Validation of nursing activities in a material and sterilization center

Validação das atividades de enfermagem em centro de material esterilizado

Validación de actividades de enfermería en un centro de material esterilizado

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ABSTRACT: Objective: To validate the nursing activities of the diagnosis "Risk of contamination of health products". **Method:** This is an exploratory, descriptive, methodological, validation study, using the model adapted from Fehring. According to predefined criteria, 128 nurses specialized in the surgical center and material and sterilization center participated. An instrument composed of closed questions was used, in which a value according to the Likert scale was assigned to each activity. In this study, activities that presented a content validity index of 0.95 were considered validated. This study was approved by the Research Ethics Committee. **Results:** Twenty nursing activities were validated for 12 risk factors and 5 interventions. The risk factor that was not representative in its activities was "Sterilization of loads without the use of the process challenge device". **Conclusion:** The nursing activities related to the risk factors have been found adequate, since they were validated with a content validity index of 0.95. The knowledge produced helps in the implementation of validated activities, promoting quality care indirectly, based on the principles of patient safety.

Keywords: Sterilization. Validation study. Consensus. Nursing diagnosis. Nursing methodological research.

RESUMO: Objetivo: Validar as atividades de enfermagem do diagnóstico "Risco para contaminação de produtos para saúde (PPS)". **Método:** Trata-se de um estudo exploratório, descritivo, metodológico, de validação, utilizando-se o modelo adaptado de Fehring. Participaram 128 enfermeiros especialistas na área de centro cirúrgico e centro de material e esterilização, segundo critérios predefinidos. Utilizou-se instrumento composto de questões fechadas em que se atribuiu um valor conforme escala Likert para cada atividade. Neste estudo, consideraram-se validadas as atividades que apresentaram índice de validade de conteúdo de 0,95. Estudo aprovado pelo Comitê de Ética em Pesquisa. **Resultados:** Validaram-se 20 atividades de enfermagem para 12 fatores de risco e cinco intervenções. O fator de risco que não obteve representatividade em suas atividades foi "Esterilização de cargas sem o uso do pacote teste desafio". **Conclusão:** Conclui-se que a disposição das atividades de enfermagem relacionadas aos fatores de risco está adequada, uma vez que foram validadas com índice de validade de conteúdo de 0,95. O conhecimento produzido auxilia na implementação de atividades validadas, promovendo um cuidado de forma indireta de qualidade, baseando-se nos princípios da segurança do paciente.

Palavras-chave: Esterilização. Estudo de validação. Consenso. Diagnóstico de enfermagem. Pesquisa metodológica em enfermagem.

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RESUMEN: **Objetivo:** Validar las actividades de enfermería del diagnóstico "Riesgo por contaminación de productos sanitarios". **Método:** Se trata de un estudio exploratorio, descriptivo, metodológico, de validación, utilizando el modelo adaptado de Fehring. Participaron 128 enfermeras especialistas del centro quirúrgico y del centro de material y esterilización, según criterios predefinidos. Se utilizó un instrumento compuesto por preguntas cerradas, donde a cada actividad se le asignó un valor según la escala de Likert. En este estudio, se consideraron validadas las actividades que presentaron un índice de validez de contenido de 0,95. Estudio aprobado por el Comité de Ética en Investigación. **Resultados:** 20 actividades de enfermería fueron validadas para 12 factores de riesgo y cinco intervenciones. El factor de riesgo que no fue representativo en sus actividades fue "Esterilización de cargas sin utilizar el paquete de prueba de desafío". **Conclusión:** Se concluye que la provisión de actividades de enfermería relacionadas con los factores de riesgo es adecuada, una vez que fueron validadas con un índice de validez de contenido de 0,95. El conocimiento producido ayuda en la implementación de actividades validadas, promoviendo indirectamente una atención de calidad, basada en los principios de seguridad del paciente.

Palabras clave: Esterilización. Estudio de validación. Consenso. Diagnóstico de enfermería. Investigación metodológica en enfermería.

