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Risk in reprocessing of health products in Basic Units of Salvador, BA

Risco em processamento de produtos para saúde em Unidades Básicas de Salvador, BA

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ABSTRACT

Introduction: There are gaps in the reprocessing of products in primary health care services. **Objective:** To analyze the reprocessing of medical products in Basic Units of Salvador, BA. **Method:** Multiple case study, carried out in Basic Health Units (UBS) of Salvador. The search for data was by interview and observation *in loco*. The analytical categories: management of the reprocessing practices of medical products; Physical structure of the Material and Sterilization Centers (CME); Product reprocessing protocols; Monitoring of processes and traceability of products. **Results:** 11 UBS (84.6%) were analyzed. Of these, the reprocessing activities of products are carried out by the auxiliary of oral health in 81.8%. Absence of air conditioning in 100.0% of CME. Protocols exist in 36.3% of CME. Physical and chemical monitoring of the sterilization process is absent in 100.0% of the cases and biological monitoring is performed in 45.4% of the cases. In no CME is performed annual thermal qualification of the sterilizing equipment, nor is there traceability of the sterilized products. **Conclusions:** The practices identified herein pose a potential risk to users of reprocessed products and urges an effective sanitary control of these services in order to prevent damages related to the reuse of medical products.

KEYWORDS: Sterilization; Equipment and Supplies; Risk Management; Health Centers

RESUMO

Introdução: Existem lacunas acerca do processamento de produtos em serviços de atenção primária da saúde. **Objetivo:** Analisar o processamento de produtos para a saúde em Unidades Básicas de Salvador, BA. **Método:** Pesquisa de casos múltiplos, realizada em Unidades Básicas de Saúde (UBS) de Salvador. A busca de dados foi feita por meio de entrevista e observação *in loco*. As categorias analíticas foram: gerenciamento das práticas de processamento de produtos para a saúde; estrutura física dos Centros de Material e Esterilização (CME); protocolos de processamento de produtos; monitoramento dos processos e rastreabilidade de produtos. **Resultados:** Foram analisadas 11 UBS (84,6%). Dessas, as atividades de processamento de produtos são desempenhadas pelo auxiliar de saúde bucal em 81,8%. Há ausência de climatização em 100,0% dos CME. Existem protocolos em 36,3% dos CME. O monitoramento físico e químico do processo de esterilização é ausente em 100,0% dos casos e o monitoramento biológico é realizado em 45,4% dos casos. Em nenhum CME é realizada qualificação térmica anual do equipamento esterilizador, nem existe rastreabilidade dos produtos esterilizados. **Conclusões:** As práticas ora identificadas configuram risco potencial para os usuários de produtos processados e urge um controle sanitário efetivo desses serviços a fim de prevenir os danos relacionados com o reúso de produtos para a saúde.

PALAVRAS-CHAVE: Esterilização; Equipamentos e Provisões; Gestão de Risco; Centros de Saúde

INTRODUCTION

Products, devices, equipment, materials or instruments used in health procedures are defined by the manufacturer as reusable or single use articles. The latter are intended to be used in a single patient in a single procedure. The reuse of the so-called reusable products requires the action of processing, which consists of converting a contaminated product in a ready-to-use device, including not only cleaning, disinfection and sterilization of the product, but also checking the technical and functional safety through integrity and functionality tests[1,2,3].

It is a consensus in literature that the practice of processing health products is complex due to the risks related to the potential transmission of pathogens and integrity and performance issues of the reused products[4,5,6,7,8].

It is known that there is a certain risk in all health products used in healthcare and that it may cause problems in certain situations. In this sense, there is no absolute safety when it comes to the use of these materials [9,10,11].

The risk of transmission of infectious agents through instruments and equipment depends on some factors, like the presence of microorganisms (type, amount and virulence), the type of procedure to be made (invasive or not) and the site of the body where the product will be used[12]. In addition, the use of any device requires that the interaction between the health professional and the patient incorporate the risks related to the performance/skill/quality of this actor-caregiver at the time of use of the health product in the healthcare procedure[9,10,11].

These risk assertions arising from the use of products increase when the products are reused and processed, since the multiple steps of this process, when performed improperly, generate additional risks for patients, healthcare professionals and the environment[1,2,3].

Among the risks associated with the processing and reuse of health products, the literature reports infection, endotoxins, biofilms, loss of material integrity, bioincompatibility, among others[1,3,4,5,6,7,8].

Most data published about these practices comes from hospital services. There is a knowledge gap on Brazilian practices of processing products in primary healthcare services. There are only a few published studies[13,14,15], which creates the need for greater knowledge on these processes.

