Author's response to reviews

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

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Version: 4 Date: 7 February 2008

Author's response to reviews: see over
7th February 2008

Dear Biomed Central Editorial Team

RE: MS 1699410949145022

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

Thank you for considering our manuscript for publication in your journal. We have made the necessary changes and reviews as requested by the three reviewers.

Current Version 2: Dated 08 January 2007

Below please find the responses.
Reviewer's report 1

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

Version: 2 Date: 28 September 2007

Reviewer: Alan R Tait

Reviewer's report: General

The authors have addressed most of the items from the previous review but there are still some outstanding issues, particularly with respect to the content and framing of items in the semi-structured interviews. It would be helpful to include a copy of the questionnaire as an appendix.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached) 1. The introduction is far too long and can be cut significantly without losing its message.

Response: In addition to the requests from the other reviewers the introduction has been carefully edited and also shortened as specifically requested by this reviewer without significantly removing any of the messages it seeks to portray. The entire section has also been carefully edited and paragraphs have been tightening up. The paragraphs have also been rearranged and restructured to follow; theory, challenges and process of addressing the challenges as requested specifically by the third reviewer. Paragraph one now introduces the theory; paragraph two describes some of the challenges; and paragraphs three and four highlight the process of addressing the challenges.
2. Please include a copy of the semi-structured questionnaire. Since the framing of the questions can significantly influence the subjects' responses and hence their "understanding" of the information, it would be helpful to include the items used.

**Response:** The study design section has been revised to incorporate how the study questions were framed and a sample question has been incorporated as a guide and as requested by this reviewer. Specifically, the first paragraph on page 9 addresses this requirement. However, page 8 of manuscript describes the design and administration of the question. Moreover, further discussions in the last paragraph in page 15 and the first paragraph in page 16 addresses the findings in this study in the light the concerns.

3. P11, how were the validity and reliability checks performed.

**Response:** The phrase ‘validity and reliability checks’ has been removed and instead in place how the validity and reliability checks were performed has been explained at the last but two, and last but three sentences on page 6.

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

1. Table 1 was not included in the copy that I received.

**Response:** Table one is now included.

2. Why are there still two Figures 1?

**Response:** There has always been one figure (Figure 1); it might have been duplicated due to uploading process.
Discretionary Revisions (which the author can choose to ignore)

As mentioned in my previous review, there needs to be more discussion regarding the findings in light of others that show poor understanding of consent information.

**Response:** Additional discussions have been included; specifics to this request are addressed in pages 15 and 16.

Correlating understanding with education level, age, gender would be interesting and add to the paper.

**Response:** A section titled ‘Correlation of characteristics’ has been created in page 12 and two Tables 1 and 2 have been inserted to address this requirement. Gender however could not be correlated, as all the participants were females.

**What next?:** Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

**Level of interest:** An article whose findings are important to those with closely related research interests

**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.
Reviewer's report 2

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

Version: 2 Date: 24 October 2007

Reviewer: Christine Grady

Reviewer's report:

General

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached). Thank you for the opportunity to review the revisions that the authors made to their paper. The revisions have improved the paper, as it is now much clearer what the primary malaria study involved as well as how and when the parents of enrolled children were interviewed. I would recommend some further revision of the discussion/conclusions to highlight what this particular study contributes to the literature on informed consent. As the authors said, they found ‘significant but varied knowledge…” (p.17). However, rather than celebrating the significant knowledge they seemed to find, they go on to note that other studies have shown that “…many parents have poor understanding of study information, particularly among those from low income areas where poor reading skills and lower education are prevalent.” Although their population is described as poor and not well educated, their level of knowledge a whole year after consenting to the malaria study was very impressive. The authors found that more than 90% of parents knew that their child was participating in research, that the research was related to malaria, could name at least one research procedure, knew that a
blood specimen was taken from the upper arm, could name one direct benefit to their child, knew they would not be paid for participation, and remembered being told that participation was completely voluntary. That is better than most other published consent studies done anywhere! Some discussion of, and speculation about, why this is so would be very helpful.

Responses: Two additional paragraphs in the discussion, the last paragraph in page 15 and the first paragraph in page 16 discusses further the findings in this study in the light of other studies. In addition the conclusion has been revised to reflect the suggestions but of this reviewer.

