INTERNATIONAL OVERVIEW OF SINGLE-USE MEDICAL DEVICES REPROCESSING

Panorama internacional do reprocessamento de produtos médicos de uso único

Panorama internacional do reprocesamiento de productos médicos de uso único

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ABSTRACT: Introduction: The reuse of single-use products occurs worldwide and it leads to major issues. **Objective:** To analyze the international regulatory framework for the reprocessing of single-use medical products, including the Brazilian regulations. **Methods:** This is a narrative review of the literature, using databases with specific descriptors. **Results:** Internationally, there are a variety of regulations on the reuse of single-use medical products that aim at preventing damage. The regulatory environment comprises well-structured protocols, such as the American, Australian, and German protocols, to lack of regulations at a national level, as identified in developed countries such as Canada, Japan, and some European countries. **Conclusion:** Current regulatory controls have considerable gaps that hinder their implementation by the health services and manufacturers. An alternative approach may be the formulation of a regulatory framework of single-use products focused on the control of the processes instead of the current control of products.
Keywords: Patient safety. Equipment reuse. Health policy.

RESUMO: Introdução: O reuso de produtos de uso único é uma realidade mundial e implica em grandes problemas. **Objetivo:** Analisar o sistema regulatório de reprocessamento de produtos médicos de uso único a nível internacional, incluindo o brasileiro. **Método:** Revisão narrativa da literatura, utilizando bases de dados com descritores específicos. **Resultado:** Internacionalmente, as políticas de reuso de produtos médicos de uso único tendem a prevenção de danos. As regulamentações variam desde protocolos bem estruturados, como o norte-americano, o australiano e o alemão, à ausência de normatização a nível nacional, como identificado em países desenvolvidos como Canadá, Japão e alguns países da União Europeia. **Conclusão:** Os controles regulatórios existentes apresentam lacunas que dificultam sua implementação tanto para os serviços de saúde quanto para os fabricantes. Uma metodologia alternativa seria a de um sistema regulatório de produtos de uso único centrado no controle dos processos em lugar dos atuais focados no controle do produto.
Palavras-chave: Segurança do paciente. Reutilização de equipamento. Política de saúde.

RESUMEN: Introducción: El reúso de productos de uso único es una realidad mundial e implica en grandes problemas. **Objetivo:** Analizar el sistema regulatorio de reprocesamiento de productos médicos de uso único a nivel internacional, incluyendo el brasileño. **Método:** Revisión narrativa de la literatura, utilizando bases de datos con descriptores específicos. **Resultado:** Internacionalmente, las políticas de reúso de productos médicos de uso único tienden a prevención de daños. Las reglamentaciones varían desde protocolos bien estructurados, como el norteamericano, el australiano y el alemán, a la ausencia de normativa a nivel nacional, como identificado en países desarrollados como Canadá, Japón y algunos países de la Unión Europea. **Conclusión:** Los controles regulatorios existentes presentan lagunas que dificultan su implementación tanto para los servicios de salud como para los fabricantes. Una metodología alternativa sería la de un sistema regulatorio de productos de uso único centrado en el control de los procesos en lugar de los actuales enfocados en el control del producto.
Palabras clave: Seguridad del paciente. Equipo reutilizado. Política de salud.

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Received: 01 Sept. 2016 – Approved: 27 Sept. 2016
DOI: 10.5327/Z1414-4425201600040005

INTRODUCTION

Medical devices are defined by the manufacturers either as reusable or as single-use articles. Reusable or multiple-use devices require reprocessing, which consists of converting a contaminated product into a ready-to-use device, including not only cleaning, disinfection, and sterilization of the device, but also checking technical and functional safety by means of integrity and functionality tests. Single-use products are designed to be used only once in a single patient[1-6].

The practice of reuse of single-use devices has initiated in the 1970s. Since then, this practice has been occurring worldwide, and there are reports of reuse of such devices even in developed nations and in those countries where the reprocessing is prohibited[1-6]. This trend has intensified several debates and considerations on patient safety, informed consents, economic, environmental, legal, and ethical aspects, and regulatory requirements for manufacturers and reprocessors, which indicate different interests of the political actors involved: states, manufacturers of the devices, health services, reprocessing companies, academia, health professionals, associations, and users[1-12].

