Identifying the Need for Good Practices in Health Technology Assessment: Summary of the ISPOR HTA Council Working Group Report on Good Practices in HTA

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ABSTRACT

The systematic use of evidence to inform healthcare decisions, particularly health technology assessment (HTA), has gained increased recognition. HTA has become a standard policy tool for informing decision makers who must manage the entry and use of pharmaceuticals, medical devices, and other technologies (including complex interventions) within health systems, eg, through reimbursement and pricing. Despite increasing attention to HTA activities, there has been no attempt to comprehensively synthesize good practices or emerging good practices to support population-based decision making in recent years. Following the identification of some good practices through the release of the ISPOR Guidelines Index in 2013, the ISPOR HTA Council identified a need to more thoroughly review existing guidance. The purpose of this effort was to build a basis for capacity building, education, and improved consistency in approaches to HTA-informed decision making. Our findings suggest that although many good practices have been developed in areas of assessment and some other key aspects of defining HTA processes, there are also many areas where good practices are lacking. This includes good practices in defining the organizational aspects of HTA, the use of deliberative processes, and measuring the impact of HTA. The extent to which these good practices are used and applied by HTA bodies is beyond the scope of this report, but may be of interest to future researchers.

Three Learning Points

- There are many good practices related to the conduct of HTA, particularly surrounding the identification, synthesis, and interpretation of individual studies or bodies of evidence.

- There are few widely recognized good practices that address the organizational aspects of HTA, use of deliberative processes, or measuring the impact of HTA. This speaks to the need for development in these areas.

- The extent to which these good practices are used and applied by HTA bodies is beyond the scope of this report, but may be of interest to future researchers.

TEXT

Introduction

Health technology assessment (HTA) has become a standard policy tool for informing decision makers who must manage the entry and use of pharmaceuticals, medical devices, and other technologies (including complex interventions) within health systems, eg, through reimbursement and pricing. Despite increasing HTA activity, there has been no attempt to comprehensively synthesize good practices or emerging good practices to support population-based decision making in recent years.

The purpose of the ISPOR HTA Council Working Group was to provide an up-to-date review of current literature which includes guidance on good practices in the use of evidence to inform population-based healthcare decision making for pharmaceuticals (drugs and vaccines), medical devices, and other health technologies, that is HTA. Population-based decisions are those linked to management, administration, and other forms of health system governance and stewardship. The use of evidence to inform individual decisions between patients and clinicians is outside of the scope of this review, however the Working Group recognizes that HTA may be used to broadly inform clinical practice decisions through clinical practice guidelines or clinical pathway development and thus have not excluded these from the scope of the paper.

The rationale for identifying good HTA practices in using evidence to inform population-based healthcare decision making is to provide a basis for capacity building, education, and improved consistency in approaches to HTA-informed decision making. The primary audiences for this report are those who manage, design, or seek to improve HTA processes, although we hope it is informative to a wider audience of patients, care providers, payers, academics, and industry stakeholders.

Given the large scope of this work and to achieve its objectives, the HTA Council Working Group created an overview report with a summary of key references related to good practices in HTA, outlining where guidance for good practices has been identified and where good practices are still emerging or could not be identified. This overview report will focus on prioritizing next steps that may be taken by ISPOR and other interested parties, and is a summary of the effort. The full report can be found on the ISPOR website ((https://www.ispor.org/) and as a Supplementary Appendix to this article.

Methods

The Working Group's approach in developing this report was based on literature review and expert opinion. In this respect it followed a similar approach to that of ISPOR Task Forces.[2] The need for a review of best practices was first identified by the ISPOR HTA Council

