

## Maternal mortality: protocol of a study integrated to the *Birth in Brazil II* survey

Mortalidade materna: protocolo de um estudo integrado à pesquisa *Nascer no Brasil II*

Mortalidad materna: protocolo de un estudio integrado a la encuesta *Nacer en Brasil II*

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### Abstract

The Maternal Mortality Study conducts a hospital investigation of maternal deaths that occurred in 2020/2021 in the maternity hospitals sampled by the Birth in Brazil II survey, with the following objectives: estimate the maternal mortality underreporting; calculate a correction factor and the corrected maternal mortality ratio (MMR); validate the causes of maternal mortality reported in the death certificate (DC); and analyze the factors associated with maternal mortality. The Birth in Brazil II includes approximately 24,250 puerperal women distributed in 465 public, private, and mixed hospitals with  $\geq 100$  live births/year in the five macroregions of Brazil. The Maternal Mortality Study data will be completed using the same Birth in Brazil II questionnaire, from the consultation of hospital records. Trained obstetricians will fill out a new DC (redone DC) from independent analysis of this questionnaire, comparing it to official data. The database of the investigated deaths will be related to the deaths listed in the Mortality Information System of the Brazilian Ministry of Health, allowing the estimation of underreporting and calculation of the corrected MMR. To calculate the reliability of the causes of death, the kappa test and prevalence-adjusted kappa with 95% confidence interval will be used. A case-control study to estimate the risk factors for maternal mortality will be developed with the investigated deaths (cases) and the controls obtained in the Birth in Brazil II survey, using conditional multiple logistic regression models. We expect this research to contribute to the correction of the underreporting of maternal mortality and to a better understanding of the determinants of the persistence of a high MMR in Brazil.

Maternal Mortality; Risk Factors; COVID-19

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## Introduction

Maternal mortality is a recognized violation of women's human, sexual, and reproductive rights. It is a premature and highly avoidable death, which has negative repercussions on the structure and dynamics of the family <sup>1</sup>.

The magnitude of maternal mortality, expressed by the maternal mortality ratio (MMR), reveals a close and complex relationship between socioeconomic disparities and failures in women's health care and the puerperal pregnancy cycle, and reflects the level of recognition of society for women's rights <sup>1</sup>. In Brazil, MMR is one of the worst health indicators, remaining a major challenge to be overcome <sup>2,3</sup>.

According to data from the World Health Organization (WHO), it is estimated that 287,000 women died worldwide in 2020 from maternal causes, generating an average MMR of 223 maternal deaths per 100,000 live births, which is equivalent to almost 800 deaths per day. Most of these deaths are concentrated in developing countries, indicating the immense inequality in the distribution of maternal deaths, which reach an MMR of 1,047 per 100,000 live births in Nigeria, in contrast to Norway, with two maternal deaths per 100,000 live births <sup>4</sup>.

In Latin America, there was little progress in reducing MMR from 2000 to 2020. Specifically in the 2016-2020 period, the first quinquennium of the Sustainable Development Goals (SDG) <sup>5</sup>, there was an increase in maternal deaths in the region <sup>4</sup>. In Brazil, a 39% reduction in MMR from 1990 to 2019 was observed, decreasing from 111.4 to 62.1 deaths per 100,000 live births <sup>6</sup>. Nevertheless, Brazil is still far from meeting the fifth Millennium Development Goal, to reduce the MMR by 70% between 1990 and 2015, and we remain far from reaching the target agreed by the Brazilian government with the SDG, to reach an MMR of 30 per 100,000 live births by 2030 <sup>7</sup>.

Moreover, the COVID-19 emergency, declared a pandemic by the WHO, triggered a significant increase in deaths of pregnant women and puerperal women <sup>8,9,10</sup>, and Brazil became one of the countries with the highest number of maternal deaths associated with SARS-CoV-2 infection in the world <sup>11,12</sup>. Data from the report of the Brazilian Obstetric Observatory reveal 2,055 maternal deaths in women with COVID-19 registered in the country from 2020 to 2022, namely: 462 in 2020; 1,518 in 2021; and 75 in 2022 <sup>13</sup>. This scenario exposed the weaknesses of obstetric care in the country, and imposes major changes for Brazil to reach the goal of the SDG.