INTRODUCTION

The material and sterilization center (MSC) is a technical support unit whose main objective is to supply health products properly processed for the health care of individuals. The processing steps for health products correspond to: cleaning, preparation, sterilization, storage and distribution of the materials to hospital units[1].

The nursing professionals working in the MSC need to develop the skills and knowledge to apply the best practices related to their activity. These professionals are responsible for processing most of the materials used in a health institution. Thus, such activities have a significant effect on the care provided directly to the client[2].

Regarding the processing of health products, the MSC plays an important role in the prevention and control of infections. It needs proper functioning, efficiency and safety in the stages of the work process, in order to provide quality to the sterilized articles, contributing to safe care for the patient and the surgical team[2].

The activities developed at the MSC directly influence health care. A processing failure compromises the sterility of the health products and increases the risk of infections in procedures performed, such as surgeries, dressings and venipunctures[3].

Nursing care is a part of the set of actions performed at the MSC, and there are two established relationships. The first is the direct relationship with infection control, through environment care, and the second refers to the indirect relationship with the patient, given the nature of its connective-activity in the organizational process, whose production is intended for the supply of sterilized equipment and materials to be used in the final activities, in which the nursing care occurs directly in the professional-client relationship.

The nursing intervention is conceptualized as any treatment based on clinical judgment that the nurse will put into practice to achieve the expected results. For the Nursing Interventions Classification: "nursing interventions include both direct and indirect care; assistance aimed at individuals, families and the community; and assistance provided in treatments initiated by the nurse, doctor and other provider"[4].

Direct care intervention is carried out through direct interaction with the patient, while indirect care intervention is carried out from a distance, but benefits the patient or a group of patients. They support the effectiveness of direct care interventions. This definition includes actions aimed at managing the environment of patient care and multidisciplinary collaboration[4].

The phenomenon of interest in nursing interventions is the nursing activity. The interventions represent a grouping or set of separate behaviors or activities. The classification of nursing interventions is used to standardize the activities during the delivery of health care[4].

Thus, to prescribe a nursing intervention, it is necessary to have a nursing diagnosis and a plan of care or activities, so that the expected results may be achieved. They aim to minimize or solve the identified problems.

A study submitted a diagnostic proposal to the appreciation of specialist nurses for content validation, making it possible to identify the nursing diagnosis of "Risk for contamination of articles" from the integrative literature review, as well as the risk factors, the relevance of titles, concepts and arrangement in domains, according to the classification of the North American Nursing Diagnosis Association International (NANDA-I)[5].

It should be noted that the diagnostic proposal used a structure according to NANDA-I, but with an indirect focus on care, which currently prevents it from being inserted as a diagnosis in this standardized language system, but nothing prevents other language systems from using it.

Initially, the diagnosis for which the nursing activities of this study were proposed was labeled "Risk for

contamination of articles"[4], however, with the publication of the Resolution of the Collegiate Board of Directors[1] [*Resolução da Diretoria Colegiada* (RDC)] number 15, on March 15, 2012, it was decided that health products would be used instead of the term "articles", as proposed by the specialists who participated in the research carried out in 2013 and 2019.

The choice of the interventions requires clinical reasoning, and this occurs daily in the work process of the nurses at the MSC in an empiric manner, but without determination of the phases of the nursing process and without documentation with a standardized language.

A definition of the nursing diagnosis, an identification of its risk factors, the interventions/nursing activities for the indirect care in the MSC are necessary in order to characterize the work developed by the nurses in that unit.

OBJECTIVE

Validate the nursing activities of the "Risk for contamination of health products" diagnosis.

METHOD

This article was prepared from data from the first phase of the thesis "Validation of the consensus of nursing interventions for the Material and Sterilization Center", presented to the Graduate Program in Nursing and Biosciences of the Alfredo Pinto Nursing School of the Universidade Federal do Rio de Janeiro on March 27, 2020.

