'Putting your Best Foot Forward' Infection Prevention and Control (IPAC) Best Practices for Reprocessing of Critical Foot Care Equipment/Devices

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Disclosures

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- Images in this presentation were obtained from Google Images

Foot care equipment/devices have been associated with healthcare associated infections (HAI) and outbreaks across the health care continuum.

Purpose of IPAC Canada Position Statement

- To provide IPAC recommendations for the management of critical foot care equipment and/or devices
- This includes cleaning, disinfection, sterilization, and storage
- The goal of document was to develop a user friendly document with clear direction for safe reprocessing of critical devices used for foot care
- A reference list of guidelines and resources is provided

Objectives

- Provide examples of health care associated infections and outbreaks associated with foot care.
- Provide the rationale for IPAC Canada's position statement on Reprocessing of Critical Foot Care Devices.
- Discuss the three options for providing safe critical equipment for each client
- Identify key references

Process for Developing Position Statement

- IPAC members of the Community Healthcare Interest Group (CHIG) and Reprocessing Interest Group (RIG) indicated a need for a foot care best practice statement.
- IPAC Canada representatives were invited to volunteer for the working group to develop the position statement.
- An extensive review of the existing national and global practices.
- A review of outbreaks associated with foot care and the current evidence.
- Draft circulated to experts and stakeholders, including Canadian Foot Care Association (CAFCN), Canadian Association of Medical Device Reprocessing (CAMDR), CHIG, RIG.
- Following this, it was reviewed by IPAC Canada Standards and Guidelines before submission to the Board of Directors for review and approval.

Hepatitis B (HBV) and Hepatitis C (HCV) Outbreaks associated with foot care reported to CDC

Reference:

Centers for Disease Control and Prevention. Healthcare-Associated **Hepatitis B and C Outbreaks** Reported to Centres for Disease Control and Prevention (CDC) 2008-2017; 2018; August 21. https://www.cdc.gov/hepatitis/outbreaks/healthcarehepoutbreaktable.htm

Nursing home: 7 infected

- **7** infected of which sequencing of DNA from 4 acute infections matched into a cluster with one chronic case. Sequencing could not be performed for 3 cases.
- Infection control breaches related to instrument sterilization during the provision of podiatry care were identified; however, evidence was insufficient to implicate a specific source of transmission.

CDC Hepatitis B and C outbreaks(cont'd)

Assisted living facility: 2 infected

- Failure to maintain separation of clean and contaminated podiatry equipment. Improper reprocessing of contaminated podiatry equipment
- Failure to perform environmental cleaning and disinfection between patients

Nursing home: 46 infected

- Epidemiological analysis suggested podiatry care, phlebotomy, nail care performed at skilled nursing facility were associated with HCV

Examples of Outbreaks(cont'd.)

Wise ME, Bancroft E, Clement EJ, Hathaway S, High P, et al. Infection Prevention and Control in the Podiatric Medical Setting: Challenges to Providing Consistently Safe Care. 2015 J AM PodiatrMedAssoc105(3):264-272. http://www.ndhealth.gov/disease/hai/docs/wise%20infection%20prevention%20and%20control%20in%20the%20podiatric%20setting%20japma%20201....pdf

Nursing facility:

- 9 acute hepatitis B (HBV) infections identified of which 5 received care from a visiting podiatric physician on the same day. Observations revealed instruments (nail clipper, cuticle, and tissue nippers) were visibly contaminated with blood after use. 3 had the same viral sequence. Epidemiologic evidence and molecular evidence pointed to breakdowns in basic infection prevention and control procedures.

Single assisted living facility:

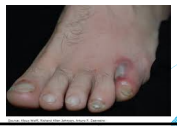
- 2 HBV cases

Examples of Outbreaks(cont'd.)

