Mobile application for evaluation of feet in people with diabetes *mellitus*

Aplicativo móvel para avaliação dos pés de pessoas com diabetes mellitus

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Keywords

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Descritores

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Abstract

Objective: To describe the process of development and validation of a mobile application on foot assessment and risk classification of people with Diabetes *mellitus*.

Methodo: Methodological study, conducted in four stages: definition of requirements for and development of the conceptual model; generation of alternatives for implementation and prototyping; testing; and, implementation. The application was developed based on the national and international guidelines on Diabetes mellitus; it followed the standard of the Brazilian Association of Technical Standards for Software Engineering, and used the Intel XDK program for IOS and Android platforms. The product was evaluated by the development team for usability through the Nielsen heuristics, and validated by nurses regarding functionality, reliability, usability and efficiency aspects.

Results: The CuidarTech mobile application "Foot examination" is composed of seven screens that integrate the elements for assessment and risk classification, and eight screens (forms) with the sequence of the examination. After its execution, a screen shows the risk classification and the clinical findings, with recommendations for each type of risk.

Conclusion: According to the nurse experts, the application is functional, reliable, adequate, and efficient.

Resumo

Objetivo: Descrever o processo de desenvolvimento e validação de um aplicativo para dispositivos móveis sobre avaliação e classificação de risco dos pés de pessoas com Diabetes *mellitus*.

Métodos: Estudo metodológico, realizado em quatro etapas: Definição de requisitos e elaboração do modelo conceitual; Geração das alternativas de implementação e prototipagem; Testes e Implementação. O aplicativo foi desenvolvido baseado nas diretrizes nacionais e internacionais sobre Diabetes *mellitus*; seguiu as normas da Associação Brasileira de Normas Técnicas para Engenharia de *Software* e utilizou o programa Intel XDK, para plataformas IOS e *Android*. O produto foi avaliado quanto a usabilidade pelas heurísticas de *Nielsen*, pela equipe de desenvolvimento e validado por enfermeiros quanto aos aspectos de funcionalidade, confiabilidade, usabilidade e eficiência.

Resultados: O aplicativo móvel Cuidar Tech "Exame dos Pés" possui sete telas que integram os elementos para avaliação e classificação de risco e oito telas (formulários) com a sequência do exame, após sua execução aparece uma tela com a classificação de risco e os achados clínicos com as recomendações para cada tipo de risco.

Conclusão: O aplicativo segundo avaliação dos juízes e enfermeiros é funcional, confiável, adequado e eficiente.

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Introduction

The World Health Organization recognizes that public health faces a serious problem in terms of diabetes *mellitus*. (1) Currently, one in 11 adults have diabetes, that is 415 million people; one in seven births is affected by diabetes and every six seconds a person dies from diabetes, which corresponds to five million deaths worldwide. The new perspective is that, in 2040, one in ten adults, totaling 642 million people, will be affected by the disease. (2)

The complications of diabetes *mellitus* are among the main causes of reduced quality of life, disability, and death, in addition to creating a great economic impact for the health services, increasing costs with hospitalizations, dialysis for chronic renal insufficiency, and surgery for inferior limb amputations, among others. Diabetic neuropathy is the most frequent among the complications, characterized by a series of clinical syndromes that affect the sensitive peripheral nervous system, motor and autonomic nervous system; the main outcome is foot ulcers that, associated with ischemia, deformities and/or infections, lead to the so-called "diabetic foot". (4)

Approximately 20% of hospitalizations of individuals with diabetes occur due to injuries to the lower limbs. The recurrent incidence of life-long foot problems among people with the disease is estimated at 25%, and 85% of lower limb amputations are preceded by ulcerations; the main associated factors are peripheral neuropathy and deformities. (4,5) The risk of foot involvement and consequent lower limb amputation in people with diabetes mellitus reinforces the need for expansion of the nurse's knowledge and understanding on the importance of monitoring and foot assessment in people with diabetes mellitus, at all levels of health care. Primary health care is of great importance, because it is considered by the Ministry of Health to be the gateway to health services. (6,7)

According to the protocols of the Ministry of Health and Primary Health Care, the nursing consultation is an opportune moment, essential for tracking and monitoring the suggestive risk factors triggering the diabetic foot, in order to identify those individuals at the highest risk for ulcers, who may benefit from prophylactic interventions, including self-care stimulation. (6-9)

