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Sanitary control about reuse of single-use medical devices: a case study

Controle sanitário do reúso de dispositivos médicos de uso único: um estudo de caso

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ABSTRACT

Introduction: The reuse of single-use medical devices is a global reality and involves technical, ethical, economic, and environmental issues. **Objective:** To analyze the sanitary control of the reuse of single-use devices exercised by health surveillances (Visa) in some Brazilian states in Brazil. **Method:** Descriptive study of multiple cases, consisting of health surveillances of some Brazilian states, which agreed to participate in the study. **Results:** The surveillances studied do not plan the sanitary control actions of health services, nor the reuse of single-use products; nor do they use any method of evaluating these practices and specific training of their professionals. They are unaware of the situation of the reuse of single-use products in large hospitals in their respective states. **Conclusions:** Data indicate that the reuse of single-use products has implications for the sanitary control to be exercised by the State and that the relevance of the problem requires planning, systematization and monitoring actions, as well as qualification of health surveillance professionals for the effective prevention of damage related to the reuse of these devices.

KEYWORDS: Medical Equipment; Medical devices; Reprocessing; Regulation

RESUMO

Introdução: O reúso de dispositivos médicos de uso único é uma realidade mundial e envolve questões técnicas, éticas, econômicas e ambientais. **Objetivo:** Analisar o controle sanitário do reúso de dispositivos de uso único, exercido pela vigilância sanitária (Visa) em alguns estados brasileiros. **Método:** Estudo descritivo, de casos múltiplos, constituído pelas Visa de alguns estados brasileiros, que aceitaram participar do estudo. **Resultados:** As vigilâncias estudadas não fazem planejamento das ações de controle sanitário dos serviços de saúde, nem do reúso de produtos de uso único; tampouco utilizam algum método de avaliação dessas práticas e capacitação específica de seus profissionais. Desconhecem a situação do reúso de produtos de uso único nos hospitais de grande porte dos seus respectivos estados. **Conclusões:** Os dados indicam que o reúso de produtos de uso único tem implicações para o controle sanitário a ser exercido pelo Estado e que a relevância da problemática requer ações de planejamento, sistematização e monitoramento, bem como qualificação dos profissionais de Visa para a efetiva prevenção de danos relacionados ao reúso desses dispositivos.

PALAVRAS-CHAVE: Equipamentos Médicos; Dispositivos Médicos; Processamento; Regulação

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INTRODUCTION

The management of health services faces some challenges related to the quality and safety of care. These services, especially hospitals, progressively incorporate an enormous inventory of drugs, equipment, medical devices and products to keep up with the ever-growing complexity of healthcare. This demands from the State, notably from health surveillance, both the regulatory apparatus and the necessary expertise for the proper health control of these institutions[1,2].

Medical devices account for a significant share of the hard and soft-hard technologies in healthcare services. These products are widely used in all fields of health to diagnose, treat or prevent diseases. They are defined by manufacturers as reusable or for single use. Reusables are considered to be durable goods and their reuse requires processing, a multi-step action that consists of converting a contaminated product into a ready-to-use device[3,4,5,6,7,8].

Single-use products are designed to be used only once, on a single patient. They appeared in the 1960s, with the progress of technology and the emergence of new plastic polymers. This transformed the medical industry, and products made of sturdy materials like glass, rubber and stainless steel, and for multiple use, made room for ready-to-use products that were declared by the manufacturers as single-use products. These products enable new diagnostic and surgical techniques, such as laparoscopic and endovascular procedures[9,10,11,12,13].

However, many hospitals have started to process and reuse these materials to save money and reduce toxic biodegradable waste, generated by the disposal of these products, which affects the environment. Since the 1970s, the reuse of these products has been reported worldwide, even in developed countries, including those where processing has been banned[14,15,16].

This trend has intensified debates and considerations on patient safety, informed consent, economic, environmental, legal, ethical and regulatory aspects for manufacturers and processors, which reveals the different interests of the stakeholders: State, product manufacturers, health services, academia, health professionals, trade associations and users[17,18].

There are many arguments for and against the reuse of single-use products[19]. Favorable arguments warrant it because of the positive impact on costs and on the environment, because of the reduction in the volume of waste from healthcare. Critics of reuse argue that these products are not designed for multiple uses and that there are risks of transmitting infection and endotoxins, functional unreliability, breaking the product's integrity or bioincompatibility[13,14,18,19].

Although the processing and reuse of single-use products theoretically pose health risks, clinical evidence states that certain products can be safely processed[3,4,5,6,7,11,12,13,15,18, 20,21]. However, this does not mean that the processing of these products is always safe[20].

