POSITION STATEMENT: Reprocessing of Critical and Semi-Critical Devices in Community Healthcare Settings

This position statement was developed by the Reprocessing Interest Group and has been reviewed by the Community Healthcare Interest Group
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BACKGROUND

Reprocessing of critical and semi-critical medical equipment/devices [1] in community healthcare settings, when not performed according to current standards [2], has been linked with healthcare-associated infections and outbreaks [3-15]. The purpose of this document is to provide infection prevention and control (IPAC) recommendations for the management and reprocessing of critical and semi-critical medical equipment/devices used in community healthcare settings so that consistent reprocessing standards are applied in all healthcare settings. This includes cleaning, disinfection, sterilization, and storage. This position statement does not address the cleaning and disinfection of endoscopes.

POSITION STATEMENT

1. **Clients expect and require safe care regardless of where the procedure is performed and standards of reprocessing shall be met in any setting where it is carried out.**

2. **All employers and healthcare providers are responsible for:**
- Adhering to best practices and standards for reprocessing when using any semi-critical and critical equipment/devices during provision of care [2,16].
- Complying with standards for transportation and storage of reprocessed medical equipment/devices and *Transportation of Dangerous Goods Act* requirements on transportation of soiled equipment/devices [2, 17-19, 20].
- Having written procedures based on current standards [2,19].
- Ensuring individuals who clean, disinfect or sterilize reusable medical equipment/devices are educated, trained, and have competency assessments to meet the national and provincial guidelines. This training shall be documented and reviewed yearly and when there are updates [2,16,18].
- As a minimum, have sufficient medical equipment/devices/kits available to accommodate daily client needs.
- Having a documented process for recall of medical equipment/devices in the event of reprocessing failure [2].
- Follow IPAC and Occupational Health and Safety guidelines, such as Routine Practices and Additional Precautions, personal protective equipment, safe sharps management, hand hygiene, disposal of high-level disinfectants (HLD), and procedures for staff exposures that occur during reprocessing [2].

3. Reprocessing critical and semi-critical medical equipment/devices (including loaned, leased or borrowed medical equipment/ devices) shall be in accordance with Spaulding's classification [1], meet manufacturers' instructions for use (MIFU) and current national guidelines (i.e., Canadian Standards Association (CSA) [2], the Public Health Agency of Canada [PHAC/Health Canada]), and provincial standards [17,21], including specialized staffing, auditing [22], and dedicated space). If there is a disagreement between the MIFU and published guidelines, the more stringent level shall be used [2].

Conflict of interest: None

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4. Prior to purchasing medical equipment/devices:
- The employer and healthcare provider shall determine that the recommended reprocessing methods, as validated by the manufacturer, meet current recommended standards and the reprocessing methods can be met by those responsible for reprocessing.
- The employer and healthcare provider shall determine if it can be cleaned/reprocessed according to MIFU. Items that cannot be cleaned/reprocessed according to the MIFU shall not be purchased. If already purchased, the item shall be replaced or be designated single-use.

5. Medical equipment/devices that are labelled as single-use by the manufacturer have not been validated to be reprocessed, therefore, these devices shall be disposed of after use. All needles and all syringes are single-use only and shall be discarded after one use [2,16,17].

6. Critical and semi-critical medical equipment/devices labelled as single use must not be reprocessed and reused unless the reprocessing is done by a licensed reprocessor. There are reprocessors in the USA licensed by the United States Food and Drug Administration [2], but none are currently based in Canada. Third party reprocessors must also be licensed in Canada [23].

7. "Non-critical and semi-critical medical equipment/devices that are owned by the client; re-used by that client and used only by that client in their home; and not used for another purpose, do not require disinfection between uses, provided that they are adequately cleaned and stored dry between uses [16]." Examples include respiratory equipment and lancet holding devices.

8. All semi-critical equipment/devices that can be sterilized, will be sterilized according to the MIFU. If a semi-critical device cannot be sterilized, then it shall, at a minimum, be high-level disinfected according to the MIFU between patient uses [2] (e.g., trans-vaginal probe).

   Note: In some jurisdictions (e.g., Ontario), high-level disinfection is not permitted in dentistry. Semi-critical reusable dental instruments that contact the mucous membranes or non-intact skin (e.g., mouth mirrors, amalgam condensers, reusable impression trays, handpieces,) shall be cleaned followed by sterilization [24].

9. The use of liquid chemicals for sterilization of instruments is not recommended for critical medical equipment/devices that are used for sterile procedures due to the limitations in maintaining sterility to point of use. "Devices cannot be wrapped or adequately contained during processing in a liquid chemical sterilant to maintain sterility following processing and during storage [19]."

10. Immediate-Use Steam Sterilization (IUSS, formerly referred to as flash sterilization) is not recommended, except where there is an urgent, unplanned need, with no other options available.

11. Glass bead sterilizer, microwave oven, boiling, chemiclave, and ultraviolet irradiation are unacceptable as means of sterilization [16].

Option 1: Use single-use disposable equipment/devices and discard after use [2,19].

Option 2: Reusable critical and semi-critical medical equipment/devices reprocessed using the contracted services of a Medical Device Reprocessing Department (MDRD) such as a hospital or private service-provider. The employer and healthcare provider are responsible to verify the MDRD meets current CSA standards (e.g., sterilization verification documents provided upon request, and documentation to demonstrate reprocessor technician training) [2]. Accreditation Canada states:

"Preferably, medical device reprocessing (MDR) is done through a centralized system that provides reprocessing services to multiple areas within the organization. From a safety and cost-effectiveness perspective, centralizing reprocessing services is preferred to replicating them in several areas of the organization. If reprocessing services are decentralized, they are held to the same standards as the MDR department [18]."

