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ORIGINAL ARTICLE

VALIDATION OF AN INSTRUMENT TO INVESTIGATE NURSES' KNOWLEDGE ON DIABETIC FOOT

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ABSTRACT

Objective: to construct and validate an instrument to investigate the knowledge of Primary Health Care nurseson diabetic foot. **Method:** methodological study carried out from January to June 2017, followed the Development Model for Psychometric Scales by Pasquali, in three stages: theoretical, empirical and analytical. In order to validate the content, the Delphi technique was adopted in two moments, with the participation of 10 judges. Construct validity was performed by 73 nurses who worked in PHC services in the municipality of Campina Grande-PB. The Content Validation Index (CVI) was applied to the data. **Results:** the "Questionnaire for Investigating Nurses' Knowledge on Diabetic Foot (QICEPeD, as per its Portuguese acronym)" was constructed with 47 elements organized into 12 domains of knowledge on the topic. After the second round of judges' assessment, all elements reached maximum agreement scores (CVI = 1.00). The analysis of the instrument's reliability and total internal consistency was considered high (α=0.860). **Conclusion:** the QICEPeD instrument was considered valid, in terms of content and construct, and can be used to assess the level of knowledge of Primary Care nurses on diabetic foot.

Keywords: Diabetic Foot. Psychometrics. Validation Study. Nursing Methodology Research. Nursing.

INTRODUCTION

Diabetic foot is the term designated to denominate the various complications occurring, singly or in combination on the feet of people with Diabetes Mellitus (DM). It is characterized by ulceration, infection, and/or deep tissue damage, resulting from neuropathy and Peripheral Arterial Disease (PAD), which can entail amputations among people with diabetes[1]. It represents a public health problem on the rise, due to its high prevalence and high degree of disabling, mutilating and recurrent disability[2], in addition to the costs to the individual and the health system[3].

It is recognized that most complications related to diabetic foot can be avoided by adopting simple self-care measures and early identification of feet at risk[4]. Nevertheless, a Brazilian multicenter study[5] showed a prevalence of 25% for diabetic ulcerations and 14% for amputations in the country, occurrences considered higher than the world estimates.

This scenario is alarming and suggests the need to invest in public health policies that prioritize the implementation of measures for preventing diabetic ulcerations and their recurrence[1-2], through foot assessment, with risk stratification and establishment of follow-up periodicity, and guidance for self-examination of the feet performed by the Primary Health Care (PHC) services[6].

In this health care context, all health professionals play an important role in the treatment of diabetic foot. Nevertheless, nurses are usually the professionals responsible for following-up people with diabetes, through counseling and health education, self-care promotion, injury prevention and treatment adherence.In addition, traditionally, the nurse is the first professional the users seeks out when they have a foot injury installed, it is also often

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the first one they ask for advice on care for injury prevention[7].

Accordingly, it is essential that, during the nursing consultation with people with DM, this professional has sufficient knowledge and skills to perform the clinical examination of the feet[6], seeking to accurately identify dermatological, musculoskeletal, vascular and neurological changes[8], and then develop strategies to promote self-care, prevention and treatment of diabetic ulcerations[9].

However, international studies[9-11] have shown that nurses' knowledge on the topic is still considered inadequate. In Brazil, in the PHC context, there is a deficit of knowledge among nurses in relation to the clinical evaluation of the diabetic foot[12-13]. It is also noted the lack of previous training on the topic[12], the low practice of systematic foot examination[6;8;12-13] and that the adherence of professionals to the guidance for preventing diabetic ulcers is still considered precarious[14].

From this perspective, the use of instruments to investigate nurses' knowledge on diabetic foot can contribute to the assessment of care. In the international literature, four questionnaires[9-11;15] were found for this purpose, namely: at first, the questionnaire applied to PHC nurses in Saudi Arabia, which was based on the Knowledge, Attitude and Practices (KAP) model[9]; secondly, there is the "Nurses' Knowledge Level Form on Diabetic Foot Management" which was designed for use with nurses in hospitals in Turkey[10]; the third was applied to hospitals in Sri Lanka[11]; and the fourth instrument, called The Nurses' Knowledge Regarding Prevention and Management of Diabetic Foot Ulcer Questionnaire (NKPMDFUQ)[15] was developed for nurses from a specialized diabetes service in Bangladesh.

