

Improving Fairness of Health Technology Assessment Frameworks

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Abstract

HTA frameworks have traditionally focused on the elusive quest for an equal measure to rationally distribute and reimburse health technologies. HTA therefore has proven itself important by allowing decision makers to be equipped with logics for the decision, at the same time allowing stakeholders including citizens to appreciate the limitation of decision to 'provide' or 'not to provide' a service/intervention. This has had impact on budgeting and financing of decisions. However, a flip side of this focus on distribution using 'one-sided rationality' makes other rationalities, including those that are value-derived but directly affect health outcomes come either at the end of the process of appraisal or largely left to the policy implementation phase. Those rationalities that do not 'fit-into' the equal-distribution based criteria tend to be undervalued in HTA methodologies. In this commentary, we investigate the extent to which selected HTA organizations around the world, apply the key constituent components of an HTA to the process, and use the analysis to propose enhanced set of components that could make HTA process more comprehensive. Multi Decision Criteria Analysis could address this central challenge in common HTA methods, to allow various partial rationalities to be combined into a more comprehensive HTA decision by making HTA process more dynamic and inclusive.

Keywords: Health Technology Assessment (HTA); Multi-criteria Decision Analysis (MCDA); Framework

Introduction

Health technology assessment (HTA) has been defined as "a multi-disciplinary field of policy analysis, studying the medical/clinical, economic, social and ethical implications of development, diffusion and use of health technology" [1]. 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. This includes good practices in defining the organizational aspects of HTA, the use of deliberative processes, and measuring the impact of HTA [2]. HTA agencies face pressures in determining their work programs. The number of technologies requiring evaluation outweighs available resources. Clients of the agencies present competing claims regarding the level of urgency to be given to their requests. Many agencies use guidelines or explicit criteria to set

priorities for assessment. The most common criteria applied by agencies in determining priorities were the clinical and economic impact of the technology, disease burden, budget impact, availability of relevant evidence from HTA or similar agencies and expected level of interest [3]. Identification of interventions emerge from societal priorities reflected in the political commitment and informed decision making. The role of political process in health policy is described as "central in determining how citizens and policy makers recognize and define problems with existing social conditions and policies, in facilitating certain kinds of public health interventions but not others, and in generating a variety of challenges in policy implementation [4]. Priority setting in health care has long been recognized as an intrinsically complex and value-laden political process that takes place in an environment of diverging social values and interests [5-9].

In such pluralist societies, stakeholders may reasonably disagree on what values can be used to guide priority setting [8]. However, pres-

ent value assessment frameworks currently employed by health technology assessment (HTA) agencies around the world do not sufficiently account for this complex reality. These frameworks are typically based on the use of predefined key principles, also labeled “substantive” criteria, which are believed to reflect the most important social values. This has led HTA agencies to use, for example, “cost-effectiveness” as an important decision criterion [10]. Ethical issues in particular are left unaddressed, thereby compromising the legitimacy of eventual decisions as perceived by stakeholders. Keeping ethical and value considerations outside of HTA methodologies often backfires, which is illustrated in countries like Brazil, Mexico, and Thailand, where patients frequently launch court challenges against decisions taken by health authorities [11-13].

We propose an alternative, hybrid value assessment framework for HTA agencies to explicitly address this issue. The framework is based on multi-criteria decision analysis (MCDA). MCDA evaluates the overall value of interventions by reference to a set of multiple explicit criteria [14]. This proposed framework aims to support HTA users and agencies in making recommendations reflecting ideals not only traditional and quantitative but also qualitative, social and in the context of global market factors such as legality and intellectual property. This framework is not intended to be used as a rigid blueprint but as an incremental aspirational goal.

Should HTA therefore, be organized as an iterative learning process, which allows the ongoing identification of values and collection of evidence on associated criteria throughout the process. This may require an expansion of the present, strict time frames that HTA agencies have for the development of recommendations [15]. Common motivators described in the literature for the establishment of HTA process are (i) to support decision-making, (ii) promote allocation efficiency and (iii) to strengthen the credibility, legitimacy and accountability [16]. Besides the assessment, reimbursement decision-making also involves appraising the evidence bearing in mind societal values and ethical considerations alongside scientific judgment. Although important, HTA is only a part of the decision-making process as a whole HTA initiation could be the result of top-down interest (political), bottom-up initiatives (academic/research) or converging [17].

