Construction and validation of an educational booklet for the preparation of healthcare products

Construção e validação de cartilha educativa para o preparo de produtos para saúde

Construcción y validación de un folleto educativo para la preparación de productos para la salud

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ABSTRACT: Objective: To construct and validate an educational booklet for the preparation of healthcare products by the Nursing team at the Materials and Sterilization Center. **Method:** A methodological study was carried out in four stages: situational diagnosis, literature review, construction of the educational booklet and content validation by six expert judges and 13 representatives of the target audience. Data analysis considered the content validity index above 0.80 and the exact binomial distribution test with a significance level of 5%. **Results:** The content validity index showed an average of 0.99. In regard to the target audience, the validation of the educational booklet obtained scores that ranged from 92.3 to 100% across the six evaluation categories. **Conclusion:** A booklet was developed and validated, and it proved to be reliable for use in nursing as an educational tool aimed at preparing healthcare products in the MSC.
Keywords: Teaching materials. Sterilization. Nursing. Validation study.

RESUMO: Objetivo: Construir e validar uma cartilha educativa para o preparo de produtos para saúde pela equipe de Enfermagem no Centro de Materiais e Esterilização. **Método:** Estudo metodológico realizado em quatro etapas: diagnóstico situacional, revisão da literatura, construção da cartilha educativa e validação do conteúdo por seis juízes especialistas e 13 representantes do público-alvo. A análise de dados considerou o índice de validade de conteúdo acima de 0,80 e o teste exato de distribuição binomial com nível de significância de 5%. **Resultados:** O Índice de Validade de Conteúdo apresentou uma média de 0,99. Em relação ao público-alvo, a validação da cartilha educativa obteve pontuação que variou de 92,3 a 100% entre as seis categorias de avaliação. **Conclusão:** A cartilha foi validada e mostrou-se confiável para ser utilizada pela Enfermagem como uma ferramenta de educação voltada ao preparo de produtos para saúde.
Palavras-chave: Materiais de ensino. Esterilização. Enfermagem. Estudo de validação.

RESUMEN: Objetivo: Construir y validar una cartilla educativa para la preparación de productos para la salud el equipo de Enfermería del Centro de Materiales y Esterilización. **Método:** Estudio metodológico realizado en cuatro etapas: diagnóstico situacional, revisión de literatura, construcción de la cartilla educativa y validación de contenido por seis jueces expertos y 13 representantes del público objetivo. El análisis de datos consideró un índice de validez de contenido superior a 0,80 y la prueba de distribución binomial exacta con un nivel de significancia del 5%. **Resultados:** El Índice de Validez de Contenido presentó un promedio de 0,99. En cuanto al público objetivo, la validación del folleto educativo obtuvo una puntuación que oscilan entre 92,3 y 100% entre las seis categorías de evaluación. **Conclusión:** La cartilla fue validada y demostró ser confiable para ser utilizada por la Enfermería como herramienta educativa orientada a la preparación de productos para la salud.
Palabras clave: Materiales de enseñanza. Esterilización. Enfermería. Estudio de validación.

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INTRODUCTION

The Materials and Sterilization Center (MSC) is a unit responsible for indirect support to patients, which processes healthcare products (HP) used in surgical, outpatient and care procedures. This process comprises several steps, which include pre-cleaning, cleaning, inspection, preparation, disinfection or sterilization, storage and distribution[1,2].

Each stage of HP processing carried out by the Nursing team requires the implementation of best practices related to structure, process and results, combined with quality management and health education system. These elements are essential for risk management, aiming for the immediate detection and investigation of any incidents or adverse events that may occur in sterilization centers[1,3]

The MSC plays a crucial role in preventing healthcare-associated infections, combining evidence-based practice, technology, safety and quality. However, when the Nursing team is not trained in the dynamics of HP processing and performs it in an inconsistent and non-standardized way, patient safety may be compromised[3,4].

Considering that providing contamination-free materials at the time of use is one of the crucial measures in preventing infections, the preparation stage gains prominence in HP processing. This phase is responsible for careful inspection of cleaning, functional testing of surgical instruments and preparation of items, including the appropriate choice of packaging to ensure that sterility is maintained[1-4].

