

RESEARCH ARTICLE (ORIGINAL)

Caring for people with chronic leg ulcers: Development and evaluation of monitoring software

Cuidados ao paciente com úlceras crônicas de pernas: Construção e avaliação de software para monitorização

Cuidados a pacientes con úlceras crónicas de pierna: Construcción y evaluación de un software de monitorización

Silvéria Lopes Ponte Prado ¹

 <https://orcid.org/0000-0003-1033-5544>

Rita Neuma Dantas Cavalcante de Abreu ¹

 <https://orcid.org/0000-0002-5130-0703>

Luís Rafael Leite Sampaio ²

 <https://orcid.org/0000-0003-1437-9421>

José Eurico Vasconcelos Filho ¹

 <https://orcid.org/0000-0002-6881-0814>

Thereza Maria Magalhães Moreira ³

 <https://orcid.org/0000-0003-1424-0649>

Karla Maria Carneiro Rolim ¹

 <https://orcid.org/0000-0002-7914-6939>

Erick Tomé de Lima ¹

 <https://orcid.org/0000-0002-9922-1684>

¹ University of Fortaleza, Fortaleza, Ceará, Brazil

² Regional University of Cariri, Nursing Department, Fortaleza, Crato, Brazil

³ State University of Ceará, Nursing Department, Fortaleza, Ceará, Brazil

Corresponding author

Silvéria Lopes Ponte Prado

E-mail: silverialopesprado@gmail.com

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Abstract

Background: The systematization of data records about the status and evolution of chronic leg ulcers improves their treatment.

Objective: To describe the development of a software for monitoring care provided to patients with chronic leg ulcers.

Methodology: This methodological study was based on Participatory Interaction Design process and developed in four interactive stages - 1) Requirements analysis; 2) (Re)design; 3) Prototype construction, and 4) Quality assessment.

Results: The software includes a description of constitutional and behavioral factors, the disease, evaluation methods, data from the consultation and monitoring of recurrences, and alerts indicating the factors involved in the healing process. Moreover, all experts agreed on the criteria of usability, functionality, appearance, organization, sequence, and understandability.

Conclusion: The developed software is adequate in terms of quality and may be useful for stoma nurses and generalist nurses.

Keywords: nursing informatics; leg ulcer; varicose ulcer; software; technology; nursing

Resumo

Enquadramento: No cuidado aos pacientes com úlceras crônicas de pernas, a sistematização do registro das informações sobre o estado e evolução das úlceras crônicas de pernas, contribui para a melhoria do tratamento.

Objetivo: Descrever o desenvolvimento de um *software* para a monitorização do cuidado aos pacientes com úlceras crônicas de pernas.

Metodologia: O estudo metodológico foi fulcrado no *design* de interação participativa e desenvolvido em quatro etapas interativas - 1) Análise de requisitos; 2) (Re)design; 3) Construção de protótipo e 4) Avaliação da qualidade.

Resultados: O *software* contém descrição de fatores constitucionais, comportamentais, doença, métodos de avaliação, dados da consulta e monitorização de recidivas, além de alertas sinalizadores dos fatores intervenientes no processo cicatricial. Ademais, houve concordância de todos especialistas quanto aos critérios de usabilidade, funcionalidade, aparência, organização, sequência e compreensão.

Conclusão: O *software* desenvolvido está adequado na sua qualidade, podendo ser útil para estomaterapeutas e enfermeiros generalistas.

Palavras-chave: informática em enfermagem; úlcera de perna; úlcera varicosa; software; tecnologias; enfermagem

Resumen

Marco contextual: En el cuidado de pacientes con úlceras crónicas de pierna, sistematizar el registro de información sobre el estado y la evolución de las úlceras crónicas de pierna contribuye a mejorar el tratamiento.

Objetivo: Describir el desarrollo de un *software* para el seguimiento de los cuidados de pacientes con úlceras crónicas de pierna.

Metodología: El estudio metodológico se centró en el diseño de interacción participativa y se desarrolló en cuatro fases interactivas: 1) Análisis de requisitos; 2) (Re)diseño; 3) Construcción de prototipos; y 4) Evaluación de la calidad.

Resultados: El *software* contiene una descripción de los factores constitucionales y de comportamiento, enfermedad, métodos de evaluación, datos de consulta y seguimiento de las recaídas, así como alertas que señalan los factores que intervienen en el proceso de cicatrización. Además, todos los expertos coincidieron en los criterios de usabilidad, funcionalidad, aspecto, organización, secuencia y comprensión.

