**Author’s response to reviews**

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

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**Author’s response to reviews:**

Review of Kenyan health stakeholder views on consent and engagement processes for the re-use of hospital inpatient data to support learning on healthcare systems: Response to reviewers’ comments.

The comments and our responses are given below, with our responses below. For clarity, we have added numbering to comments where this was not included in the original.

**Jenny Krutzinna (Reviewer 1):**

Thank you for the opportunity to review this interesting manuscript.

We thank the reviewer for careful reading and comments of this manuscript and hope that our responses and major edits to the manuscript attached will address the issues raised.

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

We understand the reviewer’s comment here and have tried to make the ethical analysis section of our discussion more clear – in relation to the main topic of this paper, that is, the ethical issue of individual consent and notification and general notification for LHS activities. We do agree that there are a large number of ethical issues around LHS in the literature, and reference this through the Sugarman and Califf (2014) paper in the introduction section. There are three main reasons we have focused on information sharing as the main focus for this paper. The first is that we are submitting to a special edition of BMC medical ethics on ‘complex consent’ so that this aspect of our work is particularly relevant. The second is that taking a grounded approach to empirical ethics is a very in-depth and complex process, so that tackling many different ethical issues at the same time can make it difficult to generate sufficiently informed or detailed discussions around any particular one. We have chosen to focus on the area of information sharing which already quite large. Many of our interviews took 2 hours to complete, which is time not easily gained, particularly with health managers, providers and researchers. Finally, following a typical qualitative paper structure, we include our own discussion of points across the main findings and the final ‘discussion’ section. Given that the paper is around 9900 words in its present version, we did not feel we should add more discussion of our findings. A second paper might be a better alternative!

2. 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.

We have tried to show in our discussion the areas where issues we found were similar in nature to those from HICs, and particularly to be very clear about the context and how this has been particular to the findings of this study. We have not come across an empirical ethics paper on LHS that involves such a detailed qualitative exploration of views in a structured way across
different dimensions of LHS, so feel that this approach, plus the fact that our data is compared to the existing papers does contribute to the literature overall. As above, we are keen not to extend this paper any further by drawing more specific and in depth comparisons with the literature from HICs, but feel that this is now an option open to scholars in the field who wish to make this comparison in more detail.

3. 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.

Thanks for this comment and we have tried to ensure that the limitations of the study are clear. We have added additional sentences to underline that this work is preliminary, and that it is based on specific perspectives and missing those of patients and the public. In our experience, the number of participants involved is not particularly low, especially for such an in–depth deliberative exercise. Sampling draws both on strategies of convenience and maximum diversity within the targeted stakeholder group, again as is common in this form of research. But we do agree that the narrow target on a particular type of stakeholder can only be justified in a preliminary piece of work in this area, as this is. We hope that future research will build on this study to expand the types of participants and geographic areas involved, but again would describe our approach as typical of qualitative enquiry.

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.
We have now revised the paper extensively throughout to take account of these comments. Specifically, we have changed the structure of the findings section to include numbered sub sections, and have included signposting at the start of each section to preview content. We hope that this helps with clarity. We have maintained separate sections to describe the arguments for and against sharing information across all scenarios used, and to offer more detailed descriptions of the way these arguments were balanced for specific scenarios. We feel that the latter is important to really understand the reasoning processes participants were working through in these interviews. We hope the reviewer will find this revised version easier to read and follow.

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.

Given the nature of this study as a qualitative piece of work, we feel it would not be helpful to give actual numbers of participants as this might imply a spurious sense of numerical accuracy that would not be appropriate to the study design. We have deliberately chosen to use words such as few, many and some to imply approximately how common certain responses were in our data.

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.

In the revised version, we have added more signposting across the entire findings section that we hope will take account of this comment.

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.

As before, we have added signposting through these sections to add clarity.
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.

