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.

Version: 3 Date: 1 May 2015

Reviewer: Kelli Allen

Reviewer's report:

This manuscript describes a study that addresses a clearly important problem and seems to have high potential for impact. The study design is appropriate and generally well described. The manuscript is well written. I have the following recommendations for clarifying some specific aspects of the study methods:

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.

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.

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.

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.

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

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

Level of interest: An article of outstanding merit and interest in its field
Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests