Author's response to reviews

Title: Severe maternal morbidity and near miss: occurrence and associated factors in Sergipe, Northeast Brazil

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Version: 4 Date: 23 July 2013

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

Thank you for considering our paper for publication. We are very grateful for the helpful suggestions put forward by the reviewers and we have responded to each comment in this document. We have also revised the entire manuscript and believe that it has been improved significantly. We hope that you will now consider it to be suitable for publication, but we would be happy to make further changes if you feel that they are necessary.

Best wishes,

Ricardo Q. Gurgel

Corresponding author
Reviewer's report

Title: Severe Maternal Morbidity and Near Miss: incidence and risk factors in the reference maternities of Sergipe, Northeast, Brazil.

Version: 2 Date: 19 May 2013

Reviewer: Jose G Cecatti

Reviewer's report (in Bold):

Major Compulsory Revisions:

First of all, the whole manuscript needs a complete review of English. It is very limited in the current way. Please consider the review by an expert in the field. The abstract also needs a complete review, not only of English language but also of its content. However I recommend to do that only after the whole manuscript is completely reviewed.

Response: The manuscript and response to reviewers were revised professionally by The Scientific Editing Company. The abstract was completely revised.

Background session: fourth paragraph, line 3: please consider changing words to: "...standardize data and calculate indicators for comparing different settings [10]".

Response: done

Background: fourth paragraph, lines 6-9: The reference given for this phrase (13) does not correspond to the study described; it is a secondary analysis from the Brazilian Demographic Health Survey which indirectly also estimated the ratio of maternal near miss but using a pragmatic definition.

Response: reference corrected

Methods session: the present study has a design that is a little different from common epidemiological designs. It is in fact a cross sectional study which used however a predefined control group selected from the same target population and presenting no obstetrical complications, using two controls for each case of near miss. There are no detailed information on how these controls were selected, just an information that this was at random. So this is similar to what is performed in a case control study, but the predictors refers only to some current clinical and socio demographic characteristics and not to past exposition. Therefore I suggest it should be better called a cross sectional with a fixe control group study.

Response: the design of the study was corrected. In addition, in response to the opinion of the reviewer Dr. J.P.Souza: “A cross-sectional study with a nested case-control component was conducted to identify pregnant women in risk situation…”

Methods session, first paragraph: when describing both maternities participating in the study, it is said that the low and medium obstetric risk has an ICU while the high obstetric risk maternity has not. Is this correct? It sounds contradictory.

Response: Unfortunately this is correct. Both maternity hospitals work together despite the different locations and belong to the public health system, but the ICU is located the
low/medium risk maternity hospital and patients are referred from the high risk maternity hospital when necessary.

Methods session, second paragraph: it is necessary to better describe how the controls were selected. It is said they were selected at random, but additional information is needed, especially considering some results presented in the correspondent session. The only inclusion criteria for controls was not having a near miss condition? And what about being still pregnant or delivered? Or being at term or preterm?

Response: It was detailed in the manuscript: “Two controls were enrolled simultaneously for each case of NM in the same hospital. When a case was identified, all patients eligible to be controls who had been admitted on the same day were listed and numbered and two numbers were selected at random from a covered box. Using such a strategy, bias selection was avoided as each eligible control had the same chance to be selected.” Considering the description above, we think that the question has been answered. Patients and controls had the same chance to be pregnant and delivered and at term or preterm.

Methods session, third paragraph: it would be welcome to have additional information on the content of the questionnaire. Did the authors investigate any kind of delays in getting care? Did they include any information regarding audit on quality of obstetric care the women received?

Response: Information on the content of the questionnaire: “A pre-coded questionnaire with 59 questions was developed specifically for this study containing information on sociodemographic profile, prenatal data, clinic and admission conditions, parity, previous pregnancy data, type of delivery, cesarean indications, complications during and after the delivery and perinatal results.”

The study intended to examine incidence and risk factors for MNM, so we did not investigate either the delays in getting care or include information regarding audit of obstetric care. We plan to evaluate this in our next study.

