

Design and validation of flowcharts of sterilization processes by professionals

Construção e validação de fluxogramas dos processos de esterilização por trabalhadores

Construcción y evaluación de diagramas de flujo de procesos de esterilización por parte de los trabajadores

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ABSTRACT: Objective: To validate, together with the nursing team of a Sterile Processing Department, the clarity and content of flowcharts of sterilization processes. Method: This is a methodological study carried out in a Sterile Processing Department of a private hospital located in the South region of Brazil. A total of 23 nursing technicians participated in the study. The steps of design and evaluation of the flowcharts took place from May to August 2020. The 17 flowcharts were based on an integrative literature review and were designed using the *Bizagi Modeler Process* tool. Data were analyzed by the content validity index, adopting percentage greater than 90% of agreement as criterium. Results: Eighteen women and five men, mostly aged 22 to 53 years, participated in the research. The average validity index of the flowcharts was 98%. With regard to the suggestions, the importance of establishing flows for daily practice, feasibility for practice, and continuing education were highlighted. Conclusions: By evaluating the flowcharts and the suggestions presented by the professionals, as well as the adaptations requested by them, the flowcharts were deemed validated.

Keywords: Sterilization Nursing Care. Workflow. Validation study.

RESUMO: Objetivo: Validar, com a equipe de enfermagem de uma central de material e esterilização, a clareza e o conteúdo de fluxogramas dos processos de esterilização. Método: Estudo metodológico realizado em uma central de material e esterilização de um hospital privado localizado na Região Sul do Brasil. Participaram da pesquisa 23 técnicos de enfermagem. As etapas de construção e avaliação dos fluxogramas ocorreram no período de maio a agosto de 2020. Os 17 fluxogramas embasaram-se numa revisão integrativa e foram construídos por meio da ferramenta *Bizagi Modeler Process*. Os dados foram analisados pelo índice de validade de conteúdo, adotando como critério percentual superior a 90% de concordância. Resultados: Participaram 18 mulheres e cinco homens majoritariamente de 22 a 53 anos. A média do índice de validade dos fluxogramas foi de 98%. No que tange às sugestões, evidenciou-se a importância de elaborar os fluxos para a prática diária de trabalho, a factibilidade para a prática e a educação continuada. Conclusão: Pela avaliação dos fluxogramas e as sugestões apresentadas pelos trabalhadores, assim como as modificações por eles solicitadas, consideraram-se os fluxogramas validados. **Palavras-chave:** Esterilização. Cuidados de enfermagem. Fluxo de trabalho. Estudo de validação.

RESUMEN: Objetivo: Validar con el equipo de enfermería de un Centro de Material y Esterilización la claridad y contenido de los diagramas de flujo de los procesos de esterilización. Método: Estudio metodológico, realizado en un Centro de Material y Esterilización de un hospital privado, en la región sur de Brasil. Veintitrés técnicos de enfermería participaron de la investigación. Las etapas de construcción y evaluación de los diagramas de flujo se llevaron a cabo de mayo a agosto de 2020. Los procesos de construcción de los 17 diagramas de flujo se basaron en la elaboración de una Revisión Integrativa, y se construyeron a través de la herramienta *Bizagi Modeler Process*. Los datos fueron analizados mediante el Índice de Validez de Contenido, adoptando como criterio el índice superior al 90% de concordancia. Resultados: Participaron 18 mujeres y cinco hombres, en su mayoría con edades entre 22 y 53 años. El promedio del índice de validez de los diagramas de flujo fue de 98. En cuanto a las sugerencias, se evidenció lo siguiente: la importancia de elaborar los flujos para la práctica diaria de trabajo; Viabilidad para la práctica; Educación continua. Conclusión: La evaluación y sugerencias de los diagramas de flujo por parte de los trabajadores y la realización de los cambios solicitados se consideran los diagramas de flujo validados.

Palabras clave: Esterilización. Atención de Enfermería. Flujo de trabajo. Estudio de validación.

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INTRODUCTION

Health services are currently seeking to implement quality management in their processes. Organizational development and the gradual transformation of the culture prevailing in institutions provide new opportunities for continuous improvement¹.

Health organizations have been modernizing and becoming more sophisticated to provide safe health care, as they have new technologies. For this purpose, process management is necessary to improve the performance of organizations and improve techniques and personnel development².

Due to this search for quality and sophistication of surgical instruments, the sterilization of health products becomes relevant, meeting the needs of technological modernization and infection control. It is noteworthy that any failure during reprocessing steps implies a possible compromise of sterility and, consequently, an increase in the risk of infection¹.