This is an exploratory, descriptive, methodological, validation study using the model adapted from Fehring[6]. This model is based on obtaining expert opinions, which is important in establishing the best clinical practices. Validation is used in some studies with the aim of refining nursing taxonomies, thus establishing links between them and setting standards of practice[6].

The validity represents the degree to which the data measures what they should measure, that is, if the result of a measurement is consistent with the phenomenon being measured[7].

The criteria for selection of the specialists in this study was adapted in order to compose a group of specialists in which the clinical practice of the nurses is one of the mandatory requirements (Chart 1). In this definition, the specialist must have at least four years of clinical practice experience in the area of interest and a minimum total score of nine points[8].

For each year of clinical experience or teaching experience, an extra point was added[8]. Thus, according to the score used, the experts were classified into:

- Junior specialist: minimum score of 5 points, with a mandatory minimum of four years of clinical experience in the specific area of the study;
- Master Specialist: score between 6 and 20 points;
- Senior Specialist: score greater than 20 points; knows as much as a junior or a master specialist, but has years of experience, which allots him senior status[8].

Chart 1. Specialist definition.

Specialist Definition	Punctuation
Clinical experience of at least four years in the field of SC or MSC (mandatory)	4
An extra point was added for each year of clinical experience after the first four years	1 point for each year
Experience of at least one year in clinical teaching in the field of SC or MSC and/or teaching nursing classifications	1
An extra point was added for each year of teaching experience after the first year	1 point for each year
Research experience with published articles on nursing classifications in reference journals	1
Participation of at least two years in a research group in the area of SC or MSC	1
Doctorate in Nursing	2
Master's in Nursing	1
Latu sensu specialization or residency in nursing	1

Source: prepared by the authors.
SC: surgical center; MSC: material and sterilization center.

The specialists were recruited through a curriculum research on the Lattes platform of the National Council for Scientific and Technological Development and also through the "virtual snowball sampling", which comprises the selection of subjects through indication or recommendation of previous subjects[9].

These two techniques are essential to reach the sample of specialists, in order to have enough quantity to assess the equivalence in the validity of the criteria[8,9].

A simple search was performed on the Lattes platform. A search for the keywords "surgical center" and "MSC" in the Subject field returned 559 CVs. The first 390 were analyzed, as it was believed to be the necessary quantity to reach the sample for the study.

Of the 390 analyzed, 132 were excluded, among which one was the own researcher's curriculum and 131 did not meet the predefined specialist criteria.

After the first selection, 258 specialist nurses were contacted via e-mail, with an invitation to participate in the research and the link to access it. Of these, 4 formally declined to participate in the research and 146 responded to the questionnaire, which contained questions to identify the master and senior specialists, pertaining to training and professional performance, in addition to the validation instrument itself. Eighteen specialists who did not meet the pre-established criteria were excluded and the final sample consisted of 128 specialists. This stage took place from January 22 to February 22, 2020.

Figure 1 summarizes and outlines the flow of the selection of the specialist for the sample composition.

Regarding the sample, Fehring[6] recommends a number of 25 to 50 participants. In this study, the formula: $n = Z\,\alpha\,2\,{*}P{*}(1\text{-}P)/e2$ was used to estimate the number of specialists suitable to validate the proposed activities. In which "$Z\,\alpha$" refers to the confidence level adopted, "P" represents the expected proportion of experts indicating the adequacy of each item and "e" represents the acceptable proportional difference in relation to what would be expected[10].

The sample consisted of 128 specialist nurses, with an acceptable sampling error of 5%, a 99% confidence level and a 95% proportion of specialists for validation of the proposed nursing activities[10].

For the specialists to have access to the instrument, the researchers sent an invitation letter by e-mail presenting the objectives of the study, the instructions on how to complete the instrument and a link to access the electronic questionnaire (Google Docs), with immediate opening of the Free and Informed Consent Form, being that its completion was a mandatory condition for access to the other pages of the instrument.

