Global Academic Nursing Journal

REVIEW ARTICLE

Incidents related to the cleaning of medical items that compromise patient safety

Incidentes relacionados con la limpieza de elementos médicos que comprometan la seguridad del paciente

Incidentes relacionados à limpeza de artigos para a saúde que comprometem a segurança do paciente

Eva Natalina Ferreira Costa[1]
ORCID: 0000-0003-2673-6967
Ivo da Silva Soares[2]
ORCID: 0000-0001-7163-3073
Liane Mendonça Monteiro[3]
ORCID: 0000-0003-0686-9973
Teresa Cristina Brasil Ferreira[4]
ORCID: 0000-0002-4780-0115
Thalita Gomes do Carmo[5]
ORCID: 0000-0002-5868-667X

[1]Universidade Federal do Estado do Rio de Janeiro. Rio de Janeiro, Brazil.
[2]Centro Universitário IBMR. Rio de Janeiro, Brazil.
[3]Universidade Veiga de Almeida. Rio de Janeiro, Brazil.
[4]Hospital Municipal Miguel Couto. Rio de Janeiro, Brazil.
[5]Universidade Federal Fluminense. Rio de Janeiro, Brazil.

How to cite this article:
Costa ENF, Soares IS, Monteiro LM, Ferreira TCB, Carmo TG. Incidents related to the cleaning of medical items that compromise patient safety. Glob Acad Nurs. 2022;3(Spe.1):e236. https://dx.doi.org/10.5935/2675-5602.20200236

Corresponding author:
Eva Natalina Ferreira Costa
E-mail: evacostaferreira@gmail.com

Submission: 03-23-2022
Approval: 04-16-2022

Abstract

The aim was to identify evidence in the literature of the main incidents/adverse events reported due to inadequate processing of health articles. This is an integrative literature review, which used the PRISMA guidelines, and was carried out in the databases: Cumulative Index to Nursing and Allied Health Literature (CINAHL) and International Literature in Health Sciences (MEDLINE/PubMed). From the PubMed database, 42 articles were identified, CINAHL 48 articles were identified, totaling 90 articles. Twenty-six articles from PubMed and 42 from CINAHL were selected for reading, resulting in a total of 68 articles. Among these, 18 PubMed and 35 CINAHL were excluded. Being elected 17 articles, which are part of this review. This study presents data that the Material and Sterilization Center (CME) acts through the implementation of good practices and evidence for recommendations or contraindications for the use of materials used in health services, a function that helps in the process of guaranteeing the quality of care and which is also related to the development of new tools. It is noticed that the MSC plays an important role when it comes to patient safety, a factor that is directly related to the improvement or not of their health status.

Descriptors: Disinfection; Medical Device; Nursing; Cirurgical Instruments; Patient Safety.

Resumén

El objetivo fue identificar evidencias en la literatura de los principales incidentes/eventos adversos reportados por procesamiento inadecuado de artículos de salud. Se trata de una revisión bibliográfica integradora, que utilizó las directrices PRISMA, y fue realizada en las bases de datos: Cumulative Index to Nursing and Allied Health Literature (CINAHL) e International Literature in Health Sciences (MEDLINE/PubMed). De la base de datos PubMed se identificaron 42 artículos, CINAHL se identificaron 48 artículos, totalizando 90 artículos. Se seleccionaron para su lectura un total de 26 artículos de PubMed y 42 de CINAHL, lo que dio como resultado un total de 68 artículos. Entre estos, se excluyeron 18 PubMed y 35 CINAHL. Siendo elegidos 17 artículos, los cuales forman parte de esta revisión. Este estudio presenta datos de que el Centro de Material y Esterilización (CME) actúa a través de la implementación de buenas prácticas y evidencias de recomendaciones o contraindicaciones para el uso de materiales utilizados en los servicios de salud, función que ayuda en el proceso de garantizar la calidad de la atención y que también está relacionado con el desarrollo de nuevas herramientas. Se advierte que el MSC juega un papel importante en lo que se refiere a la seguridad del paciente, factor que está directamente relacionado con la mejora o no de su estado de salud.

Descriptores: Desinfección; Dispositivo Médico; Enfermería; Instrumentos Quirúrgicos; Seguridad del Paciente.