Conclusión: El *software* desarrollado es de calidad adecuada y puede ser útil para estomaterapeutas y enfermeros generales.

Palabras clave: informática en enfermería; úlcera de pierna; úlcera varicosa; software; tecnología; enfermería



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Introduction

Chronic leg ulcers (CLUs) are a global issue and are common in Brazil. Venous ulcers (VUs) are the predominant category, accounting for 70% of all CLUs. Recurrence occurs in 30% of cases within the first year after VU healing and in 68-78% of cases 2 years after healing (Sánchez-Nicolat et al., 2019). The high recurrence rate of VUs has a negative impact on patients' lives, making its control socially and scientifically relevant. In this context, the use of information technology can optimize the monitoring and subsequent control of these injuries.

This study aims to describe the development of a software for monitoring care provided to patients with CLUs. This software will enable the monitoring of these patients, improve the accuracy of care, and control resources spent on treating VUs. Additionally, it will provide professional guidance and advice on the best course of action for achieving the healing process and controlling recurrences.

Background

The electronic health record (EHR) is a tool designed to meet the needs of patient care and health management. Nurses should use computerized recording systems to monitor and control these injuries (Gomes et al., 2019). The computerization of the Unified Health System (*Sistema Único de Saúde*, SUS) and the Supplementary Health (*Saúde Suplementar*) System in Brazil has many advantages. With this in mind, the Brazilian Ministry of Health created Law No. 12.401/2011 of the President of the Republic (2011), of April 28, 2011. This law provides information on therapeutic assistance and the incorporation of health technology in the SUS (Brazil, 2011). As a result, the Electronic Patient Record (*Prontuário Eletrônico do Paciente*, PEP) was implemented, which has improved the availability and quality of records.

In many hospital institutions and a large part of the Brazilian outpatient network, nursing activities and those of other health professions are still recorded manually. This is done by making annotations on sheets or cards, which can become difficult to understand due to illegible spellings and truncated texts. Moreover, these manual records hinder the quick and systematic retrieval of information, making it challenging to monitor events such as VUs and CLUs (Mottin et al., 2020).

Urgent action is required to assist nurses in standardizing systematic actions to enhance patient care. Multiple studies indicate the existence of injuries that take years to heal and cause a trajectory of suffering for patients. This suffering could be minimized by creating a specific system for documenting and monitoring these injuries (Mottin et al., 2020). National studies indicate a lack of standardization in the care of VUs at different levels of healthcare in Brazil, which hinders successful treatment (Dantas et al., 2017). Therefore, there is a knowledge gap and a need to develop software to support the monitoring of care provided to people with CLUs/VUs, based on the identified needs in the field.

Research question

How was the software for monitoring care to patients with chronic leg ulcers developed and how well is it used by stoma nurses?

Methodology

This methodological study used the Participatory Interaction Design process. It was developed in four interactive stages: 1) Requirements analysis; 2) (Re) design; 3) Prototype development, and 4) Quality assessment. The requirements and content of the software were defined based on a literature search on protocols and factors influencing the care of VUs and the experience of care of patients with CLUs/VUs, including visualization and annotation of records in patients' medical records.

The (Re)design and Prototype development stages were carried out at the Applied Information Technology Center (NATI), University of Fortaleza (UNIFOR). NATI has a software and hardware infrastructure, as well as researchers and students specialized in computer science and engineering who are able to support the technological development phase of the research, methodologically supported by the Participatory Interaction Design process (Sharp et al., 2005). A total of 28 laboratory meetings were held to design and develop the software.

This stage was followed by a software quality assessment based on the criteria of usability, functionality, appearance, organization, sequence, and understandability. The usability of the initial version of the software was pilot tested with five NATI undergraduate students. The test consisted of eight questions answered on a four-point agreement scale (*very easy/strongly agree* to *very difficult/strongly disagree*) about the easy visualization of the patient list, observations and alerts; readability of the text; easy identification of the object; difficulty in registering patients and accessing the application, and layout of the menus and icons.

Changes were made to improve the software, and its final version was analyzed based on the quality criteria. Invitations were sent by e-mail to 39 specialists - stoma nurses with extensive experience in assessing and treating injuries - explaining the research objectives and sending an Informed Consent Form (ICF). All emails were sent on November 7-8, 2017. Acceptance to participate in the study was given upon return of the signed ICF by the specialist.

After the specialists had accepted, the researcher sent the content of the software via Google Forms, together with questionnaires for participant characterization and a general evaluation of the software. A total of 12 stoma nurses returned the questionnaire.