We do agree that it's very important to be circumspect about the contributions of a small scale qualitative study like this. We do feel that 'providing insight' is quite a limited claim, and have amended this sentence to show that we recognize the gap that no patient or public voices are included. Since data were collected in an LMIC setting, we have also continued to suggest that the study provides insight useful to this setting.

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.

Thanks for pointing out this confusion. In fact, the final difference of opinion described here were between different groups although along the way to developing views (in the course of interviews) participants did change their minds, and did sometimes explain that they really couldn't judge, given inner conflicts. We have tried to make this clearer in the manuscript, particularly the discussion where we draw on core conflicts in the data.

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.

While similar broad challenges and issues arise in the existing literature on information sharing in HICs and the findings we are presenting here, any work on communication strategies for LHS would need to take account of local context including a range of individual, structural and policy
related influences. Where these contexts are as different as many such HIC and LMIC settings are, in–depth work would be needed in each. As before, our work has been quite preliminary (but we think rich) and has not included the voices of patients and participants, and we hope we have made this limitation clear. We hope that our findings provide a kind of springboard that others might use to plan the methods and content of future research in this area, including a wider group of stakeholders. And perhaps ultimately a quantitative survey based element.

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.

Thank you! Both of these points have been incorporated.

Jantina De Vries (Reviewer 2)

This is a wonderful paper on a novel topic that is completely under-explored in LMICS. I would like to commend the authors on their research design aiming to generate real insight into this complex topic, and would also like to congratulate them on the careful way they have presented their findings. That said, I have outlined several issues for consideration below.

We thank the reviewer for their positive overall response to the paper, including their insight into the qualitative research approach used and the challenges of exploring views and attitudes around complex and relatively novel topics. We attempt to respond to the very helpful major and minor comments made, in text below.
Major revisions:

1. There is some variation between what the title and what the main text say the article will do. In the title, you talk about ‘consent and engagement processes’, whilst e.g. on pg 5 line 51 you say ‘consent and governance processes’. Would be good to make sure these are the same across the paper;

Thanks for pointing this out. We have changed wording throughout the paper to make this more consistent. The title is now ‘Kenyan health stakeholder views on individual consent, general notification and governance processes for the re-use of hospital inpatient data to support learning on healthcare systems’. Throughout the paper we have removed the term ‘engagement’ as being too broad and instead used either ‘information sharing’ or more specifically ‘individual consent’ ‘individual notification’ or ‘general/public notification’ as relevant.

2. In the methods section you say you combined ‘deductive and inductive approaches’ in your analysis and it would be worthwhile to say a bit more about this in the description of the analysis. Specifically, how did you combine these two approaches?

We have explained this in more detail in the methods section to say:

“We used a framework approach to analyze our data, involving a systematic process of familiarization, identifying a thematic framework, indexing, charting, mapping and interpretation [33]. The analysis process drew on both deductive and inductive approaches, that is, through deductively following themes explored in interview guides and inductively responding to new or emergent issues raised by participants around the broad topic of enquiry” (p7/8).

3. Section ‘Individual ownership’ on pg 8/9: I think that this section raises some important (conceptual) questions that are not really dealt with sufficiently. For instance, how do the interviews define ‘ownership’ over data? Is there an ‘ownership question’ as you suggest towards this end of this section. Are ‘belonging to’ and ‘ownership’ the same thing in this context? (see line 51 pg 8) I wonder if they are not actually different things – e.g. someone may feel that data belongs to them because it reveals something about them, but that is perhaps not the same as feeling that you own the data. I think you need to expand this section somewhat to describe more clearly how you think the interviewees conceptualised ‘ownership’ in this context. (E.g. the ‘right to know’, as set out in the Charter you refer to, is not the same as saying that a
person ‘owns’ their data. In your discussion you say ‘right to control the use of’ data, which again is different from owning data);

Thanks for this important point that we completely agree with. We have removed the term ownership from the text as on reviewing our analysis charts it seems that this was our extrapolation of the views shared by participants, who talk about ‘belonging to’ generating ‘rights to know’ rather than ‘ownership’. We hope you feel this works now.

