying the information needs of cancer patients, their preferences for the means of receiving health information, and the perceived level of satisfaction of existing possibilities for acquiring cancer-related information in Ethiopia. **METHODS:** An institutional-based cross-sectional survey was employed on 556 cancer patients undergoing chemotherapy in the oncology wards of Gondar University Referral Hospital and Tikur Anbesa Specialized Hospital. Data were collected through interviewer-administered questionnaire. **RESULTS:** The principal information regarded as the most important by the majority of them (67.26%) concerned information on the specific type of cancer (name and stage of cancer), followed by the side effects of chemotherapy and their management (63.29%) and "prognosis (survival)" (51.8%). Doctors were the overwhelming information source about cancer (88.8%), followed by nurses (34%). The majority of respondents (70.3%) was not satisfied at all or satisfied a little, while 15.6% of respondents reported that they were "quite" or "very" satisfied with the existing possibilities for acquiring information regarding cancer. **CONCLUSIONS:** Medical practitioners other than doctors and nurses such as clinical pharmacists should support and identify measures that can enhance patients' satisfaction level regarding the existing possibilities for acquiring information regarding cancer. Periodic assessment of cancer patient's information

requirements is also crucial, considering the ever-changing dynamics of priorities of such information desires.

PRM170

BARRIERS AND SOLUTIONS FOR REAL-WORLD CHART REVIEW EVIDENCE GENERATION

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OBJECTIVES: The growing importance of real-world evidence (RWE) has resulted in the need to generate and evaluate more data under tighter timelines. We aim to describe challenges and propose solutions in conducting retrospective chart review studies that evaluate treatment patterns, clinical outcomes and healthcare resource use. **METHODS:** Qualitative assessment of the implementation of 3 chart review studies (1 in Europe [EU]; 2 in North America [NA]) in the last 2 years, and the identification of barriers during study conduct for future data collection improvement. Studies were evaluated based on patient selection procedures, robustness of data collection and timelines to collect data. **RESULTS:** The studies were in gastroenterology, oncology and respiratory disease therapeutic areas. Study scope ranged from 220-340 patients and 8-27 sites. Barriers identified included: patient consent requirement in the EU, electronic medical record (EMR) data accessibility and data collection duration. Consent rate for the EU study was 71%. Over 75% of sites used an EMR to abstract data, and data collection ranged from 8-12 months taking 1.7 times longer than anticipated. Potential solutions identified include: 1) working with EU ethics committees to better understand patient privacy and data protection requirements for chart review studies, 2) working with site technology departments to set-up EMR data extracts (i.e., reducing manual chart abstractions thereby reducing data collection duration) and 3) providing supportive tools for data collection and automated analytics without breaching patient confidentiality. **CONCLUSIONS:** Understanding the key challenges associated with study design and execution as well as leveraging technological innovations resulting in cost and timeline efficiencies is paramount. Since most sites are using EMR systems and patient-level data abstraction is time consuming, exploring alternative approaches to extracting data directly from site EMR systems is warranted to generate RWE more efficiently.

PRM171

IMPORTANCE OF CLINICAL OUTCOME ASSESSMENT (COA) DATA IN THE EVALUATION OF MEDICINES FOR THE TREATMENT OF RESTLESS LEGS SYNDROME (RLS): A REVIEW OF THE LABELS OF MEDICINES APPROVED BY THE FDA AND THE EMA

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OBJECTIVES: Restless legs syndrome (RLS) is a neurologic sensorimotor disorder characterized by an irresistible urge to move the legs when they are at rest. The urge to move is usually due to unpleasant feelings in the legs. Treatment includes lifestyle changes and use of medicines. The objectives of this study were 1) to identify the medicines approved for the treatment of RLS by the Food and Drug Administration (FDA) and the European Medicines Agency (EMA); 2) to find out about the use of clinical outcome assessments (COAs) in the approval process; and 3) to identify the COAs endpoint positioning. **METHODS:** The EMA and FDA websites were explored to identify all medicines approved for RLS. The PROLabels database, through the ePROVIDE platform, was used for labeling claim identification. All corresponding labels and reviews were reviewed for endpoint positioning. **RESULTS:** The agencies approved nine products with RLS indication (representing four INN, i.e., gabapentin, pramipexole, rotigotine, ropinirole); four products were approved by the FDA, and five by the EMA, including one generic of pramipexole. For the products approved by both agencies (n=2), the sponsors submitted the same data for approval. All products were evaluated using the same PRO measure, i.e., the International Restless Legs Syndrome Study Group Rating Scale (IRLS), which assesses disease severity. All had a similar claim, i.e., improvement in baseline IRLS score. The mean change from baseline in IRLS was a co-primary efficacy endpoint. The other COA used to develop a co-primary efficacy endpoint was a ClinRO, either a Clinical Global Impression scale of Improvement (CGI-I) or a Clinical Global Impression scale of Illness Severity. **CONCLUSIONS:** The patient's perspective is of paramount importance in the evaluation of medicines approved for RLS. The clinician input is also considered as a valuable endpoint since all evaluations were based on the use of co-primary PRO/ClinRO.

PRM172

SYSTEMATIC LITERATURE REVIEWS IN RARE DISEASES: CONSIDERATIONS, ISSUES AND RECOMMENDATIONS WHEN FACED WITH AN IMPERFECT EVIDENCE BASE

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OBJECTIVES: Systematic literature reviews (SLRs) of real world evidence (RWE) are often conducted to summarize evidence on treatment patterns, natural history, and the epidemiological, humanistic and economic burden of illness. When the disease of interest is rare, the evidence can be difficult to find, and conventional approaches to SLR conduct may need to be adapted. Our objectives were: 1) to highlight key differences in SLR conduct between those focusing on RWE in rare diseases versus common diseases; and 2) to present a conceptual framework outlining pertinent considerations and recommendations for researchers designing and carrying out SLRs of RWE in rare diseases. **METHODS:** We conducted a targeted review of SLRs in rare diseases that used RWE, as well as of methodological guidance on SLRs. We used this literature base to develop and synthesize key considerations and recommendations regarding the conduct of SLRs in rare diseases as it compares with SLRs conducted for more common diseases, focusing

on RWE. **RESULTS:** Our framework highlights key considerations relating to: inclusion criteria, search strategies, data sources, data extraction, risk of bias assessment, and analysis. Compared with SLRs in more common diseases, rare disease SLRs tend to require a broader approach: due to limited data availability, search strategies are often kept broad at the beginning to increase sensitivity, and may be narrowed iteratively. Furthermore, rare diseases SLRs can capture evidence from non-traditional research designs and data sources (e.g. patient or caregiver blogs) as well as employ additional analytics and modeling in order to make the best use of imperfect evidence. **CONCLUSIONS:** Limited methodological guidance is available on designing and conducting SLRs of RWE in rare diseases where evidence is scarce. Our comprehensive conceptual framework can serve as a methodological reference for researchers conducting SLRs in a rare disease.

PRM173

METHODOLOGICAL CHALLENGES OF INDIRECT COMPARISONS IN HEMOPHILIA A

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OBJECTIVES: Indirect treatment comparisons must adjust for inter-study differences in design and patient characteristics, which may strongly influence outcomes. This study investigated impact of inter-trial patient differences on the comparative effectiveness of rFVIII (ADVATE) and extended half-life rFVIII (ADYNOVATE). **METHODS:** A targeted review identified Advate or Adynovate trials for which individual patient data were available (i.e., Baxalta-sponsored). Enrolled patients aged 12-65 years with severe hemophilia A (HA) who received and complied with prophylactic treatment with Advate or Adynovate were included in the analysis. A negative binomial model was used to compare number of bleeds during the first 6 months, and logistic regression was used to compare the odds of achieving ≤ 1 bleed. All regression models controlled for the effect of patient characteristics. **RESULTS:** Two Advate studies (Tarantino 2004, n = 55; Valentino 2012, n = 49) and one Adynovate study (Konkle 2015, n = 68) were included. Patients exhibited statistically significant differences in body mass index (p = 0.03), Caucasian race (p = 0.01), and prior medications (alimentary tract and metabolism, p < 0.01; nervous system disorder, p < 0.001). Presence of target joints was not consistently recorded so could not be included in the regression models. The incident rate ratio of annualized joint bleeding rates (AJBR) was not statistically significantly different (odds ratio 1.0 for Adynovate vs Advate; 95% CI 0.5 - 2.0). Additionally, no significant difference was observed for patients who had ≤ 1 bleed (odds ratio 0.5 for Advate vs Adynovate; 0.5-1.2). **CONCLUSIONS:** No difference was found for AJBRs among adolescents and adults with severe HA treated with Advate or Adynovate targeting a trough level of 1-3%; however, clinically meaningful heterogeneity remained. Despite techniques to control for differences, patient heterogeneity remains a significant challenge for conducting comparisons of hemophilia studies.

PRM174

MAKING THE MOST OF EXTERNAL COMPARATORS: A STUDY OF FRACTURE HEALING IN PATIENTS AT RISK OF NON-UNION

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OBJECTIVES: Fracture non-unions result in significant physical, emotional, and economic burden on patients. Low-intensity pulsed ultrasound (LIPUS) is an FDA-approved device to treat established fracture non-unions and facilitate the healing of acute radius and tibia fractures. However, commercial insurers routinely cover use in patients with fractures beyond approved indications in an attempt to avoid surgical non-union repair costs later. To align LIPUS's real-world use with its labeling, a novel real-world study to establish effectiveness of LIPUS for mitigating fracture nonunion is proposed. **METHODS:** The fracture non-union rate between a prospectively enrolled LIPUS-treated cohort will be compared to untreated historical controls selected from MarketScan™ Claims. Fracture status will be obtained from presence of non-union diagnosis codes 12 months post-fracture date. The potential for selection bias will be addressed using propensity score methodology. Given underlying differences in data collection, key methodological issues include creation of equivalent operational definitions for patient selection, study time points, patient characteristics, and outcomes to maximize the probability of equivalent ascertainment across different modes of data capture. **RESULTS:** Variables were defined for controls using diagnosis and procedure codes; patient questionnaires and chart abstraction will be used for the LIPUS cohort. For example, to minimize recall bias, the LIPUS cohort will use a 3-month pre-fracture recall period, while controls will use 6 months pre-fracture claims to account for 90-day supplies. Non-unions in the LIPUS cohort will be assessed by interview and chart review, while algorithms will be developed for claims analysis to capture non-unions reported within a clinically meaningful period. Methodological solutions will be presented. **CONCLUSIONS:** This novel approach demonstrates methodology for measuring device effectiveness in the real-world comparing cohorts enrolled both prospectively and within "Big Data".

PRM175

IMPORTANCE OF CLINICAL OUTCOME ASSESSMENT (COA) DATA IN THE EVALUATION OF MEDICINES FOR THE TREATMENT OF ALZHEIMER'S DISEASE (AD): A REVIEW OF THE LABELS OF MEDICINES APPROVED BY THE FDA AND THE EMA

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OBJECTIVES: Alzheimer's Disease (AD) is a chronic neurodegenerative disease. It is the most common cause of dementia among older adults, leading to the loss of

cognitive functioning and behavioral abilities interfering with a person's daily life and activities. The objectives of this study were 1) to identify the medicines approved for the treatment of AD by the Food and Drug Administration (FDA) and the European Medicines Agency (EMA); 2) to find out about the use of clinical outcome assessments (COAs) in the approval process; and 3) to identify the COAs endpoint positioning. **METHODS:** The EMA and FDA websites were explored to identify all medicines approved for AD. The PROLabels database, through the ePROVIDE platform, was used for labeling claim identification. All corresponding labels and reviews were reviewed for endpoint positioning. **RESULTS:** Generics were neither included in the list of approved products nor reviewed, since the material used for their approval is identical to the original product. The agencies approved 14 products (representing five INN, i.e., donepezil hydrochloride, galantamine hydrobromide, memantine hydrochloride, memantine hydrochloride + donepezil hydrochloride, and rivastigmine); ten products were approved by the FDA, and four by the EMA. All products were evaluated using COAs as co-primary end-points, i.e., measures of cognitive performance [(ADAS-cog, Severe Impairment Battery (SIB)), and global impression of change [Clinician Interview-Based Impression of Change-Plus (CIBIC-Plus)], or daily functioning [Modified Alzheimer's Disease Cooperative Study Activities of Daily Living Inventory for Severe Alzheimer's Disease (ADCS-ADL-sev); Behavioral Rating Scale for Geriatric Patients (BGP) - dependency subscale]. **CONCLUSIONS:** COAs are of paramount importance in the evaluation of medicines approved for AD. Most of the COAs used are either performance outcome (PerFO) or clinician-reported outcome (ClinRO) measures, given that the self-evaluation by the patient is impossible.

PRM176

CLINICAL MANAGEMENT AS A RESOURCE FOR COST STUDIES METHODOLOGY: AN EXAMPLE APPLIED TO NON-SMALL CELLS LUNG CANCER (NSCLC)

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OBJECTIVES: In the context of a payment mechanism construction for submitting a proposal to the Chilean National Health Fund and on the basis that current payment mechanisms do not consider accurate reviews on the actual costs of diseases, it was necessary to develop an efficient and realistic strategy for costs estimation. The aim of this work was to estimate direct costs associated to NSCLC by using an efficient and appealing methodology for the public insurance. **METHODS:** A cost study based on a hybrid and novel methodology was conducted. An specialty facility and physicians familiar with the disease were identified. Clinical pathways were developed according to real clinical care and supplies consumed (variable: quantity). These results were matched with statistic data provided by local information system and complemented with national-official price lists (variable: price). **RESULTS:** Comprehensive clinical pathways reflecting clinical behaviour were developed (payment base), allowing micro-costing. Patients routes were also identified (frequencies). Afterwards, costs per disease-stage were obtained at patient level and population level (Total Cost for all stages and full treatments coverage: USD 4.077.000 (n=350 cases); Most expensive stages -IIIB and IV stage- UDS 2.141.762 (n=25 cases), which represents the 52% of expenditure. Equity costs were defined as barriers preventing patients from a specialized treatment, these were also calculated: USD 302.000 (n=25 cases). Tyrosine Inhibitors (2nd line high-cost treatment) represent the 28,05% of expenditure. By including novel strategies for funding, immunotherapy represents only a 3,81% of the High-Cost Fund, making feasible including these drugs at the current expenditure level. **CONCLUSIONS:** A cost study of high internal validity was achieved. The role of specialty facilities and medical teams it is crucial towards a more efficient and clinically validated costs studies, based on clinical pathways reflecting the accurate consumption and evidence-based medical behaviour. Based on these data, a proposal was submitted for promoting immunotherapy coverage.

RESEARCH ON METHODS – Conceptual Papers

PRM177

COHORT ANALYSIS METHODS TO ESTIMATE THE BUDGET IMPACT OF ONCOLOGY TREATMENTS BY LINE OF THERAPY

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OBJECTIVE: Estimating budget impact (BI) is relatively simple for chronic conditions and isolated acute conditions. However, estimating BI for oncology treatments is complicated by episodic treatment patterns and variable treatment times. We present cohort analysis methods to estimate the BI of oncology treatments by line of therapy. **METHOD:** BI analyses are based on the size of the treated patient population, cost of treatment per patient, and potential market share shifts over a given time horizon. In oncology, duration of treatment can vary based on differential progression-free survival by treatment regimen and line of therapy, with patients receiving initial treatment shortly after diagnosis until disease progression followed by additional lines of therapy. To model these treatment patterns, BI analyses may utilize treatment sequencing among individual patients to estimate treatment costs and BI, resulting in greater complexity and additional data requirements. We present simple cohort analysis methods to estimate the cost and BI of oncology treatments. Incidence of disease and the proportion of patients receiving each line of therapy are used to estimate the size of the annual target population. Utilizing a few plausible assumptions, the target population and average duration of treatment are used to estimate the annual steady-state treatment cost in the form of a diagonal treatment vector with an area equivalent to the incidence multiplied by the duration of treatment. We show how these cohort analysis methods relate to an individual patient level analysis and provide some worked examples to illustrate how they are used to calculate treatment cost and BI. **CONCLUSION:** Cohort analysis methods can be used to estimate the cost

and BI of oncology treatments despite episodic treatment and variable duration of therapy. Use of cohort analysis methods can reduce the complexity of oncology BI models and make it easier to communicate the results to healthcare payers.

PRM178

IMPROVING DISEASE MANAGEMENT THROUGH INSIGHTS GAINED FROM REAL-WORLD OBSERVATIONAL DATA

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Background: Predicting disease progression or adverse health outcomes can be accomplished using insights gained from real-world observational data. Information collected routinely while providing patient care enables the development of risk models that identify patients with increased likelihood of disease or poor/costly health outcomes. Such models can improve patient management, especially in populations prone to such outcomes (e.g. type 2 or gestational diabetes, asthma, mental disorders). Here we describe the process of developing risk models, along with selected successful examples. **Methods:** Large nationally representative EMR, claims, and EMR-claims linked databases were processed to evaluate demographics, vital signs, diagnoses, diagnostic tests/results, procedures, insurance, and prescription details in disease-specific patient populations. Predictive models were developed and validated using multivariable regression techniques in these populations to identify key drivers of disease and health outcomes. **Results:** Risk models successfully predicted primary and secondary medication non-adherence and non-persistence in diabetic patients, with index medication type, history of non-adherence to other chronic condition medications, HbA1C level, and prior prescription fill patterns identified as key predictors. Similar models of medication non-adherence for schizophrenia and bipolar disorder patients identified age, substance abuse and concomitant psychiatric medications as key drivers, while models of hospitalization highlighted substance abuse or other psychosis diagnosis, concomitant use of psychiatric medications and history of non-adherence to antipsychotics as key drivers. **Conclusion:** Key variables that identify patients at high risk of adverse outcomes such as those identified in our examples can be easily ascertained during physician visits, and thus used to initiate disease management interventions. Building risk models into EMR or healthcare claims systems, and arming physicians or other healthcare decision-makers with the ability to facilitate their use at the point of care, has the potential to intercept disease progression and improve outcomes. Such analytics can help both providers and payers achieve effective disease management goals.

PRM179

HOW TO EVALUATE THE IMPACT OF A REAL-WORLD QUALITY IMPROVEMENT PROGRAM ON A MEANINGFUL HEALTH SYSTEM OUTCOME THAT HAS A POLICY IMPLICATION?

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During the last two decades, there has been an increasing number of quality improvement programs for patients with chronic diseases that aim to enhance the efficiency and outcomes of chronic care. While such programs have been well generated, the evaluation tools for these real-world implementations are somewhat underdeveloped, particularly for programs that originated at the upper level of the health care system (i.e., programs that attempt to change the organizational and environmental structure of a system rather than solely individual patients). Therefore, the purpose of this study is to employ an innovative approach called a multiple baseline design to investigate naturalistic, multi-setting quality improvement programs. A multiple baseline design is a novel analytical tool in healthcare research and a class of interrupted time series analysis that involves both repeated measurements of outcomes over a period and the serial introduction of an intervention to each study unit on a staggered schedule. This study uses a multi-geographical state, community-based change program for children with asthma that has been developed in the four South Central States as an example of real-life, upper-level improvement efforts. This study also proposes the use of both longitudinal patient-level administrative claims data and clinic-level performance indicators to determine if the community-based change program subsequently decreased unnecessary utilization of health services among children with asthma. The unnecessary utilization that is imperative for healthcare policies includes emergency department visits and hospitalizations. The insights gained from this study could facilitate policy decision making if a huge investment at the upper level enhances chronic illness care.

PRM180

THE USE OF QUALITATIVE (EXIT) INTERVIEWS IN CLINICAL TRIALS: VALUE, IMPLEMENTATION AND KEY CONSIDERATIONS

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Background: As the healthcare industry becomes more patient-centric, ensuring the patient voice is heard throughout the product life cycle is critical. Patient-reported outcome (PRO) measures provide a standardized means of evaluating and monitoring the efficacy and safety of products and services from a patient perspective. However, conducting qualitative interviews as part of clinical research studies provides unique opportunities for in-depth exploration of patient experiences. **Objectives:** To discuss the application, value and key considerations for implementing qualitative (exit) interviews in clinical research with reference to illustrative examples from a range of disease areas. **Results:** When implemented in clinical studies alongside PRO assessments, rich data from interviews can be used to contextualize PRO data and provide supplementary insights as part of a mixed-

methods approach to evaluating the benefit of medical interventions. Such interviews can also capture concepts that are not adequately measured by available PRO measures (e.g., satisfaction of a novel treatment) or concepts that are too complex to capture reliably using a PRO (e.g., benefit-risk evaluations). When employed in early clinical studies, interviews may also help to generate evidence to evaluate content validity of PRO measures prior to their implementation in pivotal studies. Qualitative exploration of the significance of changes experienced by patients can be used to complement quantitative data and help to establish valid responder definitions and interpretation of meaningful change. Finally, feedback during these interviews could inform operational aspects of trial design. Key considerations for sponsors include how best to incorporate interviews into clinical trial programs (either within or outside the clinical trial protocol), timing of interviews in the study schedule, standardization of data collection and analysis and how to minimize patient burden. **Conclusions:** Qualitative (exit) interviews provide a novel and valuable means of maximizing insight from study participants but pose unique considerations for implementation into clinical research.

PRM181

DEFINING MULTI-AGENT CHEMOTHERAPY REGIMENS USING CLAIMS DATA ANALYSIS: IS THERE A ROLE FOR DATA VISUALIZATION?

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In the oncology setting, health services researchers often utilize claims-based algorithms to identify complex chemotherapy regimens and lines of therapy. The algorithms build on prior investigation of claims data and/or electronic medical records (EMR) or on prior published work. However, prior studies do not typically provide the methodological detail that permits reproduction or supports evaluation of the algorithm, which can limit opportunities to improve on a key measure for cancer studies. We show how the use of data visualization software provides longitudinal views, supports the identification of multi-agent chemotherapy regimens using claims data, and provides transparency. **Recommendation:** we propose incorporating data visualization during the process of algorithm development as follows: (a) based on clinical guidelines, clinician input, and relevant literature, identify the regimens and their constituent medications. (b) Using claims data, flag the occurrence of any of these medications following diagnosis. (c) On a random subset of the event-level data, characterize the longitudinal sequence of chemotherapeutic agents using data visualization software and compare actual patterns against expected patterns. (d) Define and describe regimens in terms of constituent medications, duration, and time between regimens. (e) Using [c] and [d], develop and apply a preliminary algorithm that specifies the medications, the acceptable period of time for treatment administration within the regimen, the acceptable period of time between regimens. (f) Confirm the face validity of the graphical and summarized quantitative output from [c], [d], and [e] with a practicing oncologist/specialist. (g) Modify and expand the algorithm as needed given the desired objective (e.g., to define first-line therapy or multiple lines of therapy). **Conclusion:** Compared to an approach that utilizes primarily claims and/or EMR data to develop algorithms for identifying treatment with multi-agent chemotherapy regimens, the incorporation of data visualization provides an efficient way to elucidate the embedded structure and assumptions of claims-based algorithms.

PRM182

MODELLING DISEASE PROGRESSION IN PATIENTS WITH GEOGRAPHIC ATROPHY

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OBJECTIVES: Geographic Atrophy (GA) is an advanced form of age-related macular degeneration (AMD). Unlike neovascular AMD (nvAMD), GA has a minimal impact on best-corrected visual acuity (BCVA) in the early stages of the disease. Therefore, modelling disease progression based on BCVA levels may not be appropriate in the context of GA. The objective of this research is to define the most appropriate attributes to model GA progression. **METHODS:** A qualitative search was undertaken to understand which disease characteristics are used to describe GA progression. The literature was screened (non-systematically) and relevant publications were identified. The disease characteristics used to describe the progression of GA and those that impacted patient outcomes were extracted and their importance assessed. **RESULTS:** In the context of GA, several disease characteristics have been identified that have a significant impact on patient outcomes. The number of eyes affected (unilateral vs. bilateral disease) and the location of the GA lesion (fovea-involved versus non-fovea-involved) appear to be the most important variables. Other variables that have an impact on patient outcomes are the total size of the GA lesions and the number of lesions in the retina (unifocal vs. multifocal GA). BCVA appears to be impacted only when the GA lesion spreads into the fovea (in the later stages of the disease). **CONCLUSIONS:** To date, disease progression for most visual disorders has been based on the level of BCVA, which is then linked to patient outcomes. In the context of GA, where BCVA is not an appropriate measure, the multi-factorial concept of visual function (which includes BCVA) should be used to model GA progression and to link GA progression to patient outcomes. This research could be applied in the context of cost-effectiveness modeling.

PRM183

RWE DECODER: A DECISION MAKER'S FRAMEWORK FOR ASSESSING REAL WORLD EVIDENCE

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Objectives: With the growth of electronic health records and large data repositories, and increasing efforts to systematically collect information from routine clinical

encounters, the potential for development and use of Real World Evidence (RWE) is exploding. However, there is not yet consensus among “post-regulatory” decision makers (see methods) on a framework for assessing RWE that accurately discriminates between studies deserving greater consideration in decision making and those inappropriate or irrelevant for use. For many decision makers, the value of RWE is still unclear, creating uncertainty for researchers using rapidly growing RWE resources. The Center for Medical Technology Policy (CMTF) and Green Park Collaborative (GPC, a CMTF program) developed a framework for decision makers more confidently and consistently to assess RWE for their unique decision making needs. **Methods:** The project approach entailed: 1) Stakeholder and Expert Engagement, 2) Background Research, 3) Vetting of Draft Framework and In-Person Meeting, and 4) Incorporation of Key Findings and Final Framework. Key stakeholders engaged were post-regulatory decision makers: payers, clinical guideline developers, health system leaders, health technology assessment groups, and accountable care organizations. Patient advocates, industry stakeholders (who were sponsors), and academic researchers were also engaged. **Results:** The Framework establishes Rigor and Relevance as the two primary domains with which to assess RWE for decision-making. It is an interactive Excel tool, composed of a series of modules: Module 1. Articulating the Research Question, Module 2A. Assessing the Relevance of each RWE study, Module 2B. Assessing the Rigor of each RWE study, Module 2C. Magnitude and Direction of Effect, Module 3. RWE Framework Visual Summary. **Conclusions:** The GPC RWE Framework offers a manageable approach for decision-makers who currently lack a systematic approach to assessing RWE for decision-making, or who otherwise have limited training, staff, or time dedicated to the regular assessment of research evidence for decision-making.

PRM184

A WORKED EXAMPLE OF USING COMPUTER-ASSISTED QUALITATIVE DATA ANALYSIS SOFTWARE (CAQDAS) TO SUPPORT CONTENT VALIDITY IN PATIENT-CENTERED OUTCOMES RESEARCH

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Background: Standards for the development of patient-reported outcome (PRO) instruments emphasize the importance of establishing content validity in the target population to ensure comprehensive and relevant assessment of the concept(s) of interest. Content validity is supported by evidence from qualitative research studies with the target population. Compiling this evidence often involves analysis of extensive and diverse sets of qualitative data (written transcripts, audio, video etc.). **Objective:** To demonstrate, through a worked example, best practice techniques when using Computer-Assisted Qualitative Data Analysis Software (CAQDAS) to support PRO development and validation. **Methods:** CAQDAS facilitates iterative coding of qualitative data and assignment of codes reflective of the underlying concepts (e.g., specific symptoms and impacts) in accordance with thematic analysis and grounded theory approaches. Multiple codes can be assigned to excerpts of data where more than one concept is discussed. Concepts can then be grouped into ‘families’ based on commonality to facilitate the interpretation of content (e.g. all pain-related symptoms). Similarly, data can be simultaneously grouped by patient profile to identify differences based on demographic or clinical characteristics such as age, sex, or severity of condition. CAQDAS functions are used to attach researcher notes of interest to the data, perform keyword searches of transcripts and codes, and conduct complex exploration of the data (e.g. co-occurrence of codes suggestive of relationships between concepts). CAQDAS allows researchers to easily export the coded data for further analysis and reporting. Advanced output functions can be used to assess conceptual saturation (i.e., full exploration of the concepts of interest) and to determine if further data collection is necessary. **Conclusion:** CAQDAS is a valuable tool that can be used by researchers to facilitate the organization and analysis of large volumes of qualitative data, while providing the necessary audit trail and evidence to support PRO development to regulatory standards.

PRM185

A POTENTIAL SOLUTION MAKING EXPENSIVE TECHNOLOGIES AFFORDABLE UNDER BUDGET CONSTRAINTS IN UNIVERSAL HEALTH COVERAGE: CASE STUDY FOR JAPAN USING DIFFERENTIAL PRICING

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OBJECTIVES: Despite the introduction of a two-year pilot policy in government for value-based re-pricing in Japan, still no chart exist on affordability of expensive technologies and sustainability of the universal health coverage (UHC). To address this fundamental question, we aimed to seek a potential solution using differential pricing (DP) for the National Formulary list. **METHODS:** A theory is developed based on cyclic bipolar-state modeling with investment and disinvestment, in which cost increase by investments for new technologies is cancelled out by cost decrease by disinvestments using DP. Since the Japanese national list prices are applied to the whole country without any differentiation, cost-saving could be achieved if the government sets the list prices discounted by region instead of applying the same price to the whole country. Our approach formulated this hypothetical DP application. **RESULTS:** Suppose two statistical distributions by region, regarding: 1) socio-economic statuses θ_i and 2) health outcomes δ_i . Then, four-step procedures were taken as follows: 1) Determine the weight w_i by region in consideration of ranking the product, $\theta_i \times \delta_i$, 2) Determine the prices by region, multiplying the weight w_i to the mean list price P_m , 3) Estimate the overall mean price at the national level based on the regional mean price estimated at Step 2, and finally, 4) Estimate the net cost-saving by subtracting the overall mean price obtained at Step 3 from the original mean list price P_m . Eventually the net cost-saving was simply formulated in the form of $P_m \times (1 - \text{the mean of the weights } w_i)$. **CONCLUSIONS:** Our DP solution for affordability of

expensive technologies can work in theory to ensure an affordable budget space to maintain sustainability of the UHC system in Japan.

PRM186

EMBEDDING A VALUE FOCUS EARLY IN THE MEDICAL TECHNOLOGY INNOVATION PROCESS: INSIGHTS FROM 5 YEARS OF EXPERIENCE AT THE STANFORD BIODESIGN PROGRAM

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OBJECTIVES: The adoption of new medical technology is increasingly based on thorough assessment and demonstration of a health-economic value proposition. Innovators need to appreciate economic and clinical effectiveness data requirements early in the translational process to develop solutions that are not only clinically relevant, but also compelling from a health-economic value perspective. We report on our approach and experience in embedding value teaching in a postgraduate innovation fellowship program. **METHODS:** The Stanford Biodesign fellowship is an immersive, one-year full time fellowship that brings together postgraduate candidates from medicine, engineering, and business. Over the last 15 years, the teaching process, which includes three main phases (identify - invent - implement) has been refined and comprehensively documented, and is now replicated in numerous innovation programs worldwide. Over the last five years, we have inserted a value focus into the teaching process, building on existing concepts of technology assessment and cost-effectiveness analysis and applying them systematically to the Biodesign innovation process. **RESULTS:** We developed a value curriculum structured in 3 phases: Value exploration, Value estimation, and Value proposition. These value phases align with the three main phases of the Biodesign teaching process. Value exploration provides introduction and high-level guidance on identifying key value drivers in clinical need areas. Value estimation supports decision making as various solution concepts are being assessed. The third phase, Value proposition, provides fellows with the tools for evidence collection and definition of a rigorous value proposal. **CONCLUSIONS:** We describe a curriculum designed to teach innovators a systematic and structured approach to health economic needs identification and value demonstration. Application of a value focus early in the innovation process improves the likelihood of developing technologies that will be successfully translated to patient care in the current health economic environment.

PRM187

BEST PRACTICES FOR IMPROVED DESIGN AND EXECUTION OF "PIGGYBACK" HEALTH ECONOMIC STUDIES

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Health economic (HE) studies comprise a variety of analytic approaches and utilize disparate data sources. Study objectives can range from determining the economic burden of a particular disease to evaluating the budgetary impact of a novel therapy. Data can be derived from payer databases, government sources, peer-reviewed literature, and myriad other sources. Health economic studies are conducted by different types of researchers working at various types of institutions. One of the more compelling types of HE study designs is a cost-effectiveness or cost-utility analysis "piggybacked" on a randomized controlled trial of an investigational pharmaceutical, biologic, or medical device or on an observational study of the real world use of a marketed product. While piggyback studies can be conducted across multiple institutions, they are perhaps most efficiently conducted in totality a singular research organization. Building on lessons learned from actual studies, this presentation will elucidate best practices for design and execution of HE analyses piggybacked on Phase 2/3 trials or observational studies. Best practices presented will range from study initiation through analysis and dissemination of findings. Beyond electronic data capture (EDC) systems historically used in earlier phase clinical trials, piggyback studies may utilize electronic health record (EHR) data, claims data, patient reported outcomes (PROs), and other data. These data are accompanied by new sets of analytic, logistic, and regulatory challenges that must be addressed through all stages of study design and execution. Negotiation of study site contracts and payments and the development of informed consent procedures must reflect regulatory expectations and requirements for both clinical trials and HE studies. Database merging and validation, including the juxtaposition of coding for registrational studies with coding for medical billing, require particular consideration. Finally, simultaneous planning for, and execution of, analysis and reporting of results are essential.

PRM188

USING REAL-WORLD DATA TO INFORM SMARTER CLINICAL TRIALS AND PROSPECTIVE OBSERVATIONAL STUDIES

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Background: The biopharmaceutical industry is evolving such that clinical development is moving from large, well-defined patient populations and highly prevalent disease areas to niche populations and new and rare diseases, making efficient design and recruitment critical. Furthermore, underperforming study sites and unanticipated enrollment and retention challenges compromise the success of clinical trials and other prospective studies. Electronic medical records (EMR), healthcare claims, hospital, and prescription drug data have the potential to guide and refine study protocol design and to inform targeted site selection to drive more efficient study execution. The utility of these data can be further enhanced through the use of both simple and advanced analytics. **Methods:** Through selected case studies, the use of real-world data to assess protocol feasibility and improve study site selection is illustrated. **Results:** In a study of respiratory syncytial virus (RSV), real-world data

were used to narrow down the RSV patient population and understand RSV care in order to shape future clinical studies. A new patient sub-population was identified, and market sizes of previously identified patient sub-populations were estimated; physician profiles were defined in order to identify potential investigators for future studies. In a global study of irritable bowel disease, real-world claims and EMR data were used to quantify current treatment flow and identify key leverage points for use in recruiting optimal clinical trial patients and sites. Finally, nationally representative EMR data were utilized to highlight clusters of eligible patients within or near currently recruiting study sites, and to provide insights on eligible patients at potential new sites to assess efficacy of a new treatment for moderate to severe rheumatoid arthritis. **Conclusion:** Insights from real-world data can inform targeted and more efficient clinical trials and prospective observational studies. Such efforts have the potential to reduce the time and cost associated with these studies.

PRM190

ADDRESSING ECONOMIC EVALUATION NEEDS OF HOSPITAL DECISION-MAKERS IN THE UNITED STATES: A LITERATURE REVIEW AND RECOMMENDED FRAMEWORK FOR MEDICAL DEVICE BUDGET IMPACT MODELS

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Healthcare reform is increasing demand economic value of hospital products. The economic evaluation of drugs is established practice with support of comprehensive methodological guidance; however the equivalent for medical devices is less developed. Traditional cost-effectiveness analyses are sometimes not applicable for devices due to limitations on endpoints such as health utility or mortality. A budget impact analysis (BIA) can be an appropriate and practical tool to support the value analysis of many medical devices, but the frequency and methodology of such use has not been explicitly characterized. Our aim was to review how economic evaluations are currently being conducted from the hospital perspective, and to provide a dynamic framework, with illustrative examples, for device BIAs. The literature review demonstrated substantially less reports on hospital BIAs for devices compared with drugs. Of device BIAs, the common focus was determining how device costs were offset by averted downstream resources such as operating time, complications, repeat procedures, materials (and waste), and length of stay. Here, we illustrate examples of budget impact models using a similar framework but with design elements adapted to different device categories and situations. Examples are presented by: 1) capital, implantable, and commodity device categories; 2) various time horizons to reflect both initial hospitalization and bundled care; 3) incremental device reimbursement status; and 4) different resource and costing methodologies (e.g., direct versus direct plus indirect costs). Examples illustrate various comparative data sources to inform resource use including randomized trials, real-world time-in-motion studies, retrospective databases, expert panels, and network meta-analyses. Using these examples and BIA guidelines for drugs, recommendations are provided on developing and adapting device BIAs for hospitals and the utilization of such tools by hospital value analysis committees. In summary, budget impact models can be very informative for hospital decision-making and need to become more standardized for effective uptake.

PRM191

AN APPROACH TO PHYSICIAN RECRUITMENT FOR EVIDENCE BASED STUDIES IN THE HOSPITAL SETTING

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Developing and implementing evidence-based studies in the preoperative setting, while vital to quality care, can be a real challenge. Not only do you need the institution's approval but you also need to recruit the surgeons, train the staff and develop programs the staff can use to communicate with and educate the surgical patients. And especially for multi-year studies, it is critical to have an internal education program in place to ensure that the reasons for initiating the study are transferred to future staff. Conducting studies related to the impact of pre-surgical immunonutrition supplements are even more challenging. Despite immunonutrition emerging as the gold standard, benefitting patients independent of their preoperative nutritional status and being one of the four components of enhanced recovery after surgery (ERAS) protocols, nutrition is often overlooked. And if nutritional intervention is considered at all, it is often times done in an uncoordinated and haphazard manner. This presentation will explore design and operational considerations for developing and implementing studies similar to the multi-year immunonutrition study conducted at Valley Health. It includes surgeon recruitment, training needs for the staff and patients as well as considerations for data collection, data base development and encouraging patient compliance. Based on the design and conduct of Valley Health's actual immunonutrition study, this presentation will conceptualize a study design, an education model for staff and patients, as well as data selection, management and analysis. Optimizing a preoperative nutritional intervention requires a multidisciplinary strategy specifically aimed to improve patient compliance. Therefore, building upon this example, the presentation will enumerate important data elements and design considerations for those who want to implement an evidence based approach to preoperative immunonutrition therapy.

PRM193

NUANCES OF ASSESSING CLINICIAN AGREEMENT IN CLINICIAN REPORTED OUTCOMES (CLINROS)

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Increased interest of pharmaceutical companies in using ClinROs for clinical trial endpoints and FDA submissions has resulted in renewed interest in the standards for their validation. ClinROs require some different approaches to validation when

compared to Patient-Reported Outcomes (PROs). For example, ClinROs can be based on readings, ratings, or even performance, which adds variability to them and nuances to their validation. One of the key components of validating a ClinRO is establishing its reliability. For most ClinROs, this means inter- and intra-rater reliability. Although often considered straightforward, reliability assessment can be the most technically challenging part of the validation analysis. An overview will be given of the primary competing statistics for assessing reliability (Pearson r , kappa, etc.) including a brief rationale and some pros and cons for each. We will focus on the intraclass correlation (ICC) statistic as the most useful for rating scale data, discussing its many forms and how to correctly choose among them. In particular, we will consider the distinction between aiming to demonstrate consistency or agreement in choosing an ICC. We will also discuss key design considerations that can seriously impact ICCs and undermine the meaningfulness of the validation, for example sample size and how flexible to be around departures from the intended test-retest interval. Also included will be a discussion of framing or identifying ICC standards or criteria for ClinRO validation. Throughout, we will share noteworthy insights from our experience with actual assessments, illustrating how key elements of this whole discussion may be realized in actual ClinRO validation work in the FDA context.

PRM194

THE GET-REAL NAVIGATOR: SUPPORTING HTA AND PAYER EVALUATION OF NEW MEDICINES

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Objectives: Payers and health technology assessment (HTA) agencies are tasked with assessing the effectiveness of new medicines relative to usual practice. There is a role for real-world evidence (RWE) to support traditional trial data in this respect but stakeholders have different views of the acceptability of using RWE. The European IMI GetReal project (www.imi-getreal.eu) was tasked with seeking clarity on the topic and communicating this to stakeholders. **Results:** We describe a web-based tool, the “RWE Navigator” (rwe-navigator.eu). The tool is an educational resource, a source of guidance, and a directory of resources related to RWE in medicines development. The tool includes a two-step process to explore potential effectiveness issues and potential options using RWE to address these issues. Other components include overviews of authoritative links to data sources, and on the governance, synthesis, quality assessment, and bias adjustment such data. The RWE navigator also contains summaries of case studies examined in GetReal and overviews of current policies and perspectives, and related initiatives. **Conclusions:** The RWE Navigator is a valuable shared platform for stakeholders to address the inclusion of alternative study designs and analyses in medicines development using RWE but further work is needed. This work has supported engagement and dialogue between industry and decision-makers, and has driven forward the scientific and policy agenda.

PRM195

ECONOMIC EVALUATIONS OF MEDICAL DEVICES - ISSUES AND CHALLENGES

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Introduction Economic evaluation of medical devices faces a number of challenges due to the issues involved in estimating the effectiveness and cost parameters. **Estimation of effectiveness** There are a number of challenges in estimating the effectiveness parameters. Randomized controlled trials are relatively rare in devices and data from observational studies may need to be used. Also, given short time cycle of medical devices, there may be multiple versions of the same device. Finally, effectiveness of a device is completely dependent on how it is used within the setting/pathway. **Estimation of costs** Costs of medical devices are dependent on organisational setting as the staff and other resource costs make up a significant proportion of the total costs. Furthermore, the costs also depend on diffusion of technology, lifetime of the medical device, redeployment and usage on multiple indications. Unit costs are also dependent on size of the patient population as the overall costs need to be divided by the number of patients. **Economic evaluation** Given the uncertainty in effectiveness estimates, modelling can help with the estimation of the cost-effectiveness of the medical devices. Modelling is useful in synthesising data from different sources which is useful as there may be variations in the parameters between different settings. It is also useful to perform sensitivity and scenario analyses to identify which parameters are the key drivers of the cost-effectiveness. Value of information techniques can also be used to estimate the benefit of performing additional studies (e.g. randomised controlled trials) to reduce the uncertainty of the key parameters. **Choosing the evaluation approach** There is no clear consensus on the methods to evaluate medical devices which may result in different devices being cost effective in different jurisdictions. For example, UK's NICE Medical Technologies Evaluation Programme uses cost-minimization analysis to evaluate medical devices while CVZ in the Netherlands uses an MCDA approach.

HEALTH CARE TREATMENT STUDIES

HEALTH SERVICES – Clinical Outcomes Studies

PHS1

CROSS-SECTIONAL ANALYSIS OF CYSTIC FIBROSIS RELATED DIABETES INPATIENT ADMISSIONS IN THE UNITED STATES

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OBJECTIVES: Cystic fibrosis-related diabetes (CFRD) is a distinct form of diabetes mellitus that is an important complication of cystic fibrosis (CF). The principal

cause is a relative insulin deficiency related to destruction of pancreatic islets. Insulin resistance also may play a role, especially in association with acute exacerbations or chronic progression of pulmonary disease. Our objective is to characterize CFRD patients, their healthcare utilization, as well as associated hospitalization costs. **METHODS:** We conducted a cross-sectional study of CFRD patients (ICD-9 277.09) from the 2012 Nationwide Inpatient Sample (NIS). A prevalence estimate for CFRD was established using the discharge weight that was included in the NIS for each observation; however all other analysis did not include the discharge weight. We compared patients with CF (ICD-9 277.00, 277.01, 277.02, 277.03) to those with CFRD on length of stay (LOS) and total cost using chi-square test of association. **RESULTS:** We estimated US prevalence of inpatients with a diagnosis of CFRD at 4,060 cases. CFRD patients were similar in age, with an average age of 23.26 versus 23.08 years ($p < 0.0231$) in their non-diabetic CF peers. Hospitalizations associated with CFRD patients had significantly greater LOS, 10.59 days compared to non-diabetic patients 8.86 ($p < 0.001$) and number of comorbidities 5.21 versus 4.29 ($p < 0.001$). As well, CFRD patients had greater mean cost of hospitalizations, \$99,772.82 versus \$76,607.43 ($p = 0.4719$). **CONCLUSIONS:** CFRD patients have increased medical cost, increased length of stay, and increased disease severity compared to those without diabetes.

PHS2

AN EXPLORATION OF DIABETES-RELATED HOSPITALIZATION DISCHARGE STATUS AND ITS ASSOCIATION WITH PERIPHERAL LOWER-EXTREMITY DISEASES

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OBJECTIVES: Peripheral lower-extremity (PLE) diseases (peripheral arterial diseases and neuropathy) are severe complications of diabetes that can impact the length and cost of a diabetes-related hospitalization. Few studies have explored diabetes-related hospitalization discharge status and its association with PLE. This study examines the association between PLE and diabetes-related hospitalization from a national database. **METHODS:** A retrospective analysis of the 2010 – 2012 National Inpatient Sample (NIS). Diabetes-related hospitalization was defined by discharge records with principal or secondary diagnosis of Diabetes (250.XX). Hospitalization discharge status was dichotomized as routine discharge and non-routine discharge in consistency with previous studies. PLE was identified using diagnosis codes and was classified (“severe” v.s. “less severe”) by combination of established severity algorithm, procedure codes and DRG. Descriptive analysis and Chi-square test were used to examine the unadjusted association between PLE and diabetes-related hospitalization discharge status. Multivariate logistic regression was employed to examine the adjusted association between PLE and diabetes-related hospitalization controlling other covariates. **RESULTS:** 804,192 diabetes-related hospitalization records were identified. Chi-square test showed that 47.7% of the hospitalized diabetes patients with severe PLE had non-routine discharges; while 28.5% of the hospitalized diabetes patients without PLE had non-routine discharges ($p < 0.0001$). Controlling for age, sex, race, household income, primary payer, and comorbidities, diabetes patients with severe PLE had a 49.4% increase in the odds of having a non-routine discharge compared to those without PLE (OR=1.494, 95% CI: 1.465 – 1.522). The odds ratio was 1.221 for diabetes patients with less severe PLE to have non-routine discharge compared to those without PLE (95% CI: 1.204 – 1.239). **CONCLUSIONS:** Severe PLE was associated with increased likelihood of having non-routine discharges for diabetes-related hospitalization, indicating elevated subsequent health care utilization after discharge. Optimal diabetes disease management programs should be designed and implemented to reduce the incidence and prevalence of diabetes complications including PLE.

PHS3

REAL-WORLD RATE OF DIAGNOSTIC REVISION AMONG PERIPHERAL T-CELL LYMPHOMA (PTCL) CASES

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OBJECTIVES: An accurate diagnosis is critical for determining prognosis and treatment options for patients with PTCL. However, the accurate diagnosis of PTCL remains challenging. Previous analyses have reported variable revision rates as high as 24%. However, the rate of revision among PTCL cases has not been characterized utilizing a large US claims database. **METHODS:** A retrospective analysis identifying newly diagnosed PTCL cases via ICD-9 and ICD-10 codes between 01/01/2010 - 12/31/2015 was conducted using the Truven MarketScan databases. Two PTCL claims during the study period were used to identify cases. Cases were indexed by the Date of first PTCL claim. Cases were required to have 6 months of pre-index baseline continuous enrollment and at least 6 months of post-index continuous enrollment. Cases with at least one prior claim for Hodgkin lymphoma, DLBCL, EMZL or unspecified, uncertain and benign neoplasms at any time in the pre-index period were considered a case with diagnostic revision. The number of claims to confirm PTCL was changed from 2 to 1 to test the impact on the observed revision rate. **RESULTS:** A total of 289 cases with PTCL diagnosis were identified of whom 166 cases were without a diagnostic revision. There were 123 cases that had a diagnostic revision resulting in a diagnostic revision rate of 42.56%. The sensitivity analysis with a single PTCL claim required for inclusion resulted in a reduction of the revision rate to 33.56%. The median time to PTCL diagnosis in the commercial and Medicare populations was 154 and 219 days from misdiagnosis claim, respectively. **CONCLUSIONS:** This study found that diagnostic revision rates of PTCL ranges from 34% to 43%, highlighting the need for more accurate diagnostic testing to reduce unnecessary clinical burden associated with PTCL. Additional clinical data are required to understand how diagnostic revision impacts PTCL patient outcomes.

PHS4

PATIENT CHARACTERISTICS AND HEALTH OUTCOMES IN CHILDREN DIAGNOSED WITH MARFAN SYNDROME IN THE UNITED STATES

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OBJECTIVES: Marfan syndrome is a rare systemic connective tissue disorder caused by mutations in the gene encoding fibrillin-1, which can contribute to serious cardiovascular (CV) and pulmonary related complications. While signs and symptoms may not appear until adulthood, some patients experience disease complications much earlier in life. Therefore, the purpose of this study was to evaluate the burden of CV and pulmonary related manifestations in children diagnosed with Marfan syndrome. **METHODS:** We used data from the 2012 Kids National Inpatient Sample. Marfan syndrome patients >10 years were identified using ICD-9 code 759.82. Patients were stratified by primary diagnosis; CV (CCS: 096, 097, 100, 101, 103-113, 115-118 or DRG: 025-027, 031-033, 219-221, 229, 230, 307) or pulmonary-related (CCS: 128-131, 133, 134) conditions. The reference group for all analyses included hospital discharges without a primary CV or pulmonary-related diagnosis. Descriptive and inferential statistics were used to compare demographics, healthcare outcomes, and hospital charges. **RESULTS:** 565 Marfan syndrome patients were identified, of which 100 (17.6%) were CV, 87 (15.3%) pulmonary, and 378 (66.9%) for the reference group. Mean CCI scores and total charges among CV patients (0.54 ± 0.7 ; \$120,105.89 \pm \$118,841.14) were significantly higher ($p=0.0073$; $p<0.001$) compared to the reference group (0.32 ± 0.74 ; \$53,644.47 \pm \$80,509.52). Among pulmonary patients, mean length of stay was higher (5.98 ± 4.44 days) but total charges (\$41,616.33 \pm \$3,946.57) were lower compared to the reference group (4.72 ± 5.75 days; \$53,644.47 \pm \$80,509.92; both $p=0.03$). **CONCLUSIONS:** Marfan syndrome patients with CV specific manifestations had a higher presence of comorbidities and greater hospital charges compared with patients with pulmonary specific or other manifestations. Children presenting with signs and symptoms early in life may represent a greater lifelong burden of illness. Early diagnosis and onset of treatment could help to reduce healthcare cost and utilization in this population.

PHS5

THE USE OF E-HEALTH TO IMPROVE MEDICATION ADHERENCE AMONG PATIENTS WITH ASTHMA: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: To systematically review the effectiveness of e-health (use of information and communications technology for health) in improving adherence to inhaled corticosteroids (ICS) among patients with persistent asthma, as well as the satisfaction of patients undergoing e-health interventions. **METHODS:** Literature searches were conducted in PubMed, CINAHL, Academic Search Premier, PsycINFO, and the International Pharmaceutical Abstracts databases in October 2016. Additional articles were identified by hand-searching, and from clinical-trials.gov. Included studies were randomized controlled trials comparing e-health interventions versus usual care in improving adherence among patients taking ICS for persistent asthma. Quantitative synthesis was performed using a random effects model. **RESULTS:** Eighty records were identified after duplicates were removed. Of these, 15 trials including 13,907 participants were eligible for qualitative synthesis. Subsets of e-health trials included - social media (1), electronic health record (1), telehealth (6), and mHealth (7). Only 6 out of 15 trials were eligible for quantitative synthesis, including 3 telehealth and 3 mHealth trials. Results show an insignificant overall effect of e-health interventions on the improvement of adherence to ICS. However, a significant improvement in adherence was observed for mHealth interventions compared to usual care in a pooled analysis of 3 trials (SMD 1.29; 95% CI 0.43 to 2.14). We considered the risk of bias in included studies to be low, however, there was considerable heterogeneity among studies ($I^2 = 89\%$). Patient satisfaction was evaluated in 6 trials comparing telehealth (2) and mHealth (4) with usual care. Moderate satisfaction was reported in 1 study and high satisfaction in 5 studies. **CONCLUSIONS:** Among e-health interventions, mHealth interventions were found to be effective and acceptable in improving adherence to ICS. However, there is a need for more studies to evaluate the effectiveness of more e-health interventions in increasing adherence to ICS. Future studies should examine patients' satisfaction with these interventions.

