REPROCESSING OF MEDICAL DEVICES: SANITARY QUALITY ANALYSIS IN PUBLIC HOSPITALS

Reprocessamento de produtos para saúde: análise da qualidade sanitária em hospitais públicos

Reprocesamiento de productos para la salud: análisis de la cualidad sanitaria in hospitales públicos

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ABSTRACT: Objective: To analyze the technical conditions for reprocessing of medical products, in the light of service quality and sanitary safety among the users of reprocessed items. **Methods:** The study presents an evaluation based on multiple case studies collected in the reprocessing facilities of ten public hospitals in the State of Bahia, Brazil. The analysis is referred to five independent variables that influence conditions for reprocessing of medical products. Each of these five variables was considered in three rating levels of quality. **Results:** Considerable inadequacies were observed for all variables, so that none of the ten observed cases showed adequate technical conditions for reprocessing medical products. **Conclusions:** We conclude, therefore, that the hospitals considered in this study adopt inadequate practices for reprocessing, which is a problem for hospital care and the regulatory agencies.
KEYWORDS: Surgical equipment. Health surveillance of products. Quality control. Patient safety

RESUMO: Objetivo: Analisar as condições técnicas do reprocessamento de produtos médicos, tendo em vista a qualidade e segurança sanitária da população usuária de produtos reprocessados. **Método:** Trata-se de uma pesquisa avaliativa de estudo de casos múltiplos. Participaram os Centros de Material e Esterilização de dez hospitais públicos da Bahia. Foram estudadas cinco variáveis independentes que influenciam as condições do reprocessamento de produtos médicos. Adicionalmente, cada variável foi analisada em três níveis de avaliação de qualidade. **Resultados:** Evidenciou-se uma generalizada inadequação de todas as variáveis estudadas. Dos dez casos pesquisados, nenhum apresentou condições técnicas adequadas de reprocessamento de produtos médicos. **Conclusão:** Conclui-se com esses dados que os hospitais deste estudo possuem práticas de reprocessamento inadequadas, apontando possíveis problemas para o cuidado assistencial e para os órgãos fiscalizadores.
PALAVRAS-CHAVE: Equipamentos cirúrgicos. Vigilância sanitária de produtos. Controle de qualidade. Segurança do paciente

RESUMEN: Objetivo: Analizar las condiciones técnicas para el reprocesamiento de productos médicos, bajo el óptica de la calidad de servicio y de la seguridad sanitaria entre os usuarios de esos artefactos reprocesados. **Métodos:** En la investigación se presenta una evaluación en base a múltiples estudios de caso realizados en las unidades de reprocesamiento de diez hospitales públicos del Estado de Bahia, Brasil. El análisis está referido a cinco variables independientes que afectan las condiciones para el reprocesamiento de productos médicos. Se consideró cada una de las cinco variables en tres niveles de calidad. **Resultados:** Se identificaron inadecuaciones presentes en todos los casos, de manera que ningún de los diez casos observados presentó las condiciones técnicas indicadas para el reprocesamiento de productos médicos. **Conclusión:** En base a esa evidencia, concluimos que los hospitales considerados en el presente estudio adoptan prácticas inadecuadas en el reprocesamiento, lo que presenta un reto para el cuidado hospitalario y para los órganos fiscalizadores.
PALABRAS CLAVE: Equipo quirúrgico. Vigilancia sanitaria de productos. Control de calidad. Seguridad del paciente

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INTRODUCTION

Thousands of different health-related products worldwide are used for detecting, diagnosing, and treating medical conditions. Despite the considerable progress in hospital care services, made possible by the advent of the industry of health-related products*, the use of such items brought, besides the benefits and prolongation of life, serious risks to the patient that needs to use them. This raises theoretical and practical questions of safety and effectiveness of processes, demanding new alternatives for the use and reuse of these materials from health-care services and the state[1-5].

Health-related products are defined by the manufacturer as reusable or single-use items. Reusable or multiple-use items are durable goods and designed to withstand the decontamination procedures. The reprocessing action is necessary for the safe reuse of these materials. This is a process that includes cleaning, performance evaluation test, disinfection, or sterilization to be applied to the medical product, ensuring a safe use, including quality control in all phases[6-8].