COVID-19 has drastically changed the relationship between direct and indirect maternal deaths in Brazil during the pandemic. Official data show that the number of maternal deaths from the main direct causes (hypertension, hemorrhage, puerperal infection, and abortion) did not change substantially during the pandemic, while deaths from infectious and parasitic causes increased 10 to 35 times compared to 2019 <sup>14,15</sup>. In 2020, 1,965 maternal deaths were officially registered in Brazil, and the Brazilian Ministry of Health itself corrected this number to 2,039. In 2021, 3,030 maternal deaths were officially registered in Brazil, raising the MMR to 113 maternal deaths per 100,000 live births, and approximately half of these deaths were due to COVID-19 <sup>14,16</sup>.

Despite the almost universal coverage of prenatal care and hospital delivery, a quality care for pregnancy, labor/abortion, and childbirth constitute one of the main challenges of the Brazilian Unified National Health System (SUS, acronym in Portuguese). Management problems in childbirth care networks exposes high-risk women, especially those living outside large centers, to complications and maternal death due to greater difficulty in accessing specialized health services, with an appropriate structure, such as an intensive care unit <sup>17</sup>, leading to delays in providing appropriate care. On the other hand, the hypermedicalization of childbirth care and the excess of cesarean sections expose women to greater risks of complications, morbidity, and maternal mortality <sup>18,19,20</sup>.

Regarding the monitoring of maternal mortality, Brazil still presents problems of underreporting of deaths and misclassification of the basic cause of death. Errors persist in determining the type of death, whether maternal or not, in addition to data incompleteness, which compromise the analysis of the care provided and the living conditions of women who died during pregnancy, labor, abortion, or puerperium, a situation that varies substantially among Brazilian macroregions and states <sup>7,20</sup>. The compromised understanding of the determinants of maternal mortality impairs the definition of health priorities, guidelines, and policies and, thus, the effectiveness of actions to prevent and control the occurrence of these deaths.

Since 2004, with the launch of the National Pact for the Reduction of Maternal and Neonatal Mortality, the Brazilian Ministry of Health, supported by states and municipalities, has adopted some strategies to address maternal mortality as a priority and increase the quality of its data, including the establishment of goals related to increasing the coverage of mortality information; the development of information monitoring panels; and the regulation of surveillance of maternal deaths, of women in childbearing age, and of poorly defined causes<sup>21,22</sup>.

Flows and deadlines were also established to expedite the compulsory investigation of these events, leaving the municipal or state health systems in charge of the investigation and analysis of deaths. These efforts contributed both to the greater collection and identification of maternal deaths and to the qualification of the information, which resulted in the reduction of the correction factor applied to MMR in Brazil from 1.16% in 2010 to 1.05% in 2019<sup>22</sup>.

National studies that allow the review of data on maternal deaths are essential to expand the potential of surveillance and the response capacity of the health system to the problem<sup>23</sup>. These initiatives contribute to increasing the accuracy of maternal mortality data, as well as the reliability of the information available in the Brazilian Mortality Information System (SIM, acronym in Portuguese), and to identifying factors associated with maternal death in Brazil, particularly deaths from COVID-19.

This article aims to present the protocol of the *Maternal Mortality Study*, integrated to the *Birth in Brazil II: National Research on Abortion, Labor and Childbirth (Birth in Brazil II)*, which will have as main objectives: (1) estimate the underreporting of maternal deaths, calculate a correction factor, and the corrected MMR in the sample; (2) validate the causes of maternal death; (3) estimate the MMR according to the main causes of maternal death; (4) investigate the association between socioeconomic, demographic, obstetric factors, access to health services, prenatal care conditions, structure of the maternity and the processes and procedures in hospital care for abortion, labor, childbirth, and puerperium with maternal death, with emphasis on maternal deaths due to COVID-19.

