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## THE IMPORTANCE OF THE VALIDATION OF THE SAFETY THERMOMETER PROTOCOL IN THE MATERNITY OF A PAULISTA PUBLIC HOSPITAL

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### ABSTRACT

The use of protocols such as the standard operating procedure assists in the sequence and standardization of conduct. In Brazil, there is a lack of data on safety in the obstetric and neonatal context, in addition to the lack of instruments. The study aimed to evaluate a protocol in the standard operating procedure model for the implementation of the instrument defined as a Maternity Safety Thermometer in a public university hospital in Sao Paulo. The methodology is a descriptive, qualitative study of technology validation of the type of development research. In the first stage, a protocol was elaborated by the researchers and it was validated by the committee of 12 specialists in obstetric nursing, professionals from the study unit. The analysis was performed using the Content Validation Index (reference value 0.8) and through a semi-structured questionnaire with the Likert scale (1 to 4), which varied between 0.84% and 1.0, with the percentage concordance was 98.7%. The second stage has dedicated to the application of the Safety Thermometer in Maternity, whose data showed that most women underwent cesarean sections (64.5%). Of those who had vaginal deliveries, there was perineal trauma (12.8%), episiotomy (3.2%), and hemorrhage (9.6%). As for newborns, it was necessary to transfer 45.2% of the babies, 35.5% of whom have already planned. The damage-free indicator was 9.6%. The protocol studied in the standard operating procedure format presented acceptable psychometric content validity indicators, reinforcing the use of this easy-to-apply instrument and enabling the creation of obstetric and neonatal care safety indicators.

**Keywords:** Obstetrics; Maternal and Child Health; Patient Safety; Quality Indicators; Validation Studies.

### INTRODUCTION

Obstetric care has been widely discussed since the 1980s in Brazil. There are high rates of cesarean sections, as well as the indiscriminate use of interventions that have been considered

harmful to care according to scientific evidence. On the other hand, there is an underutilization of more effective and safer procedures, associated with the main factors of maternal and neonatal complications, that cause near loss events and death. They are hemorrhages, blood transfusions, thrombolytic disorders, anesthetic complications, respiratory distress, damage to internal organs, infections, admission to an adult and neonatal intensive care unit, iatrogenic prematurity, maternal and neonatal death, among others, which implies the quality of the service provided and the increase in hospital costs.

Maternal mortality has become an indicator of social development proposed by United Nations Organizations, monitored within the Millennium Development Goals in the years 2000 to 2015 [1]. Currently, the obstetric scenario in Brazil stands out for a large number of cesarean sections, due to high rates of maternal morbidity and mortality and near-miss, the indiscriminate use of interventions in vaginal delivery, and the non-observance of basic rights of women, which constitute critical points of care and which have promoted several debates on the theme [2].

The World Health Organization (WHO) considers up to 20 deaths per 100,000 live births acceptable [3]. In developed countries, the maternal mortality rate is around 12 deaths per 100,000 live births, while in developing countries, there are 239 maternal deaths per 100,000 live births. The International Classification for Patient Safety comprises several concepts that provide a structure for organizing information for several purposes, such as the systematic collection of data on patient safety and adverse events, carrying out statistical analysis, supporting descriptive and evaluation studies, and allowing the long-term service monitoring [4].

In the municipality of Sao Paulo, in 2014, maternal mortality was 46.25 deaths per 100 thousand Live Births (LB) and neonatal deaths were 7.3 per thousand LB. There is a tendency for declining maternal and neonatal mortality in the municipality, with values below the national average (62 and 7.8 respectively). However, the rates are higher than the averages of high-income countries. Considering the relevance of the context presented, the purpose of this study was to develop and evaluate the Maternity Safety Thermometer (MST) protocol in a University Hospital in the Standard Operating Procedure (SOP) format. The justification for choosing the research location was the fact that the obstetrics unit does not have a standardization or protocol that assesses the specific damages of the care provided to women and newborns, in addition to the desire to collaborate to promote perinatal care safer.

Protocols are essential tools that the manager and the assistance team use to solve problems. They must be supported by validated studies and guided by the best scientific evidence. Studies have shown a greater number of research on health care protocols that have as one of the objectives the standardization of care practices [5]. The use of protocols such as SOP helps in the sequence and standardization of conducts to be taken, which facilitates the professionals' decisions to establish parameters that allow the study of cases, definitions of treatments, etc., enabling the systematization of assistance.

