

Legal and biological safety of legal reprocessing of medical-hospital materials

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Abstract

Introduction: Procedures using disposable materials in the health area began to be performed, for example in cardiac catheterization, which has a high prevalence of morbidity and mortality. **Objective:** To justify and reaffirm the reuse of single-use catheters in surgeries, as it is justified by the economic benefit gained from replacing the purchase of new materials by reusing them. **Materials and methods:** A bibliographic and documentary narrative review was carried out using LILACS and NCBI as database, with previously defined filters and selection criteria. **Resultados:** Decontamination, disinfection, conditioning, sterilization, and quality control tests are critical stages and, therefore, require training. Each of these stages also has characteristic risks, which must be minimized. In order to ensure the quality of the catheter reuse process, after the cleaning and sterilization process, techniques beyond microscopic and visual evaluation of the device are required. A diversity of techniques is addressed so that the quality of the process is assured. Although legislation and supervision are divergent around the world, many countries choose to adopt reprocessing with economic justification in most cases. The reuse of hospital devices involves several physico-chemical processes, which must be performed with quality and safety. **Conclusion:** The need for greater rigor in the norms and guidelines that address this practice is clear and urgent, as well as the greater intensity and rigidity of the responsible inspection agencies. The use of luminol as an indicator of organic contaminants may generate a false positive result. Therefore, 3M™ Clean-Trace™ is the best instrument found in the world market to ensure that the material that has been reused is free of organic waste, and thus fit for use in hospitals.

Keywords: Single use of catheters; Ablation catheter; Hospital infection; Catheter cleaning and sterilization; Quality control.

Resumo

Introdução: Procedimentos com materiais descartáveis reutilizados na área da saúde passaram a ser realizados, a exemplo do cateterismo cardíaco, que apresenta elevada prevalência de morbimortalidade. **Objetivo:** Justificar e reafirmar a reutilização de cateteres descartáveis em cirurgias, visto que se justifica pelo benefício econômico obtido com a substituição da compra de novos materiais pelo reaproveitamento. **Materiais e métodos:** Foi realizada uma revisão narrativa bibliográfica e documental utilizando o LILACS e o NCBI como base de dados, com filtros e critérios de seleção previamente definidos.

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Resultados: Os testes de descontaminação, desinfecção, acondicionamento, esterilização e controle de qualidade são etapas críticas e, portanto, requerem treinamento. Cada uma dessas etapas também possui riscos característicos, que devem ser minimizados. Para garantir a qualidade do processo de reutilização do cateter, após o processo de limpeza e esterilização, são necessárias técnicas além da avaliação microscópica e visual do dispositivo. A diversidade de técnicas é abordada como forma de garantir a qualidade do processo. Embora a legislação e a supervisão sejam divergentes em todo o mundo, muitos países optam por adotar o reprocessamento com justificativa econômica na maioria dos casos. O reaproveitamento de dispositivos hospitalares envolve diversos processos físico-químicos, que devem ser realizados com qualidade e segurança. **Conclusão:** É clara e urgente a necessidade de maior rigor nas normas e diretrizes que tratam dessa prática, bem como a maior intensidade e rigidez dos órgãos fiscalizadores responsáveis. O uso do luminol como indicador de contaminantes orgânicos pode gerar um resultado falso positivo. Portanto, o 3M™ Clean-Trace™ é o melhor instrumento encontrado no mercado mundial para garantir que o material que foi reutilizado esteja livre de resíduos orgânicos e, portanto, adequado para uso em hospitais.

Descritores: Uso único de cateteres; Cateter de ablação; Infecção hospitalar; Limpeza e esterilização de cateteres; Controle de qualidade.

Resumen

Introducción: Los procedimientos utilizando materiales desechables en el área de la salud se comenzaron a realizar, por ejemplo en el cateterismo cardíaco, los cuales tienen una alta prevalencia de morbilidad y mortalidad. **Objetivo:** Justificar y reafirmar la reutilización de catéteres de uso único en cirugías, justificado por el beneficio económico que se obtiene al reemplazar la compra de nuevos materiales por su reutilización. Se llevó a cabo una revisión narrativa bibliográfica y documental utilizando las bases de datos LILACS y NCBI, con filtros y criterios de selección previamente definidos. **Materiales y métodos:** Descontaminación, desinfección, acondicionamiento, esterilización y control de calidad son etapas críticas y, por tanto, requieren entrenamiento. Cada una de estas etapas tienen riesgos característicos, los cuales deben ser minimizados. Para asegurar la calidad del proceso de reutilización del catéter, después del proceso de limpieza y esterilización, se requieren técnicas más allá de la evaluación microscópica y visual del dispositivo. Se aborda una diversidad

