Development of a Protocol on the Processing of Health Products in a University Hospital

RESUMO | Objetivo:Desenvolver e validar um Protocolo sobre Processamento de Produtos para Saúde na Central de Material e Esterilização de um Hospital Universitário de São Paulo. Método: Trata-se de um estudo descritivo metodológico de desenvolvimento de um protocolo sobre processamento de produtos para a saúde.Realizada a revisão da literatura, elaboração do conteúdo escrito e de imagens. A validação foi feita por meio da Técnica Delphi com a participação de juízes. Para medir a concordância das respostas obtidas, foi utilizado o Índice de Validade de Conteúdo (IVC). Resultados: Após a segunda rodada do processo de validação pela Técnica Delphi, o IVC global do protocolo foi de 1.0, alcançando o nível de maior concordância. A versão final do protocolo possui 45 páginas, 8 itens abordados, 32 subitens e 20 ilustrações. Conclusão:O protocolo possibilitou reorganizar processos, estabelecer fluxos e padronizar condutas com embasamento científico para os profissionais de saúde.
Descritores: Avaliação em enfermagem; Esterilização; Desinfecção; Manuais; Protocolos.

ABSTRACT | Objective: To develop and validate a Protocol on the Processing of Health Products at the Material and Sterilization Center of a University Hospital in São Paulo. Method: This is a descriptive methodological study of the development of a protocol on the processing of health products. A literature review, written content and images were developed. Validation was performed using the Delphi Technique with the participation of judges. To measure the agreement of the answers obtained, the Content Validity Index (CVI) was used. Results: After the second round of the validation process using the Delphi Technique, the global CVI of the protocol was 1.0, reaching the highest level of agreement. The final version of the protocol has 45 pages, 8 items covered, 32 sub-items and 20 illustrations. Conclusion: The protocol made it possible to reorganize processes, establish flows and standardize scientifically based conducts for health professionals.
Keywords: Nursing assessment; Sterilization; Disinfection; Manuals; Protocols.

RESUMEN | Objetivo: Desarrollar y validar un Protocolo de Procesamiento de Productos de Salud en el Centro de Material y Esterilización de un Hospital Universitario de São Paulo. Método: Se trata de un estudio metodológico descriptivo de la elaboración de un protocolo sobre el procesamiento de productos sanitarios. Se elaboró una revisión de literatura, contenido escrito e imágenes. La validación se realizó mediante la Técnica Delphi con la participación de jueces. Para medir la concordancia de las respuestas obtenidas se utilizó el Índice de Validez de Contenido (IVC). Resultados: Tras la segunda ronda del proceso de validación mediante la Técnica Delphi, el CVI global del protocolo fue de 1,0, alcanzando el mayor nivel de acuerdo. La versión final del protocolo tiene 45 páginas, 8 ítems cubiertos, 32 sub ítems y 20 ilustraciones. Conclusión: El protocolo permitió reorganizar procesos, establecer flujos y estandarizar conductas con base científica para los profesionales de la salud.
Palabras claves: Evaluación de enfermería; Esterilización; Desinfección; Manuales; Protocolos.

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INTRODUCTION

In the organizational context of health institutions, especially in the hospital structure, the Material and Sterilization Center (MSC) is defined as a technical support unit that serves care units, responsible for the Processing of Health Products (PHP) such as surgical instruments and clothing and the sterilization of materials. MSC's principle is to promote better conditions for surgery and invasive procedures in post-surgical care. This service aims to prevent and control infections, integrating science, safety and quality. [1]

The World Health Organization estimates that, annually, 234 million surgeries are performed worldwide at a ratio of one procedure for every five people alive. The high turnover of procedures in the Surgical Center causes a great concern of the managers of the Material and Sterilization Center so that the materials of these surgeries are always ready to meet this demand. [2]

The PHP implies a set of actions that begin with the reception of contaminated products at the MSC, proceeding with cleaning, drying, disinfection, visual inspection, evaluation of integrity and functionality, preparation, (assembly and packaging), sterilization, storage, transport and distribution, thus providing the sterile article so that it is ready for safe use. In view of these considerations, each of these steps constitutes a measure of control and prevention of Health Care-Related Infections. [3]