The products are reprocessed by the Material and Sterilization Center (MSC), a functional structure of a health-care service that is responsible for cleaning, disinfection, sterilization, quality control, and product dispensing. It is a crucial service, on which all health-care activities depend, and its operation requires professionals with knowledge related to the area of production and quality control, such as physical, chemical, and biological monitoring; process validation; and product traceability[3-5].

These activities, which are usual in industries and still incipient in Brazilian hospital services, require, in addition to competent professionals, committed to the subject of medical products, a whole infrastructure that favors the execution of activities relevant to the reprocessing of products to minimize the risks envolved[3-5].

Among the risks associated with the reprocessing and reuse of health-related products, the literature mentions infection and loss of product functionality as the most relevant, but other events such as presence of endotoxins, biofilms, and bioincompatibility have also been reported[9-11].

Therefore, the importance of the work processes of an MSC is undeniable. Its actions require planning and management of the risk associated with the used products and the various activities that constitute the reprocessing.

Given the importance of the reuse of medical products for public health, we intend to answer, in this article, the central question: how does the reprocessing of medical products work in public hospitals in Bahia? From this question, we outlined the following general objective: to analyze the technical conditions of the reprocessing of medical products in public hospitals of Bahia, regarding the quality and security of the user population of reprocessed products.

METHOD

This is a survey in the area of evaluation of health practices. The methodological strategy is a descriptive and holistic study of multiple cases[12]. A case study is an empirical investigation that analyzes a contemporary phenomenon inside its real-life context, especially when the boundaries between the phenomenon and the context are not clearly defined, with a prominent place within the evaluation research. It includes both single-case (one unit under evaluation) and multiple-case (several units under evaluation) studies. They are classified as holistic if they have only one unit of analysis.

The unit analyzed in this study is the technical condition for reprocessing of medical products in public hospitals located in the countryside of Bahia, recognized by this case methodology. The strategies used in the search for empirical evidence were the structured interview using a specific form for data collection and the direct observation.

The MSCs of 10 public hospitals located in the countryside of Bahia participated in this study. They were selected of the 31 Regional Health Boards (DIRES) existing in the State to be evaluated according to the Decree of the Bahia State Health Department (SESAB) no. 1083 / 2001[13], which regulates the standards for quality of care with a focus on hospital infection control. These hospitals were selected when hospital quality of the hospitals within the countryside was evaluated, located through the data from the State Center for Infection Control (NECIH) of SESAB and constituted the 10 multiple cases of this study. Each hospital has received a code from 1 to 10 (H1 to H10) to maintain their anonymity.

*In this article, we use the term health-related product as a synonym of medical product, equipment, device, item, material to keep the same nomenclature used by the National Health Surveillance Agency (ANVISA).

The selected hospitals were contacted by telephone, when a visit was scheduled for data collection. The data were collected by a technician (nurse) of NECIH, using the assessment tool standardized by the decree mentioned earlier.

The following independent variables that influence the conditions for the reprocessing of medical products were studied:

1. physical structure of the MSC;
2. use of personal protective equipment (PPE) in the MSC;
3. in-service training on the cleaning, disinfection, sterilization, and control processes;
4. applied methods of cleaning, disinfection, and sterilization of products;
5. quality control of the sterilization; and
6. storage of reprocessed products.

Each variable was given a score based on the number of questions assigned to its group, and each question was scored as 1, which meant conformity of the response with the specific ANVISA standard for the functioning of MSCs in the country[14], and as 0, which corresponded to the inadequacy of the response according to the same standard. In addition, each variable was analyzed in three quality assessment levels: 1, 2, and 3.

Level 1, with 55 questions, evaluated the actions of the MSC that were considered structural and indispensable for the processing of products. Level 2, with 14 questions, evaluated actions associated with the organization of operational work processes. And level 3, with 20 questions, evaluated actions considered more elaborate and of excellence in the processes of cleaning, disinfection, and sterilization of health-related products, totaling 79 adequacy points.