The evaluation of these steps is crucial to guarantee their quality. Each reprocessing step must be controlled and periodically evaluated, a guidance also true to the equipment or procedures used to reprocess the products, striving for the safety of users, services, and workers involved^{1,3}.

Due to the need for well-established regulations that cover all steps carried out at the Sterile Processing Department (SPD), the Brazilian Health Regulatory Agency (ANVISA) published a Resolution of its Collegiate Board of Directors, RDC No. 15/2012, which provides for the requirements for good practice in the reprocessing of materials, recommending that, at each step, standard operating procedures (SOP), established based on updated theoretical framework, are met⁴.

Management, in addition to organizing, improving, and controlling, allows mapping the processes by using flowcharts⁵. However, the optimized control of validation and standardization of this work is essential, considering that, nowadays, this does not occur in most Brazilian SPDs. For the effectiveness of the actions, it is necessary to map the flows and processes of the sterilization steps, describing and designing their routines to enable a clear and objective view of the course of the flows, in addition to positively contributing to the organization of the sector in the administrative scope.

In this context, flowcharts are management tools graphically represented by previously stipulated symbols, allowing a clear and precise description of a given process as well as its analysis and redesign^{5,6}.

OBJECTIVES

To validate, together with the nursing team of a SPD, the clarity and content of flowcharts of sterilization processes.

METHOD

This is a study on the design and validation of flowcharts of the sterilization process of materials, in which methodological research was employed⁷. The method was applied in the SPD of a private hospital located in the South of Brazil, where there are more than 200 beds and an average of 500 surgeries performed per month.

The sample was composed of 23 nursing technicians — the nurse did not participate in the study because she was on vacation at the time of the research. The inclusion criteria were: nurses or nursing technicians with at least six months of experience in the sector; and the exclusion criteria were: being on vacation, having a medical certificate or leave of absence during the research period. The participants work at the same workplace as the researcher.

To conduct the study, three steps were followed: theoretical, by an integrative literature review; empirical, by designing the flowcharts of the sterilization process; and analytical, for the evaluation of these flowcharts by the professionals, considering the content validity index (CVI)⁷.

The design and validation steps of the flowcharts by the professionals took place from May to August 2020. Regarding the design, the researchers considered the results of a literature review. As for validation, they followed the provisions of Resolution No. 466/2012 of the National Health Council of the Brazilian Ministry of Health. Workers' participation was accepted upon signing the informed consent form.

In this step, professionals were individually contacted seeking to inform them about the objectives of the project and, in the case of consent, to sign the Informed Consent Form.

The evaluation instrument had five parts: identification data; instructions about the evaluations; evaluation concepts (structure and presentation, clarity and understanding, content, efficiency and consistency, objectivity and relevance); caption of the flowchart symbols; and the charts representing the 17 flowcharts to be evaluated based on the concepts in a Likert scale.

Participants evaluated the flowcharts following a scale containing four grades of assessment (1, 2, 3, and 4), each

assigned to one item, as follows: totally adequate (1), adequate (2), partially adequate (3), and inadequate (4). At the end of the questionnaire, there was a space available for the research participants' contribution.

Next, the researcher collected the evaluations and adapted the evaluated items and the respondents' suggestions. For alterations, the evaluations "partially adequate (3)" and "inadequate (4)" were considered.

Subsequently, a discussion was held with the workers to conclude the evaluations of the flowcharts, which were initially presented as well as a compilation of the suggestions. The discussion was conducted in such a way to allow questioning, learning, and clarification of participants' doubts. The meeting lasted about 30 minutes and was held on each shift, with the presence of 20 professionals — three of them were absent due to being on vacation. Afterward, the flowcharts were adjusted. Finally, the data were analyzed using the CVI, adopting index greater than 90% of agreement as criterium⁸.

Regarding the contribution of the professionals described in the data collection instrument, it was presented and discussed according to the contents reported by them, from which two topics spontaneously emerged: the importance of continuing education concerning the work and standardization of the cleaning process.

This study is part of the macro-project entitled *O cuidado de enfermagem no período perioperatório na perspectiva do ensino, assistência, segurança e gestão* ["Nursing care in the perioperative period from the perspective of teaching, health care, safety, and management"], under approval No. 3,701,031 (CAAE: 96646018.0.0000.0121).

