Author's response to reviews

Title: Engaging the community in the standard of care debate in a vaginal microbicide trial in Mwanza, Tanzania

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Author's response to reviews: see over
Response to Reviewer Comments

General Response
The authors would like to thank the Reviewers for their insightful comments, which we have addressed below and in the revised manuscript submitted to *BMC Med Ethics*.

Specific Responses

a) Reviewer #1

Discretionary Revisions:
1. Informal feedback from community stakeholders (e.g. in participatory workshops, CAC and SAG meetings) in regards the SoC package developed in Mwanza has been very positive to date. Stakeholders broadly share the concerns of the research team in regards the partial success of the original SoC plan and are sympathetic as to the reasons why it has not been possible to provide a broader care package during the MDP301 trial. These insights are informing plans for future HIV prevention research in Mwanza.

   Please also note comment below from Table 3, which relates to this issue:

   CAC and SAG meetings have discussed service provision for children periodically during the trial but on each occasion have accepted that a combination of logistical, funding, human resource, sustainability and other issues make it difficult for the MDP301 Mwanza trial team to provide child health services directly via study clinics. All parties have agreed that this issue be carefully assessed in future trial design.

2. The following sentence has been added to the Results section, first paragraph, Page 9:

   Stakeholders also stressed concerns that client referrals from research clinics could risk stretching already overburdened local health services; and the importance of ensuring appropriate resource inputs to offset such risks.

3. Research participants and stakeholders discussed stigma, disclosure of HIV status and social harm with the research team at community meetings and workshops but to date, these issues have not been systematically addressed through broader community stakeholder engagement.

b) Reviewer #2

Minor Essential Revisions:
1. Typo changed in line 12 of Abstract, as indicated in the text of the revised manuscript.
2. Figure 2 modified as advised.

Discretionary Revisions:

The following comment has been added to the Discussion section, paragraph 2, page 12:

The limited resources available for clinical trials in developing countries mean that community stakeholders, researchers and sponsors will continue to face extremely difficult choices when attempting to reconcile the immediate needs of trial participants with the potential for longer term benefit to the wider community.