Author's response to reviews

Title: Maternal near-miss and mortality in Sayaboury Province, Lao PDR.

Authors:

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Author's response to reviews: see over
Dear editor and expert reviewers:

Thank you very much for reviewing our manuscript entitled ‘Maternal near-miss and mortality in Sayaboury Province, Lao PDR’.
We have already modified our manuscript according to your comments and suggestions. The changes in the text have been noted in yellow highlight. Our responses to individual reviewers are attached following this letter. On behalf of all authors, we are truly grateful for your kind re-consideration our update manuscript.

Yours sincerely,
Malinee Laopaiboon
Reviewer: Pakhee Aggarwal

Reviewer's report:
Major compulsory revisions
Methods:
1. The study period was August 2010 to September 2011, in accordance with women having their LMP between August and December 2010. A normal 40 week gestation is 9 months + 7 days. That makes someone who had their LMP on 31st Dec to be 40 weeks on 6th Oct. Add to that 42 days as per definition of follow up which makes it another 6 weeks. Plus the authors have defined term gestation up to 42 weeks, and as per the given data, about 50 women delivered beyond 42 weeks. So in reality, the follow up period should extend to end of November for the last patient who had LMP in the end of December and Delivered postdated (48 weeks at least from 31st Dec). This is a major flaw in the description of methods.

Author response:
We would like to clarify what we did. After the thesis proposal was passed, Luexay, the first author, submitted the proposal to the three ethics committees in December 2010. However, we knew that it would take a long time to get approval for PhD students from our university ethics committee. So, we decided to start the study when receiving approval from Lao Ministry of Health because it was done in Lao PDR. Therefore, early in February 2011 we recruited pregnant women having their LMP between August and December 2010. We followed up them from February – November 2011. By the end of November all women in our study were followed up to six weeks postpartum.

We have modified all related information and highlighted them both in abstract (line 9-10, page 2) and methodology (line 12 page 6).

2. The article says ‘recruited pregnant women were visited daily during the study period...’ That is far more than the WHO recommendation for antenatal care. Is this due to the study protocol or such intensive care is usually the norm in these villages? Also, what parameters were checked at each visit? Was it symptoms? Or BP? Or Urine testing?

Author response:
The recruited pregnant women were visited daily during the study period by trained village health volunteers (VHV) or traditional birth attendants (TBA). This was not antenatal care visit; they only daily visit their neighborhood pregnant women. This was routine responsibility of the VHVs and TBAs of these villages. These VHVs and TBAs asked only symptoms from the pregnant women in their villages and also and whether they had delivered their baby. A sentence was added to the manuscript to clarify this issue on line 24 page 6.
3. This was a prospective study that started even before ethical clearance for the same was approved. Is that routine where this study was carried out, as my understanding is that all studies need ethical clearance before being carried out.

**Author response:**
Actually, we started data collection in February after the ethical approval from Ministry of Health in Lao PDR. A correction was made on line 12, page 6.

4. What was the means of assessing for organ dysfunction of the various systems? This should be specified in some detail.

**Author response:**
We have modified our manuscript according to this comment on line 14-15 of page 7 for using clinical criteria assessment in the communities and line 2 of page 8 for using clinical, laboratory and management criteria assessment in the hospitals.

5. ‘, limitation of the MCH staff and facilities at the district hospitals might be the important factors that did not allow investigators to apply full WHO criteria to detect a maternal near-miss. This was due to a number of factors: (a) the laboratories at the district hospitals had a limited capacity to confirm near-miss cases; (b) the supply of donated blood was inadequate; in the four study hospitals only the provincial hospital had a blood bank, although two district hospitals did have blood stores; and (c) there was a lack of medical equipment and alternative facilities for the care of severely ill patients at the district hospitals. Only the provincial hospital had an intensive care unit. As a consequence, some cases were probably not classified as near-misses because the severity of their condition was unable to be confirmed by the existing facilities’
All of these would have inflated the statistics of maternal mortality which was not the case, so it is unlikely this lead to under reporting of near miss cases. However I do feel that the criteria for diagnosing near miss could have been made more adaptable to the situation at hand, i.e. given the limitations of lab and blood backup, and relied on the next best indirect evidence to diagnose it. More so, as it was a prospective study and the parameters for evaluating the end result could be defined.

**Author response:**
We do not agree with the reviewer in this aspect. When a hospital had limited blood available in the blood bank, the patients who needed more than 5 units of blood might receive less than 5 units. Therefore, based on WHO criteria she was not classified as maternal near miss. Regarding laboratory criteria, at district hospitals many laboratory investigations, e.g. bilirubin, lactate and pH, were not available; therefore no maternal near miss would be detected following these criteria. Hopefully, these two examples could clearly explain that maternal near miss was underestimated not inflated. We do not know whether the lack of these facilities would inflate maternal mortality or not.
Minor essential revisions

Background

1. 4th para: MHC for maternal and child health

Author response:
We have already modified MHC to be ‘MCH’ in the revised manuscript.

