Reviewer's report

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

Version: 1 Date: 8 June 2007

Reviewer: Alan R Tait

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General
This study examines parents' retention of informed consent information among a rural northern Ghanian population. This is an important topic for which there are few published data. Results suggest that parents had significant understanding of the study information.

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

It is unclear as to how the information about the study was initially presented. Was written (i.e., a consent document) and verbal disclosure provided and how many elements of consent were discussed e.g., protocol, purpose, risks, benefits etc.? Was this information standardized in any way? Also, on average, how much time was taken to explain the study to the parent(s)? These all need to be clarified.

P 5, Study design: How were the parental subjects selected? Was this simply a convenience sample of consecutive parents? Please describe.

P6 Ln 1. What do the authors mean by “fair” consistency of the instrument? Were any validity/reliability checks performed?

On average, how long after the consent information was given were the parents interviewed?

Retention of information does not necessarily imply understanding. Even so, it is unclear as to how retention/understanding was measured. For example, if there were three risks to the study and the parent could only recall one, to what extent did that represent retention/understanding? Was understanding measured using a categorical response option (e.g., did not understand, understood partially, understand completely) or were the responses scored in any way? This needs to be described in more detail particularly as it applies to the interpretation of figure 1.

In addition, how were any differences in coding/interpretation of the open-ended responses between the two research assistants reconciled? Inclusion of the semi-structured questionnaire might be useful.

The results, as presented, suggest that the parents had “significant comprehension” of the study information. This is at odds with other published studies (Postlethwaite et al. Arch Dis Child 1995, Snowdon et al, Soc Sci Med, 1997, Tait et al. Anesthesiology, 2003) which suggest that many parents have poor understanding of study information, particularly those with poor reading skills or lower education. The authors should comment on their findings in the context of other studies.

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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)

What were the parents told about the potential benefits of the study? Specifically, were they told that participation would result in free treatment or better care of was this simply their perception.

Figure 1 is repeated twice. Do the bars represent confidence intervals? Please clarify.

P 6, Data analysis: Data are plural

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Discretionary Revisions (which the author can choose to ignore)

Were there any differences in understanding by any of the demographics e.g., years of education,
participation in a prior study, parental age, etc. Also, did any of the children provide assent?

**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:** 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