Expanded HTA: Enhancing Fairness and Legitimacy

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Abstract
All societies face the need to make judgments about what interventions (both public health and personal medical) to provide to their populations under reasonable resource constraints. Their decisions should be informed by good evidence and arguments from health technology assessment (HTA). But if HTA restricts itself to evaluations of safety, efficacy, and cost-effectiveness, it risks being viewed as insufficient to guide health decision-makers; if it addresses other issues, such as budget impact, equity, and financial protection, it may be accused of overreaching. But the risk of overreaching can be reduced by embedding HTA in a fair, deliberative process that meets the conditions required by accountability for reasonableness.

Keywords: Health Technology Assessment (HTA), Accountability for Reasonableness, Safety, Efficacy, Cost-effectiveness, Equity, Financial Protection, Budget Impact, Fairness, Legitimacy.

Article History:
Received: 14 August 2015
Accepted: 12 October 2015
ePublished: 6 November 2015

All societies must make choices among the various interventions, whether public health or medical care, that they can provide to their members since reasonable resource limits on health expenditures mean not all health protections can be provided to everyone. However, important health is, it is not the only important good that societies must provide, and so there are always reasonable ways to limit what can be done to protect health. For these choices to be justifiable to the public they affect, they ought to be made in light of good evidence and sound rationales. One source of good evidence is provided by health technology assessment (HTA). Historically, HTA has focused on the safety and efficacy of an intervention, but also the cost-effectiveness of an intervention, though there is an increasing awareness that a broader form of HTA is needed and some limited effort is already being made in a few countries to meet that need, most HTA reports even in those countries fail to develop ethical arguments and generally do not even mention ethical issues.

Our view is that the risk of irrelevancy is worse. Decision-makers should make judgments that go beyond safety, efficacy, and cost-effectiveness—that is, improving health equity—should be given priority over making a health system more efficient (eg, by pursuing what is most cost-effective to maximize health). Should HTA evaluate these issues as well as safety, efficacy, and cost-effectiveness?

Expanding the scope of HTA in these ways has a clear risk: HTA may be seen as overreaching its area of competency. For example, while the cost-effectiveness ratio of particular interventions (or the budget impact on society of covering them) can be evaluated quantitatively, a recommendation about which interventions are too costly to be covered may rest on non-quantified judgments about what it is more or less important to fund. Such issues may be thought beyond the scope of quantifiable methods. Yet, if HTA refrains from expanding its evaluation and recommendations to other issues, it may be judged irrelevant to the real needs of decision-makers. Which risk is worse—overreaching or irrelevancy? Our view is that the risk of irrelevancy is worse. Decision-makers should make judgments that go beyond safety, efficacy, and cost-effectiveness, so an assessment limited to these features must of necessity be insufficient to yield a decision. This lack of sufficiency will support the ultimate charge of irrelevancy, if only because it is inadequate to ground the judgments that must be made. The fact of insufficiency is not debatable, whereas the claim of “overreaching” is. In addition, the risk of overreaching can be significantly reduced by embedding HTA in a fair, deliberative process, whereas the claim of insufficiency cannot. In Daniels and Sabin, the conditions that such a fair process must meet are called “accountability for reasonableness” (A4R). If HTA is embedded in a process that meets the conditions of A4R—publicity (decisions are fully transparent), relevancy (decisions are based on rationales that appeal to reasons all think are relevant to resource allocation, and, at least in publically administered systems, all appropriate stakeholders...
argument defeats the fairness of the process, we should accept the outcome of the fair process as fair until we actually find and accept a principle that defeats it. The mere possibility that such a principle, if it is accepted, can defeat the fairness of the process shows there is a difference between a gamble and a decision about resource allocation. But it does not show that the outcome of a fair process is not plausibly viewed as fair until it actually meets with that kind of defeat. In any case, there is no challenge to the enhancement of legitimacy that embedding HTA in a fair, deliberative process can bring. How much enhancement conformance with the conditions involved in A4R brings is, however, an empirical question (and not a trivial one). Arguably, the conditions of publicity, relevance, revisability, and enforcement are theoretically justified, not empirically derived. But it should be possible to measure the effects on legitimacy of conformance with the conditions described in A4R for HTA. If an expanded version of HTA is embedded in a fair process, we should be able to measure the effect of doing so on the legitimacy of HTA. One of us (ND) was once asked by a group of Chinese health ministers if A4R “works.” They were asking “does it make decision-making better?” He could not give an evidence-based answer. Still, improving its legitimacy is one way to make decision-making about health care resource allocation better. A key aspect of its legitimacy is whether the process in which HTA is embedded establishes its “independence” to make judgments about the merits and weaknesses of various interventions. Some skepticism about the legitimacy of coverage decisions in some societies derives from the belief that HTA is in the service of vested interests that control the health system. This skepticism may be deepened if the process in which HTA is embedded yields only “recommendations” and not decisions. Indeed, in many countries, the most “independence” we can expect would still leave decision-makers accountable for their decisions nevertheless, we should require them (by law or custom) to state why they are not following a recommendation if they reject it. Then democratic forces—to the extent that they exist—can compare their reasoning about their decision with the reasoning involved in the recommendation (which, by the requirements of A4R, is public) and act accordingly. Here we can only note that the independence of the HTA process is assured by the terms of appointment of, and the charge to, participants in the process leading to the recommendations that HTA makes. The tenure of the decision-makers and the people who appointed them, or of the elected officials responsible for appointing them, is determined by the degree of accountability the political process imposes on them. The independence of the HTA process can also be strengthened if other democratic institutions can help protect it from capture by vested interests. For example, in countries that recognize a legal right to health or health care and where the courts have become an important institutional actor in the political process surrounding these issues (as in many low- and middle-income countries) the courts can play an important role critically reviewing the
fairness of the HTA process and examining whether the reasons for policy decisions are fair and consistently applied. This can enhance the accountability of the HTA process; however, the courts can have the opposite effect given that they are also subject to capture by vested interests. Once again, the independence of the courts (and thus their ability to enhance the legitimacy of the HTA process) depends on the degree of accountability that the political process imposes on them. Ultimately, no process is safe from abuse—and the remedy for such abuse is always political.

In sum, HTA should (and increasingly does) make recommendations about technologies that go beyond their safety, efficacy, and cost-effectiveness. These recommendations should be based on good evidence and arguments about all aspects of the rationales for them. These recommendations derive their legitimacy from the fair, deliberative process in which HTA is embedded. Nations must strive to make that process “independent” from vested interests, which is a tall order given the power of those interests and the complexity of managing a process that includes stakeholders. We can measure the effect on the legitimacy of HTA recommendations that emerge from such a process. Given the social disagreement that pervades many resource allocation decisions, it is harder to agree on the fairness of such recommendations, but there is considerable plausibility to accepting the outcomes of a fair process as fair.

Ethical issues
Not applicable.

Competing interests
Authors declare that they have no competing interests.

Authors’ contributions
ND contributed to conception of the work. ND, TP, and JU contributed to the collection and interpretation of related information. ND prepared the draft of the manuscript. TP and JU contributed to critical revision of the manuscript. All authors verified the final version.

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