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Value Assessment Frameworks for HTA Agencies: The Organization of Evidence-Informed Deliberative Processes

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ABSTRACT

Priority setting in health care has been long recognized as an intrinsically complex and value-laden process. Yet, health technology assessment agencies (HTAs) presently employ value assessment frameworks that are ill fitted to capture the range and diversity of stakeholder values and thereby risk compromising the legitimacy of their recommendations. We propose “evidence-informed deliberative processes” as an alternative framework with the aim to enhance this legitimacy. This framework integrates two increasingly popular and complementary frameworks for priority setting: multicriteria decision analysis and accountability for reasonableness. Evidence-informed deliberative processes are, on one hand, based on early, continued stakeholder deliberation to learn about the importance of relevant social values. On the other hand, they are based on rational decision-making through evidence-informed evaluation of the identified values. The framework has important implications for how HTA agencies should ideally organize their processes. First, HTA agencies should take the responsibility of organizing stakeholder involvement. Second,

agencies are advised to integrate their assessment and appraisal phases, allowing for the timely collection of evidence on values that are considered relevant. Third, HTA agencies should subject their decision-making criteria to public scrutiny. Fourth, agencies are advised to use a checklist of potentially relevant criteria and to provide argumentation for how each criterion affected the recommendation. Fifth, HTA agencies must publish their argumentation and install options for appeal. The framework should not be considered a blueprint for HTA agencies but rather an aspirational goal—agencies can take incremental steps toward achieving this goal.

Keywords: Health Technology Assessment, Value Assessment Framework, HTA agency, Evidence-informed deliberative processes.

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Introduction

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 [1–5]. The role of politics 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 [6].” Indeed, society, including relevant stakeholders, such as patients, providers, insurers, and citizens, has a wide range of social values and interests that result in different perceptions of what makes health interventions valuable [7]. In such pluralist societies, stakeholders may reasonably disagree on what values can be used to guide priority setting [4].

However, present 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 [8].

There is broad recognition that such frameworks are ill fitted to take into account the wide range and diversity of stakeholder values and lead to insufficient sets of information [1–3,9]. Ethical issues in particular are left unaddressed, thereby compromising the legitimacy of eventual decisions as perceived by stakeholders. This is illustrated in countries like Brazil, Mexico, and Thailand, where patients frequently launch court challenges against decisions taken by health authorities [10–12].

We propose an alternative, hybrid value assessment framework for HTA agencies to explicitly address this issue of legitimacy. Legitimacy here refers to the reasonableness, or fairness, of recommendations as perceived by stakeholders, which is an

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important prerequisite for broad societal support for these recommendations [4]. The framework is based on an integration of two increasingly popular and complementary frameworks: multicriteria decision analysis (MCDA) and accountability for reasonableness (A4R). MCDA evaluates the overall value of interventions by reference to a set of multiple explicit criteria [13]; although MCDA is generally praised for its rational pursuit, it is criticized for being technocratic and lacking a deliberative component that involves stakeholders [14–16]. A4R recognizes that stakeholders often justifiably disagree about the importance of specific social values in setting priorities and argues that stakeholders are more likely to accept priorities that are the outcome of a fair process [4,17,18]. The aim of such a process is to develop a shared basis for decision-making among stakeholders. A4R has been criticized for being largely theoretical and not providing guidance on the identification and operationalization of values [14,15,19,20].

“Evidence-informed deliberative processes,” as we name them, combine the virtues of both A4R and MCDA. They incorporate the element of structured decision-making from MCDA but not the mathematical elements, as we consider the latter to be only of limited relevance for priority setting. Evidence-informed deliberative processes are, on the one hand, based on early, continued deliberation among stakeholders to identify, reflect, and learn about the meaning and importance of relevant social values. On the other hand, they are based on structured and rational decision-making—through evidence-informed evaluation of the identified values where possible. Evidence-informed evaluation allows contributions from stakeholders in terms of their (clinical) experience and their judgments when stronger evidence is unavailable [21].

