Reviewer's report

Title: Effect of Home-Based Counselling on Newborn Care Practices in Southern Tanzania: a Cluster-Randomised Controlled Trial One Year after Implementation

Version: 2 Date: 31 March 2014

Reviewer: Luke C Mullany

Reviewer's report:

Abstract.

- some of the background language belongs in the method section
- there seems little reason to report odds ratios. Please directly estimate the relative event/practice/intervention of interest, rather than the relative odds

- I would suggest reducing the size of the results section of the abstract by perhaps removing the "intervention" visit "results" as an outcome from the results. This reads more like coverage of the randomized intervention, rather than an outcome resulting from the random intervention, and the focus should be on the newborn care practices. Again, the NCP should also be reported as relative frequency directly, rather than relative odds.

- the conclusion of the abstract does little to inform the reader of the implications or next steps. Rather, it simply restates the result

Background

- minor: is the date of the conceiving of the INSIST study actually 2006, or should this be 2009? The methods sections begins by describing the population in 2009, implying to the reader that this might have started in 2009, rather than 2006?

Methods:

- The methods section moves too quickly into the details of selection of volunteers, their training, content of training etc.. (all essential details), well before the reader even understands the primary aim/objective of the randomized trial. Please reorganize so that it clear what the objective of the trial was, and what the control and intervention groups actually are.

- How did the volunteers come to know about pregnancies? How soon were they made aware of them? What was the distribution of gestational age at enrollment? How did the volunteers know about the outcome? When were the within-pregnancy visits scheduled? What happened if a woman was enrolled late in pregnancy? What was the average time of first visit after birth?

- The reporting on the sample size requirement might be strengthened by indicating how the interviewers moved from a requirement of about 200-220 reportable deliveries per group to ~2600 households to be approached per arm.
It seems about correct, but perhaps just add in here the estimation process to justify (i.e. something like "Given average household size (x.x per household), and crude birth rate (XX.X per 1000), we estimated that XXXX households per group would need to be approached to yield XXX reportable pregnancies").

-Please explain the final (i.e. 2nd stage) selection process. Which, exactly of the many methods available was used to select the 40 households within a village? Was this method standardized across all 131 villages?

-Minor.. perhaps group all the statements on masking/blinding into one section?

**Results**

-When less than the originally planned number of households were available (i.e <40), or participated (i.e. refusal) in a village, does this shift slightly away from the self-weighting mechanism of the standard two-stage cluster design with selection? I believe it does - if so, did the authors use a post-analytic weighting strategy to account for these minor deviations?

-Table 3 - please remove the odds ratios and p-values from the table of comparisons for randomization balance.

-I would suggest removing Table 4, and keeping the text description of the coverage of the intervention in the result. Keeping both would be repetitive.

-I think you should remove the text "although these differences may be due to chance", since that statement is always true regardless of the strength statistical evidence you have

-How accurate/reasonable is the self-report of "Exclusive breastfeeding in 3 days"? If only a third of women are reporting early breastfeeding (please clarify if this is within 1 hour or within 24 hours), are the other 2/3 of babies receiving nothing (no prelacteal feeds?). In many communities it is common for people to not consider prelacteal feeds as "feedings", and thus report that the baby only received breastmilk, regardless of whether prelacteals were provided or not.

-How was clean cord care defined? What were the practices that were "unclean", which occurred 30% of the time in control areas.

-Were practices/coverage improved among the women in intervention group that reported coverage/visits by the INSIST program, relative to those in the intervention group that did not receive those visits?

-The authors may be overstating the importance of the exclusive breastfeeding result in both their own study, and when discussing NewHints.. In neither case was the increase very much, and exclusive breastfeeding as defined in both studies was already quite high to begin with.

-When reporting the finding of delaying bath in Pakistan and ghana, no need to include both conf interval and p-value, and use RR instead of "rate ratio", to be consistent with prior use of the acronym.

Given the relatively small differences between the groups on a small number of practices, the authors should spend more time in the discussion section considering the cost-benefit ratio (not quantitatively, but in a qualitative manner.. i.e. the resources required by such a program, how it fits (or does not fit) with other interventions/responsibilities of community workers etc. They should also posit for the reader some possible reasons why the changes were so minimal. While I agree that it is important to understand the scope for home-visiting approaches to reduce mortality, the authors should discuss how the intervention might need to be strengthened in order to actually achieve mortality reductions, as the data presented here do not provide much confidence that such a reduction would occur under the current implementation approach (again, given the minimal changes seen here). What were the obstacles? When did the visits occur? What is the real likelihood that referral to the health system for vulnerable babies, or those found to be ill during home postnatal visits, would result in high quality care, etc,etc?

A note on the analysis in general: I see little reason for the authors to present odds ratios throughout the paper. The svy suite in Stata allows the use of generalized linear models, and I would suggest that all analyses be redone so that the relative frequency/rate of the events, practices, coverage of interest is estimated (i.e. RR, not OR).

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

'I declare that I have no competing interests'