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ORIGINAL ARTICLE

REUSABLE MEDICAL DEVICES STORAGE AREA: RETHINKING THE SHELVES DECONTAMINATION FREQUENCY

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ABSTRACT

Objective: To evaluate the potential risk for related events, inherent to the decontamination process of storage area shelves. **Method:** Related events were recorded in a checklist, previously evaluated by specialists, through direct non-participant observation in 10 work shifts at a Central Sterile Services Department (CSSD) of a large public hospital in the Midwest Brazil. **Results:** Shelf decontamination was performed at 85 of 160 observed opportunities. The main risk actions for related events were: over handling of the package, up to 10 touches/product, with an average of 3.17 touches, most of them exceeding two touches/ product (58.8%); no hand hygiene before, during or after the procedure; improper handling/displacement of products and improper action in case of product fall on the floor (6.25%). **Conclusion:** The related events observed during the shelf decontamination process represent a risk for product sterility maintenance, suggesting the need for reflection/discussion about the decontamination frequency of this clean area.

Keywords: Product storage. Decontamination. Sterilization. Nursing.

INTRODUCTION

Reusable Medical Devices (RMDs) is one of the pillars for the prevention and control of Healthcare-Associated Infections (HAIs). This process consists of a set of interdependent steps, ranging from pre-cleaning to storage and distribution of products to consumer units[1-3], having the quality related to the success of each one. However, in order to guarantee a safe RMD, after the sterilization process of critical products, those that penetrate tissues or vascular system with no colonizing own microbiota[4], it is central that sterility be maintained[1-3]. Thus, in order to preserve sterility, the subsequent step (storage and distribution) is of fundamental importance and must comply with recommended quality indicators[2-5].

Structure quality indicators, such as exclusive area, separated by physical barrier and restricted access[4] and windows with screens[6], are required in order to minimize the circulation of people and excessive handling of the RMD, to prevent from dirt and insects entry in the area. In addition, the decontamination process of its surfaces is recommended, including its furniture, such as shelves/racks where the RMDsare placed[2,3,7-9]. Currently, there is no consensus on the routine decontamination of the storage and distribution area, which includes furniture[2], and some corporations recommend it daily[3,7]; however, decontamination with such frequency may result in an increase in the number of RMD handling and displacement opportunities. Thus, we assume that, depending on how they are performed, these actions may favor adverse conditions (related events) that may compromise the integrity of the sterile barrier system and result in RMD contamination [10].

In this sense, it is questioned: is it safe to perform daily decontamination of furniture, considering that this area must comply with structure quality indicators that minimize the presence/entry of external dirt, and that the decontamination process involves, among others, the handling and displacement of RMDs that favor the occurrence of a related event?

Given this and based on the importance of preserving the sterility of RMDs for safe patient care, the aim of this study was to evaluate the potential risk for related events inherent to the decontamination process of storage area shelves.

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The diagnosis obtained through this study may point to indicators that guide the action planning and protocol creation that guarantee the safety of the RMD and, consequently, that of its users. Additionally, it contributes to the practice of nurses who have historically assumed technical responsibility for the Central Sterile Services Department (CSSD) in Brazil.

METHODOLOGY

This is a descriptive cross-sectional study conducted in the storage and distribution area of the CSSD of a large public hospital in Midwest Brazil. The CSSD is class II, performs the processing of non-critical, semi-critical and critical RMD of complex and non-complex conformation, capable of processing and is of centralized operation[1].

The storage and distribution area is 40.5 m^2 and has an entrance chamber, an exclusive sink for hand hygiene, liquid soap and paper towel holder and an alcohol dispenser, as well as a stainless-steel storage shelf for protective equipment (cap and protective cover for shoes). Access is restricted and three pass-through autoclaves separates it from the other clean areas of the CSSD, there are natural and artificial lighting, screened windows and air conditioning equipment. As for furniture, it has 16 stainless steel shelves (open furniture with overlapping shelves), with a predominant distance between floor and ceiling of more than 20 cm and 45 cm, respectively, a carriage for the RMD and a wooden table.

