Reviewer's report

Title: Kenyan health stakeholder views on consent and engagement processes for the re-use of hospital inpatient data to support learning on healthcare systems

Version: 0 Date: 06 Jun 2018

Reviewer: Jenny Krutzinna

Reviewer's report:

Thank you for the opportunity to review this interesting manuscript.

I do have two major concerns, which I believe would need to be addressed before publishing the article:

Comments

1. My main concern is that for a paper in a medical ethics journal, the discussion of the ethical issues is rather superficial, omitting several key (and widely acknowledged) issues. The authors address only one perspective of ethics, namely the ethical issues related to learning healthcare systems, where they identified only patient consent and governance around such systems as relevant. The findings later reveal many more issues as important to the stakeholders that were interviewed, and the brevity of the ethical discussion really lets the paper down.

In addition, there is at least one more dimension to ethics in the present context: how are ethical issues different in LMICs than in HICs? Given that the authors refer to the need for their particular research on the basis that such studies have not been carried out in LMICs, I would have expected an in-depth discussion of the expected difference in ethical perceptions between the two, as well as an analysis of the findings on this point. At present, the manuscript does not provide any insight into this interesting, and I believe crucial, aspect of the authors' research. Without such discussion, the paper does not add significantly to the current literature.

2. Another concern is the failure to provide an explanation of the limitations of this study. First, the selection of interviewees was made only from health professionals and researchers. No patients or patient representatives were included in the research, and it would be insightful to learn the authors' reasons for this. Second, the total number of stakeholders interviewed is very low and limited to a small geographical area. This type of convenience sampling is understandable, but given the immense diversity in Kenya, this may seriously limit the generalisability of findings. The authors quote a stakeholder who refers to differences between religious / cultural groups within Kenya, but this point is not discussed anywhere and the authors do not address this potentially limiting effect on their research.
3. Findings: I found this section hard to follow. The authors start with a general discussion of the arguments for sharing information on data re-use with patients, followed by those against sharing. This is then followed by consideration of the four scenarios.

Discussion of these two approaches overlaps significantly and makes it somewhat hard to follow. As I did not see the interview guide, I am not sure whether this sections follows the structure of the interviews (general arguments pro/contra, then questions about scenarios), but I think this section would benefit from a clearer structure and some signposting.

4. The authors' use of "most", "many", "some" would benefit from specific numbers. How many participants are "most"? How often was a "common argument" made? An indication of n= would help to understand the frequencies of responses. This was done once during the discussion of the CERs, but it is not consistent throughout the paper.

5. Discussion of the four scenarios could be improved by starting with a 1-2 sentence summary of the findings, esp. in relation to the other scenarios. Again, an indication of what proportion of the participants expressed arguments for/against sharing information with the patient would help.

6. Scenarios 3 & 4 are discussed together, which makes it somewhat harder to follow the discussion. For clarity's sake, maybe the authors would consider some signposting after the introductory paragraph on CERs to guide the reader through what is coming.

7. Discussion: In the first paragraph, the authors refer to the limitation of their study on the basis of the group of participants, but conclude that their research does "provide insight into likely public values around core ethical issue of consent and governance for learning health system approaches in an LMIC setting". This seems an ambitious claim to make given the small group of people interviewed in coastal Kenya (see comments re: limitations above). In addition, only two ethical concerns (consent and governance) were investigated explicitly, meaning that other important aspects may have been overlooked.

8. Learning from scenarios: It is not clear to me whether the two conflicting positions, which emerged, did so within the same person (i.e. representing an inner conflict within a person), or whether these were distinct groups (i.e. representing opposing views between participants). Maybe the authors could clarify.

9. The authors claim that there is a need for careful research-based development of communication strategies. Given that they conclude that many of the concerns raised during their research are in line with what we know from HICs, should we leverage existing communication strategies and implement them in Kenya, or is there a need for elaborate research in the LMIC-context to ensure cultural fit? I believe the authors views on this point would be valuable here.
Minor comments:

- Under the heading "Considering scenarios", in the first paragraph, it should read "Figure 2" not "Figure 1".

- Precede the sub-headings with the number of the scenario, e.g. "Scenario 1: Re-use of clinical data for routine monthly clinical data reporting", etc. to link them to the table overview in Figure 2.

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

Yes

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

Unable to assess

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

Yes

**Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

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Please indicate the quality of language in the manuscript:

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