Author's response to reviews

Title: A population-based surveillance study on severe acute maternal morbidity (near-miss) and adverse perinatal outcomes in Campinas, Brazil: The Vigimoma Project.

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Answer letter for the Reviewer’s Report

We are very grateful for your comments which we believe helped improve the manuscript. See below answers to clarify some doubts and suggestions.

Reviewer # 3: Edward Fottrell

Minor essential revisions:

1) A little more context and a more detailed description of the study setting may be useful for the reader – for example, total population size, fertility rate / births per year and a brief description of health services in Campinas or Brazil as a whole... In relation to this, it would be useful to know whether deliveries outside of the included hospitals (e.g. in private institutions or at home) were excluded, in which case the claim that the study is population based and investigated all cases of NM, MD, FD and END in Campinas is likely to overstate the reach of the study and should be toned down. It would be desirable to quantify the proportion of deliveries that are hospital based in Campinas rather than state that “nearly all” are hospital based. If this is the 98% referred to in the Population and Methods section, a description of how this figure was derived or a reference is necessary.

Answer: Data on population, fertility rate, hospital-based deliveries (99.7%) were provided on Introduction and Methods sections. Data is available from the PNDS (DHS) and Tabnet system, from DataSUS-Ministry of Health, and the corresponding references were included.

2) Justification for the differing methodological approaches applied in the three largest hospitals (prospective case seeking) and the remaining six hospitals (retrospective record review) should be provided and a discussion of the strengths and weaknesses of these differing approaches based on the authors’ experiences would be interesting and useful to others wanting to implement similar systems.

Answer: The use of different methodological approaches for the largest and the smaller hospitals was necessary because these six hospitals totalize a reduced number of cases, and it was not worth the team supported by the grant provided could not have a little number of cases and we needed time to identify many cases in principal hospitals.

4) Likewise, a more detailed description of the composition of the maternal health committees would be useful.

Answer: Information on general composition of committees was also provided at the final paragraph on Introduction.

5) Some reflection on the quality, completeness and timeliness of records in the study hospitals is necessary to assess the quality of data used in the study. In relation to this, a brief discussion of the extent to which the auditing system proposed by the authors depends on high quality records would be useful.

Answer: The quality of clinical records varied according to the institution, particularly university (two) with non-university hospitals. Detailed description of major variables with lacking information will be the focus for another paper aiming to discuss the auditing system with more details. The feasibility of the process can now be discussed with support from recent published
data on other auditing near miss experiences, not available when the project was written and implemented.

The major limitation was the lack of registered information from antenatal care, usually recorded in antenatal cards that are kept with the delivering women. For ethical reasons, and according to terms of ethical approval, the project assistants were not allowed to interview the mothers, or to ask for their antenatal cards. Some cards were available because were kept with the clinical records and were copied for future discussions at the committees. Discussing the cases, it was a recurrent observation and a matter of concern. Information available at the pediatric/neonatologist clinical notes on antenatal care has been helpful. Nevertheless, the intervention proved to be useful and rewarding for the participants (pending publication from some qualitative data) with the data available.

6) Meaning of the paragraph on page 10 “Adverse prenatal events…”

**Answer:** The addition of further explanation on the characteristics of hospitals at Methods section may have clarified the content of the paragraph.

7) Page 13, last paragraph – “Nederland” should read “The Netherlands”.

**Answer:** Apologies for such a mistaken spelling.

**Discretionary revisions**

8) Some discussion of the fact that, based on the audit results and committee reviews, only about one third of adverse events were considered to be preventable by intervention would be appropriate. If this refers only to medical interventions then this should be clearly stated. This is a low proportion and contradicts commonly held opinion that the majority of adverse perinatal events are preventable given sufficient health service provision, suitable behaviour and political will. Some further discussion of this relatively low level of preventability and how this might reflect biases of the committees or how it might impact on the effectiveness of the audit process as a whole would be interesting.