## Method

The *Maternal Mortality Study* is a retrospective study integrated to the *Birth in Brazil II* survey, which will analyze all maternal deaths that occurred in 2020-2021 in the 465 hospitals participating in the *Birth in Brazil II*. The *Birth in Brazil II* is a national hospital-based survey that has several objectives, including estimating the prevalence of diseases and risk factors during pregnancy; evaluating prenatal care, labor, and fetal losses; and verifying the occurrence of negative maternal and perinatal outcomes and their associated factors. Because maternal death is a rare event and by the possibility of not including cases of maternal death in the *Birth in Brazil II* due to the survey nature, the *Maternal Mortality Study* was designed as a retrospective study integrated to *Birth in Brazil II* to investigate maternal deaths using the same variables and data collection methods.

### *Birth in Brazil II* survey

The *Birth in Brazil II*, conducted from 2021 to 2023, defined as the study population the set of women hospitalized due to labor or early fetal loss (including cases of abortion, legal termination of pregnancy, ectopic pregnancy, and molar pregnancy) in the sampled hospitals. The sample was selected in two stages: the first corresponded to hospitals and the second to postpartum women. All hospitals with 100 or more live birth/year, according to the Brazilian Information System on Live Births (SINASC, acronym in Portuguese) of 2017, were eligible for drawing lots. Stratification occurred according to Brazil's macroregion (North, Northeast, Southeast, South, Central-West); type of hospital (public/mixed/private); location (capital and Metropolitan Region/non-Metropolitan Region); and size (100-499 live birth/year,  $\geq 500$  live birth/year). The total sample corresponds to approximately 24,255 women, with an estimated 2,205 due to abortion and 22,050 due to labor, distributed into 465 hospitals. Further details of the sampling design are available elsewhere<sup>24</sup>.

The eligibility criteria for *Birth in Brazil II* were: puerperal women with live birth, regardless of the weight and gestational age, or stillbirth with gestational age  $\geq 22$  weeks or weight  $\geq 500$ g; and hospitalized women diagnosed with abortion. Women with impaired communication skills due to severe mental disorder; who do not understand Portuguese; who are deaf; and with a triplet pregnancy or more were excluded. For all women included in the *Birth in Brazil II*, interviews are conducted in the immediate puerperium; maternity booklet and ultrasound reports are photographed, when available, for later data extraction; and data are collected from the hospital record after discharge or on the 42nd day postpartum or after miscarriage, in case of prolonged hospitalization of the puerperal woman, or on the 28th day of life, in case of prolonged hospitalization of the newborn. Two telephone interviews, at two and four months after delivery or loss, are conducted to evaluate the use of services after discharge, maternal and neonatal morbidity, breastfeeding, psychosocial outcomes, and satisfaction with care.

Additionally, to evaluate the structure and care processes of obstetric and neonatology services, the maternity managers, coordinators/heads of obstetrics, neonatology, epidemiology, and pharmacy are interviewed in person. At this stage, an instrument developed based on the *Board Resolution n. 50* and Brazilian Ministry of Health Ordinances such as *n. 1,071/2005* and *n. 2,048/2002* is used. It has in its composition blocks on human resources, organization and work process, monitoring of care and care results, among others. More information available in Leal et al. <sup>24</sup>.

### **Population of Maternal Mortality Study**

All maternal deaths that occurred in the maternity hospitals included in the *Birth in Brazil II* from January 1, 2020 to December 31, 2021, either during pregnancy, labor, miscarriage, or puerperium up to 42 days (including cases of death during hospitalizations during pregnancy or puerperium, not linked to childbirth or uterine emptying) are considered eligible for the *Maternal Mortality Study*.

In 2020 and 2021, approximately 2 million live births occurred in *Birth in Brazil II* participating hospitals in Brazil. Considering the MMR of 58 maternal deaths per 100,000 live births in 2019, 6 it is estimated that around 1,200 maternal deaths were identified for this analysis.

