

## DERMATOLOGICAL SENSITIVITY ASSESSMENT PROTOCOL FOR PEOPLE WITH ELIMINATION STOMAS

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### ABSTRACT

**Objective:** To build and validate a clinical protocol aimed at evaluating the dermatological sensitivity caused by collection devices and adjuvants used by people with stomas. **Methodology:** Methodological research, developed between 2020 and 2021, for the construction and validation of a dermatological evaluation protocol for people with elimination stomas. The construction of the protocol went through the steps: theoretical situational diagnosis, survey of the theoretical framework and development of the protocol. **Results:** For validation, 21 judges, nurses, with experience in the area of enterostomal therapy, were recruited, whose instrument for content validation evaluated objectives, structure and relevance of the technology, being made available via e-mail through an electronic form on the Google Forms platform. For data analysis, descriptive statistics and the calculation of content validation index were used. A global score of agreement between the judges of 0.92 was obtained. **Conclusion:** It is concluded that the protocol created has a practical basis and validation, application versatility, enabling a care process that is more congruent with the reality of the person with an elimination stoma.

**DESCRIPTORS:** Surgical stomas. Validation study. Dermatitis, contact. Enterostomal therapy.

## PROTOCOLO DE AVALIAÇÃO DE SENSIBILIDADE DERMATOLÓGICA PARA PESSOAS COM ESTOMIAS DE ELIMINAÇÃO

### RESUMO

**Objetivo:** Construir e validar um protocolo clínico direcionado à avaliação de sensibilidade dermatológica ocasionada por dispositivos coletores e adjuvantes utilizados por pessoas com estomias. **Metodologia:** Pesquisa metodológica, desenvolvida entre os anos de 2020 e 2021, para construção e validação de um protocolo de avaliação dermatológica para pessoas com estomias de eliminação. A construção do protocolo percorreu as etapas: diagnóstico situacional teórico, levantamento do referencial teórico e desenvolvimento do protocolo. **Resultados:** Para validação foram recrutados 21 juízes, enfermeiros, com experiência na área de Estomaterapia, cujo instrumento para validação do conteúdo avaliou objetivos, estrutura e relevância da tecnologia, sendo disponibilizado via e-mail por formulário eletrônico na plataforma Google Forms. Para análise dos dados utilizou-se a estatística descritiva e o cálculo de índice de validade de conteúdo (IVC). Obteve-se escore global

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de concordância entre os juízes de 0,92. **Conclusão:** Conclui-se que o protocolo criado possui fundamentação e validação prática, versatilidade de aplicação, viabilizando um processo assistencial mais congruente com a realidade da pessoa com estomia de eliminação.

**DESCRITORES:** Estomas cirúrgicos. Estudo de validação. Dermatite de contato. Estomaterapia.

## PROTOCOLO DE EVALUACIÓN DE SENSIBILIDAD DERMATOLÓGICA PARA PERSONAS CON STOMOS DE ELIMINACIÓN

### RESUMEN

**Objetivo:** Construir y validar un protocolo clínico dirigido a la evaluación de la sensibilidad dermatológica provocada por los dispositivos colectores y adyuvantes utilizados por personas con ostomías. **Metodología:** Investigación metodológica, desarrollada entre 2020 y 2021, para la construcción y validación de un protocolo de evaluación dermatológica para personas con estomas de eliminación. La construcción del protocolo pasó por las etapas: diagnóstico situacional teórico, levantamiento del marco teórico y desarrollo del protocolo. **Resultados:** Para la validación fueron reclutados 21 jueces, enfermeros, con experiencia en el área de Estomaterapia, cuyo instrumento para validación de contenido evaluó objetivos, estructura y pertinencia de la tecnología, estando disponible vía e-mail a través de formulario electrónico en Google Plataforma de formularios. Para el análisis de los datos se utilizó la estadística descriptiva y el cálculo del Índice de Validación de Contenido. Se obtuvo una puntuación global de concordancia entre los jueces de 0,92. **Conclusión:** Se concluye que el protocolo creado tiene base práctica y validación, versatilidad de aplicación, posibilitando un proceso de atención más congruente con la realidad de la persona con ostomía de eliminación.