de técnicas como medio para garantizar la calidad del proceso. Aunque la legislación y la supervisión son diferentes en todo el mundo, muchos países optan por adoptar el reprocesamiento con justificación económica en la mayoría de los casos. La reutilización de dispositivos hospitalarios implica varios procesos físico-químicos, los cuales deben realizarse con calidad y seguridad. **Conclusión:** Es clara y urgente la necesidad de un mayor rigor en las normas y lineamientos que abordan esta práctica, así como una mayor intensidad y rigidez por parte de los organismos de inspección responsables. El uso de luminol como indicador de contaminantes orgánicos puede generar un falso positivo como resultado. Por lo tanto, 3M™ Clean-Trace™ es el mejor instrumento que se encuentra en el mercado mundial para garantizar que el material que se ha reutilizado esté libre de desechos orgánicos y, por lo tanto, apto para su uso en hospitales.

Palabras clave: Catéteres de uso único; Catéter de ablación; Infección hospitalaria; Limpieza y esterilización de cateteres; Control de calidad.

Introduction

More than one million coronary interventions occur annually worldwide. In Brazil, from January 2008 to June 2010, 286,343 diagnostic cardiac catheterizations were performed according to DataSus.^{1,2} Over 80% of the vascular catheterizations (CATs) were performed on an outpatient basis in patients with stable coronary disease.

The advancement of technology is continuous and increasingly accelerated, which, in the health area, enables several alternatives and therapeutic improvements. During the 1960s, the start of the use of disposable materials in health could be noticed.³ This practice has taken extensive and worldwide proportions. Thus, surgical procedures using those materials were positively impacted in favor of reduced disease transmission and improved performance of procedures in general.

CAT then began to be performed with disposable devices, which led to a growing increase in health care, especially in the medical area which has a higher prevalence of morbidity and mortality. As a result of this problem, many hospitals have adopted the practice of reusing single-use medical products.³

Countries such as Switzerland, Germany, the United States, and Canada already have this issue clarified and allow the reprocessing of some single use materials as long as each country's regulations are followed. In Africa, Asia, Eastern Europe, Central America, and

South America this practice is permitted, but without specific regulation.⁴

As a method of economics, many hospitals around the world began to adopt the practice of reprocessing disposable materials from 1970.⁵ Since then, studies have been emerging and answering several questions about the risks and effectiveness of such procedure.

In England, using the practice of reusing single-use medical devices, intermittent catheter costs increased from £13.5 million in 1999 to £88 million in 2013.⁶ This scenario encourages England, Brazil and several other countries already mentioned to adhere to the practice of reuse.

The reprocessing of surgical materials can be performed inside the hospital, or, most often, this service can be outsourced to companies specialized in cleaning and sterilization. Both processes need to ensure the quality and safety of the devices, and for this they must follow cleaning protocols validated by the responsible health institutions, and under a rigorous process of control of all steps.¹

The growing and imminent concern with the reuse of medical devices has led the Food and Drug Administration (FDA) to pronounce on the issue. The FDA is a federal agency of the United States Department of Health and Human Services, which in response to healthcare professionals, catheter producers and reprocessing companies, has created a guide document

on the reuse processes of single-use catheters. This guide, released in 2000, contains the process that should be used when reprocessing a catheter: cleaning, remodeling, integrity and functionality inspection, and sterilization. This document also includes a list of risks associated with the procedure, categorized as high, medium, or low risk.⁷

Currently, the process of reusing single use medical devices is provided by the United States Federal Food, Drug and Cosmetic Act (FDCA). Thus, all reprocessed material that meets the requirements of this law may be legally commercialized in the country.⁷

Current Brazilian legislation does not prescribe a specific protocol for catheter reuse, leaving it to the discretion of each hospital to create its own, and with the obligation to validate it by the competent body. On February 7, 1986, the National Health Surveillance Agency (ANVISA) classified single-use articles through Ordinance No. 3⁸ and 4,⁹ prohibiting their reprocessing. In 2006 ANVISA published Special Resolution (RE) No. 2605¹⁰ and 2606,¹¹ which lists medical products considered difficult to reprocess, also the list of materials which must contain in their packaging the term "PROHIBITED TO REPROCESS" in order not to be reprocessed. On August 11 of the same year, RDC 156 was elaborated, which updates Ordinances No. 3 and 4, and Ordinance No. 822, of July 8, 1988, providing guidelines for the prohibition or permission to reprocess single use surgical materials. Later, in 2012, RDC 15¹⁴ was published on March 15, which established good practice requirements for the processing of health products.

