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Risk and sanitary safety: analysis on medical product reprocessing in hospitals in Salvador, Northeastern Brazil

ABSTRACT

OBJECTIVE: To analyze the technical conditions for medical product reprocessing in hospitals.

METHODS: This was a descriptive study on multiple cases in materials and sterilization centers at four hospitals in the city of Salvador, Southeastern Brazil, in 2010. Semi-structured interviews were conducted and direct observations were made, based on a regulatory model for medical product reprocessing that was drawn up with the technique of consensus verification as the reference standard. The analytical categories used in this study were: management of the practice of medical product reprocessing; reprocessing protocols; monitoring of the sterilization process; and capacity for product tracking. These categories were scored according to their degree of conformity with the regulatory model for reprocessing used.

RESULTS: General inadequacy of the technical conditions for medical product reprocessing was observed, with regard to the structural conditions of the materials and sterilization centers studied and the work process conditions, along with organizational and managerial difficulties that interfered with the practices analyzed.

CONCLUSIONS: The practices of medical product reprocessing in the hospitals analyzed constitute a risk for the patient users. Risk management systems need to be introduced in these hospitals, with greater sanitary control by the state, in order to protect patients' health.

DESCRIPTORS: Consumer Product Safety. Equipment Reuse. Safety. Sterilization. Equipment Safety. Health Surveillance. Safety Management.

INTRODUCTION

Medical products used in healthcare procedures are becoming progressively more complex. These are defined by the manufacturer as reusable or single-use articles. The reusable articles are considered to be durable goods and their reuse requires reprocessing action, which includes cleansing, performance evaluation testing, disinfection or sterilization and quality control of all stages so as to ensure safety when using them.[1-3] The single-use products are designed to be used once, but the practice of reusing these materials is a worldwide reality. This tendency raises issues regarding the risks involved and the consequent lack of safety for patients, as well as in relation to the technical, regulatory, juridical, economic, ethical and environmental aspects of this practice.[4-6]

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Among the events associated with reprocessing and reuse of medical products are infection, presence of endotoxins, biofilms, loss of the integrity of the material and other matters.[4,7-13]

There are numerous public health problems relating to reprocessing of medical products. The present investigation sought to answer the question: How is the reprocessing of medical products done in hospitals in Salvador (capital of the State of Bahia, Northeastern Brazil)? It is presumed that the reprocessing of medical products in healthcare services is conditional on existence of a system with an organic-functional structure that attends to the intrinsic safety requirements for this activity and that, in the absence of such a system, could exacerbate the risks to the health of the user population.

The objective of this study was to analyze the technical conditions for reprocessing medical products.

METHODS

This was a holistic descriptive study on multiple cases,[14] evaluating technical quality. The analysis unit was the technical conditions for reprocessing medical products in hospitals in the city of Salvador, called "cases" in this methodology, in 2010.

Two hospitals in the Sentinel Network of the National Sanitary Surveillance Agency (Anvisa – *Agência Nacional de Vigilância Sanitária*) were randomly drawn among the four such hospitals located in Salvador (cases 1 and 2). Another two non-sentinel hospitals of similar size and characteristics were also randomly drawn. These were identified through data from the National Registry of Healthcare Establishments (CNES – *Cadastro Nacional de Estabelecimentos de Saúde*) and from the Health Department of the State of Bahia (SESAB) (cases 3 and 4). Four multiple cases were formed. Sentinel hospitals were evaluated because they form part of a cooperation program with Anvisa aimed at management of risks and surveillance of adverse events relating to products, drugs and care processes.

The hospitals were contacted by telephone, to schedule a visit to gather data. A letter was sent to the board of each hospital, with information on the objectives of the research and a consent statement for the data gathering. The data were obtained by the researcher by means of applying a form at a semi-structured interview with the key informer (the person with technical responsibility for reprocessing of medical products), and through direct *in loco* observation based on an observation guide.

An alternative regulatory model was drawn up and was used as the reference standard due to questioning of the Brazilian legislation on the reprocessing of medical products. This model was created using the technique of consensus verification with two diagrams. The first classified the products for the purposes of reprocessing, either as reprocessable products or as non-reprocessable products, according to criteria relating to the possibility of cleaning and maintaining the integrity and functionality of the articles, regardless of whether they were considered to be reusable or single-use. The second diagram presented a logical model of the sequential stages of the reprocessing of medical products, adapting the decontamination methods to the concepts of risk analysis, evaluation and control and constituting the risk management.