PHS6

ESTIMATING THE EFFECT SIZE FOR CHANGES IN DEPRESSION AMONG COMMERCIALY-INSURED ADULTS USING THE MYSTRENGTH SELF-CARE PLATFORM

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OBJECTIVES: To evaluate the effectiveness of managing depression on a population-level using myStrength, a digital self-care behavioral health and well-being platform. An effect size model was developed to compare the impact of myStrength on depression symptom burden reduction relative to the effectiveness of psychotherapy, the standard of care. **METHODS:** This study quantified the normalized effect size achieved for 1,143 commercially-insured adults using myStrength's self-help tools, who initially demonstrated some depression, the intervention group. The DASS-21 measured self-reported baseline symptom severity among the intervention group. Consumers with mild or greater symptom severity were included in the analysis and were prompted to complete assessments at 14, 60, 180 and 365 days post-baseline. The difference between baseline and YTD last assessment quantified the change in depression symptom severity score. The effect size was estimated as the mean change in depression score

divided by the average difference in standard deviation from baseline to last assessment. The comparator group, psychotherapy, was assumed to have an effect size of between 0.5 - 0.8 based on the literature. **RESULTS:** Of the 1,143 myStrength consumers with some baseline level of depression, 78% were female and the mean age was 45.70 years. On average, myStrength consumers accessed the platform 4.75 times in their first 30 days. The mean depression score was 21.50 among myStrength consumers at baseline (median = 20; standard deviation = 9.41). At last assessment, the mean depression score decreased to 16.10, demonstrating symptom burden reduction among the intervention group (median = 14; standard deviation = 11.87). The myStrength estimated effect size was 0.49 [95% CI: 0.41, 0.57]. **CONCLUSIONS:** Among a commercially-insured, adult population with some degree of depression, myStrength was shown to be at least 61% as effective as traditional psychotherapy. Depression management may benefit from expanding behavioral healthcare offerings to include digital platforms.

PHS7

ACHIEVEMENT OF CLINICAL GOALS OF A CARDIOVASCULAR RISK MANAGEMENT PROGRAM FROM A COLOMBIAN POOR POPULATION. A CROSS-SECTIONAL STUDY

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OBJECTIVES: "De Todo Corazón" (DTC) is a risk management program with the aim of reducing complications and improving the quality of life of patients with cardiovascular risks. The aim of this study was to compare to evaluate the clinical goals of blood pressure control, metabolic control, weight control and lipid control in patients under program care. **METHODS:** We started follow-up of a cohort of 64,668 patients with hypertension and/or diabetes mellitus between June 2014 and December 2015. Clinical goals of blood pressure control (<140/90 mmHg), metabolic (HbA1C <7.5%), weight control (BMI < 30 kg/m²) and lipid (LDL <100 mg/dl) were established. **RESULTS:** The average age was 64.5 + 13.9 years and 66.5% female. In 18 months of follow-up and independent of the number of medical controls and activities of risk management program, between 73% and 80% of patients achieved good blood pressure control; Between 6.8% and 36.7% achieved good metabolic control; 54% had good weight control; and 68% achieved good lipid control. **CONCLUSIONS:** The results in the clinical goals suggest a positive impact on the cardiovascular risk of patients under program care. Less effective was shown for weight control and metabolic control suggesting that new approaches should be undertaken to improve the results of the program.

PHS8

EFFECTIVENESS AND CLINICAL INERTIA IN ANTIDIABETIC THERAPY IN COLOMBIAN PATIENTS

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OBJECTIVES: To establish the effectiveness of antidiabetic therapy and the frequency of clinical inertia in the management of type-2 diabetes mellitus in Colombia - 2015. **METHODS:** A cross-sectional retrospective study with follow-up was conducted in 23 cities in diabetic patients who had been treated for at least one year and were receiving medical consultation for antidiabetic treatment. Effectiveness was established when haemoglobin A1c levels were <7% in general population and <8% in special situations. When clinical inertia was reached, which was defined as no therapeutic modifications despite not achieving management controls. Sociodemographic, clinical, and pharmacological variables were evaluated, and multivariate analyses were performed. The study received bioethical approval. **RESULTS:** In total, 363 patients with type-2 diabetes mellitus were evaluated, with a mean age of 62.0 \pm 12.2 years. A total of 1,016 consultations were evaluated, and the therapy was effective at the end of the follow-up in 57.9% of cases. Clinical inertia was found in 56.8% of patients who did not have metabolic control. The most frequently prescribed medications were metformin (84.0%), glibenclamide (23.4%), and insulin glargine (20.7%). Moreover, 57.6% of the patients were treated with two or more antidiabetic medications. In the logistic regression analysis having metabolic control in the first consult of the follow-up was a protective factor against clinical inertia in the subsequent consultations (OR:0.09; 95%CI:0.04-0.17; $p<0.001$). **CONCLUSIONS:** The effectiveness of treatment for patients with type-2 diabetes mellitus has increased in Colombia, and for the first time, clinical inertia was identifiable and quantifiable and found in similar proportions to other countries with previous reports. Clinical inertia is a relevant condition given that it interferes with the possibility of controlling this pathology.

PHS9

RISK OF THE FIRST MYOCARDIAL INFARCTION EVENT IN A CARDIOVASCULAR HEALTH PROMOTION PROGRAM OF A DEVELOPING COUNTRY "DE TODO CORAZON". A COHORT STUDY

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OBJECTIVES: "De Todo Corazón" (DTC) is a risk management program with the aim of reducing complications and improving the quality of life of patients with cardiovascular risks. The aim of this study was to compare the risk of first myocardial infarction event in patients under program care. **METHODS:** We started follow-up of a cohort of 12,045 patients with hypertension and/or diabetes mellitus without previous

history of confirmed cardiovascular events between June 2014 and December 2015. First event were considered to be first admissions due to myocardial infarction. Incidence is reported by 100 person years follow-up. Kaplan-Meier curves were used to evaluate time a first myocardial infarction events. Differences between survival curves were compared using Long-Rank test. Multivariate Cox proportional-hazards models were used to evaluate the risk for first myocardial infarction event, on the basis of any potentially significant predictor. **RESULTS:** The average age was 62.7 + 12.6 years and 70.1% female. Mean follow-up time was 11.6 + 6.1 months. The proportion of hypertension, diabetes mellitus and hyperlipidemia was 92.7%, 100% and 89.7%, respectively. The prevalence of blood pressure control (<140/90 mmHg), metabolic (HBA1C <7%) and lipid (LDL <100 mg/dl) was 91.7%, 27.5% and 38.7%, respectively. Incidence of first myocardial infarction event was 0.12 events per 100 person-years. Age (HR 1.02; 95% IC 1.01-1.03), male (HR 2.0; 95% IC 1.5-2.6), metabolic non-control (HR 1.44; 95% IC 1.02-2.02), blood pressure non-control > 140/90 mmHg (HR 1.48; 95% IC 1.02-2.02) and dyslipidemia (HR 4.7 95% IC 1.7-12.8) were significantly associated with the incidence of first myocardial infarction event. **CONCLUSIONS:** The incidence of the first myocardial infarction event was significantly higher in patients with blood pressure non-control and metabolic non-control.

PHS10

RISK OF THE FIRST STROKE EVENT IN A CARDIOVASCULAR HEALTH PROMOTION PROGRAM OF A DEVELOPING COUNTRY "DE TODO CORAZON". A COHORT STUDY

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OBJECTIVES: "De Todo Corazón" (DTC) is a risk management program with the aim of reducing complications and improving the quality of life of patients with cardiovascular risks. The aim of this study was to compare the risk of first stroke event in patients under program care. **METHODS:** We started follow-up of a cohort of 47,877 patients with hypertension and/or diabetes mellitus without previous history of confirmed cardiovascular events between June 2014 and December 2015. First event were considered to be first admissions due to stroke. Incidence is reported by 100 person years follow-up. Kaplan-Meier curves were used to evaluate time a first stroke event. Differences between survival curves were compared using Long-Rank test. Multivariate Cox proportional-hazards models were used to evaluate the risk for first stroke event, on the basis of any potentially significant predictor. **RESULTS:** The average age was 62.8 + 12.2 years and 67.6% female. Mean follow-up time was 1.1 + 0.4 years. The proportion of hypertension, diabetes mellitus and hyperlipidemia was 97.1%, 41.3% and 89.1%, respectively. Incidence of first stroke event was 1.35 events per 100 person-years. At 18 months follow-up, the incidence of first stroke event was higher in women patients compared with male patients (301 vs. 250 events; p < 0.001; Long-Rank test). Age (HR 1.04; 95% IC 1.03-1.05), male (HR 1.6; 95% IC 1.3-1.9), blood pressure non-control > 140/90 mmHg (HR 1.5; 95% IC 1.2-1.9), dyslipidemia (HR 1.90 95% IC 1.2-2.8) and high cardiovascular risk > 20% Coronary heart disease (CHD) risk at 10 years (HR 1.3, 95% IC 1.1-1.5) were significantly associated with the incidence of first stroke event. **CONCLUSIONS:** The incidence of the first stroke event was significantly higher in patients with blood pressure control > 140/90 mmHg under program care.

PHS11

RISK OF THE FIRST CARDIOVASCULAR EVENT IN A CARDIOVASCULAR HEALTH PROMOTION PROGRAM OF A DEVELOPING COUNTRY "DE TODO CORAZON". A COHORT STUDY

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OBJECTIVES: De Todo Corazón (DTC) is a risk management program with the aim of reducing complications and improving the quality of life of patients with cardiovascular risks. The aim of this study was to compare the risk of first cardiovascular event in patients under program care. **METHODS:** We started follow-up of a cohort of 47,894 patients with hypertension and/or diabetes mellitus without previous history of confirmed cardiovascular events between June 2014 and December 2015. First cardiovascular event were considered to be first admissions due to coronary disease, cardiac insufficiency or stroke. Incidence is reported by 100 person years follow-up. Kaplan-Meier curves were used to evaluate time a first cardiovascular events. Differences between survival curves were compared using Long-Rank test. Multivariate Cox proportional-hazards models were used to evaluate the risk for first cardiovascular event, on the basis of any potentially significant predictor. **RESULTS:** The average age was 62.8 + 12.2 years and 67.6% female. Mean follow-up time was 11.6 + 6.1 months. The proportion of hypertension, diabetes mellitus and hyperlipidemia was 97.1%, 41.3% and 42.6%, respectively. Incidence of first cardiovascular event was 34 events per 100 person-years. At 18 months follow-up, the incidence of first cardiovascular event was higher in patients with < 11 months follow-up compared with patients with > 11 months follow-up (1173 vs. 350 events; p < 0.001; Long-Rank test). Age (HR 1.02; 95% IC 1.02-1.03), male gender (HR 1.73; 95% IC 1.55-1.94), blood pressure non-control > 140 mmHg (HR 1.31; 95% IC 1.12-1.54) and high cardiovascular risk > 20% Coronary heart disease (CHD) risk at 10 years (HR 1.47; 95% IC 1.30-1.65) were significantly associated with the incidence of first cardiovascular event. **CONCLUSIONS:** The incidence of the first cardiovascular event was significantly higher in patients with blood pressure non-control under program care.

PHS12

RISK OF THE FIRST ACUTE HEART FAILURE EVENT IN A CARDIOVASCULAR HEALTH PROMOTION PROGRAM OF A DEVELOPING COUNTRY "DE TODO CORAZON". A COHORT STUDY

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OBJECTIVES: "De Todo Corazón" (DTC) is a risk management program with the aim of reducing complications and improving the quality of life of patients with cardiovascular risks. The aim of this study was to compare the risk of first acute heart failure event in patients under program care. **METHODS:** We started follow-up of a cohort of 47,867 patients with hypertension and/or diabetes mellitus without previous history of confirmed cardiovascular events between June 2014 and December 2015. First event were considered to be first admissions due to acute heart failure. Incidence is reported by 100 person years follow-up. Kaplan-Meier curves were used to evaluate time a first acute heart failure event. Differences between survival curves were compared using Long-Rank test. Multivariate Cox proportional-hazards models were used to evaluate the risk for first acute heart failure event, on the basis of any potentially significant predictor. **RESULTS:** The average age was 62.8 + 12.2 years and 67.6% female. Mean follow-up time was 11.6 + 6.1 months. The proportion of hypertension, diabetes mellitus and hyperlipidemia was 97.1%, 41.3% and 89.2%, respectively. Incidence of first acute heart failure event was 0.082 events per 100 person-years. At 18 months follow-up, the incidence of first acute heart failure event was higher in male compared with women (221 vs. 205 events; p < 0.001; Long-Rank test). Age (HR 1.02; 95% IC 1.01-1.03), male (HR 1.8; 95% IC 1.5-2.2), blood pressure non-control > 140/90 mmHg (HR 1.4; 95% IC 1.1-1.8), and high cardiovascular risk > 20% Coronary heart disease (CHD) risk at 10 years (HR 1.90 95% IC 1.5-2.5) were significantly associated with the incidence of first acute heart failure event. **CONCLUSIONS:** The incidence of the first acute heart failure event was significantly higher in patients with blood pressure non-control under program care

PHS13

TRANSITION PROBABILITIES OF CHRONIC KIDNEY DISEASE IN A CARDIOVASCULAR RISK MANAGEMENT PROGRAM

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OBJECTIVES: "De Todo Corazón" (DTC) is a cardiovascular risk management program. The aim of this study was to estimate the transition probabilities of Chronic Kidney Disease (CKD) in patients under program care. **METHODS:** We followed up a cohort of 55,915 patients with hypertension and / or diabetes mellitus between June 2014 and December 2015. The glomerular filtration rate (GFR) was calculated using the Cockcroft Gault formula. A diagnosis of CKD in GFR < 60 ml/min/1.73m² at the end of follow-up was considered. To estimate the progression of CKD, the percentages of patients at each stage of kidney disease were estimated according to the Kidney Disease Improving Global Outcomes Guidelines (KDIGO), at the beginning and at the end of follow-up. To establish association between arterial hypertension and diabetes mellitus with progression of CKD, the Odds Ratio (OR) was estimated. **RESULTS:** 50.1% of the patients were > 65 years and 66.5% were female. The prevalence of hypertension and diabetes mellitus was 96.5% and 36.1%, respectively. At 18 months follow-up, 3.0% of patients with hypertension without diabetes mellitus progressed to CKD (Stage 3B, 4 and 5). 3.8% of patients with hypertension and diabetes mellitus progressed to CKD. The risk of progression of CKD was significantly higher in patients with hypertension with diabetes mellitus (OR: 1.30 CI 95% 1.17-1.45). **CONCLUSIONS:** The presence of hypertension with diabetes mellitus was significantly associated with progression to CKD over a period of 18 months, independent of baseline GFR.

PHS14

INCREMENTAL HEALTHCARE EXPENDITURE OF ANXIETY DISORDERS AMONG US ADULTS WITH ARTHRITIS

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OBJECTIVES: To estimate the incremental total healthcare expenditures associated with anxiety disorders (AD) and examine the risk factors that contribute to excessive healthcare expenditures among a national representative sample of adults with arthritis in the United States. **METHODS:** A retrospective cross-sectional study was conducted using the 2014 Medical Expenditure Panel Survey data. Adults with self-reported arthritis who were alive and had positive healthcare expenditures were included in the study (n=7549). Total expenditures for all healthcare utilization were estimated in adults with arthritis by the presence/absence of AD. Multivariate ordinary least square (OLS) regression on log-transformed expenditures was used to evaluate the magnitude of the association between AD and healthcare expenditures. The contribution of each construct of the Andersen's Health Behavioral Model of Health Services Use to the difference in expenditures among adults with and without AD was evaluated using post-regression linear decomposition. **RESULTS:** About 19.6 % of the US adults with arthritis also reported AD. Patients with both arthritis and AD were significantly more likely to visit the emergency department (AOR=1.30, 95% CI:1.07-1.58) compared to those without AD. The mean total expenditure was \$8,516 for adults with arthritis and \$12,293 (SD: for those with arthritis and AD. Multivariable OLS regression analysis indicated that adults with AD had 35% (β=0.302, p<0.001) higher healthcare expenditures compared to those without AD.

Post-linear decomposition analyses revealed that 41.7% to 65.5% of the differences in expenditures can be explained by the differences in the need factors of the two groups, including comorbid depression, poor health status, pain, and other chronic conditions. **CONCLUSIONS:** Among adults with arthritis, the excess healthcare expenditures associated with coexisting AD were mainly contributed by the needs factors. A collaborative care model which provides timely interventions for both physical and mental conditions may potentially reduce the excessive expenditures.

PHS15

EPIDEMIOLOGY OF POSTPARTUM DEPRESSION IN A MEDICAID POPULATION- A RETROSPECTIVE STUDY

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OBJECTIVES: Postpartum depression (PPD) risk has been reported to be correlated with socioeconomic factors. More than 50% of US deliveries are covered by Medicaid, for which all pregnant women with an income <133% of the federal poverty line are eligible. Although Medicaid covers a large portion of deliveries, few estimates of PPD prevalence have examined this population. The objective of this study was to estimate PPD prevalence in the Medicaid population using a large population database. **METHODS:** This retrospective analysis used the Truven Medicaid database (>30 million patients; 11 states) to identify claims for women who were 15-50 years old at the time of delivery from 2012-2014 based on ICD-9 coding. PPD cases were identified based on a combination of inpatient and outpatient claims for PPD or major depression (MDD), adjustment disorder or depression not otherwise specified, or claims for treatment. Women with continuing MDD were excluded. Prevalence and disease severity were estimated. **RESULTS:** In this Medicaid database population, the algorithm determined a PPD prevalence of 1.7%, 1.9%, and 2.1%, for the years 2012-2014, respectively. In 2014, no difference was observed in PPD prevalence in women <17 years old (2.2%) and in either women 18-34 or 35 or older (both 2.1%). Prevalence was also estimated by race/ethnicity, with rates of 2.8% among Whites, 1.2% among Blacks, 1.3% among Hispanics, and 1.9% among others. Overall, mild cases accounted for 6.7% of the population, moderate 88.5%, and severe 4.8%. **CONCLUSIONS:** PPD prevalence estimates were determined by the algorithm in a low-income population insured by Medicaid. Previous literature indicated that lower income and socioeconomic status may increase risk for PPD. However, our findings reveal a lower prevalence within this large US Medicaid population database than cited in the literature, which suggests an estimated prevalence of 10-20%, suggesting that PPD may be markedly underdiagnosed.

PHS16

IMPACT OF TIME OF DIAGNOSIS ON PREVALENCE OF POSTPARTUM DEPRESSION IN WOMEN WITH COMMERCIAL AND MEDICAID HEALTH INSURANCE - A RETROSPECTIVE STUDY

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OBJECTIVES: Postpartum depression (PPD) has multiple definitions. The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition defines PPD as a subtype of major depressive disorder with onset during pregnancy and up to 4 weeks postpartum—i.e. “peripartum onset.” Due to differing time-based definitions of PPD, we sought to determine the impact of time of PPD onset on prevalence estimates of PPD. **METHODS:** We used the Truven Commercial Claims database (>70 million patients), the Medicaid Multi-State database, (>30 million patients; 11 states), and ICD-9 coding to retrospectively study women between the ages of 15 and 50 years at childbirth from 2011-2014. For the commercial database, women had to be continuously enrolled in health insurance for one year before and after delivery. Since Medicaid has limited coverage, continuous enrollment for 6 months before and 60 days after delivery was required. PPD was defined based on inpatient and outpatient claims for PPD, MDD, adjustment disorder, or depression not otherwise specified, or claims for treatment. Subjects with MDD prior to the last trimester of pregnancy were excluded. **RESULTS:** There were 230,927 deliveries in the commercial database and 351,533 deliveries in the Medicaid database. In months 0-2 postpartum, the prevalence estimates for PPD were 1.7% in the commercial database and 1.9% in Medicaid. The prevalence in the commercial database was 2.7% for 0-4 months postpartum. (Medicaid prevalence could not be determined due to enrollment restrictions.) The prevalence estimates for PPD at 8, 10, and 12 months were 3.4%, 4.0%, and 4.9%, respectively. **CONCLUSIONS:** Of the total PPD cases identified by the algorithm over 12 months postpartum, only one third were identified in only the first two months postpartum, suggesting that restrictive, time-based PPD definitions and the limited duration of postpartum screening may contribute to underestimates of PPD prevalence.

PHS17

PREVALENCE AND HEALTHCARE UTILIZATION BURDEN ASSOCIATED WITH RHINOSINUSITIS IN A UNITED STATES COMMERCIAL INSURED POPULATION

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OBJECTIVES: This study aimed to determine the prevalence and healthcare utilization burden associated with acute rhinosinusitis (ARS), chronic

rhinosinusitis (CRS), and recurrent acute rhinosinusitis (RARS). **METHODS:** The study involved a cross-sectional, retrospective analysis of the 2014 Truven MarketScan database. Prevalence (projected national estimates) of ARS, CRS, and RARS, and associated healthcare utilization were determined. Patients with ARS were identified using ICD-9-CM 461.x. CRS was identified where 1 medical visit had ICD-9-CM 461.x or 473.x and a second medical visit had a ICD-9-CM of 473.x, with the two visits separated by at least 12 weeks or more. RARS was classified when a medical visit had an ICD-9-CM 461.x followed by subsequent sinusitis diagnoses with ≥4 visits during the year and ≥6-weeks between visits. **RESULTS:** In 2014, more than 22 million individuals had ARS, 1.1 million had CRS, and 100,000 had RARS in the US. More than 60% of all ARS, CRS, and RARS patients were females, and close to half resided in the South. The average number of office visits were 1.18, 1.55, and 3.03, while the average number of prescription claims were 3.02, 4.03, and 5.61 among patients with ARS, CRS, and RARS, respectively. The average cost per office visit varied from \$138 among patients with ARS to \$412 among patients with RARS. The average cost per hospital outpatient visit varied from \$289 among patients with ARS to \$1,148 among RARS patients. The average annual total costs (medical visits and prescription drugs) were \$285, \$553, and \$885 among patients with ARS, CRS, and RARS, respectively. **CONCLUSIONS:** Most of the patients with rhinosinusitis were female. Though ARS is the most common form of rhinosinusitis followed by CRS and RARS, the healthcare burden in terms of medical care utilization, particularly office visits and prescription drug utilization, was observed to be higher among patients with RARS.

PHS18

A REVIEW OF THE BURDEN OF HEPATITIS C VIRUS INFECTION IN KAZAKHSTAN

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OBJECTIVES: Hepatitis C virus (HCV) infection is associated with substantial clinical and economic burden and is an important public health issue in Central Asia. The objective of this review was to characterize HCV epidemiology and related complications in Kazakhstan. With more efficacious therapies becoming available, decision-makers require accurate estimates of disease prevalence to assess the cost-benefit ratio of new treatments for HCV infection. The objective of the study was to synthesize estimates of the epidemiologic burden of HCV from Kazakhstan. **METHODS:** A review was conducted in electronic databases and conference abstracts, by two reviewers to identify population-based estimates of HCV prevalence and incidence. Additionally, patients diagnosed with HCV (ICD-10 codes 070.41, 070.44, 070.51, 070.54, 070.70, 070.71, V02.61) between 2011 and 2015 were identified in National HCV registry. **RESULTS:** A search of electronic databases and conference abstracts identified 43 potentially relevant articles. Of those, 32 were included in the epidemiology review and 6 in the review of HCV-related complications. HCV prevalence in the general population was 0.6-0.7%. Prevalence was higher for injecting drug users (56-90%) and those with human immunodeficiency virus coinfection (12-20%) and was lower for blood donors (1-2%). Annual incidence of HCV in Kazakhstan was 5.43 per 100,000. HCV genotype 1b was associated with the highest incidence of hepatocellular carcinoma (HCC). Five-year survival for patients with liver cirrhosis was 75.1%, decreasing to 36.9% following liver transplantation; the majority of deaths were attributable to HCC. Limitations were that the majority of studies included in the epidemiology review were small, regional studies conducted in specific populations, and there was an absence of large population-based studies. **CONCLUSIONS:** These population-based prevalence estimates, and the prevalence estimates from blood donors, may be useful for inclusion in disease models. Discrepancies between estimates from the different sources underscore the need for methodologically-rigorous epidemiologic studies to maximally inform decision-makers in Kazakhstan.

PHS19

BURDEN ATTRIBUTABLE TO CARDIOVASCULAR DISEASE AND CHRONIC KIDNEY DISEASE IN A COLOMBIAN POOR POPULATION

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OBJECTIVES: “De Todo Corazón” (DTC) is a risk management program with the aim of reducing complications and improving the quality of life of patients with cardiovascular risks. The aim of this study was to estimate the disease burden of cardiovascular disease and chronic kidney disease and describe its impact on the health of the population under program care. **METHODS:** Disability adjusted life years (DALYs) for cardiovascular disease and chronic kidney disease, resulting from the sum of loss of health due to premature death and disability was calculated. For the calculation of life years lost the death registration on the Program DTC for the period between January and December 2015, as well as the abridged life tables for the years lived with disability, the individual records of outpatient and inpatient service June 2014 and December 2015, bibliography and a map of weighted disability in the global study of the burden of disease were consulted. For data processing a template developed in Microsoft Excel 2007 was used, based on the methodology described by the World Health Organization. **RESULTS:** In 2015, DALYs lost due to stroke, myocardial infarction, acute heart failure and chronic kidney disease were estimated at 1111, 869, 1220 and 296, respectively. The major relative weight of the last years was given by the premature death component (96%, 85%, 82% and 93%, respectively); females contributed on average to 51.4% and 50.7% of the DALYs lost due to stroke and myocardial infarction; males contributed on average to 52.8% and 52.7% of the DALYs lost due to acute heart failure and chronic kidney disease and the most affected age was over 60 years. **CONCLUSIONS:** The major relative weight of the

DALYs lost due to stroke, myocardial infarction, acute heart failure and chronic kidney disease of the population under program care was given by the premature death component

PHS20

ESTIMATES OF POSTPARTUM DEPRESSION PREVALENCE IN A COMMERCIALY INSURED POPULATION – A RETROSPECTIVE ANALYSIS

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OBJECTIVES: Postpartum Depression (PPD) is a common complication of childbirth and is associated with impaired maternal function and poor mother-infant interactions. Prevalence estimates vary depending on setting, evaluation method, and observation period. The objective of this study was to estimate PPD prevalence in a large, nationally-representative commercial insurance claims database. **METHODS:** This retrospective study used the Truven MarketScan Commercial Claims database. To identify women who gave birth between 2011-2014, were 15-50 years old, and were continuously enrolled in insurance one year before and one year after delivery. The main analysis used a 6-month postpartum observation period to identify PPD cases based on ICD-9 coding for diagnoses and treatment claims. Women with major depressive disorder prior to the third trimester were excluded. Restrictions were removed for sensitivity analyses (SA). **RESULTS:** During the 6-month postpartum observation period, algorithm-based PPD prevalence estimates were 2.6%, 3.2%, and 3.7% for 2012, 2013, and 2014, respectively. Stratified by severity, most cases were moderate (95.4%). In SA1 (allowing pre-existing MDD), the prevalence was 4.5%, 5.4%, and 5.8%, respectively, in the 3 years studied. In SA 2 (extending to 12 months postpartum) it was 4.3%, 4.9%, and 5.5%, respectively. Combining both SAs yielded prevalence estimates of 7.3%, 8.1%, and 8.4%, respectively. **CONCLUSIONS:** Based on the algorithm, PPD prevalence in this commercially insured population increased from 26 per 1000 persons to 37 per 1000 persons from 2012-2014. In 2014, prevalence estimates ranged between 3.7% and 8.4%. These prevalence estimates are lower than in other studies in which all postpartum women in the studied population were screened for PPD at routine postpartum obstetrical visits, suggesting that PPD may be underdiagnosed.

PHS21

INCIDENCE OF CARDIOVASCULAR EVENTS IN A CARDIOVASCULAR HEALTH PROMOTION PROGRAM OF A DEVELOPING COUNTRY “DE TODO CORAZON”. A COHORT STUDY

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OBJECTIVES: “De Todo Corazón” (DTC) is a risk management program with the aim of reducing complications and improving the quality of life of patients with cardiovascular risks. The aim of this study was to describe the evolution of incidence of cardiovascular events in patients under program care. **METHODS:** We started follow-up of a cohort of 64,668 patients with hypertension and/or diabetes mellitus between June 2014 and December 2015. The cumulative incidence of cardiovascular events was considered to be admissions due to myocardial infarction, acute cardiac insufficiency or stroke per semester. The hospital readmission for cardiovascular events was considered to be first readmissions due to myocardial infarction, acute cardiac insufficiency or stroke after 30 days of the first admission for same event. The cumulative incidence and hospital readmission for cardiovascular events were reported in percentages and incidence density was reported by 100 person years follow-up. **RESULTS:** Between the second half of 2014, the first semester and the second half of 2015, the cumulative incidence for stroke was 8.0%, 6.7% and 5.1%, respectively. The cumulative incidence for myocardial infarction was 7.3%, 7.2% and 6.1%, respectively; and for acute heart failure was 5.3%, 5.2% and 3.7%, respectively. The risk of hospital readmission for stroke was 77.4%, 69.8% and 59.6%, respectively. The risk of hospital readmission for myocardial infarction was 85.3%, 80.3% and 79.2%, respectively; and for acute heart failure was 88.6%, 80.8% and 74.2%, respectively. The incidence density (events 100 person years for stroke was 15.9, 13.4 and 10.3 events per 100 person years, respectively. The incidence density for myocardial infarction was 14.5, 14.3 and 12.1 events per 100 person years, respectively. **CONCLUSIONS:** The incidence and hospitalization for cardiovascular events in patients under program care showed a downward trend between June 2014 and December 2015. The hospital readmission for cardiovascular events is high.

PHS22

ESTIMATED PREVALENCE OF POSTPARTUM DEPRESSION AMONG DELIVERIES BY WOMEN COVERED BY U.S. PRIVATE PAYERS

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OBJECTIVES: Postpartum depression (PPD) occurs in an estimated 10-20% of postpartum women and is one of the most common complications of childbirth. The research objective was to estimate the prevalence of PPD among deliveries by women covered by U.S. private payers, and to estimate severity based on resource utilization. **METHODS:** The OptumHealth Care Solutions, Inc. claims database (January 2010-September 2015) was used to identify PPD cases using both a broad (12 months postpartum) and a more narrow (third trimester through 6 months postpartum) definition requiring diagnoses of PPD/depression for at least one

inpatient (IP) or emergency department (ED) visit, or two outpatient (OP) visits, or one OP visit and an antidepressant or anti-anxiety prescription drug fill. The narrower definition excluded preexisting bipolar, schizophrenia, or other psychosis. Severity classification was based on medical resource utilization and pharmacotherapy within 6 months postpartum. Patients were characterized as severe (IP or ED visit for PPD/depression, suicidal ideation or attempt, electroconvulsive therapy, IP psychotherapy, transcranial magnetic stimulation, or partial hospital program treatment); moderate (≥ 12 psychotherapy visits or ≥ 3 drug fills); mild-moderate (3-11 psychotherapy visits or 1-2 drug fills); mild (1-2 psychotherapy visits and no drug fills); or not classified. **RESULTS:** Using broad and narrower definitions, 7.0% (N=11,514) and 3.9% (N=4,756) of 163,565 and 120,865 deliveries, respectively, met claims-based criteria for PPD. The majority of women were classified as mild-moderate (27-36%) or moderate (25-34%) using the two definitions; they received psychotherapy or prescription drug treatment only. Fewer cases were mild (4-5%) or severe (6-7%). A significant percentage of cases (39% broad, 18% narrow) could not be classified because treatment was not observed 6 months postpartum. **CONCLUSIONS:** The prevalence of PPD in this privately-insured cohort of women was 3.9-7.0%, much lower than previously published estimates of 10-20%, suggesting a potentially sizable undiagnosed population.

PHS23

PREVALENCE OF COMPLICATIONS IN PATIENTS WITH DIABETES MELLITUS IN COLOMBIA

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OBJECTIVES: The prevalence of complications in patients with Diabetes Mellitus was determined in the 8 insurance sectors that are part of the health system through the Colombian High Cost Illness Fund created by the Ministry of Health and the Ministry of Finance has managed the registry administrative work in the health of Diabetes Mellitus during 8 years, which has allowed to identify 920,000 patients at the cut of 2016. The literature has identified as the most frequent clinical complications in the countries to Diabetic Neuropathy, Diabetic Retinopathy and Diabetic Nephropathy. **METHODS:** A cross-sectional descriptive epidemiological study was performed; As well as a sample size of 3,136 patients (cluster sampling), selected in 16 health insurers (48) operating their services in 28 departments (32). The studies that were considered relevant for the research are: UKPDS, DCCT, STENO, EDC and EURODIAB. **RESULTS:** A total of 12,181 patients were identified, with complications: 4,170 patients (34.23%). Based on the 12,181 patients, the complications to be highlighted were: Diabetic Nephropathy: 23.92%, Coronary Disease: 8.83%, Diabetic Retinopathy: 4.71%, Heart Failure: 3.82%, Cerebrovascular Disease: 3.20%, Lower Limb Amputation: 0.61%. **CONCLUSIONS:** The study generates a baseline diabetic population with complications in a Latin American country, scientifically contributes a new ladder of complications for the objective pathology where the most frequent are highlighted: Diabetic Nephropathy, Coronary Disease and Diabetic Retinopathy. In turn, it is an important input for decision making in the distribution of economic resources for the planning of the delivery of health services based on the perspective of payers in health systems.

PHS24

DETERMINATION OF CHRONIC VENOUS DISEASE PREVALENCE AMONG AT-RISK INDIVIDUAL EMPLOYING CLINICAL VALIDATED SCORING PATIENT-CENTERED OUTCOMES

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OBJECTIVES: The population-based Edinburg Vein Study(EVS) was adapted for CVD prevalence assessment prior to clinical counseling and referring. We determined CVD prevalence among hairdressers within community pharmacy clinical counseling program using clinical validated,14-item Short Form Chronic Venous Insufficiency Quality-of-Life Questionnaire(CIVIQ-14) and 12-Item Short Form Health Survey(SF-12) Thai version. **METHODS:** A prospective consecutive sampling of hairdressers at Thunayaburi district geographically covering all 6 regions was performed at random. Participants eligible were current hairdresser above 18 years old, continuously over 1 year working as hairdresser. CIVIQ-14 and SF-12 assessments were conducted by two researchers separately. Baseline demographics, scale reliability, correlation between CIVIQ-14 and SF-12 score were determined with descriptive statistics using Cronbach's alpha correlation coefficient, Interclass Correlation Coefficient(ICC) with 95%CI, and Pearson Correlation. Pearson Chi-square test between two scales for subjects with ≤ 6 hours of long-standing was tested. Probable clinical diagnosis of CVD employed global CIVIQ-14 index score of ≤ 75 to indicate CVD whereas prevalence was based on risk-adjustment estimation from EVS. **RESULTS:** Overall 70 participants, mean (\pm SD)of 31.39(\pm 9.48) years old, 43(61.4%) female, 2.8(\pm 4) years working as hairdresser, 44(62.9%) had > 6 hours long-standing, 15(21.4%) smokers, 16(22.9%) regular contraceptive users, 29(41.4%) alcoholic drinkers. The overall Global mean \pm SD score, min-max, and Cronbach's alpha with mean ICC(95% Confidence Interval) for CIVIQ-14 were 86.56 \pm 14.49, 38-100, and 0.931 with 0.931(0.905 - 0.953), $p < 0.001$ whereas for SF-12 Global were 78.49 \pm 12.23, 53-98, and 0.812 with 0.812(0.740 - 0.871), $p < 0.001$. The CIVIQ-14 and SF-12 was correlated with Pearson correlation coefficient of 0.707($p < 0.001$). Specifically, the Pearson Chi-square test of two scores from subjects with ≤ 6 hours long-standing(N=26) was well correlated at p -value=0.003. Overall 13(18.6%) of participants were clinically

referring. **CONCLUSIONS:** The CVD prevalence among hairdresser at Thunyaburi was 18.6%. The CIVIQ-14 was reliable, sensitive for CVD assessment and correlated with SF-12, useful for raising awareness and early detection of CVD among at-risk individual.

PHS25

HOSPITAL VOLUME AND 30-DAY READMISSION RATES AMONG PATIENTS WITH PNEUMONIA

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OBJECTIVES: Pneumonia is one of the main causes of readmissions in the United States, with estimates of 30-day readmissions as high as 20%. Given the high costs associated with readmissions, it is important to understand what factors contribute to readmissions in this patient population. Hospital volume, an indicator of availability of resources and staff, may be associated with readmission rates. In this analysis of a large, single-network hospital system, we examined the association between hospital volume and 30-day readmission in patients with pneumonia. **METHODS:** Adult (18 or older) patients admitted to one of the 11 Advocate Health Care hospitals with a pneumonia diagnosis between 2008 and 2015 were included for analysis. Hospitals were categorized as low, medium, or high volume based on inpatient beds. 30-day readmission was compared by volume and by patient gender, race, age, length of stay, insurance, calendar year, and discharge disposition (home or home health). Logistic regression was used to examine the association between hospital volume and 30-day readmission, adjusting for covariates. **RESULTS:** 37,757 pneumonia admissions occurred between 2008 and 2015. 30-day readmission rates were 10.5%, 11.5%, and 12.6% for low-, medium-, and high-volume hospitals, respectively. In adjusted models, increased odds of 30-day readmission were seen for patients in both medium-volume (OR = 1.14; 95%CI 1.04-1.25) and high-volume hospitals (OR = 1.28; 95%CI 1.23-1.34) when compared with low-volume hospitals. **CONCLUSIONS:** In this analysis of a single hospital network, patients treated for pneumonia in higher-volume hospitals were found to have significantly greater odds of 30-day readmission than in lower-volume hospitals, even after adjustment for other risk factors. This finding is surprising and should be investigated further to better understand the reasons for these differences.

PHS26

DYSLIPIDEMIA IN THE "DE TODO CORAZON" PROGRAM. A CROSS-SECTIONAL STUDY

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OBJECTIVES: "De Todo Corazón" (DTC) is a risk management program with the aim of reducing complications and improving the quality of life of patients with cardiovascular risks. The aim of this study was to assess the prevalence of dyslipidemia in patients under program care. **METHODS:** The study comprised individuals (64,668) of all ages, living in the Colombian Caribbean. Dyslipidemia was defined as the presence of one or more of the following conditions: Triglycerides > 200 mg/dL, or total cholesterol (TC) > 240 mg/dL, or HDL cholesterol < 40 mg/dL, or LDL cholesterol > 100 mg/dL, or currently taking antilipemic agents. **RESULTS:** The average age was 64.5 + 13.9 years and 66.5% female. The prevalence of dyslipidemia was 82.5% (IC 82.2-82.8). Prevalence rates of dyslipidemia in men and women were: 32.8% and 67.2%. Prevalence LDL cholesterol > 100 mg/dl and currently taking antilipemic agents was 31.5% (IC 31.1-31.8) and 49.6% (IC 49.2-50.0). **CONCLUSIONS:** Dyslipidemia was highly prevalent in patients under program care.

PHS27

ASSESSMENT OF CARDIOVASCULAR RISK IN THE "DE TODO CORAZÓN" PROGRAM IN A COLOMBIAN POOR POPULATION. A CROSS-SECTIONAL STUDY

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OBJECTIVES: "De Todo Corazón" (DTC) is a risk management program with the aim of reducing complications and improving the quality of life of patients with cardiovascular risks. The aim of this study was to assess the prevalence of cardiovascular risk factors in patients under program care. **METHODS:** The study comprised individuals (64,668) of all ages, living in the Colombian Caribbean. Data on anthropometric parameters, blood pressure, glycosylated hemoglobin, total, low-density (LDL) and high-density (HDL) lipoprotein cholesterol, triglycerides, physical activity and smoking status were collected of the program database. We used the risk classification of Framingham Heart Study. **RESULTS:** The average age was 64.5 + 13.9 years and 66.5% female. The overall prevalence rates were as follows: hypertension (ICD-10 hypertension code or >140/90 mm Hg or pharmacologic treatment), 96.5% (96.3%-96.6%); hyperlipidemia (total cholesterol >240 mg/dl or triglycerides >200 mg/dl or LDL cholesterol >100 mg/dl or HDL cholesterol), 85.2% (84.8%-85.4%); diabetes (ICD-10 diabetes code or pharmacologic treatment or glycosylated hemoglobin >6.5%), 36.1% (35.7%-36.5%); metabolic syndrome, 6.3% (6.1%-6.5%); obesity (body mass index >30 kg/m²), 43% (42.6%-43.4%); smoking, 2.2% (1.9%-2.2%); and physical inactivity, 77.8% (77.5%-78.2%). 80% of the patients had data necessary for the classification of cardiovascular risk. 34.9% of the patients had a high cardiovascular risk according to the classification

of 80% of the patients had data necessary for the classification of cardiovascular risk. 34.9% had a high cardiovascular risk according to the classification of Framingham Heart Study. **CONCLUSIONS:** The hypertension, hyperlipidemia and physical inactivity was highly prevalent in patient under program care. One-third of patients had a high cardiovascular risk according to the classification Framingham Heart Study.

PHS28

THE IMPACT OF PHARMACIST BASED DIABETES TREATMENT ON THE ODDS OF HBA1C REDUCTION AMONG MEDICAID PATIENTS

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OBJECTIVES: A randomized control trial is ongoing in Trenton, NJ to evaluate the outcomes of using clinical pharmacists to manage chronic diabetics, on Medicaid, with severely uncontrolled HbA1c (>8%). The purpose of this study was to evaluate the impact of pharmacists on the odds of achieving a clinically significant reduction in HbA1c of ≥1% at 6 months, while controlling for potential confounders. **METHODS:** A logistic regression model evaluated the impact of the treatment provider and each factor on the odds of HbA1c reduction. Potential confounders for the model were selected from the results of a literature search. A second logistic regression model evaluated the impact of the factors on study dropout. A mathematical correction was applied to the odds ratios to estimate the risk ratio. **RESULTS:** A total of 189 patients were randomized and scheduled for follow up appointments. Of the randomized patients, 113 returned for their 6 month follow up appointment. The group treated by the pharmacist demonstrated a 72% increase in the chance of a clinically significant HbA1c reduction (Adjusted OR: 1.72, 95% CI: 1.18-1.92). Treating with a pharmacist also did not produce a statistically significant impact on the odds of study dropout (Adjusted OR: 1.37 95% CI: 0.72-1.54). None of the previously identified confounders had a significant impact on the results. **CONCLUSIONS:** In the first 6 months of treatment, utilizing a clinical pharmacist increased the odds of a clinically significant reduction in HbA1c for severely unmanaged diabetics compared to treatment by a physician without increasing the odds of discontinuing treatment. Future research is needed to determine if the results continue past 6 months.

PHS29

ASSESSMENT OF CARDIOVASCULAR DISEASES RISK IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

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OBJECTIVES: To assess the risk for developing cardiovascular diseases (CVD) in type 2 Diabetes Mellitus (DM) patients during a period of 10 years and establish the association between various risk factors and the risk score. **METHODS:** A prospective observational study conducted in a South Indian teaching hospital for a period of 6 months. Patients with type 2 DM hospitalized from October 2014 – March 2015 were included in the study and necessary data was collected from patient's case records and interview with patients or patient's representatives. The risk for developing CVD was calculated using Framingham Risk Score (FRS) and United Kingdom Prospective Diabetes Study (UKPDS) risk engine and then the significance of association of risk factors to the scores determined. **RESULTS:** Out of 100 patients evaluated for their risk scores 50%, 35% and 15% were found to have low, intermediate and high risk respectively using FRS, whereas 28%, 41% and 31% were found to have low, intermediate and high risk respectively using UKPDS risk engine. Analysis of data revealed that gender, age-group, smoking and total cholesterol level had a significant association to the risk score with p values 0.000, 0.001, 0.017 and 0.048 respectively but High Density Lipoprotein (HDL) level and Systolic Blood Pressure (SBP) had a non-significant association. Similarly, gender, age-group, total cholesterol, duration of diabetes and glycosylated hemoglobin (HbA1c) level had a significant association to the risk score with p values 0.001, 0.016, 0.044, 0.047 and 0.015 respectively despite smoking, HDL level and SBP had a non-significant association, congruent to the FRS results. **CONCLUSIONS:** Cardiovascular risk scores are useful tools in the management of diabetes. Moreover, it is indicated that the risk factors had a significant association to the scores which provides evidence that computation of CVD risk is an important part of prioritizing therapy for individuals.

PHS30

METABOLIC PROFILES IN SPOUSAL ALZHEIMER CAREGIVERS WITH POOR SUBJECTIVE SLEEP QUALITY

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OBJECTIVES: We examined the longitudinal effects of caregiving with other relevant predictors on metabolic parameters in a cohort of Alzheimer caregivers with controls. **METHODS:** A sample of 109 spousal Alzheimer caregivers and 53 non-caregiving age- and gender-matched controls were recruited for this community-based longitudinal study with annual assessments for up to four years. Among the participants, a total of 91 subjects (72 caregivers and 19 non-caregiving controls) with a baseline PSQI > 5, were included for the analysis. **RESULTS:** Metabolic profiles including body mass index (BMI), blood pressure, lipids profiles, and glucose were measured repeatedly during annual assessment. Mixed linear models with time effects for covariates known to affect metabolic parameters were used to evaluate their changes. Multivariate-adjusted metabolic parameters did not significantly differ between caregivers and non-caregivers over time except for systolic blood pressure. For male, HDL levels increased with

non-caregiving status ($p = 0.02$), higher role overload ($p = 0.02$), and baseline high HDL status ($p < 0.001$). For female, HDL levels increased with time ($p = 0.02$) and decreased with increased role overload ($p = 0.02$). **CONCLUSIONS:** Among poor sleepers (PSQI > 5), Alzheimer caregivers and non-caregiving controls had similar metabolic profiles. Role overload, caregiving status, and time had different effects on HDL levels on male and female.

HEALTH SERVICES – Cost Studies

PHS31

BURDEN IMPACT ANALYSIS OF PERITONEAL DIALYSIS VERSUS HEMODIALYSIS IN KOREA

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OBJECTIVES: To investigate the 5-year health care budget impact of variable distribution of end-stage renal disease (ESRD) patients treated with peritoneal dialysis (PD) and hemodialysis (HD) in South Korea. **METHODS:** Budget impact model was developed to estimate the dialysis-related costs from the payers perspective. Analyzed of the national administrative healthcare database data to defined the target population, prevalence, incidence, medical cost. We assumed that specific ESRD patient would choose the PD instead of HD. In the baseline model, among dialysis patients 18% of them were assumed to receive PD and 82% HD in alignment with 2003-2015 national administrative healthcare database data. Eight hypothetical scenarios were compared with this reference scenario. The scenarios were increase in the PD use of prevalence by 6%, 13%, 20%, 50% per year. The other scenarios were increase in the PD use of incidence by 30%, 50%, 70%, 100% per year. **RESULTS:** There were no differences between HD and PD's mortality, cardiovascular event in neither diabetic nor over 65 years old. The results showed all scenarios decrease the budget compared to the reference scenario. To examine the validity of this model, various sensitivity analyses were performed. Throughout the sensitivity analysis, the trend of budget impact did not change. **CONCLUSIONS:** Under the Korean Healthcare system for dialysis, increasing the proportion of patients on PD versus HD could generate substantial savings in dialysis-related costs to the payer. A PD-preferred policy for clinically appropriate patients is also a good strategy to address inequity in dialysis access.

PHS32

THE EXPERT IN HAEMOSTASIS AND THROMBOSIS: IS AN ECONOMIC ANALYSIS FEASIBLE?

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OBJECTIVES: Bleeding and thrombosis are surgery complications leading to significant clinical and economic consequences. Prevention, diagnosis and management of these complications are generally entrusted to the surgical team, more rarely with specific expertise in Haemostasis and Thrombosis (ET). The aim of the present study is to evaluate the economic impact of experts in ET from the hospital perspective by comparing mid-sized structures, with or without such professionals. **METHODS:** Hospital discharge records (HDRs) related to surgical wards were analyzed for year 2012 for two Italian Hospitals comparable in size: 1) AOPV Hospitals, in Vigevano and Voghera cities, without formal experts in ET; 2) AOCR, Cremona Hospital, with formal experts in ET. HDRs reporting thrombotic/bleeding complications occurred during hospitalizations were selected. For each HDR we compared the DRG reimbursement with and without complications, when available. **RESULTS:** 7505 and 6719 HDRs were analyzed for AOPV and AOCR, respectively. The thrombotic/hemorrhagic complications resulted 60 and 27, respectively. Since bleedings were significantly more in the "no expert" structure (21 AOCR vs. 52 AOPV, $p < 0.05$), the analysis focused on these complications. For bleedings detected in AOPV, the average difference in terms of reimbursement, in comparison to the corresponding DRG without complications, amounted to € 3,201 (range 0-33,385€), while for AOCR this value resulted € 1,936 (range 0-13,049€). The total reimbursement increase for the management of bleeding complications with and without experts in ET resulted respectively 40,656€ (28.7%) and 166,481€ (38.6%). The incremental difference of reimbursements between the two hospitals, resulted 125,826€, can be considered a proxy of the economic value associated to the annual experts' activity for the management of thrombotic/hemorrhagic complications. **CONCLUSIONS:** The study, albeit limited to the analysis of two sample structures, suggests that experts in ET in hospitals actually can represent an appropriate use of resources, from both clinical and economic perspectives.

PHS33

A NATIONAL BUDGET IMPACT ANALYSIS OF A SPECIALISED SURVEILLANCE PROGRAM FOR INDIVIDUALS AT VERY HIGH RISK OF MELANOMA IN AUSTRALIA

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OBJECTIVES: Patients at very high risk of cutaneous melanoma make up 18% of the patient population diagnosed with melanoma in Australia. We aimed to estimate the five year healthcare budget impact of providing specialised surveillance using total body photography and digital monitoring of suspicious lesions for this high-risk population, from the perspective of the Australian health care system. Currently the cost for monitoring of suspicious lesions is largely borne by

the patient, however in this study we analysed these services as health system costs. **METHODS:** A budget impact model was constructed using Microsoft Excel to assess the costs of specialised surveillance and potential savings. Data was utilised from a cost-effectiveness analysis and a micro-costing study conducted in a public hospital clinic where specialised surveillance was conducted, and Cancer Registry data to estimate the patient population and costs of surveillance from 2017-2021. **RESULTS:** If all eligible patients were monitored using specialised surveillance rather than the current service provided, the total cost savings to the Australian health care system in the first year would be \$AU 1.7 million (\$US 1.2 million), and in the fifth year \$AU 9 million (\$US 6.2 million). The cumulative cost savings over this period would be \$AU 22.6 million (\$US 15.5 million). If the introduction of the program was staggered from 60% coverage in year one to 90% coverage by year four, the cumulative cost for specialised surveillance over five years would be \$75 million (\$US 51.3 million), amounting to savings of \$AU 18.8 million (\$US 12.8 million). **CONCLUSIONS:** Specialised surveillance has the potential to lead to cost savings for the Australian health care system. Reimbursement through provision of Medicare Benefits Schedule rebates would alleviate out of pocket costs for patients. Follow-up should be conducted to investigate whether the current low rate of excisions is maintained.

PHS34

MIGRAINE IN OBESE ADULTS AND ITS IMPACT ON HEALTH CARE EXPENSES

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OBJECTIVES: Migraine and obesity add significant personal and societal burden, diminished quality of life, and increase health care utilization. Several studies suggest multifactorial pathophysiological associations between migraine and obesity that contribute to the prevalence of migraine in adults with obesity. This study aims to identify sociodemographic and health-related factors associated with migraine, and examine the effect of migraine on health care utilization and expenses in a nationally representative sample of obese US adults. **METHODS:** This study used Medical Expenditure Panel Survey (MEPS) longitudinal data (2006-2013) representing the US civilian noninstitutionalized population. The study included individuals aged > 18 years and with a body mass index (BMI, kg/m²) ≥ 30. After identifying migraine from the MEPS medical condition files, obese adults were divided into two groups: (1) obese with migraine and (2) obese without migraine. Outcomes measured included annualized per subject total health care expenses, and delineated medical services and pharmacy expenses. Multivariate logistic regression identified significant risk factors associated with migraine and a generalized linear model with a log link and gamma distribution assessed the effect of migraine on total health care expenses. **RESULTS:** Among 23,596 eligible obese adults, 4.7% (n=1025) reported migraine. Younger age, female sex, white race, poor perceived health status, and greater comorbidity increased the migraine risk among this obese cohort. Migraine versus no migraine showed higher outpatient, emergency, and prescription drug utilization ($p < 0.001$). The medical, prescription drug, and total health expenses in the migraine group were \$1221 ($p=0.007$), \$760 ($p < 0.001$), and \$1991 ($p=0.001$) higher than the non-migraine group. Migraine increased total health care expenses 31.6% in the obese population after controlling for sociodemographic and health-related variables. **CONCLUSIONS:** Sociodemographic characteristics, health status, and comorbidity level increased the risk for migraine among obese adults. Migraine in obese adults significantly increased total health care utilization and expenses.

