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Development and Content Validation of a Mobile Application for Clinical Assessment and Diabetic Foot Prevention in Primary Health Care

Desenvolvimento e validação de conteúdo de um aplicativo móvel para avaliação clínica e prevenção do pé diabético na Atenção Primária à Saúde

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Tatiana Cristina Dias de Oliveira; Laila de Castro Araújo; Alana Ferreira de Oliveira; Valéria de Castro Fagundes; Maria Pantoja Moreira de Sena; Luann Wendel Pereira de Sena
Universidade Federal do Sul e Sudeste do Pará
e-mail: luannsena@unifesspa.edu.br

ABSTRACT

Diabetic foot is one of the most severe chronic complications of type 2 diabetes mellitus and is associated with high rates of ulceration, amputation, hospitalization, and mortality. Early identification of risk factors and systematic clinical foot assessment are essential strategies for preventing these complications, particularly in the context of Primary Health Care. This study aimed to develop and validate a mobile application for clinical assessment, risk stratification, and prevention of foot lesions in individuals with type 2 diabetes mellitus receiving care in Primary Health Care settings. This methodological study focused on the development and validation of a health technology and was conducted between August 2024 and August 2026. The application was developed based on scientific evidence and national and international clinical guidelines and subsequently submitted to content validation by a panel of 34 healthcare professionals experienced in diabetes care. The tool was organized into three integrated modules: user profile, clinical assessment and risk stratification, and multidisciplinary intervention and health education. Experts demonstrated a high level of agreement across all evaluated criteria, with no inadequate ratings recorded. The highest levels of agreement were observed for items related to the relevance of the application for healthcare practice (97.1%). Content Validity Index values ranged from 0.84 to 1.00, while the overall Content Validity Coefficient was 0.86, confirming satisfactory content validity. Following refinement, improvements related to usability, social determinants of health, user monitoring, and offline functionality were incorporated. The application demonstrated satisfactory evidence of content validity and potential to support clinical assessment, risk stratification, and diabetic foot prevention in Primary Health Care, representing an innovative tool for improving healthcare quality and supporting clinical decision-making within the Brazilian Unified Health System.

Keywords: Type 2 diabetes mellitus; Diabetic foot; Primary Health Care; Mobile health; Health technology.

RESUMO

O pé diabético constitui uma das complicações crônicas mais graves do diabetes mellitus tipo 2, estando associado a elevadas taxas de ulceração, amputação, hospitalização e mortalidade. A identificação precoce dos fatores de risco e a realização sistemática da avaliação clínica dos pés são estratégias essenciais para a prevenção dessas complicações, especialmente no contexto da Atenção Primária à Saúde. O objetivo deste estudo foi desenvolver e validar um aplicativo móvel para avaliação clínica, estratificação de risco e prevenção de lesões nos pés em pessoas com diabetes mellitus tipo 2 acompanhadas na Atenção Primária à Saúde. Trata-se de um estudo metodológico de desenvolvimento e validação de tecnologia em saúde, realizado entre agosto de 2024 e agosto de 2026. O aplicativo foi desenvolvido com base em evidências científicas e diretrizes clínicas nacionais e internacionais, sendo posteriormente submetido à validação de conteúdo por um painel composto por 34 profissionais de saúde com experiência no cuidado de pessoas com diabetes mellitus. A ferramenta foi estruturada em três módulos integrados: perfil do usuário, avaliação clínica e estratificação de risco, e intervenção multiprofissional e educação em saúde. Os especialistas atribuíram elevados níveis de concordância aos critérios avaliados, sem registro de avaliações inadequadas. Os maiores percentuais de adequação foram observados nos itens relacionados à relevância da ferramenta para a prática assistencial (97,1%). Os valores do Índice de Validade de Conteúdo variaram entre 0,84 e 1,00, enquanto o Coeficiente de Validade de Conteúdo global foi de 0,86, confirmando a validade de conteúdo do aplicativo. Após o refinamento, foram incorporadas melhorias relacionadas à usabilidade, determinantes sociais da saúde, monitoramento pelo usuário e funcionamento offline. O aplicativo apresentou evidências satisfatórias de validade de conteúdo e potencial para apoiar a avaliação clínica, a estratificação de risco e a prevenção do pé diabético na Atenção Primária à Saúde, configurando-se como uma ferramenta inovadora para qualificação do cuidado e apoio à tomada de decisão clínica no Sistema Único de Saúde.