Methods session, fourth paragraph: the analytical approach needs to be detailed.

Response: The analytical approach was revised: “Categorical variables were expressed as frequency and percentage and were tested using an exact Fisher test for 2x2 tables or a chi-square test for larger tables. For continuous variables, after testing normality with a Shapiro-Wilk test we used a student’s t-test for the normal and a U-Mann-Whitney for the non-normal variables. An Odds Ratio was used when NM and control values differed. Binary logistic regression multivariate analysis was used as a backward method, with NM experience as the dependent variable. Independent variables were included when the p-value <0.150 and represented at least 80% of the sample in each group. Any variables that did not reach the above conditions were included in the model. The confidence interval (CI) was 95% and a p-value of <0.05 was considered statistically significant. The number of valid cases is indicated for each variable and missing data were excluded from the analysis.”

Why using tables 3 and 4 for evaluating predictors among three groups and then table 5 again evaluating the same predictors but just between two groups?
Response: In tables 3 and 4, we demonstrate the existence of characteristic differences between the three groups because the intermediate group (SAMM) showed the continuum of severity. Controls were selected only for the NM cases and the association tests were done comparing the two groups (Table 5).

The multivariate analysis needs to be described in details: what kind of multivariate analysis was performed? which variables entered the model? what variables were considered of clinical relevance? where are the results of this analysis?

Response: After revision, variables of clinical relevance were removed from the multivariate analysis and the results are now in Table 5. “Binary logistic regression multivariate analysis was used as a backward method, with NM experience as the dependent variable. Independent variables were included when the \( p \)-value <0.150 and represented at least 80\% of the sample in each group. Any variables that did not reach the above conditions were included in the model. The confidence interval (CI) was 95\% and a \( p \)-value of <0.05 was considered statistically significant. The number of valid cases is indicated for each variable and missing data were excluded from the analysis.”

Results session, first paragraph: why only 151 controls and not 154 (twice 77)?

Response: Three patients who were initially included as controls presented with some health complications and were recategorized as SAMM cases.

The WHO definition uses SMOR (severe maternal outcome ratio) instead women with life-threatening conditions and here the same should be used in order to be in accordance with WHO as stated.

Response: done

Results session, second paragraph: the results of the second table are not the main causes of SAMM, but the main conditions diagnosing SAMM. As well, for NM cases, what are presented are the main criteria and not the main causes.

Response: Thank you, you are right, the entire text was revised according to this suggestion.

Results session, third paragraph, line 3: probably it should be "were associated with higher age..."

Response: done

Results session, fourth paragraph: the \( p \)-values are not necessary here; in addition the values are for OR plus 95\%CI and not only CI as stated. If the idea is to present only those statistically significant, remember that 95\%CI touching 1.00 is considered as just marginally significant results.

Response: done
What is "lack of awareness"?

Response: this term has been changed. We now use the English terms conscious and not conscious.

If the idea is to select factors associated that could be considered as predictors, perinatal results are not. They are outcome, not predictors.

Response: outcomes were removed from the tables and added to the text.

Results session, fifth paragraph: as the multivariate analysis was not full explained in the methods session, it is not possible to understand what the results refer to. What are the eligible criteria? How was the severity of NM situations assessed?

Response: Eligible criteria mean the criteria adopted by WHO. The severity of each NM situation was determined by the number of criteria per case (from 1 to 6) using the univariate analysis.

There were 17 maternal deaths but the authors give the main causes for only 14. And the remaining 3? What "abnormalities of the uterine contraction" mean? If this is postpartum hemorrhage, then they should be added also to hemorrhage.

Response: Number of maternal deaths corrected: “During the study period there were 17 MD and the main causes were: hemorrhage (41.2%), hypertensive disorders (17.5%), embolism (11.8%), abortion (11.8%), baseline diseases complicated by pregnancy (11.8%) and by pelvic infection (5.9%)”. In addition, “abnormalities of uterine contraction” was added to hemorrhage causes.

