Reviewer's report

Title: A Community-based Approach to Improve Pregnancy Outcomes in Low-Resource Settings: A Global Network Cluster- Randomized Trial

Version: 2 Date: 4 June 2013

Reviewer: Craig Rubens

Reviewer's report:

Major Compulsory Revisions

The author must respond to these before a decision on publication can be reached. For example, additional necessary experiments or controls, statistical mistakes, errors in interpretation.

1. The intervention or package of interventions by the intervention teams is described in broad terms by listing 3 components of: (1) community mobilization focussing on birth planning and hospital transport, (2) community birth attendant training in problem recognition, and (3) facility staff training in the management of obstetric and neonatal emergencies. A more detailed description of the interventions/work performed are needed. Such as total hours and topics for the facility training, training hours and methods including supervision for the HBLSS community training, community mobilization outputs and resultant system changes for birth planning and hospital transport. This is important so the readers can better understand the actual interventions introduced.

2. None of the 3 sets of interventions had a measurable impact on care indicators or birth outcomes. The conclusion that no effect was found and that this indicates these settings require substantially more care infrastructure than were available is a statement that may not be fully supported in the current manuscript. More evidence is needed to support that the quality of the clinical interventions was high, and to determine if there was no effect seen between groups due to poor delivery of the clinical (versus study) interventions (lack of standardization when working at scale, quality of HBLSS and facility training, competency gained by staff). Is data available, for example, for post training improvements in competency or knowledge scores, routine uptake of evidence based clinical care measures that previous were not available. I might suspect that an additional explanation for the lack of difference between study groups may suggest a need for standardization and quality when working across large areas at scale.

3. The authors justification for including specific components in the intervention package on Page 4/5 should be specific to the components delivered in the study intervention arm. For example, the justification describes the First Breath Trial, but then states this current study utilized the HBLSS curriculum. Are these different interventions, or both studies used the same HBLSS curriculum?

4. Page 4/5. Please provide citations for impact on mortality/pregnancy outcomes
for key components of community mobilization, HBLSS, facility staff training (specific curriculum used in the study), death audits and facility audits). A table might be useful to summarize this critical evidence to assess the individual components implemented by teams in hopes of improving pregnancy outcomes. Please report efficacy and/or effectiveness evidence for the individual intervention components. If either not available, then please state this clearly.

5. The stated hypothesis is that local intervention teams can address access to and quality of care by implementing a broad intervention with three components. A more complete description of how these team operated, and what activities they prioritized is important, as this appears to be the primary study question. The findings suggest that teams are unable to effectively impact outcomes through the process used in the study. This process needs to be clearly described in the methods. The actual interventions and trainings were apparently evidence based and proven to have impact on health outcomes (it is essential that this information be presented, if this evidence does not exist please state so), so this suggest the process of administering and delivering these comprehensive interventions and/or skills training were not adequate, or secondly, there was a failure in delivering quality effective interventions. It is important to state this clearly in the conclusion section.

6. The authors state repeatedly that this was a well resources. Please provide project cost data to support this claim ($ spent per activity, cost of intervention per facility, etc).

7. This reviewer would find it helpful to state the hypothesis clearly in the abstract.

Minor Essential Revisions

The author can be trusted to make these. For example, missing labels on figures, the wrong use of a term, spelling mistakes.

1. Various terms are used to describe the study intervention made by local intervention/cluster teams, i.e. interventions, multi-faceted interventions, package of interventions. etc. Consistent use of one reference term would be clearer for the reader.

2. Teams are referred as “intervention teams” and as “cluster teams”. Consider a one term used consistently. Also there are “core groups” which can add to a new readers confusion. You might consider using the term “community core groups” or “village core groups” to help differentiate.

3. Page 8. In the community mobilization bullet: are these barriers specifically access barriers to care? Could you list the most frequently identified topics and interventions identified by the OPEAE cycle?

4. Page 8. In the HBLSS training description bullet, I suggest using the term ‘community birth attendant’ and families, rather than ‘birth attendants’ and families. Please formally cite a description of the actual curriculum used in
HBLSS.

5. Page 8. Third bullet would be more objective by stating Facility staff training for clinical care, perinatal and maternal death audits, and facility audits. The data presented does not support the statement that these measures lead to improvement of quality of care, as currently stated.

6. Page 12. Discussion. Second paragraph. The study was powered to detect a change of 25% in birth outcomes. Is it not possible the study was not powered adequately to detect a lesser change? In high mortality settings, even a 10 or 15% change would be valued.

7. Page 13, second paragraph. Clarification needed: Skilled personnel include family physicians, nurses, nurse midwives. Specialists include OBGYN, peds, anesthesiologists. The emphasis should be on skilled personnel. We have no data in the study or elsewhere to suggest specialists are needed to see a change in health outcomes in high mortality and low resource settings.

8. Page 13, last sentence. Did the study evaluate the three pronged strategy in the trial, or did it evaluate the study intervention of forming local intervention teams to address access to and quality of care by implementing a broad intervention with three components? Are the 3 strategy components already proven by an evidence base in low resource settings? I feel the important question is how do we deliver these activities effectively at scale, and this team approach providing 3 proven sets of interventions at scale does not appear to be effective.

Discretionary Revisions

These are recommendations for improvement which the author can choose to ignore. For example clarifications and/or data that would be useful but not essential.


2. A diagram depicting the key agency bodies (core groups versus the intervention or cluster teams) and how they relate to the intervention components might help readers more easily understand the broad study intervention.

3. Page 8. The a priori system for measuring integrity of the study intervention could be reported in an inset box with more detail. However was there any monitoring/evaluate the quality of the actual training or action taken to change the care system (in the community or facility)? This may be a possible explanation why no change was found between groups (poor quality of specific change actions performed, or effectively delivered). Given that the reported
indicators of quality of care in Table 3 were unchanged across groups, one wonders if quality of the actual training and community mobilization interventions were adequately/consistently delivered.

4. Page 14. Line 7 first paragraph. You might add a point that although a substantial amount of work was done in every cluster, the quality and impact of the work (training, action from death and facility audits) must be clearly monitored to an agreed adequate standard. The may be an essential step missing here. If authors have more detail intervention monitoring data for quality of training and resulting change in HCW behavior, this would be very helpful in drawing meaningful conclusions.

5. Conclusion. Third sentence (second conclusion). This sentence is not clearly supported by this study. No comparison to characteristics of systems in high-income country setting was presented in this study. I suggest deleting this sentence in the conclusion, as the authors argue that well-trained staff with a high degree of skill was attempted in this study but did not prove successful. The study is not designed to support this second conclusion.

6. Conclusion. Last sentence. For readers to appreciate what is 'substantially more resources and time" available for the current project to create a functioning care system, please report intervention cost data, or I suggest you remove this statement. This, however, would be a great addition to this report, if available.

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