

Validation of the checklist for evaluating sterilization processes: a methodological study

Validação do checklist para avaliação dos processos de esterilização: estudo metodológico

Validación de la lista de comprobación para la evaluación de los procesos de esterilización: estudio metodológico

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ABSTRACT: Objective: To develop and validate an instrument for evaluating the cleaning and sterilization processes of medical devices at the Central Sterile Supply Department. **Methods:** A methodological study with content validation was conducted in three stages: development of an instrument; validation by expert judges; and final validation of the instrument, with a level of agreement above 70% considered adequate. **Results:** The instrument was developed by the authors and validated by six nurses with experience in the Central Sterile Supply Department. In the first round, it obtained a mean content validity index of 0.96. Subsequently, a second round was conducted with three PhDs in nursing with experience in cleaning and sterilization processes, who evaluated the semantic, structural, and conceptual aspects. **Conclusion:** The validation of the checklist enabled the guidance for the performance of activities in the Central Sterile Supply Department, as well as supporting nursing practice in healthcare in a safer and more qualified manner.

Keywords: Identity and quality standard for products and services. Sterilization and materials center. Surveys and questionnaires. Sterilization. Checklist.

RESUMO: Objetivo: Elaborar e validar um instrumento para avaliação dos processos de limpeza e esterilização de produtos para a saúde no Centro de Material e Esterilização. **Método:** Um estudo metodológico com validação de conteúdo foi conduzido em três etapas: elaboração de um instrumento; validação por juízes especialistas e validação final do instrumento, considerando adequado o nível de concordância acima de 70%. **Resultados:** O instrumento foi elaborado pelos autores e validado por seis enfermeiros com experiência em Centro de Material e Esterilização. Na primeira rodada, obteve uma média do índice de validade de conteúdo de 0,96. Sem seguida, foi realizada uma segunda rodada, com três doutores em enfermagem com experiência em processos de limpeza e esterilização, que avaliaram a questão semântica, de estrutura e aspectos conceituais. **Conclusão:** A validação da lista de checagem possibilitou a orientação de trabalho para a execução das atividades no Centro de Material e Esterilização, bem como o direcionamento da atuação do enfermeiro na assistência à saúde de forma mais segura e qualificada.

Palavras-chave: Padrão de identidade e qualidade para produtos e serviços. Central de esterilização e de materiais. Inquéritos e questionários. Esterilização. Lista de checagem.

RESUMEN: Objetivo: Elaborar y validar un instrumento para la evaluación de los procesos de limpieza y esterilización de productos sanitarios en el Centro de Material y Esterilización. **Métodos:** Se llevó a cabo un estudio metodológico con validación de contenido en tres etapas: elaboración del instrumento; validación por parte de expertos y validación final del instrumento, considerándose adecuado un nivel de concordancia superior al 70 %. **Resultados:** El instrumento fue elaborado por los autores y validado por seis enfermeros con experiencia en el Centro de Material y Esterilización. En la primera ronda, se obtuvo una media del índice de validez de contenido de 0,96. A continuación, se llevó a cabo una segunda ronda con tres doctores en enfermería con experiencia en procesos de limpieza y esterilización, quienes evaluaron la cuestión semántica, la estructura y los aspectos conceptuales. **Conclusión:** La

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validación de la lista de comprobación permitió orientar el trabajo para la ejecución de las actividades en el Centro de Material y Esterilización, así como dirigir la actuación del personal de enfermería en la asistencia sanitaria de forma más segura y cualificada.

Palabras clave: Estándar de identidad y calidad para productos y servicios. Centro de esterilización y materiales. Encuestas y cuestionarios. Esterilización. Lista de verificación.

INTRODUCTION

The Central Sterile Supply Department (CSSD) is recognized as a healthcare unit, part of healthcare service organizations, that processes Medical Devices (MDs) for use in various sectors providing direct and indirect patient care¹. This healthcare unit is responsible for processing MDs, following the stages of pre-cleaning, manual cleaning, automated cleaning, rinsing, drying, preparation, disinfection/sterilization, storage, and distribution of MDs².

