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

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Reviewer: Keymanthri Moodley

Reviewer's report:

This article addresses a very important topic, namely, research on pregnant women who present with obstetric emergencies in LMICs. However, the topic itself is too broad. It appears as if the authors are based in Uganda yet are generalizing their conceptual analysis to all LMICs in the world. It might be more realistic to limit the discussion to LMICs in Africa or better still, to Uganda. There is no single philosophical system that forms the basis for ethical conceptual analysis across all LMICs globally. Even on the African continent approaches to ethical dilemmas vary from one country to another. Ubuntu is an important component of African philosophy but the word itself, of Nguni origin, differs from one country to another. I am quite surprised that African philosophy is not used in the conceptual analysis in this paper. Given the topic of emergency obstetric research, communal perspectives are particularly relevant.

Although the article is generally well written, there is far too much of the article that deals with general discussions around autonomy and consent. These discussions have already been published repeatedly and extensively in other texts and I found myself skipping over large chunks of text and losing interest in the article.

I would advise that the authors focus this article on the subject of conducting research on pregnant women presenting with obstetric emergencies in Uganda - if that is where they work - since that would be the scenario they are most familiar with. Looking at the challenges to consent in this setting would be important. The concepts of consent and vulnerability have been discussed elsewhere ad nauseum. Academics today are busy and have limited time to read journal articles. Clinicians and researchers have even less time. I suggest that the authors condense their thoughts and focus on creating an angle in this field that has not been covered elsewhere. In other words, write something that is fresh and new and adds to the body of knowledge. I really like the concept of the staged consent process for obstetric research - this
ought to begin at the first antenatal visit. How do you build this in to medical undergraduate education in obstetrics? This is important because capacity to consent is compromised in labour and in acute emergencies when women and their families are extremely anxious and stressed. Compare consent for research in obstetric emergencies with consent for research during other medical emergencies. There is other literature on research on pregnant women and ethical challenges that must be addressed. The role of the father is important. Legally there are issues around the marital status of the woman and her ability to consent. Culturally there are issues around the ability of a pregnant woman to consent to research that may impact on herself and her child. Finally, there are specific matters relating to how RECs/IRBs review research on pregnant women in emergencies. Is it possible to have protocols reviewed in advance of the proposed research as sometimes occurs in other medical emergencies? What is the role of community engagement in such circumstances?

I suggest a reworking of this paper to make it more relevant to the topic and to add something new to the literature in this field.

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

No

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

Unable to assess

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No

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