



Network for Surveillance of Severe Maternal Morbidity: a powerful national collaboration generating data on maternal health outcomes and care

JG Cecatti,^a ML Costa,^a SM Haddad,^a MA Parpinelli,^a JP Souza,^a MH Sousa,^b FG Surita,^a JL Pinto e Silva,^a RC Pacagnella,^a R Passini Jr,^a for the Brazilian Network for Surveillance of Severe Maternal Morbidity study Group

^a Department of Obstetrics and Gynaecology, School of Medicine, University of de Campinas (UNICAMP), Campinas, Brazil ^b Centre for Research on Reproductive Health of Campinas (Cemicamp), Campinas, Brazil

Correspondence: JG Cecatti, Department of Obstetrics and Gynaecology, University of Campinas, R. Alexander Fleming, 101, 13083-881 Campinas, SP, Brazil. Email cecatti@unicamp.br

Accepted 8 July 2015. Published Online 2 November 2015.

Objective To identify cases of severe maternal morbidity (SMM) during pregnancy and childbirth, their characteristics, and to test the feasibility of scaling up World Health Organization criteria for identifying women at risk of a worse outcome.

Design Multicentre cross-sectional study.

Setting Twenty-seven referral maternity hospitals from all regions of Brazil.

Population Cases of SMM identified among 82 388 delivering women over a 1-year period.

Methods Prospective surveillance using the World Health Organization's criteria for potentially life-threatening conditions (PLTC) and maternal near-miss (MNM) identified and assessed cases with severe morbidity or death.

Main outcome measures Indicators of maternal morbidity and mortality; sociodemographic, clinical and obstetric characteristics; gestational and perinatal outcomes; main causes of morbidity and delays in care.

Results Among 9555 cases of SMM, there were 140 deaths and 770 cases of MNM. The main determining cause of maternal

complication was hypertensive disease. Criteria for MNM conditions were more frequent as the severity of the outcome increased, all combined in over 75% of maternal deaths.

Conclusions This study identified around 9.5% of MNM or death among all cases developing any severe maternal complication. Multicentre studies on surveillance of SMM, with organised collaboration and adequate study protocols can be successfully implemented, even in low-income and middle-income settings, generating important information on maternal health and care to be used to implement appropriate health policies and interventions.

Keywords Audit, Brazil, maternal near miss, obstetric care, potentially life-threatening complications of pregnancy, severe maternal morbidity.

Tweetable abstract Surveillance of severe maternal morbidity was proved to be possible in a hospital network in Brazil.

Linked article This article is commented on by M Knight, p. 954 in this issue. To view this mini commentary visit <http://dx.doi.org/10.1111/1471-0528.13699>.

Please cite this paper as: Cecatti JG, Costa ML, Haddad SM, Parpinelli MA, Souza JP, Sousa MH, Surita FG, Pinto e Silva JL, Pacagnella RC, Passini R Jr, for the Brazilian Network for Surveillance of Severe Maternal Morbidity study Group. Network for Surveillance of Severe Maternal Morbidity: a powerful national collaboration generating data on maternal health outcomes and care. BJOG 2016;123:946–953.

Introduction

Using severe maternal morbidity (SMM) instead of maternal mortality as a proxy for severe complications during pregnancy and childbirth is no longer a new approach. The main advantages are the higher number of cases avail-

able, and that women are still alive and therefore able to provide information on relevant factors possibly associated with complications or with any delay in appropriate care.^{1,2} This is recognised to be especially important in high-income settings, where the number of maternal deaths is very low.³

There is currently an agreement that SMM needs to be audited in different scenarios, even in low-income and middle-income settings where the number of maternal deaths is high and still a priority.⁴ This would probably be the best way of showing health professionals and policy makers the need for adequate measures to avoid women becoming worse and dying.⁵ Ideally, this would be a routine surveillance system for women experiencing an SMM episode, using the recently issued World Health Organization (WHO) criteria.⁶ In the continuous chain of events associated with pregnancy, Potentially Life-Threatening Condition (PLTC) is the first step of more severe complications deserving special attention from healthcare providers, before any organ dysfunction or failure arises (Maternal Near Miss—MNM) or the woman dies (Maternal Death—MD).⁶ Unfortunately, this is not the reality, even for some high-income countries.^{7–9}

