Reviewer's report

Title: Ethical tensions in the informed consent process for randomized clinical trials in emergency obstetric and newborn care in low and middle-income countries

Version: 0 Date: 28 Oct 2018

Reviewer: Syntia Munung

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Review: Ethical tensions in the informed consent process for randomized clinical trials in emergency obstetric and new-born care in low and middle-income countries

Major comments

The paper aims to highlight possible challenges in obtaining informed consent in RCTs for emergency obstetric care in LMICS, and to suggest ways of mitigating these challenges.

1. I think that in identifying these challenges, the authors focus more on providing background information on ethics principles. While this is important in contextualising the discussion, it distracts from the main purpose of the paper. I suggest that the authors cut down on text that explains the principles and rather focus more on discussing the challenges. Generally, I think the manuscript could be improved if it is shorten substantially. I have highlighted, for the consideration of the authors, sections that could be shorten or deleted (Lines 67-70; 92-95; 109-121; 138-152; 182-186; 226-330; 317-320; 341-346; 370-375; 382-386; 449-459).

2. Also, for most of the ethical challenges identified, not much is said about how the challenges can be practically mitigated in an LMIC setting. While in some instances, the authors cite literature that refers to possible ways of overcoming these challenges, it is not the case for each identified challenge (see section on vulnerability, trust and transparency, respect for persons). The paper could also be improved if they authors not only rely on available literature but draw on their experiences and state how these challenges have actually been navigated in practice or if what is recommended in the literature could actually work in LMICs (and state why the agree or disagree).

3. Lines 297-300, the authors argue that "lumping all pregnant women population as a vulnerable group" denies them the opportunity to participate in research that they would otherwise have wanted to. However, they fail to put an argument for their position. Considering
that this statement challenges contemporary discourse in bioethics (and the authors rightly acknowledge this), a statement on why they think that should be the case will make a good contribution to bioethics debate on including vulnerable groups in health research.

4. Line 580-583: Citing available literature, the author's list two main approaches to navigating power dynamics that exist between clinician investigators and potential research participants in RCTS for emergency obstetrics research. While the authors state that they agree with the recommendations, they do not provide reasons for that and also why they think it would work in LMICs. This is a very important aspect that needs to be discussed further and which could enhance the debate on such power dynamics in health research in LMICs

Minor comments

Line 59-61: Sentence not clear. Consider rewording

Line 165: Needs to be re-worded. That applies to all health research and not just research on emergency care.

Line 197-198- Provide a reference

Line 239- Check wording (agreement line)

Line 278-279: Sentence not clear.

Line 460-Sentence not clear or incomplete
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Unable to assess

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?
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Unable to assess

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
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Not relevant to this manuscript

Quality of written English
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

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