Reviewer’s report

Title: Challenges for consent and community engagement in the conduct of cluster randomized trial among school children in low income settings: experiences from Kenya

Version: 2 Date: 7 February 2013

Reviewer: Penelope Phillips-Howard

Reviewer’s report:

Thank you for this revised draft.

The authors have attended to all the points of concern raised and have produced a very readable and informative paper.

Is the term ‘developing country’ as acceptable as in past years – would low and middle income countries/settings be deemed more appropriate now?

Page 11 second para… does this refer to signed consent for a study using a drug that has been approved by the government?

Page 13-15 – active engagement and involvement of teachers appears to be the most problematical (see below also, regarding last sentence, page 20). Whereas most challenges in earlier sections in the process, experiences and challenges section were acted on with some resolution – it was only in the section on teacher non-compliance / lesson fidelity that no clear action (other than deputy head and health teacher meetings) was described, instead this section focuses on the numerous problems, describing only one attempt at a solution (deputy head and health teacher meetings); if other attempts were made (even if they failed) it would be useful to know.

Page 16 – brings up a number of ethical concerns and it was not clear how they were treated in the study – authors mention they had a dilemma but not how they were acted on – in retrospect was there any other activity they consider could have better improved child participant engagement with the study?

Page 20 - very last sentence before conclusions –this is the only time in the discussion that the authors note that of all challenges they were confronted with, most they overcame, except how to engage and actively involve the teachers i.e. in the absence of ‘remuneration’. Because this was possibly the most difficult challenge, without any clear resolution achieved, and which may have impacted on fidelity, the authors could consider identifying in one or two sentences if other school-based trials referenced in the literature have encountered such problems, and if/how they were resolved, and perhaps with hindsight offer stronger suggestions/recommendations for future studies.

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'