



TECHNOLOGY VALIDITY PROCESS: INSTRUMENT FOR ASSESSING THE FEET OF PEOPLE WITH DIABETES MELLITUS¹

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ABSTRACT

Objective: to validate the content of a mode of conduct technology called *Instrumento Para Avaliação Dos Pés De Pessoas Com Diabetes Mellitus* (Instrument for Assessing the feet of people with Diabetes Mellitus). **Method:** methodological research carried out with expert nurses in diabetic foot selected on the Lattes/CNPq Platform using advanced search, resulting in 51 curricula that met established criteria. Invitations were sent by email with a link to answers and access to technology on Google Forms. Data were obtained between December 2020 and March 2021. Analysis included the pertinence of each item and the clarity and relevance of each sub-item on a Likert scale. Data were analyzed using descriptive statistics in relation to the committee agreement rate greater than or equal to 80% and in relation to the minimum Content Validity Index of 0.90. **Results:** there was feedback from 27 judges who considered that all items and sub-items reached the rates established with experts agreeing on the assessed content greater than 96%. The Content Validity Index was greater than 0.92. **Conclusion:** the technology content was validated and considered an adequate instrument for use by nurses in the care of people with diabetes, which not only indicates the items to be assessed, but also guides how to carry out assessment and also allows recording to monitor the evolution.

Keywords: Diabetes Mellitus. Diabetic Foot. Technology. Validation Study.

INTRODUCTION

Allied to the increase in the number of people with Diabetes Mellitus (DM) are the chronic complications that are increasingly frequent, especially in people who do not keep the disease under control, not always just because they do not want to, but often because they do not have adequate conditions to carry out treatment and care, due to the lack of an educational process convergent to their living conditions and a systematic follow-up of their condition⁽¹⁾.

Among the complications of DM, the chronic ones are the most devastating, as they are discovered already in an advanced state, when treatment cost becomes a great financial burden for people and for the health system, in addition to having an emotional, physical and social impact on people's lives⁽²⁾. Among these diseases, foot ulceration is one of the main ones

and is associated with high levels of morbidity and mortality. The incidence rate of diabetic foot ulceration is 19-34% over a lifetime, with an annual incidence rate of 2%⁽³⁾.

Diabetic foot is defined as "Infection, ulceration or destruction of tissues of the foot of a person with currently or previously diagnosed diabetes mellitus, usually accompanied by neuropathy and/or peripheral artery disease in the lower extremity"^(4,2). It is, therefore, a complication that encompasses several pathologies, such as neuropathy (86% of cases), peripheral artery disease (49% of cases) and foot ulceration, in addition to Charcot neuroarthropathy and osteomyelitis⁽⁴⁾.

The best diabetic foot prevention and management strategy involves adequate DM control, complete foot assessment, and health care based on prevention and education with the support of a multidisciplinary team^(5,6).

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One of the essential elements in identifying modifiable risk factors that may reduce the risk of lower limb ulceration and amputation in people with diabetes is foot assessment. Foot assessment has great repercussions in diabetic foot prevention and monitoring and is a low-complexity and easily accessible intervention^(6,7).

These data show the relevance of investments in the prevention of this complication, involving educational aspects so that people control the disease and make a daily assessment of foot conditions, including other elements that can also be a risk for the diabetic foot, such as the use of suitable footwear and socks, foot hygiene conditions, and toenail conditions^(7,8).

Technologies in nursing involve the search for new ways of providing care⁽⁹⁾. From this perspective, the *Instrumento Para Avaliação Dos Pés De Pessoas Com Diabetes Mellitus* (Instrument for Assessing the feet of people with Diabetes Mellitus) was developed, which expresses a process based on a set of existing knowledge and revisited by the authors to provide a new technology, expressed in the form of a foot assessment instrument. The technology aims to provide a complete and easy-to-use instrument to guide nurses in foot assessment, with the goal of early identification and monitoring of alterations in the feet of people with DM. After completing the technology construction, the following question was asked: is the Instrument for Assessing the feet of people with Diabetes Mellitus content pertinent, clear and relevant? This question guided the study that aimed to validate Instrument for Assessing the feet of people with Diabetes Mellitus technology content conduct.

METHOD

Methodological research was carried out for Instrument for Assessing the feet of people with Diabetes Mellitus mode of conduct technology content validity. A mode of conduct technology is a process technology built to guide professionals in carrying out a certain activity, guided by steps or phases⁽¹⁰⁾. The developed technology consists of an instrument that indicates what and how professionals should assess the feet of people with DM.