PHS35

STATE MEDICAID COST SAVINGS FROM THE NEW YORK UNIVERSITY CAREGIVER INTERVENTION FOR FAMILIES COPING WITH DEMENTIA

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OBJECTIVES: The economic burden of long term care for people with dementia is significant and substantially covered by state Medicaid programs. While no therapies exist to substantially alter disease progression, supportive services for caregivers have been shown to improve caregiver capabilities and well-being and delay patients' institutionalization. We estimated the potential cost savings from offering the New York University Caregiver Intervention (NYUCI) to eligible Medicaid enrollees from a state payer perspective. **METHODS:** Data from the Minnesota Department of Human Services and the literature informed a population-based Markov model to predict and compare costs, including intervention costs, over 15 years with and without implementation of the NYUCI for family caregivers of community-based Medicaid eligibles with dementia. We incorporated original NYUCI randomized controlled trial results as appropriate, adjusted to Minnesota implementation. **RESULTS:** Approximately 5-6% more eligibles with dementia would remain in the community from year 3 (2014) on and 17% fewer would die in nursing homes over 15 years if their caregivers received the NYUCI. The state could save \$40.4 million (2011 dollars, discounted at 3%) if all eligibles/caregivers participated in the NYUCI. Savings are expected within 5 years of program implementation. Best-and worst-case scenario estimates were \$178.9 million and -\$7.3 million, respectively, driven largely by the variation in the assumed NYUCI effect. **CONCLUSIONS:** State payers can use enhanced caregiver support to moderate the growing tax burden of dementia, even without a breakthrough in pharmacologic treatment of the disease. But because it takes time to realize savings from a program like the NYUCI, the frequently short time horizon of legislative fiscal notes presents a challenge to adoption. In deciding on program value it may be important to distinguish cost-effectiveness from return on investment and take long-term impact into consideration.

PHS36

ESTIMATING THE INCREMENTAL EFFECT OF DIABETES COMPLICATIONS TO DIABETES-RELATED HOSPITALIZATION COST

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OBJECTIVES: Peripheral lower-extremity diseases (PLE), kidney diseases, and coronary atherosclerosis are three important diabetes complications. Their incremental costs to diabetes-related hospitalization haven't been thoroughly examined in previous studies. This study explores the presence and severity of these three complications on diabetes-related hospitalization costs. **METHODS:** A retrospective analysis of the 2010 - 2012 National Inpatient Sample (NIS). Diabetes-related hospitalization was defined by principal and secondary diagnosis of diabetes (250.XX). Hospitalization costs were obtained by adjusting the total hospitalization charge by the hospital-specific cost-to-charge ratio and were adjusted to the 2012 dollar by medical CPI. The presence and severity of these three complications were identified by diagnosis codes, procedure codes and DRG. Stratified random matching was adopted to make the cohorts with/without each of the three complications comparable. Generalized linear model (GLM) was used to analyze the association between diabetes complications and hospitalization costs. The statistical significance level was p-value 0.0001. **RESULTS:** 804,192 diabetes-related hospitalization records were identified. 26.6% of the hospitalized diabetes patients had comorbid PLE; 21.6% with kidney diseases; 24.3% with coronary atherosclerosis. The mean and median diabetes-related hospitalization costs were \$10,342 and \$6,847. Controlling for covariates, the adjusted mean hospitalization costs for diabetes patients with severe PLE were \$17,212 (95% CI: \$16,610 - \$17,835); while that for diabetes patients with less severe PLE or without PLE were \$10,432 and \$10,363, respectively. Diabetes-related hospitalization costs were also significantly higher for patients with severe coronary atherosclerosis (\$12,822) than patients with less severe coronary atherosclerosis (\$11,264) or patients without coronary atherosclerosis (\$11,434). However, severe or less severe kidney diseases were not associated with significant increases in diabetes-related hospitalization costs. **CONCLUSIONS:** The incremental costs for severe PLE and severe coronary atherosclerosis were \$6,849 and \$1,388 to diabetes-related hospitalization costs. Optimal diabetes management programs are essential to reduce the burden of diabetes and its complications.

PHS37

ECONOMIC IMPACT OF ROUTINE OPT-OUT ANTENATAL HIV SCREENING: A SYSTEMATIC REVIEW[†]Ibekwe E, Ibekwe E, Prof Francis Fatoye F, Haigh C
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OBJECTIVES: To evaluate the economic impact of routine testing of HIV in antenatal (ANC) settings **METHODS:** A systematic review of published articles. Extensive electronic searches for relevant journal articles published from 1998 to 2015 when countries began to implement routine ANC HIV testing on their own were conducted in the following databases: Science Direct, MEDLINE, SCOPUS, JSTOR, CINAHL and PubMed with search terms as listed in box 1. Manual searches were also performed to complement the electronic identification of high quality materials. There were no geographical restrictions but language was limited to English. Fifty-five articles were retrieved; however, ten were eligible and included in review. **RESULTS:** The findings showed that many programmes involving routine HIV testing for pregnant women were cost effective and cost saving. Overall, in sensitivity analysis, the cost of the interventions at different settings were impacted by prevalence rate of HIV, the cost of screening for HIV, the overhead cost and the life time cost of treatment of an HIV infected baby. **CONCLUSIONS:** Routine HIV testing is both cost-effective and cost saving. However, there is wide variations in the methodological approaches to the studies. Adopting standard reporting format would facilitate comparison between studies and generalizability of economic evaluations.

PHS38

ASSOCIATION OF COMORBID DEPRESSION WITH HEALTH CARE EXPENDITURES IN ADULTS WITH RHEUMATOID ARTHRITIS

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OBJECTIVES: To estimate the incremental health care expenditures associated with depression in a nationally representative sample of US adults with rheumatoid arthritis (RA). **METHODS:** This is a pooled cross-sectional study of adults aged 21 years and older with a diagnosis of RA using Medical Expenditure Panel Survey (MEPS) data from 2010-2014. Ordinary Least Square (OLS) regression with log-transformed expenditures was conducted. The dependent variable consisted of total health care expenditures and health care expenditures by type of medical services, while the presence of comorbid depression was the primary independent variable. Covariates included socio-demographic, economic and clinical characteristics that are found to influence an individual's healthcare utilization and costs. A secondary analysis using a generalized linear model (GLM) with log-link function and gamma distribution was also performed. All expenditures were adjusted to 2016 dollars. The analyses accounted for the complex survey design of MEPS and was conducted using SAS 9.4. **RESULTS:** Depression was present in 19% of the adults with RA. The unadjusted mean annual expenditures were higher in the individuals with depression compared to those without: mean annual total expenditure (\$17,018 vs. \$10,367) and mean annual prescription drug expenditure (\$6,278 vs. \$3,047). OLS regression demonstrated that individuals with comorbid depression had 55.3% higher total annual expenditures and 110.0% higher annual prescription drug expenditure compared to those without comorbid depression. GLM with log-link and gamma distribution showed that the incremental total annual cost for patients with RA and depression was \$621,

and the incremental annual prescription drug cost was \$768, compared to those without depression. **CONCLUSIONS:** Depression is associated with higher annual healthcare expenditures in adults with RA. This underscores the importance of screening and treatment of depression in patients with RA so as to potentially lower the overall health care expenditures in this population.

PHS39

HEALTHCARE RESOURCE UTILIZATION AND COSTS OF CARE FOR MESOTHELIOMA MEDICARE BENEFICIARIES

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OBJECTIVES: To estimate the health care resource utilization (HRU) and cost associated with newly diagnosed mesothelioma, a rare and deadly disease with limited treatment options, compared to Medicare beneficiaries without cancer. **METHODS:** Using data from SEER-Medicare, we describe HRU and costs for Medicare patients diagnosed with mesothelioma between 2008 and 2009 and a matched comparison group of patients without cancer. Patients were matched on age, sex, comorbidity index, race and SEER region, and were followed through 2010. The proportion of mesothelioma patients using each type of health care service within the study observation was compared to the matched sample using chi-square tests. A t-test and a non-parametric test (Wilcoxon-Mann-Whitney) were used to compare continuous cost variables. **RESULTS:** We identified 175 mesothelioma patients and 350 comparison subjects who were enrolled in Medicare Parts A, B, and D, and were not HMO members. Nearly all aspects of HRU that we examined, including inpatient hospitalization (92% of mesothelioma patients had an inpatient hospitalization versus 20% of comparisons; p<0.001), outpatient hospitalization (89% versus 61%; p<0.001), emergency room visit (41% versus 22%; p<0.001), physician office visit (98% versus 93%; p<0.001), hospice (52% versus 0.3%; p<0.001), use of durable medical equipment (56% versus 28%; p<0.001), and home health care (41% versus 10%; p<0.001), as well as actual mean costs for the total observation period associated with HRU (except pharmacy) (\$US 66,659 versus \$US 12,911; p<0.001) are higher in mesothelioma patients compared to matched comparisons without mesothelioma. Pharmacy use was similar between the groups (97% versus 94%, p=0.2551), and costs were higher for the comparison group (\$US 1,917 versus \$US 2,725; p<0.001). **CONCLUSIONS:** Mesothelioma-associated medical resource utilization and associated expenditures are substantive, and similar to other cancers. In order to reduce the burden of illness associated with mesothelioma, continued efforts in the development of more efficacious treatments are needed.

PHS40

COMPARISON OF HOSPITAL COSTS VS OUTPATIENT OF APPLICATION OF INTRAVENOUS INJECTABLE THERAPY IN THE TREATMENT OF PERIPHERAL OCCLUSIVE ARTERIAL DISEASE IN COLOMBIA

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OBJECTIVES: To develop a costing exercise that allows comparing the hospital vs ambulatory costs of application of intravenous injectable vasodilator therapy in the treatment of Peripheral Occlusive Artery Disease (POAD) in Colombia. **METHODS:** The increase in ambulatory or domiciliary medical care is in effect a systemic response to the increased needs of the Colombian health system, specifically the cost of beds occupancy and hospital rooms, which in some cases are not necessary. Through the collection of clinical data on the management of the application of a vasodilator pharmacological therapy for patients with POAD in the Fontaine III and IV stages, an exercise of economic cost was developed that allows comparing the options of intrahospital vs ambulatory application, in cases where this procedure can be performed ambulatorily according to medical criteria. The costs of resources and inputs were taken from the SOAT 2001 + 30% tariff manual and were adjusted when quartiles 25, 50 and 75 were required to ensure that the extreme values found in the database were not to affect the average estimation. **RESULTS:** The results are presented as the sum of the expenditure in the application and use of inputs and resources, such as single room of average complexity, macro drip equipment, intrahospital care by general medicine, among others. The option of application for ambulatory or domiciliary management represents a saving of about 28.14% to the Colombian health system in this specific therapy for POAD. **CONCLUSIONS:** The results of the exercise suggest the existence of thrifty alternatives of management options for the application of medications in an outpatient or domiciliary way without having to carry costs to the health system directly with the occupation of spaces in hospitals that can be used in a more efficient way.

PHS41

ENROLLMENT PATTERNS FOR HOSPICE AND COST OF END-OF-LIFE CARE AMONG ELDERLY PATIENTS WITH DIFFUSE LARGE B-CELL LYMPHOMA: A SEER-MEDICARE ANALYSIS

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OBJECTIVES: Hospice has historically been underutilized for end-of-life care in hematological malignancies. We aimed to identify hospice enrollment patterns among patients with diffuse large B-cell lymphoma (DLBC) and compare end-of-life cost of care with non-hospice patients. **METHODS:** Using the SEER-Medicare database from 2002-2012, we identified predictors of hospice enrollment within

the last 30 days of life for DLBCL patients >65 years. We evaluated adjusted and unadjusted costs among hospice and non-hospice users. **RESULTS:** We identified 12,644 DLBCL patients. Hospice users were older than non-users (mean 80 vs. 78 years, $p < 0.001$), more often white ($p = 0.02$), less often married (45.1 vs. 53.7, $p < 0.001$), more often female ($p < 0.001$), and more often had advanced stage disease ($p = 0.004$). There were no significant differences in enrollment by urbanicity, poverty level, hospital type, and Charlson comorbidity index (CCI). Non-hospice patients received more transfusions ($p < 0.001$) and chemotherapy ($p < 0.001$) in the last 30 days of life. During the last month of life, costs continually increased for non-hospice users from \$2,063 for days 26-30 prior to death to \$3,068 for days 0-5 ($p < 0.001$). Hospice users' costs decreased from \$1,752 to \$1,326 ($p = 0.002$). Our results were consistent after adjusting for age, CCI, disease stage, race, marital status, urbanicity, and census poverty level (non-hospice: \$2,041 days 26-30 vs. \$3,109 days 0-5, $p < 0.001$; hospice: \$1,800 days vs. \$1,348, $p = 0.001$). For non-hospice patients, inpatient admissions drove costs (\$2,289). Our propensity score weighted models provided similar results. **CONCLUSIONS:** We found age, race, marital status, and sex were associated with hospice use among older DLBCL patients. Those who received transfusions or chemotherapy in the last 30 days of life were less likely to enroll in hospice. Total health care costs were higher in non-hospice patients, primarily driven by inpatient admissions. Earlier hospice intervention may reduce costs of care in the last 30 days of life.

PHS42

BURDEN OF ILLNESS IN PATIENTS WITH TENOSYNOVIAL GIANT CELL TUMORS

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OBJECTIVES: Little is known about the burden of illness in patients with tenosynovial giant cell tumors (TGCT), which are rare, typically benign, lesions of the synovial tissue including giant cell tumor of the tendon sheath (GCT-TS) and pigmented villonodular synovitis (PVNS). The objective of this study was to describe healthcare resource utilization and costs for patients with GCT-TS and PVNS. **METHODS:** A retrospective cohort study design was used to analyze administrative claims for adult commercial and Medicare Advantage health plan enrollees with diagnosis codes for GCT-TS (ICD-9: 727.02) and PVNS (ICD-9: 719.2x) between 1/1/2006 and 9/30/2014. Patients were continuously enrolled for 12 months before (pre-index) and 12+ months after (post-index) the date of the first TGCT claim (index date). One-year pre-index and post-index measures were compared using chi-square and Wilcoxon tests to account for skewed cost data. Results were stratified by TGCT type. **RESULTS:** The study identified 4,664 TGCT patients, 284 with GCT-TS and 4,380 with PVNS. Mean age (GCT-TS: 50 years; PVNS: 51 years) and sex distributions (GCT-TS: 60.2% female; PVNS: 59.5% female) were similar for each group. Approximately half of PVNS patients had a lower leg location on the index claim, and 2,133 (48.7%) had at least one post-index surgery versus 239 (84.2%) of GCT-TS patients. Mean total healthcare costs increased from \$8,943 pre-index to \$14,880 post-index ($p < 0.001$) for GCT-TS patients and from \$13,221 pre-index to \$17,728 post-index ($p < 0.001$) for PVNS patients. Pre-index to post-index ambulatory costs increased nearly 120% for GCT-TS patients (\$4,340 to \$9,570, $p < 0.001$) and 50% for PVNS patients (\$6,782 to \$10,278, $p < 0.001$), including costs for a significant increase in post-index physical therapy use (GCT-TS: 18% to 40%, $p < 0.001$; PVNS: 38% to 60%, $p < 0.001$). **CONCLUSIONS:** Higher post-index healthcare costs, with large increases in ambulatory care including physical therapy use, suggest a high healthcare burden once TGCT is identified.

PHS43

A 10-YEAR REVIEW OF ACUTE MYOCARDIAL INFARCTION HEALTH CARE COSTS IN ALBERTA, CANADA

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OBJECTIVES: Acute myocardial infarction (AMI) is a global health problem. Little is known as to the cost burden of the disease to the Alberta health care system. We sought to examine the health care costs associated with AMI in Alberta, Canada between 2004-2013. **METHODS:** We linked six Albertan health databases, including ambulatory care, discharge abstract database, practitioner claims, pharmacy information network, population registry, and vital statistics to identify patients with a primary diagnosis of AMI (ICD-10 codes I21 or I22) during 2004-2013. We used Alberta Health Data Application to provide unit cost for ambulatory care and inpatient services and Alberta Drug Benefit List to provide unit drug price. AMI health care costs were grouped in to ambulatory care, inpatient, practitioner claims and drug costs. All costs were inflated to 2016 Canadian dollar values. **RESULTS:** 52,912 patients (55,384 hospitalizations; 75,309 ambulatory care visits; 497,716 practitioner claims; and 4,003,982 drug dispensing events) with AMI were included in the analysis. Females accounted for 32.7% of study population. Patient age (median (IQR)) decreased during the study period (2004: 68 (56-79); 2013: 65 (56-77); $p < 0.001$). Total hospitalization, ambulatory care, practitioner claims, and drug costs were \$760.5 million (2004: \$80.4 million; 2013: \$70.7 million), \$91.5 million (2004: \$9.6 million; 2013: \$6.4 million), \$71.4 million (2004: \$5.6 million; 2013: \$8.8 million), and \$118 million (2008: \$19.1 million; 2013: \$17.7 million), respectively. Cost per hospitalization and ambulatory care visit decreased from \$16,191 and \$1,282 in 2004 to \$11,544 and \$1,191 in 2013 ($p < 0.001$), respectively. **CONCLUSIONS:** Health care costs for AMI in Alberta are significant; however, they decreased during the study period, except for practitioner claims costs. Not surprisingly, hospital services accounted for the most of the AMI care costs. Strategy to shift AMI management to outpatient settings is needed to alleviate the AMI care cost burden.

PHS44

COST OF CONGESTIVE HEART FAILURE: THE CASE OF AN INSURED COLOMBIAN POPULATION

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OBJECTIVES: To evaluate the direct inpatient costs of patients with Congestive Heart Failure (CHF) from an insured population enrolled to "De Todo Corazón" cardiovascular risk management program in Colombia, 2015. **METHODS:** Data were collected retrospectively from 283 patients with arterial hypertension (AH) or AH + type 2 diabetes mellitus (DM2) who suffered a CHF. These patients were enrolled into a cardiovascular risk management program of a state-subsidized insurance company (IC). The direct hospital costs were estimated through a top-down analysis from the third payer perspective. Costs were extracted based on billing and hospitalization records of the IC and converted to US dollars 2015. We used median and interquartile ranges (IQR) to describe costs by age group, risk level and risk factors. **RESULTS:** In total, 58.3% of the patients who suffered a CHF had both risk conditions (AH+DM2). According to the Framingham risk score, 18.4% of patients were classified as low-risk (LR), 4.6% as medium-risk (MR), 32.9% as high-risk (HR) and 44.17% were unclassified. The median inpatient cost per patient with CHF by risk groups was: LR: US\$2,256 (IQR \$510-\$4,998), MR: US\$4,184 (IQR \$895-\$9,988) and HR: US\$2,096 (IQR \$935-\$4,850). By risk group of factor, the median cost per patient with AH was: <65-year-old: US\$1,973 (IQR \$855-\$7,225) and ≥65 years-old: US\$1,548 (IQR \$662-\$3,675) in. Patients with AR+DM2 registered higher costs [US\$2,666 (IQR \$1,026-\$5,283) in under-65 years and US\$2,822 (IQR \$935-\$5,953) in ≥65 years]. Differences in cost by risk factor were statistically significant (Wilcoxon rank-sum $p < 0.01$). However, differences by age groups and risk factors were not statistically significant ($p > 0.05$). **CONCLUSIONS:** Direct costs of CHF increased by having one or more risk factors. Our findings are relevant for policy making focused on saving costs on patients with cardiovascular disease.

PHS45

HEALTH CARE COSTS OF STROKE IN CARDIOVASCULAR RISK PATIENTS IN INSURED COLOMBIAN POOR POPULATION

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OBJECTIVES: "De Todo Corazón" is a risk management program to reduce complications and improve the quality of life of patients with cardiovascular risk. The aim of this study was to estimate the direct medical costs related to confirmed stroke in an insured population enrolled in a risk management program in Colombia-2015. **METHODS:** We retrospectively collected data from 380 patients with confirmed stroke enrolled in a cardiovascular risk management program of a subsidized insurer who presented arterial hypertension (AH) or AH+ type 2 diabetes mellitus (DM2). We designed a top-down analysis to estimate direct medical costs due to stroke from a third payer perspective. Costs were calculated based on hospitalization billing records and expressed in US Dollars 2015. Median costs and interquartile ranges (IQR) were described by age group, risk level and risk factors. **RESULTS:** In total, 50% of patients who suffered a stroke had as underlying cause DM2+AH. According to the Framingham risk score, 22.9% of the patients were classified as low-risk, 2.4% as intermediate, 32.6% as high and 42.1% were unclassified. The median costs of hospital care due to a stroke per patient by risk groups were \$864 (IQR \$2,414), \$730 (IQR \$3,141) and \$1,902 (IQR \$4,256) for low, intermediate and high-risk patients, respectively. By risk factor groups, the median cost for patients under-65 with DM2+AH was \$1,531 (IQR \$3,536) and \$1,876 (IQR \$4,796) for ≥65 years. Patients under-65 years who presented only HTA had median costs of \$805 (IQR \$937) and ≥65 years of \$1,561 (IQR \$3,077). Differences in cost per age group regarding to risk factors were statistically significant (Wilcoxon rank-sum $p < 0.01$). **CONCLUSIONS:** Direct costs of stroke care increased with risk level and age. Our results are important to design policies focused on the cost and risk management of patients with cardiovascular disease.

PHS46

INCREMENTAL HEALTHCARE COSTS AND PRODUCTIVITY COSTS ASSOCIATED WITH DEPRESSION AMONG WORKING AGE (18 TO 64 YEARS) ADULTS WITH RHEUMATOID ARTHRITIS

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OBJECTIVES: This study estimated the excess direct medical costs and indirect costs due to missed work days associated with depression among working-age adults (18 to 64 years) with Rheumatoid Arthritis (RA). **METHODS:** A retrospective cross-sectional study of working-age adults was conducted using data from the nationally representative Medical Expenditure Panel Survey (MEPS) for the years 2007, 2009, 2011 and 2013. Depression was identified using ICD9 codes. Indirect cost for each individual was calculated by multiplying missed work days with average daily wage of each individual. Adjusted total annual medical expenditures was estimated using generalized linear model with gamma distribution and log link in 2013 U.S. dollars. Adjusted annual missed work days were estimated using negative binomial regressions. Adjusted indirect costs were estimated in 2013 U.S. dollars using two-part logit-generalized linear regression models. The incremental direct medical costs and

indirect costs associated with depression in RA patients were calculated using recycled prediction methods. **RESULTS:** Compared with RA patients without depression ($n = 1,050$), those with depression ($n = 370$) had significantly higher direct medical costs (\$5,605) and higher indirect costs due to productivity loss (\$743) after controlling for differences in predisposing factors (age, sex and race), enabling factors (marital status, education and poverty status), need factors (number of chronic conditions, health status), and personal health practices (e.g. physical activity, obesity and smoking). **CONCLUSIONS:** Direct medical costs and indirect costs due to missed work days were higher among working age adults with depression and RA. Future studies need to evaluate whether depression treatment can reduce the direct and indirect costs among adults with RA.

PHS47

DIRECT MEDICAL COSTS DUE TO HYPERTENSION IN A COLOMBIAN POOR POPULATION, A TOP-DOWN MACRO COSTING ANALYSIS

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OBJECTIVES: To estimate the direct annual medical costs of hypertensive patients from a Colombian cardiovascular risk management program of a state-subsidized health insurance company in 2015. **METHODS:** Retrospective cross sectional study of 61,611 patients affiliated to a cardiovascular risk management program of a state-subsidized health insurance company in Colombia 2015 was conducted. Direct medical annual costs in inpatients and outpatients hypertensive patients were analyzed from the healthcare payer's perspective using the top-down costing approach. Costs were quantified based on financial and hospitalization records of the insurance company and converted to US dollars 2015. Costs were described using the framinghan risk score of the program. Medians and interquartile ranges (IQRs) were calculated and two groups of patients were defined based on the reported total cost (TC). Low cost: TC < percentile75 + 1.5*IQR and high cost: TC > percentile75 + 1.5*IQR. **RESULTS:** Out of total patients at risk of a cardiovascular event, 62.9% (38,802) are hypertensive (non-diabetes). Of these, 8.5% are classified as high-risk (HR), 49.2% as low-risk (LR) and 3.58% as medium-risk (MR) according to the Framinhan risk score (FRS). The remaining 42.3% were not classified by the program FRS. The median outpatient cost of a hypertensive patient was US\$102.3 (IQR: USD\$45.9-US\$237.4). The median inpatient costs per patient (MIC) for the low cost group of patients were: HR: USD\$461.3 (IQR: USD\$353.2-US\$543.9), MR: USD\$437.6 (IQR USD\$311.8-US\$528.8), LR: USD\$367.7 (IQR USD\$251.3-US\$501.1) and the MIC per patient for the high cost group of patients were: HR: USD\$2,066.4 (IQR USD\$1,231.7-US\$5,902.3), MR: USD\$2,064.2 (IQR: USD\$1,137.5-US\$6,451.2), LR: USD\$1,593.1 (IQR: USD\$1,028.1-US\$3,250.1). **CONCLUSIONS:** In both groups of patients, inpatient cost in (non-diabetic) hypertensive patients increases as the risk level does. These findings may justify investments by the insurance company to control high blood pressure in order to save downstream health care budgets.

PHS48

EVALUATING THE ECONOMIC BURDEN AND HEALTH CARE UTILIZATION DUE TO DEPRESSION COMORBIDITY IN DEMENTIA

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OBJECTIVES: To assess the type and extent of health care utilization and medical care expenditures in adults with dementia and depression comorbidity. **METHODS:** Using the 2014 Medical Expenditure Panel Survey (MEPS), dementia patients with and without depression were compared to determine differences in health care utilization and costs of health care with respect to inpatient care, ambulatory care, ER visits and prescription drugs. Differences in utilization and costs stemming from demographic and socioeconomic variations in the two groups were examined. A series of Student's t-test was carried out to discern differences in utilization and costs. **RESULTS:** In 2014, about 32% of the 1.4 million adults (weighted) who had dementia were also diagnosed with depression. The extent of comorbidity was found to be greater in individuals aged 60 years and over (35.8%) than in the younger age group (18-59 years; about 4%). Compared to the main sample, the comorbid depression sample was found to have a greater proportion of females (68% vs 66%), Caucasians (85% vs 79%) and low income individuals (16% vs 8%, $p < 0.0001$). Depression comorbidity was also related to higher outpatient visits (0.91 vs 0.82, $p < 0.0001$), office-based provider visits (11 vs 9, $p < 0.0001$), and prescription drug use (67 vs 33, $p < 0.0001$). The group also had higher expenditures for outpatient visits (\$1379 vs \$253, $p < 0.0001$), office based provider visits (\$2226 vs \$1987, $p < 0.001$) and prescription drug use (\$4504 vs \$3110, $p < 0.001$). **CONCLUSIONS:** Depression comorbidity in dementia is associated with greater utilization of medical care and higher medical costs in the United States. Substantial differences are found in the use of prescription drugs and cost of outpatient care. Depression being both a risk factor and a prodrome of dementia, there is a strong need to identify high-risk individuals and emphasize screening for depression, especially in younger adults.

PHS49

ASTHMA-RELATED DIRECT COSTS AND HEALTH CARE UTILIZATION BY SEVERITY IN COLOMBIA

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OBJECTIVES: To estimate health care utilization and direct costs of asthma in Colombia from the health care system perspective **METHODS:** A retrospective prevalence-based study was used to analyze claims data on health services utilization and costs in all-age patients with asthma (CIE-10: J45-J46) for the year 2015. Patients were identified and selected between Jan-1-2004 and Dic-31-2014 using a nationally large-scale medical claims database from a subsidized-regime insurance company that required at least 12 months of continuous insurance coverage for eligibility. Sample was divided into 4 different levels based on the Leidy criteria, an established algorithm for assessing asthma severity with claims data based in rescue medication fills. Exacerbations were included for a more accurate classification. Costs were converted to international dollars using mean exchange rate of 2015 adjusted for purchase parity power **RESULTS:** Among 20,890 patients completing study criteria, 53.3% were female, mean age (SD) was 21.4 (± 21.6) years. In regard to severity of symptoms, 69.9% had mild intermittent, 17.8% mild persistent, 6.7% moderate persistent and 5.4% severe persistent asthma. The most common co-morbidities were chronic obstructive pulmonary disease ($n=2,251$; 10.8%) and rhinitis ($n=1,222$; 5.9%). Overall median (IQR) cost per patient was \$60.8(137.1). According to severity, cost were \$35.1(57.6), \$181.7(273.5), \$481.1(1,026), \$1,205.2(2,149) in level 1-4 respectively ($p < 0.001$). Relative frequencies of prescriptions and services were: oral corticosteroids, 19.5%; inhaled corticosteroids, 24.5%; inhaled corticosteroids-long-acting B2-agonists combination, 2.3%; hospitalizations, 5.5%; ambulatory services, 34.5%; specialist outpatient visits, 27.6%; general physician visits, 55.7% and emergency department visits (ED), 3.4%. Median cost of ED visits and hospitalizations were \$165.2(36.8) and \$904.6(1,478.5), respectively. **CONCLUSIONS:** Health service utilization and direct costs of asthma in Colombia are high and related to severity of symptoms. Nationwide health policies aimed at the effective control of asthma are necessary and will play an important role in reducing the associated economic impact.

PHS50

HEALTH CARE COSTS OF ACUTE MYOCARDIAL INFARCTION IN A COLOMBIAN POPULATION AFFILIATED TO A CARDIOVASCULAR RISK-MANAGEMENT PROGRAM: A MACRO COSTING ANALYSIS

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OBJECTIVES: To estimate the direct annual medical costs of Acute Myocardial Infarction (AMI) from a Colombian cardiovascular risk management program of a state-subsidized health insurance company in 2015. **METHODS:** Retrospective cross sectional study of 61,611 patients affiliated to a cardiovascular risk management program of a state-subsidized health insurance company in Colombia 2015. Direct medical annual inpatient costs of hypertensive and type2 diabetic patients were analyzed from the healthcare payer's perspective using the top-down costing approach. Costs were quantified based on billing inpatient records of the insurance company and converted to US dollars 2015. Costs were described using the framinghan risk score of the program. Medians and interquartile ranges (IQRs) were calculated. **RESULTS:** 472 patients suffered an average of 1.08 AMI in 2015. Of these, all patients resulted to have hypertension (HP) as a cardiovascular risk factor and 58.3% resulted to have type2 diabetes mellitus (DM2) in addition to HP. Out of total of patients, 38% were classified as high-risk patients, 4% as medium-risk and 26% as low-risk according to the framinghan risk score. The remaining 32% were not classified by the program. The median costs per patient by risk score were: high-risk: USD\$2,625 (IQR USD\$1,183-US\$7,162) and low-risk: USD\$2,336 (IQR USD\$914-US\$7,314). The median cost per patient with HP was: > 65 years-old patients: USD\$2,486 (RIC USD\$1,074-US\$6,998) and < 65 years-old: USD\$1,899 (IQR USD\$681-US\$5,293), and the median cost per patient with HP+DM2 was: > 65 years-old patients: USD\$2,814 (IQR USD\$1,278-US\$8,290) and < 65 years-old: USD\$2,033 (IQR USD\$1,104-US\$8,168). **CONCLUSIONS:** Age, level of risk and having one or two risk factors increase health care costs associated to AMI. These findings serve as evidence to support investments to control these risk factors in order to save downstream AMI costs.

PHS51

PRIMARY OPEN ANGLE GLAUCOMA: A REAL WORLD EVIDENCE ANALYSIS OF ASSOCIATED PREVALENT AND INCIDENT COSTS AND HEALTHCARE RESOURCE UTILIZATION

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OBJECTIVES: Assess total healthcare costs and resource utilization for primary open angle glaucoma (POAG) patients; examine real-world treatment patterns for POAG patients, including types and combinations of treatments for incident and prevalent cases; and assess the level of medication adherence with POAG-related medication. **METHODS:** Retrospective database analysis using administrative claims and eligibility records from Truven MarketScan Commercial and Medicare Supplemental databases (2012-2014) for patients ($n=54,281$) with ≥ 2 claims with an ICD-9-CM 365.11 (POAG) diagnosis or one POAG-related surgery after January 1, 2013. Index date was that of the first claim identified. Incident cases were patients

without POAG claims and prevalent cases had ≥ 1 POAG claim during the one-year prior-index period. The analysis period was one year following the index date. Adherence was assessed as the patient being without medication 30+ days at least once during the year. **RESULTS:** Mean Charlson Comorbidity Index was 2.4 (2.6) for incident (prevalent) patients. Component analysis demonstrated ambulatory visits were primary cost drivers (mean \$614/\$1,252 for incident/prevalent patients), followed by prescription medications (mean \$488/\$778 for incident/prevalent), then inpatient visits (mean \$6,009/\$10,834 for incident/prevalent). Per patient treatments included POAG medication (64%), laser trabeculoplasty (25%), no treatment (22%), drainage device implantation (internal and external approaches and drainage) (5%), trabeculectomy (4%) and other procedures (4%). Prevalent patients (81%) were approximately two-fold likelier to receive POAG medication than were incident patients (44%). "No treatment" was substantially greater in incident (44%) than in prevalent (3%) patients. Patients were non-adherent 58% of the time. **CONCLUSIONS:** Similar to recent American Academy of Ophthalmology expert consensus guidelines, medications were treatment drivers, followed by laser trabeculoplasty. Prevalent patients received treatment more frequently/aggressively than did incident patients. Regardless, poor medication adherence might be indicative of the need for procedures to be more frequently pursued.

PHS52

IMPACT OF DISEASE SEVERITY AND COMORBIDITY ON INFORMAL COSTS IN DEMENTIA: A SYSTEMATIC REVIEW OF AVAILABLE EVIDENCE

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OBJECTIVES: To characterize different types of informal care costs (ICC) in dementia and assess how they are affected by comorbidity and disease severity, as measured by physical and cognitive functioning. **METHODS:** A systematic and comprehensive review of empirical studies conducted in the USA, published between 2000-present, retrieved from PubMed, EMBASE, Medline, SciDirect, and databases in health care and economics. Articles were grouped according to the setting of care, indirect cost type (paid Vs unpaid), and type of caregiving services performed. Evidence of disease severity was documented by reviewing assessment of ADL/IADLs and cognitive functioning. Comorbidity information was recorded if any coexisting conditions were also reported. A narrative analysis was used to synthesize the results. Meta-analysis was not performed due to a lack of homogeneity in studies. **RESULTS:** The review identified 17 eligible full-text articles. Nearly all the studies were cross-sectional and focused on community-dwelling adults; most care was given by spouses and female caregivers or adult children; and assistance with IADLs was a frequent care given. Reported costs of ICC range from \$2000-\$60,000 per year, with hours spent ranging from 13-107 hrs per week. Replacement Cost Approach was the most common method of valuing caregiver lost earnings (n=13). Mini Mental State Examination (MMSE) was the most frequently used (n=11) screening tool for study enrollment and cognitive assessment. Most cross-sectional reports show that recipient use of informal care rises over time and costs increase substantially with worsening cognition and physical functioning. None of the studies examined, however, a direct correlation between the extent of comorbidity and ICC. **CONCLUSIONS:** Available evidence demonstrating association among severity-comorbidity-cost triad is scarce. Modeling of direct costs in economic studies continues to be dominant, but indirect costs often can be as high as direct costs, often surpassing direct costs.

PHS53

HEALTHCARE BURDEN AMONG PATIENTS NEWLY DIAGNOSED WITH MULTIPLE MYELOMA WITH COMMERCIAL AND MEDICARE INSURANCE COVERAGE IN THE US

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OBJECTIVES: To evaluate healthcare costs among newly diagnosed patients with multiple myeloma (MM) in the US. **METHODS:** Patients newly diagnosed with MM who did not receive stem cell transplant were identified from the MarketScan Commercial and Medicare claims databases (1/1/2009-9/30/2015). All patients had continuous medical/prescription coverage 12 months before (baseline) and ≥ 12 months after the index date of MM treatment initiation. Demographics and clinical characteristics were evaluated during the baseline period. Healthcare costs (payments paid by insurance, patient, and other payers) and out-of-pocket (OOP) payments (copayments, co-insurance, and deductibles paid by patients) were determined among patients with age < 65 and ≥ 65 years old and were inflation adjusted to 2015 US dollars. **RESULTS:** Among younger MM patients (< 65 years; n=1,315), mean age was 56.7 years and 55.6% were male. During the follow-up, total mean healthcare costs (inpatient, outpatient, outpatient prescription) were \$15,183 per-patient-per-month (PPPM). Inpatient costs were \$4,204 PPPM, total outpatient medical costs were \$8,100 PPPM. The total outpatient pharmacy costs were \$2,880 PPPM including MM drug prescription costs of \$2,521 PPPM. Among older MM patients (≥ 65 years; n=1,923), mean age was 76.6 years and 55.2% were male. During the follow-up, total mean healthcare costs were \$8,277 PPPM. Inpatient costs were \$1,583 PPPM, total outpatient medical costs were \$4,448 PPPM, total outpatient pharmacy costs were \$2,245 PPPM including MM drug prescription costs of \$2,004 PPPM. Approximately 2% of total healthcare costs were OOP for both younger (\$297 PPPM) and older MM patients (\$181 PPPM), with approximately 16% of total OOP payments attributed to MM drug related outpatient services. **CONCLUSIONS:** Monthly total healthcare costs among both younger and older patients with MM are substantial with outpatient medical costs representing over half of the total healthcare costs.

PHS54

DIRECT COSTS FOR PATIENTS WITH CHRONIC KIDNEY DISEASE FROM A CARDIOVASCULAR RISK MANAGEMENT PROGRAM IN A COLOMBIAN POOR POPULATION

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OBJECTIVES: To estimate costs of care for patients with chronic kidney disease (CKD) from an insurance company (IC) of a state subsidized in Colombia. **METHODS:** Patients with CKD were identified from a cardiovascular risk management program of an IC. Outpatient and inpatient costs were estimated from the ambulatory and hospitalization financial records of 2015 and from the health systems perspective. Medians and interquartile ranges were calculated and two groups of patients were defined based on the reported total cost (TC). Low cost: TC < 75 percentile + 1.5 IQR and high cost: TC > 75 th percentile + 1.5 IQR. Results were classified by stages of disease and converted to US dollars 2015. **RESULTS:** Out of 61,611 patients affiliated to the program, 22.4% (13,816) were found to have CKD. In the defined low-cost group of patients, median hospitalization costs (MHC) and median outpatient costs (MOC) were as the following: stage 3a: US \$720.1 (IQR US\$1819.3), US\$128.4 (IQR US\$248.2); stage 3b: US\$895.2 (IQR US\$2060.6), US\$135.7 (IQR US\$264.0); stage 4: US\$1074.2 (IQR US\$2790), US\$182.1 (IQR US\$401.8); stage 5: US\$2148.4 (IQR \$2856.9), US\$ 362.4 (IQR US\$2226.7). In high cost group of patients, MHC and MOC were: stage 3a: US\$12346.6 (IQR US\$7704.2), US\$5051.8 (IQR US\$6158.4); stage 3b: US\$12295.9 (IQR US\$6486.1), US\$3645.6 (IQR US\$5282.8); stage 4: US\$13014.7 (IQR US\$12305.0), US\$4850.9 (IQR US\$8802.9); stage 5: US\$11814.3 (IQR \$10064.3), US\$18869.2 (IQR US\$6868). **CONCLUSIONS:** Among low cost patients, MHC stage 5 was 2.9 times higher than stage 3a and twice as high as stage 4. For high cost patients, stage 5 MOC was 3.7 times higher than stage 3a.

PHS55

HEPATITIS C COST STUDY C, BRAZIL, 2014

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OBJECTIVES: Identify and measure direct medical, non-medical and indirect costs related to Hepatitis C and associated conditions in Brazil. **METHODS:** The costs of hepatitis C and associated conditions were estimated using the base year 2014. The perspective of the Unified Health System (SUS) and that of society was adopted. The data were obtained from universal access information systems provided by the Ministry of Health. Direct medical, non-medical and indirect direct costs were evaluated using the macro-costing methodology for each of the clinical conditions identified through the International Classification of Diseases (ICD 10). **RESULTS:** The estimated total medical direct cost of the different stages of HCV infection accounted for more than 399 million reais in 2014. Chronic hepatitis C, liver transplantation and liver fibrosis and cirrhosis were responsible for the largest portions of this amount, respectively 86.9, 12.1 and 0.6% of total direct medical costs. The non-medical direct cost, for all clinical conditions (CID), accounted for more than 1,400,000 reais. Where transport costs of patients and caregivers in chronic hepatitis C accounted for 69.4% of this value. The estimated total cost for the indirect cost of hepatitis C and associated conditions was over 6 million reais in 2014. The clinical condition responsible for 50% of this value was liver fibrosis and cirrhosis. **CONCLUSIONS:** This study allowed to show the economic impact of hepatitis C and associated conditions in Brazil, from the perspective of the Unified Health System and that of society. Health expenditures and losses evidenced the need for actions aimed at the prevention of HCV infection, as well as policies to reduce the price of antivirals; Which may be important strategies to reduce the consumption of resources in this reality. Both those used by the health service to defray the various actions and services, as well as the expenses or lost by society.

PHS56

HEALTH CARE COSTS DUE TO DIABETES MELLITUS 2 IN A COLOMBIAN POOR POPULATION AFFILIATED TO A CARDIOVASCULAR RISK MANAGEMENT PROGRAM

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OBJECTIVES: To estimate the direct medical costs due to type 2 diabetes mellitus (DM2) in a poor population affiliated to a cardiovascular risk management program. **METHODS:** A retrospective cohort of 61,611 patients affiliated to a cardiovascular risk management program of a Colombian state-subsidized health insurance company was followed during 2015. Direct medical annual costs in inpatients and outpatients with DM2 were analyzed from the third party payer perspective using the top-down costing approach. Costing information were retrieved from the financial ambulatory and hospitalization records of the insurance company and converted to US 2015 dollars. Patients were analyzed by cardiovascular risk according to the Framingham score. Medians and interquartile ranges (IQRs) were calculated and two groups of patients were defined from total costs results: low cost: TC $<$ percentile 75+1.5 IQR and high cost: TC $>$ percentile 75+1.5IQR. **RESULTS:** 36.4% (22,412) of patients of the program resulted to be diabetic. Of these, 59.7% are classified as high risk, 19.4% as low risk and 1.3% as medium risk. The remaining 19.6% were not classified by the program. The median outpatient health care cost of a DM2 patient was USD\$ 93.8 (RIC: USD\$37.6-USD\$206.2). The median inpatient cost

of a high risk patient from the low cost group was USD\$1,631.9 (RIC: USD\$814.03-USD\$3,539.9), of a medium risk patient was USD\$1,179.1 (RIC: USD\$559.2-USD\$2,640.03) and of a low risk patient was USD\$1,159.9 (RIC: USD\$600.6-USD\$2,177.7). The median inpatients costs of the high cost group of patients were: high risk: USD\$17,114.2 (RIC: USD\$13,440.1-USD\$24,111.2), medium risk: USD\$16,767.8 (RIC: USD\$12,134.7-USD\$23,304.5) and low risk: USD\$12,953 (RIC: USD\$9,269.8-USD\$19,893.6). **CONCLUSIONS:** Cardiovascular risk level is related to health care costs of DM2 Patients. These findings justify the investment to control DM2 high risk patients.

PHS57

EVALUATION OF MEDICAL RESOURCE USE AND COSTS AMONG PATIENTS WITH NON-CARDIOEMBOLIC ISCHEMIC STROKE IN BEIJING

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OBJECTIVES: To estimate medical resource use and direct medical cost of patients with non-cardioembolic ischemic stroke (IS) in Beijing, China. **METHODS:** This was a retrospective cohort study using Beijing Urban Employee Basic Medical Insurance database. Patients (≥ 18 years old) hospitalized with a primary diagnosis of non-cardioembolic ischemic stroke (index event) between Oct.01 2012 and Dec.31 2014 were included. High-risk patients were further identified by Essen Score ≥ 3 , with absence of smoking information in the database. 2-year before and 1-year after index date was observed to analyse the baseline characteristics and direct medical cost. SAS 9.2 was used to conduct the statistical analysis. **RESULTS:** A total of 33,730 patients were included in the study, with mean age of 67.1 years and 68.7% male. 59.1% (N=19,942) were identified as high-risk patients. On average, patients experienced 1.2 ± 0.7 IS-related hospitalizations including index event every year. For all patients, the mean length of stay (LOS) was 15.3 days and the mean medical cost was 19651.5 RMB per admission. High-risk patients had a LOS of 16.0 days and medical cost of 20752.4 RMB. Among the annual IS-related hospitalization cost (RMB 24417.9) for total patients, medication cost accounted for 47.6%, followed by diagnosis/examination cost (37.7%), material cost (9.4%) and others. However, the 4 types of evidence-based secondary preventive drugs all together only accounted for 6.7% of medication cost above: 2.2% for antiplatelet therapy, 1.1% for antidiabetic medication, 1.9% for lipid-lowering medication and 1.5% for antihypertensive medication, with 86.2%, 46.6%, 81.0% and 72.7% of patients were prescribed, respectively. Similar cost distribution was found for high risk patients. **CONCLUSIONS:** Patients with ischemic stroke suffered considerable economic burden. The major component of the medical cost was medication cost while the secondary prevention medications for ischemic stroke only accounted for a small proportion of it.

PHS58

MEDICAL COSTS ASSOCIATED WITH 30-DAY READMISSIONS AMONG PATIENTS WITH HEART FAILURE AND PERSISTENT HYPONATREMIA

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OBJECTIVES: To estimate the medical costs among hospitalized heart failure patients discharged with or without corrected sodium. Hyponatremia (HN), defined as a serum sodium level < 135 mmol/L, commonly occurs among patients hospitalized with heart failure (HF). Donzé et al. (Am J Med.2016;129(8)) established an association between persistent HN (sodium level < 135 at both admission and discharge) and increased risk of all-cause 30-day readmissions. Since readmission rate is an important quality measure, healthcare professionals may benefit from understanding the costs associated with discharging patients with uncorrected sodium. **METHODS:** An interactive Microsoft® Excel-based economic model was developed to monetize (2016 \$US) the risk of 30-day readmissions. Per the multivariable logistic regression analyses in Donzé et al., patients who were admitted and subsequently discharged with sodium < 135 mmol/L are 1.28 times (95% CI 1.11-1.48) more likely to be readmitted compared to patients discharged with corrected sodium. To translate the risk of readmission into a practical metric such as costs, the current economic model calculated the average cost for patients discharged with corrected sodium as: [(Number of patients discharged with corrected sodium X Hospitalization cost) + (Number of patients readmitted X Hospitalization cost)] / Number of patients discharged with corrected sodium. Similarly, average cost for patients discharged with uncorrected sodium was calculated. The numerical difference was the economic burden associated with discharging patients with uncorrected sodium. The model used readmission rate inputs from Donzé et al. and hospitalization costs from the Healthcare Costs and Utilization Cost Project and Premier Inpatient data, with an interactive functionality allowing users to specify costs for their own hospitals. **RESULTS:** Discharging HF patients with uncorrected sodium increased costs by \$488-\$507 per discharge compared to patients with sodium > 135 mmol/L. **CONCLUSIONS:** Due to outcomes improvement over the continuum of care, results support the financial value of upfront monitoring and correction of low sodium before discharge.

PHS59

ECONOMIC BURDEN OF VERY PRETERM BIRTH: A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: We conducted a systematic literature review to evaluate healthcare resource utilization (HCRU) and costs associated with very preterm birth (< 32 weeks' gestational age [wGA]) in North America (NA) and Europe. **METHODS:** Searches were conducted systematically in indexed literature databases for English-language

articles published from January 2011 to July 2016. Eligible studies reported results on the economic burden (HCRU/costs) of very preterm birth in NA or Europe. **RESULTS:** Twenty-eight studies from NA (20 US, 8 Canada) and 20 from Europe (16 countries) were included. The majority reported HCRU/costs during the neonatal/infancy period (age < 1); 5 studies in NA and 10 in Europe reported follow-up at ≥ 1 year, of which 1 in NA and 4 in Europe reported follow-up at ≥ 5 years. Most studies reported inpatient or drug utilization/costs, whereas limited data were found on outpatient HCRU/costs. Total direct costs (reported in 6 studies; 4 NA, 2 Europe) among very preterm infants were generally high, particularly for those with lower GA at birth (e.g. \$67,467 for children born at < 28 wGA [extremely preterm], \$54,554 at 28-32 wGA, \$10,010 at 33-36 wGA, from birth-10y, in a Canadian study) and surgery (\$196,196 vs \$104,577, for infants with patent ductus arteriosus with and without surgical ligation, respectively, from birth to discharge, in a US study). Presence of chronic lung disease and congenital heart disease were also shown to increase inpatient costs from birth to discharge (2 US studies). Only 1 study in each of NA and Europe reported indirect costs, limiting conclusions that can be drawn for such outcomes. **CONCLUSIONS:** HCRU and costs associated with very preterm birth are substantial, and likely increase with lower GA at birth, comorbidities or need for surgery. Evidence on indirect costs and long-term economic consequences of very preterm birth is limited, with few studies reporting HCRU/costs beyond early childhood.

PHS60

ECONOMIC IMPACT OF UNINTENTIONAL CARBON MONOXIDE POISONING IN THE UNITED STATES

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OBJECTIVES: The purpose of this study was to estimate the morbidity cost of Unintentional Non-fire (UNFR) Carbon Monoxide (CO) poisoning, including medical costs and non-health-sector costs. We also compared the costs and benefits of installing CO detectors in residences. **METHODS:** We used 2009-2013 charges and cost data from the National Inpatient Sample (NIS), Nationwide Emergency Department Sample (NEDS) of Healthcare Cost and Utilization Project (HCUP), and Truven® Health MarketScan Commercial Claims and Encounters and Medicare Supplemental data. We directly measured the morbidity cost as the summation of medical and non-health-sector costs from different health care services using micro-costing method. Benefit of installing CO detector was estimated by summing up the morbidity cost and mortality cost (value of life). All the costs were converted into 2013 dollar. **RESULTS:** Total annual medical cost ranged from \$33.6 to \$38.1 million. Hospitalizations, outpatient hospital visits, and emergency department (ED) visits accounted for approximately two thirds of the medical cost. Annual non-health-sector costs varied from \$3.7 to almost \$5 million, approximately 80% of which were related to time spent on hospitalization and ED visits. Total morbidity cost (resulting from medical cost and non-health-sector cost) was between \$37.3 and \$43.1 million annually. Total annual benefit of installing CO detectors, including 60% of the morbidity cost averted and 50% of the mortality cost averted, ranged from \$1.6 billion to \$2.2 billion. Therefore, the benefit-to-cost ratio of installing CO detectors in residences can be as high as 7.9 to 1 in the least expensive case. **CONCLUSIONS:** UNFR CO poisoning causes significant economic burden in the U.S. The benefit of using CO detectors in homes can considerably exceed the cost of installation. Public health programs should use these findings to promote broad installation of CO detectors in homes.

