OBJECTIVES: Many initiatives (e.g., PROTECT, FESP) are exploring quantitative methods to appraise the risk/benefit assessment of medicines. Objectives of this study were to combine quantitative methodologies that can capture expert knowledge and decisionmakers’ insights to genuinely support real-world decisions. METHODS: Using the case study of elafuzumab, approved by the EMA in 2004 for the treatment of psoriasis, we developed a decision analysis method that integrates different outcome measures and patient preferences, and develops a decision model that combines advanced pharmacoeconomics and MCDA for quantitative benefit-risk assessment. Development involved application of: MCDA principles to ensure applicability to any therapeutic area and comparability across medicines and, with patient participation to ensure validity over product cycle (re-evaluation); and advanced pharmacoeconomics and Bayesian modeling to identify/generate most useful data. Overarching design was guided by ethical implications of criteria and data selection as well as accessibility in real-life settings including validity, time constraints, complexity and comparability. RESULTS: The hierarchical multicriteria model consists of two major domains: Benefits (favourable effects, covering the criteria Clinical efficacy/effectiveness and Patient-related outcomes), and Costs (unfavourable effects – clinical safety). The benefit criteria are subdivided into specific subcriteria that correspond to the most relevant outcomes for a treatment for plaque psoriasis. All performance are assessed relative to existing alternatives or placebo. Each subcriteria contributes to the output of the model, the Benefit/Risk Estimate, which is the sum of normalized weights for each subcriteria multiplied by the respective performance score. Pharmacoeconomic data is provided in a standardized format for each subcriteria and includes meta-analytic comparative statistics based on clinical trials, observational data and Bayesian models. Uncertainty is explored in sensitivity analyses. CONCLUSIONS: Integration of pragmatic MCDA modeling with advanced pharmacoeconomics can support decisionmaking and development of regulatory guidelines that can be applicable and meaningful in real life regulatory settings.

PHP212
PERSPECTIVE OF SOCIAL PARTICIPATION IN THE EVALUATION PROCESS OF INCORPORATING TECHNOLOGY IN HEALTH CARE
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OBJECTIVES: The Brazilian Public Health System (SUS) was established in 1988, thereby ensuring that the citizen universal right to health, having as one of its principles to the participation or social control. The performance of the SUS in the field of technology incorporation of pharmaceuticals and medical technologies is the subject of intense discussion, which also is of increased interest as defined by universal policies are committed to the equity and based on knowledge scientific consistent. The year of 2011 represented a breakthrough in transparency and social participation in the process of incorporating technology, with the publication of the law no 12,401, of 28/04/2011, which has set up a National Commission for the Incorporation of Technology in the SUS/CONITEC. The aim of this study is to clarify the participation in the public consultations on technology incorporation in the civil society participation, public and private institutions. METHODS: This is a descriptive, cross-sectional study, which was developed from the analysis of technical reports of Conitec which related to public consultation by the committee were published in 2011 and 2012, with the support decision-making on technology incorporation in the SUS. RESULTS: In the years 2012 and 2013, 78 public consultations and more than 4,182 contributions were examined by CONITEC published arising from health care institutions, patient association, educational institutions, medical, etc., that recommended to incorporate 64 new technologies in the SUS. CONCLUSIONS: The Ministry of Health, responsible for enforcement of the law n. 12.401, use systematically the public consultations as the instrument to gather contributions from segments of society. In a social and political context, the extent to which such participation is intended to subsidize the decision about incorporating technology in the SUS, there are significant gains in building the public policy agenda, adding legitimacy and transparency in government decision-making.

PHP215
HEALTHCOST MEDICINES IN BRAZIL: CENTRALIZED PURCHASE FOR OPTIMIZATION OF BUDGETARY RESOURCES AND INCREASING ACCESS IN THE PUBLIC HEALTH SYSTEM
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OBJECTIVES: The Brazilian public health system ensures universal, equitable, and comprehensive access to health technologies, including medicines. The high-cost medicines of the Brazilian public health service were prioritized for technology incorporation on the SUS. METHODS: In the centralized purchasing, the MoH expanded the amount of centralized procurement medicines, from 13 to 51 products. This deed was focused in medicines with a concentrated market. As a consequence, this action allowed a saving of US$ 403.8 million in four years, compared to the price in 2010. The medicines that most contributed to the economy were: efalizumab (US$120 million), etanercept (US$100 million) and infliximab (US$64 million). Betabaterona (50%), etanercept (48%), infliximab (48%), adalimumab (37%) and elfapaginterferona (37%) were the products with a greater reduction in the unit price, considering the accumulated value at period. The increase in the number of units distributed was 263%. CONCLUSIONS: The SPSC was designed in 2010 for the budgetary resources optimization and to expand access to medicines for diseases that require complex health services or high-cost medicines. The purchasing power of the MoH is a strategy that allowed expansion of access to medicines. The purchasing power of the MoH is a strategy that allowed expansion of access to medicines and optimization of resource allocation in the SUS. As a result, there are significant gains in building the public policy agenda, adding legitimacy and transparency in government decision making.