Healthcare delivery at the CSSD is organized through the implementation of effective management methods that improve the efficiency of activities, reduce adverse events and procedure costs and, consequently, have a direct impact on the work routine of nurses and their teams³. The use of guidance tools for executing the stages of MD processing can be outlined through operational procedures, clinical and care protocols, and audit tools, such as those developed by the Institute for Healthcare Improvement, which has been a leading authority on healthcare quality processes since 1984 for identifying process failures or preventing adverse events⁴.

Another resource for the nursing process is the implementation of tools based on the structure-process-outcome triad, systematized by the Nursing-Sensitive Quality Indicators, which aim to measure the quality of activities performed by the team, with a focus on operational behavior and monitoring of nursing practice⁵.

In Brazil, the National Health Regulatory Agency (ANVISA), through Collegiate Board Resolution No. 15 of 2012, established best practices for the processing of MDs and the minimum architectural, equipment, workflow, and occupational health requirements². Through this technical regulation, safety for patients and professionals is ensured by defining minimum requirements for the proper functioning of the CSSD sector and processing companies².

At the state level, the Paraná State Department of Health, through Resolution No. 165/2016, developed a framework to inspect, educate, and establish best practice requirements for healthcare facilities, covering public, private, civil philanthropic, and military entities, including those engaged in

teaching and research, so that they comply with “essential and necessary” requirements, thereby enabling the subsequent granting of a health license⁶.

However, there is a certain difficulty in developing an assessment tool that focuses on the criteria determined by ANVISA. The absence of a tool to evaluate the processing of MDs and the steps that must be systematically observed and treated as a guide for planning the work routine has proven to be a significant gap in clinical practice⁷.

Developing a tool to assess the work process and quality in the CSSD can be challenging and multifaceted, encompassing characteristics crucial to patient safety and facilitating the implementation of changes, including aspects such as: workflow, physical structure and resources, documentation and record-keeping, staff qualifications, and quality indicators⁴.

The development of a checklist for nursing care aims to reduce errors, incidents, and adverse events associated with the CSSD, ensuring adequate care and maximum patient safety⁷. Thus, this study aimed to develop and validate an instrument for evaluating the cleaning and sterilization processes of MDs at the CSSD.

METHODS

Study design, location, and period

A methodological study was conducted, consisting of the development, validation, and evaluation of methodological tools and strategies used in clinical, epidemiological, or health promotion contexts. The methodological study is based on the premise of developing, validating, and evaluating scientific research instruments, techniques, and methods that can be applied in research or professional practice in a manner consistent with and appropriate to the phenomenon under investigation⁸.

The methodological framework was based on a study comprising three stages:

1. Development of the research instrument/structuring of items through a literature review, focusing on cleaning and sterilization in the CSSD;

2. Validation of the content by judges with expertise in the subject matter; and
3. Validation of the content by the authors and modification of the items according to the judges' suggestions, followed by the presentation of the updated version of the instrument.

The development and validation of the instrument took place from March 2025 to September 2025; the instrument was developed by the authors, validated by judges from the state of Paraná, and finally validated by experts in the CSSD.

Study protocol

Stage 1: Definition of the topic, development of the research instrument and structuring of the items.

The first stage involved a documentary review to analyze Resolution No. 165/2016 of the Paraná State Health Secretariat, the chapter on the Materials Processing Unit from the 2023 version of the National Accreditation Organization, and the 2025 version of the Joint Commission International Accreditation Standards Manual for hospitals. The search for documents took place between March and April 2025.

To develop the instrument, ten domains were established based on technical and knowledge-related characteristics,

covering each stage of the CSSD nursing team's work (Chart 1). Each domain consisted of guiding questions, whose answers were marked with "yes", when the unit meets this requirement; "no", when the unit does not meet this requirement; or "not applicable."

Stage 2: Content validation among the judges

In the content validation stage, participants from the first stage were selected via convenience sampling, with the following included as judges: nurses with expertise who hold a postgraduate certificate (verified by the submission of a copy of the certificate) in Operating Room, CSSD, and/or Hospital Infection Control; a minimum of one-year experience in CSSD activities and/or currently working in the CSSD of the state of Paraná.

Judges who partially completed the electronic form or did not provide a suggestion regarding the requirement that should be changed were excluded. The number of judges was determined as six professionals, in accordance with Lynn's study⁹. Judges were invited via virtual communication (WhatsApp) through a group of nurses with experience in CSSD in the Southern region of Brazil. Upon agreeing to participate in the study, the survey form and the informed consent form were sent electronically (Google Forms).