Discussion session: this is the weakest part of the manuscript. In the first paragraph, line 2, what means "reached significant values"?

Response: OK, the paragraph now reads: “Using the official WHO definitions, we could identify the situations characterized as SAMM/NM that occurred in patients in Sergipe state. The main condition diagnosing SAMM was hypertensive disorders. For NM, 87.1% were more frequently associated with management-based criteria and secondly with clinical criteria (21.4%). These numbers reinforce the specificity of the management-based criteria for NM in detecting patients with real severe obstetric problems [16]. Hypertension was the most frequent obstetric pathology and was the main cause of morbidity in the SAMM group. This was similar to the results reported for the rest of the country and to results from other developing countries [1,15].”

Discussion session, second paragraph, line 1: from where comes from the information that "...hemorrhage was more related to the management-based criteria..."? I was not able to find this in any table.
Response: we have presented the NM criteria according to its general definition (WHO, 2009). The requirement for ≥ 5 blood units is one of the management criteria and was the most frequent.

**Line 3: please always refer "maternal mortality ratio" instead of "mortality ratio"**

Response: done

**Discussion session, third paragraph: maternal age is not included in Table 5 as an associated factor. How is then explained here? Just with data from table 3?**

Response: it was put on table 5 and reclassified as categorical, a binary variable.

**Discussion session, fourth and fifth paragraphs: current cesarean section, lower birth weight, admission to neonatal intensive care unit are considered among those factors associated with near miss as risk factors. However they could not be considered as predictors, but just as outcomes.**

Response: done, the entire text was revised.

**Discussion session, sixth paragraph: how was the model built? The results do not allow any interpretation. NM are compared to SAMM group or to controls?**

Response: It was better described in methods section: “Three groups were selected according to the definition criteria and defined as SAMM, NM and the control group [10]. This last group was selected from the same hospital, on the same day and with a ratio of two control subjects to one near miss subject.”

**References: all the titles in Portuguese should be provided as English translated**

Response: done

**Ref number 20 is incomplete. It probably refers to "Maternal mortality and morbidity: a human rights imperative" from Pillay N, but this should be completed.**

Response: done

**Table 1: I suggest to change the title as "Indicators of maternal morbidity and mortality for the population in the referral maternities of Sergipe". The figure for maternal near miss: mortality ratio is probably changed (it should be 4.5:1).**

Response: done

**Instead "Women with life threatening conditions", please use "women with SMOR" as recommended by WHO.**

Response: done

**In the footnote, please state the number of LB.**

Response: done
Table 2: I suggest to change the title as "Main conditions diagnosing cases of SAMM/NM in the referral maternities in Sergipe".

Response: done

The criteria used to identify NM can, of course, not be displayed also for SAMM. However, the main conditions for SAMM can also be showed for NM cases and this is necessary in fact.

Response: We did not intend to relate SAMM to NM. We just present the sub items of each category and we feel it is enough for public understanding. As the two categories are defined as a continuum of severity but using different definitions, it is not necessary to show the main conditions of SAMM for the NM cases.

Table 3 and 4: I really do not see the reason why these tables are presented.

Response: We think it is necessary to show both separately: clinical/obstetric from socioeconomic conditions. If we put them in only one table, it would be long and confusing. However, to remove these data would compromise the paper.

Apart from the information on the SAMM group, they give exactly the same results as table 5 for NM and control groups.

Response: Table 5 is constructed based on odds ratio determination for the comparison of NM x controls and the other two tables compare the three groups, so the table shows a different analysis of the same variables.

Mean should be used instead of average.

Response: done

Age and years of educations could be reclassified as categorical binary variables.

Response: we have reclassified this into age ≥ 35 vs. < 34 years and years of education ≥ complete secondary level vs. incomplete secondary level.

In table 4, MMG should be SAMM; BMC should be BMI.

Response: done

Regarding BMI, the percentage numbers for controls group are changed.