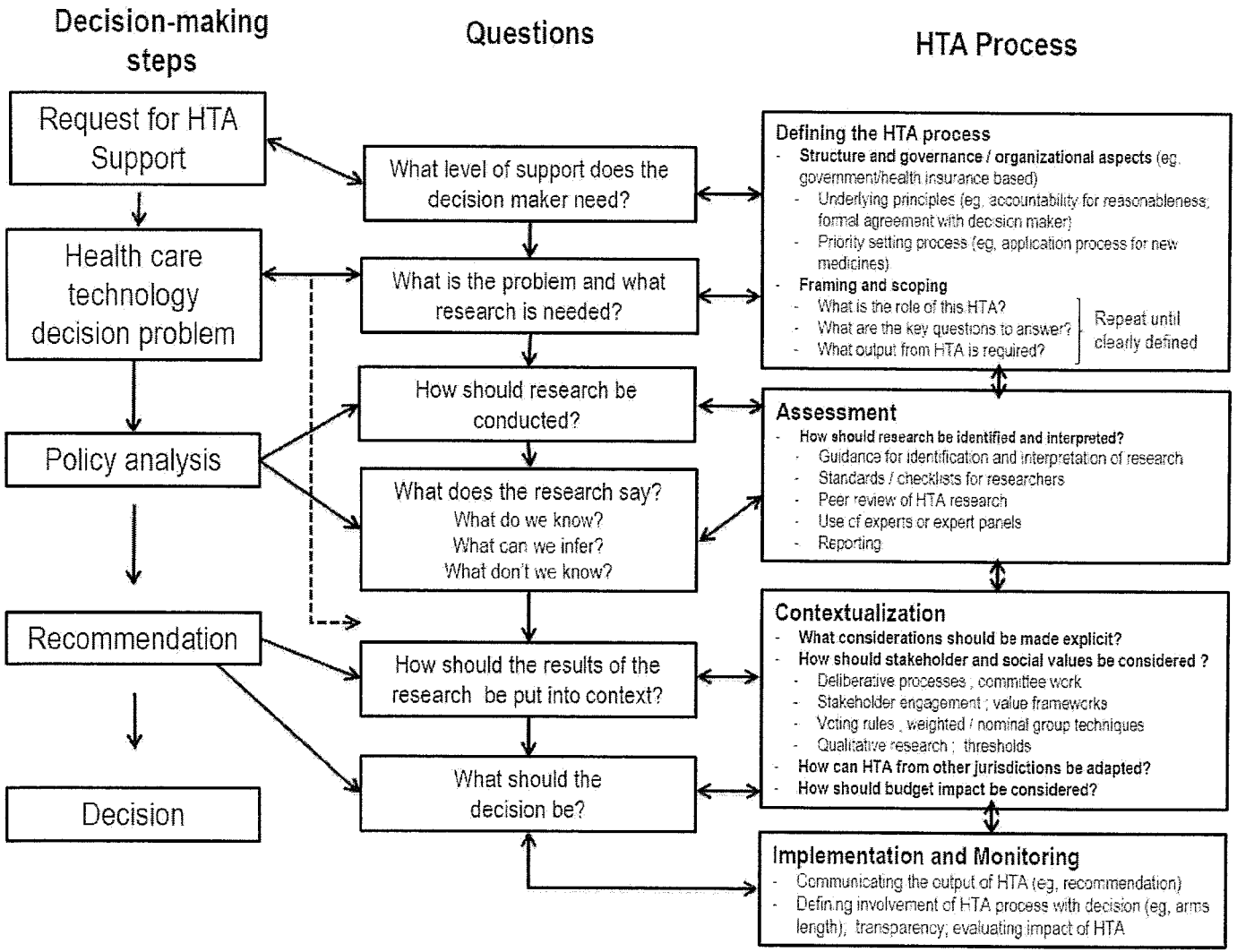
following a review of the ISPOR Guideline Index for Outcomes Research.[3] The Council then identified Co-Chairs who invited members of the Working Group. An outline for the report was then drafted and reviewed by members of the Working Group.

An early challenge for the working group was arriving at consistent conceptual definitions of an HTA process, as well as its associated terminology. In the end, HTA processes were characterized using a combination of concepts derived from healthcare decision making [4] , along with a description of components of an HTA process [5,6] and the structure proposed by the ISPOR Guideline Index for Outcomes Research (Figure 1). [3] The proposed framework assumes that the goal of HTA is to support healthcare decision making and it addresses all aspects, including how HTA processes are governed and defined ("Defining the HTA process"), how research information is identified, analyzed and interpreted ("Assessment"), how these interpretations are applied and weighed to the context of a decision ("Contextualization"), and how this ultimate interpretation and weighting is intended to support healthcare decisions ("Implementation and Monitoring HTA").

