Cogitare Enfermagem

ORIGINAL ARTICLE

VIGIPÉ®: FOOT RISK STRATIFICATION TECHNOLOGY FOR PATIENTS WITH DIABETES *MELLITUS*

HIGHLIGHTS

1. The Vigipé® technology supports nurses in foot examination and risk classification.
2. It improves the prevention practices during Nursing consultations.
3. It contributes to excellence in the care provided to diabetic patients.
4. Early detection and prevention of changes in the feet.

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ABSTRACT

Objective: to create and validate an app that establishes the diabetic foot risk degree by associating the patients' health conditions. **Methodology:** a methodological study conducted between March 2019 and December 2021 in Crato – CE – Brazil, and divided into three phases: 1) Review of the national and international guidelines; 2) Creation of the educational technology; and 3) Face and content validation of the technology. This study followed the guidelines set forth in the *Revised Standards for Quality Improvement Reporting Excellence* guide. **Results:** in the review phase, similar content was identified between the guidelines for designing and organizing the content. The technology that was created enabled data collection, as well as diabetic foot risk assessment and classification. A total of 18 judges evaluated the instrument in the validation stage, obtaining a CVI value of 0.96. **Conclusion:** the study may contribute to improving the indicators referring to hospitalizations, amputations, reduced mobility, dependence, frailty and mortality resulting from diabetic foot.

DESCRIPTORS: Nursing: Stomatherapy; Diabetic Foot; Wounds and Injuries; Health Technologies.

HOW TO REFERENCE THIS ARTICLE:
Oliveira CRT de, Macedo LFR, Pinheiro PG, Meneses JCBC de, Menezes LCG de, Marques ADB, *et al.* Vigipé®: foot risk stratification technology for patients with diabetes mellitus. Cogitare Enferm. [Internet]. 2023 [cited in "insert year, month, day"]; 28. Available in: https://dx.doi.org/10.1590/ce.v28i0.91597.

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INTRODUCTION

Chronic conditions are ranked as with certain importance in health systems. One of the most relevant of these conditions is Diabetes *Mellitus* (DM), a group of metabolic disorders caused by hyperglycemia, resulting from a deficiency in the secretion of insulin, defects in its action, or both[1].

Increased prevalence of DM is associated with the complex interaction of socioeconomic, demographic, environmental and genetic factors such as rapid urbanization, epidemiological and nutritional transition, sedentary lifestyle, excess weight, population growth and aging[2].

Approximately 537 million adults had DM in 2021 and that number is estimated to rise to 783,000 millions by 2045. Half of the people with DM had not yet been diagnosed (232 millions). There were 6.7 million deaths due to the disease and at least US$ 966 billions were spent on health expenditures in 2021, which represented 10% of the total adult-related expenses[2].

In 2012, there were 12 million diabetics in Brazil, and it is believed that the disease will have affected 19.2 million Brazilians by 2035. In 2021, Brazil was the fifth country in the world in terms of number of cases in the ranking of the ten countries with the highest prevalence values, with 16.8 millions[1-2].

Data from the NCD Risk Factor Collaboration point out that this condition reaches pandemic proportions. The disease causes early death, is considered the leading cause of acquired blindness, and is associated with cardiovascular and renal diseases and to lower limb (LL) amputations[3].

A large percentage of the LL amputation cases in people with DM can be avoided[4]. Periodic foot examinations represent a strategy that favors early identification of the changes and, thus, allows establishing their timely treatment, preventing diabetic foot complications[3]. Some data point out that more than 15% of the people with DM are susceptible to developing foot ulcers at some point in their life, and it is usual for ulcers to precede 85% of the amputations[5-7].

Development and implementation of strategies that provide valuable clinical information to better assist these patients are of utmost importance. In this sense, technological innovation in the health area enables rapid and precise information support and better health assistance quality[8].

The use of computational tools in the health area is in increasing expansion. This type of support provides greater precision and agility to health professionals; furthermore, it can be applied in several contexts, especially remote monitoring, diagnostic support, and decision-making support[9].

Given this situation, the objective was to create and validate an app that establishes the diabetic foot risk degree in patients with DM by associating their health conditions.

METHOD

This is a methodological study conducted between March 2019 and December 2021 at *Universidade Regional do Cariri* (URCA) aiming to develop, evaluate and improve research instruments and techniques focused on the development of a reliable, accurate and useful instrument. All three phases of the method were followed: 1) Literature review;

2) Creation of the educational technology: and 3) Face and content validation of the technology by a number of judges[10]. This study followed the guidelines set forth in the *Revised Standards for Quality Improvement Reporting Excellence* (SQUIRE 2.0) guide[11].