Among the risks associated with the reuse of both single-use and reusable medical devices, several authors mention the following[1,3-7]: infection, biofilms, material contamination with endotoxins, presence of toxic waste of the products used for cleaning, disinfection, or sterilization, bioincompatibility with proteins of the previous users that eventually remained in the material, functional unreliability, lack of physical integrity, and protection barriers, among others.

In Brazil, the reprocessing of single-use products is a reality in the health services. National data show that these practices are common in all regions of the country, regardless of the size and hospital's sponsor organization. These data also reveal that reuse protocols are adopted in few institutions, and in most of them the protocols are inappropriate, representing actual risks for patients who are users of these products[13-16].

Therefore, in this scenario of global growth of medical products used in the care process, regulations on the use and reuse of these technologies are crucial for the implementation of safe practices and for the prevention of adverse events related to these products. In this regard, this article seeks to answer the following central question: to what extent does the sanitary regulation framework for single-use medical products adopt policies aimed at preventing risks to patients? This study aims at reviewing the international regulatory framework for the reprocessing of single-use medical products, including the Brazilian regulations.

METHOD

This study is a narrative review of the literature carried out by searching the electronic databases Web of Science, PubMed, Lilacs, and SciELO, using the following descriptors: "reprocessing device medical," "reprocessing device single use," "reuse device medical," "regulation device materials," and "regulatory devices medicals." There was no restriction on the publication dates and languages.

We included primary and secondary studies, which were selected by their title and abstract. After reading the abstracts, only those papers that addressed regulatory aspects of single-use medical products and regulations on the reuse and reprocessing were read in full. References of selected articles were also incorporated to the search. The articles that were included in more than one database were analyzed only once. Therefore, of the 110 articles found in the electronic databases mentioned earlier, 33 met the inclusion criteria and were analyzed. In this study, we used the term "medical product" as a synonym for health product, apparatus, equipment, material, and medical article, in agreement with the National Health Surveillance Agency (ANVISA) definitions.

RESULTS

International policies on reuse and reprocessing of single-use medical products

The reprocessing of single-use items is regulated and supervised by the Food and Drug Administration (FDA), which, in 1999–2000, restructured its policy on reuse of single-use devices. The FDA applied the principle of regulatory equity, in which manufacturers of original equipments, outsourced reprocessing companies, and hospitals are subject to the same regulatory control level. Non-hospital medical institutions were

excluded from this legislation (clinics, day hospitals, long-term care facilities, home care), opened but not used single-use devices, permanent pacemaker, and hemodialyzers[3,4,6,9,12].

The core aspect of this regulatory policy is a classification scheme through which the products are categorized according to the risk of harm to the patient, based on the product intended purpose. There are three risk classes – I, II, and III – and two types of premarket submission requirements: premarket notification 510 (K) and the premarket approval application (PMA). The type of submission depends on the risk categorization of the product[3,4,6,9,12].

The 510 (K) or premarket notification is the simplest and most common method for marketing a medical product. Through this submission, the manufacturer should demonstrate that the new product is "substantially equivalent" to a product that is already legally marketed. The assumption is that the new product is as safe, effective, and performs its functions with the same consistency for the intended use as a product that is already marketed. The FDA then reviews the product by means of an assessment of equivalence with the device that is legally marketed. PMA is the route to be used if the new product is not similar to a legally marketed product. In this case, the manufacturer must carry out clinical studies to demonstrate product's safety and effectiveness, and the FDA conducts an inspection at the manufacturer's premises prior to the approval of the PMA. The time required by the FDA for the approval of the 510 (K) is approximately 75–90 days and 180 days for the PMA[3,4,6,9,12].

Currently, the FDA allows the reprocessing of over a hundred different products for single use. Cardiovascular catheters, guide wire, breathing circuits, biopsy forceps, cautery devices, anesthesia equipment circuits, and tracheal tubes are the most reused in the United States of America. According to the FDA, reprocessed single-use products are 50% less costly than new devices[3,4,6,9,12].