Recently these criteria have been used worldwide, with important findings towards improving maternal health.^{10,11} Multicentre studies have shown that collaboration is the key answer to empower relevant rulings.¹² The current study is the result of an organised nationwide network in Brazil, for the surveillance of SMM, resulting in more than 80 000 pregnancies screened and detailed information on almost 10 000 cases of SMM. This was the first study to prospectively test the new WHO criteria in the field.^{13,14} Some analysis on this study has already been performed and published.^{15,16} Now the core findings of this successful study are presented and the most relevant conclusions and future steps to influence health policies and diminish the burden of maternal morbidity and mortality are discussed. In addition, this study showed how an organised collaboration among health facilities from a middle-income country is possible and powerful, and how it can gather important evidence for policy changes when financial and structural resources are available and the correspondent research priorities are already established.

Methods

Ethics statement and financial support

This study was reviewed and approved by the National Council for Ethics in Research (CONEP, Brazilian Ministry of Health) and by each of the Institutional Review Boards of all participating sites. All data were retrieved from medical records after discharge and did not identify participants; for that reason, a waiver of individual informed consent was obtained. This was considered a key point; otherwise, no complete coverage of all cases of severe conditions and deaths would be obtained.

The financial support for the study was obtained from the Department of Science and Technology of the Brazilian Ministry of Health and CNPq (the National Research

Council), which played no other role in the development, data collection, analysis or interpretation of results.

Study design and selection of facilities

The research protocol and specific methodological details for implementation of the research proposal are published elsewhere.^{12,13} The coordinating centre has been interested in maternal morbidity since 2002, with a pioneering scientific production on the subject and participation in national and international discussions over its relevance.¹⁶

This was a multicentre, cross-sectional study carried out in 27 Brazilian referral maternity hospitals, from July 2009 to June 2010. In order to select the health facilities for this network, a convenience sampling strategy was adopted to guarantee the organisational structure needed and a minimum number of deliveries and live births (LB) per year (1000 LB/year). The first approach towards interested centres occurred in 2007. There was a concern to lessen the impact of nonrandom sampling and an effort towards representativeness of the national territory (with at least one health facility from each of the country's five macro-regions) and of facilities from public and private sectors, university and nonuniversity hospitals. The total number of health facilities selected was accomplished based on the number of MD and MNM calculated as necessary to validate the use of the WHO criteria for pregnancy-related PLTC and MNM that had recently been released,⁶ as well as to perform other relevant primary and secondary analyses.

All selected centres had to provide a set of information regarding their characteristics, including location, complexity of level of care, population covered, number of maternity beds and availability of resources for specialised care of severe cases (blood bank, obstetric and neonatal intensive care units, specialist care for high-risk pregnancies, surgical specialties on duty, ultrasonography, laboratory, anaesthetists available round the clock, capacity for parenteral administration of antibiotics, oxytocin and magnesium sulphate, mechanical ventilation, cardiorespiratory resuscitation of adults and newborns, and hysterectomy). The availability of written protocols to guide medical interventions and evidence-based procedures was also assessed. Quality of obstetric care among the participating institutions and use of the index of maternal severity that was developed have already been explored.¹⁷

Sample size was calculated considering the number of deliveries that would need to be screened to identify around at least 100 MD and 600 MNM. A previous report of eight MNM per 1000 deliveries¹⁸ was used for sample size estimation and therefore a total of at least 75 000 deliveries should be followed to get those numbers.