**Answer:** The low level of preventability may be viewed as a consequence of the challenge posed for the committees to propose interventions to qualify the care provided which could cause impact. In the revised manuscript, it is included a discussion on the impact of a category on “incidental” substandard care (Lewis 2007), meaning substandard care not considered responsible for the morbidity observed. Also there is a potential discussion on the difference on preventability when near miss cases and maternal death are compared. In our case, the inclusion of all unsuccessful events may have changed the expected high rate of preventability.

9) Other than the factors that they already describe, what infrastructure-related factors do the authors think are essential for the successful implementation of such an auditing system in other settings?

**Answer:** This topic is the focus for another paper being prepared. Besides a more spread knowledge on the advantages of using near miss, now already in place in this particular region, in Brazil and elsewhere, the integration among professional societies and health system is a key factor. The time for the discussions has to be saved for professionals. And marketing the findings (communication) using strategies translational research suggest as efficient is essential. Last but not least, there is the need to provide political and financial support for the implementation of remedy interventions.

10) It would be useful to know how causes of maternal and perinatal death were diagnosed in the study – were post-mortem examinations carried out or are the diagnoses based on clinical diagnoses and records?
Answer: Besides clinical diagnosis, there were post-mortem examinations as part of the routine care, depending on family agreement.

11) Table 3 is missing the adverse event of maternal mortality – this should be added for completeness.
   Answer: It was added as requested.

12) Tables 4 and 5 – there does not seem to be a logical order to the listing of prevention measures listed in the tables. I suggest listing them by descending mean or total scores within each category.
   Answer: Table revised as requested. We opt for presenting in descending order for total mean to highlight the potential impact of focusing on the top interventions.
Reviewer #2: Mattias Rööst

Minor Compulsory Revisions:

1) Abstract: In the objective, the study is described as an intervention. This phrasing is unfortunate as no intervention is actually done within the study. Rather, it suggests measures that could be used in future intervention studies.

The objective, as described in the introduction section, includes “to evaluate the feasibility of a shared process of confidential enquiry between the municipal, the regional committees, and the researchers as facilitators”. How this was done is not described in the methods section and the theme does not appear in the results section. Consequently, it is unclear how this objective was evaluated.

Answer: Objectives were revised on Abstract and Introduction sections: “To describe a population-based investigation on adverse perinatal events including severe acute maternal morbidity (near-miss), maternal and perinatal mortality, as a health intervention to help improve the surveillance system.” The focus on feasibility was reviewed. The intervention mentioned is the research project itself, which added near miss cases and perinatal death and another approach for discussing the preventability of cases on the routine of committees, which previously focused their activities exclusively on maternal and infant death.

2) In the methods section it is not clearly described which information was collected and how this information was collected. Were clinical records used only? Did the research include other sources of data, such as staff discussions or interviews with relatives or women with a near-miss event? This is especially relevant for the results presented in Table 6 about the first and second delay, which are generally difficult to investigate using clinical records

Answer: The data was collected from clinical records and administrative records available, with no interview or staff discussions. This information was made clearer at Methods section: “A team consisting of an obstetrical nurse and a doctor from each institute visited the wards, intensive and emergency units of the three largest maternity hospitals daily, for collecting data available on cases of adverse perinatal events from the medical and administrative records…”

The project expected to test the potential for a revising process supported by information already available. Even if we agree take more qualified information would be provided by interviews with patient, family or staff, this would request a more complex and expensive support. Nevertheless, for only 6.9% of cases the committees considered the information was insufficient to draw a conclusion on delays, meaning they recognized the time intervals adequate for seeking, reaching and/or receiving care.

3) The study uses a mix of clinical, management-based, and organ dysfunction based criteria. It would be interesting to know which criteria generated most near-miss cases. That would make it easier for the reader to compare with other studies or settings.

Answer: The study used mixed criteria, essentially drawn from Waterstone and Mantel, both relevant for the profile of cases expected when the project was delineated and implemented. The revision of the contribution of group is the objective of another manuscript on the same data being prepared. Nevertheless, from the list of interventions emerged, contribution of hypertensive disorders and inclusion of perinatal death, clinical criteria is certainly relevant.
4) As I understand the Preventability Score, it should be regarded as an ordinal

Answer: It is absolutely correct that an ordinal scale commonly request median, instead of mean for central tendency. Nevertheless, we opted for using mean due to the reduced range of the scale (up to 5), reducing its susceptibility to extreme values, and possibility of presenting standard deviation as a more informative measure for variability of the data.