Multi Criteria Decision Analysis (MCDA) has emerged as another tool to support complex decision-making in healthcare, moving beyond the evidence generation stage mentioned before. MCDA are designed to help people make better choices when facing complex decisions involving several dimensions. In theory, MCDA are especially helpful when there is a need to combine hard data with subjective preferences or make trade-offs that involve multiple decision-makers [18], and allows a structured and objective con-

sideration of the factors that are both measurable and value-based in an open and transparent manner [18,19]. In MCDA, the decision problem (e.g. the choice of intervention) is analyzed to identify all the factors (i.e. criteria) that may affect the decision and thus develop the full set of decision criteria. Decision makers assign weights to each criterion, thereby making their values and objectives explicit to themselves and others [20]. The technical element of MCDA addresses the analytical questions: how to ensure criteria properties and criteria set properties comply with good practice, how to measure performance against these, how the criteria are weighted, and how performance and weights are aggregated. The social element of MCDA is concerned with which stakeholders are involved in the MCDA, and when and how they contribute. There is no a priori optimal position on this spectrum. Technical and social elements need to work in concert to achieve the aims of the MCDA, and the appropriate combination of elements will depend on the decision problem [21]. Despite these shortcomings, there is no comprehensive analysis of the extent to which methodological issues related to the application of MCDA in the context of HTA affect the credibility and policy-usefulness of published literature, and the range of challenges and limitations that need to be addressed by MCDA in this context [22]. The flexibility to not have weights attached at all, to the multiple criteria further boosts the utility for contexts that allow partial rationalities to compete with total value based rationalities in terms of their potential impact in the decision-making process.

The multi criteria overview in this study therefore aims to synthesize the positions and judgements applied for conducting an HTA. However, the study also brings out some criteria that are not used or applied at all, and therefore adds to the knowledge body of application of criteria in HTA. Inclusion of more criteria that are contextual or societal has the potential to make technology assessment more inclusive and impactful.

Methods

Various components of an HTA process has been applied in HTA frameworks to different extents or sometimes, an important component, is even excluded based on the objectives of the framework. It is therefore necessary to undertake a horizon scanning of frameworks and provide for a comprehensive analysis. Subjecting this to a Multi Criteria Decision Analysis provides for a SWOT (strength, weakness, opportunities, threats) analysis of the available frameworks. In this setting, it is necessary to find techniques that include in the decision-making process, the greatest number of criteria that guide and influence decisions, in order to reduce errors. However, most of the time this procedure is not easy to perform, since in many situations, the criteria for decision making are conflicting, increasing the level of uncertainty of the final response [23-25]. In order to increase

the reliability and credibility of the chosen solution, decision support methodologies, such as Multi-Criteria Decision Support Methods (MCDA), have emerged [26,27]. These methods are intended to assist in the decision-making process, in order to minimize the responsibility of the final decision-maker, and to guarantee a solution in accordance with the criteria in question [28]. In the health area, these procedures are even more complex, since they involve not only technical or economic issues, but also the human factor, causing conflicts of interest and hindering the final decision [24]. Therefore, many studies, using MCDA, are carried out with the aim of optimizing health systems as a whole [29-32]. The research therefore included a scoping review of HTA best practices, studies impact of societal practices and thereafter enabled an MCDA of globally accepted HTA frameworks.

We conducted a review on the frameworks applied by 5 global HTA agencies: EUnetHTA (European Network for Health Technology Assessment), RRE (Rapid Relative Effectiveness Assessment model by EUnetHTA), HTAi (Health Technology Assessment international), INAHTA (International Network of Agencies for Health Technology Assessment), and ISPOR (International Society for Pharmacoeconomics and Outcomes Research) for HTA good practices and frameworks. Preferred Reporting Items for Systematic Reviews and Meta-Analyses, guidelines, recommendations, reports and best practices as published by the scientific societies were taken into consideration in the development of the study. Frameworks which provided details of use of multiple criteria for the evaluation of health technologies were reviewed.

The main sources used include EUnetHTA tools such as the Handbook on Health Technology Assessment Capacity Building [33], the report on best practice in undertaking and reporting HTA [34], the INAHTA checklist to present HTA information [35] and the principles for HTA programs in different countries of the International Working Group for HTA Advancement [36] and ISOPR report on identifying the need for best practices in HTA [2].