In each of the selected facilities, there was a qualified team of researchers, with a local medical investigator (that supervised data collection and system update) and a medi-

cal or nursing local coordinator who should perform the daily surveillance for identification of cases and data collection. All the procedures involved were previously covered in training during an initial study meeting and a manual of operations with detailed information on every step for procedures was developed and available in each setting.¹³

Subjects and data collection

During the study period, all women admitted to the participating health facilities were prospectively screened for the presence of any of the criteria defined by WHO for PLTC and MNM (Table S1) or MD. For that purpose a screening form with all these criteria was developed and implemented to avoid missing cases. In daily rounds on hospital wards, emergency rooms, intensive care units and obstetric rooms the research coordinator applied the inclusion criteria and identified cases. The medical charts of these women were retrieved for further data collection immediately after hospital discharge, transfer or death. Complete information on all deliveries occurring in the same period was not collected because of budget and logistical restrictions.

For cases thus identified, information was collected using an 80-item pre-coded form including data on demographic and economic characteristics, obstetric history, antenatal care provided, 16 previous morbid conditions, occurrence of PLTC, MNM (WHO criteria) and main complication in the chain of events leading to these conditions, duration of hospitalisation (before delivery, following delivery and total time), maternal and perinatal outcomes and information on the occurrence of delays in the provision of care.¹⁴ When there was missing information or doubts, the attending medical team was approached for clarifications.

For data management, an open access, web-based platform called OPEN-CLINICA[®] (OpenClinica LLC, Waltham, MA, USA) was used, because it is a system compliant with good clinical practice and regulatory guidelines, allowing differentiated user roles and privileges, password and electronic signatures, SSL encryption and de-identification of Protected Health Information. A user-friendly form was developed in accordance with the standardised pattern existing in the system, with the inclusion of different sections comprehending all the relevant variables in the study. It was important to have investigators, coordinators, supervisors, data managers at central and local levels granted different levels of accessibility for the inclusion and evaluation/consistency of data.¹³

Quality control

To guarantee high-quality data and reliability of information, several procedures were implemented from the beginning of the study. Preparatory meetings were crucial to train the team of researchers and also to explain the innovative project and the possibility of excellence in an investi-

gation in a middle-income country, due to organisation and adequate funding. Sharing the relevance of collaboration made the whole team proud and helped to ensure high-quality data collection.

A very detailed manual of operations was available and the coordinating centre was also always accessible for solving doubts. There was a close monitoring of data collection and data entry with concurrent query management from the coordinating centre. Electronic messages were used to share similar difficulties and further instructions. During the study period, site visits were performed for evaluating the facilities' involvement, degree of completeness for the study standard and organisational procedures, with the review of randomly selected cases (around 5% of those identified) and cross-checking of local data with the information already stored in the web-based system.

Half way through data collection, there was another meeting, with researchers from all participating centres and also the steering committee including people from the WHO, international research leaders in the field, and representatives from the Ministry of Health and the Brazilian National Research Council. Partial results were presented and difficulties were discussed to improve the continuity of the study.

After the end of data collection, there was an intensive period of data consistency checking and cleaning during a 4-month period, with auditing by a set of validation/cross-checking rules as part of online data management. The coordinating centre analysed a list of inconsistencies for each facility and checked case by case, to see if it was a simple typing error or an important piece of missing or mistaken information. In all the cases where an inconsistency remained, the health facility was further questioned. All the answers were used to correct the database and were stored in a text box, open for commentaries, in the end of each form. There were in addition special checking rules related to delays, which are already detailed elsewhere.¹⁴ Briefly, as examples, when there was 'absent antenatal care' or 'direct inter-hospital transfer' (when a woman with a severe complication was transferred from one facility to a higher-level hospital with no previous contact between institutions) the researchers considered delay related to health service accessibility. For severe pre-eclampsia/eclampsia without magnesium sulphate administration as a management criterion, researchers were asked to identify the criterion used to classify the severity of disease and to evaluate the possibility of delay related to quality of medical care; if 'discharge required by the patient herself' or 'evasion' was identified, the delay was attributed to user factors.