In addition, nursing care has undergone several transformations with technological advances. The introduction of computer technology and the emergence of sophisticated gadgets such as computers, notebooks, palmtops, tablets, smartphones, and hand-held phones with internet support have brought many benefits, and swiftness, to the battle against disease. They have improved care by enabling practitioners access, at any place or time, to a vast amount of information about the patient, by means of their health record, and on the best clinical practice.⁽¹⁰⁾

It is worth remembering that the more specific the information that is possessed, the better the decision that can be made, therefore, it is essential to develop technological tools that make the clinical management of the diabetic foot more efficient, as well as to minimize the difficulties and deficiency of nurses in relation to clinical practice. (10,11)

In the search for mobile applications related to risk/diabetic foot in the virtual stores (*Play Store* and Apple Store), no Brazilian product was found; there were six developed in other nations. Among those, one intended for professional use was called *Diabetic Foot 2017*. The remainder were designated for use by the person with diabetes: *Diabetic Foot Care*; *Diabetic Foot and Shoe*; *AQR - Diabetic Foot*; *Foot Care*, and *Diabetic Foot*.

In view of the presented aspects, the objective of this study was to describe the process of development and validation of a mobile application on foot assessment and risk classification of people with diabetes *mellitus*.

Methods

This was a methodological study developed in four stages: 1- definition of the requirements and development of the conceptual map for the application; 2- generation of implementation and prototyping alternatives; 3- testing; 4- implementation.

In the first step, international and national guidelines on care for people with diabetes and diabetic foot, published in the last five years were selected: National Institute for Health and Care Excellence (NICE);⁽¹²⁾ International Working Group on the Diabetic Foot - IWGFD,⁽⁶⁾ and the Diabetic foot manual: strategy for the care of person with chronic disease,⁽⁷⁾ and the Clinical Guidelines of the Brazilian Society of Diabetes⁽¹³⁾ for text production of the screens, and development of the application's conceptual map.⁽¹⁴⁾

In the second stage, due to the specificity of technological knowledge required in the creation of a mobile application, a partnership was established with the Laboratory and Observatory of Ontologies Project - LOOP, and the Laboratory of Nursing Technologies - CuidarTech, both of the Federal University of Espírito Santo (UFES). Prototyping alternatives were generated using Intel XDK software⁽¹⁵⁾ based on ABNT ISO/TR 16982: 2014⁽¹⁶⁾ for the application's functionalities, organized in repetitive design cycles, with a view to adopting free and open technologies whenever possible.

In the third step for evaluation and validation of the application, two strategies were used. First, the application development team, consisting of ten students from the Design Course of the Federal University of Espírito Santo, evaluated it by means of the heuristics developed by Jakob Nielsen, (17) which consist of ten general principles for the development of evaluation: 1- system visibility; 2- correspondence between the system and the real world; 3- control and freedom of individual; 4- consistency and standardization; 5- recognition rather than memorization; 6- flexibility and efficiency of individual; 7- aesthetic and minimalist design; 8- error prevention; 9- helping individuals to recognize, diagnose and recover from errors; 10- help and documentation. Three more specific heuristics(18) were included for evaluation in mobile devices, which are: 1- little man/device interaction; 2- physical interaction and ergonomics; 3- legibility and layout.

Initially, the evaluators were given a check list to inspect the entire system using the heuristics⁽¹⁹⁾ as a

guide to detect possible problems. Then, degree of severity was classified according to the problem, using a scale of zero to four, where zero= unimportant (does not affect the operation of the interface); 1= cosmetic (there is no immediate need for solution); 2= small problem (low priority - can be repaired); 3= large problem (high priority - must be repaired); and 4= catastrophic problem (serious - must be reapaired immediately).

Four catastrophic problems and four large problems were detected. As a result, the application was improved by correcting all detected failures, before proceeding with the evaluation and validation by nurses.

In the second strategy, the application was evaluated and validated according to the Brazilian standard ABNT ISO/IEC 25062:2011,⁽²⁰⁾ which recommends a minimum sampling of eight participants in the test stage. Eight nurses participated, with at least two years of experience in caring for people with diabetes. The evaluations occurred in May of 2017.

Initially, the nurses received a case study with the purpose of simulating the practice of examining the feet of people with diabetes mellitus. Analyzing the case, the evaluator consulted the CuidarTech application "Foot Examination" for assessment and risk classification of diabetic foot. Then, the nurse answered a questionnaire, validated in another study and adapted to the present test, (21) that addresses aspects of functionality, reliability, usability, efficiency and sustainability. (21-23) This questionnaire uses a Likert scale that allows answers from one (strongly disagree) to five (strongly agree); a score of three indicates cases of doubt as to whether to agree or disagree, or if the evaluator does not feel prepared to respond. Scores equal to or greater than four were considered appropriate.