In Canada, there is no federal regulation, and the reprocessing of single-use products has historically been delegated to the ministers of health of the provinces and territories of the country. There are reports that the reuse of these products occurs in 40% of provinces and in 28% of national intensive care hospitals. The most reused products are breathing circuits and saws. Most health services (85%) perform reprocessing internally; however, since 2014, there is a growing trend of reprocessing by outsourced companies, most of which North American licensed by the FDA[17-19].

When reprocessing is outsourced, Canadian hospitals have adopted two commercial reprocessing systems, namely "closed-loop procurement model," in which the hospital receives back only its own medical devices that were sent to the third-party reprocessor, or "open-loop procurement model," in which the hospital does not receive its own products back, but rather buys them from a "pool" of reprocessed single-use products[19].

Large provinces have adopted two positions:

1. to prohibit the reuse of single-use products, which was adopted, for example, in Prince Edward Island, Newfoundland, and Labrador, in addition to all three territories (Northwest, Yukon, and Nunavut), Alberta, Quebec, and New Brunswick; or
2. to allow the reprocessing of single-use products only by contractors who are certified by health authorities such as Health Canada or the FDA in the United States of America. This position has been adopted, for example, in British Columbia, Manitoba, Ontario, Nova Scotia, and Saskatchewan[17-19].

In Europe, the European Union (EU) does not have a common policy on the reprocessing of single-use products, and the Member States adopt different regulatory processes[19]. In Germany, since 2001, current regulatory framework only handles quality standards and reprocessing validation procedures, and denominates as illegal the distinction between single- and multiple-use medical products. Reprocessing conducted by the hospital and outsourced reprocessors is allowed, but both should implement quality management systems in accordance with the German Act on Medical Devices[1,2,11,19].

In other EU countries such as the UK, Spain, and France, the reprocessing of disposable items is prohibited by law since 2005; however, France is the only country that does not reuse single-use devices. In Spain, a survey conducted, in 2005, in 42 hospitals in Madrid revealed that 82.4% of them reprocessed single-use devices, with no federal rules to evaluate this practice in the country. The UK allows the reuse of disposable items only in controlled situations, owing to great concern with prions. In Belgium, Denmark, The Netherlands, Slovakia, Sweden, and Switzerland medical products for single use are reprocessed according to strict quality standards. In Greece, Estonia, Cyprus, Latvia, Malta, and Poland, there is no regulation on these practice[17,19,20,21].

In Asia, the reuse of disposable products is common in most countries, and there are no national regulations guiding these practice[19,20]. In Japan, the reprocessing of single-use products is not systematically regulated. Data showed that 86.2% of hospitals reused disposable products, and that such practices were carried out inconsistently, without established standards and protocols[20,21].

In India, hospitals routinely reuse single-use products, without existing regulations on this practice[17,19,20].

In Australia, reprocessing is similar to the American. In 2003, The Australian Therapeutic Goods Administration (TGA) – national governing body for medical products – introduced regulations for hospitals and reprocessing companies of single-use products, naming the as "manufacturer" as described in the legislation. These companies need to follow the same regulatory standards as the original manufacturer and are required to demonstrate that the reprocessed single-use products are as equally safe and perform exactly as a new product. The regulation on reprocessing single-use products excludes "opened but unused" single-use products and individuals who reprocess disposable devices for their own personal use[19,20,22,23].

In New Zealand, the governing body Regulator Medsafe requires compliance with the US regulatory policy or approval according to the Australian policy to reprocess a single-use product[20].

In the Middle East, data indicate that, despite the absence of a regulatory framework, the reuse of these products is common in Arab countries, particularly of cardiac catheters[19,20].

Israel does not have a specific regulation for the reprocessing of single-use products, but, in general, every medical product must be registered with the Ministry of Health before they can be sold in the country. If the product is approved by the US FDA, it shall be registered in this country without any additional testing. As in many other countries, Israel's hospitals are reusing many single-use products without federal government control[20].