Resumo

Objetivou-se identificar na literatura evidências dos principais incidentes/eventos adversos notificados devido ao processamento inadequado dos artigos para a saúde. Trata-se de uma revisão integrativa de literatura, que utilizou as diretrizes PRISMA, e foi realizada nas bases de dados: *Cumulative Index to Nursing and Allied Health Literature* (CINAHL) e Literatura Internacional em Ciências da Saúde (MEDLINE/PubMed). Da base de dados PubMed foram identificados 42 artigos, CINAHL foram identificados 48 artigos, totalizando 90 artigos. Foram selecionados para leitura 26 artigos da PubMed e 42 da CINAHL sendo selecionados um total de 68 artigos. Dentre estes foram excluídos 18 PubMed e 35 da CINAHL. Sendo eleitos 17 artigos, os quais fazem parte desta revisão. Este estudo apresenta dados de que a Central de Material e Esterilização (CME) atua através da implementação de boas práticas e evidências para recomendações ou contraindicação de uso dos materiais utilizados em serviços de saúde, função que auxilia no processo de garantia da qualidade da atenção e que também tem relação com o desenvolvimento de novas ferramentas. Percebe-se que a CME desempenha uma importância de destaque quando se trata de segurança do paciente, fator que está diretamente relacionado com a melhoria ou não do estado de saúde deles.

Descritores: Desinfecção; Dispositivo Médico; Enfermagem; Instrumentos Cirúrgicos; Segurança do Paciente.

Introduction

Healthcare-associated infections affect 5% to 10% of hospitalized patients, resulting in 99,000 deaths per year in the US at a cost of 20 billion dollars[1].

According to the authors, surgical site infections account for 20% of infections associated with care and health and some were associated with deficiencies in the sterilization process[2-7].

Surgical infections are a major cause of morbidity and mortality in low- and middle-income countries, and rates in these countries are at least twice as high as in high-income countries[8-11].

Factors that may contribute to an increased risk of surgical site infections in low- and middle-income countries are late patient presentation, ineffectiveness of antimicrobial agents, poor perioperative infection prevention practices, and variable postoperative care routines[12-14].

A third of hospitals have deficiencies in the reprocessing of surgical instruments. The Material and Sterilization Center (CME) is the "Functional unit located in the health services for the processing of health products", which has cleaning as a fundamental step in the process. Cleaning is considered the most important step in the surgical instrument processing cycle, especially because it influences the effectiveness of sterilization[12,15-17].

The Brazilian Society of Surgical Center Nurses, Anesthetic Recovery and Material and Sterilization Center understands as cleaning the removal of visible dirt - organic and inorganic - and, therefore, the removal of the microbial load, constituting an essential and indispensable step for the processing of all medical and hospital articles. Studies have shown that this phase removes approximately 10^{-6} (logs) of the microbial contingent present in materials and surfaces[18].

Medical equipment cleanliness is among the 10 most common compliance errors and the Centers for Medicare and Medicaid Services (CDC) and the Joint Commission International (JCI) reported that 1/3 of hospitals have deficiencies in the reprocessing process[15].

Process efficiency depends on several factors such as article complexity, water quality, quality of cleaning agents, handling, cleaning method, rinsing and drying. This step follows disinfection and sterilization, as the non-removal of organic and inorganic residues forms a physical barrier against the action of disinfectants and sterilants, thus compromising the effectiveness of processing[19].

Due to the complexity of the process, notifications from the Food and Drug Administration (FDA) have identified cases of instruments that were reused without being properly cleaned and sterilized. Eighty reports of inappropriate reprocessing were received between 2007 and 2010 and 28 cases of infection may have occurred. Outbreaks or incidents related to improper reprocessing of endoscopes have recently highlighted the urgency of ensuring excellence in sterilization practices[20].

Therefore, this article aims to identify in the literature evidence of the main incidents/adverse events reported due to inadequate processing of health articles.

Methodology

This is an integrative literature review, which used the PRISMA guidelines, and was carried out in the databases: Cumulative Index to Nursing and Allied Health Literature (CINAHL) and International Literature in Health Sciences (MEDLINE/PubMed). The first search was carried out on May 17, 2021, with no time cutout.

This type of study includes the analysis of relevant research that supports decision-making and the improvement of clinical practice, enabling the synthesis of the state of knowledge on a given subject. It also allows pointing out knowledge gaps that need to be filled, in addition to containing the synthesis of published studies with general conclusions regarding a particular area of study[21].

The integrative review also provides the synthesis of knowledge and the applicability of the results of significant studies in practice. It involves the steps of the scientific method, such as definition of the research problem, search for information in the literature, critical evaluation of the included studies and identification of the applicability of the collected data[22].