The elaboration of the instrument was based on consulting the recommendations of the Brazilian Association of Surgical Center Nurses, Anesthetic Recovery and Material and Sterilization Center[11] and the Association of periOperative Registered Nurses[12], as well as the current Brazilian regulations of the National Health Surveillance Agency[1].

The instrument consisted of closed questions, in which the experts assigned a value from 1 to 5, on a Likert scale, for each activity. They scored as per their judgment as follows:

1. Strongly disapprove;
2. Disapprove;
3. Undecided;
4. Approve;
5. Strongly approve.

Below each activity, there was a space for suggestions and criticisms.

The final score of the content validity index (CVI) was obtained, it corresponds to the sum of the averages of all the activities, with the exception of items with a score equal to or less than 0.50 (excluded), divided by the total number of activities[6]. In this study, the activities that presented a CVI of 0.95 were considered validated.

The collected data was organized in a spreadsheet generated by Microsoft Office Excel 2010 application.

The project was submitted to the Research Ethics Committee of the Hospital Federal Cardoso Fontes, approved under the Ethical Appreciation Presentation Certificate protocol: 16957219.3.3001.8066.

RESULTS

In this first phase, the sample consisted of 128 specialist nurses who had at least four years of experience in the surgical center (SC) or MSC area. Of these, 62 were classified as master specialists and 66 as senior specialists.

Table 1 presents the characterization of the specialists who participated in the first phase of the research.

Table 2 presents the proposed activities, analyzed by the specialists, for the nursing diagnosis "Risk for contamination of health products". For each risk factor, nursing activities were proposed, as well as its justification and a definition of the empirical reference. The specialists should assign an