Analysis and Results

While assessing the components used in HTA frameworks, it was necessary to enlarge the comprehensiveness of components, inclusion of some of this may not be critically necessary from the mandate perspective of HTA societies considered in this review, but beneficial for the decision-making process for user organizations. It is also to be noted that inclusion of components in HTA process could be a dynamic process and the list may continue to get evolved or modified. Also considering the fact that evaluation of many/all the components in an HTA process may result in higher costs of conducting HTA and substantially more time, the users of HTA may be more prudent in selecting the criteria depending on the needs, time constraints and resources available. HTA results feed into the decision-making process in a manner that is relevant and meaningful to decision makers, using a fair, deliberative process [37]. To

map the level of comprehensiveness of the HTA system and to identify (potential) best practices, we used a simple scoring system for each judgment criteria: “yes (+++)”, “to some extent (++)”, and “no or very limited (+)”. This scoring system has been used previously in a study to map the level of HTA development at country level in selected countries [38]. Make sentence here about modification of scores to make them more coherent and intuitive.

1. MCDA components	EUnet HTA	RRE	INAHTA	HTAi	ISPOR
2. Defining the health problem and current solution	+++	+++	+++	+++	+++
3. Clinical effectiveness	+++	+++	+++	+++	+++
4. Cost effectiveness	+++	+++	+++	+++	+++
5. Safety analysis	+++	++	+++	++	++
6. Technical Characteristics of Technology	+++	++	+++	++	++
7. Budget Impact analysis	+	+	+	++	++
8. Patients/Care givers' choices incorporation	++	+	++	++	++
9. Social aspect of technology adoption	++	+	++	++	++
10. Legal compliance review	++	+	++	+	+
11. Ethical perspectives	++	+	++	++	++
12. Organizational implications	+	+	++	+	++
13. Intellectual property	+	+	+	+	+
14. Post implementation social Impact measurement	+	+	+	+	+
15. Stakeholder Consultation of results and publication	++	++	++	++	++
16. Recommendations for periodicity of next review	+	+	++	+	++

Table 1: Level of comprehensiveness of the HTA process in selected frameworks/systems.

Discussion and Findings

It was noted that there exists a distinct differentiation between technology assessment process and technology appraisal process, the latter generally performed as a quality assurance check to ensure validity of the former. However, this phasing seems to weaken the inclusion of many important criteria in assessment with assumption that they would be incorporated in appraisal phase. Some literatures have also pointed out the need for merging or streamlining the components within these two phases of an HTA. While assessing the inclusion of components in the HTA frameworks, it was evident that while all frameworks provide sufficient inclusion/importance to measurable inputs such as clinical effectiveness or cost effectiveness, the inclusion of semi-rational inputs such as societal impact, legality, and intellectual property are either left undefined or excluded. Components such as role of intellectual property and social impact assessment post implementation of an HTA based decision were non-existent in all frameworks that were reviewed.

Patent laws decide access to drugs and medical devices, and all individuals from the World Trade Organization (WTO) are committed to present the minimum benchmarks of licensed innovation assurance into their national patent laws. Patent enactment gifts legitimate insurance to novel creations. Advocates of a powerful patent framework contend that licenses advantage both the innovator and society [39]. The Doha Declaration was considered to redress a portion of the abnormalities developing nations found in utilizing the TRIPS adaptabilities. The assertion expresses that nothing inside the TRIPS (Trade Related Agreement on Intellectual Property Rights) will be deciphered and executed in a manner that is unfavourable to the general wellbeing of developing nations [40]. Access to cutting edge medical devices is more of an issue for developing nations than access to pharmaceuticals and immunizations [41]. For example, access to radiology is a genuine case of the difference among developing and developed nations as far as the accessibility of medical devices. X-Rays, sonograms, mammograms, and other such diagnostics are vital to general wellbeing. In any case, the WHO assesses that 66% of the total population has no access to medical devices that give such diagnosis [42]. The ability of intellectual property to influence cost of technology therefore remains unarguable.