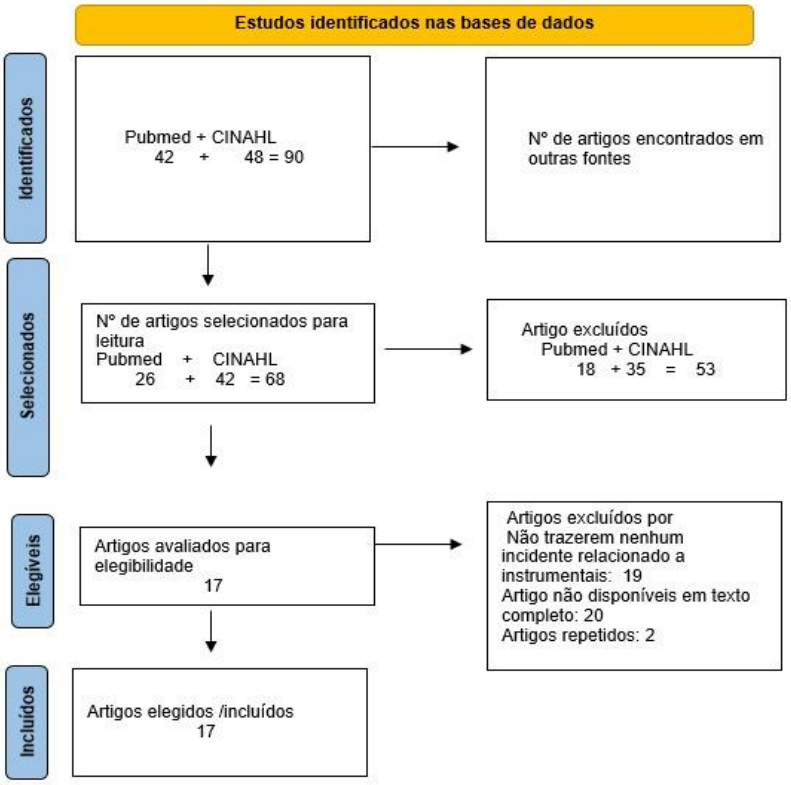
In the first step, the research question was formulated "What is the evidence in the literature about errors in cleaning reusable health instruments or devices that compromise patient safety?" and the inclusion criteria for the studies were defined: articles searched in PubMed databases; CINAHL; use of the following keywords/descriptors: Disinfection AND Surgical Instruments OR Medical Devices AND Patienty Safety AND Nursing, as seen in Chart 1.

From the PubMed database, 42 articles were identified and from the CINAHL database, 48 articles were identified, totaling 90 articles. Twenty-six articles from PubMed and 42 articles from CINAHL were selected for reading, resulting in a total of 68 articles. Among these, 18 and 35 were excluded from PubMed and CINAHL, respectively. Therefore, 17 articles were chosen, which were included in this review. In this step, the PRISMA[23] flowchart below was used.

Chart 1. Descriptors. Rio de Janeiro, RJ, Brazil, 2021

Descrpitors	Portuguese	English	Spanish
P (Patient or problem)	Instrumentos Cirúrgicos	Surgical Instruments	Instrumentos Quirúrgicos
I (Intervention)	Desinfecção	Disinfection	Desinfección
Co (Context)	Segurança do Paciente	Patient safety	Seguridad del paciente

Figure 1. Flowchart of search and selection of studies. Rio de Janeiro, RJ, Brazil, 2021



For data collection, an instrument containing the items author/title, year/country of the journal/database was used. In the evaluation phase of the chosen studies, the full reading was carried out in search of evidence on the reported incidents related to the processing/cleaning of health articles/medical devices.

Some factors affect the ability of medical devices to clean effectively and should be considered before cleaning. Therefore, the cleaning process for a medical device depends on the following factors: instructions for use written by the device manufacturer; cleaning the surface of the equipment/device, if the device was possibly exposed to prions; features or design of the equipment/device; other characteristics or type and concentration of the cleaning product; duration and temperature of exposure to the cleaning product; and physical properties of the reprocessing environment[24].

Results and Discussion

Chart 2 presents the selected studies.