Therefore, this study looks into the risk of reusing products in primary healthcare services and aims to analyze product processing at Basic Units of Salvador, Bahia, Brazil, considering the sanitary safety and health protection of the population who uses processed products.

METHODS

This is an evaluative study, whose methodological strategy is the descriptive study of holistic multiple cases. A case study is an empirical investigation that analyzes a contemporary phenomenon within its real-life context, especially when the boundaries between phenomenon and context are not clearly defined, in which case there is a special importance in evaluative research. It includes both single case studies (one unit under evaluation) and multiple case studies (several units under evaluation). They are classified as holistic if they have only one unit of analysis[16].

The unit of analysis of this study is the technical condition of healthcare product processing in Basic Health Units (BHU) of the Cabula-Beiru Sanitary District, located in the city of Salvador, Brazil. In this methodology, these health units will be referred to as “cases “.

The choice of this sanitary district was due to the fact that it is a district with great geographical and population density. The area is home to many BHU and the State University of Bahia (UNEB), the headquarters of this scientific initiation project, which was approved by the Ethics Committee of the university under protocol number 15277713.0.0000.0057.

The study included the BHU located in the chosen sanitary district that had Material and Sterilization Centers (MSC), identified through the National Registry of Health Facilities (NRHF).

The strategies used to search for empirical evidence were interviews using a form with semi-structured questions with MSC professionals and onsite observation.

The selected BHU were contacted by telephone and a visit was scheduled for data collection. Data was collected from October to December 2016. The collection was done by two 7th semester students of the Nursing school, properly trained for this purpose, under the supervision of the project coordinator. The healthcare professionals who were working on the day of the data collection were interviewed.

The independent variables that influence the processing conditions of healthcare products were: 1) Management of the practices of processing products; 2) Physical structure of the MSC; 3) Product processing protocols; 4) Monitoring of the processes of disinfection, sterilization and traceability after sterilization.

A data collection form was prepared to contemplate the variables to be analyzed, having as the gold standard the regulations of the Brazilian Sanitary Surveillance Agency (Anvisa), which regulates the good practices in MSC[17], and recommendations of national and international institutions[18,19,20].

In this study, the term “health product” was used as a synonym for medical products, materials, equipment, items and devices in harmony with Anvisa.

RESULTS

The Cabula-Beiru Sanitary District has 25 BHU, of which nine have no MSC, two are non-official BHU with no telephone, one is located inside a penitentiary complex and, therefore, inaccessible to the research, two units refused to participate in this study, resulting in a total of 11 (84.6%) BHU analyzed.

The description of the results of the empirical data of this study was initiated by the characterization of the physical structure of the MSC of the multiple cases, according to Table 1.

Data presented in Table 1 shows that the majority of the MSC of the BHU we studied have adaptations related to their physical structure: 72.7% (eight cases) present a physical barrier between product decontamination activities and disinfection and sterilization activities; in 81.8% (nine cases), there is a reception room for products to be cleaned and a preparation and sterilization room; the environments of eight MSC (72.7%) are eligible for cleaning (they have materials resistant to water, detergent and disinfectant) and 90.9% of them have artificial lighting (ten cases). The physical structure inadequacies were: absence of a central air conditioning system in all MSC (100%) and absence of a chemical disinfection room in nine cases (81.8%).

Table 2 presents the practices of management of processing health products in the BHU we studied.

According to data of Table 2, of the 11 cases examined, seven (63.6%) centralize all cleaning, disinfection and sterilization activities in their MSC. These activities are performed by the oral health assistant in nine cases (81.8%).

The health products used in the MSC are registered in Anvisa in 90.9% of the cases (ten). The professionals responsible for the activities related to the processing of products are immunized against hepatitis B, diphtheria and tetanus in 90.9% of the cases (ten), although in only four of these cases (36.3%) there are protocols for prevention of biological exposure during work activities.

No MSC we studied reuses products considered to be of single use and proscribed from processing according to Anvisa regulations[21].

The Sanitary Surveillance inspects annually at least 72.7% of the cases surveyed (eight MSC).

The steps of the protocols of processing products of the BHU we studied are presented in Table 3.

From the data of Table 3, we observed the existence of written protocols about the steps that make up the processing of products in only four MSC (36.3%). No case (100%) had defined criteria to evaluate whether the product is eligible for cleaning and, consequently, for processing. The cleaning process in all MSC (100%) is performed manually. Rinsing with drinking water without antimicrobial filter is performed in ten cases (90.9%). The products are dried with a clean dry cloth in seven MSC (63.6%) and with paper towels in four MSC (36.3%). There is no evaluation of the cleaning process in any case (100%). The sterilization process is performed with the physical method of saturated steam under pressure with gravitational autoclave in five cases (45.5%) and the sterilization device is not identified in six (54.5%). The packaging used for the sterilization of the products is the crepe paper in ten MSC (90.9%) and the sterile packages are identified with the content of the material and the date of processing in six cases (54.5%). The sterilization expiration date is based on the usage time of the products in all MSC (100%).