Palavras-chave: Diabetes mellitus tipo 2; Pé diabético; Atenção Primária à Saúde; Saúde móvel; Tecnologia em saúde.

1. INTRODUCTION

Diabetes mellitus (DM) is one of the leading non-communicable chronic diseases and represents a major global public health challenge. It is characterized by metabolic abnormalities resulting from defects in insulin secretion and/or action, leading to chronic hyperglycemia and the development of complications that significantly compromise patients' quality of life and survival. It is estimated that more than 589 million adults are living with diabetes worldwide, with projections indicating continued growth over the coming decades, particularly in low- and middle-income countries[1]. In Brazil, approximately 10.2% of the adult population reports a medical diagnosis of diabetes, placing the country among those with the highest absolute number of cases globally[2].

Among the chronic complications of DM, diabetic foot stands out due to its high prevalence and severity. This condition results from the interaction of peripheral neuropathy, peripheral arterial disease, structural deformities, and external factors, potentially progressing to ulceration, infection, and amputation. Evidence indicates that between 19% and 34% of individuals with diabetes will develop foot ulcers during their lifetime, while recurrence rates may reach 40% within the first year after healing and exceed 60% within three years[3]. In addition to its clinical burden, diabetic foot is associated with increased mortality, healthcare costs, and utilization of health services[4].

The prevention of these complications largely depends on the early identification of risk factors and the systematic clinical assessment of the feet. In this context, Primary Health Care (PHC) plays a strategic role as the main entry point to the Brazilian Unified Health System (SUS) and the level of care responsible for the longitudinal follow-up of individuals with chronic diseases. Despite the relevance of this healthcare setting, challenges remain regarding the standardization of clinical assessment, risk stratification, and implementation of preventive actions aimed at diabetic foot management,

particularly in settings characterized by structural limitations and high healthcare demands.

Simultaneously, advances in digital health technologies have expanded opportunities to improve healthcare delivery, with mobile health (mHealth) applications emerging as valuable tools for clinical support, health education, and patient monitoring. These technologies have the potential to optimize healthcare processes, increase access to information, and support evidence-based clinical decision-making, particularly within PHC services[5,6]. In the context of diabetes care, recent studies have demonstrated that digital tools can contribute to strengthening self-care practices, improving treatment adherence, and facilitating the early identification of foot-related complications[7,8].

Despite these advances, there remains a scarcity of digital technologies specifically designed to support clinical assessment, risk stratification, and diabetic foot prevention within the Brazilian PHC context. Furthermore, many currently available tools present limitations related to integration into healthcare workflows, adaptation to structural conditions of health services, and incorporation of social determinants relevant to comprehensive diabetes care[9,10]. Therefore, there is a need for technologies that combine scientific evidence, clinical applicability, and alignment with the needs of healthcare professionals and users of the SUS.

In this context, the development of a mobile application aimed at clinical assessment, risk stratification, and prevention of foot lesions in individuals with type 2 diabetes mellitus (T2DM) has the potential to improve healthcare quality, support clinical decision-making, and strengthen preventive actions within PHC settings.

Therefore, this study aimed to develop and validate a mobile application for clinical assessment, risk stratification, and prevention of foot lesions in individuals with T2DM receiving care in Primary Health Care settings.

2. METHODS

2.1 STUDY DESIGN

This was a methodological study involving the development and validation of a mobile health (mHealth) application using a quantitative approach. Methodological studies aim to develop, refine, and validate instruments, technologies, or methods intended for healthcare practice, ensuring their theoretical consistency, applicability, and potential for use in different healthcare settings[11,12].

The study was conducted between August 2024 and August 2026 and comprised sequential stages of content development, digital prototype construction, expert content validation, and application refinement, focusing on clinical assessment, risk stratification, and prevention of foot lesions in individuals with T2DM receiving care in PHC settings.