RESULTS

Based on the results of the literature review, 17 flowcharts of the steps of reprocessing health materials were designed using the *Bizagi Modeler Process* tool, in which the formatting and review were assisted by a quality assurance analyst from the hospital. Each flowchart was identified by a number, to which a step corresponded:

1. Macroprocess of sterilization (Figure 1);
2. Macroprocess of the cleaning of medical devices;
3. Manual and automated cleaning of health products;
4. Chemical test of automated cleaning (*All Clean Test*);
5. Chemical test of automated cleaning (cannula test);
6. Cleanliness test – ATP test (Figure 2);
7. Visualization and preparation of materials;

8. Preparation and disinfection of respiratory equipment;
9. Preparation of critical devices to be forwarded to sterilization;
10. Hydrogen peroxide autoclave sterilization process;
11. Autoclave steam sterilization process (Figure 3);
12. Physical sterilization test;
13. Biological test;
14. Class I chemical test;
15. Class II chemical test;
16. Classes IV and V chemical test; and
17. Material storage flow (Figure 4).

A total of 23 nursing technicians participated in the validation step, namely 18 women (78.2%) and five men (21.8%). Regarding the age group, four of them aged 20 to 31 years; eight, 31 to 40 years; seven, 41 to 50 years; and four, 51 to 60 years.

As for time since graduation, ten reported from 1 to 10 years; nine, 11 to 20 years; and four, 20 to 30 years. One professional had a higher education degree; one had an specialization degree; one was taking a Graduate Course in Operating Room, Post-anesthesia Recovery and Sterilization Department; one held a technical degree in pharmacy; and six, in surgical instrumentation.

Finally, as for time working at the study unit, nine workers reported from six months to one year; eight, 2 to 10 years; and six, 11 to 20 years. The values analyzed by the participants according to each evaluated aspect are shown in Table 1.

The average overall CVI of the 17 flowcharts was 98%, an index recorded in a single round with the workers. However, flowcharts 3 and 8 obtained the lowest index in relation to the others. In flowchart 3, the concept of structure and presentation accounted for 86%, and that of clarity and understanding, 86.6%. In flowchart 8, the evaluation reached 91.3%.

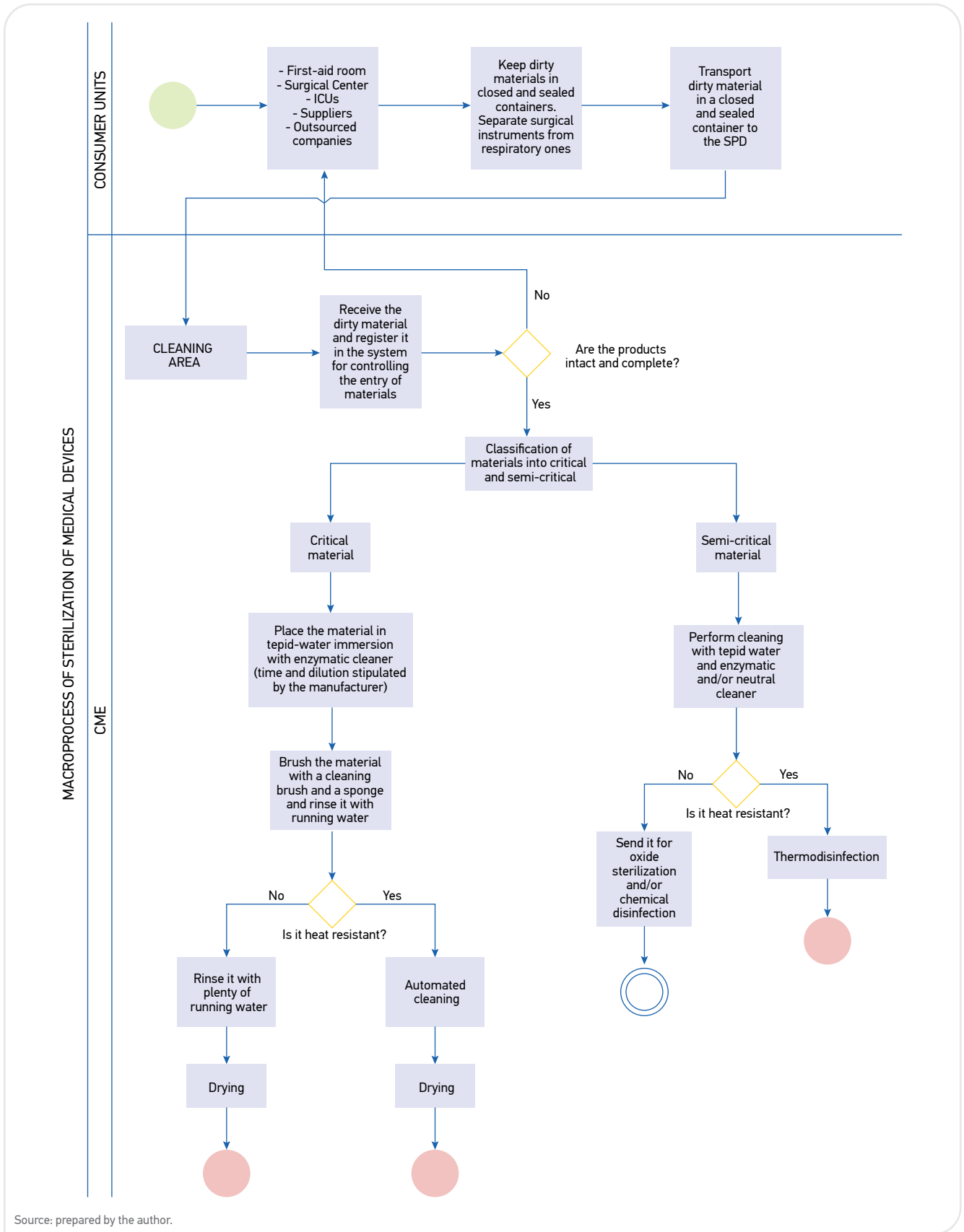
Regarding the items clarity and understanding, followed by objectivity, the surveyed professionals emphasized that the flows guide the work developed by the team, in addition to highlighting the importance of continuing education, considering it a differential to expand and improve the process as a whole:

These flows really help to clarify our day-to-day work, because they are easy to visualize [...] (T1)

Another tool that will provide learning, improvement of our daily practice [...] (T8)

There's a lack of training and qualification courses (T9)

There must be more courses on cleaning materials (T4)



Source: prepared by the author.

Figure 1. Flowchart 2: macroprocess of the cleaning of medical devices

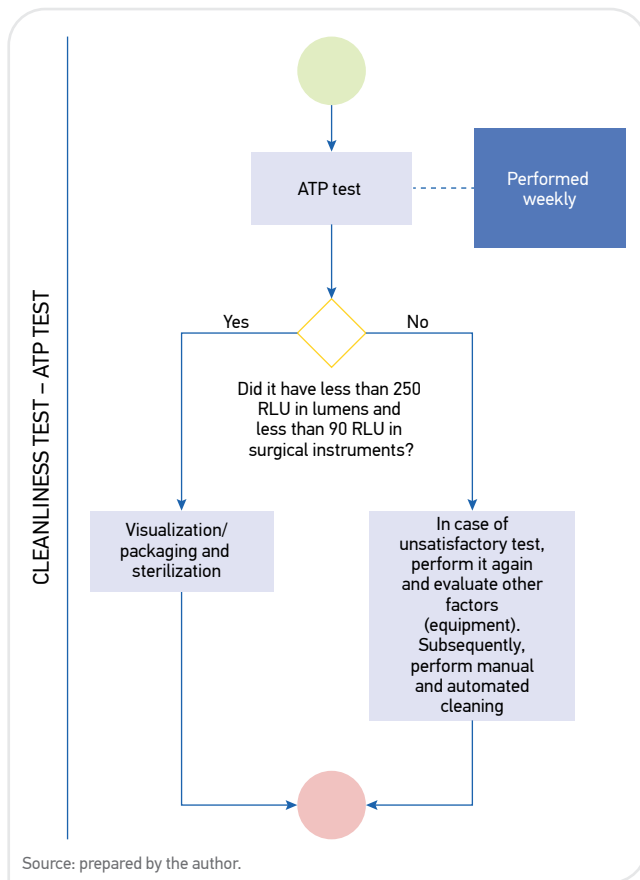


Figure 2. Flowchart 6: cleanliness test (ATP test).

Regarding the content, they stressed the importance of standardizing actions for cleaning the materials, especially the ATP test and including the visualization of this cleaning through a magnifying glass:

We don't usually check the materials with a magnifying glass, sometimes because it is not working or because we're in a rush (T4)

Cleaning standardization is lacking (T6)

ATP testing is extremely important for cleaning effectiveness, but it's not feasible in today's practice (T2)

There's lack of knowledge and training about ATP test (T1)

DISCUSSION

The SPD must meet minimum quality standards aiming at patient safety. To this end, it is highly recommended that health institutions develop actions and establish policies involving structure, processes, and results, always in

accordance with current legislation and good practices, so that the work is effective⁹.