The regulatory model that was used made it possible to exclude the list of products for which reuse or reprocessing is prohibited in Brazil, like the one that exists in the current regulatory standard[a]. The criteria used in selecting the products on this list are unclear and the list is difficult to update, due to continual launching of products on the market.

The analytical categories constructed were: 1) management of the practice of medical product reprocessing; 2) reprocessing protocols with definitions of the cleansing, disinfection and/or sterilization processes on the products; 3) monitoring of the sterilization process; and 4) capacity for product tracking.

Each category was constructed with the independent variables that influenced the technical conditions for the reprocessing of the medical products. The categories were scored as one (1) if they were in conformity with the response of the proposed regulatory model and zero (0) if the response was inadequate, thus totaling 87 points, allocated according to the categories described. The greater the number of questions in the analytical category was, the greater its score was, which did not mean that one category had greater importance or value in relation to the other. After scoring each category, the percentages of responses in conformity with the regulatory model were calculated.

Each hospital unit received a score according to its level of technical conditions for medical product reprocessing, which was classified into three levels: 0 – inadequate technical conditions (0% to 40%); 1 – technical conditions required adjustment (41% to 80%); 2 – adequate technical conditions (81% to 100%). The technical conditions for medical product reprocessing were assessed based on the final score obtained: final score = obtained score/maximum score (87) X 100. The attained score showed the conformity of the technical conditions with the normative standards proposed in the regulatory model for each hospital.

[a] Agência Nacional de Vigilância Sanitária. Resolução RE No. 2.605, de 11 de agosto de 2006. Contém a lista de produtos que não podem ser reprocessados. Diário Oficial da União. 2006; 14 ago.

The present study was submitted to the Research Ethics Committee of each of the hospitals studied and was approved by all of them.

RESULTS

Two hospitals were considered to be size 4 (cases 1 and 4) and two, size 3 (cases 2 and 3). The hospitals in the Sentinel Network provide general healthcare and the two state facilities provide specialized hospital care: one of these was a reference hospital for surgical-clinical cardiology and nephrology (case 3); and the other was a reference hospital for emergency traumatology (case 4). The hospitals had their own material and sterilization centers (MSCs) and carried out the reprocessing of their medical products internally.

The MSCs carried out the cleansing, disinfection and sterilization activities on the medical products in a decentralized manner (cases 1, 3 and 4), i.e. other units of the hospital also carried out some of these processes. In all cases, the MSC was coordinated by a nurse. This person with technical responsibility only partially knew the current legislation on medical product reprocessing in case 2; in case 4, this professional was unaware of the legislation. In these hospitals, the service coordinator was unaware whether the medical products used in the institution were registered with Anvisa.

Sanitary inspections carried out by the Sanitary Surveillance of Bahia (VISA-BA) were reported in cases 1 and 3. These hospitals received reports of non-conformities regarding the reprocessing of medical products. In two hospitals (cases 2 and 4), the respective individuals with technical responsibility were unaware whether VISA-BA inspected the MSCs where they worked. There was no registry of sanitary surveillance actions in these organizations.

None of the cases had a committee or group responsible for management of medical products in the institution.

Out of the four cases, two presented all the recommended areas for the activities performed by a MSC (cases 1 and 3). In all cases, there was a physical barrier between the areas considered contaminated and clean. The floor, wall, door and ceiling conditions were inadequate in three cases (2, 3 and 4). The temperature and relative air humidity were, equally, inadequate in the areas of

Table 1. Characterization of the Material and Sterilization Centers according to the cleansing process. Salvador, Northeastern Brazil.

