REUSE OF SINGLE USE MEDICAL DEVICES AND IMPLICATIONS FOR PATIENTY SAFETY

Reúso de dispositivos médicos de uso único e implicações para a segurança do paciente

Reutilización de dispositivos médicos de uso individual e implicaciones para la seguridad del paciente

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ABSTRACT: Objective: to describe aspects of the reuse of single-use medical devices and implications for patient safety. **Method:** academic essay, using integrative review data and author's expertise. **Results**: the reuse of single-use products is a worldwide reality and causes regulatory, technical, economic, ethical and patient safety debates, denoting several interests of the different actors involved: State, manufacturers, health services, academia, professionals and users. Although there is a theoretical risk, data do not identify a causal relationship between adverse events and reuse of these products. There are arguments for and against and are involved: risks and benefits, distributive and social justice. The label of these products represents a critical node and fomenting element of the dilemmas that permeate this practice. **Conclusion:** There is consensus that the reuse of a medical product should have the same safety standard, regardless of whether labeled as single-use or multipurpose. Some so-called single-use products can be safely reused, but this practice requires organo-structural conditions of health services, as well as expertise, adoption of protocols and supervision of these activities.
Keywords: Medical device. Risk-taking. Patient safety.

RESUMO: Objetivo: Descrever aspectos do reúso dos dispositivos médicos de uso único e as implicações dessa prática para a segurança do paciente. **Método:** Ensaio acadêmico, utilizando dados de revisão integrativa e expertise da autora. **Resultados:** O reúso de produtos de uso único é realidade mundial e ocasiona debates regulatórios, técnicos, econômicos, éticos e de segurança do paciente, denotando diversos interesses dos distintos atores envolvidos: Estado, fabricantes, serviços de saúde, academia, profissionais e usuários. Embora haja risco teórico, dados não identificam relação causal entre evento adverso e reúso desses produtos. Existem argumentos a favor e contra que compreendem riscos e benefícios e justiça distributiva e social. O rótulo desses produtos representa nó crítico e elemento fomentador dos dilemas que permeiam essa prática. **Conclusão:** Há consenso de que o reúso de um produto médico deve ter o mesmo padrão de segurança, independentemente se rotulado como de uso único ou de multiuso. Alguns produtos ditos de uso único podem ser seguramente reusados, mas essa prática requer condições organoestruturais dos serviços de saúde, além de expertise, adoção de protocolos e supervisão dessas atividades.
Palavras-chave: Dispositivos médicos. Exposição ao risco. Segurança do paciente.

RESUMEN: Objetivo: Describir aspectos de la reutilización de dispositivos médicos de un solo uso e implicaciones para la seguridad del paciente. **Método:** ensayo académico, utilizando datos de revisión integradores y la experiencia del autor. **Resultados:** La reutilización de productos de un solo uso es una realidad mundial y provoca debates regulatorios, técnicos, económicos, éticos y de seguridad del paciente, que denotan diversos intereses de los diferentes actores involucrados: Estado, fabricantes, servicios de salud, academia, profesionales y usuarios. Aunque existe un riesgo teórico, los datos no identifican una relación causal entre el evento adverso y la reutilización de estos productos. Hay argumentos a favor y en contra y están involucrados: riesgos y beneficios, justicia distributiva y social. La etiqueta de estos productos representa un nodo crítico y un elemento que fomenta los dilemas que impregnan esta práctica. **Conclusión:** Existe un consenso de que la reutilización de un producto médico debe tener el mismo estándar de seguridad, independientemente de si está etiquetado como de uso único o multipropósito. Algunos de los llamados productos de un solo uso pueden reutilizarse de manera segura, pero esta práctica requiere condiciones organoestructurales para los servicios de salud, además de experiencia, adopción de protocolos y supervisión de estas actividades.
Palabras clave: Dispositivos médicos. Asunción de riesgos. Seguridad del paciente.

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INTRODUCTION

Medical devices represent a significant portion of the hard technologies used in healthcare services, and are used to diagnose, treat, or prevent diseases. These devices, widely used in all healthcare fields, are defined by manufacturers as reusable or single-use items. Reusable devices are considered to be durable goods, and their reuse requires reprocessing, which is a multistep process that consists in converting a contaminated product into a ready-to-use device[1].

Single-use products are designed to be used only once, with a single patient. These products emerged with the advent of the plastics industry and gained popularity due to, among other reasons, the growth of infections caused by the human immunodeficiency virus. As a result, many healthcare products, which were initially manufactured as reusable, started being manufactured with low-cost plastic polymers, being disposable after a single use, which brought great economic benefit to manufacturers[1].

