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The marketing authorisation of a new medicine is granted on the basis of a favorable benefit-risk balance for its target population and indication. However, not all risks will have been identified at the time when an initial authorisation is sought and many of the risks associated with the use of a medicinal product will only be discovered/fully characterised when the medicine is widely used in everyday medical practice. A full HTA should provide for an evaluation of adverse drug reactions (ADR) including those identified during long term follow- up or which are rare. In addition to knowledge of risks, a relevant consideration for both individual patients and policy makers is the performance of risk minimization measures (RMM) in everyday medical practice. The new European pharmacovigilance legislation embeds the RMP as a key tool in proactive pharmacovigilance. The RMP, as the documented set of pharmacovigilance activities and interventions designed to identify, characterise, and prevent/minimise risks associated with exposure to a medicine, may include specific RMM. RMM should be shown to achieve the desired effect of reducing the burden of ADR and optimising health outcomes. Implementation of RMM may involve a substantial investment of resources and their performance in health care systems should be assessed. In case a RMM proves ineffective, alternative interventions must be identified implemented. We introduce an approach to evaluating the effectiveness of RMM that builds on the assessment of two distinct levels of evidence. The evaluation of the effectiveness of RMM should differentiate between the actual implementation of the RMM, and the attainment of its final objective(s). If the RMM is unsuccessful, this strategy will help to ascertain whether the intervention was inherently ineffective or badly delivered. The assessment requires research encompassing analysis of implementation (process indicators), and traditional epidemiological research addressing the attainment (final outcome indicators) of RMM.

PHP202

BRIDGING THE GAP BETWEEN INSTITUTIONAL LEVELS USING SYSTEMS ANALYSIS

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Transforming the provision of health care involves collaboration and change on many levels. Too often health care delivery decisions are made without considering the complex and dynamic nature of the health system. Approaching these problems from a systems thinking perspective integrates these traits and encourages long term thinking about solutions. Despite being widely used in other disciplines, only recently has systems analysis started to play a larger role in transforming health care provision. The purpose of this work is to outline how systems analysis tools can bridge multiple levels of health care to make more informed decisions. The aforementioned will be illustrated using a Canadian case study. Currently, a provincial strategy to diagnose and treat epilepsy in adults and children in Ontario is being examined. The organization of epilepsy specific care centres (ESCC) into district and regional services is being recommended which will modify current practice patterns and access to care. Subsequently, any changes in delivery will have an impact on referral rates and patterns as well as resource utilization (i.e. beds, staff, and diagnostic tests). The use of systems analysis tools can bring insight into how the inter-relationship between ESCCs can be modeled and how access to care will be affected and aid in capacity planning (i.e. resources and costs).System changes can be graphically illustrated and quantified using the systems analysis tool discrete event simulation. Mapping the clinical pathways and patient flow of epileptic patients through the current system, a simulation model was developed to help inform the planning process. This was useful in understanding how the system might respond and in identifying potential bottlenecks or where resources may be limited. Using discrete event simulation facilitated the ability to take on multiple perspectives by conducting analyses at multiple institutional levels (i.e. government, hospital and health care practitioner).

PHP203

HOW TO OPTIMISE CHANCES FOR SUCCESSFUL AMNOG ASSESSMENTS – BEST PRACTICE APPROACH FOR GERMAN MARKET ACCESS

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Since the introduction of AMNOG in January 2011, manufacturers in Germany are required to submit a "benefit dossier" and show additional benefit in relation to a so-called appropriate comparative therapy to the Federal Joint Committee for every NCE in order to gain access to price negotiations. If an additional benefit is shown, the new reimbursed price will be a surplus on the reimbursed comparator price. Market access in Germany changed significantly due to AMNOG and requires early preparation, an interdisciplinary approach and clearly defined internal processes. Market access strategies and processes have to be reviewed in light of the new framework and adapted in order to optimize the chance to be successful in the AMNOG process. Preparation for AMNOG should start as early as in the planning of clinical studies to implement the right questions into the study and not to rely on surrogate drivers. The FJC will respond best to data providing the most credible scientific clinical evidence. Building RCTs powered to capture such information does present important issues for pharmaceutical companies to address. Early planning of clinical studies should be part of an early strategy development for the NCE that can be informed by early phase modeling of the likely outcome of the benefit assessment. Early identification of the patient groups that are most likely to benefit is vital in order to plan for patient (sub-) populations big enough to achieve statistical significant results and positive outcomes in the AMNOG process. An interdisciplinary approach is required at a stage in the product development where there are no common processes and communication paths established between headquarter and affiliates. A best practice approach requires a well defined process including road maps and checklists per stage of product development in form of standard operating procedures in order to optimize market access.