In the fourth stage, implementation, a release version will be published based on the tests results, in the *Google Play* application store, free of charge, and the site will be updated at the address by UFES. Subsequently, an intervention with a clinical trial is intended to be developed, where the efficiency of the product will be evaluated.

The research was approved by the Research Ethics Committee of the Health Sciences Center of UFES, under CAAE number 65500516.0.0000.5060.

Results

The CuidarTech application, "Foot Examination", is a hard technology (23) because it is the production of software that provides the nurse with a tool to assist in the assessment and classification of risk in a person with diabetes *mellitus* for the development of diabetic foot.

After a thorough reading by the authors, and identification of similar content of the mentioned

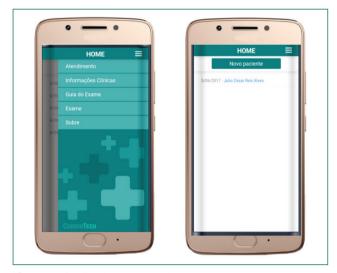


Figure 1. Application presentation screen

guidelines, a conceptual map was developed, which means the design and organization of the necessary text was produced for the risk classification of the feet of people with diabetes *mellitus*, and the contents of each screen were developed, as well as application tutorials and examination execution.

Seven screens were developed that integrate the necessary elements for assessment and risk classification of the feet of people with diabetes *mellitus*, and eight screens (forms) have the examination sequence. After its execution, a screen appears with the risk classification and the clinical findings with recommendations for each type of risk, according to figures 1 and 2.

In the evaluation of usability by the Nielson⁽¹⁷⁾ heuristic, four catastrophic problems and four large problems were detected. Six evaluators considered it to be a catastrophic problem when the individual experienced difficulty in completing a topic, clicked the "?" symbol which opened the help screen, but he could not return to the original screen where he had been. It was only possible to return to the first registration screen, violating the heuristic of control and freedom of the individual.

Three evaluators identified a catastrophic problem when, after completing all the check boxes on the screen, a message still appeared saying that the topics on the screen must be checked or, in other words, complete the items. In this case, the heuristic violated was Flexibility and Efficiency of use.



Figure 2. Sample application screens

Table 1. Mean and standard deviation of the nurses' responses

| Question | Mean | Standard deviation |
|---|------|--------------------|
| 1.Are you confident in using mobile applications? (functionality) | 3.75 | 1.03 |
| 2. Does the software perform its functions accurately? (functionality) | 4.75 | 0.46 |
| 3. Does the software provide the main functions necessary to evaluate and classify the risk of the feet of people with Diabetes Mellitus? (functionality) | 4.75 | 0.46 |
| 4. Does the software respond properly when errors occur? (reliability) | 4.12 | 0.83 |
| 5. Does the software inform the individual of invalid data entry? (reliability) | 4.50 | 0.53 |
| 6. Is it easy to understand the software concept and application? (usability) | 4.60 | 0.51 |
| 7. Is it easy to learn how to use the software? (usability) | 4.62 | 0.51 |
| 8. Does the software offer clear help? (usability) | 4.75 | 0.46 |
| 9. Is the software tutorial easy to understand? (usability) | 4.75 | 0.46 |
| 10. Is the software runtime adequate? (efficiency) | 4.75 | 0.46 |
| 11. Are the features provided in the software adequate? (efficiency) | 4.75 | 0.46 |

Three evaluators indicated a catastrophic problem when pressing the "back" button of the cell phone the menu is open and the application execute the action back to the page on which the menu is open.

For example: during the data completion for the physical examination, the application returns to the home screen, causing the individual to lose all the progress made during the examination, violating the heuristic of Control and Freedom of the individual. An evaluator characterized a problem as catastrophic when, after saving data, it was not possible to edit the patient's examinations, infringing on the heuristic, Control and freedom of individual.

As a result, the application was improved by correcting all detected failures before proceeding with the assessment and validation by nurses.

In the meeting with the nurses a case study was distributed with the purpose of simulating the practice of examining the feet of people with diabetes *mellitus*. With this case, the evaluator consulted the CuidarTech APP "Foot examination" and answered the questionnaire, addressing aspects of functionality, reliability, usability, efficiency, and maintainability. (21,22) Data obtained from assessment responses performed by the nurses are presented in Table 1. Scores equal to or greater than four were considered to be adequate. Table 1 presents the mean and standard deviation of the nurses' responses.