In this context, the Nursing team that works in the MSC not only performs usual and recurring activities, but also provides essential technical support to patients, ensuring the preparation of HP in a safe and effective manner. It is imperative that professionals understand the relevance and importance of these processes for patient care. Therefore, educational strategies that strengthen the improvement of MSC professionals should be considered for the dissemination of knowledge, thus contributing to the continuous improvement of quality in the various processes and reinforcing patient safety by guaranteeing the delivery of contamination-free products[4].

It is worth mentioning that health education aimed at preparing HP must be carried out periodically, as this will contribute to appropriate and organized work, in line with the quality of the process. However, the literature is still incipient, and little is explored in investigations on this topic. This is justified by the fact that health services train health professionals using standard operating procedures (SOPs), forgetting to incorporate low-cost teaching materials, for example, the educational booklet, to contribute to the construction of knowledge by the nursing team[4,5].

Study related to the creation and validation of an educational booklet on HP processing included only the technique intended for preparing boxes and trays, excluding issues of biosafety, surface disinfection, preventive and corrective maintenance of equipment in the preparation area and the complexity of the place, which directly affects the effective knowledge of professionals and elucidates the gap in this research[5].

In view of this, the following guiding question arises: "Can the creation of an educational booklet aimed at preparing HP be validated and reproducible for health education for the Nursing team?"

OBJECTIVE

The objective of this study was to develop and validate an educational booklet for the preparation of HP carried out by the Nursing team in the MSC.

METHOD

A descriptive, methodological study was carried out in four stages: situational diagnosis, literature survey, construction of the booklet and validation with experts/target audience. This research was guided by the recommendations of the tool Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)[6].

The situational diagnosis was carried out by the researchers themselves using the nurse's work plan model, authored by the Regional Nursing Council of Minas Gerais (COREN-MG), which provides information on the evaluation of the structure and process of the service[7]. This publication was chosen because it provides support in identifying problems. Direct on-site observation of the Nursing team was carried out during the HP processing stages, from March to April 2023, in the morning and afternoon shifts. The approach was carried out discreetly, aiming to avoid changes in attitudes, with the purpose of deepening the understanding of the MSC routine, identifying the reality of the service and the weaknesses present in the support sector.

The second stage was conducted by the bibliographic survey through a comprehensive literature review, carried out between April and May 2023. A search strategy was used in the Nursing Databases (BDENF), Latin American and Caribbean Literature in Health Sciences (LILACS), MEDLINE via PubMed, Scopus and the Scientific Electronic Library Online (SciELO) platform, with the MeSH descriptors: "Sterilization", "Nursing" and "Methods". In addition, Resolutions from the Collegiate Board of Directors (RDC), manuals from Brazil's National Health Surveillance Agency (Anvisa), international guidelines and books were included. The MeSH descriptors used were: "Sterilization", "Disinfection", "Nursing" and "Teaching Materials", with the help of Boolean operators ("AND" and "OR"). The time frame established was from 2012, justified by the publication of the resolution in force in Brazil[3]. The languages included were Portuguese, English and Spanish.

On the fourth stage, content validation was carried out by expert judges. Six MSC professionals were selected who met the following inclusion criteria: has 5 or more years of experience; works in public, private or philanthropic services, including teaching activities; and has specialization as a minimum qualification.

Data collection was carried out by the researchers themselves from June to September 2023. Participants were chosen by convenience and were invited through invitation letters sent by email or delivered in person. The places where the expert judges worked were:

- Large public teaching hospital, located in the Zona da Mata region, Minas Gerais, which served patients from the Unified Health System (SUS);
- Higher education institution, in which these professionals taught the subject titled "Fundamentals and Technology of Care III", which addressed the processing of HP.

An instrument was used that contained variables aimed at the validation process of the educational booklet, in addition to sociodemographic information. This tool was adapted from previous research found in the literature[8,9]. The questions were accompanied by a Likert scale with scores ranging from 1 to 4, where: 1=item not equivalent; 2=item requires major revision to assess equivalence; 3=equivalent item, requires minor changes; and 4=absolutely equivalent item[10].

Validation with the target audience involved 13 nursing technicians of the 22 invited professionals, with the inclusion criterion being carrying out activities aimed at processing HP. The validated Suitability Assessment of Materials (SAM) instrument was used, consisting of 22 questions subdivided into six categories: "content", "literacy requirements", "illustrations", "layout and presentation", "stimulus/motivation for learning" and "cultural adequacy". All questions had three possible multiple-choice answers: "yes", "partly" and "no"[11].

