

Instrument for the evaluation of the chronic wounded patient: clinical, care and financial indicators*

Instrumento de avaliação do paciente com ferida crônica: indicadores clínicos, assistenciais e financeiros

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ABSTRACT

Objectives: to validate an instrument for the assessment of patients with chronic wounds, and to propose clinical, care and financial indicators for Primary and Secondary Health Care. Methods: methodological study involving the development and validation of an instrument consisting of four dimensions with 90 items. The sample was composed of 21 judges, nurses working in Primary or Secondary Care, who evaluated the dimensions of each item regarding comprehensiveness, clarity, relevance and representativeness. Data were analyzed by descriptive statistics and validation by the Content Validity Index. Results: the mean experience of the judges in Primary Care was 7.4 years and in Secondary Care 7.8 years. The index of content validity of each item of the instrument ranged from 0.95 to one, and of each dimension from 0.99 to one, resulting in an overall value of 0.99. **Conclusion:** this study enabled the development and validation of the instrument. Contributions to practice: the instrument can parameterize data collection and support the generation of clinical, care and financial indicators of the service.

Descriptors: Wounds and Injuries; Primary Health Care; Secondary Care; Health Status Indicators; Nursing Process.

RESUMO

Objetivos: validar um instrumento para a avaliação do paciente com ferida crônica, e propor indicadores clínicos, assistenciais e financeiros para a Atenção Primária e Secundária à Saúde. Métodos: estudo metodológico, envolvendo a elaboração e a validação de um instrumento constituído de quatro dimensões com 90 itens. A amostra foi composta por 21 juízes, enfermeiros atuantes na Atenção Primária ou Secundária, que avaliaram as dimensões de cada item quanto à abrangência, à clareza, à pertinência e à representatividade. Os dados foram analisados por estatística descritiva e a validação pelo Índice de Validade de Conteúdo. Resultados: a experiência média dos juízes na Atenção Primária foi de 7.4 anos e na Atenção Secundária 7.8 anos. O Índice de Validade de Conteúdo de cada item do instrumento variou de 0,95 a um, e de cada dimensão entre 0,99 e um, resultando em valor global de 0,99. Conclusão: este estudo possibilitou a elaboração e a validação do instrumento. Contribuições para a prática: o instrumento pode parametrizar a coleta de dados e amparar a geração de indicadores clínicos, assistenciais e financeiros do serviço.

Descritores: Ferimentos e Lesões; Atenção Primária à Saúde; Atenção Secundária à Saúde; Indicadores Básicos de Saúde; Processo de Enfermagem.

Introduction

The systematic performance of nurses in the care of patients with wounds is essential to achieve healing. To ensure efficient care, however, the professional should consider the implementation of standardized records that enable the production of data capable of supporting the generation of health indicators and the evaluation of results⁽¹⁾.

However, this is not the reality in certain countries and healthcare settings. In countries like Slovakia⁽²⁾ fragmented and inconsistent documentation among nursing professionals is observed. Similarly, in Brazil, at the levels of Primary and Secondary Health Care, the documentation includes only aspects related to the wound, is incomplete, and does not present data on the evolution of healing⁽³⁻⁴⁾.

This often stems from a lack of standards for recording, interpreting results and setting goals for the management of chronic wounds. Instruments for data collection and wound assessment have been identified since the 1980s and have shown considerable growth since the 2000s. Among them, we highlight those validated in Brazil, such as the Pressure Ulcer Scale for Healing, Bates-Jensen Wound Assessment Tool, Leg Ulcer Mensuring Tool, Resvech 2.0, Skin Tear Classification, Skin Tear Classification System, Tissue, Infection, Moisture and Edge⁽⁵⁾.

However, these instruments focus on aspects restricted to the assessment of the wound bed, the healing process, treatment, wound classification or risk for its development⁽⁵⁻⁶⁾. It is important to reinforce that the record of nursing care should be supported by the Nursing Process, which consists of five fundamental steps for the generation of data and the evaluation of results that support decision making in clinical practice⁽⁷⁻⁸⁾, based on scientific evidence⁽⁹⁾.