- 6 *Proteus mirabilis* wound infections related to contaminated bone drills used in outpatient podiatry surgery

Multi reports from unsafe practice of injections:

- 13 *Methicillin-resistant Staphylococcus aureus* (MRSA) soft tissue infections after injections in a podiatry medical clinic
- *10 cases of Mycobacterium abscessus* soft tissue infections related to a jet injector used to administer lidocaine
- Others



Examples of Outbreaks (cont'd.)

Wise ME, Marquez P, Sharapov U, Hathaway S, Katz K, et al. Outbreak of acute hepatitis B virus infections associated with podiatric care at a long-term care facility. Am J Infect Control. 2012 Feb;40(1):8-21. *https://www.ncbi.nlm.nih.gov/pubmed/21835502*. [Accessed 28 August, 2018].

HBV outbreak in psychiatric long-term care residents:

- 5 of 15 residents (33%) undergoing podiatric care on a single day developed acute Hepatitis B infection. Infection control observations of consulting podiatrist revealed opportunities for cross-contamination of instruments with blood
- exposure to HBV during podiatry was likely the dominant mode in this outbreak. Long-term care facilities should ensure compliance with infection control standards among staff and consulting health care providers.

Client Safety

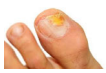
Clients expect and require safe care regardless of where the procedure is performed.

Clients and providers can be put at risk of acquiring infections

Viral Blood borne pathogens

- Hepatitis B & C
- Human Immunodeficiency Virus (HIV)

Bacteria and Fungi



How can infections be spread?

- penetrating skin accidently
- sharp instrumentation contaminated with blood/body fluids during care and used on clients without correct sterilization
- organisms moved from client to client through contaminated devices
- weeping areas or non intact skin; e.g., hands of provider

Stakeholders and Health care providers

- **Stakeholder:** Healthcare provider performing foot care in any health care setting, which includes, but is not limited to care provided in private homes, clinics and healthcare settings.
- **Healthcare provider:** Any healthcare professional delivering foot care service to a client as well as those performing reprocessing duties.

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Health care settings include

- **Healthcare setting:** Any location where healthcare is provided, including home healthcare, offices of other health professionals, outpatient clinics, emergency care, hospitals, complex continuing care, rehabilitation hospitals, long-term care homes, mental health facilities, community health centres and clinics, physician offices, dental offices, independent health facilities, out-of-hospital premises and public health clinics.

Why Equipment is to be Sterile?

Each client interaction requires a **sterile set** of foot care equipment/devices.

Why?

- In the delivery of foot-care services, equipment/devices may intentionally or unintentionally come into contact with blood, body fluids, or non-intact skin, requiring sterilization. Therefore **it is imperative to manage all equipment as if it has been contaminated. Soil is not always readily visible.**
- Infection prevention and control best practices indicate there should be one reprocessing system for all equipment from any client.

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Position statement indicates:

1. **Reusable foot care equipment/devices are considered critical devices.***

- Therefore each client interaction requires a sterile set of foot care equipment/devices.
- ***Critical:** medical equipment that enters sterile tissues, including the vascular system (e.g. biopsy forceps, foot care equipment, etc.) Critical medical equipment present a high risk of infection if the equipment is contaminated with any organism.
- Reprocessing critical equipment involves meticulous cleaning followed by sterilization.

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'Examples' of Critical devices

- Scalpel handle
- Scissors
- Callus parer
- Halsted mosquito forceps
- Probe
- Nail Splitter
- Curette
- Nail elevator
- Debris evacuator
- Single ended Blacks file
- Double ended Blacks file
- Barrel nail nipper
- Diamond Deb file
- Stainless steel foot paddle handle

Single Use Devices/Equipment

- Scalpel blades
- Callus Parer blade
- Foot paddle sanding pad
- Monofilament 
- Nail Clipper
- Nail files/emery board/orange stick
- Toe and/or Ingrown Nail Nipper - unless the Manufacturer provides instructions for steam sterilization

Position statement indicates:

2. **All healthcare providers:**
   - shall have sufficient numbers of foot care equipment/devices/kits to ensure sterile equipment, either single use or properly reprocessed, for each individual client treatment.
   - are responsible to ensure that the client is not placed at risk of infection when reusing any foot care equipment/devices during the provision of care.

