

VALIDATE consensus statement: integrating empirical and ethical inquiry in health technology assessment

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This statement reflects the views of the consortium membersⁱ involved in the VALIDATE (VALues In Doing Assessments of healthcare TEchnologies) project, funded by the Erasmus+ programme of the European Commission, regarding the key tasks of health technology assessment (HTA) and the type of knowledge and skills that those who have an interest in HTA need to develop in order to further enhance HTA's scientific rigor and policy relevance.

HTA: where facts and values meet

An ultimate objective of HTA is to inform decision-makers to arrive at a reasoned judgement about the value of a health technology, supported by appropriate relevant evidence, while taking into account the specific context in which the health technology is or will (not) be used (anymore) (O'Rourke, Oortwijn and Schuller, 2020).

The question is, then, how, where and when do facts and values meet in this process?

One way of envisioning how such a meeting of facts and values takes place is strictly sequentially: HTA is held to start with the identification and selection of health technologies in need for assessment, followed by scoping the relevant question, the collection, critical analysis and synthesis of the evidence to be used in the assessment, and then setting this evidence against values that are considered constitutive of the relevant society.

There is definitively an intuitive logic to this view. For, how could those involved arrive at a value judgement of a health technology in the absence of the relevant evidence? Surely that would be impossible. However, there is one important aspect that this view is unable to explain: how can HTA doers know what facts they would need to collect in the first place? Surely, the facts that are being collected are those facts that are considered *relevant*; facts that matter since they could make a difference to our judgement of the value of the health technology under study. Such values are, then, *anticipated*; they are operative *throughout* the HTA process, also to provide guidance to the collection of empirical evidence. Hence,

rather than strictly sequentially, facts and values 'meet' in a more iterative way during the HTA process (Hofmann, Bond and Sandman, 2018).

HTA: a question of commitment

A useful way to envision how facts and values interact is to acknowledge certain commitments on the part of those who are conducting or using HTA. These commitments are, at least for a part, ethical in nature. Not so much in the sense of HTA doers and users being privately committed to certain ethical values (although this is not ruled out either), but in the sense of their being committed to certain ethical values that may be considered emblematic of those that are held in the wider community. For instance, because a general commitment to the value of avoiding harm may be presumed, it is imperative for HTA doers and users to examine whether the use of specific health technologies is associated with unintended and unforeseen harmful outcomes (safety). Likewise, because a general commitment to the value of helping people to overcome the suffering and agonies that can be associated with ill health may be presumed, it is imperative for HTA doers and users to examine, for instance, whether the use of specific health technologies improves quality of life or avoids premature death (effectiveness). Similarly, because a general commitment to the value of equity may be presumed, it is incumbent to examine whether the use of specific health technologies incurs costs that are commensurate to the associated health benefits (cost-effectiveness).

HTA: providing insight into alternative courses of action

This notion of commitments, acting to provide guidance to the HTA process can be generalized further. For this, it has to be remembered that HTA from its original intent is a form of policy research aimed at providing decision makers with insight on alternative actions (Banta and Luce, 1993). But which alternative actions (comparators) should be considered? To be sure, ethical commitments are operative here, too, establishing the range of options that are provisionally considered acceptable and appropriate, pending the outcomes of further inquiry. But alongside ethical commitments, another type of commitment is at work, defining what may be considered potentially fruitful approaches to resolve a specific health problem. This type of commitment may be called ontological: they reveal something about the general purview that someone takes on a specific health

problem: given its presumed contributory causes, what health interventions have the potential to significantly help reduce their impact, either through prevention, care or cure? A final type of commitment underlying HTA that we wish to mention here relates to knowledge: what are considered acceptable types of inquiry, and what are the sort of issues of which we can obtain valid knowledge, provided that those types of inquiry are correctly used? This type of commitment may be designated as epistemological commitment: it testifies of views of what is considered valid knowledge, and how such knowledge may be obtained.

The upshot of the foregoing is that HTA, rather than a matter of collecting *the* facts, should be considered as a matter of collecting and evaluating the facts that are considered relevant, plausible, and amenable to accepted methods of inquiry.

Practical implications

Acknowledging the role of these various commitments underlying HTA has important practical consequences. The reason for this is that people can differ in their commitments in a way that affect the content of an assessment: what alternatives would have to be taken into account, what sort of outcomes should be explored, and what type of inquiry seems to be most appropriate toward those ends? This raises an intricate question for HTA doers, HTA commissioning organizations and decision makers (i.e. users) alike, namely: to whom do they wish to be answerable? Should differences in commitments that appear to have implications for the content of the HTA be taken seriously, and, if so, what does that mean, and how may this be achieved?