In Brazil, there is still no standardization of safety indicators related to obstetric care in health services, and some research and government initiatives point to such a need at the three levels of health care. Health regulatory agencies should encourage, inspect and regulate the

systematic use of these indicators by services, given the importance of knowing the reality of the problems related to the safety and quality of obstetric care in the country [4]. For these reasons, the question of this research is how can the MST Protocol contribute to the management of indicators and the quality of obstetric care provided in the studied hospitalization unit?

Perinatal and neonatal mortality rates are sensitive indicators of the adequacy of obstetric and neonatal care and the impact of intervention programs [6]. Meantime, the proposal of the MST instrument was inserted. The objective is to measure maternity care in five areas: perineal and abdominal trauma: postpartum hemorrhage; maternal infection; Apgar score, less than [7] in the fifth minute of life; admission of full-term newborns to the Neonatal Therapy Unit (NTU); and women's perception of security about the assistance received [7]. The great innovation of the MST is to measure the indicators of obstetric care, showing the damage caused by the care provided, as well as the morbidities that are often ignored or normalize as inevitable so that professionals know their prevalence for reflection and change in the work context [4]. Community SOPs can be described as the standardization of procedures that detail instructions for performing tasks to ensure the quality of the entire procedure, to obtain results with greater reliability, and to make specific functions to be performed uniformly.

In this context, the MST is a data identification tool that allows, according to the National Health Service (NHS) guidelines, to calculate indicators that provide health services with rates and proportions of adverse events related to obstetric care [4]. It also makes it possible to assess and name situations that had been considered inherent or unavoidable at birth: unnecessary cesarean sections, episiotomy, separation of the mother-baby at birth, and behaviors considered abusive and disrespectful evaluated by women in the assistance received [7].

The information system for capturing adverse events related to the care process has been developed based on the International Classification for Patient Safety of the World Alliance for Patient Safety [8]. The system allows the option of notification by citizens (patients, family members, caregivers, and caregivers) and by the Patient Safety Centers, regulated by RDC No. 36 of July 25, 20139. It is worth mentioning the pioneering spirit of anesthesia and transfusion organs and services blood, infection control, and prevention associated with health care [9]. Table I shows the concepts of patient culture established by the Patient Safety Culture.

**Table I: Concepts of Patient Safety Culture - Ordinance MS / GM n° 529/2013**

Culture in which all workers, including professionals involved in care and managers, take responsibility for their safety, for the safety of their colleagues, patients, and family members.
Culture that prioritizes safety over financial and operational goals.
Culture that encourages and rewards the identification, notification, and resolution of security-related issues.
Culture that, from the occurrence of incidents, promotes organizational learning.
Culture that provides resources, structure, and accountability for the effective maintenance of security.

**Source: Ministry of Health, 2018**

According to data from the Mortality Information System, in 2015, the country recorded 1,738 cases of maternal deaths [10]. It includes deaths caused by problems related to pregnancy or childbirth or that occurred up to 42 days later. In 2016, 1,463 cases were registered, a decrease

of 16% concerning the previous year<sup>10</sup>. Although the maternal mortality ratio showed an annual decrease of 3.72% in the period from 1990 to 2011, in Brazil, these values are high and discrepant concerning the country's progress in the performance of the health system, the improvement of the socioeconomic level, and the fall infertility [11].

## METHODOLOGY

It is a descriptive, qualitative study of technology validation of the type of development research. It sought to validate a protocol in the SOP model for the implementation of the instrument defined as MST in the obstetric unit of a university hospital, a tool created by the NHS of England. It aims to provide the instantaneous prevalence of damage [12] and to identify patients who go through the health system without damage or who are affected by one or more damages [13]. The place of study was an Obstetric Inpatient Unit of a large and highly complex Public University Hospital, currently with 370 beds, located in the city of Sao Paulo.

The study unit is a reference in high-risk obstetric care, with 8 infirmary beds and 01 Obstetric Center with 2 beds Pre-Childbirth/Childbirth and Puerperium, 02 operating rooms, 01 RPA with 02 beds, and 01 resuscitation room where newborns are received. Data collection was carried out from September to November of 2018. The expert committee was composed of obstetric nurses who work in the study unit. There were invited individually and with an Invitation Letter. Other forms were sent to the participants through Mobile Learning tools such as WhatsApp and electronic mail, according to the option of each participant, respecting criteria such as skill and practicality for use, after providing guidance and clarification on the proposal of the search.

The inclusion criteria for participation in the study were nurses with a specialization in obstetrics who worked at the unit and with minimum clinical experience of one year in the area of obstetrics and the exclusion criteria were nurses who did not comply with the proposed stages of researcher and the researcher who was part of the nursing staff. The staff is composed of 13 obstetric nurses distributed in four different shifts (morning, afternoon, and two at night). The inclusion of nurses in the sample to validate the instrument was justified by the fact that the NHS recommends the professional category as the most appropriate for the application of the instrument.

