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Opinion

Reusable Medical Device Pre-Cleaning in Care Units: What Are the Indicators to Prevent Biofilm Formation and Control Occupational Biological Risk?

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Abstract: The pre-cleaning of reusable medical devices is essential for successful cleaning, as it prevents biofilm formation that can compromise disinfection and sterilization. This study aimed to reflect on the recommendations regarding the pre-cleaning of reusable medical devices carried out in care units, such as wards, based on recommendations from guidelines/standards related to this important step in reusable medical device reprocessing. However, recommendations for pre-cleaning in care units are not unanimous and contrast with detailed recommendations on reusable medical device reprocessing in the Central Sterile Services Department (CSSD). This topic is an unresolved issue, strongly related to patient and worker safety, which points to the lack of investigations to provide indicators of best practice and highlights the need for shared responsibility management between care units and CSSD.

Keywords: practice guideline; process assessment; health care; sterilization; biofilms

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1. Introduction

Technologies such as reusable medical devices subsidize health care and have the potential to bring therapeutic benefits. However, they can also cause adverse events [1]. These are defined as incidents resulting from health care that end in harm to the patient and bring about harmful effects or undesirable care results [2].

Reusable medical devices are classified by manufacturers as single-use or reusable. The reusable devices are durable goods and their reuse requires reprocessing [3], a method that converts them from "contaminated" to "aseptically safe" [4,5]. Thus, the quality of reprocessing is a vital condition for the safe reuse of medical devices multiple times.

The proper reprocessing of reusable medical devices, such as surgical instruments, is essential for safe care and requires multiple sequential and interdependent operational steps, including the following: pre-cleaning, reception, cleaning, drying, assessment of integrity and functionality, packing, disinfection or sterilization, storage, and distribution [2–5]. It depends on mandatory compliance with quality indicators and standards [2–6]. Moreover, it also depends on good practices involving the handling of sterilized reusable medical devices. It begins with the quality of each operational reprocessing step, continues with the maintenance of the aseptic chain, until the end of the use of reusable medical devices, and extends to the proper handling of the devices soon after use, when they become contaminated by body fluids and other contaminants [7].

Although some steps in reusable medical device reprocessing have received great attention throughout history, such as the sterilization step itself, to which many advances have been added, including important outcome indicators, others have only recently attracted attention, and there is no consensus on how to ensure the expected quality, such

as the pre-cleaning of reusable medical devices at the point of use, which is essential for the following cleaning step.

Pre-cleaning and cleaning are recognized as essential prior steps for the sterilization of critical reusable medical devices, for removing inorganic and organic matter, and for reducing the residual microbial load [2,4,8]. One of the major concerns inherent to inadequate pre-cleaning and the cleaning of reusable medical devices is biofilm formation, which consists of a community of microorganisms adhered to each other and to a surface, immersed in a matrix of extracellular polymeric substances [9]. The biofilm that forms on reusable medical devices over various cycles of use and reprocessing is called build-up biofilm [10,11].

However, other than for surgical theater, recommendations for pre-cleaning critical reusable medical devices post-use in care units do not seem to receive the necessary attention. Thus, we aim to reflect on the recommendations regarding the pre-cleaning of reusable medical devices carried out in care units. The expectation is to contribute with subsidies that encourage good practices in the pre-cleaning step outside the central sterile services department (CSSD) and advances in discussion and research on this topic to formulate quality indicators for pre-cleaning in this context.

This reflection was conducted based on recommendations for the pre-cleaning of reusable medical devices carried out in care units, present in guidelines from specialized societies/associations and national and international government bodies. Table 1 presents a summary of the recommendations identified and discussed according to the time elapsed between reusable medical devices contamination and the beginning of pre-cleaning; a place to carry out pre-cleaning; and how to perform pre-cleaning. Moreover, biological occupational risk during the pre-cleaning step was also approached.

Table 1. Recommendations for handling reusable medical devices (RMD) after use in care units.

