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THE CHALLENGE OF ASSESSING HEALTH TECHNOLOGIES EARLY IN THE DEVELOPMENT. SYSTEMATIC LITERATURE REVIEW OF METHODS IN USE

Markiewicz K, van Til J, IJzerman MJ
University of Twente, Enschede, The Netherlands

Medical devices are being developed continuously and their developers are under pressure to provide better evaluations of their products. Early assessment gathers the preliminary evidence to estimate clinical, financial, organizational, and social/ethical consequences of a particular technology. It seems a useful tool in predicting the potential of medical devices at the stage in which it can be adapted to fit the environment or the environment can be prepared for the technology. If the potential is low, further development can also be stopped. Although early assessment is recognized as an important part of medical device development process, there are many uncertainties in its nature and regarding the methods that are being used for its purpose. **OBJECTIVE:** To review different methods and their use in the early assessment of medical technologies. **METHODS:** An extensive systematic literature review of different early assessment methods. The authors systematically searched: computerised databases; published bibliographies of related topics; citations in articles reviewed; and references provided by colleagues. **RESULTS:** We identified 40 studies that met the inclusion criteria. 18 papers were either systematic literature Reviews (5) or theoretical papers (13). 10 papers were addressing specific applications of early assessment methodologies, and 12 papers were addressing theoretical concepts combined with examples. Those 22 articles were analysed and categorised with regard to the stage of development of the technology, innovation type, perspective and aims of the analysis. Aims, outcome and uncertainties with regard to the outcome of the analysis were assessed. **CONCLUSIONS:** There is a need to clarify and communicate the aims and value of early assessment methods of medical devices to developers and policy makers, if early assessment methods are to become an integrated part of early activities in the development process.

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THE VALUE OF CHOICE IN A COLLECTIVELY FUNDED HEALTH SYSTEM: AN EXTENDED ANALYTICAL APPROACH TO EXAMINE THE CONFLICT BETWEEN DECISIONS AT INDIVIDUAL AND SOCIETAL LEVEL

Espinoza MA
University of York, Heslington, York, UK

Cost-effectiveness analysis is a well recognized tool to support decisions about resource allocation in health care, particularly in the context of collectively funded health systems. When a new technology is restricted based on cost-effectiveness (because it is deemed too expensive relative to its expected benefits) a potential conflict can arise between the social interests (i.e. maximization of the population health subject to fixed budget constraint) and individuals who want to maximize their own health or utility. It has been previously argued that decisions that consider heterogeneity add value to the health care system. On the one hand, if a centralized decision process is implemented (e.g. NICE in the UK), subgroup analysis is appropriate. On the other hand, if a decentralized process is to be implemented, the effect of unrestricted choices on the social interests must be assessed. I have recently presented an analytical approach to estimate the expected health forgone (or gained) as a consequence of implementing a decentralized decision process. In the simplest case it was assumed that social planners and patients focus on the same metric of health, i.e. patients maximise health (for example, QALYs) and social decision makers maximise net health (net QALYs). This piece of work examines the case where patients choose according to a different maximand. The analysis shows that if a single and different argument of the patient's maximization function can be identified, the expected net health benefits forgone (or gained) from implementing unrestricted choices can be estimated as an extension of the base-case analysis. It also highlights the role of a robust estimation of the joint distribution of potential outcomes, discussing gaps that require further research. The contribution of this analysis for policy decisions about individualized care is illustrated with a stylized numerical example.

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AN INTEGRATED FORMAL FRAMEWORK FOR REIMBURSEMENT, RESEARCH AND PRICING DELIBERATIONS IN HEALTH TECHNOLOGY ASSESSMENT

Griffin S[1], Spackman E[2], Soares MO[3], McKenna C[3], Claxton K[4]
[1]*University of York, York, North Yorkshire, UK,* [2]*University of York, Heslington, North Yorkshire, UK,* [3]*University of York, York, UK,* [4]*University of York, Heslington, York, UK*

Reimbursement and research decisions about the utilisation of health care interventions can be formally characterised using methods for economic evaluation. Reimbursement decisions are informed by establishing the expected cost-effectiveness of the intervention. Research decisions are informed by establishing the expected value of additional information (the cost of uncertainty). Price negotiation can be used to alter conclusions about the benefits of reimbursement and the need for further research. In practice each of these elements may be considered separately, but they could routinely be combined within a single evaluation. Previous research has shown (i) the impact of future changes on the payoff from reimbursement in the presence of irrecoverable costs and uncertainty that will be resolved over time, and; (ii) how the reimbursement and research decisions interact in terms of the ability to acquire additional information and the impact of delay on the payoffs and the size of the populations that can benefit. The objective of this paper is to bring together established methods, using a consistent set of notation, to describe a general algebraic framework. The aim is to show systematically how irrecoverable costs, uncertainty that can be resolved through research and uncertainty that will be resolved over time can be formally incorporated in an integrated framework to estimate both cost-effectiveness and the value of further research that reflects the interaction between the reimbursement and research decisions. Furthermore we show how effective price negotiation would affect the payoff and ranking of the alternative policy options. A simple numerical example is used to demonstrate the application of this general algebraic framework and how the results might be presented to decision makers. The advantage of a single integrated framework is that reimbursement, research and pricing decisions can be informed simultaneously, transparently and consistently.

