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Perspective

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Addressing Health System Values in Health Technology Assessment: The Use of Evidence-Informed Deliberative Processes

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Abstract

Health technology assessment (HTA) is increasingly used around the globe to inform resource allocation decisions. Furthermore, the importance of using explicit and transparent criteria for coverage decision making in line with health system values has been acknowledged. However, the values of a health system are often not explicitly taken into account in the HTA process. This situation influences the allocation of scarce resources and could lead to a discord between the HTA outcome and the values of the health system. We describe how evidence-informed deliberative processes (EDPs) can help to improve this situation. EDPs are integrating two theoretical frameworks; multi-criteria decision-analysis and accountability for reasonableness. Through the use of EDPs, HTA agencies can ensure that health system values are more explicitly and consistently taken into account in the HTA process, enhancing the legitimacy of coverage decisions.

It is well known that governments around the globe are faced with the challenge to balance available resources against social pressure to ensure that populations enjoy equitable access to effective, affordable, and sustainable health care. Increasingly, health technology assessment (HTA) is used to inform such decision-making processes, including coverage decisions. HTA is a process that includes several interrelated components; governance and structure of the process, scoping, assessment, appraisal, and implementation and monitoring. These components are described elsewhere (1).

From its original intent, HTA has been intended to inform decision making. This means that HTA is context-dependent and as such should reflect what is considered important to society, taking into account the complexity and dynamics of health systems (2;3). Velasco Garrido et al. (4) show that health systems in Europe share common values and principles, including universality (i.e., equal access to health care), access to good quality of care, equity, and solidarity. The key question is how such broad criteria are explicitly defined and applied by HTA agencies and ultimately interpreted by decision makers who use HTA to support coverage decision making. It appears that contemporary HTA's focus is mainly on the properties of the health technology to be assessed, and especially the economic dimension in terms of cost per outcome. As such, most coverage decisions are based on economic evaluations, using for example the cost per quality adjusted life-years (QALY) approach. It is known that the QALY approach does not explicitly incorporate considerations of equity (5).

Lysdahl et al. (6) mention that "the majority of health economics guidance is based upon the assumption that assessment is seeking to support a global decision maker engaged with maximizing the efficiency of an overall health system….", using cost-effectiveness thresholds. Especially in many low and middle-income countries, the use of cost-effectiveness thresholds could lead to flawed decisions on how to allocate scarce resources because decision makers do not consider maximizing efficiency to be the main value or objective of the health system (7). This means that the ethical underpinning of cost-effectiveness analyses (e.g., maximizing efficiency) in themselves do not assure adequate ethical reasonableness in coverage decision making (8). Therefore, it is important that the HTA community addresses more clearly what matters to the relevant health system and the reasons why. We describe how evidence-informed deliberative processes (EDPs) can be useful to supporting HTA agencies in doing this. The underlying premises is that the involvement of relevant stakeholders to identify, reflect, and learn about the meaning and importance of relevant values and questions, and an evidence-informed evaluation of the identified values (criteria) can contribute to the legitimacy of recommendations and/or decisions, for example, by improving the quality, consistency, and transparency of the HTA process.

To What Extent Do HTA Processes Reflect Health System Values?

Several HTA scholars stated that current HTA processes are not fully suitable for coverage decision making without taking into account specific health systems aspects, including country size, gross domestic product per capita, social values, and public health priorities (9). Goetghebeur et al. (10) recently presented the values on which eight HTA agencies (in Belgium, Canada, Colombia, England and Wales, Italy, Netherlands, Norway, and Spain) were founded, and what criteria they use to inform coverage decision making. One of the criteria included the mandate and scope of the health system. The authors defined this criterion as "alignment of the intervention with the mandate/scope of the healthcare system. The goal of healthcare is to maintain normal functioning. Mission and scope of healthcare plans/systems derive from this principle. The ethical foundation is to promote and protect the health of the population served." They found that only two of the eight HTA agencies formally considered this criterion in their HTA process (i.e., appraisal). However, it was mentioned that this criterion could also be used for selecting health technologies for assessment (i.e., prioritization). The extent to which values at the system level are taken into account in the HTA process remains largely unexplored. This has been confirmed by other authors (11;12).

Does It Matter?

We believe that the legitimacy of coverage decision-making processes informed by HTA can be strengthened by linking health system values and the criteria used, that is, by making them explicit and transparent. In the United Kingdom (U.K.), the debate about the Cancer Drugs Fund (CDF) shows the complex interface between health systems values, the use of HTA and political reality. In 2011, the government initiated the CDF, consisting of a separate budget for oncology indications that were not approved by the National Institute for Health and Care Excellence based on HTA. It was believed that the CDF was circumventing the use of HTA for coverage decision making and that favoring only cancer drugs led to inequality, while the U.K. health system is founded on the principle of equal access to patients in equal need (13).

Part of the problem is that health system values are general and not explicitly operationalized in a way that they can be used in a meaningful way at the aggregate level by decision makers, for example, for coverage decision making. For example, the Commission on the Future of Health Care in Canada (2002) used the underlying values of the Canada Health Act (equity, fairness, and solidarity) in shaping health policies. Juzwishin (14) pointed out that such health system values can easily be contested and need to be translated and made explicit, also in HTA processes to understand their meaning and relevance in policy and practice.