All the aforementioned instruments include multiple choice questions and aspects of care specific to Asian culture, have not yet been translated into Portuguese, and are aimed at assessing the knowledge of nurses working in specialized services on diabetic ulcers.

In the Brazilian context, no validated instruments or rating scales were found to obtain specific results on the level of knowledge of PHC nurses on diabetic foot. Given the above, it is necessary to develop a validated tool that allows the recognition of eventual gaps in the nurses' knowledge on the topic, which should be addressed in the development of training programs or continuing education for these professionals[10].

Based on these aspects, this study had the objectiveof constructing and validating an instrument to investigate PHC nurses' knowledge on diabetic foot.

METHOD

Methodological study, with a quantitative approach, carried out from January to June 2017. In order to developand validate the measurement instrument, the Development Model for Psychometric Scales[16] was adopted, which was developed in three stages: theoretical, empirical and analytical.

The theoretical stage comprises the construction and validation of the instrument's content, and was developed in five steps: 1) definition of the system; 2) properties or attributes; 3) construct dimensionality; 4) operationalization of the pilot instrument; 5) theoretical analysis of the elements. The description of these steps is introduced in Figure 1.

The theoretical construction of the knowledge assessment elements was held by searching for the guidelines and care recommended by the Brazilian Ministry of Health[16] and by international guidelines on diabetic foot[1,2;4].

Based on the literature review, the first version of the instrument consisted of 47 elements distributed in 12 domains of knowledge: 1. definition of diabetic foot; 2. risk factors for diabetic foot; 3. complications related to diabetic foot; 4. signs and symptoms of motor neuropathy; 5. signs and symptoms of autonomic neuropathy; 6. prevention of foot ulcers; 7. tests to assess the loss of protective sensation (LPS) of the foot at risk; 8. application sites for the Semmes-Weinstein monofilament test; 9. recommended application number of tests for LPS assessment; 10. interpretation of tests to assess loss of protective sensation; 11. assessment of foot biomechanics; 12. frequency of assessment of the feet according to the risk classification.

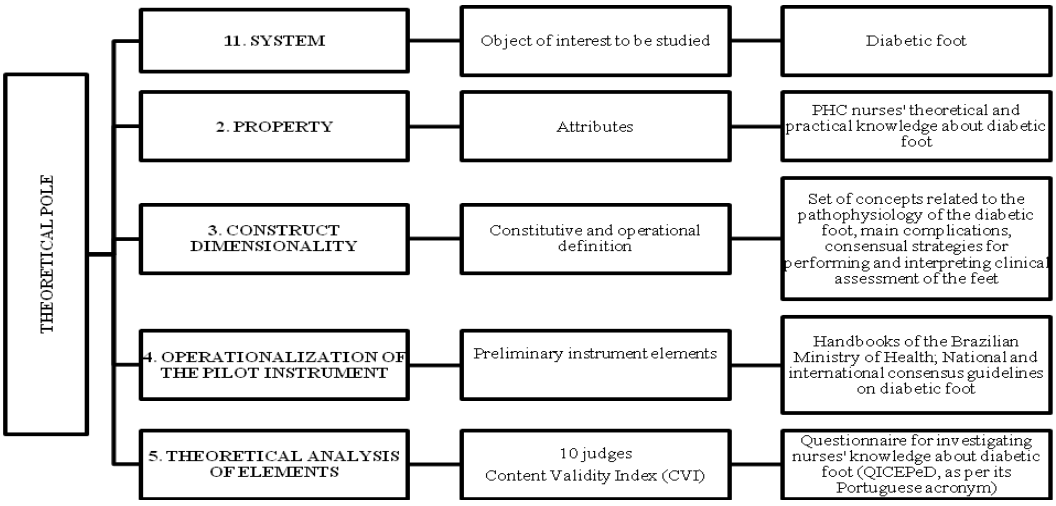

Figure 1. Theoretical procedures used to construct and validate the instrument. Campina Grande, PB, Brazil (2017).