### **Identification of maternal deaths and data collection**

In parallel with the *Birth in Brazil II* data collection, to identify maternal deaths for inclusion in the *Maternal Mortality Study*, the manager of each hospital is requested to provide a nominal list containing all maternal deaths that occurred in 2020 and 2021 in the institution, as well as authorization to access the medical records of these cases. The data for the *Maternal Mortality Study* are then extracted exclusively from the hospital record and the pregnant woman's medical record (when available attached to the record), using the same data collection instrument applied in the collection of information from the *Birth in Brazil II* maternal record, by the same data collectors who collect medical records for the women included in the *Birth in Brazil II* sample in each maternity hospital. Data collection is carried out by electronic forms in the REDCap application (<https://redcap.fiocruz.br/redcap>), which allows one to evaluate the consistency and control the quality of the collected data, thus reducing typing and archiving errors. Furthermore, online access to the database allows real-time monitoring of fieldwork by a team of supervisors.

The data collectors are predominantly nurses with training or experience in obstetrics, trained specifically for the procedures of *Birth in Brazil II* and *Maternal Mortality Study*. To clarify possible questions of the field team in filling out the questionnaire of the hospital medical record, a group of professionals with expertise in obstetrics was constituted, called "medical record advisors", who are available via WhatsApp seven days per week during the entire data collection period. More details on the training program and data quality monitoring activities at *Birth in Brazil II* and *Maternal Mortality Study* are available in Leal et al. <sup>24</sup>.

### **SIM and Maternal Mortality Study relationship**

To meet the objective of estimating the underreporting of maternal deaths, the relationship of deaths identified in *Maternal Mortality Study* will be made with the nominal database of deaths of women of childbearing age that carried out from January 1, 2020 to December 31, 2021, registered in the SIM, by access granted by the Department Health and Environment Surveillance of the Brazilian Ministry of Health. For the relationship, the following variables will be used: number of the death certificate (DC), maternity code in the Brazilian National Registry of Health Establishment (CNES, acronym in Portuguese), first and last names of the deceased, date of birth, date of hospitalization, and date of death. By this relationship, it will be possible to identify deaths reclassified after the investigation and available in SIM as maternal deaths, as well as deaths identified as maternal by the maternity hospital, but not reported in SIM as such. Maternal deaths found in SIM without identification by the hospitals will be informed to the maternity hospitals for the location of the medical records, and subsequent retrieval of the data. Thus, a new database of *Maternal Mortality Study* will be created, now including the maternal deaths identified in SIM. Likewise, maternal deaths not declared in SIM will be informed to the State Departments and to the Department Health and Environment Surveillance/ Brazilian Ministry of Health.

### **Revision of causes of death**

To meet the objective of validating the causes of death, for each maternal death medical record questionnaire, a new DC (redone DC) will be completed independently by two obstetricians, who do not know the original DC. Based on the information contained in the maternal death hospital record questionnaire and the pregnant woman's record, if available, each obstetrician will complete a new DC with the following fields: selected socioeconomic and demographic factors and the certification of causes of death – Part I lines a, b, c, and d and Part II, available in the REDCap application. In case of disagreement between the large group of causes or categories of the 10th revision of the International Classification of Diseases (ICD-10) or in the detailing/specification of the cause group or subcategories of the ICD-10 between two obstetricians, a new DC will be filled by a third trained obstetrician. The redone DC will be subjected to the codification of causes of death independently by two technicians trained by the Brazilian Center for Classification of Diseases, according to the rules of the ICD-10<sup>25</sup>.

To ensure the quality of the data, these professionals participated in a 20-hour refresher course on the completion of the maternal DC, by remote classes, coordinated by the Fernandes Figueira National Institute of Women's, Children's, and Adolescent's Health (IFF, acronym in Portuguese) in partnership with the Women's, Children's, and Adolescent's Health Research Group of the Sergio Arouca National School of Public Health (ENSP, acronym in Portuguese), Oswaldo Cruz Foundation (Fiocruz, acronym in Portuguese). Aspects of the care process were addressed considering the context and circumstances of maternal deaths, according to the root cause methodology, to qualify and subsidize the certification of causes of death, in line with the general guidance for completing the DC with the correct sequencing of causes according to ICD-10<sup>25</sup>.