Data collection took place in two phases. First, all obstetric nurses from the study site were invited to compose the expert committee. After the acceptance of the 12 nurses, all the relevant orientations to the process have been carried out including the presentation of the study proposal. To clarify all doubts the link to the ICF sent a semi-structured questionnaire with open and closed questions and the SOP-type protocol. It has developed by the researchers based on the MST instrument cross-culturally adapted to Brazilian Portuguese by Melo [4]. The answers to the closed questions were scalar, to obtain a more objective measure of the analysis for each item evaluated by the specialists based on the model developed by Quaglio [14] and were adapted, as well as the other forms using the tool for digital version in the Google Docs. The time estimated to complete the questionnaire was 15 minutes.

The questionnaire was designed with 5 questions on the rating scale, starting with 1-inadequate, 2-partially adequate, 3-adequate, 4-totally adequate. Each question contained sub-items that

varied in quantity from 4 to 7. After each question, there was space for the judge to describe the reason why he would evaluate items with a value of 1 or 2. The last question has designated for comments and suggestions. The variables applied to evaluate the instrument were the following: objectivity, effectiveness, practicality, usefulness, and the need for adjustments or changes to improve the instrument.

The second part of the collection has taken place after the validation process of the MST protocol in the SOP format. It was the training of all obstetric nurses in the unit and students of the 4th year of Nursing Graduation [15], besides nurses from the Residence in Obstetric Nursing [4], who was in the internship at the Obstetrics Unit of the University Hospital during the data collection period. All of them have been instructed on how to apply and complete the instrument according to the SOP. After a month of collection, the data listed on the instrument has been tabulated and the safety indicators for obstetric and neonatal care and damage-free care have calculated as recommended by the NHS. The number of patients with damage was used as a numerator and the number of patients exposed to damage as a denominator, multiplying the result by 100 [15].

## RESULTS

The first part of the study refers to the process of elaborating and validating the SOP MST protocol. All obstetric nurses from the obstetrics unit of the University Hospital participated in it, totaling 12 nurses (100%). All-female and who have worked in the obstetric area for over a year, with 01 (8.3%) of them also works as a university professor, with 11 (91.7%) specialists and 01 doctors (8.3%) and 02 (16.6%) have publications in the obstetric area. The age range ranged from 30 to 53 years. As for the time working in the area, those with between 6 and 10 years (33.4%) of experience predominated, followed by those from 1 to 5 years (25%), more than 20 years (25%), 11 to 15 years (8.3%), 16 to 20 (8.3%) respectively.

The second part of the study refers to the application of the instrument in the study unit that occurred in October, after validation of the MST Protocol in the SOP format. All obstetric nurses [12] in the unit has been instructed on the application and completion of the instrument and students from the 4th year of Nursing Graduation [3] and nurses from the Obstetric Nursing Residency [4] who was on internship at the Obstetrics Unit of the Sao Paulo hospital during the collection period. The application of the protocol occurred for all the mothers (31) who had birthed in October and were in the interval above 12 hours postpartum. The predominant skin color self-declared by the mothers was brown (41.9%), followed by white (38.7%) and black (19.35). The prevalent age group was 20 to 34 years old (70.9%) and the majority spoke Portuguese (96.7%). Single (100%) and full-term pregnancies for 37 to 42 weeks were predominant (74.2%), followed by preterm pregnancies (25.8%).

As for the Body Mass Index (BMI), most women were classified between the ranges of 18.6-24.9 (35.5%) and 25-29.9 (29%) respectively. Regarding the type of delivery prevalent in the period, it was cesarean (64.5%) and vaginal (35.5%), all of which occurred at the Obstetric Center. Of the 31 (100%) puerperal women, 05 (16.1%) did not answer the instrument's questions related to the woman's perception of security, for reasons of refusal or other unspecified and in 21 (67.7) there was no record about the estimated blood loss in the postpartum period.

## DISCUSSION

In the first stage of the research, referring to the MST protocol validation phase, the content validation index varied between 0.84 and 1.0, thus, in the judgment process, all items evaluated in the protocol obtained agreement within the level recommended and the percentage of agreement between the judges was 98.7%. According to Silva et al. [16], this is an important phase of the content validation process; however, it must be followed by the clinical application stage of the evaluated instruments. Regarding the only open question in the questionnaire, referring to the fifth evaluated aspect of the instrument, it has proposed comments and suggestions to readjust and improve the instrument. There was little participation by specialists, only 3 (25%) of the sample, which shows their little exploitation of the instrument.

