Author’s response to reviews

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

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Point by point response to the comments
(All the line numbers are according to the highlighted version of the manuscript)

Editor Comments:

I'm afraid the quality of the English used throughout your manuscript does not currently meet our requirements, as there are several spelling and grammatical errors throughout. We recommend that you ask a native English speaking colleague to help you copyedit the paper. If this is not possible, you may need to use a professional language editing service. Use of an editing service is neither a requirement nor a guarantee of acceptance for publication.

Response: Thank you for your suggestion. We have edited the manuscript through a professional language editing service ‘American Journal Experts (http://bit.ly/AJE_BS ) ’ for help with English usage.

BMC Infectious Diseases operates a policy of open peer review, which means that you will be able to see the names of the reviewers who provided the reports via the online peer review system. We encourage you to also view the reports there, via the action links on the left-hand side of the page, to see the names of the reviewers.

Reviewer reports:

Pedro Moro (Reviewer 2): Please include all comments for the authors in this box rather than uploading your report as an attachment. Please only upload as attachments annotated versions of manuscripts, graphs, supporting materials or other aspects of your report which cannot be included in a text format.

Please overwrite this text when adding your comments to the authors.

This study evaluated the safety of a bivalent, killed, whole cell oral cholera vaccine, Duchoral (OCV), among pregnant women inadvertently exposed to the vaccine during pregnancy. The study participants were part of a randomized placebo-control trial conducted in Dhaka, Bangladesh. The authors addressed most of the comments of the first round of reviews. I find though that in general, the manuscript has several areas where the English could be greatly improved. I would suggest the authors have the manuscript reviewed and revised by a native English speaker familiar with medical journals and terminology.
The only major comment I have is what is the rational for including cohort 2? These are women who were pregnant after vaccination, so exposure did not occur during vaccination but before women were pregnant. How much time elapsed between vaccination and getting pregnant? I can see the importance of including these women if there in uncertainty as to the timing of vaccination, if the authors think many of them may have been exposed to the vaccine while pregnant. If this is not the case, then this data should be presented separately, in a separate table or maybe even not presented at all as it may confuse some readers.

Response: The rational for including cohort 2 in this analysis was to look at if there is any effect of the vaccine exposed right before the pregnancy on pregnancy outcome. Elapsed time between vaccination and getting pregnant is already in Table 1 (time of vaccination prior pregnancy). The median (IQR) time was 4.71 (2.17, 8.14) weeks in OCV group and 5 (2.43, 8.29) weeks in placebo group. We have also mentioned this the method as this is a secondary analysis (lines 157-159).

Other comments:

Page 4, line 72: observed instead of observing. Much of the, instead of many Page 4, line 73, "…during pregnancies has reported pregnancy loss with the magnitude…”

Response: Corrected as per suggestion (now lines 70-71).

Page 5, line 90: "…safety data in this population group. Since most of the studies were carried out in African countries during cholera outbreaks"

Response: Revised according to your suggestion (lines 86-88).

Page 6, line 112: '…and the study procedure were published elsewhere"

Response: Corrected (line 108).

Page 6, line 113: " only the women of child bearing-age who had received the study agents"

Response: Corrected (line 109).

Page 6, line 122: " in identical vials in a double blind manner."
Response: Corrected (line 119).

Page 8, line 180-181: the analysis were performed by using R.3.2.3. What is this? State the complete name of the program or statistical package.

Response: The complete name of the statistical package has been included in the manuscript (lines 175-176).

Page 9, line 185-186: "clinical trial of whom 71,202 were women of reproductive age."

Response: Revised as per suggestion (lines 179-180).

Page 10, line 211: "The rate of preterm delivery…"

Response: Corrected (line 204).

Page 10, line 230: replace this sentence with something like: "the results of our study suggest that administration of OCV during pregnancy was not associated with adverse pregnancy outcomes".

Response: The sentence has been replaced as per your suggestion (lines 221-223).