This technology was developed by

researchers from the NUCRON research laboratory, from the Graduate Program in Nursing at the *Universidade Federal de Santa Catarina* (UFSC), who were inspired by a script developed and used by health professionals at the outpatient clinic of USFC's university hospital; researchers' experiences in assessing the feet for more than 10 years; extensive literature review; consulting the consensus of international (ADA) and national (SBD) societies; and publications of the Ministry of Health. The intention was to provide an instrument to be used by nurses in their care actions for people with DM.

The instrument developed is a script composed of: 1) identification of a person with DM; 2) health history; 3) foot inspection; 4) neurological assessment; 5) motor assessment; 6) vascular assessment; 7) risk stratification system and foot assessment frequency. It is a script that assists professionals in assessment actions and in recording the assessment carried out, with drawings indicating how and where to carry out assessment. For its application, only easily accessible materials are needed, such as a tuning fork, a 10-gram monofilament and a reflex hammer.

Content validity assesses the degree to which each element of a measurement instrument is relevant and representative for a particular assessment purpose, with the instructions, response format, and individual items being considered the elements that make up the instrument⁽¹¹⁾.

The proposal was to verify if the Instrument for Assessing the feet of people with Diabetes Mellitus content was clear, whether the elements that compose it were relevant, and whether the necessary aspects are covered in an assessment of the feet of people with DM.

The research was carried out in an online virtual environment, via email using Google Forms, one of Google's applications. A separate account was created that made the whole process possible, facilitating the distribution and application of electronic instruments for data collection.

Content validity was carried out by professional nurses who had experience in care and carried out studies on diabetic foot. Participant selection was carried out by

accessing the CNPq *Lattes* Platform with the advanced search using the expression “diabetic foot” and applying the following filters: education: PhD; professional performance: health/nursing sciences. This search resulted in 72 curricula that were analyzed and scored according to criteria adapted from Fehring (1987)⁽¹²⁾: PhD training (3 points); minimum of three years of experience in clinical nursing practice, including people with DM (1 point); development of research carried out on the theme of care for people with DM (2 points); article published on the theme of care for people with DM (1 point per article, up to a limit of five points). Participants with a minimum score of seven points were included. From this analysis, 51 reached the established minimum score, and the contact (email) of 49 of them was obtained in the *Lattes* curriculum itself, on the websites of the institutions where the selected ones worked or through contacts on social platforms.

An invitation letter was sent to 49 potential participants by email, inviting them to participate in the research. If they accepted, the link to the Informed Consent Form (ICF) and access to the content validity questionnaire were included. Answers were obtained from 27 of those selected, even after two attempts to send an e-mail. This number met the previously established in the project, which was at least 10

experts⁽¹³⁾. Data collection took place from December 2020 to March 2021.

The content validity questionnaire of the technology mode of conduct for assessing the feet of people with DM was presented on Google Forms. This questionnaire also included access to technology as it would be used to assess the feet of people with DM so that judges could understand its organization and the questions for assessing the six items that make up the instrument, in addition to identifying it. Initially, an assessment was requested on the pertinence of the six items with yes and no answers, and then, they were asked to analyze the sub-items in relation to clarity and relevance on a Likert-type scale, each with four points. Regarding clarity: (1) Strongly disagree; (2) Partially disagree; (3) Partially agree; and (4) Strongly agree; and regarding relevance: (1) Not relevant; (2) Needs major review; (3) Needs minor review; and (4) Relevant.

Data were analyzed by descriptive statistics in relation to the committee agreement rate (CAR) and in relation to the Content Validity Index (CVI). It was established that the CAR should be greater than or equal to 80%⁽¹³⁾ for an item to be considered valid, and items with an index below that should be reformulated or eliminated, based on judges' suggestions. The following formula was used⁽¹³⁾:

$$\text{CAR} = \frac{\text{Number of participants who agreed}}{\text{Total number of participants}} \times 100$$

The CVI calculation considered in each sub-item the set of options 3 and 4, both in relation to clarity and relevance, which should reach the minimum index of 0.90, using the formula below⁽¹¹⁾:

$$\text{CVI} = \frac{\text{Number of answers "3" or "4"}}{\text{Total number of answers}}$$

The research project was sent to the Research Ethics Committee of the *Universidade do Estado do Amazonas* and approved by Opinion 4,363,008, CAAE (*Certificado de Apresentação para Apreciação Ética* - Certificate of Presentation for Ethical Consideration) 37178320.0.0000.5016.