Response: done

Table 4 also provides some indications that make me doubt the random selection of the control group: how is it possible that the mean gestational age at admission (for delivery I suppose) for controls to be 35,2 weeks? It does not make sense at all. The same can be argued for weight of LB. How is it possible that for NM group, with mean gestation age of 31.9 weeks, the mean weight of LB to be 3100g?! And for control group, with mean gestation age of 35.2 weeks, the mean weight of LB to be 3200?! These numbers are not convincing.
The last information regarding destination of LB informing that 14.3% of neonates from the control group were admitted to ICU or died definitely shows that this control group is not a "normal" group to be compared with either SAMM or NM.

Response: The patients were included according to MATERNAL RISK and the gestational age was calculated for all patients independently. This is the reason for the discrepancy. A large number of neonates were admitted to the ICU or they died; this is due to the frequency of situations where a fetus is at risk, without risk for the mother and other situations with some risk for the mother (not classified as SAMM/NM) leading to prematurity and/or neonatal risk or death.

Table 5 (not Tabela 5): this is supposed to present OR (and 95% CI) of factors that could be understood as predictors (risk factors) for near miss. However, a series of results (from tables 3 and 4) are lacking, including maternal age, income, gestation age at admission, BMI, previous C-section, Blood pressure, etc. In addition, some other variables (like current C-section and destination of LB) that are outcome and not predictors are included.

Response: all variables were tested for the three groups (SAMM, NM and controls). However, except for age (which was added), other variables were not added because they were not statistically significant. A footnote was placed in table 5 explaining this.

Minor Essential Revisions

Please consider changing the title for "Severe maternal morbidity and near miss: occurrence and associated factors in Sergipe, Northeast Brazil"

Response: Title change done

Discretionary Revisions

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Not suitable for publication unless extensively edited

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no financial competing interests. Regarding non-financial competing interests, I had previous message contact with the first author of the manuscript during the development of the study providing some technical suggestions.
Reviewer's report

Title: Severe Maternal Morbidity and Near Miss: incidence and risk factors in the reference maternities of Sergipe, Northeast, Brazil.

Version: 2 Date: 20 May 2013

Reviewer: Joao Paulo Souza

The authors posed a well-defined question (i.e. determine the prevalence of SAMM and NM, describe associated risk factors and calculate the indicators described by WHO). Methods are well described though I would like to suggest the authors to change their description of study design. This is a cross-sectional study with a nested case-control component. Case identification was prospective and data collection was concurrent to the case identification. Data is sound but I would like to recommend the authors to strengthen their report through adhesion to the STROBE statement. The discussion is balanced and I believe that when STROBE is applied by the authors before resubmission additional points can be highlighted in the discussion, including the study limitations section. The existing body of knowledge has been adequately used by the authors.

The writing is acceptable but I have made several minor suggestions in the paper by hand which could be useful to the authors in their revision. Below are my main suggestions:

**Major Compulsory Revision:**

1. **Adhere to the STROBE statement and revise the paper accordingly**

Response: According to the STROBE statement we have revised the 22 items and we believe that the manuscript now adheres to the statement.

   Item 1: title changed to “Severe maternal morbidity and near miss: occurrence and associated factors in Sergipe, Northeast Brazil”.

   Item 2: the background was revised

   Item 4: defined according to suggestion

   Item 6: control selection was described

   Item 7: definitions of SAMM and NM were included

   Item 11: variable discrimination was included

   Item 12: missing information was less than 20% for all variables

   Item 14 a: characteristics of the study participants were included in the text and tables

   Item 14 b: all variables have less than 20% of the information missing

   Items 18-21: Discussion was changed and generalisability was stated as suggested

   All other items were in accordance with the STROBE statement.
2. Revise the description of the study design (see above).

Response: Yes, we have changed the study design description to: “A cross-sectional study with a nested case-control component was conducted to identify pregnant women who were at risk of SAMM/NM in two reference maternity hospitals in Sergipe state, Northeast-Brazil between June 2011 and May 2012. Case identification was prospective and data collection was performed.”