HEALTH CARE USE & POLICY STUDIES – Conceptual Papers

PHP127
PRAGMATIC MCDA COMBINED WITH ADVANCED PHARMACOECONOMICS FOR QUANTITATIVE BENEFIT/RISK ASSESSMENTS OF MEDICINES
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OBJECTIVES: Using the case study of elafuzumab, approved by the EMA in 2004 for the treatment of psoriasis, we developed a decision analysis method that integrates different outcome measures and patient preferences, and develops a decision model that combines advanced pharmacoeconomics and MCDA for quantitative benefit-risk assessment. Development involved application of: MCDA principles to ensure applicability to any therapeutic area and comparability across medicines and, with patient participation to ensure validity over product cycle (re-evaluation); and advanced pharmacoeconomics and Bayesian modeling to identify/generate most useful data. Overarching design was guided by ethical implications of criteria and data selection as well as accessibility in real-life settings including validity, time constraints, complexity and comparability. RESULTS: The hierarchical multicriteria model consists of two major domains: Benefits (favourable effects, covering the criteria Clinical efficacy/effectiveness and Patient-related outcomes), and Costs (unfavourable effects – clinical safety). The benefit criteria are subdivided into specific subcriteria that correspond to the most relevant outcomes for a treatment for plaque psoriasis. All performance are assessed relative to existing alternatives or placebo. Each subcriteria contributes to the output of the model, the Benefit/Risk Estimate, which is the sum of normalized weights for each subcriteria multiplied by the respective performance score. Pharmacoeconomic data is provided in a standardized format for each subcriteria and includes meta-analytic comparative statistics based on clinical trials, observational data and Bayesian models. Uncertainty is explored in sensitivity analyses. CONCLUSIONS: Integration of pragmatic MCDA modeling with advanced pharmacoeconomics can support decision making and development of regulatory guidelines that can be applicable and meaningful in real life regulatory settings.

PHP128
ASSESSING THE IMPACT OF A MULTI-MILLION PUBLIC-PRIVATE PARTNERSHIP FOR TRANSLATIONAL RESEARCH: THE CENTRE FOR TRANSLATIONAL MEDICINE (CTMM) IN THE NETHERLANDS
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OBJECTIVES: The Center for Translational Molecular Medicine (CTMM) is a multi-technology, multi-interest, translational research institute brought together by the Dutch public and private stakeholders. CTMM aims to accelerate molecular diagnostics and imaging technologies to enable determination of predisposition, early prognosis, and, personalized treatment of patients. It is unique in that it dates early Health Technology Assessment (HTA) in each of its 21 projects. This study assessed the impact of CTMM on scientific, translational, clinical, and economic aspects. METHODS: The impact assessment was guided by the “Research Impact Framework” (RIF). Since 2008, data were gathered from extensive CTMM administrations, including publications, patents, project proceedings, early HTA results, etc. Perceived impact was investigated using a CTMM-wide survey (n=167) and two focus groups. RESULTS: CTMM focuses its impact on disease areas with high Disability Adjusted Life Years and high societal costs, i.e. oncology, cardiovascular, neurologic, infection and immunity diseases. Its scientific impact is as high as the overall impact of Dutch biomedical research, i.e. 15%-80% above international values. Its financial impact is estimated to be €3.5 million annually. CONCLUSIONS: CTMM is perceived to stimulate translation of technology to the clinic, with a median score of 4 out of 5 (IQR 3-5). Its main strength lies in pre-clinical and phase 1 development (median score of 4 out of 5). Early HTA results (median score of 3 out of 5) are focused on translation, (future) clinical and economic aspects. Its impact on translational, (future) clinical and economic aspects is generally perceived as large. Metrics to objectively measure this need improvement as well as longer follow-up. The early HTA analyses have provided critical insights and exemplar approaches for future early HTA work in public-private partnerships.

PHP129
HOW TO CONSIDER EQUITY IN DECISIONS TO INCORPORATE NEW TECHNOLOGIES IN BRAZILIAN UNIFIED HEALTH SYSTEM (SUS)
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OBJECTIVES: In 2011 was published 12401 law establishing the National Committee for Technologies Incorporation in SUS (CONITEC) and defining the criteria and deadlines for the analysis and adoption of technologies. According to the law, CONITEC’s assessment must considers necessarily scientific evidences about efficacy, accuracy, effectiveness and safety of technologies and economic evaluation studies of benefits and costs in relation to the technologies already incorporated in SUS. Studies of economic evaluation traditionally ignore equity in health, and because this gap, researches have been undertaken to develop methods to incorporate equity into economic evaluation in health. Thus, this paper aims to analyze the viability of using an economic evaluation framework in the decision making process about incorporation of new technologies. METHODS: We performed a systematic literature review on the incorporation of novel technology in SUS, a system that offers universal coverage to approximately 201 million citizens. RESULTS: Until end of 2013, CONITEC recommended the incorporation of 64 technologies for diagnosis, prevention and treatment of various diseases, and no so-cost economic evaluation had been addressed. The analysis of this research found a systematic review conducted by Jobri & Norheim (2012) having found three distinct approaches: integration of distributional concerns through equity weights and social welfare functions, exploration of the opportunity costs of alternative policy options, through mathematical programming and multi-criteria decision analysis. The multi-criteria decision analysis is the most popular method, which involves the use of a weight matrix for each category. The weight matrix is used to assess the impact of each category on the overall decision.