For data analysis, descriptive statistics and measures of central tendency were used to survey the profile of the expert judges included and the answers completed by the target audience. The content validity index (CVI) was considered satisfactory when it reached a result equal to or greater than 0.80, according to the following formula: number of responses 3 or 4 divided by the total number of responses[9,12]. The exact binomial distribution test, with a significance level of 5%, was used for content validation, considering a proportion of 80% and a statistical significance of $p>0.05$, since the null hypothesis was agreement, as observed in previous studies[-16].

This project was approved by the University Hospital Research Ethics Committee, under Approval No. 5.660.025, on September 22, 2022. All participants read and signed an informed consent form.

RESULTS

In relation to the situational diagnosis, the existence of non-conformities was verified, predominantly in the preparation area. Among the main failures observed, the following stood out: lack of adherence to the use of magnifying glasses during the inspection of instruments; lack of thorough attention to inspection of recesses and racks; negligence regarding biosafety measures, including hand hygiene when handling HP; use of personal protective equipment (PPE); and adherence to SOPs.

Regarding the validation process of the educational booklet, the participants in this study stood out. The age of the expert judges ranged from 31 to 48 years old, with a mean of 38.5 years old (±6.6), with females predominating (83.3%). In relation to degrees, there were specialists (50%), doctors (33.3%) and those with master's (16.7%). Training time ranged from 9 to 21 years, with a mean of 12.6 years (±4.8). Regarding experience working in the MSC, the judges had a minimum of 6 years and a maximum of 10 years, with a mean of 7.6 years (±4.8).

The expert judges' assessment instrument had a total of 18 variables. Most questions received a score of 3 or 4, thus presenting a satisfactory CVI (1.00), with the exception of item 13, equivalent to the number of pages that received a score of 2, obtaining 0.83 in the item's score. It is noteworthy that the global average achieved by the CVI was 0.99 and that there was consensus among the participants, verified by the binomial test ($p>0.05$). This information is presented in Table 1.

Of the total of six expert judges, five suggested changes in the educational booklet. Participants E1 and E6 proposed making the text more objective, explaining that the booklet is for an audience that already has knowledge of many issues relating to HP processing; Furthermore, E1 also suggested the standardization of terms. Regarding the font color, changes were indicated by both E1 and E5. Participant E3 requested the exchange of some images. However, expert judge E4 pointed out the need for inclusion regarding the dispensation of HP for the requesting sectors, which was not accepted as it did not apply to the objective of the study (Chart 1).

The process of validating the educational booklet with the target audience saw the participation of 13 people. Table 2 shows that the majority of responses were "yes", with only one negative response. This resulted in a minimum rating of 92.3% and a maximum of 100%.

The educational booklet was titled "Good practices in preparing health products", measuring 140×210 mm in blue and white. The final product was characterized as the social contribution of this research, being stratified into themes: "introduction"; "good practices in preparation", "biosafety", "hand hygiene", "use of PPE", "cleaning and disinfection of surfaces", "protocol and standard operating procedures",

Table 1. Evaluation items of the educational booklet examined by the expert judges. Juiz de Fora (MG), Brazil (n=6).

Variables	Judges						CVI	p-value*
	E1	E2	E3	E4	E5	E6		
1. The objectives of the educational booklet are consistent with the need to promote the quality of the preparation of HP in the MSC..	4	4	4	4	4	4	1.00	0.26
2. It has the potential to promote changes in behavior and attitude.	4	3	4	4	4	3	1.00	0.65
3. It can circulate in scientific circles.	4	3	4	4	4	3	1.00	0.65
4. The educational material is appropriate for guiding health professionals working in the MSC regarding recommended practices for preparing HP.	4	4	4	4	4	4	1.00	0.26
5. Messages are presented in a clear and objective manner.	4	3	4	4	4	3	1.00	0.34
6. The information presented is scientifically correct.	4	4	4	4	4	4	1.00	0.26
7. There is a logical sequence of the proposed content.	4	4	4	4	4	4	1.00	0.26
8. The material is appropriate for the sociocultural level of the target audience.	4	3	3	4	4	4	1.00	0.65
9. The information is well structured in terms of agreement and spelling.	4	4	4	4	4	3	1.00	0.34
10. The writing style corresponds to the knowledge level of the target audience.	4	3	4	4	4	4	1.00	0.26
11. Information on the front and back cover is consistent.	4	4	4	4	4	4	1.00	0.26
12. The illustrations are meaningful and sufficient.	4	4	3	4	4	4	1.00	0.65
13. The number of pages is appropriate.	4	2	4	4	4	4	0.83	0.65
14. The size of the title and topics is appropriate.	4	4	4	4	4	4	1.00	0.26
15. There is no unnecessary information.	4	4	4	4	4	4	1.00	0.26
16. The themes portray key aspects that must be reinforced.	4	4	4	4	4	4	1.00	0.26
17. The material encourages professionals to acquire knowledge regarding good HP preparation practices.	4	4	4	4	4	4	1.00	0.26
18. It is suitable for use by any healthcare professional in educational activities.	4	3	4	4	4	3	1.00	0.65
Mean CVI: 0.99								