2.2 STUDY SETTING

The study was carried out in the state of Pará, located in northern Brazil, a region characterized by extensive territorial dimensions, sociocultural diversity, and significant challenges related to healthcare access and service organization. The state presents a high burden of non-communicable chronic diseases, including DM, particularly among populations exposed to social vulnerability.

The selection of this setting was justified by the need to develop technologies adapted to the realities of PHC in the Amazon region, where geographical and structural limitations may affect the longitudinal follow-up of individuals living with chronic diseases.

2.3 STUDY PARTICIPANTS

The content validation stage included 34 healthcare professionals working in PHC services in the municipality of Parauapebas, Pará, Brazil, with experience in the care of individuals with DM.

The expert panel consisted of nurses (n = 7), physicians (n = 7), physiotherapists (n = 4), pharmacists (n = 2), nutritionists (n = 5), social workers (n = 4), and psychologists (n = 5), ensuring a multidisciplinary approach consistent with the principles of comprehensive care advocated by the SUS.

Participants were selected through purposive sampling based on professional expertise, clinical experience in PHC, and involvement in the management of individuals with DM. Expertise was determined based on professional experience in diabetes care, length of clinical practice in PHC Care, and academic or professional qualifications related to chronic disease management.

2.4 INCLUSION AND EXCLUSION CRITERIA

Healthcare professionals working in PHC who had at least one year of experience in the management of individuals with diabetes mellitus and agreed to participate by signing an Informed Consent Form were eligible for inclusion, in accordance with Resolution No. 466/2012 of the Brazilian National Health Council.

Professionals without experience in the area or those who declined participation were excluded from the study.

2.5 DEVELOPMENT OF THE MOBILE APPLICATION

2.5.1 CONTENT DEVELOPMENT

The application content was developed based on scientific evidence and national and international clinical guidelines related to the prevention, assessment, and management of diabetic foot. The development process considered essential aspects for healthcare technology design, including language clarity, logical organization of content, clinical applicability, and suitability for the PHC context[9,12].

The application structure was designed according to a clinical decision-making framework aimed at the early identification of risk factors for ulceration and amputation. To achieve this, criteria based on the Wagner–Meggitt classification system and the recommendations of the International Working Group on the Diabetic Foot (IWGDF) were incorporated.

The Wagner–Meggitt classification was selected due to its widespread use in clinical practice, ease of application by PHC professionals, and potential for future integration with more comprehensive risk classification systems, such as SINBAD and WIfI[13].

Considering the limitations of using the Wagner–Meggitt classification alone for assessing more complex vascular involvement, additional variables related to amputation history and peripheral pulse assessment were incorporated, thereby enhancing the application's clinical risk stratification capacity[14].

2.5.2 DIGITAL PROTOTYPE DEVELOPMENT

Following content definition, a functional prototype was developed in the form of a mobile health (mHealth) application. The development process considered principles of usability, accessibility, navigation, and integration into the workflow of Family Health Strategy teams, aiming to facilitate its use within PHC settings.

The application was structured into three integrated modules. The first module, User Profile, was designed to collect sociodemographic, clinical, and behavioral information, enabling patient characterization and identification of factors associated with diabetes-related complications. The second module, Clinical Assessment and Risk Stratification, was developed to support foot examination, identification of neuropathic and vascular alterations, and automated classification of ulceration and amputation risk. The third module, Multidisciplinary Intervention and Health Education, included clinical recommendations, educational guidance, and strategies aimed at strengthening self-care practices and preventing complications.

The application was developed following an iterative design model of continuous development and improvement, as proposed by Pressman[15], allowing successive modifications throughout the validation and refinement stages to enhance functionality, applicability, and suitability for healthcare practice.

2.5.3 CONTENT VALIDATION

Content validation was conducted according to the methodological framework proposed by Pasquali[16], using a multidisciplinary panel of experts.

Participants evaluated the application regarding clarity, relevance, adequacy, organization, and applicability through a structured assessment instrument composed of the domains objectives, structure and presentation, and relevance.

Items were assessed using a four-point Likert scale ranging from 1 (inadequate) to 4 (fully adequate), as recommended for content validation studies. Subsequently, responses were grouped for descriptive analysis into three categories: adequate, partially adequate, and inadequate.