In the Netherlands, equality, solidarity, and equity are considered to be important principles of the Dutch health system. With regard to coverage decision making, the Ministry of Health makes the final decision, using the recommendations of the HTA agency (i.e., the National Health Care Institute - ZIN). Even though ZIN is quite transparent about the way in which coverage decision-making criteria (necessity, effectiveness, cost-effectiveness, and feasibility) are defined, they are not explicitly derived from the relevant health system values and their application in practice proved difficult to be understood (15). We have noted that the interpretation of the criterion necessity was used differently in coverage decisions, as testified for example by the cases of Viagra (favorable cost-effectiveness ratio but not reimbursed) and Myozyme and Fabrazyme (unfavorable cost-effectiveness ratio but reimbursed) (16). This has led to a request of ZIN to operationalize the necessity criterion, as well as a public debate regarding the reimbursement of expensive drugs (for rare diseases) and about how to address social values in coverage decision making.

In Sweden, where there has been an explicit process for coverage decision making, there are still some challenges regarding its transparency, the inclusion of all relevant stakeholders such as citizens, and the interpretation of the guiding principles. The Health and Medical Services Act stipulates the goals of the health system that are translated into principles to guide national and local health decisions, referred to as an ethical platform (17). The principles are human dignity (all individuals have equal value), which precedes the principle of needs and solidarity (resources should be primarily allocated to areas of greatest need); which subsequently influences the principle of cost-effectiveness (a reasonable incremental cost-effectiveness ratio).

With regard to HTA, the Dental and Pharmaceutical Benefits Agency (TLV) makes decisions regarding pricing and reimbursement of new prescription drugs, and they are obliged to consider the ethical principles. Heintz et al. (2014) noted that the application of these principles is not straightforward. They found that, although the government made clear that severe (e.g., rare) diseases and significant impairments in the quality of life should be prioritized, even at a higher cost for society, it is not clear how high those costs may be (18).

Furthermore, the TLV calculates the cost-effectiveness of non-prescription drugs (i.e., those paid by hospitals, county councils) that feeds into the decision-making process of the New Therapies (NT) Council. The NT-Council is commissioned to make recommendations to the county councils regarding the use of new drug therapies. The county councils are highly autonomous and have a high degree of decision-making power for the introduction of new health technologies (19). Even though the county councils have to adhere to the principles of the ethical platform, this situation runs the risk of using the principles differently as described in a study on the county council of Stockholm (20).

The examples demonstrate that not clearly explicating health system values and the criteria used in the HTA process can result in nontransparent processes and inconsistent decisions that ultimately influence the legitimacy of coverage decision making. It is increasingly recognized that health authorities and policy makers should be held accountable to the populations they serve (21). Meaningful public accountability can facilitate democratic decision making in various ways (22). It forces policy makers to be more systematic, explicit, and transparent, by making decisions sensitive to a wider range of health system values, and by promoting consistency across decisions. It can also make the implementation of decisions more efficient by addressing disagreement at an earlier stage and by facilitating ownership, by discouraging fraud and waste, and by promoting collaboration within the community.

How to Move Forward?

We identified that HTA agencies and health authorities need guidance on how to explicitly address health system values and how to involve all relevant stakeholders (23). The involvement of relevant

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stakeholders is important to address the issue of legitimacy. We acknowledge that handling diverging views makes decision making complex and not easy. However, if the diverging values of relevant stakeholders are ignored in the HTA process, the legitimacy of decisions may be questioned. In the end, as stated by Klein et al. (24) it is the decision-making process that warrants the legitimacy of decisions and not only the robustness of the evidence or the formal procedure followed. We believe that using EDPs could be a promising way forward. EDPs are an approach for gathering evidence on the health system values related criteria considered important by stakeholders and for opening-up decision-making processes to public scrutiny and appeal. EDPs are integrating two theoretical frameworks: multi-criteria decision-analysis (MCDA) and accountability for reasonableness.

EDPs consist of several steps, which have been described in detail elsewhere (25) and guidance for HTA agencies is under development, using input from members of the International Network of Agencies for HTA (INAHTA). EDPs allow the political–economic assessment of (coverage) decision-making processes (e.g., which stakeholders are involved, when and how in the HTA process, which evidence is collected, and how are recommendations developed). We are aware that EDPs may not be a suitable fit for all contexts, and that some HTA agencies already have some of the EDP steps in place. For example, in the Netherlands EDPs are applied by ZIN for optimizing the process of the appraisal committee in terms of using deliberative MCDA.

During the annual 2018 HTAi meeting in Vancouver, we organized a panel about EDPs (Value Frameworks and Decision Making around the Globe, from Evidence to Action), asking three HTA experts around the globe to reflect on the added value of EDPs for the HTA process in their countries (Sweden, Uruguay, and China). All experts had the opinion that EDPs provide added value for HTA in terms of explicating the values guiding HTA, including how this relates to the relevant health system values. Therefore, it is expected that, by using EDPs, HTA agencies are able to ensure that all relevant stakeholders as well as health system values are more explicitly and consistently taken into account in their processes. This will better ensure that these values are included in the HTA process, enhancing legitimate evidence-informed decision making.

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