The Brazilian Society of Interventional Hemodynamics and Cardiology (SBHCI) does not oppose the reuse of hospital materials such as cardiac catheters, but recommends several procedures until ANVISA regulates all stages of the reprocessing of single use materials and also supervises this activity. In practice, SBHCI recommends that hospitals and companies reprocessing these materials follow the practices already established by ANVISA itself: validation of the technique, training of professionals involved, surveillance of possible adverse effects on patients who used such materials, and quality control of all steps.¹⁵

Hospital-acquired infection is a major cause of morbidity, mortality, prolongation of hospitalization, and represents an increase in patient treatment costs.¹⁶ According to Humphreys,¹⁷ there has been an increasing importance of blood-focused infections, which represent the highest cause of mortality, and

also infection at the surgical incision site, which remains one of the most routine acute complications in hospitals.

Infectious disease is the main criticism of reprocessing single use materials, and often the reason why such practice should not be performed.¹⁸ Although few studies show data proving the increased risk for the patient using such materials, this subject is still regulated by several researchers. The risk is imminent and potential when devices have contact with blood and body fluids, so they must be thoroughly reprocessed. Even with proper disinfection and sterilization processes, infectious agents may pose a risk to the patient, although the most frequent data found in the literature do not show significant differences between infectious occurrences using new and reused devices.¹⁹

This situation, besides being a worldwide problem in public health, still impacts the economy. Health care expenditures for patients who acquire infections in hospitals are estimated to reach \$ 5.7 million each year.²⁰ Thus nosocomial infections, which are the most common adverse events in the hospital setting, become the focus of many public health research studies.

Reprocessing catheters is justified by the economic benefit gained from replacing the purchase of new materials with their reuse. However, this practice has negative factors, which weigh on the decision making by hospitals.

The reuse of hospital devices involves several physical and chemical processes, which must be performed with quality and safety. Decontamination, disinfection, packaging, sterilization, and quality control testing are critical steps and therefore require training. Each of these steps also has characteristic risks that should be minimized.²¹

The initial lavage of a catheter already used is either performed inside the hospital, at the Sterilization Center (CME) or at the External Sterilization Center (CEE), depending on the hospital in question. This activity is intended to keep the material "minimally" clean, free of coarse and apparent dirt, to continue to the sterilization process.²⁰

Sterilization can take place at the CME itself or from the EEC to outsourced companies, which will proceed with the material reprocessing procedure. At this stage, various techniques or a combination of these are used to eliminate viable microorganisms such as viruses and bacteria, and the toxic and virulent substances released by them, as well as remnants of blood cells that may have "deposited" in the catheter.²⁰

Finally, after reprocessing, the catheters should be tested for quality and process effectiveness. These tests, here in Brazil, mostly boil down to visual and mechanical inspections, to certify that they are, in fact, fit for use again.¹

Chemical residues and biological agents are the major concern regarding the source of contamination due to the use of reprocessed catheters. Blood is one of the biological agents possibly found in materials used multiple times. Remnants of blood cells and proteins, in particular, are able to adhere to catheter material and can be a potential source of contamination.²²

Optical microscopy, scanning electron and transmission techniques are used to detect these biological residues. Because the indicators are rarely used in Brazil, due to their high cost, the process of cleaning and sterilization of catheters becomes a determining factor for the elimination of such dirt.²³

However, there are more advanced and specific methods for determining the effectiveness of the catheter cleaning process that will be reused. And while simple visual inspection is still widely used as a final quality control method of the process, specific testing for the presence of particles and blood cells is now available worldwide. Tests such as TEST SOIL and TOSI® are used to monitor the quality of electronic cleaners used during the catheter cleaning process. However, end-of-process methods can be equally effective in quality control of reused medical and surgical devices. Chemiluminescent techniques such as luminol and bioluminescence techniques such as 3M™ Clean-Trace™ ATP Surface devices, 3M™ Clean-Trace™ ATP Water and Clean Trace Protein HS are viable options for analytical markers for detecting blood cells and their remnants in these devices.²⁴

Methods

The present work used as methodology a bibliographic and documentary narrative review. From the article selection, explained below, this article was written using the most important and pertinent references.

The databases used were the Latin American and Caribbean Health Sciences Database (LILACS) and the National Center for Biotechnology Information (NCBI). Data were collected from April 1 to 4, 2018. In this research, the descriptors used were divided into stages, since the diversity of subjects is extensive, and many of them were not found in related articles. A total of

348 articles were searched through advanced searches.