PHS61

COSTS OF THE ACUTE OTITIS MEDIA IN PEDIATRICS, IN A CITY OF THE COLOMBIAN CARIBBEAN COAST

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OBJECTIVES: To estimate the costs of acute otitis media (AOM) in pediatric patients in Cartagena Colombia. **METHODS:** Prospective study of microcosting from 2014 to 2015. The direct and indirect costs of AOM were determined through forms applied to parents or caregivers. Loss of productivity was estimated based on the monthly legal minimum wage of 2014 (COP \$ 616,000) (USD \$ 308). **RESULTS:** A total of 62 episodes of AOM were present. Total economic costs attributed per OMA episode were COP \$ 358,954 of \pm \$ 254,903 (USD \$ 179). The total economic burden was COP \$ 22,503,141 (USD \$ 11,250), indirect costs per episode were COP \$ 101,402 (USD \$ 51) and the average time spent by parents on care was 3.7 days. **CONCLUSIONS:** The estimated costs of AOM in this study are lower than the costs estimated in a review of high income countries (1) and similar to low income countries such as Nigeria (2). Information on total costs (direct and indirect) of AOM are necessary for public health decision-making and for full cost-effectiveness assessments.

PHS62

ASSOCIATION BETWEEN ASTHMA MEDICATION USE AND TOTAL HEALTHCARE COSTS AMONG PATIENTS WITH ASTHMA

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OBJECTIVES: To compare health care costs among persons with asthma who took daily asthma medications with those who did not. We also evaluated whether costs differed by age or race/ethnicity. **METHODS:** This cross-sectional study used data from the 2012-2013 Medical Expenditure Panel Survey (MEPS) to identify persons with asthma age ≥ 18 who reported taking one or more daily medication to prevent

asthma exacerbations (asthma medication). Medication use and health care costs were self-reported. A two-part linear regression model was used to calculate total health care costs for persons with asthma controlling for age, gender, race/ethnicity, insurance status, Charlson's comorbidity index (CCI), and asthma attack in past 12 months. Tests of homogeneity were used to determine if costs differed by age or race/ethnicity. **RESULTS:** Of 1,336 adults who reported having asthma, 60.2% reported taking daily asthma medication. About half were non-Hispanic white, women, and aged 41-64 years. Nearly 85% reported at least one comorbidity at baseline; 60% reported having an asthma attack in the last 12 months. In adjusted results, total direct healthcare costs were significantly higher for persons who reported taking daily asthma medications compared with those who did not (\$15,149 vs \$7,485; $p < 0.001$). This association differed by race/ethnicity and age: non-Hispanic whites and persons aged 41-64 years reported greater total healthcare costs ($p < 0.001$). **CONCLUSIONS:** Persons with asthma who took daily asthma medication had higher health care costs compared to those who did not. It would be useful for future research to identify factors that may be associated with higher costs and to explore racial/ethnic disparities. Results could help medical and public health practitioners to better understand issues related to high healthcare costs, and may be useful to develop strategies to reduce these costs among persons with asthma.

PHS63

BURDEN OF ILLNESS IN CYSTIC FIBROSIS: A RETROSPECTIVE ANALYSIS OF MEDICAL EXPENDITURE PANEL SURVEY (MEPS) DATA

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OBJECTIVES: Cystic fibrosis (CF) is a chronic lung disease occurring at a rate of 1 in 3,400 births and affecting 30,000 people in the U.S and 70,000 globally. Current understanding of the burden of CF within the health care system is lacking. The goal of the present study is to estimate the cost of illness of CF using publicly available data. **METHODS:** The study is a retrospective analysis of Medical Expenditure Panel Survey (MEPS) data from 2010-2014 using ICD-9-CM diagnosis code for principal diagnosis CF (277.xx). Descriptive analyses were conducted to assess patient demographics, clinical characteristics such as comorbidities and resource utilization related to events in different settings. Cost calculations included expenditures occurring in inpatient, outpatient, office, home health and emergency visits, as well as prescription drugs utilization. Unweighted and weighted annual and cumulative out-of-pocket (OOP) costs and total health care costs were calculated. All statistical analyses were conducted using Statistical Analysis System 9.4 (SAS Institute; Cary, NC). **RESULTS:** A total of 130 unique CF cases were available, of whom 109 (83.8%) reported using a CF-related medical service. The mean age of the sample was 38.2 ± 25.3 years with a mean household income of \$59,903.78 \pm 54,970.57. The cohort was predominantly female (n=70; 64.2%), Caucasian (n=71; 65.1%), privately insured (n=73; 67.0%) and most commonly had comorbid hypertension (n=45; 41.3%). Over 5 years, unweighted cumulative OOP costs were \$31,828.58 and total health care costs were \$455,539.70. Prescription medications accounted for 57.5% of OOP costs (\$18,328.66) and 33% of total health care costs (\$150,634.20). Using weighted data, the cumulative OOP costs was \$615,098,138 and total healthcare costs was \$6,691,134,764. **CONCLUSIONS:** The study provides health care expenditure estimates for individuals with CF. These estimates can serve as a guide for policy makers to better determine resource utilization and cost-effectiveness of treatments in CF.

PHS64

HEALTHCARE RESOURCE UTILIZATION AND COSTS OF RENAL IMPAIRMENT IN PATIENTS WITH MULTIPLE MYELOMA

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OBJECTIVES: Renal impairment (RI) is a common complication of multiple myeloma (MM). Up to 61% of MM patients experience RI. This study estimated economic burden associated with RI in MM patients in the US. **METHODS:** In this retrospective cohort study patients ≥ 18 years old with ≥ 1 inpatient or ≥ 2 outpatient MM diagnoses between 1/1/2008 - 3/31/2015 were identified from MarketScan[®] Commercial and Medicare Supplemental Databases. RI patients had ≥ 1 diagnosis of chronic kidney disease (CKD) Stage I-V (first CKD diagnosis date = index date) on or after the first MM diagnosis, and were propensity score matched 1:1 to MM patients without RI (controls). All patients had ≥ 6 -month continuous enrollment prior to index date and were followed for ≥ 1 month from index date until the earliest of inpatient death, end of continuous enrollment, or end of the study period (9/30/2015). The average per-patient per-year (PPPY) healthcare resource utilization and costs were measured during follow-up. Costs were total reimbursed amount in 2016 dollars. **RESULTS:** A total of 2,541 MM patients with CKD and 2,541 matched controls met the study criteria (mean age: 69.3-69.6 years; male: 55%; mean days in follow up: 533-572). They were well-balanced on baseline demographic, clinical characteristics and costs. Compared to controls, CKD patients had significantly higher proportions (57.1% vs. 32.1%) and number (1.2 vs. 0.5) of inpatient admissions, emergency room visits (5.1 vs. 3.3), and total costs (\$106,634 vs. \$71,880). Sensitivity analyses found that patients with CKD stage III-V had \$38,412 higher costs and patients with CKD or end stage renal disease had \$78,455 higher costs (PPPY) than matched controls. $P < 0.001$ in all comparisons. **CONCLUSIONS:** The economic burden associated with RI in patients with MM was estimated to be between \$34,754 and \$78,455 PPPY. Given its substantial impact, preservation of renal function is important in MM patient care.

PHS65

TOTAL COST OF CARE AMONG PATIENTS WITH EXTENSIVE DISEASE SMALL CELL LUNG CANCER (ED-SCLC)

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OBJECTIVES: Cost-of-care information in ED-SCLC is limited. Most studies include only treated patients and do not provide costs over time or by chemotherapy status. This study was designed to quantify total direct medical costs 90 days and 1 year post-diagnosis for a cohort of US Medicare patients with ED-SCLC (overall and according to receipt of outpatient chemotherapy within 90 days of diagnosis). **METHODS:** Using Surveillance, Epidemiology, and End Results (SEER) data linked to Medicare claims, we identified patients aged ≥ 66 years with Medicare Parts A and B coverage and a first primary, ED-SCLC SEER diagnosis (pathologically confirmed) between 1/1/2007 and 12/31/2011. Patients were followed from diagnosis until death, second primary cancer, coverage change, or 12/31/2013. Treatment was determined using Medicare claims. Medicare-paid amounts were adjusted to 2013 US dollars using the Consumer Price Index medical component. Cumulative incremental direct medical costs were estimated, accounting for censoring with bootstrapped confidence intervals (CI). **RESULTS:** In our cohort of 5498 patients with ED-SCLC, mean age was 75 years (range: 66-98), 49% were male, and 86% were white. Median survival time for all patients was 4.7 months. Mean cumulative incremental cost per patient was \$29,213 (95% CI: \$28,589-\$29,838) at 90 days and \$50,206 (95% CI: \$49,151-\$51,260) at 1 year. Hospitalizations accounted for 56% of first-year costs. Of 3014 patients initiating outpatient chemotherapy within 90 days of diagnosis, 87% received platinum/etoposide. Mean costs were higher for chemotherapy-treated patients than untreated patients (n=2484) 90 days post-diagnosis (\$30,182 [95% CI: \$29,464-\$30,901] vs \$27,949 [95% CI: \$26,877-\$29,022]) and 1 year post-diagnosis (\$61,532 [95% CI: \$60,187-\$62,877] vs \$36,068 [95% CI: \$34,585-\$37,550]). **CONCLUSIONS:** A substantial portion of first-year costs for patients with ED-SCLC were incurred within 90 days of diagnosis. First-year costs were higher for patients initiating outpatient chemotherapy within 90 days than for untreated patients. Novel therapies could affect costs by reducing hospitalizations.

PHS66

COST-EFFECTIVENESS ANALYSIS OF A KIDNEY TRANSPLANT PROGRAM IN A PRIVATE, PHILANTHROPIC AND TERTIARY HOSPITAL IN BRAZIL

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OBJECTIVES: In 2015, according to Brazilian Transplant Register, there were 19,440 patients on kidney waiting list. Kidney transplantation (KT) remains the most effective treatment for end stage renal disease. However, there are few studies about cost in transplant in Brazil and decided to conduct a cost-effectiveness analysis of our KT program. **METHODS:** We conducted a retrospective analysis where we included all patients that underwent KT in 2015. We collected data about costs per patient including the pre transplant phase (eligibility evaluation for the transplant, listing and outpatient follow up), the transplant and post-transplant phases, until 1 year of follow up. The unit costs of materials and medicines correspond to the average direct costs of acquisition. For the survival analysis we used Cox model, including all KT performed from 2002 to 2016. The values of GDP per capita and dollar exchange rate were the ones from 12/2015, being US\$ 6.963,94 and BRL 3.91, respectively. Cost-effective therapy was defined here when the cost for each year of life saved was lower than 3x GDP (US\$20,891.82). **RESULTS:** In 2015, 95 renal transplants were carried out. The mean and median costs of KT were US\$ 37,329.50 and US\$ 29,375.29, respectively. For survival analysis 967 KT were included. The calculated survival was 14.3 years. The cost per year of life saved was US\$2,606.81. Considering the limit of 3x of GDP, the KT was considered a cost-effective therapy and 5.3 years of lifespan would be necessary for the treatment to be paid off. There would still be 9 years for the recipient to produce wealth, generating US\$62,675.46 during that time span. **CONCLUSIONS:** The KT was considered cost-effective once it has generated enough survival results to cover the transplant costs and still generate wealth for the country.

PHS67

COST EFFECTIVENESS OF STROKE UNIT EQUIVALENT CARE FOLLOWED BY EARLY SUPPORTED DISCHARGE IN RURAL AREA

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OBJECTIVES: To improve the outcome of stroke care in rural areas, a model of Stroke Unit Equivalent Care (SUEC) with/without early supported discharge (ESD) services was developed in Alberta, Canada. The objective of this study was to evaluate the cost-effectiveness of SUEC and SUEC followed by ESD (SUEC&ESD) compared with the pre-setting (nonSUEC). **METHODS:** We developed a three-arm cost-effectiveness model to compare three stroke care models: nonSUEC, SUEC and SUEC&ESD using health administrative data. We estimated the 180-day mortality in a generalized linear model with binomial family and estimated costs with gamma family. We applied the predicted mortality to Alberta age-sex specific life expectancy to calculate life-year expectancy for each patient after stroke onset. We applied a multi propensity score method with multinomial logit model to correct potential bias from observation data. We calculated the risk-adjusted incremental cost (IC), incremental effectiveness (IE), and then incremental cost-effectiveness ratios (ICERs). We performed 2,000 bootstrapping on study populations and presented them in cost-effectiveness plane for sensitivity analysis. **RESULTS:** Of 988 patients retrieved, 895 new stroke patients were selected for the analyses. SUEC was less costly and more effective than the nonSUEC (IC= -\$3,378, IE=0.45 year, ICER= -\$7,522 per life-year gain). The SUEC&ESD was more costly but also more effective than either the SUEC (IC=\$5,179, IE=1.64 year,

ICER=\$3,154 per life-year gain) or the nonSUEC (IC=\$8,557, IE=1.19 year, ICER=\$7,174 per life-year gain). **CONCLUSIONS:** With a willingness-to-pay value threshold of \$50,000, the SUEC was dominant strategy with lower in-hospital mortality and lower direct health care costs than the nonSUEC. The SUEC&ESD was also cost-effective when compared with the nonSUEC or the SUEC. This new model of care reduces urban/rural care discrepancies providing lower mortality for stroke while providing good value to the healthcare system.

PHS68

TO EVALUATE THE COST-EFFECTIVENESS OF BRENTUXIMAB VEDOTIN IN PATIENTS WITH RELAPSED/REFRACTORY HODGKIN LYMPHOMA WHO HAVE RECEIVED CHEMOTHERAPY/ CHEMOTHERAPY WITH STEM CELL TRANSPLANTATION AS FIRST LINE THERAPY FROM A US HEALTHCARE PERSPECTIVE

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OBJECTIVES: To evaluate the cost-effectiveness of brentuximab vedotin in patients with relapsed/refractory Hodgkin Lymphoma as compared to Chemotherapy/Chemotherapy with stem cell transplantation as first line therapy from a US healthcare perspective. **METHODS:** An Excel based Markov model was developed with three health states to follow the clinical end points reported in the AETHERA clinical trial. Health states included were Progression free survival, Progressed disease and Death. Progressed disease was defined as disease that progressed with time in scope and/or severity. Brentuximab vedotin was compared with the first line treatments like chemotherapy or chemotherapy with stem cell transplantation. The model outcomes were quality-adjusted life years (QALYs) and incremental cost per QALY. Model inputs such as transition probabilities, cost of drug and procedures, resource utilization and utilities of each health states were used from previously published literature. Due to short follow-up of patients in the trial, an extrapolation was assumed by holding fixed the relative rates observed in the trial to observed overall survival and progression free survival for a life time horizon. Deterministic and probabilistic sensitivity analysis was performed in the end to assess the effect of uncertainties in the model. **RESULTS:** In the base case analysis, the QALYs gained with brentuximab vedotin as compared to standard of care was 0.31 and incremental cost was \$26,000. The incremental cost-effectiveness ratio for the base-case was \$80,345/QALY gained. The probabilistic sensitivity analysis yielded incremental cost-effectiveness ratios in the range of \$55000 – 111000/QALY. **CONCLUSIONS:** The brentuximab vedotin cost-effectiveness findings appear to be in-line with or more favorable than many other newly approved anti-cancer therapies. At a willingness-to-pay of \$100,000/QALY, brentuximab vedotin was found to be cost-effective more than 50% of the time.

PHS69

COST EFFECTIVENESS OF A HOME VISITATION PROGRAM FOR MOTHERS WITH POSTPARTUM DEPRESSIVE SYMPTOMS

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OBJECTIVES: To evaluate the mental health benefits and cost-effectiveness of HOPE, a home visitation program for mothers at risk for postpartum depression. **METHODS:** A pre-post study was performed among women who were seen for postpartum visit within 8 weeks after giving birth (n = 169) during October 2014 - September 2016. The Edinburgh Postnatal Depression Scale (EPDS) and Brief Symptom Inventory-18 (BSI-18) assessments were administered at first and last home visit and at 3-month or 6-month follow-up. Mean pretest scores were compared with mean posttest scores, either at last home visit or at follow-up. The percentage of individuals who screened positive for depression was compared between pre and post intervention periods. Cost effectiveness analysis was conducted from the health care provider's perspective to estimate the average cost per unit change in EPDS and BSI-18 score and per reduction in the number of depressed woman. Program cost data in 2014 dollars included costs of office supplies, assessments, transportation, and program personnel. **RESULTS:** Among 169 HOPE participants, 52 and 32 women completed both pretest and posttest EPDS and BSI-18 assessments, respectively. There was an average improvement of 7.48 points (p<0.05) in EPDS score between pre- (16.46 ± 4.37) and post-intervention (8.98 ± 5.66) scores. The proportion of participants with depression was reduced by half, from 98.1% (51 women) to 44.23% (23 women) post-intervention. An average improvement in BSI-18 score of 14.09 points (p<0.05) was achieved. With an average cost per visit of \$131, cost per unit of scale score improvement on EPDS and BSI-18 score was \$88.1/unit and \$47.9/unit, respectively. The cost per additional person improving from depressed to not depressed was \$23.50. **CONCLUSIONS:** HOPE, the home visitation program demonstrated significant benefits including reduced severity of depression and psychological distress. The health improvement was achieved at modest cost suggesting the program is cost effective.

PHS70

MINIMUM COST-ANALYSIS OF METASTATIC MELANOMA TREATMENT BASED ON PATIENTS'S WEIGHT

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OBJECTIVES: Incorporation of new therapies for the treatment of metastatic melanoma(mM) in our hospitals has resulted in the requirement of measures to

optimize available resources. The aim of this study is to perform a cost-minimization analysis for the treatment of mM based on current therapies, immunotherapy and antiBRAF-antiMEK targeted drugs. **METHODS:** Treatments were: nivolumab, pembrolizumab and vemurafenib-cobimetinib and dabrafenib-trametinib. Only direct costs of acquisition of drugs were assessed. Linear-modeling was made, which allowed us to represent the annual-costs of each treatment against the patient's weight with a timeframe of one year. A deterministic model for the sensitivity analysis was performed incorporating the costs of staying in oncology-day-hospital and the outpatient-units and vial use optimization. **RESULTS:** Base-case: nivolumab is shown as the least expensive treatment regardless of the patient's weight, but with an equal cost to pembrolizumab in patients weighing between 74-76kg. Moreover in patients over 76kg weight is less expensive to use vemurafenib-cobimetinib than pembrolizumab. Sensitivity-analysis1(with cost of staying in ODH): nivolumab is the less expensive therapy again, except for patients weighing 50kg; in which pembrolizumab is the most cheap treatment. The base-case results for patients over 76kg weight are repeated in this scenario. Sensitivity-analysis2(with vial-use optimization): nivolumab reappears as less expensive treatment for all weights studied. Again for patients over 76kg, the base case results are repeated in this analysis. **CONCLUSIONS:** Our results shows that nivolumab is the less expensive treatment for most patients, so with this study we wanted to show a tool to optimize resources indicating lower-cost therapy for the treatment of mM base of patient's weight. Of course, will be the characteristics of the pathological process of each patients that will determine the ideal treatment. However, in those situations where it's considered that two therapies are equivalent for a patient, this model can help to choose the suitable therapy.

PHS71

LONGTERM CLINICAL AND ECONOMIC OUTCOMES OF INTENSIVE VS STANDARD BLOOD PRESSURE REDUCTION IN NON-DIABETICS AT HIGH CARDIOVASCULAR RISK - EXTRAPOLATIONS FROM THE SPRINT TRIAL

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OBJECTIVES: Results from the recent SPRINT trial demonstrate lower rates of fatal and non-fatal major cardiovascular events and all-cause mortality in non-diabetics at high cardiovascular risk with intensive versus standard treatment, i.e., less than 120 versus less than 140 mmHg systolic, respectively. However, the long-term outcomes remain unknown. **METHODS:** A validated state transition model with multivariate risk equations was populated with the baseline characteristics of the SPRINT trial, and cost and health-related quality of life data for the United States. Model projections, based on trial-observed blood pressures, were compared to actual median follow-up trial results for calibration. To assess long-term outcomes, we projected 20-year incidence in myocardial infarctions, strokes, heart failure, and endstage renal disease, and derived relative risks and numbers needed to treat (NNT). Direct medical costs and incremental cost-effectiveness ratio (ICER in \$/quality adjusted life year [QALY]), discounted at 3% p.a., were computed for both strategies. **RESULTS:** The calibrated model outcomes matched the published SPRINT trial results at a median followup of 39 months. Over the 20-year horizon, intense blood pressure control was projected to lead to lower incidences of all studied events; NNTs varied largely between clinical events such as heart failure (696) and cardiovascular and all-cause death (28 and 11, respectively). Life expectancy increased by 2.5 years (85.8 vs. 83.3 years), at similar discounted lifetime costs of about \$47K and an ICER of \$15,901/QALY. **CONCLUSIONS:** Our model-based projections suggest intensive blood pressure control in nondiabetics at high cardiovascular risk is associated with significant longterm benefits. Numbers needed to prevent mortality are particularly attractive. Cost savings seem to be consumed by additional life expectancy. Patient-level data analysis via bootstrapping is necessary to quantify the uncertainty.

PHS72

COST UTILITY ANALYSIS OF A HEART FAILURE CLINIC PROGRAM IN A SPECIALIZED CLINIC IN COLOMBIA

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OBJECTIVES: Although there have been clinical and technological advances in the management of heart failure, high hospital readmission rate remains as a problem. There is clinical evidence that multidisciplinary and comprehensive management strategy is associated with important reduction in hospital readmission. This analysis aims to estimate the impact, in terms of quality of life, hospitalization costs, and cost-utility of a Heart Failure Clinic Program (HFCC) compared to Conventional Medical Management (CMM) in a cardiovascular institution in Colombia. **METHODS:** an Excel based cost-utility Markov model was developed. Clinical and admission rates were taken from 511 patient's institution database for 18-months follow-up period. Four Health states, one for each NYHA functional Class patient classification was considered, as well as the amount of admissions and LOS per admission. Effectiveness was calculated from the probabilities of moving from one NYHA Class to better one. Colombian general mortality rate, 3.5% discount rate and 20-years horizon were applied. Specific mortality rates for HF, were taken from Inglis-2011. The average cost for decompensated Heart Failure hospitalization was taken from local work done by Tamayo-2011, inflation updated. Incremental analysis and univariate sensitivity analysis were done. **RESULTS:** Discounted hospital cost for CMT was estimated in USD\$ 143.278 vs. USD\$ 58.902 for HFCC, and USD\$ 84.376 cost savings. HFCC yield 4,72 discounted QALYs compared to 3,15 for CMT. The greatest QALYs gain was obtained in NYHA IV Class patients, with 13,3% improvement, followed by Class III with 7,4%. Because the low percentage participation of class IV in the total

group, it had low weigh in the final result. HFPC was dominant over CM. **CONCLUSIONS:** Compared to CMT, the HFPC yielded a higher total Quality of life to a lower admission total cost. Therefore, HFPC is dominant over CMT and is a cost-saving strategy that should be considered by policy makers.

PHS73

ESTIMATING HEALTH BENEFITS AND COST-SAVINGS FOR REDUCING THE INCIDENCE OF INVASIVE COLORECTAL CANCER IN THE UNITED STATES

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OBJECTIVES: Healthy People 2020 (HP 2020) Objective C9 is to reduce invasive colorectal cancer (CRC) incidence from 46.9/100,000 population in 2007 to 39.9/100,000 population in 2020. This study aims to quantify the aggregate potential life-years (LYs) saved and the aggregate healthcare cost-savings if this objective were met. **METHODS:** We identified patients (n=886,380) diagnosed with invasive CRC between 2001 and 2011 from the National Program of Cancer Registries and the Surveillance, Epidemiology, and End Results Program. We stratified these patients by sex, race/ethnicity, and age into 12 cohorts. Using these data and data from the 2001-2011 US life tables, we estimated a survival function for each CRC patient cohort and the corresponding cohort of a reference population from the general population. We then computed potential LYs saved per person from the difference in life expectancies between each CRC cohort and the corresponding reference cohort. Annual healthcare cost-savings per person were estimated using data from the 2008-2012 Medical Expenditure Panel Survey. We calculated aggregate LYs saved and cost-savings by multiplying the reduced number of CRC patients with the per-person LYs saved and lifetime healthcare cost-savings, respectively. **RESULTS:** We estimated an aggregate of 150,000 LYs for males and 9,548 LYs for females would have been saved, which accounted for aggregate healthcare cost-savings of \$584 million and \$43 million, respectively. Per person, we estimated potential 6.3 LYs saved for both males and females, and healthcare cost-savings of \$24,440 and \$28,433, respectively. Among all racial/ethnic cohorts, non-Hispanic whites had the highest aggregate LYs saved and cost-savings. **CONCLUSIONS:** Achieving the HP 2020 objective for reducing invasive CRC rate by 15% by 2020 would potentially have public health impact by saving lives and healthcare costs.

PHS74

HEALTHCARE RESOURCE UTILIZATION ASSOCIATED WITH MANAGING DISEASE- AND TREATMENT-RELATED HEALTH EVENTS IN US MULTIPLE MYELOMA (MM) PATIENTS: REAL-WORLD ADMINISTRATIVE CLAIMS BASED ANALYSIS

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OBJECTIVES: This research estimated the real-world frequency of and healthcare resource use (HCRU) associated with health events during MM treatment. **METHODS:** MM patients initiating therapy between 01/01/2013-01/31/2016 were selected from the Inovalon More2 administrative claims database. Health events were identified by reviewing safety information from MM treatment labels and registration trials. Patients with a diagnosis of an event during MM treatment were identified (cases). Events that occurred in ≥5% of patients were included in the analysis. HCRU was assessed during a 30-day interval following the event and compared (using chi-square statistic) to a 30-day interval following a shadow date for controls (patients who did not have the event and propensity-score matched to cases). Shadow dates were determined by adding the number of days from treatment start date to event date among cases to the treatment start date among controls. **RESULTS:** Among 775 MM patients, 25 events were included in the analysis. Over the course of MM treatment, 80.8% had a claim for bortezomib, 58.3% for lenalidomide, 25.6% for cyclophosphamide, 7.2% for melphalan, 5.3% for carfilzomib, 4.7% for pomalidomide. The proportion of patients with an event ranged 5.2%-19.0%. The 5 most common events were: asthenia/fatigue (19.0%), dehydration (17.7%), nausea (17.2%), constipation (13.2%), hypokalemia (12.8%). The proportion of inpatient admissions observed among patients with an event ranged 17.7%-82.6% vs 3.8%-18.3% among controls. Inpatient admissions were most commonly observed among patients with sepsis (82.6% vs 8.7%), confusion (78.4% vs 10.8%), hyponatremia (68.9% vs 6.7%), pneumonia (68.5% vs 5.6%), and hyperkalemia (63.3% vs 8.2%) for cases vs controls, respectively; p<0.0001 for all. **CONCLUSIONS:** This study suggests that health events during the course of MM treatment occur frequently and with significant HCRU potentially imposing a substantial burden to patients and the healthcare system. Use of newer MM treatments with improved clinical profiles may help to reduce this burden.

PHS75

A REAL-WORLD CLAIMS ANALYSIS OF GLIOBLASTOMA COST OF CARE IN THE UNITED STATES

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OBJECTIVES: Glioblastoma (GBM) is the most common form of primary brain cancer. Prognosis is poor, with survival beyond 2 years being rare, and the economic burden being high. The objective of this study was to evaluate total cost of care (TCC) in patients treated for GBM. **METHODS:** A retrospective GBM cohort study was conducted using US commercial and Medicare administrative healthcare claims data from Truven Health MarketScan®. Eligible patients were ≥18 years, had a malignant brain cancer diagnosis between 1/2010 and 9/2015, had brain-related surgery 90 days within diagnosis, received temozolomide (TMZ), radiation, or both within 90 days of diagnosis. TCC was calculated over 6- and 12-month periods following initiation of first-line (1L) or second-line (2L) treatment. **RESULTS:** 3,696 eligible patients with GBM

were identified as receiving 1L with an average follow-up of 466 days. The majority 2,695/3,696 (73%) were treated with TMZ + radiation in 1L. During the 6 months prior to GBM diagnosis, cumulative mean direct medical costs was \$12,040, with 82% incurred in the 3 months leading up to diagnosis, primarily as a result of hospitalizations. During the 6- and 12-month periods following 1L treatment start, mean total per-patient costs were \$173,200 and \$332,477, respectively. These were heavily driven by radiation costs. From 2L treatment to 6 and 12 months, the mean total per patient cost was \$152,154 and \$303,481, respectively, mainly resulting from systemic cancer therapy. Of the 3,696 patients identified in 1L, 31% patients received 2L. Most common treatments in 2L included bevacizumab (BEV) monotherapy (39%) and BEV in combination with other agents (30%). **CONCLUSIONS:** This large real-world evaluation of TCC in patients with GBM demonstrates an extensive cost burden across the treatment continuum. Novel interventions are needed to improve outcomes as well as reduce TCC by influencing outpatient and inpatient costs.

PHS76

HEALTHCARE UTILIZATION AND COSTS IN LUNG CANCER PATIENTS WITH PRE-EXISTING COPD AMONG SEER-MEDICARE BENEFICIARIES

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OBJECTIVES: In 2010, lung cancer accounted for \$12.6 billion in total direct medical costs. We examined the healthcare utilization and costs in elderly lung cancer patients with and without pre-existing COPD. **METHODS:** Using SEER-Medicare data, we identified patients with lung cancer between 2006 to 2010, > 66 years, and continuously enrolled in Medicare Parts A and B in the 12 months prior to cancer diagnosis. Pre-existing COPD in lung cancer patients were identified using ICD-9 codes. Healthcare utilization and costs were categorized as inpatient hospitalizations, skilled nursing facility (SNF) use, physician office visits, ER visits, and outpatient encounters for every stage of lung cancer. The adjusted analysis was performed using a generalized linear model for healthcare costs and a negative binomial model for healthcare utilization. **RESULTS:** We identified 66,963 patients with lung cancer. Of these, 22,497 (33.60%) had documented COPD before lung cancer diagnosis. Healthcare utilization and costs were significantly higher in the COPD group compared to the Non-COPD group, increasing for every stage of lung cancer. Stage IV lung cancer patients with pre-existing COPD had the highest adjusted utilization per 100 person-months compared to the Non-COPD group (hospitalizations: 49.5 stays vs 31.24 stays, p<0.0001; SNF: 9.34 stays vs 4.78 stays, p<0.0001; physician visits: 2311.94 visits vs 681.84 visits, p<0.0001; ER: 56.58 visits vs 33.26 visits, p<0.0001; outpatient encounters: 2825.73 visits vs 2422.26 visits, p<0.0001). Similarly, the adjusted costs per person-month among stage IV lung cancer patients in the COPD group were highest compared to the Non-COPD group (hospitalizations: \$3925.36 vs \$2537.42, p<0.0001; SNF: \$730.26 vs \$380.49, p<0.0001; physician visits: \$1169.49 vs \$336.39, p<0.0001; ER: \$199.71 vs \$131.03, p<0.0001; outpatient encounters: \$16021.90 vs \$14025.50, p<0.0001). **CONCLUSIONS:** Healthcare utilization and costs among lung cancer patients with pre-existing COPD was approximately two to three times higher than the Non-COPD group.

PHS77

THE IMPACT OF COMORBID CONDITIONS ON HOSPITAL RESOURCE UTILIZATION AMONG PATIENTS WITH CYSTIC FIBROSIS

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OBJECTIVES: Cystic fibrosis (CF) a common life-limiting autosomal recessive condition. Aside from respiratory complications the degenerative nature of CF is a causal factor for many other complicating conditions both acute and chronic. The objective of this study is to examine the impact of comorbid conditions on hospitalized CF patients. **METHODS:** A retrospective descriptive study was conducted on CF patients hospitalized in the MedAssets health system data from October 2015 through September 2016. Multivariable regression was used to identify complicating conditions that are significant drivers of inpatient admission, length of stay (LOS), and hospitalization cost. **RESULTS:** The sample included 7,936 unique patients from 298 hospitals. Half of the population was female (54.0%) with an average age of 22.4 years, and average Charlson comorbidity score of 1.4. The patient population averaged 3.7 outpatient visits during the study period. Over 29% of patients were admitted as an inpatient with an average LOS of 10.4 days and an average cost of \$25,749. The population averaged nearly three comorbidities which primarily fell into respiratory (64.3%), gastrointestinal (41.6%), cardiovascular (30.4%) anxiety/depression (19.6%) disease groups. Primary predictors of inpatient admission included malnutrition (OR 5.5, 95% CI 4.8 - 6.3), chronic lower respiratory disease (OR 3.4, CI 3.3 - 3.8), epilepsy (OR 4.3, CI 3.0 - 6.1), and anemia (OR 4.2, CI 3.6 - 5.0). Once admitted respiratory failure (RR 1.6, CI 1.5 - 1.7), malnutrition (RR 1.4, CI 1.3 - 1.4), and arrhythmias (RR 1.2, CI 1.1 - 1.4) contributed to longer LOS. Additionally, coagulation defects (RR 1.2, CI 1.1 - 1.3), and coronary artery disease (RR 1.5, CI 1.3 - 1.9) contributed to higher cost. **CONCLUSIONS:** Cystic fibrosis patients admitted to the hospital have a large number of comorbidities and complications. Improvements in disease management may lead to better patient outcomes and a reduction in hospital utilization and healthcare costs.

PHS78

HEALTH CARE RESOURCE UTILIZATION AND COSTS ASSOCIATED WITH COMORBIDITIES AMONG HIV-POSITIVE PATIENTS

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OBJECTIVES: The study objective was to evaluate the impact of renal-, cardiometabolic- and bone-related comorbidities on health care resource utilization and

costs in HIV-positive patients, using the Quebec (RAMQ) public drug plan database. **METHODS:** Patients who had received antiretroviral treatment for at least six months from January 2006 to June 2012 were selected. HIV-positive patients with no comorbidities were matched 1:1 for age, sex and time of follow-up and compared to HIV-positive patients with at least one comorbidity. Index date was defined as the date of the first medication, diagnosis or medical procedure related to comorbidities for the patient with at least one comorbidity, and the corresponding date of the case was defined for the controls. Cases and controls were compared with independent t-test for continuous variables and chi-square test for categorical variables. **RESULTS:** For the analysis of 1,336 HIV-positive patients with at least one renal-, cardiometabolic- or bone-related comorbidity and a matched control group of 1,336 HIV-positive patients with no comorbidities, the mean age was 45.1 years (SD=9.5) with 78.5% being male. The mean total health care cost per patient per year in the 2 years following index date was higher in HIV-positive patients with at least one comorbidity than in HIV-positive patients with no comorbidities (22,037 CAN\$ SD=16,974 vs. 15,093 CAN\$ SD=8,945, $p<0.01$). The higher cost in HIV-positive patients with at least one comorbidity can be explained by the higher number of hospitalization days (3.4 SD=10.9 vs. 1.0 SD=4.0, $p<0.01$) and the higher number of prescriptions (151.3 SD=261.6 vs. 76.1 SD=193.8, $p<0.01$) than in HIV-positive patients with no comorbidities. **CONCLUSIONS:** The presence of comorbidities has an impact on the burden associated with HIV leading to a significant difference in total health care cost observed between HIV-positive patients with at least one comorbidity and HIV-positive patients with no comorbidities.

PHS79

UTILIZATION AND COST OF HEALTHCARE SERVICES DURING EPISODES OF ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI) INVOLVING ADMISSION TO UNITED STATES (US) HOSPITALS: A RETROSPECTIVE OBSERVATIONAL ANALYSIS USING A LARGE HEALTHCARE CLAIMS DATABASE

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OBJECTIVES: To assess patterns of utilization and cost of healthcare during episodes of ABSSSI known/suspected to be due to methicillin-resistant *Staphylococcus aureus* (MRSA) involving admission to US hospitals. **METHODS:** We identified all admissions in the database from July 2010 to November 2014 with a principal diagnosis consistent with ABSSSI (ICD-9-CM codes 035.XX, 681.XX, 682.XX, 686.XX, 958.3, 998.5X). Among all such admissions, we selected those with continuous enrollment for 6 months prior to and 44 days following admission, and either secondary diagnoses of MRSA or receipt of anti-MRSA antibiotics. Admissions were excluded with secondary diagnoses of other infections. Care episodes were constructed, beginning with the first claim associated with ABSSSI within 7 days before the admission and ending on the earliest of either: (1) a 14-day gap in relevant claims; or (2) a claim for a non-ABSSSI infection post discharge. We examined patterns of healthcare utilization and cost during the episode (inpatient and outpatient). Reimbursed amounts were used in lieu of costs. **RESULTS:** Mean (SD) cost of ABSSSI episodes ($n=30,241$) was \$11,894 (\$10,167), of which inpatient care represented 78% (\$9,287 [SD \$8,153]). ABSSSI episodes lasted an average of 15.9 (5.6) days. Length of stay was ≥ 4 days for 25% of admissions. Fifty-three percent and 73% received outpatient care during pre- and post-admission, respectively; 93% were discharged home. While 97% received antibiotics post discharge (primarily with anti-MRSA agents), only 7% had evidence of receipt of outpatient intravenous therapy. **CONCLUSIONS:** Results of our study suggest that annual total costs of care to US payers for ABSSSI episodes known/suspected to be due to MRSA are \$81.4 million. Treatment included limited use of outpatient intravenous therapy. Opportunity may exist to reduce costs of care for episodes of ABSSSI by leveraging existing guideline-driven outpatient treatment pathways and/or novel, long-acting antibiotics.

PHS80

HEALTH CARE RESOURCE UTILIZATION AND COSTS IN HIV-POSITIVE VERSUS HIV-NEGATIVE PATIENTS

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OBJECTIVES: The study objective was to evaluate the impact of HIV on health care resource utilization and costs, using the Régie de l'Assurance Maladie du Québec (RAMQ) public drug plan database. **METHODS:** Patients who had received antiretroviral treatment (ART) for at least six months from January 2006 to June 2012 were selected. HIV-negative individuals from a random sample were matched 3:1 for age, sex and time of follow-up and compared to HIV-positive patients. Cohort entry was defined for the HIV-positive patients as the date of the first script of ART and for the matched control group of HIV-negative individuals as the date of the first any diagnosis or any prescription recorded in the database. Cases and controls were compared with independent t-test for continuous variables and with chi-square test for categorical variables. **RESULTS:** For the analysis of 3,905 HIV-positive patients and the matched control group of 11,715 HIV-negative individuals, the mean age was 45.3 years (SD=11.9) with 77.3% being male. The HIV-positive patients had a higher Charlson comorbidity score (3.3 SD=3.3 vs. 0.3 SD=0.8, $p<0.01$), a higher proportion of drug or alcohol abuses (14.3% vs. 7.8%, $p<0.01$) and a higher proportion of smoking cessation medication utilization (26.7% vs. 19.4%, $p<0.01$) than the HIV-negative individuals. The mean total health care cost per patient per year in the 2 years following cohort entry was higher in HIV-positive than in HIV-negative patients (18,153 CAN\$ SD=13,714 vs. 2,326 CAN\$ SD=7,538, $p<0.01$). The higher cost in HIV-positive patients can be explained by the higher number of hospitalization days (2.2 days SD=8.2 vs. 0.9 days SD=6.5, $p<0.01$) and the higher number of prescriptions (105.3 SD=202.8 vs.

26.6 SD=71.0, $p<0.01$) compared to HIV-negative individuals. **CONCLUSIONS:** The impact of HIV significantly increased health care resource utilization and costs when we compared HIV-positive to HIV-negative individuals.

PHS81

HEALTHCARE UTILIZATION AND SURVIVAL ASSOCIATED WITH CLINICAL CARE PATHWAY FOR RECTAL CANCER TREATMENT

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OBJECTIVES: To quantify resource utilization and to analyze survival associated with the use of an integrated care pathway (ICP) for rectal cancer treatment in a Brazilian tertiary academic oncology hospital. **METHODS:** Two cohorts of rectal cancer patients were compared: a control cohort from May06th, 2008 through May11th, 2011 (before ICP implementation - Pre-ICP group), and a cohort from May12th, 2011 through December 31, 2013 (after ICP implementation - ICP group). We included consecutive patients treated with neoadjuvant radio-chemotherapy followed by surgery. Patients with prior treatment or who have not performed the neoadjuvant treatment or with metastatic disease at diagnosis were excluded. Time intervals between treatment steps and resources used, including consultations, exams, hospitalizations, chemotherapy, radiotherapy and surgery were assessed. Survival analyses were performed. **RESULTS:** From a total of 624 patients, 330 were included: 112 Pre-ICP and 218 ICP. Interval between first medical consultation and neoadjuvant chemo-radiotherapy decreased 39.5% (Pre-ICP: 79.7 days, ICP: 48.2 days, $p<0.001$); interval between neoadjuvant step and surgery decreased 33% (Pre-ICP: 22.2 weeks, ICP: 14.8 weeks, $p<0.001$). Total time of treatment from initial consultation to surgery decreased 31% (Pre-ICP: 278.2 days, ICP: 191.8 days, $p<0.001$). We found higher utilization of consultations with clinical oncologists, CT, MRIs and radiotherapy in Pre-ICP compared to ICP ($p<0.001$). There was no statistical difference in overall survival in the time periods examined. **CONCLUSIONS:** Implementation of a rectal cancer ICP reduced all treatment intervals and promoted rational utilization of oncology consultations and imaging, without detrimental effects in overall survival.

PHS82

HEALTH CARE RESOURCE UTILIZATION AND COSTS OF METASTATIC NON-SMALL CELL LUNG CANCER IN SELECT EUROPEAN COUNTRIES

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OBJECTIVES: Assess health care resource utilization (HCRU) and costs of metastatic non-small cell lung cancer (mNSCLC) among patients receiving ≥ 2 treatment lines in the United Kingdom (UK), Spain (SP), Germany (GE), and France (FR). **METHODS:** mNSCLC-related HCRU and treatment data were abstracted from medical records of patients aged ≥ 18 years who initiated 2nd line treatment for mNSCLC between January 2008, and December 2014 (UK)/January 2015 (SP, GE)/October 2015 (FR). HCRU (inpatient, outpatient, and specialist visits) was assessed as the mean number of visits per patient per month of active treatment. Costs were estimated by multiplying unit costs (obtained from official health service estimates and formulary listings) by resource use. **RESULTS:** Among 821 patients, over 70% were male and the median age at metastatic diagnosis was 62.4 years. Most tumors were adenocarcinoma (48.7%) or squamous cell carcinoma (45.1%). At metastatic diagnosis, 85.5% of patients had a performance status of ≤ 1 . While receiving systemic treatment, median number of health care visits per month was 1.9 UK, 2.1 SP, 2.1 GE, and 2.0 FR. The most frequent type of visit in each country were outpatient consultant/hospital visits (1.5 UK, 1.4 SP, 2.0 GE, and 1.1 FR). The proportion of patients with at least one hospitalization was 14.6% UK, 20.8% SP, 32.5% GE, and 46.8% FR. Among patients with at least one hospitalization, the monthly median number of hospitalizations during systemic treatment was lowest in SP (0.1) and highest in FR (0.9). The total median monthly health care costs during active treatment were £1941 UK, €2134 SP, €2712 GE, and €3151 FR. Chemotherapy incurred the highest cost in the UK, SP, and GE. Inpatient visits incurred the highest cost in FR. **CONCLUSIONS:** Total monthly HCRU is similar across countries; however, utilization by visit type varied. Costs differed by country, with the highest total cost incurred in FR.

PHS83

SICKLE CELL DISEASE INPATIENT DATA ANALYSIS OF MEDICARE PATIENTS

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OBJECTIVES: Among the genetic-based anemias, sickle cell disease (SCD) is a major cause of morbidity and mortality. In addition to anemia, patients present with, vaso-occlusive crisis (VOC), a prevalent painful complication of SCD in adolescents and adults. Limited information is available to understand causes and types of readmissions for patients with SCD VOC to determine the quality and efficiency of SCD care, the potential budget impact and the need for improvement. The objective is to understand the frequency and charges of readmission among SCD patients discharged following a VOC. **METHODS:** Using Medicare data, we calculated readmission rates among patients with a primary diagnosis of unspecified VOC (International Classification of Diseases, 9th Revision, Clinical Modification diagnosis code 282.62, 282.64, 282.69, 282.42). Readmission was defined an all-cause hospital admission or VOC admission within 3, 7, 15 and 30 days after the index admission. **RESULTS:** There were 1, 753 institutions (individual and organization

health care providers) with VOC related discharges from January to December 2013. The average all cause readmission rate for this institution was 42% and for VOC readmissions was 36%. Within these institutions there were 23,753 VOC related patient discharges from January to December. Of these discharges, 4,412, did not have a readmission, 8,179 discharges had an all cause readmission and 6,995 had a VOC specific readmission within 30 days. A total of 19,678 discharges from January to October in an inpatient setting resulted in 33% returning to an ER visit within 30 days. Of these discharges the average charges ranged from \$1,589.54 to \$2,036,824.40. **CONCLUSIONS:** Our findings suggest there is a high readmission rate of adult patients with SCD/VOC. It indicates the need for improvement in the management of pain during hospitalization and at home post discharge.

PHS84

THE LONG-TERM IMPACT OF PULMONARY EXACERBATIONS AMONG PATIENTS WITH CYSTIC FIBROSIS (CF) IN COMMERCIAL MANAGED CARE PLANS

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OBJECTIVES: To describe the impact of pulmonary exacerbations (PEX) on subsequent long-term healthcare resource utilization and recurrence of PEX among patients with CF enrolled in commercial health plans. **METHODS:** Healthcare utilization claims for patients with CF from MarketScan® Commercial Claims and Encounters database (N=16,943) between 2008-2015 were analyzed. Patients who were not treated with a CFTR modulator were continuously enrolled for ≥24 months from first claim in the database until date of disenrollment or end of data availability. PEX (total, requiring hospitalization [PEXhosp], requiring IV antibiotics [PEXIV], or requiring outpatient oral antibiotics only [PEXOPoral]) and healthcare utilization (hospitalizations, total days in hospital) over the follow-up period were evaluated. Outcomes were compared between those with a PEX in the initial year vs those without. **RESULTS:** A total of 5295 patients (50.4% female; mean [SD] age, 21.6 [17.45] years) were included. Mean (SD) follow-up was 4.25 (1.72) years (range, 2.00-7.80). During year 1, 85.2% of patients had ≥1 PEX of any type, 32.8% had ≥1 PEXhosp, 50.1% ≥1 PEXIV, and 49.9% ≥1 PEXOPoral. With each additional PEX in year 1, patients had ≈3 more PEX, ≈1 more hospitalization, and ≈5 more hospital days over the follow-up period. Patients with an initial year 1 PEXhosp had ≈11 more PEX, ≈6 more hospitalizations, and ≈54 more hospital days during follow-up compared with patients without PEX during year 1; these patients also had ≈4 more hospitalizations and ≈42 more hospital days than patients with an initial year 1 PEX requiring oral antibiotics only. **CONCLUSIONS:** Commercially insured patients with CF who experienced greater numbers of, or more severe PEX during the initial year had higher numbers of subsequent PEX, hospitalizations, and more hospital days. These findings emphasize the long-term burden of PEX in CF and the importance of prevention of PEX. Sponsored by Vertex Pharmaceuticals Incorporated

PHS85

COST OF VISITS ASSOCIATED WITH MANAGEMENT OF INTERNATIONAL NORMALIZED RATIO (INR) RESULTS IN ATRIAL FIBRILLATION (AF) PATIENTS TREATED WITH VITAMIN K ANTAGONIST (VKA)

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In AF patients, VKA treatment requires a close follow-up and dose-adjustments to achieve targeted INR (2-3). Initiation phase is critical but modifications like diet or comedication could also impact INR level and efficacy of VKA treatment. A follow-up by physicians is needed and represents an economical burden which is difficult to estimate as reasons for consultations are uneasily available. **OBJECTIVES:** To assess cost of physician visits motivated by management of INR in AF patients treated with VKA from collective and National Health perspective (NHI) perspective. **METHODS:** A survey about the number of visits linked to INR management only was performed among 100 GPs and 50 cardiologists. Two phases of treatment (initiation and maintenance) have been distinguished. Unit costs were obtained from French official sources. Costs are reported in 2014 Euros. **RESULTS:** According to GPs, duration of the initiation phase is 4.4 weeks and 3.3 weeks according to cardiologists. During this phase, GPs indicated that 54% of patients are followed by phone, 34% require 2 visits in doctor's office, 12% require 1.8 visits at home. In cardiologists practices, these rates are respectively 66%, 26% require 1.6 visits and 8% require 1.5 visits. During the maintenance phase, 64% of patients are followed by phone, 26% require 3 visits in doctor's office and 10% require 2.8 visits at home per year according to GPs and 67% of patients are followed by phone, 25% require 2.8 visits in doctor's office and 8% require 1.8 visits at home per year according to cardiologists. Daily costs of visits motivated only by INR management in AF VKA-treated patients are estimated to €0.10 and €0.09 from collective and NHI perspective respectively. **CONCLUSIONS:** In addition to drug cost, INR analysis and time spent by phone, physician management of INR represents additional spending for NHI.

PHS86

DRIVERS OF HOSPITAL UTILIZATION AMONG PATIENTS WITH SPINAL MUSCULAR ATROPHY

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OBJECTIVES: Spinal muscular atrophy SMA is a genetic disorder that affects the control of muscle movement. The objective of this study is to examine patterns of hospital utilization in patients diagnosed with SMA. **METHODS:** A retrospective descriptive study was conducted on a cross-section of SMA discharges in the MedAssets health system data for inpatient (N=1,928) and outpatient (N=10,373) visits from October 2015 through September 2016. Multivariable logistic regression was used to identify significant drivers of inpatient admission. **RESULTS:** The

sample included 5,376 unique patients from 319 hospitals. The just over half of the population was male (54.0%), and was comprised of adults > 40 years of age (80%) with an average Charlson comorbidity score of 0.83. Cardiopulmonary disease (16.4%), hypertension (15.1%), dysphagia (14.5%), gastronomy (7.8%), and diabetes (9.2%), 33% of patients were admitted as an inpatient, with an average length of inpatient stay of 15.1 days, and an average cost of \$19,337. In the inpatient population 6.2% of the population was readmitted within 30 days. UTI (OR 8.5, 95% CL 9.7 - 11.7), hypertension (OR 8.2, CL 7.1 - 9.6), bed confinement (OR 4.6, CL 2.9 - 7.3), and gastrostomy (OR 3.5, 95% CL 2.9 - 7.3) largest predictors of inpatient admission. **CONCLUSIONS:** SMA patients admitted to the hospital have a large number of comorbidities and complications which contribute to longer hospital stays. Improvements in disease management may lead to better patient outcomes and a reduction in hospital utilization and healthcare costs.

HEALTH SERVICES – Patient-Reported Outcomes & Patient Preference Studies

PHS87

PHARMACIST LED COUNSELING AND THE IMPACT ON PATIENT ADHERENCE FOR ANALGESIC TREATED PAIN

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OBJECTIVES: The purpose of the study was to assess the impact of a specialty pharmacy's (SP) medication therapy management (MTM) program on the incidence of self-reported missed/skipped doses (M/SD) of analgesic(s) in patients with chronic moderate to severe pain associated with various disease states. **METHODS:** A six month study was conducted to assess the association of pharmacist counseling (PhC) on the incidence of patient self-reported M/SD of a non-narcotic analgesic. A start-of-care (SOC) assessment prior to the initial/first prescription fill at the SP included an opt-in for PhC (n = 1,410). M/SD of analgesics during the most recent prescription fulfillment period were compared at SOC and at the six month refill, using a Chi-Square analysis, Yates Correction for data continuity at p<0.05. **RESULTS:** Of the 4,103 patients on an analgesic, (72% migraine/headache, 27% bone pain), 1,410 (34%) opted to receive PhC at SOC. Of the initial 4103, 1,696 continued to refill analgesic prescriptions six months after SOC with 360 (21%) being in the PhC cohort. 81 of 1,696 (4.8%) patients at SOC reported having recently M/SD and 2 of the 360 (0.56%) patients reported M/SD at six months refill, a statistically significant difference (p<0.05 level). **CONCLUSIONS:** This SP MTM program incorporating PhC was associated with an 88% reduced incidence of M/SD doses of non-narcotic analgesic use. Further research is recommended to determine the impact of patient counseling and to identify sub groups of patients where counseling may be of particular value. Extension of the study to additional therapeutic areas and specialty drug classes is recommended.