RESULTS

The technology mode of conduct foot assessment tool for people with DM (Figure 1) was assessed by 27 judges. The characterization

of these judges was of a majority of females (89%), with an average age of 48 years (31 to 67 years), average training time as a nurse of 23 years and length of graduation as a PhD of 13 years. The link of 25 participants was with higher education institutions (universities, faculties and university centers) and two linked to health departments (one municipal and the other state).

The result of judges' judgment was that all items and subitems of the technology mode of conduct assessment of the feet of people with DM reached the established indexes with

experts' agreement on assessed content (CAR) with the majority reaching 1.0, as shown in greater than 96% and CVI greater than 0.92, Table 1.

Table 1. Judges' committee agreement rate and Content Validity Index for clarity and relevance. Manaus -AM, 2021

Assessment items and subitems	CVI* Clarity	CVI** Relevance
ITEM 1 – Health history – CAR** 100.0%		
1.1 Presence of other diseases	1	1
1.2 Medications for DM in use	1	1
1.3 Other complications of DM	0.92	0.96
1.4 Use of tobacco	0.96	1
1.5 Previous foot assessment by a health professional	1	1
1.6 Help to take care of health	1	1
1.7 Value of the last glycated hemoglobin	1	1
1.8 Previous lower limb injuries	1	1
1.9 Lower limb pain	1	1
1.10 Muscle weakness in lower limbs	1	1
1.11 Cramps in lower limbs	1	1
1.12 Numbness in lower limbs	1	1
1.13 Tingling in lower limbs	1	1
1.14 Twinge in lower limbs	0.96	0.96
1.15 Type of shoes they are wearing	1	1
ITEM 2 – Foot inspection - CAR 96.3%		
2.1. Foot skin conditions	1	1
2.2 Foot hygiene conditions	1	1
2.3 Presence of calluses	1	1
2.4 Presence of injuries	1	1
2.5 Presence of foot deformities	1	1
2.6 Changes in skin color	1	1
2.7 Skin temperature	0.96	1
2.8 Nail conditions	1	1
2.9 Presence of edema	0.96	1
ITEM 3- Neurological assessment - CAR 100%		
3.1 Plantar protective sensitivity	1	1
3.2 Painful sensitivity	1	1
3.3 Thermal sensitivity	1	1
3.4 Sensitivity to vibration	1	1
ITEM 4 – Motor assessment - CAR 100%		
4.1 Achilles reflex	1	1
4.2 Muscle strength	1	1
ITEM 5 – Vascular assessment - CAR 100%		
5.1 Foot pulse	1	1
5.2 Posterior tibial pulse	1	1
ITEM 6 - Risk stratification system and foot assessment frequency - CAR 96.3%		

* CVI: Content Validity Index. **CAR: committee agreement rate

With these results, all instrument items were validated, without the need for modifications. Some suggestions were given and, among them, the indication of the designation of item 1.4, which was “Use of cigarettes” for “Use of tobacco” as a more appropriate expression, was accepted. Additionally, in subitems 1.9 to 1.14, the indication of the affected limb was added: left lower limb and right lower limb.

DISCUSSION

Delimiting what involves foot assessment in people with DM is complex due to the articulation of this complication with the changes that the disease causes in different systems, such as the vascular, neurological, locomotor and integumentary systems.

The absence of symptoms in people with DM

does not exclude the existence of a diabetic foot, as neuropathy, vascular changes and pre-ulcer signs may not be clearly manifested to people⁽¹⁴⁾.

Knowing health history, such as the time of disease diagnosis, disease control, use of tobacco, presence of comorbidities and alterations in lower limbs, is recommended in different studies and consensuses, even though there is no unanimity among them about what should be included as part of foot assessment^(3,4,15). The main question remains about what is more specific for foot assessment and what is part of the general assessment of disease.

The option in foot assessment mode of conduct technology construction was to include 15 sub-items that represented the most relevant information. Health history includes key perceptions of lower extremity tenderness (pain, cramps, tingling, numbness, twinges, and weakness), more general information about the disease (presence of other diseases, medications for DM in use, other complications of diabetes, tobacco use), in addition to seeking information on previous foot assessments and support availability. The intention of including some of these items was to invest in preventive and/or care activities when changes were detected, following different recommendations^(3,15).

