

Medical device reprocessing: a regulatory model proposal for Brazilian hospitals*

REPROCESSAMENTO DE PRODUTOS MÉDICOS: UMA PROPOSTA DE MODELO REGULATÓRIO PARA HOSPITAIS BRASILEIROS

REPROCESAMIENTO DE PRODUCTOS MÉDICOS: UNA PROPUESTA DE MODELO REGULADORIO PARA HOSPITALES BRASILEÑOS

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ABSTRACT

Medical device reprocessing is extremely important and complex, thus requiring both the operational skills for its implementation and the technical qualification of the professionals involved in the activity. The typical issues of medical device reprocessing involve technical, economical and regulatory aspects when involving either the so-called reusable articles or those considered as for a single use. The objective of the present study is to propose a new regulatory model for medical device reprocessing in Brazil that would, on the one hand, satisfy the requirements for quality and safety, as recommended in the literature and, on the other hand, prove to be operational under the conditions prevailing in Brazilian hospitals. The elaboration of the present normative proposal was based on the Consensus Conference technique among specialists in the area. Guided by the contribution of these specialists, a proposal is put forth of a regulatory model for reprocessing medical products, so as to address some previously identified gaps in the normative body currently used in Brazil.

DESCRIPTORS

Equipment and supplies
Equipment reuse
Cross infection
Health surveillance of products

RESUMO

O reprocessamento de produtos médicos constitui um processo de extrema complexidade e importância, que requer tanto capacidade operacional para sua implantação, como qualificação técnica especializada dos profissionais envolvidos. As questões típicas do reprocessamento de produtos médicos envolvem aspectos técnicos, econômicos e regulatórios, tanto para os artigos ditos reusáveis quanto para aqueles considerados de uso único. Este estudo objetiva desenvolver um modelo regulatório para o reprocessamento de produtos médicos no Brasil, que atenda aos requisitos de qualidade e de segurança recomendados na literatura e que seja operacional nas condições dos serviços hospitalares brasileiros. A construção dessa proposta para o Sistema Nacional de Vigilância Sanitária baseou-se na técnica de Conferência de Consenso entre especialistas no tema. A partir das contribuições coletadas, foi elaborado um modelo regulatório para o reprocessamento de produtos médicos considerando as lacunas previamente identificadas no marco regulatório hoje vigente no Brasil.

DESCRITORES

Equipamentos e provisões
Reutilização de equipamento
Infecção hospitalar
Vigilância sanitária de produtos

RESUMEN

El reprocesamiento de productos médicos constituye un proceso de extrema complejidad e importancia, que requiere tanto de capacidad operativa para su implantación, como calificación técnica de los profesionales involucrados. Las preguntas típicas del reprocesamiento de productos médicos envuelven aspectos técnicos, económicos y regulatorios, tanto para los artículos reutilizables como para aquellos considerados de uso único. Se objetiva desarrollar un modelo regulatorio para el reprocesamiento de productos médicos en Brasil que respete los requisitos de calidad y seguridad recomendados en la literatura y que sea operacional en las condiciones de los servicios hospitalarios brasileños. La construcción de la propuesta para el Sistema Nacional de Vigilancia Sanitaria se basó en la técnica de Conferencia de Consenso entre especialistas del tema. A partir de las contribuciones recolectadas, se elaboró un modelo regulatorio para el reprocesamiento de productos médicos, considerando las lagunas previamente identificadas en el marco regulatorio vigente en Brasil.

DESCRIPTORES

Equipos y suministros
Equipo reutilizado;
Infección hospitalaria
Vigilância sanitária de productos

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INTRODUCTION

The reprocessing of medical devices is a routine practice in Sterile Processing Departments (SPD) of health services around the world. It is a process intended to ensure safe reuse of a medical device through a sequence of stages consisting of cleaning activities, integrity and functionality tests, disinfection or sterilization and quality control⁽¹⁻⁵⁾. Even though these activities are part of the routine in this department, they are extremely important and complex, require operational capacity for the implementation of actions and also expertise from the professionals involved.

In the field of medical device reprocessing, one has to take into account that the clinical use of a medical device, whether it is considered to be a single or multiple-use device, contributes to its natural degradation, which may be insignificant after many uses or occur after a single use, even if the manufacturer labeled it as reusable and in such a condition, this device is not safe for providing health care in any circumstances. It is important to clarify that every medical device has a certain degree of risk and may cause problems in certain situations. Thus from this perspective, there is no absolute safety in relation to the use of medical devices^(1,6-7).

