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Original Article

Development of a barrier system for disinfected products: cooperation between industry and services

Desenvolvimento de sistema de barreira para produtos desinfetados: cooperação entre
indústria e serviço

Carmen Eulalia Pozzer[1], Heloisa Helena Karnas Hoefel[2], Ivana Gottardo Rocha[1], Leria Rosane Holsbach[1], Rita Catalina Aquino Caregnato[3].

[1]Santa Casa de Misericórdia de Porto Alegre, Porto Alegre, RS, Brazil.
[2]Universidade Federal do Rio Grande do Sul, Porto Alegre, RS, Brazil.
[3]Universidade Federal de Ciências da Saúde de Porto Alegre, Porto Alegre, RS, Brazil.

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pozzer@santacasa.tche.br

ABSTRACT

Background and Objective: There are many studies on the Sterile Barrier System (SBS) and sterility preservation; however, it is difficult to present data on the preservation of disinfection. This is related to the lack of supply of the barrier system (BS) available in the market, specific for this purpose. While searching for the validation of the thermal disinfection process preservation, the lack of an available BS became evident. This study aims to validate the BS developed by the industry, according to the service requirements for the preservation of the thermal disinfection of semi-critical Healthcare Products (HCP) used in respiratory care. **Method:** This is an experimental, laboratory study carried out as a technological cooperation between services of a Health Care Facility in Porto Alegre, Rio Grande do Sul, Brazil, and an industry in São Paulo, Brazil, aiming to develop a BS to preserve thermal disinfection. Thermal disinfection of semi-critical pediatric HCP was carried out, and all disinfection phases were controlled, with 204 samples being analyzed and submitted to microbiological studies, between October 2013 and June 2014. **Results:** Quantitative and qualitative microbiological analyses showed no pathogen growth and epidemiological relevance during the 49-day period of storage of thermal-disinfected

HCP and packed with the BS. **Conclusion:** The study concluded that the developed BS exerted its protective function, preventing cross-contamination of the HCP.
DESCRIPTORS: Nursing research. Disinfection. Equipment Contamination.

RESUMO

Justificativa e Objetivo: Existem muitos estudos sobre Sistema de Barreira Estéril (SBE) e preservação de esterilidade, entretanto há uma dificuldade de apresentar dados sobre a preservação da desinfecção. Isto se atribui à falta de oferta no mercado de Sistema de Barreira (SB) específico para esta finalidade. Durante a busca pela validação do processo de preservação da desinfecção térmica evidenciou-se a inexistência de SB disponível no mercado. Este trabalho teve como objetivo validar o SB desenvolvido pela indústria, conforme as necessidades do serviço, para a preservação da desinfecção térmica de Produtos Para Saúde (PPS) semicríticos utilizados na assistência respiratória. **Método:** Estudo experimental laboratorial realizado em cooperação tecnológica entre serviços de um Estabelecimento de Assistência à Saúde de Porto Alegre, Rio Grande do Sul, e de uma indústria de São Paulo, Brasil, no desenvolvimento de um SB para preservação da desinfecção térmica. Realizou-se termodesinfecção de PPS semicríticos pediátricos, com todas as etapas controladas, analisadas 204 amostras submetidas a estudos microbiológicos, entre outubro de 2013 e junho de 2014. **Resultados:** As análises microbiológicas quantitativas e qualitativas não evidenciaram crescimento de microrganismos patogênicos e relevância epidemiológica durante o período de 49 dias de armazenamento dos PPS termodesinfetados e embalados com o SB. **Conclusão:** O estudo concluiu que o SB desenvolvido cumpriu sua função de proteção, prevenindo a contaminação cruzada dos PPS.
DESCRITORES: Pesquisa em enfermagem. Desinfecção. Contaminação de equipamentos.

INTRODUCTION

Healthcare-Associated Infection (HAI) prevention and control depend on a set of actions, including the correct processing of Healthcare Products (HCP), aiming to prevent harm to patients.[1] The emergence of microorganisms that are increasingly resistant to antimicrobials currently available for therapy adds even more importance to the treatment of HCP and, consequently, to the Central Sterilization Supply Department (CSSD). The sterilization quality control processes are traditional and the quality indicators for safe sterilization processing are innumerable in the research in this area. However, there is a gap in the literature on disinfection and corresponding packaging aiming to maintain the safety obtained by the disinfection process after the products have been packaged and stored.