The way of performing the activities developed at the SPD is complex, thus emphasizing the relevance of its validation, as this measure controls quality and consequently prevents infections. In this sense, nursing professionals must adopt national and international regulations and receive training periodically¹⁰.

As for the time working in the sector, most of the respondents had from six months to ten years, similar to the study by Bugs et al., in which 43.75% of professionals had between one and ten years¹¹. Another study shows an average time of eight years working in the SPD, which corresponds to the data presented in our study, demonstrating that the longer the working time, the greater the experience with the activities related to the sterilization process¹².

The time working in the unit may reflect professional maturity, according to which the worker can develop critical awareness and perspective of their processes, especially in a sector such as the SPD, in which there is a smaller contingent adequately equipped to perform their duties. Conversely, in some cases, SPD is sometimes the destination of employees with low qualification and/or at the end of their careers, as well as those with physical and functional limitations, which can lead to work overload of the team and reduced productivity.

The SPD is a fundamental sector in the hospital context, responsible for the distribution of contaminant-free health products, requiring qualified employees. The lack of instrumentalization of some professionals can overburden others, causing disagreements, staff turnover, and repercussions on production, resulting in a negative concept of the work.

A gap in the importance of the work process in this unit is noteworthy, which is often associated with the culture of institutional leadership, the education of professionals themselves, and the lack of continuing education¹¹.

Regarding practice, sterilization must occur in four steps, methodologically and sequentially:

1. Cleaning;
2. Visualization and packaging;
3. Sterilization; and
4. Storage.

All of them are listed in the 17 flowcharts designed and evaluated by the professionals.

Regarding the hygiene of health materials, flowcharts 3 to 6 were designed in such a way to address the risk classification, the manual and automated cleaning methods, and the *All Clean*, cannula, and ATP tests.

