

## TECHNOLOGICAL INNOVATION

# DEVELOPMENT AND VALIDATION OF NURSING CONSULTATION FOR PEOPLE WITH DIABETIC FOOT IN PRIMARY CARE\*

### HIGHLIGHTS

1. Standardization and qualification of nursing care.
2. Effectiveness of nursing care for diabetic foot.
3. Contribute to the development of methodological studies.
4. The instrument showed a satisfactory Content Validity Index.

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### ABSTRACT

**Objective:** Develop and validate a nursing consultation instrument for people with diabetic foot in primary health care, based on Wanda de Aguiar Horta's theoretical model of Basic Human Needs. **Method:** Methodological study, conducted from October 2022 to June 2023 in Montes Claros - Minas Gerais - Brazil, in three stages: scoping review to identify sociodemographic, clinical characteristics, and psychobiological, psychosocial, and psycho-spiritual needs; development of the instrument and content validation by experts. Descriptive statistics and a Content Validity Index equal to or greater than 0.80 were used for data analysis. **Results:** Content validation was performed by 15 experts. Three items of the instrument were evaluated, obtaining a Content Validity Index of 0.93 in objectives, 0.97 in structure and presentation, and 1.00 in relevance. **Conclusion:** The instrument will contribute to the qualification of nursing consultation for people with diabetic foot in primary health care.

**KEYWORDS:** Nursing Care; Diabetic Foot; Primary Health Care; Nursing Process; Validation Study.

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## INTRODUCTION

Foot ulceration is among the most serious complications of Diabetes *Mellitus* (DM) and is associated with high levels of morbidity and mortality<sup>1-2</sup>. The estimated DM in the general Brazilian population is 9.4%, and among the complications, foot ulcers or wounds stand out, with a prevalence of 6%<sup>3</sup>.

Osteomyelitis, sepsis, and amputation are common complications of the diabetic foot. It is estimated that it is responsible for 50% to 70% of non-traumatic lower limb amputations, with the frequency of amputation being 15 times higher in people with DM compared to the general population<sup>4</sup>.

Given the above, actions and services provided in Primary Health Care (PHC) to users with diabetic foot can promote prevention by facilitating early access and comprehensive care to the individual, family, and community. From this perspective, the nurse, part of the APS multidisciplinary team, plays a significant role in caring for people with DM, as they have skills and abilities directed towards health promotion and disease prevention<sup>5</sup>. Therefore, the effectiveness of diabetic foot screening by this professional is crucial to improving the management of individualized care and the quality of assistance and life of the patient<sup>6</sup>.

Regarding the quality of care, the Nursing Process (NP) is configured as a scientific and clinical approach to nursing. This tool effectively achieves positive results and indicators for patients and nursing professionals<sup>7</sup>. The PE consists of five interrelated and dynamic stages, the first of which is the nursing assessment<sup>8</sup>, which is fundamental for developing the other stages. Notably, using comprehensive and easy-to-understand data collection tools enables identifying and acquiring relevant data<sup>9</sup> from Nursing Diagnoses (ND) and planning and implementing accurate care.

It is emphasized that the PE must be based on a theoretical framework that guides data collection. However, despite the importance of the topic, the complexity of care for people with diabetic foot, and the nurse's role in their care, no scientifically validated instruments were found in the researched databases for the context of Primary Health Care (PHC), that guide care management, specifically from the perspective of the theory of Basic Human Needs (BHNs) proposed by Wanda de Aguiar Horta<sup>10</sup>.

The theory of NHBs aims to enable the development of a broad and holistic therapeutic plan that provides preventive and health promotion care without abandoning the uniqueness of the subject<sup>10</sup>. Thus, this theory aligns with the principles of the Unified Health System for PHC<sup>11</sup>, as it advocates for comprehensive human care.

In this sense, an instrument based on the theory of NHBs standardized for nursing consultation to people with diabetic foot in PHC can provide a robust data collection, making it possible to perform a concise analysis for the generation of health indicators, clinical profile of patients, main needs, and the care to be implemented<sup>12</sup>. In this way, this study aimed to develop and validate a nursing consultation instrument for people with diabetic foot in Primary Health Care, based on Wanda de Aguiar Horta's theoretical model of Basic Human Needs.

## METHOD

### Study design

This is a methodological study<sup>13</sup>, conducted from October 2022 to June 2023, divided into three stages: identification of sociodemographic, clinical characteristics and psychobiological, psychosocial, and psycho-spiritual needs; development of the instrument; and expert content validation.