In Brazil, the processing of single-use products is a reality in health services. National data reveal that these practices are common in all regions of the country, regardless of the size of the hospital or the entity supporting it. Reuse protocols are adopted in a few institutions, most of which inappropriately, and this poses risks for the patients of these products and challenges to the current regulation in the country[21,22,23,24].

The National Health Surveillance Agency (Anvisa) is the body responsible for regulating the processing of medical devices. In 2006, three regulations were issued: i) Resolution of the Collegiate Board (RDC) n. 156, of August 11, which provides for the registration, labeling and reprocessing of medical products[25]; ii) Special Resolution (RE) n. 2.605, of August 11, which establishes a list of 66 single-use products banned from reprocessing in Brazil[26], and iii) RE n. 2.606, of August 11, which determines the guidelines for the design, validation and implementation of protocols for the reprocessing of medical products[27].

Despite much criticism, these regulations remain in force. In December 2018, Anvisa made three Public Inquiries: i) n. 584[28], which deals with the classification of medical devices as single-use or reusable and, among other provisions, admits the reuse of single-use medical devices as long as the health service or the processing company complies with good practice requirements for such processing; ii) n. 585[29], which provides for good practices for the processing of products and iii) n. 586[30], which standardizes guidelines for validating and monitoring the cleaning and sterilization processes of medical devices. These Inquiries, which have not yet produced results, propose the recall of the 2006 regulations.

In this context of global increase in medical devices in healthcare, the regulation and health control over the use and reuse of these technologies play a critical role in the adoption of safe practices and the prevention of adverse events related to these products. This study aimed to analyze the health control over the reuse of single-use products done by Brazilian State Health Surveillance bodies (Visa).

METHOD

This is a descriptive, holistic, multi-case evaluation study[31] of Brazilian state health surveillance bodies. To meet the inclusion criterion, a health surveillance body should be located in the most populous state of each of the five regions of the country. The exclusion criterion was the opposite, that is, health surveillance bodies of the least populous states in the five regions of the country.

Services that did not agree to participate and did not justify their refusal were replaced by those from the second most populous state in each region. Health surveillance bodies from states in three regions of the country participated in the study: Northeast, North and South.

After identification and selection of the health surveillance bodies, each state service was preliminarily contacted, by telephone, for an explanation of the research objectives, confirm agreement to join the study and set the date for data collection.

Data were produced via online communication with the following instruments: 1) telephone interview with the coordinator/responsible for the area of health control of health services and 2) electronic submission of a semi-structured questionnaire with closed-ended questions and with fields for open-ended answers to be answered by professionals appointed by the coordinator.

A text was attached to the questionnaire explaining the nature of the research and the questions of the instrument and its importance and the need for answers, in order to trigger the participants' interest in filling out and returning the questionnaire within 10 days of the date of submission.

Each participating institution was also emailed the following documents: a letter to the board ratifying the research objectives and a free and informed consent form (ICF) with the terms of the interview. The participating professionals signed and returned the ICF.

To assess the health control over the reuse of single-use medical devices done by state health surveillance bodies, the following analytical categories were considered: 1) health control planning actions for health services (HS); 2) infrastructure related to personnel (number of professionals dedicated to the health control of the processing of medical devices and technical training) and 3) technical-operational activities.

The questionnaire consisted of two parts: the first sought to characterize the health surveillance body and its functional structure and the second was prepared based on the categories of analysis, using as the gold standard the Anvisa provisions that regulate the matter[25,26,27]. Data were collected in October 2018 and, after data organization, qualitative and quantitative analyses were performed.

In this study, the term "medical device" was used as a synonym for health product, in accordance with the nomenclature adopted by Anvisa. The terms "reprocessing" or "product processing" were also used interchangeably, despite considerations about their differences.

The multiple cases in this study are represented by three state health surveillance bodies that met the inclusion criteria and agreed to participate in the study. To keep their anonymity, here they are called Visa 1, Visa 2 and Visa 3.

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RESULTS

The three health surveillance bodies we studied have a functional structure that is under the health departments of their respective states. Their names are: Health and Environmental Surveillance Board, Health Surveillance Department and Health Surveillance Division, respectively, according to the administrative particularities of each state.

Each health surveillance body structures its own competences and responsibilities in the form of coordination, management or centers, to perform the health surveillance of health services, products, technovigilance and engineering, in addition to the administrative sectors that support their work.

The composition of the workers in the studied cases is different, with a total of about 403, 52 and 46 professionals, respectively, in Visa 1, 2 and 3. Chart 1 details the profile of the professionals in health control actions in health services.

The data reveal disparities in the number of professionals responsible for the health control of health services, possibly because of the size of the population and the particularities of the researched health surveillance bodies. There was a variation of 240 to six professionals assigned to the coordination/management or health control centers for health services, according to the different designations adopted in the studied regions; technicians assigned to these services are also responsible for controlling the reuse of single-use products.

