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Major Article

Bundles for the central sterile supply department

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Background: Traditional resources, such as bundles, can help experts define essential steps of health product processing to prevent infections. The present study developed bundle content construction and validation criteria for central sterile supply departments (CSSDs).

Methods: The present study employed a Delphi technique modified for content evaluation. Eleven professionals with at least 4 years of experience in sterilization were enlisted. Participants discussed main stages of the process virtually and compiled a list of items based on scientific references justified by law and/or logical reasoning. Agreement, disagreement, and/or suggestions on each step resulted in bundles for a CSSD. Items were then reassessed by experts using a Likert scale with a 90% approval criterion.

Results: Six bundles were developed: cleaning, inspection, preparation and packaging, sterilization, and storage resulting from 384 responses and 373 agreements (Interassessor coefficient = 97%).

Discussions: Items obtained from the criteria assessment received majority agreement from the first document.

Conclusions: Agreement among varying professionals was achieved, and bundles were successfully developed to evaluate the processing of goods in CSSDs.

The Institute for Healthcare Improvement, formed in 1991, is committed to redesigning health care in a system without errors, waste, delays, and unaffordable costs. They developed the concept of bundles or packages to help health professionals provide the best care for patients subjected to specific treatments with inherent risks.[1] Bundles are resources used by infection control teams that help show important measures for preventing infections. Infection control is a large multidimensional field, and bundles simplify observations, promote credibility, show results to managers, and can be used for benchmarking. Standards and guidelines for infection control and a central sterile supply department (CSSD) are extensive, and although used by specific field professionals, it can be difficult to extern people (workers that not are familiar with this area) to identify the main steps to evaluate.

Visible and comparable outcomes can be obtained using bundles for CSSDs. These could be used in the same way as others for infection control. To achieve this goal, specific CSSD bundles will be developed and later used in a systematic way as a tool by infection control teams, quality programs, and accreditation to judiciously evaluate steps of medical devices and product (MDP) processing, which is considered to be of key importance by area experts.

Known bundles or checklists are packages of measures taken together to prevent healthcare associated infections (HAI).

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Compliance verification lists are composed of measures noted to be preventive across studies according to the type of action.[2] A bundle is a structured way of improving care processes and results among patients. Bundles are a simple set of 3-5 evidence-based practices; when these practices are carried out in a collective, reliable way, they demonstrate a positive outcome.[3]

MDP processing involves different steps such as cleaning, inspection, functionality tests, storage, and sterilization. The final aim of the procedure is to guarantee safety for patients when using processed material. To ensure that MDPs are safely available, all processing steps are planned. The execution of each step must be tested for efficiency and effectiveness using relevant indicators and records.

In several health care areas in which MDPs are included, the volume and complexity of information of what is currently known exceeds our individual ability to ensure correct and safe actions.[4] Decisions in all care areas are safer when they involve technical and scientific values and/or produce conscious criteria that, although still in development, follow coherent clinical reasoning. Therefore, bundles developed by professionals from specific areas could help quality evaluator programs assess several different specialties and target the most important issues.

During MDP processing, various steps are investigated. For steam sterilization, some examples are exposure time, temperature, and steam characteristics needed for a safe process, as well as complete removal of dirt before sterilization.[5,6] Other aspects acknowledged by experts as important need evidence at the same level. Cleaning is a good example. There are products that suggest cleaning efficiency, which is based on scientific principles and rationality; however, the impact of robust clinical research evidence is lacking. There are gaps in existing knowledge and technology on the efficient removal of dirt such as fats, endotoxins, biofilms, and proteins. Although MDP cleaning is fundamental, there are few products available that have been deemed effective based on clinical research evidence.

New technology for increasingly sophisticated surgical procedures, such as robotic surgery and minimally invasive procedures, require new cleaning equipment and new forms of work organization.[7] The speed of technological evolution requires new decisions and assessments of criteria for MDP safety. Responses for specific questions are not always observed in existing literature. In the absence of robust evidence, professionals adopt practices after a logical and rational theory passed down from others and/or according to their practical experience.[8-10]

The entire process for the safe use of medical supplies involves work details from each professional. The process starts from the moment the worker receives the item, inspects it, and performs the cleaning with appropriate materials and supplies. Each of these steps involves responsibility and awareness as to the importance of these steps. The technical aspects of safe reuse of MDPs and related concerns involving complex and social impacts must be seriously considered. Relying only on a sense of security when using MDPs (ie, because the products were submitted to a sterilization phase in an autoclave) leaves patients and untrained professionals vulnerable.