In a similar way, the authors suggest that it was problematic that more parents recalled study benefits than recalled study risks. Given that the malaria study was a low risk study (a blood draw and questions every 2 months) with possibly significant benefit to the enrolled children (diagnosis and treatment of malaria), the parents recall seems absolutely appropriate- why should they remember risks when the risks are so minimal? The authors conclude (p.20) that “there is a need to continue to evaluate existing practices in order to ensure that information disclosed during the informed consent process rather than anticipated benefits influence research participation.” I am not sure why, unless the anticipation of benefits is misguided and the information in the consent would correct the misconception. Neither of which seems to be the case here. Also, although I absolutely agree that there is a need to evaluate and improve existing practices, their findings suggest that their practices are fairly effective in informing participants.

Response: The discussion in paragraph one page 18 has been revised to explain in detail the findings.
Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct) A couple of additional points:

p. 16 mentions Table 1- but it is not included

**Response:** Table one included

p. 18 2nd par starts with “This finding…” – not sure which finding they are referring to.

**Response.** Corrected

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 whose findings are important to those with closely related research interests

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 I have no competing interests
Reviewer's report 3

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

Version: 2 Date: 13 November 2007

Reviewer: Sassy S Molyneux

Reviewer's report:

I think this paper has been significantly strengthened, but I still have some concerns about publication in its' current form.

- Major Compulsory Revisions

1 - The entire paper needs careful editing for typos (and eg gaps between paragraphs and when a new one is needed, full stop positioning etc) and ideally to tighten some sentences, key points and arguments. Re sentences, see for example the first in the abstract, and re the key points and arguments, see some ideas below.

Response: In addition, to the requests from the other reviewers the introduction has been carefully edited and also shortened without significantly removing any of the messages it seeks to portray. The entire section has also been carefully edited and paragraphs have been tightening up.

2 - Under background, it's important to highlight the difference between theory and practice in informed consent, and this could help structure the argument (ie first two paragraphs are what informed consent can achieve in theory, then move to challenges in practice, and finally documented efforts to strengthen informed consent processes?)

Response: The paragraphs in the introduction have been rearranged and restructured to follow; theory, challenges and process of addressing the challenges as requested
specifically by this reviewer. Paragraph one now introduces the theory; paragraph two describes some of the challenges; and paragraphs three and four highlight the process of addressing the challenges. In addition the introduction has been carefully edited and the paragraphs have been tightened up.

3 - Under methods I am not clear on how validity and reliability checks would be done on the consent document. Same for study instruments. It would also be very helpful to see the questions asked as an annex to help deal with the concern I am re-raising as point 4.

Response: The phrase ‘validity and reliability checks’ have been removed, however, how the validity and reliability checks were performed has been explained at the last but two and last but three sentences on page 6. Moreover, the study design section has been revised to incorporate sample question to guide readers of this manuscript on how the question was structured as requested by reviewer. Specifically, the first paragraph on page 9 addresses this requirement. In addition, Page 8 of manuscript describes the design and administration of the question.

4- 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 (NB this figure is 90% in the abstract), 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. If it's impossible to deal with this concern, perhaps it can be mentioned as a limitation needing further exploration in future studies (important given for eg that only about half knew at least one correct reason for taking the blood specimen... )

**Response:** The last paragraph in page 15 and the whole of page 16 of the discussions has address the findings in this study in the light of the concern raised by this viewer.

5 - It would be good to see a table of the results - ie that gives a better indication than Figures 1 and 2 of what comprehension of study risks is considered to be.... eg what did they have to say to get a tick on understanding of study risks.

**Response:** Two tables on the baseline characteristics and correlation of characteristics to selected responses have been inserted.

6 - Clearly a year's recall is huge for informed consent information. This should be mentioned as a key limitation. I believe it would be good to have a whole paragraph in the discussion section highlighting the limitations. The importance of trust and of non information related reasons for joining studies is good to highlight (could also be in intro under informed consent in practice?). It it also worth discussing more. eg does it matter ethically if this is the main reason for joining? Is it a strength? Other papers have discussed this in the literature and might be worth referencing briefly.

**Response:** Additional discussions have been done and a whole paragraph on study limitations have been inserted in pages 20 and 21.

7 - Given some of the above concerns, the findings and conclusions are rather unconvincing and do not seem to link well to 'suggested 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. This has been shown elsewhere and is important. The question is does it matter? Is that not good, especially given that they do understand the research and have important health needs? It's a good balancing of benefits to researchers and benefits to participants? 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 efficiency 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 whether or not this matters).

Response: All these have been discussed and where necessary stated as a limitation.

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

Thank you very much and hope this addresses the remaining concerns.

Dr. Abraham oduro

Author of correspondence