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: 2 Date: 20 Jan 2019

Reviewer: Pedro Moro

Reviewer's report:

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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 ha 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.

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…”

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

Page 6, line 112: '…and the study procedure were published elsewhere"
Page 6, line 113: "only the women of child bearing-age who had received the study agents"

Page 6, line 122: "in identical vials in a double blind manner."

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.

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

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

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".

**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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