**DESCRIPTORES:** Estomas quirúrgicos. Estudio de validación. Dermatitis por contacto. Estomaterapia.

## INTRODUCTION

The term *stoma* has a Greek origin, meaning mouth or opening and is used in medicine to indicate the exteriorization of any hollow viscera of the body, for different reasons, causing a deviation from normal transit<sup>1</sup>. The orifice constructed using specific surgical techniques may be temporary or permanent, and this will depend on the characteristics and extent of the disease that generated it<sup>2</sup>. However, regardless of the length of stay, the ostomy is an invasive procedure.

Stomies are classified according to the affected body segment. Urinary elimination ostia are called urostomies; those facing the segments of the intestinal loops are called colostomies when they involve portions of the large intestine, and ileostomies when they have an exteriorization relationship with the small intestine<sup>3</sup>. Other stomies can also be constructed in the patient, such as gastrostomies and esophagectomies, for the purpose of feeding, and tracheostomies, aimed at lung ventilation processes.

Current Brazilian estimates, according to the *Associação Brasileira de Ostomizados* (Brazilian Association of Ostomates), indicate a number of approximately 33,900 patients with stomas, with a predominance of the southeastern region of the country with a number of 17,669 patients and, specifically, in the state of Rio de Janeiro, with 3,000 patients<sup>2,4</sup>.

In recent years, the number of people with some type of ostomy has been growing continuously. Estimates already demonstrate that approximately 120,000 ostomy construction surgeries are performed annually in North America<sup>3</sup>.

In general, these procedures make it possible to promote the treatment or even the cure of patients diagnosed with serious chronic diseases such as: colon and small intestine neoplasms, intestinal inflammatory diseases (ulcerative colitis and Crohn's disease), congenital etiology diseases, trauma from abdominal region, resulting from accidents or injuries by firearms and/or bladed weapons<sup>5</sup>.

Also, according to Selau et al.<sup>5</sup>, intestinal category stomas are the most frequent and the realization of this new physiological path is marked by many challenges. In addition to the change in the elimination pattern, the person will face

changes in daily life, changes in eating habits, reconstruction of beliefs and values and, consequently, changes in quality of life, in the social, physical and psychological spheres.

In addition to the fact of body change, there are aspects related to care for the ostomy, because, regardless of whether it has a temporary or permanent nature, daily management needs to be followed to avoid possible complications. The evaluation of the ostomy and peristomal skin, the collection equipment and the adjuvants used, as well as self-care guidelines are important measures for injury prevention.

It is worth noting that complications related to the ostomy and adjacent regions may occur, such as contact dermatitis, retraction, cutaneous-mucous separation, fistula, parastomal hernia, loop prolapse and stenosis. Among these, dermatitis is the condition most present in the care context that affects most people with a stoma, which injures the area surrounding the stoma, being classified according to its etiology (contact, allergic, trauma and infection) and its intensity ( mild, moderate or severe)<sup>6,7</sup>.

In contact dermatitis, the object of study of this investigation, the lesion occurs due to direct exposure of the skin to irritating substances that are present in effluents, in adhesives for fixing collection equipment and in products used on site, such as soaps and solvents<sup>6,8</sup>.

In this context, care and educational technologies have been considered instruments that facilitate dialogue, strengthen the relationship between patient and professional and form a critical conscience oriented towards a healthy life<sup>9</sup>. Hence the importance of building care technologies that can facilitate and streamline care for people with stomas with regard to building protocols aimed at implementing sensitivity tests for collection and adjuvant equipment.