### **Variables**

The outcome variable for *Maternal Mortality Study* will be: maternal death occurred during hospitalization during pregnancy, for labor or uterine emptying or until the 42nd day postpartum, abortion due to maternal death – chapter XV of ICD-10.

The main exposure variables obtained by the medical record data collection instrument (used for both *Birth in Brazil II* and *Maternal Mortality Study*) include:

- (1) Demographic and socioeconomic: maternal age, race/skin color, years of education, marital status, macroregion of residence;
- (2) Clinical and obstetric: history of chronic disease, obstetric history (total number of pregnancies, labors, and abortions; previous cesarean section), previous negative outcomes (low birth weight, prematurity, stillbirth, newborn death);

- (3) Current pregnancy: number of prenatal visits, Robson classification, type of delivery, complications in current pregnancy;
- (4) Hospital care for childbirth, abortion, or related to hospitalization during pregnancy or puerperium: data on care received, delays in receiving critical interventions, maternal morbidity, causes of death.

Based on the form of structure and care processes of obstetrics and neonatology services of hospitals, the following variables will also be analyzed: location; level of complexity of the hospital; volume of deliveries; density and distribution of health professionals; field of teaching practice certified by the Brazilian Ministry of Education and Brazilian Ministry of Health; access to equipment, supplies; and degree of implementation of good practices in childbirth and birth care.

### **Data analysis**

In the first stage of the analysis (to meet objectives 1 to 3 of the *Maternal Mortality Study*), the correction factor for maternal deaths will be calculated by macroregion by the ratio between maternal deaths reported to the SIM and those identified in *Maternal Mortality Study*, over deaths reported in SIM. The process of identifying maternal deaths in the maternity hospitals studied and estimating the correction factors will allow generalizing the total number of maternal deaths for all Brazilian hospitals. Then, the total hospital MMR and by cause of death of the *Birth in Brazil II* maternity sample will be estimated: number of maternal deaths divided by the number of live birth registered in SINASC in 2020 and 2021 per 100,000 live births. In this step, a comparison will also be made between the original coding of the basic cause of death and other DC data available in SIM, with the redone DC data. It will be determined by the percentage of agreement, kappa, and kappa adjusted to the prevalence and the degree of agreement classified according to Landis & Koch <sup>26</sup>.

At the second stage of the analysis, a descriptive analysis of deaths by socioeconomic, demographic, clinical characteristics, structure, and care processes of obstetric services will be conducted. The basic and associated causes will be analyzed considering direct obstetric and indirect obstetric causes. Special attention will be paid to deaths that were caused by COVID-19 and to the hospital care received by these women. The causes of death will also be analyzed according to the grouping of causes of the ICD-Maternal Mortality (ICD-MM) <sup>27</sup>. The sample design of the study will enable a thorough investigation of the set of variables described above according to macroregions and type of hospital.

In the third stage of the analysis, to determine the factors associated with maternal deaths (sociodemographic, obstetric, behavioral, access to health services, structure and care processes of obstetrics services), a case-control study will be conducted, in which the group of cases will be composed of all maternal deaths that occurred in the *Birth in Brazil II* study hospitals in 2020 and 2021, and the controls will be selected in an unpaired manner among the representative sample of women interviewed in the *Birth in Brazil II* postpartum or post-abortion survey, whose collection took place between 2021 and 2024. To minimize the impact of the temporal difference, a calibration of the *Birth in Brazil II* controls will be performed for the period of occurrence of the *Maternal Mortality Study* cases, using sociodemographic and obstetric characteristics extracted from SINASC.

Non-conditional multiple logistic regression models will be used to estimate the gross and adjusted odds ratios, considering the 95% significance level. All statistical analyses will be performed using procedures for complex samples, with weighting and calibration of the data and incorporation of the design effect, using the SPSS 22.0 program (<https://www.ibm.com/>) and the R program, version 3.5.1 (<http://www.r-project.org>).