Sections of the report identified through the framework were assigned and drafted by individual Working Group members who were encouraged to use comprehensive approaches towards searching for existing descriptions of current practice, guidance for best practice, and to provide expert opinion (preferably based on published reports) identifying issues related to each section assigned. Systematic reviews were typically not conducted by working group members, although all authors were encouraged to conduct them or identify systematic reviews in their assigned areas.

Once drafted, the report was reviewed by all members, revised and circulated to members of a larger review group (see acknowledgements); it was then further revised leading to this final report. In parallel, findings were summarized and presented at open workshops during ISPOR meetings (Boston, MA, USA and Glasgow, Scotland, UK).

Figure 1: Components of HTA within the healthcare decision-making process



Findings

General findings

In some areas, we were unable to identify good practices specific to HTA. This included good practices in defining the organizational aspects of HTA, the use of deliberative processes, and measuring the impact of HTA. In some areas, such as guidance for the interpretation of individual studies or bodies of evidence, there was an abundance of available practice guidance that was either discipline or HTA-specific.

A summary of our findings appears in Table 1.

HTA Practice	Good Practices Identified	Example(s)	Notes	Refs
Define the HTA process				
Structure / Governance / Organizational aspects of HTA	Few	WHO and World Bank frameworks	Not specific to HTA	[7–11]
Framework / Principles for the HTA process	Yes	Various	Some developed for comparison and benchmarking	[12–17]
Priority setting process	Yes	EUnetHTA procedure		[18–22]
Framing and scoping	Yes	HTA Core Model, Danish guidelines, NICE	Assumed many scoping processes unpublished	[23–25]
Assessment (Synthesizing evidence)				
Identifying and interpreting individual studies	Yes	Summarized Research in Information Retrieval for HTA (SuRe Info) Cochrane Risk of Bias Tools EuNetHTA Guidance ISPOR-AMCP-NPC Good Practice Task Force Questionnaire MedTecHTA Recommendations HTA Core Model	Tools for some study types still nascent	[24, 26–71]
Interpreting bodies of evidence	Yes	Assessing methodological quality of		[72–86]

		systematic reviews (AMSTAR) tool GRADE-CERQual		
Contextualizing (Using evidence)				
Deliberative processes	Few	OHTAC Deliberative Framework	Few good practices dedicated to HTA	[87–90]
Patient engagement and patient preferences	Yes	HTAi Values and Preferences Tool	Many approaches	[91–102]
Weighted stakeholder preferences and multi-criteria decision analysis	Yes	EVIDEM		[103–111]
Use of thresholds	Yes	UK NICE	Specific to certain health systems	[112–115]
Interpreting or adapting HTAs from other jurisdictions	Yes	EUnetHTA adaptation checklist ISPOR Good Research Practices Task Force report on transferability of economic evaluations	Specific guidance for economic evaluation also available	[55,116–120]
Use of budget impact analyses	Few	Institute for Clinical and Economic Review		[121–123]
Implementing and monitoring HTA				
Implementing HTA	Yes	SUPPORT Tools	Different approaches	[124–130]
Measuring HTA Impact	Few	"Six step" model		[131–139]

Discussion

Twenty years ago, the EUR-ASSESS Project made it clear that HTA is not defined by a set of methods but by its intent, and given the wide scope of HTA it should not be viewed as a single discipline or field. Rather, HTA is multidisciplinary and rooted in good practices in evaluation including sound research methods [140]. Today, HTA still uses a range of approaches intended to inform decision making and based in research. There is now a more widely shared understanding of the standards that HTA should aim to meet and understanding of the importance of developing, agreeing, and implementing good practices.

