Author's response to reviews

Title: Effectiveness of an integrated approach to reduce perinatal mortality: Recent experiences from Matlab, Bangladesh

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Author's response to reviews: see over
Date: November 4, 2011

The editor,
BMC Public Health

RE: MS: 1384514280585203

Dear Sir
We were very pleased for providing us the opportunity to submit the revised version of our
manuscript titled “Effectiveness of an integrated approach to reduce perinatal mortality: Recent experiences from Matlab, Bangladesh”.

Please find attached the revised version of the manuscript (a copy highlighted the changes and a clean copy). Also, comments in the decision letter and in the two reviews and our responses to them are given below.

All authors have read and approved the manuscript and accept full responsibility for the contents. Neither the manuscript, not any results included in the manuscript, has been submitted to any other journal that the BMC Public Health. Upon acceptance we transfer the copyright of the manuscript to your publisher.

Thanks you again for giving us the opportunity to submit the revised version.

Sincerely,

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Manuscript title: **Effectiveness of an integrated approach to reduce perinatal mortality: Recent experiences from Matlab, Bangladesh**

We were very pleased for giving the opportunity to submit the revised version of our paper. Here we list the comments in the editor’s letter and in the two reviews, and our responses to them.

**Comments in the editor’s letter and our responses**

1. Please provide the full name of the ethics committee within their ms.
   **Response:** The full name of the ethics committee is Ethical Review Committee of icddr,b.

2. Title page: This should contain; Title, Author list, Affiliations (department names, institution name, street name, city, zip code, country), email addresses. The author list and email addresses must be identical in the manuscript file and on the submission system, and it must be clear which affiliation pertains to each author.
   **Response:** We have revised the title page accordingly.

3. Competing interests: Please include a 'Competing interests' section after the Conclusions. If there are none to declare, please write 'The authors declare that they have no competing interests'.
   **Response:** We have added the text as instructed.

4. Authors' information: Please place the Authors' Contributions section after Competing interests.
   **Response:** We have done accordingly.

5- 8. Formatting of Tables and Figures
   **Response:** We have checked and formatted tables and figures as per advice. Also, we excluded figures from text.
Reviewer 1.

1. Provide examples of some perinatal mortality remains a major public health concern in low- and middle income countries in which perinatal mortality is a public health challenge.
   
   Response: We have added additional references as suggested (page 4, 26).

2. If the women were illiterate who gave informed consent on their behalf? Please specify (All women gave written informed consent prior to enrollment in the study).
   
   Response: Thanks for identifying this oversight. In fact, all women from the icddr,b service area gave consent for participation in the MNCH study. However, for women who were illiterate, we took the left-thumb impression. In addition we also used routine data collected by the ongoing Health and Demographic Surveillance System (HDSS). These routine data include demographic information as well as selected morbidities of women and under-five children. This has been corrected in the text (page 15).

3. Antenatal care coverage was significantly associated with perinatal mortality in the icddr,b SA but not in the government SA (Table 4). Please clarify the reasons for this?
   
   Response: This is probably reflected by the absence of evidence-based interventions within the ANC package. Also, lack of quality of services offered in different levels of health system and absence of efficient referral chain may explain the lack of effect of ANC in government service area. We added additional text to clarify this (page 20, 21).

4. Conclusion needs to be more specific and what additional recommendations do the authors suggest?
   
   Response: We have now revised the text (page 24).
Reviewer 2

1. Study site.

The areas of study are next to each other which raise the issue of ‘contamination’. To what extend the non-intervention area is not contaminated partially by the intervention? It is likely that some level of diffusion would have taken place. To address this, it will be suitable to look at change in indicators tracked in neighboring Upazilas (districts) to the intervention area.

Response: Thanks for mentioning this issue. It is expected that there will be some transfer of knowledge due to extensive intervention taking place in the icddr,b area. This diffusion of knowledge is expected to have reduced perinatal mortality in the government service area. However we did not observe any difference in perinatal mortality between the two time periods in the government SA. We further tested this by dividing the study area by geographical location (north and south), and observed a similar pattern of perinatal mortality over the years (page 14, 17). All these findings indicate that even though knowledge transfer might occur between the areas, this did not play any role in the final outcome. Also, it is important to note that the Matlab HDSS only covers half of the Matlab Upazila. Therefore, in the present study, there is in no scope to track similar changes in the neighboring Upazilas.

2. Study design.

The study is referred to as quasi-experimental. In order to use the term ‘quasi-experimental’ we will need to ensure we have enough comparability of settings at baseline, especially with regards to end points indicators. This is not the case with this study where we have serious differences at baseline between intervention and non-interventions areas with regards antenatal care, institutional delivery, and access and uptake of comprehensive emergency obstetric care (c-sections). We recognize human populations are not laboratories and thus comparability will always be difficult to achieved; however, just like a factor that will be studied cannot be used during randomization, it would not rigorous to compare two settings using indicators for which both are significantly different at baseline. In this study the intervention area is disproportionately better off compared to the non-intervention area: 37% had more than 3 ANC visits compared to 13.4% (nearly threefold); 54.7% deliver in facility compared to 13.4% (more than threefold); cesarean rates is 7.8% compared to 5.3% (nearly 50% increase); This suggest that other conditions and context specific factors are already contributing to maternal and newborn outcomes regardless of any new intervention.