Therefore, the lack of systematic recording and generation of data that supports the generation of indicators makes it impossible to measure, analyze and interpret the results for the evaluation of the quality of care offered in the Health Care Network. The scenario described gives a great challenge to nurses, especially because these units represent the main gateway for patients with chronic wounds in health services.

In this sense, this study aims to answer the following guiding question: does the development of an instrument for the assessment of patients with chronic wounds, capable of supporting the generation of clinical, care and financial indicators in Primary and Secondary Care, have content validity for nurses in care practice? Therefore, this study aimed to validate an instrument for the assessment of patients with chronic wounds, and to propose clinical, care and financial indicators for Primary and Secondary Health Care.

Methods

This is a methodological study⁽¹⁰⁾ in which we built an instrument for the evaluation of patients with wounds, treated in Primary and Secondary Care, considering the production of clinical, care and financial indicators. The idealization of indicators and the bases of calculation for their determination was based on the basic matrix of health indicators, referenced by the Pan American Health Organization, used in Brazil. By considering aspects of health system performance, such as technical and scientific adequacy, efficiency and effectiveness, and acceptability⁽¹¹⁾.

The methodological reference⁽¹²⁾ for the development of clinimetrical instruments was used in the construction of the instrument. Thus, the steps were followed for the identification of the theoretical framework, the construction of dimensions and items, considering the steps of the Nursing Process, and the organization of items to support the generation of indicators and, finally, the content validation by judges.

To develop the instrument, four dimensions were structured based on specific national and inter-

national guidelines for wound assessment and treatment, such as Wound, Ostomy and Continence Nurses Society (WOCN)⁽¹³⁾, Brazilian validated version of Bates-Jensen Wound Assessment Tool⁽¹⁴⁾, ABC Model for Leg Ulcer Management⁽¹⁵⁾, Assessment of diabetic foot⁽¹⁶⁾, European Pressure Ulcer Advisory Panel National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance (NPIAP) Guideline⁽¹⁷⁾.

The dimensions of the instrument included a set of items, each of which supports the generation of indicators of interest. Thus, dimension 1 was determined, corresponding to the Nursing History (26 items), which allows the compilation of clinical indicators. Dimension 2, Anamnesis and Physical Examination of the Patient (31 items), dimension 3, Wound Assessment (17 items), and dimension 4, Wound Care (16 items), allow for the conversion of data into care indicators and cost indicators.

After preparation, the instrument was submitted for content validation by 21 judges. The determination of the number of judges was based on Pasquali's criteria, which considers acceptable and satisfactory, for content analysis, the minimum number of five to twenty judges⁽¹²⁾.

To be considered a judge in this study, the following eligibility criteria were considered: being a nurse, having at least three years of professional training, being inserted and working in the care of patients with wounds in Primary or Secondary Health Care. Nurses on maternity leave or sick leave at the time of data collection were excluded, as well as those who hold exclusive management, management or supervision positions, without performing direct assistance in the care of patients with wounds.

The recruitment of the judges occurred by non-probability sampling, by snowball technique. The first nurses were identified through a list of graduates of the Specialization Course in Stomal Therapy Nursing at the Federal University of Minas Gerais. These graduates were pre-selected according to the eligibility criteria, and five of them met all of them. Thus, the snowball technique was chosen for the complementation of the sample, considering the presence of nurses who are not stomal therapists, which represent the main composition of the Primary Health Care scenario.

The initial contact with the participants was made by the researchers via e-mail to invite them and confirm the inclusion criteria. To be admitted as a judge, a ten-point scale adapted from Fehring was used, considering experience and professional training⁽¹⁸⁾.

In this scale, the professional should reach a minimum of five in the sum of the criteria: length of experience in the care of patients with chronic wounds in Primary or Secondary Care (6.0 points) and academic background (4.0 points). The time of experience was categorized as one to five years (5.0 points) and more than five years (6.0 points). Education included Specialization in Dermatology (2.0 points), Stomal Therapy (4.0 points), Master's Degree (3.0 points), and Ph.D. (4.0 points).

Data collection occurred between November 2020 and January 2021. The Delphi method was used for data collection, which consists of a systematized way of judging information to obtain consensus, from the opinion of professionals with expertise, specialists, experts or judges, with the purpose of evaluating a given subject⁽¹⁹⁾.