Chart 2. Selected studies. Rio de Janeiro, RJ, Brazil, 2021

Authors	Title	Year	Country	Journal	Data base
Seavey	High-level disinfection, sterilization, and antisepsis: Current issues in reprocessing medical and surgical instruments	2013	USA	American Journal of Infection Control	PubMed
Franklin Dexter, MD, PhD, FASA, * Michelle C. Parra, MD* Jeremiah R. Brown, PhD, and Randy W. Loftus, MD	Perioperative COVID-19 Defense: An Evidence-Based Approach for Optimization of Infection Control and Operating Room Management	2020	USA	International Anesthesia Research Society	PubMed
ML, Ching P, Widitaputra A, Stewart A, Sirijindadirat N, Thu	APSIC/ Asia Pacific Society of Infection Control. Guidelines for disinfection and sterilization of instruments in health care facilities	2018	SINGAPORE	Antimicrobial Resistance Infection Control.	PubMed
Myrtede Alfred ,1 Ken Catchpole ,1 Emily Huffer,2 Larry Fredendall,3 Kevin M Taaffe2	Work systems analysis of sterile processing: decontamination	2019	USA	BMJ Qual Saf	PubMed
Evangelista S de S, dos Santos SG, de Resende Stoianoff MA, de Oliveira AC	Analysis of microbial load on surgical instruments after clinical use and following manual and automated cleaning	2015	BRAZIL	American Journal of Infection Control	PubMed

Forrester JA, Powell BL, Forrester JD, Fast C, Weiser TG	Surgical Instrument Reprocessing	2018	USA	Surgical Infections	PubMed
Cowperthwaite L, Holm RL	Guideline Implementation: Surgical Instrument Cleaning	2018	USA	AORN jornal	PubMed
Cloutman-Green, Melisa Canales, Qizhi Zhou, Lena Ciric, John C. Hartley MRCP, FRCPath a, Gerald McDonnell BSc,	Biochemical and microbial contamination of surgical devices: A quantitative analysis	2015	USA	American Journal of Infection Control	PubMed
Malchesky PS, Chamberlain VC, Scott-Conner C, Salis B, Wallace C.	Reprocessing of Reusable Medical Devices	1995	USA	ASA/O /journal	PubMed
Hut A, Yildirim D, Donmez T, Tatar C, Mirapoglu S, Erdogan RN, Isık Saglam ZM, Kilincaslan H	The Effect of Sterilization Methods of Endoscopic Instruments on the Body: A Study on Rat Model	2018	TURKEY	Journal of Investigative Surgery	PubMed
Ellen Evashwick; Sylvia Cumplido; Glen Eleby; Teresa Washington; Sneha Krishna; Alicia Hammonds-Reed; Sharon Fawcett; Michael Ben-Aderet; Jonathan Grein.	A Tale of Two Departments: How Collaboration Between Infection Prevention and Sterile Processing Departments Can Improve Patient Safety	2019	USA	APIC 46th Annual Educational Conference & International Meeting|	CINAHL
Jose A. Rodriguez, Gwendolyn Hooper	Adenosine Triphosphate-Bioluminescence Technology as an Adjunct Tool to Validate Cleanliness of Surgical Instruments	2019	USA	AORN Journal	CINAHL
Tyronne Johnson	Decontamination 101 Point-of-Use Cleaning, Containment and Transporting Contaminated Surgical Instruments	2019	USA	The Surgical Technologist	CINAHL
Sharon Greene-Golden, Crcst, Fcs	Creutzfeldt-Jakob Disease: Perioperative Team Collaboration for Patient Safety	2014	USA	AORN JOURNAL	CINAHL
Nancy Chobin	Surgical Instrument Decontamination: A Multistep Process	2019	USA	AORN JOURNAL	CINAHL
Síntia de Souza Evangelista MSc a, Nat alia Rocha Guimaraes MSc b, Naiara Bussolotti Garcia BS a, Simone Goncalves dos Santos PhD b, Adriana Cristina de Oliveira	Effectiveness of manual versus automated cleaning on Staphylococcus epidermidis biofilm removal from the surface of surgical instruments	2019	BRAZIL	American Journal of Infection Control	CINAHL
Yuhei Saito, MS; Hiroshi Yasuhara, MD, PhD; Satoshi Murakoshi, MD, PhD; Takami Komatsu, MD, PhD; Kazuhiko Fukatsu, MD, PhD; Yushi Uetera,	Priority of Patient Safety Associated With Robotic Surgical Instruments	2017	JAPAN	Infection control & hospital epidemiology	CINAHL

The CME aims to be a support unit for all other services and other units, guaranteeing the quality of health instruments and promoting patient safety, thus reducing the risks of damage[25]. Several factors compete for surgical procedures to be performed safely, among them: trained professionals, effective communication, environment, equipment and materials appropriate for the procedure, in accordance with current legislation, among others[26].