Data analyses

Data analysis initially consisted of the distribution of women with severe complications identified as PLTC,

MNM or MD, whichever was the worst condition presented. Health indicators related to maternal morbidity and mortality as recommended by WHO were calculated: MNMR (maternal near-miss ratio per 1000 LB), severe maternal outcome ratio per 1000 LB, maternal mortality ratio per 100 000 LB and MNM:MD (the ratio between MNM and MD).⁶ Then the distribution of outcomes of obstetric complications by main determining causes was performed, followed by the evaluation of the WHO criteria for MNM used alone or in combination for identifying cases of MNM and MD. Subsequently, the distribution of previous maternal conditions according to groups of maternal outcomes was provided. In addition, information on sociodemographic and obstetric history, and delays in care according to the outcome of maternal complications was also assessed. The significance of differences among these groups was assessed using chi-square or exact tests. The *P*-values were adjusted for the effect of the cluster design¹⁹ and SPSS (SPSS, Inc., 2009, Chicago, IL, USA) was the main statistical package used in this analysis.

Results

During 1-year, a total of 82 388 women were admitted to the 27 health facilities included in the study for any pregnancy-related condition. These women had 82 144 LB. The final study population consisted of 9555 women presenting pregnancy-related severe complications, meeting the established inclusion criteria and 910 of those presented severe maternal outcome, with 140 MD and 770 MNM, giving a severe maternal outcome ratio of 11.08 per 1000 LB. The maternal mortality ratio in the screened population was 170/100 000 LB (Table 1). The MD included in this study represented about 8% of all MD registered nationwide in 2010.²⁰

Table 1. Indicators of severe maternal morbidity according to the WHO definition

PLTC	MNM	MD	Total	LB	Deliveries
8645	770	140	9555	82 144	82 388
90.4%	8.1%	1.5%			
MNM incidence ratio: $MNM/LB \times 1000 = 9.37/1000$ LB					
Severe Maternal Outcome Ratio = $(MNM + MD)/LB \times 1000 = 11.08/1000$ LB					
MNM:mortality ratio $MNM:1 MD = 5.5:1$					
Mortality index $MD/(MNM + MD) = 0.154 = 15.4\%$					
Maternal mortality ratio $MD/LB \times 100\ 000 = 170.4/100\ 000$ LB					

Mortality Index is the proportion of women with near miss who died. Severe Maternal Outcome Ratio is the proportion of all women delivering an alive newborn who had a maternal near miss or died.

Table 2. Distribution of outcomes of obstetric complication by main determining causes; *n* (%)

Cause*	PLTC	MNM	MD	<i>P</i> **
Haemorrhage	1929 (22.3)	312 (40.5)	37 (26.4)	0.009
Hypertension	6315 (73.0)	349 (45.3)	42 (30.0)	<0.001
Infection	51 (0.6)	44 (5.7)	5 (3.6)	<0.001
Clinical/surgical	773 (8.9)	185 (24.0)	65 (46.4)	<0.001
More than one	423 (4.9)	117 (15.2)	8 (5.7)	<0.001
Total	8645	770	140	

*They are not mutually exclusive.

***P*-values adjusted for the effect of the cluster design using chi-square or exact tests.

Table 2 shows that the main determining cause of maternal complication was hypertensive disease (accounting for 73% of PLTC, 45% of MNM and 30% of MD), followed by haemorrhage (22% of the total PLTC, 40.5% of MNM and 26% of MD), clinical/surgical (8.9% of PLTC; 24% of MNM and 46% of MD) and infection (with uterine/obstetric aetiology: 0.6% of PLTC, 5.7% of MNM and 3.6% of MD). Causes were not mutually exclusive, with around 6% of cases with more than one underlying cause of complication. Considering maternal mortality, the most significant cause of complication was clinical/surgical, defined as indirect causes, including infection not related to pregnancy (such as urinary tract infection or respiratory infection) or surgery due to appendicitis, for example.

When evaluating the WHO criteria used for identifying MNM, it is clear that none of them (clinical, laboratory or management criteria) was superior alone, for this identification. As severity of outcomes increases, the criteria are more frequently identified, all combined in over 75% of MD (Table 3).

