Author's response to reviews

Title: Newborn Infection Control and Care Initiative for Health Facilities to Accelerate Reduction of Newborn Mortality (NICCI): study protocol for a cluster randomized controlled trial.

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Response to Reviewer's report

Title: Newborn Infection Control and Care Initiative for Health Facilities to Accelerate Reduction of Newborn Mortality (NICCI): study protocol for a cluster randomized controlled trial.

Major compulsory revisions

1. Hypothesis 1 will examine improved knowledge, more rapid case detection, and more rapid and appropriate referral. It would be helpful to describe the specific comparison – e.g., even though this is a stepped wedge design in which all clinics will eventually receive the intervention, the hypothesis may be clearer that the comparison is between the clinics with the intervention vs. whose without (at the time)…rather than to a historical period for that clinic.

   *We have added language at the end of the Hypothesis 1 sentence to clarify this issue.*

2. Many of the listed primary outcomes are related to infection prevention behaviors, but this broad category of outcomes was not listed in the hypotheses. This is a minor issue, but worth considering whether that could be included in the statement of the hypothesis.

   *We have added this to the Hypothesis 1 sentence.*

3. There are many outcomes listed as primary, potentially raising concerns about multiple comparisons. Please describe why this is not a concern with the large number of “primary” outcomes.

   *We have inserted a statement regarding application of a Bonferroni correction to address this.*

4. The paper states that the study “may not be sufficiently powered to show reductions in mortality,” but then sample size is based on this as an exploratory outcome. It is not typical for sample size to be based on an exploratory outcome, so more justification of this choice is warranted.

   *The initial primary outcome was neonatal mortality, but the funding agencies felt that we would be insufficiently powered to detect this outcome and so recommended that we make this an exploratory outcomes. Our statistical team felt that in order to be conservative we should keep the original sample size so that we could potentially provide some information on mortality while adequately*
addressing the other outcomes. This is a lengthy explanation to insert into the manuscript, but we welcome a suggestion for text to provide clarification on this point.

5. Please provide more information on the “comparison areas” briefly noted in the last paragraph of “trial design.”

We have clarified this paragraph.

6. Will pregnancies / births involving more than one baby be eligible? (I just wondered because of the reference to mother-newborn “dyads.”)

As stated in Trial Design all live births will be eligible. We have clarified this sentence and removed reference to “dyads”.

7. The data collection section would be strengthened by a closer linkage to the outcomes described earlier. It would be helpful to have a clear description of how each of those data elements will be collected (though presumably some of them can be grouped because they will be collected using the same process).

We have added clarification to the Data Collection section on this point.

Editorial Requests:

1. Please ensure the title conforms to journal style for study protocol articles. The title should follow the format “___________: study protocol for a randomized controlled trial.” Please ensure to change the title in both the manuscript and the submission system.

   The title has been amended in both the manuscript and submission system.

2. Please include a sentence in the authors’ contributions section that confirms whether all authors have read and approve of the final version of the manuscript.

   This sentence has been included.