Consensual and normative actions, which meet this objective, were published in the Resolution of the Collegiate Board of Directors No. 15 March 2012 (RDC No. 15), which provides for the requirements of good practices for the processing of health products. In compliance with this resolution, MSCs are now classified as Class I, which receive critical, semi-critical and non-critical materials of non-complex compliance and that have a lumen greater than five millimeters with a technical barrier between the areas. The MSC class II performs the processing of critical, semi-critical and non-critical health products with complex conformations with a lumen smaller than five millimeters. They are divided into areas separated by physical barriers. [4]

However, the protocols used in the services benefit the quality of care provided, however, they demand continuous management of physical and human resources, as well as scientific, periodic reviews and analysis of the cost/benefit ratio. In this way, the protocols facilitate teamwork and adjustments must be made to organize the processes in accordance with the need and reality of the health service.[5]

In this conception, the protocol reflects the imposition of a shared, consolidated work that points to results that can bring a differential to the work process. It must be built collectively, with solid, ethical, legal and scientific foundations. [6] Thus, the present study aims to develop and validate a protocol on the Processing of Health Products at a University Hospital in São Paulo.

METHOD

The present study was approved by the Research Ethics Committee of UNIFESP under opinion No. 2,726,616 and CAAE: 894916.18.0.0000.5505.

This is a descriptive study with a methodological approach for developing a protocol and validating content through the application of the Delphi Technique by judges aimed at professionals at the Material and Sterilization Center.

For the development of the Protocol, literature searches were carried out in the scientific databases LILACS; SCIELO; MEDLINE The inclusion criteria established were articles published in Portuguese, Spanish and English; with a time frame of 10 years (2008 to 2018). Articles that were repeated in the databases were excluded; monographs, dissertations and theses; articles that were not available in full and that did not contain data on the topic. as content related to the material and sterilization center, as well as a protocol for processing health products. The parts of the protocol were defined and the written content was elaborated, as well as the definition of figures and images.

The 11 judges were contacted electronically, by email, by means of an invitation letter with explanations about the study. For those who agreed to collaborate, a request for consent was sent, through the signature of the ICF. Then, the protocol was sent by Google Forms electronic form. The inclusion criteria of the judges were: being a nurse in a material and sterilization center, with a specialist degree and two years of experience in the area. Generalist nurses or specialists from other areas and specialties were excluded.

The material to be evaluated consisted of two parts: the first referred to the characterization of the specialists, and the second contained instructions for analyzing the protocol, with the evaluation of the items using the Likert scale, with categories in four levels of importance, with the selection of a single answer for each variable of the instrument: Inadequate (1); Partially Adequate (2); Adequate (3); Fully Adequate (4).

For analysis, the following categories were considered: Totally Adequate (TA), Adequate (A) that obtained judgments approved in a favorable consensus of 80%. Still at this stage, a space for suggestions and considerations was made

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available, in an observation column, for each item of the instrument, which after the first evaluation was carried out the second round to obtain and consensus of the judges.

RESULTS

The protocol is divided into topics that are: Introduction, Human Resources, Processing of Health Products, Cleaning Area, Preparation and Sterilization, Storage and Distribution and References.

As for the characterization of the 11 judges, 91% were women with a mean age of 49.6 years (±2.26), nurses with a graduation time of 21 years (±3.32), time of specialization in MSC (±2.92) and working time in the area of 17.2 years (±3.12).

From the answers related to the protocol content and considering for the data analysis the answers marked with classification "1" Inadequate (I), "2" Partially Adequate (PA), "3" Adequate (A), "4" Totally Adequate (TA), it was possible to verify that of the 20 questions presented to the judges, a total of 220 answers were obtained.

Tables 1, 2, and 3 show the Content Validity Index (CVI) related to each question answered by the judges in the 1st and 2nd rounds. In the first round, of the 220 responses, two were considered Partially Adequate, 123 Adequate and 95 Totally Adequate, with the overall CVI = 0.99.

Two questions were evaluated as (PA), in the item relevance, and are described in Table 1. All requested details were included in the protocol and suggestions for an action plan addressing how and when the manual would be used at MSC were included in the dissertation as a study perspective.

After the protocol corrections, the 2nd round was performed, with 88 responses being (A) and 132 (TA) and the global CVI = 1.0, therefore, being considered adequate by all the judges.

Table 1 - Judges' responses in the validation process regarding the purpose of the protocol, (2019).