Bundles idealized for HAI prevention and control were originally developed based on scientific studies that demonstrated a positive impact.[2] For simplification, some steps were not included in some bundles for HAI. For instance, adequate hand hygiene while patients are being assisted is known to prevent health care–related infections. Although bundle design includes hand hygiene to prevent specific infections, the design does not include different steps comprising the hand hygiene process. Institutions carry out bundles with the corresponding steps separately,[11] given that including different steps would make the process extensive and slow and divert attention away from the main focus. There is no scientific evidence regarding the impact of hand hygiene steps considered individually; past work has only considered hand hygiene as a whole.

Likewise, MDP sterilization is essential for surgical success; instrument examination available for surgical procedures is part of some checklists for safe surgeries.[2] Therefore, specific steps for processing these MDPs are carried out according to several key components. These components are not part of this checklist (and they *should not be*), given that verification is also extensive and complex.

In a recent study, an analysis was carried out focusing on quality CSSD indicators within accredited public hospitals. Results revealed that the production and client satisfaction indicators measured by these hospitals did not reflect effective quality of the processing center services. Specifically, the processes were fragmented, did not consolidate results when seeking improvement, and were simply related to production and client satisfaction surveys.[12] In addition to parametric indicators for steam sterilization, among other traditional indicators within CSSD practice, an information set indicating that all actions are performed efficiently and effectively is needed.

The present study created a package for a cohesive program enabling the implementation of synergistic and standardized efforts to evaluate basic aspects of MDP process quality. A consistent methodology across study centers would standardize the evaluation process, allow an initial comparison of results, and enable future validation and comparative assessments. An integrated approach may lead to the prevention and sustained reduction of postoperative complications.

As the final proposal should not be inflexible, provisions could be modified according to specific needs within CSSD teams and expanded in accordance to the laws of different countries. Therefore, our goal was to develop bundle content construction and validation criteria for CSSDs.

METHODS

This project follows Resolution 466/12 of the Brazilian National Health Council. The study was submitted for evaluation by the ethics committee of the research commission of the Federal University of Rio Grande do Sul. This study was based on an instructional method for validating an instrument.[13] Content validity for determining representativeness of items was adopted based on expert opinion in a certain knowledge area. The items reflect an interest in identifying general development principles or specific recommendations of a given situation. Consequently, the experts may develop a certain concept, technique, or tool, and identify the conditions facilitating successful use of those items.[14]

A modified Delphi[15] technique was used for evaluating the content validation strategy during 2017-2018. This study was developed in 3 stages based on an online expert panel. According to a theoretical reference,[15] the ideal number of evaluator participants is not well established, whereas 6-12 participants is the number defended by some researchers.

This study used a convenience sample, initially comprising 9 expert investigators during Phase 1; after Phase 3, 11 experts were enlisted. The inclusion criteria were: having at least 4 years of work-related experience in a CSSD and health products processing, experience evaluating processes concerning practical and management activities of a CSSD, being acknowledged as an expert in the area for participating in the Brazilian Technical Standards Association on materials treatment, and active in the Board of Directors of the Brazilian Society of Nursing in Surgical Centers or university professors with teaching experience in this area. Selected professionals were an engineer, a biologist, a university hospital nurse, a public hospital nurse, a private-law public nurse, an infection control committee nurse, a state health surveillance nurse, a professional association nurse, and an academic chair nurse. Being linked to MDP marketing companies and giving suggestions after the set deadlines to answer

the questions were adopted as exclusion criteria. During Phase 3, 2 experts quit, and 4 others were then invited to participate.

