Author's response to reviews

Title: Easier said than done!: Methodological challenges with conducting maternal death review research in Malawi

Authors:

Viva Combs Thorsen (v.c.thorsen@medisin.uio.no)
Johanne Sundby (johanne.sundby@medisin.uio.no)
Tarek Meguid (tmequiv@unam.na)
Address Malata (addressmalata@kcn.unima.mw)

Version: 3 Date: 12 April 2013

Author's response to reviews: see over
Date: Friday, 12 April 2013
To: BMC Health Research Methodology
Re: Re-submission of the manuscript

Dear Ms Arlene Pura

Thank you for the opportunity to improve and resubmit the attached manuscript, “Easier said than done!: Methodological challenges with conducting maternal death review research in Malawi” (MS: 5908942368535994) for consideration for publication in BMC Medical Research Methodology. In response to the detailed comments provided, we have made major revisions which are itemized in the next 10 pages. We believe that we have done our best to address the reviewers’ comments. Please let us know if you need anything clarified.

As stated earlier, this manuscript has not been previously published. Nor is it currently under review elsewhere. The research herein adheres to basic ethical considerations for the protection of human participants in research. There are no real or potential conflicts of interest related to the manuscript.

Lastly, all of the authors listed in the byline have consented to the byline order, and have agreed to the submission of the manuscript in its current form.

Thank you for the consideration!

Sincerely,

Viva C. Thorsen, MPhil
Tarek Meguid, MD
Address Malata, PhD
Johanne Sundby, MD
Reviewer's report

Title: Easier said than done!: Methodological challenges with conducting maternal death review research in Malawi
Version: 2 Date: 17 February 2013
Reviewer: Jody Lori

Reviewer's report:

Major Compulsory Revisions

Thank you for the opportunity to review the manuscript entitled: Easier said than done!: Methodological challenges with conducting maternal death review research in Malawi.

While this is important information that would be of interest to the readership of BMC: Medical Research Methodology, it needs significant revisions before it is a publishable scholarly article.

Background: There is more current information available on the number of maternal deaths worldwide. The authors cite WHO, 2008. The Trends in Maternal Mortality, published by WHO, UNFPA and others in 2012 should be used.

Response: we have revised it accordingly (page 4).

This sentence needs re-wording. There is misspelling (observations) and the sentence does not make sense. “They conducted participant observations and in-depth interviews with 23 healthcare workers and managers and found out that audit sessions were held only when the head of department of obstetrics and gynaecology was available, participants have inadequate knowledge of the purpose of audits.”

Response: it has been revised as follows, ‘They conducted participant observations and in-depth interviews with 23 healthcare workers who reported that audit sessions were only convened when the head of department of obstetrics and gynecology was available.’ (page 5).

Methods: The methods section needs more detail. Was this a secondary analysis of data collected by another group? The authors state: “The methodology and findings for the study upon which this paper is based have been described in detail elsewhere.” But do not cite a reference for the primary data. It is not clear to the reader at all what methodology was used other than participant observation at 4 audit meetings.

Response: The methodology section has been revised and a citation has been included (pages 6-8).

Findings and Discussion: The manuscript is poorly organized. The authors jump from the methods to the findings and discussion, yet they discuss some of the data analysis in the finding section. This should be re-written in a more acceptable style. There is no detail about how the data (and it is not clear what those data looked like) were analyzed.

Response: The methodology section has been revised to include more information on how data were analyzed (page 8). The reason some of the data analysis is discussed in the findings section is because the third step in the 5-step maternal death surveillance cycle deals with reviewing cases and analyzing the data. Therefore findings were related to the challenges for this
step. The findings and discussion sections for this step, and all the other steps, are now separated (pages 16 and 17, and 24-28).

Data Collection: The data collection section (under findings and discussion) seems to say there was primary data collection involved. Please make this clear for the reader.
Response: The paper is based on primary data that were collected by the first author and two research assistants (bottom of page 7, and top of page 8).

Chart review/extraction: Was a standardized form used for chart review? What data was attempted to be retrieved? It would be helpful for the reader to know this. The authors state: “Furthermore there may be disagreement between data collectors reviewing the same chart (intragroup reliability) or one data collector reviewing the same chart twice (intrarater reliability).” How was this handled?
Response: A standardized medical extraction form was adapted from the WHO guidelines: Beyond the numbers reviewing maternal deaths and complications to make pregnancy safer. A brief list of what was attempted to be retrieved is provided (page 7). The statement was a general statement that has now been taken out but is reflected in the following statement, ‘The first author regularly met with the two assistants to assess the progress and quality of their extractions, as well as double checking her own entries.’ Found at the end of the chart extraction section page 11).