The national and international guidelines targeted at the care of people with DM and diabetic foot were selected in the first phase, namely: Ministry of Health (*Ministério da Saúde*, MS) (Primary Care Handbook - Strategy for the care of people with chronic diseases)[12]; Diabetic foot manual: Strategy for the care of people with chronic diseases[13]; Clinical Guidelines from the Brazilian Diabetes Society (*Sociedade Brasileira de Diabetes*, SBD)[1]; International Working Group Diabetic Foot (IWGDF)[14]; National Institute for Health and Care Excellence (NICE)[15], American Diabetes Association (ADA); and Scottish Intercollegiate Guideline Network (SIGN)[16].

All three steps from the *Scrum* framework[17] were followed when creating the technology. The first step concerns the view regarding the product, as well as a technical analysis about the software. Subsequently, the step called "Product Backlog" was carried out, in which the functional and non-functional requirements were assessed, as well as the importance degree and the details of each functionality. The "Sprints" were mounted in the last step, corresponding to a period that will lead to creating some selected functionalities from the "Product Backlog"[18]. While developing the software, fortnightly meetings were held among the researchers in order to assess advances and difficulties and to propose adaptations to the new "Sprints".

The programming language used for the backend was *JAVA*, with the aid of *Ireport* version 4.5, to issue the report and the database and of *MySql Server 5.1.11* to store the information.

Face and Content Validation was performed in third phase. According to the literature[19], it becomes necessary to validate face and content of the material produced in order to render it reliable and valid for a give purpose. Face and content validation was in charge of proficient nurses; researchers and teachers with experience in DM and in the care of patients with diabetic foot, educational technologies and validation of instruments; in addition to nurses with experience in the clinical care of patients with DM and in diabetic foot care. In order to take part in the study as judges, the specialists had to obtain a minimum score of five points, according to the scoring criteria shown in Chart 1. This recruitment process was conducted in the Lattes Platform and sampling was intentional and non-probabilistic[10].

Chart 1 - Scoring criteria to select the judges. Crato, Ceará, Brazil, 2023**.**

Criteria for proficient judges in Face and Content Teachers, Researchers and Care Professionals	**Score**
Being a PhD	4 points
Being an MSc	3 points
Having some specialization	2 points
Thesis/Dissertation/Specialization Conclusion Paper in the area of interest	2 points per paper
Papers published in the area of interest	1 point per publication
Having professional experience (clinical, teaching or research) of at least five years in the area of interest	2 points per year of experience
Supervising papers in the area of interest	0.5 points per paper
Participation in exam boards for papers involving the area of interest	0.25 points per board

SOURCE: Adapted from the study[19], by the authors, 2023.

For the analysis of Vigipé®, an email message was sent to the judges with an invitation letter, an Informed Consent Form (ICF), the assessment instrument, and the technology produced attached in the *Windows PowerPoint* format.

The validation instrument for the judges was organized in two sections. The first one was related to participants' identification data and the second one was a compilation of instructions to answer the instrument and evaluative items regarding objective and content, structure, presentation and relevance. The answers to the evaluative questions were presented on a *Likert*-type scale, according to the following scores: Not adequate at all (1); Little adequate (2); Adequate in average terms (3); Very adequate; and (4) Extremely adequate (5). Scores equal to or above four were considered satisfactory, and those equal to or below three were reviewed or removed.

There is yet no consensus regarding the ideal number of specialists to validate instruments, with suggestions varying between five and twenty subjects. The Content Validity Index (CVI) was calculated considering the value of 0.80 as minimum acceptable for adequacy of the objectives, structure and relevance of the technology and 80% for agreement. The data were tabulated and processed in *Microsoft Excel* for *Windows*. Subsequently, they were organized in charts and discussed in the light of the pertinent literature.

The study was approved by the URCA Research Ethics Committee[20] under Opinion No. 3,707,189.

RESULTS

In order to establish the content to be included in each screen of the construct, the guidelines were read and similar contents were identified for designing and organizing the required textual production about the diabetic foot risk classification and the sequence to perform foot inspections. Chart 2 shows the risk level, the classification and the variables used in the classification systems.