All these items were agreed by the judges who participated in the study, showing their pertinence and suitability for foot assessment. Some suggestions were to expand the information with detailed information; however, they were not specific for foot assessment, but information about DM, which is included in nursing/health history.

The second item is foot inspection, which refers to an assessment of foot general conditions, identifying some important risk factors, such as foot hydration and hygiene conditions, skin color and temperature, presence of injuries, calluses and edema, nail clipping, deformities, and other abnormalities^(3,14).

Neurological assessment is part of the instrument's third item and involves testing the perception of foot sensitivity. Technology guides how to carry out this assessment with specific designs and guidelines that help professionals to perform uniformly, since this type of assessment is not always the nurses' domain. In addition to

sensitivity assessment, assessment of other signs of neuropathy is indicated, such as dry skin, callus formation, distension of the dorsal veins of the foot and small loss of muscle mass⁽¹⁵⁾.

The lack of sensitivity in the feet in relation to pain and temperature results from prolonged exposure to hyperglycemia, associated with cardiovascular changes that promote changes in fine nerve fibers^(6,15). On the other hand, the impairment of thick fibers can promote lack of balance with the risk of falls (altered proprioception) and the gradual onset of neuropathic deformities (claw or hammer toes, prominences of metatarsal heads and plantar arch accentuation or rectification). This changing condition, which implies neurovascular control, can lead to changes in capillary flow, fluid filtration and inflammatory response, making people with DM more susceptible to injuries and development, such as Charcot neurosteoarthropathy^(15,16).

Motor assessment may indicate weakness of minor muscles and absent ankle reflexes as assessed by the Achilles reflex⁽¹⁷⁾. Achilles tendon reflex assessment is obtained by tapping the reflex hammer or tapping the Achilles tendon. The test is considered altered when reflex plantar flexion of the foot is absent or diminished⁽¹⁶⁾. Achilles tendon stiffness leads to increased pressure in the forefoot and favors the development of plantar ulcers, justifying the importance of this assessment⁽³⁾.

Non-invasive vascular assessment involves palpation of peripheral pulses (pedis and tibial) and can also use diagnostic means such as manual Doppler, digital-arm index. However, this equipment (Doppler) is often not available in health services, with the exception of specialized services, and the digital-arm index is performed by specialists^(4,15).

Late diagnosis of vascular alteration contributes to diabetic foot evolution, favoring amputation in people with DM. Furthermore, between 25 and 50% of people with vascular disorders have no symptoms or these are atypical, 30% have intermittent claudication and 20% manifest more severe forms, progressing to critical ischemia^(15,17).

The sixth item of the foot assessment instrument includes the presentation of a risk stratification system and foot assessment

frequency. These systems help indicate the risk of the foot and indicate the deadline for a new assessment. There are several stratification systems, such as Wagner-Meggitt at the University of Texas, which are the most widely used, followed by others such as the SADstratification and the PEDIS system⁽¹⁹⁾. The option to include a risk rating in the technology considered the one recommended by the most internationally recognized group in terms of their evidence-based proposals⁽³⁾.

The primary purpose of nurse foot examination is the early detection of foot problems, identifying those at imminent risk, and planning to reduce the development of foot ulcers. Foot examination should be performed annually for those who have a very low risk stratification and for others, according to risk stratification. However, in all nursing consultations, people should be asked to remove their shoes and nurses should carry out an inspection, regardless of the time indicated by risk stratification, and if any alteration is detected, a complete inspection must be carried out using a specific instrument, such as the one validated in this study.

The choice of these items to integrate the technology is supported by a study that aimed to critically assess the current guidelines for screening feet in patients with diabetes and examine their relevance in terms of advancing clinical practice, improving technology and changing the sociocultural structure⁽²⁰⁾. In that study, structured bibliographic research was carried out, selecting 10 guidelines that were analyzed in a comparative way. They found that there is a lot of variation in the terms used in these guidelines and that the methods also vary. According to the study, some aspects, not only related to foot assessment, were present in all guidelines: peripheral neuropathy and vascular disease assessment; foot deformation assessment; indication of assessment and screening frequency; footwear inspection and supply; patient foot care education⁽²⁰⁾.

Assessing the feet of people with DM by nurses is an essential recommendation, especially in primary care, where care can be provided in the early stages of the disease, favoring diabetic foot prevention⁽²¹⁻²⁴⁾.