	Society/Association/Research Center/Government Body (Year of Publication) [Reference Number]	Time to Begin Pre-Cleaning	Place to Perform Pre-Cleaning	How to Perform Pre-Cleaning
1	Associação Brasileira de Enfermeiros de Centro Cirúrgico, Recuperação Anestésica e Centro de Material e Esterilização (SOBECC) (2021) [3].	As soon as possible after use.	Central Sterile Services Department	Apply a water jet to remove excess debris, and immerse RMD in a detergent solution as soon as possible after use.
2	Associação Paulista de Epidemiologia e Controle de Infecção Relacionada à Assistência à Saúde (2021) [12].	Cleaning must begin as soon as possible after use.	Preferably where the RMD was used.	Surfaces and lumens of RMD must be rinsed to remove debris, instead of being kept moist only. If devices are reprocessed by outsourced companies, pre-cleaning of RMD must be performed equivalently as cleaning, as it takes a longer time (transport) for reprocessing to begin.
3	Association of Perioperative Nurses (2020) [6].	After use (time not mentioned).	Where the RMD was used.	Humidify and remove excess debris.
4	Alberta Health Services (2019) [13].	Immediately after use.	Not presented.	Keep RMD humid by using foam, spray, or gel recommended for pre-cleaning or a cloth moisturized with water.

Table 1. *Cont.*

	Society/Association/Research Center/Government Body (Year of Publication) [Reference Number]	Time to Begin Pre-Cleaning	Place to Perform Pre-Cleaning	How to Perform Pre-Cleaning
5	World Federation for Hospital Sterilisation Sciences (2017) [14].	Immediately after use.	Where the RMD was used, when transporting the device to the Central Sterile Services Department takes more than 6 h.	Continuously irrigate lumen during use of RMD, followed by immersion in appropriate solution in an exclusive container. Solution concentration and immersion time must follow the manufacturer's instructions for use, as well as solution-changing frequency. Cover the device with a towel moistened with water (not saline) if device immersion does not occur immediately after use or the time elapsed between device contamination and the beginning of cleaning and disinfection is longer than 6 h. Fixing processes such as dry heat or aldehyde solution should be avoided.
6	Asia Pacific Society of Infection Control (2017) [15].	Not presented.	Preferably at the Central Sterile Services Department.	Not presented.
7	World Health Organization (2016) [2].	Not presented.	Where the RMD was used.	Removal of excess debris from RMD should be performed with a moist and clean cloth.
8	National Health Service England (2016) [16].	As soon as possible after use.	Central Sterile Services Department or where the RMD was used if transporting the device is not possible on time.	RMD must be constantly exposed to a humid environment using appropriate methods, such as closed containers with disposable moist pads, gels, foams, water sprays, or other approved methods.
9	Australian Standard/New Zealand Standard (2014) [17].	According to the time specified by the respective health services.	Where the RMD was used.	Apply methods that remove coarse debris; do not cause damage to the RMD; do not compromise subsequent cleaning, disinfection, and sterilization; and minimize the risk of contaminants drying out.
10	Agência Nacional de Vigilância Sanitária (2012) [4].	Not presented.	Central Sterile Services Department for critical RMDs.	Not presented.
11	Centers for Disease Control and Prevention (2008) [8].	Immediately after use for endoscopes, or as soon as possible for other RMD.	Where the RMD was used for those with heavy debris (feces, sputum, blood, or others).	Immerse or rinse RMD (not in saline). Perform manual pre-cleaning when automated cleaning is not available.

2. Time Elapsed between Reusable Medical Device Contamination and Beginning Pre-Cleaning

The time to start pre-cleaning after using a reusable medical device is crucial to prevent debris from drying out on the device and, consequently, to facilitate cleaning [2,16,18]. A delay in carrying out this step favors biofilm formation, compromises the disinfection and sterilization [6], hinders the removal of prions [16], and decreases the useful life of devices (surface damage) [2,19]. Therefore, some guidelines recommend carrying out pre-cleaning as soon as possible after use [3,8,12,16,19]. However, the minimum time for this step is not specified and depends on the characteristics of each service. Furthermore, it is reinforced that long intervals between the use of a reusable medical device and their reprocessing must be avoided and, in the case of surgical instruments, guidelines warn that the removal of gross contaminants and residues in hemostats must be carried out in the surgical center [19].