Chart 2 – Variables adopted in the classification systems. Crato, Ceará, Brazil, 2023**.**

Guideline	Risk level	Classification	Variables
IWGDF	0	Very Low	No LPS or PAD
	1	Low	LPS or PAD
	2	Moderate	LPS + PAD or LPS + Deformity or PAD + Deformity
	3	High	LPS or DAP, and at least one of the following: - Previous ulcer - Lower limb amputation (minor or major) - End-stage renal disease
ADA	0	Very Low	Np LPS or PAD
	1	Low	LPS with or without Deformity
	2	Moderate	PAD with or without LPS
	3	High	Previous ulcer or Previous amputation

SBD	0	Very Low	Np LPS or PAD
	1	Low	LPS with or without Deformity
	2	Moderate	PAD with or without LPS
	3	High	Previous ulcer or Previous amputation
MS	0	Very Low	No neuropathy
	1	Low	Neuropathy with or without Deformity
	2	Moderate	PAD with or without LPS
	3	High	Previous ulcer or Previous amputation
NICE		Low	No risk factors, except for isolated callus
		Moderate	Deformity or Neuropathy or Non-critical ischemia
		High	Previous ulcer or Previous amputation or Renal disease or Neuropathy and Non-critical ischemia or Neuropathy with callus and/or Deformity or Non-critical ischemia with callus and/or Deformity
		Active disease	Ulceration or Infection dissemination or Limb critical ischemia or Gangrene or Suspected and unexplainable acute Charcot arthropathy; hot, red or swollen feet, with or without pain.
SIGN		Low	No LPS and no signs of PAD
		Moderate	LPS or PAD or Deformity or Pre-ulcer injury or Unable or no help for self-care or Renal failure (Dialysis).
		High	Previous ulcer or Amputation or Consolidated Charcot or more than 1 risk factor: LPS PAD Deformity Pre-ulcer injury Unable or no help for self-care Renal failure (Dialysis)
		Active disease	Ulcer Infection with or without Ischemia Gangrene Infection dissemination Hot, red foot, edema with or without pain

Source: The authors, 2023.

In order to render it more understandable, the following terms were adopted for risk stratification: low risk; moderate risk; high risk; and active disease. The criteria presented in Figure 1 were used to define the risk.

Figure 1 – Risk stratification criteria. Crato, Ceará, Brazil, 2023.

Source: The authors, 2023.

The contribution from a professional of the Information Technology area was considered in this stage. In its final version, the technology has the following interfaces: home screen, with the app symbol and three buttons (Figure 2). The "*Avaliação*" ("Evaluation") button leads to the person's data and to the evaluation script (six screens); the at-risk foot classification (eight screens). The "*Histórico de Avaliações*" ("Evaluation History") button leads to the summary of all the evaluations (one screen). Finally, the "*Impressão da Avaliação*" ("Print the Evaluation") leads to a screen where the users can select the evaluation they want to print (three screens).

After finishing the evaluation stages, the system presents the risk classification. To render it more understandable from a visual point of view, a color and drawing system was adopted to indicate the risk. The chosen drawing was that of a foot. The colors assigned vary according to the risk.

For the risk classification, a visual identification was adopted with colors and the risk level in terms that ease understanding: green for low risk; yellow for average risk; orange for high risk; and red for active disease.

Figure 2 – Vigipé® initial interface. Crato, Ceará, Brazil, 2023.

Source: The authors, 2023.

In terms of content validation, 18 judges who were specialists in the health area took part in the face and content validation stage, most of them women (14; 77.7%), aged from 32 to 58 years old and with a mean age of 41. Within the sample, the highest academic degree was PhD with five (27.7%), followed by MSc with 10 (55.6%) and by graduate studies with three (16.7%). In relation to academic-scientific involvement, 12 (66.7%) participated in some research group and 16 (88.9%) reported having experience in studies for the validation of health technologies, whereas only two (11.1%) reported not having this experience. Regarding publications in the area of interest, 10 (55.6%) had published on diabetes and/or health assistance/care/promotion for people with DM, seven (38.8%) had done so on diabetic foot and 11 (61.1%) in terms of educational technologies.

As for the professional performance of the judges participating in the validation process, eight (44.4%) were teachers when the research was conducted. 16 (88.9%) had experience in assistance. Referring to performance time, six (33.4%) had more than 10 years of clinical performance, followed by four (22.2%) with more than five years of experience. In relation to teaching, only one participant reported not having such experience. As for the teaching time, eight (44.4%) had more than 15 years and four (22.2%) had devoted to the activity for more than five years.

The validation instrument asked the judges in terms of meeting the objectives and content, structure and functionality, in addition to relevance of the technology. In a general way, the form consisted of 23 items distributed across the three aforementioned sections.