Cleansing Process	Case 1	Case 2	Case 3	Case 4
Written, updated and available protocol for the cleansing process	Yes	Yes	Yes	No
Manual method	Yes	Yes	Yes	Yes
Automated method	No	Yes	Yes	No
Use of enzymatic detergent	Yes	Yes	Yes	Yes
Rinsing with drinking/running water	Yes	Yes	Yes	Yes
Rinsing with drinking water with filter (< μm) for all MPs	No	No	No	No
Rinsing with treated water for ophthalmological, bloodstream, neurological and orthopedic implant MPs	No	No	No	No
Drying	Clean compresses and medical compressed air	Clean compresses and medical compressed air	Sterile compresses and medical compressed air	Clean compresses and medical compressed air
Systemized visual inspection for each MP after cleansing	No	No	No	No
MP integrity/functionality test	No	No	No	No
Chemical test after cleansing	No	No	No	No
Registry of the cleansing cycles	No	No	No	No
Elaboration of indicators for the cleansing process	No	No	No	No
PPE used	Surgical gloves, protective goggles, surgical masks, waterproof lab coats, closed shoes	Surgical gloves, protective goggles	Surgical gloves, surgical masks, waterproof lab coats	Surgical gloves, protective goggles, waterproof lab coats

MP: medical product; PPE: personal protective equipment

all the MSCs studied. The lighting was adequate in all the cases. The air ventilation system was centralized in two cases (2 and 3), inadequate in case 3, and absent in cases 1 and 4. The operational flow of the activities was unidirectional, with no crossing between clean and dirty activities in two cases (1 and 3), but it was inadequate in cases 2 and 4. There were sinks for the MSC professionals to wash their hands during the work activities in two cases (2 and 3), but not in the other two (1 and 4).

In all the MSCs of the hospitals studied, the taps for cleaning contaminated products provided cold water; none of them had hot water, which is necessary when using enzymatic detergents. Case 3 had a tap with a device to clean cannulated products. The articles for performing the cleansing manually (sponges, brushes and straws) were in a good condition for use in only two cases (1 and 3), and were inadequate in cases 2 and 4, which made it difficult to create mechanical friction and remove external dirt from the contaminated products. The work benches presented dimensions compatible with the activities to be carried out in three (1, 2 and 3) of the four cases (Table 1).

None of the MSCs had a drinking water system with a bacterial filter (filters < 5 μm) to retain microbial content in the water used to clean the articles. There were no image intensifier lenses that would allow detailed viewing of the articles after cleansing, so as to examine them for any presence of residues and to perform a visual evaluation of the physical integrity of the clean products. There was a source of medical compressed air to dry the products with internal structures (Table 2).

The plastic containers that held detergent and disinfectant solutions were identified according to the type of solution and presented a lid in only one case (3). In the other cases, these containers were used without lids, and without

Table 2. Characterization of the Material and Sterilization Centers according to the sterilization process. Salvador, Northeastern Brazil.

Sterilization Process	Case 1	Case 2	Case 3	Case 4
Written, updated and available protocol for the sterilization process	Yes	Yes	Yes	No
Sterilization method	Saturated vapor under pressure (thermoresistant MP) Outsourcing with EO (thermosensitive MP)	Saturated vapor under pressure (thermoresistant MP) Formaldehyde vapor (thermosensitive MP)	Saturated vapor under pressure (thermoresistant MP) Outsourcing with EO (thermosensitive MP)	Saturated vapor under pressure (thermoresistant MP) Outsourcing with EO (thermosensitive MP) Dry heat
Type of package	Cotton fabric Surgical grade paper	Cotton fabric Surgical grade paper	Cotton fabric Surgical grade paper	Cotton fabric Surgical grade paper
Identification of the sterilized MP	Content, batch no., reprocessing date, expiration date of the sterilization, sterilization method, name of operator	Expiration date of the sterilization	Content, batch no., reprocessing date, expiration date of the sterilization, sterilization method, name of operator	Content, reprocessing date
Physical monitoring of each cycle	Yes	Yes	No	No
Chemical monitoring (class) in each surgical package/box	Yes	Yes	Yes	Yes
Monitoring with B&D test	No	Yes (done by hand)	Yes	Yes
Biological monitoring	x/week	Daily	Daily	Weekly
Thermal qualification of the sterilizer	Yes	Not done	Not done	Not done
Systematized maintenance of the sterilizer	Yes	Yes	Yes	Yes
Tracking system with CI	Inadequate	Not done	Adequate	Inadequate
Tracking system with BI	Inadequate	Not done	Inadequate	Inadequate
Registry of the physical, chemical and biological monitoring	Incomplete	Complete	Incomplete	Incomplete
Expiration of the sterilization process	Fixed date system	Fixed date system	Fixed date system	Fixed date system

MP: medical product; EO: ethylene oxide; CI: chemical indicator; BI: biological indicator

labeling giving the name, concentration or date of the dilution of the germicide solutions. These are inadequate practices that increase the potential for various risks. There were no ultrasonic washers (indispensable for washing cannulated products) or automated driers in any of the cases. Thermal sealers, which are necessary for adequate sealing of paper packages, were present in all cases, but there was no temperature control on the equipment or control over the quality of the sealing (Table 3).