### **Ethical issues**

The *Birth in Brazil II* survey, including the integrated study of maternal mortality, was approved by the Brazilian National Research Ethics Commission (CONEP, CAAE: 21633519.5.0000.5240), on March 11, 2020. Regarding the *Maternal Mortality Study* specifically, since it was a retrospective study based on a review of medical records of cases of maternal death, the waiver of the signing of the informed consent form was approved, and access to the medical records was authorized by the hospital unit.

## Discussion

Although it is one of the most relevant events in public health in Brazil, studies on maternal mortality are mostly descriptive, focusing on the discussion of methods to improve the estimation of maternal mortality or identify the underlying cause of death, with few proposing to investigate the determinants of maternal deaths, almost always restricted to municipalities or hospitals. Moreover, the use of the main source of maternal mortality data – SIM – is still limited due to the persistence of inequality in coverage, in the quality of maternal death data between the macroregions and Federation Units (UF, acronym in Portuguese), and in the difficulty of assessing the sociodemographic profile of maternal deaths, due to the limited availability of these data in the DC <sup>6</sup>.

These questions justify a broader and more comprehensive study, which aims to investigate the hospital context, where most maternal deaths occur; to study variables beyond those included in the DC; to estimate factors of macroregional correction of the number of maternal deaths, allowing the calculation of an MMR closer to reality; and to identify the determinants of maternal deaths. This will be the first Brazilian study on maternal mortality with primary data conducted in a nationally and macroregional representative sample of public, mixed, and private hospitals in state capitals, metropolitan cities, and other municipalities.

A previous study conducted in 2010 by the National Severe Maternal Morbidity Surveillance Network analyzed 140 deaths that occurred in 27 hospitals over the course of one year, seeking to identify demographic and clinical characteristics of the cases, as well as causes and delays in accessing adequate care <sup>28</sup>. In this sense, the proposal of this study advances in the understanding of the complexity of maternal mortality in Brazil by making a census of maternal deaths occurred in hospitals of the *Birth in Brazil II* sample, ensuring representativeness of maternity hospitals in Brazil, throughout 2020 and 2021, allowing robust statistical analyses, reaching an initially estimated number of 1,200 deaths. Additionally, for the case-control study, the complete medical records of the puerperal women interviewed at the *Birth in Brazil II* will be available, obtained from the same maternity hospitals and using the same standardized data collection procedures as those employed at the *Maternal Mortality Study*.

The causes of deaths will be analyzed by ICD-MM <sup>27</sup>, a classification proposed by WHO, which groups the causes of deaths, using ICD-10 codes: group 1, pregnancy with abortive outcome; group 2, hypertensive causes in pregnancy, childbirth, and puerperium; group 3, obstetric hemorrhage; group 4, pregnancy-related infection; group 5, other obstetric complications; group 6, unanticipated management complications; group 7, non-obstetric complications. This classification helps in identifying the cause of death, its interpretation and analysis <sup>27</sup>.

Because maternal death is a rare event, we chose to conduct a case-control analysis to investigate the factors associated with maternal death, with the controls selected in the same sample of hospitals, minimizing biases, since the characteristics of the population served and the treatment offered tend to be similar. Although there is a temporal difference in the time of occurrence of cases and controls, substantial changes are not expected in the characteristics of women and the hospital structure in this period. To minimize the impact of temporality, a calibration of controls can be performed from SINASC data to verify whether there was a significant change in the sociodemographic and obstetric characteristics of the women. The results can be generalized to most health facilities that perform childbirth and abortion care in the country. The significant number of maternal deaths that is expected to be identified will expand the power of the study, enabling assessments of less frequent exposures.

The use of the same instrument for the collection of medical records data in the *Maternal Mortality Study* and *Birth in Brazil II* will allow the calculation of several sociodemographic, obstetric, and care indicators related to maternal death using variables defined and collected in a standardized manner, which are not included in the DC. In addition, the assessment of the structure and care processes of obstetric and neonatology services in the sample hospitals will make it possible to draw a more comprehensive picture of the capacity of the services provided by maternity hospitals <sup>24</sup>.

