

From Good to Better: New Dutch Guidelines for Economic Evaluations in Healthcare

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1 Introduction

Many countries have national guidelines for performing economic evaluations in healthcare.¹ These guidelines should ensure the comparability and quality of such evaluations, which should facilitate making well informed policy decisions regarding reimbursement of interventions. Given the developments in both the methodology and policy context of economic evaluation of healthcare interventions, these guidelines require periodical revision. Recently, the Dutch National Health Care Institute issued new guidance for economic evaluations in healthcare [1]. The new guidelines update and replace three separately published previous guidelines: those for pharmaco-economic evaluation (latest version 2006), outcomes research (latest version 2008) as well as the Dutch costing manual (latest version 2010). In this editorial, we highlight the distinguishing features of the new Dutch guidelines. Moreover, we highlight which developments, in our opinion, are desirable in coming updates, but are still in development or controversial.

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2 Unchanged Features

2.1 Societal Perspective

A key feature of guidelines is which perspective they prescribe researchers to take in an evaluation. In line with the welfare economic roots of economic evaluation, influential textbooks as well as all previous Dutch guidelines, the new guidelines prescribe taking a societal perspective. This implies that all significant societal costs and benefits need to be included in the analysis, regardless of where these fall. Thus, evaluations should also include costs and benefits that fall outside the healthcare sector, such as time costs for patients (e.g. time lost from paid work, unpaid work or leisure time), travel costs, costs related to informal care (e.g. time of caregivers), costs of special education or those related to criminal activity.

2.2 Productivity Costs

Productivity costs are an important example of costs falling outside the healthcare sector. When productive people, either paid or unpaid, become less productive (due to illness, disability, death or treatment), this causes real societal costs. The guidelines indicate how to value these components, including the often ignored unpaid work [2, 3]. For absenteeism from paid work, the friction cost method is prescribed as the most accurate estimation of societal costs [4, 5]. This method limits productivity to the period it takes to replace an absent worker [6]. The measurement and valuation of production losses due to

¹ For an overview of guidelines around the world visit <http://www.ispor.org/PEguidelines/index.asp>.

presenteeism are acknowledged as relevant. The costing manual (as part of the guidelines) indicates that productivity losses, including presenteeism, can be measured using, for example, the iMTA Productivity Cost Questionnaire (iPCQ) instrument [7].² Unpaid work is valued at €14 per hour.

2.3 Informal Care

Another important cost (and effect) category is informal care, which commonly is a large part of total care provided to patients. Several methods for measuring, valuing and including these costs exist [8], but the current guidelines suggest they should be included on the cost side of the economic evaluation. This facilitates their inclusion in the most common type of economic evaluation: cost–utility analysis.

2.4 Cost–Utility Analysis

Cost–utility analysis, using quality-adjusted life-years (QALYs) as outcome, continues to be the reference case in the current guidelines. Effects in terms of health-related quality of life have to be captured with EQ-5D-5L valued with Dutch population preferences [9]. Remarkably, EQ-5D-5L scores have to be presented in the reference case, even when they might be considered inappropriate. Then, alternative measures can be presented *alongside* EQ-5D-5L outcomes.

2.5 Differential Discounting

Discounting costs and effects in economic evaluations is much debated (e.g. [10]). The previous guidelines (from 2006) already prescribed differential discounting (4 % for costs and 1.5 % for effects) rather than an equal discount rate of 4 %, to account for the growing value of health benefits in the future [11]. The current guideline also prescribes differential discounting; using the same rates (4 and 1.5 %).

3 New Features

The new guidelines also include new elements, reflecting the methodological developments in performing economic evaluations in healthcare. We highlight three of them.

3.1 Value of Information Analysis

Previous guidelines requested information on the uncertainty of the outcome of economic evaluations through

² Questionnaires for measuring and valuing productivity costs and informal care can be found here: <http://www.imta.nl/questionnaires>.

univariate sensitivity analyses, probabilistic sensitivity analyses (PSA) and scenario analyses. The new guidelines require quantifying uncertainty through value of information analysis for all uncertain policy decisions, which can help in decision making, using conditional reimbursement schemes and priority setting of further research [12, 13]. In all instances where there is decision uncertainty, i.e. PSA indicates that the probability of an intervention being cost effective (given a relevant cost-effectiveness threshold) is <100 %, a value of information analysis is required.

3.2 Inclusion of Indirect Medical Costs in Life-Years Gained

Another major and quite unique change is the requirement to include so-called unrelated indirect medical costs in life-years gained. For example, when assessing the cost effectiveness of heart surgery, the costs related to treating hip fractures in gained life-years after successful heart surgery are also to be included. These costs were explicitly excluded from consideration in the previous guidelines, and this is still the case in most other guidelines, including those of NICE [14]. The inclusion of these latter costs has been much debated [15], but the case for their inclusion is strong [16]. Especially given that the health gains due to these unrelated costs typically are (implicitly) included in economic evaluations, making their exclusion inconsistent from both a societal and a healthcare perspective [17]. These unrelated healthcare costs can be estimated, correcting for the characteristics of the patients involved, using a simple tool that was recently developed [18].³ Clearly, including these costs can increase incremental cost-effectiveness ratios (i.e. decrease cost effectiveness of life-prolonging interventions), which may result in different reimbursement decisions that collectively increase health gained per euro, but which may also raise important ethical and policy questions. Given the new Dutch guidelines, these questions cannot and should not be circumvented by ignoring these real costs.

