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Editorial

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.

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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.[1] 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,[2] though there is an increasing awareness that a broader form of HTA is needed[3] 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.[4] One important advantage of focusing on safety, efficacy, and cost-effectiveness is that these aspects of an intervention can be evaluated with highly quantifiable methods that are replicable and serve to compare interventions.[5]

Decision-makers must, however, decide to provide interventions on the basis of additional considerations. They generally need to know what the budget impact of coverage is likely to be for society and what are its opportunity costs. For example, providing coverage for pharmacological therapy of chronic hepatitis C infection can save many lives, but if there are many instances of such a condition, a society may not sustainably cover the service for everyone. Covering it for some and not others poses difficult ethical issues and may prove to violate concerns about equitable treatment. Decision-makers also need to know what the degree of financial protection is—for though ill health compromises opportunity and well-being, so does poverty induced by ill health and attempts to address it. Sometimes, as well, reducing the unfair distribution of health in a population—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,[6] 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

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vet the rationales), revisability (decisions can be revised in light of new evidence or arguments), and enforceability (decisions are all made in keeping with these conditions)—then the increased legitimacy and fairness of the decisions will reduce the charges that HTA is overreaching. These conditions may seem less controversial than they are in practice, since everyone applauds transparency (publicity) until his or her practices are exposed by it. Improvements in transparency encounter much political foot-dragging in HTA and in decision-making in general.

Recently, World Health Organization (WHO) released ethical guidance about how fairness can be assured in the pursuit of universal coverage.[7] It recommended that, as decision-makers expand a benefit package—whether to cover more people, to cover more interventions, or to reduce co-pays and fees—cost-effectiveness gives important guidance. Decision-makers ought to know how much health benefit a population receives for the resources they have to invest in health. But, as the report suggested, appeals to cost-effectiveness must also be tempered by judgments of fairness made as the result of a deliberative process that assures accountability for reasonableness. This recommendation provides a model for how we should think about HTA. If HTA is embedded in a fair, deliberative process that meets the conditions involved in A4R, its recommendations about equity and other aspects of fairness would similarly face a reduced risk of encountering the charge of "overreaching."

Does A4R enhance only legitimacy, failing to assure the fairness of decisions? Or does A4R enhance both legitimacy and fairness? This is an important question since many think that a fair process can only improve legitimacy, not fairness (D. Brock, oral communicaton, February 2013). The judgment that fairness is also enhanced rests on this point: If we lack prior agreement on a substantive principle for making a particular decision, we may agree on a fair process for making it and we may then accept the outcome of that process (viewed as a form of procedural justice) as determining what is fair. That is what happens when we accept the toss of a coin to determine who goes first in a game or the toss of dice or the spin of a wheel to allocate winnings in a gamble.

Suppose, however, we can agree over time (it might take a long time—more than decision-makers have to arrive at a persuasive and acceptable argument) that a particular principle should determine how much priority to give to those who are worse off than others, or how to make other similarly difficult judgments. Then we might view the outcome of a process that yielded a different result as "wrong" or "unfair," leading us to reject the view that we can accept the outcome of a fair process and regard it as fair. We claim that what we should then say is that the argument for the principle we come to accept "defeats" the appeal to the process. The support for this claim is that we often do not need a process if we have a substantive principle instead. (We may sometimes still need a fair process if we cannot apply the principle without one, as in a criminal trial where the principle we all agree to is "Convict all and only the guilty." In this case, we still need a fair process to decide whether a particular defendant is guilty and should thus be convicted). But even if we allow for the possibility of such an argument for a principle in the case of resource allocation cases and then conclude that such an 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 actually responding only to "recommendations" coming from an expanded HTA process, not surrendering to that process the power to make actual decisions. To hold 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.[8] 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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