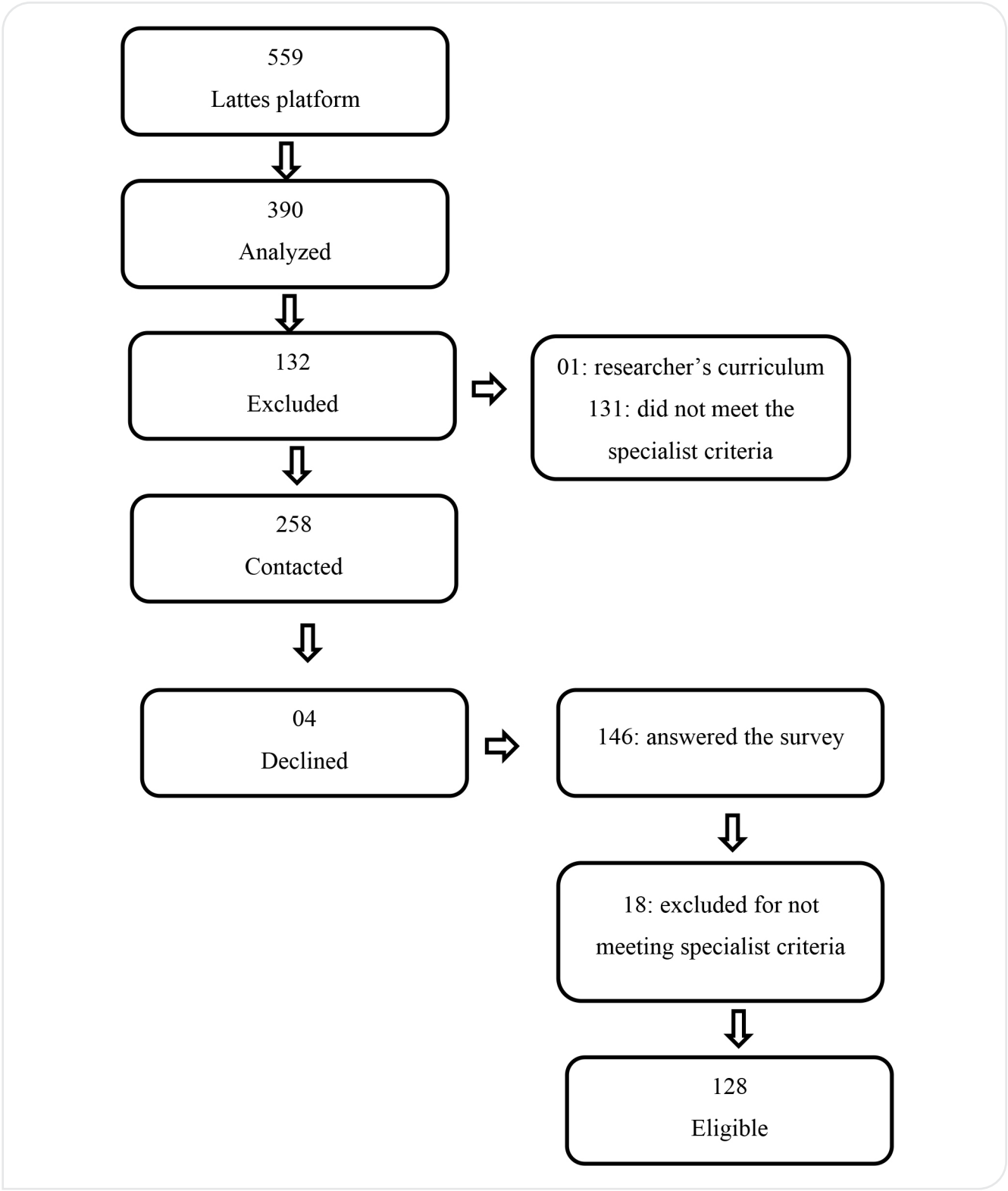

Figure 1. Specialist selection.

evaluative grade based on a Likert scale ranging from 1 to 5, assessing how relevant that activity was for the associated risk factor.

The proposed activities were gathered in five groups of interventions, according to their characteristics. There were 20 nursing activities proposed for 12 risk factors and 5 interventions that were validated, with an average equal to or greater than 0.95.

The risk factor that did not obtain a CVI of 0.95 and was considered unrepresentative in this study was the "Sterilization of loads without the use of the Process Challenge Device (PCD)".

DISCUSSION

The activities validated for the "Cleaning" intervention were: "Perform a careful cleaning of the article" (CVI 0.984); "Perform a visual inspection with an image intensifier lens after cleaning" (CVI 0.979); "Use chemical cleaning monitors" (CVI 0.977); "Complement the manual cleaning of instruments with lumen in an ultrasonic washer" (CVI 0.978), corroborating what is found in other studies[11,13,14].

Good cleaning practices are essential in biofilm removal. When performed improperly and incompletely, the sterilization will not achieve its goal of promoting microbial death. The dirt acts by forming a protective layer on the microorganisms, the biofilm, preventing the action of the sterilizing agent[13].

Monitoring of the cleaning evaluates the presence of organic and inorganic residues in the instruments. Studies recommend performing a visual inspection, with the aid of image intensifying lenses and complemented, when necessary, by chemical monitoring tests[11,14].

For the "Physical, chemical and biological monitoring" intervention, the specialists validated the activities: "Perform the Bowie & Dick test daily for equipment release" (CVI 0.988); "Record the physical parameters of the autoclave cycle" (CVI 0.976); "Reprocess the entire load" (CVI 0.969) — when there is evidence of inadequate physical parameters at the end of the cycle; "Check the condition of the external chemical indicator after the sterilization process" (CVI 0.974); "Perform a biological control of the implant loads" (CVI 0.990); "Use implantable material only after the biological indicator is negative" (CVI 0.989); "Perform biological control of the autoclaves daily" (CVI 0.971); "Interdict equipment until it is possible to carry out its biological control" (CVI 0.953).

Regarding physical, chemical and biological monitoring, good practices recommend[1,11,12,15,16] daily monitoring of autoclaves using the Bowie & Dick test. It detects the presence of air and non-condensable gases inside the chamber. During a sterilization cycle, the presence of air and non-condensable gases represents a threat to the process, as it prevents the steam from reaching the surface of the health products[17].

If the result of the Bowie & Dick test is satisfactory, the equipment is released for use. Thus, the first load with material of the day is processed together with a biological test (biological indicator) [1,11,12,15,16].