Two main types of risks are associated with the reuse of medical devices, regardless of whether it is a single or multiple-use device: the risk of transmission of infectious microorganisms and the risk of altering the device's performance after reprocessing. In this field, evaluation of risk refers to the potential danger of a medical device, which may result in harm or in a safety issue for patients and/or health professionals^(1,6-9).

Internationally, there is a variety of regulatory levels in the establishment of policies concerning the reuse of medical devices, which in general, tend to have a preventive character with recommendations aiming for the safety of public health⁽⁹⁻¹⁰⁾.

Current Brazilian regulations concerning reprocessing of medical devices dates from 2006, when the National Health Surveillance Agency (ANVISA) published, after some regulations were established in the field, Collegiate Board Resolution – RDC No. 156 on August 11th. It provides for the registration, labeling and reprocessing of medical devices; Special Resolution – RE No. 2,605 defines a list of 66 devices whose reprocessing is forbidden in Brazil, and RE No. 2,606 defines the guidelines for the development, validation and implementation of protocols for medical device reprocessing^(2,11-12). Despite advancements in Brazilian regulation concerning the reprocessing of medical devices, in practice these standards are being slowly

implemented in Brazilian facilities. Several provisions in the ANVISA resolutions are poorly formulated, contain inaccuracies and vague content, giving rise to different interpretations on the part of health services, outsourcing reprocessing firms, and manufacturers or importers of these devices. In addition to the issues it raises, the difficulty in putting the Brazilian regulatory law concerning reprocessing of medical devices into operation challenges the very legitimacy of the regulatory guidelines, reaffirming the importance of the problems that involve the reuse of medical devices, both the reusable and single-use devices. The proposal of this model to the National Sanitary Surveillance System (SNVS) is expected to contribute to the development of policies directed to the control of quality improvement in health services in Brazil.

METHOD

This study is an integrating part of a doctoral dissertation in collective health in the planning and management field at the Collective Health Institute, Federal University of Bahia, Brazil. This is a descriptive study addressing the development of a regulatory model for reprocessing medical devices developed with the Consensus Conference Technique adapted from the original proposal⁽¹³⁻¹⁴⁾. It was organized in four stages over a period of three months, from November 2009 to January 2010.

The development of this regulatory model included requirements essential for the sanitary safety in reprocessing medical devices as published in the literature as well as technical issues of hospital facilities that reprocess material. It is a result of a consensus achieved among experts in the field. The group of experts was composed of three Brazilian professionals renowned in the field of medical device reprocessing, selected based on their specific intellectual production in the study's theme. The experts were contacted and informed concerning the study's objectives, methodology and characteristics of each stage of the Consensus Conference; none refused to participate.

Consensus Conference

In the 1st stage, the participants received a regulatory proposal concerning medical device reprocessing through e-mail and were asked to manifest, individually and confidentially, either agreement or disagreement in relation to it. At this point, the experts were asked to score from zero (elimination of criterion) to ten (maximum acceptance) the criteria presented according to their scientific relevance and operational practicality and to justify each score assigned. The experts returned their answers, also by e-mail, within 10 days from the date the proposal was sent.

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In the 2nd stage, the original proposal was presented to the experts in a face-to-face meeting along with the scores they attributed to the criteria suggested in the first stage, respective averages and standard deviations, to support the discussion and align divergent issues. Some time was set aside for the experts and researcher to discuss criteria considered polemic in order to achieve consensus. Given the divergent suggestions presented by the experts in the first stage, the researcher developed two regulatory models and presented them in the second stage so that one model would be chosen and scored by the experts. These models were analyzed in an open session and were rejected by the experts who recommended the researcher develop a third regulatory model to be later sent by email for a new evaluation.

In the 3rd stage the experts received the recommended model that resulted from the face-to-face meeting through collective e-mail and were asked to assign scores to the criteria already known. At this point the inclusion of new criteria was considered, provided inclusions were unanimous and consensual among the three experts. A very high standard deviation (above 5) in the scores assigned by the experts was observed at the time the averages and standard deviations were computed, which indicates considerable dissension among the experts concerning the analyzed sub-criteria. Hence, a new proposal of regulatory model concerning the reprocessing of medical devices was required in order to achieve consensus on suggested criteria and sub-criteria. At this point, one expert decided to withdraw from the study and the Consensus Conference proceeded with the researcher and two experts.