The items from each section assessed if it was possible to achieve the objective by developing the technological device. In addition to that, they analyzed if the structure and face were suitable to present all the information, as well as coherence, format and the relevance referring to the meaning degree attributed to the content[10].

When the answers to the instruments were returned to the researcher, the CVI calculations[10] were performed, synthesizing the opinions of the judges participating in the validation process.

Table 1 presents the results obtained in the analysis of the technology by the expert judges participating in the research. Vigipé® obtained an overall rating of "Excellent", with a CVI of 0.96. In relation to the "Objectives and content" section of Vigipé®, it obtained minimum and maximum CVI values of 0.94 and 1.00, respectively. This first section obtained a global CVI of 0.97, evidencing that the desired objectives with the technology were achieved.

The global CVI related to the second section, corresponding to Vigipé® "Structure and functionality", presented a value of 0.93, varying from 0.83 to 1.00. The global CVI obtained in relation to relevance of the technology was 0.98, varying between 0.94 and 1.00 for the CVI values calculated individually. In relation to the overall Agreement Index (AI) among the judges included in this study, it was 95.6%. With an overall CVI of 0.96, the Vigipé® app can be considered valid in terms of face and content (Table 1).

The specialists made the following suggestions in relation to the technology: including a glossary to make it easier for nurses to consult terms in case of doubts (accepted); adding images (possibly); including the urea test to assess renal function (accepted); replacing "use of stockings" by "proper use of stockings" (accepted); a screen to calculate the ankle-arm index, in which the user would only indicate the blood pressure values and the index would be calculated by the system itself (possibly); excluding the thermal sensitivity test (accepted); including the "reduced" option in vibration sensitivity (not accepted – the "present" and "absent" options were maintained); creating a specific screen for laboratory tests and another one for daily recording of the glycemic levels (accepted); and including a Nursing diagnosis screen (possibly). The other improvement suggestions mentioned by the judges were mostly related to spelling and grammatical corrections (accepted).

Table 1 - Distribution regarding the Vigipé® assessment by the specialists in terms of objectives, structure, presentation and relevance. Crato, Ceará, Brazil, 2023**.**

Variables	CVI
1.1 The text is compatible with the target audience.	0.94
1.2 The terms are suitable for the target audience.	1.00
1.3 It describes all the information that should be contemplated in the foot examination of people with diabetes.	1.00
1.4 The content is motivating and encourages to keep browsing the instrument.	0.94
1.5 It will be able to promote behavioral changes in professionals in relation to the foot examination and ulceration risk assessment in patients with diabetes.	0.94
1.6 It may circulate in the Nursing area scientific environment.	1.00
GLOBAL CVI	0.97
Variables	**CVI**
2.1 The app is appropriate to assist professional nurses in relation to the foot examination in patients with diabetes.	0.88
2.2 The messages are presented in a clear and objective way.	0.94
2.3 The information presented is scientifically correct.	1.00
2.4 There is a logical sequence of the content proposed.	1.00
2.5 The material is suitable for the target audience proposed.	1.00
2.6 The information is well structured in agreement and spelling.	1.00
2.7 The writing style corresponds to the level of knowledge of the target audience.	1.00

2.8 The illustrations (images) are pertinent to the content of the material.	0.83
2.9 The type of font used eases reading.	0.94
2.10 The letter size in titles, subtitles and text is adequate.	0.88
2.11 The text colors are pertinent and easy to read.	0.83
2.12 The amount of information contained in the app is adequate.	0.88
2.13 The number of screens is adequate.	1.00
GLOBAL CVI	**0.94**
Variables	CVI
3.1 The app describes the key aspects that should be evaluated in the foot examination of people with diabetes.	1.00
3.2 The app has the main functions required to assess and classify the diabetic foot risk in people with diabetes.	1.00
3.3 The app addresses the necessary aspects for risk stratification and follow-up.	1.00
3.4 The app is suitable to be used by the target audience as an ancillary tool to assess diabetic foot risk in people with diabetes.	0.94
GLOBAL CVI	0.98
OVERALL GLOBAL CVI	0.96

Source: The authors, 2023.

DISCUSSION

The recommendations highlight the need to prevent diabetic foot ulcers through measures that include daily foot care, periodic evaluation, ulceration risk stratification and referral of individuals with DM whenever necessary and in a timely manner[21]. Therefore, the technology developed was designed to ease foot inspections and risk stratification in patients with DM in order to prevent complications such as ulcers and amputations.