3. Please provide additional details on the selection of controls, particularly what is meant by “at random”. Was there any formal random selection strategy? Was there any algorithm or hard rule to be followed? How the authors minimized the selection bias?

Response: Yes, we have detailed the selection of controls to: “Patients were included in the study only once, even if they were admitted on more than one occasion, and were excluded in the case of maternal death.

Three groups were selected according to the definition criteria and defined as SAMM, NM and the control group [10]. This last group was selected from the same hospital, on the same day and with a ratio of two control subjects to one near miss subject. When a case was identified, all patients who were eligible to be controls (admitted on the same day) were listed and numbered and two numbers were selected at random from a covered box. Using such a strategy, bias selection was avoided as each eligible control had the same chance to be selected. The exclusion condition for controls was not having any eligible criteria for SAMM or NM or if they refused to participate.

Minor essential revisions:

4. The authors should note in the introduction the differences between the broad SAMM and the more specific NM concepts

Response: “SAMM is more broadly defined and cases are less serious than the NM situations. The latter is more specific and is often the stage that immediately precedes maternal death [9,10]. ”

5. The authors should note that while maternal deaths were not individually included in the study (actually, it would have been good to have reviewed the hospital records of maternal deaths and do a combined assessment), the number of maternal deaths was retrieved at hospital level.

Response: We have decided not to include maternal deaths in the analysis, but we have retrieved all such occurrences as follows: “During the study period, there were 16,243 LB deliveries and we identified 1,102 SAMM cases, 77 NM and 17 MD.”

6. Please correct the reference 13 and its content in the text.

Response: done
7. Table 4: Please replace MMG by SAMM in the table heading

Response: done

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
'I declare that I have no competing interests'

Reviewer's report

Title: Severe Maternal Morbidity and Near Miss: incidence and risk factors in the reference maternities of Sergipe, Northeast, Brazil.

Version: 2 Date: 23 May 2013

Reviewer: Tom Witteveen

Reviewer's report:

1. This study is relevant because of its importance to show the difference between major city hospitals in other smaller hospitals because the near miss rate is higher in low economic regions and should be recognized.

2. Major Compulsory Revisions

   Some method parts are unclear to me. What are the economic levels of both regions?

   Response: The region characteristic was explained and patients’ socioeconomic level was determined by ABEP, 2008 [14]

   Why is this hospital seen as high risk?

   Response: The two hospitals are references for other services and we assumed it was high risk because all patients of high risk are usually referred to this hospital.

   The authors speak in the results about management en clinical indications for SAMM, what are the criteria? Severe management indicators?

   Response: The definition and criteria adopted were according to reference [10].
Many terms in this manuscript are unclear what is meant by this. Unconscious state? Glasgow coma scale, shock, what were the criteria? Hemorrhagic? How many blood loss?

Response: The terms were used due to medical records. We did not use any coma scale. For the severity of the hemorrhagic process, we counted the number of blood units according to reference [10].

3. If I would reproduce this study I would not be able to based on the method explanation.

Response: We have improved the methods.

4. Minor Essential Revisions

Results: The incidence is calculated based on live births while births with death might be cases of maternal near-miss.

Response: The WHO definition for maternal near miss incidence ratio is the number of maternal near misses per 1,000 live births; please see reference [10].

5. Hypertensive disorders are the main cause, here might be underreporting of the hemorrhagic disorders? Criteria?

Response: We have changed the end of the first paragraph and the beginning of the second to: “Hypertension was the most frequent obstetric pathology and was the main cause of morbidity in the SAMM group. This was similar to the results reported for the rest of the country and to results from other developing countries [1,15].

However, inside the group of management-based criteria (the most common for NM) hemorrhage was the most frequent, highlighting the importance of this condition in the context of NM and the correlation with death.”