Objective	1st round CVI	2nd round CVI
It is consistent with the goals to be achieved with the use of the protocol.	1,0	1,0
It is consistent with the needs of the intended team.	1,0	1,0
It is consistent with the criteria of the technique described in the protocol.	1,0	1,0
It can circulate in the scientific environment in the health area.	1,0	1,0
Meets the objectives and needs of the Institutions' Material and Sterilization Center.	1,0	1,0

Source: Prepared by the authors, 2019.

Table 2 - Judges' responses in the validation process regarding the structure and presentation of the protocol, (2019)

Objective	1st round CVI	2nd round CVI
The protocol is appropriate for the guidelines of the techniques, the sequences are suitable for the planning of activities in the MSC.	1,0	1,0
The material has adequate content for what was proposed.	1,0	1,0
The information presented in the techniques and guidelines is scientifically correct.	1,0	1,0
The proposed protocol is appropriate to the sociocultural level of the target audience.	1,0	1,0
The information is well structured in concordance and spelling.	1,0	1,0
The writing corresponds to the level of knowledge of the target audience.	1,0	1,0
The cover, back cover, presentation and references information are correct.	1,0	1,0
The size of the title, subtitles, font and font size is adequate.	1,0	1,0
The illustrations express enough necessary information.	1,0	1,0
The number of pages and illustrations is adequate.	1,0	1,0

Source: Prepared by the authors, 2019.

Table 3 - Judges' responses in the validation process regarding the relevance of the protocol, (2019).

Objective	1st round CVI	2nd round CVI
Themes address the key aspects that should be.	1,0	1,0
The protocol proposes to the professional to acquire knowledge of the MSC activities.	1,0	1,0
The protocol addresses the techniques necessary for the preparation of the health professional who is part of the MSC.	0,90	1,0
The Protocol is suitable for use by professionals in their MSC activities	0,90	1,0

Source: Prepared by the authors, 2019.

DISCUSSION

The MSC, also known as the Sterile Material Center or Sterilized Material Center, is a sector dedicated to cleaning, preparing, packaging, sterilizing and distributing all products for medical and hos-

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pital health.

Its mission is Guidelines, moving on to Practical Health Products, Diagnostic Service Providers with Materials, Quality Assistance Processes and Quality necessary for safe assistance. It is a unit seen as an indirect service provider for the patient, because from the processing of health products, performed correctly in this sector, direct benefits to health care are guaranteed. [7]

Implementation of up-to-date guidelines and proper training on cleaning and decontamination of surgical materials are critical to ensuring that surgical instruments do not transmit infectious pathogens to patients. [8]

Due to the demand and complexity of surgical materials and equipment, there was a need to implement new ways of preparing and processing them. In order to have a positive impact, the protocols must be supported by criteria appropriate to the real conditions of the service, to avoid a fragmented and unplanned work process. [9]

Thus, the Protocol for Processing Health Products at the Material and Sterilization Center (MSC), it has 45 pages with illustrative texts and images to facilitate the understanding of the activities developed, it was developed for its target audience using simple language so that the subject was widely accessible to professionals in the area, regardless of training. Consisting of photos of materials, products, equipment, procedures and illustrative figures.

For the validation of the protocol, the Delphi technique was used and the participation of expert judges in the area. Invitations were sent to the eleven judges and all agreed to participate in the study and signed the informed consent. Then, a questionnaire was made available using Google Forms, a copy of the protocol was sent by e-mail to each participant, with no dropouts in any of the rounds.

As in other studies, two rounds were carried out to validate the protocol, considering that the questionnaire answered, in the first round, presented a Content Validity Index higher than the stipulated minimum of 0.78. The suggestions addressed for improvement were accepted and incorporated into the protocol that was sent along with the second version of the protocol with corrections and considerations suggested by the judges. [10]

The judges' responses regarding the topics were objective, structure, presentation and relevance, were analyzed individually and globally. For each topic, spaces were included so that the judges could insert opinions and suggestions. Through the Delphi Technique, it was possible to obtain consensus from MSC experts on the subject of the study. [11]

The protocols provide information that contribute to the adequacy of the physical structure, organization of processes and human resources that comply with current legislation. Therefore, by adapting these aspects, there is a direct reflection on working conditions, providing safety in the environment, improving the quality of work processes and promoting the recognition and visibility of nurses' work. [12]

In the validation process, the judges contributed with suggestions that were fundamental to deepen some themes. These topics were addressed in this protocol, which aims to qualify professionals to carry out specific activities in each area. In addition, standardize the techniques and procedures performed at each stage to promptly meet demand at consumer units.