None of the MSCs had scales for the necessary weight control for packages to be sterilized.

In all cases, medical products on the Anvisa RE list no. 2605/2006,[a] which categorizes the single-use products for which reprocessing is prohibited, were found to be undergoing reprocessing and reuse. Case 1 was reprocessing disposable scalpels with the blade fixed to the handle and disposable surgical compresses; case 2, non-dismountable needles with plastic components, Shaiver blades < 3 mm, non-dismountable tweezers and scissors for video-laparoscopy and plastic cardiac punch devices; case 3, hemodynamic catheters and thorax drains; and case 4, surgical gathering pouches, surgical fields, non dismountable trocars and skin expanders with valves (Table 4).

The classification of the hospitals according to their technical conditions for medical product reprocessing is presented in Table 5.

DISCUSSION

The present study differs from others on reprocessing of medical products because here, these practices are

Table 3. Characterization of the Material and Sterilization Centers according to the disinfection process. Salvador, Northeastern Brazil.

Disinfection Process	Case 1	Case 2	Case 3	Case 4
Written, updated and available protocol for the disinfection process	Yes	Yes	Yes	No
Method used	Manual liquid chemical disinfection	Manual liquid chemical disinfection	Manual liquid chemical disinfection Thermodisinfection	Manual liquid chemical disinfection
Type of disinfectant	Glutaraldehyde % Sodium hypochlorite,%	Glutaraldehyde % Sodium hypochlorite,%	Glutaraldehyde % Sodium hypochlorite,%	Glutaraldehyde % Sodium hypochlorite,%
Existence of an exclusive room	Yes	Yes	Yes	Yes
Ventilation system	Inadequate	Inadequate	Inadequate	Inadequate
Rinsing after disinfection	Drinking water	Reverse osmosis	Drinking water	Drinking water
Monitoring of the disinfectant concentration	Not done	Not done	Weekly	Not done
Discharge criteria for the disinfectant in use	Manufacturer's guidance	Manufacturer's guidance	Presence of dirt Expiration date of the solution	Manufacturer's guidance
PPE used	Surgical gloves, anti-chemical masks	None	Butyl gloves, waterproof lab coats, anti-chemical masks	Surgical gloves

PPE: personal protective equipment

Table 4. Characterization of the Material and Sterilization Centers according to analytical categories of the reprocessing of medical products. Salvador, Northeastern Brazil.

Analytical categories	Case 1 (%)	Case 1 (%)	Case 3 (%)	Case 4 (%)	Mean performance
Management of the medical product reprocessing practices	33.3	22.2	55.6	33.3	36.1
Medical product reprocessing protocols	36.8	31.6	40.4	7.0	28.9
Medical product monitoring	20.0	60.0	40.0	30.0	37.6
Medical product tracking	45.5	0	81.8	18.2	36.3
Mean performance	33.9	28.5	54.4	22.1	

Table 5. Classification of hospitals according to the technical conditions of medical product reprocessing. Salvador, Northeastern Brazil.

Classification	Case 1	Case 2	Case 3	Case 4
Adequate technical conditions (81% to 100%)	0	0	0	0
Technical conditions needing adaptation (41% to 80%)	0	0	54.4%	0
Inadequate technical conditions (0% to 40%)	33.9%	28.5%	0	22.1%

assessed from a sanitary safety viewpoint. Therefore, it presents a broader perspective of risk control and public health, using a regulatory model developed as a reference standard.

The results from this investigation ratify the emblematic questions that involve reuse of the medical products presented in the case descriptions and prove the initial proposition of this study.

None of the four hospital organizations studied presented adequate technical conditions for reprocessing of medical products, according to the regulatory model developed. Three presented inadequate technical conditions for reprocessing and one presented a need to adapt its technical conditions.

Inadequacies in the technical conditions for reprocessing of medical products were observed in all the categories selected for evaluation, except in the traceability of the products (in one case). The smallest percentages of conformity were observed in the management of practices and in the protocols for reprocessing. These data indicate that the rationality of practicing product reprocessing is debatable when done in facilities that lack structural conditions to carry out basic reprocessing and reuse activities. These basic but crucial activities include validated cleansing and product function and integrity tests, and lead to actions that can be considered to be more elaborate (such as monitoring and traceability).