PHS88

SELF-REPORTED ADHERENCE OF VETERANS LIVING WITH HIV USING MAIL-ORDER PHARMACY

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OBJECTIVES: The efficacy of HIV medication depends on near perfect adherence to medication regimens by individuals. The aim of this study was to examine the degree of adherence and associated factors for Veterans using the Consolidated Mail Order Pharmacy (CMOP) System at one Veteran Administration (VA) site. **METHODS:** A cross-sectional study design was used to assess self-reported Veteran's adherence rates at one Midwestern VA Hospital Infectious Disease Clinic. A combination of telephone and in-person methods were used for recruitment and data collection to reach maximum number of patients. Adherence was measured using the Brief Medication Questionnaire (BMQ) survey. All 57 Veterans who were contacted consented to participate. Thirteen others with HIV could not be reached. **RESULTS:** The sample consisted primarily of white (66.7%), male (96.5%) respondents with a mean age of 54.4 years (SD=8.0) and an average of 4.3 comorbidities (SD=2.2) along with a positive diagnosis for HIV. More than half used a combination of two medications to keep their viral loads in check (57.89%). Almost 48% of patients were non-adherent (30% sporadically and 17.5 % regularly non-adherent) with HIV medications. About 33% reported having refill issues for their HIV medications and 43% doubted how well the medication worked for them. Raltegravir was the most commonly used medication amongst Veterans, followed by a combination medication of tenofovir & emtricitabine. The combination drug with lopinavir and ritonavir was found to be the least well tolerated drug, followed by the combination drug with rilpivirine, tenofovir and emtricitabine. Adherence was significantly associated with finding the medication bothersome (p=0.031). **CONCLUSIONS:** The results suggest both practical issues and medication beliefs may affect adherence rates. Tailored interventions targeting these factors should be explored to address non-adherence by this vulnerable population, particularly given that the VA system is the largest single healthcare provider for patients with HIV.

PHS89

EXPECTATION AND SATISFACTION OF HIV/AIDS PATIENTS TOWARD THE PHARMACEUTICAL CARE PROVIDED AT GONDAR UNIVERSITY REFERRAL HOSPITAL, NORTHWEST ETHIOPIA- A CROSS-SECTIONAL STUDY

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OBJECTIVES: To assess human HIV/AIDS patients' expectation from and satisfaction with the pharmaceutical service delivered at Gondar University Referral Hospital, Ethiopia. **METHODS:** An institution-based cross-sectional study was performed from May 11 to 25, 2015. A total of 291 patients living with HIV/AIDS were included using a

simple random sampling method. Data were collected using structured questionnaires measuring expectation and satisfaction of respondents using a Likert scale of 1-5 through face-to-face interviews. The data collected were entered into and analyzed using Statistical Packages for Social Sciences. Comparison was made between those respondents who lived in and outside the town. **RESULTS:** The overall mean expectation and satisfaction of respondents toward pharmacy setting and services were 3.62 and 3.13, respectively. More than half (56.1%) of the participants were dissatisfied with the comfort and convenience of waiting area and private counseling room. Similarly, 69.3% of the respondents claimed that pharmacy professionals did not give information about side effects and drug-drug and drug-food interactions of antiretroviral medications. There was a statistically significant difference between respondents who live in and outside Gondar town in overall expectation ($t=3.415$, $P=0.001$) with the pharmacy setting and services. **CONCLUSIONS:** In this study, the overall satisfaction level of respondents with pharmaceutical service (pharmacy setting and services) provided at Gondar University Referral Hospital was found to be low, while the overall respondents' expectation from the pharmaceutical services were exceedingly high. The hospital should implement good dispensing practice systems in relation to the services and continuing professional development to professionals in order to improve the satisfaction of patients.

PHS90

TREATMENT OUTCOMES OF TUBERCULOSIS AND ASSOCIATED FACTORS IN AN ETHIOPIAN UNIVERSITY HOSPITAL

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OBJECTIVES: To assess the outcome of tuberculosis treatment and to identify factors associated with tuberculosis treatment outcome. **METHODS:** A five year retrospective cross-sectional study design was employed and data were collected through medical record review. This study uses the following operational definitions: **Successful treatment outcome:** If TB patients were cured or completed treatment with resolution of symptoms. **Unsuccessful treatment outcome:** If treatment of TB patients resulted in treatment failure, default, or death. Data were analyzed using Statistical Package for Social Sciences of windows version 16, binary and multiple logistic regression methods were used. A p value of less than 0.05 was considered as statistically significant in the final model. **RESULTS:** Out of the 1584 pulmonary TB patients (882 males and 702 females) included all age group, 60.1% had successful outcome and 39.9% had unsuccessful outcome. In the final multivariate logistic model, the odds of unsuccessful treatment outcome was higher among patients weight category (30-39.9Kg) (AOR = 1.51, 95% CI: 1.102-2.065), smear negative pulmonary TB (AOR=3.204, 95% CI: 2.277-4.509), extra pulmonary TB (AOR=3.175, 95% CI: 2.201-4.581), retreatment (AOR = 6.733, 95% CI: 3.235-14.013), HIV positive TB patients (AOR = 1.988, 95% CI: 1.393-2.838), unknown HIV status TB patients (AOR=1.506, 95% CI: 1.166-1.945) as compared to their respective comparison groups. **CONCLUSIONS:** In this study high proportion of unsuccessful treatment outcome was documented. Therefore emphasis has to be given for patients with high risk of unsuccessful TB treatment outcome and targeted interventions should be carried out.

PHS91

IMPACT OF COLLABORATIVE CUSTOMIZED PATIENT EDUCATION IN PSYCHIATRIC DISEASES

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OBJECTIVES: o study the impact of Pharmacist-Psychiatrist Collaborative customized Patient Education in patients with depression, Bipolar Affective Disorder (BPAD), Schizophrenia and alcohol dependent Syndrome(ADS) in an Ambulatory Care Setting. **METHODS:** A prospective randomized control study was conducted in the psychiatry out-patient department of a tertiary care hospital for a period of 9 months. Eligible patients (225) were randomized into test group and control groups by simple randomization in each disease and followed for a period of six months. Customized patient education was provided to the test group with the help of patient education materials while the control group was on usual care. The medication adherence and quality of life (QOL) of both the groups were assessed and compared once in every two months by using Medication Adherence Rating Scale (MARS) and World Health Organization Quality of Life (WHOQOL) - BREF questionnaire respectively. **RESULTS:** Among the study population 210 completed all the follow-ups out of which 100 were in control group and 110 in test group. Mean age was found to be 38.07 ± 11.60. Majority [n=75 (35.71%)] of patients were diagnosed to have had depression followed by BPAD [n=73 (34.76%)]. A statistically significant increase in the mean medication adherence score of test group was observed in all the follow-ups. The mean medication adherence scores was high in BPAD (1.4) and depression (1.4) compared to schizophrenia and ADS. Upon the analysis QOL, the difference in the overall mean score between test group and control was 8.45 which was statistically significant. Comparison of mean medication adherence scores of all patients in each disease showed that BPAD patients had a mean increase of 2.04 than depression, 1.36 than ADS and 2.01 than schizophrenia patients. **CONCLUSIONS:** Provision of customized patient education by pharmacist and psychiatrist improved the patient medication adherence and QOL.

PHS92

STRUCTURED TELEPHONE FOLLOW-UP OF PATIENTS DISCHARGED AFTER STROKE: A LONG-TERM QUALITY IMPROVEMENT PROGRAM

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OBJECTIVES: Stroke is the most important cause of death in Brazil a major cause of disability all over the world. The follow up of patients with Stroke is important in

order to detect recurrence, as well as to measure the impact of acute treatments in the long-term follow up. Objective: Our objective was to describe the implementation of a program of long term follow up ("célula de desfecho") of patients admitted with acute stroke in a private tertiary center in Brazil, as well as the difficulties in implementing this follow up. **METHODS:** A group of health professionals were trained in application of the modified Rankin Scale using telephone contact as well as in the delivery of a structured questionnaire containing questions regarding stroke recurrence and use of medications. We describe the results of the follow up of patients admitted to our hospital from January 2012 to December 2016. A telephone interview was planned 30, 90, 180 days and one year after hospital discharge. **RESULTS:** A total of 779 patients were discharged home after a stroke in this time period. Only 508 patients (67%) responded to the first telephone interview (30 days after discharge), 516 (73%) in 90 days, 464 (73%) in six months and 374 (72%) in one year. The main reasons for loss of follow up were: lack of answer to telephone contact and hospital readmissions at the time of the contact. **CONCLUSIONS:** A structured follow up of patients discharged after a stroke is feasible, however alternative methods of personal contact such as email and protected digital social networking should be further evaluated in order to improve adherence to the program.

PHS93

ASSESSMENT OF BENEFITS SUITABLE FOR INCLUSION INTO AN ECONOMIC EVALUATION FOR CHILDREN WITH MOTOR SPEECH DISORDER IN CEREBRAL PALSY

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OBJECTIVES: To review the Quality of Life (QOL) tools suitable for capturing the benefits of an internet delivered speech therapy in children with speech and language difficulties in cerebral. **METHODS:** PubMed, Embase, Medline, PsycINFO, NHS Economic Evaluation Database and Evidence Based Medicine Reviews (Ovid) databases were searched to identify literatures on QOL tools for children with speech, language and communication disabilities aged 3-18 years. Full text articles were included with no year limitation but language restricted to English. **RESULTS:** 1052 studies were identified from the search with eight studies meeting the inclusion criteria for the review. Of the six tools identified from the review, Health Utility Index 3 (HUI3) was recommended as the most appropriate tool as it can be used to derive Quality Adjusted Life Years (QALYs) and preferred by decision-makers for utility estimation. Studies also reported the reliability and sensitivity of the tool in capturing different ranges of speech and language disorder as it includes a domain on speech. Strong correlation was found in the HUI3 scores and level of impairment in children with cerebral palsy reinforcing its sensitivity. Paediatric Speech and Language Quality of Life (PedSal QoL), a condition specific measure was also identified as being suitable for this group of children but cannot be applicable because further work would be needed to assign utility scores to responses to this tool. **CONCLUSIONS:** HUI3 was identified to be the most suitable tool for the assessment of benefit in children with motor speech disorder and cerebral palsy. Another alternative for consideration would be PedSalQoL, but further research would be required before this tool could be used as the basis of health state utilities.

PHS94

FACTORS AFFECTING PROXY REPORTING OF PATIENT OUTCOMES

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OBJECTIVES: Patient experience and health status measures are part of surveys which are included in pay for performance approaches and public reporting. If patients are unable to respond, family members such as proxies are asked to report on their behalf. It is not known if proxy-specific information affects how proxies report on patient care experience and health status. The aim of this study was to evaluate if proxy-specific covariates impact proxy reporting of patient cancer care experience, quality, and quality of life, and determine if these covariates are important for data collection. **METHODS:** Secondary analysis of data from the Cancer Care Outcomes Research and Surveillance (CanCORS) study, a cross-sectional survey. Respondents were proxies for living patients with colorectal or lung cancer. Outcomes included experiences with medical and nursing care, care coordination, care quality rating, physical and mental health. All outcomes were on 0-100 scales (0=worst, 100=best). Proxy characteristics included relationship to patient, sex, education, frequency of proxy-patient contact, frequency of attending consultations, and frequency of discussing medical decisions and discussing the patients' feelings with the patient. Analyses used linear regression models with patient sociodemographic and clinical characteristics and proxy-specific covariates. Multiple imputation was used for missing data. **RESULTS:** Of the 1,011 proxies, most were the patient' spouse/partner (49%) or child (36%). Although most proxies (66.3%) always attended medical visits, a minority reported never attending (2.6%). In adjusted analyses, child proxies reported worse average care experiences and lower quality ratings than spouses (-3.5 to -8.8 points lower on average). For medical care and care coordination, proxy responses became progressively more negative as proxy frequency of attendance decreased. Proxies who never attended reported significantly worse medical care (-10.5 points, 95% CI: -18 to -3) and care coordination (-13.4 points, 95% CI -20.4 to -6.4). **CONCLUSIONS:** Collection of proxy-specific covariates in surveys using proxy data is warranted.

PHS95

PATIENT EXPERIENCES WITH LOW-DOSE CT LUNG CANCER SCREENING IN THE VETERANS HEALTH ADMINISTRATION SYSTEM

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OBJECTIVES: The Veterans Health Administration (VHA) was an early adopter of low-dose CT (LDCT) lung cancer screening for heavy smokers (≥ 30 pack-year history, age 55-80) in 2013, and continues to be a critical research resource in this area. The objective of this study was to use qualitative inquiry to understand patient experiences with LDCT lung cancer screening in the VHA system. **METHODS:** We conducted a semi-structured telephone-based qualitative evaluation of patient experiences with LDCT screening at Portland, OR and Charleston, SC VHA sites. Participants met U.S. Preventive Services Task Force screening criteria and the sample was enriched for Lung-RADS positive results (50% of sample). Trained staff interviewed 20 participants in the summer of 2016. Interviews were recorded, transcribed, and independently evaluated by two study investigators using inductive content analysis methods to identify major themes. **RESULTS:** Among the 20 participants, mean age was 64 years, 95% were male, 60% were Caucasian, and 60% self-reported current smoking. Most participants were unaware of lung cancer screening before having it offered by their clinician. The majority of participants discussed a screening benefit ('early detection' was most common), and few discussed any screening harms. Nearly all described the experience of the screening scan as "easy", "quick", and/or "painless". Most participants with positive results expressed desire for more information about screening and results, whereas few with negative results did. Participant quotes supporting these themes will be presented. **CONCLUSIONS:** Among participants who recently received LDCT screening in the VHA system, screening was frequently introduced by clinicians, screening benefits were noted more often than harms, the screening exam was often described as 'easy', and patients with positive results wanted more information about screening. Our findings provide insights to help VHA and other stakeholders understand patient perspectives on LDCT screening, and can be used to inform efforts to improve screening processes.

PHS96

EFFECT OF PATIENT INVOLVEMENT ON INTENTION TO INITIATE BREAST CANCER CHEMOPREVENTION

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OBJECTIVES: The purpose of this study was to test the effect of patient involvement levels, developed using different breast cancer risk scenarios on their intention to initiate breast cancer chemoprevention. **METHODS:** In this experimental field study involvement was manipulated at 2 levels (high and low) and was developed using two scenarios. Breast cancer risk levels were considered using the Gail risk score. A breast cancer risk level of 16% with family history was used for low risk scenario and breast cancer risk level of 55% with family history and a breast biopsy was used for high risk scenario. Women across the Houston metropolitan area evaluated two chemoprevention drug decision aids after reading scenarios simulating high and low involvement. A pre-validated, self-administered survey instrument was used to measure their intention to start chemoprevention using a Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). ANCOVA and post-hoc analyses were done using SAS® 9.3. **RESULTS:** Of the 320 women included in the study (81.4% response rate) majority were married 144 (46.45%), white 160 (51.61%) with a mean age of 40.25 (± 11.27) years. Majority 182 (58.52%) had at least one family member with a history of cancer. A univariate and post hoc analyses indicated women with high involvement level had significantly higher mean (4.14 ± 0.99) intention to start chemoprevention when compared to women in a low involvement scenario (2.52 ± 1.1). **CONCLUSIONS:** Patient involvement manipulated using breast cancer risk levels plays an important role in intention to initiate chemoprevention. Interventions can be targeted among women emphasizing on their breast cancer risk.

PHS97

PATIENTS' PREFERENCES AND TRADE-OFFS IN CHOOSING A SURGEON TO DECREASE WAITING TIMES

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OBJECTIVES: Patients face significant waiting times for hip and knee total joint replacement (TJR) in Canada. One waiting time management strategy is the single-entry model (characterized by pooled referrals, central intake and triage for referral to specialist). Central intake can improve access by offering the choice of next available surgeon. We aimed to assess patients' preferences and trade-offs for reducing waiting times for TJR including surgeon choice. **METHODS:** We administered a questionnaire, including a discrete choice experiment (DCE) with 12 choice tasks, to Canadian patients (>18 years) referred as candidates for TJR. Five attributes were included based on our previous research, pre-testing and pilot testing: surgeon reputation, surgeon selection process, waiting time to surgeon visit, waiting time to surgery and travel time to hospital. Preferences were assessed using hierarchical Bayes analysis and evaluated for goodness-of-fit. We conducted simulation analyses for alternative scenarios representing various combinations of attributes. **RESULTS:** Of 422 participants, 59% were female and 68% were referred for knee TJR. Overall, mean baseline EQ-5D was 0.4 (SD=0.2) and mean Oxford score was 19.8 (SD= 8.7). The most important attribute was surgeon reputation followed by waiting time to surgery, waiting time to surgeon visit, surgeon selection process and travel time. Patients appear willing to wait 10 months for consultation with an excellent reputation surgeon before switching to a good reputation surgeon. Simulations indicate that patients in the lowest pain category have stronger preferences for choosing their surgeon than those in the highest category. Patients

in the highest pain category were willing to wait 7.3 months, after which they would accept the next available surgeon. Those experiencing the least pain were willing to wait 12 months. **CONCLUSIONS:** Next available surgeon increases choice and may result in shorter waiting times. However, surgeon reputation is a dominant consideration, albeit poorly assessed by patients.

PHS98

"WHAT MATTERS IN HEMOPHILIA" – A QUANTITATIVE SURVEY OF PEOPLE LIVING WITH OR CARING FOR SOMEONE WITH HEMOPHILIA

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OBJECTIVES: A quantitative patient study was conducted to better understand symptoms experienced, quality of care, and overall impact of hemophilia. **METHODS:** An email invitation was sent to all U.S. members of MyHemophiliaTeam, a social network of 890 people diagnosed with or caring for someone with hemophilia. In total, 47 members responded to a 16 question survey between July 18 and August 10, 2016. **RESULTS:** Both adults and children with hemophilia are impacted well beyond bleeding episodes. In fact, 65% of adults rank depression as having as much of an impact on their daily lives as bleeding. General pain (57% of adults, 30% of children) and physical limitations (57%, 15%) are also quite prevalent. Respondents are generally satisfied with management of bleeds (60% for adults, 85% for children), but there is dissatisfaction with how their other symptoms are being treated. Respondents indicate their depression/anxiety is not being addressed (87%, 86%), and pain is not being well managed (62%, 83%). Many also described the care provided by their multiple providers (HTCs, doctors, nurses, etc.) as not well coordinated (55%, 39%). Parents worry about their child's future and ability to have a "normal" life and are burdened by its impact on their children and their own time/careers. Many have struggled to be financially secure and some adults with hemophilia still feel the stigma from the HIV/Hep C tainted blood issues. **CONCLUSIONS:** People with hemophilia responded that their bleeding episodes are under control, however, their depression, anxiety and pain are not being properly treated. There is an opportunity to provide a more holistic, coordinated approach to treating hemophilia and associated symptoms in this community. Understanding the range of symptoms and the impact in totality will better allow medical professionals to treat individual with hemophilia more effectively.

PHS99

ONE-YEAR PREVALENCE AND HEALTH CARE UTILIZATION OF DIABETES IN LUNG CANCER-RELATED INPATIENT ADMISSIONS IN THE UNITED STATES

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OBJECTIVES: The incidence of type 2 diabetes (T2D) in patients with lung cancer (LC) may vary from that of the general population, as there is a likely association with hyperinsulinemia, which is a result of insulin resistance characteristic of T2D. Insulin's role in cell proliferation, through the action of insulin-like growth factor-1, could play a significant role in the development of cancerous tissues. Our objective is to characterize healthcare utilization and associated hospitalization costs in LC patients with diabetes. **METHODS:** We conducted a cross-sectional study of LC patients (ICD-9 162.xx) from the 2012 Nationwide Inpatient Sample. A prevalence estimate for T2D patients with LC was established using the discharge weight that was included in the NIS for each observation; however, all other analysis did not include the discharge weight. We compared patients with diabetes (ICD-9 250.xx) to those without on length of stay (LOS) and total cost using chi-square test of association. Finally, we assessed factors predicting increased LOS and inpatient mortality using logistic regression. **RESULTS:** We estimated US prevalence of inpatients with a diagnosis of LC and diabetes at 91,240 cases. LC diabetic patients were older, with an average age of 70.27vs.68.47 years ($p < 0.001$) compared to their non-diabetic LC-peers. Hospitalizations associated with diabetic LC patients were associated with a significantly longer LOS 6.31vs.6.11 days ($P < 0.001$), compared to non-diabetic patients. Significant positive predictors of increased LOS among diabetic LC patients included visiting a hospital in a rural location (Odds Ratio(OR)=1.20, 95%Confidence Interval=1.11-1.31) and Private Insurance (OR=1.25 95%CI=1.04-1.50). Significant positive predictors of inpatient mortality included Medicare (OR=2.52 95%CI=1.81-3.5), Medicaid (OR=2.01 95%CI=1.37-2.97), and hypertension as a comorbidity (OR=1.32 95%CI=1.18-1.48). **CONCLUSIONS:** These data suggest that LC patients with diabetes have extended hospitalizations compared to those without diabetes. Clinical strategies to better manage diabetes in LC patients could enhance metabolic health, reduce hospitalization time, and lower healthcare costs.

PHS100

DEVELOPMENT OF AN EYE DROP COMFORT MEASURE FOR TOPICAL OCULAR DROP APPLICATION

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OBJECTIVES: To develop a new patient-reported outcomes (PRO) measure assessing the comfort of topical ocular drop applications - the Eye Drop Comfort Scale (EDCS) in an adult population who have an ophthalmologic condition. **METHODS:** In alignment with FDA PRO Guidance, development occurred across three ocular categories (inflamed, non-inflamed, and post-surgical) and included literature review, and the conduct of two sets of interviews with topical ocular drop users: focus groups interviews to elicit concepts for a draft measure, and cognitive debriefing interviews to refine items and further establish content validity. **RESULTS:** Results from the nine

focus groups (n=61 eye drop users; 3 groups per category) provided concepts that were appropriate, comprehensive, and relevant to patient experiences with topical ocular drop application comfort in each of the categories. Qualitative analysis demonstrated that saturation was achieved for these concepts, resulting in a fifteen item measure assessing sensations or symptoms experienced after instillation of a topical eye drop. Patient input from the cognitive debriefing interviews documented patient understanding of the items, response scale and recall period as well as confirmation of concept relevance. The interview results supported content validity of the tool. The EDCS is designed to be self-administered and may be completed in hard copy or on an ePRO tablet. **CONCLUSIONS:** The EDCS is a brief, comprehensively developed measure designed to assess the comfort or discomfort experienced after the instillation of eye drops in patients with inflamed, non-inflamed or post-surgical conditions. Results of the qualitative research provided evidence to support the content validity of the EDCS. The next phase of development of the EDCS is psychometric evaluation. Future uses of the measure in clinical studies may facilitate identification of improved treatment modalities in development as well as allow comparison of topical ocular drop comfort and safety between products to inform patients, and prescribers.

PHS101

ASSESSMENT OF KNOWLEDGE ATTITUDE AND PRACTICE OF FAMILY PLANNING AMONG MARRIED WOMEN ATTENDING TERTIARY CARE HOSPITAL QUETTA

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OBJECTIVES: Study aimed to assess Knowledge Attitude and Practice of Family Planning among married women attending tertiary care Hospital Quetta. **METHODS:** A cross sectional study was conducted in obstetrics & gynaecology wards from public sector hospitals of Quetta. Data was collected from February-September 2016 from 503 Females who were sexually active, willing to participate and able to understand Urdu and local languages. Knowledge, attitude and practices on family planning were assessed with the help of pre-designed questionnaire. Statistical analysis was done by using SPSS version 20. Descriptive and inferential statistics used where applicable. **RESULTS:** Result showed that out of 503 women, majority (41.2%) were uneducated, house wife (79.1%), Pashtun (40.6%), (89.7%) belong to urban area and (43.7%) had married life span of 6-10 years. 500 (99.4%) had knowledge about family planning and their methods and its source was TV/Radio (28.8%) followed by health care personal (22.7%). 497(98.8%) believed that use of family planning methods is beneficial, (62.0%) health care providers encourage the use of family planning services. 430 (85.5%) women were practicing family planning methods out of which most of them were using condom (39.4%) followed by Oral Contraceptive (20.3%). Reason for practicing these methods were Prevention of unwanted birth (35.9%), followed by Spacing of birth (27.6%). The relationship between Knowledge and Attitude was investigated using Pearson product-moment correlation coefficient. There was a small, positive correlation between Knowledge-Attitude [$r=0.83$, $p=0.064$], Knowledge-Practice [$r=0.119$, $p=0.008$] and Attitude-Practice [$r=0.119$, $p=0.001$] was observed. **CONCLUSIONS:** Study concluded that overall KAP was good among women towards contraception. Husband being dominant member plays the pivotal role in approving the family size and contraceptive practices. Women education and counseling of couples can play an important role to adopt family planning methods. There is a need to improve the educational status of the females to improve understanding and uptake of modern contraceptives.

PHS102

ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE AMONG PATIENTS WITH TUBERCULOSIS IN GOVERNMENT INFECTIOUS DISEASE HOSPITAL, GUNTUR

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OBJECTIVES: Tuberculosis is one of the oldest infections known to affect humans. The aim of the study was to assess the quality of life including physiological, general health perception and social role functioning among patients with tuberculosis in Govt. Infectious Disease Hospital, Guntur. **METHODS:** Total 180 Tuberculosis patients with tuberculosis who registered were included in the study by using multi stage sampling method. From DOTS Centre we had taken 10 Sputum positive newly diagnosed, 6 category II (2 for each defaulter, relapse, failure), 2 MDR and 2 HIV patients. We excluded pediatric patients. Thus, a total of 180 cases were interviewed using a pre-designed, pre-tested questionnaire. Socio-demographic data, perception about the Quality of Life (QoL) was collected using RAND-SF 36questionnaire. **RESULTS:** Mean age of cases was 33.3+11.7years and 124 (68.9%) were male and 56(31.1%). The mean score of all domains was 53.4 with SD of 11.2. The worst affected domains were vitality (44.6 +13.8), general health (45.7+ 18.7) and mental health (47.7 + 16.6). MDR patients had lower mean score for physical health (56.3 + 15.2), vitality (35.8 + 13.5) and pain (46.3 + 16.1) as compared to other TB category patients. Mean score of social function (43.6 + 13.8), emotional role (37.1 + 27.9) and emotional wellbeing (38.3 + 13.7) were lower in TB with HIV patients. In all domains female have better scores except two domains, which are emotional health and social function. **CONCLUSIONS:** We recommend that early diagnosis and treatment decrease severity and infectivity to other person and improve QoL. Health education during diagnosis and family support may reduce social stigma and improve the mental component of QoL.

PHS103

EVALUATION OF AWARENESS, BENEFITS AND WILLINGNESS TO PAY FOR PHARMACEUTICAL CARE (PC) SERVICES AMONG OLDER ADULTS

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OBJECTIVES: To evaluate the awareness, benefits and willingness to pay for Pharmaceutical Care (PC) services among older adults. **METHODS:** A consecutive cross sectional survey was conducted for 4 weeks among 300 older adults visiting

four community Pharmacies in Ijebu Ode, South Western Nigeria using a self administered 4 sectioned, 30 item pretested structured questionnaire which inquired on sociodemographics, awareness of PC, benefits of PC (anchored on a Likert scale of 1 (Not Beneficial) to 5(Very Beneficial)), and willingness to receive and pay for core components of PC Services. Data were analyzed using SPSS Version 17, P value was set at < 0.05. **RESULTS:** Reliability of the instrument was 0.930, most respondents 133(44.3%), 167(55.7%) ; 223(74.3%) ; 189(63.0%);89 (29.7%), 153(51%); and 159(53%) were 50-59.years, females, married, Christian(s), Traders, had tertiary education, and had an average income of N20,000-N99,999 (63.42 -317.09 US Dollars) respectively. Ninety (30.0%) respondents knew about PC, "Promoting increase in compliance/adherence to medications" was rated most beneficial 266(88.7%). Two hundred and seventy four (91.3%), 215(71.7%), and 252 (84.0%) respondents had purchased prescription or OTC medicines in the past, were not currently receiving but are willing to receive PC respectively, 85(28.3%) were willing to pay for such services and 33(38.8%) of them were willing to pay between N500- N999 (1.59-3.17 US Dollar) for PC services. Average income ($P=0.04$), Level of education ($P=.003$) and having heard of pharmaceutical care before ($P=.024$) had significant associations with willingness to pay for PC. **CONCLUSIONS:** Most respondents were not aware of PC, however they believed it could be beneficial and were willing to receive PC services though few were willing to pay. This needs to be addressed by way of increase in awareness and other educational interventions for Pharmacists, older adults and the entire society.

HEALTH SERVICES – Health Care Use & Policy Studies

PHS104

EXPLORING CONSUMERS' DECISION MAKING FOR USING COMPREHENSIVE MEDICATION REVIEW (CMR) SERVICE

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OBJECTIVES: To explore consumers' decision making on using government-promoted Comprehensive Medication Review (CMR) service and factors affecting the uptake of CMRs among elderly residents in Iowa. **METHODS:** Semi-structured personal interviews were conducted among a purposive sample of 13 elderly residents in Iowa. Participants were recruited through either a local pharmacy or a registry of seniors maintained by University of Iowa, if they were 65 years or older and used medication(s) with Medicare Part D coverage. An interview guide informed by a conceptual framework in consumer behavior was developed, including domains of internal need, external influence, perceived risk in service use, and alternative comparison. Interview data were audio-recorded, transcribed and thematically analyzed, using MaxQDA. **RESULTS:** Five of thirteen participants received CMRs previously, and three of the eight non-recipients would like to receive one in the near future. The thematic analysis yielded four themes: CMR-recipients' experiences, consumers' perceived reasons for CMRs use, consumers' perceived reasons for no CMRs use, and promotion strategies for increasing CMR-uptake. Overall, CMR-recipients were highly satisfied with their CMR process and results. Perceived reasons for using CMRs included: seeking knowledge of personal medications, recommendation from pharmacists or physicians, and being worried about medication safety. Main perceived reasons for not using CMRs were poor awareness or understanding of CMRs, complete trust on physicians, and privacy concerns. Recommendation from either physicians or pharmacists was considered the most effective promotion approach to increase CMR-uptake. **CONCLUSIONS:** Consumers who received CMRs expressed a positive attitude toward them. However, awareness of CMRs remains low after being available for 7 years. Safety worriers or knowledge seekers appear more likely to use CMRs while physician believers or privacy worriers are more likely to not use CMRs. Recommendations from health professionals and understanding of service benefits were identified as factors affecting consumers' decision making for using CMRs.

PHS105

HOW COMMON ARE DIGITAL WRAP-AROUND PRODUCT TIE-INS WITH FDA-APPROVED NEW MARKET ENTRANTS?

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OBJECTIVES: The objective of this study was to evaluate the extent by which the life sciences industry develops and promotes digital wrap-arounds that tie-in with new FDA-approved product introductions in order to optimize patient adherence, monitoring and health outcomes. **METHODS:** A review of recent novel product approvals in 2016 and the presence of digital wrap-arounds associated with these product introductions was conducted. We defined digital wrap-arounds as any digitally-based mechanism such as a web-enabled device, platform or mobile applications intended to improve patient outcomes, adherence, and treatment costs through enhanced monitoring, education, support and/or a feedback loop to providers. Literature review of scientific and medical literature; product package inserts; and lay media sources (Internet, trade journals, tech websites, etc.) were scrutinized to determine if there were any mentions of a digital wrap-around that was promoted concurrently with new product approvals. Key words and phrases using terms such as 'digital', 'mobile', 'apps', 'connected devices', 'internet of things', 'e-health', 'mobile health', and 'm-health' along with generic names of the drugs was utilized in these searches. **RESULTS:** A total of 22 new and novel product approvals were identified from the FDA website (www.fda.gov). Based on the search strategy described above, we found that there were just two specifically designed digital wrap-arounds associated with these compounds; primarily educational mobile apps associated with product patient support programs. **CONCLUSIONS:** While there has been a lot of interest in 'wrapping' new therapeutic products with digitized tools to enhance outcomes, improve adherence and reduce costs; these efforts appear to be promising but largely unfulfilled.

PHS106

ANALYSIS OF FORMULARY COVERAGE AND COST OF HUMAN IMMUNODEFICIENCY VIRUS ANTIRETROVIRAL DRUGS IN MEDICARE PART D (2006-2015)

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OBJECTIVES: This study examined trends in Medicare Part D plans' coverage of single ingredient and combination HIV ARV drugs; analyzed trends in cost sharing, premiums, and deductibles; and evaluated restrictions set by drug plans on HIV ARV drugs. **METHODS:** Data were obtained from the Centers for Medicare and Medicaid Services Prescription Drug Plan Formulary and Pharmacy Network Files for the month of December for the year 2005-2015. Information for each plan included: dosage forms, active ingredients (single or fixed-dose combination) formulary information (coverage, prior authorization, specialty tier), and cost-sharing structure (coinsurance or copayment). Descriptive statistics were conducted. **RESULTS:** The study included 37 HIV ARV drugs marketed in the US in the period 2006-2015. There were 10 fixed-dose combination HIV ARV drugs and 27 single active ingredient HIV ARV drugs. There were 3 drugs subject to prior authorization and 1 drug subject to step-therapy during part of the study period. The median quantity limit ranged from 26.8 to 31.9 days. Most formulary plans required patients to pay co-insurance instead of copayments for covered HIV ARV drugs. The use of specialty tiers (tiers 4-6) increased during the study period. The percentage of formularies using tier 5 for at least 1 HIV ARV drug was 1.6% in 2006 and 13.6% in 2015. **CONCLUSIONS:** Part D plans covered all HIV ARV drugs marketed in the US in the period of 2006-2015. Prior authorization or step therapy requirements were not common restrictions to access to HIV ARV drugs. Conversely, quantity limit days were common restrictions in drug coverage. Most plans required patients to pay a coinsurance and a higher percentage of HIV ARV drugs were placed in specialty tiers.

PHS107

FINANCIAL INFLUENCE OF CURRENT AND ALTERNATIVE PRICING BENCHMARKS FOR PHARMACY DISPENSED MEDICATIONS IN CALIFORNIA WORKERS' COMPENSATION SYSTEM

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OBJECTIVES: California's Workers' Compensation (CWCS) questioned adequacy of current Medi-Cal pricing benchmark and requested analysis of alternatives that maximize price availability and maintain access and budget neutrality. Objectives are to compare CWCS drug prices under alternative fee schedules, and identify efficient alternative benchmarks which improve price availability. **METHODS:** Claims transaction-level data (2011-2013) from (CWCS) were used to estimate total annual pharmaceutical costs. Medi-Cal pricing data was from WCIS. Average Wholesale Prices (AWP), Wholesale Acquisition Costs (WAC), Direct Prices (DP), Federal Upper Limit (FUL) prices, and National Average Drug Acquisition Costs (NADAC) were from Medi-Span matching NDCs, pricing dates, and drug quantity. We report pharmacy dispensed (PD) claims frequency, reimbursement matching rate, and paid costs by WC as the reference price against all alternative price benchmarks. **RESULTS:** Of 20,373,477 claims submitted to CWCS, 12,529,977 were for pharmaceutical products and 11.6% (1,462,814) were pharmacy dispensed (PD). Prescription drug WC cost was over \$152M; \$63.9M, \$47.9M, and \$40.6M in 2011-2013. WC spent over half of total amount paid on analgesics, anti-inflammatory agents, and antidepressants; \$37.7M (59%), \$27.3M (57%), and \$22.5M (55.3%) across 2011-2013. Ninety seven percent of WC PD claims had a Medi-Cal price. Alternative mechanisms provided a price for fewer claims; NADAC 94.23%, AWP 90.94%, FUL 73.11%, WAC 66.98%, and DP 14.33%. Analgesics claims had highest percent of claims with no Medi-Cal prices (30.94%). Among WC drugs with no Medi-Cal price in PD claims, AWP, WAC, NADAC, DP, and FUL provided prices for 96.7%, 63.14%, 24.82%, 20.83%, and 15.08% of claims. For WC drugs not benchmarked by Medi-Cal, WC paid NADAC+40% or AWP-44%. **CONCLUSIONS:** CAWCS current Medi-Cal coverage for PD drugs is better than all alternatives except AWP, so alternative reimbursement approaches would require combinations of pricing benchmarks. Physician dispensed/administered drugs may have fewer Medi-Cal prices and require different alternatives.

PHS108

INVESTIGATION OF RELATIONSHIP BETWEEN DEMOGRAPHICS AND TYPE 2 DIABETES MORTALITY IN TWO TERTIARY HOSPITALS IN SOUTHEAST NIGERIA; EXPLORING EPIDEMIOLOGICAL DETERMINANTS

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OBJECTIVES: Type 2 diabetes mellitus (T2DM) is a major cause of complications and mortality. The study examined the relationship between marital statuses, age, and death associated with T2DM to evidence-based data for pharmacoepidemiological studies. **METHODS:** The study was a retrospective cross sectional descriptive survey of postmortem records and death register of T2DM patients who died between January 2009 and December 2014. All the records, which met the inclusion criteria of death, associated with T2DM for patients who have been diagnosed with the disease and have been on antidiabetes medications for more than 12 months were used to increase reliability and consistency of results. Study was conducted between July and December 2015. Study was summarized using descriptive and inferential statistics. A confidence interval of P < 0.05 was considered statistically significant. **RESULTS:** Out of 431.0 deaths associated with T2DM, 336.0 (78.0%) were married, 49.0 (11.4%) were widows, 25.0 (5.8%) were

singles while 21.0 (4.8%) were widowers. The highest T2DM mortality was recorded within the age range of 66.0- 85.0 years (44.1%), followed by 46.0- 65.0 years (31.6%) and 22-45 years (16.3%). The least group affected was those above 86 years (8.0%). Result showed that females had prevalence of 58.0% while males had 42.0%. P = 0.068 for relationship on the causes of death associated with T2DM in the two hospitals. **CONCLUSIONS:** Study suggested that married peoples have the highest prevalence of T2DM while T2DM patients above 65.0 years are at greatest risk of mortality associated with T2DM.

PHS109

HOSPITAL REIMBURSEMENT UNDER THE MEDICARE PPS: WHAT IS THE RELATIONSHIP BETWEEN COST AND QUALITY?

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OBJECTIVES: The 2010 Patient Protection and Affordable Care Act (ACA) and other recently enacted health policies attempt to improve the efficiency of hospitals through the use of "value based" payments. The purpose of this exploratory study is to explore the relationship between the cost and quality of hospital care delivered by the Medicare program. **METHODS:** This study utilized hospital demographics, Medicare payments, and hospital charge measures for 9 diagnosis related groups (DRGs) for acute myocardial infarction (AMI), pneumonia, and heart failure under the Medicare Inpatient Prospective Payment System (IPPS). The data came from a set of 3,007 acute care hospitals in the U.S. that accepts Medicare payments. We analyzed the distribution of hospital costs by applying principal components analysis (PCA) to the relative cost of care for these 9 DRGs. The cost analysis was combined with a previously validated measure of hospital quality for these hospitals through a correlation analysis. **RESULTS:** The distribution of hospital cost scores resembled a bimodal distribution of high and low cost hospitals with relatively few close to the mean. A small segment of hospitals were high-cost outliers. After matching cost scores with previously generated quality scores, the correlation coefficient for the cost and quality scores was 0.73 (95% CI: 0.72-0.75, P < 0.0001). **CONCLUSIONS:** The results of this study suggest that higher cost hospitals also tend to deliver higher quality care. Additional analyses are required to validate and determine the validity of these results. This type of analysis can be used to set the optimal reimbursement level under the Medicare program and other value based health insurance reimbursement systems.

PHS110

METABOLIC CONTROL IN PATIENTS WITH DIABETES MELLITUS TYPE 2 IN A DISEASE MANAGEMENT PROGRAM FROM PRIVATE HEALTH INSURANCER IN COLOMBIA

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OBJECTIVES: Suramericana is a private health insurer in Colombia. A multidisciplinary chronic care model (Disease Management Model) was designed, based on evidence-based care guidelines and monitoring of the indicators offered to the insured on a voluntary basis. Patients with type 2 diabetes mellitus voluntarily enroll in our DMM. The objective is to evaluate the optimal metabolic control (HbA1c < 6.5%) and associate it with the adherence to the program during one year. **METHODS:** The study is a retrospective analysis from September 1, 2015 to August 31, 2016. We included data from 353 patients in DMM and 274 in conventional care, with a mean age of 63 years. It was conducted a comprehensive statistical analysis from the descriptive stage to a logistic regression to evaluate the effect of the adherence to the program in the glycated hemoglobin (whether it was controlled or not) considering the impact of the other relevant variables such as amount of Medication, hospitalizations, number of months in the policy, age of patient, among others. **RESULTS:** HbA1c < 6.5% was found in 57.2% of DMM patients and 52.5% in conventional care. Patients in DMM used fewer antidiabetic medications (p < 0.00), had fewer outpatient visits (p 0.028) and fewer hospitalizations (p 0.003). In the multivariate analysis, the only variables associated with metabolic control were adherence to the program OR 1.6 (p 0.05) and any hospitalization during the period OR 4.86 (p 0.005). **CONCLUSIONS:** A DMM for chronic diseases allows value-based health care and is associated with clinically significant outcomes in type 2 diabetic patients, such as metabolic control and fewer hospitalizations. It is possible that a greater follow-up will reveal greater differences with lower costs of health care.

PHS111

DETERMINANTS OF PATIENT-CENTRED CARE FROM THE PUBLIC AND PROFESSIONALS' PERSPECTIVES

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OBJECTIVES: To assess the determinants of patient-centred care (PCC) from Canadian public and professionals' perspectives. We expected that respondents who strongly support team care models for chronic disease (CD) management will have a high level of support for attributes of PCC. **METHODS:** This study used the data from a national population-based survey, the 11th edition of the Health Care in Canada (HCIC) Survey, conducted by Pollara Strategic Insights between November 2013 and January 2014. The survey assessed the perceptions of 1000 Canadian adults, 101 doctors, 100 nurses, 100 pharmacists, and 104 administrators who were randomly selected from online panels based on multiple source recruitment. PCC was assessed using a summary score across 7 items. Two separate hierarchical regression models were run to estimate the association between several covariables including age, gender, type of CD, and e-technology and PCC. **RESULTS:** Of 1000 Canadian public adults surveyed, 51% were female, 74% were living with another person, 17% were living in rural areas, and 62% have

at least one chronic condition. Only 18 % of health professionals were working in teams. Multivariable regression models showed that older age (0.59, 95%CI:0.32, 0.86), work in teams (0.24, 95%CI:0.20, 0.28), adherence to medications (-0.81, 95% CI: -1.16, -0.47), use of e-technology (0.29, 95%CI:0.17, 0.42), and patient involvement in decision making (0.42, 95%CI:0.30, 0.55) were significantly associated with PCC of PCC. Variables such as gender and years in practice were not significant. **CONCLUSIONS:** The findings confirmed that perceptions of requiring health professionals to work in teams and the use of technology in healthcare are associated with support for patient-centred care from both the public and health professionals. Programs to accelerate the implementation of health care teams supported by information and communication technologies are needed, particularly for individuals living with chronic conditions.

PHS112

CORRELATES OF GOOD DIABETES MANAGEMENT AMONG AMERICANS WITH TYPE 2 DIABETES

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OBJECTIVES: This study aims to examine factors that are associated with diabetes management among United States adults. **METHODS:** Data from the 2011-2014 Behavioral Risk Factor Surveillance System (BRFSS), a random-digit-dialed telephone survey of the civilian, noninstitutionalized adult population aged 18 years, were analyzed for 78,698 individuals who self-reported diabetes. The outcome variable was diabetes management; good diabetes management was defined as monitoring blood glucose and foot sores daily as per the American Diabetes Association's recommendation, and engaging in regular physical activity. Independent variables included sociodemographic and healthcare access factors. Weighted, multivariate logistic regression models were constructed to examine the association between independent variables and diabetes management. **RESULTS:** Approximately 28% of the respondents engaged in good diabetes management. Weighted multivariable logistic regression revealed that compared to non-Hispanic Whites, non-Hispanic Blacks were more likely to engage in good diabetes management (aOR = 1.35; 95% CI: 1.24 - 1.47) as were respondents who had prior diabetes management education (aOR = 1.57; 95% CI: 1.48 - 1.67). Respondents who had a high school diploma (aOR = 0.90; 95% CI: 0.83 - 0.97) and did not graduate from high school (aOR = 0.87; 95% CI: 0.79 - 0.98) were less likely to engage in good diabetes management compared to those that had a college degree or higher. Respondents who were never married (aOR = 0.88; 95% CI: 0.80 - 0.98); who did not have a regular provider (aOR = 0.70; 95% CI: 0.60 - 0.81); and who self-reported poor/fair health (aOR = 0.77; 95% CI: 0.71 - 0.84) were less likely to engage in good diabetes management. **CONCLUSIONS:** Race, marital status, education, healthcare provider, and health status are associated with diabetes management. Increasing public health interventions aimed at educating diabetics and removing barriers to good diabetes management might provide a means for improving health outcomes.

PHS113

MANAGEMENT OF MINOR AILMENTS IN A COMMUNITY PHARMACY SETTING: FINDINGS FROM A QUALITATIVE STUDY IN GONDAR TOWN, ETHIOPIA

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OBJECTIVES: The aim of this study was to assess community pharmacists' management practice, and to identify potential barriers in the management of minor ailments in a resource limiting settings. **METHODS:** A qualitative based structured in-depth interview was conducted from May 16 to June 1, 2016. The study participants were recruited through personal contacts and convenience sampling technique. The identified participants were contacted in person or on phone to fix interview appointments. In-depth interview guide was adopted and the content validity of the interview guide was confirmed by a team of experts. The transcripts were then analyzed line by line, read repetitively by the investigators and thematically analyzed for its content. **RESULTS:** One of the main reasons customers encounter in community pharmacies were to get medications for minor ailments and most of the community pharmacists deliver management of minor ailments service. Most of the participants reported that the diagnoses of minor ailments in community pharmacies were entirely depends on history taking. This study also revealed that headache, diarrhea and cough are the most common minor ailments presented in community pharmacies. Moreover, most participants of this study take in to consider sex, age pregnancy status and cost before dispensing drugs for minor ailments. However, lack of training, knowledge and poor community awareness were the barriers to implement the service in community pharmacy setting. **CONCLUSIONS:** In areas where there is shortage of physicians, the communities can access primary health care service in community pharmacies. Though community pharmacists have an important role in the management of minor ailments, lack of training, knowledge and poor community awareness hinders them from appropriately managing patients of various needs.

PHS114

GENDER DIFFERENCES IN HEART FAILURE IN A REAL WORLD CONTEST: IMPACT ON DRUG UTILIZATION AND COSTS FOR THE MANAGEMENT OF THIS CLINICAL CONDITION

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OBJECTIVES: Heart failure has a high burden of morbidity and mortality, which imply substantial healthcare costs. It is the main hospitalization cause in elderly

patients. Gender is important risk factor for CV diseases. Using data from a large Italian database, we analyzed drug utilization and healthcare costs of managing HF from a gender prospective, in a "real world" scenario. **METHODS:** Data from "Osservatorio ARNO Cineca". This report refers to a sample of 54,059 patients with heart failure, for whom hospitalizations, specialist visits, and drug prescriptions, were available. Re-hospitalizations were analysed and costs were evaluated using Italian tariffs during the 1-year follow-up period: drugs, diagnostic and therapeutic procedures, hospitalizations. Mean cost was calculated per patient per year for 1-year follow-up or until death. Gender analysis was performed for a number of variables including drugs use and healthcare costs. **RESULTS:** Women medium age was 80.4 years (± 10.1) and men 75.5 (± 11.4). Distribution by age was different in the two genders: only 25% of women developed CHF before age 75, while 43% of men had CHF before age 75. Hospital admissions were major determinant of costs for management of HF and were analyzed from a gender prospective. Women were more likely to be admitted to general medicine services, while men to cardiology units. 54.6% and 15.2% of women were hospitalized in "General medicine" or "Geriatrics", compared to 44.6% and 12.0% of men, respectively. Only 16.3% and 4.3% of women are admitted to "Cardiology" or "Coronary Heart Disease" units, compared to 23.5% and 9.4% of men, respectively. Men were more likely prescribed ACE-i or ARBs and BB. **CONCLUSIONS:** Our data confirm, in a real world setting that gender makes difference in CV diseases. Moreover, costs for NHS are mainly driven by hospital costs and patient gender seems to influence them, so it must be taken into account.

PHS115

MEDICINES SEEKING AND TAKING BEHAVIOUR AMONG GENERAL PUBLIC IN THE STATE OF PENANG, MALAYSIA

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OBJECTIVES: This study was conducted to evaluate the health seeking behaviour among general public and its associated factors; and to evaluate the medicine taking behaviour in public and the practice of self-medication. **METHODS:** A cross-sectional study was undertaken among general public in Penang Island, Malaysia. A convenience sampling of 888 participants successfully completed the survey. Self-administered questionnaires were distributed among the residents in the north east of Penang Island. **RESULTS:** This study showed that most of the participants chose to consult the doctor when they experience any health problems (66.7%), followed by self-medication (20.9%). The first action for consulting the doctor was significantly predicted by Malay respondents and retired people (OR 3.05, 95% CI 1.04-8.89). The prevalence of self-medication was 54%. The practice of self-medication was significantly associated with Chinese participants, educated people, people with alone living status and people with more self-care orientation. **CONCLUSIONS:** Increasing the awareness of the public about the rational choice of getting medical assistance is a very important issue to control their health. A health education program is needed to increase the awareness about the use of medicines among the general public and to enable them to make the right decisions relating to health problems.

PHS116

TREND IN 30-DAY READMISSION RATES AMONG PATIENTS WITH CONGESTIVE HEART FAILURE: RESULTS FROM A LARGE, SINGLE HEALTHCARE ORGANIZATION

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OBJECTIVES: Congestive heart failure (CHF) is the most frequent reason for hospital admissions and readmissions. Healthcare providers are striving to identify ways to reduce readmission rates to improve patient's health outcomes and avoid penalties. We investigated the trend over time in all cause 30-day readmission rates among patients with CHF in a large, single healthcare organization with 11 hospitals. **METHODS:** Patients with primary diagnosis of CHF admitted between 2008 and 2016, ≥ 18 years and discharged to home, home health, or home infusion were included for analysis. Logistic regression model with Generalized Estimating Equations (GEE) was utilized to account for clustering of repeated admissions within patients adjusted for age, gender, race, insurance, length of hospital stay, and discharge disposition. **RESULTS:** The records of 29,107 CHF patients were reviewed with 14% of these patients having a 30-day readmission. Demographic characteristics define the population as primarily White (49%), more males (52%) and with an average age of 70.5 years (± 14.5). The majority of patients had public insurance (77%) and were discharged to home (60%). Readmitted patients were younger (69 vs 71) and had longer length of hospital stay (5.4 vs 4.5 days). Males were more likely to be readmitted (14.5% vs 13.7%) and so were patients on public insurance (14.7% vs 12.5% for public vs private, respectively). Patients discharged to home health were more likely to be readmitted compared to those discharged to home (15.1% vs 13.5%). A significant downward trend over time was observed in 30-day readmission rates in the fully adjusted model (OR = .96; CI = .94-.97) for this patient population. **CONCLUSIONS:** In an attempt to explore 30-day readmission rates over time in the CHF patient population, we found a steady reduction in 30-day readmission rates over time between the years 2008 and 2016, an encouraging finding from both medical and economic perspectives.

PHS118

HOW EFFECTIVE ARE DIABETES DIGITAL HEALTH TOOLS? A REVIEW OF THE SCIENTIFIC AND MEDICAL LITERATURE 2011-2016

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OBJECTIVES: The objective of this study was to evaluate the effectiveness of diabetes digital health tools in improving diabetic patient outcomes when

deployed in the 'real world'. **METHODS:** A literature review was conducted in PubMed using key terms such as 'diabetes', 'digital', 'health', 'e-health', 'm-health', 'mobile', and 'randomized'. Only English language publications published from 2011 through 2016 were targeted for abstraction. Abstracts were included if they were interventional studies, utilized a parallel group randomized design, enrolled diabetes only patients and evaluated diabetic study end-points. Studies were excluded if they were screening or prevention studies; product feasibility evaluations, meta-analyses; systematic reviews, and small pilot studies (<20 patients). Full articles from study eligible abstracts were retrieved for review. **RESULTS:** A total of 186 abstracts were initially identified and 28 articles (15%) were deemed to be eligible for study inclusion. More than half (57%) of these studies were US studies. 83% of these studies were published between 2014-2016. Three quarters of these studies focused on tools that promoted self-management or improved overall diabetes management. The remainder focused on tools that improved lifestyle education (7%), telemedicine/telehealth (14%), and treatment adherence (4%). A thorough review revealed that across these studies, the populations were small (range: 30-567 patients); were of short duration (range: 30 days-1 year); and had a modest or no impact on glycemic outcomes such as hemoglobin A1-C. (average hemoglobin A1-C difference, active vs. control arms: 0.3%). **CONCLUSIONS:** The effective clinical management of diabetes may be enhanced using digital health technologies. However, a review of the studies conducted recently to evaluate the clinical effectiveness of diabetes-focused digital health tools revealed modest or no impact on important diabetes outcomes.