In the initial research, the descriptors used were divided into four stages, since the diversity of subjects is extensive, and many of them were not found in related articles. The keywords used were: “Catheter AND Reuse”, “Hospital AND (infection control OR infection)”, “Luminol And Blood”, “Blood And Contamination And Infection”.

In addition, filters were used in order to preserve the relevance of the researched literature. They were: human species, literary revision as article type, title and abstract. The language was not filtered, but the input only contained articles in English, Portuguese or Spanish.

At first it was also defined as exclusion criterion the publication time of up to 5 years, however, initial surveys indicated the precariousness of articles related to the theme. Thus, the criterion “date of publication” was excluded and the search redone.

The exclusion criteria for articles found from descriptors were the title and the abstract. Thus, the content should be in accordance with the research theme for the article to be used. Thus, 271 articles were excluded for not having relevant content for the current work. The rest was completely read and the relevance to the current work was evaluated.

Other searches in the same databases were conducted for specific issues, such as the concept of nosocomial infection, blood cells and red blood cell cycle. Such articles were chosen for the content relevant to the theme, and found both in the databases cited and in the references of articles already selected as pertinent to the theme. In total, 46 papers were used through this differentiated selection, since the scarcity of material was affecting the development of this research.

Of all the articles read and used, some of their references that had relevance to the subject were included. After the initial selection and exclusion phase of the articles based on the pre-defined criteria, the exploratory and analytical reading of the remaining articles began, followed by data analysis and writing.

Results

The economic issue is the main reason for the reuse of single use hospital supplies. And it also explains the cost-benefit of possible infections with the practice. Malanoski and colleagues,²⁵ in a study of the complications of unusual infections due to

catheterizations performed in the United States in 1995, said that this year the country spent \$4.5 billion on treating infectious complications, contributing to over 88,000 deaths.

In developing or underdeveloped countries, the reuse of single-use surgical materials has a poor regulation and almost no supervision, as it can be seen in table 1 below. As is the case in South America, where Brazil^{26,27} and Chile²⁸ are the only ones with legislation, however, there are still many controversies about the practice, in which lists are available in both countries, containing the devices whose reuse is permitted. In Brazil, ANVISA⁸⁻¹⁴ is responsible for such regulations and leaves the adopted method to the establishment, requiring only that it be duly validated and approved. In contrast, there are no regulations or recommendations in Ecuador.²⁸

In Europe, the reuse of single-use surgical items is very common in hospitals in countries as Denmark,²⁹ Madrid³⁰ and Germany,³¹ and in Spain, where this practice occurs in approximately 37%, 80% and 40% of hospitals,³¹ respectively. However, each European country may differ in the practices adopted for reprocessing, depending on their current laws. According to the European Association for the Reprocessing of Medical Devices, this practice can be performed in almost all European countries, and especially without requiring quality standards.³²⁻³⁴

However, high quality standards are required by regulations in Germany, the Netherlands, Denmark, Sweden, Belgium, Slovakia and Finland. Austria, Luxembourg, the Czech Republic and Slovenia are still undergoing evaluations of the procedure, where

Table 1. Current conditions of each continent, and in some cases specific countries, regarding the procedure for reuse of single-use surgical materials and their legal implications, as well as supervisory bodies, where relevant

Continent	Country	Inspection	Regulation	Procedure
North America	United States	FDA	Yes	Permitted according to materials manufacturers.
	Canada	CCOHTA	Yes	Each region defines its own legislation.
Latin and South America	Brazil	ANVISA	Yes (poor)	Allowed but with little regulation.
	Chile	ANAMED		
	Ecuador	-	No	With the help of the Pan American Health Organization (PAHO) and the US Society of Hospital Epidemiologists (SHEA), they have hospital infection control programs. ⁵⁰
Asia	Japan	-	No	There are no regulations, although there is 86.2% of hospitals reuse disposable products by inconsistent methods without protocols and standards. ³⁰
	India	-	No	Each hospital has its own committee of doctors, microbiologists, nurses, administrators who, together with the CCIH staff, create protocols (mirrored in the FDA) and supervises reprocessing. ⁵¹
Africa	Sub-Saharan Africa	-	No	Poor practice due to lack of supervision.
	South Africa	CAP	Yes	Allowed from WHO Good Manufacturing and Management Practice Guidelines.
Europe	Spain	EU Medical Device Regulation	No	Forbidden.
	Germany	-	Yes (high standard)	Allowed and required high quality standards.
	France	-	Yes	Forbidden.
	United Kingdom	MHRA	Yes	Recommendations against practice.
Middle East	Arabian countries	-	No	The hospital is responsible for developing the protocol and performing reprocessing locally, but there is no regulatory system. ³⁰
	Egypt	-	Yes	MS has set guidelines, but poor working conditions prevent compliance.
Oceania	Australia	TGA e AHMAC	Yes	It is up to the manufacturers to determine if the material can be reprocessed.