Content validity was assessed using the Content Validity Index (CVI) and the Content Validity Coefficient (CVC), according to the recommendations of Hernández-Nieto[17] and Teixeira and Mota[18].

Values equal to or greater than 0.80 were considered satisfactory for both validity indicators.

2.5.4 REFINEMENT AND CONSOLIDATION OF THE TECHNOLOGICAL PRODUCT

Following content validation, the application was revised and improved based on the recommendations provided by the experts.

The modifications involved clinical, psychosocial, structural, and technological aspects, including the expansion of content related to social determinants of health, interface improvements, incorporation of educational resources, and adjustments aimed at enhancing usability and accessibility.

The final version was consolidated as a mobile health (mHealth) technological product designed to support clinical assessment, risk stratification, and prevention of foot lesions in individuals with T2DM within PHC settings.

2.6 DATA ANALYSIS

Data were analyzed using descriptive statistics, including absolute and relative frequencies for the characterization of experts and presentation of validation results.

Content validity was determined through calculation of the Content Validity Index (CVI) and the Content Validity Coefficient (CVC), both widely used indicators in methodological studies focused on the development and validation of healthcare technologies.

2.7 ETHICAL CONSIDERATIONS

The study was approved by the Research Ethics Committee of the Institute of Health Sciences, Federal University of Pará, under approval number 7,318,540.

All participants were informed about the study objectives and signed an Informed Consent Form prior to data collection, ensuring compliance with the ethical principles established by Resolution No. 466/2012 of the Brazilian National Health Council.

3. RESULTS

3.1 DEVELOPMENT AND STRUCTURE OF THE MOBILE APPLICATION

The mobile application was developed to support clinical assessment, risk stratification, and prevention of foot lesions in individuals with T2DM receiving care in PHC settings. Its structure was based on scientific evidence and national and international clinical guidelines, aiming to integrate scientific knowledge and practical applicability within the context of the SUS.

The application architecture was organized sequentially and included sociodemographic, clinical, and behavioral information, targeted diabetic foot assessment, automated stratification of ulceration and amputation risk, as well as multidisciplinary recommendations and educational guidance focused on self-care.

The clinical decision-making framework was based on the Wagner–Meggitt classification system combined with the recommendations of the IWGDF, enabling a standardized clinical assessment process and supporting healthcare professionals in clinical decision-making.

Following content definition, a functional prototype was developed as a mobile health (mHealth) application and organized into three integrated modules (Table 1).

Table 1. Functional structure of the mobile application for diabetic foot prevention.

Module	Purpose	Main Components
User Profile	Clinical and sociodemographic characterization	Sociodemographic data, clinical history, lifestyle habits, treatment adherence, anthropometric indicators, and laboratory parameters
Clinical Assessment and Risk Stratification	Early identification of alterations and risk classification	Foot examination, neuropathic and vascular assessment, Wagner–Meggitt classification, amputation history, and automated risk stratification
Multidisciplinary Intervention and Health Education	Support for clinical decision-making and promotion of self-care	Multidisciplinary recommendations, educational guidance, and preventive strategies

In addition to the main modules, the application incorporated a specific component for assessing social determinants of health, including educational level, housing conditions, and family support network, thereby broadening the clinical approach toward a comprehensive model of care.

3.2 CHARACTERISTICS OF THE EXPERTS

Content validation involved 34 healthcare professionals experienced in the management of individuals with DM within PHC settings. The expert panel had a multidisciplinary composition, including nurses (20.6%), physicians (20.6%), physiotherapists (11.8%), pharmacists (5.9%), nutritionists (14.7%), social workers (11.8%), and psychologists (14.7%).

A predominance of female participants was observed (79.4%). Most experts had extensive professional experience, with 76.5% reporting more than five years of professional practice, and a high level of academic qualification, as 67.6% held postgraduate degrees (Table 2).

Table 2. Characteristics of experts participating in content validation.