In order to validate the material, interrater agreement (AI) was used to analyze the quality criteria using a Likert scale ranging from 1 to 4 (*totally disagree*, *par-*

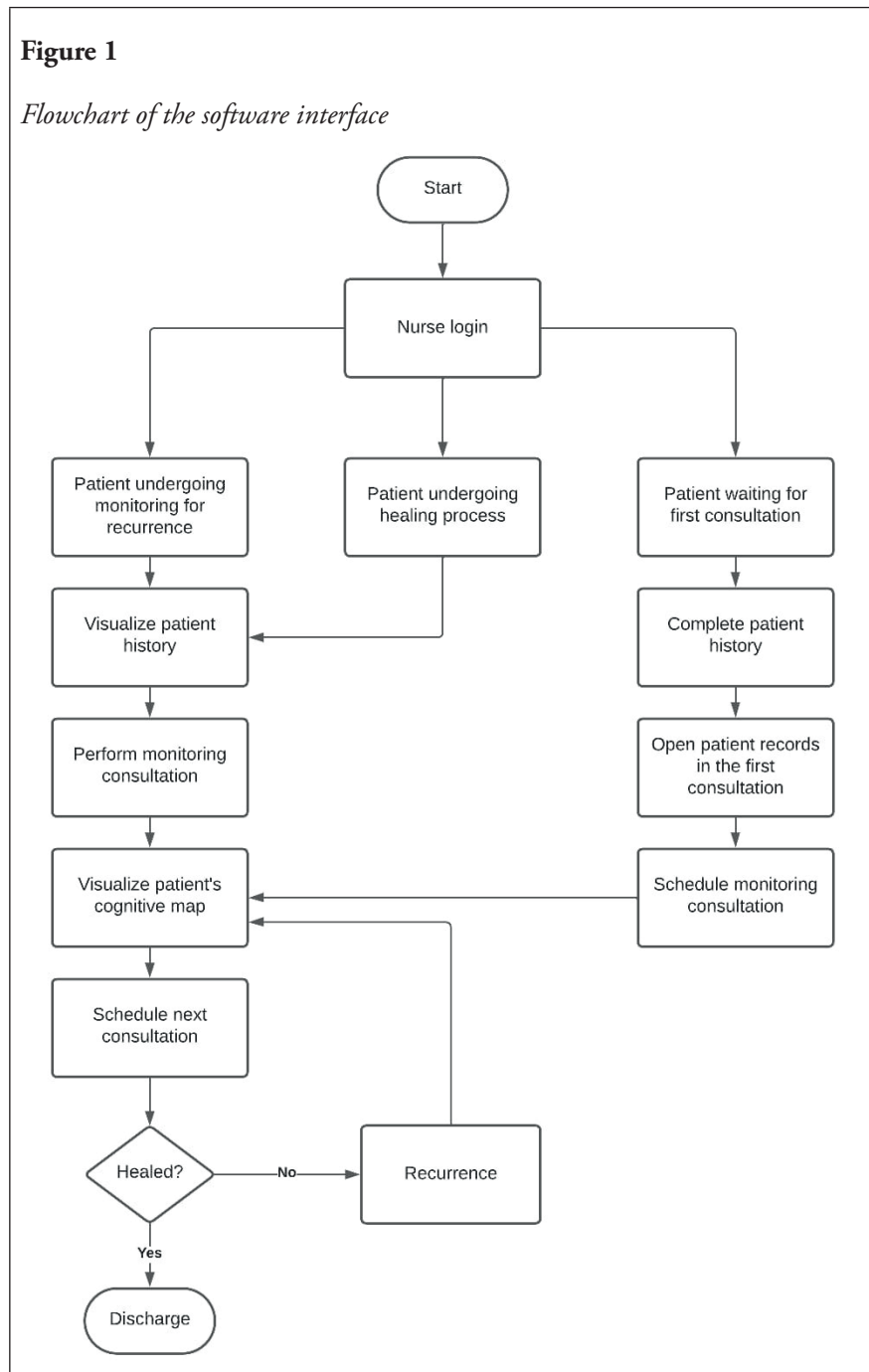
tially disagree, partially agree, and totally agree). Criteria with an IA $\geq 80\%$ were considered valid, while those that did not reach an IA $\geq 80\%$ were re-evaluated. This research was only conducted after approval of the project by the Research Ethics Committee, under protocol no. 2.300.822.