This has the impact of expanding the coverage of technologies, and in not applying component of IP in an HTA process, creates a boundary to the access of technological interventions. While cost is the basis of cost effectiveness analysis which plays an extremely important role in HTA process, yet, negotiations and working of intellectual property while safeguarding the core principles of IP

ownership has remained well outside the ambit of HTA discourse. Since the intellectual property dimension of technology has overwhelming impact on the cost of the technology/intervention, and cost thresholds can allow a technology/ intervention to be include or excluded from the 'coverage' or benefit package, it is surprising how none of the frameworks incorporated intellectual property as a factor to be considered in technology assessments. In a central Asian country which allows polygamy and pro-creation has remained a religious and societal priority, a drug used for erectile dysfunction was accorded 'generic' status despite being in 20 years- intellectual property safeguard period. Doha Declaration and TRIPS agreement allows a nation in event of a national emergency to ignore the intellectual limits thereby allowing such a technology to be declared as generic within the country. Application of such caveats in formal process of HTA could enable transparent negotiations, cost reductions and expansion of healthcare basket.

In similar context, the need for social impact assessment subsequent to implementation of an HTA decision is not within the current ambit of any of the frameworks. A reason may be simply for the fact that measuring societal impact of a complex technology might be different. However, given that patient groups also forms a smaller societal boundary within the larger society, an impact on patient groups would improve understanding of technology application and allow changes in costs and resource parameters to blend with need. An urgent need for inclusion of societal impact assessment is therefore felt. The case of ultra-sonography and its application in India is apt in this perspective. In 2015, portable ultrasonography was introduced in global markets. The portal ultrasonography system was evaluated through the HTA framework. While it was found to be clinical effective, extremely cost effective and could alter the maternal health care system positively, a unique contextual problem was encountered. India has in place a law- PCPNDT Act which prohibits gender identification of foetus. The law has been put in place to check female foeticide as male babies were a preferred choice for many decades in India, given their future earning potential for the family in the erstwhile male dominated society. While economic empowerment in past couple of decades has changed the situation for the better, the residual traditional practices have survived in some communities and regions. Ultrasonography for maternal health application has therefore been a guarded professional practice. While every machine needs to be registered in the name of a sonologist (a doctor specialising in ultrasonology), gender identification of the foetus is a criminal offence. Portable ultra-sonography could allow, if were to be introduced in the market, a direct negative impact on societal balance, despite its gold standard clinical effectiveness and cost-efficiency. Societal impact has in this case, over scored all available value based criteria. Application of community based issues has on many instances guided

an informed decision to be made, particularly where in contexts where local or native population are challenged with very unique situations and circumstances.

The need for a more focused budget impact assessment as a component of HTA process is also seen during the analysis. This would enable decision makers to make better choices within the fiscal space available institutionally or nationally, depending upon the user case. Improving methods to include choices of patients and care providers also requires more broad-based acceptance as currently it is given much lesser importance that measurable criteria such as cost effectiveness analysis. If it is difficult to incorporate it in core assessment, its inclusion as a very important component of appraisal is recommended. Needless to say, role of legal and ethical dimensions requires stricter inclusion.

Conclusion

With this study, we go beyond previous studies on the organization of HTA by focusing on a more systematic evaluation of the HTA frameworks applied and/or recommended by professional societies with global memberships. One of the restrictions of this research lies in the scope of the literature retrieved (limited to tools, frameworks, best practice recommendations that are available on the websites of respective global societies including publications). However, those tools or checklists that are available online for purchase were excluded from review. The results of this first mapping exercise can be used as a baseline measurement for improvements in frameworks and in their applications by users. As a subject of further study, it would be beneficial to evaluate how various country specific HTA agencies would correspond to the use of different indicators. This could help stakeholders to improve the practice of HTA and even justify additional resource allocation for HTA process. It will be crucial to learn more from ongoing initiatives to include a wider set of criteria, especially those regarding IP, social and budget impact, in current HTA methods. At the same time the analysis of current initiatives to do so show that we need to acknowledge that adding criteria will never become a summative exercise of adding up different criteria. Frictions may emerge and one criteria may way so heavily that it overrules all other findings, no matter how scientifically sound the evidence for those may be. The development of HTA methodologies that include a wider set of criteria therefore will need to be matched with fostering HTA knowledge appraisal and integration as a professional practice in which multi-stakeholder groups will still need to take decisions about how criteria need to be weighed when they cannot be added up. It is this combination of technical/methodological and professional development of HTA practice that is most promising for matching HTA to public needs.

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