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Position statement indicates:

3. Reprocessing of reusable foot care equipment/devices shall (CSA definition) meet manufacturers' instructions for use (MIFU), current national guidelines such as Canadian Standards Association (CSA), the Public Health Agency of Canada (PHAC/Health Canada), and provincial standards.
4. Reusable equipment/devices are sold with manufacturer instructions for use (MIFU), including for proper cleaning and sterilization, and shall not be purchased, used, or reprocessed without these.
5. Determine reprocessing methods in advance of purchase.

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Position statement indicates:

6. Single-use medical equipment/devices do not have MIFU's and shall not be reprocessed.
7. If the process used for reprocessing cannot meet the current standards identified previously, single use disposable items shall be used and discarded after use.
   - Nail clippers should be deemed single use if no MIFU is available or if the MIFU do not meet recognized standards.

Position statement indicates:

Medical equipment/devices used to provide foot care should be approved or licensed for medical use and designed for use on humans, specifically feet (e.g., rotary sanding devices and accessories including burrs).

- **Burrs/disks and rotary sanding tools -** if used, should be purchased from an authorized medical manufacturer. The burrs/disks must be considered to be a single use device and cannot be reprocessed unless the manufacturer provides a MIFU that meets the CSA and PHAC Guidelines.

Three Options to achieve a sterile set of foot care equipment/devices for each client interaction

All options must meet the previously identified standards.

Option 1:

- Use single-use sterile disposable equipment/devices and discard appropriately after use

Option 2

- Multi-client reusable foot care equipment/devices reprocessed using the contracted services of a centralized Medical Device Reprocessing Department (MDRD). The contracted MDRD meets the CSA standards and has qualified technicians to perform the reprocessing (cleaning and steam sterilization).

Option 2 (cont'd.)

- This equipment requires thorough **decontamination (cleaning and disinfection), packaging, and steam sterilization** between each client use, and shall follow CSA standards for storage of sterile supplies to ensure they maintain sterility.
- Best practices for **transportation and storage** of soiled and reprocessed equipment/devices shall be incorporated and meet current CSA standards.
- There shall be a robust process for **recall** of reprocessed equipment/devices in the event of reprocessing failure. Load records, proper labelling, and chemical and biological indicators are required.

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Option 3

The healthcare provider chooses to reprocess reusable equipment/devices themselves, with the following considerations incorporated into practice:

- purchase current pertinent CSA standards documents for reprocessing practices and purchasing, and follow these along with provincial reprocessing guidelines.
- healthcare provider shall have written procedures based on current standards.

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Option 3 (cont'd.)

Education: "Personnel involved in all medical device reprocessing functions shall be prepared for the tasks that they are required to perform through formal education and training . . ."[3] including at a minimum:

- **following national and provincial guidelines.**
- ensure education and competency related to all equipment/devices used in the process; maintenance, quality testing, monitoring of the sterilization process; packaging, storage and transportation of reprocessed equipment/devices including chemicals and sterilization equipment.
- training to a level required for the volume and complexity of the equipment.

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Option 3(cont'd.)

- Reprocess equipment following the MIFU for the device and the sterilizer.
- Ensure the MIFU for each piece of equipment meet recognized accepted standards for reprocessing.


Manufacturer's Instructions

- **Steam sterilization** is required for *critical* foot care instruments and the sterilizer requires a printout or electronic record for each cycle.
- Follow **quality assurance** recommendations, including monitoring and documentation of mechanical, chemical, and biological indicators.

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Option 3(cont'd.)

- There shall be a robust **process for recall** of reprocessed equipment/devices in the event of reprocessing failure, including labeling of all packages with the sterilization date, load, sterilizer number, name of the medical device, and initials of the person who performed the packaging.
- Best practices for **transportation and storage** of soiled and reprocessed equipment/devices shall be incorporated. If using event-related sterility, a quality system is required with policies and procedures for the storage process.