PHP204

APPROPRIATE METHODS FOR ECONOMIC EVALUATION OF PROGRAMMES WITH COSTS AND EFFECTS EXTENDING ACROSS SECTORS

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Public policies/interventions impact on many areas of activity including areas beyond the main focus of them ; the costs and (dis)benefits falling on other areas of the economy, government and/or private sector, and different individuals. However, there is no consensus on the appropriate way to analyse such policies/interventions to decide which are beneficial and should be implemented. One form of economic evaluation, cost-effectiveness analysis, has been widely used to inform decisions about policies/interventions which affect only a single sector where there is a single agreed output (as in most health care evaluations), however, its use for evaluating interventions with multi-sector impacts is limited. Cost-benefit analysis (CBA), another form of economic evaluation, based on welfarism, has been proposed as a method which allows the evaluation of policies/interventions where costs and benefits fall on several sectors, by aggregating costs and benefits into a given numeraire, normally consumption. However, a key weakness of CBA is it fails to acknowledge the relevance of sectors' budget constraints. This despite the process by which budget constraints are set being viewed as having (democratic) legitimacy. We consider how decisions on policies/interventions with multi-sectoral impacts could most appropriately be informed by economic evaluation. Two options are considered: first, where there is an implied or explicit social welfare function (which could be based on welfarist or extra-welfarist principles); and second, a societal decision making approach. We aim to demonstrate that trade-offs are inevitable and have to be made, but budget constraints cannot be ignored and shadow prices on budget constraints are central no matter which approach is accepted. We also consider whether compensation payments between 'losing' and 'gaining' sectors are a potential means of understanding the net benefit associated with policies with multi-sectoral effects, and whether it is possible, necessary or even appropriate in practice to make such payments.

PHP205

PRIMARY CARE TRANSFORMATION AS A SOLUTION TO THE EPIDEMIC OF CHRONIC DISEASES

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That the world faces an epidemic of chronic diseases is unmistakable. Chronic diseases represent 63% of all deaths worldwide. Against the background of demographic aging, the prevalence of comorbidity or multi-morbidity is as high as 60% among individuals aged 55 to 74 years. In the context of financial crunch wrought by the financial crisis, the financial and non-financial burden of chronic diseases make their management a priority concern globally. Primary care plays a critical role in dealing with this epidemic. To harness the full potential of primary care, however, the way it is organized needs transformation. At present 1) primary care is still organized around the primary care physician even as the shortage of primary care physician is worsening and is unlikely to improve in the immediate future; 2) models of care for the chronically ill are directed to the management of each disease separately, and despite its attribute of continuity, comprehensiveness and patient-centeredness; 3) fails to harness the contribution of patient self-management even as role of patient involvement in their health and health care is recognized; and 4) and overcome the barriers resulting from the structure of the health care system. These challenges are true for primary care in low and middle-income settings and high-income settings. A global framework for the transformation of primary care, consequently, offers promise to every health care system. The critical elements of such involve 1) the development of primary care teams that include physician services extenders such as primary care physicians or nurse practitioners; 2) that will deal with the health needs of the population – rather than the those of the individual patient; 3) by way of engaging chronically ill patients in co-managing their condition; 4) using ehealth technologies and point-of-care-testing facilities.

PHP206

ASSESSING THE VALUE OF ACCESS TO INDIVIDUAL PATIENT DATA FOR REIMBURSEMENT DECISIONS

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To successfully support health care decision-making, cost-effectiveness analysis (CEA) must consider and synthesise all (relevant) available evidence relating to the clinical effectiveness, health-related quality of life (HRQoL) and costs of the health technologies under scrutiny. Evidence based medicine tells us that statistical evidence synthesis of multiple individual patient level data (IPD) sources (e.g. IPD meta-analysis and its extensions) is the gold standard for deriving relative treatment effect estimates, one of the key parameters in any cost-effectiveness model. Unfortunately the evidence base available to the cost-effectiveness modeller is often multifaceted and fragmented, comprising a mix of aggregate (AD, or summary level) and individual patient level data. This scenario poses a series of methodological issues and it is not uncommon for the analyst to end up collapsing the IPD into AD, with consequent loss of information, for use in a standard evidence synthesis model (e.g. meta analysis or mixed treatment comparison of AD). Such a