Regardless of the manufacturer's label, the practice of reusing single-use products is a worldwide reality, which began in the 1970s. Since then, there have been reports on the reuse of such products in several countries worldwide, even in developed nations, especially in those where reprocessing is forbidden[2,3]. This trend has intensified several debates and considerations on patient safety, informed consent, technical, economic, environmental, legal, and ethical issues, and regulatory aspects for manufacturers and those who perform reprocessing, denoting different interests on the part of the political actors involved: State, manufacturers of goods, healthcare services, academia, healthcare professionals, trade associations, and users[4-9].

There are many arguments that advocate for and against the reuse of single-use products[1,4]. According to the favorable ones, the positive impacts on costs and the environment are justified, since they reduce the volume of waste generated from health care. Critics of reuse argue that these products are not designed for multiple uses and that reuse may pose a risk of transmitting infections and endotoxins, lack of functional reliability, loss of product integrity, or bioincompatibility[4-10].

Although the reprocessing and reuse of single-use products pose a theoretical risk to health, clinical evidence show that certain products can be safely reprocessed. Nevertheless, this does not mean that the reprocessing of these products is always safe[11,12].

Accordingly, this study aims to answer the following guiding question: Is the reuse of single-use medical devices harmful to the safety of patients using these products?

OBJECTIVE

To describe historical and current aspects about the reuse of single-use products and the implications of this practice for the safety of the patient using these materials, in order to contribute to the analysis of emblematic issues related to the reuse of these devices.

METHOD

This is an academic essay conducted with the use of data from an integrative literature review, a method that allows the synthesis of results from studies with different methodologies, with no harm to the epistemological affiliation of these results. The study consists of five steps: problem formulation, data collection, data analysis, synthesis, and dissemination of results[13].

The studies were obtained from the Virtual Health Library (VHL) portal, which includes searches in the following databases: Latin American and Caribbean Health Sciences Literature (LILACS), Spanish Bibliography Index of Health Sciences (IBECS), National Library of Medicine/NLM (MEDLINE), The Cochrane Library, Scientific Electronic Library Online, National Library of Medicine/NLM (PubMed), and Web of Science.

The used health sciences descriptors were: *reprocessing single use medical device*, *reuse single use medical device*, *risk of reuse single use medical device*, *risk of reuse single use medical device*, with the assistance of the Boolean operator "AND."

The inclusion criteria were: articles written in English, Spanish, and Portuguese, which addressed the topics of risk, reprocessing, and reuse of single-use products, with no restriction on publication time. The exclusion criteria were: articles on reuse and reprocessing of products in hemodialysis services and in dental services, and those published in other languages.

The data search was done online, from October to December 2017, obtaining 870 articles. After reading the title and the abstract, according to the established criteria, 827 articles were excluded and 20 were selected, among which some were cited in the references of the selected articles, composing the total of studies included in this study.

After selection, articles were read and analyzed using a data collection instrument that included: authors' names, title of the article, references, objectives, materials and methods, results, and conclusion.

In this study, the term "medical device" is used as a synonym for healthcare product, equipment, material, and medical commodity, in accordance with the Brazilian Health Regulatory Agency (*Agência Nacional de Vigilância Sanitária do Brasil* – ANVISA). The terms "reprocessing" or "product processing" are also interchangeably used, despite considerations about the differences between them.

RESULTS AND DISCUSSION

Reuse of single-use products and implications for patient safety

The practice of reprocessing and reusing single-use products has been essentially studied from an ethical point of view ("should it be done?") and from a technical point of view ("how should it be done?")[3]. In this sense, there are many publications whose authors suggest safety and efficacy in the reuse of disposable products, especially in the field of cardiac intervention procedures; however, these studies vary in methodology and quality, which makes it difficult to reach consensus on the reuse of these products. Furthermore, information on adverse events related to medical products is often voluntary and, therefore, is underreported and may not represent all cases[2,5,8,11,12,14].

In 1990, the Food and Drug Administration (FDA), of the United States of America (USA) undertook a study on the safety of the reuse of single-use products and concluded that the pattern of adverse events of patients exposed to the reuse of these products does not depend on being single-use or multipurpose[2,5,11]. In 2008, the United States Government Accountability Office (GAO) stated that there is no causal relationship between injuries and deaths of patients and the reuse of single-use products[11].

Thus, there is not enough data, neither from the FDA, nor from other studies, on the safety of reprocessed single-use products when compared with original ones[8,11,15,16]. For such a comparison, it would be necessary to identify the types of products and adverse events, the control number of the original single-use products informed by the manufacturer and of the service when it is reprocessed, the number of times each single-use product has been reused, and the rate of adverse events associated with the original product[11]. The FDA has analyzed data on adverse events related to reprocessed single-use products, and has not identified a causal association between the adverse events and reprocessed single-use products[11].