Table 3. WHO criteria used alone or in combination for identifying life-threatening maternal conditions

Criteria	MNM	MD	<i>P</i> *
Only Clinical (C)	112 (14.5)	1 (0.7)	
Only Laboratory (L)	172 (22.3)	– (–)	
Only Management (M)	174 (22.6)	1 (0.7)	
C + L	37 (4.8)	1 (0.7)	
C + M	98 (12.7)	25 (17.9)	
L + M	37 (4.8)	5 (3.6)	
C + L + M	140 (18.2)	107 (76.4)	
Total	770	140	<0.001
Clinical	387 (50.3)	134 (95.7)	<0.001
Laboratory	386 (50.1)	113 (80.7)	<0.001
Management	449 (58.3)	138 (98.6)	<0.001

**P*-values adjusted for the effect of the cluster design using Chi-square or exact tests.

The impact of previous morbid maternal conditions was extensively considered and Table 4 shows that around half of the population studied had any of the assigned previous conditions. For some conditions, their frequency was directly associated with the severity of maternal outcome, which is the case for cardiac disease, sickle cell disease, HIV/AIDS, cancer, drug addiction, thyroid diseases, any of them, and others not specified. For a few conditions, there was a fluctuation in the frequency of the previous condition with severity, such as self-reported obesity, diabetes, respiratory disease and renal disease. For hypertension as a previous condition, on the other hand, there was a decrease from 18% of cases of PLTC to 6.4% of cases of MD.

The Supplementary material (Table S2) describes some sociodemographic and obstetric history characteristics of women according to the outcome of obstetric complication. Cases identified as MNM had a significantly higher proportion of higher maternal age and parity, and hospital admission at lower gestational ages than PLTC. Delays for care were identified in increasing proportions with the severity of maternal outcome.

Table 4. Previous maternal conditions according to the outcome of maternal complications

Previous conditions	PLTC	MNM	MD	P**
Any of below	3633 (48.6)	333 (50.8)	62 (56.9)	0.491
Chronic hypertension	1342 (17.9)	107 (16.3)	7 (6.4)	0.035
Obesity	1884 (25.2)	87 (13.3)	18 (16.5)	<0.001
Low weight	21 (0.3)	5 (0.8)	1 (0.9)	0.166
Diabetes	176 (2.4)	30 (4.6)	3 (2.8)	0.036
Smoking	413 (5.5)	44 (6.7)	9 (8.3)	0.420
Cardiac disease	202 (2.7)	32 (4.9)	8 (7.3)	0.007
Respiratory disease	197 (2.6)	34 (5.2)	3 (2.8)	0.008
Renal diseases	77 (1.0)	23 (3.5)	2 (1.8)	<0.001
Sickle cell disease	50 (0.7)	12 (1.8)	3 (2.8)	0.004
HIV/AIDS	76 (1.0)	11 (1.7)	4 (3.7)	0.018
Thyroid diseases	98 (1.3)	17 (2.6)	4 (3.7)	0.008
Neurological diseases	86 (1.2)	12 (1.8)	2 (1.8)	0.289
Collagenoses	36 (0.5)	11 (1.7)	– (–)	0.213
Cancer	16 (0.2)	4 (0.6)	5 (4.6)	<0.001
Drug addiction	75 (1.0)	17 (2.6)	8 (7.3)	<0.001
Others (not specified)	334 (4.5)	82 (12.5)	16 (14.7)	<0.001
Total (n = 8241)*	7477	655	109	

*Missing information for 1314 cases.