During the initial stage (Phase 1), a document was developed using an online discussion panel. The document comprised a list of 30 main items regarding different MDP processing steps, including details on cleaning, inspection, preparation and packaging, sterilization, and MDP storage in CSSDs. Content validity was assessed through a discussion. Experts were expected to analyze and mark each item based on agreement that the item was important for systematic verification of processing quality. In the case of a disagreement, partial agreement, and/or suggested exclusion, a written explanation based on literature or other rationale was required to determine item inclusion or exclusion. New items could also be suggested and/or exempted. Each item included in the list should be based on current scientific references when available, justified by the Resolution of the Board of Directors of the Brazilian Health Regulatory Agency (ANVISA) 15/2012[16] or rational criteria guiding CSSD practices.[12]

During Phase 2, the evaluation document was reorganized from items acknowledged by participants as fundamental to MDP.[5-12] Items and/or details were either added to or withdrawn from the original document as per experts' suggestions.

During Phase 3, the MDP bundles were drawn up based on item organization and experts' suggestions. The following infection control bundle guidelines were followed[3]: having 3-5 items, each being relatively independent and used for a specific population/place; items needed to be descriptive, nonprescriptive, enabling local personalization, include appropriate judgment, and have an all-or-nothing final measurement.

Each participant received the document with the bundles already produced. Participants were expected to rate each item on a 5-point Likert scale (strongly agree, agree, neither agree nor disagree, disagree, strongly disagree).

With this approach, the bundles included both technical and socioadaptive items.[6] The purely technical items were those already defined as existing; the expected decision was whether or not to use that item. The socioadaptive items required commitment from hospital leadership regarding the decision to purchase supplies and/or other hurdles (such as schedules) to be met collectively, requiring extensive engagement in the tasks. Depending on the institution, the items could be either socioadaptive or strictly technical (ie, when already implemented and used regularly). For example, if certain inputs were already being purchased, professionals wanted to know whether or not the inputs were used. If there was a joint decision to purchase an input, the implementation efforts should address teamwork, communication, and culture.

For determining content validity, an interassessor index was adopted. To decide on the final inclusion of items, content validation indices (CVI) of the total number of bundles by dimensions (CVID) and items (CVII) were calculated. CVI was calculated by the total number of items with answers agreed on plus the total agreement divided by the total number of valid answers. The indicator was considered valid when approval was over 80%, which should influence the decision to include the item for preparing bundles.[17]

RESULTS

The initial document discussed by the research coordinators and experts resulted in 30 items involving the main processing steps, ranging from cleaning to product distribution. All experts made suggestions during Phase 1, answering whether they agreed or not and justifying their answers. Acceptance of the majority determined the permanence of the list. Five items were included per suggestions, and others were modified, totaling 36 elements subdivided into 6 bundles, as shown in Table 1.

During Phase 2, the document was returned to all respondents with suggestions and justification for confirmation or withdrawal. No new modifications were suggested.

During Phase 3, items were reorganized resulting in 6 bundles (Table 1). The dimensions generated 2 cleaning bundles (with 6 items each), a preparation and packaging bundle (7 items), an inspection bundle (5 items), a sterilization bundle (6 items), and a bundle for storage and general aspects (6 items).

The evaluation included 394 answers. Among these, 9 items presented neither agreement nor disagreement replies, and 11 indicated disagreement. Two items were left blank. The general interassessor CVI was 97% (373 items with agreement and strong agreement) across all dimensions. This result helped finalize the bundles. Some items had a description as to how to perform the verification. The descriptions were withdrawn, as all elements were considered valid only if there was evidence that each step was contemplated. Table 1 presents the bundles according to the CSSD dimensions and corresponding CVII and CVID values.

All the bundles presented at least a 90% CVI for each dimension. Although the results between dimensions were different based on a χ^2 test (4.45), this difference was not significant ($P = .35$). To evaluate all the instrument bundle items, the minimum score was 36 for each assessor, and the maximum was 180, with an amplitude equal to 144. The additions and substitutions suggested by experts led to the complete bundles.

For the Cleaning I dimension (prerequirements) in bundle I, the inclusion of "visible dirt" was suggested. In item 2, different types of personal protective equipment (PPE) were included based on the suggestion of 3 experts. The words "of automatic cleaning" were added to item 3 for the "schedule and record of preventive intervention in equipment." The suggestion, "signed by the professional responsible for the CSSD," was accepted and added to item 4, "record of qualification of equipment."