In order to guarantee the criterion of variety among the elements in the questionnaire[16], it is noteworthy that, of the 47 elements of the first version, 29 statements were unfavorable and 18 favorable. For each of the proposed elements, answer options such as "I agree", "I disagree" and "I don't know" were created when the topic was unknown, in an attempt to curb random hits. In question 8 only, the respondent had to mark, on an illustration of the dorsal and plantar surface of the foot, the locations of application of the Semmes-Weinstein monofilament test (hallux, first, third and fifth metatarsals) [1].

Once the preliminary version of the instrument was completed, the theoretical analysis of the 12 domains and their respective elements was carried out by a panel of judge nurses, selected through an advanced search in the Lattes Platform of the National Council for Scientific and Technological Development (CNPq, as per its Portuguese acronym), using the keywords: "Diabetic foot" and "Nursing".

The initial search strategy resulted in the identification of 106 Lattes Curricula eligible for the study. The panel of judges was composed of the nurses who met at least three of the following criteria[18]: to have worked for more than two years in the care of people with DM; to have specialization or residency in an area related to DM; to have a master or PhD degree; to be the author of publications related to nursing care to people with diabetes; to participate in a research group/project involving people with diabetes; to have knowledge on diabetes.

After reading the abstract of all curricula found to confirm their performance in the topic, 34 eligible nurses were identified, to whom an invitation letter was sent via email, clarifying the research objectives; the Free and Informed Consent Form (FICF); the electronic instrument assessment form, constructedvia Google Docs.

Of the 34 invited nurses, 10 agreed to participate in the study. The online Delphi technique was used in two moments[19-20]. At first, the judges were asked to assess the understanding (semantic analysis) and the relevance of the 12 dimensions of knowledge present in the initial instrument, considering the criteria of clarity/understanding and relevance/representativeness, indicating, in a binomial scale, "I agree" or "I disagree". There was also a space to suggest changes, additions or deletions. In the second moment, the judges were asked to assess the entire instrument, using the same approval criteria.

In order to analyze the experts' agreement, the Content Validity Index (CVI) was used. An agreement greater than or equal to 0.80 (80%) was considered acceptable for any of the assessed criteria (clarity, relevance) [21].

In the second stage of the research, corresponding to the empirical or experimental pole, the construct validity of the instrument was performed by the target audience, nurses working in PHC services in the municipality of Campina Grande, Paraíba, Brazil, through the

analysis of internal consistency and reliability. The professionals were invited by the Municipal Health Secretariat by means of electronic mail.In order to define the sample size, the formula for surveys with finite populations was used, considering a 95% confidence level (Zα= 1.96), a 5% sampling error and a population of 105 professionals. The application of the formula resulted in a final sample of 73 nurses. In order to select the participants, the adopted inclusion criteria were: to have worked in the municipality's PHC services for a minimum period of 12 months and to care for people with DM. Professionals who were on vacation or sick leave at the time of data collection were excluded.

The instrument was applied individually, in an auditorium of a public higher education institution, considered a neutral space, thus guaranteeing the privacy of the participants. The average time to complete the questionnaire was 25 minutes.

In the third and last stage of the research, referring to the analytical pole, the set of statistical analyses applied to check and/or confirm the instrument's validity was carried out. Data were organized in an electronic spreadsheet and analyzed through the version 21.0 of the statistical package, using the Statistical Package for the Social Sciences (SPSS) software for Windows.

The instrument's internal consistency and reliability were assessed using Cronbach's alpha coefficient, which assesses if the elements proposed to measure the same construct produce similar results. The value of the Alpha coefficient can range between 0 and 1, where values between 0.7 and 0.9 are considered ideal. The closer to 1, the greater the reliability among the indicators. Type I error probability or significance level was set at 5%.

