Reviewer's report

Title: Consent and community engagement for school-based health research in Africa: experiences from a cluster randomised impact evaluation on the Kenyan south coast

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Reviewer: Penelope Phillips-Howard

Reviewer's report:

Thank you for providing an opportunity to review this interesting paper. This is well worth publishing as it is very important to build experience in the literature on real life challenges when conducting complex field trials. Trials involving schools in LMIC countries are particularly problematical, and the findings from this paper will be of great value for other studies.

The comments below are largely discretionary on the part of the authors, however, it is worth noting that it requires quite a 'dedicated' read, due to its length and complexity, and it would be helpful if the authors could consider some cutting of text, without spoiling the flow.

Minor Essential Revisions

Title: The paper clearly represents data generated from a trial. Could the authors thus change the title - currently it eludes to an evaluation rather than a trial. i.e. it may better as 'Evaluation of consent and community engagement for school-based research in Africa: experiences from a cluster randomized impact trial on the Kenyan south coast ' (authors could also drop south)

Abstract: Well over half the abstract is preamble - it would be good to include some of the key issues (after...in this paper we discuss).

Abstract: While the paper demonstrates many issues with consent and participation, can the authors really say that the paper demonstrates how a proactive engagement strategy involving communication and regular feedback ...strengthened consent/assent? In its current format, challenges are grouped and described in the results; The process of learning appears to be iterative and evolving over the trial. There does not appear to be a clear cut before and after the continuous community engagement and feedback system was set up. It is thus suggested that the abstract is amended slightly to reflect this (For example, state that the communication and feedback approach facilitated understanding of issues at an earlier stage, allowing faster resolution of issues and preventing potential failure of trial activities).

Discretionary Revisions

Methods: While it is important this is a standalone paper, I wonder if the amount
of detail in the methods is really required. Could the authors consider some reductions, since by the time readers get to the results, they have already gone through 5 pages of solid text. The authors have already published a number of methodological and baseline papers from the trial, thus, some cutting and referencing would be plausible. Further, I am not convinced how essential two of the tables (1, 2) are - if there were changes over time in approaches to keeping children in the study and reducing withdrawals, perhaps a timeline showing improved acceptance (lower withdrawal) would be more informative and substantiate the claim that the communication and feedback strategy worked. The authors could signpost when the communications and feedback strategy started, to show problems or withdrawals reduced after this date. If there is some personal attachment to the inclusion of tables 1, 2, perhaps they could be web pages?.

Methods: (note there are no page numbers). Ethics and Qualitative methods: The ethical approval would fit better after Qualitative methods, clarifying ethics covers all aspects of the study.

Results: There are many interesting issues arising in the various sections, and some are somewhat hidden within the text. Could the authors consider making a little more of Table 4 - it misses a number of quite critical issues from some sections, such as around teachers’ involvement, and some other missed sections. Would the authors be able to have a resolution/response column also? It is quite difficult for readers to spot how the issues were best resolved in the text.

Discussion: This, in a way, is a continuum of the results section. It does not really link up with the international literature, discuss other trials and the way they have handled issues, similar and differing. It is also a little unclear why there was no discussion section on the involvement of teachers in a school trial, since this appeared to be an underlying critical component working with (and through) them, to engage the participants.

**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’