Author's response to reviews

Title: Stakeholder views of ethical guidance regarding prevention and care in HIV vaccine trials

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Author's response to reviews: see over
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Re: Stakeholder views of ethical guidance regarding prevention and care in HIV vaccine trials

Dear Editors,

Thank you for sending our revised manuscript on to the reviewers. We are grateful for the thoughtful feedback on our original submission, and apologize for the delay in resubmitting our manuscript.

All comments and suggested revisions have been reviewed, and our revised manuscript reflects these recommended changes. A detailed response can be found below.

We thank you in advance for considering our manuscript.

Rika Moorhouse
For the Authors
Response to Reviewers

REVIEWER #1

1. [The manuscript]…reads somewhat long-windedly – there is considerable overlap between what appears in the tables and what in the text, and the paper can be shortened substantially.

Response:
To reduce overlap between the Results section and tables, we have removed Tables 1 and 2. The Results section has also been reduced by several hundred words. While this section of the manuscript has been shortened substantially, all key findings have been retained in the text. Additional data is presented in Table 1 (formerly Figure 2).

2. The ‘figures’ are essentially screen-shots of data and these are difficult to read – they would be better formatted as conventional tables.

Response:
Figure 1 (screenshot) is a sample item from the study questionnaire. As this screenshot does not present study data it cannot be formatted as a conventional table. To best address the reviewer’s comment, we have removed Figure 1 from the revised manuscript. We have retained Figure 2, and re-labeled it as “Table 1”. For more on this new Table 1, please see page 4 of this response letter.

3. I am not convinced that the conclusions and recommendations are actually conclusions and recommendations from the work – the authors need to think a little more about the implications of what they have and have not found.

Response:
We have tried to strengthen the linkage between the results sections and conclusions/recommendations sections by clearly denoting that it was low dimension scores under ‘understanding’ and ‘ease of implementing’ that drove the low overall merit scores for prevention recommendations. We then speculate that more operational guidance might be needed to elaborate on key concepts in the prevention recommendations but concede that more detailed qualitative exploration might be needed to further explore the issue.

4. A reflection on the strengths and limitations of the methods used (beyond simply recommending qualitative studies) would be helpful.

Response:
In the revised manuscript, we more fully discuss the strengths and weaknesses of our methods on pages 19-20. More specifically, we set out that we adopted an empirical approach – utilising descriptive ethics - even while some might argue that conceptual analysis would be a better approach.
1. This is an interesting paper that is mostly well written, although arguably of limited interest to anyone who does not have very closely related interests. This is primarily because the authors do not draw any wider conclusions or engage in any theoretical discussion that might inform the field more generally.

Response:
In the revised manuscript, we now describe the study’s target audience. We also identify a secondary audience for this research. The updated text can be found under the Study Aim section on page 7.

2. This paper falls within the broad field of empirical (bio)ethics, and I feel it needs some discussion of where that paper is located within that methodological literature. Even reference to something like Sugarman and Sulmasy’s text (methods in medical ethics), in which they talk about the role of surveys in medical ethics research, would go some way to addressing this gap.

Response:
The revised manuscript now includes additional text locating the study within the broader field of bioethics. Sugarman and Sulmasy’s ‘Methods for Medical Ethics’ is also cited on pages 6 and 8.

3. [The] tables and figures…look like too much like raw data. I think the paper would be much improved, and would be much more digestible, if the authors condensed that section, made the figures and tables more simple and transparent, and explained more clearly and simply what their findings are in a narrative rather than what seems at times to be a list.

Response:
In response to the reviewer’s comment on clarity and readability, Tables 1 and 2 have been removed from the revised manuscript. The Results section has also been shortened and edited. The revised manuscript has retained Figure 2 (now labeled Table 1). While we are amenable to omitting Table 1 (formerly Figure 2), we feel it provides valuable additional information for the study’s target audience. Through the use of numbers, spatial placement, and colour scheme, this table displays three ranking types: (1) global ranking for each of 20 recommendation, (2) disaggregated ranking of the five dimensions for each recommendation, (3) disaggregated ranking for all 100 listed dimensions. Most importantly, it also provides the full list of care and prevention recommendations around which the study’s questionnaire was designed. This one table provides a great deal of useful information for guideline developers and other stakeholders while taking up relatively little space. Therefore we request that it be retained.

4. I felt that whilst the conclusions appeared sensible and plausible, it was not really
clear how they were arrived at from the data that was presented; or at least more argument is needed before they can be convincing.

As set out above, we have tried to strengthen the linkage between the results sections and conclusions/recommendations sections by clearly denoting that it was low dimension scores under ‘understanding’ and ‘ease of implementing’ that drove the low overall merit scores for prevention recommendations. We then speculate that more operational guidance might be needed to elaborate on key concepts in the prevention recommendations but concede that more detailed qualitative exploration might be needed to further explore the issue.

(a) For example, the conclusion that prevention recommendations need to be prioritised because they tended to be lower ranked does not follow. They may be lower ranked because they are less important. More argument is needed to explain why they are important and why participants were wrong to rank them so low.

The revised manuscript has been edited to more clearly explain that the participants were not wrong to rank prevention recommendations relatively low. Instead, the study examines the relative ‘functionality’ of these norms and their practicability. This is done by describing stakeholder attitudes about the listed recommendations. We have also provided more information on how a low global ranking is interpreted within the study context. Please see page 10, paragraph 1.

As the reviewer noted, prevention recommendations, in theory, may be ranked lower than care recommendations because they are perceived to be less important. However, the pattern of responses from our sample demonstrated relatively high rankings for “Agreement with” but low rankings for ‘Ease of implementing’ and ‘Ease of understanding’ of many prevention recommendations. The pattern of these rankings suggests that vaccine stakeholders endorse these recommendations but perceive them to be hard to understand and implement. Therefore, a logical focus might be to try to make them easier to comprehend and action. Please see pages 16-17 for more on this.

(b) Does this paper aim to simply describe attitudes (which it seems to do) or use those descriptions to derive some kind of normative conclusions about what ought to be done (which it seems to want to do, but does not provide adequate argument for).

The manuscript aims to describe attitudes towards ethical guidelines, with a view to using this data to make ethical recommendations more responsive. On page 6, we state,

“Sugarman and Sulmasy propose several roles for empirical research in bioethics including describing facts relevant to normative arguments. As set out in Slack (2014) empirical research can inform a critical reflection on ethical norms (Kon, 2009) by for example shedding light on ethical problems that require attention (Draper & Ives, 2007) or by providing the details that
inform more responsive ethical recommendations (Carter, 2009). This empirical study attempts to describe the perspective of stakeholders regarding key guidance to assist to make changes to guidance to make it more responsive to the perceptions and implied needs of users of the guidance.”

(c) In addition, the speculation about the causes of the different rankings seems plausible but the authors need to make clear why it is interesting and why it counts as useful knowledge.

We submit that the data is interesting and new because it represents for the first time the perceptions of stakeholders (at the coal-face of vaccine trials) about the ethical recommendations they are meant to fulfill, and provides some information about how ethical recommendations should be refined to improve their helpfulness to such stakeholders.