The framework aims to support HTA agencies, at a centralized or decentralized level, in making reimbursement recommendations. The framework reflects our vision of how HTA agencies should ideally organize their processes, that is, in such a way that all stakeholders can confer legitimacy to the recommendations. This ideal should not be interpreted as a blueprint for HTA agencies but rather as an aspirational goal—HTA agencies are advised to take incremental steps toward this goal.

This article first describes the key elements of the framework—stakeholder deliberation to facilitate learning—and then presents the implications for the conduct of HTA. We use the term “values” to refer to the preferences of stakeholders and “criteria” to refer to their more formal operationalization.

Stakeholder Deliberation to Facilitate Learning

The aim of stakeholder involvement in HTA processes is three-fold. First, it serves to identify the full range of relevant values that society holds in relation to a particular recommendation and to ensure relevant evidence collection on these values. Second, it intends to improve the understanding among stakeholders of each other's values. Third, it seeks to achieve maximum coherence among stakeholders in their argumentation regarding a recommendation [22]. Together, this may lead to an enhanced sense of legitimacy, in the sense that the recommendation is considered to be more reasonable. Importantly, the objective of stakeholder involvement is not necessarily to reach mutual consensus on a recommendation or to come to a joint decision. In a democratic society, policymakers hold the final authority and should be held accountable for their final decisions.

Value assessment through stakeholder involvement is an intrinsically complex task. It requires that stakeholders gain, as much as possible, an in-depth understanding of the health intervention under scrutiny, including the consequences of its implementation. In addition, stakeholders need to interpret these

consequences in the context of their own values, other stakeholders' values, and widely endorsed public health values, such as respect for autonomy and nonmaleficence [23]. Stakeholders are thus required to engage in intellectually demanding moral reasoning.

Learning among stakeholders is considered essential in this process and is most likely to occur when stakeholders with different backgrounds deliberate on a specific issue [24–26]. Deliberation among stakeholders can facilitate learning by clarifying the different ways in which stakeholders frame policy problems. By making their underlying assumptions and preferences explicit, participants may learn from one another and gain a better understanding of their own position. If confronted with interpretive frames that are different from their own, stakeholders may be triggered to reflect on their own frames, to verify their own assumptions, and to partially revise them [25,27].

In this process, evidence is key to inform stakeholders' understanding, and evidence collection should be focused on providing answers to key questions raised by stakeholders during their deliberation [7,24,28]. There is anecdotal evidence that deliberation leads to significant learning effects in HTA [27,29,30]. However, knowledge of how best to foster learning among stakeholders is still limited in the field of HTA.

Implications for the HTA Process

The use of evidence-informed deliberative processes as value assessment framework has five important implications for how HTA agencies can best organize their processes.

Stakeholders' Involvement

Relatively little is known about optimal stakeholders involvement in HTA [31–36]. The A4R framework specifies a number of key conditions for fair processes, including the nature of stakeholders' argumentation [4,17,18], but does not provide specific guidance. In practice, active stakeholder involvement in HTA can take different shapes [37,38]. First, stakeholder involvement can be organized as an exercise independent of HTA agencies through, for example, round table conferences [29], deliberative dialogues [39], or interactive technology assessment [7,40]. A disadvantage of organizing stakeholder involvement independent of HTA agencies is that it could hamper the uptake of its findings by these agencies, and we do not recommend this approach.

Second, HTA agencies can initiate stakeholder involvement under their own responsibility. They can commission studies involving stakeholders deliberation on specific topics, such as cochlear implants in The Netherlands [27]. More formally, they can integrate stakeholder involvement in the various phases of the HTA process. For example, stakeholders, including the public, can nominate topics for assessment in Sweden [41]. In the appraisal phase, stakeholder involvement can be organized through, for example, granting speaking time during appraisal committee meetings, as in The Netherlands [42]; organizing a citizen council, as in the United Kingdom [43]; or soliciting input and feedback from patients, as in Canada [44] and Scotland [45].

We recommend that HTA agencies take responsibility for organizing stakeholder involvement, as the agency's commitment is essential to the political leverage of eventual findings. As an important component, we argue that, ideally, an appraisal committee should include both permanent and temporary stakeholders. Permanent members should be installed to endorse the broad public interest and take the responsibility of developing recommendations on the basis of the deliberative process. Temporary members should be included to represent specific

stakeholders, including their interests and expertise, with their appointment dependent on the recommendation under scrutiny. HTA agencies are advised to take incremental steps toward this ideal.