Similar to a study carried out by other authors[15], each evaluated MSC was given a score, according to their corresponding degree of technical condition for the reprocessing of medical products, and thus classified into three levels: (0) inadequate condition for reprocessing of products; (1) condition for reprocessing of products requiring adaptation; and (2) adequate condition for reprocessing of products, as shown in Table 1.

RESULTS

We start the description of the results of the empirical data of this study with the characterization of the multiple cases, as shown in Chart 1. The studied cases are found to be located in regions far from the state capital, mostly in the West (4 cases, 40%) and North (2 cases, 20%) regions. Of the 10 MSCs studied, 9 (90%) are in public hospitals, of which 3

Table 1. Classification score of Material and Sterilization Centers of the analyzed hospitals, Salvador, 2013.

Classification regarding the reprocessing of medical products	Final score (%)
Adequate MPR condition	81–100
MPR condition requiring adjustment	41–80
Inadequate MPR Condition	0–40

MPR: medical product reprocessing

Chart 1. Characterization of the analyzed hospitals, Salvador, 2013.

Case/ hospital	Regional Health Board	Administrative authority	Region	Number of beds
H1	25th	Public, state level, with management by a private health organization	West	225
H2	15th	Public, state level	North	150
H3	22th	Public, state level	West	50
H4	30th	Public, state level	Southwest	106
H5	25th	Public, state level, with management by a private health organization	West	24
H6	15th	Public, city level	North	70
H7	7th	Public, state level, with management by a private health organization	South	208
H8	6th	Private	South	8
H9	8th	Public, state level	Extreme South	125
H10	25th	Public, city level	West	42

are managed by an outsourced organization. Regarding the number of beds, five hospitals (50%) are considered medium-sized and five (50%) small-sized.

Charts 2 to 4 present the data of the MSCs regarding quality level (1, 2, and 3), and the studied variables of product reprocessing.

Chart 2 shows the data from the variables of reprocessing of medical products for the cases studied, correlated with the level 1 of quality. At this level, which assesses the actions of MSCs considered basic and indispensable for the processing of the products, the studied variables had scores between 3.6% (H10) and 51% (H1 and H9). The physical structure presented adequacies ranging from 2.1% (H10) to 51% (H1 and H9). The use of PPE ranged from 100% adequacy in six MSCs studied (H2, H4, H5, H6, H7, and H9), 50% adequacy in two MSCs (H1 and H3), and no PPE use in two MSCs (H10

Chart 2. Characterization of Material and Sterilization Centers of the analyzed hospitals according to the level 1* of quality and variables of reprocessing of medical products, Salvador, 2013.

Cases	Physical structure (n = 47)	PPE use (n = 2)	Training (n = 2)	MP processing (n = 3)	Quality control of sterilization (n = 1)	MP storage (n = 0)	Total score (n = 55)
H1	24 (51%)	1 (50%)	0	2 (66.7%)	1 (100%)	0	28 (51%)
H2	20 (42.5%)	2 (100%)	0	2 (66.7%)	1 (100%)	0	25 (45.4%)
H3	11 (23.4%)	1 (50%)	0	1 (33.3%)	1 (100%)	0	14 (25.4%)
H4	13 (27.6%)	2 (100%)	0	2 (66.7%)	1 (100%)	0	18 (32.7%)
H5	14 (29.7%)	2 (100%)	2 (100%)	2 (66.7%)	0	0	20 (36.5%)
H6	11 (23.4%)	2 (100%)	0	2 (66.7%)	0	0	15 (27.2%)
H7	11 (23.4%)	2 (100%)	0	1 (33.3%)	0	0	14 (25.4%)
H8	12 (25.5)	0	0	1 (33.3%)	0	0	13 (23.6%)
H9	24 (51%)	2 (100%)	0	2 (66.7%)	0	0	28 (51%)
H10	1 (2.1%)	0	0	1 (33.3%)	0	0	2 (3.6%)

*Level 1 assesses the actions of the Material and Sterilization Center considered structural and indispensable for the processing of the products; PPE: personal protective equipment; MP: medical product.

Chart 3. Characterization of Material and Sterilization Centers of the analyzed hospitals according to the level 2* of quality and variables of the reprocessing of medical products, Salvador, 2013.