One of the judges' suggestions was the inclusion of care at the points of use (pre-treatment, time for removal and specific care by type of PHP) is one of the inclusion requests and is inserted on page 15 of the protocol, referring to cleaning the tweezers immediately after use, in or-

Table 4 - Suggestions from the judges to improve the Protocol (1st round), 2019.

Topics requested by judges to be detailed	Conduct
Include care with PHP at the points of use (pre-treatment, time for removal, specific care by types of PHP);	All requested details were included in the protocol.
Include PHP care in the removal of the OS, procedure rooms and inpatient units and their referral to the MSC cleaning area;	
Include care with PHP upon receipt in the cleaning area: Manual pre-cleaning always? When to proceed? Cold water vs hot water? Care in the assembly of baskets and rackies (number of pieces, arrangement, types of PHP);	
Include cleaning quality control: Why and how to establish? Detail more about cleaning chemical indicators and for cleaning equipment validation;	
Detail about manual cleaning: needs more detail;	
Include complex PHP cleanup;	
Include other types of detergent, in addition to enzymatic ones;	
Explore saturated steam under pressure sterilization. Include an approach regarding process parameters, qualification and validation of autoclaves, assembly and validation of sterilization loads, leak-test wet loads, formation of non-condensable gases;	
Include other sterilization methods used in the various PHP in our hospitals: ETO, Formaldehyde Vapor, Gamma Radiation, as well as the use of outsourced services for these methods;	
Include pipelines in the reprocessing of single-use PHP;	
Include an action plan addressing how and when the protocol would be used at MSC: periodic training.	

Source: Prepared by the authors, 2019.

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der to prevent the drying of organic matter and the production of biofilm. In the literature, this information is described in the first stage of the PHP. [13]

In the approach to cleaning quality control, a judge suggested that the topic of indicators and equipment validation be more detailed. In the literature, indicators are values or variables associated with an activity that indicate some relationship, they are quantitative measures of quality related to the structure, process and results. [14]

As for the validation of cleaning equipment, this process comprises the stages of installation qualification, washing machine operation and process performance performed annually, in accordance with current legislation. [15]

It was suggested by a judge to explore more about the manual cleaning of PHP, which is performed by means of friction, with the aid of brushes with different diameters on the surface of the products with water and enzymatic detergent. In the literature, the recommendation is that this technique be limited due to variations between professionals in the way of performing this service, reducing the effectiveness of the process.[16]

Care for more complex products was described in the protocol. Cleaning complex PHP is considered difficult to access due to the fact that the product has long and narrow lumens, multiple internal and external channels, valves, gaps, joints, fittings, rough surfaces, with grooves and clamps that do not allow disassembly. [17]

A judge suggested the inclusion of types of enzymatics, which are compounds based on enzymes that act on organic matter and have surfactants in their composition that help to reduce fat. The concentrated detergents for cleaning materials are neutral, alkaline and enzymatic. This information was inserted into the protocol, making it more consistent with this practice in the PHP cleaning process. [18]

The most used sterilization process in the hospital area is the steam method, saturated under pressure, performed by equipment called autoclave used in health care, considered the lowest cost method. The essential parameters are time, temperature and pressure, detailed information has been added in the protocol. [19,20]

> The World Health Organization estimates that, annually, 234 million surgeries are performed worldwide at a ratio of one procedure for every five people alive.

One judge noted the need to describe other sterilization methods that are used by MSC, hydrogen peroxide plasma sterilization was highlighted, described in the literature as a physical-chemical method for materials such as catheters with at least 1 mm of internal diameter, rigid and flexible endoscopes, as well as video surgery material. [21]

Another request was to include information on the processing of reprocessable materials, which takes place through an outsourced company as it is a process with validated protocols. The literature addresses this process with Resolution No. 2,606, of August 11th, 2006, which provides guidelines for the elaboration, validation and implementation of protocols for medical products. [22]

As a perspective, it is necessary that more studies on the processing of Health Products be created and encourage MSC professionals to enhance work processes with regard to patient safety in health care.

CONCLUSION

The construction of the protocol made it possible to organize processes, establish flows and standardize conduct. In this way, it provided scientifically based assistance for health professionals. In view of the findings of this study, a greater number of publications on the search for best practices in the processing of health products will be necessary to expand nurses' knowledge in the material and sterilization center, since each step of the process, whether cleaning, preparing and sterilizing a product, characterizes an indicator of the quality of care provided.

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