Integration of Assessment and Appraisal Phases

HTA agencies typically separate the assessment from the appraisal phase in the HTA process. The assessment phase involves the collection of evidence of a standard set of criteria, pushing the consideration of further criteria into the appraisal phase. However, this often leaves an appraisal committee with incomplete evidence upon which to base their recommendation. We argue that the assessment and appraisal phases should be integrated, in the sense that the relevant considerations should be explored from the outset—this would then allow the timely collection of evidence on these aspects and their inclusion in the appraisal of the health intervention. The Netherlands is now introducing an early scoping exercise in its HTA process, in which stakeholders are consulted to determine relevant outcome measures for the effectiveness of an intervention [46].

Ideally, HTA should 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. If such an expansion is not possible, we instead recommend HTA agencies to intensify their decision-making process.

Specification of Criteria

Priority setting may involve a wide range of criteria, as repeatedly demonstrated in international surveys [47], decision frameworks [48–50], and guidelines [49]. Among this wide range, many HTA agencies consistently use a number of explicit criteria for the evaluation of every intervention. For example, “safety,” “effectiveness,” “cost-effectiveness,” “severity of disease,” and “budget impact” are often considered as such by HTA agencies [51–53]. We label these criteria as “generic criteria.” At the same time, more “contextual” criteria appear to be used for specific interventions only, and these include many considerations (e.g., “responsibility for own health” for interventions targeting behavior-related diseases, such as smoking, or “size of the population affected” for interventions targeting orphan diseases).

The use of “generic” criteria in particular give the impression of being politically sanctioned and therefore justified. In reality, however, they are often the manifestation of how HTA agencies (attempt to) specify the more abstract and fundamental politically ratified values in a country [22]. This specification by HTA agencies, typically lacking proper stakeholder participation, risks compromising the legitimacy of this use of standard criteria and any forthcoming recommendations. HTA agencies should subject their decision-making criteria to public scrutiny by means of a democratic process [54]. In doing so, HTA agencies may learn from other countries in terms of how to organize this democratic process and/or specify their criteria.

Development of Recommendations

The criteria that are identified throughout the process likely require further assessment. This may take the shape of generating an evidence base for criteria that are quantifiable—for example, an intervention’s performance on the criterion “cost-effectiveness” can be assessed quantitatively by means of cost-effectiveness analysis [55–57]. Criteria that are nonquantifiable may be subjected to qualitative analysis (e.g., ethical analysis or [expert] stakeholder opinions). These pieces of quantitative and

qualitative information are inputs into the deliberative process. HTA agencies are advised to develop a checklist, including their range of identified and specified criteria. They can use this checklist to verify whether these criteria are relevant to particular recommendations in order not to overlook criteria.

For every criterion, the appraisal committee should argue whether and how it affects the recommendation (in a positive or negative way). The committee must eventually come to a final recommendation, thereby providing argumentation for which criteria are considered to be of overriding importance. We stress that this process should not be considered as a one-time exercise but, ideally, as an iterative learning process in the committee—of course, within the time frame of the HTA agencies. Also, we stress the importance of deliberation in dealing with the full range of criteria and wish to emphasize that, in our view, quantitative decision aids can never fully replace the force of argumentation [58].

An important issue in stakeholder involvement in formal HTA processes is that of vested interests, wherein stakeholders (initially) plead in favor of their own interests. As such, stakeholder involvement in the presence of vested interests likely captures private values, but it is less able to capture public interests that countries may rightfully choose to endorse, such as safeguarding equal access to good quality health care, efficiency, and cost containment. These public interests are not typically acknowledged as important by individual stakeholders. As noted earlier, we advise HTA agencies to install permanent members in the appraisal committee, being stakeholders representing public interests. In the appraisal process, all argumentation that is tabled must be subjected to deliberation and, in the end, balanced against each other. The permanent members have the responsibility to develop recommendations on the basis of this process, and the final decision rests with the accountable policymaker.