Each judge received from the researcher a selfadministered questionnaire containing information about work and training characteristics (age, time since graduation, time of experience). They received the instrument with the four dimensions and the set of items. The judges had to judge each item and each dimension according to the criteria of comprehensiveness, clarity, relevance, and representativeness.

To evaluate, below each dimension, a five-point Likert scale was presented, in which the judges should issue their opinion as: 1 - inappropriate, 2 - partially inappropriate, 3 - indifferent, 4 - partially appropriate, and, 5 - appropriate. Collection of the completed questionnaire and instrument took place within five weeks of delivery.

The data were analyzed by descriptive statistics, and for continuous numerical variables, the Shapiro-Wilk normality test was used to determine the adoption of the mean when the data were normally distributed, and the median when they were not normally distributed.

The content validation occurred by the Content Validity Index (CVI). For this calculation, the number of answers four or five divided by the total number of answers was considered. The index value was considered acceptable for satisfactory content validity when a result of 0.80 or higher was obtained⁽²⁰⁾. Besides the CVI, the binomial test was performed adopting a significance level of 5% (p<0.05), and was used as a reference for the acceptance of the item and the dimension.

This study was approved by the Research and Ethics Committee of the Federal University of Minas Gerais, under protocol number 4.329.008/2020. The consent of the judges was obtained by signing the Free and Informed Consent Term.

Results

Twenty-one nurse judges who worked in Primary or Secondary Health Care in the Central and Midwestern regions of the State of Minas Gerais participated in this study. Regarding socio-demographic, work and educational characteristics, the age of the judges ranged from 30 to 55 years (standard deviation (SD) = 7), median of 36, with 11 (52.4%) \leq 36 years and 10 (47.3%) > 36. 20 (95.2%) were female and 1 (4.8%) was male. The length of professional practice ranged from four to 28 years, median of 9, 11 (52.4%) \leq 9 years and 10 (47.3%) > 9 years.

Regarding post-graduate latu sensu, 17 (81%)

were specialists, five (23.8%) in stomal therapy and one (4.8%) in dermatology. In the *stricto sensu* post--graduation, three (14.3%) had a completed Master's degree, one (4.8) was in progress, and one (4.8) had a PhD.

Regarding the area of work, 18 (85.7%) were from Primary Care and three (14.3%) from Secondary Care. Regarding the position and function performed at the time of data collection, 10 (47.6%) were Care Nurses. Of these, six (28.6%) concomitantly held the coordination position, two (9.5%) the management position and three (14.3%) declared they performed the three functions (care, coordination and management).

Regarding having experience in Primary and Secondary Care, five (23.8%) judges had experience in both points of care. From the total number of judges, 19 (90.5%) had experience in Primary Care, 12 (57.1%) for \leq 7 years and seven (36.8%) >7 years. While in Secondary Care, seven (33.3%) had experience, five (71.4%) \leq 7 years and two (28.6%) >7 years. In Primary Care the time of experience ranged from one to 19 years (SD=5), an average of 7.4 years, and in Secondary Care from one to 20 years (SD=7) an average of 7.8 years.

They were asked about knowing a standardized instrument for the assessment of a patient with a wound. Of all professionals, 12 (57.1%) said they knew and nine (42.9%) denied it. And about using the Nursing Process in clinical practice, in similar proportions, 14 (66.7%) said they used it and seven (33.3%) did not.

Regarding the CVI evaluation of each dimension and items of the instrument on the criteria of comprehensiveness, clarity, pertinence and representativeness, the partial index of each item ranged from 0.95 to one (p<0.05). Table 1 shows the CVI results for each item that composes dimension 1, Nursing History.

Item	Scope*	Clarity*	Relevance and Representativeness*	
1. Color	1	1	1	
2. Religion	1	1	1	
3. Marital status	1	1	1	
4. Has children	1	1	1	
5. Level of education	1	0.95	1	
6. Profession	1	1	1	
7. Occupation	1	1	1	
8. Professional status (currently)	1	1	1	
9. Approximate individual income	1	1	1	
10. Approximate family income	1	1	1	
11. Housing Situation	1	0.95	1	
13. Number of residents	1	1	1	
14. Presence of treated water in the region/residence	1	1	1	
15. Presence of garbage collection in the region/residence	1	1	1	
16. Presence of sewage network in the region/residence	1	1	1	
17. Dietary composition	0.95	0.95	1	
18. Number of meals per day	1	1	1	
19. Dietary restriction due to illness	1	1	1	
20. Dietary restriction due to wound	1	1	1	
21. Daily water intake in ml (5 glasses=11)	1	1	1	
22. Associated Illnesses	1	1	1	
23. Disease that delays wound healing	1	1	1	
24. Continuous medication use	1	1	1	
25. Medication in sporadic use	1	1	1	
26. Topical allergy	1	1	1	