Variable	n	%
Sex		
Female	27	79.4
Male	7	20.6
Professional Category		
Nurses	7	20.6
Physicians	7	20.6
Physiotherapists	4	11.8
Pharmacists	2	5.9
Nutritionists	5	14.7
Social Workers	4	11.8
Psychologists	5	14.7
Professional Qualification		
Postgraduate Degree	23	67.6
Professional Experience		
> 5 years	26	76.5

3.3 CONTENT VALIDATION

The results demonstrated high acceptance of the mobile application across all evaluated criteria. The highest levels of agreement were observed in items related to the relevance of the application to healthcare practice, particularly its ability to meet healthcare professionals' needs and contribute to improved clinical outcomes, both receiving 97.1% of ratings classified as adequate.

No evaluations were classified as inadequate for any of the assessed items, indicating a high level of acceptance among the experts. The item "Thematic Coverage" showed the highest proportion of partially adequate ratings (14.7%), suggesting opportunities for expanding specific content and contributing to the refinement process of the application (Table 3).

Table 3. Experts' evaluation of content validity criteria for the mobile application for diabetic foot prevention (n = 34).

Dimension	Evaluated Item	Adequate, n (%)	Partially Adequate, n (%)	Inadequate, n (%)
Clarity and Objectivity	Comprehensiveness	32 (94.1)	2 (5.9)	0 (0.0)
Clarity and Objectivity	Applicability in Primary Health Care	31 (91.2)	3 (8.8)	0 (0.0)
Coherence and Structure	Textual Clarity	32 (94.1)	2 (5.9)	0 (0.0)
Coherence and Structure	Logical Organization	32 (94.1)	2 (5.9)	0 (0.0)
Coherence and Structure	Illustrations	32 (94.1)	2 (5.9)	0 (0.0)
Coherence and Structure	Layout	30 (88.2)	4 (11.8)	0 (0.0)
Functionality	Instructions	31 (91.2)	3 (8.8)	0 (0.0)
Functionality	Thematic Coverage	29 (85.3)	5 (14.7)	0 (0.0)
Functionality	Digital Compatibility	32 (94.1)	2 (5.9)	0 (0.0)
Relevance	Meets Professional Needs	33 (97.1)	1 (2.9)	0 (0.0)
Relevance	Improves Clinical Outcomes	33 (97.1)	1 (2.9)	0 (0.0)
Relevance	Prevention of Complications	32 (94.1)	2 (5.9)	0 (0.0)
Overall	General Evaluation	31 (91.2)	3 (8.8)	0 (0.0)

The validity indices demonstrated satisfactory performance across all evaluated domains. The "Objectives" domain achieved complete consensus among experts (CVI = 1.00; CVC = 0.97), while the domains "Content" (CVI = 0.93; CVC = 0.89), "Language" (CVI = 0.87; CVC = 0.84), and "Adequacy" (CVI = 0.84; CVC = 0.81) presented values above the recommended threshold for content validation.

The overall CVC was 0.86, confirming the methodological consistency of the application and the agreement observed among experts during the validation process (Table 4).

Table 4. Content Validity Index (CVI) and Content Validity Coefficient (CVC) of the mobile application for diabetic foot prevention.

Domain	CVI	CVC	Interpretation
Objectives	1.00	0.97	Excellent
Content	0.93	0.89	Very High
Language	0.87	0.84	High
Adequacy	0.84	0.81	Adequate
Overall	–	0.86	Valid

Source: Research data, 2026.
Note: CVI and CVC values ≥ 0.80 were considered adequate for content validation.

3.4 APPLICATION REFINEMENT

The qualitative contributions provided by the experts enabled improvements in clinical, psychosocial, technological, and operational aspects of the application.

Within the clinical domain, additional nutritional indicators, a more detailed nutritional assessment, and visual resources for standardizing anthropometric measurements were incorporated. In the psychosocial domain, variables related to social determinants of health were included, such as information from the Brazilian Unified Registry (Cadastro Único) and family support networks.

Regarding usability, visual tutorials, mobile-responsive design adjustments, and functionalities for user-based monitoring of blood glucose levels and symptoms were incorporated. Offline functionality was also recommended and implemented to expand the applicability of the application in settings with limited internet connectivity.

3.5 FINAL TECHNOLOGICAL PRODUCT

Following the validation and refinement processes, the final version of the mobile application was obtained and characterized as a validated technological product for use in PHC.

