Validation and applicability of the Wounds Monitoring software in wound assessment and monitoring

Validación y aplicabilidad del software Wounds Monitoring en la evaluación y seguimiento de heridas

Validação e aplicabilidade do software Wounds Monitoring na avaliação e monitoramento de feridas

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Abstract

The aim was to validate an application software for recording, monitoring and evaluating wounds. Methodological, applied, quantitative study. The references adopted in this project were described in Standard No. 25010 of the International Organization for Standardization/International Electrotechnical Commission. The results were analyzed by a rule proposed by the Brazilian Association of Technical Norms in its Normative No. 14598-6. The feasibility of the system was evaluated through a test of the prototype, with the group of evaluators that was composed of two categories: specialists in information technology and nurses. In the evaluation of the nurses' expertise, the characteristic functional adequacy, reliability, usability, efficiency in performance, compatibility, and safety, obtained 100% of the responses in agreement. Professional IT experts also rated maintainability with 97.3% reliability with 84.9%, usability with 84.6% of the answers in agreement. The software was validated, allowing evaluating the technical quality and functional performance applied to the evaluation and monitoring of wounds.

Descriptors: Nursing; Validation Study; Validation of Computer Programs; Technology; Wounds.

Resumén

El objetivo fue validar un software de aplicación para el registro, seguimiento y evaluación de heridas. Estudio metodológico, aplicado, cuantitativo. Las referencias adoptadas en este proyecto fueron descritas en la Norma No. 25010 de la Organización Internacional de Normalización/Comisión Electrotécnica Internacional. Los resultados fueron analizados por una regla propuesta por la Asociación Brasileña de Normas Técnicas en su Normativa n.º 14598-6. La factibilidad del sistema fue evaluada a través de una prueba del prototipo, con el grupo de evaluadores que estuvo compuesto por dos categorías: especialistas en informática y enfermeros. En la evaluación de la pericia de los enfermeros, las características adecuación funcional, confiabilidad, usabilidad, eficiencia en el desempeño, compatibilidad y seguridad, obtuvieron el 100% de las respuestas de acuerdo. Los expertos profesionales en TI también calificaron la mantenibilidad con un 97,3 %, la confiabilidad con un 84,9 % y la usabilidad con un 84,6 % de las respuestas de acuerdo. El software fue validado, permitiendo evaluar la calidad técnica y desempeño funcional aplicado a la evaluación y seguimiento de heridas.

Descriptores: Enfermería; Estudio de Validación; Validación de Programas Informáticos; Tecnología; Heridas.

Resumo

Objetivou-se validar um software aplicativo para registro, monitoramento e avaliação de feridas. Estudo metodológico, aplicado, quantitativo. As referências adotadas neste projeto foram descritas na Norma n.º 25010 da Internacional Organization for Standardization/International Electrotechnical Commission. Os resultados foram analisados por regra proposta pela Associação Brasileira de Normas Técnicas em sua Normativa n.º 14598-6. Foi avaliada a viabilidade do sistema através de um teste do protótipo, com o grupo de avaliadores que foi composto por duas categorias: especialistas em tecnologia da informação e enfermeiros. Na avaliação dos expertises enfermeiros, a característica adequação funcional confiabilidade, usabilidade, eficiência no desempenho, compatibilidade, e segurança, obtiveram 100% das respostas em acordo. Os expertises profissionais de informática também avaliaram manutenibilidade com 97,3% confiabilidade com 84,9%, usabilidade com 84,6% das respostas de acordo. O software foi validado permitindo avaliar a qualidade técnica e desempenho funcional aplicado à avaliação e monitoramento de feridas.

Descritores: Enfermagem; Estudo de Validação; Validação de Programas de Computador; Tecnologia; Feridas.

Introduction

The immense economic and social impact of wounds on our society calls for the allocation of a greater level of attention and resources to understand the pathophysiological mechanisms, wound-related complications and the implementation of adequate care at different levels of health care.

The task of evaluating a wound is a complex process and requires skills, abilities and attitudes of professionals, especially nurses. Therefore, the use of assessment applications currently available do not include the criteria for a complete clinical assessment, especially those that use photographic imaging to define different types of tissue (granulation, epithelialization, necrosis) or assessment of wound edges. Wound assessment is part of the clinical examination at the first visit. In subsequent evaluations, the physical examination is directed, that is, the etiology of the wound and information on factors that interfere with healing, topography of the lesion, edges, background, size, depth, exudate, pulses, varicose veins, skin should be considered adjacent dermatitis, swelling and pain[1].