The judges evaluated each item in the domain, scoring them on a Likert scale from 1 to 4, where 1=Inadequate, 2=Somewhat inadequate, 3=Adequate, and 4=Fully

Chart 1. Domains of the Central Sterile Supply Department Guidance Instrument.

Domain	Domain Characteristics	Number of questions per domain
Human resources	Human resources management support to meet the unit's dynamics.	9 questions
Material resources	Related to the unit's infrastructure and equipment.	17 questions
Soiled area: waste disposal	Intended for the reception and cleaning of medical devices.	16 questions
Clean area: preparation room	Checking cleanliness, selecting the sterilization and disinfection method.	7 questions
Clean area: sterilization room	Activities related to saturated steam and hydrogen peroxide sterilization.	9 questions
Clean area: medical devices disinfection	Care regarding the chemical disinfection of medical devices.	8 questions
Clean area: storage room	Procedures for storage and distribution.	6 questions
Transport	Healthcare precautions for transporting medical devices within the hospital and outside it.	2 questions
Processing Committee	Criteria for the operation and maintenance of the committee within hospital settings.	8 questions
Management	Actions related to the management of the unit.	6 questions

Source: The authors, 2025.

adequate. If a question was rated “1” or “2,” a suggestion for improvement regarding the sentence or aspects of that domain was requested.

At the end of this stage, an instrument was developed incorporating the information suggested by the judges and submitted to a second round of judges.

Stage 3: Content validation by the authors and revisions to the items based on the reviewers' suggestions, followed by the presentation of the updated version of the instrument

In the second round, the judges were required to be nurses, hold a doctoral degree, and have experience in studies on cleaning and sterilization of medical equipment; they were invited via email to participate in the study. The PhD holders were selected via the Lattes Platform and evaluated the criteria presented in Chart 2 of the instrument, according to the parameters established by Alexandre and Coluci¹⁰.

This stage involved making changes to the items based on the judges' suggestions and, subsequently, presenting the updated version of the instrument. Validation process was based on consensus among experts through responses to the instrument. An item is considered valid when the responses show consensus according to the content validity index (CVI), which is calculated by summing the agreement of items rated “3” and “4” and dividing by the total number of responses. A $CVI \geq 0.80$ is considered acceptable; a CVI between 0.70 and 0.79 may require item revision; and a $CVI < 0.70$ indicates a weak or inadequate item.

Ethical considerations

The study was approved by the Human Research Ethics Committee of the Hospital Instituto Paranaense de Otorrinolaringologia under CAAE: 88688925.6.0000.5529, with opinion no. 7.790.491.

RESULTS

Six judges participated in the first stage, with ages ranging from 25 to 65 years (mean of 45 years). Their professional experience since graduation ranged from 5 to 25 years (mean of 15 years). Only one participant held a master's degree, while the remaining five had completed a *lato sensu* postgraduate programs. The judges' experience in the context of the CSSD ranged from seven months to 18 years (mean of 9.5 years).

The judges' evaluation in the first round yielded a $CVI=96\%$, with suggestions and modifications from the evaluators to improve the content; most of these were related to grammar and the way the question was formulated, including the addition of terms such as the names of regulatory agencies, methods, and evidence of sterilization, among other changes. It was also suggested that certain words and/or phrases be removed from some questions, and two questions were completely reworded to facilitate understanding, reading, and interpretation of the instrument. The changes are described in Chart 3.

The changes suggested by the first-round panel of judges regarding the inclusion and replacement of scientific terms resulted in the “Nurse's Work Checklist at the Central Sterile Supply Department” (Chart 4).

This instrument was submitted for a new validation process involving three judges who had not previously reviewed the first version. At this stage, the judges were nurses holding a PhD in nursing, with a mean of ten years of experience working in the CSSD sector, and who served as faculty members in undergraduate programs in the field of perioperative nursing.

In this stage, the instrument showed a $CVI=92\%$ among the judges in the second round (Chart 4).

Based on the judges' evaluation in the second round, the checklist (Chart 4) was recognized as an essential guidance tool for nurses' work in the CSSD. It uses standardized and easily understandable terminology, in accordance with

Chart 2. Instrument evaluation criteria.

