Reviewer's report

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

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Reviewer: Christine Grady

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This manuscript describes a study of comprehension and retention of study information from 270 parents who enrolled a child in a malaria study. The authors conclude that there was 'significant understanding' on the part of the parents, with some bias toward benefits.

This is an interesting study, and the report could be strengthened by some revisions/additions/clarifications.

First, it would be helpful to know more about the malaria study. What kind of study was it and what did it entail? What were the likely risks and benefits? What procedures were involved, etc. It says that participants were contacted every 2 months- what did this contact involve?

Secondly, it would be helpful to be clearer about several features of the consent study.
1. The authors talk about understanding, retention, and perception, but don't describe what they mean by each of these and they are different. What kind of questions or analysis was used to measure each? Including at least a sample of the questions used to evaluate understanding or retention would also be useful.

2. It appears as if the parents were interviewed after the malaria study was over- in some cases up to 1 year after they gave consent, is that correct? If so, their recall of events surrounding the initial consent might be murky- not necessarily because they didn’t understand, but because they don’t remember. How was this taken into account? What was the initial consent process like? How much time had elapsed? How much information were the participants likely to have received since their initial consent?

Third, some aspects of the report could be clearer:
1. On page 7 under results- were 100% of the participants female or is a number missing here? If they were all female and 96% were the biological parent- why not use the descriptor “mother” instead of “parents” in the rest of the paper? This may be also important because one statement in the discussion and reference to citation #10 implies that women may not always have control over decisions.

2. Some of the results are a bit confusing. For example, on page 8, at the end of the first paragraph, it says “Again 70.7% remembered being told the total number of children to be enrolled; only 20% knew the study involved children under 5.”
As written, it looks like 2 very different things were measured here- the first part a question about whether the parent remembers being told something- without assessment of whether what they remember is correct or not; and the second- a factual question- which may or may not have assessed whether they were actually told that the study involved children under 5. It is hard to make sense out of the meaning of these results without some further clarification.

3. Similarly, at the bottom of the same page, it says “There was a significant difference between the proportions of respondents who recalled that they were told the study involved direct benefits compared with direct risks.” If this means that people remember being told about benefits more than they remember being told about risks, are they remembering incorrectly or not? Are there risks that they were told about that they don’t remember? Or benefits that they perceive but that they were not told about? From the statements following this, it seems as if those who remember being told about benefits got at least one right. Also, later (on page 10) it lists as motivations- free treatment and health care among other benefits, so it makes me wonder whether the benefits of participating in this study were actually more important and memorable than the risks. On page 11, the discrepancy between those who remembered being told about benefits versus risks is described as a “very relevant finding”- I do not understand why.

Fourth, I am not entirely clear from the discussion/conclusion whether the authors think this study shows that understanding among these parents is pretty good or not- where they think improvement is needed, and how it compares to other studies that collected data about informed consent in developing world communities. They note challenges in conducting research in these settings, such as translating consent information into local languages or dialects- but don’t describe what was done in this case. They say “fewer than the expected number of respondents knew the reason for biological specimens…” – but what was the expected number and what was that expectation based on? At the end of the discussion- they mention that >90% of respondents knew participation was voluntary, “However, only 62%...” believed nothing would be lost if they refused to participate. These two statements are not incompatible and can both be true- people can be clear that participation is voluntary and still be aware that something will be lost if they choose not to participate.

More specific comments:

1. page 3, middle of background par says “Several studies have suggested that research participants do not fully understand…..” Should add some citations here.

2. On page 10, it lists reasons for participation for 170 participants. What happened to the other 100?

3. The data analysis section on page 6 describes t tests and #2 tests, confidence intervals, etc. Yet, the only data I see is descriptive. Were any correlations run?

4. Page 8, under study procedures, 2nd sentence says: “When asked specifically about the duration….., however over 40% did remember the approximate amount of time….” did you mean “however, only 40% remembered”, or “over 40% did not remember”? Or is the ‘however’ misleading?
5. Many typos, e.g. mid page 3, “if the goal of the consent process is to achieve a high level of understating…”, or page 11, “…the usual subtles of human communication…”. The Conclusion par on page 12 needs rewriting.

**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 importance in its field

**Quality of written English:** Needs some language corrections before being published

**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'