In Brazil, the processing of HCP used in healthcare is an activity regulated by the Federal Nursing Council (COFEN) and usually developed by nursing professionals in the MSC, which is responsible for its processing, regardless of whether it is processed in the Healthcare Facility (HCF) service itself or at an external service.[2]

The traditional system of device classification is used to determine the required processing of the HCP according to its potential risk of transmitting infection.[3,4] This definition has been used since 1971 to determine the type of treatment required for the HCP.[5] Based on this concept, HCP classified as critical requires sterilization; the semi-critical products require at least disinfection; and non-critical ones, at least cleaning.[4,6] Disinfection can be classified into three levels: high, intermediate and low.[7] The difference between levels is due to the degree of contamination of the body sites where the different HCPs will be used.

Cleaning is the first step in the preparation of HCPs, crucial for any material processing; thus, in all levels and types of disinfection, the previous cleaning of the HCPs is a determining factor for its effectiveness. The cleaning and thermal disinfection of products using an automated method allows greater control of the process, because dirt residues are eliminated during the cleaning process and the microbial load is reduced under controlled conditions (time, temperature), whereas during the thermal disinfection process, the controlled temperature of the water is the main agent of disinfection.[7] The level of thermal disinfection (low, intermediate or high) depends on the time and temperature. [7,8] A high level of thermal disinfection is achieved with higher temperatures and longer time. In Brazil, there are no official normative rules for the operationalization (time and temperature) of thermal disinfection washers, but the sporadic evaluation of their performance is indispensable.

After the processing, it must be ensured that the HCP will be used without causing any damage, i.e. that the elimination or reduction of the microbial load achieved through processing will be maintained until the moment of its use. This guarantee is attained by using a Barrier System (BS), formerly known as packaging, which aims at protecting the product.[8,9]

There are many studies on Sterile Barrier System (SBE) and preservation of sterility, as well as the types of SBE used to pack devices that will be sterilized. The scarcity of studies on disinfection preservation is attributed to the lack of supply in the BS market that is specific for this purpose, because when the validation of the thermal disinfection preservation process was assessed, the lack of BS available in the market was demonstrated.

The identification of this problem motivated the research and technological cooperation with the industry to develop a BS called “Packaging for Products submitted to High-Level Disinfection” (*Embalagem para Produtos submetidos à Desinfecção de*

Alto Nível - EPRODAN®). This study aimed to validate the BS developed by the industry, according to the needs of the service, aimed at the thermal disinfection preservation of semi-critical HCPs used in respiratory care.

METHODS

This is an experimental, laboratory study carried out in technological cooperation between the services of an HCF, at the Federal University of Rio Grande do Sul, Federal University of Health Sciences of Porto Alegre, in the state of Rio Grande do Sul, Brazil, and the industry, for the development of a BS aimed to preserve the thermal disinfection of HCPs used in pediatric respiratory care.

The MSC of this study belongs to an HCF comprising seven hospitals, with a total of 1,240 beds, located in Porto Alegre, state of Rio Grande do Sul, Brazil. The study took place between October 2013 and June 2014, involving four previously established care units of the pediatric hospital.

In order to perform the experiment, respiratory assistance HCPs (masks, humidifiers and pediatric extensors) were processed through the automated cleaning method, with thermal disinfection and drying. The HCPs were packaged in experimental BS to preserve the disinfection and stored in the pediatric hospital care units. Microbiological studies with 204 samples of these semi-critical products were carried out.

The BS used was developed, produced, tested and validated for this study. This BS consists of four layers of polyester and polypropylene transparent film, with triple sealing on the sides. The characteristics considered to prevent recontamination of disinfected products are resistance to tears and breakage, being non-toxic, impermeable, heat-sealed and transparent. As the sterilization containers are intended to allow the passage of the sterilizing agent and, subsequently, preserve the sterilization, the tested BS is intended to preserve the disinfection.[7]

HCP processing was performed according to the following steps: 1) cleaning and thermal disinfection: automated cleaning process consisting of three phases and thermal disinfection at 93°C for 10 minutes, followed by drying in the thermal disinfection washer, with previously defined and tested physical parameters; 2) additional drying in HCP dryers, with dry heat at 60°C for 20 minutes; 3) packaging in transparent, waterproof, multi-laminated BS made of polyester and polypropylene; 4) Package sealing in semiautomatic thermal sealer at 400°F; and 5) storage of HCPs packed with

BS in a disinfected material ward, in the four pediatric care units (Intensive Care Unit, Emergency Unit and two Hospitalization Units and at the Nurses' Station) in closed cabinets, with an average of 60% of air relative humidity and 25 °C of room temperature, controlled by a digital hygrometer.

The microbiological studies were carried out in five phases, with each phase being termed P, followed by the sequence number of the P phase, as follows: a) P0 - before processing (n = 12); b) P1 - after cleaning, disinfection and drying (n = 12); c) P2 - after additional drying in an HCP dryer (n = 12); e) P3 - after being packed and unpacked (n = 12); e) P4 - after being stored during the different periods (n = 156 samples).