Some international organizations have taken a stand on the reuse of single-use products.

The US Center for Disease Control and Prevention (CDC) take a positive position on the reuse of single-use products, and states that these products are not harmful if properly cleaned and sterilized[5].

The European Medical Technology Industry Association opposes the reuse of single-use products, and states that patient safety is threatened when these products are reused due to the risk of cross-infection transmission, inability to clean these devices, presence of waste, alteration of material's components, mechanical failure, among other arguments[15-17].

The European Association of Medical Devices Reprocessors (EAMDR) convoked member states to analyze how European regulations are implementing the reuse of these products, and states that the "high quality of product reprocessing in all member states can only be guaranteed if performed regardless of the label chosen by the manufacturer"[15-18], a statement that prioritizes the quality of the process, regardless of the product, whether single-use or not.

For the Joint Commission International (JCI), if a hospital decides to reuse single-use products, it must critically assess the conditions of the products cleaning, disinfection, and sterilization department , as well as its procedures and personnel[8].

According to the World Health Organization (WHO), the reuse of single-use products requires registered formulated policies, and critical and semi-critical products should only be reused by a licensed reprocessor[8].

For experts, such as professors Axel Kramer and Marc Kraft, from the Medical Technology department in Berlin, "the crucial criterion is that there is a validated procedure for reprocessing a medical product. Whether the product is multipurpose or single-use is irrelevant." For Marc Kraft, "the validation of the reprocessing procedure tends to disregard an increase in risk." In this case, there are no hygienic-related or technical-functional threats[5].

According to the International Federation of Infection Control, five questions must be positively answered by reprocessors in such a way the reuse of disposable products can be considered safe:

- Does the product remain intact and functional?
- Is it cleanable?
- Can it be sterilized?
- Is reuse cost-effective?
- Who will be responsible if an adverse event occurs?[8,19]

It is not recommended for single-use products to be reused and reprocessed if:

- it cannot be properly cleaned;
- the sterility of the reprocessed product cannot be safely demonstrated;
- the integrity, functionality, and safety of the reprocessed single-use product differ from the original one.

The safety and effectiveness of the reprocessing of single-use products must be conducted according to standardized and monitored processes, with the same quality assurance as the original products[2,5-6,8,16].

There are three practices concerning single-use products that involve discussions about reuse and different conducts adopted by many services:

- single-use products opened, but not used;
- single-use products placed on an operating table, but not used;
- single-use products opened and used on a patient.

Authors argue that open and unused single-use products should be eligible for reuse without discussion. Others defend that each practice requires careful consideration[20].

The number of times single-use devices can be reused is also a challenging situation concerning patient safety. Authors state that the maximum sustainable reuse of a disposable product is a fundamental parameter and should be evaluated through physical, chemical, and microbiological analyses in addition to functional testing[2,12]. This situation can be equally applied to multipurpose products, since they also cannot be indefinitely reprocessed and reused[20].

Regarding labels, the statement that the product is single-use or multipurpose is only based on the manufacturers' decision, who qualify a product as single-use for two reasons: because they believe the product is neither safe nor reliable to be used more than once, or because they choose not to conduct the necessary studies to demonstrate that the product can be labeled as reusable. Hence, there is a lack of consistent considerations regarding the definition of single-use by manufacturers[2,4,5,8,11,16].

When a medical product is registered as a single-use product, it only means that it can be safely and reliably used once; however, it does not imply that it cannot be safely used more than once, if properly reprocessed. It is worth noting that manufacturers often change labels of reusable products into single-use ones, sometimes without any significant change in design, performance, or material that could compromise safe reuse[15].

Moreover, products can be manufactured in a similar way and differently classified according to the manufacturers' choice, who benefit from the single-use label, since products defined so do not require the same degree of documentation and validation to be registered in regulatory agencies, as opposed to products classified as multipurpose. In addition, regulatory agencies do not require manufacturers to provide evidence that the single-use product cannot be reprocessed, and that reuse may be inappropriate or harmful[2,4,11,13,15,19].

In practice, most single-use products are reusable in technological terms. It is estimated that from 10 to 20% of products classified by manufacturers as single-use can be reprocessed a limited number of times[16]. Regarding the manufacturers, researchers argue that many single-use products can be safely reprocessed and reused in hospitals[4,5,16,20].

The stipulation that single-use products cannot be reused makes healthcare systems and the society financially dependent on what is said by the manufacturers[2]. Some authors are challenging the assumptions that single-use products are strictly developed for a single use, not only due to financial considerations, but also environmental ones[2,20].