In this way, this study is based on the need to be able to provide people with stomas with a differentiated form of care, based not only on purely biological elements and from the perspective of the traditional Cartesian model, but, above all, seeking transversal instruments and facilitators who can promote the systematization of care, greater autonomy and the integralization of care. In addition, the research and the consequent validation of the protocol will make it possible to streamline the subject in question and may encourage the development of new developments, reaching groups of patients with ostomies of different etiologies.

The objective of this research was, therefore, to construct and validate a clinical protocol for the evaluation of dermatological sensitivity for people with elimination stomas.

## METHODS

Methodological research focused on the development, evaluation and improvement of an instrument or a strategy that can improve a given methodology<sup>10</sup>. Thus, a clinical protocol was constructed and validated to be used by nurses in the evaluation of dermatological sensitivity in people with elimination stomas. The development of the technology started from gaps in the authors' performance scenario in the laboratory of clinical practice in stomatherapy at the *Universidade Regional do Cariri -URCA* (Regional University of Cariri), Crato, Ceará.

The protocol construction process took place in three stages: theoretical situational diagnosis, theoretical reference survey and protocol development. Therefore, initially, for the viability of the protocol in the practical sphere, an integrative literature review was carried out, which clarified, through the selected studies, the need to develop a technological-educational material for conducting assistance in the follow-up of elimination ostomies. Based on this evidence, a survey of the theoretical framework in the literature was carried out, based on the most recent educational material available by the Ministry of Health on patients with elimination stomas<sup>8</sup>.

Thus, the development of this protocol provides nurses with a tool for prior assessment of the dermatological condition of the person with a stoma, in order to avoid the formation of allergic or irritant contact dermatitis, caused by collectors or adjuvants.

The evaluation script consists of three stages: anamnesis, physical examination and follow-up, seeking to reach all age groups, audiences and different social classes, in the perspective of being a viable, practical and resolving instrument in

each and every health scenario, thus facilitating the work of generalist nurses and those with specific training, whether in the field of dermatology or stomatherapy.

For the validation process, expert judges were selected according to the inclusion criteria: having a degree in nursing, completing a specialization in Stomal Therapy or having a specialist title in Stomal Therapy, experience working in the subject of study, whether in teaching, research or assistance; and the exclusion criterion: not responding to the research instrument within the requested period. The conclusive criterion was considered if the judge already had at least two years of experience in the area.

As for the number of judges, as there is no consensus in the literature for the appropriate number, Pasquali's recommendations were adopted for content validation of 6 to 20 participants<sup>11</sup>. In this perspective, in order to recruit the research judges, 21 participants were recruited from different Brazilian locations, using the snowball technique, whose line of reasoning implies that the researcher's work must be centered on specific groups, enabling the formation of an intentional sample, by judgment, or rational selection<sup>12</sup>. In this research, the specific group directed to the judges was nurses with experience in stomatherapy. Data collection took place from March to April 2021.

The judges were contacted via publicly available email or by the participants themselves who participated in the selection technique sampling. The email was sent with the research presentation letter, highlighting the objectives and relevance of their participation, followed by the elaborated protocol and data collection instrument for validation via an electronic form on the Google Forms platform. The research started with acceptance of the Free and Informed Consent Form, presented as the first part of the form.

The collection instrument for validating the clinical protocol had sociodemographic variables (gender, age, schooling/academic level of training), professional variables (time since training, publications in the field, participation in a research group, guidance for completion of course work, experience in the area of stoma therapy — teaching, research or assistance) and protocol evaluation variables involving the dimensions: objectives, structure and relevance of the technology.

For the dimensions of the elaborated protocol, questions were directed with answers in the Likert scale format, with scores ranging from 1 to 5, being: 1 (no adequacy), 2 (little adequacy), 3 (medium adequacy), 4 (very adequate) and 5 (very suitable). In addition to these objective and punctual answers, the judges had the possibility to give a subjective opinion at the end of each of the dimensions in a space for contributions about the general profile of the protocol.