The obstetric nurses proposed the application of the instrument according to the bed division scale to perform the nursing systematization (SAE), the obstetrical nurse when carrying out the visit and physical examination for the preparation of the SAE. At that moment, if pertinent, the protocol will be applied to respect the minimum time of 12h postpartum and the nurse responsible for the discharge of the puerperal woman will check if the filling was done properly, otherwise, she will do it. The information has been added to the SOP MST in item 3, responsibility in the observations.

In the Second Stage, the results obtained through the application of the instrument, according to the MST protocol regarding the safety indicators of obstetric and neonatal care and diagnoses of damages obtained in the first part of the instrument - Place and Type of Delivery. All births occurred at the Obstetric Center (100%) of the studied unit, the prevalence of cesarean sections was 64.5%, more than three times the value considered acceptable by WHO [8] the rate of vaginal deliveries was 35.5%. In this study, as for Skin Color, most women declared themselves to be brown (41.9%) and black (19.3%), both groups accounted for 61.2% of the sample, the importance of studying this aspect is mainly by the social inequalities evidenced by the literature, mainly about black women.

The age group prevalent in the present study was 20 to 34 years old. The best maternal age from the reproductive point of view considered by the literature is between 20 and 29 years old, because, at this stage, the best maternal and perinatal results are observed [17]. The importance of evaluating this criterion is given that available data on the extremes of the age of women, very young and very old, attribute a greater risk to adverse outcomes and complications of pregnancy, childbirth, and perinatal [18]. Regarding body mass indexes (BMI), there was a higher prevalence of the group 18.6 to 24.9 (35.5%), followed by 25 to 29.9 (29%).

Regarding the evaluated component Perineal Trauma/Abdominal Surgical Incision, the prevalence of 1st-degree laceration was 3.2%, the second degree was 9.6% and, as already presented, episiotomy and cesarean section were respectively 3, 2%, and 64.5%. As a result of vaginal delivery, most women have some degree of perineal trauma that can be characterized by the occurrence of spontaneous laceration, episiotomy, or both. About the assessed component Postpartum Hemorrhage: the prevalence of blood loss > 1000 ml was 9.6% and that of blood transfusion 3.2% according to the completed data. However, 67.7% of the instruments applied there were no records of estimated blood loss the data did not find in the medical record.

Mortality rates due to postpartum bleeding vary widely in different regions of the world an important risk factor attributed to the problem is the lack of a protocol of conduct.

The main associated causes are uterine atony, traumas such as laceration of the birth canal, uterine inversion, retention of placental remains, and coagulation disorders. The infection rate presented during the period of application of the instrument was 12.8%, with 01 (3.2%) referring to urinary tract infection, 01 (3.2%) surgical site after cesarean section; 01 (3.2%) uterine infection, and 01 (3.2%) active genital herpes infection. Active surveillance contributes to the identification of infection and the literature points to the need for studies that use surgical risk to assess surgical wound infection in cesarean sections. Surgical wound infections are one of the main postoperative complications and the lack of active surveillance is one of the main causes of underreporting, which often occurs due to early discharge and the woman's return to services other than where the birth occurred.

About the evaluated component Baby, the data obtained from newborns reveals that 1 (3.2%) presented Apgar in the 5th minute  $\leq 6$ , 14 (45.5%) were transferred to the NICU, with 11 transfers (35.5%) were foreseen. Analyzing this data is fundamental to understand and determining factors related to neonatal morbidity and mortality. Regarding the Perception of Postpartum, the item assessed on safety, 9 (39.1%) reported that she was separate from the baby at term from birth. The complaints were separation for immediate care right after birth at the Obstetric Center for exams in the joint accommodation [2]. 7.4% of women reported having left alone during labor or delivery when they felt some type of concern and [5], 38.4% answered yes to the question "if a safety concern was expressed, they did not consider it was taken seriously".

It is worth mentioning that no woman expressed a desire to speak or talk to the obstetrician/nurse or any other health professional. From the application of the protocol, it was possible to show that assistance in the obstetric unit of the studied hospital presented a greater number of damages than harm-free care. The components that had the highest "damage temperature" related to childbirth were cesarean sections 20 (64.5%), need to transfer the baby to the NICU 14 (45.2%), infection 4 (12.8%), lipothymia or fainting 4 (12.8%), 2nd-degree lacerations 3 (9.6%). The psychosocial components are related to women's perception of safety 9 (39.1%), who were left alone during labor when they felt worried 5 (38.4%) and harm-free care 3 (9.6 %).