6. In the discussion there is not much spoken of limitations of this study, which is never possible for a study.

Response: We have acknowledged the limitations of the study and included the following explanation: “There were a number of limitations to this study, such as the lack of electronic medical record storage making it difficult to have access to cases, limitations to the diagnostic and therapeutic resources in the services and the overcrowding of the maternity hospitals. We have exhaustively revised patients’ records and made use of the available hospital database to minimize information loss. The lack of antenatal care, the lack of resources (e.g., no maternal intensive care unit available in the high risk maternity) were the main problems which led us to classify some patients as
SAMM/NM, but the same criteria were used throughout the entire study without investigator interference.”

5. **Conclusion should be shorter in my opinion. Give a clear answer to the main research question.**

Response: We have revised the last two paragraphs, reducing the size of the discussion. We have also included our final results and the suggested improvements we feel are essential. It now reads as follows:

“In summary, the prevalence of SAMM/NM in the state of Sergipe was high, though within the ranges described in the literature. The mortality ratio for the population studied was also high, at least 40% higher than the Brazilian average. Hypertensive disorders were more commonly associated with morbidity, while hemorrhage was the main cause of mortality in this population. The only significant variable from the sociodemographic profile was higher age. Patients who have previously undergone a caesarean and/or an abortion should be noted and these should be considered obstetrical antecedents. The lack of regular antenatal care, high rates of caesareans and prematurity with adverse perinatal outcomes were also statistically significant. The existence of more than one criterion for NM eligibility demonstrates the complex management required for these patients and enhances the biological *continuum* for this situation.

The use of the WHO maternal near miss criteria was feasible in the Northeast of Brazil and provided useful information. Decreasing maternal mortality is more than ever a matter relevant to human rights and everyone has a part to play: government, human rights organizations, health service providers and civil society [20]. From an epidemiological point of view, it is necessary to enhance the coverage and the quality of antenatal care, to improve the infrastructure of maternity wards to enable proper management of severe complications and to promote the work of multidisciplinary obstetric teams. Protocols based on adverse situations like SAMM/NM, which identify the exact point of failure prior to death, may allow us to recommend interventions that save lives.”

7. **Overall: English grammar and spelling mistakes are sometimes wrong and unclear. This might also influence my opinion on the manuscript.**

Response: The manuscript and the response to reviewers have been revised professionally by The Scientific Editing Company.

Level of interest: An article of limited interest
Quality of written English: Needs some language corrections before being

Published Statistical review: Yes, but I do not feel adequately qualified to assess the
statistics.

Declaration of competing interests:
I declare that I have no competing interests

Reviewer’s report:

Title: Severe Maternal Morbidity and Near Miss: incidence and risk factors in the
reference maternities of Sergipe, Northeast, Brazil.

Version: 2 Date: 19 May 2013

Reviewer: Jose G Cecatti

Reviewer's report:

Major Compulsory Revisions:

First of all, the whole manuscript needs a complete review of English. It is very
limited in the current way. Please consider the review by an expert in the field.
The abstract also needs a complete review, not only of English language but also
of its content. However I recommend to do that only after the whole manuscript is
completely reviewed.

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to: "...standardize data and calculate indicators for comparing different settings
[10]".

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does not correspond to the study described; it is a secondary analysis from the
Brazilian Demographic Health Survey which indirectly also estimated the ratio of
maternal near miss but using a pragmatic definition.

Methods session: the present study has a design that is a little different from common epidemiological designs. It is in fact a cross sectional study which used however a predefined control group selected from the same target population and presenting no obstetrical complications, using two controls for each case of near miss. There are no detailed information on how these controls were selected, just an information that this was at random. So this is similar to what is performed in a case control study, but the predictors refers only to some current clinical and socio demographic characteristics and not to past exposition. Therefore I suggest it should be better called a cross sectional with a fixe control group study.

Methods session, first paragraph: when describing both maternities participating in the study, it is said tha the low and medium obs while the high obstetric risk maternity has not. Is this correct? It sounds contradictory.

Methods session, second paragraph: it is necessary to better describe how the controls were selected. It is said they were selected at random, but additional information is needed, especially considering some results presented in the correspondent session. The only inclusion criteria for controls was not having a near miss condition? And what about being still pregnant or delivered? Or being at term or preterm?