Again the authors state: “In summary, with the medical record, and more specifically the information documented therein, being poorly maintained and marred with errors, omissions, and idiosyncrasies it has been deemed an unreliable source”. For this study or in general?
Response: This was a general statement. It has since been revised and moved to the discussion section and reads, “In summary, even though the information documented within the medical records have been characterized in the literature and through our observations as being poorly maintained and marred with errors, omissions, and idiosyncrasies [26,30,31] the data extractors were still able collect some valuable data and triangulate it with the other information to glean a better picture of what did or did not occur.” (page 20).

Facility Based Interviews: How was informed consent obtained for the interviews? A description of this is needed.
Response: Written consent was obtained and is now stated as such (page 11). We do not think a description of how it was obtained is needed.

The authors state: “Lastly, in a couple of the cases where the circumstances surrounding the deaths were very controversial some participants actually omitted key information, or gave misleading information.” How do they know this?
Response: We know this through interviewing more than one healthcare worker and interviewing family members for the controversial cases in question. We triangulated the transcripts.

“The situation posed a dilemma for us because we had to decide whether to probe until the true accounts of the event were revealed or to respect
participants’ rights to decide on what information to divulge. In these instances more than one healthcare worker were interviewed to ensure greater accuracy."

If the authors already knew the answer way were they asking the question?

Response: It was not that we already knew the answer. It emerged due to interviewing more than one healthcare worker and corroborating or refuting the story via the family members’ accounts.

“...distance travelled from point A to B to C, etc was difficult to determine as well.” Remove etc.

Response: Done.

The authors state: “Another related problem was with the recording device itself. At one point it was inoperable so the voice recorders on the mobile phone and laptop computer were used, while the research assistant took as detailed notes as possible. Because most interviews took place outside, there was a lot of background interference. The wind howled frequently so voices were cancelled out. In those instances field and debriefing notes supplemented the transcripts.” This should be under a Limitations Section.

Response: This was a technical problem, and not necessarily a methodological challenge. It occurred during the data collection phase (during interviews). We do not believe a limitations section should be added.

Traditional Birth Attendants: Again the authors make many suppositions: “Based on fear or skepticism our motives, two of the TBAs were not as forthcoming about the degrees to which they assisted the women, e.g. whether they delivered the baby, the placenta, or only gave advice.” “(or perhaps selective memory)” should be removed.

Response: Done.

Language barrier: More detail is required in this section. How were translators identified? Were forms back translated for accuracy? What was the background of the translators used in the field for oral translation?

Response: Both were referred due to their previous work. The questionnaires were back translated due to the College of Medicine Research Ethics Committee (COMREC) requiring that they be revised. Two Malawian researchers reviewed each question, translated it into English and corrected the Malawian translation if it was not correct. The revised versions of the questionnaires were then approved by COMREC. A brief description of the data collectors and a summary table of the data collectors (and the participants’) characteristics have been included (bottom of page 7 and Table 1, page 35, respectively).

The authors should tell the reader how many people were interviewed, describing the demographics of the participants to give some context to the results.

Response: The numbers are given in the methodology section (page 7) and a summary table of characteristics included (Table 1, page 35).

Reviewing cases and analyzing data: “The main outcomes of this step are the medical, or pathophysiologic, causes of death, with their being either direct and indirect;” This sentence is grammatically incorrect.
Response: it has been corrected and reads, ‘The primary outcomes of this step are the medical causes of death which are either direct or indirect; and a maternal death epidemiologic profile based on reproductive characteristics that describe the magnitude and distribution of the maternal death problem in a specified time period.’ (page 16).

Causes of death and International Classification of Diseases: This is all interesting information but it needs to be tied to the study. There is no clear link made by the authors. I would delete everything down to the paragraph starting with “The International Classification of Diseases tenth version (ICD-10) was used…” and then talk about the results from this study and not “cases” in general. This only serves to distract the reader.

Response: this information has been moved to the discussion section (pages 24-28). For the findings section, we highlight the varying classifications (comparing the reported causes of death and those of the independent reviewers, pages 16 and 17). We also include a summary table (Table 2, pages 36 - 38).

Synthesizing the findings: If the three delay model is going to be used to synthesize the findings this should be talked about in the methods section and not near the end of the manuscript. When describing the results using this model – give the reader the accurate numbers instead of “some” or “commonest” or “very few”.