## CONCLUSION

In conclusion, the limitations of the research have related to the application of the process in a single place of study and with only one type of specialist. As a result, failures in filling in the instrument and medical records ended up making it impossible to fully record the data. Thus, the results were underestimated. Therefore, there is a need to use these instruments in other institutions and contexts of childbirth and birth care for more comprehensive comparative and data correlation studies.

## REFERENCES

- [1] Souza JP, Souza JP (2015). Maternal mortality and the new objectives of sustainable development (2016-2030). *Revista Brasileira de Ginecologia e Obstetrícia*, 37(12), 549–551. <https://doi.org/10.1590/SO100-720320150005526>
- [2] Salgado H de O (2017). *Cuidado materno livre de danos e prevalência de depressão pós-parto: inquérito/nascer no Brasil, região Sudeste, 2011 e 2012* (Tese de Doutorado). Universidade de São Paulo.
- [3] Martins ACS, Silva LS (2018). Perfil epidemiológico de mortalidade materna. *Revista Brasileira de Enfermagem*, 71, 677–683. <https://doi.org/10.1590/0034-7167-2017-0624>
- [4] Melo CR de. (2015). *Adaptação transcultural do maternity safety thermometer para o português do Brasil* (Tese de Doutorado). Universidade Federal de Santa Catarina.
- [5] Monteschio LSF, Agnolo CMD (2017). Procedimento operacional padrão em unidade de terapia intensiva. *Revista Uningá Review*, 4(1), 3–3.
- [6] Borba GG, Neves ET, Arrué AM, Silveira A, Zamberlan KC (2014). Fatores associados à morbimortalidade neonatal: um estudo de revisão. *Saúde (Santa Maria)*, 40(1), 9–16.
- [7] Salgado H de O, et al. (2017). Patient safety in maternity care in Brazil: the maternity safety thermometer as a tool to improve the quality of care. *Revista Brasileira de Ginecologia e Obstetrícia*, 39(5), 199–201.
- [8] OMS OM de saúde. (2009). The conceptual framework for the international classification for patient safety. August 2, 2018, <http://www.who.int>
- [9] Ministério da Saúde, Fundação Oswaldo Cruz, Agência Nacional de Vigilância Sanitária. (2014). Documento de referência para o programa nacional de segurança do paciente.
- [10] Ministério da Saúde. (2018). Ministério da saúde investe na redução da mortalidade materna. Recuperado 9 de agosto de 2018, de <http://portalms.saude.gov.br/noticias/agencia-saude/43325-ministerio-da-saude-investe-na-reducao-da-mortalidade-materna>
- [11] Domingues RMSM, et al. (2015). Adequação da assistência pré-natal segundo as características maternas no Brasil. *Revista panamericana de salud pública*, 37(3), 140–147.
- [12] Power M, Fogarty M, Madsen J, Fenton K, Stewart K, Brotherton A, Provost L (2014). Learning from the design and development of the NHS safety thermometer. *International journal for quality in health care*, 26(3), 287.
- [13] Buckley C, Cooney K, Sills E, Sullivan E (2014). Implementing the safety thermometer tool in one NHS trust. *British Journal of Nursing*, 23(5), 268–272.
- [14] Quaglio C (2018). *Análise da situação da implantação do protocolo de avaliação do freio lingual com escores para bebês em uma maternidade de São Paulo* (Programa de Mestrado Profissional em Administração Gestão em Sistemas de Saúde). Universidade Nove de Julho,
- [15] National Health Service. (2014). Maternity safety thermometer pilot data 09/04/2014. Recuperado de <http://safetythermometer.nhs.uk/index.php?>
- [16] Silva FA, et al. (2015). Validation of the content of the prevention protocol for early sepsis caused by Streptococcus agalactiae in newborns. *Revista Latino-Americana de Enfermagem*, 23(4), 635–641. <https://doi.org/10.1590/0104-1169.0179.2598> São Paulo.
- [17] Canhaço EE, et al. (2015). Perinatal outcomes in women over 40 years of age compared to those of other gestations. *Einstein (São Paulo)*, 13(1), 58–64. <https://doi.org/10.1590/S1679-45082015AO3204>



- [18] Costa AL do RR, Araújo Junior E, Lima JW de O, Costa F da S (2014). Fatores de risco materno associados a necessidade de unidade de terapia intensiva neonatal. *Revista Brasileira de Ginecologia e Obstetrícia*, 36(1), 29–34. <https://doi.org/10.1590/S0100-72032014000100007>