In the 4th stage a new proposal for a regulatory model, the result of work developed in the previous stage, was sent to the two experts for them to definitively assign new scores to the criteria already known and analyzed. Standard deviation of the scores assigned to sub-criteria was not computed because at this point there were only two experts. Hence, averages of scores were computed, setting the gold standard for the regulation of medical device reprocessing in this study.

Criteria scores

The criteria suggested in this proposal were presented in matrices according to the regulatory classification of medical devices and each regulatory criterion originated sub-criteria that represented operational categories of medical device reprocessing. Each sub-criterion of this proposal was scored from 0 to 10, meaning, respectively, low and high acceptance. The criterion score resulted from the average of scores attributed to the corresponding sub-criteria. Average and standard deviation were computed for all the evaluated criteria and sub-criteria. Thus, the higher the average, the greater the criteria's importance/relevance/robustness and the lower the standard deviation, the greater the criteria's consensus.

The individual recommendations/suggestions of each expert that were not included in the original proposal developed by the researcher and, therefore, not scored, were accepted only when they related to the writing form and style.

The following cutoff points were used in this study: 1) Relevance of criteria: a) average score < 7 = criteria with low relevance. Criteria with this average were not included in the final version of the regulatory proposal; b) average score > or equal to 7 and < 9 = medium relevance criteria; c) average > or equal to 9 = high relevance criteria. 2) In relation to standard deviation (SD): a) SD < or equal 1 = great consensus criteria; b) SD > 1 < or equal 3 = low consensus; c) SD > 3 < or equal to 4 = great dissension criteria.

RESULTS

During the stages of this methodology, great consensus was observed among the experts and the researcher concerning the need to classify medical devices for reprocessing to completely clean and monitor for integrity, functionality and sterility, regardless of whether these devices are considered reusable or single-use. This distinction introduces a guiding axis for classification and decision-making concerning the devices to be reprocessed in health services, which differs from the current classification adopted by Brazilian law. There was also consensus for the need to establish a quality standard for water used for rinsing devices according to the type of device and stages of reprocessing. We opted for using the term 'monitoring' instead of 'validation' given the polysemy involved in this concept and how to implement it in the hospital context. We also understand that the validation stage is part of a larger program of quality monitoring, a process that still challenges most Brazilian SPDs. The term 'traceability' was used as synonymous with 'tracking' to designate the process through which data resulting from the sterilization process are used to monitor and recall devices when there is suspicion of any inadequate result that may pose a risk to patients using the reprocessed device.

DISCUSSION

The regulatory model of medical device reprocessing proposed in this study is presented here. This model is based on the conclusion of studies addressing the risks associated with the reprocessing of medical devices, especially those considered single-use that were discussed in the introduction. In this study, we assert that some single-use devices can be reused and reprocessed provided they are subjected to monitoring in the controlled situations of decontamination processes, functionality and integrality tests and have appropriate documentation.

The developed regulatory model of medical device reprocessing is self-explanatory and is presented in two

figures. Figure 1 classifies the medical devices for reprocessing into two categories: reprocessing medical devices and non-reprocessing medical devices. The reprocessing devices are those marketed as reusable and are, *a priori*, resistant to decontamination processes and also single-use devices that can effectively undergo cleaning and sterilization processes and still maintain their physical and functional properties. Non-reprocessing devices are those unable to be appropriately cleaned and consequently sterilized, regardless of being considered reusable or

single-use devices. This classification supports decision-making as to whether to reuse medical devices according to their characteristics and to the operational conditions of SPDs in relation to the possibility of performing monitored cleaning and testing of the integrity and functionality of reused devices. The traditional classification of medical devices according to the risk of infection remains but the already known critical devices are separated into two groups: complex critical devices, which require specific cleaning technology, and simple critical devices.