Option 3: The healthcare provider and/or organization chooses to reprocess reusable equipment/devices themselves. The current pertinent CSA standards shall be followed for reprocessing practices. If there is sufficient capacity to reprocess the critical and semi-critical medical equipment/devices to meet current CSA standards, then the reprocessing may occur on the site.

In addition to #1-11 above, the employer and healthcare provider must follow quality assurance recommendations:
- Monitor and document physical, chemical and biological indicators, for all sterilizers following MIFU [2].
- Monitor and document high-level disinfectants (e.g., minimum effective concentration, date of dilution/replacement, contact time) following the MIFU.
- Incorporate a preventative maintenance schedule according to medical equipment/device MIFUs.

STAKEHOLDERS

All employers and healthcare providers (HCPs) in community settings include, but are not limited to, client homes in which healthcare is provided, ambulatory clinics, physicians, and other healthcare practitioners' offices, outreach settings, and other community settings where reusable medical equipment is used. Also, healthcare organizations and policymakers whose patients receive care in the same community and which could play a role in facilitating their community partners to meet the applicable standards

GLOSSARY/DEFINITIONS

Capacity: Employer and healthcare provider has sufficient resources (e.g. financial, equipment, space, personnel) to verify they meet all the current national reprocessing guidelines: CSA, the Public Health Agency of Canada (PHAC/Health Canada).

Client: Includes patient, resident, or any other person who receives treatment.

Community healthcare setting: (Adapted from CSA [2]): Any location outside of an acute care hospital where healthcare is provided, which includes (but is not limited to):

- client homes in which healthcare is provided
- medical clinics or the clinics/offices of other healthcare providers (with or without treatment spaces/overnight stays);
- laser eye clinics;
- outpatient and other office surgical facilities;
- dental general and surgical facilities;
- standalone laboratory facilities and diagnostic imaging centres;
- nursing homes, long-term care facilities, assisted living facilities;
- mental health facilities;
- group homes;
- hospice care facilities;
- stand-alone dialysis clinics; and
- public health clinics.

Critical Medical Equipment/Devices: Medical equipment/devices that enter sterile tissues, including the vascular system (e.g., biopsy forceps, foot care equipment, dental hand pieces, etc.). Critical medical equipment/devices present a high risk of infection if the equipment/device is contaminated with microorganisms, including bacterial spores. Reprocessing critical equipment/devices involves meticulous cleaning followed by sterilization [1].

Healthcare provider: Any healthcare professional delivering healthcare service to a client as well as those performing reprocessing duties.

High-Level Disinfection (HLD): The level of disinfection required when processing semi-critical medical equipment/devices. A process capable of killing vegetative bacteria, mycobacteria (including *Mycobacterium tuberculosis*, fungi, and lipid and non-lipid viruses), as well as some, but not necessarily high numbers of, bacterial spores [2].

Immediate-use steam sterilization (IUSS) (formerly referred to as flash): The shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. Immediacy implies that a sterilized item is used during the procedure for which it was sterilized and in a manner that minimizes its exposure to air and other environmental contaminants. A sterilized item intended for immediate use is not stored for future use, nor held from one case to another. Immediacy, rather than being defined according to a specific time frame, is established through the critical analysis and expert collaboration of the healthcare team [2].

Loaned Equipment: Medical equipment/devices used in more than one facility, including borrowed, shared or consigned equipment/devices, which are used on patients/clients/residents. Reprocessing is carried out at both loaning and receiving sites. Loaned equipment may also be manufacturer-owned and loaned to multiple healthcare facilities [2].

Limited Capacity: Employer and healthcare providers have insufficient resources (including space, personnel, financial, equipment) to meet all the current national reprocessing guidelines CSA, the PHAC/Health Canada. If these minimum standards cannot be met, single-use disposable items, or a centralized Medical Device Reprocessing Center should be used.

Manufacturer's Instructions for use (MIFU): The written instructions for use provided by the manufacturer or distributor of a product, which contain the necessary information for the safe and effective use of the product [7].

Medical Device Reprocessing Department (MDRD): Any reprocessing area/department whose sole industry is reprocessing of medical devices [2].

Minimum effective concentration (MEC): The lowest concentration of the active ingredient(s) in a disinfectant solution at which the product is still effective.

Semi-Critical Medical Equipment/Device: Medical equipment/device that comes in contact with non-intact skin or mucous membranes, but ordinarily does not penetrate them (e.g., respiratory therapy equipment, transrectal probes, and specula).

Single-use/Disposable: Medical equipment/devices designated by the manufacturer for single-use only. Single-use equipment/devices shall not be reprocessed.

Single patient use: Medical equipment/devices that may be used on a single client and may be reused on the same client, but may not be used on other clients.

Sterilization: The level of reprocessing required when processing critical medical equipment/devices. Sterilization results in the destruction of all forms of microbial life, including bacteria, viruses, spores and fungi. Equipment/devices shall be cleaned thoroughly before effective sterilization can take place.

As per the Canadian Standard Association (CSA) [2]:
"SHALL" is used to express a requirement, i.e., a provision that the user is obliged to satisfy in order to comply with the standard.
"SHOULD" is used to express a recommendation, or that which is advised but not required and "MAY" is used to express an option, or that which is permissible within the limits of the standard, an advisory or optional statement.

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