CVI: content validity index; HP: healthcare products; MSC: Materials and Sterilization Center. *p-value using the binomial test.

Chart 1. Summary of suggestions made by expert judges, Juiz de Fora (MG), Brazil.

Judge	Changes suggested
E1	The text needs to be more objective, as the booklet is for MSC workers who already have knowledge of many issues regarding HP processing; standardize the term "healthcare products" (use the acronym HP, if applicable) instead of "materials". The text with the white font on the blue sheet makes it difficult to see, as does the light blue font on the white sheet.
E3	On page 4 there is a scalpel handle with a blade; generally, this type of material is disposable. The text refers to scissors; So, I suggest changing the image of the scalpel handle with blade to scissors. In the CME, we really have to test them, especially when there is a complaint, and provide replacements when necessary.
E4	I suggest including the importance of the demanding sectors obeying the rules/schedules/processes for successful care and dispensing of HP.
E5	I suggest reviewing the coloring of the table described in the "hand hygiene" topic. The color of the font makes it difficult to see the text.
E6	Small adjustments in spelling and structuring of paragraphs, to make it more objective.

MSC: Materials and Sterilization Center, HP: Healthcare products.

Table 2. Target audience responses to the instrument Suitability Assessment of Materials, Juiz de Fora (MG), 2023 (n=13).

Variables	Yes	Partly	No
	n (%)	n (%)	n (%)
1. Is the purpose evident?	13 (100)	0 (0)	0 (0)
2. Does the content cover HP preparation?	13 (100)	0 (0)	0 (0)
3. Does the content focus on the purpose?	12 (92.3)	1 (7.7)	0 (0)
4. Does the content highlight the main points?	13 (100)	0 (0)	0 (0)
5. Is the reading level appropriate?	13 (100)	0 (0)	0 (0)
6. Is active voice writing used?	13 (100)	0 (0)	0 (0)
7. Does vocabulary in the text have common words?	12 (92.3)	0 (0)	1 (7.7)
8. Does context come before new information?	13 (100)	0 (0)	0 (0)
9. Is learning facilitated by topics?	13 (100)	0 (0)	0 (0)
10. Is the purpose of the text illustrations clear?	13 (100)	0 (0)	0 (0)
11. Suitable type of illustrations?	13 (100)	0 (0)	0 (0)
12. Are the figures/illustrations relevant?	13 (100)	0 (0)	0 (0)
13. Lists, tables, etc. Do they have an explanation?	13 (100)	0 (0)	0 (0)
14. Do the illustrations have captions?	12 (92.3)	1 (7.7)	0 (0)
15. Is the layout appropriate?	13 (100)	0 (0)	0 (0)
16. Are the size and font appropriate?	13 (100)	0 (0)	0 (0)
17. Are subtitles used?	13 (100)	0 (0)	0 (0)
18. Is interaction used?	12 (92.3)	1 (7.7)	0 (0)
19. Are the guidelines specific and give examples?	12 (92.3)	1 (7.7)	0 (0)
20. Does the booklet promote motivation for reading?	13 (100)	0 (0)	0 (0)
21. Is it similar to one's logic, language and experience?	13 (100)	0 (0)	0 (0)
22. Are the cultural image and examples adequate?	13 (100)	0 (0)	0 (0)

HP: healthcare products.

"qualification and training of professionals", "preventive and corrective maintenance of equipment", and finally, the references. The themes covered in the educational material were defined after categorizing the results found in the literature review, as well as reading and exploring the bibliographic content selected for this study (Figure 1).