4. I don’t think that arguments in favour of or against disclosing an intention to use routine clinical data for secondary research purposes automatically translates to arguments about consent and patient and public engagement, yet this is what you seem to suggest in the manuscript. Did you ask your interviewees specifically also about consent and engagement? This could be clarified a bit more. For instance, in the section on ‘arguments in favour of’, you don’t seem to talk about ‘consent’ so much as about reasons for the disclosure of the intention to re-use, yet in the follow-up section you talk about the dangers of people refusing consent.

We agree that our description did not sufficiently distinguish between forms of information sharing i.e. between creating awareness or notifying individual patients, seeking consent from individual patients and notifying a wider public. We have extensively re-written the manuscript across the findings and discussion section to take account of this (and other) points and hope we have now made our descriptions clearer on i) how views we collected detailed different forms of information sharing and ii) how we have drawn on this data to inform our analysis about different forms of information sharing.

5. I am not entirely convinced that your observations on the 2nd half of pg 22 imply your first recommendation on pg 23 (research-based communication strategies on when people are likely to refuse). It seems to me that neither of the two observations on pg 22 suggests that individual consent is the solution – your observations talk about ‘engagement’. Shouldn’t the recommendation be therefore about research into effective engagement and whether engagement could ever lead to the pervasive effect of undermining public trust?

This section is now re-written as we did not feel that it was sufficiently clear. The section now reads:
“An immediate implication of this finding is the need for more empirical research to explore the likely outcomes of individual and public information-sharing on clinical data re-use, before future policies on individual or public information sharing are developed. Patient and public perspectives would be a critical component of such research” (p25).

6. What I would have liked to see in the paper is a strong section on the study limitations. For instance, in relation to your discussion on pg 23 – to what extent did you nuance discussion of non-MoH stakeholders, and are there scenarios imaginable where use of data by non-MoH stakeholders fulfils the public benefit criteria set out on pg 22? Would that change the recommendation for consent where re-use of data involves non-MoH stakeholders? I appreciate that it is very difficult to do research on this topic and commend you for being so careful in designing your research project to get at the nuances – but it would still be good to add a limitations section to help the reader better understand the strengths and weaknesses of the rich data you present.

Please see our responses to reviewer 1 on the of study limitations (point 3 above), which we have tried to expand carefully without adding too much the overall length of this paper.

Minor revisions:

1. In Line 6 pg 4 you say ‘morally important distinctions’ but I wonder whether it is appropriate that you use ‘morally’ in this context – seems a bit over-heavy? Maybe rather say ‘ethically important distinctions’?

We have made this change, thanks for pointing out

2. Pg 5 line 37: “relatedly…in relation” reads odd;

This has been amended

3. Pg 7 line 40: “we used Framework Analysis to analyse our data” – maybe say ‘used the framework approach to analyse our data’?

Also addressed as suggested
4. Pg 8 line 33: “This position was both underpinned and made conditional by” – I am not sure I understand this sentence. Just after that sentence, what does ‘providing public information’ mean (what is ‘public information’ in that context?)

This section has been re-written and the relevant section now reads:

“Most participants consistently felt that it would be important to explain to individual patients that their routine clinical data might be used in a number of ways beyond their own care. This position was underpinned by a number of interrelated arguments, including around an individual’s rights to know; trust in the physician-patient relationship; a value of openness and accountability; and the perceived sensitivity of data. While these arguments are presented separately in the sections following, they often flowed into each other during discussions, and were drawn upon across all scenarios.”

5. Pg 9 line 33 – value in openness – I wonder if you could qualify this by saying ‘openness about secondary use of routine clinical data’ as I was initially thinking about ‘openness’ in the ‘open access’ way, thus referring to opening up clinical data to research. Or could you call this ‘transparency’?

Thanks and we’ve qualified our use of the term openness in the text in the way you suggest.

6. P9 11 line 39: are the

This point was unfinished in the version we received but please let us know if the point has not been responded to in the current revision.