The final version integrated structured clinical assessment, automated risk stratification, social determinants of health, multidisciplinary recommendations, and health education resources into a single platform. Additionally, it incorporated patient self-monitoring functionalities, a responsive interface, and offline accessibility.

These characteristics provide the application with the potential to support clinical decision-making, standardize diabetic foot assessment, improve healthcare delivery processes, and strengthen preventive and educational actions aimed at reducing diabetes-related complications.

4. DISCUSSION

The findings of this study demonstrated a high level of agreement among experts, indicating that the developed mobile application presents content that is consistent with and aligned with its intended objectives. The predominance of evaluations classified as "adequate" suggests that the application's content and functionalities were clearly understood by the evaluators, reinforcing its potential applicability in healthcare practice and its suitability for meeting the demands of diabetes care within SUS.

This performance is consistent with recent evidence from methodological studies focused on the validation of health technologies and diabetes-related instruments, in which high levels of agreement among experts are interpreted as indicators of conceptual consistency and clinical applicability[17]. Furthermore, the literature demonstrates that high CVI values reflect clarity, relevance, and representativeness of items regarding the construct under evaluation and are widely recognized as robust validation parameters in health-related methodological studies[10,11].

The relevance of the developed application becomes even more evident when considering the substantial burden of morbidity associated with diabetic foot disease. This complication represents one of

the leading causes of hospitalization, infection, and non-traumatic lower-limb amputation among individuals with diabetes mellitus and is frequently associated with delayed identification of risk factors and the absence of systematic monitoring. In this context, strategies focused on routine foot assessment, health education, and early detection of clinical abnormalities are recognized as essential measures for reducing preventable complications, reinforcing the importance of digital tools capable of supporting longitudinal care within PHC settings.

The multidisciplinary composition of the expert panel constituted one of the major strengths of this study, enabling a comprehensive and integrated evaluation of the application. The inclusion of different professional categories facilitated the incorporation of multiple perspectives on care, an aspect particularly relevant to diabetic foot management, which encompasses clinical, behavioral, and social dimensions. Recent studies emphasize that the development of effective instruments depends on the integration of interdisciplinary knowledge and validation by experts from different fields, especially within PHC settings, where care is patient-centered and collaboratively organized[9].

The CVI and CVC values obtained in this study further support the content validity of the application, as all domains achieved results above the recommended threshold (≥0.80). This finding corroborates evidence indicating that instruments and technologies with high validity indices tend to demonstrate greater reliability and potential for clinical use[19]. Therefore, the results suggest that the developed application demonstrates adequate clarity, relevance, and applicability, supporting its potential use as a clinical decision-support tool in PHC.

The highest proportion of partially adequate evaluations was observed for the "thematic coverage" item, indicating the need to expand certain content areas, which may be directly related to the complexity of diabetic foot care. Diabetic foot disease is a multifactorial condition involving clinical, behavioral, and social factors, requiring comprehensive and sensitive tools capable of addressing multiple dimensions of care. The literature suggests that recommendations for the inclusion of additional items during validation processes are common and should be interpreted as part of the technology refinement and improvement process rather than as a structural limitation[17].

Previous studies have reported mobile applications primarily focused on foot monitoring, ulcer surveillance, and self-care support among individuals with DM. In contrast, the application developed in the present study integrates clinical assessment, automated risk stratification, multidisciplinary recommendations, and social determinants of health within a single platform. This broader approach may enhance its usefulness in PHC Care settings by supporting both clinical decision-making and comprehensive patient management.

In this context, the qualitative contributions provided by the experts played a central role in improving the application, highlighting the importance of adopting a broader perspective of care. The inclusion of nutritional, psychosocial, and social determinants of health-related aspects demonstrates alignment with contemporary approaches that recognize the influence of structural and behavioral factors on diabetes management. Recent studies have shown that technologies integrating both clinical and social dimensions have greater potential to positively impact healthcare practice, contributing to the prevention of complications and improvement of health outcomes[8].

One of the distinguishing features of the developed application is precisely the integration of multiple dimensions of care within a single digital platform. In addition to clinical assessment and automated risk stratification, the application incorporates information related to social determinants of health, multidisciplinary recommendations, and health education strategies. This characteristic enhances its potential use as a clinical decision-support and care management tool, promoting a more comprehensive and patient-centered approach.