Results

The software was developed after the requirements had been identified and the content defined. The ideal practical reality assistance system was devised for the virtual instrument. The monitoring of people with VUs was planned to take place in three phases, detailed in a flowchart (Figure 1).

Figure 1

Flowchart of the software interface



This study identified the requirements needed to develop the software (Table 1), which involved registering users; recording information; storing data; generating reports; programming alerts, and monitoring patients. The literature search revealed the need to include in the software a

description of constitutional and behavioral factors, the disease, evaluation methods, data from the consultation and monitoring of recurrences, as well as alerts signaling the factors involved in the healing process, topical therapy, indication of compression therapy, and counter-referral.

Table 1*Software requirements*

Record ulcer measurement.
Store measurements.
Generate a report of ulcer measurements, signs and symptoms, therapies, sites, risk factors.
Generate an alert if the parameters are exceeded in the case of smoking, alcoholism, signs of ulcer infection, continuous pain, presence of necrotic tissue in ulcer bed, high PUSH score, patients with ABI < 0.8, higher limb edema since last consultation, BMI > 30.
Be able to show suggestions for referral to other professionals.
List all patients and allow the user to register new patients.
Allow the administrator to register new users.
Allow patient search by name/patient record number.
Generate cognitive maps of variables.
Be able to suggest topical therapies according to ulcer bed.
Be able to suggest compression therapy according to the characteristics of each ulcer.
Record what has been established with the patient for their first consultation.
Record what has been established with the patient for their follow-up consultations.
Record what has been established with the patient for their recurrence monitoring consultations.
Be able to record VU recurrences.
Monitor patients with healed VUs to track adherence to recurrence control measures.
Monitor patients undergoing healing processes.
Possibility of recording the patient's presence, even without conducting tests, provided it is justified.
Allow the administrator to manage other users.
Allow user access through COREN login and password.

The low-fidelity design of the software was developed, followed by the high-fidelity design, with the screens already defined and colored showing the software's final layout. Then the software prototype was run on a smartphone, smart TV, or computer. The experts approved the content of the software prototype, which demonstrated good usability, simple handling and identification, suitable content for stomal therapy nursing and follow-up consultations for people with CLUs. It should be noted that the system indicated the patient's cognitive map (information that expresses the essence of their care, involving all the variables that influence the health-disease process) obtained from the first consultation during follow-up consultations. At this point, it was necessary to fill in behavioral factors specific to the ulcer, new medications and tests conducted recently, and record the patient's presence, even without

an assessment, as long as it was justified.

Regarding recurrence control after healing and new recurrence, the system requested data on adherence to compression therapies and other care, with the patient returning to the follow-up group. The system allows monitoring via alerts (Table 2) in the presence of factors intervening in the healing process, as a type of response to previous guidance, care, and assessments. The system numbers and measures ulcers on each limb and generates reports with items desired by the professional, including identification of referral and counter-referral, enabling the planning and effectiveness of nursing care for patients with CLUs. The system suggests topical therapies according to ulcer bed and compression therapy based on the ulcer's characteristics. All records are stored in the system, to which new records and elements can be added.

Table 2*Software alerts*

Alert	Description of the condition that aggravates it
1 - Smoking	Increases the risk of limb ischemia and amputation.
2 - Alcoholism	May slow down the healing process.
3 - Signs of infection	Delays healing and increases the risk of worsening.
4 - Continuous pain	Continuous, severe pain is uncommon in venous ulcers. Arterial disease should be investigated.
5 - Necrotic tissue	Necrotic tissue inhibits granulation and epithelialization.
6 - Increased Pressure Ulcer Scale for Healing (PUSH) score	The PUSH assesses ulcer healing in terms of surface area, exudate amount, and wound bed. Scores range from 0-17.
7 - Ankle-brachial index (ABI) < 0.8	Identifies people with peripheral arterial obstructive disease, which contraindicates compression therapy.
8 - Increased edema in the limb	Increased edema in the lower limb delays healing and progresses to subcutaneous fibrosis.
9 - Body Mass Index (BMI) > 30	Obesity is a risk factor for chronic venous ulcers and delayed wound healing.

The initial screen of the final version of the prototype has a login (COREN) and password fields. Screen 2 shows the different types of consultation (for patients undergoing a healing process, waiting for their first consultation, healed, and undergoing monitoring). Screen 3 shows constitutional factors and underlying diseases (hypertension, diabetes, ankle ankylosis, peripheral arterial disease, lower limb

fractures, previous vascular surgery, multiparity, history of venous thrombosis, smoking, alcoholism, prolonged sitting or standing). Finally, after the raters' assessment and the adaptations they suggested, the software was finalized, with an interactive version including typography, layout, iconography, and color palette, according to the software screens below, followed by the usability analysis.