**P-values adjusted for the effect of the cluster design using chi-square or exact tests.

Discussion

Main findings

Our results show a maternal mortality ratio of 170/100 000 LB; this is from a sample of tertiary referral facilities in the country with a high-risk population and so is not representative of the entire country, for which the ratio is around 58/100 000 LB,²¹ with an important decrease during the last decades. Brazil still has a high mortality, but with a high proportion of indirect obstetric causes and with marked improvement in many social and economic parameters. This triggers an obstetric transition for the country, where quality of care becomes a major determinant of health outcomes. Secondary and tertiary prevention are necessary to improve maternal health at this stage.²²

The MNM ratio for this study was very close to that from the WHO Multicountry Survey.²³ These figures are important to support the hypothesis that SMM occur at approximately the same rates everywhere, irrespective of the level of income or development. What really matters is when and how these morbidities are identified and managed and the consequent mortality. Additionally, the main factors currently identified as associated with MNM and MD were the same for both, suggesting that what really makes the difference is the care received. Our Mortality Index was 15.4%, an acceptable performance considering that high values (>20%) indicate an inadequate quality of obstetric care, whereas high-income countries present Mortality Index <2%.²⁴

Strengths and limitations

An important finding of this study is that an organised collaboration among health facilities from a middle-income country is possible, and powerful in gathering evidence for policy changes, whenever financial, structural and organisational resources are available and research priorities are established. Having quality and detailed data on almost 10 000 cases of SMM would be impressive even for high-income scenarios. The initiative of building a national network of facilities was the key point for further research proposals, the expertise developed through this work enabling future studies^{25–27} and empowering local changes and adjustments in quality of care.²⁸ Some similar initiatives have already been developed mainly in high-income countries such as Canada, the Netherlands and Scotland.^{7–9,29} However, such a broad surveillance system for middle- or low-income countries is rarely available even for study purposes.³⁰ In addition, although the results of a similar but much bigger and multinational study from WHO have already been published,²³ this was the first to test in the field the WHO criteria for PLTC and MNM on a large scale, and served as a pilot for the implementation of the larger WHO study.⁶

This study has some limitations. Considering the data were collected only after the women's discharge, some variables had a high missing data rate, as was the case for body mass index, ethnic group and education level, just because they were not included in the clinical records of some facilities. This was not associated with any other condition. In addition, we did not consider evidence-based interventions for each complication, which could have helped to understand delays in care and to derive some rates of unmet needs on quality of obstetric care. We also did not collect information for all delivering women, and therefore we could not estimate risks for adverse maternal outcomes according to any characteristic because a reference group without morbidity was not available.

This study generated and validated the maternal severity index¹⁵ that was used afterwards in the WHO Multicountry Survey on Maternal and Neonatal Health.²³ Since then, data from new studies or routine surveillance, using the same criteria, can be compared with information collected using these standard methods. Another key implication was to demonstrate that such a network for surveillance is also possible in middle-income and perhaps low-income settings if some resources are available, if a detailed and well-organised planning is performed, and mainly if political willingness exists. Some of the participating centres had very limited previous experience in clinical research but they were able to perform well with training and resources provided.

Interpretation

The current main causes of morbidity and mortality gave some surprising results. Indirect causes (classified as clinical/surgical) were responsible for 8.9% of PLTC, but for over 46% of maternal deaths. Previous reports have shown that indirect causes were responsible for about 25% of all maternal deaths in Brazil.²¹ A possible explanation for our higher rate of MD due to indirect causes is the impact of the influenza H1N1 pandemic during data collection.³¹ We had over 200 cases suspected and 30 MD among those. In addition, the country is experiencing an obstetric transition, moving to decreasing direct obstetric causes and increasing indirect causes as recently described.²²

On the other hand, the most frequent cause of maternal morbidity, hypertensive disorders, represented only 30% of MD. This is probably the result of adequate and timely interventions, with management of associated complications.²³ While postpartum haemorrhage is predominant mainly in low-income settings, hypertensive disorders as the leading cause indicates a real transition to a relatively better condition in terms of quality of obstetric care, generally associated with a transition to middle-income or upper middle-income countries.

Characteristics of women possibly associated with severity of maternal outcomes are not the main focus of the current analysis because they could only be properly assessed with reference to women without any complications. Anyway, this topic should be addressed in detail in future studies.