The position that is taken by the VALIDATE consortium is that HTA doers and users have a joint responsibility to explore whether relevant differences in commitments among stakeholders (i.e. those affected) exist, and what implications this might reasonably have for the HTA to be conducted. Drawing on theory and methods from policy sciences (Fischer, Miller and Sidney, 2006), the VALIDATE project has developed practical means to achieve this. In practice, this boils down to giving a structural and integral place to a number of developments in HTA, including stakeholder involvement, scoping, and inquiry into a health

technology's context. This will lead to a less mechanistic and more constructive type of HTA, true to its original intent and aspirations and responding to the increasingly felt need amongst the HTA community (Gagnon et al., 2021) to more systematically include values and contextual data in HTA studies.

Knowledge and skills

In addition to the knowledge and skills that are considered mandatory for HTA doers (Mueller et al, 2021), and to which we subscribe unconditionally, the VALIDATE approach to HTA requires that doers and users, firstly, come to appreciate the interplay between various types of normative commitments (as mentioned above) and scientific inquiry in the context of HTA, and, secondly, learn how to make such commitments explicit and establish an appropriate content of an HTA, answerable to the different perspectives. In short, they should be able to adopt the concept of HTA *as learning* (Grin and Van de Graaf, 1996; van der Wilt, Rüter and Trowman, 2019). Such general qualifications can be translated into the following steps that those conducting HTA should be able to undertake as part of an HTA:

- Identify and collect the claims and concerns (statements to the advantage or disadvantage of a technology, respectively) that have been expressed by or were solicited from the various stakeholders regarding a specific health technology, either through interviews, document analysis, participatory observation or a combination thereof (as described by, for instance, Guba and Lincoln, 1989);
- Reconstruct the ensemble of general commitments that underlie the various claims and concerns and that give rise to specific definitions of the problem and associated judgements of solutions that are distinguished (using the method of reconstruction of interpretive frames¹ as described by Grin et al, 1997);
- Explore the reasonableness of the various claims and concerns by assessing the coherence of the underlying interpretive frame, its evidential support and its relation with general ethical principles (Fischer, 2003). This activity encompasses, but is not

¹ An interpretive frame, here, may be thought of as an individual's judgement of one or more proposed solutions (e.g., is this technology likely to work in this context, is it feasible, appropriate, etc.?), as a function of his or her problem definition, background theory and normative commitments. It can be reconstructed on the basis of semi-structured interviews, document analysis, or participatory observation, and serve to examine how well- or ill-structured a specific policy problem is (see, for instance, Daviter, 2019).

confined to, the retrieval, critical appraisal and synthesis of evidence that are constitutive of current approaches to HTA.

- Present the findings and provide a methodological justification for the approach that was adopted, indicating whether it is plausible that use of a specific health technology in a particular setting could have the alleged outcomes and explaining the relevance of such outcomes.
- Formulate recommendations for policy actions regarding both, measures to mitigate the specific health problem and inquiries which are required to address key uncertainties. In addition, HTA doers should be able to indicate whether ancillary measures are needed to ensure desired outcomes and prevent undesired outcomes, what such measures might be, and the reasons why they are likely to be feasible and (cost)-effective.

Against this background, the knowledge and skills that HTA students need to develop on top of their basic HTA knowledge and skills are:

- The ability to recognize that all types of evidence (e.g. on safety, effectiveness, social and ethical implications) have a value, and evaluate their underlying normative assumptions by using ethical argumentation models.
- Knowledge and skills that help them in reconstructing, exploring, and critically evaluating stakeholders' interpretive frames and their relation with the questions and evidence that is taken into account in an assessment.
- An understanding of how to integrate the above insights, and choose proper HTA methods, into an effective policy advice, making use of concepts and methods from policy science that are relevant to HTA.

The VALIDATE approach: a practical means for scoping and stakeholder involvement in HTA

A key rationale underlying the VALIDATE approach to HTA is the recognition that regarding health and health technology, stakeholders can, and frequently do, differ in their views of how things are and are brought about, what matters, and what sort of inquiries are likely to provide us with usable knowledge. In addition, it is recognized that such differences may result in different views of what evidence is required in order to decide how the challenges

associated with specific health problems can best be met, and how such evidence is to be obtained. Such views are not self-evidently valid, but should not be completely ignored either. What is needed, as part of an HTA, is an analysis that shows why (or why not) the relevant views were taken into account, and what implications this has for the evidence collection and interpretation. Taking stock of stakeholders' claims and concerns, reconstructing the associated interpretive frames, and conducting a critical frame analysis are precisely geared toward this objective. As such, these steps may be considered as a means for conducting a scoping analysis, specifying the relevant questions that will be addressed in the HTA and how these will be addressed. In this way, the VALIDATE approach offers a means to more systematically and constructively involve stakeholders in the HTA process by means of participation (i.e. active engagement). Jointly, these aspects of the VALIDATE approach also hold the potential of further enhancing the relevance of HTA to health policy making.

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