To reduce the possibility of information bias caused by the non-blind data collection process of cases and controls, different strategies will be employed: use of the same questionnaire for data collection from hospital records, instruction manual with the description of standardized procedures, in

addition to systematic training of field collectors and continuous monitoring of data quality and of the work of the collection team.

It is worth noting that the probabilistic relationship of the records of the *Maternal Mortality Study* databases, after the hospital investigation of maternal death, with the SIM database, will allow the identification of undeclared maternal deaths. The review of the medical records and the completion of the causes of death in the DC performed by two obstetricians, independently, marks a highlight of this research, conferring greater accuracy in the information of the basic cause and multiple causes of death. These data will provide subsidies to the death committees and to SIM on the main causes of death that have a filling error.

However, there will still be gaps regarding the deaths of women of childbearing age not investigated by the committees, which in the period from 2018 to 2020, corresponded to about 10% of the cases listed in SIM, with important variations among Brazilian macroregions, from 3.1% in the South to 14.1% in the Northeast of Brazil <sup>29</sup>.

It is possible that deaths occurring at home, on public roads, or in health facilities with less than 100 live birth/year, which between 2018 and 2020 represented less than 10% of maternal deaths registered in SIM, present a different profile from the women who had access to the hospital services studied <sup>29</sup>. Although these situations are infrequent, they can affect the estimates of maternal mortality, because it is a rare event.

Due to the coincidence with the peak years of the COVID-19 pandemic, in this study, there may also be over or underreporting of deaths due to COVID-19 in a certain UF, whether the reference hospitals for COVID-19 cases in pregnancy and puerperium have been included in the sample or not. In addition, the inclusion of a referral hospital for COVID-19 in a state may eventually mean selective loss of deaths from direct obstetric causes that were being referred to another unit not selected in the sample. Certainly, the number of indirect maternal deaths in these years was disproportionate to the average of previous years, and this should be weighted to calculate the correction factor <sup>13,14</sup>.

Due to the fact that the *Maternal Mortality Study* is based exclusively on data from hospital medical records, often with a significant number of unfilled, incomplete, or inconsistent variables, the study may not reflect all the care gaps and barriers faced by women, in particular those associated with delayed access to hospital care. We also anticipate the possibility of absence of information obtained by the prenatal card, if these are not available in the hospital records. Some strategies will be adopted to circumvent this problem, such as multiple imputation of data with chained equations. Still, the primary data source brings advantages in terms of data completeness regarding secondary sources, usually used for the analysis of maternal death in Brazilian studies.

Studies of this nature can contribute to the surveillance and monitoring of maternal mortality by highlighting the relevance of complete and accurate data, as well as the establishment of objective benchmarks to expand the “response capacity” of the health system, as it shows the needs for the formulation and implementation of recommendations aligned with the results found. The continued integration of surveillance with response capacity will build the foundation for controlling future preventable maternal deaths.

Considering the high frequency of negative maternal outcomes in the country, we hope that the results of this study will provide relevant information for the elaboration of national and local public policies, aimed at ensuring the safety of the parturient and expanding access to good practices in assisting women in pregnancy, labor, delivery, and abortion. In addition, it may increase the satisfaction of women and health professionals with care for childbirth, early fetal losses, and clinical and obstetric complications from gestation to puerperium.



## Contributors

S. G. N. Gama contributed to the study conception, data acquisition and writing; and approved the final version. S. A. Bittencourt contributed to the study conception, data acquisition and writing; and approved the final version. M. M. Theme Filha contributed to the study conception, data acquisition and writing; and approved the final version. M. L. S. Takemoto contributed to the data acquisition and writing; and approved the final version. S. Lansky contributed to the data acquisition and writing; and approved the final version. P. G. Frias contributed to the data acquisition and writing; and approved the final version. B. V. S. Ayres contributed to data acquisition and critical review; and approved the final version. R. M. S. M. Domingues contributed to the study conception and critical review; and approved the final version. M. A. B. Dias contributed to the study conception and critical review; and approved the final version. A. P. Esteves-Pereira contributed to the data acquisition and management and critical review; and approved the final version. M. Nakamura-Pereira contributed to the study conception and writing; and approved the final version. M. C. Leal contributed to the study design, data acquisition and critical review; and approved the final version.

