Author’s response to reviews

Title: Can clinical ethics committees be legitimate actors in bedside rationing?

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Version: 1 Date: 14 Jun 2019

Author’s response to reviews:

We are grateful for the insightful comments from the reviewers, which have enabled us to improve the manuscript in a number of respects. We here respond to the comments:

R1: Juergen Wallner (Reviewer 1): Relevance
This article is important in two ways: First, by taking up the issue of resource allocation (aka "rationing"), it covers an ethical challenge that is present in all healthcare systems on a macrolevel and a microlevel. With very costly therapies on the horizon (e.g., immunotherapy), allocation decision-making will certainly not go away. Secondly, the article contributes to the field of clinical ethics consultation from a methodological perspective: How could clinical ethics committees (CECs) contribute to allocation decision-making at the bedside?

General Feedback
I would like to give my feedback from two perspectives: (1) moral philosophy and (2) practical ethics.

Ad (1). The article develops an approach that I would associate with discourse ethics. It clearly argues how legitimacy through institutional procedures works, especially by the seven requirements (p. 8/9). For those who work in legal or political philosophy, this approach is convincing in context of a pluralistic society and complex societal questions to be decided. The authors' presumption that "CECs do not have the mandate to make bedside rationing decisions" (p. 6) fits into the idea of deliberative justice, where consultative bodies (like CECs) are part of the decision-making process without determining it. So, from the perspective of moral philosophy, I think the article argues convincingly for the involvement of CECs in allocation decision-making and elicits how this decision-making may benefit by the involvement in terms of legitimacy.

Our response: We agree that discourse ethics is an appropriate and very helpful theoretical framework for both clinical ethics consultation and bedside rationing.

R1: Ad (2). Coming to the question of how CECs could be involved in resource allocation at the bedside (p. 10), the article tackles problems of practical ethics. The typology of roles (table 2) CECs could play in this context are comprehensive and helpful for developing a CEC's profile in resource allocation issues. Case 1 clearly elucidates how bedside allocation decision can gain legitimacy by ethics consultation.

Case 2, however, is not the best example for the article's message. First, it is not so clear how the patients' wish (a drug they bought themselves to be administered in a public hospital) is an allocation
decision. Certainly, it is not an allocation decision regarding the cost of the drug, because this does not affect the hospital's resources. One could argue that administering a privately bought drug by hospital staff affects personnel resources, i.e., time and effort that has to be allocated between patients on this immunotherapy and others. However, this argument would fall short if the cancer patients would have to be admitted to the hospital anyway, for the standard therapy. Because then, the human resources would be allocated to them anyway (maybe even in a greater amount if the standard therapy would demand more personal care than the immunotherapy). So, the resource allocation decision lies on another level, namely the public one. In accordance with this assessment, the authors point out that the CEC referred the issue to the political level (p. 16). Hence, case 2 exemplifies macrolevel allocation decisions better than microlevel ones. It could help the focus of the paper if the authors point the (necessary) interdependence between micro- (bedside), meso- (hospital), and macrolevel (public system). In other words: When CECs are involved in bedside allocation issues, they often must be willing the engage in issues of organizational and social ethics (which may be too heavy for some CECs).

Our response: This helpful comment has led us to clarify how case 2 does indeed have consequences for micro-level priority setting. It was indeed the case as the reviewer suggests that the new drug required a different and much more labour- and resource-intensive kind of follow-up from the hospital. We have now added the following clarifying sentence to the case description (p. 13): “If the hospital were to provide the treatment, then this would entail substantial additional use of resources such as outpatient visits, clinician time and attention and additional radiological examinations and blood tests.” In addition, we now point out on p. 17: “Case 2 illustrates the necessary interdependence between micro-, meso- and macro-level priority setting decisions.”

R1: A final observation from the point of practical ethics: Is it really feasible that a whole committee is involved in bedside resource allocation decisions? It seems to me that a CEC's primary role would be in giving policy advice (as the paper also explains).

Our response: We now write (p. 14): “It might matter here whether the CEC handles the case as a full committee or whether only some CEC members are involved in the consult.”

R1: Specifics
1. Although the term "rationing" is frequently used in ethics debates, it may help the interdisciplinary discourse (with economists, managers) to use the technical term "allocation”.

Our response: We now use the term ‘allocation’ in the abstract and the start of the Background section together with ‘rationing’ and ‘bedside rationing’.

R1: 2. The paper's structure could be better: The section "background" could be subdivided in 2-3 subsections. The subheading "main text" (p. 7) sounds somehow generic; a more substantial wording could help.

Our response: We have now introduced three subheadings in the Background section. We have now substituted ‘Main text’ for ‘Discussion’.

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R2: George Agich (Reviewer 2): Your introduction of the Procedural Approach of Daniels and Sabin as
complemented by Baeroe's seven criteria of legitimacy proceeds to a segue to Aristotle's formal principle of equality. This is quite intrusive and does not seem to do any work in the ensuring discussion. Also, you fail to cite a source for the four demands of justice that you say comprise Aristotle's principle of equality. I understand that these principles inspired Baeroe's requirements for legitimacy of clinical decisions about priority-setting, but unless you show how they inspired the requirements, your reader is left in the dark. Also, how important is this link to Aristotle for your account? That is not clear.

Our response: We agree that the link to Aristotle is not important to our account, and so we have now removed it.

R2: It's immediately evident to your reader that Baeroe's requirements for legitimacy of clinical decisions about priority-setting is relevant to your task. They provide the substance of the position you take about legitimacy, namely that it must be grounded in this set of procedural requirements. But they you introduce Magelssen et al.'s roles of CECs, but their connection to the substantive procedural requirements are never made clear. You need to spell out this linkage and argue for it.

Our response: Thanks for pointing out this lack of clarity. We have now spelled out this linkage explicitly and argued for it as follows (p. 6): "For these roles to be considered legitimate in lack of any particular, formal decision-making authority, they will have to be assessed according to requirements addressing the broader picture of both macro- and micro level requirements for fair priority setting in general. Bærøe's framework is a response to exactly this complex, general challenge as it addresses the over all legitimacy of the implicit priority-settings taking place on the micro-level under influences of macro-level decisions. Therefore, when being without any formally assigned authority, the roles of CECs in contributing to bedside rationing will have to be subjected to at minimum the same requirements of legitimacy as clinician/managerial bedside decisions. With Bærøe’s normative framework as the backdrop we then discuss whether and how CECs by fulfilling the six roles contribute to the legitimacy of the decisions reached..."

R2: My main problem with your paper is that you analysis of the two cases draws more from Magelssen et al. than Baeroe's requirements for legitimacy even though you say at the beginning that this is your main concern. You fail to show, for example, how the procedural requirements are met by the CECs. Talking about the roles that the CEC played is beside the point if they failed to meet the procedural requirements. That's what needs to be shown.

Our response: This is an important point, and we have now done several revisions to make the text clearer on this issue:
1) We have clarified in the beginning why we are involveving these roles in the discussion of legitimacy according the framework (p. 6):
"After setting out the seven criteria for legitimacy in Bærøe’s framework we present two empirical, real world priority setting dilemmas wherein CECs were involved, outlining six roles CECs played in the two cases and might play in priority setting cases in general. In order to reach general conclusions with relevance across particular settings, we then discuss the legitimacy of these roles rather than the particular cases in question."
2) We have underscored the use of Bærøe's framework in the discussion of the different roles (as it was to some extent only implicitly referred to in the previous version), and added explicit references to it. In this way, it is now hopefully clearer that this discussion section indeed relates to Baereoe's framework of legitimacy (while linking this framework to the identified, potential roles are important, too).