Cleaning, Disinfection and Sterilization of Medical Equipment/Devices in the Community Setting

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Presenter: Risa Cashmore, Infection Prevention and Control Consultant, CWICN (NSMICN)

Acknowledgements:

• Karen Clinker, Infection Prevention and Control Consultant, NWOICN
• Reprocessing Project Team, PHO
Objectives

• Describe PIDAC’s best practice guideline for reprocessing
• Define Spaulding’s classification
• Define “reprocessing” and associated terms
• Describe the steps required for reprocessing
• Briefly describe scenarios related to reprocessing
• Describe resources and reprocessing education
Best Practice Guideline - PIDAC

Best Practices For Cleaning, Disinfection and Sterilization in All Health Care Settings was developed by the Provincial Infectious Diseases Advisory Committee (PIDAC).

“PIDAC is a multidisciplinary scientific advisory body that provides evidence-based advice to the Chief Medical Officer of Health regarding multiple aspects of infectious disease identification, prevention and control.”

The document can be accessed at http://www.oahpp.ca/resources/pidac-knowledge/
Updates in February 2010

• Incorporate revisions from updated Canadian standards:
  – CSA Z314.3-09 Effective Sterilization in Health Care Facilities by the Steam Process
  – CSA Z314.2-09 Effective Sterilization in Health Care Facilities by the Ethylene Oxide Process
  – CSA Z314.8-08 Decontamination of Reusable Medical Devices (updated – available for comment)


• **NEW: CSA Z314.23-12** - Chemical sterilization of reusable medical devices and others
### References to consider:

<table>
<thead>
<tr>
<th>Organization</th>
<th>Title</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>PIDAC</td>
<td>Cleaning, Disinfection and Sterilization</td>
<td>2010</td>
</tr>
<tr>
<td></td>
<td><em>Infection Prevention and Control in Clinical Office Practice</em></td>
<td>2013</td>
</tr>
<tr>
<td>Health Canada</td>
<td>Infection Prevention and Control Guideline for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy</td>
<td>2011</td>
</tr>
<tr>
<td>CDC</td>
<td>Guideline for disinfection and sterilization in healthcare facilities</td>
<td>2008</td>
</tr>
<tr>
<td>American Society for Gastrointestinal Endoscopy</td>
<td>Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 2011</td>
<td>2011</td>
</tr>
<tr>
<td>CCAR</td>
<td>Best Practices for Long Term Care, Home and Community Care including Health Care Offices and Ambulatory Clinics</td>
<td>2007</td>
</tr>
<tr>
<td>Ontario RCDSO</td>
<td>Infection Prevention and Control in the Dental Office</td>
<td>2009</td>
</tr>
</tbody>
</table>
Reprocessing

“The steps performed to prepare used medical equipment/devices for use (e.g. cleaning, disinfection, sterilization).”

(CSA, 2009 as referenced in PIDAC, 2010, pg. 9)
### Spaulding’s Classification

<table>
<thead>
<tr>
<th>Classification</th>
<th>Definition</th>
<th>Level of Processing/ Reprocessing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical equipment/device</td>
<td>Equipment/device that enters sterile tissues, including the vascular system. Ex. Foot care instruments, needle driver</td>
<td>Cleaning followed by Sterilization</td>
</tr>
<tr>
<td>Semicritical equipment/device</td>
<td>Equipment/device that comes in contact with nonintact skin or mucous membranes but do not penetrate them. Ex. speculums, otoscopes, respiratory equipment, laryngoscopes. Finger nail equipment</td>
<td>Cleaning followed by High-Level Disinfection (as a minimum). Sterilization is preferred.</td>
</tr>
<tr>
<td>Noncritical equipment/device</td>
<td>Equipment/device that touches only intact skin and not mucous membranes or does not directly touch the client/patient/resident. Ex. bedpans, stethoscopes, environmental equipment</td>
<td>Cleaning followed by Low-Level Disinfection (in some cases cleaning alone is acceptable).</td>
</tr>
</tbody>
</table>
Think about all the medical equipment/devices you use in your health care setting.......