standards, methods and legislation are not yet conclusive and practice is still poorly regulated. There is no legislation available in Estonia, Latvia, Lithuania, Malta, Cyprus, Greece and Poland. And yet, Ireland, Portugal, Spain, Italy and Hungary do not yet have recommendations for reprocessing to occur in hospitals.³⁰⁻³⁴

In France, reprocessing is prohibited and in the United Kingdom, the Medicines and Healthcare Products Regulatory Agency (MHRA), which is a union of The Medicines Control Agency, and The Medical Devices Agency issued a statement in 2003 against the practice, claiming that the practice may compromise the safety, performance and effectiveness of the devices, and that the risk to patients outweighs any benefit.²⁸

One of the countries with the highest quality control of the catheter reuse process is the United States, which has a disposable medical device reuse rate in about 25% of hospitals. The FDA has created a list of 70 products that can be legally reprocessed within hospitals themselves, or even by third parties (which account for 40-50% of reprocessing practice), and still requires that original manufacturer's regulations must be met.³⁵⁻³⁸

In Canada each province has its own jurisdiction, and that is why the practice of catheter reuse still happens with poor or none regulation in some territories. Competent federal agencies argue that single use devices should not be reused unless the institution wishing to do so has adequate facilities and quality service. Thus, given this issue of provincial jurisdiction and national determination, most hospitals do not adopt catheter reprocessing (72%). However, among those which reuse surgical materials, 85% do so through in-hospital procedures, most of them without even having a written policy on the subject (approximately 40%).³⁹

Koh and Kawahara⁴⁰ conducted a survey in 2005 in Japan in which hospitals were asked about the reuse of single-use surgical materials. The response rate was 30%, and 80 to 90% of the hospitals that responded said they performed such practice.

The most available literature data on reprocessing single-use materials in Asia is about syringes and needles. WHO⁴¹ estimates that around 300,000 people die each year in India from the use of unsterile or reused syringes, and this practice is often repeated also in countries south of the continent, the Eastern Mediterranean and the Western Pacific.⁴²

In the 1980s in Australia, 50% of hospitals reprocessed single use devices. Even before regulations were introduced in the country in 2005, the number of reprocessing had already been reduced in 2001.⁴³ Currently, the country only permits the reuse of disposable materials by meeting all requirements regulated by the device manufacturer.⁴⁴ A Guide to Disposal Control Infection⁴⁵ was created in 2003 with the support of the Australian Regulatory Agency (Therapeutic Goods Administration - TGA) and the Advisory Council of Health Ministers of Australia (AHMAC) to prevent contamination among patients who have reused single use equipment. Accordingly, such materials labeled "SINGLE USE" cannot be reprocessed in the country.⁴⁶

WHO estimates sub-Saharan Africa to be slightly better off than Asia, where approximately 18% of reused syringes and needles do not undergo any sterilization process.^{41,47} Some of these countries have no structure for the production of surgical materials, as distribution centers, do not even have national logistics for such an area. This fact requires many hospitals to reprocess single-use materials so that health care delivery in Africa occurs minimally.²⁸ South Africa is one of the countries that has regulation on the WHO Good Practice Reprocessing Regulation Manufacturing and Management and also guidelines for infection control in hospital units.⁴⁸

Limited health resources extend to Arab countries, which justifies the need for reuse of catheters and some other materials, such as masks and mist tubes, in some hospitals in the region. Reprocessing is done locally at the hospital level, and there are no defined regulations for such practice, and each institution is responsible to formulate its own protocol.⁴¹ In Egypt, the Ministry of Health has formulated National Infection Control Guidelines outlining appropriate procedures for reuse single use materials. However, poor working conditions, such as overtime and lack of human resources, compromise the correct application of such practices.⁴⁹

In the current context of Brazilian health, the predominance of diagnostic and therapeutic procedures encourages legislation to adapt to the reality of the country. The high cost of surgical materials, such as ablation catheters, also justifies the practice of reuse in hospitals. And while Brazilian law does not determine a specific protocol for reprocessing, some requirements are mandatory to ensure the safety, effectiveness and quality of the process. Decisions and

Resolutions of the Collegiate Board (RDC) competent to the activity are described in table 2.

ANVISA acts by directing and supervising the re-sterilization activity of surgical materials. Special Resolutions (RE) have established product lists and parameters that are prohibited from being reused, as explained in table 2.

