Author's response to reviews

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

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Version: 3
Date: 29 May 2014

Author’s response to reviews: see over
Dear editors,

Thank you to the reviewers for their helpful and detailed comments on the manuscript. I have addressed each of the comments in the revised version as follows:

**Reviewer 1**

**Background:**
- This can be enriched by a brief description of the maternal and newborn health situation in Tanzania and the policy environment.
- *This has been done in the last paragraph of the background*

- The objective of the study is clear but the rationale of the study needs to come out clearly
- *Additional context has been added to the last paragraph of the introduction to highlight the need for effective interventions to improve newborn survival in Tanzania, particularly the southern region.*

**Methods:**
- A good attempt has been made to describe the methods, however; under Design and implementation of the INSIST intervention section the phrase ‘see for example’ could be deleted. The statement ‘The development of the intervention will be reported separately’ is not necessary and authors may consider omitting it since a brief description is given
- *These have been deleted*

- The implementation period is not clearly stated. Although it is mentioned that piloting was in first half of 2010, followed by recruitment and training of 800 volunteers, one wonders for how long such preparatory activities took before implementation.
- *It took approximately 6 months to recruit and train all of the 800 volunteers in their communities, as described in the text. I have added the sentence ‘all trained volunteers were conducting home visits by June 2010’ to clarify the time when full implementation was underway.*

- Under the implementation the authors mention that ‘for home births the volunteers were trained to measure foot size as a proxy for birth weight’ yet the results for low birth weight babies describe them as perceived ‘smaller than normal at birth’ by their mothers. Thus making it un clear whether the volunteers ever measured the foot lengths of the babies born at home
- *Survey respondents were asked if they thought their baby was normal size, larger than normal or smaller than normal at birth. The same question was asked to respondents in intervention and comparison areas, as in the latter there was no strategy for babies to have their foot size measured.*

- Data collection and quality control: Were the data collection tools pretested? What were the exclusion criteria?
• Information regarding the development and testing of the questionnaire has been added under ‘data collection, processing and quality control’. The exclusion criteria have also been described in this section and ‘sampling’.

• Data Analysis: Be more specific on how you adjusted for clustering
• More detail has been added to the methods here

Results:
• Coverage of home-based counselling visits: The data are silent about the proportion of women who received the three CHW visits in pregnancy and those who received the two visits after delivery. Since each visit had targeted messages for behavioural change it is important to know the coverage of the prescribed visits in order to understand the effects of the intervention better
• The proportion of women who received 3 pregnancy visits and 2 postnatal visits have been added

• There were 12 smaller than normal babies in the intervention area but there is no mention on the extra visits they received by CHWs or results of foot measurement
• The number of visits for babies who were perceived to be smaller than normal has been added. The results of foot measurement were not recorded in the household survey.

Discussion:
• Although the authors made comparisons with other studies, they did not give explanations in areas where their findings varied. Where they attempted foe the low babies breast fed within 1 hour the explanation (paragraph 6) of ‘the different categories for answers to questions on breastfeeding initiation’ is not clear
• More detail has been added to this paragraph

• Explanations and implications for the low uptake of some practices like drying and wrapping of babies < 5 minutes after birth need to be pointed out- what are the lessons from the study for the readers?
• Explanations of the low uptake of immediate drying and wrapping, and suggestions for the future have been added.

• Limitations and mitigations specific to the home-based counselling intervention are not mentioned
• A paragraph discussing some possible limitations has been added

• Weaknesses in the health system are acknowledged but no mention of strategies put in place to mitigate them in the intervention area
• An outline of the original plan and actual QI activities has been added to the methods. The limitation of health system weaknesses has been highlighted in the discussion.

Abstract:
Background: The statement that ‘we developed a counselling intervention in rural southern Tanzania: trained volunteers made home visits during pregnancy and after childbirth to promote recommended newborn care practices including hygiene, breastfeeding and identification and extra care for low birth weight babies’ fits better in the methods than background. I suggest that this statement gets shifted to the methods section of the abstract.

This has been done

The conclusion where the authors mention that a volunteer-led home-based counseling strategy, supported by the health system; the health system support does not appear in the methods

This has been removed from the methods of the abstract. A brief description of the (scaled back) health system intervention has been added to the main methods, and this will be reported separately.

Reviewer 2

Abstract.

• some of the background language belongs in the method section
  • this has been done

• there seems little reason to report odds ratios. Please directly estimate the relative event/practice/intervention of interest, rather than the relative odds
  • Please see below for response to query about modelling using GLM and presenting RRs.

• 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 coverage estimates have been removed from the abstract

• the conclusion of the abstract does little to inform the reader of the implications or next steps. Rather, it simply restates the result
  • The conclusion has been amended to include implications and next steps

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?
  • The dates of the steps in the study have been clarified in the methods

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 is clear what the objective of the trial was, and what the control and intervention groups actually are.

- **The methods now start with the aim of the cRCT. The second section is about randomisation, which explains what the intervention and comparison areas receive.**

- 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?
- **Details about the identification of pregnant women and notification of births have been added under ‘design and implementation of INSIST community intervention’. The mean month of gestation at first visit and timing of first postnatal visit have been added to the results.**

- 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").
- **Extra detail about the sample size calculation has been added**

- 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?
- **This has been added under ‘sampling’**

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

- **This has been done**

**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?
- **We have added details of the number of the number of households missing from the anticipated full sample size in the results. While weighted analysis would be possible, given the low numbers of refusals and missing data the**
effect of weighting would be minimal, and we prefer to present unweighted results in the interests of transparency and simplicity.

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

- 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.
  - The text has been updated in order to summarise the main findings of table 4 and reduce repetition.

- 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
  - This has been done

- 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.
  - Immediate breastfeeding has been clarified to mean within one hour of birth throughout the results. With regard to the accuracy of the self-report of exclusive breastfeeding in the first three days, interviewers were carefully trained with regard to this issue and closely supervised during data collection but we cannot rule out the possibility of some mothers giving false-positive or false-negative reports of exclusive breastfeeding in the first three days.

- How was clean cord care defined? What were the practices that were "unclean", which occurred 30% of the time in control areas.
  - These have been explained, and data on the unclean cord care practices added to the end of the results.

- 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?
  - We have added a description of intention to treat analysis to the analysis section of the methods. Our primary aim was based on intention-to-treat and we did not consider it appropriate to conduct per protocol analysis owing to the large likelihood of recall bias.

- 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.
• The wording of the discussion of these results has been adapted to reflect the high coverage and small differences between areas

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

• We have checked through the text and used RR to mean risk ratio/relative risk, and put in full rate ratio where needed (e.g. when referring to Kumar et al 2008)


• Thank you for the suggestions. These papers have been included.

• 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.

• We have added several additional points to the discussion as to why the changes were relatively small. In addition, extra information has been included on the characteristics of the counsellors (residents of their villages, not existing community workers, working as volunteers) and the attention on intervention sustainability and scalability has been increased. A paper detailing the economic analysis of the intervention will be published separately.

• 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?

• The discussion now suggests how improving intervention coverage may be beneficial, and reasons why it was not optimal, and what the impact may have been. Limitations relating to quality of care for mothers and babies at health facilities have been added.

• 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).

- The analyses were redone using GLM and calculating RRs as suggested, however several of the models did not converge. We therefore prefer to leave the results in terms of logistic regression accounting for clustering using svy.