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multivariate analysis needs to be described in details: what kind of multivariate analysis was performed? which variables entered the model? what variables were considered of clinical relevance? where are the results of this analysis?

Results session, first paragraph: why only 151 controls and not 154 (twice 77)?

The WHO definition uses SMOR (severe maternal outcome ratio) instead women with life-threatening conditions and here the same should be used in order to be in accordance with WHO as stated.

Results session, second paragraph: the results of the second table are not the main causes of SAMM, but the main conditions diagnosing SAMM. As well, for NM cases, what are presented are the main criteria and not the main causes.

Results session, third paragraph, line 3: probably it should be "were associated with higher age..."

Results session, fourth paragraph: the p-values are not necessary here; in addition the values are for OR plus 95%CI and not only CI as stated. If the idea is to present only those statistically significant, remember that 95%CI touching 1,00 is considered as just marginally significant results. What is "lack of awareness"? If the idea is to select factors associated that could be considered as predictors, perinatal results are not. They are outcome, not predictors.

Results session, fifth paragraph: as the multivariate analysis was not full explained in the methods session, it is not possible to understand what the results refer to. What are the eligible criteria? How was the severity of NM situations assessed? There were 17 maternal deaths but the authors give the main causes for only 14. And the remaining 3? What "abnormalities of the uterine contaction" mean? If this is postpartum hemorrhage, then they should be added also to hemorrhage.

Discussion session: this is the weakest part of the manuscript. In the first paragraph, line 2, what means "reached significant values"?
Discussion session, second paragraph, line 1: from where comes from the information that "...hemorrhage was more related to the management-based criteria..."? I was not able to find this in any table. Line 3: please always refer "maternal mortality ratio" instead of "mortality ratio".

Discussion session, third paragraph: maternal age is not included in Table 5 as an associated factor. How is then explained here? Just with data from table 3?

Discussion session, fourth and fifth paragraphs: current cesarean section, lower birth weight, admission to neonatal intensive care unit are considered among those factors associated with near miss as risk factors. However they could not be considered as predictors, but just as outcomes.

Discussion session, sixth paragraph: how was the model built? The results do not allow any interpretation. NM are compared to SAMM group or to controls?

References: all the titles in Portuguese should be provided as English translated.

Ref number 20 is incomplete. It probably refers to "Maternal mortality and morbidity: a human rights imperative" from Pillay N, but this should be completed.

Table 1: I suggest to change the title as "Indicators of maternal morbidity and mortality for the population in the referral maternities of Sergipe". The figure for maternal near miss: mortality ratio is probably changed (it should be 4.5:1).

Instead "Women with life threatening conditions", please use "women with SMOR" as recommended by WHO. In the footnote, please state the number of LB.

Table 2: I suggest to change the title as "Main conditions diagnosing cases of SAMM/NM in the referral maternities in Sergipe". The criteria used to identify NM can of course not be displayed also for SAMM. However, the main conditions for SAMM can also be showed for NM cases and this is necessary in fact.

Table 3 and 4: I really do not see the reason why these tables are presented. Apart from the information on the SAMM group, they give exactly the same results as table 5 for NM and control groups. Mean should be used instead of
average. Age and years of educations could be reclassified as categorical binary variables. In table 4, MMG should be SAMM; BMC should be BMI. Regarding BMI, the percentage numbers for controls group are changed. Table 4 also provides some indications that make me doubt the random selection of the control group: how is it possible that the mean gestational age at admission (for delivery I suppose) for controls to be 35.2 weeks? It does not make sense at all. The same can be argued for weight of LB. How is it possible that for NM group, with mean gestation age of 31.9 weeks, the mean weight of LB to be 3100g?!
And for control group, with mean gestation age of 35.2 weeks, the mean weight of LB to be 3200?! These numbers are not convincing. The last information regarding destination of LB informing that 14.3% of neonates from the control group were admitted to ICU or died definitely shows that this control group is not a "normal" group to be compared with either SAMM or NM.
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Minor Essential Revisions
Please consider changing the title for "Severe maternal morbidity and near miss: occurrence and associated factors in Sergipe, Northeast Brazil"

Discretionary Revisions
Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Not suitable for publication unless extensively edited
Statistical review: Yes, and I have assessed the statistics in my report.
Declaration of competing interests:

I declare that I have no financial competing interests. Regarding non-financial competing interests, I had previous message contact with the first author of the manuscript during the development of the study providing some technical suggestions.