Monitoring of the physical, chemical and biological parameters of the BHU sterilization process is described in Table 4.

Table 1. Physical structure of the Material and Sterilization Centers of the Basic Health Units studied. Salvador, 2016.

	Yes n. (%)	No n. (%)
Physical barrier between activities	8 (72.7%)	3 (27.2%)
Existence of reception/cleaning room	9 (81.8%)	2 (18.1%)
Existence of preparation and sterilization room	9 (81.8%)	2 (18.1%)
Disinfection room	3 (27.2%)	8 (72.7%)
Environments eligible for cleaning	8 (72.7%)	3 (27.2%)
Artificial lighting	10 (90.9%)	1 (9.0%)
Central air conditioning system	0	11 (100.0%)

Table 2. Characterization of Material and Sterilization Centers of the Basic Health Units according to the management of the practices of processing health products. Salvador, 2016.

	Oral Health Assistant n. (%)	Nursing Technician n. (%)
Professional responsible for the RPM	9 (81.8%)	2 (18.1%)
	Yes n. (%)	No n. (%)
Centralization of MSC activities	7 (63.6%)	4 (36.3%)
MSC Inspection by Sanitary Surveillance	8 (72.7%)	3 (27.2%)
Products with Anvisa registration	10 (90.9%)	1 (9%)
Existence of Biological Protocol	4 (36.3%)	7 (63.6%)
Immunization of the professionals (HBV, Diph, Tet)	10 (90.9%)	1 (9%)
Reuse of products Anvisa List RDC n. 2.606/2006	0	11 (100.0%)

HBV: Hepatitis B; Diph: Diphtheria and Tet: Tetanus.

Table 3. Characterization of Material and Sterilization Centers of the Basic Health Units according to the protocols of processing health products. Salvador, 2016.

	Sim	Não
Existence of protocols of the HP processing steps	4 (36.3%)	7 (63.6%)
Criteria for evaluating whether the HP are eligible for cleaning	0	11 (100.0%)
Manual cleaning	11 (100.0%)	0
Rinse with clean water and no filter	10 (90.9%)	1 (9.0%)
Drying with clean dry cloth	7 (63.6%)	4 (36.3%)
Drying with paper towel	4 (36.3%)	7 (63.6%)
Evaluation of the cleaning process	0	11 (100.0%)
Existence of a gravitational autoclave	5 (45.4%)	6 (54.5%)
Crepe paper as packaging material	10 (90.9%)	1 (9.0%)
Sterile product identification: content and date of processing	6 (54.5%)	5 (45.4%)
Sterilization expiration date based on time	11 (100.0%)	0

HP: Health Products

Table 4. Characterization of the Material and Sterilization Centers of the Basic Health Units according to the monitoring of the processes of sterilization and traceability of the processed products. Salvador, 2016.

	Yes	No
Physical monitoring of the sterilization process	0	11 (100.0%)
Chemical monitoring of the sterilization process	0	11 (100.0%)
Biological monitoring of the sterilization process	5 (45.4%)	6 (54.5%)
Annual thermal qualification of autoclaves	0	11 (100.0%)
Traceability of the sterilized products	0	11 (100.0%)

There is no physical and chemical monitoring of the sterilization process in any case and the biological monitoring is performed weekly in five MSC (45.4%). In no MSC the annual thermal qualification of the sterilizing device is carried out, nor is there traceability of the sterilized products.

DISCUSSION

The data obtained about the practices of processing health products on the evaluated CME revealed inadequacies in all the independent variables studied, described next.

Regarding the physical structure, most of the MSC (72.7%) have a physical barrier between the cleaning and drying activities of the contaminated products (room with activities considered "dirty") and preparation, disinfection and sterilization activities (rooms with "clean" activities).

There is a reception room for products to be cleaned and a preparation and sterilization room in 81.8% of the services, unnecessary physical requirements for MSC in primary healthcare units (PHU) that do not reprocess complex products (those with lumen, blind bottom, tubular). Therefore, their MSC are classified by RDC n. 15, of March 15, 2012, of Anvisa[17], as class I, whose requirement is a "technical barrier" and not a "physical barrier" between these activities. There was also no central air conditioning system in any MSC (100%) and no chemical disinfection room in nine cases (81.8%). These are mandatory requirements of great importance for the prevention of workers' exposure during product processing activities. Therefore, we observed project failure of the physical structure of these MSC, with inadequate destination of both physical spaces and allocation of material resources.