DISCUSSION

In this study, we developed and validated an educational booklet with the aim of improving practices related to HP preparation. This tool used light technology (health education) to guide processes, raise awareness and train MSC

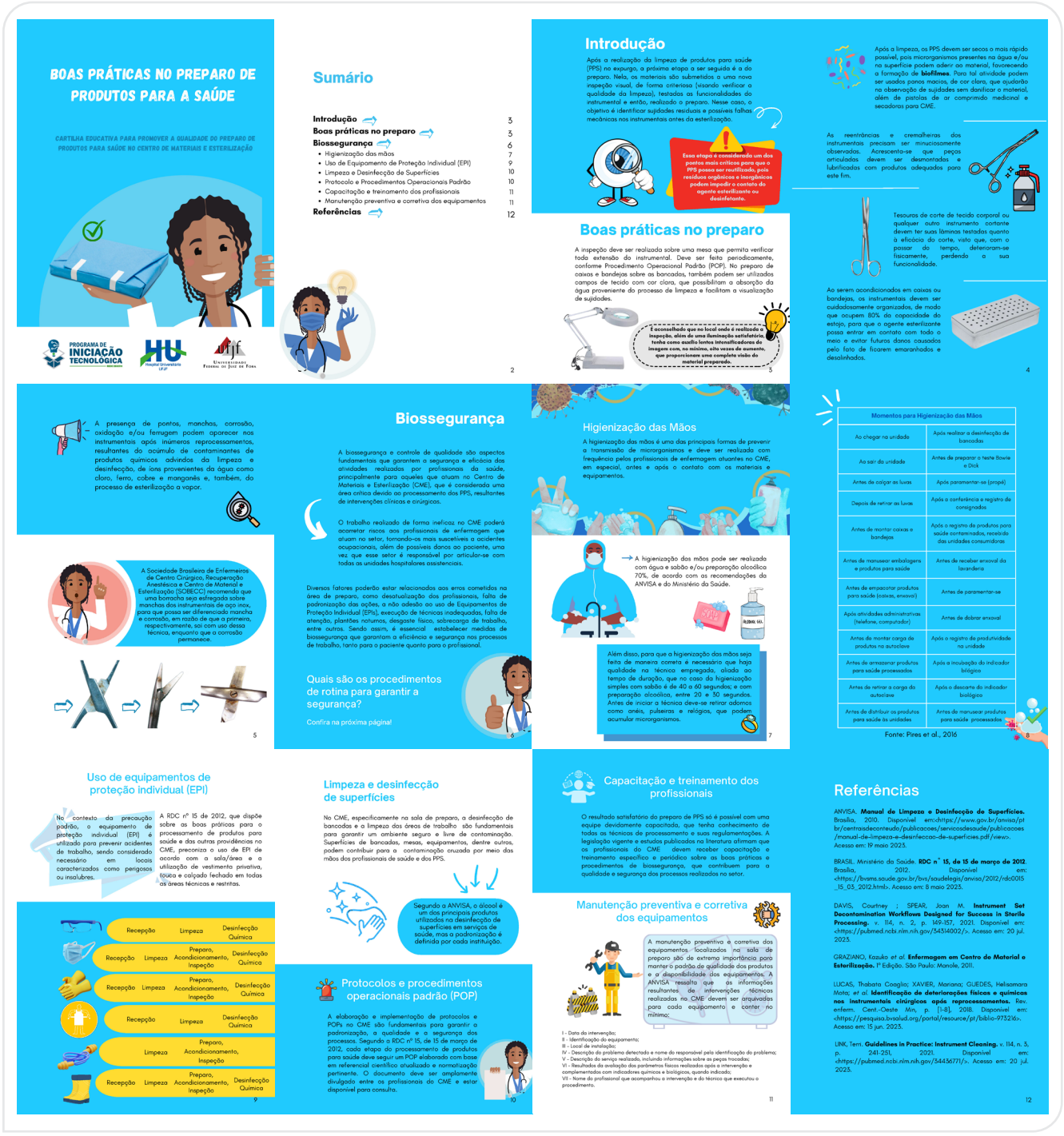

Figure 1. Final version of the educational booklet titled "Good practices in preparing healthcare products", Juiz de Fora (MG), Brazil.

professionals, thus contributing to ensuring patient safety and reducing the number of failures.