Response: We recognize the concern. It is right that the groups are not strictly comparable due to substantial differences at baseline on process indicators those are strongly related with final outcomes. Therefore, we primarily evaluated the intervention based on before-after study design in the icddr,b service area. However, to support the findings we also exploited the available information collected by HDSS in the government services area and used this as the comparison area. We believe that three separate observations: (1) the historical data from icddr,b area before intervention, (2) the pre-post changes in the icddr,b area, and (3) the difference-of-differences analysis that compares changes with the government service area support our claim about effectiveness of the intervention. Nonetheless, we have avoided the term ‘quasi-experimental’ and added new text to inform the readers more about the weaknesses of the present study (page 2, 7, 17, 19).
3. Analysis method.
We suggest authors use an ecological design (with upazilas or sub-upazilas as unit of analysis) with multiple comparison areas, historical change, and difference of difference to assess any added value of the intervention. Alternatively, the authors will need to consider more complex analysis such as propensity score adjustment, propensity score matching, instrument variable etc. to adjust for the significant differences at baseline. Without either of the suggested way forward analysis performed cannot accurately support the conclusion reported.

Response: As suggested, we have now divided the study into more areas by geographical importance. We divided the icddr,b and government service area into two: the south and the north. We also analyzed the historical change and pre-post difference of the outcome (pate 17). However, the pattern of perinatal mortality was similar as we observed when analyses were limited to whole area. We restricted ourselves to perform the propensity score adjustment –as we believe that ANC, delivery rate, caesarian section rate are within the potential pathways between cause (here MNCH intervention) and effect relationship (perinatal mortality).

4. Indicators
It is very surprising that there is no reference to maternal deaths (absent from the list of outcomes) given maternal and perinatal mortality are interlinked, and given community health workers would enquire about authors outcome of the pregnancy, the newborn, and nothing on whether or not the woman was alive or not. No maternal mortality is expected for comparison purposes, but given this is a demographic surveillance system area, and given the intervention is using community health workers, we should be able to indicate over the observation period the number of maternal deaths in intervention and non-intervention areas. This is important to build the case of the likelihood of success attributable to the intervention. In order words, without a proper design and comparable settings we need a compelling story about outcomes about the mothers and babies.

Response: The number of maternal deaths was similar in both intervention and non-intervention areas (9 vs. 10, respectively). However, we did observe a decrease in the number of maternal deaths following the end of intervention in the icddr,b area. As the number of maternal deaths is small, we decided to wait for another two years of data collection by HDSS and then report findings in a separate manuscript.

5. Results
One can see clearly from Figure 2 that perinatal mortality started to decrease significantly before the intervention in 2007 (nearly 20% decrease from 2006 to 2007) and continue throughout 2009. The discussions need to explain this initial important decrease even before the intervention package. Also, it is only in the discussion section that we have details about demand –side financing initiated in 2008 in government SA only, and lump sum for c-section performed. It is important to map out all interventions in both intervention and non-intervention areas at baseline so that we can disentangle added value of components.
Response: The initial reduction of perinatal mortality in 2007, immediate after initiation of the interventions, reflected the improvement of knowledge and skills of health care providers and the interventions already in place at facility levels in a short period of time. We have added new text to address this (page 16).

6. Limitations
Response: We have now added additional text and also added the reference as suggested (page 19, 28).

7. Ethical issues
Stating that the study design ensures ‘equity in service coverage’ is not accurate and should be removed from the manuscript. The intervention area did not receive a single service for which we did not know the effectiveness in advance. Even what is referred to as ‘package’ is what is desired for all women worldwide, and thus it is not surprising to have a better outcome when we provide to populations all required services from a continuum of care point of view. We recommend authors just mentioned ‘the study was approved by…..’. In another hand, there may be an ethical issue if the lower fees for intervention area (icddr,b) only apply to patients from that area, as women in their pursue of quality and affordable care will travel longer distance to seek care where affordable and of quality. We recommend authors address this in the ethical session of the manuscript.
Response: We have changed the text and added new text as suggested in the ethical section (page 15).

8. Conclusion
The paper will need significant revisions with regards to description of interventions (in intervention and non-intervention area), design (include other areas and compare before and after indicators) analysis (to address unbalances at baselines), before consideration for publication. There is no added value in basically saying when we have a complete package of interventions we will have success, always this will be the case. The added value may be to convincingly demonstrate effectiveness of an intervention using appropriate design or to discuss issues of sustainability and scaling up, etc.
Response: Matlab HDSS does not collect the information other than those presented in Table 1 in the government service area. Therefore, it is not feasible to provide additional details on services provided in the government SA. However, we added new text to understand more about available services in the government service area (page 12).

Based on the reviewer’s advice, we also divided the study sites by geographic location and compared the difference before and after the intervention periods. In addition, we have changed the text to explain the weakness of the study. Furthermore, we included a detailed discussion on scalability in the manuscript (page 23, 24). We have mentioned that the model used in the study can be adopted with minimum efforts by the local health system and also
recommended that this model now should be tested in the other areas of the country so that a locally applicable model can be obtained.

The most important finding from this study is the substantial reduction of perinatal mortality within a short period of time through implementing an integrated package of interventions, even in an area with initial low rates of perinatal mortality. We respectfully disagree with the reviewer’s assertion that a complete package of interventions will always have success. Indeed, interventions often fail to accomplish their intended goals, and so the finding of reduction in perinatal mortality is not trivial.