PHS119

KNOWLEDGE AND PRACTICE OF NURSES TOWARDS PREVENTION OF PRESSURE ULCER AND ASSOCIATED FACTORS IN GONDAR UNIVERSITY HOSPITAL, NORTHWEST ETHIOPIA

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OBJECTIVES: This study was aimed to assess knowledge, practice and factors associated with pressure ulcer prevention among nurses in Gondar University Hospital, North-west Ethiopia. **METHODS:** An institution-based cross-sectional survey was conducted from March 15 - April 10, 2014 among 248 nurses in Gondar University hospital. A structured self-administered questionnaire was used for data collection. Descriptive statistics was used to describe the study population. Bivariate and multivariate logistic regression was also carried out to see the effect of each independent variable on the dependent variable. **RESULTS:** In this study nearly half (54.4 %) of the nurses had good knowledge; similarly 48.4 % of them had good practice on prevention of pressure ulcer. Educational status, work experience and having formal training were significantly associated with knowledge on prevention of pressure ulcer. While, satisfaction with nursing leadership, staff shortage and inadequate facilities and equipment were found to be significantly associated with the practice on prevention of pressure ulcer. **CONCLUSIONS:** Knowledge and practice of the nurses regarding prevention of pressure ulcer was found to be inadequate. Having higher educational status, attending formal training and being experienced were positively associated with knowledge; while shortage of facilities and equipments, dissatisfaction with nursing leadership and inadequate staff number showed negative association with practice of nurse's pressure ulcer prevention. In-service training and upgrading courses are some of the important steps to improve nurses' knowledge and practice on prevention of ulcer pressure.

PHS120

A COMPREHENSIVE REVIEW OF ORPHAN DRUGS POLICIES, PROCEDURE, LEGISLATION, REGULATION, ESTABLISHED IN THE UNITED STATES AND AUSTRALIA

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OBJECTIVES: The objective of the study was to review and evaluate the policies and procedures of orphan drug programs in the US (FDA) and Australian (TGA). The availability of orphan drugs is a major global concern. It is essential to understand the dynamics and the efficiency of these policies to ensure that those who require these resources can get them. Accordance to their current policies on orphan drugs in order to ensure easy access by patients who need them. **METHODS:** A comprehensive Orphan Drug database was reviewed and focusing on data from the FDA and biotech pharmaceutical companies and furthermore the actual information was gathered from the experts, research articles, policy documents, regulatory framework, regulations. Multiple databases such as PubMed, Google Scholar, Springer Links, Scopus, and the Cochrane Library were searched. **RESULTS:** The results of this study found that the Therapeutic Goods Administration (TGA) implemented orphan drug legislation, regulations and policy after the U.S Food and Drug Administration (US-FDA) had initiated to do so in 1983. Regulations and policy tools from both agencies were reviewed with a focus on six broad categories: orphan drug designation; national orphan policies; incentives; marketing authorization; pricing and repayment plan; and marketing exclusivity. **CONCLUSIONS:** Patients with rare diseases have the same right to pharmaceutical products as patients that have more common diseases. The difficulty is enticing drug companies to put the expense and time into the development of orphan drugs that represent only a small portion of the market share. As a solution to the problem, several countries have developed some orphan drug policies, regulation, legislation, that provides incentives to help convince drug companies to develop drugs for the specific populations. Both countries have very nicely managed program in place. Both agencies have similar challenges in terms of availability, affordability and accessibility of the product by patient.

PHS121

USE OF ORAL CHEMOTHERAPY DRUGS AND FALLING INTO THE COVERAGE GAP IN MEDICARE CANCER SURVIVORS

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OBJECTIVES: Given the high costs of oral chemotherapy agents, Medicare cancer survivors are particularly vulnerable to Part D coverage gaps. However, few studies have focused on the economic burden associated with the initiation of oral chemotherapy. We examined the use of oral chemotherapy drugs and the entry rate into the coverage gap for elderly Medicare beneficiaries with cancer. **METHODS:** A retrospective cross-sectional study was conducted using national representative sample obtained from Medicare Current Beneficiary Survey. Cancer patients aged over 65 who continuously enrolled in Medicare Part A during 2006 through 2010 were included in the analysis. Selected oral chemotherapy drugs were identified using pharmacy claims and self-reports. Drug costs and entry into the gap were compared between with vs. without oral chemotherapy. Logistic regression models were used to predict the probability of falling into coverage gap. Generalized linear models were used for healthcare costs. **RESULTS:** The study sample included 7,665 Medicare beneficiaries with cancer. Beneficiaries filling oral chemotherapy agents had significantly higher drug costs (\$7,305 vs. \$2,676; p<0.001) and out-of-pocket costs (\$4,263 vs. \$1,396; p<0.001), compared to those without oral chemotherapy. In 2006-2010, 38.8% cancer beneficiaries without oral chemotherapy reached the coverage gap, while 84.3% beneficiaries having oral chemotherapy reached the gap. After adjusting for socio-demographic and clinical characteristics, the use of oral chemotherapy drugs was associated with a 10.7 times increased risk in reaching coverage gap (Odds Ratio [OR]=11.7, 95% confidence interval [CI]= 8.9-15.5), and \$2,167 more in out-of-pocket costs for prescription drugs. The predictors of falling into coverage gap include race, income, having low income subsidy or other drug benefits, and number of chronic conditions. **CONCLUSIONS:** The majority of beneficiaries receiving oral chemotherapy had high out-of-pocket drug costs and reached coverage gap. Beneficiaries who had low socioeconomic status or more clinical conditions were at particularly high risk for reaching coverage gap.

PHS122

NATIONAL DISEASE AND ECONOMIC BURDEN OF MULTIPLE SCLEROSIS IN TAIWAN

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OBJECTIVES: Multiple Sclerosis (MS) is a rare disease in Taiwan due to its low prevalence. Few studies have estimated the disease and economic burden of MS in Taiwan overtime. This study aims to examine the trends in prevalence of MS and its health related economic burden in Taiwan. **METHODS:** We examined 2003-2014 (12 years) MS-related claims data from National Health Insurance Research Database. We used time series analysis to assess trends in prevalence of MS, and overall healthcare use and expenditures, including drugs. We also compared these burdens between Taiwan and other countries. **RESULTS:** During the 12-year study period, the estimated prevalence of MS increased from 1.8 to 4.7 per 100,000 population, an average rate of 14.68% increase per year. Higher number of patients was found for female (7.35 per 100,000 population) than male (1.98 per 100,000 population), and 35-39 years old female and male patients accounted the highest number in 2014. Total health expenditures for MS treatment increased from US \$2.20 million to US\$9.22 million, however, proportion of health expenditure for patients with MS among all patients with rare diseases decreased from 14.37% to 6.62%. Proportion of drug expenditure divided by health expenditure for all patients with MS increased from 16.92% to 84.18%. Proportion of drug expenditure for patients with MS among all population increased from 0.01% to 0.14%. We found a 9.64-fold difference in average health expenditure and a 31.09-fold difference in average drug expenditure between patients with rare diseases and all patients in 2014. **CONCLUSIONS:** Prevalence of MS and related health/drug expenditures have substantially grown in Taiwan over the past 12 years, but proportion of both health and drug expenditures for MS patients among all patients with rare diseases gradually decreased. Drug expenditures accounted for the increasing proportion of health expenditures. Accessibility and value assessment of drugs for MS treatment are getting important.

PHS123

GEOGRAPHICAL DIFFERENCE IN PROCESSES OF CARE IN CHRONIC KIDNEY DISEASE AMONG MEDICARE PART D ENROLLEES

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OBJECTIVES: Previous research has shown there is a geographical clustering in health behaviors, access to healthcare, and healthcare utilization. Few studies have assessed geographical variation in processes of care in chronic kidney disease (CKD) patients across the United States. This study aimed to explore local variations in receiving nephrologist services, use of angiotensin-converting enzyme inhibitors (ACEIs) and angiotensin-receptor blockers (ARBs), and hospitalization among CKD patients with Part D coverage. **METHODS:** This retrospective cohort study was conducted using the 2013-2014 Medicare 5% sample claim data. CKD patients covered by a stand-alone Part D plan were selected. A one-year baseline period (2013) was applied to assess patients' medical history, and utilization of health services was assessed for year 2014. Geographically weighted logistic regression was used to explore predictors of using ACEIs/ARBs. In addition, utilization rate of nephrologist services, ACEIs/ARBs, and hospitalization rate were calculated at county level. Moran's I was calculated to examine spatial autocorrelation at county level and results were presented in spatial maps. **RESULTS:** A total of 100,159 CKD

patients residing in 3022 counties of the United States were selected. About 27%, 56% and 36% of them had receiving nephrologist services, ACEIs/ARBs and experiencing hospitalization in 2014. CKD patients with non-white race, having mild and moderate damage, having onset of diabetes and hypertension were more likely using ACEIs/ARBs (all $p < 0.05$ in multivariate geographically weighted regressions). Patients with Part D Low-income subsidy were less likely using ACEIs/ARBs. Significant spatial clustering was observed in all of investigated health services. **CONCLUSIONS:** Findings from this study indicated there were spatial effects associated with use of nephrologist services, guideline-recommended ACEIs/ARBs, as well as hospitalization. Local interventions are needed to promote access to healthcare, healthcare utilizations, and in turn reduced CKD disparities.

PHS124

STATIN UTILIZATION AMONG PATIENTS WITH DIABETES IN AN EMPLOYEE SPONSORED PHARMACIST PROGRAM

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OBJECTIVES: Upon enrollment in the Patient Pharmacist Partnerships (P3) program, pharmacists conduct Comprehensive Medication Therapy Management (CMTM) monthly for the first three months, and then quarterly thereafter, with medications lists documented at each encounter. Statin use is recommended among patients with diabetes and utilization of this medication is indicative of good quality diabetes care. Quality metric NQF# 2712 assesses the proportion of people with diabetes aged 40-75 years on a statin. The objective of this study is to characterize changes in the use of statin therapy among P3 enrollees with diabetes. **METHODS:** The dataset used includes medication lists of P3 enrollees from each encounter in the mid-Atlantic region from two participating employers. Patients were included in the study if they were between 40-75 years old and had diabetes defined by the presence of anti-hyperglycemic medication and followed-up in at least one additional time point. NQF# 2712 is the proportion of statin utilized among diabetes patients. Therefore, we used chi-square tests to assess changes in this quality indicator at each time point (0.5, 1, 1.5, and 2 years) compared to program entry. **RESULTS:** There were 401 enrollees with at least 1 encounter with mean age of 56.4 years (SD: 7.7), 215 (53.6%) female, and 203 (50.6%) white. The proportion of statin utilization (range 27.5%-28.1%) ($p > 0.05$) remained unchanged at 0.5 and 1 years. At 1.5 and 2 years, there were increases in statin utilization from 24.24% to 28.79% ($p < 0.05$), and from 23.38% to 30.09% ($p < 0.05$), respectively. **CONCLUSIONS:** Overall, statin utilization among P3 enrollees with diabetes is low. However, at 1.5 and 2 years after entry, there was a higher percentage of enrollees utilizing statins. P3 pharmacists improved statin use at time points greater than one year from entry into the program highlighting their contribution in improving statin utilization and this quality measure.

PHS125

ESTABLISHING SCREENING STRATEGIES FOR PROSTATE CANCER PATIENTS (ESCAPE)

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OBJECTIVES: Prostate cancer (Pca) screening has generated considerable controversy after recent recommendations to discontinue the use of the prostate-specific antigen (PSA). Our objective was to propose effective screening strategies for promoting early detection of Pca. **METHODS:** We applied generalized odds ratio hazards (GORH) model for interval-censored data to the Pca subset of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening trial data. The final regression analysis on the PLCO data provided accurate estimates of the effects of significant risk factors for Pca and an estimate of the cumulative incidence function (CIF) which was used to propose the screening strategy. Participants with < 2 PSA tests and those with missing values in important risk factors were excluded. Risk models depicting probabilities of developing Pca in the next 't' years were generated using 5 year age increments. **RESULTS:** The final dataset consisted of 33735 subjects. Majority of participants were on average 62 years of age, non-hispanic White males. About 89% of participants had not developed Pca during the course of the trial. Most participants (55%) had undergone 6 PSA tests. About 8% had undergone at least 1 biopsy. Age, race, baseline PSA, biopsy, diabetes and family history of Pca were identified as significant risk factors for the model used to develop the screening strategy. For men studied in 5 year increments beginning at age 50 with a family history of Pca and concurrent diabetes, Asian men were at the lowest risk with significant increase in risk occurring between 6-7 years of follow up, followed by White men. African American men had the highest risk of developing Pca. **CONCLUSIONS:** Our findings have significant implications for risk assessment for Pca by race and time elapsed since 50. How the risk factors and PSA values affect likelihood of Pca can help identification of specific and sensitive screening strategy.

PHS126

RACIAL AND ETHNIC DISPARITIES IN MEETING MTM ELIGIBILITY CRITERIA BASED ON STAR RATINGS COMPARED TO MMA

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OBJECTIVES: Racial and ethnic disparities were found in meeting Medication Therapy Management (MTM) eligibility criteria implemented under Medicare Modernization Act (MMA). Therefore, the objective is to examine whether an

alternative MTM eligibility standard based on Medicare Part D Star Ratings system can reduce racial and ethnic disparities. **METHODS:** The study analyzed 2012-2013 Medicare claims data for 3 million beneficiaries. Patients were considered MTM-eligible if they had any issues with measures of medication utilizations in Star-Ratings. Logistic regression and Blinder-Oaxaca approach were used to test disparities in meeting eligibility criteria of Star-Ratings across racial/ethnic groups. Multinomial logistic regression was used to examine whether there was disparity reduction by comparing individuals who were MTM-eligible under MMA but not Star-Ratings and those who were MTM-eligible under Star-Ratings but not MMA. Disease-specific analysis was conducted for each of the top ten MTM-targeted chronic conditions. Main and sensitivity analyses were conducted for MMA-based thresholds (used in 2009 and 2013 by Part D plans, and proposed for 2015 by the Centers for Medicare & Medicaid Services) and Star-Ratings measure combinations. **RESULTS:** Adjusted odds ratios to non-Hispanic Whites (Whites) were 1.394 (95% Confidence Interval (CI)=1.375-1.414) for non-Hispanic Blacks (Blacks) and 1.197 (95% CI=1.176-1.218) for Hispanics, indicating likelihood of MTM eligibility under Star-Ratings 39.4% higher among Blacks and 19.7% higher among Hispanics than Whites. Disparities were not completely explained by difference in patient characteristics based on Blinder-Oaxaca approach. Multinomial logistic regression found significant racial and ethnic disparity reduction in main analysis, e.g., Black-White and Hispanic-White disparities in MTM eligibility were reduced by 55.1% (Relative Risk Ratios (RRR)=0.449, 95% CI=0.434-0.465), and 45.6% (RRR=0.544, 95% CI=0.521-0.569), respectively, when using Star-Ratings compared to 2013 MMA criteria. Similar patterns were found in sensitivity and disease-specific analyses. **CONCLUSIONS:** Star-Ratings criteria would reduce racial and ethnic disparities in the general Medicare population and those with specific chronic conditions.

PHS127

THE EFFECT OF INSURANCE COVERAGE AND COPAYMENT LEVELS ON DILATED EYE EXAMS FOR PATIENTS WITH DIABETES MELLITUS IN A US NATIONAL SAMPLE

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OBJECTIVES: Insurance coverage has been suggested as a potential barrier of routine dilated fundus eye examinations (DFEs). This study was to assess the associations between insurance coverage and/or copayment levels on performing DFEs among patients with diabetes. **METHODS:** Using the 2009-2014 Medical Expenditure Panel Survey two-year longitudinal files, diabetic patients aged 18-75 years old were identified. Insurance coverage was categorized into 1) none; 2) any private; 3) public insurance only; and the quartiles of copayments for ophthalmologist/optometrist visits (\$0, \$1-\$15, \$16-\$40, > \$40) were investigated using year 1 data. DFEs were determined at year 2 through a self-reported questionnaire and ≥ 1 ophthalmologist/optometrist office visits. Multivariate logistic regressions were used to investigate the associations between insurance coverage and/or copayments and DFEs controlling for covariates and applying sampling strata and weights. **RESULTS:** A sample of 4,186 adult patients with diabetes was identified of which 9.7% was uninsured, 60.1% had any private insurance, and 30.2% had only public insurance. About 61.7% of the total respondents reported the receipt of DFEs at year 2, however, only 45.2% of those had ≥ 1 ophthalmologist/optometrist office visits. Insurance coverage was highly associated with higher odds of DFEs [adjusted odds ratios (OR) (95% CI) = 4.09 (1.81-9.26) for any private insurance vs. uninsured; OR = 3.18 (1.31-7.73) for public insurance vs. uninsured]. The copayment levels were also associated with DFEs. Less than \$40 of copayments was associated with higher odds of DFEs compared to > \$40 [OR = 2.02 (1.12-3.65) for \$1-\$15 vs. > \$40; OR = 1.69 (1.08-2.65) for \$16-\$40 vs. > \$40]. Older age, longer duration of diabetes, and higher education levels were also associated with higher odds of DFEs. **CONCLUSIONS:** Insurance coverage as well as lower copayments were associated with a likelihood of receiving DFEs in patients with diabetes. Future value-based insurance design efforts may be necessary to increase adherence to DFE recommendations.

PHS128

DO MEDICAL HOMES INFLUENCE HEALTHCARE UTILIZATION RATES AND PROCESS OF CARE MEASURES?

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OBJECTIVES: This study sought to compare healthcare utilization rates and process of care measures between patient populations served by physicians affiliated with newly established medical homes (MH) and those not affiliated with MHs. **METHODS:** This population-based cross-sectional study of 2015 administrative healthcare data from the Local Health Authority of Parma, Emilia-Romagna, Italy included all residents ≥ 14 years old. Utilization measures included hospital admissions, including ambulatory care sensitive conditions (ACSC) hospitalizations, readmissions, pharmacy, specialty services such as diagnostic imaging, and emergency department (ED) visits. Process of care measures comprised diabetes care metrics (e.g., HbA1c monitoring, microalbumin, eye exam). Negative binomial regression models using generalized estimating equations (GEE) compared healthcare utilization rates and logistic GEE regression models compared the prevalence of process of care measures between populations of MH patients and non-MH patients. **RESULTS:** The study population comprised 368,917 residents. Age and gender distributions were similar between patients cared for (32.1%) and not cared for (67.1%) in MHs. Multivariable adjusted hospitalization rates overall (IRR 0.98; 95%CI: 0.95-1.01) and for acute ACSCs (IRR: 1.02; 95%CI: 0.87-1.19) were similar. The hospitalization rate for chronic ACSCs (IRR: 0.86; 95%CI: 0.74-1.00) and the ED visit rate (IRR: 0.86; 95%CI: 0.81-0.91) were

lower among patients in MHs. MH patients had lower readmission rates for select chronic conditions. Rates of specialty service use and pharmacy utilization were comparable between groups. Within the sub-population of 25,223 with diabetes, a larger proportion of MH patients obtained recommended diabetes care processes than non-MHs patients. **CONCLUSIONS:** This early evaluation of recently implemented MHs suggests that while aggregate measures of inpatient utilization were similar between groups, differences may exist in the rates of ED utilization, readmission, and hospitalization for chronic ACSCs. Longitudinal research will help elucidate processes and outcomes of care for populations served by MHs.

PHS129

SERIOUS PSYCHOLOGICAL DISTRESS AND EMERGENCY DEPARTMENT USE AMONG ADULTS WITH MULTIMORBIDITY IN THE UNITED STATES

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OBJECTIVES: We sought to 1) examine the association between serious psychological distress (SPD) and emergency department (ED) use among adults with multimorbidity in the US and 2) investigate the association between SPD and the reasons for ED use. **METHODS:** A cross-sectional, retrospective, observational study design was conducted using data from the 2014 National Health Interview Survey (NHIS). The study sample consisted of 13,708 US adults with multimorbidity. Chi-square tests were used to examine unadjusted subgroup differences. Multivariable logistic regression models were used to assess the association between SPD and ED use. Among ED users, adjusted logistic regression models were conducted to examine the association between SPD and the reasons for the ED use in the past 12 months. **RESULTS:** After controlling for other variables, adults with SPD were more likely to use ED than those without SPD (AOR = 1.73, 95% CI = 1.40, 2.15). Among ED users, we found that adults with SPD were more likely (AOR = 1.43, 95% CI = 1.03, 1.98) to report "the clinic was not open" as the reason for using ED than those without SPD. **CONCLUSIONS:** Combination of SPD and multimorbidity was associated with higher ED use. Inconvenient clinic hours were more likely to be reported by adults with SPD as the reason for their ED use. Management programs addressing SPD among adults with multimorbidity are needed to minimize the risk of ED use.

PHS130

DOES ROUTINE SCREENING FOR CARDIOVASCULAR RISK FACTORS WIDEN MEDICINE INEQUALITIES IN HEALTH? : A SYSTEMATIC REVIEW

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OBJECTIVES: Primary care treatment approaches for cardiovascular diseases (CVD) focus on intervening individual's lifestyle choices through identifying and reducing modifiable risk factors for CVD such as blood pressure and cholesterol. While screening for cardiovascular disease risk targets to reduce CVD risk factors in high-risk individuals, it tends to benefit the predominant population and those with more socioeconomic ability. The aim of this review is to understand the impact of CVD screening on health inequalities. This systematic review investigates the uptake rates of health checks for multifactorial cardiovascular disease (CVD) risk factors to understand their impact on socioeconomic inequalities in health. **METHODS:** We searched Medline, Cochrane Database of Systematic Reviews; Cochrane Central Register of Controlled Trials (CENTRAL); Cochrane Methodology Register; Database of Abstracts of Reviews of Effects (DARE); NHS Economic Evaluation Database (EED); Health Technology Assessments Database (HTA); and Econlit. We selected all studies conducted at primary/ community care level, which screens for CVD multifactorial risk factors with uptake and risk factors as outcomes for all population and geographical location, published between 1985 and 2016. **RESULTS:** The included studies evaluated CVD health checks in various screening sites, including those conducted in General Practitioners' clinics. There was a higher likelihood of women attending health checks when compared to men. Uptake of health checks was less likely in men from low socioeconomic status. Higher uptake rates in health checks were detected in the less deprived and older age groups. Some evidence also observed higher prescription and uptake rates of health checks in south Asian patients. **CONCLUSIONS:** Socioeconomically disadvantaged population benefits less from screening for cardiovascular disease risk factors due to a generally low uptake rate. While CVD screening reduces CVD risk factors, it could threaten the socioeconomic inequalities gap. Further research could be conducted to combat the specific health inequalities.

PHS131

INEQUITY IN HEALTHCARE ACCESS IN ASIAN COUNTRIES WITH REPORTEDLY HIGH UNIVERSAL HEALTH COVERAGE LEVELS

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OBJECTIVES: To investigate inequity in access to inpatient and outpatient healthcare under universal health coverage (UHC) schemes in countries across Asia with reportedly high levels of coverage. **METHODS:** A pragmatic literature review was conducted using PubMed and Google Scholar. The most frequently reported measure of inequity was the concentration index (CI). This index demonstrates the concentration of healthcare resource distribution; a score of 0 indicates equal distribution, while values >0 indicate resource is disproportionately concentrated on the rich and values <0 on the poor. Comparisons of CIs

before and after implementation of UHC and between rural and urban areas were conducted along with analysis of the relationship between CIs, UHC levels and government expenditure on healthcare (GEH). **RESULTS:** Data were available for China, Korea, Thailand and Taiwan. Both before and after UHC implementation in Korea and Thailand, CIs for inpatient and outpatient care were marginally in favour of the poor. In China, healthcare was generally concentrated on the rich, although the CIs reduced after UHC. Data for urban versus rural areas were available for Thailand, where there was a pro-poor CI (CI=-0.14) for inpatient care in urban areas but almost equal healthcare distribution (CI=-0.04) in rural areas. Across all four countries, higher levels of UHC and GEH (2013 Purchasing Power Parity) corresponded to lower CIs for outpatient care, with strong negative correlations ($r=-0.7414$ and $r=-0.50721$, respectively). Negative correlations, albeit weaker, were also observed for inpatient care ($r=-0.2814$ and $r=-0.34833$, respectively). **CONCLUSIONS:** Despite reportedly high levels of UHC in China, Korea, Thailand and Taiwan, inequities in access to inpatient and outpatient care were identified, and increasing UHC coverage and GEH were correlated with increasing distribution of healthcare resource towards the poor. Furthermore, the situation in Thailand highlighted a discrepancy in access to healthcare between urban and rural populations.

PHS132

STATUS ANALYSIS OF HOSPITALIZATION UTILIZATION AMONG DIFFERENT TYPES OF MEDICAL INSTITUTIONS WITHIN BEIJING URBAN EMPLOYEE BASIC MEDICAL INSURANCE SCHEME: A CASE STUDY OF A CERTAIN ONCOLOGY INSTITUTION

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OBJECTIVES: China has entered the era of universal health insurance, and Urban Employee Basic Medical Insurance Scheme (UEBMS) is one of the most important parts. Cancer is the first cause of death, but there is a lack of data on its status in health care system. This study analyzed hospitalization utilization among tertiary General Hospital (GH), Traditional Chinese Medical Hospital (TCMH), Specialized Hospital (SH) within UEBMS in Beijing, and identified an Oncology Specialized Hospital (OSH) for typical case. **METHODS:** We used official database released by Municipal Bureau to disclose the status from 2013 to 2016 (The year 2016 only contained the first three quarters). Indicators covered average hospitalization expense (AHE), drug proportion (DP) and actual compensation rate (ACR). Two-way ANOVA test was adopted on comparison among different types of medical institutions. **RESULTS:** There were 53 GH, 21 TCMH and 18 SH tertiary hospitals in 2015, and respectively the number of hospitalized patients were 637,130,90 thousand, the hospitalization costs were 12.65,2.37,1.94 billion RMB. The average annual growth rate among SH, GH, TCMH and OSH were 2.44%, 2.98%, 4.07% and 4.16% in AHE, and cost ranged in 20909-22479, 19008-20756, 16958-19113, and 17163-19949 RMB respectively; by ANOVA test, $R^2=0.946$, year $F=12.66$ ($P=0.001$), institutional type $F=39.46$ ($P=0.000$). SNK test showed that institutions can be divided into three levels of OSH&TCMH, GH and SH in AHE ($P<0.001$). The average annual descending rate among OSH, TCMH, SH and GH were 0.13%, 1.54%, 1.75% and 3.00% in DP, and the ratio ranged in 49.3%-50.0%, 42.0%-44.0%, 31.2%-32.9% and 38.7%-42.5% respectively; $R^2=0.992$, year $F=5.02$ ($P=0.026$), institutional type $F=20.36$ ($P=0.000$). The average annual descending rate of TCMH, GH, SH and OSH were 0.05%, 1.06%, 1.57% and 3.04% in ACR, and the ratio ranged in 80.4%-80.9%, 71.5%-73.8%, 66.1%-69.3% and 57.9%-63.57% respectively; $R^2=0.986$, year $F=4.36$ ($P=0.037$), institutional type $F=36.51$ ($P=0.000$). SNK showed that there were significant differences among all four groups in DP and ACR ($P<0.001$). As for OSH, 75.6-78.4% accounted for out-of-pocket payment. **CONCLUSIONS:** The GH took the predominant role in UEBMS medical service market. The TCMH had the lowest AHE but the highest ACR. The AHE and DR of SH were relatively high, but had the lowest ACR. The out-of-pocket expenditure of OSH concentrated on drugs.

PHS133

EFFECT OF PAY-FOR-PERFORMANCE IN PRIMARY HEALTH CARE ON INFANT MORTALITY: EVIDENCE OF SYNTHETIC CONTROL FOR ARGENTINA

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OBJECTIVES: To analyse whether the pay-for-performance mechanism proposed by the SUMAR program - a maternal and child health program implemented in Argentina in 2004 (then called Plan Nacer) - had a causal effect in reducing the infant mortality rate (<1 year), neonatal mortality rate (<28 days) and under-five mortality rate in the country. **METHODS:** Because the SUMAR Program was implemented in Argentina and not in other middle-income countries, the Synthetic Control Method (Abadie and Gardeazabal, 2003; Abadie, Diamond and Hainmueller, 2014) is used to construct a counterfactual for the country as a convex combination of a set of control countries. To do this, a panel of data was constructed from information published by the World Bank, where the observation units are each of the middle-income countries and the time period analysed is 1990-2015, with Argentina being the unit treated and the year 2004 the beginning of the intervention. **RESULTS:** After the implementation of the incentives proposed by the SUMAR Program there was a moderate reduction in the infant mortality rate in Argentina in relation to the synthetic control. In particular, there was a decrease of 1.41 percentage points (p.p.) in the infant mortality rate, a reduction of 0.86 p.p. in the neonatal mortality rate and 1 p.p. in the under-five mortality rate. These results appear to be robust for a series of placebo experiments. **CONCLUSIONS:** It is expected that the results obtained in this work will contribute to the informed debate on the role of payment mechanisms and the results of maternal and child health in low- and middle-income countries, with the intention of designing and implementing care policies more timely and efficient for the vulnerable population.

PHS134

KEYS TO YOUR CARE: A MATERNITY HEALTH PROGRAM DRIVES IMPROVEMENTS IN PRENATAL/POSTPARTUM CARE AND INFANT BIRTH WEIGHTS

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OBJECTIVES: Early, periodic maternity care is important in managing risk for delivering low birth weight (BW) babies. Keys to Your Care® (K2YC) is a Pennsylvania-based maternity engagement program that helps pregnant members schedule maternity checkups, provides evidence-based resources for improved self-care, and connects high-risk members to maternity care management. **METHODS:** Outreach to pregnant Medicaid managed care members was followed by enrollee engagement in English or Spanish up to twice weekly through text messaging and login to a mobile-optimized website. Gift cards, baby supplies, and portable cribs were sent to participating members who met the appropriate engagement criteria throughout the length of the program. Primary outcome measures included percent of members with a claim in first trimester (PPC1) and postpartum care 21–56 days post-delivery (PPC2), frequency of ongoing pregnancy care making $\geq 81\%$ of recommended visits (FPC), and frequency of low BW events. **RESULTS:** Between April 2 and December 31, 2016, 2,654 subjects [median age, 27 years; interquartile range (IQR), 23–31 years] had claims for 9,049 prenatal and postpartum visits (median, 11 visits/subject; IQR, 8–14 visits; 1,426 deliveries). Importantly, 6.5% of participants enrolled in K2YC before their first prenatal claim. The median gestation ages were 23.1 weeks and 39.3 weeks during opt-in and delivery periods, respectively. Median infant BW was 3,203 g (IQR, 2,892–3,515 g); 55.9% delivered at normal BW (range, 2,500–3,999 g) versus 52.7% in the nonparticipating control cohort (N=3,948). High-, low-, and very low-BW babies accounted for 3.4% ($\geq 4,000$ g), 5.8% (1,500–2,499 g), and 1.1% ($< 1,500$ g), respectively (control: 4.1%, 6.5%, and 2.8%, respectively). Other performance measures were: PPC1, 82.68%; PPC2, 59.78%; and FPC, 56.46% (control: 73.98%, 62.24%, and 48.52%, respectively). **CONCLUSIONS:** K2YC alerted care managers of pregnancies (often before first member claim), increased the number of maternity checkups and BWs of delivered babies.

PHS135

TRENDS IN REALIZED ACCESS TO RECOMMENDED CARE AMONG US ADULTS WITH DIABETES

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OBJECTIVES: The Affordable Care Act may produce significant changes in preventive and recommended care by improving access and eliminating cost barriers. The aim of this study was to (1) estimate realized access to recommended tests among adult diabetes populations and (2) examine the equity of access to the recommended care. **METHODS:** Data from the Medical Expenditure Panel Survey from years 2012 and 2014 was used to determine annual realized access to recommended care among people with diabetes. Recommended care was defined per recommendations of American Diabetes Association and included—bi-annual HbA1c testing and annual foot, eye, cholesterol test and flu vaccination (5 recommended tests/services). Population characteristics of diabetes populations during years 2012 and 2014 were compared using descriptive statistics. Hierarchical logistic regression was used to determine the equity of access. The outcome variable was defined as receipt of four or five of the preventive tests/services. The predictors were categorized into three broad categories including Predisposing, Enabling and Need. Access to care was considered equitable when need factors were the main determinants of healthcare use. **RESULTS:** In 2014, realized access was highest (86% [CI 84.07%–87.94%]) to annual cholesterol test followed by the foot exam (70.5% [68.22–72.87]). Similar trends were observed in 2012. Access to the bi-annual A1c test was lowest compared to all other measures in 2014 (58.1% [55.28%–60.89%]) as well as 2012 (55.8% [52.94–58.74]). Realized access to four out of five tests/services in 2014 remained very low as well (23.3% [20.87–25.69%]). Results obtained from hierarchical logistic models for both the years, 2014 as well as 2012, confirmed that access was driven still by predisposing and enabling factors rather than need. **CONCLUSIONS:** Despite policy changes that supported increased potential access, realized access to recommended care among adult diabetes populations remained low.

PHS136

CANCER CENTRE FOLLOW-UP CARE OF CANCER SURVIVORS: A POPULATION-BASED ANALYSIS

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OBJECTIVES: To investigate (1) patterns of cancer centre routine follow-up (CC-FUP) care for breast, colorectal, gynecological, and prostate cancer survivors; (2) factors associated with receipt of CC-FUP; and (3) changes in CC-FUP over time. **METHODS:** From the Nova Scotia Cancer Registry, we identified all persons diagnosed in Nova Scotia, Canada, with an invasive breast, colorectal, gynecological, or prostate cancer between 01/01/2006 and 31/12/2013. We linked this population-based dataset, at the patient level, to cancer centre/clinic and census data. Next, we identified a non-metastatic survivor cohort (n=12,267) and developed decision rules to differentiate routine follow-up visits from non-routine visits during the follow-up care period (commencing one year post-diagnosis). Descriptive statistics were computed to describe patterns of care by patient and provider characteristics. Negative binomial regression was used to examine factors associated with the number of CC-FUP visits received and changes over time, adjusting for other covariates. **RESULTS:** Nearly half of survivors (48.4%) had at least one CC-FUP visit, which varied by disease site (range: 30.2–62.4%). Variation existed across providers,

with six oncologists providing 34.7% of the CC-FUP visits to the study population. Disease site and stage at diagnosis were associated with receipt of CC-FUP care. For instance, gynecological cancer survivors had more visits [incidence rate ratio (IRR)=1.48, 95% confidence interval(CI)=1.34–1.64] whereas colorectal cancer survivors had less (IRR=0.45, 95%CI=0.40–0.51) compared to breast cancer survivors. Sex and geography did not impact the likelihood of receiving CC-FUP visits. Year of diagnosis was associated with receipt of CC-FUP care, with each successive calendar year associated with an 8% increase in visits (IRR=1.08, 95%CI=1.07–1.10). **CONCLUSIONS:** Despite evidence that follow-up care can be effectively and safely delivered in primary care, and intensifying demands on oncology services, many survivors continue to receive CC-FUP. Tailored interventions may improve survivors' discharge to primary care post-treatment.

PHS137

HEALTH INSURANCE AND FEMALE LABOUR FORCE PARTICIPATION IN RURAL CHINA

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OBJECTIVES: In 2003, a heavily subsidized voluntary health insurance scheme - the New Cooperative Medical Scheme (NCMS) - was launched for rural residents in China. This paper investigates the impact of the NCMS policy on adult daughters/in-law's informal care-giving and their labour force participation outcomes. **METHODS:** This study is based on data from the China Health and Nutrition Survey, which is a commonly used longitudinal Chinese dataset focusing on health and nutrition of Chinese. We use data from the 2004 and 2006 waves to cover the critical phase of the progressive introduction of the NCMS. We use propensity score matching combined with difference-in-difference estimation to estimate the "average treatment effect on the treated". Our method addresses the selection bias resulting from the voluntary enrolment in the health insurance plan. **RESULTS:** Our results show that the NCMS has significantly decreased the propensity of older Chinese needing care and has significantly increased adult daughters/in-law's working hours. We also find heterogeneous impacts across household income groups. Older Chinese in low-income household group benefit more from NCMS enrolment in terms of care demand. **CONCLUSIONS:** Our results suggest that the NCMS helps to reduce health inequality in rural China. The paper contributes new findings to the literature on the beneficial impact of government-sponsored health insurance on health, informal care and labour markets in developing countries.

PHS138

IDENTIFICATION OF PATIENTS AT-RISK FOR 30-DAY READMISSION WHO SHOULD BE INCLUDED IN PREVENTION INTERVENTIONS: ASSESSMENT OF HOSPITAL AND COMMUNITY HEALTHCARE PROVIDERS

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OBJECTIVES: Increasingly, big-data electronic health record warehouses are used for developing and implementing high-risk identification algorithms for targeted readmission prevention programs (RPPs). However, the ability of these electronic tools to accurately detect the "appropriate" patients for RPP according to personal and clinical characteristics (termed "care sensitivity") has not yet been established. The aim of the study is to examine the ability of electronic readmission prediction risk tools to detect care-sensitive patients for inclusion in RPPs. **METHODS:** Hospital physicians and nurses and primary care physicians and nurses were asked to complete a questionnaire on the clinical characteristics of discharged patients. The questionnaire assessed the degree to which each patient's automated risk score for 30-day readmission was care-sensitive and the degree to which the patient should be included in RPPs. The correlations between hospitals' and clinics' healthcare provider's assessments and between physicians' and nurses' assessments were examined. **RESULTS:** A total of 605 questionnaires regarding 276 patients were completed by physicians and nurses. Among patients with low risk scores (i.e., 0–39), both hospital physicians and clinic nurses found that 17% of the patients should have been included in RPPs whereas hospital nurses thought 28% should have been included. Among patients with high risk score (i.e., 50+), 17%, 28%, and 42% should not have been included in RPPs according to hospital nurses, hospital physicians, and clinic nurses, respectively. A significant correlation was found between hospital physicians and nurses regarding the assessment of patients' risk scores ($r=0.159$, $P=0.018$) and the appropriateness for inclusion into RPPs ($r=0.289$, $P<0.001$). The most common reasons for patients to be included in RPPs were polypharmacy, the need for continuous monitoring, and low adherence. **CONCLUSIONS:** Combining electronic data with patients recorded characteristics allows for better adaptability and synchronization across different healthcare providers and for better selection of patients for inclusion in RPPs.

PHS139

PREVALENCE, INCREMENTAL COST AND RESOURCE UTILIZATION ASSOCIATED WITH OPIOID OVERDOSES IN THE UNITED STATES

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OBJECTIVES: The objectives of this study were to estimate the prevalence of opioid overdoses in prescription opioid users, their family members and in overdose victims with no identifiable source of prescription opioid ("others"), and to estimate incremental costs and resource utilization associated with

opioid overdoses in these groups. **METHODS:** This study was a retrospective analysis using claims data from SelectHealth, a not-for-profit health insurance organization serving members in Utah and southern Idaho. The data were from June 2010 through July 2015. We estimated the prevalence of opioid overdoses by year for each group. For cost estimation, family members and others were collapsed into a "non-medical users" category. We used an incremental cost approach whereby cases (patients who suffered from an opioid overdose) were propensity-score matched to controls (did not suffer from an opioid overdose) and estimated the direct medical costs and resource utilization incurred in each group in the year following an overdose. Generalized Linear Models were used to estimate incremental costs and resource utilization. **RESULTS:** The prevalence of overdoses increased by 84.8% in prescription opioid users (102.8 per 100,000 in 2014), by 37.9% in their family members (8.2 per 100,000 in 2014) and by 179.9% in others group from 2011 to 2014 (23.1 per 100,000 in 2014). Incremental direct medical costs associated with opioid overdose were estimated to be \$65,277 per patient per year in prescription opioid users and \$41,102 (p-values < 0.05) in non-medical users. Overdose-specific costs were estimated to be \$12,111 for prescription opioid users and \$11,070 for non-users. Resource utilization was significantly higher among those who experienced an overdose across all places of service. **CONCLUSIONS:** The prevalence of opioid overdoses increased steadily from 2011 to 2014. Differences between overdose-specific costs and total incremental costs may suggest that overdoses are associated with substantial downstream costs.

PHS140

HEALTH CARE UTILIZATION AND EXPENDITURES FOR CHILDREN WITH SPECIAL HEALTH CARE NEEDS: A CROSS-SECTIONAL ANALYSIS FOR MEDICAID AND PRIVATE INSURANCE ENROLLEES

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OBJECTIVES: To describe the differences in health care utilization and expenditures between Medicaid and privately insured children with special health care needs (CSHCN). **METHODS:** We conducted a cross-sectional analysis using 2013 insurance claims from a payer offering commercial and managed Medicaid coverages in the Upper Midwest. CSHCN were identified using a validate algorithm that applied the CSHCN screener to claims. Inverse probability treatment weighting was applied to balance Medicaid and private insurance cohorts. A standardized fee schedule was used to account for variation in reimbursement rates. We modeled expenditures using a two-part model adjusted for CSHCN characteristics, neighborhood socioeconomic status, and conditions. **RESULTS:** A total of 17,702 CSHCN were included in our sample and 31% had Medicaid coverage. After weighting and adjusted for covariates, CSHCN with Medicaid were more likely than privately insured CSHCN to use care in a hospital outpatient setting (OR=1.192, 95% CI:1.085-1.309) and in places other than hospital and office-based settings, including emergency department (ED: OR=1.794, 95% CI:1.628-1.977), urgent care(UC: OR=1.221, 95% CI:1.089-1.370), and other settings (OR=1.638, 95% CI:1.495-1.796). Medicaid coverage was also associated with a decreased use of office-based services (OR=0.247, 95% CI:0.178-0.341) relative to private coverage, especially visits for evaluation and management. Conditional on accessing care, places other than hospital and office-based settings were associated with significantly higher average expenditures for Medicaid CSHCN (ED=27.3%, p<0.001; UR=9.3%, p=0.027; and other=92.4%, p<0.001), and lower expenditures for hospital inpatient (-36.6%, p<0.001) and outpatient care (18.9%, p<0.001). **CONCLUSIONS:** Medicaid CSHCN relied on ED, UC, and other non-hospital and non-office-based settings as the sources of care. They also had significantly higher average expenditures when accessing care. This access pattern is consistent with the Medicaid literature and suggests that care for Medicaid CSHCN was not optimal. This vulnerable population requires extra attention to develop efficient patterns of care.

PHS141

HOSPITALIZATION COST ESTIMATION MODEL USING A MULTILEVEL ANALYSIS

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OBJECTIVES: To construct a model in order to predict the hospitalization cost of patients based on demographic, clinical and care-associated characteristics. **METHODS:** Based on the records of health care services for more than 3 million affiliates to a Colombian insurer, a base with 68,939 inpatient care services for 1 year was built. The analysis was developed using a regression model, where the dependent variable is the natural logarithm of the hospitalization cost per day and the independent variables were dichotomies. The multilevel model was adjusted using the smearing coefficient. We performed the necessary tests to validate the biggest possible explanatory capacity of the multilevel model: tests of individual statistical significance (t-test) for each variable and the level of explanation of this model compared to others (Chi2 test). **RESULTS:** A multilevel model with three levels was obtained: the characteristics of patients in the first level (age, gender, type of service and diagnosis of admission or discharge), previous comorbidity conditions in a second level and characteristics of Hospital development in a third level. All variables were statistically significant at a 95% confidence level. The multilevel model presented a higher level of explanation compared to the linear model, as indicated by the Chi2 test. **CONCLUSIONS:** It was possible to construct an explanation model that allows to estimate the hospitalization cost in order to be able to improve the management and allocation of the resources.

PHS142

DIRECT COSTS OF MEDICAL CARE FROM INTENSIVE CARE UNITS IN COLOMBIA

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OBJECTIVES: To estimate the direct medical costs of inpatient care, in Intensive Care Units (ICU) from a Colombian government subsidized health insurer. **METHODS:** A sample of 9,763 inpatients from intensive care units distributed in 726 hospitals in 2015. Direct costs of medical care were calculated from the third party payer's perspective, with the micro-costing technique and the bottom-up methodology. Annual average costs were estimated by diagnosis groups and cost centers. Results are shown in international dollars adjusted for purchasing power parity (PPP). **RESULTS:** ICU care represents 13.4% [CI 13.2 - 13.6] of total hospital events and 24.3% [CI 24.19% - 24.42%] of bed days. Cost in ICU amount to 130.5 million PPP\$ which represents 16.4% of the insurer total cost. The most important diagnoses in the ICU cost were: Cardiovascular 23.1%, Perinatal conditions 16.9%, Respiratory 13.3%, Parasitic infections 10.4% and trauma 5.3%. The diagnoses from ICU with the highest cost per stay day were: Cancer - 1,160.7 PPP\$ [IQR 779.1-1,656.8]; HIV- 1,127.6 PPP\$ [IQR 713.5-1,834.4]; Trauma - 1,103.8 PPP\$ [IQR 655-1,744.3]; Benign tumors - 1,065.2 PPP\$ [IQR 615.7-1,537.1] and Respiratory-chronic - 1,017.5 PPP\$ [IQR 635.8-1,531.2]. Hospital stay, medications, diagnostic aids and medical procedures represents 41.2%, 38.3%, 10.2% and 7.4% of the ICU costs respectively. The highest average age group corresponds to people between 15 and 44 years old (mean = 1,198 PPP\$ and median = 968.9 PPP\$) mainly explained by the high impact of gestational care in women and trauma in men. **CONCLUSIONS:** Identifying spending patterns and health services consumption in ICUs, are fundamentals for a planning and efficient allocation of resources in insurance companies.

PHS143

DIRECT AND INDIRECT ECONOMIC BURDEN OF ADULTS WITH RENAL FAILURE: NATIONAL U.S. ESTIMATES USING MEDICAL EXPENDITURE PANEL SURVEY DATA, 2008-2013

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OBJECTIVES: Renal failure (RF) imposes a significant burden on patients, providers, payers, and society. Economic evaluation from a national representative data isn't well-documented. Therefore, the aim of our study was to comprehensively evaluate the direct and indirect cost of RF in the USA. **METHODS:** A cross-sectional study was performed using MEPS 2008-2013. Direct healthcare (HC) cost and indirect cost (employment, wages, missed days, and cost to loss of productivity LOP) were compared between adults with and without RF. Propensity score matching (PS) to control for baseline differences and linear regression with logarithmic transformation to identify predictors of total healthcare expenditure were incorporated. All expenses were adjusted to 2016 USD. **RESULTS:** There was a total of 466 (0.31%) adults with RF compare to 148,045 without RF. RF patients had significantly (p<.0001) higher prevalence of hypertension, diabetes and other important comorbid conditions. With PS, 394 RF were matched to 788 no-RF (1:2 ratio) and the average annual cost per person were \$40,804 vs. \$15,851 (additional cost = \$24,953, p<.0001). Events coded RF-specific had average annual cost of \$16,708 per person. Compared to no-RF, patients experienced significant extra expenses (p<.02) for medications, ambulatory care and medical supplies due to RF disease. RF was significantly associated with lower employment (p<.0001), wages (p<.0001) and more missed days (p<.0034) but insignificant associations were observed post PS matching. The per person annual indirect cost of LOP for RF Patients was \$42,893 before propensity score matching and \$12,466 after (2016 UD dollars). For RF patients, age, gender, ethnicity, region, poverty level, education, insurance type, smoking, key comorbidities and perceived health status were identified as significant independent predictors (p<.0001) for direct total healthcare utilization cost. **CONCLUSIONS:** Compared to the general population, RF is associated with significant economic burden. Further investigation of the causes of higher utilization and expenses in this group is recommended.

PHS144

BUDGET IMPACT ANALYSIS ON A PHARMACIST-PROVIDED TRANSITIONAL CARE PROGRAM

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OBJECTIVES: To estimate the budget impact of adding an outpatient pharmacy-based transition of care (TOC) program to the benefit of a US managed Medicaid health plan. **METHODS:** A dynamic budget impact analysis was conducted using a decision-tree model developed in Microsoft Excel. The effect on inpatient and total healthcare costs from the payer perspective was estimated in the 2-year period following initial hospital discharge. Inputs were based on a total plan population of 240,000 lives, with a high-risk population of 7.5%. The TOC program was assumed to initially cover 30% of the high-risk group, with expansion to 60% over the 2 years. We previously reported that this program reduced readmission risk by 32% and saved the health plan \$2,139 per patient referred, inclusive of program cost. Sensitivity analyses were performed to test the impact of uncertainty of model inputs on the results, with the cost of TOC services ranging from \$99 to \$2,000 per patient referred. **RESULTS:** The model showed that the TOC program was cost-

saving at over \$3 per member per month, translating into over \$25 million in total healthcare cost savings over 2 years. These results were primarily driven by the estimated reduction in inpatient costs associated with the program, which were estimated at \$20 million over the 2 years. Sensitivity analyses illustrated that within all the reasonable ranges of model input parameters, including the upper limit of TOC services set to \$2,000 per patient referred, the TOC program resulted in cost savings to the health plan. **CONCLUSIONS:** The TOC program resulted in cost savings of over \$25 million to the health plan over a period of 2 years.

PHS145

ESTIMATES OF INCREMENTAL HEALTHCARE EXPENDITURES ASSOCIATED WITH DEPRESSION TYPE AND SYMPTOMS AMONG US ADULT POPULATION WITH DIABETES

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OBJECTIVES: Produce national estimates and compare healthcare expenditures associated with depression among adult diabetes populations. **METHODS:** The 2014 Medical Expenditure Panel Survey was used. Presence of diabetes and depression among adult (>18 Years) populations was confirmed using ICD-9-CM and Clinical Classification codes. Participants were classified by (1) presence of depression and (2) presence of depressive symptoms. For the latter, participants were identified as having no depression, unrecognized depression, asymptomatic depression or symptomatic depression based on an algorithm using PHQ-2 Scores and ICD-9-CM codes. Mean unadjusted healthcare expenditures associated with inpatient, outpatient, office-based, emergency room, prescription drugs as well as total healthcare expenditures were compared by depression categories. Adjusted relative healthcare expenditure ratios for each depression category by expenditure type were estimated using multivariate regression analyses with log-transformed data. Disease risk adjustment was made using Charlson Comorbidity Index. **RESULTS:** Based on the weighted sample of 25.6 million adults with diabetes, 18.96% had depression and had significantly greater mean annual total medical expenditures (\$21,351 vs. \$11,710) than those without depression. After adjustment, diabetes adults with depression spent 72% more on annual total healthcare expenditures compared to those without depression (RR = 1.72, 95% CI [1.41, 2.09]). When adults with diabetes were categorized based on the presence of depressive symptoms, 7.3% had unrecognized depression, 12.6% had asymptomatic depression and 6.3% had symptomatic depression. The mean annual total medical expenditures were significantly higher among adults with symptomatic depression (\$23,794) and asymptomatic depression (\$20,125) compared to the adults with unrecognized (\$13,668) depression and no depression (\$11,514), and similar expenditure patterns existed even after adjustment. **CONCLUSIONS:** Among people with diabetes, over 7 percent had unrecognized depressive symptoms. As expected, adults with diabetes and recognized depression had higher healthcare expenditures.