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INTERNAL AND EXTERNAL VALIDITY IN ECONOMIC MODELING: CONSIDERATIONS BASED ON A PUBLISHED EXAMPLE

Porzsolt F
University of Ulm, Ulm, Germany

OBJECTIVES: Economic modeling is an established tool used for allocation of health care resources. Modeling was designed to demonstrate the influence of variables on defined outcomes (e.g. cost-effectiveness) in complex systems. Valid information for health care decisions can be obtained if five types of bias can be avoided: selection-, performance-, attrition-, detection-, and sampling-bias. In this study the validity of results derived from economic modeling is investigated addressing these five types of possible biases. **METHODS:** A published economic model of costs and benefits of drug treatment in mild-to-moderate Alzheimer's disease (Guo et al., J Med Econ 2010;13:641-654) was used for this analysis. Nine questions were asked to confirm the validity of the obtained results. Internal validity was tested by checking the first four of the above types of bias, external validity by checking for a possible sampling bias. **RESULTS:** The presented model is flawed by absence of an explicit study question. Selection bias cannot be excluded as the patient data were obtained from pooled clinical trials and other sources. Performance bias is likely as the outcomes in patients extracted from pooled clinical trials differed considerably to the outcomes of patients treated outside of trials. A detection bias is likely as observed data were compared with extrapolated data. Also the external validity of the study is likely to be impaired as the patients profiles were not derived from real world conditions but from patients enrolled in two clinical trials. **CONCLUSIONS:** This appraisal shows that phrasing a study question is essential for selection of the appropriate study method. Economic modeling is useful to discuss models and to generate hypotheses but always implies a high risk of bias. Therefore, results from modeling should only be accepted when internal as well as external validity of the used method has been confirmed.

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OPTIMIZING PUBLIC HEALTH DECISION OVER TIME: A DYNAMIC BUDGET OPTIMIZATION MODEL WITH MULTIPLE CRITERIA DECISION MAKING

Ethgen O[1], Topachevskyi O[2], Connolly M[3], Standaert B[2]
[1]*University of Liege, Liege, Belgium,* [2]*GlaxoSmithKline Vaccines, Wavre, Belgium,* [3]*Global Market Access Solutions, St Prex, Switzerland*

To guide health care decision, modeling efforts have mainly focused on cost-effectiveness appraisals (CEAs) between two mutually exclusive interventions. As CEAs do not document the impact of interventions on health care budget, they are generally complemented with budget impact analysis (BIAs). BIAs provide financial projections only and do not detail the beneficial health effect an intervention may have on the population targeted. Additionally, decision makers may have different and several competing preferences and priorities on what constitutes the population health value of an intervention. A typical example is the public health impact of large childhood vaccination campaigns. Reduction of incidence, prevalence, hospitalizations, deaths, costs, etc. are the many criteria assessed by decision makers beyond the QALYs gained when they contemplate vaccination campaigns. In this research, we design a transparent dynamic budget optimization model based on a multi-criteria decision making framework. The model is a sequential multi-birth cohort model with yearly cycle and adaptable time-horizon (from 3 years onwards). Optimization is realized yearly based on the population outcomes achieved the year before, the annual budget constraints and through different combinations and weightings of decision preferences. Decision maker preferences can be weighted on number of cases avoided, GP visits avoided, hospitalizations avoided, length of in-hospital stay reduction, number of in-hospital beds avoided, number of death avoided, Life-Years gain and QALYs gain. The model is intended to address specific questions that usually emanate from decision makers confronted with the introduction of mass vaccination campaigns: What is the yearly budget needed to achieve specific public health goals? What are the yearly and overall expected outcomes at the population level (i.e. the public health impact or in others words, the return-on-investment in terms of public health benefit)? Which intervention should be given additional (*less*) resources to maximize (*minimize*) impact if the available budget is increased (*decreased*)?

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OPTIMAL SHOPPING: AN EVAUATION OF DECISION RULES IN COST-EFFECTIVENESS ANALYSIS (CEA)

McKenna C[1], Claxton K[2]
[1]*University of York, York, UK,* [2]*University of York, Heslington, York, UK*

Standard decision rules in CEA are founded on a single objective to maximise health subject to a single and exogenous budget constraint. In essence, this is a well-specified constrained optimisation problem. The difficulty of using mathematical programming (MP) solutions to inform the allocation problem is that the informational demands are not feasible. However, it does provide an opportunity to evaluate the performance of simple ex-ante decision rules that have been proposed, some of which are being used to make decisions about health care technologies. Different decision rules are evaluated which compare: 1) the health gained and forgone for a new technology based on an estimate of the cost-effectiveness