5) In row 3 paragraph 1 in the Results section it is described that "maternal death comprised 1.9% of cases". However, in Table 1 the figure 2.5% is given for maternal death. As far as I can see, the latter is the correct figure

Answer: The proportion was corrected for 2.5%.

6) Page 14 second paragraph: It is not clear what the sentence "Although data was not collected, the exercise of thinking about the causal process separately ....".

Answer: The phrase was rewritten as “The exercise of thinking about the causal pathway for the unsuccessful event as a separate exercise from identifying the aspects of substandard care motivated the learning process of the group.”, hoping to made clearer. Nevertheless, the concept under the phrase is that training the group members to review the expected natural history of the disease and recognize how it applies to the case under study, before jumping into what should be better, contributed to their thinking as experts and to helped them to understand that there is also “incidental” substandard care (Lewis 2007) which may not be responsible for the outcomes.

7) The reference list should be checked.

Answer: The list has been reviewed, updated and the reference 31 (now #32) was corrected. Also reference 14 was reviewed.

8) Table 2 should be checked for consistency.

Answer: Table 2 was revised accordingly, excluding duplication of data on women which were counted as near miss/maternal death, and perinatal death.

9) There are some spelling mistakes and unclear language in the manuscript that should be corrected. For example on page 6 ..."World Health Organization has." should be changed to had. The first sentence on the third paragraph page 7 should be rewritten. Further, mixed tenses are used, for example in the result section, which is confusing.

Answer: Spelling mistakes were corrected.

10) Most of all the manuscript focuses on quality of care. The title might be improved by including this.

Answer: We preferred to avoid the use of quality of care for the title, keeping the message as a descriptive study.

11) The objective in the abstract and in the introduction could be more similar.

Answer: The same objective is now presented in both
12) Are there any other figures of for example near-miss frequencies in the region that the results of the present study can be compared with?

Answer: Many other national figures published are institution-based, from the same institutions being now described. So they were avoided. There is a recent paper published on line, showing the same figures, derived from household survey on five categories of maternal morbidity reported on previous pregnancies.

Souza JP, Cecatti JG, Parpinelli MA, Sousa MH, Lago TG, Pacagnella RG, Camargo RS. Maternal morbidity and near miss in the community: findings from the 2006 Brazilian demographic health survey. BJOG. Published online: 24/09/2010

Data from four selected hospitals Bolivia, using a mixed criteria (clinical and management) show a higher ratio (50/1,000). This manuscript was added to the reference list.

Reviewer #1: Olufemi Taiwo Oladapo

Major compulsory revision:

1) Introduction: There is a disparity between the objectives in the introductory part of the paper and that in the abstract. The ‘question’ posed in the latter part of the objectives in the last paragraph of the introduction is not well defined: "...to evaluate the feasibility of a shared process of confidential enquiry...". It appears unlikely that the researchers set out to perform a feasibility study as there is little in the Methods section to describe how this could be achieved. It looks redundant and is better deleted.

Answer: The disparity between objective stated in the abstract and the introduction, as well as comments on feasibility were reviewed. The objective was corrected as informed for Reviewer #2: “To describe a population-based investigation on adverse perinatal events including severe acute maternal morbidity (near-miss), maternal and perinatal mortality, as a health intervention to help improve the surveillance system.”

2) Results: The authors need to differentiate between the denominators used for maternal death, near miss and perinatal death rather than lump them together as adverse perinatal events. Usage of total adverse perinatal events as the denominator as performed in many instances is confusing. For instance in the second paragraph of the result, references were made to the total number of women in percentages while the denominator also included fetuses who died in utero and those that suffered early neonatal death. These corrections need to be made in the result section.