Surgical site infections (SSI) account for 38% of all hospital infections. In Brazil, they rank third among Health Care-Related Infections (HAI). Not unlike in the United States, SSI is the second leading cause of HAI in postoperative patients. In numbers, more than 500,000 cases of infections from the surgical incision site are detected every year.⁵²

The high cost provided by the increased length of hospitalization, associated with the expense of antimicrobial therapy, laboratory tests and diagnosis has led to further studies in this area. A US health data survey showed that the number of extra hospitalization days added for all patients diagnosed with SSI was \$3.7 million, representing an extra \$1.6 billion in the nation's health budget.⁵²

Several researchers have come to the conclusion that the practice of reusing catheters rather than buying new ones would economically benefit the healthcare industry without complicating the patient.

Veras and colleagues,⁵⁴ in their cost-effectiveness analysis of catheter reuse in the city of Rio de Janeiro, emphasizes that this strategy can cost 2.5 times less than the purchase of new medical devices. In the same vein, Dunn (cited Bomfim and colleagues), in 2002, stated that savings can reach 50% when cardiac procedures are performed with catheters reused by third parties.

Within hospitals, reprocessing single use devices is routinely performed by the Sterile Material Center (SME) worldwide.²⁰ According to Resolution RDC no. 307 of November 14, 2002, CME is considered a technical support industry, which has the function of providing properly cleaned and sterile materials, providing care to patients within the health facility.⁵³

The SME is an intrahospital unit of high complexity and importance, and must have trained professionals to operate the actions performed in the sector. It is the process of receiving materials considered dirty and contaminated from the entire hospital, for subsequent decontamination and sterilization.²⁰

As provided by ANVISA,⁵⁴ it is the responsibility of each institution to determine a protocol for the material cleaning and sterilization practices, provided that it is validated and within the Good Practice recommendations determined by the health surveillance agency itself. Given this, the most diverse types of practices are

Table 2. Legislation pertaining to the reuse of medical-hospital materials said to be of single use in Brazil

Legislation	Publication date	Guideline
Ordinances No. 3 and 4	February 7, 1986	Standardization of the use and reuse of disposable medical and hospital materials. Forbidden to reprocess needles with plastic components (including fistula cannulas), scalpels; disposable scalpels and blades; venous puncture catheters; equipment for administration of intravenous solutions, blood, plasma and parenteral nutrition, blood bags; plastic syringes; simple urethral aspiration and gastric tubes; open drainage urine collectors; Penrose and Kehr drain; peritoneal dialysis catheters.
Ordinances No. 8	July 8, 1988	Authorizes the execution of re-sterilization service and processing of medical-hospital articles
RE 2605	August 11, 2006	Establishes the list of single-use medical products forbidden from being reprocessed, a total of 63 items.
RE 2606	August 11, 2006	Establishes parameters that guide the elaboration, validation and implementation of medical device reprocessing protocols by health services and reprocessing companies in order to guarantee the safety and efficacy of the products.
RDC 156	August 11, 2006	Provides for the registration, labeling and reprocessing of medical products, and makes other arrangements.
RDC 15	March 15, 2012	Establishes the best practice requirements for the operation of services that perform the processing of health products aiming at the safety of the patient and the professionals involved.

Legend: RE: Especial Resolution in Portuguese.

Authorship: The authors.

performed in different hospitals in the country. The combination of these techniques is also very common in Brazil and around the world.

When this procedure is performed externally, the External Sterilization Center (ESC) is the sector responsible for the steps of pre-washing and packaging of materials until they are sent to third parties that will actually perform the washing and sterilization procedure, which follows same protocols as the SME.

Cleaning and disinfection are responsible for eliminating most contaminants from surgical devices. However, some microorganisms in their vegetative or sporulated form are able to survive the most extreme conditions. The sterilization process is effective and indispensable for catheter reuse in order to eliminate even those forms of microorganisms.¹

After the cleaning step, the catheter is normally subjected to enzymatic disinfection preparations to eliminate organic materials such as blood by breaking it. It is of utmost importance to take into consideration the instructions of the manufacturers of each material at all times. Characteristics such as product residence time in diluents, dilution pH and appropriate procedure environment are uniquely relevant for steps involving device washing. Equally important, having a skilled professional and validated techniques throughout the reuse process is of utmost necessity.¹

The FDA, as the world's leading regulator, sets maximum plasma concentrations of ethylene oxide and various other substances, which are followed by many hospitals across the globe. Nevertheless, observations of ethylene oxide residue levels in resealed electrophysiology catheters up to 8 times above allow attention to concern about imminent toxicity risks during reprocessing. Therefore, the 14 days rest time after reprocessing is essential to detoxify the material after exposure with ethylene oxide.²²

The Hospital Infection Control Program (PCIH) was created in 1988 and regulated by Ordinance No. 2616/1998¹¹ of the Ministry of Health, which determined the actions that should be taken by each hospital to reduce the incidence of nosocomial infections and its severity. Thus, the PCIH guides Hospital Infection Control Commission (HICC) professionals in setting objectives and priorities for each institution. There is also the Inspection Roadmap for the Hospital Infection Control Program, established by RDC No. 48/2000,⁵⁵ which, together with the PCIH, can be used as a basis to guide the elaboration of CCIH standards in hospitals.