To achieve this objective, it is necessary to go through the processes of cleaning, disinfection and/or sterilization of materials, processing the instruments and preventing the transmission of microorganisms[27]. It is extremely necessary to sterilize reusable instruments. These are crucial points to consider, preventing infections, protecting the functionality of health items and ensuring patient safety[28].

Confirming this information, it is highlighted that:

> *"The CME is the place where most materials used in medical, dental, physiotherapy and nursing care are received, whose purpose is to submit materials to the sterilization and disinfection process in a standardized way, offering contamination-free and safe items to be used in the assistance of the health team"* [29].

A practical study was carried out, developed in order to monitor the microbial load after using surgical instruments to provide care and after cleaning / disinfection / sterilization, a significant reduction of this microbial load of 1 to 2 logs in cleaning was observed. manual and 1 to 3 logs in mechanical cleaning, although neither method completely

removes the biofilm. Pre-cleaning conditions and instrument design influence cleaning quality[30].

However, some other data should also be presented, for example, in the research developed by the author, which observed 30 possible failures in this process, including 16 process variations and 10 result variations, this may occur due to errors and/or problems related to the instrument and human work[31].

This guarantee of patient safety gained greater prominence than was already considered during the pandemic. It has been stimulated and implemented for years, however, during the SARS-CoV-2 or COVID-19 pandemic, the need to act firmly in this area was perceived, due to the easy transmission within the health unit itself, that is, decontamination and cleaning gained more prominence[32].

Confirming the safety issue, this study presents data that the CME acts through the implementation of good evidence for recommendations or contraindications for the use of materials used in health services, a function that helps in the process of guaranteeing the quality of care and that is also related to the development of new tools aimed at supervising this entire area[24,33].

Currently, a scenario is being experienced in which the performance of CME professionals is highlighted, in view of the provision and guarantee of patient safety, through the entire process of cleaning, disinfection, preparation, sterilization, adequate storage, control, processing and distribution for the other units. This relationship between MSC and Patient Safety is often cited, as such, safety depends on the treatment of the instruments to be used; these materials used in patient care must be free of health risks, so they need to be reprocessed[34].

That is, the materials can be one of the main factors for the improvement or worsening of the user's health condition, the health professionals themselves report that among the safety steps, it is mentioned the revision of the instruments, so that they are ready in urgent and emergency cases[35].

However, in this study, the author provides data on the opinion of professionals working in the unit, which also confirm that the MSC effectively contributes to the provision and maintenance of the patient's health. This type of contribution is made through the processing of materials, so that sterilization allows the use of that instrument in invasive procedures, without the risk of causing damage. In addition to contributing to the environment and financially, as some materials end up being "reused"[36-37].

The training is recommended for the material center, with an annual assessment of competences and continuous monitoring of the procedures carried out for the reprocessing of articles of health products in order to guarantee the quality and a corporate strategy to deal with the equipment and medical devices handled in its institution[24].

The lack of continuity of effective training, continuing education, sufficient resources, appropriate policies and procedures were cited as common impediments. Of the number of cases that reprocessed surgical instruments with patient results were investigated, neurosurgical articles inadequately cleaned and sterilized with contaminated water rinsing were associated with Pseudomonas aeruginosa vasculitis and mycobacterium site infection, evidencing a series of adverse events[38].

Technology is constantly changing. Alternatives are needed to perform lumen cleaning, such as fluent steam or air guns; this justifies the concern for studies that have not yet found a perfect solution. When testing or developing cleaning processes, it is important to understand the levels of dirt present in healthcare products after surgical use. Decontamination of instruments requires the participation of all those present, the surgical team and the Material and Sterilization Center[39-41].

Conclusion

Based on what has been studied, it is concluded that the Material and Sterilization Center performs several functions within the health unit, in such a way that it provides quality assurance of health articles, promoting greater safety for the health professional, institution and patients. It was noticed that the CME plays a prominent role in terms of acting in the face of patient safety, a factor that is directly related to the improvement or not of their health status.

During the search, it was possible to observe the absence of studies on the subject within the Portuguese language, thus evidencing the lack of this aspect and the need to prioritize studies involving the theme.

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