Response: we have taken the actual findings out and just discussed how we have expanded on it. For concrete numbers related to the 3-Delays Model we refer you to the published article upon which the current paper is based: Combs Thorsen V, Sundby J, Malata A: Piecing together the maternal death puzzle through narratives: The Three Delays Model revisited. *PLoS ONE* 2012, 7: e52090.

Health system perspective: This section can be deleted as well. It does not add value to the manuscript and is not developed enough.

Response: We agree; we have deleted this section.

Recommendations: Are the authors making general recommendations or specifically for this institution? Again, the authors refer to other publications with no citations.

Response: Firstly, providing recommendations is the 4th step of the maternal death surveillance cycle. This step is discussed in the findings and discussion sections (pages 18 and 28, respectively) Recommendations for researchers conducting similar research are provided at the end each step in the discussion section. Also recommendations have been summarized in a table for the two facilities where the study took place (Table 3, page 39).
Reviewer's report
Title: Easier said than done!: Methodological challenges with conducting maternal death review research in Malawi
Version: 2 Date: 25 February 2013
Reviewer: Sue Fawcus

Reviewer's report:
The paper was an interesting description of methodological problems encountered during a maternal death enquiry of 32 maternal deaths in a hospital in Malawi.

It was a very small series in which causes of death, avoidable factors and actions were identified for these deaths using the enquiry process. These results are published elsewhere. The current paper focusses on methodological problems encountered at each stage of the audit cycle. The authors describe many challenges which are well known to those performing audit in low resource settings and have been described in a previous audit performed in Malawi by E. Kongnyuy and published in your journal in 2008. The topic is therefore not original.

Response: The pool of researchers conducting maternal death research is dynamic, and growing, especially as the 2015 deadline for the Millennium Development Goals (MDGs) draws nigh. And as such not all who should know about the potential challenges do. We agree that the topic is not original, however, we place more emphasis on the steps prescribed to carry out such investigations and highlight challenges along the way. Other studies have discussed the challenges in general or focus mostly on the challenges with implementing the recommendations.

In addition the 2008 paper presents a SWOT analysis which is a much more comprehensive and balanced assessment of the audit process. However the in depth literature review in the paper under review which accompanies the description of problems encountered at each stage of the audit process is particularly informative and relevant for health professionals performing audit in these settings.

However there are several problems with the presentation of material and severe limitations of the recommendations and conclusions which are described below and mean that the paper needs considerable reworking (MAJOR REVISION) before it could be published.

1. Clear Aims and Objectives of this paper are not stated and could potentially be confused with the aim of the primary study of a maternal mortality audit. Response: the last paragraph on page 6 starts with, ‘the main objective of this paper…’ Though we believe it was stated clearly there, we have added another sentence at the end of the methodology section to reiterate what the aim of the paper is (page 8).

2. There is no mention of the Methodology used to evaluate the audit process. The paper provides a descriptive list of problems but does not indicate from what data source these observations were obtained; from record review, from observation at audit meetings etc. Were checklists used to evaluate the process? Also, were any aspects of the process thought to have been useful or have been done well, and / or did the problems described relate to all the cases
investigated.

Response: This is a critical reflection paper which means we reflected upon the work—the process of conducting the research—and critically thought about how one could do it better, avoid potential pitfalls in the future, and provided recommendations. The 5-step maternal death surveillance cycle served as a framework for the discussion. The entire process was deemed useful, which is now conveyed in the conclusion section (page 29).

3. The section on Findings and Discussion mixes up the actual descriptive observations of the study with a literature review and discussion. It would be less confusing if the findings and observations are first described and then the literature review is used to expand further on the problems described in a Discussion section.

Response: we have now separated the findings and discussion sections (9-18 and 19-28, respectively).

4. The literature cited on each stage of the audit cycle is interesting and informative. In particular the section on ICD 10 codes and classification of cause of death, underlying factors and final cause of death have been issues for the South African Confidential Enquiry into Maternal Deaths and have been partly addressed in the new ICD 10 adaptation by WHO for classification of maternal deaths.

Response: Thank you. We have now moved the section on ICD 10 codes and classification of cause of death to the discussion section. Was there more you wanted us to do with that section?

5. If the study aims to review methodological issues associated with the audit cycle, it would be expected that it would be more than a list of problems but present a more balanced list of the components which were valuable as well as those that were problematic.

Response: this was a critical reflection where we deliberately wanted to highlight the challenges. We have in fact included some recommendations as well.