Important characteristics associated with severity of maternal outcomes were identified, including previous maternal conditions, any delays for care and admission before 37 weeks of gestation or postpartum. Any delay identified as associated with worse maternal outcome is a milestone for the discussion on the topic, mainly for middle-income countries where quality of obstetric care is a key point.¹⁴

Conclusion

The long-term goal from this study is to scale up the capacity of data collection and create a surveillance system with real-time input of information for decision-making. This could have a significant impact towards improvement of maternal health. To accomplish that, policy makers need to understand that with prompt identification of severe cases and adequate management, maternal mortality and morbidity can be effectively reduced. In addition, as another future goal to better address the problem of severe maternal morbidity, we propose a broad pragmatic randomised controlled trial with a package of interventions to be applied specifically for each condition identified, for each level of the health structure, and by trained health personnel. This would probably be the only way to test whether evidence-based information on the care of women with maternal complications could accelerate the process of changing the stage of obstetric transition to higher levels and then approaching the ideal situation for maternal health in the challenging new era we will be facing after 2015.

Disclosure of interests

None declared. Completed disclosure of interests form available to view online as supporting information.

Contribution to authorship

The idea for the study and this specific analytical approach arose in a group discussion among JGC, MAP, JPS and SMH. Analyses were planned and performed by JGC, MHS, MLC, FGS and SMH. The first version of the manuscript was drafted by JGC, MLC, RCP, MAP, SMH and then complemented with suggestions from all the other authors, mainly JPS, MAP, FGS, and RP. All authors contributed to the development of the study protocol and approved the final version of the manuscript.

Details of ethical approval

The research protocol was approved by the Institutional Review Board of the coordinating institution on 5 May 2009 (Document CEP 027/2009).

Funding

This study was funded by CNPq/DECIT (The National Research Council and the Department of Science and Technology of the Brazilian Ministry of Health), grant number 402702/2008-5. The content is solely the responsibility of the authors and does not necessarily represent the official views of CNPq. It did not influence the content of the manuscript.

Acknowledgements

Brazilian Network for the Surveillance of Severe Maternal Morbidity Group: Rodrigo S Camargo, Daniely S Santana, Vilma Zotareli, Lúcio T Gurgel, Eliana M Amaral, Lale Say, Robert C Pattinson, Marilza V Rudge, Iracema M Calderon, Maria V Bahamondes, Simone P Gonçalves, Olímpio B Moraes Filho, Simone A Carvalho, Francisco E Feitosa, George N Chaves, Ione R Brum, Gloria C Saint-Ynes, Carlos A Menezes, Patricia N Santos, Everardo M Guanabara, Elson J Almeida Jr, Joaquim L Moreira, Maria R Sousa, Frederico A Peret, Liv B Paula, Luiza E Schmaltz, Cleire Pessoni, Leila Katz, Adriana Bione, Antonio C Barbosa Lima, Edilberto A Rocha Filho, Melania M Amorim, Debora Leite, Ivelyne Radaci, Marilia G Martins, Frederico Barroso, Fernando C Oliveira Jr, Denis J Nascimento, Cláudio S Paiva, Moises D Lima, Djacyr M Freire, Roger D Rohloff, Simone M Rodrigues, Sergio M Costa, Lucia C Pfitscher, Adriana G Luz, Daniela Guimaraes, Gustavo Lobato, Marcos Nakamura-Pereira, Eduardo Cordioli, Alessandra Peterossi, Cynthia D Perez, Jose C Peraçoli, Roberto A Costa, Nelson L Maia Filho, Jacinta P Matias, Silvana M Quintana, Elaine C Moises, Fátima A Lotufo, Luiz E Carvalho, Carla B Andreucci, Elvira A Zanette, Márcia M Aquino, Maria H Ohnuma, Rosiane Mattar and Felipe F Campanharo.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. The WHO criteria for potentially life-threatening conditions and maternal near miss (6).

Table S2. Estimates of PLTC and severe maternal outcome (MNM and MD) according to some socio demographic and obstetrics characteristics of women. ■

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