In the last decades, several standardized methods have been developed to allow professionals to monitor injuries and, consequently, to evaluate the effect of an intervention. The development of these tools is an important step towards a systematic approach to wound care. Assessment instruments can improve and stimulate communication between health team professionals and make it possible to achieve the expected goals more quickly[2]. However, what is observed are instruments developed for evaluation, most of the time, specific for pressure injuries and not for chronic wounds.

In the context of information technologies, the use of software is a resource that has been expanding and has presented itself as an innovative area with a great contribution to the access of information with efficiency and reduction of time. Information systems can be inserted in the praxis of care, helping in all stages of the nursing process, also contributing to the formatting of management indicators[3].

Currently, there are no exact numbers of how many nursing professionals use information technologies in their daily work, nor even what type of platform or access device they use. It is believed that these professionals are willing to make use of the technologies, as there is the possibility of having online, up to date information, and most importantly, the standardization of language, increasing the availability to perform direct care with the patient and providing a more humanized practice[4]. Therefore, it is clear that there are few software, applications specifically aimed at nursing professionals, reinforcing the need to bring the field of information technology closer to the practice of these professionals.

In this sense, the evaluation of a software is essential to identify the weaknesses and limitations of the product, analyze its performance and diagnose the need for adaptations[5]. This assessment must be carried out by specific standards, such as the International Organization for Standardization (ISO), International Electrotechnical Commission (IEC) and Brazilian Association of Technical Standards (ABNT), which proposed two Brazilian Standards (NBR), ISO/IEC No. 14598 and ISO/IEC No. 9126, which address the quality of software products[6,7]. These standards were updated in 2011, giving rise to ISO/IEC standards No. 25010 – System and Software engineering – System and software quality models; and ISO/IEC 25040 – System and Software engineering – Evaluation process[8,9]. It can be said that studies on the process of product development and software validation in the nursing area are still incipient, not only in Brazil, but in all over the world. Some Brazilian studies have adopted these regulations for the creation of software and its evaluation in different scenarios of care practice[5,10].

This study started after the researchers developed a prototype software for the monitoring and evaluation of wounds (Wounds Monitoring). Thus, there was a need to evaluate the functional performance and technical quality of this product. Thus, the present study aimed to validate an application software for recording, monitoring and evaluating wounds.

Methodology

This is a methodological, applied, quantitative study. It was carried out from 2018 to 2020, carried out in two stages: content validation and applicability.

The validation was performed by 18 experts, nine nurses and nine information technology professionals. The selection of initial participants and those nominated by their peers followed the following selection criteria: having a degree in nursing, having a specialist title in dermatological nursing or stomatherapy nursing or having knowledge in the area of wound prevention and treatment; have a degree in information technology and knowledge in operating systems in relation to functionality, reliability and usability of software, and also have experience of at least one year in the area of programming or systems analysis (information technology professionals).

The number of participants for each group complied with NBR ISO/IEC No. 14598-648, which indicates a minimum of eight evaluators for each group in order to obtain reliable results[6]. The choice of participants was based on the snowball methodology, in which the identification of expertise was carried out by the recognition of their peers, that is, the initial participants indicated new participants, who in turn indicated others, and so on until to reach the recommended number. Thus, it is not possible to determine the probability of selection of each participant[11].

The evaluators were invited by e-mail sent by the researcher-coordinator, requesting to participate in the study. The invitation contained instructions: if the person agreed to participate, they should access the link corresponding to the address of their questionnaire and accept the Free and Informed Consent Form. The message also oriented that the software link should only be accessed after acceptance of the term, inserting username and password provided by the researcher for each evaluator.

To guide the evaluators, a document with guidelines for accessing the system was sent, in addition to a tutorial, presented in the software itself, which contained a fictitious

clinical case with all its respective data, necessary for completing the instrument (physical examination, indicators, prescription care, among others). The completion of the evaluation questions was carried out by nurses and information technology professionals through access to the link, using the Google® form. The answers to the questionnaires were automatically received by this tool, from the conclusion of the evaluation, forming a database for further analysis. All responses applied to each characteristic and sub-characteristic were received, as judged by the evaluators. After obtaining the data, they were organized and analyzed in an Excel® spreadsheet.