The activities of cleaning, disinfection and sterilization of products are centered on the MSC of the BHU we studied in 73.7% of the cases. These activities are carried out by "oral health assistants" in the vast majority (81.8%) of the cases. This suggests possible technical problems, since these professionals are not qualified for these activities and may use inadequate product processing practices. Moreover, this situation can be characterized as a deviation from function and in disagreement with the Resolution of the Federal Nursing Council (Cofen) n. 424, of April 19, 2012, which formalizes the competence of nurses and their staff in the processing of products in Brazil[22]. It is important to emphasize that Cofen is the only Professional Council to define the technical roles and responsibilities regarding the activities related to the processing of health products and, therefore, we consider that this exercise is exclusive to the Brazilian Nursing area until then.

The professionals responsible for product processing are immunized against hepatitis B, diphtheria and tetanus in 90.9% of the cases, despite the absence of protocols to prevent biological exposure during work activities in most of the MSC surveyed (63.6%), suggesting that these immunizations originate from individual and non-institutionalized initiatives. This suggests flaws in the biosafety policy of these services.

Standardized product processing protocols were identified in only four MSC (36.3%), which denotes the lack of planning of the nuclear activities to the reuse of products in most of these evaluated services. The cleaning process, essential for the success of the later stages of the processing of materials, is very deficient, given the absence of evaluation in all MSC surveyed. Furthermore, there is a lack of criteria for evaluation of the product as to the possibility of cleaning and, consequently, processing. Drying of materials after cleaning is performed with paper towels in 36.3% of the services, an inadequate practice that can generate residues on the clean product and affect the subsequent process of sterilization in these cases.

The product sterilization process at the BHU we studied also has some weaknesses, despite the fact that in all MSC (100%) the sterilization method for thermoresistant critical products is saturated steam under pressure, a gold standard method for sterilization of these products. However, the type of sterilizing device is not identified in 54.5% of the MSC, which raises doubts about how this process is performed, since there is a lack of understanding of how the sterilizing device works, whether by gravity or high vacuum and which are its specific controls. Furthermore, in no MSC the annual thermal qualification of the autoclave used in the services is carried out; that is an indispensable process for assessing the performance of the machine and for the achievement of the essential parameters of the steam sterilization process. Additionally, it is key for the standardization of the cycles of sterilization in relation to time, temperature and pressure to be adjusted according to the qualification result. The absence of this control, therefore, means that the autoclaves of the BHU we are being used in an empirical form, without the control of the essential parameters for its operation.

The packaging used for the sterilization of the products is adequate in 90.9% of the cases, however, the identification of the sterilized products is deficient in 54.5%, with only the record of the contents of the material and the date of the processing. The sterilization expiration date is based on the usage time of the products in all MSC (100%), which is an obsolete practice, since the validity of the sterilization is conditioned to an event that can contaminate the packaging and, consequently, the sterilized product, and not related to defined sterilization times[18,19].

Another element that negatively affects the sterilization process of the MSC studied is the absence of physical (time, temperature and pressure controls of each cycle performed) and chemical monitoring of the sterilization process in 100% of the cases. Biological monitoring is performed once a week in only 45.4% of the MSC, in total disagreement with the current recommendation that this control should be daily. The absence of the physical, chemical and biological monitors of product sterilization raises uncertainty about the effectiveness of the sterilizing process and consequently disqualifies this process. How to use a product that requires the condition of sterility, if there is no certainty that it is sterile? This is an unanswered question in the MSC of the BHU we studied and a reality also identified in BHU in the state of São Paulo[13].

No product of the negative list of Anvisa Resolution n. 2.605, of August 11, 2006[21], is used in the cases studied and to that extent these services comply with those rules.

The Sanitary Surveillance inspects at least 72.7% of the MSC surveyed annually, but despite these inspections, the notifications of this institution do not indicate inadequacies related to the processing of the products described herein, nor is there decision-making based on sanitary control, which could improve the work processes in the MSC studied.

CONCLUSIONS

The results of this study demonstrate that the problem involving the processing of health products in hospital services is also identified in primary healthcare services, such as those studied here.

We observed that the processing of products in the MSC we studied is inadequate, with shortcomings in all stages of product processing, especially in the cleaning and sterilization processes. This contributes to the lack of sanitary safety of reused products in these services.

Therefore, we conclude that the practices of product processing of the BHU researched constitute a potential risk for the users of processed products in the basic attention services and that effective sanitary control of these services in order to prevent damage related to the reuse of health products is urgent.

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Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.