#### **Step 1 – Identification of sociodemographic, clinical characteristics, and psychobiological, psychosocial, and psycho-spiritual needs**

A scope review of the literature was conducted between the months of October to December 2022, using the mnemonic PCC (Population, Concept, and Context) assigning the following contents: P: person with diabetic foot; C: nursing care; C: Primary Health Care, in the data sources *Medical Literature Analysis and Retrieval System Online* (MEDLINE) via PubMed, *Cumulative Index to Nursing and Allied Health Literature* (CINAHL), *Nursing Database* (BDENF), *Latin American and Caribbean Literature in Health Sciences* (LILACS) and *Scientific Electronic Library Online* (SciELO). The descriptors "Nursing Care", "Diabetic Foot" and "Primary Health Care" were used, as well as the index terms identified in the databases.

Articles in English, Spanish, or Portuguese were included, without time limitation of publication, that addressed the theme "nursing care directed to the person with diabetic foot in PHC". Exclusion criteria were opinion articles, letters to the editor, conference abstracts, and studies where the full text was unavailable or did not answer the review question. Subsequently, a reverse search of the references of the articles was conducted and in the gray literature available in documents produced by the *International Working Group on the Diabetic Foot and Wound, Ostomy, and Continence Nurses Society* and at the governmental level by the Ministry of Health of Brazil.

#### **Step 2 – Development of the instrument**

In the second stage, the *Nursing Minimum Data Set – NMDS*<sup>14</sup>, (Nursing Minimum Data Set) was used to structure the initial section of the instrument where the patient's identification data and sociodemographic information were inserted. For the preparation of the part of the instrument related to patient data collection, the characteristics of the patient's history and their psychobiological, psychosocial, and psycho-spiritual needs were identified in the literature review, based on Wanda Horta's NHBs framework<sup>10</sup>.

#### **Step 3 – Content validation by experts**

The finite population formula  $n = Z^2 \cdot P(1-P) / e^2$  was used to determine the number of experts. A confidence level ( $Z_\alpha$ ) of 95% was considered an expected proportion of experts who agree with the evaluated item ( $P$ ) of 90% and an expected difference ( $e$ ) of 15%. Thus, the number was 15 experts<sup>15</sup>.

The sample selection was carried out for convenience, using the *snowball sampling*<sup>16</sup> technique with referrals among professionals. The screening and invitation of experts were carried out based on the curriculum analysis on the Lattes Platform of the Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq).

For participation in the study, the experts had to fit at least 5 (five) points from the sum of the following criteria<sup>17</sup>, which were adapted for the present study: master's degree in nursing and primary health care (4 points); master's degree in nursing and primary health care with a dissertation in the area of interest of the study (1 point); PhD in nursing and primary health care with a doctoral thesis in the area of interest of the study (2 points); specialization in the area of interest of the study (nursing with an emphasis on family health, primary health care, basic care, and related areas) (2 points); clinical or academic practice of at least one year in the area of interest of the study (1 point); publication of research relevant to the area of interest (2 points); publication of an article on the topic of interest of the study in a reference journal (2 points).

The invitation letter was sent to the experts via e-mail and *WhatsApp*. It was accompanied by an online form containing the Informed Consent Form (ICF), a characterization questionnaire of the experts, and the nursing data collection instrument for people with diabetic foot in the context of PHC based on the NHB theory.

The experts evaluated the instrument to be validated according to the following sections, which were adapted for the present study<sup>18</sup>: a) Objectives – purposes, goals, or similar aims to be achieved with the use of the instrument; b) Structure and Presentation – the way of presenting the guidelines, its overall organization, structure, presentation strategy, coherence, and formatting; and c) Relevance – a characteristic that assesses the degree of significance of the presented material.

For the validation of the content of the instrument, the degree of relevance/representativeness of each item was analyzed through four levels of valuation: 1 – inadequate; 2 – partially adequate; 3 – adequate and 4 – fully adequate<sup>13,19</sup>.

## Data Analysis and Processing

To determine the level of agreement among the experts, the Content Validity Index (CVI) was calculated. For validation of each item, the CVI was considered equal to or greater than 0.80. For calculating the CVI per item, the number of "3" or "4" responses was added and divided by the total number of experts<sup>20</sup>. The average CVI of each section – a) Objectives, b) Structure and Presentation, and c) Relevance – was calculated based on the arithmetic mean of the CVI of each item. The mean and standard deviation per item and section were also presented.