For the final catheter evaluation, after all cleaning and sterilization steps, most hospitals and third parties still use simple visual inspection as the final process quality control. As its name implies, this assessment basically consists of the naked eye examination of the catheter that is ready to be reused in its final packaging.¹

Visual inspection, although the most commonly used, is the least effective. Currently, it is already recommended that microscopic techniques that guarantee the visualization of possible microscopic changes, as well as determine the presence of particles and blood cells, should be used for this purpose in surgical materials to be reused, being one of the most reliable and safe. Tessarolo and colleagues also emphasizes the importance of using scanning electron microscopy to observe possible macro and micro residues of coagulated blood in catheters.^{1,23}

In addition to microscopy equipment, other methods can be employed for the same purpose, such as TEST SOIL and TOSI®,¹ which are useful for monitoring the control of cleaning efficiency in relation to blood and blood components after the cleaning process of surgical materials.²⁴

In just 30 seconds, any of the three Clean-Trace Systems can quantify the cleanliness level using ATP as an indicator. ATP is found in most cells and is a source of energy for metabolic processes such as respiration and cell reproduction, as well as muscle contraction.⁵⁶ The presence of ATP in all life forms favors its excellent use as an indicator of the presence of cell viability, since it is only present in living cells.⁵⁷ Thus, it can be used to identify the existence of microorganisms as bacteria and fungi, but also human cells. Hence, ATP measurement represents the measurement of the presence of viable cells, which represent contamination levels of the studied sample, whether catheters, surfaces or water, being a conclusive factor for determining the effectiveness of quality control of the reprocess of surgical devices.

The 3M™ Clean-Trace™ ATP Surface device is based on ATP quantification to assist the cleanliness of medical devices and environmental surfaces. The higher the presence of ATP on a surface, the higher the level of organic contamination present on it. This system has suggested applications in the hospital environment, especially with regard to terminal room cleaning, transplantation center, hemodialysis, isolated environments, staff hand cleaning, and surgical instruments that have been reused, and CME stands.²⁴

The 3M™ Clean-Trace™ ATP Water System,²⁴ as its name implies, quickly assesses the level of contamination of a water sample. The assessment of water contamination used throughout the cleaning and sterilization process is of utmost importance as it may be the source of toxins causing pyrogenic reactions, as previously discussed. Thus, this system is used as a quality control of the process, not of the final product control itself. However, it is equally relevant and effective in ensuring catheter non-contamination.

Lastly, 3M™ Clean Trace™ Protein HS²⁴ has high sensitivity in detecting protein residues from around 3 µg, a value considered safe for minimal measurement that should be considered as a sign of contamination. The mechanism of action of this device is through the semi-quantitative evaluation of proteins present in blood and other body tissues in surgical materials and also on surfaces. The Association for the Advancement of Medical Instrumentation (AAMI),⁵⁸ an organization for the advancement of the safe and effective development and use of medical technology, has developed a guide to health care sterilization, which has been quoted as indicating that protein is the most common marker used to evaluate cleaning efficiency by determining the presence or absence of organic matter in hospital settings.

Discussion

The reuse of single use medical supplies is a problem worldwide. In general, developed countries already have legal regulations that support the reprocessing of such devices. In addition, they have strict enforcement agencies, such as the FDA in the United States.

Concerns about SSIs increases when surgery is performed with reused catheters. The additional risk of contamination by infectious agents, toxic substances and other harmful substances has been the target of scholars. The monetary incentive is of great value to hospital institutions wishing to reuse such surgical materials. However, it is extremely important to determine the safety of the process, thus ensuring the improvement of patients' health, without exposing them to greater risks.

The reuse of catheters has several justifications, especially the economic one. However, the budget benefit cannot be above health security. To be reused, the catheters must be free of any particles with a potential risk of infection. Viruses, bacteria and fungi are examples of microorganisms that can cause harm to the patient and must be eradicated from reused surgical

materials. Blood cell debris, pyrogenic agents and toxic residues also need to be disposed of before reuse.

