Reviewer's report

Title: Stakeholder views on the acceptability of Human Infection Studies in Malawi

Version: 0 Date: 31 Aug 2019

Reviewer: Richard Lessells

Reviewer's report:

This manuscript presents findings a stakeholder consultation exercise exploring the acceptability and ethics of human infection studies (HIS) in Malawi. This was primarily focused around HIS in pneumococcal disease but also explored more general issues about HIS for other infectious diseases of importance in Malawi. The authors synthesise data from a number of focus group discussions, follow-up in-depth interviews (with specifically selected participants from the FGDs), and a few key informant interviews. It seems that there was good understanding and discussion of the key issues around HIS and the study captured a range of views.

The paper is very well written and I enjoyed reading it. I have just a few comments which the authors might want to consider - mainly where I feel a bit extra information might help the reader by giving more context to the findings.

Minor comments

1. Methods, p6: It would be helpful to just briefly explain the composition of the MLW Community Advisory Board.

2. Methods, p6: It would also be helpful to know if the chiefs and religious leaders involved in the study had much previous engagement with MLW or other research activities. This would help to understand the issue you bring up around how objective the views expressed might be and whether they might have potentially been influenced by positive attitudes to MLW and other research in the community.

3. Findings, general: One issue that I couldn't see come out was to what extent people understood the pathways through which HIS findings would ultimately lead to health impact and the responsibility of researchers to have a plan for following through on the HIS. Sometimes it seemed to come across that there was an implicit assumption that research would proceed seamlessly and effective vaccines would be available to the population following the HIS. I would also be interested to know if people had perspectives of the involvement of pharma/vaccine manufacturers in this process.
4. Findings, p11: I got slightly confused because here you state you are presenting the findings under three broad headings but then it's a bit unclear in the rest of the paragraph what exactly the three headings are, and the section then has four subheadings (3.1-3.4)

5. Findings, p29: In the discussion on p29, I would have been interested to know whether there are national guidelines in Malawi about reimbursement for research participation and how HIS might fit within these guidelines

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

Yes

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

Unable to assess

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

Yes

**Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

**Quality of written English**
Please indicate the quality of language in the manuscript:

Acceptable

**Declaration of competing interests**
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?
3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

I declare that I have no competing interests

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal