

## **Author's response to reviews**

**Title:** Brazilian network for the surveillance of maternal potentially life threatening morbidity and maternal near-miss and a multidimensional evaluation of their long term consequences

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Dear Editor of Reproductive Health

First of all I would like to thank the reviewers for their careful work in reviewing our research protocol. I am absolutely sure their comments were responsible for improving the quality of the manuscript. I will be answering point by point below.

**Reviewer's report 1:** This protocol describes a very important project on three dimensions:

1. The establishment of a national network for prospective collaborative research in Brazil; a country that presents unique challenges owing to its size and its diverse ethnic and sociocultural structure
2. The study of a relatively new concept i.e. maternal near-miss at great depth and breadth
3. Follow-up evaluation of physical and psychological consequences of such severe morbidity up to six months after birth.

I have some minor comments for the authors to consider:

1. Terminology: The terms severe acute maternal morbidity and severe maternal morbidity seem to be used interchangeably. It may be useful to check these for consistency and perhaps put definitions somewhere in a box or so if necessary. **JGC: in fact both research protocols joined here were written before the WHO issue of concepts and criteria for defining maternal near miss. Now we adapted all terms to these definitions and criteria.**
2. Methods/design second para: it is not easy to follow from 8/1000 incidence to 25% safety index and to 75,000 women to be studied. Perhaps more detail would be helpful to the reader. **JGC: OK, modified accordingly.**
3. Methods/design, second para on page 8: those transferred to another health care service (add because of their health condition?). **JGC: OK, included.**
4. Methods/design, third para, page 8: The design of the multidimensional analysis of consequences seems to be a case-control study but it is not clearly mentioned as such. Here I think it is important to clarify the terminology is it women who are near-miss or a larger group that will be eligible? **JGC: no, it is not a case control design. It is a cohort design because we will be looking for long term consequences of severe maternal morbidity (both maternal potentially life threatening conditions and maternal near miss). The difference is that we will not following all women without severe maternal morbidity due to logistic restrictions. We will be randomly selecting an equal number of women without complications for follow up and comparison. This is now clearer in the text.**
5. Main outcomes: This section seems to be a mixture of outcomes and definitions of variables collected. For example, 'abortion' seems to be a definition, also,

non-near-miss severe maternal morbidity is used only here? **JGC: OK. In fact “non near miss severe maternal morbidity” is now defined as “maternal potentially life threatening condition” and the outcome had been changed accordingly. Instead of abortion, it is much more appropriate to refer to the main causes of complications or death.**

I understand that it may be difficult to make changes in an approved protocol but if the authors make some changes after peer-review the context of the changes pertaining to the publication could perhaps be explained. **JGC: no problem. We are doing just some adjustments for clearness and not really modifying the protocol.**

Overall, a very impressive project and perhaps will be a model for other countries to follow. As such it may be useful to describe the process (and perhaps publish) in detail at some point. **JGC: Thank you. We loved the suggestion and then we are already preparing this new manuscript on the process because we are collecting data for the cross sectional component of the study.**

**Level of interest** An article of importance in its field

**Quality of written English** Acceptable

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

**Declaration of competing interests** I work with the main authors on several other collaborative projects but not on this one.

#### **Reviewer's report 2: General**

1. Is the question posed by the authors new and well defined?  
This study aims to describe the burden of severe acute maternal morbidity based on the new WHO criteria among a network of institutions in Brazil. It also plans to identify the long term consequences of women who nearly died from severe obstetric complications by comparing them with those who also suffered serious but not potentially fatal complications. The questions posed by the authors are not new but the concept of near miss morbidity is being taken a step further to extensively include associated important but poorly studied postpartum and infant/childhood developmental outcomes. The questions are well defined although the rationale for conducting the 'multidimensional long term evaluation' of women with maternal near-miss is not clear. **JGC: the rationale for conducting a multidimensional long term evaluation is provided in paragraphs 5-7 of the introduction session. We do understand that perhaps this is too short, but this manuscript is a protocol. We are almost finishing another article which is exactly a theoretical presentation of a long rationale for such multidimensional evaluation, also discussing methodological aspects including standard forms and questionnaires to be used.**
2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work? The protocol is voluminous and requires a great deal of concentration to maintain comprehension. The combination of

two study designs further compounds its complexity and makes one to wonder how internal validity of the data can be maintained. The methodology also contains so many definitions of outcome measures that require various instruments with varying number of items (some with large number of questions). It is unclear whether these questionnaires would be used at the same time for each patient and how long the survey might take for individual patient. **JGC: in fact, here we have two protocols joined in just one manuscript. We tried to be as clearer as possible without extending a lot the manuscript, thus facilitating an overall understanding for the reader. Regarding the internal validity, what we can say is that we have a big team working in both projects, with specific professionals being responsible for specific topics to be evaluated. In addition there is a group responsible for developing the system for data collection using standardized questionnaires. In the sub-item "longitudinal component" of the item "Data collection and procedures" there are some details on that. Each telephone interview (3<sup>rd</sup> and 6<sup>th</sup> month will take no longer than 20 minutes; 6<sup>th</sup> month visit will take no more than 35 minutes for 3 questionnaires plus the time for the baby to be evaluated, around 20 minutes). This information on time spent were added to the text.**