Answer: The intention was consider the unsuccessful events altogether to reduce the distance and avoid unnecessary work on considering strategies form improvement looking maternal and neonate/fetus sides in different moments, as it uses to be. Understanding it is a novel approach, we understand that using live-births as the denominator can be considered adequate for composing these proportions (Table 1)

2) Is the potential preventability scoring method validated? If not, it should be stated as such.

Answer: The scoring method has not been validated.

3) The methods used by the committee to arrive at PPS for fetuses could be questioned. Considering the cause of death described as ‘intrauterine anoxia’ for most of the cases; intrauterine anoxia has numerous causes and one wonders if the committee took all their preventability into account. The true cause of intrauterine anoxia can only be confirmed after several investigations which include that on the mother, placenta and fetal autopsy.

Answer: At the time the discussions took place, all possible information from clinical records, including post-mortem examination and placental biopsies were taken in account.

4) Tables: Table 1: Can the authors explain what they meant by and how they came about "figures expected by the project design" and its importance?

Answer: These figures were a projection for the time-frame proposed at the design phase and it was considered important to explain the “sample” selected and also the higher-than-expected ratio of severe maternal morbidity observed after data collection.

5) Table 2: Needs to be clarified; the title noted that the figures were for women involved in adverse perinatal events (n=99; NM+MD) but the figures reported came from women, dead fetuses and neonates combined e.g. 93/99 is not equal to 58.1%. In the same vein, 136 that ‘received prenatal care’ also included the fetuses and neonates. This is assuming that mothers who suffered perinatal adverse events are completely separate from fetuses and neonates who suffered the same fate. Whereas, there were women with NM or MD whose babies also died. Therefore saying 136 received prenatal care would mean the fetuses and neonates received prenatal care regardless of that received by their mothers who have already been counted. The denominator for women needs to be separated from that of fetuses and neonates.

Answer: Thanks for the question. Numbers were corrected as appropriate, excluding duplicated mothers.
5) Table 3: Maternal deaths are missing from the table

**Answer:** They were added to the table.

**Minor Essential Revisions**

6) In the text of the paper, authors should please describe the following items in detail; Vigimoma, CAISM/UNICAMP, SINASC

**Answer:** Modified accordingly, with descriptions.

7) The reference to Safe Motherhood Initiative failures in the introduction should be deleted as it is less relevant today. Too many references overall. Authors should streamline them to 20 to 25 important and recent ones. Referring to a 2003 publication (Jamtvedt et al) as recent needs to be corrected.

**Answer:** References were updated, but we were unable to reduce the number of references as requested, considered necessary to support discussions. Page 5 corrected and Jamtvedt reference updated.

8) Result, last paragraph, ‘a quarter’ should be corrected to ‘a third’ since 34% is not a quarter.

**Answer:** Paragraph revised accordingly.

9) Is ‘Puerperal haemorrhage’ meant to represent postpartum haemorrhage? Please correct where it appears in the text.

**Answer:** Text modified as requested.

10) Table 6 can described in the text and should therefore be deleted.

**Answer:** We opted for maintaining Table 6 to stress the data, particularly the most relevant delay identified – in receiving appropriate care.

11) References: there are two redundant references numbered 1 & 2 at the bottom of the reference list. Was this intentional or erroneously done? Authors should please amend as appropriate.

**Answer:** References amended as appropriate.

12) Discussion: Recommending an audit process where the loop is not yet closed may be misleading and should be done with caution. Having conducted a rigorous fact finding exercise and making recommendations based on some newly devised scores may not necessarily translate to improvement in maternal and perinatal outcomes. Such recommendation can only be backed by improvement in maternal and perinatal profile that follows implementation of the suggestions that emanate from the audit process.

**Answer:** We are fully aware and certainly agree with this caution note. Many recommended practices improved during the 5-years interval since the project was developed. It is time now to revise data and potential contribution of suggested interventions (developed as routine activity for health system managers). Another round of similar procedure closing the loop is a proposed project for 2011, pending financial support.

**Minor issues not for publication**

The paper requires significant copy-editing specifically regarding style and certain medical terms.

**Answer:** We expect major problems on style and medical terms have been overcome.

We will be waiting for your revision. Many thanks.

Eliana Amaral