With regard to data organization and analysis, with regard to sociodemographic and professional variables, the data obtained were formatted in a Microsoft Excel database, version 2019, and analyzed according to descriptive statistics. For the agreement between the judges, the calculation of the content validity index (CVI) was used. This methodology makes it possible to calculate the proportion or percentage of agreement of the judges regarding the evaluation of the categories and dimensions of a given instrument<sup>13</sup>.

Thus, the calculation of the sum of responses with a higher score (4 or 5 for the protocol in question) was calculated for each item in the questionnaire, dividing this value by the total number of responses. A CVI value equal to or greater than 0.80 was considered as the cutoff point to validate the instrument in terms of content<sup>13</sup>.

With a view to the ethical aspects of scientific research, the study was approved by the Research Ethics Committee under opinion number 3,753,247 and CAAE 22423119.0.0000.5055. The judges were previously informed of the research objectives and voluntary participation, with minimal risks and a possible withdrawal at any time of the study, in case they presented or manifested any type of discomfort in relation to the research process.

## RESULTS

### Protocol construction process

The dermatological sensitivity assessment protocol for people with elimination stomas was constructed in three stages (anamnesis, physical examination and follow-up), whose script is described below.

## Stages of the script

### Clinical anamnesis

It is the act of assessing the quality of the patient's skin from a global and mainly dermatological point of view, seeking to identify elements predisposing to alterations or already existing in the first contact. The anamnesis of the protocol is summarized in Table 1. The objective is to avoid the formation of injuries in the short, medium and long term, resulting from the use of collection equipment and adjuvants. If, at the time of the initial consultation, any type of dermal alteration is noticed, must be treated as soon as possible.

**Table 1.** Anamnesis of the dermatological sensitivity evaluation protocol for people with elimination stomas. Crato, Ceará. 2021.

Intervention	Description	Targeting
Clinical anamnesis	Approach general aspects of the patient's life, presence of comorbidities, daily habits, diet, practice of physical activities, the use of licit or illicit substances.	Deal with all elements of the patient's life history, investigating from the earliest age until the moment of consultation. You, a professional, need to listen carefully and not detract from any evaluation point. After global knowledge of the patient, pay attention to their dermatological elements.
Assessment of family history and associated genetic factors	Investigate in the hereditary line whether there have been or are currently having dermatological health problems in family members, especially in those considered of the first degree.	Evaluate whether there are remote or current cases of relatives with dermal sensitivity in the family; if they use any pharmacological or behavioral therapy and level of resolution (control or relapses).
Occupational history	What kind of work does the person currently do? What is the degree of exposure? Use of personal or community protective equipment? Performing unhealthy work?	Investigate whether the work involves handling chemicals, radioactive products, waste (dust). Evaluate type of exposure (daily or sporadic). Identify the presence or absence of PPE protection (which type).
Occupational history (pediatric audience — consider up to 12 years of age)	Evaluate activities developed in the daily context.	For newborns and infants, identify which type of breastfeeding is adopted by the mother. For older children, investigate habits adopted at school (food, water, school products), leisure activities and activities developed and exposure in the home context.
Identification of triggering and neutralizing factors of dermal sensitivity	Dermatological crises are precipitated by triggering elements, that is, triggers that provoke the reaction. On the other hand, there are factors that soften the sensitivity reaction when it is increased.	Identify whether the person has been in contact with cleaning products, caustic products, insect poisons, fabric softeners, perfumes, cosmetics. Type of clothing (fabrics) used or used daily. Use of medications for continuous or sporadic use (special attention to unaccompanied intake). Contact with clean or possibly contaminated water (also investigate its temperature). Food eaten (type and amount). In a sensitivity crisis: the patient makes use of personal measures (breathing and relaxation techniques, use of antiallergics, ointments)
Quality of the dermal reaction	The dermal sensitivity reaction can be graded, based on the degree of exposure to which the patient has been subjected.	Classify the reaction as minor (+), moderate (++), severe (+++).

Professional Attention: For any and all actions, even if there are no alterations in the analyzed points, record your evaluation in the medical record, without forgetting to explain the most significant findings to the patient. Source: Elaborated by the authors.