During the study period, the unit did not have a written routine for decontaminating the shelves, but there was recommendation for daily cleaning with 70% alcohol, according to the availability of the worker assigned to the unit.

Data collection took placethrough direct non-participant observation recorded in a checklist (Axes: Actions preceding decontamination process, Actions during cleaning and materials used, Actions during decontamination and materials used, Number of RMDs touches during decontamination and actions between shelves decontamination), previously evaluated and tested, of the occurrence of RMDs-related events during the shelf decontamination procedure performed by the scheduled worker in 10 six-hour shifts in which decontamination of shelves was expected. To count the number of touches, RMDs at an easy sightseeing (first or second upper shelf) was chosen from each rack.

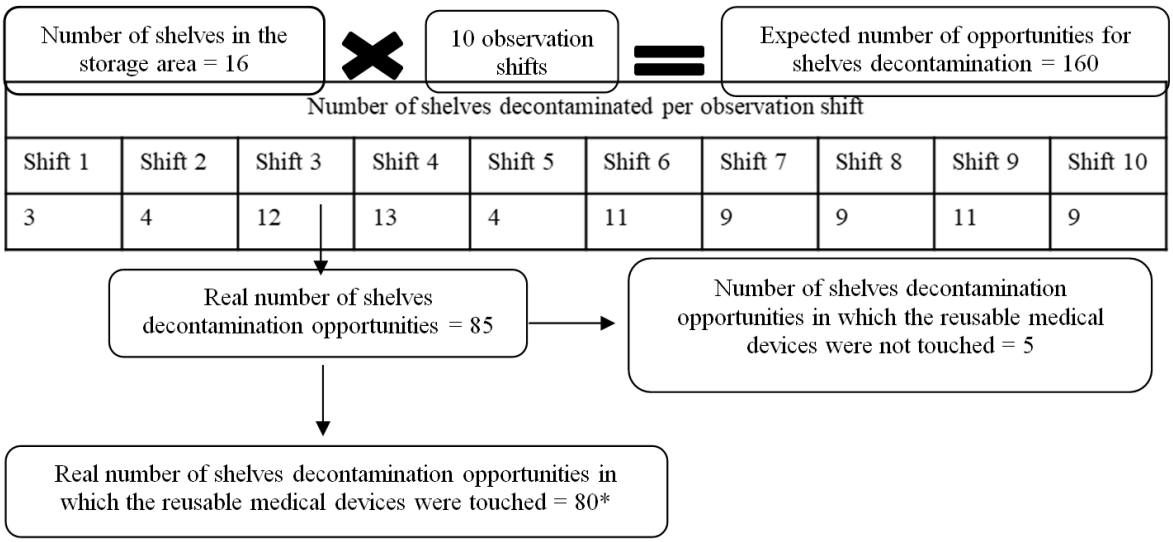
The collection was performed by a nursing student who had been in the unit for three months for academic activities (supervised internship) and was close to the CSSD workers, without revealing in advance the purpose of the observation.

The study was approved by the Research Ethics Committee (protocol n. 167/2011) and, at the end of the data collection, all workers subjected to observation were individually informed about the purpose of the study and signed an Informed Consent Form. Data were entered into an EXCEL® for Windows XP® Program spreadsheet and transported to Statistical Package for Social Sciences (SPSS) for Windows®, version 22.0.

RESULTS

During the study period, furniture decontamination was performed by seven workers, nursing technicians. For decontamination, cloths soaked in 70% alcohol (weight/volume) were the materials used, applied without previous cleaning in most times (n=9/90%). When cleaning was performed, cloths soaked in water and mild soap were the materials used. A total of 85/160 decontamination opportunities were observed because this procedure was not performed on all available shelves (n=16) in the ten shifts in which data collection took place (Figure 1).