Reviewer's report

Title: Severe Maternal Morbidity and Near Miss: incidence and risk factors in the reference maternities of Sergipe, Northeast, Brazil.

Version: 2 Date: 20 May 2013

Reviewer: Joao Paulo Souza

Reviewer's report:

Dear Editors,

Many thanks for the opportunity to review this interesting paper from Brazil. I would like to congratulate the authors for carrying such study, which provides additional experience and insights to the application of the near miss concept in maternal health.

The authors posed a well-defined question (i.e. determine the prevalence of SAMM and NM, describe associated risk factors and calculate the indicators described by WHO). Methods are well described though I would like to suggest the authors to change their description of study design. This is a cross-sectional study with a nested case-control component. Case identification was prospective and data collection was concurrent to the case identification. Data is sound but I would like to recommend the authors to strengthen their report through adhesion to the STROBE statement. The discussion is balanced and I believe that when STROBE is applied by the authors before resubmission additional points can be highlighted in the discussion, including the study limitations section. The existing
body of knowledge has been adequately used by the authors.

The writing is acceptable but I have made several minor suggestions in the paper by hand which could be useful to the authors in their revision. Below are my main suggestions:

Major Compulsory Revision

1. Adhere to the STROBE statement and revise the paper accordingly.
2. Revise the description of the study design (see above).
3. Please provide additional details on the selection of controls, particularly what is meant by “at random”. Was there any formal random selection strategy? Was there any algorithm or hard rule to be followed? How the authors minimized the selection bias?

Minor essential revisions

4. The authors should note in the introduction the differences between the broad SAMM and the more specific NM concepts;
5. The authors should note that while maternal deaths were not individually included in the study (actually, it would have been good to have reviewed the hospital records of maternal deaths and do a combined assessment), the number of maternal deaths was retrieved at hospital level.
6. Please correct the reference 13 and its content in the text.
7. Table 4: Please replace MMG by SAMM in the table heading.

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

'I declare that I have no competing interests'
Reviewer's report

Title: Severe Maternal Morbidity and Near Miss: incidence and risk factors in the reference maternities of Sergipe, Northeast, Brazil.

Version: 2 Date: 23 May 2013

Reviewer: Tom Witteveen

Reviewer's report:

1. This study is relevant because of its importance to show the difference between major city hospitals and other smaller hospitals because the near miss rate is higher in low economic regions and should be recognised.

2. Major Compulsory Revisions

Some method parts are unclear to me. what are the economic levels of both regions? Why is this hospital seen as high risk? The authors speak in the results about management and clinical indications for SAMM, what are the criteria? Severe management indicators? Many terms in this manuscript are unclear what is meant by this. Unconscious state? Glasgow coma scale, shock, what were the criteria? Hemorrhagic? how many blood loss?

3. If i would reproduce this study i would not be able to based on the method explanation.

4. Minor Essential Revisions

Results

The incidence is calculated based on live births while births with death might be cases of maternal near-miss.

5. Hypertensive disorders are the main cause, here might be underreporting of the hemorrhagic disorders? criteria?

6. In the discussion there is not much spoken of limitations of this study, which is never possible for a study.

5. Conclusion should be shorter in my opinion. Give a clear answer to the main
research question.

7. Overall: English grammar en spelling mistakes are sometimes wrong and unclear. This might also influence my opinion on the manuscript.

Level of interest: An article of limited interest

Quality of written English: Needs some language corrections before being

Published Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interests