The Kingdom of Saudi Arabia is in the process of implementing a regulatory policy on medical products. The Saudi Food and Drug Authority issued a provisional regulation in 2008 stating that a medical product in Saudi Arabia can be marketed if it "adheres to regulatory requirements applied in one or more jurisdictions of Australia, Canada, Japan, and US." It seems that Saudi Arabia government prohibits the reuse of single-use products[20].

In Africa, South America, and Central America the practice of reprocessing single-use devices is prevalent owing to the lack of medical and financial resources[19,20].

Brazilian regulation on the reuse of single-use medical products

In Brazil, ANVISA is responsible for regulating the reprocessing of medical products, and in 2006, it issued three regulations that are still in force:

1. Collegiate Board Resolution (RDC) No. 156, which provides for the registration, labeling, and reprocessing of medical products;
2. Special Resolution (RE) No. 2,605, which establishes a list of 66 single-use products whose reprocessing is prohibited in the country; and
3. RE No. 2.606, which defines the guidelines for development, validation, and implementation of medical products reprocessing protocols[24-26].

ANVISA is the Brazilian agency responsible, among various activities, for the oversight to ensure compliance with the rules intended to protect population's health, such as the reprocessing of medical products.

DISCUSSION

The United States of America, by means of the FDA, currently has the broader established regulatory control on practices for reuse and reprocessing of medical products in the world. However, this institution's regulations have some issues that weaken the system in crucial aspects of the products reprocessing control, raising questions for the implementation of these regulations, especially to the hospitals. Initially, FDA regulatory framework on medical devices has as its policies guiding principle the marketing of these products, which differs from the traditional risk assessment, according to the potential of infection involved on their use. Articles considered critical such as surgical instruments and needles are classified by the FDA as class II (medium risk), and therefore, only require the 510 (K) for their licensing and reprocessing. On the other hand, 510 (K) allows marketing most of the products even when high-quality studies are missing, and therefore, class I and many class II products are granted marketing clearance without more accurate quality controls.

In addition, current FDA policy on single-use products reprocessing requires a great adaptability for its fulfillment, particularly for hospitals that reprocess medical products. The two premarket and/or reprocessing medical devices submissions — 510 (K) and PMA — are ambiguous in their requirements for authorization of such processes. For example, how should manufacturers and outsourced reprocessors or hospitals prove that the "class I and II reprocessed medical device is equivalent in safety and effectiveness to an original unprocessed product," which is required to comply with the 510 (K)? The 510 (K), considering its control focused on the "substantial equivalence" with a product legally marketed, allows marketing the majority of products in the US without more strict quality studies.

Moreover, what are the control standards that the reprocessors of medical products will use to demonstrate "scientific validity and clinical evidence of safety and effectiveness of reprocessed class III single-use medical devices," required by the PMA? Without a clear methodology, there will certainly exist different experiments and clinical trials for compliance with this legislation. Are all the presented methodologies accepted? Another uncertainty is whether the FDA accepts similar groups of products or if the submission of 510 (K) or PMA is mandatory for each product model. Finally, this regulation exempts other health institutions that also reuse and reprocess single-use medical devices, such as clinics, care units for chronic patients (as psychiatry), day hospitals, and home care units, which remain unregulated. We considered these pending issues as gaps and limitations of this regulatory framework.

In Brazil, current regulatory framework that regulates the reprocessing of single-use medical products represents advancements in the standardization of medical products reprocessing in our country. However, there are several inaccuracies and abstract content in these laws, which facilitate various interpretations and hinder their implementation by the health services, outsourced reprocessors, and manufacturers or importers of these products.

Resolution No. 156/2006 categorizes medical products as "subject to reprocessing" and "reprocessing not allowed" and establishes that this categorization need to be performed during the product registration, when the manufacturer or importer shall submit to ANVISA the documentation substantiating this categorization. However, this norm does not specify the required documentation and evaluation parameters for manufacturers or importers, in the registration process of multiple- and single-use products. The main question is: what are the criteria that this agency uses to accept or reject the product classification informed by manufacturers at registration? What are the tests required by ANVISA to the manufacturers to prove that the product is reusable or single-use on registration?