3. Will the data be sound and well controlled? Although the authors made attempt to provide a control group for the near miss population, it is unlikely that the method of selection of the control group would suffice to make reasonable inferences at the end of the day since there would be many other factors (both known and unknown) that may influence long term outcomes which have not been included in their consideration. **JGC: the research group thought a lot on this. After several discussions we came to the conclusion that this would be the only feasible way of doing a control. The controls will be randomly selected at the same hospital facilities where the cases came from. So they would be representative of the population attended by these facilities. Considering there are more and less complex hospitals in this network, we thought that probably this under/over representation could be minimized. Another point to be taken into account is that the rate of home births in Brazil is almost zero. Therefore we think that even there could be any bias, this the best feasible way of controlling in this study.**
4. Do the title and abstract accurately convey what has been planned? The title can be amended slightly to avoid confusing a reader that is new to the concept of near miss. Including 'severe maternal morbidity' and 'maternal near miss' in the same sentence means the reader must be aware of the new WHO criteria that describes maternal near miss otherwise it might just appear as tautology. **JGC: OK, and following the recommendation of the Reviewer 1 for terminology, we changed using the new concept of WHO.**
5. Is the writing acceptable? The writing is acceptable. However, the quality may be improved by copy-editing by someone whose first language is English. For practical purposes, I would suggest that the protocol be simplified to improve comprehension and usability among investigators on the field. **JGC: Well it**

**was translated into English for a native speaking also skilled in reproductive health.**

- Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

#### Abstract

Needs to be shortened particularly its background section. In the objective, 'multidimensional long-term evaluation' needs to be well described to provide a clearer understanding at first glance. The Method/Design section should provide more information. Rather than say 'multidimensional analysis', what the authors really plan to do should be clearly stated. e.g. 'Questionnaire based interviews using validated instruments will be performed to assess woman's quality of life variables (e.g. posttraumatic stress disorders,.....) and resultant childhood developmental outcome measures e.g. neuro-motor development,....). The fact that the WHO near miss criteria will be used in identifying maternal near miss should be stated somewhere under the Method section. Is there any measure put in place to avoid women transferred from one facility to another from being counted twice in the same study or does it not matter when it comes to assessment of the burden of maternal near miss? **JGC: OK, suggestions accepted and changes performed. The women transferred will not be counted twice. In the system for data collection already developed, when the woman is transferred to another center also included in the network, her ID is also transferred to the other center who continues to fill the same form. We thought that this information is too much to be included in this manuscript. It is however included in the article on the process of implementing such study in the network as suggested by the first reviewer.**

#### Background

It is important to differentiate between 'severe maternal morbidity' and 'maternal near-miss' in the background since they are both mentioned in the objectives of the study (which comes right after the background section). **JGC: OK, done. This was the same suggestion of the first reviewer and has been provided.**

#### Methods

Some overlaps between the criteria for maternal near miss and diagnoses for severe maternal morbidity need to be dealt with as appropriate in order not to compromise the internal validity of the study. For instance, indicators such as shock, coagulation disorders, stroke, acute renal failure e.t.c. appear in both systems of classification. Is there any factor that determines where women who suffer any of the mentioned complications are classified? **JGC: OK, in fact the same diagnosis could appear in both. However to be classified as maternal near miss, a specific criteria should be fulfilled.**

- Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct).

See comments about presentation above.

Provide appropriate reference for the Classification of institutional capacities under the WHO Global Health survey (Shah et al) rather than the publication by Villar et

al on caesarean delivery outcomes in Latin America.**JGC: Sorry, the first description of this score for classification of institutional capacities is in this article from Villar in 2006, page 1821.**

Check Index Medicus citation of journals included in the Reference list and make adjustment where appropriate. **JGC: OK, done.**

- Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore).

Include how long the questionnaire may take per patient. **JGC: OK, done as requested.**

**Level of interest** An article of outstanding merit and interest 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.

**What next?** Accept after minor essential revisions

I hope I have properly addressed all points from the reviewers. Please do not hesitate to contact me if any other doubt arises.

Sincerely yours

Jose Guilherme Cecatti