In Brazil, a study carried out by researchers of the Brazilian Society of Cardiac Arrhythmias on the labels of single-use products registered by manufacturers at ANVISA identified that, of the 121 medical products used in electrophysiology procedures and registered as single-use, 86 (71.7%) labels were in compliance with the regulations in force, and 34 (28.9%) were not. The authors concluded that inconsistencies in the labels of these products can lead to interpretation errors and improper decisions in relation to their use[21].

Other complex issues are also important and worthy of discussion regarding the reuse of single-use products:

- The issue of informed consent, which concerns the patients' autonomy in choosing what is best for them;
- Fiscal responsibility for promoting the disposal of a product that can be safely reused;
- Ethical behavior in relation to the environment and the communities where we live.

Thus, the question to be asked is: are we behaving ethically in relation to the environment and the communities where we live by promoting the single use of a product that can be reused[14,20]?

The analysis of these issues can be done considering the Principlism Theory, or the theory of the four principles, which has greatly contributed to providesolutions in terms of individual and collective ethics: beneficence (obligation to do good and to act for the patients' and the community's best interests), non-maleficence (obligation not to cause harm to patients), autonomy (obligation to respect the individual's will), and justice (a principle that values the appropriate allocation of resources and the need to decide what and who should have prioritized access to goods deemed as finite and scarce). However, these principles, although clear and accessible, also present difficulties in their operation when it comes to the reuse of so-called disposable products: Which patient should receive a single-use product that has never been used and which should receive a reused and reprocessed product? Who is responsible for this decision? Are patients able to choose or should they be informed[4,16]?

The legal responsibilities are obvious, and healthcare institutions must take responsibility for the reuse of single-use products, since it goes against the manufacturers' instructions, when they, by labeling the product as single-use, are only responsible for the quality and effectiveness of the such solely according to their recommendations[8,14,16].

Another aspect regarding the reuse of these products concerns distributive and social justice, which requires the distribution of burdens and benefits among all patients[12]. According to the literature, there are many risks related to the reuse of multipurpose products as well and, in this sense, focusing only on the reuse of disposable products diverts attention to the process of decontamination of the so-called reusable products, which, *a priori*, require the same quality and safety standards. Therefore, the safe reuse of single-use products, aiming at improving access to health care, seems to be ethically justified as an attempt to generate conditions of equal opportunity and access to health care and well-being.

Synthesis of the results

This study addressed several emblematic issues regarding the reuse of medical devices, both from a technical-operational point of view and from an ethical, legal, and environmental perspective.

According to the published data, authors question such reuse based on technical considerations. Several researchers suggest safety and efficacy in reuse for many products labeled as single-use, and no causal association between harms to the patient and the fact that the single-use product is reprocessed[11]; however, it is also evident that some single-use products are not safe for reprocessing and reuse, given the impossibility of cleaning and sterilization, a condition also applied to the reuse of products classified as reusable.

In this sense, the decision to use a product, regardless of the single-use or multipurpose labels, requires standardized, validated, and monitored processes to guarantee quality and minimize risks for patients using reprocessed products.

In addition to the proposed issues, labels of single-use products represent a critical node and the fomenting element of dilemmas that permeate the reuse of these products.

The lack of studies, at the time of registration, whose authors prove that a product registered as single-use cannot be reprocessed and that reuse may be inappropriate or harmful to the patient, not only makes the definition of single-use inconsistent, but also creates a conflict situation for regulatory agencies and healthcare services whose authorities follow the manufacturers' instructions.

Thus, demystifying the label of these products is crucial for regulatory decision-making and its consequences. Are products registered as single-use in fact unsafe for reuse or does the manufacturer have other reasons for this label?

This issue is the key point concerning the reuse of medical products. The focus of regulatory policies should be on standardization systems of processes developed for the reuse of healthcare devices, in such a way that manufacturers would not be responsible for classifying the products, considering that, even products classified as reusable, cannot be continuously reused, despite this indication.

FINAL CONSIDERATIONS

The reuse of products stipulated as single-use involves many issues, starting with their very dubious label.

There are reasons for manufacturers to choose this alternative, and authors of studies show that the reuse of these products, when properly carried out, can be safe for the patient, allowing effective health treatment and cost reduction of medical products.

Furthermore, it is worth considering ethics in relation to the environment — land ethic — and, in this growing

profusion of waste disposal, the reuse of single-use products is deemed one of the best practices for environmental protection.

There is still room for this topic to be investigated as for technical, ethical, economic, environmental, and regulatory issues. It is also necessary to understand that some products classified as single-use can be reused, but this practice requires organo-structural conditions of healthcare services, in addition to expertise, adoption of protocols, and supervision of each of the reprocessing steps.

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