## Physical examination

The physical examination is one of the essential steps for the outcome of the care, as it is possible to identify the absence or presence of a dermatological injury, especially with regard to the abdominal quadrant that will be submitted to the construction of the elimination ostomy. The physical examination of the protocol is described in Table 2. The objective is to merge the data from the anamnesis, with the identification of the patient's physical findings, regarding the dermatological sensitivity assessment; specifically in the area of ostomy construction. The aim is to anticipate possible changes and/or treat existing ones.

**Table 2.** Physical examination of the dermatological sensitivity assessment protocol in patients with elimination stomas. Crato, Ceará. 2021.

Intervention	Description	Targeting
Total skin assessment	Thoroughly examine the entire dermal extension of the patient, seeking to identify signs of alterations.	In case of presence of alteration of medium and great intensity, request a medical opinion (preferably, specialized training, dermatologist or allergologist).
Specific skin assessment	Focus on the dermatological area, where the ostomy will be made.	Pay attention to any type of dermal alteration present (irritation or allergy). Presence of hair, pimples, blackheads, folliculitis, blisters, pigment spots. In case of absence, monitor dermal evolution on an outpatient basis.
Performing sensitivity tests	Examination to be carried out after exposing the patient's skin to the products that form the basis of the collection equipment (fragment of the hydrocolloid plate).	Perform a dermal provocation test 48 to 72 hours before the elective surgical procedure. In the case of surgeries to create emergency ostomies, perform tests on an outpatient basis, in a specialized sector and with a qualified professional, after the procedure. Use at least three brands of collection equipment as a test, with the aim of establishing comparisons and a greater degree of cutaneous acceptability.
Evaluation of clinical responses	Crucial stage, as the necessary conducts will be delimited from it.	At that moment, the professional will read the test performed, assessing the presence or absence of identified dermatological alterations, such as: pruritus, erythema, edema, intense local sweating.

Professional Attention: For any and all actions, even if there are no alterations in the analyzed points, record your evaluation in the medical record, without forgetting to explain the most significant findings to the patient. Source: Elaborated by the authors.

## Monitoring

The stage, presented in Table 3, corresponds to the moment that encompasses after the completion of the surgical act, going through the postoperative period and culminating in the follow-up consultations, which will take place in a specialized setting, with duly trained professionals, as is the case of the stoma care nurse. The objective is to assist the patient more closely, establishing effective communication and listening, clarifying doubts and implementing assistance actions consistent with each case.

**Table 3.** Follow-up phase of the dermatological sensitivity assessment protocol for people with elimination stomas. Crato, Ceará. 2021.

Intervention	Description	Targeting
General condition assessment	This is the moment of inspection and anamnesis of the patient.	Seek information about the patient's state of health/disease, raising possible complaints, in addition to clarifying how to cope with their current situation.

continue...

Table 3. Continuation...

Intervention	Description	Targeting
Evaluation of the stoma and peristomal skin	Period of performance of the general physical examination and that directed to the ostomy and peristomal skin.	At that moment, the professional needs to carry out a careful physical assessment, focusing on the dermatological elements of the peristomal skin, seeking to highlight elements such as: dermatitis in the peristomal skin; occurrence of granulomas; infections; traumas; maladaptation of the collector equipment in use; reaction to adjuvants.
Change of conduct	In all clinical treatment, post-surgery follow-up and adaptation, depending on the case, may require alterations or changes in its approach.	Once the physical examination has been carried out and alterations are identified, even if they are considered minor, the behaviors that were initially outlined must undergo changes, in order to establish quality of life for the person being assisted. Examples: collection equipment incompatible with the skin; dermal reaction to adjuvant; inadequate cutting of the diameter of the hydrocolloid plate.
Referral to multidisciplinary support	Depending on the clinical and social context of each patient, assistance from other professionals is necessary.	Refer the person for evaluation with the following professionals: social worker, psychologist, nutritionist, lawyer and physical educator. It is worth noting that this referral will take place upon availability of this professional staff and complaints identified in nursing consultations
Return scheduling	It consists of giving periodicity to the follow-up of the patient, according to his clinical condition and his global and specific clinical needs (dermatological complaints related to the collection equipment and adjuvant products in use).	Perform return appointments, according to the need identified in the clinical evaluation of the patient.