Criterion	Items to be analyzed
Content	Refers to academic knowledge and regulatory standards relevant to the topic addressed.
Appearance	Refers to the aesthetics of the document and the clarity of the terms used, ensuring adequate understanding.
Objectivity	Ensures that items express preferences or desirability in a direct and unambiguous manner.
Simplicity	Each item should convey only one central idea, avoiding ambiguities.
Clarity	The instrument must be understandable even to population groups with lower levels of education.

Source: Alexandre and Coluci¹⁰.

Chart 3. Judges' considerations.

Domain	CVI	Original Phrase	Judge's suggestion
Clean area: preparation room	0.06	1) Sterilization and disinfection packaging is registered with ANVISA. 2) There is a plan containing criteria for the acquisition and replacement of the fabric packaging inventory, with records of these transactions maintained.	1) Sterilization and disinfection packaging is registered with ANVISA and complies with ABNT standards. 2) The facility has a plan for replacing fabric packaging and criteria for purchasing sterilization and disinfection packaging.
Disinfection area	0.06	1) Records of disinfection procedures are maintained, including equipment identification, date of the procedure, and start and end times of the process. 2) Medical devices, sanitizers, and cleaning solutions are registered with ANVISA, are within their expiration dates, and are packaged and stored in accordance with the manufacturer's instructions. 3) There is a record or other control system for the preparation of disinfectant dilutions, when applicable.	1) Maintains a record of chemical and/or thermal disinfection procedures, including equipment identification, date of the procedure, and start and end times of the process. 2) Medical devices and solutions are registered with ANVISA, are within their expiration dates, and are packaged and stored in accordance with the manufacturer's instructions. 3) It maintains a record or control system for the preparation of disinfectant dilutions, when applicable, when not performed at the CSSD.
General aspects	0.06	1) It has traceability for the processing of medical devices processed by the CSSD.	1) Manual or computerized traceability is available for the processing of medical devices processed by the CSSD.
Dirty area: purging	0.05	1) It has established a cutoff limit for the adenosine triphosphate test.	1) The facility has a cutoff value for adenosine triphosphate reference values or follows the manufacturer's recommendation.

ABNT: Brazilian Association of Technical Standards; ANVISA: National Health Regulatory Agency; CSSD: Central Sterile Supply Department.

Source: The authors, 2025.

Chart 4. Content validity index of the Central Sterile Supply Department assessment checklist.

Domains	Content	Appearance	Clarity/Comprehensibility	Objectivity
D1	1.0	1.0	1.0	1.0
D2	0.9	0.8	0.9	0.8
D3	1.0	0.9	0.9	0.9
D4	1.0	1.0	1.0	0.9
D5	1.0	1.0	0.9	1.0
D6	0.8	0.9	0.8	0.9
D7	0.9	0.9	1.0	0.9
D8	0.9	1.0	0.9	0.9
D9	0.8	1.0	1.0	0.8
D10	0.8	0.9	0.9	0.9
Mean	0.93	0.95	0.94	0.92

D1: Human Resources; D2: Material Resources; D3: Dirty Area: Decontamination; D4: Clean Area: Preparation; D5: Clean Area: Sterilization; D6: Chemical Disinfection; D7: Clean Area: Storage; D8: Transportation; D9: Processing Committee; D10: Management.

Source: The authors, 2025.

Collegiate Board Resolution No. 15/2012. In addition, the checklist's structure enables the qualification of nurses' work in the CSSD, providing support for the organization, monitoring, and optimization of material reprocessing processes, thereby facilitating the traceability of steps and the identification of potential non-conformities.

DISCUSSION

Based on this methodological study, it was possible to develop and validate a checklist designed to assist nurses working in the CSSD unit in ensuring continuous improvement in quality and patient safety processes. The checklist provides

comprehensive information, aiming to identify quality levels in items and materials to facilitate the optimal performance of activities carried out in that sector¹¹.

With regard to the packaging process for MDs, it is ensured that the packaging must be properly registered with ANVISA, as established by RDC No. 15/2012, which underpins the requirements set forth by Brazilian Association of Technical Standards (ABNT) 14990-1:2004^{2,12}.

The technical standards established by ABNT within the scope of the CSSD are intended to ensure specific technical requirements regarding the safety of MDs processed at that facility, particularly concerning sterilization, equipment validation, and the selection of Sterile Barrier Systems (SBS), given that the type of barrier to be used for that specific MD and sterilization method is a crucial factor in meeting safety requirements¹³.