Pre-cleaning and cleaning are in fact key steps in continuing the entire process, and while all steps are critical, these are the most important and key when looking at the macro process. In these phases there should be the extinction of wastes that favor the emergence of infections.¹

The time between catheter use and the first step of catheter reprocessing, pre-cleaning, should not be too long. Decontamination of possible infectious causes should occur as soon as possible, as they may adhere to the catheter material and pass intact through the cleaning agents, thereby compromising the entire procedure and consequently, the reuse of the material.¹

After all the cleaning and sterilization steps previously discussed, it is noted that problems related to nosocomial infections deserve continuous attention from all relevant sectors of the hospital. In this context of awareness of the risks of infection transmission through the use of reused catheters in surgical procedures, the HICC plays an essential role, especially in the disinfection and sterilization processes of such materials. The CCHI then has the responsibility to standardize the procedures of each hospital, and through these rules, establish rules to be followed by health professionals, aiming to minimize the occurrences and risks of hospital infections. Equally important is the installation of educational actions that disseminate the fundamental knowledge for the implementation of preventive activities, through lectures, courses or posters, for example.

Thus, the HICC acts in the control of nosocomial infections, and it is therefore responsible for the quality assurance of the reprocessed surgical materials. In order to minimize and avoid the imminent risks of infection associated with the reuse of single use medical devices, control methods should be adopted in addition to naked eye examination or visual inspection with microscopes.

The criticality of eliminating organic waste such as blood, tissues and bones, as well as microorganisms such as fungi and bacteria, is due to the need to minimize health risks such as postoperative infections, for example. Thus, the standardization, monitoring and quality control of this process are fundamental for the quality of life of patients undergoing surgical procedures using reprocessed materials.

Although luminol is widely used in the detection of blood in criminal environments, its use in hospital settings can be considered limited, since, according to Bergervoet and colleagues,⁵⁹ luminol is not only

specific for hemoglobin, but other substances are also responsible for the reaction of luminescence of luminol as environmental, domestic and industrial substances. This compound has a positive reaction (luminescence emission) with others who have peroxidase activity, and therefore, the most commonly found false positive results are related to peroxidases of plant origin, copper, cupric sulfate, ferric sulfate and iron.

The luminescence produced by the reaction of luminol with reused hospital material may result in a false positive result due to interference from various other substances, which then function as reaction catalysts, thus generating luminescence emission in the same way as with iron present in his own blood.^{60,61}

The 3M™ Clean-Trace™ ATP²⁴ Cleaning Monitoring System is one of the tools used to evaluate medical device contamination through a bioluminescence reaction. Thereby, catheters, surfaces and the water used for cleaning and sterilizing these materials can be evaluated for the effectiveness of the entire reuse process. The results provided by the luminometer are two possible, “Pass”, ensuring that the collected sample is clean, or “Fail”, suggesting that the test be performed again to ensure a safe result.

There are standards for the use of biological indicators worldwide. In Brazil, the Brazilian Association of Technical Standards (ABNT)⁶² has published the standard ABNT NBR ISO 11138-1: 2016 - Sterilization of Health Products - Biological Indicators - Part 1: General Requirements, prepared by the Brazilian Dental-Medical-Hospital Committee (ABNT / CB-026), an addendum to ISO 11138 which establishes “the general requirements for production, labeling, test methods and performance characteristics of biological indica-

tors, including inoculated carriers and suspensions, and their components, to be used in the validation and routine monitoring of sterilization processes”. In this sense, international standards are also followed by Brazilian hospital institutions and in several countries. AAMI itself issued the ANSI / AAMI ST79 standard, regarding the use of biological indicators, standardizing the frequency of organic load monitoring in hospital devices and environments, in favor of a high-quality standard offered by these health institutions, always ensuring improving patient health care.⁶³

Conclusion

Despite the numerous possible risks, studies indicate that there is no impact on the number of cases of infections with reused catheters, as there is assurance that the entire reuse process is carried out by validated and quality-controlled procedures. The need for greater rigor in the norms and guidelines that embody such practice is clear and urgent, as well as the greater intensity and rigidity of the responsible supervisory bodies. Also, the presence of competent professionals and the guarantee of the quality of the final product infer in a beneficial result to the patient’s health, regarding care practice.

Despite the use of indicators in chemiluminescence reactions are more specific for detecting possible organic contaminants, luminol has the huge disadvantage that it may generate a false positive result. Finally, it is concluded that 3M™ Clean-Trace™ is, in fact, the best instrument found in the world market to ensure that the material that has been reused is free of organic waste, and thus fit for use in hospitals.

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