The load must be monitored with a process challenge device containing a biological indicator and a chemical indicator type 5 or 6. The release of the processed load occurs after the negative result of the biological indicator[1,11,12,15,16].

It is important to observe the thermochromic reaction of the type 1 indicator, placed externally on the packaging, as well as the physical parameters of the cycles that were mechanically recorded before storing the processed material[1,11,12,15,16].

For the "Package preparation and sterilization" intervention, the specialists considered these activities relevant: "Fill in the label with the name of the product; lot number; sterilization date; use-by date; sterilization method and name of the person responsible for the preparation" (CVI 0.985); "Perform sterilization of the implants using a conventional cycle" (CVI 0.959).

Filling out of the label described in the research follows RDC 15/2012 recommendations, but other literature[5] points to different items from what was proposed, with the absence of some of them.

Table 1. Characterization of the specialists.

Characteristics	Number (%)
Worked in SC or MSC	
SC	62 (48.4)
MSC	66 (51.6)
Length of professional experience in SC and/or MSC	
4–6 years	17 (13.2)
7–9 years	34 (26.6)
10 years or longer	77 (60.2)
Specialist classification	
Master Specialist	62 (48.4)
Senior Specialist	66 (51.6)

SC: surgical center; MSC: material and sterilization center.

Table 2. Activities proposed for the nursing diagnosis "Risk of contamination of health products".

Risk factor	Intervention	Proposed Activities	Weighted Average	Standard deviation
Presence of dirt on the article after cleaning	Cleaning	Carry out careful cleaning of the article	0.984	0.170
		Perform visual inspection with an image intensifier lens after cleaning	0.979	0.156
		Use chemical cleaning monitors	0.977	0.171
Manual cleaning of instruments with lumen	Cleaning	Clean the instruments with lumen in an ultrasonic washer	0.798	0.413
		Complement the manual cleaning of instruments with lumen in an ultrasonic washer	0.978	0.191
Vacuum pump failure	Physical, chemical and biological monitoring	Perform the Bowie & Dick test daily to release the equipment	0.988	0.177
		Request a clinical engineering/maintenance evaluation	0.946	0.177
		Authorize the use of the autoclave after three consecutive Bowie & Dick tests with a negative result	0.875	0.352
Inadequate physical parameters at the end of the cycle	Physical, chemical and biological monitoring	Record the physical parameters of the autoclave cycle	0.976	0.197
		Request a clinical engineering/maintenance evaluation	0.945	0.198
		Reprocess the entire load	0.969	0.227
Chemical indicator failure after sterilization	Physical, chemical and biological monitoring	Check the condition of the external chemical indicator after the sterilization process	0.974	0.197
		Request a clinical engineering/maintenance evaluation	0.907	0.297
		Reprocess the entire load	0.945	0.250
Use of implantable material before the biological indicator result	Physical, chemical and biological monitoring	Perform biological control of the loads with implant	0.990	0.155
		Use implantable material only after a negative result of the biological indicator	0.989	0.167
Use of autoclaves without biological control	Physical, chemical and biological monitoring	Perform biological control of the autoclaves daily	0.971	0.207
		Interdict the equipment until it is possible to carry out the biological control	0.953	0.22
		Use biological indicator readers calibrated at least annually	0.912	0.306
Sterilization of loads without the use of the process challenge device (PCD)	Physical, chemical and biological monitoring	Use a PCD in each processed load (subsequent load control)	0.916	0.315
Packages not identified correctly	Package preparation and sterilization	Properly fill in package labels	0.862	0.377
		Fill in the label according to the institution's routine	0.804	0.411
		Fill in the label with the product name; lot number; sterilization date; use-by date; sterilization method and name of the person responsible for the preparation	0.985	0.159
Cycle implant sterilization for immediate use	Package preparation and sterilization	Perform implant sterilization in a conventional cycle	0.959	0.297
		Prohibit the use of sterilized implants in immediate use cycle	0.952	0.287
Use of autoclaves without periodic preventive and/or corrective maintenance	Maintenance of autoclaves	Request preventive maintenance of autoclaves periodically (according to the institution's routine) and whenever necessary	0.986	0.152
		Interdict the equipment until it is possible to carry out the corrective maintenance	0.958	0.249
		Qualify the autoclave after preventive and/or corrective maintenance	0.921	0.311
Storage of sterile packages in a non-restricted area	Storage and distribution	Store sterile packages in a place with restricted access and environmental control	0.988	0.156
		Perform daily temperature and humidity control	0.984	0.174
Transport of sterile packages in an open transport cart	Storage and distribution	Carry out the transport of sterile packages in a closed transport car, exclusive for this purpose	0.980	0.190
		Use closed boxes to transport sterile materials	0.975	0.201

