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Letter to the Editor

Comments on A Conceptual Framework for Life-Cycle Health Technology Assessment

Thi Hao Pham, MSc, Jurjen van der Schans, PhD

Introduction

Nowadays, countries strive to deliver universal health coverage but must make choices on which health technologies and interventions to invest in, given their limited resources. In this context, health technology assessment (HTA) becomes essential to systematically evaluate the properties, effects, and impacts of the informed strategies. To address the challenges of ensuring health system sustainability, involving new evidence, and uncertainty in HTA, a recently published article by Kirwin et al[1] proposed a framework for a life-cycle HTA (LC-HTA). The framework emphasizes the need for de novo models conducted by HTA agencies and proposes using the risk-based price in decision making when a high level of uncertainty exists. This approach can bring many advantages as mentioned in the article; nevertheless, it also presents some methodological limitations and challenges when applied as a routine activity in the HTA processes. We reflect on these aspects and how they can be compromised given the diversity in organization and functionality of HTA agencies worldwide.

Comments on the Methods and Applicability of LC-HTA

The Need for De Novo Models Developed by HTA Agencies

We agree with the authors that de novo models developed by HTA agencies in the HTA process may support advanced analytic steps later, for instance, simultaneously considering more than 1 proposed technology. Nevertheless, the recommendation of developing de novo models as a routine practice should be applied with caution according to the local HTA guidelines, the capacity of HTA agencies, and the availability of local data.

First of all, local HTA guidelines play an important role in determining the need for de novo models. Although sponsor models in the HTA dossiers are often developed for global markets, they may need to be adjusted according to the local requirements, especially in countries that have legislative requirements to consider the results of the HTA analysis in decision making. For instance, the national HTA agency in the Netherlands (Zorginstituut Nederland) sets clear requirements for economic models in the pharmacoeconomic dossiers in terms of model adaptation to the local setting.[2] This includes the use of Dutch epidemiological data, utility data, units of costs, and resource consumption to be validated for the Dutch situation.[2] To ensure the dossier fulfills all requirements of HTA, global models developed by sponsors are often carefully adjusted with assistance from consultancy companies and the involvement of academic experts in countries where the dossiers are submitted. Therefore, newly developed models seem to be redundant and, subsequently, lead to a delay in the use of the technology in the target population.

Second, it is uncertain that de novo models always lead to better outcomes in the HTA process because of the capacity of the HTA agencies and data availability. A survey conducted by the World Health Organization in 2015[3] found that 80% of responding countries had formal HTA, but most countries did not have academic or training programs to build HTA capacity. A further study by Teerawattananon et al[4] showed that a lack of technical skills for HTA was still the main barrier to HTA operation nowadays. This organizational gap potentially hampers the quality of the de novo models. Finally, concerning data availability, the development of new models may result in the same outcome if the local data are not available, which is often the case in low- and middle-income countries.

Risk-Based Price

The authors suggest using the risk-based price in the LC-HTA when uncertainty is high. We agree that this approach can encourage risk-sharing between payers and sponsors. Nevertheless, this novel term poses questions regarding 2 main components of the proposed formula, namely the independent expected value of perfect information (iEVPI) and the payer risk tolerance value.

First, when 2 or more technologies of interest are considered in the economic model, iEVPI is calculated underlying a principle of head-to-head comparison in which those strategies are mutually exclusive. On the one hand, it may not always be appropriate especially when 2 or more technologies could be adopted at the same time. This parallel adoption can provide more treatment/prevention options in clinical practice, as well as help to prevent shortages when one of them is under supply disruption. On the other hand, the uncertainty surrounding input parameters cannot be addressed well under the proposed iEVPI formula that involves comparing the technology of interest and "the best alternative under certainty."[5] The term indicates that uncertainty would be omitted in the first stage by applying the deterministic result to find the best alternative. Instead, we suggest using the standard of care as a constant comparator in the iEVPI formula. It allows the analysis to consider all proposed technologies for adoption, as well as to take into account uncertainty throughout the analysis process.

Second, before the risk-based price can be applied in HTA, it is important to determine how "payer risk tolerance" will be calculated. According to the definition, it is "the maximum per-patient risk of making the wrong decision that payers are willing to accept."[1] This value seems to be dependent on the local context where the technology is considered. Therefore, future research or initiatives should aim to establish national or international consensus on how to define this threshold to balance potential losses of sponsors and risk of payers.

Future Directions

Given the advantages of the LC-HTA approach in ensuring healthcare sustainability, involving evidence, and reducing uncertainty, we encourage the use of this framework through international HTA collaboration, especially across countries having similar healthcare systems. This can help to share HTA guidance documents, especially to encourage using value of information to inform decision making. Although value of information is underutilized by HTA agencies in many reference countries, The Netherlands is one of the pioneers in encouraging this technique to inform adoption decisions by including it in the Dutch guideline for economic evaluations in healthcare.[6]

Besides, sharing data and tools through international HTA collaboration can help to facilitate research-oriented managed access. Because of the extensive need of both human and monetary resources of research-oriented managed access, it is important to emphasize the collaboration of and to specify tasks for the sponsor and HTA agency. This could assist to make the HTA evaluation process faster, more efficient, and even more transparent.

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Author Affiliations: Unit of Global Health, Department of Health Sciences, University Medical Center Groningen, Groningen, The Netherlands (Pham, van der Schans); Asc Academics, Groningen, The Netherlands (Pham); Department of Economics, Econometrics & Finance, University of Groningen, Groningen, The Netherlands (van der Schans); Faculty of Management Sciences, Open University, Heerlen, The Netherlands (van der Schans).

Correspondence: Thi Hao Pham, MSc, Unit of Global Health, Department of Health Sciences, University Medical Center Groningen, PO Box 30.001, 9700 RB Groningen, The Netherlands. Email: t.h.pham@umcg.nl

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