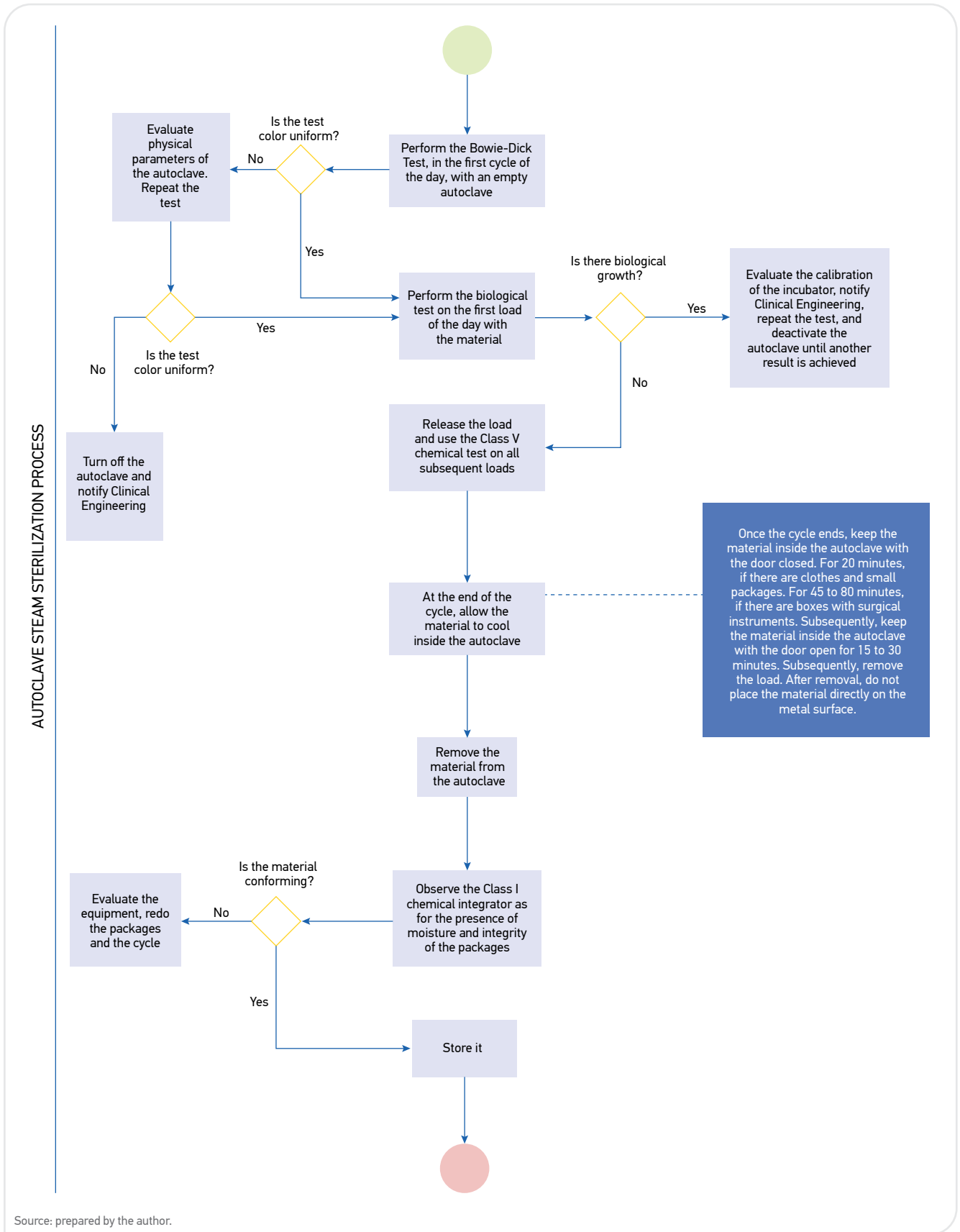


Figure 3. Flowchart 11: Autoclave steam sterilization process

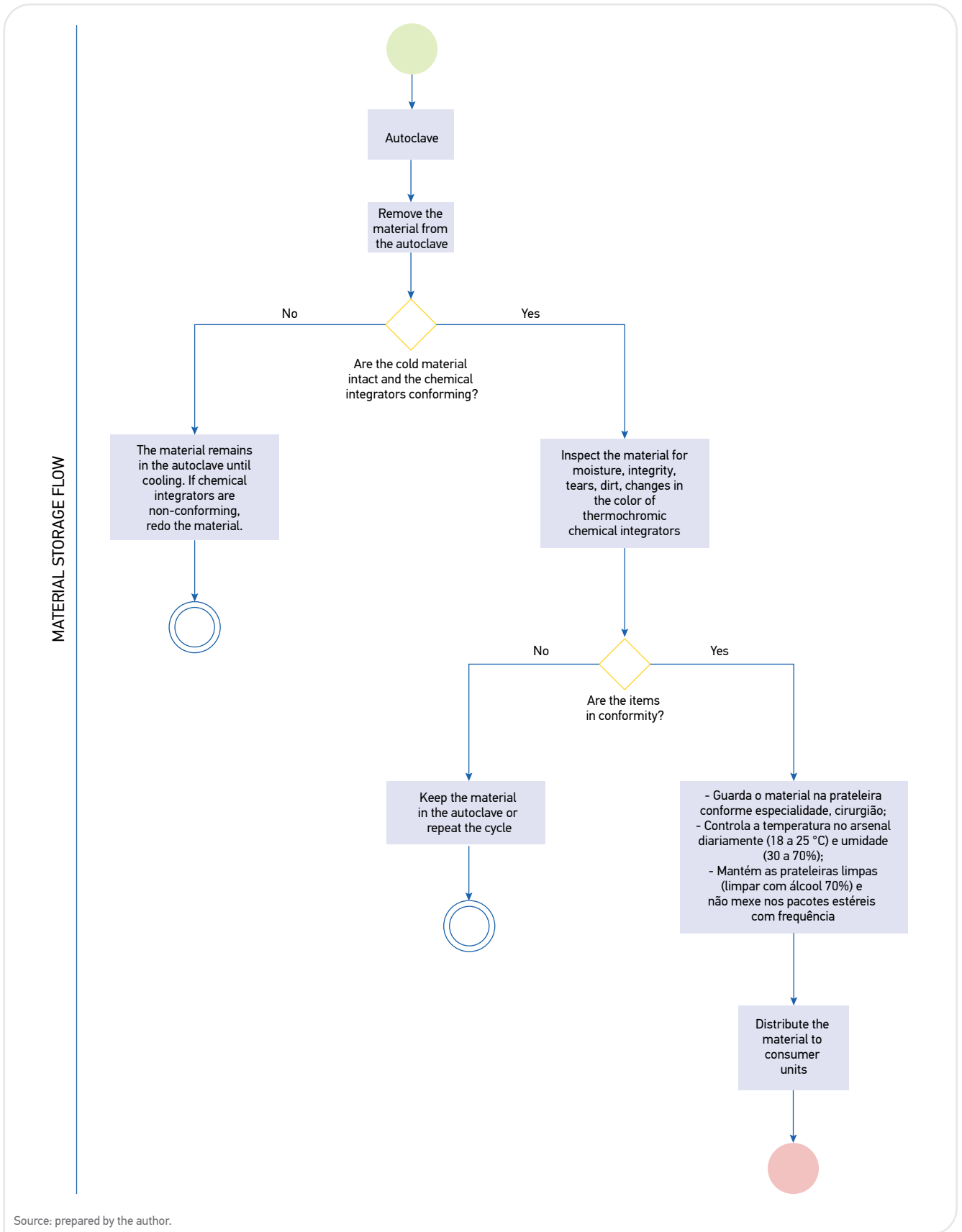


Figure 4. Flowchart 17: material storage flow.

Table 1. Content validity index of the evaluated flowcharts.

Flows	Structure and presentation	Clarity and understanding	Content	Efficiency and consistency	Objectivity	Relevance	CVI
1	95,6	95,1	94,6	95,6	95,6	95,6	95.3
2	99,2	99,2	100	100	100	100	99.7
3	86	86,4	95,1	92,5	91	90	90.1
4	100	100	100	98,9	100	100	99.8
5	95,6	95,6	95,6	95,6	95,6	95,6	95.6
6	99,2	99,2	100	100	100	100	99.7
7	100	100	100	98,5	100	100	99.7
8	91,3	91,3	91,3	91,3	91,3	91,3	91.3
9	98,5	98,5	100	100	100	100	99.5
10	98,5	100	100	100	100	100	99.7
11	100	97,8	100	100	100	100	99.6
12	100	100	100	100	100	100	100
13	100	100	100	100	100	100	100
14	100	98,5	99,2	100	100	100	99.6
15	100	100	100	100	100	100	100
16	98,5	100	100	100	100	100	99.7
17	100	100	100	100	100	100	100

Source: Research data, 2020.

Cleaning consists of removing dirtiness from the instruments, usually using water and validated detergents. Detergents containing enzymes facilitate the breakdown of organic matter, as they are catalyzing substances, which accelerate chemical reactions and can be classified as lipophilic, glycolytic, and proteolytic enzymes. Conversely, neutral detergents have pH between 6.5 and 7.5 and can be used to clean materials with low amount of organic matter. Its use must comply with manufacturers' guidelines regarding dilution water temperature, concentration, and immersion time to ensure its effectiveness¹³.

Due to their design, health products are increasingly complex, making manual cleaning difficult, which is why they require automated complementary action. In this context, a Canadian research states that tests for automated cleaning are the most sensitive and most relevant indicators compared with post-cleaning visual inspection¹⁴. The adenosine triphosphate (ATP) test allows the evaluation of parameters that surpass manual cleaning, ensuring process safety^{15,16}.