PHS146

MODELING BED NUMBER REQUIREMENTS FOR ISOLATED SURGICAL AORTIC VALVE REPLACEMENT CENTERS

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OBJECTIVES: Modeling the number of hospital beds needed to cover a hospital patient population for isolated surgical aortic valve replacements (sAVR). **METHODS:** To simulate the skewed hospital length of stay (LoS) distribution a 3 layered gamma distribution of hospital LoS was fit to the 2014 Medicare Medpar (N=18,889) reported data. Mean LoS was 8.4 days with a 6.4 day standard deviation. One thousand, 52 week (364 day) simulations were created for each hypothetical hospitals with volumes of 1, 5, 10, and 15 sAVR/week. **RESULTS:** For a center with 1, 5, 10, and 15 sAVR/week volume, the number of beds required to cover 100% of patients for every one of the simulated 364 day period was modeled to be 6, 13, 22, and 30 beds respectively. When reducing patient day bed coverage rates to 95%, 90% and 80%, scale effects can be seen. Low volume centers see no or lower change in required number of beds when compared to higher volume centers. A 95% coverage leads to a substantial reduction in the number of required beds with 1, 5, 10, and 15 sAVR/week centers only requiring 4, 11, 18, and 25 respectively. 90% and 80% coverage rates for a 1 sAVR/week center remained at 4 beds, while a 5 sAVR/week center had a bed requirement of 10 and 9 respectively. 50% coverage for 1, 5, 10, and 15 sAVR/week centers were projected to be 2, 8, 14, and 19 beds respectively. **CONCLUSIONS:** Identifying the number of hospital beds needed to cover a patient population is critical in hospital resource planning. Simulating patient LoS variability can provide insight on the estimated number of beds required to service centers of varying isolated sAVR patient volumes and coverage requirements.

PHS147

IDENTIFICATION OF TYPE 2 DIABETES COST DRIVERS USING MEDICAL BILLING CODES IN ADMINISTRATIVE CLAIMS

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OBJECTIVES: To identify medical billing codes that are cost drivers for Type 2 diabetes. **METHODS:** Medical billing codes were assessed using US administrative claims (Truven Health MarketScan® Database) between 1/1/2010-6/30/2015. Cost drivers were identified for Type 2 diabetes (DB) vs non-diabetes (NonDB) [Group 1] and complicated Type 2 diabetes (CompDB; ICD-9-CM=250.1X-250.9X where x= 0 or 2) vs Type 2 diabetes without complications (NoCompDB) [Group 2]. A random sample (n=500,000) from the DB and CompDB groups were matched 1:1 to the NonDB and NoCompDB groups on age, gender, region, payer type and months of eligibility. An empirical algorithm using code frequency (sensitivity, specificity,

precision or accuracy between comparators and minimum claim counts) and cost parameters (cost ratios between comparators, minimum cost to include or exclude) qualitatively identified procedure, diagnosis and drug codes that differed between cohorts. **RESULTS:** For Group 1, 194 codes accounted for 12.2% of the DB cohort costs and 3.9% of the NonDB cohort. The 12.2% of costs in the DB cohort represented 36.4% of the overall cost difference between the DB and NonDB cohorts. The top qualitatively assigned categories in the DB cohort accounted for >90% of the identified costs and included diabetes-specific codes (51.5%), renal (18.7%), cardiovascular (14.5%), lipid (3.3%) and physician services (3.1%). For Group 2, 303 codes accounted for 17.0% of CompDB cohort costs and 5.9% of NoCompDB cohort costs. The identified costs in the CompDB cohort accounted for 46.4% of the cost difference between cohorts. The top categories in the CompDB cohort, renal (32.4%), diabetes-specific codes (24.7%), infection (7.6%), physician services (6.9%), cardiovascular (5.5%) and wound care (4.2%) accounted for 81.3% of the identified costs. **CONCLUSIONS:** Small code sets accounted for disproportionately large percentages of costs. Use of empirically derived disease-related codes may provide an efficient approach for assessing disease-related costs in administrative data.

PHS148

COSTS OF HOSPITAL ACQUIRED PRESSURE ULCERS

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OBJECTIVES: The purpose of this study was to calculate and analyze the costs of treatment of the Hospital-acquired pressure ulcer (HAPU). **METHODS:** The study was developed as a pair-wise matched (1:2) case control study. The cases were defined by patients who HAPU during the march, 2015 until march, 2016 and the controls have been defined for patients who not developed pressure ulcer at the hospital during the same period. The pairing was carried out age, primary and secondary diagnoses and presence of the comorbidities. Sample were excluded patients who developed PU prior to hospital admission. Costs were obtained in Reais and converted to US dollars considering the exchange rate of R\$ 3.189 per US dollar. **RESULTS:** One hundred eighteen patients with HAPU were identified and fifty four were included in the final analysis. The incremental length of stay (LOS) of the cases was 83 days. Analyzing the results according to the last score collected the Braden Scale, the median costs were \$134,105 for patients with very high risk, \$ 93,840 for high risk, \$ 110,339 for moderate risk and \$ 94,645 for mild risk. Concerning costs, the average cost for cases was higher than for controls. The incremental cost associated with a HAPU episode was \$ 75,311 and the incremental length of stay (LOS) of the cases was 83 days. **CONCLUSIONS:** This study demonstrated the excess LOS and high costs associated the treatment the hospital-acquired pressure ulcer. This result can be avoided with the revision of the protocol for prevention of pressure ulcer by the use of evidence-based practice, adoption of new technologies and the multidisciplinary team based care (nurses, physicians, nutritionist, physiotherapist). In addition, the protocol has the potential to eradicate enormous suffering and save thousands of lives.

PHS149

COST-EFFECTIVENESS ANALYSIS OF SOLID ORGAN TRANSPLANTS IN A PRIVATE, PHILANTHROPIC AND TERTIARY HOSPITAL IN BRAZIL

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OBJECTIVES: To perform a cost-effectiveness analysis of solid organ transplants carried out in a private philanthropic hospital in Brazil. **METHODS:** For cost analysis we included all patients that underwent kidney, liver, heart and lung transplants in 2015 in our Hospital. We collected data about costs per patient including the pre transplant phase (eligibility evaluation for the transplant, listing and outpatient follow up), the transplant and post-transplant phases until 1 year of follow up. Unit costs were associated to each health resource, obtained from the hospital costing system. For the survival analysis we used Cox model, using all the transplants performed from 2002 to 2016 in our institution. For the cost-effectiveness analysis we used the following calculations: 1. Calculation of average cost for each year of life = (average total cost/mean survival time); 2. Calculation of lifespan in years for the repayment of the transplant by the recipient = (average total cost /GDP per capita); 3. Calculation of wealth production after the transplant [(mean survival time)-(average total cost /GDP per capita)*GDP per capita]. The values of GDP per capita and dollar exchange rate were the ones from 12/2015, being US\$ 6.963,94 and BRL 3,91, respectively. **RESULTS:** All types of transplant analyzed here were cost-effective; all of which had a cost of life saved per year less than 3x GDP and the dialysis treatment cost. Considering all of them together, there will still be a wealth production after paying off the treatment, in mean of US\$ 32,672.67. **CONCLUSIONS:** In a private Hospital, where the Transplant Program is funded by the Public Health System, kidney, liver, heart and lung transplants were considered cost-effective therapies. This analysis can support our Hospital Managers and transplant teams to take the best decision in an era of growing chronic diseases.

PHS150

COSTS AND RESOURCE UTILISATION ASSOCIATED WITH COMORBID

CONDITIONS OF TYPE 2 DIABETES PATIENTS IN A SOUTH AFRICAN PRIVATELY MANAGED HEALTHCARE ORGANISATION

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OBJECTIVES: Type 2 diabetes (T2DM) is rapidly becoming one of the most common non-communicable diseases of lifestyle. Managed healthcare organisations view

T2DM as a discrete condition, with little interaction with comorbid conditions. Coronary artery and cerebrovascular diseases are the predominant outcomes in T2DM. The impact of comorbid conditions such as cancer, rheumatoid arthritis and CNS diseases, referred to as discordant comorbidities are rarely considered in resources utilisation studies in T2DM. We compared the costs and resource utilisation of T2DM patients that were either enrolled on a Capitation Model (CM) or a standard Fee for Service Model (FSM). Comorbidities were defined as concordant such as cardiovascular diseases or discordant (e.g.: cancer, major depression). **METHODS:** Data was extracted retrospectively from claims database of adult T2DM patients (n=1060) for the year 2014. Costs per annum for concordant and discordant comorbidities were identified using ICD10 codes. **RESULTS:** The cohort of patients in the CM (n=714) were older than in the FSM (n=346). The resource use per diabetic patient was US\$ 4,075 in the CM and US\$ 4,305 in the FSM. When the capitation fee of US\$ 1,368 per patient per annum was accrued, the average cost per patient was US\$ 5,443 in the CM. The estimated expenditure per patient for the concordant comorbidities was US\$ 2,059 (CM) and US\$ 2,177 (FSM) and US\$ 928 (CM) and US\$ 666 (FSM) for the discordant comorbidities. Resource intensive comorbidities were kidney disease US\$ 7,360 (CM) vs US\$ 15,604 (FSM) and cancer that cost US\$ 1,089 (FSM) and US\$ 2,356 (CM) per affected patient. **CONCLUSIONS:** While capitation models are well-established, our data suggests that in this limited setting, CM accrued similar costs to a traditional FSM. Healthcare systems need to focus on combined integrated multiple disease management in T2DM patients to lower the financial burden.

PHS151

PERSONAL HEALTH DEVICES AND THEIR IMPACT ON HEALTH CARE COSTS AND UTILIZATION AND MEMBER ENGAGEMENT

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OBJECTIVES: Determine if self-monitoring of physical activity using PHDs (Garmin, Fitbit, etc.) affects patient health care costs and utilization. **METHODS:** Analyzed administrative claims records of 1,258 health plan members by their length of PHD usage (3+ months, 6+ months, 9+ months and 12+ months). Compared the cost and count of members' emergency room, office, inpatient and outpatient visits before and after they received PHDs, and the share of costs attributable to preventive services. **RESULTS:** Office visits increased 7% for members who used the devices 9+ months, and 10% for those who used them 12+ months. Total costs increased 21% in the 12+ group. Preventive service office visits increased 14% for the 9+ month group and 12% for the 12+ month PHD usage group. In addition, the total cost of preventive visits increased 11% for those who monitored their physical activity with PHDs for at least 9 months, and 12% for those who monitored their physical activity for at least 12 months. **CONCLUSIONS:** Providing PHDs to health plan members resulted in increased usage and spending on health care services, including preventive health services, in the 12-month period that followed. Follow-up research is needed to determine if the increase in preventive service visits, associated with PHD usage, drives down the need for costly ER and inpatient visits.

PHS152

ECONOMIC EVALUATION OF DIABETES MELLITUS TYPE 2 BURDEN AND IT'S MAIN CARDIOVASCULAR COMPLICATIONS IN THE RUSSIAN FEDERATION

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OBJECTIVES: Diabetes Mellitus Type 2 (DMT2) is a complex medical and social problem in the world and in the Russian Federation also due to prevalence (5.4% in population) and probability of cardio-vascular complications (CVC). Economic burden evaluation of DMT2 and it's main CVC complications in the Russian Federation is unknown. **METHODS:** Complex analysis of expenditures (direct and non-direct costs) based on epidemiological, pharmacoeconomics and clinical investigations, real world studies, population and medical statistics data. **RESULTS:** Calculated expenditures for DMT2 in the Russian Federation are 569 bln RUR (\$8,247 bln) per year, that is correspond to 1% of the Russian GDP, and 34.7% of that are expenditures for main CVC (ischemic heart disease, cardiac infarction, stroke). Main part of expenses are non-medical (losses GDP) due to temporary and permanent disability, untimely mortality - 426.7 bln RUR (\$6,185 bln) per year. Expenses of the Healthcare System (direct medical cost) in the general structure of expenditures were equal to 8.72%, direct non-medical cost (social security budget) - 16.26%, economic losses are - 75.02%. Expenditures in estimated group of patients with non-diagnosed DMT2 but with already having CVC were at least 107 bln RUR (\$1,550 bln) per year (18.8% from total cost). Relationship between cost of DMT2 and degree of it's control was found in the Russian conditions. Estimated cost for compensated patient (HbA1c<6.5%) per year was 88 982 RUR (\$ 1290), in the same time cost of non-control patient (HbA1c>9.5%) was in 2.8 times higher due to more often main CVCs in this group. **CONCLUSIONS:** DMT2 diagnosis improvement as well as effective treatment of early stages of illness can decrease probability of CVC and social economic expenditures. Economic efficacy should be calculated as result between additional expenditures for DMT2 effective control and potential savings due to CVC decreasing.

PHS154

IMMEDIACY TRENDS OF EMERGENCY DEPARTMENT (ED) VISITS, AND FACTORS PREDICTING NON-URGENT AND SEMI-URGENT ED VISITS IN THE UNITED STATES

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OBJECTIVES: Study assesses latest trends of emergency department (ED) visits and associated socio-demographic and facility level factors of non-urgent

and semi-urgent ED visits to explore if non-urgent ED visits deserve special attention anymore and if semi-urgent visits should be discussed more closely. **METHODS:** Present study performed retrospective cross-sectional analyses of nationally representative ED visit data from National Hospital Ambulatory Medical Care Survey (NHAMCS) 2006 through 2011. Trend analysis, designed based F test, and weighted multinomial logistic regression were performed as statistical tools. **RESULTS:** Proportion of non-urgent ED visits were decreased each year until 2009 from 14% to 8% and almost got stuck for rest of the years. Most of the non-urgent visits received some sort of diagnostic or therapeutic services. Percentage of semi-urgent ED visits increased largely over the study period (25% to 36%), while proportion of urgent increased little, and immediate and emergent acuity level decreased. In cross tabulation, residence type, source of payment, episode of care, availability of non-urgent fast track, and use of EMR are found significantly associated with all ED visits. In multivariable analysis, patients with Medicaid, no insurance, younger, male, non-Hispanic Black, and who visit in nonurban hospitals are highly likely to visited ED for non-urgent health conditions, whereas, self-pay patients, younger, male, and who visited voluntary non-profit hospitals are highly likely, and Medicare recipients and patient living in nursing home are less likely to visit ED with semi-urgent health conditions. **CONCLUSIONS:** Non-urgent ED visits, along with semi-urgent visits deserve close attention and efforts to reduce these visits should focus on some particular groups who pose higher risks rather than blocking access to EDs.

PHS155

COST-EFFECTIVENESS ANALYSIS OF EARLY CANCER SURVEILLANCE FOR PATIENTS WITH LI-FRAUMENI SYNDROME

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OBJECTIVES: To compare the cost-effectiveness of an early cancer surveillance strategy versus no surveillance for patients with TP53 germline mutations. **METHODS:** A Markov decision analytic model was developed to estimate cost-effectiveness over a lifetime from a US third-party payer perspective. The model consisted of 4 possible health states: no cancer, cancer, post-cancer survivorship, and dead. Model probabilities and costs were populated using estimates from SEER database and published literature. Model outcomes included costs (2015 USD) and effectiveness (life years [LY] gained) of each surveillance strategy and incremental cost-effectiveness ratios (ICERs) comparing surveillance versus no surveillance strategies. Sensitivity analyses examined parameter uncertainty. **RESULTS:** The model showed a mean cost of \$46,496 and \$117,102 and yielded 23 and 27 LY for the non-surveillance and surveillance strategies, respectively. The ICER for early cancer surveillance versus no surveillance was \$17,125 per additional LY gained. Sensitivity analyses showed that probability of tumor development and cost of surveillance had the largest impact on model result. At the commonly accepted willingness to pay above \$50,000/life-year gained, surveillance had a 94% probability of being the most cost-effective strategy for early cancer detection in this high-risk population. **CONCLUSIONS:** Early cancer surveillance is cost-effective for patients with TP53 germline mutations. This is one of the first studies to explore cost-effectiveness of LFS cancer surveillance; the model will continue to improve in accuracy as it is validated with real world data.

PHS156

IMPACT OF AFFORDABLE CARE ACT COVERAGE EXPANSION ON WOMEN'S PREVENTIVE SERVICES

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OBJECTIVES: The Affordable Care Act (ACA) expansion mandated the private health plans to cover women's preventive services starting August 2012. With limited and contradictory evidence, this study intends to assess the impact of ACA on the utilization rates and the cost burden of women's reproductive preventive service. **METHODS:** A pre-post analysis was conducted using nationally representative sample of females (aged 15-44 years, n=4,397) participating in 2011-2013 National Survey of Family Growth. The utilization rates and cost burdens were compared for six services using bivariate and multivariate logistics regression models. **RESULTS:** After the ACA expansion, there wasn't a significant increase in the utilization rates of birth control/prescription (33.7% vs. 30.7%), birth control counselling (17.7% vs. 16.9%), sterilization counselling (3.3% vs. 3.5%), STI counsel/test/treat (15% vs. 14.6%) and HIV screening (24.1% vs. 23.1%). Respondents paying through insurance increased after ACA, but out-of-pocket spending (cost-sharing) didn't decrease for respondents. Type of insurance was an important predictor of utilization rates with publicly insured having significantly higher Odds Ratio (OR) or likelihood of receiving birth control counselling (OR:1.71), sterilization counselling (OR:2.67), STI counsel/test/treat (OR:1.54) and HIV screening (OR:1.69) compared to privately insured. **CONCLUSIONS:** The early-on impact of ACA expansion on utilization rates of women's reproductive preventive services didn't appear to be significant. Private health plans, however, might have expanded their coverage but burden of cost sharing still existed. Future research should evaluate the long term impact of ACA expansion on women's health and the economic gains.

PHS157

CHARACTERIZATION OF SPINAL MUSCULAR ATROPHY POPULATION IN A LARGE US FULLY-INSURED HEALTH PLAN POPULATION

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OBJECTIVES: Characterize a spinal muscular atrophy (SMA) population to identify SMA utilization patterns based on demographics within a large US

health plan. **METHODS:** Descriptive statistics were generated from retrospective analysis on medical and pharmacy claims from Aetna fully-insured commercial and Medicare members between January, 2013 and August, 2016 with an ICD-9/10 code for SMA without age restrictions. Additional analyses were performed to improve specificity due to potential provider miscoding and rule-out claims by comparing members identified with 1 vs. 2 claims of SMA to increase the likelihood of accurate SMA coding. Further specificity analyses were performed to determine the percentage of members with > 1 SMA claim having another SMA claim or followed by a claim for amyotrophic lateral sclerosis, muscular dystrophy, or non-SMA anterior horn disease ("SMA-like conditions"). **RESULTS:** A total of 3,145 unique members with at least one month's eligibility following their Index Date were identified based on > 1 ICD-9/10 and 438 unique members based on > 2 ICD-9/10 claims for SMA, respectively. Of the total group, 96% (> 1 claims) and 80% (> 2 claims) were age 18 and older. Age at first SMA claim ('Index Date') may not reflect initial diagnosis. Only 2.5% of the > 1 claims population later showed claims for an SMA-like condition. **CONCLUSIONS:** The > 2 claims population had more per-patient inpatient and ER visits, and less outpatient claims, health resource utilization (HRU) and generally higher costs, compared with the > 1 claims population. These health services differences may be due to increased likelihood of having SMA, greater concentration of younger members, and/or increased SMA HRU. This analysis provides insight into real-world SMA patient journey through costs and health services utilization considerations for managing SMA and the usefulness of claims data for identifying and characterizing patients with this rare and often devastating condition.

PHS158

HEALTH CARE PROVIDER AND HEALTH CARE FACILITY FOR ADULT FILIPINO PATIENTS HOSPITALIZED FOR CONGESTIVE HEART FAILURE

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OBJECTIVES: To describe the available health care providers and the number and type of health care facilities where Congestive heart failure (CHF) patients were hospitalized in 2014. **METHODS:** This is a cross-sectional descriptive study of patients aged ≥ 19 years old, admitted for heart failure in Philippine Health Insurance (PhilHealth) accredited hospitals. Data were collected from the PhilHealth database and from the website of three specialists, namely: Family Medicine physicians, Internists and Cardiologists. Qualitative data were expressed as frequency and percentage. **RESULTS:** There were 17 regions in the Philippines. The highest number of hospitalized CHF cases was in Region IV-A (13.5%), while least number of cases was 2.2%, found in Region IV-B and Region XIII. Among the specialists, Internists had the number of members (56%) practicing in the Philippines, while Cardiologists were the least (9.0%). National capital region (NCR) had the most number of the cardiologists (58%), Internists (49%) and family medicine doctors (26%). Among the three specialists, Cardiologists had the most number of CHF patients to attend to across 16 regions in the Philippines (excluding Region IV-B). The region with the highest ratio was Region XII (281 cases to one cardiologist). In terms of type of facilities, 68.7% was categorized as tertiary, while 28.9% was secondary. Region IV-A had the highest numbers of tertiary (14%) and secondary hospitals (13.4%). Region IV-B had the lowest number tertiary facilities (0.62%). **CONCLUSIONS:** Region IV-A had the highest number of patients hospitalized for CHF, the highest number of tertiary and secondary hospitals and belonged to the top five regions with the most number of specialists but ranked 9th in the ratio of patients to cardiologist (86 patients for every one cardiologist) The information can help the health advocates/policy-makers identify areas that need more attention in terms of health providers and facilities.

PHS159

KAP ASSESSMENT REGARDING BREAST CANCER: AWARENESS AMONG PAKISTANI FEMALES

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OBJECTIVES: Aim of the study is to assess the awareness, knowledge, attitude and practice regarding breast cancer, its early detection and preventive measures. **METHODS:** Cross-sectional descriptive study was conducted in the using Breast Cancer Awareness Measure (B-CAM) v2 of validated survey instrument. Chi square and logistic regression statistical tools were chosen for the analysis of study dependent variables and to evaluate the association strength between parameters on SPSS 20. P value of ≤ 0.05 was considered statistically significant. **RESULTS:** More than half of the respondents had insufficient knowledge of sign and symptoms, risk factors and breast cancer screening methods available but 89% respondents showed positive attitude towards breast cancer. On the other hand, poor practice of the screening strategies has been seen by 71% respondents. Age, occupation, monthly income and ethnicity were significantly associated with the knowledge and attitude towards breast illness. Students were twice more likely to practice breast cancer screening methods in comparison to employed females. Major barrier encountered by females in practicing screening methods was unavailability of educational forums. **CONCLUSIONS:** Educational programs and interventional study plans along with risk reduction strategies should be organized for healthy community for their self-prevention and disease management to cope up the elevating fatality and mortality rate of the ailment.

PHS160

ASSESSMENT OF PUBLIC KNOWLEDGE ABOUT LUNG CANCER IN ABBOTTABAD KPK, PAKISTAN

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OBJECTIVES: To assess public knowledge regarding lung cancer about the disease symptoms and risk factors. **METHODS:** A prospective cross-sectional study was conducted in Abbottabad, Khyber Pakhtunkhwa, Pakistan. **RESULTS:** Lung Cancer Awareness Measure (CAM) and a section of general CAM were employed for assessing public awareness about lung cancer. Simple random sampling technique was deployed with 385 sample size calculated by raosoft calculator. The cronbach's alpha value of questionnaire was 0.731. Respondent's knowledge about disease was categorized as poor, average or good on the basis of disease knowledge score. SPSS version 20 was used for statistical analysis of data by employing chi square test of independence and Mann Whitney U test of difference. P value of ≤ 0.05 was considered statistically significant. Majority of the respondents had good knowledge about the signs and symptoms of lung cancer but were unaware of the risk factors associated with this illness. Public knowledge was statistically significantly associated with gender, marital status, educational status, residency and smoking status of the respondents. None of these associations were strong according to gamma values. In case of any health related complaint, majority respondents experienced emotional barriers in approaching physician as compared to practical and service related barriers. There was no statistically significant difference in the responses of various population groups. **CONCLUSIONS:** Lack of public knowledge about disease risk factors highlights the importance of conducting awareness campaigns with prime focus on the disease causing agents. It can help in controlling the spread of this enervating ailment. Implementation of smoking cessation strategies should be emphasized to combat the most prevalent risk factor of cigarette smoke.

PHS161

HEART RATE RECOVERY IN INFLAMMATORY BOWEL DISEASE (IBD)

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OBJECTIVES: Inflammatory bowel disease (IBD) is a chronic idiopathic inflammatory disease which includes Ulcerative colitis (UC) and Crohn disease (CD). Various types of dysfunctions associated with cardiovascular system were documented in these patients. It has been shown that heart rate recovery (HRR) after exercise was an estimate of impaired parasympathetic tone and predictor of all cause and cardiovascular mortality. The aim of the study was to assess HRR in patients with inflammatory bowel disease. **METHODS:** 52 consecutive patients, admitted to clinics of Keçiören Training and Research Hospital, with diagnosis of inflammatory bowel disease and 50 healthy subjects were included in the study. Heart rate recovery index was defined as the decrease in the heart rate from peak exercise value to 1 min and 2 min after the termination of the exercise. This HRR was calculated for the first (HRR1) and the second (HRR2) minutes of recovery phase. **RESULTS:** According to basic clinical and demographic characteristics, groups were similar with regard to age and gender. No significant differences were observed in the initial systolic blood pressures or maximal systolic blood pressures or resting heart rates between three groups. All patients and control group participants had sinus rhythm and normal 12 lead ECG results at rest. The maximal heart rate and baseline heart rate during exercise stress test were similar in UC, CD and control groups (153.8±12.7 vs 152.7±13.6 vs. 156.6±13.3, p=0.432; 94.05±14.8 vs. 86.5±13.9 vs. 93.18±16.37, p=0.313, respectively). The first and the second minute HRR indices of patients with UC and CD were similar to those of the control group (HRR1: 30.7±11.8, 34.5±8.8, 33.9±13.5, p=0.403; HRR2: 51.4±15.4, 54.1±14.6, 55.1±16.9, p=0.807). **CONCLUSIONS:** The HRR index, which is calculated by an exercise stress test and associated with autonomic nervous system function, is not affected in UC and CD.

PHS162

THE IMPACT OF A CARE MANAGEMENT ENTITY ON PSYCHIATRIC EMERGENCY DEPARTMENT VISITS AND HOSPITALIZATIONS AMONG YOUTH WITH SEVERE MENTAL OR BEHAVIORAL DISORDERS

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OBJECTIVES: Care management entity (CME) model is a coordinated, intensive, short-term care delivery model that improves functional outcomes symptoms among youth with serious emotional and behavioral disorders. Few studies have examined clinical outcomes after youth are discharged from CME care and the sustainability of this care intervention is unclear. The study objective was to examine the association between receiving CME care and mental health outcomes one-year post discharge. **METHODS:** Data from CME administrative claims were linked with Medicaid claims for youth enrolled in CME anytime from December 2009 through December 2013. Inverse probability treatment weighting (IPTW) was used to balance baseline characteristics between CME-enrolled youth and a non-CME comparison group. Study outcomes were psychiatric inpatient and emergency department (ED) visits one-year following CME discharge. A two-part model was used where the first part modeled the probability of any psychiatric service and the second part modeled the number of visits for each outcome. **RESULTS:** A total of 2,381 IPTW-adjusted study cohort (488 CME and 1,893 non-CME youth) was identified. In part 1 of the two-part model, the impact of CME care was associated with a significantly lower likelihood of any use of the psychiatric service (any psychiatric ED visit: OR=0.65, p=0.017; any psychiatric hospitalization OR= 0.60,

$p=0.011$). In part 2, no significant differences were observed between the CME care model and number of psychiatric ED visits or hospitalizations. **CONCLUSIONS:** Reduced psychiatric inpatient and ED services following CME care could be sustainable after youth are discharged from the model. Coordinated, high quality services may have prevented subsequent intensive service needs. Further multi-agency collaboration will be needed to enrich the ability to assess outcomes in broader perspectives.

PHS163

NEWS AT HOME , A SAFE AND EFFICIENT TRACK AND TRIGGER MECHANISM

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OBJECTIVES: To evaluate the safety and feasibility of an acute hospital at home model of care using the national early warning score (NEWS) as an early predictor of need for hospital transfer **METHODS:** Suitable patients in the ED requiring admission were offered a choice of hospital at home versus inpatient treatment. Patients were transferred home from the ED or acute ward under the hospital at home team. NEWS is recorded at admission and daily thereafter on a tablet by the nurse attending the patient at home. All patients' record and NEWS data are available electronically to the doctors at the base hospital, who are available 24h/day to review deteriorating patients. We reviewed NEWS data from 502 patients cared for in an acute hospital at home. **RESULTS:** Of the 502 patients, 444 were discharged from home; 58 (11.5%) required transfer to hospital. Mean NEWS at admission of those who were discharged from home was 1.77 ± 1.90 versus 1.02 ± 1.34 on discharge; mean NEWS for the transfer group was 2.22 ± 2.17 at admission and 3.10 ± 2.79 on transfer. We compared day to day change in NEWS (Δ NEWS) of transfer group to that of the discharge group. At 95% confidence level there is no significant difference in the Δ NEWS between both group. However, at 90% confidence level, analysis showed a small but significant difference, 90% CI (0.798 - 0.046), in the change in news from day 3 to 4 between the two groups. Mean Δ 3-4 NEWS for the transfer group was + 0.35; Mean Δ 3-4 NEWS for the discharge group was - 0.07. **CONCLUSIONS:** The results indicate that NEWS correlates well with clinical deterioration at home. As well as being an efficient track and trigger mechanism, NEWS in the first 4 days of admission may be used to predict which patients will require transfer.

PHS164

THE EVALUATION OF MEDICAL BENEFIT SPECIALTY MEDICATION UTILIZATION MANAGEMENT PROGRAM- 1-YEAR EXPERIENCE

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OBJECTIVES: To evaluate the effect of a real-time, multidisciplinary medical benefit management (MBM) program for specialty drug on utilization and cost. **METHODS:** A holistic end-to-end MBM program for specialty drugs was implemented by a Medical Services Organization (MSO) that manages multiple independent practice associations (IPAs) in Southern California which are at financial risk for specialty drugs. Specialty drug requests were evaluated by a team of medical specialists, sub-specialists and clinical pharmacists using nationally recognized evidence-based guidelines and peer-reviewed journal publications. Clinical recommendations were provided to the payor for final approval. Claims from the MSO were collected to analyze the specialty drug spend before and after MBM program implementation during the period from 2014 to 2016. A dollars spend per-utilizer-per-month (PUPM) metric was applied for the comparison of medication utilization. All dollar values were reported in 2016 terms. **RESULTS:** 2,684 patients in Southern California utilized the MBM service during the study period. After a 1-year program implementation, the average spend of per-utilizer-per-month (PUPM) decreased 11% among top-10 diagnoses by specialty drug spend: pre-term labor (\$1529, -34%, $p < 0.05$), colorectal cancer (\$3604, -59%, $p < 0.05$), cervical cancer (\$3132, -61%, $p < 0.05$) and melanoma (\$15487, -80%, $p < 0.1$) have statistically significant average PUPM reductions chronologically. **CONCLUSIONS:** An effective MBM program is capable of reducing the cost of specialty drug therapies. Overall specialty spending and diagnosis-specific specialty spending were reduced effectively after 1-year of program implementation. The long-term benefit on clinical outcomes of the MBM program implementation requires further investigation.

PHS165

BREAST CANCER SCREENING PRACTICES IN ASIAN-AMERICAN COMPARED TO NON-HISPANIC WHITE WOMEN: A BEHAVIORAL RISK FACTOR SURVEILLANCE SYSTEM ANALYSIS

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OBJECTIVES: To assess racial and ethnic disparities in breast cancer screening between Asian-American (AAs) and non-Hispanic White (NHW) women in the United States. **METHODS:** The study was a cross-sectional analysis, using pooled data from the 2014 Behavioral Risk Factor Surveillance System. Women aged 40+ years were included. Descriptive analysis was conducted to describe sociodemographic and economic characteristics (age, education, marital status, household income), general health, access to health insurance, health care cost burden, routine health checkups, and mammography screening rates of the analytic sample (means(SD), percentages). Bivariate analysis was used to examine relationships between independent and outcome variables. Multivariable logistic regression models were used to assess receipt of recommended mammography screening as a function of race independent of potentially confounding factors. **RESULTS:** The analytic sample included 179,127 NHW and 2,959 AA women,

respectively. The mean age was 63.18 (SD 11.56) years, 41.91% had household incomes < \$35,000, and 38.30% had less than or equal to high school education. About 60.42% of the sample was married and 94.12% had 1+ type of health insurance. Among NHWs, 92.99% have ever had mammography and 72.73% have had a mammography within the past 2 years. Among AA women, only 90.04% have ever had a mammography; 74.26% of them have had a mammography within the past 2 years. After adjusting for potential confounders, AAs were significantly less likely to have ever had a mammogram compared to NHWs (OR 0.68 [95% CI 0.67, 0.68]). **CONCLUSIONS:** Our study finds that AA women were less likely than NHWs to receive recommended mammographies. Given the increased prevalence of breast cancer among AA women, future research should examine reasons leading to lower mammography rates in this population.

PHS166

MEDICATION ERRORS (WRONG DOSE ERRORS) IN ADMITTED PEDIATRIC PATIENTS IN SANDEMAN PROVINCIAL HOSPITAL, QUETTA, PAKISTAN

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OBJECTIVES: Study aimed to identify the medication errors (wrong dose errors) in admitted pediatric patients in Sandeman Provincial Hospital, Quetta, Pakistan. **METHODS:** The study was conducted as retrospective study by obtaining the data from the pediatric ward of Sandeman Provincial Hospital, Quetta, Pakistan for period of three months i.e. May to July, 2016. Data was collected from the patients records and were analyzed for correction of doses prescribed to patients on the bases of age and body weight of each patient. **RESULTS:** A total of 203 patients were registered in the pediatric ward of Sandeman Provincial Hospital during the study period. Out of which majority of the respondents ($n=94$, 46.3%) were between the age group of 1-6 years and with majority ($n=118$, 58.1%) were having body weight ranges 1-10kg and were male patients ($n=107$, 52.7%). The total number of medicines prescribed to all patients were 1036 and the average number of prescribed medicine per patients were 5 with 4 being the most frequent number (21.7%) of medicines prescribed. The results showed 50 (4.9%) medicines were prescribed with wrong dose. **CONCLUSIONS:** Although the results of the study showed that there was only small no of the medicine were prescribed with wrong dose, yet it could be lethal to hospitalized patients whose condition may be critical and the wrong dose could contribute to worsen of the condition. Pharmacist working in the hospitals should thoroughly check the dose of all prescribed medicine to the patients in hospital.

PHS167

ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE (KAP) OF PHYSICIANS TOWARDS ADVERSE DRUG REACTION (ADRS) REPORTING AND PHARMACOVIGILANCE IN PUBLIC HOSPITALS OF QUETTA CITY, PAKISTAN

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OBJECTIVES: The study was conducted to assess knowledge, attitude and practice (KAP) of physicians towards adverse drug reaction (ADRs) reporting and pharmacovigilance in public hospitals of Quetta city, Pakistan. Additionally, the study aimed to evaluate the correlation between knowledge, attitude and practices towards ADR reporting. **METHODS:** A cross-sectional study was conducted whereby physicians practicing at seven public hospitals of Quetta city, Pakistan were targeted for data collection. A self-administered questionnaire was used for data collection. Descriptive analysis was conducted through SPSS v. 20 to identify the KAP towards ADR. Spearman rank correlation was used to identify the association among study variables and $p < 0.05$ was taken as significant. **RESULTS:** Three hundred and fourteen physicians responded to the survey. Male dominated the cohort ($n=185$, 70.1%) having age ranges between 24 - 34 years ($n=175$, 55.7%) and experience of between 1-10 years ($n=192$, 61.1%). Majority, 230 (73.2%) of the respondents had poor knowledge about pharmacovigilance and ADR reporting system. However, 297 (94.6%) had positive attitude towards pharmacovigilance and ADR reporting system. Moreover, majority of the respondents 182 (58%) had poor practices of ADR reporting. Correlation analysis revealed significant positive association between knowledge-attitude ($r=0.230$, $p < 0.01$) knowledge-practice ($r=0.399$, $p < 0.001$) and attitude-practice ($r=0.649$, $p < 0.026$). **CONCLUSIONS:** The study indicates that the respondents have an inadequate knowledge yet positive attitude toward ADR reporting and pharmacovigilance. The positive associations reveal a relationship between knowledge, attitude and practices that reports a need for educational and training programs for physicians regarding pharmacovigilance system and ADR reporting.

PHS168

IMPACT OF INTRODUCTION OF NEW TECHNOLOGIES FOR MATERNAL FETAL MONITORING AT CLINICA MATERNIDAD RAFAEL CALVO C, CARTAGENA - COLOMBIA

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OBJECTIVES: Establish the impact of the introduction of new technologies for maternal-fetal monitoring in the epidemiological indicators at the Clínica

Maternidad Rafael Calvo C -**CMRC**. **METHODS:** Cross-sectional and descriptive study. The target population was formed by patients who attended CMRC from January 1, 2013 to April 30, 2016. The information on this population was extracted from the databases and clinical records of the Department of Statistics and Epidemiological Surveillance of the CMRC. Statistics tests such as Wilcoxon rank-sum and Pearson correlation test were applied. The discontinuity regression model and Chow test were used to evaluate possible structural changes in the series. **RESULTS:** Perinatal Mortality and Late Neonatal, stillbirths and vaginal deliveries had changes in their trend with the introduction of new technologies. The regression showed that before the new technologies, detected cases of congenital defects increased at a rate of 5.2% [CI95%= -14.8-25.3] and those of extreme maternal morbidity at 6.5% [CI95%= 5.7-18.7]. In the new technologies exposure period, the average rate of congenital defects decreased at a rate of 8.4% [CI95%= -17.6-0.7] and extreme maternal morbidity at 1% [CI95%= -6.6-4.5], implying a real growth rate of 3% and 5% respectively. Regarding the number of procedures performed with the new medical equipment, a 1% increase before the technologies implied a decrease of 0.44% [CI95%= -3.2-2.3] in diagnoses of congenital defects and one of 0.3% [CI95%= -1.9-1.3] in the diagnoses of extreme maternal morbidity. After one year, 1% increase effect on procedures turned into an average increase of 1.3% [CI95%= 0.1-2.5] in diagnoses of congenital defects and 0.6% in extreme maternal morbidity [CI95%= -0.1-1.3]. **CONCLUSIONS:** The new medical equipment allows us to make more complex diagnoses, providing the opportunity to intervene and impact in a timely manner and thus avoid and mitigate problems in the fetus and the mother.

PHS169

DRUG UTILIZATION PATTERNS AMONG "HEAVY DRUG USERS" IN AN ELDERLY HOSPITALIZED POPULATION IN PUNJAB, PAKISTAN

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OBJECTIVES: To evaluate the drug utilization pattern among the elderly hospitalized patients who were heavy drug users. **METHODS:** A descriptive, cross-sectional study was carried out from December 2015 to March 2016 in six tertiary-care hospitals of the Punjab province of Pakistan. The study population was patients aged ≥ 60 years, taking ≥ 5 medicines/day and being hospitalized in the hospitals. Data was collected from 600 hospitalized elderly patients (100 patients per hospital). All medicines prescribed in each in-patient chart were noted on a pre-designed pro-forma and were classified under ATCI classification system. Multiple linear regression analysis was used to find the independent factors associated with heavy drug use. A P-value of $< .05$ was considered statistically significant. **RESULTS:** In 600 hospitalized in-patient (male 52.7% and female 47.3%) charts, 3,179 medicines were prescribed. The most commonly prescribed drug classes were: A: alimentary tract and metabolism 80% (A02: drugs for acid related disorders 64.5%, A03: drugs for functional gastrointestinal disorders 21.5%, etc.), N: nervous system 66.3% (N02: analgesics 67.2%, N03: antiepileptic's 11.2%, etc.), J: anti-infectives for systemic use 62.2% (J01: antibacterial for systemic use 82.5%, J04: antimycobacterials 15.3%, etc.) and C: cardiovascular system 48.3% (C07: beta blocking agents 19.8%, C10: lipid modifying agents 16.5%, etc.), respectively. The most commonly prescribed active substances were: A02BC01 (omeprazole 51.3%), N02BE01 (paracetamol 50.8%) and J01DD04 (ceftriaxone 40.2%), respectively. In multiple linear regression analysis, male gender (95% CI -.205, -.006, $p = .039$), being divorced (95% CI -.604, -.136, $p = .002$) and presence of comorbidity (95% CI .068, .267, $p = .001$) were the independent predictors of heavy drug use. **CONCLUSIONS:** The rational use of medicines is of utmost importance, most particularly in the elderly population. It is highly recommended that more consideration should be given to the elderly hospitalized patients who are heavy drug users.

PHS170

A NATIONWIDE SURVEY ON IN-HOSPITAL CLINICAL PHARMACIST'S ACTIVITY IN INFECTION CONTROL TEAM AT A HOSPITAL ALLOWED TO CALCULATE PREFERENTIAL INFECTION PREVENTION COUNTERMEASURE FEE IN JAPAN

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OBJECTIVES: The preferential Infection prevention countermeasure fee (PIPCF) requires the full-time assignment of a pharmacist at the infection control team of a hospital with PIPCF 1 in 2012. This study aims to investigate the actual situation of the infection control activity including the role of a pharmacist at hospitals with the PIPCF. **METHODS:** A nationwide survey was performed at hospitals with the PIPCF under the social medical fee schedule by using a questionnaire. **RESULTS:** Of 3,680 target hospitals (all 8,484 domestic hospitals in 2015) in Japan, 718 hospitals responded, and the statistical analysis was performed for 708 eligible hospitals, 304 hospitals with PIPCF 1 and 404 hospitals with PIPCF 2. The number of hospitals assigned part-time pharmacists for infection control team at hospitals with PIPCF 1 and 2 were 173 (59.6%) and 141 (34.9%), being similar to the assignment of physicians and medical technologists. However, the number of hospitals assigned full-time pharmacists at hospitals with PIPCF 1 and 2 were only 3 (1.0%) and 12 (3.0%), respectively. These results were the lowest among health care professionals. The working hours of pharmacists at hospitals with PIPCF 1 (13.7 person-hours) were higher than those at hospitals with implementing PIPCF 2 (8.8 person-hours). Furthermore, the amount of participation in infection control of pharmacists was less than other professionals, especially at hospitals with PIPCF 1. Although the participation rate of pharmacists in walk rounds were 94.4% at PIPCF 1 and 84.2% at PIPCF 2 hospitals, the numbers of participating pharmacists were 1.2 at PIPCF 1 and 0.3

at PIPCF 2 hospitals per an walk round. **CONCLUSIONS:** Although the working hours of pharmacists for infection control was limited due to the routine practice at a hospital, pharmacists play an important role in infection control by contributing to the walk round and the confirmation of permission and registration system.

PHS171

A NATIONWIDE SURVEY ON INFECTION CONTROL ACTIVITIES WITHIN HOSPITALS ALLOWED TO IMPLEMENT PREFERENTIAL INFECTION PREVENTION COUNTERMEASURE FEE IN JAPAN

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OBJECTIVES: The preferential Infection prevention countermeasure fee (PIPCF) was revised in April, 2012 in Japan, and it was divided into PIPCF 1 and 2 in case of meeting the requirement for securing infection prevention within a hospital. This study aims to explore the current status of infection control activities in hospitals allowed to calculate the PIPCF. **METHODS:** We nationwide surveyed the situation of infection control activities in hospitals implementing the PIPCF by using a questionnaire. **RESULTS:** Of 3,680 target hospitals (all domestic hospitals: 8,484 in 2015), 718 hospitals responded, and the statistical analysis was performed for 708 eligible hospitals, 304 hospitals with PIPCF 1 and 404 hospitals with PIPCF 2. With regard to the staff assignments for infection control of physicians, nurses, pharmacists and laboratory technicians, full-time nurses were working at 277 hospitals (91.1%) of hospitals with PIPCF 1. However, full-time nurses were working at only 38 hospitals (9.5%) of 404 hospitals with PIPCF 2. More than 90% of any health care professionals were participating in in-hospital walk round at 304 hospitals with PIPCF 1. However, less than 70% of physicians were participating in in-hospital walk round at 404 hospitals with PIPCF 2, and the participation rate of in-hospital walk round for physicians was the lowest among health care professionals. No pharmacist and laboratory technicians participated in in-hospital walk round for infection control at 404 hospitals with PIPCF 2. **CONCLUSIONS:** The hospitals with implementing PIPCF 2 were owned by small-scale and private corporations, and it was difficult for hospitals with PIPCF 2 to set up the in-hospital infection control system. This suggested that this issue has to be considered when performing infection control in near future.

PHS172

ANALYSIS OF CHANGES IN COSTS AND CLAIMS FOR CAPSULE ENDOSCOPY FOLLOWING THE INTRODUCTION OF SELECTIVE HEALTH BENEFIT IN KOREA

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OBJECTIVES: This study attempted to examine the changes in costs and the use of capsule endoscopy after the medical service became a selective health benefit. **METHODS:** This study investigated the changes in costs and use of capsule endoscopy since September 2015, when the National Health Insurance began to cover it as a selective health benefit (with a coinsurance rate of 80%). As such, this study examined the results of a 2014 survey on the prevailing charges for medical services at five major hospitals to extract the costs of capsule endoscopy before it became a selective health benefit. As for demand for the service, the study reviewed sales of companies that manufacture devices for endoscopy. Finally, it utilized the HIRA Service's data on claims to measure the use of capsule endoscopy. **RESULTS:** Patients, who undergo capsule endoscopy, are now charged 555,910 won, which is about 43% less than the lowest cost of the service at 971,000 won before it became a selective health benefit. Since the shift, patients' deductible expenditure has reduced by approximately 54% from 971,000 won to 444,728 won. In the use of capsule endoscopy in two years after the shift, it grew about twofold from 1,120 cases to 3,250 cases. Meanwhile, cases of small bowel radiological special study, conducted on patients, as an alternative to capsule endoscopy, reduced from 13,212 to 10,654, marking a decrease of about 20%. **CONCLUSIONS:** This study performed the first analysis of costs, coinsurance rate, and use of a medical service that has become a selective health benefit. However, this study showed that the listing of the service as a selective health benefit has reduced patient burden considerably and made it easier to manage the use of the service within the National Health Insurance program, indicating that the new system is successfully achieving its purpose.

PHS173

ASSOCIATION OF FINANCIAL INCENTIVES WITH PATIENT-CENTERED MEDICAL HOME ADOPTION AMONG PRIMARY CARE PHYSICIANS

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OBJECTIVES: To understand the associations between PCMH adoption and physician compensation with characteristics of primary care practices. The National Ambulatory Medical Care Survey (NAMCS), a nationally representative, annual dataset of physician visits, was used for this study. The sample size was 1,356 physicians for 2012. **METHODS:** A cross-sectional study using logistic regression was performed. NAMCS variables were used to construct a medical home infrastructure score and to identify practice-level characteristics for analysis. **RESULTS:** 70% of physicians in the study practiced in settings with PCMH infrastructure present. Physician compensation structure and size of the practice were significantly associated with PCMH infrastructure. Financial incentives based on quality were significantly associated with physicians' compensation structure, employment status, managed care payer mix, and regional location. **CONCLUSIONS:** Although the adoption of PCMH is at the highest level to date, small practice settings are lagging behind. Financial incentives for physicians appear to contribute to the adoption of PCMH.

PHS174

ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PERCEPTION AMONG FUTURE PHARMACISTS TOWARDS PHARMACOVIGILANCE IN PUNJAB, PAKISTAN

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OBJECTIVES: The present study was aimed to evaluate the knowledge, attitude and perception of future pharmacists towards pharmacovigilance. **METHODS:** A cross-sectional study was conducted for a period of 5 months from December 2015 to April 2016 using a pre validated semi-structured questionnaire distributed to senior pharmacy students at different universities of Punjab, Pakistan. To demonstrate students' demographic data and their response to the questionnaire items descriptive statistics were used. Chi square test was applied to assess the association of gender, institution and academic year of students to their response. **RESULTS:** The overall response rate was 84.4%. The mean score for knowledge about pharmacovigilance was 9.52 out of 18. Students of private institutes had slightly lower score (8.86) than those of Government i.e. 9.63. 44.9% respondents were able to define the pharmacovigilance correctly while 53.1% (448) participants knew about the pharmacovigilance as a part of National Drug Policy and 48.3% knew about the organization involved in ADR reporting in Pakistan. 60.4% students were willing to report ADRs in future while 51.5% (435) participants considered it necessary to add ADR reporting procedure in Pharmacy course. Furthermore 54.7% (462) respondents suggested the pharmacovigilance as a core topic in pharmacy education and 64.5% (544) suggested it as compulsory. **CONCLUSIONS:** It was concluded that pharmacy undergraduates do have basic theoretical knowledge of pharmacovigilance but there is lacking in practical approach towards ADR detection and reporting. However, pharmacy undergraduates have positive attitude towards pharmacovigilance and are willing to report ADRs in future.

PHS175

HOSPITAL UTILIZATION PATTERNS AMONG PATIENTS DIAGNOSED WITH PRIMARY BILIARY CIRRHOSIS

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OBJECTIVES: Primary biliary cirrhosis (PBC) is an auto-immune disease in which the bile ducts in the liver are slowly destroyed. The objective of this study is to examine drivers of hospital utilization in patients diagnosed with PBC. **METHODS:** A retrospective descriptive study was conducted on a cross-section of PBC discharges in the MedAssets health system data for inpatient (N=1238) and outpatient (N=6043) visits from October 2015 through September 2016. Multivariable logistic regression was used to identify significant drivers of inpatient admission and mortality. **RESULTS:** The sample included 4028 unique patients from 285 hospitals. The population was predominantly female (89.0%) with an average age of 61.7 years and average Charlson comorbidity score of 2.8. The most common comorbid conditions were diabetes (19.1%), chronic pulmonary disease (19.0%) and renal disease (13.9%). Only 17% of patients were admitted as an inpatient, however the average length of inpatient stay was 7.3 days and the average cost of inpatient admissions was \$16,697. In the inpatient population 4.7% expired during the hospital stay. Hepatic encephalopathy (OR=7.3, p<.0001), myocardial infarction (6.0, p<.0001), portal hypertension (OR=5.7, p<.0001), osteoporosis (OR=3.7, p<.0001), and plegia (OR=3.6, p=.0016) were the largest predictors of inpatient admission. The largest predictors of mortality included hepatic encephalopathy (OR=13.9, p<.0001), old myocardial infarction (OR=9.2, p=.0304), cerebral vascular accident (OR=3.4, p=.0018), and renal disease (OR=3.1, p=.0004). **CONCLUSIONS:** Patients diagnosed with PBC have a large number of comorbidities and complications, particularly chronic conditions. Improvements in disease management may lead to better patient outcomes and a reduction in hospital utilization and healthcare costs.

PHS176

COST CONSEQUENCE ANALYSIS OF A RENAL DISEASE MANAGEMENT MODEL CURRENTLY IMPLEMENTED IN A COLOMBIAN PAYER

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OBJECTIVES: To assess, from the payer perspective, the cost and consequences of RTS-Baxter's Renal Disease Management Model (DMM) for patients in dialysis, that is currently implemented in a Colombian Payer since 2013. **METHODS:** A one year Markov model, applying a three stages structure, was used to project ambulatory care, hospitalizations and deaths from 2,500 dialysis patients with and without DMM. Hospitalization and death rates were obtained from retrospective real world patient level data from RTS-Baxter registries. Ambulatory costs were estimated from referent dialysis tariffs. Inpatient care costs were collected from administrative database in a referent health care provider. Outcomes included: direct costs, events of hospitalizations, days in hospitalization and deaths. Both deterministic and probabilistic sensitivity analyses were done. **RESULTS:** Base case results for 2,500 cohort with DMM: Total cost COP 96,759,074,327; Inpatient care cost COP 24,804,142,382; Hospitalizations 2,572; Days of hospitalization 21,550; deaths 302. Base case results for 2,500 cohort without DMM: Total cost COP 98,266,101,230; Inpatient care cost COP 29,549,539,186; Hospitalizations 3,076; Days of hospitalization 24,453; deaths 332. Deterministic analysis: Dialysis tariff, hospitalization rate and hospitalization costs are sensitive parameters. Probabilistic analysis: The DMM is dominant in 60% of the simulations. **CONCLUSIONS:** DMM is a cost saving alternative from the perspective of the analyzed payer, improving hospitalization outcomes and mortality.