Cases	Physical structure (n = 1)	PPE use (n = 0)	Training (n = 0)	MP processing (n = 5)	Quality control of sterilization (n = 7)	MP storage (n = 1)	Total score (n = 14)
H1	0	0	0	4 (80%)	5 (71%)	1 (100%)	10 (71.4%)
H2	0	0	0	4 (80%)	4 (55%)	1 (100%)	9 (64.2%)
H3	0	0	0	0	1 (14.2%)	1 (100%)	2 (14.2%)
H4	0	0	0	2 (40%)	1 (14.2%)	1 (100%)	4 (28.5%)
H5	0	0	0	2 (40%)	3 (42.8%)	1 (100%)	6 (42.8%)
H6	0	0	0	0	2 (28.5%)	1 (100%)	3 (21.4%)
H7	0	0	0	1 (20%)	0	0	1 (7.1%)
H8	0	0	0	0	0	1 (100%)	1 (7.1%)
H9	0	0	0	3 (60%)	3 (42.8%)	0	6 (42.8%)
H10	0	0	0	1 (20%)	1 (14.2%)	1 (100%)	3 (21.4%)

*Level 2 assesses actions related to the organization of operational work processes in the Material and Sterilization Centers; PPE: personal protective equipment; MP: medical product.

and H8). The MSC professionals were trained in methods of cleaning, disinfection, and sterilization of products in only one MSC (H5). The adequacy of cleaning, disinfection, and sterilization processes had scores of 33.3% in four MSCs (H3, H7, H8, and H10) and 66.7% in six MSCs (H1, H2, H4, H5, H6, and H9). In four MSCs, there was 100% adequacy to the sterilization quality controls (H1 to H4) and no control in six MSCs (H5 to H10). No MSC had adequacy to the standards of storage of sterilized products.

At level 2, which evaluates the actions of MSCs associated with the organization of operational work processes, the studied variables had scores between 7.1% (H8 and H7) and 71.4% (H1). The standardization of the product processing had 80% adequacy in just two MSCs (H1 and H2), 60% in one MSC (H9), 40% adequacy in two MSCs (H4 and H5), and no standardization in three MSCs (H3, H6, and H8).

Similar to the low percentages of adequacy presented by the MSCs at level 1, this pattern is observed to be maintained at level 2 also. Of the 10 analyzed MSCs, only 2 (20%, H1 and H2) have total percentage of adequacy at level 2 above 50%, with 8 MSCs (80%) showing percentages ranging from 7.1 to 42.8%, showing difficulties in establishing work processes inherent to the activities of processing products.

At level 3, in which the actions regarding the processing of products are considered more elaborate and of excellence, four MSCs (H2, H7, H8, and H10) had no score, one MSC had 10% adequacy (H6), two MSCs had 20% adequacy (H4 and H5), one MSC had 40% adequacy (H3), and two MSCs had 60% and 70% adequacy (H9 and H1, respectively). The variables of quality control for product sterilization are absent in six MSCs (H2, H4, H5, H7, H8, and H10), one MSC had 14.2% adequacy (H6), and another had 42.8% adequacy (H3). Only two MSCs had adequate control of the sterilization process over 50% (H1 and H9).

We present next the classification of the analyzed cases according to the degree of the technical condition for the

Table 2. Classification of Material and Sterilization Centers of the analyzed hospitals according to the degree of the technical condition for reprocessing of medical products, Salvador, 2013.

Cases	Adequate technical conditions n (81–100%)	Technical conditions requiring adjustments n (41–80%)	Inadequate technical conditions n (0–40%)
H 1		45 (56.9%)	
H 2			34 (43.0%)
H 3			20 (25.3%)
H 4			24 (30.6%)
H 5			28 (35.4%)
H 6			19 (24.0%)
H 7			15 (18.9%)
H 8			14 (17.7%)
H 9			40 (50.6%)
H 10			5 (6.3%)

Chart 4. Characterization of Material and Sterilization Centers of the analyzed hospitals according to the level 3* of quality and variables of the reprocessing of medical products, Salvador, 2013.