Each load that contains implantable material must contain a biological indicator for control. The implantable material can only be used after the biological indicator's result is negative. The daily use of the biological indicator in the first cycle and in loads with implantable material is a mandatory condition throughout Brazil[1].

Regarding the "Maintenance of autoclaves" intervention, the activities validated were: "Request preventive maintenance of autoclaves periodically (according to the institution's routine) and whenever necessary" (CVI 0.986); "Interdict the equipment until it is possible to carry out the corrective maintenance" (CVI 0.958).

The preventive maintenance of equipment increases their useful life, reducing costs and promoting improved safety and performance. It's been observed that scarce financial resources have contributed to the restriction of programs for this purpose[18]. The use of maintenance-free equipment is an inconceivable practice, given that it directly impacts patient safety.

And for the "Storage and distribution" intervention, the following activities were validated: "Store sterile packages in a place with restricted access and environmental control" (CVI 0.988); "Perform daily temperature and humidity control" (CVI 0.984); "Carry out the transport of sterile packages in a closed transport car, exclusive for this purpose" (CVI 0.980); "Use closed boxes for the transport of sterile material" (CVI 0.975).

The RDC 15 recommends controlling the parameters of temperature and relative humidity of the air in environments where sterilized material is stored. The literature points out that the recommended values for temperature range from 18°C to 25°C, while humidity ranges from 30 to 70%, but there is no evidence that they promote a negative impact on the maintenance of sterility of the health products[1,19,20].

External events can affect the integrity of the packaging and compromise the sterility of the material, such as proper packaging and handling of materials, packaging and transport. It is essential that the material maintains its sterility until the moment of its use, thus reducing the risk of infection related to health care. For this reason, it is important that the material be transported in cars or closed boxes exclusive for this purpose, mitigating the risk of damage during transportation[1,11,12,15,16].

The non-application of the Delphi technique is admitted as a limitation of this study, which may have contributed to the discussions of the risk activities listed not having been expanded.

CONCLUSIONS

The arrangement of nursing activities related to the risk factors is considered adequate, since 20 nursing activities proposed for 12 risk factors and 5 interventions were validated, with an average equal to or greater than 0.95.

The risk factor that did not obtain validation of its activities in this study was "Sterilization of loads without the use of the PCD". The need for adequacy and a new appreciation is admitted.

The knowledge produced helps in the implementation of validated nursing activities, favoring indirect quality care, based on the principles of patient safety. The evidence contributes to the reduction of knowledge gaps and promotes scientific progress in the area, thus characterizing the relevance of this study.

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CONFLICT OF INTERESTS

The authors declare that there is no conflict of interest.

AUTHOR'S CONTRIBUTIONS

RCSG: conceptualization, data curation, investigation, methodology, resources, writing – original draft. **ACSS:** investigation, methodology. **PEH:** project administration, formal analysis, supervision, validation, visualization. **BMF:** project administration, formal analysis, supervision, validation, visualization. **RBC:** methodology, writing – review & editing, visualization. **TT:** project administration, formal analysis, conceptualization, data curation, investigation, methodology, resources, writing – review & editing, supervision, validation, visualization.

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