Professional Attention: For any and all actions, even if there are no alterations in the analyzed points, record your evaluation in the medical record, without forgetting to explain the most significant findings to the patient. Source: Elaborated by the authors.

## Validation process of the elaborated protocol

The study included 21 nursing judges, with experience in the field of stomatherapy, as shown in Table 4.

According to Table 4, there was a prevalence of female participants (94.6%), with a mean age of 42 years (maximum 62; minimum 26), specialists (42.8%) in the area of expertise or in areas correlated. As for professional activity, the majority had more than 20 years (38%) of Nursing practice and 95.2% worked in the area of Stomatherapy in the care segment or in scientific production.

It was found that stoma therapist nurses actively participated in research groups (76.1%) and had publications in national or international journals with themes related to stoma therapy (52.3%). However, when asked about the guidance of course completion work in the area, 57.3% of respondents did not perform such activity.

Considering the context of the clinical protocol for dermatological sensitivity, the following evaluation profile was obtained according to the recommended calculations for the CVI, shown in Table 5.

**Table 4.** Characterization of the profile of the judges participating in the evaluation of the dermatological sensitivity clinical protocol. Crato, Ceará. 2021.

Variables	Nº	%	CI 95%*
<b>Gender</b>			
Male	2	5.4	0.94–2.0
Female	19	94.6	80.4–99.0
<b>Publication in the field</b>			
Yes	11	52.3	30.3–73.6
No	10	47.7	26.3–69.6
<b>Research groups</b>			
Yes	16	76.1	52.4–90.8
No	5	23.9	9.11–47.5
<b>Guidance on Course Completion Work</b>			
Yes	9	42.8	22.5–65.5
No	12	57.3	34.4–77.4
<b>Studies degree</b>			
Bachelor	1	4.7	0.24–25.8
Graduate specialist	9	42.8	22.5–65.5
Master	7	33.3	15.4–56.8
Doctorate	4	19.2	6.2–42.5
<b>Time experience</b>			
> 1 and < 5 years	2	5.4	0.9–2.0
> 5 and < 10 years	2	5.4	0.9–2.0
> 10 and < 15 years	7	33.3	15.4–56.8
> 15 and < 20 years	2	5.4	0.9–2.0
> 20 years	8	38.0	18.9–61.3
<b>Experience in stomatherapy</b>			
Yes	20	95.2	74.1–99.7
No	1	4.7	0.24–25.8
	<b>Average</b>	<b>SD**</b>	
Age	42	10.1	

\*Intervalo de confiança; \*\*Desvio-padrão. Fonte: Elaborado pelos autores.

Through the representation of the protocol analyzed by judges with expertise in the area, three main dimensions were covered, as mentioned in the study method. The first of them, which concerns the purpose of the built technology, is divided into six categories of analysis, nurses needed to understand the purposes, goals and purposes that they wanted to achieve with the use of this instrument in the care field. In turn, the CVI in this first item was between 0.81 and 1.00.

Regarding the second dimension, structure, the items ranged from the objectivity of the messages to the style of the construct, seeking to extract from the evaluators the perception of versatility and usability of the material in a possible practical care scenario; therefore, the CVI values were in the range of 0.85 to 0.95.

For the last dimension, called relevance, the judge needed to understand the instrument's significance in terms of reality and its implication in the life of a given patient, in addition to assessing its possibility of use as a professional and academic teaching-learning tool. For this block, the CVI value was around 0.85 and 0.95.



**Table 5.** Evaluation of the categories present in the clinical protocol and their respective CVI scores. Crato, Ceará. 2021.

