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# Development and validation of a nursing care protocol for pregnant women and newborns in Brazil

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## Abstract

**Background:** The standards for the care of women and newborns are a collaborative plan of care based on the prioritization of diagnoses, problems, health issues, and mutually established goals, involving the interprofessional team, the patient, their supportive network, or community. Thus, it is crucial to develop a plan of care and implement it in this field to promote the health of women and newborns. This study aims to develop and validate a clinical protocol modeled on the nursing process for implementation in a Normal Birth Center (NBC) in Brazil.

**Methods:** This methodological study with a qualitative approach was developed in four distinct phases: scoping reviews, qualitative discussions with nurses, and the construction and validation of the protocol.

**Results:** The scoping review on diagnoses yielded 26 nursing diagnoses. The scoping review on interventions underscored the significance of employing non-pharmacological techniques for pain relief and maternal and neonatal care, highlighting the importance of providing physical and emotional support to women and their babies. The clinical protocol was developed utilizing the minimum nursing dataset, correlating with the 35 evaluated diagnoses in consultations with nurses, and integrating interventions and linkages from NANDA-NIC-NOC. 10 nursing experts validated the protocol.

**Conclusion**: The clinical protocol will be implemented in an NBC to enhance nursing care for pregnant women and neonates. Additionally, it is anticipated that this study will stimulate the development of new research on the topic, linking various contributions to the field of obstetric nursing and increasing awareness of its value through individualized, targeted diagnoses, interventions, and activities.

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## Highlights

### What is current knowledge?

Maternal and neonatal care has advanced through evidence-based, humanized approaches centered on basic needs. Obstetric nursing employs the Nursing Process to provide safe, organized care. Despite progress, Brazil faces high cesarean rates and maternal mortality, highlighting the need for standardized clinical protocols to improve care quality in normal birth centers.

### What is new here?

The clinical protocol developed for normal birth centers supports nurses in providing evidence-based, individualized care to pregnant women and newborns. It enhances clinical judgment, promotes safe and humanized care, and encourages further research in obstetric nursing.

## Introduction

Over the years, maternal and neonatal care has evolved significantly, enabling the adoption of qualified healthcare practices through an integrative approach centered on basic human needs (1,2). In 1986, the World Health Organization (WHO) released a practical guide for childbirth and delivery (1), aimed at guiding healthcare practices for the proper management of labor, delivery, and birth, based on scientific evidence (3,4).

In this context, obstetric nursing provides humanized and safe care based on scientific literature, taking into account women's autonomy to promote maternal and fetal well-being (5). Considering and active listening are crucial for effective service aimed at the woman and her baby. It is evident that humanized childbirth positively influences the experience of this event, with various benefits, including a good and rapid recovery, reduced risk of infection, skin-to-skin contact that enhances the bond between the woman and her baby, and early breastfeeding, which is considered a protective factor in reducing neonatal mortality, among others (6,7).

Despite obstetric and neonatal care advancements, Brazil remains among the countries with high cesarean section rates. Despite various efforts, the government has not managed to reduce maternal deaths to 35 per thousand live births, a target set by the United Nations Member States by the year 2015 through the "Millennium Declaration" (8,9). It is observed that, even with the implementation of strategies aimed at improving maternal and neonatal healthcare through protocols, guidelines, and manuals, these deliberations have been insufficient, leading to deductions that the shortcomings persist due to insufficient interventions in maternal and infant care (4).

Nursing in Brazil employs the Nursing Process (NP) as a guide for its practices, aiming to improve care for women and infants during the childbirth process. During this period, healthcare professionals apply their knowledge and skills to promote maternal and neonatal health, assessing the need for specific actions at determined moments. This results in effective care and strengthens the implementation and operationalization of the NP in hospitals.

The Nursing Process (NP) is a methodological tool that guides and documents nursing services, encompassing various stages of planning, execution, implementation, and evaluation of care (10). In January 2024, a resolution was published in Brazil addressing the implementation of the Nursing Process within the entire socio-environmental context in which nursing care is provided (11). In Brazilian obstetric nursing, the NP is essential to guide care provision. By utilizing the NP, nursing can direct actions during labor and delivery, offering organized and planned care focused on basic human needs (12). This study focuses on the following question: What nursing diagnoses, outcomes, and interventions are essential for planning daily activities and services in Normal Birth Centers (NBCs) in Brazil? Additionally, what represents the best practices in this field?