Figure 2

Software screens (Login, New patient register, monitoring of relapses and alerts)

NOVO PACIENTE

Nome Completo: _____

CPF: _____

Nº do Cartão do SUS: _____

Data de Nascimento: _____ Telefone: _____

Digite o número do seu COREN: _____

Digite sua senha: _____

ENTRAR **CANCELAR** **SALVAR**

ESQUECI MINHA SENHA

< CONSULTA DE MONITORAMENTO DA RECÍDIVA - NOME DO PACIENTE **RESUMO DA ÚLTIMA CONSULTA**

OBSERVAÇÕES

Monitoramento da Recidiva

Recidiva: ☐ Sim ☐ Não

Fatores Constitucionais e Patologias de Base do Indivíduo

Hipertensão arterial: ☐ Sim ☐ Não Multiparidade: ☐ Sim ☐ Não

Diabético: ☐ Sim ☐ Não História de trombose venosa: ☐ Sim ☐ Não

Presença de anquiose tibiotársica: ☐ Sim ☐ Não

Doença arterial periférica: ☐ Sim ☐ Não

Úlceras dos MMII: ☐ Sim ☐ Não

Cirurgia venosa prévia: ☐ Sim ☐ Não

Fatores Comportamentais

Imobilização prolongada em posição ortostática: ☐ Sim ☐ Não Alcoolismo: ☐ Sim ☐ Não

Imobilização prolongada em posição sentada: ☐ Sim ☐ Não Tabagismo: ☐ Sim ☐ Não

CANCELAR **SALVAR** **CANCELAR** **SALVAR**

< CONSULTA DE RETORNO - NOME DO PACIENTE **RESUMO DA ÚLTIMA CONSULTA**

OBSERVAÇÕES

Fatores Comportamentais:

Tabagismo: ☐ Sim ☐ Não

Alcoolismo: ☐ Sim ☐ Não

Higiene da Bandagem: ☐ Boa ☐ Péssima

Medicação de Uso Contínuo ou Frequente

☐ Antidiabéticos orais

☐ Anti-hipertensivos

☐ Flebotômicos

☐ Estatinas e fibratos

☐ Anti-inflamatórios não-esteróides

☐ Outros _____

CANCELAR **SALVAR**

The usability analysis (Table 3) was conducted by five undergraduate students in computer science and advertising, who were at least in their fifth semester. From the analysis,

the software proved to be easy to use, with legible and easily identifiable texts. Its menus and icons are arranged in such a way as to facilitate access to information.

Table 3*Software usability*

Questions	Normal	Easy/ Partially agree	Very easy/ Totally agree	IA (%)
	<i>f</i> (%)	<i>f</i> (%)	<i>f</i> (%)	
1. "The patient's cognitive map is easy to visualize".	-	01 (20.0)	04 (80.0)	100.0
2. "The texts in the application are legible".	-	-	05 (100.0)	100.0
3. "It is easy to identify the object of the application".	-	01 (20.0)	04 (80.0)	100.0
4. "The layout of the patient lists makes it easy to visualize patient information".	-	01 (20.0)	04 (80.0)	100.0
5. "The observations/alerts are easy to visualize".	-	-	04 (80.0)	100.0
6. "How difficult is it to register the patient?".	01 (20.0)	01 (20.0)	03 (60.0)	100.0
7. "Are the menus and icons arranged in such a way as to facilitate the access to information?".	-	02 (40.0)	03 (60.0)	100.0
8. "How difficult is it to access the application?".	01 (20.0)	02 (40.0)	02 (40.0)	100.0

Note. *f* = Absolute frequency; % = Relative frequency; IA = Interrater agreement (percentage).

Twelve stoma nurses assessed the final version of the software. Of these, five (41.7%) held a master's degree, five (41.7%) were physicians, and two (16.6%) were specialists, aged 29 to 62 years, with a training period of between 2

and 18 years. All of them totally agreed on its suitability in terms of functionality (12; IA = 100%), appearance (12; IA = 100%), organization (12; IA = 100%), sequence (12; IA = 100%), and understandability (12; IA = 100%; Table 2).

Table 2*Software quality*

Quality criteria	TA (n)	IA (%)
Functionality	12	100.0
Appearance	12	100.0
Organization	12	100.0
Sequence	12	100.0
Understandability	12	100.0
Total IA	-	100.0

Note. TA = Totally agree; *n* = Total number of stoma nurses; IA (%) = Interrater agreement (percentage).