6. The conclusions and recommendations were disappointing. The conclusion stated was that the first and third delay were the problems that would need to be addressed in order to reduce maternal deaths. However this would be the conclusion of the primary study - the maternal mortality audit. The current study aimed to evaluate methodological issues so its conclusions and recommendations should have been of a different nature.

Response: We agree and as such have modified the conclusion section.

After the detailed description of methodological challenges with supporting literature, it was expected that the authors would provide thoughtful discussion and a critique of the implications of their findings. Do they indicate fundamental and inherent problems with the audit process or do they represent problems for which the challenges can be overcome by specific interventions. If so, what interventions could be suggested to overcome the problems encountered with the audit process. There is literature available which describes more successful audit processes in low resource settings such as Zimbabwe and in some of the
Response: The findings and discussion sections have been separated and significantly revised (9-18 and 19-28, respectively). We believe that the discussion section now goes deeper. We also provide suggestions on what could be done to overcome the problems encountered and a summary table of implications for the health facility (Table 3, page 39).

In summary, the description of challenges with supporting literature is useful and informative for low resource settings. However it does not add significantly to the other paper published from Malawi which also addressed the challenges of maternal death review. If published, the article needs to be considerably reorganized and reworked. The findings should be used to give more of balance sheet of the audit process and what can be recommended for others to overcome the methodological problems.'

Response: We strongly disagree with the reviewer’s statement that the paper “does not add significantly to the other paper published from Malawi which also addressed the challenges of maternal death review.” The other paper focused heavily on implementing the recommendations that resulted from the audit while our paper goes through each step of the process and provide more details on how to overcome the challenges. Both the research side and the program side are discussed. What is more, the literature that supports the discussion of the challenges is very informative and useful.

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Reviewer's report
Title: Easier said than done!: Methodological challenges with conducting maternal death review research in Malawi
Version: 2 Date: 18 February 2013
Reviewer: Catherine Pirkle

Reviewer's report:
- Major Compulsory Revisions
This paper brings up a number of important obstacles to conducting maternal death review (MDR) in a resource-limited setting and could be informative to others attempting MDR in the future. However, as written, the paper is not in a publishable form. My biggest criticism of the paper is that it is overly vague. This is particularly true of the methods section, which needs substantial expansion. In regards to the methods section of this paper, the authors do not provide enough information for the reader to judge if the MDR performed in this setting was rigorous and adequate. They state that the methodology and findings upon which this study were based have been described in detail elsewhere, but they do not provide any references. Much more detail is needed about the MDR process employed in this study in order for the reader to judge if the criticisms about the MDR process are legitimate or rather, reflect poorly conducted MDRs.

Response: We agree and have revised the methodology section and have included the citation for further details (pages 6-8).

For example, it is unclear in this paper whether the authors are describing
facility-based audits, community audits, or a combination of both. They do not mention who performed interviews with healthcare staff, family members, etc. (middle of the paragraph on page 7). They mention that the causes and characteristics of maternal deaths were assessed by descriptive analysis but do not define what descriptive analysis is. From their description, it is unclear if this study was conducted at one health structure or several. We do not know what kind of health structure was involved (rural or urban, university, regional, district, health post). No description of context is provided. Moreover, we do not know what preliminary steps were taken to prepare medical professionals for the MDR process, including arriving at a mutually understood definition of maternal mortality and the main obstetrical complications that lead to a maternal death; establishment of an audit team and the composition of that team; how data collectors were select, who were the data collectors, and what training they received, etc. No information is given on how data from the audit process were collected, such as whether standardized data collection forms were used. We highly recommend that the authors return to key publications on maternal death review, such as Beyond the Numbers (which they cite), and structure their methods according to the guidelines mentioned in such works. If they did adhere to the WHO recommendations on how to conduct MDR, a detailed explanation of why their methods differed is needed.

Response: All of the issues that the reviewer raised have now been addressed (pages 6-8).

For the results, the authors present a laundry list of problems encountered while conducting MDR. However, they do not provide enough information for the reader to judge just how serious these problems were, describe what they did to manage these problems, nor provide possible solutions. For example, they state on page 8 that the number of maternal deaths reported in the sources varied and presume that maternal deaths were underestimated. However, they do not provide numbers that allow the reader to judge just how varied the numbers of recorded maternal deaths were. Was one source of data better than another? Finally, I struggle to understand why the authors would presume that the admission registry, the delivery room registry, and the operating theatre registry would all record the same numbers of maternal deaths, as not every case of maternal death would be sent to the surgical theatre, for example. Similarly, the authors state on page 9, “in some instances the charts themselves were missing.” Approximately 18% of medical charts were missing, but the authors do not state what steps they took to locate the records and whether or not these records were missing at random or in a systematic fashion. They complain about the use of abbreviations in the medical charts. However, most medical staff understands common abbreviations and it is easy enough to create a lexicon of these terms for audit staff to refer back to. There are many more examples of issues encountered where the authors do not provide enough information for the reader to judge the seriousness of the problem and what steps audits teams can take to deal with those problem. The authors may want to consider adding a table that lists difficulties, provide a judgement on the seriousness of the issue (with an explanation), and offer solutions. In any respect, the authors need to closely consider each obstacle described and ask themselves, is this problem insurmountable, how serious was it, and what can be done about it. For many of these problems, I suspect that the MDR process itself was not well conducted.
and the problem would have been entirely avoided had the MDR been better carried out.