The study complied with national and international standards of ethics in research involving human beings, thus being approved by the Human Research Ethics Committee of the Federal University of Paraíba (UFPB), under opinion nº 0577/2015. All participants in this study were informed about the purpose of the investigation and the nature of data collection. Those who agreed to participate signed the FICF.

RESULTS

The committee of judges consisted of 10 nurses at both times. All were female nurses (100%), aged between 27 and 67 years old, with an average of 45 years old. As for qualification, 50% were doctors, working in teaching (80%), living and working in the South (20%), Southeast (50%) and Northeast (30%) regions of Brazil.

In the first round of judges'assessment (Delphi I), all elementsof the preliminary version of the questionnaire obtained satisfactory agreement (CVI ≥ 0.80) in both assessed criteria.

All experts were unanimous about the need to chance the answer pattern of questions 1,2,3,4,5,6,9,10,11 and 12 to allow the respondent to indicate only one answer alternative. The changes suggested by the judges were made, as it was considered to give greater understanding and clarity to the elements.

In the second round of judges' assessment (Delphi II), all (100%) proposed elementsreached maximum agreement scores (CVI = 1.00) regarding clarity and relevance, showing satisfactory content validity. The judges did not suggest changes in the instrument in Delphi II.

After the analyses, the theoretical procedures for constructing the measurement instrument were completed. Subsequently, the steps foreseen in the empirical and analytical poles were performed. The analysis of the internal consistency and reliability of the instrument was applied to a sample composed of 73 PHC nurses. Regarding sociodemographic characteristics, educational background and professional performance, it was noted that 98.6% (n=72) of the nurses were female, aged between 23 and 63 years old (average 40.9 years), with 15.8 years of graduation in Nursing and 9.4 years of work in PHC.

Concerning the detailed analysis of the internal consistency and reliability of the QICEPeD instrument, it was found that the instrument obtained a total Cronbach's alpha of 0.86, and that the value would not change much if any elements were deleted.

DISCUSSION

The construction and validation of measurement instruments play an important role in research, clinical practice and health evaluation. Their creation requires methodological rigor, well-defined steps and accurate procedures[21].

In this research, we chose to adopt the Development Model for Psychometric Scales[16], as it contemplates specific methods, grouped into three poles: theoretical, empirical and analytical. Although this methodological reference comes from Psychology, the growth of its use by Nursing denotes the recognition and reliability of this model in the development of instruments[22].

In the theoretical pole, the theoretical dimensionality was defined, the constitutive and operational definitions were established, the elements were developed and the content validation was performed[16]. In the process of constructing the instrument, it was decided to measure knowledge in 12 domains related to central areas of diabetic foot management by PHC nurses. The elements were extracted from national[17] and international[1,2;4] guidelines directed to health professionals[1;4;17]. This strategy was also used by other studies[9-12;18] to construct the elements of measurement questionnaires to assess knowledge on diabetes.

The sum of the scores for the 12 multiple-choice questions on the QICEPeD instrument ranges from zero to 18 (100% right answers), depending on the number of answers correctly marked. One point must be added for each of the four alternative answers referring to domain 7 (Tests for assessing the LPS of the foot at risk) and one point for one of the four sites recommended for application of the Semmes-Weinstein monofilament test (hallux, first, third, and fifth metatarsals)[1].The nurses' level of knowledge on diabetic foot should be classified into two groups: excellent knowledge the general average of correct answers (> 80%) and poor knowledge (<55%). The scoring strategy of the instrument was similar to those of other studies[9-11] and the knowledge classification is similar to instrument applied with PHC nurses in Saudi Arabia[9].

It is underlined that nurses need to have sufficient knowledge and skills to prevent, diagnose and care for foot problems of people with diabetes[10], as their knowledge positively affects patient education[9]. Nevertheless, research conducted with hospital nurses in Turkey found that nurses do not have enough knowledge on diabetic foot examination or do not have enough time to accomplish it. The knowledge gaps on the topic may be attributed to lack of formal training in diabetic ulcer care[15].