## Ethical aspects

The present study was approved by the Proposing Institution with opinion No. 5,408,706 of 05/14/2022.

## RESULTS

Regarding the scoping review, out of a total of 354 studies found in the review, 18 were excluded due to duplication, 320 were screened, with 235 excluded after reading the title and abstract, and 71 were put under consideration; of these, 68 were excluded after full reading, leaving 14 articles and three gray literature documents relevant to the research.

For the development of the instrument, the clinical characteristics related to the medical history were identified in the literature, as well as the terms that would represent the focus of nursing care for people with diabetic foot in the context of PHC, according to the NHBs. In the previous history, data related to the type of diabetes, comorbidities, complications, smoking, and alcoholism were highlighted.

Regarding NHBs, the focus of nursing care in psychobiological ones was neurological regulation, perception of sense organs, hydration, nutrition, sleep and rest, exercises and physical activities, shelter, hormonal regulation, oxygenation, thermal regulation, eliminations, sexuality, locomotion, vascular regulation, skin-mucosal integrity, and therapy. The psychosocial aspects focused on learning, leisure, gregariousness, and emotional and social security. In the psycho-spiritual ones, the focus is on religiosity/spirituality.

The content validation team comprised 15 nursing professionals who were experts in the area of interest. Table 1 presents the characterization and training of the experts.

**Table 1** - Characterization and training of experts. Montes Claros, MG, Brazil, 2023 (n=15)

| Variables  | n  | %    |
|--|----|------|
| Sex  |    |      |
| Female   | 12 | 80   |
| Male   | 3  | 20   |
| Working time in the area   |    |      |
| ≤ 10 years   | 9  | 60   |
| <10 years  | 6  | 40   |
| Graduation Time  |    |      |
| ≤ 10 years   | 9  | 60   |
| <10 years  | 6  | 40   |
| Highest degree   |    |      |
| Specialization   | 4  | 26.7 |
| Master's degree  | 9  | 60   |
| Doctorate  | 2  | 13.3 |
| Clinical or academic practice of at least one year in the area of interest             | 15 | 100  |
| Relevant research publication for the area of interest                                 | 8  | 53.3 |
| Publication of an article on the topic of interest of the study in a reference journal | 4  | 26.7 |

Source: The authors (2023).

Regarding the experts' assessment of the objectives, purposes, or goals to be achieved using the data collection instrument, this study showed that the classification translated the concept of material adequacy. The average CVI of this evaluation was 0.93 (Table 2).

**Table 2** - Evaluation of the experts regarding the objectives of the nursing data collection instrument for people with diabetic foot treated in Primary Health Care. Montes Claros, MG, Brazil, 2023 (n = 15)

| Objectives  | I | PA | A | TA | IVC         | Mean (SD)        |
|---|---|----|---|----|-------------|------------------|
| Facilitates the nurse's consultation with the person with diabetic foot treated in primary health care.   | 0 | 1  | 4 | 10 | <b>0.93</b> | <b>3.5(1.0)</b>  |
| Allows understanding of the care process for the nurse's consultation with the person with diabetic foot attended in primary health care.                         | 0 | 2  | 1 | 12 | <b>0.86</b> | <b>3,4(1,4)</b>  |
| It helps clarify possible doubts about the care process for people with diabetic foot treated in primary health care.   | 0 | 1  | 5 | 9  | <b>0.93</b> | <b>3.4(1.0)</b>  |
| Encourages the use of this technology in the practice/ performance of the nurse during the care of the person with diabetic foot attended in primary health care. | 0 | 1  | 3 | 11 | <b>0.93</b> | <b>3.5(1.0)</b>  |
| It reflects the care process in the nurse's consultation with the person with a diabetic foot attended in primary health care.                                    | 0 | 0  | 5 | 10 | <b>1</b>    | <b>3.7(0.5)</b>  |
| <b>Average CVI</b>  |   |    |   |    | <b>0.93</b> | <b>52.4(1.7)</b> |

Legend: I: Inappropriate; PA: Partially adequate; A: Adequate; TA: Totally Adequate; CVI: Content Validation Index; SD: Standard Deviation.

Source: The authors (2023).

Items related to the instrument's structure and presentation were also evaluated. It was found that 11 out of 16 reached the maximum CVI value (1.0). The overall CVI evaluated as a sum of the 16 criteria reached the average IVC of 0.97 (Table 3).