Foot ulcer risk stratification systems are important tools in the screening of patients with DM, and their central variables are very similar; however, the data collection procedures differed much among the studies, especially for diabetic neuropathy and Peripheral Artery Disease (PAD)[22]. In this logic, it is understood that Vigipé® will be useful to standardize the collection of data related to clinical histories and foot inspections and to support future research studies, in addition to guiding follow-up actions so as to include foot inspections as part of routine care in health services in order to improve the assistance provided, representing a timely health promotion strategy.

In this perspective, health-related information allows understanding the factors that can trigger ulcers and foot risk degree. Therefore, health professionals will be able to encourage favorable patient's health care attitudes and the development of strategies that allow individuals to have greater control over their health conditions.

The contribution of these technologies is quite satisfactory when helping control the risk factors, thus preventing complications and worsening of signs and symptoms. There are many studies on diabetic foot and mobile technologies[23-24]. Studies that address software programs to help establish the professional practices in the diabetic foot treatment are described in the literature; however, prevention is still crucial to cope with this problem[25].

The MS states that Nursing consultations (NCs) are essential to screen for risk factors in order to identify feet at a higher risk for ulcers, which might benefit from preventive

measures. A previous study[26] points that proper assistance includes foot care and that, for such purpose, requires two extremely simple measures: clinical history and foot inspection, both contemplated in this technology. Therefore, the creation of Vigipé® contemplated fundamental aspects to ensure a tool to be used in NCs to survey these risk factors and their classification.

Some studies that tested educational technologies for the feet[24] emphasized the importance of validation as essential to reduce the risk of designing inadequate materials. In order to ensure validation, Vigipé® was subjected to an evaluation by judges who were specialists in the area of interest. This stage was strictly followed and its various criteria were respected, in order for the validation to in fact become a reliable process complying with the recommendations[27]. None of the items obtained values lower than the recommended one. The evaluated items obtained excellent CVI and agreement levels among the judges, evidencing that the material proposed is adequate and allowing to infer that it can meet the needs of its final users.

A minimum value of 0.80 is considered for the CVI, as recommended for validations with the participation of more than six judges. The items with CVI values from 0.80 to 1.00 can be considered valid, whereas lower values should be reviewed or excluded[10]. CVI values above 75% are considered acceptable, and those above 90% are classified as high, as observed in this study.

However, it is noted that the actions developed by nurses to prevent diabetic foot are not limited to the physical examination, and most of the studies indicated that health education actions can raise people's awareness about the development of self-care skills[28]. It is worth noting the importance of public employees participating in the development of apps, as the incorporation of evidence-based elements minimizes risks and increases adherence[29-30].

In relation to the suggestions made by the judges, they open the possibility for a new version of the technology, with the adoption of resources (animations and/or images), for example, due to the cost of the process for creating the technology. The idea of adding images to the app was pointed out as an improvement to be sought. Concerning this aspect,[29] the judges indicate images as important in any educational material because they ease understanding of the information by the vast majority of people, in addition to making the material less tiring and, therefore, representing a possibility to be reviewed.

The fact that the tool was not validated by people working in the Information/Communication Technology area and not having its usability tested represent limitations of this study. The intention is to develop a clinical trial intervention to assess the efficiency of the product developed.

CONCLUSION

This research allowed creating and validating the technology called "Vigipé®", which support nurses in foot inspections and risk classification. The CVI values were satisfactory, evidencing that the material proposed is adequate and allowing to infer that it can meet the needs of its final users. Using this technology may improve nurses' practice during consultations in the identification of the diabetic foot risk in people with DM. It may also contribute to early prevention and detection of foot abnormalities, in addition to standardizing the collection of data related to clinical history and foot inspection and supporting future research studies, as well as guiding follow-up actions so as to include foot inspections as part of routine care in health services, aiming to improve the assistance provided.

This research is expected to contribute to the provision of excellent care to patients with DM and to the practice of other nurses. Thus, the study may contribute to improving

the indicators related to hospitalizations, amputations and other consequences arising from diabetic foot, such as falls, fractures, reduced mobility, dependence, frailty and mortality in Brazil.

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Received: 18/09/2022
Approved: 08/05/2023

Associate editor: Dra. Juliana Balbinot Reis Girondi

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Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work - **Oliveira CRT de, Macedo LFR, Pinheiro PG, Meneses JCBC de, Menezes LCG de, Sampaio LRL**. Drafting the work or revising it critically for important intellectual content - **Macedo LFR, Meneses JCBC de, Menezes LCG de.** Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved - **Oliveira CRT de, Marques ADB.** All authors approved the final version of the text.

ISSN 2176-9133