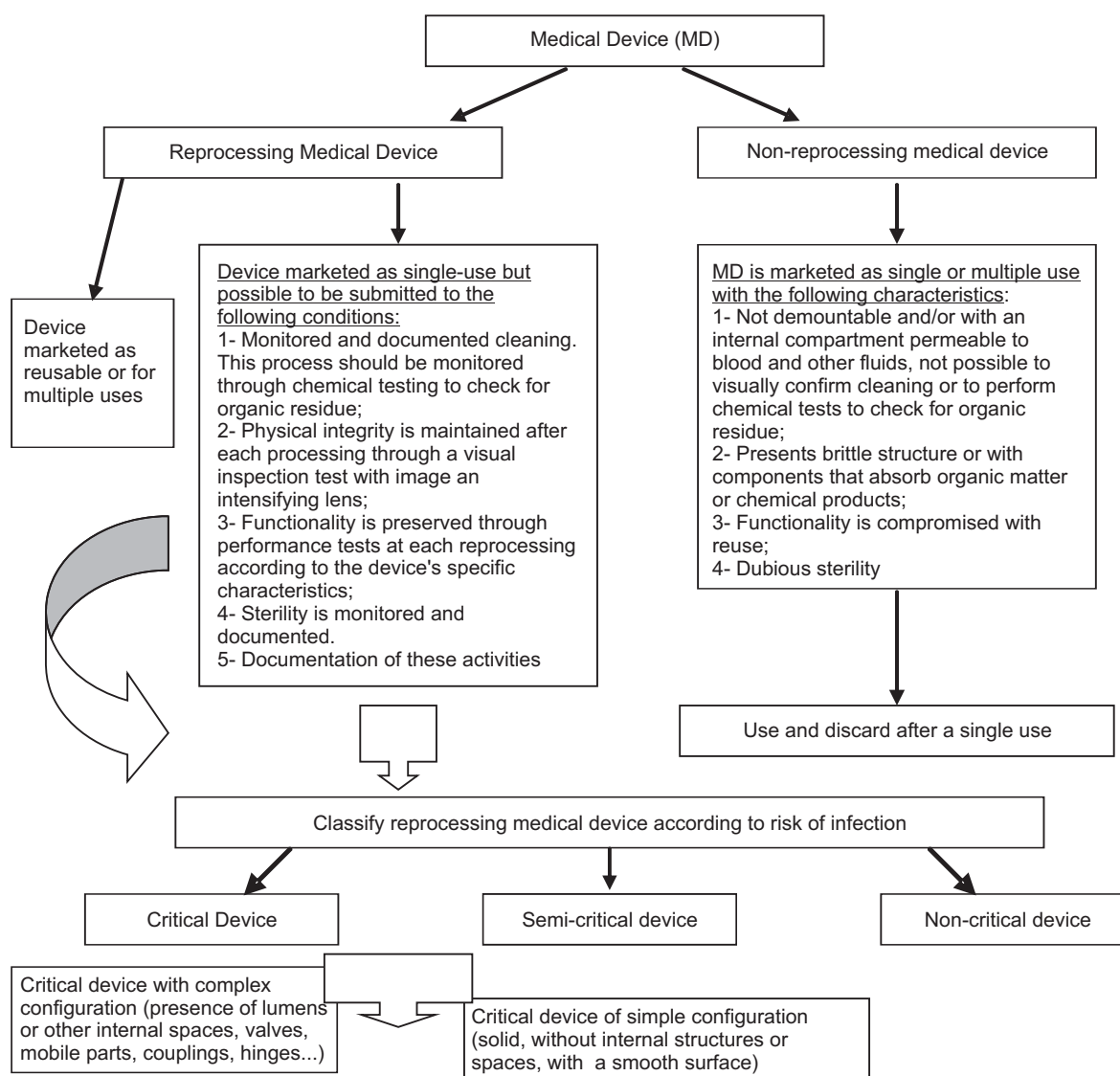


Figure 1 – Classification of Medical Device

Figure 2 describes the stages required for reprocessing medical devices in the form of a logical model, regulating the processes of device decontamination. In this figure, the activities that compose the reprocessing of

devices are compatible with the reality of Brazilian SPDs and in line with the recommendations of safety and quality of processes, thus a viable and efficient way to reuse devices.