Information on the professional categories responsible for health control is incomplete for Visa 1 and 2, but, based on the information above, they vary, with highlights to nurses, dentists, dietitians and architects, which confirms the diversified educational background of health surveillance workers. Some

Chart 1. Profile of health control workers in health services. State Health Surveillance Bodies (Visa), 2018.

Cases studied	Number of technicians in the health control of health services	Degree in	Postgraduate in	Training on health control over the reuse of single use products
Visa 1	240	Nurses*	Specialization (3) and Master's (1)	Absent
Visa 2	14	Not informed	Specialization (3)	Absent
Visa 3	6	Pharmacist, Dentist, Nurse, Dietitian and Architect	All with specialization	Absent

Source: Prepared by the authors, 2019.
* Only four nurses responded.

Chart 2. Planning and technical-operational activities of the health control of health services exercised by the State Health Surveillance body (Visa), 2018.

Cases studied	Action plan for the health control of health services	Specific plan for the health control of the reuse of single-use medical devices	Method for evaluating the reuse of single-use devices	Regulations used for the health control over the reuse of single-use medical devices	Action taken after identification of reuse of devices whose reprocessing is prohibited (RE n. 2.605/2006)
Visa 1	Absent	Absent	None	RDC n. 156/2006, RE n. 2.605/2006, RE n. 2.606/2006	Reporting and recommendation
Visa 2	Absent	Absent	None	RDC n. 156/2006, RE n. 2.605/2006, RE n. 2.606/2006	Notice of Infraction and Notice of Confiscation
Visa 3	Absent	Absent	None	RDC n. 156/2006, RE n. 2.605/2006, RE n. 2.606/2006 RDC n. 15/2012; RDC n. 63/2011	Recommendation

Source: Prepared by the authors, 2019.
RDC: Resolution of the Collegiate Board; RE: Special Resolution

Chart 3. Health control over the reuse of single-use products in large hospitals. State Health Surveillance Bodies (Visa), 2018.

Cases studied	Number of large hospitals that reuse single-use products	Percentage of large hospitals that reuse single-use products	Percentage of large hospitals with validated medical device reuse protocols	Percentage of Sentinel Network hospitals that reuse single-use devices
Visa 1	Unknown	Unknown	Unknown	Unknown
Visa 2	Unknown	Unknown	Unknown	Unknown
Visa 3	Unknown	Unknown	Unknown	Unknown

Source: Prepared by the authors, 2019.

of these professionals have post-graduate education, and the lack of this information stands out in in Visa 1. According to the respondents, none of the studied health surveillance bodies promoted training of their staff in the health control of the reuse of single-use products.

According to Chart 2, the studied health surveillance bodies do not plan for the health control of health services, nor do they have a specific action plan on the reuse of single-use products. They do not use any method to evaluate these practices either.

The regulations used for the health inspection of health services are Anvisa's medical device regulation resolutions. Visa 3 also uses RDC n. 15, of March 12, 2012, and RDC n. 63, of November 25, 2013, which address good product processing practices and good health service operation practices, respectively. However, no state has its own supplementary rule for the health control of the reuse of single-use products.

The respondents claimed: a) to be familiar with and use the list of single-use products banned from being processed in Brazil, according to RDC n. 2.605/2006[26]; b) that the control over the reuse of single-use products occurs during routine health service inspections, by a team that inspects the hospital as a whole, using an inspection script; c) that the resulting actions are reporting, recommendation, Notice of Infraction and Notice of Confiscation of the products (Chart 2).

According to the respondents, the factors that facilitate the control of the reuse of single-use products are the current legislation and the instructions for use from the product manufacturers. The following factors were mentioned as hindering factors: scarcity of resources for public health services, shortcomings in training to understand the problem, weaknesses in the functioning of Hospital Infection Control Commissions and Patient Safety Centers, as well as the lack of information about how many times a single-use product can be reused.

Chart 3 shows the health situation of the reuse of single-use products in large hospitals.

The data indicate that the studied health surveillance bodies are unaware of the health situation of the reuse of single-use products in hospitals in their states. Some large hospitals provide assistance to high-risk patients and include public, private organizations and hospitals in the Sentinel Network. Furthermore, none of the health surveillance bodies prepares or uses indicators for the reuse of single-use products in their states in order to subsidize control actions and the adoption of health measures related to the reuse of these products.

DISCUSSION

This study reveals that the problem of reusing medical devices is also challenging for the states, responsible for the health safety of theircitizens[21,22,23,24].

Health surveillance work is considered a health service and as such, it requires definitions about agents, work routines and processes according to specific objects. It must be anchored in planning frameworks to guide the work, determine action strategies and support the achievement of its goals[32].