Table 1 - Summary of the content and Content Validity Index assigned by the judges to the items of the dimension - Nursing History (n=21). Belo Horizonte, MG, Brazil, 2021

*Binomial test - p-values<0.05

In table 2, referring to dimension 2, of Anamnesis and Physical Examination, the items presented CVI between 0.95 and one on the criteria of comprehensiveness, clarity, pertinence, and representativeness.

The items in the Wound Assessment dimension scored a Content Validity Index value of one out of 17 items for comprehensiveness, clarity, relevance and representativeness, as described in table 3.

ltem	Scope *	Clarity*	Relevance and Representativeness*	
1. State of consciousness	1	1	1	
2. Emotional state	1	1	1	
3. Family support for the treatment of the injury	1	1	1	
4. Difficulty communicating with the family	1	1	1	
5. Social difficulty to attend the service	1	1	0.95	
6. Understanding of health condition	0.95	1	1	
7. Communication with the nurse	0.95	1	1	
8. Demonstrates a lack of trust in the nurse	0.95	1	1	
9. Mobility	1	1	1	
10. Anthropometric data	1	1	1	
11. Vital signs	1	1	1	
12. Number of injuries	1	1	1	
13. Location/region of injury(ies)	1	1	1	
14. Etiology of the lesion(s)	1	1	0.95	
15. Time of existence of the lesion in months	1	1	1	
16. Reason of appearance of the wound	1	1	1	
17. Pain	1	1	1	
18. Itching complaint	1	1	1	
19. Appearance of the previous bandage	1	0.95	0.95	
20. Lower limb circumference	1	1	0.95	
21. Resting with legs elevated	1	1	1	
22. Waiting time in hours	1	1	1	
23. Edema on the leg	1	1	1	
24. Peripheral Perfusion	1	1	1	
25. Ankle/arm pressure index measurement	1	0.95	0.95	
26. Surgical wound	1	1	1	
27. Time of existence of the surgical wound	1	1	1	
28. Foot evaluation: e.g. tactile/pain/thermal $^{\rm t}$	1	1	1	
29. Pressure ulcer staging	1	1	1	

Table 2 – Summary of the content and Content Validity Index assigned by the judges to the items of the dimension - Anamnesis and Physical examination (n=21). Belo Horizonte, MG, Brazil, 2021

*Binomial test - p-values<0.05; †Represents the grouping of three items related to the feet evaluation

Itom	Scono*	Classity*	Relevance and	
em scope*		Clarity*	Representativeness*	
1. Area size	1	1	1	
2. Depth	1	1	1	
3. Edges	1	1	1	
4. Detaching	1	1	1	
5. Type of necrotic tissue	1	1	1	
6. Amount of necrotic tissue	1	1	1	
7. Type of exudate	1	1	1	
8. Amount of exudate	1	1	1	
9. Color of the skin around the wound	1	1	1	
10. Peripheral tissue edema	1	1	1	
11. Hardening of the peripheral tissue	1	1	1	
12. Granulation tissue	1	1	1	
13. Epithelialization	1	1	1	
14. Total wound area	1	1	1	
15. Wound odor characteristic	1	1	1	
16. Signs of critical colonization in the lesion bed	1	1	1	
17. Signs of infection in the wound base	1	1	1	
*Binomial test - p-values<0.05				

Table 3 – Summary of the content and Content Validity Index assigned by the judges to the items of the dimension - Wound assessment (n=21). Belo Horizonte, MG, Brazil, 2021

Table 4 shows the CVI values for each item in dimension 4, Wound Care, where only item eight was evaluated with a CVI value of 0.95 for the clarity criterion. The other items, were evaluated with a value of one for the three criteria: comprehensiveness, clarity, relevance and representativeness.