Response: Most of the issues raised by the reviewer have now been addressed (pages 9-18). We did not include “a table that lists difficulties, provide a judgement on the seriousness of the issue (with an explanation), and offer solutions”. However, we have discussed the challenges and what we did to remedy them, and in the discussion section we included recommendations for the respective challenge (pages 19-28).

We can see how the reviewer could surmise “that the MDR process itself was not well conducted and the problem would have been entirely avoided had the MDR been better carried out”. However, this is incorrect. The MDR process was conducted in a systematic, thorough manner, but it just was not conveyed in writing adequately. We have now made major revisions to the entire paper to accurately reflect what was and was not done.

Finally, I do not understand the point of the Recommendations section and would suggest removing it all together as there are almost no recommendation in that section. The paper could also use a good edit.

Response: The 4th step of the maternal death surveillance cycle is Recommendations. In the findings section we simply present what type of recommendations were provided and to whom. In the discussion section we discuss what the potential challenge might be and included supportive literature. In addition to this, for each step discussed in the discussion section we have now included recommendations on how to avoid the challenges in the future (pages 18-28). Moreover we have included a summary table of recommendations for the facilities where the study was conducted (Table 3, page 39).

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Reviewer’s report

**Title:** Easier said than done!: Methodological challenges with conducting maternal death review research in Malawi  
**Version:** 2  
**Date:** 25 February 2013  
**Reviewer:** Sally SR Rankin  
**Reviewer’s report:**  
This manuscript is an important addition to the literature on maternal death reviews. It is a readable, thoughtful and helpful piece. The manuscript is well organized and the use of the mortality surveillance cycle provides a clear and useful framework.

My primary concerns requiring revision are:

1) The size of the sample is unclear; the authors make reference to 43 cases but then point out the problems with many of these cases.  
Response: The sample from which eligible cases were purposively selected has now been included (end of identification of cases section, page 9).
2) I am unclear why the size of the sample is so small since the maternal mortality rate in Malawi is relatively high. This needs to be addressed by the authors.

Response: what we had provided was just the number and not the rate. The institutional maternal mortality rate of 715 per 100,000 for the 6-month period has now been included (end of identification of cases section, page 9). The maternal death number itself may seem small because we’ve selected cases from only two CEmOC facilities, not the entire country; it’s for six months, not an entire year (or number of years); lastly maternal deaths at these two facilities have in fact declined while the number of live births have increased which may help explain our small sample size.

3) Because the sample was so small some of the recommendations are inappropriate, especially the recommendation that there should be greater focus on skilled birth attendants. This is especially relevant in light of Malawi’s frequently changing recommendations and support for traditional birth attendants.

Response: The recommendation was based on the fact that this was a facility-based study. When the data were synthesized based on the three-delays model the majority of the cases experienced a mishap when they had reached the hospital. The verbal autopsy component of the study was a supplementary piece. Had the study setting been the community from the outset, then the recommendations would certainly have focused more on the issues there, such as the TBAs (but our study only involved four TBAs).

4) Some of the references are very outdated, i.e., 1951, 1982. There are many newer books on diagnosis. Additionally, we usually refer to differential diagnosis rather than medical diagnosis.

Response: Some of the outdated references were kept to illustrate how old the facility-based maternal death review approach it, while the Thaddeus and Maine citation is kept because their framework guided the synthesis process. The other outdated references have been replaced with more current ones. The term medical diagnosis has been replaced with differential diagnosis.

Minor essential revisions:
5) There are a number of spelling errors as well as incorrect choice of words but these are easily remedied. I would recommend that the primary author obtain an editor whose first language is English.

Response: We agree. The grammatical and spelling errors have been corrected. The first author is in fact a native English speaker, an American who has been living in Norway for the last eight years. With that said, we have used an editor to proof this version of the manuscript.