The availability of instruments that help nurses to assess the feet has grown, but not always with the necessary quality. An example of this are the demo videos whose quality was assessed in a study that recognized that they attract a considerable audience, but are considered of low quality and reliability⁽²⁵⁾. It is in this perspective of offering quality technology that the Instrument for Assessing the feet of people with Diabetes Mellitus was developed and validated, which could be transformed into a video or mobile application in future studies.

Some limitations should be noted in the assessment of results presented here, because, although this study was conducted following a rigorous method, it only assessed content, not advancing in its testing in care practice.

CONCLUSIONS

The technology mode of conduct for assessing the feet of people with DM had its content validated in all its items and sub-items, showing that it is a suitable instrument for use by nurses in the care of people with DM. The complexity of this assessment can be overcome with the help of instruments of this type that not only indicate the items to be assessed, but also provide guidance on how to carry out assessment and allow recording for monitoring progress.

For the success of this assessment, it is essential that nurses seek to update themselves on the subject, have access to more advanced training in DM, more specifically in diabetic foot, and that they are multipliers in their services. Moreover, there is a need to implement existing policies that indicate carrying out prevention and monitoring actions, ensuring the existence of basic materials for assessment to take place fully, which are low cost, and the training of professionals for this specific care.

PROCESSO DE VALIDAÇÃO DA TECNOLOGIA: INSTRUMENTO DE AVALIAÇÃO DOS PÉS DE PESSOAS COM DIABETES MELLITUS

RESUMO

Objetivo: validar o conteúdo da tecnologia modo de conduta denominada Instrumento para Avaliação dos pés de pessoas com Diabetes Mellitus. **Método:** pesquisa metodológica realizada com enfermeiros experts em pé diabético selecionados na Plataforma Lattes/CNPq com a busca avançada, resultando 51 currículos que atenderam critérios estabelecidos. O convite foi realizado por e-mail com link para respostas e acesso à tecnologia no Google Forms. Os dados foram obtidos entre dezembro de 2020 e março de 2021. A análise contemplou a pertinência de cada item e a clareza e relevância de cada subitem em escala Likert. Os dados foram analisados por estatística descritiva em relação a Taxa de Concordância do Comitê maior ou igual a 80% e em relação ao Índice de validade de conteúdo mínimo de 0,90. **Resultados:** houve a devolutiva de 27 juízes que consideraram que todos os itens e subitens atingiram os índices estabelecidos com concordância dos experts sobre o conteúdo avaliado superior a 96%. O Índice de validade de conteúdo foi superior a 0,92. **Conclusão:** o conteúdo da Tecnologia foi validado e consideramos instrumento adequado para uso por enfermeiros no cuidado às pessoas com diabetes, que não só indica os itens a serem avaliados, como orienta como realizar a avaliação e também permite o registro para acompanhamento da evolução.

Palavras-chave: Diabetes mellitus. Pé diabético. Tecnologia. Estudo de validação.

PROCESO DE VALIDACIÓN DE LA TECNOLOGÍA: INSTRUMENTO DE EVALUACIÓN DE LOS PIES DE LAS PERSONAS CON DIABETES MELLITUS

RESUMEN

Objetivo: validar el contenido de la tecnología modo de conducta denominada Instrumento para Evaluación de los pies de personas con Diabetes Mellitus. **Método:** investigación metodológica realizada con enfermeros expertos en pie diabético seleccionados en la Plataforma Lattes/CNPq con la búsqueda avanzada, resultando 51 currículos que atendieron criterios establecidos. La invitación se realizó por correo electrónico con enlace a respuestas y acceso a la tecnología en Google Forms. Los datos se obtuvieron entre diciembre de 2020 y marzo de 2021. El análisis ha tenido en cuenta la pertinencia de cada ítem y la claridad y relevancia de cada subelemento en escala Likert. Los datos fueron analizados por estadística descriptiva en relación a la Tasa de Concordancia del Comité mayor o igual al 80% y en relación al Índice de validez de contenido mínimo de 0,90. **Resultados:** hubo la devolutiva de 27 jueces que consideraron que todos los ítems y subelementos alcanzaron los índices establecidos con la aprobación de los especialistas sobre el contenido evaluado superior al 96%. El índice de validez de contenido fue superior a 0,92. **Conclusión:** el contenido de la Tecnología fue validado y considerado un instrumento adecuado para uso por enfermeros en el cuidado de las personas con diabetes, que no solo indica los ítems a ser evaluados, sino también orienta cómo realizar la evaluación y además permite el registro para seguimiento de la evolución.

Palabras clave: Diabetes mellitus. Pie diabético. Tecnología. Estudio de validación.

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