Another study indicates that ATP is considered a relevant variable for the monitoring of manual and automated cleaning, demonstrating feasibility to prove decontamination

of surgical instruments, thus deemed a good practice to be disseminated among health services¹⁴. The professionals considered the inclusion of this test in their routine important, but reported not knowing it and/or not being trained to operationalize it.

Concerning visualization and packaging (flowchart 7), the respondents reported not using a magnifying glass to inspect the materials for the presence of organic matter that interferes with the efficiency of the sterilizing agent, according to the guidelines set out in the current protocols. Mechanical faults are another item to be evaluated by using a magnifying glass. Regarding packaging, this study highlights the need for packaging to be standardized and validated^{17,18}.

During sterilization, all microorganisms, including sporulating ones, must be destroyed to such an extent that it is no longer possible to detect them by standard microbiological tests¹⁹. This process must comply with essential criteria so that procedures involving critical devices do not transmit pathogen infections to users. These criteria are validated by chemical and biological tests and according to physical parameters²⁰.

Of all the methods available for sterilization, moist heat in the form of saturated steam under pressure is widely used

and the most reliable one, in addition to being preferable for heat-resistant critical materials¹³.

Flowcharts 12 to 16 address the chemical (class I: zebra thermochromic tape, class II: Bowie-dick; and classes IV and V) and the biological validation processes and physical parameters of the autoclave¹⁸.

Subsequently, there is the storage of the products, which must follow a standard of cleanliness, temperature, and humidity. The storage location must be sized according to the number of beds in the institution²¹.