The low performance percentages for management of the practices and protocols for medical product reprocessing reflect the structure and process inadequacies of the MSCs studied, such as flaws in cleaning, disinfection and sterilization activities. These are reflections of difficulties of a managerial and organizational nature in the MSCs, which are consequent to lack of investments and limited input of material resources.

Medical products do not seem to be a prioritized topic in these hospitals' policies, since there is no institutional involvement in information on the processing of products, its results and the consequences for patients and healthcare professionals, or even with regard to which medical devices are reused and reprocessed, how this is done and how many times it is done. These decisions are delegated and limited to the MSC without the broad commitment and responsibility that this issue demands.

None of the MSCs carried out systematized visual inspection of the products that were in a reusable condition, or any integrity and functionality tests, which are necessary for preventing risks relating to cleansing failure and possible alterations to the characteristics of products that have been subjected to multiple reprocessing cycles. Investigation of the functionality of reprocessed medical products requires specific knowledge and specialized equipment, which is rarely found in hospital services. Nevertheless, it is imperative that Brazilian MSCs should incorporate the culture of evaluating and validating the cleaning process, which is currently restricted to sterilization, through adopting the practice of systematic visual inspection, even in the simplest facilities. Chemical tests are necessary in order to prove the absence of organic and inorganic loads in critical products (i.e. those that have a high risk of transmitting infections if inadequately decontaminated) and in devices with a complex configuration, in which visual examination is not possible or sufficient. The practice of cleansing associated with integrity and functionality tests needs to be the main and defining stage for all medical product processing, whether done on single-use articles or on reusable ones, as proposed in the regulatory model.

The practice of reprocessing single-use medical products that are listed by Anvisa shows that hospitals are infringing the normative standards that regulate the reprocessing of products in this country. Even though sanitary inspections had taken place in two of the MSCs studied, this infraction was not detected, which endangers the quality of the sanitary surveillance action and its capacity to identify the risks associated with reprocessing of medical products in MSCs in Bahia.

The risks relating to reprocessing of articles are valid both for products considered to be for single use and for those considered to be capable of reprocessing or multiple use, given that most of the adverse events, or infection outbreaks, are related to flaws in the reprocessing stages and not to the reprocessing itself.[5,10,11] The work processes of an MSC require planning and risk management, and this is only possible with an adequate physical-operational structure and, most of all, professionals who are committed to the issue. The safety of patients who use these devices depends on this.

This study has introduced the concept of residual risk into the topic of reuse of medical products. The

concept may facilitate understanding of the factors that contribute towards occurrences of adverse events relating to health technologies and can be used as a planning, surveillance and coordination instrument by healthcare service professionals and managers. These individuals will be able to understand that, if residual risk is a condition inherent to reprocessed medical products, risk control needs to be concentrated in the work processes within MSCs.

Thus, the debate on the possibility or impossibility of reprocessing products that are considered to be for single use ceases to make sense. Based on the assumption that residual risk exists in the processing of both reusable products and single-use articles, hospital managers will know that the decision on the reprocessing and reuse must be based on the organizational capacity of the facilities. The definition of which materials will be reused will then be supported by controls that are adequate for evaluate the products and by monitoring the decontamination processes.

Incorporation of the concept of residual risk in medical products forces MSC professionals to act in a systematized manner, applying risk management actions at all levels, cycles and stages of the reprocessing of these products. Based on the risk references, a certain degree of rationality regarding use of materials can be adopted. Thus, MSCs will have a highlighted function within hospital organizations, as autonomous facilities that define and carry out processes, without which other hospital services would not function.

With the increasing incorporation of technologies that bring benefits and risks to healthcare services, the responsibility of the State as the sanitary controller of products, processes and services linked to human health also increases. Hence, it is necessary to invest in expertise for sanitary control that can control the risks and protect the health of healthcare service users. In a country that has succeeded in implementing and maintaining a very wide-ranging public policy (the Brazilian National Health System), and despite forces interested in transforming healthcare into market commodities, but without entering into the merit of insufficiencies regarding coverage, comprehensiveness and problem resolution among the services that make up this system, this challenge can be surmounted.

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