Reviewer’s report

Title: Safety of a bivalent, killed, whole-cell oral cholera vaccine in pregnant women in Bangladesh: Evidence from a randomized placebo-controlled trial

Version: 1 Date: 19 Apr 2018

Reviewer: David Sack

Reviewer's report:

This study of pregnancy outcomes of women who inadvertently received oral cholera vaccine (OCV) when pregnant is a valuable confirmation of the safety of OCV during pregnancy. While previous studies have found similar results, this study is unique in several respects. 1) The data is from a randomized placebo controlled trial and is thus, much less likely to be biased compared to previous studies. 2) Most of the exposures of OCV in pregnancy occurred during the first trimester. 3) The follow-up included data on low-birth weight. Thus, this study adds valuable information to support safety of the vaccine.

Unfortunately, some of the sentences need to be revised by a native English writer. Some of the sentences which need revision are listed below, but there are other sentences which will benefit by some edits.

Some specific comments include:

Line 82. I recommend revising this statement, "However, the OCVs are still not recommended for the pregnant women due to limited data on its safety profile." As stated earlier (line 75), WHO does recommend that OCV be given to women who are pregnant, but the package insert is ambivalent. The wording might be, "the package insert for OCV still recommends caution for use during pregnancy due to lack of data."

Line 99 typo on the number of residents.

Line 129. This sentence should be clarified. I interpret this to mean, If a pregnancy outcome had already occurred at the time of the screening visit, this was considered a retrospective follow up.

Line 179. Remove the word "could."

Line 206. I am not familiar with the term "accidental abortion." Please explain.
Line 219. Change wording to "Previously reported studies in pregnant women receiving OCV have observed a non-significant increase in adverse pregnancy outcomes among women receiving OCV."

Line 229 - change the awkward sentence.

Line 241. I am not sure why the authors feel these high rates are not surprising. It would seem that these high rates need to be explained. It seems likely that the surveillance for adverse pregnancy outcome was much more intense than the previous studies; but the authors should provide their own explanation. Although induced abortion is illegal, menstrual regulation is widely available, so it would seem there is less stigma in Bangladesh. This should be explained.

Line 247. I assume the authors are talking about placental blood volume; this should be clarified.

Line 249. Revise this awkward sentence.

Line 281. Change sentence to "...cholera vaccination campaigns frequently exclude pregnant..." In fact most OCV campaigns now do not exclude pregnant women and this is consistent with WHO recommendations. This should be highlighted.

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

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.

I am able to assess the statistics
Quality of written English
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

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I have no conflicts as listed above. I do however work closely with the second author (Dr Ali). When I agreed to review the paper, I did not notice this potential conflict. In spite of this issue, I feel I was able to review the manuscript without bias, and I have certainly not discussed the paper with him. When I agreed to review the paper, I was not aware of the Open Peer Review Policy.

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