For this reason, the specialists reported that the software's ability to generate reports was relevant and helped planning care through the visualization of previous information.

Discussion

The major challenge in using software is to keep the system fed, functional, easy to use and with quality data, which is the concern after designing the prototype. The use of information and communication technology (ICT) in everyday nursing is a current trend, requiring nurses to change their attitude towards this reality. Many studies point to positive outcomes and improved storage standards for documentation of care interventions (Barros et al., 2020).

In this study, a flowchart of actions was adopted to make

the software more dynamic and usable. A logical and comprehensive sequence was devised, with strictly necessary data, optimizing filling time and resistance to using the software. The study on the development of software for nursing shows that this tool can assist the nursing team in developing clinical judgment and assessing accuracy, contributing to the quality of care (Domingos et al. 2019). Given that its content was drawn from the literature, especially validated protocols (Abbade et al., 2020; Dantas et al., 2017), and suggestions from experts and patients, the software included up-to-date, evidence-based information, which is essential for improving the care provided by stoma nurses.

In addition, tools tested and validated in Brazil have been added, such as the Pressure Ulcer Scale for Healing (PUSH) to assess wound healing (Machado et al., 2018); the Ankle-Brachial Index (ABI) to assess tissue perfusion in the lower limbs (Lima et al., 2020); the Body Mass

Index (BMI) to classify individual obesity levels (Silveira et al., 2020); and limb perimetry (Builders et al., 2020), which detects the presence of edema and the effectiveness of compression therapies. These tools are essential for clinical assessment and diagnostic reasoning.

The software screens were designed to help nurses document the care provided to people with CLUs/Vus and monitor the evolution of the healing process and influencing factors. Considerable efforts have gone into developing software that is quick and easy to access with features that cannot be found in other studies, such as the cognitive maps that help professionals monitor patients based on objective parameters. This characteristic is relevant because the cognitive map helps users to structure and understand the problem situation based on evidence (Lant, 2017). The use of an alert system is an important resource to make the system safe. The purpose of any alert system is to enable the user to take the necessary steps to reduce/eliminate imminent danger. The care provided to people with CLUs requires this vigilance. Many studies call for reflection on a safe multi-professional approach to the prevention of CPUs/VUs and its complications, as well as the restoration of tissue integrity through therapies appropriate to the type of circulation compromised (Plais et al., 2021) and consultations with people with healed and recurrent ulcers to monitor the factors influencing care and adherence to treatment (Silva, 2016).

The development of the software was also motivated by the need to resolve recurring issues in traditional medical records. Problems such as confusing records and the absence of crucial data for monitoring people with CLUs/VUs were identified as significant obstacles. Manual annotations often result in disorganization, making it difficult to read and understand these records. This complexity may be challenge to an effective nursing practice. Computerization of patient records not only organizes and streamlines nursing care, but also adds a humanized dimension to this process. It also allows generating and printing management reports and storing information from consultations and evaluations. This feature gives computerization the advantage of being a resource with greater security and data integrity.

Good usability plays a crucial role in promoting and strengthening relationships between people and systems. On the other hand, poor usability leads to inefficiency (Fucushima et al., 2020). In this context, it is important to emphasize the nurses' full approval of this technology, considering it a significant advance in the nursing field.

Conclusion

After its development, the software was registered as Ulcer-Care®. It proved to have an adequate validity and usability for monitoring these patients and to be useful for stoma nurses and generalist nurses. It can optimize the monitoring and management of care provided to people with CLUs/Vus by controlling factors involved in the healing process, as well as improve the quality of

nursing care and patient records. The current challenge is to develop the external software validation process.

Author contributions

Conceptualization: Prado, S. L., Abreu, R. N.

Data curation: Prado, S. L., Abreu, R. N.

Formal analysis: Abreu, R. N.

Investigation: Prado, S. L., Abreu, R. N.

Methodology: Prado, S. L., Abreu, R. N., Sampaio, L. R., Filho, J. E., Moreira, T. M., Rolim, K. M.

Software: Filho, J. E., Lima, E. T.

Supervision: Abreu, R. N.

Validation: Abreu, R. N.

Visualization: Abreu, R. N., Sampaio, L. R., Moreira, T. M., Rolim, K. M.

Writing - original draft: Prado, S. L., Abreu, R. N.

Writing - review and editing: Abreu, R. N., Sampaio, L. R., Filho, J. E., Moreira, T. M., Rolim, K. M.

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