3.3 Beyond Medicines and Curative Care

A final important development is the explicit attention in the guidelines for methodological issues that arise in sectors other than the conventional areas of curative care and pharmaceuticals. While for these other sectors the now-included reference case requires QALY measurement with EQ-5D-5L-based quality-of-life corrections, it is acknowledged that this outcome measure may have limitations in particular contexts. Issues may specifically arise in economic evaluations in the contexts of prevention (e.g.

³ The tool can also be found here: <http://www.imta.nl/paid>.

uncertainty and modelling based on intermediate outcomes), diagnostics (e.g. consequences of false positives and negatives as well as value assessment in patients), medical devices (e.g. value of user friendliness), long-term care (e.g. wellbeing rather than health improvement as the goal) and forensic (e.g. reduction of criminal activity as the goal of an intervention). Many of these issues pertain to accurately capturing the value of interventions when this exceeds or deviates from health gains (in terms of length of life and quality of life as measured with the EQ-5D). The guidelines suggest other possibilities, ranging from measuring patients' preferences for medical devices, use of effectiveness measures such as 'criminal-activity-free years' in forensic interventions, to the use of new instruments such as the ICECAP (Icepap Capability) measure [19] in case of long-term and social care [20]. For the purpose of standardization, the ICECAP is recommended in the guideline for outcome assessment in this field, be it alongside EQ-5D. This marks the broadening of the scope of the guidelines and use of economic evaluations in healthcare. The guideline also highlights the need for Multi-Criteria Decision Analysis in this context.

4 What is Expected and Desired in Future Updates?

The new Dutch guidelines present a long awaited update incorporating important improvements in theory and methodology of economic evaluations. A committee with broad representation of health technology assessment (HTA) experts was involved in creating these new guidelines. Cyclic updates are foreseen to guarantee that the guidelines keep up with methodological advances and are useful in the policy context. Below, we suggest four topics that could be included in future versions of the Dutch guidelines.

4.1 Expanding the Scope of Economic Evaluations

The current guidelines began the first step in broadening the scope of economic evaluations by looking at the specific issues related to, for instance, long-term care. It is important and expected that future guidelines will develop stronger and clearer guidance as to how to perform economic evaluations in these contexts. This will probably include a further standardization of non-QALY outcomes, such as wellbeing measures like the ICECAP [19]. It may also involve guidance on how to obtain preferences from patients through methods such as discrete choice experiments. Wellbeing measures may well become the preferred outcome measures in economic evaluations in non-curative settings, rather than being presented next to QALY

estimates. However, it has to be acknowledged that experience with these instruments is currently limited. Moreover, there may be other pressing challenges related to obtaining good quality economic evaluations in the non-curative setting, most notably those related to adequate study designs for assessing comparative effectiveness of interventions. Indeed, appropriate wellbeing measures should be used in the context of well designed studies capable of detecting the wellbeing changes due to interventions.

4.2 Inclusion of Non-Medical Consumption

Given that Dutch guidelines prescribe taking a societal perspective and that, where relevant, productivity costs and indirect medical costs in gained life-years are now included, it is likely that the inclusion of non-medical consumption in life-years gained (housing, food, etc.) will gain more attention. Similar to indirect medical costs, prolonged survival of individuals increases such non-medical consumption. Moving towards a more complete and consistent trade-off of costs and effects will require inclusion of these costs in evaluations, as well as more discussion on whether the QALY adequately captures the related benefits [21, 22]. We do foresee, however, that inclusion of these costs will require both methodological work as well as further discussion to increase the acceptance of their inclusion.

4.3 Inclusion of QALY Variation

The current guideline prescribes the use of EQ-5D with Dutch tariffs obtained in the general public in all evaluations. This guidance enhances the uniform assessment of QALY gains, but also ignores important heterogeneity in QALY instruments. One important missed issue is the valuation of health states by patients themselves. Using both patient and general population values can inform the decision makers about the likelihood of adaptation to a condition, and use this information in the decision-making context. In a context of limited resources, decision makers might, for instance, use this information to, *ceteris paribus*, prioritize treatments of conditions for which adaptation is less likely and, therefore, treatment effects from a patient perspective are relatively large [23].

4.4 Two Perspectives and Costs of Displacement

Economic evaluations ultimately aim to inform resource allocation decisions in healthcare. The current framework for decision making in The Netherlands adopts a societal perspective, informally using an (equity weighted) threshold value for QALY gains that represents the social willingness to pay for QALY gains—the trade-off between

health and other consumption. However, a full assessment, in the context of limited healthcare budgets, also requires knowledge about the opportunity costs within the healthcare sector [11, 17]. An intermediate step is to present the results from two perspectives: the societal and the healthcare perspective [24]. This allows relevant stakeholders to understand the tension between the two perspectives (if any).

Meaningfully interpreting the results from both perspectives still requires appropriate threshold values from both perspectives. While some experience with using equity-weighted, societal values of QALYs is present in the Dutch context, more knowledge on the opportunity costs of spending within the Dutch healthcare sector is required. In the coming period, more research can be devoted to this issue, along with gaining experience in the decision-making process using two perspectives.

5 Conclusion

The new Dutch guidelines are an important step forward in improving the requirements for economic evaluations in healthcare in the context of reimbursement decisions. We feel that the changes have moved the guidelines from good to better. We also feel that the foreseen periodical updates of the guidelines will allow further improvement in the future.

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