It is noteworthy that examining the feet of people with DM is a key element to prevent ulcerations and complications associated with the disease[1;4;8]. PHC nurses play an important role in this care[6-9;12-13], and should become familiar with it and incorporate it into their health care practice[5].

In order to construct the QICEPeD domains, it was considered that nurses working in PHC services must have knowledge on the physiopathogenesis of the diabetic foot, since most of the associated complications, including lower limb amputations, can be prevented with the adoption of simple measures implemented through anamnesis, early detection of complications, and appropriate management of risk factors[7-8;14].

It is known that the main factors underlying the development of diabetic ulcers are diabetic polyneuropathy, deformities related to motor neuropathy, trauma and PAD[1-4]. Contrary to popular belief, infection is not the main cause of foot ulcers, but it is a secondary phenomenon after epidermal injuries[1;4].

Thus, when evaluating the feet of people with DM, the nurse should seek not only the influence of factors that may be directly or indirectly involved in the installation of these complications, but also their consequences in the life of the person, highlighting, in addition to glycemic control, the self-examination of the feet[6-8].

Four questions related to the clinical examination of the feet were prepared, which emphasize the nurse's knowledge on tests to assessLPS[1;4;17]. In one of the questions, an illustration of the plantar and dorsal regions of the foot is displayed for the nurse to point out the test sites for application of the 10g monofilament (Semmes-Weinstein). This is the most recommended test to screen for diabetic polyneuropathy and the risk of foot ulceration, as it detects changes in coarse fibers (beta and A alpha) directly related to LPS[1;4].

Consensus guidelines[1;4;17] recommend that

inspection and careful examination of the feet be included in the follow-up consultation for people with diabetes. During this evaluation, the diagnosis of LPS should be made by means of the 10 g monofilament test and one or more altered neurological tests: 128 Hz tuning fork (vibratory sensation); pin or toothpick (painful sensation); reflex hammer (Achilles reflex) or bioaesthesiometer (vibratory sensation threshold) [1;4;17].

Although most PHC services do not have the tuning fork and the hammer, these instruments were included in the QICEPeD tool, as they are recommended by the Brazilian Ministry of Health and by current guidelines[1;4]for the early detection of ulcerative processes in the feet, associated with decreased vibration sensation and ankle areflexia[4].

The process of content validation of the instrument involved the participation of 10 judges in Delphi I (DI) and Delphi II, a number considered sufficient for this process[16]. The selection of judges was carried out through a search on the Lattes Platform of CNPq. This type of strategy has been used by various research studies focused on the construction and validation of protocols and instruments in various areas of Nursing[18,19], allowing access to researchers from different geographic regions of the country.

It is noteworthy that the use of the Delphi method promoted a dynamic process of data collection and analysis, allowing, through controlled feedbacks, a consensus to be reached among the judges as to the clarity and pertinence of the elements of the assessed instrument[20].

The pertinent literature[19] points out that the acceptable agreement coefficient among the judges' committee members should be at least 0.80 and, preferably, higher than 0.90. In the QICEPeD assessment, the judges showed significant CVI in all assessed elements. It was noticed that, after the second round of assessment, the instrument proved to be valid with regard to clarity and pertinence; all elements obtained CVI = 1.00. These results are higher than those found by other studies[10;13,14].

With respect to the internal consistency of the QICEPeD elements, it was found that the instrument obtained a total Cronbach's alpha of 0.860 and that the value would not undergo major changes if any element were deleted. In this perspective, it is possible to emphasize that the QICEPeD has content quality and reliability, being adequate to investigate the knowledge of PHC nurses on diabetic foot, which allows its reproducibility in future studies.

It is recommended that the QICEPeD instrument be disseminated and used in other surveys, reapplied by educational institutions and health services, through continuing education programs, so that the results introduced here can be confirmed, or to receive the necessary adjustments.