Cases	Physical structure (n = 3)	PPE use (n = 0)	Training (n = 0)	MP processing (n = 0)	Quality control of sterilization (n = 7)	MP storage (n = 0)	Total score (n = 10)
H1	2 (66.6%)	0	0	0	5 (71%)	0	7 (70%)
H2	0	0	0	0	0	0	0
H3	1 (33.3%)	0	0	0	3 (42.8%)	0	4 (40%)
H4	2 (66.6%)	0	0	0	0	0	2 (20%)
H5	2 (66.6%)	0	0	0	0	0	2 (20%)
H6	0	0	0	0	1 (14.2%)	0	1 (10%)
H7	0	0	0	0	0	0	0
H8	0	0	0	0	0	0	0
H9	1 (33.3%)	0	0	0	5 (71%)	0	6 (60%)
H10	0	0	0	0	0	0	0

*Level 3 assesses actions considered more elaborate and of excellence in cleaning, disinfection, and sterilization processes of health-related products; PPE: personal protective equipment; MP: medical product.

reprocessing of medical products. In Table 2, of the 10 MSCs studied, none had adequate technical conditions according to the studied variables. Just one MSC (H1) presented technical conditions requiring adequacy, and nine MSCs presented inadequate scores regarding processes of reuse of medical products. The lowest percentage of adequacy (6.3%) was observed in H10, and the highest percentage (56.9%) in H1, both of the Western region of Bahia. The first is a city hospital and small-sized (42 beds), and the latter is a state hospital, with outsourced management and large-sized (225 beds).

DISCUSSION

The data about the reprocessing of medical products of the evaluated MSCs showed inadequacies of the independent variables in correlation with the three quality levels that were studied.

The analysis showed a general inadequacy in all the studied variables such as the infrastructure of material resources; the use of PPE; training of professionals; cleaning, disinfection, and sterilization processes; sterilization quality control; and conditions for storage of the products in the MSCs of the evaluated hospitals, which certainly contributed to the fact that no MSC in this study presented technical conditions for reprocessing that could be considered appropriate.

The analyzed variables are directly related to the effectiveness of the processing of products, and the inadequacies presented here indicate key issues for the safety of the reuse of products, evidenced in the absence of protocols for cleaning, disinfection, and sterilization, as well as absence of quality control of the sterilization.

Moreover, no MSC had adequacy of the variable of storage of sterilized products. This can lead to events that may contaminate the products after sterilization and compromise the maintenance of the sterility of the stored products, constituting another problem related to the processing of products in these institutions.

These results show serious issues concerning the reuse of medical products in these hospitals, compromising one of the dimensions of the quality of health care, which is the safety of the patient, and, in this case, also the safety of the professionals involved in these processes because they execute their activities under exposure to chemical and biological hazards, making the reuse and reprocessing of medical products in these 10 studied hospitals a major risk factor for patients using these products and professional handlers.

Other researches on the subject of product reuse have similar results to those presented here, such as, a multiple-case study that aimed to analyze the technical conditions for the reprocessing of medical products in four hospitals in a large Brazilian capital. Two were public hospitals in the state network and two belonged to the ANVISA sentinel network, in which the authors used as the gold standard for processing of products a regulatory model in the light of the recommendations of the literature. The data from this study showed inadequacies in cleaning, drying, disinfection, sterilization, and traceability of the products, concluding that no hospital organization studied, even those linked to the ANVISA network, presented adequate technical conditions for the reprocessing of products[5].

A research that aimed to evaluate structure, process, and outcome of an MSC of a large hospital in Paraná, in which the studied indicators were divided into three groups (cleaning; preparation, packaging and sterilization; storage and distribution), obtained noncompliance for the variables cleaning (32.4%); preparation and packaging (26.9%); and sterilization, storage, and distribution (26.2%). The overall rate of compliance with the adopted evaluation instrument was 61.9%, and the authors concluded that this MSC needs improvements to upgrade the carried out processes[15].

A study that analyzed the conditions of storage of sterilized medical products in large hospitals also found irregularities in the storage conditions after sterilization, such as inadequate storage sites regarding both the physical structure and the ventilation conditions, besides the excessive handling of sterilized products, concluding that the recommendations of ANVISA for the storage of sterilized products are not being fully implemented in all the analyzed institutions. It also corroborates the findings of our study[16].

