The marketing authorisation of a new medicine is granted on the basis of a favor- able 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 not all the risks associated with the medicinal product have been discovered/fully characterised when the medicine is widely used in everyday med- ical 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 pa- tients and policy makers is the performance of risk minimization measures (RMM) in everyday medical practice. The new European pharmacovigilance legislation embeds the RMM as a key tool in proactive pharmacovigilance. The RMM, as the documentation of risk minimization 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. Implement- ation of RMM may involve a substantial investment of resources and their perfor- mance in health care systems should be assessed. In case a RMM proves ineffective, alternative interventions must be identified implemented. We introduce an ap- proach 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 ascer- tain whether the intervention was inherently ineffective or badly delivered. The assessment requires research encompassing analysis of implementation (process and outcomes) 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 consider- ing the complex and dynamic nature of the health system. Approaching these problems from a systems thinking perspective integrates these traits and encour- ages long term thinking about solutions. Despite being widely used in other disci- plines such as computer science, systems analysis started to play a larger role in transform- ing 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 chil- dren in Ontario is being examined. The organization of epilepsy specific care cen- tres (ESCC) into district and regional services is being recommended which will modify current practice patterns and access to care. Subsequently, any changes in delivery of the care will 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 capacity). The ESCC's ability to be graphically illustrated and analyzed 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 poten- tial necks or where resources may be limited. Using discrete event simulation facili- tated the ability to take on multiple perspectives by conducting analyses at multi- ple 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 system. Evidence for AMNOG (i.e. effect, risk, costs and cost-effectiveness) 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 evidence of clinical effectiveness, health-related quality of life (HRQoL) and costs of the health technologies under scrutiny. Evidence based medicine tells us that statistical evi- dence synthesis of multiple individual patient level data (IPD) sources (e.g. IPD meta-analysis and its extensions) is the gold standard for deriving relative treat- ment effects with least parameters in any cost-effectiveness model. Unfortunately the evidence base available to the cost-effectiveness modeler is often multifaceted and fragmented, comprising a mix of aggregate (AD, sum- mary level) and individual patient level data. This scenario poses a series of meth- odological 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