Author's response to reviews

Title: Lessons and implications from a mass immunization campaign in squatter settlements of Karachi, Pakistan: an experience from a cluster-randomized double-blinded controlled trial [NCT00125047]

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Author's response to reviews: see over
Dear Editors,

On behalf of the authors I would like to thank the reviewers for their valuable comments on our revised manuscript. We believe the quality of the manuscript has improved a lot and would be more beneficial for the readers and those involved in future field trials in developing countries.

We have very carefully read the comments of the reviewers and have addressed them point by point. The comments have been incorporated in the manuscript and the location is mentioned below for your consideration.

Please feel free to contact if you have any questions.

Sincerely,

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From Dr Gluud (major points):
1. The authors have responded in detail to the comments about sample size, but they do not address the potential impact low recruiting will have on chances to make conclusions on the trial. I still suggest that this issue should be addressed briefly in the Discussion section.

This has been included in the text page 17 line 15

2. If trials sponsors had no role in this trial apart from donating vaccines or money for conducting the trial, why should sponsor representatives sign the protocol (appendix A, Ethical approval)?

Response: The “sponsor” in the Appendix and in the protocol means international vaccine institute (IVI) as Bill and Melinda Gates foundation donated funds to IVI and IVI was further responsible for disbursing money for the conduct of this trial and other research activities. IVI coordinated all research procedures. Hence IVI director or his representative signed-off final protocol/s following ICH-GCP guidelines.

3. P 18, line 2: ‘was not seen.’ ought to read ‘was seen’. This has been added to the text page 18 line 15.

From Dr Sterne (minor points):

Although happy to see this published, I would note that the authors have not fully responded to the following points:

1. When I asked "How, precisely, were the randomization strata defined (these could be displayed in a table or depicted in a figure)?", I was hoping that the authors would display the randomization strata and the areas within these allocated to C or M. This has not been done, although the addition of a CONSORT-type flow chart is Figure 2 is welcome. Figure 1 is not clearly labelled.

Authors’ response: We have added Figure 3 based on the recommendation. We hope that this will suffice. The number of individuals vaccinated in each stratum and arm has also been displayed in figure 2, last row of each box.

2. The authors have now stated the primary outcome that will be used. However they have provided no information about other planned outcome measures. This has been added to the text, Page 14 line 3

From the Trials editorial office:

1. The pharmaceutical company’s input into the study design should be mentioned in the manuscript, probably in competing interests, to make clear exactly what the companies did in regards to the design and execution of this study, even if all they did was donate vaccine.

This has been added to the text, Page 22 line 2

2. The appendices should be uploaded as extra files to the manuscript when the manuscript is re-submitted so they can be correctly linked to the final published version.