The first step to carry out the evaluation was to identify the requirements necessary to measure the quality of this software, that is, the model and the characteristics and sub-characteristics of quality evaluated. The reference adopted in this project was described in the ISO/IEC standard No. 25010[8], composed of eight characteristics (functional suitability; reliability; usability; performance efficiency; compatibility; security; maintainability and; portability) that are subdivided into 25 sub-characteristics (functional integrity, functional correctness and functional aptitude; maturity, fault tolerance, recoverability and availability ; recognition of suitability, apprehensibility, operability, error protection, user interface aesthetics; time, resources and capacity; interoperability; confidentiality, integrity, non-repudiation; analyzability, modifiability, testability, modularity; adaptability, installability) that were able to provide consistent terminology for specifying, measuring and evaluating systems and product quality. These evaluation criteria have already been tested on similar products[5,12]. As well as the quality that was also evaluated by the experts (nurses and information technology), the specific characteristics and sub-characteristics related to maintainability and compatibility were specific for professionals with expertise in information technology.

The evaluation techniques and metrics applied to measure the quality requirements, according to the specific questions for each characteristic and sub-characteristic, were through valuation, established by three criteria[12]: Agree, Disagree and Not applicable. For each sub-characteristics, ABNT NBR ISO/IEC No. 14598-6[6] considers more than one metric, with a corresponding meaning; for each attribute: "positive" answer (the metric is in accordance with what was proposed), "negative" answer (considers that the attribute does not correspond to what was proposed) and "not applicable" answer (the evaluator did not evaluate the attribute or deems it not applicable to the software and should be discarded). This scale made it possible to individually measure the quality of each characteristic. At the end of the questionnaire, there was a space for the evaluator to describe any suggestions or problems identified. To obtain the values of each characteristic and sub-characteristic, the rule proposed by ABNT NBR ISO/IEC No. 14598-6 was applied[6].

In the functional evaluation applied to the software, the evaluator did not evaluate the internal behavior and structure of the program (Black Box Test), and his evaluation consisted of the functional part of the program, according to the proposed specifications. The results were interpreted according to the ABNT NBR ISO/IEC rating scale No. 14598-648[6], where each functionality sub-characteristic is related to the percentage of positive responses.

To carry out this study, all ethical precepts determined by Resolution No. 466/2012 of the National Health Council were respected. This research project was approved by the Research Ethics Committee of the Federal University of Health Sciences of Porto Alegre (CAAE: 54748216.3.0000.5345/2016). Opinion approval number 1,500,677/2016.

Results

The construction of the Wounds Monitoring software prototype emerged from reflections on the difficulties that professionals have in systematizing actions in wound care, as well as in the effective monitoring of these actions. Wounds Monitoring was designed and validated, taking into account the minimum and necessary items to assess a wound (wound measurement, tissue type, exudate, amount of exudate, signs of inflammation and/or infection, among others). In addition, it allows the technology user to choose different types of coverage that can be used in the treatment. The software prototype was evaluated as a tool capable of helping the health professional in the evaluation and monitoring of injuries, as well as in choosing the appropriate coverage.

It was considered the highest degree for the categorization of expertise. Among the group of nurses, 56.0% had a specialization, 22.0% had a master's degree and 22.0% a doctorate, four of whom are university professors, three of these participants do not work as clinical nurses. Among the information technology professionals, four are undergraduate professors; the others work in the area of software development. Regarding training, three are programmers, six are system analysts, four have a master's degree in technology in systems development and one has a doctorate in informatics.

Table 1 presents the percentage of approval of each characteristic (PA) and sub-characteristic of the instrument and the percentage of approval by category calculated according to NBR ISO/IEC No. 14598-648.