The task of HTA agencies is not restricted to development of strictly positive or negative recommendations. The above process may lead to recommendations for price negotiation or the collection of further evidence. Together with stakeholders, agencies may also identify alternative ways of implementing interventions, which may optimize their value.

Communication and Appeal

In a democratic society, policymakers hold the authority to make decisions and are accountable for the decision-making process. It is, therefore, important that HTA agencies communicate all argumentation to justify the recommendation on the use (or rejection) of criteria. Doing so in accountable ways will increase the likelihood that stakeholders, including citizens who did not participate [4,7]—and did not go through a learning process—can understand and accept the reasoning underlying the final decision.

In addition, societal perceptions of what should count as legitimate arguments for recommendations are subject to change over time or as new evidence becomes available. Health authorities should, therefore, organize an appeal mechanism—or at least be receptive to new input and arguments that were initially not taken into account [1,4].

Discussion

This article presents evidence-informed deliberative processes as a hybrid value assessment framework that integrates the virtues of A4R (i.e., the deliberation among stakeholders to incorporate relevant social values) and MCDA (i.e., structured and rational decision-making informed by evidence on multiple criteria). The

framework includes various elements that are frequently mentioned in the HTA literature (e.g., involving stakeholders), ensuring that all potentially relevant criteria are considered and explaining the reasoning for recommendations.

These are now, for the first time, being presented in a unifying framework and translated into practical guidance for HTA agencies. Adopting evidence-informed deliberative processes as a value assessment framework could be an important step forward for HTA agencies in optimizing the legitimacy of their priority-setting decisions.

To achieve this, HTA agencies can probably best incorporate elements of the framework incrementally, adjusting them to local needs and affordances. For example, HTA agencies may decide to include scoping exercises with stakeholders on the relevant contextual criteria for a specific decision, organize deliberative dialogues, or decide to publish their argumentation vis-à-vis their recommendations. Again, evidence-informed, deliberative processes should by no means be considered a blueprint for HTA agencies—they should, rather, be considered an aspirational goal, and HTA agencies can implement components to progress toward that goal. We are now undertaking research activities under the heading of the REVISE2020 project to develop practical guidance for HTA agencies. This will take the shape of a menu of options that HTA agencies can consider to improve the legitimacy of their decision-making process [59].

Evidence-informed deliberative processes require the collection and/or development of evidence on all identified values where possible, supplemented with experiences and judgments where relevant. The interpretation of this information may be challenging in terms of the great uncertainties involved. Yet, we see this challenge as merely reinforcing the need to deliberate on these values as informed by available evidence, rather than ignoring it altogether.

We recommend that HTA agencies use a comprehensive checklist of criteria that may be relevant in particular contexts, including their range of identified and specified criteria. Yet, one may question whether a good deliberative process would not lead to the consideration of the same values and to the same recommendation. We believe that, as the development of such processes is in its infancy, the use of a checklist may still be useful to avoid overlooking certain criteria.

On a more methodological note, evidence-informed deliberative processes can also be considered a general heading for various HTA approaches that are based on the same principles of stakeholder deliberation and evidence gathering, for example, program budgeting and marginal analysis [60] and choosing health plans all together [61]. These approaches share the same challenges in their processes, such as avoidance of stakeholder dominance. Shared research activities can inform the optimal form and implementation of evidence-informed deliberative processes, per decision context. The fields of general policy and technology assessment [24], political sciences, and governance studies [62,63] can provide important lessons.

Ideally, evidence-informed deliberative processes are also applied in the early phase of the development of interventions, to take into account stakeholder values vis-à-vis medical innovations. In the early phase, this inclusion offers great opportunity to better steer the practice of medical innovation toward high-value interventions, to more efficiently collect relevant evidence, and to avoid the implementation of low-value interventions [64]. Yet, to our knowledge, this has rarely been applied.

Finally, as countries around the world face challenges regarding the sustainability of their health systems, driven by medical innovations, growing needs of aging populations, and higher public expectations [65], they will be increasingly confronted with the need to make difficult choices. We see the develop-

ment of evidence-informed deliberative processes as a suitable response and a necessary condition to safeguard societal support for the choices that are made.

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