Quality control at all stages of HP processing, by following a plan with systematic methods and pre-established criteria, impacts the reduction of incidents and adverse conditions related to the activities of the Nursing team. In this context, it was identified, through situational diagnosis, that the preparation area is more susceptible to errors made by professionals, attributing them to failures in inspection, selection, preparation, packaging and identification of packages to be subjected to disinfection/sterilization[5].

The content presented in the educational booklet transmitted information in a clear and objective manner, as highlighted by expert judges and confirmed by the target audience. Based on this, the material was validated in this study, highlighting its potential for circulation in the scientific community, reproducibility and its usefulness by the Nursing team in educational activities associated with MSC, which benefits the planning of actions aimed at qualification and training in the area of HP preparation[7,17].

The validation process in this study included the participation of experts with extensive experience in the MSC area, which strengthened the reliability of the evaluation process[10]. In relation to all aspects, such as objectives, structure, presentation and relevance, the booklet obtained satisfactory results both with expert judges and the target audience, presenting an overall CVI of 0.99 and a binomial test with $p>0.05$. This demonstrates a consensus among participants, in line with several studies that produced similar results[9,14-17].

Although there was no consensus among researchers on the exact number of experts needed to review and validate instruments, the literature recommends that this process involve five to ten professionals[11]. In this sense, this research managed to meet the recommendation, with the participation of six judges. The importance of having professionals specialized in this area evaluating this type of content is highlighted, as it not only makes the booklet reproducible throughout Brazil, but also offers the opportunity to standardize and formalize the process of preparing HP.

Although the material received good evaluations, the expert judges left some observations and contributions on record. This includes the recommendation to restructure some information, replace and standardize terms, and revise illustrations. These suggestions contribute to the improvement and quality of the educational material intended for the target audience in the final version. It is inferred that these changes will result in the delivery of a more efficient and appropriate technology, in accordance with the suggestions also obtained through the scientific method[7,18].

The validity of the educational booklet with the Nursing team must be considered during the process of construction and development of educational technologies. Researchers demonstrate that the active participation of this population, through observation of their own needs, plays a fundamental role in the development of methodological studies, as it allows the identification of what still needs to be added, what was not understood and the gap between what was addressed and what was effectively understood[19,20]. In this context, the validated tool used in this research (SAM) made it possible to evaluate requirements aimed at more effective communication and interaction between researchers and the Nursing team, obtaining satisfactory results above 92.3%[10].

As limitations of this study, the difficulty in finding articles that addressed the preparation of HP stands out. Furthermore, the participation of the target audience faced withdrawals at the beginning of data collection due to concerns about being evaluated in their work routine, even after explaining the objective of the research and reading the informed consent form. Finally, the way in which participants were chosen based on convenience must be considered, although this did not prevent the achievement of the study objective.

It is believed that the present study is capable of promoting advances in the practice of the Nursing team by providing scientific, care and academic circles with a booklet with an educational approach, aimed at a little explored area such as MSC, which requires new investigations for the advancement of knowledge. It is important to highlight that the educational booklet was not only made available in digital format for professionals in the sector, but was also distributed in physical form, facilitating access to information. It is expected that this constructed tool can be implemented in these support services, which provide health care indirectly to patients. Furthermore, the production cost is low, which benefits professionals in improving applied knowledge.

CONCLUSION

The booklet developed was validated with regard to content and presentation, after a thorough evaluation process by expert judges (nurses) and the target audience (nursing technicians). In this way, the objective of creating and validating an educational booklet on the preparation of HP and its good practices was achieved, marking the first initiative

in this topic. As a result, this tool should be considered an option for the health education strategy, as it could contribute to practical guidance in HP processing and ensure the reduction of incidents and adverse events that compromise patient safety.

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CONFLICT OF INTERESTS

The authors declare no conflict of interests.

AUTHORS' CONTRIBUTIONS

PMS: Conceptualization, Data curation, Writing – original draft, Writing – review & editing, Supervision, Visualization, Validation. ACPCP: Writing – review & editing. LRF: Writing – review & editing. FCC: Writing – review & editing. ALSA: Project administration, Conceptualization, Data curation, Writing – original draft, Writing – review & editing, Supervision, Visualization, Validation.

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