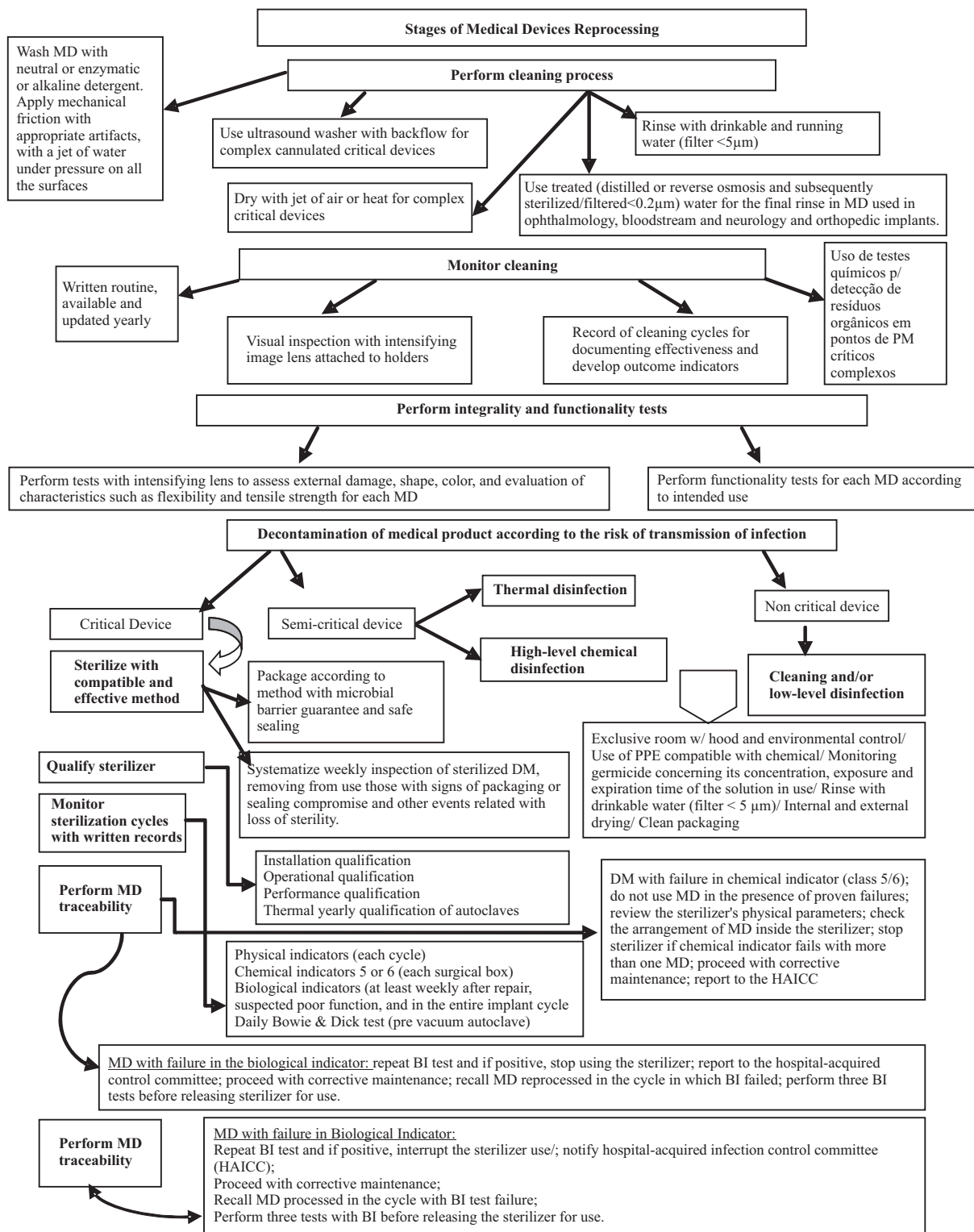


Figure 2 – MD reprocessing stages

In the cleaning process, we emphasize the recommendation of ultrasonic washers for complex cannulated devices and distinct rinses according to the type of device with instruction to rinse after cleaning with potable and running water with filter <math><5\mu\text{m}</math> for all

the devices, and with treated (distilled or reverse osmosis and subsequently sterilized) water for the final rinse of devices used in ophthalmology, bloodstream and neurologic and orthopedic implants to prevent adverse events attributed to water containing organic contami-

nants. This covers the monitoring of devices after cleaning and the systematization of integrity and functionality tests for each product.

The decontamination of medical devices is regulated according to the classification of risk, thus a sterilizing process is recommended for critical devices, high-level thermal or chemical disinfection for semi-critical devices, and cleaning and/or low-level disinfection for non-critical devices. It describes the need for qualifying the sterilizing machine and monitoring sterilization cycles according to mechanical, chemical and biological indicators as well the traceability of devices according to their sterilization processes. It recommends an exclusive room for the liquid chemical process of disinfection in addition to control related to the monitoring of the use of germicidal solutions, rinsing and drying of disinfected devices.

CONCLUSION

The analysis of issues related to the reuse of medical devices, especially those marketed as single-use devices, reveals this is a complex subject, which includes diverse interests and the need to answer to the distinct actors involved, as well as the consideration of patients' rights and legal consequences of adverse events accruing from these practices both for health facilities and health workers.

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