A study that simulated the time elapsed between the use and pre-cleaning of surgical instruments [20] identified an increase in the amount of protein after 240 min of drying, corresponding to 4000%. The increased difficulty in removing tissues and prions from stainless steel after prolonged exposure to drying, 30 to 120 min, was also evidenced [21]. In addition to biofilm formation, reusable medical device damage due to dried blood and saline deposited on surgical instrument surfaces is also a concern [20]. Although a similar study did not identify an association between residual protein and a waiting time of up to 6 h before reprocessing [22], it is known that dried organic matter favors biofilm formation on medical devices [3].

An investigation into the influence of prolonged periods of storage of endoscopes on cleaning and disinfection performance indicated that, in cases where pre-cleaning was carried out immediately after use, the storage of endoscopes for up to 16 h did not represent any influence on the quality of reprocessing. Moreover, if pre-cleaning is performed, emerging biofilm formed before the cleaning step starts can be removed by brushing [23].

3. Place to Carry out Pre-Cleaning

Regarding a place where pre-cleaning should be carried out, guidelines recommend that all reprocessing steps, including pre-cleaning, should be performed at the CSSD [3,4,15], as it is a department dedicated to reprocessing, and thus is expected to accomplish structure, process, and results indicators accordingly [3,4]. Therefore, the potential of the CSSD for the quality control of reusable medical device reprocessing stands out. However, in practice, it is known that keeping the routine of receiving reusable medical devices from care units at the CSSD is not operationally easy, as it necessarily implies that CSSD has a continuous flow of contaminated devices being received for all consumer units, as occurs for surgical center demand. Thus, it is common for CSSDs to establish fixed times for the delivery of reusable medical devices from care units, which may result in devices remaining contaminated for a long period depending on the time of use and the time established for delivery.

In a large public university hospital in the Midwest region of Brazil, over 12 h of observation, 40.8% of critical reusable medical devices remained stored in care units for more than 5 h before being transported to the CSSD [24]. Additionally, 84.3% of critical devices did not receive any post-use pre-cleaning until they were sent to the CSSD, warning that, depending on the routine of referral of reusable medical devices to the CSSD, performing pre-cleaning in a care unit may be necessary.

However, when considering the recommendation that pre-cleaning should be carried out "where the assistance takes place", and the fact that there are differences in the levels of complexity of device consumer units, such as the Surgical Center, and emergency care units, wards, and others, it becomes essential that all these units have the operational technical capacity for pre-cleaning when this step cannot be performed at a CSSD [2,6,8,12,14]. At minimum, safe conditions should be assumed, such as deep sinks for rinsing, personal protective equipment (PPE) (appropriate gloves, waterproof apron, protective glasses, and face shields), and others.

Thus, it appears that the topic is an unresolved issue that requires investigations and discussion to provide indicators of best practices, taking into account different hospital realities. For CSSD with a continuous flow to receive contaminated reusable medical devices, immediate pre-cleaning can be ensured. However, when the option is for pre-fixed times, the care units must be prepared accordingly to carry out safe pre-cleaning.

Considering that each step is crucial for safe reprocessing and that one of these steps is carried out outside the CSSD, it is necessarily implied that there must be shared responsibility management between care units and the CSSD.

4. How to Perform Pre-Cleaning

Recommendations on how to perform reusable medical device pre-cleaning in care units are not addressed in some reprocessing guidelines [3,4,15]. Other guidelines point to the removal of coarse debris [2,6,14] by applying pressure water jets [3]; using a damp, clean cloth [2] and/or a specific cleaning system for humidifying reusable medical devices [6,13,14,16], such as foam, spray or gel [13]; covering the devices with a towel moistened with non-saline solution [14]; or rinsing them to avoid drying out organic matter and to facilitate its removal [8,12]. Point-of-use immersion can be performed for complex devices (e.g., devices with lumens) [14]. However, the lack of detail that allows the reproduction of pre-cleaning outside the CSSD is noteworthy and may result in workers' omissions and improvisations. One of the causes of the lack of consensus regarding the best practices for pre-cleaning in care units is the lack of understanding of its integration with the subsequent steps carried out in the CSSD. In the CSSD, there is more emphasis on aspects such as physical structure, human resources, PPE availability and use, and others [2–4,8,12,25]. In our perception of clinical practice, there seems to be no specific person responsible for pre-cleaning in care units, thus becoming an invisible step.