PHS177

ADULT PATIENT SATISFACTION WITH INPATIENT NURSING CARE AND ASSOCIATED FACTORS IN AN ETHIOPIAN REFERRAL HOSPITAL, NORTHEAST, ETHIOPIA

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OBJECTIVES: The aim of this study was to assess adult patients' satisfaction with inpatient nursing care and associated factors in an Ethiopian referral hospital, Northeast Ethiopia, 2013. **METHODS:** Institution based quantitative cross-sectional study was conducted among patients admitted in medical, surgical, orthopedics, gynecology and ophthalmology wards of Dessie referral hospital from March 24 - April 30, 2013. All admitted patients who stayed in the study wards for at least two days during the data collection time were interviewed. The data collection technique was structured interview by using standard questionnaire adapted from Newcastle Satisfaction with Nursing Scale. Data were entered into EPI-Info version 3.5.3 and exported to SPSS version 20 for analysis. Multiple Logistic regression and odds ratio with their 95% confidence interval were used to identify factors associated with patient satisfaction with nursing care and control confounding effect. **RESULTS:** The overall patient satisfaction rate was 52.5%. Respondents' sex (AOR= 2.20, 95%CI:1.30,3.73), age (AOR=4.77, 95%CI:1.97,11.55), admission ward (AOR= 9.99, 95%CI:3.47,28.79), self reported health status (AOR=2.07, 95%CI:1.27,3.37) and class of admission (AOR=2.56, 95%CI:1.41,4.67) were the variables significantly associated with patient satisfaction with nursing care. **CONCLUSIONS:** The rate of patient satisfaction with nursing care was found to be low in this study. Being female, age group 18 - 30 years old, good self reported current health status, being admitted in ophthalmology ward and first class of admission were significantly associated with patient satisfaction with nursing care. In-service training programs for nurses, with special emphasis on communication skills are recommended.

PHS178

HOSPITALIZATIONS AND THE PRIMARY HEALTH PROVIDER IN THE NC MANAGED MEDICAID POPULATION

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OBJECTIVES: Patients' involvement in a medical home is thought to advance the objective of minimizing client hospitalizations, a key objective of managed care. We investigated the association between a client's relationship with a personal health provider (PHP) and overnight hospitalizations in the adult North Carolina Medicaid population. We also evaluated other key potential drivers of hospitalization. **METHODS:** A 2015 survey of 3,596 Medicaid patients using the Consumer Assessment of Healthcare Providers and Systems provided 6 previous months' utilization and health status data. Relevant variables were overnight hospital stays, having a PHP for at least 6 months (vs. none identified), health status, and patient demographics. We conducted binary logistic regression of hospitalizations on PHP presence alone and after adjusting for patient clinical and demographic factors. **RESULTS:** The presence of a PHP was associated with hospitalization (odds ratio(OR)=1.409; p<0.0001; unadjusted). Adjustment for the number of specialist visits (compared to 0) was associated with hospitalization at OR of 1.686, 2.902, and 4.157 for 1, 2-3, and 4 or more visits, respectively, (each with p<0.0001). Receiving care for the same condition >=3 times (OR=1.761; p<0.0001) and overall health status of fair/poor (OR=1.399; p=0.001) were also associated with hospitalization. The final adjusted model failed to show an association between PHP and hospitalization (OR=0.946; p=0.683), patient sex, age, race, or education. **CONCLUSIONS:** The strong positive association between a PHP relationship and hospitalizations was surprising given the belief that quality primary care prevents hospitalization compared with similar populations lacking a PHP. The adjusted model noted very significant positive associations between 3 measures of chronic illness and hospitalization but could not determine the impact of a PHP. Further research might consider whether in similar Medicaid populations, PHP diagnostic acumen can overcome long-term health deficits, leading to fewer short-term hospitalizations for those with provider relationships.

PHS179

DECREASED RATES OF HEALTH PLAN DISENROLLMENT FOR PATIENTS WITH RHEUMATOID ARTHRITIS

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OBJECTIVES: To estimate the time to and rates of health plan disenrollment for rheumatoid arthritis (RA) patients compared with a matched group of non-RA patients. **METHODS:** RA patients (≥ 18 years) were identified from the HealthCore Integrated Research Database (HIRD) and matched to non-RA patients using exact 1-to-1 matching according to demographic characteristics, primary policy holder status, ACA plan, and length of pre-index enrollment. Patients were identified as having RA if they had ≥ 1 claim with a diagnosis of RA and ≥ 1 claim with DMARD use. Non-RA patients were those who did not meet the criteria for RA. Index date for RA cases was the earliest date at which they met the criteria for RA during 1/1/2007-12/31/2014. Non-RA patients were assigned same index date as their matched RA case. All patients were required to have 12 months of pre-index enrollment. **RESULTS:** 63,908 members were matched (31,954 per cohort). Median follow-up time was 3.1 years for RA and 1.9 for non-RA patients. Members with RA had lower rate of disenrollment compared with non-RA members (rate ratio=0.60; 95% CI=[0.59, 0.61]). Within those who disenrolled, time to disenrollment was longer for RA patients (median=806 vs 470 days). Cox regression showed similar results (hazard ratio (HR)=0.61) and results were consistent across sensitivity analyses: (1) including death as disenrollment (HR=0.61) and (2) excluding patients who died during the first 30 days of follow-up (HR=0.63). Results were

mainly driven by higher disenrollment during the first 12 months in the non-RA group, with the difference between the cohorts weakening over time. **CONCLUSIONS:** RA patients stayed with health plan longer and were less likely to disenroll than non-RA patients. This may be due to phenomenon called job-lock in which patients with chronic disease are reluctant to leave their job due to the fear of losing their health insurance.

PHS180

RACIAL AND ETHNIC DISPARITIES IN THE UPTAKE OF THE COLORECTAL CANCER SCREENING

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OBJECTIVES: To evaluate whether the provision of ACA has increased being up-to-date on colorectal cancer (CRC) screening (blood stool test, sigmoidoscopy, or colonoscopy) among age-eligible population with private insurance and to examine racial and ethnic disparities in the uptake of CRC screening. **METHODS:** This was a quasi-experimental study using data from the Medical Expenditure Panel Survey 2007-2014. We examined changes in the prevalence of being up-to-date on the CRC screening by race/ethnic groups between pre-ACA (2007 to 2010) and post-ACA (2011 to 2014). Our study population included nonelderly US adults aged 50 to 64 years with family income at 138% or more of the Federal Poverty Level (FPL) and private insurance plans. We included the uninsured as a comparison group not directly affected by the ACA. **RESULTS:** Our study sample comprised 25,298 individuals, representing 303,358,483 US adults aged 50-64 years with private insurance (weighted n=169,187,558 in pre-ACA and 176,782,642 in post-ACA period). Overall prevalence of being up-to-date on the CRC screening increased from 59.8% in the pre-ACA to 63% in the post-ACA period ($p=0.001$). By race/ethnicity, we observed significant increases ranged from 3% among non-Hispanic (NH) whites ($p=0.005$) to 7.2% among Hispanics ($p=0.001$). However, using difference-in-differences analysis, we found that those changes in screening uptake were not associated with the provision of the ACA (i.e., elimination of the cost-sharing). Prevalence of being up-to-date was significantly lower among NH Asians, compared with NH whites in both Pre- and Post-ACA (44% vs. 61.4%, $p<0.0001$ in the pre-ACA and 48.5% vs. 64.5%, $p<0.0001$, respectively). NH black had the highest prevalence (65.4%) followed by NH whites, others (56.6%), and Hispanic (55.5%) in the post-ACA ($p<0.0001$). **CONCLUSIONS:** Although the prevalence of being up-to-date on CRC screening among age-eligible US population increased slightly after the implementation of the ACA, the ACA has not reduced racial and ethnic disparities in screening uptake.

PHS181

PHARMACISTS' PATIENT SAFETY CULTURE IN JAPAN

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OBJECTIVES: This study aims to explore pharmacists' factors of patient safety culture in Japan using Hospital Survey on Patient Safety Culture developed by AHRQ. **METHODS:** We surveyed nationwide the situation of patient safety culture in 37 hospitals by using a questionnaire in 2011 and 2012. The questionnaire consists of four composites including the communication, organizational activity for patient safety, organizational learning-continuous improvement and frequency of events reported. **RESULTS:** Number of the valid data was 16,670 persons including 1,160 physicians, 9,308 nurses, 498 pharmacists, and others. The overall average positive response rates (PRRs) of the 12 patient safety factors were 50.9% for physicians, 51.5% for nurses, and 51.7% for pharmacists. The average PRRs of five factors regarding the communication for pharmacists (50.0%) was the lowest among three professionals (physicians: 54.7%, nurses: 52.8%), and those of other five factors regarding the organizational activity for patient safety for pharmacists (47.7%) was the highest among three professionals (physicians: 46.7%, nurses: 45.8%). Although the composite of communication includes five factors with factor 1: Communication openness, factor 2: Feedback and communication about errors, factor 11: Teamwork across units, factor 12: Teamwork within units, and factor 4: Hands-offs and transitions, the PRRs for pharmacists of factor 1, factor 2, factor 11, factor 12, and factor 4 were 43.9%, 59.1%, 70.5%, 40.2%, and 36.1%. For example, factor 1 includes three items, c2: Staff feel like their mistakes are held against them, c4: Staff will freely speak up if they see something that may negatively affect patient care, and c6: Staff are afraid to ask questions when something does not seem right, and the PRRs of them were 52.1%, 32.5%, and 47.7%. **CONCLUSIONS:** Therefore, it is possible to foster patient safety culture for pharmacists by making an effort to improve the item with low PRR among items.

PHS182

APPLICATION OF INDIVIDUAL LEVEL DCE MODEL INTO PATIENT CENTERED CARE: LITERATURE REVIEW AND SIMULATION TEST

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OBJECTIVES: Measuring individual patient's true preferences (trade-offs) across treatment outcomes and assessing them precisely in a consistent manner is essential for patient centered care (PCA). However, the recognition of individual heterogeneity by current DCE studies usually confounds estimates of the aggregated (population) mean and variance of random uncertainty, ignoring the patient's specific scale of random components based on their clinical condition and other personal characteristics. The purpose of this study is twofold: 1. Recognize individual level estimation techniques based on systematic literature review, tracing back to basic linear probability estimation since the inception of

discrete choice model. 2. Provide empirical evidence by simulation, which tests the applicability of estimation techniques for PCA in terms of decision rules (assumptions), convergence status, statistical efficiency and accuracy. **METHODS:** Systematic review of individual level estimation techniques of DCE was conducted to determine the use of linear probability estimation and nested logit estimation. Simulation was constructed for 1000 pseudo patients in the routine care setting under two most common scenarios of individual decision rules (lexicographic and compensatory). Based on previous qualitative results from clinical setting, each pseudo patient answered 6-12 question in a well-balanced orthogonal DCE design, including five treatment outcome attributes and each attribute has two levels. **RESULTS:** Considerable heterogeneity remains, as evidenced by the range of the estimates and standard deviation. The linear probability estimation yielded the similar pattern of coefficients indicating trade-offs as nested logit estimation did, while the logit exhibited poorer convergence and statistical power. **CONCLUSIONS:** Since we are not aiming at predicting choice probability but understanding patient's trade-offs of treatment outcomes, linear estimation can be served better at individual level. The preliminary results are the subject of ongoing research, further research are needed because the applicability of estimation techniques in PCA is conditioned on survey design and clinical environments as well.

PHS183

DECREASED RATES OF HEALTH PLAN DISENROLLMENT FOR PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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OBJECTIVES: To quantify the time to and rates of health plan disenrollment for patients with Chronic Obstructive Pulmonary Disease (COPD) compared with a matched group of patients without COPD. **METHODS:** Patients ≥ 40 years old were identified from the HealthCore Integrated Research Environment (HIRE) as having COPD if they had ≥ 1 inpatient claim with primary diagnosis of COPD; or, ≥ 1 ED claim or ≥ 2 outpatient/SNF/inpatient claims with non-primary COPD diagnosis. The index date for COPD cases was the earliest date at which they met the criteria for COPD during 1/1/2007-12/31/2014. Non-COPD patients include those who did not meet the criteria for COPD. COPD patients were matched to non-COPD patients using exact 1-to-1 matching according to age, gender, health plan type, region, primary policy holder status, ACA plan, and length of pre-index enrollment. Non-COPD patients were assigned an index date equal to that of their matched COPD case. All patients were required to have 12 months of pre-index enrollment. **RESULTS:** 657,766 health plan enrollees were matched (328,883 per cohort). Median follow-up time was 2.5 years for COPD and 1.7 for non-COPD patients. During follow-up, 55% of COPD patients disenrolled compared with 63% of non-COPD patients (rate ratio=0.69; 95% CI=[0.69, 0.69]); within those who disenrolled, time to disenrollment was longer for COPD patients (median=688 vs 346 days). Accounting for censoring, Cox regression showed similar results (hazard ratio (HR)=0.71) and were consistent across sensitivity analyses: (1) including death as a disenrollment event (HR=0.77), (2) excluding patients who died during the first 30 days of follow-up (HR=0.77). **CONCLUSIONS:** Presence of COPD was found to be associated with a longer duration of health plan enrollment and decreased risk of disenrollment. This may be due to job-lock, in which patients with chronic medical conditions do not leave their employer due to the threat of losing their health insurance.

PHS184

FIVE DIMENSIONS TO EVALUATE BREAST CANCER DIAGNOSTIC PROCESS

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OBJECTIVES: Determine the minimum variables to be taken into account to perform an integrated breast cancer diagnosis process that facilitates decision-making under care characteristics of the Colombian Health System. **METHODS:** A literature review was made with the following terms: ("Breast Neoplasms"[Mesh]) AND "Quality Indicators, Health Care"[Mesh]; ("Quality Indicators, Health Care"[Mesh]) AND "Breast Neoplasms"[Mesh] AND "Diagnosis"[Mesh]. Based on the review of original articles, observational studies and Clinical Practice Guidelines, a panel of experts defined the variables and established the categories of measurement for each. **RESULTS:** 110 determinant variables were defined in breast cancer diagnostic process, grouped into 5 dimensions: 1) Histopathological diagnosis, 37.2% (41 variables); 2) First time care (attending and primary care physician), 25.4% (28); 3) Imaging diagnosis, 15.4% (17); 4) Staging, 11.8% (13). Finally, Sociodemographic variables 10%, (11) were taken into account. Approximately, 13.6% (15) were dates variables related with request and registration of histopathological and images reports, as well as, dates of staging and request for first attending physician care. About 31% of histopathological diagnosis (13 variables) were related with treatment defining biomarkers as Her2. **CONCLUSIONS:** The analysis by dimensions will make it possible to compare and give them weight, so through consensus, the impact of their evaluation can be determined within the diagnostic process. Evaluation of breast cancer diagnostic process through dimensions will enable decisions-making in order to improve the health care of women with breast cancer.

PHS185

COMPARATIVE ASSESSMENT OF THE BRICS HEALTHCARE SYSTEM

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OBJECTIVES: Brazil, Russia, India, China, and South Africa (BRICS) bear half of the population burden at the same time are the fastest growing economies of the

world. However, the healthcare system of BRICS nation faces unique challenges due to demographic burden and inadequate healthcare infrastructure. Hence, an assessment of the healthcare system of BRICS nation was done. **METHODS:** Secondary research was done to collect data pertaining demographic profile, national health workforce strength, health resources and financing, immunization programmes and other health indicators for BRICS nations and were extracted on a pre-specified template. Latest data was considered and adjusted accordingly. **RESULTS:** Russia is at the top position in terms of gross national income per capita (23%), While China has the maximum GDP in the year 2015. In terms of health workforce Russia is leading with more than four physicians per 1000 peoples, while India and South Africa had less than one physician per 1000 peoples. India has only seven hospital beds per 10,000 people. The out-of-pocket (OOP) expenditure as total expenditure on health was highest for India (62.42%) whereas lowest for South Africa (6.49%). Among the broad range of health indicators, South African healthcare system was found heavily burdened with worst life expectancy at birth (60 yrs). Indian healthcare system was second worst performer with lowest life expectancy at age 60 (17), infant mortality rate (38) and sanitation facilities (40%). Brazil was found to be the best performer with highest life expectancy at birth (75 yrs.) & at age 60 (22 yrs.), lowest crude mortality (6), TB incidence (44), and more than 80% improved sanitation facilities. **CONCLUSIONS:** Among the BRICS nations, South Africa & India are struggling for improvement in health sector. For India high OOP could be one potential reason while for South Africa the shortage of health workforce is also of concern.

PHS186

ASSESSMENT OF HEALTHCARE QUALITY AND PATIENT SATISFACTION LEVEL TOWARDS HEALTHCARE SERVICES PROVIDED IN THE HOSPITALS: A CROSS-SECTIONAL SURVEY

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OBJECTIVES: The study aimed to determine the health care quality in public and private hospitals of Punjab province of Pakistan and to recognize the shortage of facilities and numerous provider and facility factors in hospitals that seriously affect the patients' health status. **METHODS:** A cross-sectional questionnaire based survey was conducted from December 2015-March 2016. A total of 424 patients were selected who were admitted and utilizing the services of different public and private hospitals of selected cities using systemic random sampling technique. Data was summarized by applying descriptive statistics like frequencies, percentages, mean, median, standard deviation and inter quartile range while significant association and difference between various dependent and independent variables was determined by chi square test, Mann-Whitney U test and Kruskal Wallis tests. A p value less than 0.05 was determined as significant level. **RESULTS:** On an average 46% respondents had good expectations towards healthcare services provided in the hospitals (before their visit) but when we assessed their satisfaction level (after their visit) it was found that majority of the respondents (n=320; 80%) had overall satisfaction score below the average expectation score (median=6, IQR=4; 46% of total expectation score). Only 20% (n=80) of the respondents had percent satisfaction score greater than the percent average expectation score. The overall satisfaction score in private sector hospitals was significantly greater (p<0.05) than public sector hospitals. **CONCLUSIONS:** Results of study demonstrated that patients were more satisfied with the services provided by private hospital services but respondents were especially dissatisfied from the insufficient time given by the doctors for their proper examination and diagnosis.

PHS187

STUDENTS' HEALTH STATUS IN A PRIVATE UNIVERSITY OF MALAYSIA: A CROSS-SECTIONAL STUDY

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OBJECTIVES: To assess health of medical and paramedical students and find out current major and minor illnesses and also evaluate the correlation of illnesses with last year illnesses. **METHODS:** A cross-sectional, descriptive study carried out using convenience sampling. A pre-validated questionnaire is distributed in university. The response items were on close-ended and likert scale options. Descriptive statistics (SPSS version 20) is applied, means, standard deviations, and frequency distributions calculated. Pearson coefficient of correlation test also used to analyze data and $p \leq 0.05$ is considered significant for all study variables. The reliability of the questionnaire was assessed via Cronbach's Alpha measure (0.704). **RESULTS:** 400 students of a various departments were participated, 149 students (37.2%) from MBBS, 122 students (30.5%) from Pharmacy, 117 students (29.25%) from BDS, 12 students (3.0%) from Nursing department. 61 students (15.3%) found that their health was excellent, 101 students (25.3%) found that their health was very good, 191 students (47.8%) found that their health was good, 42 students (10.5%) found that their health was fair, and 5 students (1.3%) found that their health was poor. From Pearson bivariate correlation analysis, this study found that illnesses in last one month has a correlation with illnesses in last 12 months ($r = 0.60, p = 0.01$). **CONCLUSIONS:** The Cross sectional study indicates that most of the students of surveyed university were

healthy and their health statuses were still in the scale of excellent or good and with a definite correlation as last year illness.

PHS188

EFFECTIVENESS OF KNOWLEDGE TRANSLATION (KT) INTERVENTIONS TO IMPROVE PATIENTS AND COMMUNITY ADHERENCE TO CLINICAL PRACTICE GUIDELINES (SYSTEMATIC REVIEW)

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OBJECTIVES: To assess the effectiveness of knowledge translation (KT) interventions to improve patients and community adherence to clinical practice (CPG) **METHODS:** Systematic Review of KT interventions compared with a classical developed guideline for patients or community. The risk of bias (ROB) was tested with the Risk of bias Cochrane tool and the quality of evidence was tested using the Grading of Recommendations Assessment, Development and Evaluation (GRADE). Two independent raters qualified relevance, ROB and quality of included studies **RESULTS:** 2653 (CPG) were initially scanned. After deleting duplicates 2607 (CPG) papers were tested. Seven studies were finally included related with CPG. The follow-up time of interventions was between 6 and 18 months. Patients adherence to recommendations was observed in 2 studies. There was a high heterogeneity because of the variability of the population and of measurement tools. Randomized controlled studies had low ROB in the majority of the categories. We did not find in the studies the inclusion of costs or equity issues of the interventions, considering potential inclusion of disadvantaged populations or potential differences related to a different effectiveness of the intervention on them. **CONCLUSIONS:** Research to improve patients adherence to CPG using KT interventions are recent. The use of KT strategies improves the outcomes in the implementation of the guidelines. However, new studies with less heterogeneity are necessary to confirm these results

PHS189

KNOWLEDGE OF RISK FACTORS REGARDING THYROID CANCER AMONG COMSATS UNIVERSITY STUDENTS IN ABBOTTABAD PAKISTAN

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OBJECTIVES: Study focuses on accessing knowledge and perception of students about thyroid cancer risk factors and awareness. **METHODS:** A cross-sectional study was conducted using self-administered questionnaire from August 2015 - December 2015 in Comsats Institute of Information technology Abbottabad Pakistan. Data analysis was done using SPSS 23 and Pearson Chi square was used for correlations between dependent and independent variables. **RESULTS:** Questionnaire were filled giving the response rate of 87.6%. Among respondents 22% students perception was that neck swelling or a lump is a sign of thyroid cancer. However 21% of students was aware that neck palpation method is commonly used to detect thyroid cancer. Out of all respondents, 42% people believed old age, radiation and positive family history of thyroid cancer are significant risk factors of thyroid cancer. Almost all students perceived that females are more prone to thyroid cancer as compared to males. **CONCLUSIONS:** Study shows moderate knowledge about risk factors of thyroid cancer in Comsats University students. The results show a clear need of health educational activities for educating more people about thyroid cancer knowledge, risk factors, early detection signs and prognosis of early detected thyroid cancer which will eventually lead to better health outcomes and decreased prevalence of thyroid cancer in Pakistan.

PHS190

PREDICTION OF HOSPITALIZATION COST IN DIALYSIS PATIENTS

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OBJECTIVES: To assess, the hospitalization episode cost, and the clinical / demographic determinants from the payer perspective, for patients in dialysis currently treated in RTS Disease Management Program. **METHODS:** Data collection: Episodes of hospitalization, demographic and clinical variables were identified by reviewing RTS Disease Management Program clinical records. Each episode was matched with the billing data base from a referent high complexity hospital in order to collect the cost per episode charged to the payer. A harmonized, adjusted and validated data base was built with 59 variables and 752 episodes. Descriptive analysis: measures of central tendency and variability were applied for continuous variables, and proportions for categorical variables. Correlations among episode cost and other explicative variables were assessed. Inferential analysis: A log lineal and quantile regression analysis was used to study covariates that influence the hospitalization episode costs. **RESULTS:** hospitalization episode cost estimation: mean COP 7,088,009, median COP 3,507,080 and Standard Deviation COP ±13,008,555. Covariates with downsized effect on cost: hypertension as unique cause of renal disease (p<0.05), high socioeconomic level (p=0.08), albumin > 4 mg/dl (p=0.05), hemoglobin > 9mg/dl (p<0.01), normal KTV (p=0.09). Covariates with expanded effect on cost: Length of stay (p<0.01), Diabetes Mellitus (p<0.05), cardiac valve disease (p=0.09), peripheral artery disease (p<0.01), cardiovascular disease (p<0.05), intensive care unit requirements (p<0.01), surgery (p<0.01) and overweight (p=0.05). F test of the model $p < 0.000$ R-squared = 0.6. **CONCLUSIONS:** hospitalization episode cost in dialysis patients is a skewed variable that in the average is estimated in COP 7,088,009. Thirteen clinical and demographic covariates were found to explain some of the variability in the hospitalization episode cost.

PHS191

THE EVIDENCE BEHIND 'CHOOSING WISELY' RECOMMENDATIONS: A BIBLIOMETRIC ANALYSIS

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OBJECTIVES: To evaluate the current list of Choosing Wisely recommendations, and assess the quality and quantity of evidence used to characterize "low value" services. **METHODS:** All recommendations presented on the Choosing Wisely initiative's website were identified, along with the references that accompany each recommendation. In addition to standard reference elements, Medical Subject Headings and MEDLINE publication type assignment data were collected. References not indexed in Pubmed were verified using online websites to obtain complete details pertaining to the source and type of publication. **RESULTS:** The Choosing Wisely initiative consists of 475 recommendations produced by 74 specialty societies. Each specialty society describes recommendations in detail and presents evidence supporting that determination. All included specialty societies describe the process by which their recommendations were developed. A variety of clinical services were targeted by Choosing Wisely recommendations. The majority (238, 50.1%) were clinical tests that relate to patient diagnosis, prognosis, or monitoring. The quality, quantity, and applicability of the cited evidence were highly variable. A total of 1,768 citations were retrieved. Out of 1,548 peer-reviewed references, 77.71% were published between 2005 and 2016. Clinical guidelines (578, 32.7%) and real world evidence (405, 22.9%) represented the most common types of evidence. 89 (18.7%) specialty society recommendations made economic claims of cost or value; however, only 20 (22.47%) cited supporting economic evidence. **CONCLUSIONS:** These findings suggest that the Choosing Wisely initiative's recommendations should be based on systematic reviews of the evidence and should be developed in a structured, clear, and transparent manner. Clear evidentiary justification for the selection of low value services is necessary for the ongoing success and sustainability of the Choosing Wisely initiative. Potential explanations for the observed variation include the amount of evidence available, the thoroughness of the relevant specialty society, and the evolving nature of the clinical evidence base.

PHS192

A QUALITATIVE STUDY EXPLORING PERCEPTIONS OF POLICY MAKERS ABOUT COMMUNITY PHARMACY PRACTICE AND EXTENDED PHARMACY SERVICES IN LAHORE, PAKISTAN

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OBJECTIVES: The focus of pharmacy practice has shifted from product- to patient-focused services. This transition of role is least reported from developing countries. The present study aimed to explore the perception of health policy makers (PMs) about practice change and provision of extended pharmacy service (EPS) by community pharmacist (CP) in the city of Lahore, Pakistan. **METHODS:** A qualitative approach was used to gain an in-depth knowledge of the issues. Government officials involved in regulation and policy making were targeted for the study. Seven conveniently sampled respondents were interviewed through a validated semi-structured interview guide. All interviews were audio-taped, transcribed verbatim, and were then analysed for thematic contents by the standard content analysis. **RESULTS:** Thematic content analysis (TCA) yielded four major themes, (1) Current standard of community pharmacy practice, (2) Current knowledge of EPS, (3) Practice change and readiness of CPs toward practice change and (4) Barriers towards practice change. Only one respondent had knowledge about EPS while for majority of the PMs, EPS was a new concept. They were not confident about the current status of community pharmacy practice in Lahore, however, in Lahore the standard was perceived to be slightly better. In their view the practice should be changed as government had recently introduced new rules and regulations. The barriers and limitations indicated were the lack of pharmacists' professional attitude, mindset and interest, academia, and lack of acceptance of pharmacists as health team member in society and by other health professionals. The prevailing Drug Act 1967 was considered as the one of the major barriers toward the practice change. **CONCLUSIONS:** The government, policy makers, academicians, and health professionals to work together to bring about the change in practice of community pharmacy. Amendments in existing laws and evidence-based legislation regarding extended roles of pharmacist are needed in Pakistan.

PHS193

DISEASE STATUS, SYMPTOMOLOGY, AND REMISSION RATES OF NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS AND ANKYLOSING SPONDYLITIS PATIENTS IN THE UNITED STATES

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OBJECTIVES: To better understand the symptoms and clinical characteristics of non-radiographic axial spondyloarthritis (nr-axSpA) patients and how they compare to ankylosing spondylitis (AS) patients in the United States. **METHODS:** Data from the 2015 SpA Disease Specific Programme, a cross-sectional, multi-national survey of patients and rheumatologists conducted in the United States were analyzed. Rheumatologists (n=92) completed forms containing patient demographics, clinical results and symptomatology. Symptoms, disease activity, and disease status (defined as improving, stable, unstable, and deteriorating) of ankylosing spondylitis and non-radiographic axial spondyloarthritis patients were compared. **RESULTS:** A total of 980 patients (AS: 498; nr-axSpA: 482) were included in this analysis. A higher proportion of AS patients were male (77% vs. 56%), older (Mean Age: 46.1 vs. 42.6), had a higher mean BMI and were

employed when compared to nr-axSpA patients. Nr-axSpA patients' current disease status were less likely to be stable (p=0.0259) in comparison to AS patients. Nr-axSpA patients were also less likely to be in remission (p=0.0027). AS patients had more axSpA symptoms, such as sacroiliitis, spinal fusion, and loss of movement, however, nr-axSpA patients were more likely to have inflammatory back pain, enthesitis, or no reported symptoms currently. **CONCLUSIONS:** In the US, nr-axSpA and AS patients share many similar clinical features with few differences between them. In spite of these similarities, nr-axSpA patients show lower rates of stability and are less likely to be in remission. These findings may suggest that nr-axSpA is as burdensome as AS, and that both conditions may warrant similar treatment approaches from an early stage.

PHS194

AVAILABILITY OF ESSENTIAL OBSTETRIC DRUGS AND EQUIPMENT AND MATERNAL MORTALITY IN PRIMARY HEALTH CARE SETTING IN INDIA

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OBJECTIVES: Primary health centers (PHCs) are important source of maternal health services in India. The average maternal mortality ratio in India is 178 per 100,000 live births. This study aims to find out whether the drugs and equipment in PHCs are adequate according to Indian Public Health Standards and whether there is any effect of their availability on maternal mortality. **METHODS:** The study was conducted in 3 districts of Andhra Pradesh state of India. 30 PHCs were selected in each district using simple random sampling. 90 PHCs were visited and data was collected. The study was done between May 2012 and April 2013. Maternal mortality data was obtained from records of each primary health centers for the year 2012-2013. Regression analysis using Maternal Mortality as dependent variable and availability of essential drugs and equipment as independent variables is done. **RESULTS:** Only 30% of PHCs had an emergency obstetric drug tray consisting of all the essential drugs. Only 60% of PHCs had labor table and Suction machine. Oxygen administration facility was available in 40% of PHCs and sterilization equipment in 50%. Normal delivery kits were available in 90%, while complete assisted delivery kits were present in less than 10%. Average maternal mortality in surveyed PHCs was 97/100,000 live births. For every unit increase in availability of Emergency Obstetric kit with all 6 contents, maternal mortality decreased by 8/100,000 live births and for the availability of a fully equipped sterile labor room, the maternal mortality decreased by 11/100,000 live births. **CONCLUSIONS:** PHCs in India show poor availability of essential drugs and delivery equipment even after 5 years of full implementation of IPHS of National Rural Health Mission. Availability of emergency obstetric drugs and supplies significantly reduce maternal mortality. India should ensure continuous availability of emergency obstetric drugs, supplies and equipment for rapid improvements in maternal mortality.

PHS195

FACTORS OF CARDIOVASCULAR DISEASE RISK SCREENING UPTAKE AMONG POPULATIONS WITH LOW SOCIOECONOMIC STATUS: A SYSTEMATIC REVIEW

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OBJECTIVES: Populations with low socio-economic status (SES) are at higher risks of cardiovascular morbidity and mortality. This systematic review aimed to identify, classify and present factors associated with cardiovascular disease (CVD) risk screening uptake into appropriate themes. **METHODS:** We systematically searched and screened articles from databases, complemented with hand-searching of references in included articles. We included full-text articles of studies which identified factors associated with CVD risk screening uptake among the adult population with low SES. We excluded review articles, book chapters and those not published in English. We extracted study characteristics, classified the factors and recorded the magnitude and direction of association for each factor with screening uptake, as well as the strength of the evidence for the association. **RESULTS:** Five out of 1363 articles were included which examined screening conducted in healthcare facilities, participants' homes or nearby community centers, as well as screening conducted as an outreach program. We identified and categorized 33 factors positively or negatively associated with screening uptake into 6 themes. Besides lack of awareness and poor health beliefs, the factors influencing the screening uptake of low SES population include opportunity cost from missing work, concerns about judgmental screening staff and absence of companion to attend screening together. **CONCLUSIONS:** Our findings provide a comprehensive overview of factors associated with CVD risk screening uptake among population with low SES. The findings are particularly useful for clinicians, researchers and policy makers who are developing interventions and screening programs targeting the low SES group. Studies are required to identify other unique factors associated with CVD risk screening in this group.

PHS196

ASSOCIATION BETWEEN ACCESS TO HEALTH-PROMOTING FACILITIES AND PARTICIPATION IN CARDIOVASCULAR DISEASE (CVD) RISK SCREENING AMONG POPULATIONS WITH LOW SOCIOECONOMIC STATUS (SES) IN SINGAPORE

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OBJECTIVES: Little attention has been given to associations between physical environment and screening participation. This study examined associations between minimum distances (proxy of access) to health-promoting facilities and door-to-door, cardiovascular disease risk screening participation, among

populations with low socioeconomic status (SES) residing in public rental flats in Singapore. **METHODS:** We obtained corresponding block screening participation rates from 66 blocks housing a total of 2619 residents, from Health Mapping Exercises conducted from 2013-2015. Uni- and multi-variate negative binomial regression were used to test associations between minimum distances to facilities (private subsidized clinics, certified healthy eateries, polyclinics and parks) and block screening participation rate, adjusting for age, ethnicity, gender and planning region. We also repeated the multi-variate analyses, to test if the associations varied according to regions. **RESULTS:** Uni-variate analyses showed an association between block screening participation rate and minimum distance to polyclinics – which disappeared in multi-variate analyses. After adjusting for interaction, 3 independent variables, minimum distance to subsidized private clinics (IRR 1.52, 95% CI 1.12–2.05) in the East region, as well as polyclinics (IRR 0.92, 95% CI 0.88–0.96) and parks (IRR 1.42, 95% CI 1.11–1.81) in the North/North-East regions were shown to be significant. No association was observed for healthy eateries for all 3 regions. **CONCLUSIONS:** These findings could be important considerations in the planning of future door-to-door screenings in urban cities, for efficient prioritisation of resources. To increase participation rates among this low SES population, access to health-promoting facilities in each region and their perception of such facilities should be considered.

PHS197

THE ROLE OF PHARMACISTS IN THE PREVENTION AND TREATMENT OF HOSPITAL-ACQUIRED INFECTIONS

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OBJECTIVES: Background: Required public reporting and reimbursement penalties have contributed to the increased focus by hospitals to reduce hospital-acquired infections (HAI). Although management of HAI requires a multidisciplinary approach, we explore the different roles and contributions of hospital pharmacists to summarize approaches that could be adopted by pharmacists and pharmacy directors in other institutions. **METHODS:** Face-to-face guided interviews of eight pharmacists from eight different hospitals were conducted on the role of pharmacists in addressing HAI. The interviews were transcribed and summarized using NVIVO thematic analysis. **RESULTS:** The most common HAI reported by the pharmacists was Clostridium difficile. Interventions to prevent these infections included antibiotic stewardship, hygiene, and effective catheter management policies. All respondents saw the role of pharmacists as stewards of appropriate use of antibiotics to prevent and treat HAI. Although some mentioned an interdisciplinary approach, working with physicians and nurses, the majority of pharmacists deferred to nurses on the question of prevention and to pharmacists on the question of treatment. Clostridium difficile management remains a challenge but most of the respondents consider that policies in place to reduce infections are generally effective. Not all had an antibiotic stewardship program. **CONCLUSIONS:** Pharmacists are actively involved in designing and implementing strategies to reduce HAI. Pharmacists view antibiotic stewardship as the area where pharmacists can have the most impact

PHS198

AVAILABILITY AND ALLOCATION OF HEALTHCARE SERVICES AND THE EFFECT ON HEALTH OUTCOMES IN FLORIDA: A SPATIAL PERSPECTIVE

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OBJECTIVES: This study assessed the availability and allocation of healthcare services in the State of Florida with respect to their effect on health outcomes as measured by age-adjusted mortality (AAM) rates and mortality amenable to healthcare (MAH) rates. **METHODS:** This retrospective cross-sectional study examined the availability and allocation of healthcare services in the State of Florida at the county level. Data was obtained from the US Census, the Area Resource File, and the Florida Department of Health for 2010. AAM rate was calculated at the county level. The MAH rate for each county was calculated based on the age of the individual's death and primary cause of death being associated with conditions that could have been prevented. A gravity model was implemented to measure the availability and allocation of health care services. Separate multivariable regression models were performed to assess the effect of health care services on AAM and MAH. Sensitivity analyses were performed to ascertain if differences existed in urban or rural counties. **RESULTS:** In the overall analysis, the allocation and availability of primary care physicians and physician assistants were found to account for an approximately 2% ($p < 0.05$) decrease in the AAM rate. However, these results did not hold when examining the MAH rate. In the urban counties primary care physicians, nurse practitioners, and physician assistants were associated with a 2% ($p < 0.05$) decrease in the MAH rate. In the rural counties the availability and allocation of health care services was not significantly associated with the AAM rate or MAH rate. **CONCLUSIONS:** This study found that the allocation and availability of healthcare services in Florida does not meaningfully impact AAM or MAH. Caution in evaluating the proposed benefits of programs that are designed to increase availability and/or allocation of healthcare services is warranted.

PHS199

A ZIKA COSTING MODEL FOR SOCIAL INSURANCE SYSTEMS: THE CASE OF THE NATIONAL INSURANCE BOARD OF TRINIDAD AND TOBAGO

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OBJECTIVES: To compare the total cost of Zika to the National Insurance System (NIS) and the Productivity Loss as a result of the absenteeism of employees in

Trinidad and Tobago during the Financial Year (FY) 2016. **METHODS:** An average of the likely Cases of Dengue Fever reported by the Pan American Health Organization (PAHO) Epidemiological Weeks for calendar: EW 52 (2013), EW 52 (2014) and EW 53 (2015), an Expansion Factor of 15% and an estimated 20% Symptomatic cases were used to derive a comparative sample of likely Zika cases of 54555. Additionally, a ratio of the Labour Force, 645,300, and the country's population, 1324699 (2010) was expressed as a proportion of likely cases to derive 26575. Further, the NIS Actively Insured Persons (FY2015), 519926, and the country's Paid Employees (2015), 494828, were expressed as a proportion of the likely cases to obtain an adjusted sample of 27922. This was further adjusted to obtain a representative sample of the NIS by deriving a ratio, .007, based its claimants for Influenza (ICD-10, 168) and Flu (Unspecified) to the total Sickness Beneficiaries for the financial year July 1 to June 30 from 2013 to 2015. The result was expressed as a proportion of the likely Zika cases to obtain an adjusted sample of 188. To estimate the cost of absenteeism to the NIS, .007/188 was used to derive a Confidence Interval of ± 4 for a 4-day period using its respective rates. Productivity Loss was calculated using Daily per capita GDP PPP\$ (2015) with a 3.3 conversion rate. **RESULTS:** The estimated Total Cost to the NIBTT was between PPP\$50,188.03 and PPP\$47,305.38. The estimated Productivity Loss was PPP \$119,778.41. **CONCLUSIONS:** The estimated Cost to the economy as a result of absenteeism was greater than the cost to the National Insurance System of Trinidad and Tobago.

PHS201

EVALUATION OF RISK FACTORS AND THE PERCEPTION OF PREGNANT FEMALES REGARDING FACTORS ASSOCIATED WITH CAESAREAN IN DIFFERENT HOSPITALS OF QUETTA, PAKISTAN

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OBJECTIVES: The current study was done to evaluate the risk factors and the perception of pregnant females regarding factors associated with Caesarean in different hospitals of Quetta, Pakistan. **METHODS:** A cross sectional study was conducted from March to September 2016 in the public and private hospitals of Quetta by using a pre-validated questionnaire. Five hundred and ten (510) women were registered in the different hospitals at the time of the study out of 310 were agreed to participate. The primary source of data was revalidated self-administrative questionnaire. Inferential statistics ($p < 0.05$) were used to assess the significance among study variables by using SPSS vs 20. **RESULTS:** A total of 310 pregnant women who were in their third trimester and expect to deliver soon were enrolled in the study. The results show that increase number of pregnancies was associated with caesarean (67.1%). Majority of the females ($n=229$, 73.1%) preferred to caesarean as their current type of birth. Most of the females ($n=107$, 34.5%) had their one previous Caesar. Overall the only 58.1% ($n=180$) had adequate knowledge regarding the risk factors associated with caesarean. But the small number of respondents ($n=89$, 28.7%) were not familiar with the factor that the age of the mother can affect the complications which leads to caesarean birth. **CONCLUSIONS:** The study concludes that females preferred caesarean rather than a vaginal delivery. And large number of females had poor knowledge regarding risk factors associated with caesarean. The factors associated with high Caesarean rates may be reduced if females were provided with better education, facilities, & ante natal care that care which provided throughout the pregnancy. It is also important to educate woman that childbirth is a normal process and vaginal birth can be achieved in women safely.

PHS202

ANALYSIS ON THE CURRENT SITUATION OF HEALTH EDUCATION OF REPRODUCTIVE AGE WOMEN IN SHANGHAI

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OBJECTIVES: To investigate the health education state among reproductive age women and explore improvement strategy of health service in Shanghai. **METHODS:** From September to December in 2015, convenience sampling was adopted to investigate reproductive age women in nine districts, who accorded with the inclusion and exclusion criteria. The general condition (age, occupation, education, income, pregnancy, childbirth, household register) and health education channels (number, type, content) were surveyed by self-designed questionnaire. **RESULTS:** We distributed 226 questionnaire and recovered 204 questionnaire, with an effective returning rate of 90.3%. Among the women, the age ranges from 18 to 24, 60.3% for 21 to 30, 68.5% for enterprises, 81.3% for college degree or above, 61.3% for income over 5000 CNY, 71.6% for non-pregnancy, 64.7% for unbearing, 97.1% for ready pregnant and 83.3% for locality household register. The income level of nonlocal women was higher than local women ($P < 0.05$). Education channels of nonlocal women were less than local women ($P < 0.05$). The channels were no statistical difference ($P > 0.05$) between different age women. The utilization rate of web education was higher than traditional media, family member and social activities among 21 to 30 and 31 to 40-year-old women in education channels ($P < 0.05$). The utilization rate of traditional media was less than social activities among 21 to 30-year-old women ($P < 0.05$). Baidu, friends and BBS were the top three education channels in 14 active channels. Magazines or books, friends and mother or mother-in-law were the top three channels in 14 passive channels. **CONCLUSIONS:** The health education degree of nonlocal women was lower than local women. In all education channels, the utilization rate of internet was higher than traditional media, family member and social activities among 21 to 30 and 31 to 40-year-old. The government should explore multi-sectoral cooperation mechanisms and supervise the credibility of internet information to improve maternal health care services.

PHS203

THE PREVALENCE OF CANCER RELATED DISTRESS AMONG URBAN-DWELLING VETERANS: A PILOT STUDY

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OBJECTIVES: The National Comprehensive Cancer Network and American College of Surgeons Commissions on Cancer requires cancer centers to evaluate psychosocial distress and provide appropriate triage and treatment for all patients (Standard 3.2). Clinically-significant distress includes biopsychosocial stressors which are highly prevalent in individuals with cancer and lead to negative health outcomes. Currently programs identifying veteran's distress are limited and can help clarify treatment needs and improve future outcomes. **METHODS:** Participants were screened during their initial oncology consult visit utilizing the biopsychosocial "NCCN Distress Thermometer and Problem List for Patients" (n=53). The majority of patients were men(87%), mean age 70(SD=8.16) presenting with cancer of the lung(23%), prostate(15%), GI(13%), ENT(13%), and others. Distress scores ranging between 0 and 3 resulted in documentation in the electronic medical record; those >4 received telephone follow-up and triage to appropriate care clinics. **RESULTS:** The mean distress score was 3.72, falling below the "significant distress cutoff" with the median of 4.00, meeting significant distress. Overall, 47 percent reported significant distress related to physical, psychological, social, and spiritual needs(score>4). Eight percent reported severe, significant distress(score>7). Further analysis identified fatigue(47%), pain(43%) worry(41%), and insurance/financial concerns(31%) as primary symptoms of distress. For the 47% who reported significant distress, symptoms included significant worry(67%), pain(59%), fatigue(51%), nervousness(48%), sleep(44%), and loss of interest(41%), with primarily emotional health symptoms and physical health symptoms secondary. Interestingly, 33% reported distress scores below 4, yet marked experiencing significant symptoms physical and psychological symptoms. Three patients reported active suicide ideation/plan and were provided care accordingly. **CONCLUSIONS:** A large majority of veterans receiving oncological care reported significant cancer-related distress and unmet needs, with elevated symptoms of emotional and physical demands. There may be a continued trend towards under-reporting among veterans, such that as individuals reporting low scores of distress nevertheless endorsed emotional and physical symptomatology to marked degrees.

PHS205

HOSPITAL-LEVEL TRENDS IN PATIENTS' PERSPECTIVE OF OVERALL EXPERIENCE AS MEASURED THROUGH THE HCAHPS PATIENT SURVEY: ANALYSIS OF HOSPITAL COMPARE DATA (2011-2014)

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OBJECTIVES: The Centers for Medicare and Medicaid Services (CMS) Hospital Compare website provides information about the quality of care at over 4,000 Medicare-certified hospitals nationwide. One of the goals for these data is to encourage hospitals to improve the quality of care they provide. The purpose of this research was to examine the Hospital Compare database HCAHPS Patient Survey to observe trends in patient satisfaction with care over time. **METHODS:** We accessed HCAHPS Patient Survey data from 2011-2014. Patients rate their overall satisfaction on a scale from 0 (lowest) to 10 (highest). We defined the lowest ranking hospitals as those with the highest percentage of patients rating their hospital a score of 6 or lower. Low ranking hospitals were tracked for four years to observe trends in overall satisfaction. A subgroup analysis was performed on select hospitals to determine whether any specific survey components contributed to overall improvement in satisfaction with care. **RESULTS:** In 2011, there were 3,572 hospitals with reported data on HCAHPS scores. In the lowest 30 ranking hospitals, 22% to 33% of patients gave their hospital a rating of 6 or lower. Of these hospitals, 25 had data available in 2011-2014 to follow trends. Of the hospitals examined, 21 showed improved patient satisfaction in 2012. Of these 21 hospitals, 18 improved further in 2013 and 10 improved even further in 2014. Only two hospitals showed a downward trend in patient satisfaction from 2011 to 2014. **CONCLUSIONS:** When examining a publicly available, self-reported database, the majority of hospitals with low rates of patient satisfaction in the initial year then had higher patient satisfaction in subsequent years. These trends indicate that hospitals modify their behavior to increase patient satisfaction, though more research is needed to determine what other factors impact patient satisfaction scores over time.

PHS206

HOSPITAL-LEVEL TRENDS IN CENTRAL LINE ASSOCIATED BLOODSTREAM INFECTIONS: ANALYSIS OF HOSPITAL COMPARE DATA 2011 - 2013

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OBJECTIVES: The Centers for Medicare and Medicaid Services (CMS) Hospital Compare website provides information about the quality of care at over 4,000 Medicare-certified hospitals nationwide. One of the goals for these data is to encourage hospitals to improve the quality of care they provide. The purpose of this research was to examine one data element of the Hospital Compare database (central line associated blood stream infections – CLABSI) to observe

trends in rates over time. **METHODS:** We accessed hospital-level Hospital Compare CLABSI rates for the years 2011 – 2013. We then ranked hospitals based on their 2011 CLABSI rates to identify hospitals with the highest rates of CLABSI and tracked those hospitals for the subsequent two years to observe trends in data. A subgroup analysis was performed to determine whether there were any specific hospital demographics or other quality of care measures that may contribute to these trends. **RESULTS:** There were 1,937 hospitals with reported data on CLABSI rates in 2011. Of those, 46 hospitals had both a CLABSI rate of 2.0 per 1,000 discharges or greater in 2011 and data available in 2012 and 2013 to examine trends. Of the 46 hospitals examined, 43 hospitals had lower CLABSI rates in 2012 compared to 2011. Of those 43 hospitals with lower CLABSI rates in 2012, 19 hospitals then had increased CLABSI rates in 2013. Only one of those hospitals had higher CLABSI rates in 2013 than in 2011. **CONCLUSIONS:** When examining a publicly available, self-reported database, the majority of hospitals with high rates of infection in the initial year then went on to have lower rates of infection in subsequent years. This would support the hypothesis that hospitals improve the quality of care they provide, though more research is needed to determine what other factors impact hospital infection rates over time.

PHS207

PHARMACEUTICAL POLICY IN NEPAL: RECENT DEVELOPMENTS AND THE NEED OF PHARMACOECONOMICS

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OBJECTIVES: Need and feasibility study of Pharmacoeconomics and Outcomes Research (POR) in Nepal **METHODS:** Field study and personal communication with stakeholders conducted on the need and feasibility of POR in Nepal. **RESULTS:** Few researchers have identified and stressed the need of Pharmacoeconomics and Outcomes Research (POR) in Nepal, however then, the inference is largely undetermined. Poor access to safe and quality medicines, price variation among brands, scarcity of specialists, poor stakeholders' (pharmaceutical companies, researchers and payers) concern, inadequate health care investment are among several factors for its confounding growth. Few Asian countries have considered Health Technology Assessment, HTA (in making drug use reimbursement decisions); and Nepal has also conducted HTA programs (but with poor attention on the cost of medicines). Therefore, to initiate POR, the Department of Drug Administration (DDA), medicines regulatory authority of Nepal, with my contribution as well, has recently fixed prices of 117 common/long term use medicines and we are now working to identify causes of price variation of different registered brands. Recently implemented National Health Policy (NHP) has now made a strategy for basic health services (free of cost), quality health services (universal health coverage) and financial protection of health expenditure. **CONCLUSIONS:** Therefore, for implementing above objectives of NHP and incorporating spirit of POR in National Medicines Policy (which is in process of revision), an approach to develop a national capacity on POR is urgently needed.

PHS208

UNITED STATES (US) REAL-WORLD TREATMENT PATTERNS IN ELDERLY PATIENTS WITH NEWLY-DIAGNOSED GLIOBLASTOMA (GBM) USING SURVEILLANCE, EPIDEMIOLOGY, AND END RESULTS (SEER)-MEDICARE DATA

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OBJECTIVES: The standard of care for first-line (1L) therapy in GBM, a high-grade brain tumor with poor prognosis, is maximal safe resection followed by radiation therapy (RT) concurrent with temozolomide and maintenance temozolomide. However, beyond 1L, there is no standard of care that improves overall survival and there are limited treatment options, especially for elderly/frail patients. This analysis characterized real-world treatment patterns for US elderly GBM patients. **METHODS:** Newly diagnosed patients ≥66 years of age with histologically confirmed GBM between 2007 and 2011 were identified from the SEER-Medicare linked database. Patients were followed from diagnosis to death, Medicare disenrollment, HMO enrollment, or 12/31/2013 to characterize their treatment patterns with respect to receipt of systemic treatments—in 1L, second-line (2L) and third or subsequent lines (3L+). The proportion of patients receiving RT was reported. **RESULTS:** Among 3,012 eligible GBM patients (median age: 74 years; male: 53%; Charlson comorbidity index [CCI] ≥2: 13%; and median follow-up: 5 months), 1,459 (48.5%) received systemic therapy ± RT, 841 (27.9%) received RT alone, and 712 (23.6%) did not receive any intervention. Among patients who received 1L (n=1,459), 1,169 (80.1%) received temozolomide. Of 1L patients, 483 (33.1%) and 126 (8.6%) received 2L and 3L+, respectively. The most prevalent 2L and 3L systemic therapies were bevacizumab/chemotherapy (44.7% of 2L; 58.7% of 3L) followed by bevacizumab monotherapy (32.9% of 2L; 19.1% of 3L). Median (IQR) durations of 1L, 2L, and 3L therapies were 72 (43–196), 98 (43–207), and 84 (41–162) days, respectively. **CONCLUSIONS:** Only about half of elderly GBM patients received systemic therapy at 1L (mostly temozolomide), and about a third of those were given a subsequent line of systemic (mostly bevacizumab-based) therapy. This analysis documents an unmet medical need for elderly GBM patients despite a host of clinical trial activity, especially in later lines.