Table 1. Percentage of approval of each characteristic of the experts in relation to the agreement; disagreement; not applicable. Porto Alegre, RS, Brazil, 2018

Features and sub-features	Nurses					Information technology professionals		
	A (%)	D (%)	NA (%)	PA (%)	CV (%)	D (%)	NA (%)	CV (%)
Functional suitability								
Functional integrity	100,0	-	-		100,0	-	-	

Characteristic								
Functional fix	100,0	-	-	100,0	100,0	-		100,0
Functional fitness	100,0	-	-		100,0	-	-	
Reliability								
Maturity	88,9	-	11,1		100,0	-	-	
Fault tolerance	66,7	-	33,3		100,0	-	-	100,0
Recoverability	66,7	-	33,3		100,0	-	-	
Availability	100,0	-	-		100,0	-	-	
Usability								
Recognition of suitability	77,8	-	22,2		77,8	22,2	-	
Apprehensibility	100,0	-	-		100,0	-	-	
Operability	100,0	-	-		77,8	22,2	-	
Accessibility	100,0	-	-	97,8	100	-	-	93,3
Error protection	77,8	22,2	-		100	-	-	
User interface aesthetics	100,0	-	-		77,8	22,2	-	
Performance efficiency								
Time	100,0	-	-		100,0	-	-	
Resources	100,0	-	-	100,0	100,0	-	-	100,0
Capacity	100,0	-	-		100,0	-	-	
Compatibility								
Interoperability	100,0	-	-	100,0	88,9	11,1	-	94,4
Coexistence	100,0	-	-		100,0	-	-	
Safety								
Confidentiality	100,0	-	-		100,0	-	-	
Completeness	100,0	-	-	100,0	77,8	22,2	-	92,6
No repudiation	100,0	-	-		100,0	-	-	
Maintainability								
Analysability	-	-	-		77,8	22,2	-	
Modifiable	-	-	-		77,8	22,2	-	
Testability	-	-	-		100,0	-	-	89,1
Modularity	-	-	-		100,0	-	-	
Portability								
Adaptability and ability to be installed	-	-	-		100,0	-	-	
Ability to replace	-	-	-		100,0	-	-	100,0

Note: PA – Percentage of approval of each characteristic; A - Agreement; D - Disagreement; NA – Not applicable; CV - Approval percentage of each characteristic.

The functionality characteristic is related to the ability of the Wounds Monitoring software prototype to provide the functions that satisfy the users' needs, when it is used under specific conditions. For a result considered positive, the stipulated target was 80%. The results of this characteristic were above expectations, as all subcategories had a final score of 100% in both groups of expertise.

Between the two groups of experts that evaluated the Wounds Monitoring software prototype, the comments were that this tool meets the implicit and explicit needs of the user. One of the information technology professionals pointed out that the prototype, although it has the required functions, still has limited accuracy, even if the product generates results within the expected. However, interoperability, that is, the ability to interact within other programs, was not evaluated. In the evaluation of the two groups of expertise, the Wounds Monitoring software prototype was considered a useful tool in the monitoring and evaluation of wounds. This percentage of satisfaction can be explained by the fact that it is a simple instrument, with a friendly interface and self-explanatory icons.

The characteristic "reliability" obtained the same percentages in the responses of the expertise nurses and information technology professionals, 100% of the responses agreed. The characteristic "availability" and "maturity" reached the goal proposed for this study. The response levels in these categories reveal a level of approval, with a percentage above 70%.

According to the evaluation of the expertise, the evaluation of "Usability" reached an excellent level of quality, with 97.8% approval by nurses and 93.3% by information technology professionals. The sub-characteristic "adequacy recognition" received two responses as "not applicable" and two responses as "disagreement". The sub-characteristics "apprehensibility and operability" obtained 100% approval. On the other hand, the sub-characteristic "protection against errors" was evaluated by the nurses' expertise, with seven (78.2%) responses as agreement and two (22.8%) as disagreement.

Among the information technology professional expertise, the answer was 100% in agreement. The sub-characteristics "testability and maintainability" obtained 100% of the responses in agreement. Regarding the sub-

characteristic "user interface aesthetics", which is related to how pleasant the user evaluates the screens and the interface, 100% of the nurses' expertise responded accordingly to both questions and 7 (77.8%) of the professional expertises of information technology in the first question agree and 2 (22.8%) as disagree.

The "Usability" assessment provided testing the software with standard users, which allowed developers to be provided with the correct information to fulfill the users' needs. Testing with the expertise was a reliable way to determine unnoticed needs in a first assessment. Regarding the category "performance efficiency" and the percentage of software quality, the expertise nurses and information technology professionals unanimously evaluated (100%) in agreement with all questions.