The Association of Women's Health, Obstetric, and Neonatal Nurses recommends developing a collaborative plan of care based on the prioritization of diagnoses, problems, health issues, and mutually established goals, incorporating the interprofessional team, the patient, their supportive network, or community as appropriate (13). Based on this recommendation, it is essential to develop a plan of care and implement it in this field to improve healthcare among this population.

Furthermore, the implementation of the nursing care tool can standardize care, enabling professionals to provide humanized and individualized assistance during labor, delivery, and birth. The use of forms containing pertinent patient history information and scientific foundations can facilitate effective communication among teams. Clinical protocols describe all nursing actions and promote the effective participation of professionals in the care continuum and decision-making.

In this context, this study aimed to develop and validate a clinical protocol, based on the nursing process, for pregnant women and neonates in a Normal Birth Center (NBC), situated in the northern region of Brazil.

## Methods

This methodological study, employing a qualitative approach, aimed to develop, validate, and assess tools and research strategies for creating new technologies essential to enhancing and implementing improvements in nursing care (14). The validation procedure examines a particular instrument or inference based on established items. Content validation is a two-stage process (Reference), assessing whether an instrument accurately measures the intended concept, represents all relevant content, and is understandable to the target audience (15). In this study, content validation was chosen, which examines the ability of items to represent the content addressed in the instrument accurately.

The care protocol (The proposed instrument) was constructed according to the Nursing Process, recommended by the Federal Nursing Council (COFEN) through Resolution 736. This protocol includes data collection, nursing diagnoses, nursing interventions, implementation, and finally, the expected and achieved outcomes, to be carried out in public or private health units (11,16).

To assist in the development of the protocol, a scoping review was employed as a theoretical framework to inform the entire research discussion regarding nursing diagnoses and interventions, with a particular focus on those relevant to women and their babies during prenatal care. Additionally, the construction of the tool drew upon the Nursing Minimum Data Set (NMDS) to define client identification items, nursing care, and service (17).

### First stage - Identification of nursing diagnoses and interventions

The first stage of the project was conducted through two scoping reviews: the first aimed to identify nursing diagnoses, and the second focused on nursing interventions related to care for pregnant women and neonates in the Normal Birth Centers, using reference databases and grey literature, including the Regional Portal of the Virtual Health Library (BVS), Latin American and Caribbean Health Sciences Literature (LILACS), Spanish Bibliographic Index in Health Sciences (IBECS), Nursing Database (BDENF), Scientific Electronic Library Online (SciELO), Medical Literature Analysis and Retrieval System Online (MEDLINE), Business Source Complete (EBSCO), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Elsevier (Embase and Scopus), and Clarivate Analytics (Web of Science).

The acronym PCC, which stands for Population, Concept, and Context, was used to frame the research question. It includes the following elements: P - pregnant women and neonates; C - nursing diagnoses and interventions; and C - a normal birthing center. Search terms were identified using controlled vocabularies, such as Health Sciences Descriptors (DECS), Medical Subject Headings (MeSH), and Emtree (Embase Subject Headings).

In the first scoping review, standardized terms and their variations were identified, incorporating pregnancy, childbirth, and newborn-related terminology in English, Portuguese, and Spanish. The Boolean operators "AND" and "OR" were used to assist in searches across the information databases, forming the search strategy applied to all databases using the following combinations: "Gestantes" OR "Pregnant Women" OR "Mujeres Embarazadas" AND "Recém-Nascido" OR "Newborn Infant" OR "Recién Nacido" AND "Diagnóstico de Enfermagem" OR "Nursing Diagnosis" OR" Diagnóstico de Enfermería" AND "Salas de Parto" OR "Delivery Rooms" OR "Salas de Parto" AND "Trabalho de Parto" OR "Labor Obstetric" OR "Trabajo de Parto".