Table 4 – Summary of content and Content Validity Index assigned by the judges to the items of the dimension
- Wound care (n=21). Belo Horizonte, MG, Brazil, 2021

Itom		Clarity*	Relevance and	
	Scope	Clarity	Representativeness*	
1. Performing wound cleaning	1	1	1	
2. Collect swab for culture	1	1	1	
3. Request antibiogram	1	1	1	
4. Prescription of antibiotics	1	1	1	
5. Antibiotic use time	1	1	1	
6. Culture result	1	1	1	
7. Antibiogram result	1	1	1	
8. Photographic record with service equipment	1	0.95	1	
9. Hydration of the leg skin	1	1	1	
10. Hydration of the peripheral area	1	1	1	
11. Use of topical corticoid	1	1	1	
12. Covering used	1	1	1	
13. Materials	1	1	1	
14. Compression therapy used	1	1	1	
15. Time spent by the professional to perform the dressing (in minutes)	1	1	1	
16. Occurrence of some adverse event	1	1	1	

Binomial test - p-values<0.05

Some comments were made by the judges in order to improve the understanding of certain items. They were considered by the researchers without changing the content of the instrument. Thus, it was not necessary to carry out a new round of evaluation by the judges and the instrument, considering that the partial CVI of each item was higher than the reference adopted in this study, i.e., 0.80. Thus, the instrument was finalized considering an overall CVI of 0.99; maintaining the dimensions and respective items evaluated: 1 - Nursing History; 2 - Anamnesis and Physical Examination of the Patient; 3 - Wound Assessment; 4 - Wound Treatment (Table 5).

Table 5 – Content Validity Index assigned by judges to the items of the instrument for the evaluation of the patient with chronic wound (n=21). Belo Horizonte, MG, Brazil, 2021

Evaluated aspect	Partial	Average	Global
Evaluated aspect CVI*		CVI	CVI
Nursing History			
Scope	0.99		
Clarity	0.99	0.99	
Relevance and representativeness	1.0		
Anamnesis and physical exam			
Scope	0.99		
Clarity	0.99	0.99	
Relevance and representativeness	0.99		
Wound Assessment			0.99
Scope	1.0		
Clarity	1.0	1.0	
Relevance and representativeness	1.0		
Wound treatment			
Scope	1.0		
Clarity	0.99	0.99	
Relevance and representativeness	1.0		

*CVI: Content Validity Index

With the validated items in the four dimensions, it is possible to generate clinical, care and financial indicators. The clinical indicators (4) consist of: prevalent diseases of patients, etiology of injuries, prevalent microorganisms in infected wounds, and prevalent antibiotics in the treatment of infected wounds.

The care indicators (16): percentage of patients who developed wound infection, percentage of culture tests performed in wounds with infection, adverse events, average time (months) of treatment of patients in the service, average time (months) of patient treatment in the service according to etiology of the wound, percentage of patients submitted to cleansing with saline solution, percentage of patients submitted to cleansing with polyhexamethylene biguanide solution, percentage of patients with record of measurement of the injured area, percentage of wound healing rate by etiology, rate of discharge for healing, rate of discharge for abandonment, percentage of Nursing diagnoses, percentage of patients with venous ulcers receiving compression therapy, percentage of patients with diabetic ulcers receiving foot-specific evaluation, percentage of patients with critical colonization and infection receiving antimicrobial coverage, percentage of patients with wound infection receiving systemic antibiotics.

And the financial indicators (5): overall cost of the service with wound patient care, average cost of wound patient care, cost with compression therapies, cost with interactive dressings, and cost with polyhexamethylene biguanide solution for wound cleansing.

Discussion

This study presents a technology that advances knowledge, because it innovates by proposing a parameterized instrument for assessment of patients with wounds, capable of providing data for the generation of health indicators. The proposed content validation by experienced nurses, who work in the direct care of these patients, confers practical applicability, favoring the construction of a feasible instrument with the reality of the Unified Health System.

The instrument developed was validated by the judges with a high rate of approval for the four dimensions and their respective items, in only one round of evaluation. Validation studies require that the evaluators or judges have expertise in the subject studied and in the area for which the instrument or technology is being created. These professionals are responsible for judging whether or not the items meet the objective they are intended for⁽²¹⁾, and contribute as to understanding, clarity, reliability and applicability⁽²²⁻²³⁾.