For the decontamination of 5/85 observed shelves, the professional did not touch the RMD, performing rubbing with cloth soaked in alcohol only on the surface that surrounded the products. Therefore, of the items targeted by the observation, 80 RMD (1 RMD per shelf) were touched. In these, one to ten touches per product were checked (Figure 2), averaging 3.17 touches, and in most cases the number of touches was more than two touches/product (n=50/85 - 58,8%). Hand hygiene was not performed before, during or after decontamination procedures, and the use of gloves was observed on one occasion (10%).



*One Reusable Medical Device (RMD) was observed per shelf, so 80 RMDs were touched/handled.

Figure 1. Flowchart of the number of expected and real opportunities for shelves/racks decontamination and handling/touch of reusable medical device in the storage and distribution area of a Central Sterile Services Department.

During decontamination of the shelves, the RMDs were displaced in several ways: removed from the shelves and placed on a table covered with cotton cloth; held between worker's body and shelf; kept close to the worker's body; placed on a ladder or on top of other RMDs on the same shelf; dragged to empty spaces on the same shelf; or placed on another shelf. At the moment of relocating the RMDs for decontamination, five products (6.25%) fell to the floor, and in two cases, the RMD was sent for reprocessing and three returned to the shelves.

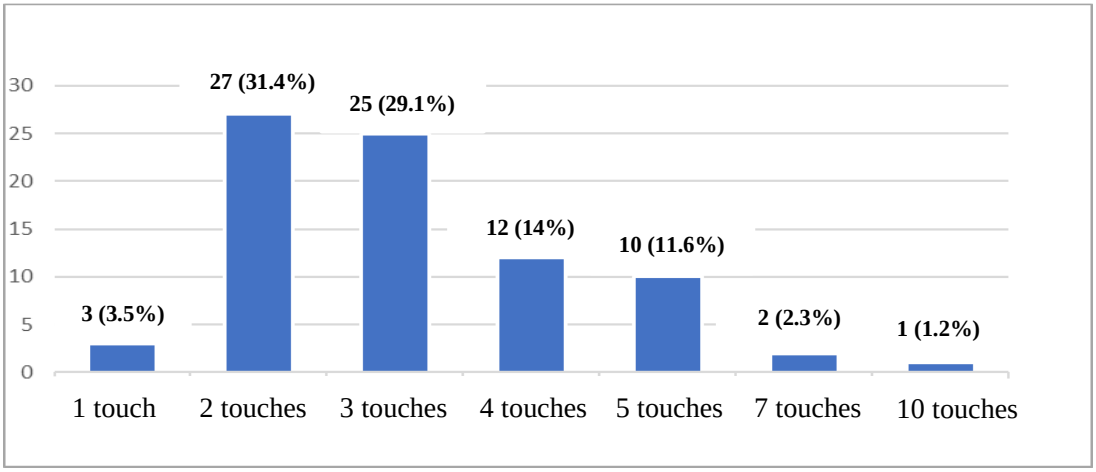


Figure 2. Frequency of touches on reusable medical devices (n=80) on shelves decontamination in the storage and distribution area of a Central Sterile Services Department.

DISCUSSION

The prevention of events related to RMD contamination is widely accepted/recognized as the main measure for maintaining the sterility of critical products[10,11]. To the authors' knowledge, this study is a pioneer in addressing/investigating potential related events

resulting from furniture decontamination in this area and in analyzing the risk/benefit ratio of performing this procedure on a daily basis, considering the structure requirements for this location.

The study revealed actions of potential risk for related events during shelves decontamination such as: disinfectant (70% alcohol) applied to the shelves without prior cleaning and only around the RMDs (without removing them from where they were placed); excessive number of touches (up to 10 touches); no hand hygiene before, during or after the procedure; improper handling/displacement and improper actionswhen the RMDs fell on the floor.