Option 3(cont'd.)

- Incorporate a **preventative maintenance** schedule according to equipment MIFU, including maintenance procedures, cleaning frequency of steam sterilizer and reprocessing area as well as annual steam sterilizer calibration by a certified technician.
- There shall be a procedure outlining actions to be taken if parameters of cleaning and sterilization are not met, including documentation of steps taken to remediate.

Option 3(cont'd.)

- The foot care provider shall follow Occupational Health & Safety and IPAC guidelines (e.g., Routine Practices and Additional Precautions, appropriate personal protective equipment for the task, safe sharps management, hand hygiene, and the procedure for staff exposures that occur during reprocessing).

Unacceptable methods of sterilization for critical foot care equipment

Note:

- The use of liquid chemicals for sterilization of instruments is not recommended for critical 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." *

*Reference: Centres for Disease Control (CDC). Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.Last updated Feb 15,2017 [cited 2018 Feb 6] Accessed at: https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines.pdf.

Unacceptable methods of sterilization for critical foot care equipment

- Unacceptable methods of sterilization include Immediate-Use Steam Sterilization (IUSS), formerly referred to as Flash sterilization, glass bead sterilizer, microwave oven, boiling, chemiclave, steam sterilizers without printouts or electronic recording and ultraviolet irradiation

Checkpoint

What is happening in your long term care facility or Out Patient clinic or your foot care practice?

Does the equipment/device used meet the CSA Z314.18 standard and the IPAC Canada Position statement on reprocessing of critical equipment?

- Users and the health care providers are **accountable** to verify the equipment is reprocessed according to CSA standards.
- Verify foot care providers are following current recommendations on management of critical care devices between clients and following Routine Practices as well as Occupational Health and Safety Guidelines.

Accountability when choosing Options

When choosing options- must meet CSA Standards including:

- costing & liability analysis
- verify workflow, work spaces
- utilize equipment that meets standards as well as preventative maintenance
- storage and transportation
- ensure ongoing quality assurance, training and competencies

Are we required to use a steam sterilizer to sterilize 'critical' reusable foot care devices?

Answer: YES

- Multi client reusable foot care devices classified as critical items are to be cleaned thoroughly and steam sterilized in the correct cycle as per CSA and the manufacturers recommendations.
- Option 2: this is done through contracting services of a centralized Medical Device Reprocessing Dept (MDRD)
- Option 3 indicates that if the provider chooses to reprocess reusable equipment/devices themselves, they shall follow the CSA standards along with provincial reprocessing guidelines
- Verify you are not reprocessing single use critical devices

Resources

1. Infection Prevention and Control Canada, (IPAC Canada) Position Statement: Reprocessing of Critical Foot Care Devices, November 2018https://ipac-canada.org/photos/custom/Members/pdf/Position%20Statement%20%20_ReprocessingCriticalFootCare_Nov_2018_FINAL.pdf

2. IPAC Canada. Infection Prevention and Control Audit for Foot Care. Audit Toolkit Version 2. Jan. 2014.

3. Canadian Standards Association. CAN/CSA-Z314-2018 Canadian medical device reprocessing. Rexdale, ON: Canadian Standards Association; 2018.

4. Public Health Agency of Canada. Infection Control Guidelines: Foot Care by Health Care Providers. Can Commun Dis Rep 1997; 23S8 (Supplement). Available from: http://publications.gc.ca/collections/collection_2016/aspc-phac/HP3-1-23-S8-eng.pdf

5. National Competencies for Advanced Nursing Foot Care in Canada, (CAFCN), 2017. Available from: https://cafcn.ca/wp-content/uploads/CAFCN-National-Competencies-for-Advanced-Nursing-Foot-Care.pdf [Accessed 28 August 2018].

6. Canadian Association of Medical Devices Reprocessing (CAMDR)

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