For the characteristic "compatibility" and the sub-characteristic "interoperability", the experts considered that the software has an adequate level of quality. Among the group of professional IT experts, one evaluated it as "disagreement" and the others, eight, evaluated it as agreement. In the first question, (does the software have the capacity to exchange information with other systems?), the group of professional information technology experts obtained eight (88.9%) responses in agreement, one (11.1%) in disagreement. In the question, does the software perform its functions efficiently even when using more windows on the computer or mobile device? The answers were 100% of agreements for all expertises.

The "security" category, according to the assessment of nurses and information technology professionals, the percentage of approval of the "security of access" category to the software was 100%. In the assessment of information technology professionals, in the sub-characteristics "integrity", seven (77.8%) rated it as in agreement and two (22.2%) as disagreement. On the other hand, the nurses' expertise obtained 100% agreement. However, in the sub-characteristic "non-repudiation" nine (100%) of the groups of expertise rated accordingly.

The assessment of maintainability and portability was performed only by information technology experts. The sub-characteristics "analyzability and modifiability" obtained the same responses, that is, seven (78.2%) of the responses agreed, two (22.8%) disagreed. The sub-characteristics "testability and maintainability" reached 100% of the responses in agreement. Portability is the ability of software to adapt to other environments. This category was evaluated through the subcategory "adaptability" and "ability to be installed". As for the sub-characteristics "portability" and "ability to be installed", the experts agreed in 100% of the answers.

Discussion

Due to the complexity of wound care and the resources available, there were some limitations in the validation of the Wounds Monitoring software. One of these limitations was retrieving some evidence, obtaining new primary data, interpreting the available evidence, synthesizing the evidence and formulating other results and recommendations, certainly due to time constraints. The greater amount of scientific evidence could justify the use and faster dissemination of the proposed technology. Likewise, limitations in conducting other studies restricted the ability to respond to questions about the effectiveness of certain software monitoring actions[13].

Technologies such as Wounds Monitoring strengthen the culture of using scientific evidence in the decision-making process, influencing concepts and languages adopted in clinical deliberations by health professionals. From the technological propositions made by this study, nurses will be able to access information, as well as allow the formation of a database. It is important to emphasize that the tool enables assessment and monitoring of wounds in an agile and systematic way, through a system with a friendly and self-explanatory interface, with the possibility of low cost.

Wounds Monitoring is a software prototype, a health technology to be used, in principle, by nurses. This software prototype can be a potentiator in linking and a contribution in the practices of health professionals, as well as in health services. In the case of people with wounds, the care quality indicators can be raised from the systematization of the assistance provided, since most of the time the care with the lesions (wound assessment, replacement of dressings, evolution of what was performed and intercurrences) are not properly recorded[14].

A software prototype is not intended to replace the professional's critical thinking and clinical reasoning. The guidelines, protocols, booklets and algorithms continue to direct nursing professionals towards a process of greater accuracy in wound assessment. And it is also necessary to reinforce that adequate documentation guarantees the success of the treatment and evolutionary follow-up of the wound[1,14,15].

As for the prototype validation process, contributions from experts were included, which provided relevant information for modifying the writing and even the graphic presentation. Most experts agree with its applicability in clinical practice, that is, they consider it a tool with relevant potential capable of supporting the professional's decision in the evaluation, monitoring and choice of wound treatment[14,15].

As for the dissemination of results, they should be presented in different formats and styles, depending on the audience to which they are aimed and the means available to disseminate them (e.g. detailed report for researchers and policy makers, quick reference guide for clinicians , etc.). In addition, impact assessment may be difficult to determine due to competing factors: product marketing, dissemination technique, target group, time and environment.

The Wounds Monitoring software prototype is in the process of registering the technical documentation, consisting of excerpts from the program and other data to identify it and characterize it for its originality, except for the rights of third parties and the responsibility of the Government, which pass after this stage to constitute the collection of documentation of the National Institute of Industrial Property.

Conclusion

The results of this study made it possible to describe the validation of the application software for recording, monitoring and evaluating wounds. The validation methodology adopted opens perspectives to believe that the use of software is of great effectiveness in clinical practice in the treatment of wounds, and for Nursing teaching with regard to technology.

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