The recommended technique for surface disinfection with 70% alcohol requires prior cleaning, application with a clean cloth and friction for about 30 seconds, in one-way movements, in three repetitions[1]. The current World Health Organization guideline[9] recommends the use of 70% alcohol weekly on shelves, however does not mention prior cleaning. Despite evidence of efficacy of this product, under laboratory conditions, for disinfection of contaminated surfaces without prior cleaning[12], another study conducted with RMDs clinical practice (high-rotation dental pens) showed that, without prior cleaning, alcohol was not able to inactivate the microorganisms for which this agent has proven biocidal action in 46/70 samples evaluated[13]. In addition, the fixative action of organic matter and the reduction of the bactericidal action of alcohol at different concentrations, including 70%, in stainless steel without prior cleaning have been reported[14,15].

It is expected that in the storage and distribution area the microbial load and the presence of dirt are minimal, the non-cleaning before the alcohol application requires investigation in order to substantiate the correct use of this disinfectant agent in this area. Especially, given the risk that reduced biocidal action and fixation of organic matter favor to biofilm formation[14]. The presence of this microbial consortium, consisting of a three-dimensional aggregation of microorganisms adhered to a surface, interface and/or among each other immersed in extracellular polymeric substances produced by them and which provides protection to infectious agents against disinfectant action, has been evidenced in studies which investigated surfaces of health services[16,17] that included alcohol use in their disinfection protocols[18,19]. In addition, it is worth noting that products suitable for surface disinfection that do not require prior cleaning are commercially available, thus more appropriate to the characteristics of areas intended for storage and distribution of sterile RMDs.

The expected number of touches on RMD during decontamination of furniture in the storage and distribution area is two, one to remove it and another to put it back on the shelf. However, in this study, there was an average of touches/product greater than two, which is the case for most handled RMD (50/85). This fact, added to the non-hand hygiene of workers before, during or after the decontamination procedure, leads to a reflection on the risk/benefit of the recommendation of frequent decontamination of furniture in this clean area of the CSSD. Particularly, in the light of evidence indicating the presence of bacteria, coagulase-negative *Staphylococcus*, which makes up the endogenous microbiota of the human skin, including the hands, as the most isolated in studies evaluating RMDs after sterilization, suggesting that contamination of these products is more likely to be related to their handling than to storage time or processing failures[10,11].

These findings also reinforce the practice of hand hygiene as imperative in this area. The non-adherence observed in this study ratifies the results of low adherence to this practice in all areas of CSSD, including the storage and distribution[20]. Similar reality extends to inpatient units, since the handling of RMDs processed without hand hygiene was the most frequent related event observed in the storage areas of these units[21]. The hand hygiene interval was significantly correlated with the increased presence of Adenosine triphosphate (ATP) and microbial load in RMDs, handled during preparation for sterilization, in which, the longer the interval, the greater the contamination[22], reinforcing the need for adherence to this practice, above all, for the maintenance of sterility of RMDs in the storage and distribution area.

The non-adherence to hand hygiene in the storage and distribution area observed in this study contrasts with the available structure, since, even in the presence of necessary structure, the work process was not performed properly. This fact reinforces that the care with RMDs is not exclusively linked to the storage area structure indicators, but has an important relation with the work processes.

Regarding the average of 3.17 touches on a RMD for the decontamination procedure, by simulating a projection for seven days of storage and complying with the daily decontamination recommendation[3.7], a RMD would be touched about 22 times. Would that number be safe? What if this RMD was touched only twice as expected, 14 touches in a week, would it be safe? The limitation of this study to answer these questions regarding its design and the description of the reality of a health service is acknowledged. However, the intention is to bring up discussion of the topic and the need for controlled studies to determine the frequency and best method and way of decontamination of the sterile RMDs storage and distribution area. Thus, besides the excessive number, the ways of handling the RMDs favored the occurrence of related events, which could compromise sterility, since they were kept under pressure (between the worker's body and the shelf) and improperly displaced (dragged to empty spaces in the same shelf).

Holding the RMD between the body and the shelf points to the need for a free surface to place the products while the shelf is being decontaminated as a requirement to perform this procedure and thus avoid the "improvisation" of strategies that favor the "break" of RMD sterility. When dragging the product on the shelf surface, the frictional force exerted between the surfaces (shelf and packaging) can damage the sterile barrier system, especially in the case of heavy products such as surgical trays. In addition, moving the RMD for decontamination increases the likelihood of a serious adverse event, which is the product falling to the floor, as evidenced in this study. This fact was aggravated by the action taken for most of the RMD that fell, which were placed back on the shelf, contrary to the recommendation of sending the product to the cleaning area for reprocessing when this event occurred[8].