Two items were added in this bundle based on expert suggestions: "discard detergent solution after each use of the ultrasonic washing machine and manual cleaning tubs" and "surface disinfection routine systematically carried out as per written protocol."

For the Cleaning II dimension, "air and water pistols and flowing steam" was added. Although it was discussed that availability is still rare, the decision to add this item was unanimous. For the proper MDP detergent item, "with opening date," was added.

Item 5, "for rinsing ophthalmologic, cardiac, neural, and orthopedic items, reverse osmosis, ozonated," was modified to, "purified water for critical product rinse." Item 6 in bundle II (cleaning verification chemical tests at fixed intervals), despite everyone's agreement for maintenance, had the following note: "This is one of the recommendations influenced by the industry, companies, and professionals who do not have experience and knowledge regarding CSSD realities in most institutions." There is no ideal test, and some government sanitary control teams demand such within certain Brazilian states.

We added to item 5 in bundle IV that the label must contain information enabling product traceability. Items 6 and 7, "file with checklist of kits and/or products used at each preparation" and "cleaning and disinfection of surfaces as established routines," were suggested and added, respectively.

The sterilization bundle V item 1 was modified to, "printed record of parametric and/or specific indicators of the process." In item 2, in addition to the verification of indicators before removing the MDP from the rack, verification of, "integrity, humidity, and packaging conditions," was added. In item 4, "corrective" was added to preventive interventions. A new item, "standardized load prepared as in the performance tests," was added to this bundle (item 6).

Bundle VI, Storage and general aspects, comprised 4 items; 2 were added, and 1 was modified. Item 2 was named, "clean and dry storage

Table 1
Assessor agreement on the items comprising the CSSD bundles

I. Cleaning I: Cleaning processes for determining cleaning quality	**CVII***	**CVID†**
1. Precleaning: removing visible dirt immediately after use.	0.90	0.95
2. Professional use of full personal protective equipment for the activity—facial protector or mask + glasses, long-sleeved impermeable apron, resistant long-length gloves, black shoes, closed shoes, cap, area-restricted clothes, earplugs.	1.00	
3. Schedule and record of preventive intervention for the automatic cleaning equipment.	0.90	
4. Record of equipment qualification signed by the professional responsible for CSSD.	1.00	
5. Discard detergent solution after each use of the ultrasonic washing machine and manual cleaning tubs.	0.90	
6. Surface disinfection routine systematically carried out as per written protocol.	1.00	
II. Cleaning II: Processes for determining cleaning quality	**CVI***	**CVID†**
1. Inputs (eg, brushes) compatible for precleaning (according to lumens, air and water pistols, flowing steam).	1.00	1.00
2. Proper detergent (such as enzymatic, alkaline, neutral) for MDP with opening date.	1.00	
3. Water that meets the potential potability standards defined by specific standards.	1.00	
4. Device for cleaning and drying cannulated items.	1.00	
5. Purified water to rinse critical products.	1.00	
6. Cleaning verification tests with periodicity defined by the institution.	1.00	
III. Inspection	**CVII***	**CVID†**
1. Annual visual acuity examination of all professionals and each 6 months base as of 40 years and above.	0.81	0.94
2. Verification of cleaning and integrity of all MDPs with a magnifying lamp or microscope for products with difficult visualization.	0.81	
3. Medicinal compressed air pistol to complement drying in the inspection area.	1.00	
4. Lubrication with a standard oil-free product to instrumental use of joints for better MDP performance.	1.00	
5. Protocol use test to verify functionality of scissors and clamps.	0.81	
IV. Preparation and packaging	**CVI***	**CVID†**
1. Professional uses PPEs (mask, cap, and gloves) in the preparation and packaging area.	0.81	0.96
2. Sterile Barrier System (SBS) is standardized for the type of packaged MDP.	1.00	
3. MDP is adequately packaged according to SBS type (with adequate folds) sealed in a proper sealing machine or in proper sterilization containers.	1.00	
4. The sealing machines have a preventive schedule and intervention record.	0.81	
5. Complete label with identification of the MDPs and information enabling traceability.	1.00	
6. File with checklists for kits and/or products used at each preparation.	0.81	
7. Cleaning and disinfection of surfaces according to an established routine.	1.00	
V. Sterilization	**CVI***	**CVID†**
1. Printed record of parametric and/or specific indicators of the process for each sterilization cycle signed by the university-level professional responsible for checking all process stages.	1.00	1.00
2. Record of verified indicators, integrity, humidity, and packaging conditions before removing MDPs from the autoclave rack.	1.00	
3. Thermal comfort for the operator.	1.00	
4. Schedule and record of corrective and preventive interventions, as well as qualification of the sterilization equipment.	1.00	
5. Schedule and record of cleaning equipment, as well as clean and preserved equipment.	1.00	
6. Standardized load prepared as in the performance qualification tests.	1.00	
VI. Storage	**CVI***	**CVID†**
1. Verification of SBS integrity before storing MDP and during their distribution to users.	1.00	0.97
2. Clean and dry storage place (containers may be stacked) with easy access and identification.	1.00	
3. Clean and dry storage place outside the CSSD at care units.	0.90	
4. Disposition of the MDPs stored so as to not damage the SBS.	1.00	
5. Ergonomic furniture and thermal comfort in all CSSDs.	0.90	
6. Transit of people is restricted, and MDP manipulation is minimal.	1.00	