The inclusion criteria involved studies published between 2015 and 2021, written in Portuguese, English, or Spanish. Articles were excluded if they were duplicates, editorials, or did not align with the research objectives. Of the initial 1,743 articles meeting the criteria, 92 were excluded as duplicates, 1,369 were excluded based on titles and abstracts, and 177 underwent full-text review. After this, 166 articles were excluded, leaving 11 relevant articles for the research.

In the second scoping review, similar terms and variations were identified, focusing on nursing interventions and terminologies in English, Portuguese, and Spanish. The inclusion and exclusion criteria mirrored those of the first review. Of the initial 612 articles meeting the criteria, 55 were excluded as duplicates, 411 were excluded based on titles and abstracts, and 74 underwent full-text review. Subsequently, 64 articles were excluded, leaving 10 relevant articles for the research.

### Second stage - Discussion of challenges and factors essential for enhancing nursing care for pregnant women and newborns, as well as the professional's perspective and contribution to the development of clinical protocols in a normal birth center

The 26 potential nursing diagnoses for pregnant women and the eight nursing diagnoses for infants identified in the scoping review were grouped, similarities examined, and correlated with the diagnoses in the NANDA-I 2021-2023 taxonomy (18). These nursing diagnoses were then discussed in the first meeting with the nurses. The discussion and evaluation of the diagnoses took place at the research institution during two meetings with local nurses. A total of nine nurses, including eight clinical nurses and one coordinating nurse, were recruited through an online invitation letter sent via WhatsApp or email. Among them, six nurses specialized in obstetric nursing participated, all of whom had experience in caring for women and their babies, with five having more than five years of experience.

It is worth noting that during the second meeting, an obstetric nurse suggested one additional nursing diagnosis for pregnant women, bringing the total to 27 possible nursing diagnoses. This suggestion was sent via email for final approval by the professionals. Consequently, equivalence was identified among 27 nursing diagnoses for pregnant women and eight diagnoses for newborns.

The condensed information, comprising 26 nursing diagnoses for pregnant women and eight for newborns, was discussed and approved at the first meeting. One additional nursing diagnosis, suggested by a participant based on literature and the researcher's experience, was compiled to bring the total to 35 nursing diagnoses and sent via email for professional approval.

The 35 approved nursing diagnoses from the meetings were used in the development of the protocol and were subsequently validated by experts.

### Third stage - Instrument development through the utilization of a minimum nursing data set, correlated with nursing diagnoses, interventions, and linked to NANDA-NIC-NOC

In constructing the initial part of the instrument, the Nursing Minimum Data Set (NMDS) was employed, incorporating data from the healthcare service, patient demographic information, and nursing care data. The

section of the instrument related to planning nursing care comprised diagnoses, interventions, activities, and nursing outcomes. Consequently, the professionals identified diagnoses and interventions based on the collected data, along with nursing activities specific to the patients and desired outcomes.

**Fourth stage: Validation of the nursing protocol by experts through the Delphi technique, and restructuring of the final version of the protocol**

The Delphi Technique was employed to obtain, compare, and guide expert judgment to reach a consensus on data for instrument validation. Experts were selected following a review of their resumes available on the CAPES Lattes Platform and recommendations from other specialists. The CAPES Lattes Platform is a comprehensive system designed to collect and disseminate information on academic and scientific output within Brazil's higher education sector. The modified Fehring criteria were applied for this selection (19).

The experts conducted validation, considering the relevance of patient identification data, institutional information, and data to be collected for assessing the human needs of the pregnant woman and the newborn, as well as information related to planning nursing care. The instrument's content was assessed based on the validated items after rounds with 10 nursing experts. Following the validation of the instrument components and incorporating suggestions from the experts, the final version of the instrument was developed.

**Data analysis**

The data analysis regarding the scope review was conducted through descriptive statistics. For the assessment of nursing diagnoses by nurses from the research source institution, only those with an agreement of 50% or higher were included in the instrument. The 50% cut-off was established to ensure a minimum level of agreement among the nurses, considering it a threshold indicative of substantial consensus (20). The validation of instrument items by experts was conducted through evaluation using the Content Validity Index (CVI), which allowed for the assessment of each element using a Likert scale with scores ranging from 1 to 5 (20). This approach ensured that experts could systematically evaluate the relevance of each item.