CONCLUSION

The results of this study confirmed the regional problems involving the reprocessing of medical products, as evidenced by the low quality of the data from the researched variables, and indicated gaps in the functional conditions of these services, enhancing the risks for the patients and health professionals.

From these data, we concluded that the hospitals of this study have inadequate reprocessing practices, pointing out possible problems to the area of health-care service and the regulatory agencies.

REFERENCES

1. Costa EAM, Costa EA. Reutilização e reprocessamento de produtos médicos de uso único: risco aceitável? Rev SOBECC. 2011;16(2):50-6.
2. Costa EAM. Gerenciando risco em reprocessamento de produtos para saúde: uma metodologia para serviços hospitalares. Rev SOBECC. 2013;18(2):33-44.
3. Costa EAM, Costa EA, Graziano KU, Padoveze MC. Reprocessamento de produtos médicos: uma proposta de modelo regulatório para hospitais brasileiros. Rev Esc Enferm USP. 2011;45(6):1459-65.
4. Costa EAM, Costa EA. Reprocessamento de produtos médicos: da política regulatória à prática operacional. Ciênc Saúde Coletiva. 2011;16(12):4787-94.
5. Costa EAM, Costa EA. Risco e segurança sanitária: análise do reprocessamento de produtos médicos em hospitais de Salvador, BA. Rev Saúde Pública. 2012;46(5):800-7.
6. Kraft M. Framework conditions and requirements to ensure the technical functional safety of reprocessed medical devices. GMS Krankenhhyg Interdiszip. 2008;3(3):Doc23.
7. Großkopf V, Jäkel C. Legal framework conditions for the reprocessing of medical devices. GMS Krankenhhyg Interdiszip. 2008;3(3):Doc24.
8. Krüger CM. Processing single-use medical devices for use in surgery: importance, status quo and potential. GMS Krankenhhyg Interdiszip. 2008;3(3):Doc21.
9. Rutala WA, Weber DJ. Sterilization, high-level disinfection and environmental cleaning. Infect Dis Clin North Am. 2011;25(1):45-76.
10. Donlan RM. Biofilm elimination on intravascular catheters: important considerations for the infections disease practitioner. Clin Infect Dis. 2011;52(8):1038-45.
11. Bentley K, Dove BK, Pucks SR, Walker JT, Bennett AM. Hydrogen peroxide vapour decontamination of surfaces artificially contaminated with norovirus surrogate feline calicivirus. J Hosp Infect. 2012;80(2):116-21.
12. Yin RK. Estudo de Caso: planejamento e métodos. 3. ed. Porto Alegre: Bookman; 2005.
13. Bahia. Secretaria da Saúde do Estado da Bahia. Portaria nº 1083, de 2001. Padrões de qualidade da assistência para auto-avaliação hospitalar com foco no controle de infecção hospitalar. Bahia: Secretaria da Saúde; 2001.
14. Agência Nacional de Vigilância Sanitária - ANVISA. Resolução da Diretoria Colegiada RDC nº 15, de 15 de março de 2012. Dispõe sobre requisitos de boas práticas para o processamento de produtos para saúde e dá outras providências. Brasília: Diário Oficial da União; 2012.
15. Souza LEP, Vieira da Silva LM, Hartz Z. Conferência de consenso sobre a imagem-objetivo da descentralização da atenção à saúde no Brasil. In: Hartz Z, Vieira-da-Silva LM (orgs.). Avaliação em saúde: dos modelos teóricos à prática na avaliação de programas e sistemas de saúde. Salvador/Rio de Janeiro: Edufba/Fiocruz; 2005.
16. Tillvitz LR, Nascimento LA, Ribeiro RP, Fonseca LF. Avaliação da qualidade de uma central de materiais e esterilização em um hospital escola pública. Rev Enferm UFPE on line. 2012;6(9):2077-85.
17. Oliveira AC, Mussel IC, de Paula AO. Armazenamento dos produtos para saúde estéreis em unidades assistenciais: estudo descritivo. Rev SOBECC 2014.19(4):188-194.