CONCLUSIONS

It was concluded that the actions resulting from the decontamination process of the furniture of the CSSD storage and distribution area, study site, resulted in the occurrence of related events, such as excessive handling of the RMD and fall to the floor that compromise the maintenance of sterility.

This fact added to the lack of consensus on the practice and frequency of decontamination of the storage and distribution area and the requirement to establish actions for the control of related events by the CSSD professional[1], historically done by nurses in Brazil, suggests that the findings of this study should be considered by those responsible for adopting a decontamination routine to prevent related events, aiming to ensure the integrity of sterile RMDs packaging and its safety up to its use. This requires skilled workers for this work process[23].

ÁREA DE ARMAZENAMENTO DE PRODUTOS PARA SAÚDE: REPENSANDO A FREQUÊNCIA DA DESCONTAMINAÇÃO DE PRATELEIRAS

RESUMO

Objetivo: Avaliar o risco potencial para ocorrência de eventos relacionados, inerente ao processo de descontaminação de prateleiras da área de armazenamento e distribuição.**Método**: A ocorrência de eventos relacionados foi registrada em *checklist,* previamente avaliado por especialistas, por meio de observação direta não participante em 10 turnos de trabalho em um Centro de Material e Esterilização de um hospital público de grande porte da região Centro-Oeste do Brasil.**Resultados:** A descontaminação das prateleiras foi realizada em 85 das 160 oportunidades observadas. As principais condutas de risco para eventos relacionados foram:excesso de toques na embalagem, até 10 toques/produto, com média de 3,17 toques, sendo a maioria superior a dois toques/produto (58,8%); não higienização das mãos antes, durante ou após o procedimento;manuseio/deslocamento inadequado dos produtos e conduta inapropriada em caso de queda do produto ao chão (6,25%). **Conclusão:** Os eventos relacionados observados, durante o processo de descontaminação de prateleiras,representam risco para a manutenção da esterilidade dos produtos,o que sugere a necessidade de uma reflexão/discussão sobre a frequência de descontaminação dessa área limpa.

Palavras-chave: Armazenamento de produtos. Descontaminação. Esterilização. Enfermagem.

ÁREA DE ALMACENAMIENTO DE PRODUCTOS PARA SALUD: REPENSANDO LA FRECUENCIA DE LA DESCONTAMINACIÓN DE ESTANTERÍAS

RESUMEN

Objetivo: evaluar el potencial riesgo para la presencia de eventos relacionados, inherente al proceso de descontaminación de estanterías del área de almacenamiento y distribución. **Método**: la incidencia de eventos relacionados fue registrada en *checklist,* previamente evaluado por especialistas, por medio de observación directa no participante en 10 turnos de trabajo en un Centro de Material y Esterilización de un hospital público de gran tamaño de la región Centro-Oeste de Brasil. **Resultados:** la descontaminación de las estanterías fue realizada en 85 de las 160 oportunidades observadas. Las principales conductas de riesgo para eventos relacionados fueron: exceso de toques en el embalaje, hasta 10 toques/producto, con promedio de 3,17 toques, siendo la mayoría superior a dos toques/producto (58,8%); no higienización de las manos antes, durante o después del procedimiento; manejo/desplazamiento inadecuado de los productos y conducta inapropiada en caso de caída del producto en el suelo (6,25%). **Conclusión:** los eventos relacionados observados, durante el proceso de descontaminación de estanterías, representan riesgo para el mantenimiento de la esterilidad de los productos, lo que sugiere la necesidad de una reflexión/discusión sobre la frecuencia de descontaminación de esta área limpia.

Palabras clave: Almacenamiento de productos. Descontaminación. Esterilización. Enfermería.

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