CSSD, central sterile supply departments; *CVI*, Content Validation Indices; *MDP*, medical devices and product; *PPE*, personal protective equipment.
*Content Validity Index applied to Items (CVII).
†Content Validity Index Applied to Dimensions (CVID).

place without stacking (containers may be stacked), for easy access to identification." This bundle also included the item, "people transit is limited, and manipulation is minimal." The 11 items that elicited disagreement were related to Cleaning I (prerequisites), Preparation, Inspection, and Storage and general aspects. Cleaning II and Sterilization did not elicit disagreements.

Justifications (if present) for disagreements reported by the experts are described.

For the Cleaning I prerequisites, there was disagreement on removal of visible dirt immediately after use. Another disagreement was on the need for complete PPE to conduct activities in this area. The professional who disagreed raised doubts on the practicality of using the different types of PPEs because of the raw material, comfort, and undesirable costs. Discarding detergent solutions after each use was an inclusion added by another participant. However, during Phase 3, this item received unjustified disagreement.

In the Inspection domain, there was disagreement regarding proof of visual acuity. The same assessor apparently changed his mind from the first to the final evaluation. The test of protocol items, developed to verify the functionality of scissors and clamps, also led to disagreement; however, this disagreement was unjustified. Another disagreeable item was the verification of cleaning and integrity of all MDPs with a magnifying lens, with a lamp, and/or with a microscope/stereoscope for products with difficult visualization details. This aspect had already been addressed, highlighting that not all details would need this degree of visualization.

In the Preparation domain, there was disagreement on the need for PPEs. The assessor argued that it is only necessary to use PPEs for maximum reduction in contamination/recontamination/increase in MDP bioburden. Gloves need not be used, and adequate hand hygiene is sufficient. There can also be MDP contamination due to latex proteins. In the occupational protection aspect, the assessor argued that the level of MDP decontamination after cleaning must be sufficiently safe so as to not expose professionals to diseases/pathogen/drug-resistant microorganism transmission risk. Two other unjustified disagreements were over sealing machines having a schedule and record of preventive intervention, as well as a record with a checklist of kits and/or products used each time the material is prepared.

Regarding Storage and general aspects, there was disagreement on the clean and dry storage place outside the CSSD, but no justification was provided. Ergonomic furniture and thermal comfort throughout the CSSD also led to disagreements. In the first document, this item was contemplated in only 1 area (not all CSSDs), and 1 of the participants mentioned that thermal comfort would not interfere with the work.

DISCUSSION

Results revealed that most items were agreed on from the first document. After final restructuring, a 97% CVI enabled the inference that the bundles could be used adequately across different CSSDs. Some suggested items were recommended based on logical and rational theory such as cleaning "visible dirt" after use. Nevertheless, it must be noted that infection outbreaks owing to cleaning cannulated products (ie, in ophthalmology), as well as dirt, have already been reported, especially internal dirt (which is not visible), leading to recommendations for immediate cleaning.[18]

A signature from a professional, or some type of record that proves that he or she is in charge, is a recommended practice within a CSSD production system; therefore, a person must be responsible for all processes[19] (ie, someone who takes responsibility for participating and verifying that the activity was correct and effective).