The assessment of each item in the constructed instrument was performed by analyzing each element, where numerical values were assigned: [1] not important, the item was considered by the judge regarding patient data and care planning; [2] slightly important, the item had little relevance; [3] relatively important, when analyzed, it showed some importance; [4] important, when considered significant; [5] very important, where the judge deemed its relationship with the basic needs of the pregnant woman and newborn highly important.

After expert assessments, the data were tabulated and statistically analyzed using Microsoft Excel 2013. The CVI formula was employed to calculate the agreement sum for items with ratings of 4 and 5, considering items with a minimum of 70% agreement (0.7). The following formula was used to evaluate each element (20).

$$\text{CVI} = \frac{\text{Number of responses 4 or 5}}{\text{Total number of responses}}$$

## Results

The first stage of this study consisted of scoping reviews that identified potential nursing diagnoses and nursing interventions for pregnant women and neonates. The second stage involved discussions with nurses working in the unit. A total of nine nurses, including eight clinical nurses and one coordinating nurse, were recruited through an online invitation letter sent via WhatsApp or email.

Based on the scoping reviews and discussions with nurses, the third stage of this study was developed, during which the researchers created the nursing protocol. The fourth stage involved validating the document with nursing experts.

Table 1 presents the demographic data of nursing experts in Brazil.

Consequently, after the instrument validation process, considering statements with a CVI of 0.70 or higher as validated, the recommendations and suggestions from the experts resulted in an instrument that encompassed the assessment of the human needs of each client. Table 2 shows that the instrument obtained a CVI of 1.0 in the first round, and the suggestions, validated in the second round, achieved 100% confirmation, with no need for additional rounds. The "yes" responses indicated expert agreement with the nursing diagnoses and interventions included in the proposed protocol. Thus, the content validation of the instrument was concluded.

The full protocol is available in the institutional repository of the university where the Master's degree study was conducted (21).

**Table 1**. Demographic data of expert nurses, Acre, Brazil, 2022

| Experts' demographic data | | N (%) |
|---|---|---|
| Gender | Female | 10 (100) |
| | Male | 0 (0) |
| Age (Year) | 20 to 30 | 0 (0) |
| | 31 to 40 | 8 (80) |
| | 41 to 50 | 2 (20) |
| | 51 and over | 0 (0) |
| Region of practice in Brazil | North | 4 (40) |
| | South | 2 (20) |
| | North East | 2 (20) |
| | Southeast | 1 (10) |
| | Midwest | 1 (10) |
| Degree | Specialty | 10 (100) |
| | Master | 8 (80) |
| | PhD | 7 (70) |
| Time of practice in the field of obstetrics | Less than 5 years | 0 (0) |
| | 5 to 10 years | 6 (60) |
| | 11 to 20 years old | 4 (40) |
| | 20 to 30 years old | 0 (0) |
| | 31 years and over | 0 (0) |
| Article published on the topics | Yes | 5 (50) |
| | No | 5 (50) |
| Participation in scientific events on the topics in the last two years | Yes | 10 (100) |
| | No | 0 (0) |

**Table 2.** Content validity analysis and expert agreement on the items in the second round. Acre, Brazil, 2022

| Expert / Item | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Agreement (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Pregnant women's data collection | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 100 |
| Neonate data collection | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 100 |
| Nursing diagnoses related to pregnant women | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 100 |
| Nursing diagnoses related to neonates | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 100 |
| Nursing interventions related to pregnant women | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 100 |
| Nursing interventions related to neonates | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 100 |
| Nursing interventions related to pregnant women | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 100 |
| Nursing interventions related to neonates | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 100 |
| Expected outcomes related to pregnant women | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 100 |
| Expected outcomes related to neonates | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 100 |

## Discussion

Nurses play a fundamental role in healthcare by providing evidence-based care throughout childbirth, ensuring the well-being of both mother and baby. To fulfill this role, nurses must possess up-to-date technical and scientific knowledge. Furthermore, the implementation of the Nursing Process is critical, as it directs and guides their care (22). Obstetric nurses have a vital role in obstetric and neonatal care by promoting the restoration of childbirth physiology, avoiding unnecessary interventions, applying best practices for childbirth and delivery, and recognizing and evaluating patterns of abnormalities (23). They also play an influential role in referring cases that require specialized care (24).