2. 5th para: ‘An annual reported of Sayaboury PHO 2009 showed that 39% of pregnant women delivered in the hospital and 61% at home delivered’: English needs revision: delivered at home.

Author response:
We have already modified this in the revised manuscript.

3. ‘The referral system for pregnant women is ill-equipped for the selection of appropriate options, especially when they are in danger of developing some complications.’: too wordy, the language needs to be simplified

Author response:
We have already modified this to be
‘The referral system for pregnant women was ill-equipped, especially when they were high risk for developing complications.’

Methodology

1. 243 villages and only 1200+pregnancies over 6 months: what was the population of these villages and what proportion were women?

Author response:
These are small villages with a total population of 199,238 people and only 98,164 women. We have added this sentence to the manuscript on line 15-16, page 6 for having clear information.

2. ‘confirm the diagnosis of a MNM using CRF”: what is CRF? It should be expanded at first mention.

Author response:
We have already expanded CRF to be case record form (CRF).

3. The tense of this para is sometimes present sometimes future tense. This needs revision.

Author response:
We do not see a paragraph containing present and sometime future tense. Could you kindly specify which paragraph?
4. What was the role of the authors in data collection, i.e. what was the source of the data for the authors?

**Author response:**
Supervision and monitoring.

5. The description of Table 1 in text form is too detailed, only the salient points should be mentioned in text to avoid duplication of table info. Same goes for descriptions of tables 2, 3, 6.

**Author response:**
We have modified to make it less detailed.

6. ‘They had prolonged duration of labour from the latent phase of labour to fetal expulsion for more than 12 hours in multiparous women, 45 cases and more than 24 hours in nulliparous women, 28 cases’: English needs revision.

**Author response:**
The text was revised.

7. What were the underlying medical conditions included in the study?

**Author response:**
Underlying medical conditions included heart diseases, diabetes mellitus, anemia, hyperthyroidism, etc. These conditions were added to the manuscript on line 22-23 page 10.

Discussion
1. From the huge difference in numbers from previous published literature, could it be that more intensive healthcare for the purposes of the study accounted for such low numbers of morbidity and mortality? Or is it because the 4 districts chosen do not accurately reflect the situation of the whole province?

**Author response:**
We did not implement any intensive healthcare for the purposes of the study. We just observed the outcomes of the exiting healthcare. The four districts represented Sayaboury province because they were randomly selected from three stratified regions of the province with differences in geography and social-economic status.
2. ‘The local co-coordinators (VHV, TBA, MCH health center staff) might have difficulties in the concept and process of MNM identification and led to miss some MNM in the communities’: English needs revision.

**Author response:**
The sentence was revised.

3. ‘Our findings show the mortality index (MI) for 15%, compare to 8.5 % in the study of Cecatti et al to evaluate WHO criteria for maternal near miss and death related to organ failure in Brazil [25]. and 12% of Thomas et al study used of organ-failure based criteria for maternal near miss in Southern Malawi’: English needs revision.

**Author response:**
The sentence was revised.

4. ‘TBAs in the village and local coordinator at the health centers might had limited to confirm MNMs and diagnoses of organ dysfunctions at the district hospitals were limited by poorly resourced supports, such as the lack of access to good laboratory techniques and modern medical equipment, limited the supply of donated blood transfusion’: English needs revision.

**Author response:**
The sentence was revised.

**Reviewer:** Eliana Amaral

**Reviewer's report:**
All comments and suggestions are marked in a revised file attached. Some findings:

For essential revisions =
1) Few English revisions (Ex: pg 2, line 11; pg 11 line 12; pg 13 line 2; pg 15 - many lines)

**Author response:**
Thanks and they are revised.

2) Some information to clarify (E: pg 3, line 4-5; pg 5, line 12 & 14); pg 7, line 16; pg 8 line 3

**Author response:**
One sentence was added to the manuscript for clarification.
3) Delete-move text - pg 11, line 10-11

Author response:
We have deleted the sentence.

4) Discuss pg 13, line 20 - compare with literature - quality of institutional care indicator

Author response:
A phase was added for clarification.

5) Check references

Author response:
We have already modified the references based on the journal format.

6) Tables duplicated

Author response:
They were deleted.

7) Review tables formatting and titles

Author response:
They were revised.

8) Add discussion using the terminology Potentially life threatening condition x complication as presented in the Results.

Author response:
It was not the objective of this study.

Discretionary revisions =
1) Add discussion on the project design as action research - the intense surveillance may have affected positively the results! (pg 6, line 19-20)

Author response:
We did not implement any interventions in this study. We only observed the outcomes of the current healthcare services.

Reviewer: Amita Pandey

Reviewer's report:
The title of the paper could be more descriptive of its contents
Author response:
We think that the current title describe the objectives of the study.

Reviewer: Alex SR Souza

Reviewer's report:
The paper is very simple, but with most important results then may be published.

Author response:
Thank you for your suggestion.