We observed that the health surveillance services we studied operate without any formal planning of the health control of their health services and, consequently, of the control of the reuse of single-use medical devices. This indicates that action planning is still a shortcoming in these institutions, in which, traditionally, work processes are mainly concerned with responding to the spontaneous demand of regulated segments and to emergency situations[2,33].

The health professionals who work in the health control of the health surveillance services of this study have diverse backgrounds and specializations, confirming the multiprofessionality of the area. However, no health surveillance body has trained its workers on the health control of the reuse of medical devices for single use. This hinders the performance of these professionals, considering that the reuse of medical devices involves complex issues related not only to the functional capacity of the services, but also to expertise on the suitability of product cleaning and sterilization processes. Shortcomings in training to understand the problem were cited by health surveillance professionals as some of the obstacles to the health control of the reuse of single-use medical devices.

For the health control of health services to be effective and, specifically, to control the reuse of medical devices, health surveillance professionals must know the risks involved in the reuse of these products and the conditions required for processing. These professionals must understand that processing a medical device, regardless of whether it is for single use or multipurpose use, involves disassembly, cleaning, inspection, function testing, disinfection, packaging, sterilization, labeling and quality controls to ensure that that device can be reused safely. They require fundamental conditions like availability of technology for processing activities; staff education and training; environmental and structural requirements; occupational safety; establishment of policies and procedures; certification of quality management systems; safety and functionality testing; tests of biocompatibility and exclusion of reactions caused by pyrogens, in addition to validation procedures[13,14,15,16].

In this sense, awareness of the complexity involved in the processing of medical devices and their controls is essential for the health surveillance professional to be able to work according to the concept of risk and scientific evidence, guided by references of health surveillance practices aimed at protecting the health of the population, as determined by the Brazilian Constitution[1,2].

As noted, health surveillance bodies are unaware of the situation regarding the reuse of single-use products, as well as whether there are validated protocols for processing these products in the most critical hospital services, like large hospitals or even hospitals in Anvisa's Sentinel Network. This denotes the absence of any data about the reuse of single-use devices and the suitability of these processes in the surveyed states. Since they are unaware of how these practices are implemented in hospitals under their control, these health surveillance bodies lack information to guide their work, as well as data on the compliance of health services with the current regulations on medical devices. This suggests that these regulations are not enforced by the studied health surveillance bodies.

Additionally, none of them prepares nor uses indicators for the reuse of single-use products in their states, which indicates a gap in the requirements for good health service operation practices, as provided for in many current regulations, like RDC n. 63/2011[34], which is applied by one of the health surveillance bodies, as informed. How can we demand indicators from the regulated sector if the supervisory body itself does not prepare these indicators?

Since the health surveillance of the reuse of medical devices occurs as part of a set of health control initiatives from the health service, perhaps the services studied here do not adopt strategies to minimize different interpretations among their professionals about the risks associated with the reuse of these devices. This can lead to different analyses depending on the perspective of the health surveillance professional and jeopardize evaluation and monitoring processes[31].

Despite criticism of the current regulations on the reuse of single-use products[25,26,27], no state has a complementary regulation designed to subsidize the health control of the reuse of these products and improve initiatives in this area. In this sense, the great challenge of the health control of the reuse of single-use products includes not only a regulatory framework consistent with the potential risks related to the reuse of these devices, but also the functional capacity of health surveillance services that, based on legislation and knowledge, must manage the risks involved in this practice, without under or overestimating them.

CONCLUSIONS

This study achieved its objective by analyzing the main characteristics of the health control situation regarding the reuse of single-use products in some state health surveillance services. This control requires greater efficacy in the planning, systematization and monitoring of initiatives in this specific area, and also further training of the related professionals. These results confirm the understanding that the problem involving the reuse of these products, already identified in health services, also has implications for the health control to be exercised by the state – by the specific segment of the public health system, that is, institutionalized health surveillance.

A limitation of this study lies in the fact that it does not cover all health surveillance bodies in the most populous states in the five regions of the country, as provided for in the methodology, which limits the scope of the cases studied and indicates the need to expand studies on this topic.

This study also shows that the reuse of single-use products is not yet a concern of the studied health surveillance bodies, which points to the need for further the debate on this issue, which is global and whose relevance in Brazil is expressed in standards created to protect the health of the ever-growing population that uses these devices.

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Authors' Contribution

Costa EAM - Conception, planning (study design), acquisition, analysis, interpretation of data and writing of the paper. Costa E - Analysis, interpretation of data and writing of the paper. All authors approved the final draft of the paper.

Conflict of interest

The authors report that there is no potential conflict of interest with peers and institutions, nor political or financial conflicts in this study.