For the different periods, the samples processed during the P4 phase were collected and sent in groups of 12 samples (3 from each of the four units), initially in the first 7 days and subsequently, on the last day of the following 6 weeks, totaling 156 samples on the 49th day. The samples were coded with the letter "D" for Day, followed by the number of the day on which the collection was performed, and the number of samples collected (D1-12 = 1st Day, 12 samples collected): D1-12 samples; D2-12 samples; D3-12 samples; D4-12 samples; D5-12 samples; D6-12 samples; D7-12 samples; D14-12 samples; D21-12 samples; D28-12 samples; D35-12 samples; D42-12 samples; D49-12 samples. The samples for the microbiological HCP tests were performed sequentially up to the 7th day (3 samples from each unit).

The sample calculation was performed considering the mean number of HCPs used per day in ventilatory care and processed by the MSC in 2012.

Quantitative cultures were carried out using the microbiological method of microbial load assessment (list of viable microorganisms), with readings in 24 hours, 48 hours and 72 hours, according to ISO 11737-1, ISO 11737-2 and the FDA (Food and Drug Administration), for non-sterile products, and results were expressed as Colony-Forming Units per milliliter (CFU/ mL).[10-12] As for the qualitative method, the HCP samples were directly inoculated into Tryptone Soy Broth (TSB) and Thioglycolate Broth (TIO) culture medium and incubated for five days. Daily readings were performed. If there was apparent turbidity in TSB and / or TIO, the isolation and identification of the microorganisms were carried out in selective culture media.

During the study period, the thermal disinfection washer used in the MSC operated according to the following parameters: 1) pre-washing for 3 minutes with cold water at 25-35°C temperature; 2) washing for 5 minutes with water and multi-enzymatic

detergent (5 enzymes), at 35-50°C temperature; 3) first rinsing cycle for 3 minutes with water at 30-50°C; 4) second rinsing cycle for 3 minutes at 35-50°C; 5) thermal disinfection, for 10 minutes, at 90-93°C; and 6) drying cycle for 15 minutes at 75-80°C. Chemical cleaning indicators, two per cycle, were used in all cycles in which the semi-critical HCP samples used in the study were processed, and a satisfactory result was obtained.[13]

Preventive maintenance and the Installation Qualification (IQ), Operation Qualification (OQ) and Performance Qualification (PQ) of the thermal disinfection washer were performed immediately before the start of the study. The performance of the thermal disinfection washer was assessed by clinical engineering technicians throughout the study.

RESULTS

The results of the microbiological tests performed at the five phases of the study are shown in two tables below. Table 1 shows the results of the quantitative microbiological study for fungi and bacteria in the first four phases, before and after HCP cleaning.

Table 1 – Values of Quantitative Microbiological Cultures found in the first 4 phases of the study in 48 samples (12 in each phase) of semi-critical HCPs used in pediatric ventilatory assistance in an HCF in southern Brazil, May 2014.

	Bacteria			Fungi		
	Cult (-)	Cult (+)	CFU	Cult (-)	Cult (+)	CFU
P0 – before processing	3	9	1.0×10^2 5.5×10^6	12	-	-
P1 - after cleaning, thermal disinfection and drying in thermal disinfection washer	10	2	1.56×10^2 2.19×10^2	12	-	-
P2 - after cleaning, thermal disinfection, drying in thermal disinfection washer and drying.	12	-	-	12	-	-
P3 - after cleaning, thermal disinfection, drying in thermal disinfection washer and additional drying in HCP dryer and packed in BS.	12	-	-	12	-	-
TOTAL	**37**	**11**		**48**	**-**	**-**

The results of Table 1 show growth in the first two phases P0 (9 positive) and reduction in P1 with two samples, showing 156 and 219 CFU. In P3, with the additional drying, there was no microorganism growth after the incubation period.

Table 2 displays the quantitative results for fungi and bacteria in the P4 phase, after HCP storage, carried out between the 1st and the 49th day. Daily analysis were carried out from the 1st to the 7th day; from the 7th to the 49th day, analysis were carried out every seven days.

Of the 156 samples that were sent to be analyzed, one hundred and thirty-four (134) did not show microbial growth, twenty-two (22) showed bacterial growth, and five (5) showed fungal growth. Although the cultures were positive, the values was up to 10^2 CFU (or 100 CFU).

Table 2 – Values of quantitative microbiological cultures identified in the 156 semi-critical HCP samples used in ventilatory assistance, in the P4 phase of the study, from the first to the 49th day of storage in pediatric care units of an HCF in southern Brazil, between May and June of 2014.