The Nursing Process is the application of systematic and interconnected practices that facilitate the organization of healthcare through approaches that prioritize ethics and humanization, aiming to solve problems by identifying the basic human needs (25). In the scope review stage of this study, nursing diagnoses addressing the mother and newborn in the Normal Birth Center were investigated. In addition, to facilitate a more comprehensive assessment of nursing problems and diagnoses, meetings were held with nurses from the institution where the validated instrument would be implemented.

A potential nursing diagnosis for pregnant women identified in the review is Self-Care Deficit for Bathing/Hygiene, a distinct diagnosis in the new edition of NANDA International (2021-2023), with the following definitions and defining characteristics: Code 00108 - Self-Care Deficit for Bathing and Code 00110 - Self-Care Deficit for Hygiene (18).

The diagnosis suggested by the obstetric nurse was excessive fluid volume. The inclusion of this diagnosis is justified because nurses can perceive it during the anamnesis and physical examination of the pregnant woman in the Normal Birth Center; the accurate identification of this diagnosis is crucial to avoid clinical complications for the patient. In the institution's Normal Birth Center, pregnant women with various common pregnancy-related conditions are treated, including gestational anemia, gestational hypertension, preeclampsia, and gestational diabetes (26).

The success of NANDA-I diagnoses in both integrative reviews and meetings with obstetric nurses at the institution confirms the idea that constructing a Nursing Care Protocol with nursing diagnoses and interventions can enhance the care provided at the study site, as well as in other health units that provide obstetric and neonatal care, thereby promoting advanced nursing practices.

The diagnoses, interventions, activities, and nursing outcomes were components of the care planning section of the instrument. A previous study implemented an evidence-based guideline to promote respectful maternity care among intrapartum nurses and assessed its impact on their attitudes and beliefs. Although the results were not statistically significant after three months, a positive trend toward a more physiological and woman-centered model of care was observed. These findings highlight the relevance of structured protocols, such as the one developed in this study, in supporting changes in professional practice and promoting respectful and humanized care during labor and birth. The proposed protocol reflects these principles by guiding nursing care that respects the autonomy, dignity, and specific needs of women and their newborns (27).

It is worth noting that, although the findings of the scoping review were insufficient to address all diagnoses for the clients in question, they still informed and validated the researcher's decisions regarding the selection and screening of interventions based on NANDA-NIC-NOC links and activities from the NIC literature, which were used to address the chosen interventions and essential diagnoses for care planning (18).

Although the meetings with the group of nurses from the research hospital did not take place in person due to the pandemic, there were no adverse effects on the evaluation of diagnoses. The information was sent by email, and the recipients could assess all the listed diagnoses. The limited availability of scientific articles on the study's theme in academic research sites had a restrictive effect on the choice of nursing diagnoses and interventions that would compose the developed instrument.

## Conclusion

The development and validation of a clinical protocol for implementation in a normal birth center can promote nursing care for pregnant women and neonates. This tool can empower nurses to make decisions based on clinical judgment, taking into account the unique characteristics of clients and their families. The scoping review conducted in the first phase of the study focused on identifying nursing diagnoses and interventions related to the care of this population, which promotes evidence-based practice in the development of the clinical protocol.

It is demonstrated that care protocols are crucial in supporting nursing professionals' clinical judgment, guiding them in all aspects of care through an evidence-based care plan, thereby ensuring the well-being of both mother and baby. This nursing protocol aims to enhance care practices by enabling nurses to actively perform their roles, providing humanized and secure care to women, their babies, and their families. Additionally, this study can stimulate the development of new research on the topic, linking various contributions to the field of obstetric nursing and increasing awareness of its value through individualized, targeted diagnoses, interventions, and activities.

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## Ethical statement

This study was submitted to the Plataforma Brazil, where it was evaluated and approved by a Research Ethics Committee in accordance with the principles outlined in Resolution 466 of the National Health Council regarding research involving human subjects (28).

## Conflicts of interest

The authors declare that they have no conflicts of interest.

## Author contributions

All authors actively participated in all stages of manuscript preparation and approved the final version.

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