The convergence between expert recommendations and scientific evidence reinforces the interdisciplinary nature of the application. The concerns raised by psychology professionals regarding terminological standardization and the contributions from social workers related to the incorporation of social determinants of health highlight the need to move beyond the traditional biomedical model and adopt a more holistic perspective of individuals. This understanding is consistent with studies arguing that the success of clinical tools

depends on their ability to consider individuals in their entirety, including social, economic, and cultural dimensions[20].

Contributions related to usability and technological aspects emphasize the importance of ensuring that the application is not only technically sound but also operationally feasible within routine healthcare services. The literature indicates that the effectiveness of digital health technologies is directly influenced by factors such as accessibility, intuitive interfaces, and integration into healthcare workflows[7]. In this regard, the recommendation to incorporate offline functionality reflects the experts' awareness of structural limitations commonly encountered in PHC settings, particularly in regions with restricted internet connectivity.

Although formal face validation was not conducted as a separate methodological stage, the evaluation of clarity, organization, layout, and applicability by the expert panel contributed indirectly to assessing the comprehensibility, presentation, and practical suitability of the application. These aspects are particularly important for digital health technologies intended for routine use by healthcare professionals in PHC settings.

This aspect is directly aligned with IWGDF recommendations[4], which emphasize the importance of standardized clinical assessment combined with feasibility of implementation across different healthcare contexts. Therefore, the proposed adjustments do not indicate weaknesses of the application but rather a process of methodological consolidation that enhances its acceptability, applicability, and potential impact on healthcare practice.

Another relevant finding was the recommendation to increase patient participation in monitoring their own health condition through the incorporation of self-care-oriented functionalities. This observation is consistent with evidence indicating that strengthening self-care is a central component of diabetic foot prevention and is associated with improved clinical outcomes, greater treatment adherence, and reduced complication rates[8].

The final version of the application, consolidated after the refinement process, constitutes a validated technological product structured as a mobile health (mHealth) application with potential incorporation into PHC practice. Its organization into integrated modules, combined with a clinical decision-making framework and the inclusion of social determinants of health, represents an advancement over traditional assessment tools by expanding its capacity to support clinical decision-making and care organization.

Despite the promising results, an important limitation of this study is the absence of clinical validation in real-world settings, which currently prevents the assessment of the application's effectiveness in routine healthcare practice. Therefore, future studies evaluating usability, acceptability, effectiveness, and clinical impact across different PHC contexts are recommended. Future investigations should also include usability testing with healthcare professionals and clinical validation under real-world PHC conditions to further establish the applicability and effectiveness of the application in routine practice.

5. CONCLUSION

This study enabled the development and content validation of a mobile application designed for clinical assessment, risk stratification, and prevention of foot lesions in individuals with T2DM receiving care in PHC settings. The high validity indices obtained, together with the strong agreement among specialists, demonstrated that the application presents clear, relevant, appropriate, and clinically meaningful content aligned with healthcare demands related to diabetic foot management.

The application was structured to integrate sociodemographic, clinical, behavioral, and social determinants of health information with standardized clinical assessment, automated risk stratification, and multidisciplinary recommendations. This approach enhances its capacity to support clinical decision-making, improve longitudinal follow-up, and strengthen preventive and health education actions within PHC services.

In addition to its methodological robustness, the application has the potential to contribute to the standardization of diabetic foot assessment, optimization of healthcare team workflows, and promotion of patient self-care. The incorporation of usability features, responsive design, and offline functionality further expands its applicability across different healthcare settings, including regions with structural and connectivity limitations.

As a limitation, this study was restricted to expert-based content validation and did not include clinical validation or performance assessment in real-world healthcare environments. Therefore, future studies should investigate the usability, acceptability, effectiveness, and clinical impact of the application to further establish its potential integration into healthcare practice and its contribution to the prevention of diabetic foot-related complications within the SUS. Additionally, usability testing with healthcare professionals and clinical validation in real-world PHC settings are necessary to confirm the practical performance, feasibility, and effectiveness of the application in supporting diabetic foot prevention and management.

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