P4	Bacteria	Fungi

	Cultures (-)	Cultures (+)	UFC	Cultures (-)	Cultures (+)	CFU
D1	10	2	1.0 x 10; 2.0 x 10	12	0	
D2	12	0		12	0	
D3	11	1	1.5 x 10; 2.0 x 10	12	0	
D4	7	5	1.0 x 10; 4.0 x 10	11	1	1.0 x 10
D5	7	5	1.0 x 10; 2.3 x 10	11	1	1.0 x 10
D6	10	2	1.0 x 10; 2.0 x 10	12	0	
D7	11	1	1.0 x 10	12	0	
D14	11	1	1.0 x 10	11	1	1.0 x 10
D21	10	2	2.0 x 10; 5.0 x 10	12	0	
D28	12	0		11	1	1.0 x 10
D35	11	1	2.0 x 10	12	0	
D42	10	2	1.0 x 10; 2.0 x 10	12	0	
D49	11	1	1.0 x 10	11	1	1.0 x 10
TOTAL	**134**	**22**		**151**	**5**	

The results of the Qualitative Analysis of the study, obtained by the Microbiology Laboratory in the 156 samples of semi-critical HCPs used in ventilatory assistance at the P4 phase from the 1st to the 49th day of the study were negative, since the insufficient number in the quantitative analyses prevented the qualitative one to be carried out.

After 24, 48 and 72 hours, there was no microorganism growth (fungi and bacteria in the 156 analyzed samples. The isolated microorganisms were not pathogenic and had no epidemiological relevance after the 72-hour period.

DISCUSSION

The first step to evaluate the effectiveness of the BS in preserving the thermal disinfection of semi-critical HCPs used in respiratory care was to establish a cooperation with the industry, aiming to develop a BS for semi-critical HCPS submitted to thermal disinfection. As there are several types of SBS for HCPs submitted to the sterilization process, there are publications in the literature addressing the indication and required characteristics to preserve sterilization; however, the differential of this study

was the focus of a BS for thermal disinfected HCPs.[14,15]

There was a high microbial load in the HCP samples prior to cleaning, and after the cleaning and disinfection process, the microbial load was decreased and considered low and acceptable in the disinfection process.[13] There was a significant reduction of Bioburden, allowing us to say that the thermal disinfection washer showed a good performance, considering the defined and utilized parameters.

The semi-critical HCPs used in respiratory care should be submitted to at least intermediate level disinfection.[5,6,8] The elimination of viruses, fungi and bacteria is attained at the intermediate and high level disinfection, but there is a limitation regarding the elimination of bacterial spores.[9,14]

The results demonstrated in P4 show that the absence of microorganism growth for the qualitative processing during the 49-day period of storage, allows the safe use of these products in healthcare. Safety, in this case, is different in studies assessing critical HCP processing, which require sterilization, since only the absence of bacterial growth can be accepted.[15]

One of the study's limitations consisted of the polymers that make up the structure of some of the HCPs used in this study, used in the MSC routine. These polymers are heat-sensitive and show damage or reduced life span when exposed to high temperatures. The maximum time used to maintain their integrity was 10 minutes with a maximum temperature of 93°C, which is sufficient to promote thermal disinfection.[7] Another limitation was the lack of knowledge about the initial microbial load of each HCP sample, which varied from 10^2 to 10^6. If microorganism growth occurred after the processing and storage, it would not be possible to identify whether it was residual or if it was contaminated after processing, which would cast doubts on the BS effectiveness.

The present experimental study validated the BS developed after the evaluation of its effectiveness for the preservation of thermal disinfection of semi-critical HCPs used in pediatric respiratory care. The HCP samples, submitted to the thermal disinfection process and packaged in the developed BS, retained their effectiveness as semi-critical HCPs during the forty-nine days of the experiment. This study concluded that BS exerted its protective function, preventing cross-contamination of HCPs. The forty-nine days were considered sufficient to validate the process, as these HCPs are not stored for periods longer than 30 days, as they are used before that period expires.

It is worth emphasizing the importance of developing protocols to define

physical parameters (time and temperature) for the processing of semi-critical HCPs used in respiratory care, and performing them correctly, as well as using an adequate BS that preserves disinfection, contributing to the decrease in hospital infections through the use of safe products for healthcare assistance.

The multidisciplinary participation of the University, Industry, Clinical Engineering, Laboratory of Microbiology, Care Units and MSC was considered a factor that positively contributed to the attainment of this study.

The development of new products in cooperation with the industry, seeking to improve the quality of healthcare, is a task that can be more often accomplished by nurses, as they can clearly identify the needs for such developments during the course of their work activities.

CONFLICTS OF INTEREST

The authors declare there are no conflicts of interest regarding the present study.

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