Dimension	Rating category	CVI	Overall CVI
Purpose of technology	Compatibility with target audience	1.00	0.92
	Terminologies	0.95	
	Logical sequence	0.95	
	Linking information with care reality	0.81	
	Promoting behavior change	1.00	
	Circulation in the scientific environment	0.95	
Structure	Objectivity of messages	0.85	
	Information science	0.85	
	Logical sequence of content	0.90	
	Level of understanding	0.90	
	Concordance and spelling	0.95	
	Writing style	0.95	
Relevance	Portrait of key aspects	0.95	
	Approach to the reality of care	0.85	
	Teaching-learning tool	0.95	
Support dimension* - 1	Importance of script creation	1.00	
Support dimension* - 2	Affinity with Evidence-Based Health	0.95	

Caption: \* Dimension that refers to questions with a dichotomous response (yes or no). Source: Elaborated by the authors.

It is worth mentioning that, in the list of evaluative questions with a Likert-type scale, there were two questions with a dichotomous response, which were called Support Dimension 1 and Support Dimension 2, since they brought a unique contribution to the enrichment of the protocol. The first of them was about the importance of creating a script in this segment of assistance to people with an elimination ostomy and, as a result, the judges unanimously understood the need for such technology, thus obtaining a CVI: 1.00. As for the second dimension, the question dealt with the instrument's proximity to current evidence-based practices, and the protocol, once again, reached a significant value among the evaluators' opinions, obtaining a CVI: 0.95.

## DISCUSSION

The use of health technologies, without a doubt, is a great challenge, both in terms of elaboration and operationalization of its construction; after all, the instrument needs to present scientific coherence and also usability, from the perspective of the professional and the patient.

The development of health technology instruments aims to generate questions, unify care actions, provide insights, gather information and clarify doubts about the selected behaviors<sup>14</sup>. Which, in a way, minimizes anxieties and fears, whether on the part of the family or the patient himself.

The construction stage of a technology prototype needs to be closely linked to the type of technology that will be developed<sup>15</sup>. In turn, language adaptation permeates written and spoken content (for the development of audiovisual technologies) and graphic content, so that the communication process can remain open and noiseless.

It is worth noting that, for the object of study related to this research and in view of the various investigative approaches to validity available in the literature (construct validity, content validity, criterion validity and face validity), content validity was adopted, which seeks to systematically evaluate whether the instrument used obeys and complies with the objective of a detailed evaluation regarding the subject in question<sup>16</sup>.

The construction of the clinical protocol for evaluating dermatological sensitivity for people with elimination ostomies aims to ensure not only a directive, scientific and resolute care, but also to offer better comfort, since elimination ostomies generate many stigmas and, if not assisted in a correct, can trigger many complications for the clinical condition of the patient.

In turn, the strategy of implementing the CVI as a point of evaluation of the clinical protocol items was used as a way to quantify the level of agreement of the 21 judges in relation to the three dimensions analyzed. It is noted that the 17 elements studied and critically evaluated by nurses with expertise in the area of stomatherapy presented scores higher than the stipulated minimum value of CVI, and even some items managed to reach maximum CVI, bringing the question and the protocol considered a margin of significance and, at the same time, security. Thus, when there is a positive evaluation, it can be inferred that the professional, when using that tool, will be able to conduct assistance safely and make appropriate decisions.

It is worth noting that the instrument was distributed and analyzed in just one cycle or round, by the judges, with a global CVI of 0.92, making it unnecessary to return for later adjustments (Delphi technique). It is clear that, even in the face of the values achieved through specialized criticism in the area, there will still be the application of the instrument in patients, with the obtaining of evaluative feedback from them, in the sense of identifying whether the tool is in fact achievable from the perspective of the assistance scenario.

Thus, in the validation phase, the internal quality of the health technology must be tested, regardless of the focus or its therapeutic purposes. It should not be forgotten that validity means the hypothetical artifact that the supposed technology will be able to perform the task it proposes to do with the minimum presence of error. Thus, this stage defines how accurate the health technology developed is<sup>15</sup>.

