Reviewer's report

Title: Understanding and Retention of informed consent process among Parents in a Rural Northern Ghana

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Reviewer: Sassy S Molyneux

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General

The paper addresses an important topic and has the potential to contribute to a relatively small body of empirical data looking at levels of comprehension of studies in developing countries. I do however have several important concerns about this study being published in its' current form.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1) Background:

There are now several detailed empirical studies that have been carried out in low-income settings; including within rural sub-Saharan Africa. Greater reference to this literature, including around levels of understanding and factors contributing to this, is required to convince readers of the contribution the paper is making. Examples of the papers include:

- Fairhead, Leach M and Small (Gambia); A Leach et al (Gambia); Lynoe (Bangladesh); Molyneux et al (Kenya x3); Sanwal (India); Preziozi (West Africa); Tindana et al. (x2)

More information is needed about the main study for which understanding and retention is being examined (eg what were the procedures, benefits and risks involved? What was the blood for? – only for research? any findings returned to participants?), and the consenting processes and information given out by the main study. Ie Who did the consenting, what steps were involved/where, what was the key information imparted, and what was considered an adequate understanding in each main theme? How long after this information was the consent study carried out? This is important in order to meet the stated goal of suggesting ways to improve current practice.

Methods:

In for example Kiswahili (Kenya) and Zulu (South Africa) there is no universally understood term for research. The words for research also mean investigation and are often interpreted in a clinical/illness setting at the individual level (eg investigation on my child’s sample to find out what’s wrong with him/her). In this
paper, where the investigators report that 98% of the participants knew their children were involved in research, are the participants understanding research in the same way that researchers are? This level of understanding is far higher than in the majority of high income settings and therefore of major interest if true. A problem with a lack of clarity on this issue is that the remaining information - eg on risks, benefits, disease - can be based on a fundamental confusion about the purpose of the activity.

Contributing to the above concerns are: a) no indication of what the questions looked like; b) no stated preliminary qualitative work in the study areas suggesting that assumptions have been made regarding understanding of terminology, and that these assumptions would also apply to pre-testing; c) no reported additional methods to validate participants’ responses to the questions (this is a concern given that understanding is complex to measure (and differentiate from retention), and that using different methodologies can produce different responses – see for example recent publication from South Africa by Lindegger et al. 2006 – J Acqui Imm Def Syndr. In the Lindegger et al paper the authors note that levels of understanding are often reported to be highest in closed ended studies); d) information is needed on who was carrying out the survey and what their relationship to the main study team was. Might this have had an impact on the findings?

Findings and conclusions
Given some of the above concerns, the findings and conclusions are rather unconvincing and lacking in detail. They would also have to be compared with the broader literature noted above, and be related to practicable recommendations in order to ‘suggest ways to improve upon the existing practices’ (study goal). For example it seems very likely in the context that participants join studies for the perceived and probably real benefits of being involved (although we do not know the benefits from this paper). What ethical dilemmas and potential interventions does this introduce for the research centre? How can research review committees ‘be proactive in informed consent process and monitoring so as to guarantee the sanctity of the process’? (and if there’s significant comprehension of information disclosed what is the main issue that the review committees are having to resolve? Is it that there are too many benefits? – back to the importance of understanding the context of the study more, and discussing the key findings and their implications in order to build up to the conclusions).

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Discretionary Revisions (which the author can choose to ignore)
What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of limited interest

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.