Our findings suggest that many good practices have been developed in areas of assessment and in some aspects of defining HTA processes (priority setting, framing and scoping principles, as well in areas of implementation). Few good practices were found related to structure / governance / organizational aspects of HTA and measuring HTA impact.

Using these underlying concepts, the challenge for the Working Group was to arrive at consensus regarding the extent to which good practices can be identified and are available. The wide scope of this overview and the approach taken to search and identify relevant guidance, coupled with many approaches not widely publicized and a rapidly growing literature means that it is possible some good practices may have been overlooked.

HTA, encompassing evidence synthesis, may be viewed as informing evidence-based decision making – two related but distinct concepts [141]. The process of rigorous review and synthesis of scientific evidence focuses on assessing the relative benefits, harms, and costs of healthcare technologies using sound analytic judgments. Evidence-based decision making, in most cases, explicitly or implicitly incorporates other considerations (eg, affordability, ethical issues, feasibility, and acceptability) that may require mechanisms of contextualization of assessment results, such as deliberative processes, to support them.

These latter considerations, the discussion of which is sometimes called "appraisal", can be supported or coordinated by HTA bodies and have recently received heightened attention; their crucial importance in HTA has been recognized. This has led to a fuzzy distinction between the activities of HTA and decision making, particularly in processes of contextualization, for example in appraisal and reimbursement committees, and the recommendations that come from them. Such recommendations may involve both analytic judgments (such as willingness to include indirect comparison and surrogate endpoints as source of evidence, or how quality adjusted life

years (QALYs) were derived) and consideration of social values (such as weighing the value of a QALY in the very young or old).

The ability of decision makers to override recommendations of HTA bodies, based on other considerations and variations in approaches to HTA, makes its role even more difficult to discern, even to experts in the field [142]. This has led to much criticism of HTA in recent years, resulting from the decision-making processes and the extent to which they are transparent and deliberative. Unfortunately, this criticism may result in some spillover and skepticism regarding the assessment process. The future acceptance of HTA may depend on greater clarity regarding the scope of these two processes, largely identified with "assessment" and "contextualization" in this document, and additional measures to enhance the transparency by decision makers regarding the key elements that actually are driving decisions.

Moving systematic review and synthesis beyond clinical, epidemiological, and economic research into qualitative and quantitative research in patient, caregiver, and citizen generated information (such as perceptions, valuation, and outcomes) is an immediate need in HTA. As part of this effort, there is a need for more research into the structured approaches to deliberative decision-making. Such research could potentially support the application of multi-criteria decision analysis (MCDA) [143]. This will represent a continuation of the EUR-ASSESS approach as implemented in the HTA Core Model and would help further "populate" the non-clinical domains of the Model such as "patient and social" and organizational aspects with good methodologies and more evidence.

Beyond a clear delineation of the roles of HTA and decision-making (as well as scientific judgment and value judgment), HTA bodies may also need to consider what healthcare decisions are best supported by HTA. The move to early dialogue and scientific advice on evidence generation to technology developers can be seen as advancement toward more constructive HTA processes, where alignment between patients, payers, regulators, and technology producers is created through shared information requirements and collaborative planning. [144,145]. It is also a stepping-stone to HTA considering the costs of innovation, when informing healthcare decision makers. Recognition of the overlapping roles of regulatory and HTA processes is another key area of evolution and development for HTA[146,147].

Efforts by researchers in the disciplines that contribute to HTA will undoubtedly continue to include review of their own good practices and produce guidelines and textbooks that will have immediate relevance for HTA. Taken together, priorities for good practice guidance in HTA as reflected in this paper and the ISPOR Outcomes Research Guidelines Index [3] will likely need to

focus on developing good practices in *using* evidence to support decision making through implementing and monitoring of HTA rather than concentrating the focus of guidance production on HTA research practices (eg, evidence review and synthesis, outcomes research and health economics), while encouraging and increasingly building on high quality research guidance from these "contributing" fields of research. With the evolving ISPOR Guidelines Index, and this review of current guidance it may be easier to prioritize where efforts should be put in developing good practices in HTA.

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