With regard to the technological instrument and its respective phases (anamnesis, physical examination and follow-up), it is noted that the person with an elimination ostomy undergoes preparation in relation to their care. Before implementing any conduct, it is necessary to collect personal and professional information, especially with regard to triggering factors for their complaints. Understanding the patient's history allows the professional to have an overview of the current and past situation to elucidate the problem and subsequent treatment.

In addition to the general life characteristics of the person with a stoma, it was necessary to address in the instrument possible dermatological signs, indicative or triggers of very common sensitivity reactions in daily activities and evident in the presence of some type of elimination stoma. Therefore, prior investigation is necessary in all aspects.

Following the service, there is the implementation of the physical examination, with the purpose of identifying the presence and quality of sensitivity, especially with regard to signs of dermatitis, allergic or irritative, associated with collection or adjuvant equipment. Elements such as blisters, erythema, pruritus, scratches and small fissures are potential indicators of skin tissue injury and triggers of potential problems in the treatment of the person with an elimination ostomy; after all, if the skin is not intact, there is no way to have the adhesiveness of the collection equipment.

The professional stoma therapist or generalist who is conducting the clinical case through the use of the protocol needs to be aware of the physiological and pathological changes, therefore, the examination is one of the most important steps in achieving this assistance, since it directs the adoption of conducts assertions for positive evolution.

For follow-up, the last stage of the clinical protocol, assistance will focus on clinical review elements, always seeking to identify whether the person has any complaints or whether there are visible changes in the ostomy or in the peristomal skin. An important detail lies in the fact that the person being assisted will also be welcomed by other professionals, at the referral level, when necessary. The multidisciplinary care aims to achieve comprehensive care, as needs may arise during the monitoring and treatment of injuries.

Another important factor in the follow-up stage is directly related to changes in behavior initially adopted. Often, and depending on the clinical circumstance, a given intervention may not be beneficial, requiring readjustments. This phenomenon

is very common when the person uses collector equipment of a certain brand that may be causing allergic dermatitis or that has a hydrocolloid plate that wears out very quickly, which does not direct the effluents into the equipment, causing them to fall directly on the skin, causing injuries. Thus, the professional needs to be attentive to the follow-up consultations to direct appropriate care strategies that can promote comfort.

Therefore, the nursing consultation in stomatherapy emerges as a challenge for the nurse, since it requires personalization of nursing interventions adjusted to the specific needs of each person, facilitating the process of their transition and training for self-care with the stoma<sup>17</sup>.

Notwithstanding what was exposed above and according to the dialogue about the construction of technologies, it is necessary to understand that clinical and educational materials with an emphasis on health, constructed and validated, provide educational interventions, based on actions to promote health, strengthen the ability of the health team and the person receiving care to identify their demands and recognize self-care attitudes<sup>18</sup>.

## CONCLUSION

The design and materialization of the protocol are based on three stages: anamnesis, physical examination and follow-up, which are important for the evaluation of the dermatological sensitivity of people with elimination stomas, obtaining practical validation approved by expert judges. The developed protocol could make the care practice more congruent with the reality of these people, however, new studies are suggested that can carry out the evaluation of its effectiveness in clinical practice and the application of the protocol elaborated in different contexts for dialogue between professionals and managers in order to provide care improvement strategies for people with elimination stomas.

## AUTHORS' CONTRIBUTION

**Conceptualization:** Alves DA and Feitosa YS; **Methodology:** Alves DA; Feitosa YS and Sampaio LRL; **Investigation:** Alves DA and Feitosa YS; **Writing – First version:** Alves DA; **Writing – Reviewing and Editing:** Alves DA; Feitosa YS; Sampaio LRL; Sousa FC; Gadelha NAS; Martins RMG; Formiga NPF and Carvalho TB; **Supervision:** Feitosa YS and Sampaio LRL.

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