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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Author's response to reviews: see over
Dear Editors,

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

Thank you for your own comments on this manuscript. We have addressed each of them in the updated version, as detailed below:

i. Authors need to address all the issues raised by the individual reviewers or indicate where they have difficulties agreeing with the suggestions with sufficient explanations.

*All the comments raised by the reviewers have been addressed in the manuscript and explained in the accompanying cover letter.*

ii. Additional queries:

- The conclusion in the abstract should contain the implications of the findings and not a repeat of the findings.

*The conclusion has been amended to include the implications of the study findings*

- What is the Tanzanian pattern of newborn mortality that would justify a community-based intervention?

*We have added detail to the introduction to illustrate the pattern of mortality globally, and to the methods (study design and area) to illustrate the use of health facilities before, during and after child birth in the study area.*

- Was any effort made to prevent "spill-over" effects between the intervention and comparison areas?

*This was not considered to be a major problem for the study area, given the relatively large cluster sizes and mode of recruitment to the intervention (through village antenatal registers), and the receipt of the intervention (using the clearer definition of receipt of the intervention) was found to be minimal in comparison areas.*

- How was counseling done? What was the mode of fact-delivery?

*More details about the mode of counselling have been added to the methods (design and implementation of the community intervention).*

- Retention of information after counseling is often reported a major challenge. How was retention of information ensured in this study? What information did the counseling card contain? Why was the counseling card left behind? Was the doll left behind?
Further details on the content and reasons for leaving the counselling card – which include to aid message retention - have been added to the methods (design and implementation of the community intervention). The use of the doll has also been clarified.

-The description of data collection given in the manuscript assumed that, all the women aged 13-49 years at the time of interview, who delivered a baby the previous year must had been counseled during pregnancy and/or after child birth. Is that universally correct? How was counseling carried out the previous year - one-on-one interaction or group discussion within each enumerated household?

Details about the counselling process have been added to the methods. For example, the counselling intervention strategy was intended to reach all women who had given birth in the previous year in intervention areas, and the evaluation was intended to estimate the coverage of counselling. Counselling was carried out in the women’s homes. The main focus was one-on-one interaction with the woman but some discussion with others was also involved, bringing in those making decisions about newborn care behaviours, including fathers and mothers-in-law. The description of the sampling and data collection steps have been amended to clarify eligible participants and what they were asked.

-WHY was the emphasis in this study on the first three days of life?

The majority of newborn deaths are in the first few days of life. In addition, evidence of the impact of early postnatal visits has been added to the introduction, and highlighted again in the discussion.

-Were there exclusion criteria? For example, were there situations in which some mothers were not available for the counseling during pregnancy but were available for counseling after child birth? If there were, how were such situations handled?

There were no exclusion criteria for pregnant women in communities. Details about how delayed or missed visits have been added to the methods (design and implementation of community intervention).

-Did all the respondents receive all the planned three visits during pregnancy and two visits after childbirth? Or were there attritions? It will be interesting to see data analysis done in line with the quantity of counseling received. For instance, what were the pre-lacteal feeding rates among mothers who received only one counseling compared to mothers who got all the five scheduled counseling sessions?

More details on the number of pregnancy and postnatal visits received have been added to the results. It would be interesting to compare the behaviour change between level of receipt of the intervention. However, this study is underpowered to conduct such analysis and in addition the
interpretation of the analysis would be subject to issues of recall bias. Our paper has focussed on an intention-to-treat approach.

Why did 11% and 4% of respondents in the non-intervention areas receive counseling? Were they supposed to receive counseling as well?

These figures have been updated using a more specific definition (the definition of ‘receipt of counselling’ was too vague in the original analysis and has been changed to include reporting receiving a visit by a counsellor and use of the study counselling materials during pregnancy or the neonatal period) and reasons for receiving counselling suggested in the discussion.

Issues for discussion: if there were spill-over effects, to what extent did that affect the interpretation of the findings in the study? Why was the coverage of postnatal visits remarkable lower than the coverage during pregnancy? Was this taken into consideration during evaluation? What were the limitations of the study?

These aspects have been further elaborated in the discussion following similar comments by the reviewers.