In previous reports, the same detergent was used without being replaced for many different processes during the day. This is no longer permitted given that we now know of associated outbreaks and biofilm related to reuse and inadequate use of detergent.[18,20-22] The necessity of alternatives for cleaning lumens, such as air pistols or fluent steam, is a concern justified by studies that have not yet found an ideal solution.[8] Several cleaning indicators, such as adenosine triphosphate or proteins, may be used to verify whether a cleaning process is adequate.[23] Although appointed by consensus, most cleaning indicators are of little help, as more robust evidence is needed. Purified water and other instruments is highly recommended within ophthalmology due to tissue sensitivity and risks related to inflammatory reactions.[24] This is all part of the general MDP guidelines.[18,22,25] Lubrication with oil-free products has also been recommended as being more biocompatible given the similarity with implants,[24] making oil-free lubrication a key recommendation for MDPs.

The need for a standardized load, and using specific containers, integrate current recommendations from these associations, as well as processes and quality programs.[6,21] PPE suggestions in the area should follow from cleaning being carried out rationally and supported by national legislation and international standards. Nevertheless, PPE use discussions, such as the need for gloves and masks in the preparation area, are at odds with different international recommendations.[25,26] There was an agreement for the inclusion of PPEs in the present preparation bundle based on regulations from Brazilian legislation.[16]

The experts' suggestions on details, including the equipment qualification record, signatures from the person responsible for the CSSD, transit of people and materials, space and form of storage, and maintenance of clean and dry areas, are equally covered within recommendations from international standards. The publications include the need for documenting and maintaining records for all the stages of temperature and humidity processing, storage space, control of material transit, and whether the area/materials have already been decontaminated.[8,25,26]

The disagreement items were not adopted, as these items did were not justified. However, the discordant items could be justified from another technical point-of-view, on the condition that such items are listed in national standards.[16] Details regarding evaluation of the present bundles are only noticeable to those who engage in day-to-day routines within a sterilization plant. No matter the variability in appraisers who know the processes, important details are only perceived by those who are at the forefront of the relevant activities. For this reason, some details are likely to be disagreed on, either owing to implementation challenges based on infrastructure constraints, a lack of clinical evidence supporting the recommendation, and/or the expense associated with the action.

CONCLUSIONS

Developing bundles for evaluating CSSD processing is based on the fact that there is insufficient information regarding what is effective for certain phases of processing and related impacts on security incidents. Although the autoclaving process has good evidence, other details are complex, and external evaluators typically demand provisions that are not of utmost importance based on expert opinion.

The present study developed an instrument comprising 6 bundles containing items considered essential for process quality and safe MDP use: 2 cleaning bundles, an inspection bundle, a preparation bundle, a sterilization bundle, and a storage and general aspects bundle. Discussions and justifications presented by experts provided consensus on the national, legal, and validity questions within the literature (with a CVID equal to 0.9 across all processing dimensions). For the final version, each bundle comprised 5-7 elements, with a total 36 items.

According to the index obtained from each item and dimension, all could be applied to different sterilization plants. Although all items and the final bundles were submitted to a content validation process, these items could still be adjusted in accordance with the unique features of an individual health products processing center. Consequently, this could promote greater reliability of the present results. To achieve this, it is suggested that new research on this theme be carried out so as to perform additional validations based on the content of different environments.

Complementary to this stage, there was a phase in which the bundles were tested for their applicability, and the CSSD inspection qualification continued. Evaluations will be carried out through application by the infection control commission linked to each participant. Each infection control commission will apply different bundles, and confirmatory indicators will be established. The noncompliant items will be identified and evaluated. CSSD professionals who evaluated items using noncompliant bundles will be invited to specify reasons so that nonconformities can be studied and corrected when necessary. The results, after application, can be used for benchmarking many CSSD processes, and comparisons will be a further challenge to development in this area.

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