According to table 1, the scores ranged between 3.9 and 5, therefore the application achieved adequacy for all the questions. A second analysis of the assessment was performed, from the answers of the different experts to the same question. These means ranged from 3.75 to 4.75.

When the evaluators were questioned regarding ease of use of mobile applications, the responses showed a greater diversification among the nurses, with a standard deviation of 1.03 (Table 1). In several questions (2, 3, 8, 9, 10 and 11) a smaller variability was identified, revealing that there was no difficulty in handling the application. According to the nurses' assessment, the application is functional, reliable, adequate, and efficient.

After completing the evaluation phase, and finalizing all corrections, the application was registered at the Institute of Technological Innovation of the Federal University of Espírito Santo.

Discussion

Mobile applications have gained momentum in health care in recent years. (24) Online stores offer a multitude of application options that grow daily, ranging from fitness systems to monitoring and controlling of various diseases. When these are well developed and used, they are teaching tools that can bring benefits to patients and health professionals. (25) Similar studies conducted in Brazil, that considered the use of mobile applications focused on nursing practice, highlight the importance of investment in this field of research. (25-27)

Applications developed for this purpose may have features that help to improve accessibility to treatments, as well as the speed and accuracy of exams and diagnostics. These can also be provided with functions that bring patients closer to caregivers, contributing to adherence to therapy or care, reminding the patient to take medications, as well

as helping health professionals to be more effective and efficient in theoretical-practical information. (25)

Developing an application in a coherent and appropriate manner is paramount, in addition to recognizing the needs of the individual, so that the development is appropriate to the specific demands, tested through research and implemented in practice. (25-27) Unlike the currently available applications, which mostly deal with theoretical aspects, and are little related to clinical practice, the CuidarTech "Foot Examination", developed in this study, sought to meet the needs of nurses for the assessment and risk classification of the feet of people with diabetes mellitus, helping to identify the clinical findings, to perform the foot examination, and showing as an outcome the risk classification and its necessary recommendations for the patient examined.

CuidarTech "Foot Examination" is a technological innovation in health, as it is the first mobile application developed in Brazil that can bring benefits to nurses, the person with diabetes, the Health Care Services, and the Unified Health System in coping with the problem of the diabetic foot.

The CuidarTech "Foot Examination" allows the nurse, through the use of smartphones and tablets, quick access during the nursing consultation to information of primary national and international guidelines. It assists in the nursing process by collecting data, assessing and rating the feet of people with diabetes, and providing recommendations for each clinical finding. It contributes to the nurses' routine, by increasing their scientific knowledge; due to the complexity of the guidelines, it places in the nurse's pocket an updated tool that assists in the practice of the role in developing actions for risk prevention, clinical monitoring, control of the disease and its complications, such as amputation of the lower extremities of people susceptible to foot problems due to diabetes mellitus.

From this perspective, adequate care, especially in primary care, can improve the quality of life of these people, reduce hospitalization rates, disabilities and deaths, and reduce the socioeconomic impact on the health services.

The use of technologies provides nurses with a continuous, updated training process; however, the study showed that some professionals have not yet adhered to the use of this type of technology. (24)

Some limitations need to be highlighted, and it is necessary to reflect on the improper and abusive use of mobile devices, with prejudice to the work process, which has led to many discussions about its prohibition in health institutions in Brazil and in the world. In addition, hand hygiene, infection, and patient safety must be considered, as mobile devices can lead to risks of contamination. In order to minimize risks and limitations in the use of mobile devices, it is necessary to raise the awareness of nurses on the importance of following safety standards, highlighting the proper hygiene for personal use objects such as mobile devices, in order to prevent the spread of possible infections.⁽²⁹⁾

Conclusion

This study developed and validated the CuidarTech mobile application, "Foot Examination", for assessment and risk classification of the feet of people with diabetes mellitus. According to the evaluators and nurses, the application is functional, reliable, adequate, and efficient. Use of the CuidarTech "Foot Examination" by nurses can improve their scientific knowledge, provide support during the nursing consultation in the prevention of risks, monitoring and controlling complications in the feet of people with diabetes mellitus, and increase the ability of Primary Health Care to prevent and detection early changes in the feet of people with diabetes mellitus. It is hoped that this research will engage the interest of other nurses to develop new technologies, aligning the theoretical-practical knowledge of nursing, and seeking to improve the quality of care in the Unified Health System.

Collaborations

Vêscovi SJB, Primo CC, Sant' Anna HC, Bringuete MEO, Rohr RV, Prado TN and Bicudo SDS contributed to the study design, analysis,

data interpretation, relevant critical review of the intellectual content, and final approval of the version to be published.

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