SBS can take various forms, including disposable (woven or non-woven, surgical-grade, and crepe paper) or reusable (rigid containers or cotton fabric), the latter being one of the most commonly used in healthcare institutions¹⁴.

It is crucial that each sterilized MDS have a shelf life determined by an analysis of the risks of sterility loss, such as damage to the SBS (holes, tears, improper sealing), as well as humidity and heat at the site and during transport¹⁴. Although RDC No. 15/2012 requires institutions to establish a packaging integrity assessment plan, it does not specify a method for doing so¹⁵.

Regarding the results and validity of records, it is necessary for the CSSD unit to maintain in its documentary archives the records of thermal, chemical, or pasteurization disinfection cycles, since certain parameters must be observed and noted, such as the exposure time of the material, the use of the disinfectant by concentration, and the temperature and pH of the water¹⁶.

RDC No. 15/2012 also mandates the maintenance of these same records, which must be performed at specific intervals and defined in standard operating procedures, including the measurement of water hardness levels, chloride, copper, iron, microbial load, among others².

Records and monitoring of water quality are essential for the prevention of healthcare-associated infections, given the vital role of water in cleaning and sterilization, as poor water quality can cause corrosion and processing failures in medical devices, thereby increasing the risk of infections¹⁷.

Another concern regarding care provided in the CSSD relates to the control and recording of disinfectants, as they play a significant role in the preparation and dilution of

disinfectants used for the disinfection of MDs. Routine testing is necessary to ensure their effective concentration, and it is recommended that the solution be discarded when its minimum effective concentration is not achieved¹⁸.

The use of CSSD care resources approved by ANVISA is mandatory to ensure excellence in the cleaning, inspection, and packaging of MDs; the latter must be carried out in packaging that meets the validation and standardization requirements of agencies currently in force in Brazil². In the final process involving the storage of these MDs, the institution must also follow strict rules to prevent contamination, as it is at this stage that a commitment to maintaining sterility must be upheld, through actions such as organization, cleaning, and climate control of the environment¹⁹.

Quality parameters must begin with the manual cleaning phase of medical devices, which is an effective method, as this is where the microbial load is reduced and foreign materials are removed, thereby ensuring successful sterilization²⁰. Overcoming the ineffectiveness of visual inspection and magnifying glasses in validating cleanliness, modern methodology has adopted detection via adenosine triphosphate bioluminescence testing, which is of paramount importance for identifying the presence of organic matter and microbiological contamination on the surfaces of MDs, since adenosine triphosphate is the primary energy currency present in all living beings, providing immediate results²¹.

The cutoff values for these tests must follow scientific standards since there is evidence that concentrations below 500 relative light units (RLU) are considered acceptable for clean surfaces and values below 200 RLU for less complex instruments. In addition, the historical trend of the data can be considered, and it is crucial to document and store the results obtained²².

The results presented in Chart 4 regarding the CVI reveal a high level of agreement among the evaluated items. It is observed that all domains recorded values equal to or greater than 0.8 in the criteria of content, appearance, clarity, and objectivity, indicating the instrument's consistency and representativeness in relation to the proposed construct, since scores close to 1.0 suggest that the items were well formulated, clear, and relevant, reinforcing and demonstrating their potential for application in similar contexts with minimal need for adjustments¹⁰.

This study's limitations include the exclusion of specialists not working in the Operating Room, CSSD, and Hospital

Infection Control Committee sectors, as well as the low representativeness of the expert sample during the initial data collection phase, and the extended time required for data collection, which may have impacted the study's dynamics and participants' availability.

CONCLUSION

The checklist developed and validated in this study proves to be relevant in conducting the activities and processes carried out in the CSSD sector, thereby assisting nurses in managing their teams, providing them with better guidance, and thus ensuring the safety of the team and the patients who will be treated at that healthcare institution. However, there is a need to apply the checklist within the CSSD context, given the diversity of units based on hospital size and characteristics.

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CONFLICT OF INTERESTS

The authors declare there is no conflict of interests.

AUTHORS' CONTRIBUTIONS

FJK: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Visualization Writing — original draft, Writing – review & editing. FLC: Data curation, Investigation, Methodology, Visualization Writing — original draft, Writing – review & editing.

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