This denotes the assertiveness of the instrument designed to meet the needs of nurses in clinical practice. The format of the instrument encourages nurses to develop clinical and critical reasoning, by presenting a broad, detailed and based on guidelines and scientific evidence, and especially in care practice, which guides the investigation and complete evaluation of the patient with wound.

Thus, the content proposed to support the collection of data and compile indicators maintains a consonance with the basic matrix of health indicators and are based on criteria such as relevance to understand the health situation, guide political, social and management decisions of the public health system⁽¹¹⁾. The indicators that are not produced in Primary and Secondary Health Care services in the Brazilian scenario currently.

Therefore, the results of these indicators enable the evaluation of the service and work processes, supporting the improvement of the quality of care. Furthermore, it consists of an instrument that can be adapted and used in different scenarios, considering the peculiarities of each health institution. It also constitutes an instrument that supports nurses in the development of the Nursing Process, providing clinical and critical reasoning to develop and execute the care plan, through the collection of data in a systematized manner.

Data collection instruments aimed at the care of patients with wounds are often built by institutional demands, without evidence support, aimed exclusively at recording the evolution of the wound. They are not built with methodological rigor, do not have peer review, which results in not being used by all professionals. They use their own knowledge, and report the difficulty of implementation due to resistance from the team for its use⁽²⁴⁾. This fact compromises the standardization of records and data that could generate clinical, financial and care indicators within the Unified Health System.

Importantly, almost half of the judges were unaware of the standardized instrument to assess the patient and the wound. However, there was unanimity of opinion on the importance of its existence. This result shows that there is a lack of a well-founded instrument that can cover all the necessary steps for the systemic, careful and standardized assessment of the patient, and that is applicable in Primary and Secondary Health Care⁽⁹⁾.

Therefore, the instrument validated in this study aims to enable the recording and documentation of data in a specific, accurate and standardized manner, to permeate the production of clinical, care and financial indicators. These indicators allow critical analysis by nurses and managers about the service and care provided⁽²⁵⁾.

The indicators proposed in this study can support decision making in treatment, optimization of costs and resources spent in the service, evaluation of quality of care. They also support the determination of possible adverse events and failures that impede patient progress and wound healing, as well as the occurrence of infection and assertive use of antibiotics.

Study limitations

The limitation of this study is the selection of judges by non-probabilistic sampling, using the snowball technique. This method allowed the inclusion of professionals with different levels of education, however, it did not follow a specific criterion of academic and scientific score as commonly occurs in validation studies.

This action, therefore, was necessary to obtain a representative sample of the reality of Primary and Secondary Health Care services. Another limitation is that the judges were selected in Central, Midwestern and Zona da Mata regions of the State of Minas Gerais only. With the occurrence of the pandemic of CO-VID-19, it was not possible to hold a focus group with the committee of judges to discuss the recommendations together, so the synthesis was carried out by the researchers.

Contributions to practice

The validated instrument allows the assessment of the person with a wound in a comprehensive way, which differentiates it from other published tools. Another factor of impact is the presentation of indicators for assessing the clinical, care and financial situation in the two points of care of the Brazilian National Health System.

Conclusion

The study resulted in an instrument composed of four dimensions for the assessment of the chronic wounded patient, in which the items were designed and organized to support the generation of clinical, care and financial indicators for Primary and Secondary Health Care.

The instrument was validated, presenting CVI of each dimension between 0.99 and an overall of 0.99, which demonstrates its successful validation. The items validated in the instrument allow the elaboration of 25 health indicators that can assist in care management and cost management, impacting the quality of care in these services.

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Authors' contribution

Conception and design or data analysis and interpretation: Garcia TF, Borges EL. Writing of the manuscript or relevant critical review of the intellectual content: Garcia TF, Borges EL.

Final approval of the version to be published: Garcia TF, Borges EL, Alonso CS, Abreu MNS.

Agreement to be responsible that all aspects of the manuscript related to the accuracy or completeness of any part of the manuscript are properly investigated and resolved: Garcia TF, Borges EL, Alonso CS, Abreu MNS.

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