CONCLUSION

The proposed instrument was considered valid, in terms of content and construct, and can be used to assess the level of knowledge of PHC nurses on diabetic foot. Although the results introduced here suggest evidence of the validity of the QICEPeD tool, since it is a recently developed instrument and new in Brazil, it is essential to continue the validation process through future studies that assess its psychometric properties, with factor analysis of the elements to accommodate them in domains according to their statistical loadings, in order to obtain a greater generalization of the results.

The limitation of this study is related to the need for the nurse respondent to have knowledge of the technical terms used in the construction of the elements to make it possible to reliably record the answers during the application of the instrument.

It is believed that the use of QICEPeD in clinical practice will support the understanding of knowledge gaps of PHC nurses regarding the topic under study, favoring the planning and implementation of educational interventions and/or perhaps curricular changes in such a way as to obtain better professional training in this area.

VALIDAÇÃO DE INSTRUMENTO PARA INVESTIGAÇÃO DO CONHECIMENTO DE ENFERMEIROS SOBRE PÉ DIABÉTICO

RESUMO

Objetivo: construir e validar um instrumento para investigação do conhecimento de enfermeiros da Atenção Primária à Saúde sobre pé diabético. **Método:** estudo metodológico realizado de janeiro a junho de 2017, que seguiu o Modelo de Elaboração de Escalas Psicométricas de Pasquali, em três etapas: teórica, empírica e analítica. Para validação de conteúdo, adotou-sea técnica de Delphi em dois momentos, com a participação de 10 juízes. A validade de construto foi realizada por 73 enfermeiros que atuavam nos serviços de APS do município de Campina Grande-PB. Aos dados, aplicou-se o Índice de Validação de Conteúdo (IVC). **Resultados**: construiu-se o "Questionário de Investigação do Conhecimento do Enfermeiro sobre Pé Diabético (QICEPeD)" com 47 itens organizados em 12 domínios de conhecimentos sobre a temática. Após a segunda rodada de avaliação dos juízes, todos os itens atingiram escores máximos de concordância (IVC = 1,00). A análise da confiabilidade e da consistência interna total do instrumento foi considerada elevada (α=0,860). **Conclusão:** o instrumento QICEPeD foi considerado válido, quanto ao conteúdo e construto, podendo ser utilizado para avaliar o conhecimento de enfermeiros da Atenção Primária sobre pé diabético.

Palavras-chave: Pé Diabético. Psicometria. Estudos de Validação. Pesquisa Metodológica em Enfermagem. Enfermagem.

VALIDACIÓN DEL INSTRUMENTO PARA LA INVESTIGACIÓN DEL CONOCIMIENTO DE ENFERMEROS SOBRE PIE DIABÉTICO

RESUMEN

Objetivo: construir y validar un instrumento para la investigación del conocimiento de enfermeros de la Atención Primaria de la Salud (APS) sobre pie diabético. **Método**: estudio metodológico realizado de enero a junio de 2017, que siguió el Modelo de Elaboración de Propiedades Psicométricas de Pasquali, en tres etapas: teórica, empírica y analítica. Para la validación de contenido, se adoptó el método de Delphi en dos momentos, con la participación de 10 jueces. La validez del constructo fue realizada por 73 enfermeros que actuaban en los servicios de APS del municipio de Campina Grande-PB-Brasil. Para los datos, se aplicó el Índice de Validez de Contenido (IVC). **Resultados**: se construyó el "Cuestionario de Investigación del Conocimiento del Enfermero sobre Pie Diabético (CICEPeD)" con 47 ítems organizados en 12 dominios de conocimientos sobre la temática. Después de la segunda ronda de evaluación de los jueces, todos los elementos alcanzaron puntajes máximos de concordancia (IVC=1,00). El análisis de la confiabilidad y de la consistencia interna total del instrumento fue considerado alto (α=0,860). **Conclusión**: el instrumento CICEPeD fue considerado válido, en cuanto al contenido y constructo, pudiendo ser utilizado para evaluar el conocimiento de enfermeros de la Atención Primaria sobre pie diabético

Palabras clave: Pie Diabético. Psicometría. Estudios de Validación. Investigación Metodológica en Enfermería. Enfermería.

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