Thus, it appears that the topic is an unresolved issue that requires investigation to provide indicators of best practices, taking into account different hospital realities. For a CSSD with a continuous flow of receiving contaminated reusable medical devices, immediate pre-cleaning can be ensured. However, when the option is for pre-fixed times, the care units must be prepared accordingly to carry out safe pre-cleaning.

When considering the importance of each step for the reprocessing success, and when a step is carried out outside the CSSD, it is necessarily implied that there must be shared responsibility management between care units and CSSD for reprocessing quality.

5. Biological Risk during Pre-Cleaning in Care Units

In CSSD, workers are exposed to various occupational risks (chemical, physical, biological, ergonomic, and psychosocial) [26], such as the handling of chemical solutions and aerosols, high temperature, excessive light, repetitive movement, accelerated work pace, and the handling of blood and other bodily fluids that may contain infectious agents [27]. Among these, occupational biological risk is highlighted as it is inherent, mainly, to the pre-cleaning and cleaning steps.

Partial information is found in guidelines on biological risk and biosafety measures during reusable medical device reprocessing [3,8,12,13,15,17], which includes the importance of informing workers about their exposure to infectious agents; the identification of areas and tasks where there is potential exposure; the education of workers in the proper use of PPE, ensuring the supply and use of PPE, and monitoring occupational exposure; a description of the PPE that must be used in the contaminated area, such as rubber or plastic gloves, face masks, protective glasses or face shields, and appropriate aprons for exposure to blood and other body fluids [8]; hand hygiene; environmental cleaning and the handling of waste and sharps [13], such as guidelines on not bending, breaking, or recapping used needles; and measures to be taken after exposure to blood and other bodily fluids [15].

It is noticeable that even in the guidelines that address the pre-cleaning of reusable medical devices at the place of use, there is no mention of occupational safety or the use of PPE in places outside the CSSD, such as care units [6,12,13,16]. No individual guideline

has the full set of biosafety measures necessary to address the risks inherent in the pre-cleaning process outside the CSSD. Only by compiling recommendations from different guidelines can a set of appropriate measures be identified. The lack of clear guidance regarding biological risk when cleaning reusable medical devices was a weakness found by regulatory bodies in Brazil [28]. In this sense, it is important to highlight the role of scientific societies in guiding best reprocessing practices and the necessary clarity and cohesion with health standards.

Although biological occupational risk is part of the daily work of healthcare workers, the specificities of exposure modes during pre-cleaning bring recommended PPE and work process techniques as aspects that, in the case of pre-cleaning outside of the CSSD structure, should be part of the ongoing education processes for teams in consumer units. This reinforces the need for shared management between those responsible for CSSD technicians and consumer units, combining reusable medical device care (patient safety) with the occupational safety of those involved in reprocessing in all its steps.

6. Conclusions

In conclusion, the whole set of information required for safe pre-cleaning in care units is not well established, and there is a lack of details that will allow the process to be reproduced. Furthermore, the recommendations include imprecise and subjective terms such as "as soon as possible".

Thus, current recommendations on reusable medical device reprocessing regarding the time and place in which to pre-clean these devices after use in care units, how to carry out this step, and the control of biological risk are not sufficient to guarantee safe reprocessing. Aspects well established to prevent biofilm formation are omitted, partially presented, and/or are not unanimous. Only when different guidelines are brought together can the set of practices necessary for adequate pre-cleaning be achieved, as is the standard for CSSD. The same applies to biosafety measures.

This draws attention as it contrasts with detailed recommendations on the reprocessing of reusable medical devices in CSSD. However, as all reprocessing steps are important, clear and full recommendations should be available independently at the location in which these steps are carried out, including pre-cleaning, which is a crucial step to prevent biofilm formation, which is a major challenge for reprocessing. Advancement regarding these gaps is necessary and expected.

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