Therefore, the norms and routine of all sterilization steps must be recorded in documents that guarantee the standardization of the processes, which must be annually reviewed⁴.

Flowcharts are often used to describe and design these routines, as they allow a clear and objective visualization of the course of the production flows and positively contribute to the administrative-organizational process, in addition to being a fundamental tool to plan and improve the process. These are graphic representations that use previously established symbols, with a precise and clear description of the sequencing of the processes^{22,23}.

The situational diagnosis, the estimation of the compliance index, the identification of structural indicators, as well as the procedures applied by nurses in the SPD service, are extremely important for the quality of the processes²⁴.

In this study, the flowcharts were validated by 23 SPD professionals, proving the effectiveness of the process and ratifying the conclusion of similar studies, which had a smaller sample, from 10 to 16 evaluators²⁵.

Researchers at a private hospital in the state of Minas Gerais (Brazil) used the situational diagnosis together with a mapping of the processes with a flowchart to outline the profile of the SPD; they identified nonconformities, generating subsidies to prepare and execute a project to adapt the sector. According to the study's conclusion, the tools were relevant to devise strategies necessary to achieve quality and implement improvements and adjustments, as they enabled in-depth knowledge of the SPD environment and of the processes performed there²⁶.

Regarding the tests to analyze the validation process, the CVI accounted for 98%, a value higher than that recommended by Alexandre and Coluci, who recommend that, with six or more evaluators, the CVI be higher than 0.78²⁷. The validation process is essential to prove the reliability and validity of the instruments, seeking to minimize the possibility of subjective assessments²⁸.

The professionals highlighted the importance of developing tools, such as flowcharts, to support the everyday work, standardizing processes, and making it safer.

Knowing the way of thinking and acting of the involved professionals is imperative, as they are immersed in practice, experiencing the context. One of the quality indicators in the management of health care in health institutions is the reprocessing of products, which is one of the pillars of the prevention of nosocomial infections. A study conducted in public hospitals in the state of Goiás (Brazil) showed that most of them are concerned with parameters dictated by the literature; however, nonconformities were found both in the structure and in the process of cleaning, preparation, sterilization, and storage of products, which may contribute to the failure of processing and posing risk to patients²⁹.

According to the professionals, the lack of instrumentalization was also evident, which interferes with their praxis. Training, production supervision, in addition to professional performance, are relevant indicators established by the Food and Drug Administration (FDA) and which should be adopted in the SPDs³⁰. Training is essential to update these professionals about the new technologies aimed at the SPD, as the sector is characterized as critical and of high complexity, and the presence of poorly trained professionals can result in discrediting nursing actions, in addition to harming patients³¹.

As a limitation of this study, we highlight the lack of internal validation of the flowcharts by the nurse in the sector, due to her absence from work activities during the study period. In addition, the study was not applied to other units for comparison purposes.

The process of validating the flowcharts by SPD professionals contributed to reflect on their praxis, exposing their perspective of the process and their critical sense regarding the activities in the SPD, as they are immersed in the process, conferring the practice more reality and feasibility of the research. It is also worth mentioning that the flowcharts standardize the daily routine of the sector in a simple and effective way.

CONCLUSION

The content validity index for the design and evaluation of flowcharts intended for the sterilization process was 98%, therefore higher than the recommended.

The evaluation on the part of professionals allowed them to expose their view of the process and to critically reflect on their own practice in the SPD.

Studies similar to ours are recommended, addressing the development of applicable sterilization tools by the instrumentalization of professionals working in this sector, as well as the training and improvement of the nursing team.

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None.

CONFLICT OF INTERESTS

The authors declare no conflict of interests.

AUTHORS' CONTRIBUTIONS

AAC: Project management, Formal analysis, Conceptualization, Data curation, Investigation, Methodology, Resources, Writing — original draft, Writing — review & editing, Software, Supervision, Validation, Visualization. JBRG: Project management, Formal analysis, Conceptualization, Methodology, Writing — original draft, Writing — review & editing, Supervision, Validation, Visualization. LFS: Methodology, Writing — original draft, Writing — review & editing, Validation, Visualization. LNA: Methodology, Writing — original draft, Writing — review & editing, Validation, Visualization. AGA: Methodology, Writing — original draft, Writing — review & editing, Validation, Visualization. RW: Methodology, Writing — original draft, Writing — review & editing, Validation, Visualization. JCG: Methodology, Writing — original draft, Writing — review & editing, Validation, Visualization.

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