**Reviewer’s report**

**Title:** Ethics review of studies during public health emergencies - The experience of the WHO Ethics Review Committee during the Ebola Virus Disease epidemic

**Version:** 0 **Date:** 05 Mar 2017

**Reviewer:** Bridget Haire

**Reviewer’s report:**

This article provides very valuable information about the processes of ethical review during the West African Ebola outbreak, and makes important recommendations about how these processes could be further streamlined in future health emergencies.

**Comments:**

1. The abstract does not mention the importance of collaboration with affected communities (both partnerships with local researchers and consultations at grassroots levels), though this is significant in the main text (p 6, pp 7-8). Including this in the abstract would be valuable.

2. Some awkward sentences need revision, such as the first sentence of the introduction (p 3); p4 under subhead 'review times', lines 22-24; p6 lines 14-15 (was this intended to mean volunteers in Ebola-affected communities, perhaps?); p8 lines 1-3.

3. There are a couple of lists that throw together 2 positive aspects with a 3rd negative aspect, which is jarring to read, see p4 lines 50-58 - these lists would be easily revised to make all element on the list either positive or negative.

4. p 1 lines 6-8 - I suggest mentioning observational intervention research that occurred during past outbreaks, such as interventions that used survivor blood.

5. The section on scientific validity and trial design could be expanded. For example, some exploration of the term 'scientifically valid' is warranted, as it appears that RCT advocates suggest this is the only valid form of research. It seems that the WHO ERC reviewers did not accept this (incorrect) view, and it would be good to see this articulated for posterity.

6. p 5 item c) - the issue about varying standards of care in different ETC and how these would impact on RCT designs is not clearly articulated in this point. As written, it is hard to understand.

7. P 6 - I think that in paragraph 2, last line, the authors are talking about study volunteers in Ebola-affected areas, not study volunteers generally. This needs to be clarified.

8. p 6 paragraph 3, the explanation of the 'ring' trial does not capture the cluster element in its design. This section needs a minor rewrite to ensure the design is clear.
9. P 6 paragraph 3 item b) - not only does the 'delayed vaccination arm' enhance social value by providing a comparator, it also has a more direct benefit to participants as they are vaccinated by a promising candidate that might provide them with protection against future exposure.

10. P 6 item 3 Justice - exclusion of women and children - I congratulate the authors for the clarity of this section.

11. P 8-9 item 5 - the issues of consent, partnership and community engagement are of critical importance, and as I have noted above, should also be included in the abstract.

12. P9 Template agreements about biospecimen ownership and use need to be negotiated with communities and local researchers during non-emergency circumstances.

13. Might it be possible for the authors to include a section on the monitoring and ethical evaluation of the implementation of trials post-emergency? Articulating where the responsibility for monitoring of the implementation of trials during an emergency would be a very valuable addition to this article, if it is possible, and would add greatly to the sends of transparency in the elevation of what occurred during this particular outbreak.

**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.

Yes

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

Yes

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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

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