Author's response to reviews

Title: Qualitative Assessment of Innovations in Healthcare Provision

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Author's response to reviews: see over
We appreciate the helpful comments from the reviewers. On the basis of these comments, the paper has been revised. Following we offer summaries of how we have changed the paper in response to reviewer suggestions.

**Reviewer 1.**

1. **Concern:** “The authors do not address, however, how present day mechanisms to gather the long term data they seek would or should mesh with their proposed public fund

   **Response:** We now note that the FDA and the corresponding agency in Germany are primarily concerned with safety in Phase IV trials. Further, we propose a separate agency to continue to evaluate clinical effectiveness.

2. **Concern:** “the FDA collect the kind of information they want, without a public fund to support them. Although the data are collected in the U.S., they are certainly of value to public systems elsewhere”

   **Response:** We now show that the FDA does not offer the kind of clinical effectiveness evaluation required for public funding agencies. We suggest that another agency is needed to provide oversight over the continuing stream of effectiveness and outcome data.

3. **Concern:** “The authors should answer the question of why their proposed public/ Private fund would be more useful than the present FDA requirements and the Incentives that CAUSE diagnostic firms like Genomic Health to conduct their novel clinical trials”

   **Response:** We now argue that current agencies do not require the ongoing clinical evaluations required for resource allocation decisions.

**Reviewer 2**

1. **Concern:** ” it is not clear whether the authors are discussing regulatory change at those agencies governing payment for new medical innovations, changes in normative practice of research evaluation in the medical profession, or more narrowly changes in the cost benefit analysis of innovations either by individual physicians or by health provider organizations. Given this vagueness in the question addressed, it subsequently is difficult to judge the significance of the paper

   **Response:** We are proposing that a new agency be developed to address these issues. That is described in the revised manuscript.

2. **Concern:** , it is unclear what the authors mean with the words "system," "decision" and "decision-making." More specifically, it is not clear whether they are referring to decisions made within treatment, more generally as policy within healthcare service provision or even more generally as state policy.

   **Response:** The revision now separates different levels of decisions

3. **Concern:** “ the authors do not always attribute actions to a specific actor and sometimes it is unclear who should take responsibility for the actions proposed”
Response: The revised paper clarifies that the perspective is at the level of a public agency. However, individual level decisions are still considered. We clarify this distinction.

4. Concern. “The authors discuss comparisons across countries with no information on the regulatory and/or medical practice differences across countries that may affect comparisons. Hence, it is difficult for the reader to judge the utility of comparisons across countries that include the US, Canada, the UK and Germany.”
Response: The paper was intended to be generic and apply to all health care systems.

5. Concern: “Table 1 includes many redundancies across steps for preventive, diagnostic and therapeutic innovations”
Response: In the first version of our table we tried to use a common description for all three categories (prevention, diagnosis, and therapy) but agreed that this common version was too confusing. So we decided to offer the more extended version which, of course, produces some redundancies.

6. Concern:” The dimensions of figure 1 need to be clarified. Uncertainty in what? And Positive expectations for whom (the provider, the patient, society or whom)?”
Response: The text now clarifies that uncertainty is about expected long term benefit and positive expectations are from the provider and patient perspective.