**Table 3** - Evaluation of the experts regarding the structure and presentation of the nursing data collection instrument for people with diabetic foot treated in Primary Health Care. Montes Claros, MG, Brazil, 2023 (n = 15)

| Structure and Presentation   | I | PA | A | TA | IVC         | Average (DP)    |
|--|---|----|---|----|-------------|-----------------|
| The content is presented in language suitable for nurses who care for people with diabetic foot in primary health care.  | 0 | 1  | 5 | 9  | <b>0.93</b> | <b>3.4(1.0)</b> |
| The content features interactive language, allowing active engagement between patient and nurse during the nursing consultation.   | 0 | 0  | 4 | 11 | <b>1</b>    | <b>3.7(0.5)</b> |
| The content follows a logical sequence.  | 0 | 3  | 3 | 9  | <b>0.8</b>  | <b>3.0(1.6)</b> |
| The language is interactive, allowing active involvement in the assistance during the nurse's consultation with the person with a diabetic foot attended in primary health care. | 0 | 1  | 3 | 11 | <b>0.93</b> | <b>3.5(1.0)</b> |



|  |   |   |   |    |             |                  |
|--|---|---|---|----|-------------|------------------|
| The content of the data collection instrument includes relevant information for guiding and executing the next steps of the Nursing Process/ Nurse Consultation.   | 0 | 1 | 4 | 10 | <b>0.93</b> | <b>3.5(1.0)</b>  |
| The instrument is appropriate for guiding the clinical reasoning of the nurse during the care of a person with diabetic foot who is attending primary health care. | 0 | 0 | 3 | 12 | <b>1</b>    | <b>3.8(0.4)</b>  |
| The instrument is appropriate for guiding the critical reasoning of the Nurse during the care of a person with diabetic foot attended in primary health care.      | 0 | 0 | 3 | 12 | <b>1</b>    | <b>3.8(0.4)</b>  |
| The instrument is appropriate for guiding the Nurse's diagnostic reasoning during the care of a person with a diabetic foot attended in primary health care.       | 0 | 0 | 4 | 11 | <b>1</b>    | <b>3.7(0.5)</b>  |
| The information presented is scientific.   | 0 | 0 | 1 | 14 | <b>1</b>    | <b>3.9(0.3)</b>  |
| The information is well-structured and in agreement.   | 0 | 1 | 1 | 13 | <b>0.93</b> | <b>3.7(1.0)</b>  |
| The information is well structured in spelling.  | 0 | 0 | 4 | 11 | <b>1</b>    | <b>3.7(0.5)</b>  |
| The information is objective and clear   | 0 | 0 | 1 | 14 | <b>1</b>    | <b>3.9(0.3)</b>  |
| The information is enlightening.   | 0 | 0 | 2 | 13 | <b>1</b>    | <b>3.9(0.4)</b>  |
| The information is necessary and relevant.   | 0 | 0 | 2 | 13 | <b>1</b>    | <b>3.9(0.4)</b>  |
| The theme is current.  | 0 | 0 | 0 | 15 | <b>1</b>    | <b>4.0(0.0)</b>  |
| The theme is relevant.   | 0 | 0 | 0 | 15 | <b>1</b>    | <b>4.0(0.0)</b>  |
| <b>Average CVI</b>   |   |   |   |    | <b>0.97</b> | <b>55.8(3.9)</b> |

Legend: I: Inappropriate; PA: Partially adequate; A: Adequate; TA: Totally Adequate; IVC: Content Validation Index; SD: Standard Deviation.

Source: The authors (2023).

Table 4 highlights the experts' evaluation of the instrument's relevance and degree of significance. For this item, the average CVI was one.

**Table 4** - Evaluation of the experts regarding the relevance of the nursing data collection instrument for people with diabetic foot treated in Primary Health Care. Montes Claros, MG, Brazil, 2023 (n = 15)

| <b>Relevance</b>   | <b>I</b> | <b>PA</b> | <b>A</b> | <b>TA</b> | <b>CVI</b> | <b>Average (DP)</b> |
|--|----------|-----------|----------|-----------|------------|---------------------|
| The content of the instrument facilitates data collection.                                   | 0        | 0         | 4        | 11        | <b>1</b>   | <b>3.7(0.5)</b>     |
| The content contributes to developing the other stages of the Nursing Process.               | 0        | 0         | 4        | 11        | <b>1</b>   | <b>3.7(0.5)</b>     |
| The content of the data collection instrument contributes to qualifying the nurse's actions. | 0        | 0         | 1        | 14        | <b>1</b>   | <b>3.9(0.3)</b>     |
| <b>Average CVI</b>   |          |           |          |           | <b>1</b>   | <b>57(1.7)</b>      |

Legend: I: Inappropriate; PA: Partially Adequate; A: Adequate; TA: Totally Adequate; CVI: Content Validation Index; SD: Standard Deviation.

