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Commentary

Beyond the Black Box Approach to Ethics!

Comment on "Expanded HTA: Enhancing Fairness and Legitimacy"

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Abstract
In the editorial published in this journal, Daniels and colleagues argue that his and Sabin's accountability for reasonableness (A4R) framework should be used to handle ethical issues in the health technology assessment (HTA)-process, especially concerning fairness. In contrast to this suggestion, it is argued that such an approach risks suffering from the irrrelevance or insufficiency they warn against. This is for a number of reasons: lack of comprehensiveness, lack of guidance for how to assess ethical issues within the "black box" of A4R as to issues covered, competence and legitimate arguments and finally seemingly accepting consensus as the final verdict on ethical issues. We argue that the HTA community is already in a position to move beyond this black box approach.
Keywords: Health Technology Assessment (HTA), Accountability for Reasonableness (A4R), Ethics, Ethical Competence, Ethical Analysis

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In the editorial published in this journal, Daniels and colleagues argue that since societies cannot cover all health interventions, decision-makers face the challenge of how to prioritize different health interventions. According to the authors such prioritizing should be made on the basis of sound evidence. Health technology assessment (HTA) might provide such evidence, and generally does when it comes to safety, efficacy and cost-effectiveness. However, there is more to making an ethically well-founded decision on which health interventions to cover and the authors argue that HTA should incorporate ethical assessment in general and considerations of equity and fairness in particular. Since we cannot agree on principles for how to prioritize, Daniels and colleagues suggest that accountability for reasonableness (A4R) framework should be adopted to achieve both legitimate and fair decisions. The appeal to procedural justice is made in part on the belief that a fair process secures fair outcomes, as the following statement indicates: "…there is considerable plausibility to accepting the outcomes of a fair process as fair."[1]

Even if it could be argued that Daniels et al do not give full notice to the fact that ethical assessment has been part of the concept of HTA for long and that lately there are a large number of ethics initiatives on how to systematically implement ethical assessment at different levels of the HTA-process within the HTA-community, there is a long way to go before this is satisfactory. Moreover, Daniels et al are right in that irrelevance is a greater threat for HTA than is overreaching. With irrelevance they seem to mean insufficiency, rather than strictly irrelevance (since the basic considerations of clinical effectiveness, safety and cost-effectiveness might still be relevant but insufficient) [1]. In the following, we will hence use the term insufficiency. The problem seems to be that the authors do not go far enough and, the result from their suggested approach risks suffering from insufficiency when it comes to assessing ethical aspects of health technologies. First, ethical aspects cover a larger field than just considerations about fairness – including aspects like autonomy, integrity, privacy, dignity, etc. If a technology fails to pass the test of living up to norms about dignity or autonomy, it does not help if it is equitably distributed. The editorial does acknowledge that there can be defeating values to the procedural approach but fails to suggest which they are or how these ethical aspects should be assessed or allowed to defeat the procedural approach.

Second, A4R could be seen as a kind of black box approach to ethical issues. You gather a group, set up a set of administrative constraints and then, what comes out, should be accepted as fair (if having followed the constraints). Even following the transparency and publicity criterion, and presenting all the considerations openly – it is still a black box approach in that there are no substantial ethical guidelines, constraints or principles that provides guidance as to how this process should take place. Hence, almost anything might turn up at the end of the box depending on the group in question. This is not very helpful to provide relevant ethical assessment within HTA, even if it might give part of the answer, as other authors also have pointed to.[2] In our experience, having worked with ethical issues in HTA for quite a few years – what is needed are concrete tools highlighting relevant ethical aspects and helping HTA-agencies to provide consistent assessments that are not biased by what the assessment groups happen to focus on.[3-6]

Third, the editorial discusses the argument that ethical assessment goes beyond the competence of the HTA-agency. Surprisingly enough, there is no mentioning of ethics competence in this discussion. Making a proper ethical analysis, including identifying relevant ethical issues, and

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implications for fairness, requires competence. As the authors should be well aware of, since they are heralded by a highly distinguished philosopher, this requires philosophical skills and ethical sensitivity. Sorting out conceptual issues, assessing the logic and consistency of argumentation, providing insight into how the arguments fit into the more general ethical discourse etc. Even if we do not argue that philosophers or ethicists can provide the final verdict on what ought to be done, they can provide a well-analyzed and reasoned account of the ethical landscape of the intervention for decision-makers to take into account (besides the data on safety, efficacy, and cost-effectiveness).

Fourth, decisions concerning coverage in a specific healthcare jurisdiction are not made in an ethical vacuum. Most healthcare legislations, official guidelines, and established practices provide some guidance on how to interpret ethical values and norms in that context.

Fifth, the argument in favor of A4R rests, to a large extent, on the problem of achieving consensus. As people have different views on how resources should be distributed we cannot apply substantive principles of fairness. If the day comes when such agreement is reached, we could, according to ND, judge "…different result as 'wrong' or 'unfair'…."[1] But why place such a weight on consensus when it seems quite clear that we historically have been able to formulate convincing ethical arguments against things like slavery or in favor of gender equality – despite lack of consensus. Rather, the ethical arguments have precluded and influenced social attitudes. Moreover, consensus is a poor guarantee for moral rightness. For example, social approval of slavery does not make that practice morally right.

In conclusion, we should move beyond the black procedural box approach to ethical issues in HTA, filling the box with structured frameworks for comprehensiveness concerning ethical issues, with skilled ethicists, with established and codified interpretations of ethical values and norms. This work has already started with a number of good initiatives on its way. Unfortunately, the suggestions in the editorial do not add much of substance to this development and thereby falls in the trap they warn about - insufficiency (or irrelevance using their original term).

Ethical issues

Not applicable.

Competing interests

Authors declare that they have no competing interests.

Authors' contributions

LS drafted the first version of the paper and LS and EG then rewrote this draft in turns.

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Endnotes

[1] We owe this observation to an anonymous reviewer.

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