RE No. 2,605/2006 listed 66 products classified as single use whose reprocessing is prohibited, but did not explain the criteria used for selecting the medical products that compose this negative list. This resolution does not favor the understanding of the technical and scientific bases for the regulation of a practice that involves relevant aspects of health in the country. There are many questions to be answered: why are some possibly reusable products, such as dental suckers and rubber dams, gloves, and pads included in the negative list while others that proved to be of high risk, such as endoscopic biopsy forceps, papillotomes, vitrectomy kits, and many others of high risk used in the care process were not included? How to handle the inclusion of an increasing technological arsenal in a finite list of products? Why do they choose to work with a list subject to become obsolete, as it is already, focusing on the product and not on processes involved in the reprocessing steps?

RE No. 2,606/2006 states that the contractors and health services that reprocess critical and semi-critical items must elaborate, validate, and implement protocols for each selected product brand and type, containing detailed description of all reprocessing steps, in addition to the quality assurance of all stages, including the assessment of functionality, sterility, traceability, and storage and disposal conditions of each reprocessed product.

This resolution also defines that each critical and semi-critical product to be reprocessed, without specifying whether it is single- or multiple-use, should have a chart with information related to the devices, such as size, structure, composition, registration at ANVISA, manufacturer and supplier, name of the reprocessing responsible, and place and date of each reprocessing. Although this legislation requires development, validation, and implementation of medical products reprocessing protocols, it does not indicate what is the acceptable methodology for the processes validation to be carried out by hospitals, which not only hinders their implementation, but also facilitates the elaboration of dubious validation protocols, leading to safety issues in the products reprocessing.

Moreover, this regulation is vague on the quality assurance requirement in all stages of the process, including assessment of functionality, sterility, pyrogenicity, non-toxicity, and integrity. We ask again what is the acceptable methodology for these quality controls. Is it necessary to perform these tests to all critical and semi-critical products? How, who, and when should one evaluate functionality and integrity of all reprocessed products, given the large number of existing medical products in a health institution? What should be the minimum frequency of these tests? How should a medical record be created for each critical and semi-critical product containing the data required by this legislation, considering the structural, functional, and organizational contexts of most of the Central Sterile Supply Departments (CSSD) of hospitals in Brazil, and the large number of products that compose their arsenal? Pending questions of this regulatory framework negatively impact the operation of health services.

In addition to the questions elaborated earlier, how can ANVISA monitor, supervise, and control these rules in many health facilities in the country? Do health surveillance professionals have the expertise necessary to carry out the sanitary control of medical products reuse? These are other pending issues of this theme in Brazil.

Studies show that without proper supervision, the regulation on medical products reprocessing, published since 2006, has been delayed or boycotted in its implementation in Brazilian hospitals[13-16]. In addition to the issues it raises, such delay challenges the regulation legitimacy, which reinforces the problems surrounding the reuse of single- or multiple-use medical products.

CONCLUSION

The literature review showed that there are a variety of international regulations on the reuse of single-use medical products, which generally tend to have a preventive character, with recommendations aimed at the safety of public health.

Although these regulations have substantial differences, the risk management principle should be their guiding principle and the degree of regulatory scrutiny imposed for any medical product, regardless whether single- or multiple-use, should be proportional to the intended purpose of the device, to their risk level, and degree of invasiveness of the product in the human body.

The regulatory environment comprises well-structured protocols, such as the North American, Australian, and German protocols, to the lack of regulations at a national level, which was also identified in developed countries such as Canada, Japan, some European countries, Asia, and the Middle East, indicating a lack of political priority to the issues surrounding the reuse of medical products.

Even current regulatory controls in countries such as the United States of America, Australia, and Brazil have considerable gaps, as those mentioned in this study, which hinder their implementation by the health services and manufacturers.

In Brazil, the monitoring of the implementation of these regulations by ANVISA is another pending issue which relates to the actual technical and operational capability of this body to perform sanitary control of the medical products reuse in country.

An alternative approach is to develop a regulatory framework for reuse and reprocessing of single-use products focused on the control of the processes instead of the current control of products, which is currently implemented internationally.

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