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## Resumo

O Estudo da Mortalidade Materna conduz uma investigação hospitalar dos óbitos maternos ocorridos em 2020/2021 nas maternidades amostradas na pesquisa Nacer no Brasil II, com os seguintes objetivos: estimar o sub-registro da mortalidade materna e calcular um fator de correção e a razão de mortalidade materna (RMM) corrigida; validar as causas de mortalidade materna informadas na declaração de óbito (DO); e analisar os fatores associados à mortalidade materna. O Nacer no Brasil II inclui aproximadamente 24.255 puérperas distribuídas em 465 hospitais públicos, privados e mistos com  $\geq 100$  partos de nascidos vivos/ano nas cinco macrorregiões do país. Os dados do Estudo da Mortalidade Materna serão preenchidos utilizando o mesmo questionário do Nacer no Brasil II, a partir da consulta aos prontuários hospitalares. Obstetras treinados preencherão uma nova DO (DO refeita) a partir de análise independente desse questionário, comparando aos dados oficiais. A base de dados dos óbitos investigados será relacionada com os óbitos constantes no Sistema de Informações sobre Mortalidade do Ministério da Saúde, permitindo a estimativa do sub-registro e cálculo da RMM corrigida. Para o cálculo da confiabilidade das causas de morte, serão utilizados os testes kappa e kappa ajustado à prevalência com intervalo de 95% de confiança. Um estudo de caso-controle para estimar os fatores de risco para mortalidade materna será desenvolvido com os óbitos investigados (casos) e os controles obtidos na pesquisa Nacer no Brasil II, utilizando-se modelos de regressão logística múltipla condicional. Espera-se contribuir para a correção do sub-registro da mortalidade materna e para a melhor compreensão dos fatores determinantes da persistência de RMM elevada no Brasil.

Mortalidade Materna; Fatores de Risco;  
COVID-19

## Resumen

El Estudio de Mortalidad Materna evalúa las muertes maternas ocurridas en 2020-2021 en las muestras de maternidades del encuesta Nacer en Brasil II con los objetivos de estimar el subregistro de mortalidad materna y calcular el factor de corrección y la tasa de mortalidad materna corregida (TMM); validar las causas de mortalidad materna reportadas en el certificado de defunción (CD); y analizar los factores asociados a la mortalidad materna. La Nacer en Brasil II incluye aproximadamente 24.250 mujeres puerperales, distribuidas en 465 hospitales públicos, privados y mixtos con  $\geq 100$  nacidos vivos/año en las cinco macrorregiones de Brasil. Los datos de Estudio de Mortalidad Materna se completarán con la información del cuestionario Nacer en Brasil II a partir de una búsqueda de los registros médicos hospitalarios. Los obstetras capacitados completarán un nuevo CD (CD rehecho) desde un análisis independiente de este cuestionario, comparándolo con los datos oficiales. La base de datos de muertes investigadas se relacionará con las muertes que constan en el Sistema de Informaciones sobre la Mortalidad del Ministerio de Salud para permitir la estimación del subregistro y el cálculo de la TMM corregida. Para calcular la exactitud de las causas de muerte, se utilizarán las pruebas kappa y kappa ajustada a la prevalencia con un intervalo de 95% de confianza. Un estudio de casos y controles se aplicará para estimar los factores de riesgo de las mortalidad materna con las muertes investigadas (casos) y los controles obtenidos en el estudio Nacer en Brasil II utilizando modelos de regresión logística múltiple condicional. Se espera que este estudio pueda contribuir a la corrección del subregistro de la mortalidad materna y a una mejor comprensión de los determinantes de la persistencia de alta TMM en Brasil.

Mortalidad Materna; Factores de Riesgo;  
COVID-19

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