Source: Research data (2023).

The instrument obtained CVI between 0.93 and 1.0 in the first round. The experts' suggestions for orthographic adjustments in writing and illustrations stand out. Since there was no need for new rounds, the instrument's content was validated in the initial round.

The instrument developed and validated for data collection during the nursing consultation for people with diabetic foot in PHC, based on Wanda de Aguiar Horta's theoretical model of Basic Human Needs, is presented in Figure 1 as a QR Code for access to the full document.

**Figure 1** - QR Code for full access to the instrument. Montes Claros, MG, Brazil, 2023



Source: The authors (2023).

## DISCUSSION

In nursing, the progressive growth of studies on the construction and validation of instruments for clinical practice<sup>12,18,21-22</sup> contributes to care and the evolution of the profession as a science. Instruments<sup>21-22</sup> related to nursing consultation for people with DM have been considered important as they impact the improvement of care quality and promote nurse autonomy and independence. They are also understood as technological innovations in health, as they direct and enable care provision.

Regarding PE, the use of instruments can promote rationality and scientific justification in the knowledge and practice of nursing<sup>23</sup>.

In this study, to guide the development of the instrument, the NHB theory was used, which is based on João Mohana's three levels: psychobiological, psychosocial, and psycho-spiritual needs. These needs are characterized by being vital, latent, flexible, cyclical, dynamic, interrelated, energetic, infinite, hierarchical, individual, and universal, as they are common to all human beings and can be verbalized or not, apparent, conscious, differing only in their way of manifesting and satisfying themselves<sup>10</sup>.



That said, the instrument was built by grouping related information to organize the data to be collected and the nurse's clinical reasoning without losing sight of the theoretical framework of the NHBs. A previous validation study of an instrument for nursing consultation with people with DM and hypertension was based on the conceptual model of NHBs and Dorothea Orem's self-care theory.

The instrument allows for the identification, evaluation, and full disclosure of all necessary information about this clientele. Furthermore, it aims at objectivity and focuses on the possible problems of these patients, with the intention that irrelevant information is not recorded, which could divert the nurse's clinical and critical reasoning or waste the time of the interviewee and interviewer.

Clarity and objectivity are imperative aspects of the language of a good instrument<sup>3,24</sup>. Furthermore, the data collection instrument must be easy to understand and complete; the absence of these particularities may lead to the failure to identify important characteristics for patient care and filling errors or omissions<sup>9,25</sup>. To avoid problems of this nature, these characteristics were prioritized in the present study. Other studies<sup>18,21-22</sup> used aspects related to objectives, structure, presentation, and relevance as evaluative properties in validating the instruments.

If well structured, the PE's first stage will support the others. It will facilitate the development of critical thinking and clinical reasoning, formulating nursing diagnoses, and establishing individualized, priority, specific, effective, and accurate nursing outcomes and interventions.

It is emphasized that when implementing the instrument in the care of people with diabetic feet in PHC, demands for adjustments may arise and that professionals should approach the person holistically, that is, beyond the diabetic foot, seeking to understand the cause of the problem, possible related factors, and risk factors. Furthermore, it is pointed out that nurses may need prior training to apply some tests, such as the Ankle-Brachial Index (ABI).

This research's limitations are based on the lack of available publications in the literature regarding the nursing assessment of people with diabetic foot in PHC based on NHBs, which impacts the comparison of the results found. Also, it is difficult to develop a brief instrument that includes the necessary and essential items to ensure comprehensive and quality care without making its application in clinical practice unfeasible.

## CONCLUSION

This study enabled the development and content validation of a data collection instrument for nursing consultation for people with diabetic foot in PHC, based on Wanda de Aguiar Horta's NHBs theoretical model. Its use in assistance will enable the standardization and qualification of nursing care, allowing clinical reasoning, critical thinking, and decision-making by the nurse, considering the individuality of each patient.

This study is believed to contribute to developing research by offering a model for methodological procedures for developing and validating nursing data collection instruments. Furthermore, it can positively impact nursing care and the quality of life of the person with diabetic foot assisted in PHC.

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