What kinds of medical equipment/devices do you use in your health care setting?
Assessment related to reprocessing

- Single use/disposable or multi-use?
- How is it going to be used/How has it been used?
- Who “owns” cleaning it? Disinfecting or sterilizing?
- How do you know it is clean/disinfected/sterile?
- Do I have manufacturer’s directions for reprocessing?
- Do I have the right products/tools/space?
- Is your equipment assessed for its ability to be cleaned/disinfected/sterilized prior to purchase?
- Do I know what I am doing?
Examples of multi-use items

<table>
<thead>
<tr>
<th>Item</th>
<th>Level of reprocessing required</th>
<th>Reprocessing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure cuff, stethoscope, oximeters</td>
<td>LLD (non-critical)</td>
<td>“wipe” e.g., 0.5% accelerated hydrogen peroxide (5 minutes)</td>
</tr>
<tr>
<td>Fingernail care equipment used on multiple clients/patients/residents</td>
<td>HLD (semi-critical)</td>
<td>e.g., 7% accelerated hydrogen peroxide (20 minutes)</td>
</tr>
<tr>
<td>Foot care</td>
<td>Sterilization (critical)</td>
<td>Steam autoclave or cold chemical sterilization*</td>
</tr>
</tbody>
</table>
PIDAC – Appendix A: Reprocessing Decision Chart

- Manufacturer’s recommendations for product, concentration and exposure time must be followed
- Level of reprocessing (cleaning vs. LLD vs. HLD vs. Sterilization)
- Classification of equipment/device
- Example of equipment/devices
- Products

COMMUNITY SETTINGS
PIDAC and Home Care

Noncritical and semicritical medical equipment/devices that are owned by the client and re-used by a single client in their home do not require disinfection between uses, provided they are adequately cleaned prior to reuse.
C. Equipment/Devices in Home Health Care

Equipment/devices owned by the client that are re-used in their home must be adequately cleaned prior to reuse. Home health care agencies may consider re-using single-use semicritical medical equipment/devices for a single client in their home when reuse is safe and the cost of replacing the equipment/device is prohibitive for the client.
PIDAC and Home Care

A. Boiling

The use of boiling water to clean instruments and utensils is not an effective means of sterilization.\textsuperscript{23} Boiling water is inadequate for the destruction of bacterial spores and some viruses.

In the home care environment, boiling may be used for high-level disinfection for equipment/devices reused on the same client, following adequate cleaning.
CHICA-Canada Position Statement and Practice Recommendations

http://www.chica.org/links_position.php

Cleaning and Disinfection of Non-critical Multi-Use Equipment/Devices in Community Settings
Background

“Multi-use equipment and medical devices in health care have been linked to an increased infection risk. The practice of cleaning and disinfecting non-critical equipment in the community between clients, or even on a regular basis, has not been well established.¹ Outbreaks related to lapses in infection control procedures have been associated with physician offices and clinics.² “
Position Statement

“Each community health care organization has the responsibility to identify non-critical equipment used in the delivery of care and to ascertain the appropriate cleaning and disinfection method and frequency. Written policies and procedures need to be in place and reviewed annually. Multi-use equipment should not be purchased until it is confirmed that it can be reprocessed using established modes and products. As well, audits of cleaning and disinfection practices and the implementation of a quality improvement process related to the audit results are important. It is essential to reprocess non-critical multi-use equipment and devices appropriately, safely and consistently using an approved ‘hospital-grade’ low-level disinfectant which must have a Health Canada Drug Information Number (DIN). \textsuperscript{4,5,6,7,8,9,10}”
Practice Recommendations

• Hand hygiene as per Routine Practices

• Cleaning and low-level disinfection
  • Spaulding’s
  • Clean when visibly soiled (immediately), after direct contact with a client, after each use (prior to another client), after storage in a client’s home
  • 2 step process
  • Risk assessment re frequency
  • Document and communicate
  • Written policies and procedures
  • Audits
  • “hospital-grade” (DIN number)
Practice Recommendations - continued

• Materials and design of multi-use equipment
  • Watch for evidence of damage e.g., toys, upholstered items
  • Non-cleanable equipment can’t be multi-use
  • Consider disposable items, covers

• Equipment in the home
  • Limit amount
  • Dedicate equipment
  • Transport of contaminated equipment
  • Contracted equipment
Practice Recommendations - continued

• Equipment bag
  • Place on a clean, dry surface
  • Hand hygiene
  • Clean and disinfect on a regular basis and when grossly soiled
  • Document

• Ambulatory Clinics and Outreach settings
  • Storage cupboards
  • Stretchers and tables
  • Contracted equipment
  • Documentation of cleaning and disinfection
  • Clean vs. dirty (identify)
THE BASICS
Multi-use equipment

• All multi-use equipment must be cleaned and disinfected after each use

• Correct disinfectant

• Correct dilution

• Correct contact time

• Allow to air dry
Cleaning

“Cleaning is always essential prior to disinfection or sterilization. An item that has not been cleaned cannot be assuredly disinfected or sterilized.“

CCDR. 1998; 24S8

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Q: Why do we need to clean?

A:
- To physically remove contaminants
- If an item is not cleaned, soil (e.g., blood, body fluids, dirt) can protect the microorganisms from the action of the disinfection or sterilization process → ineffective.
- It also inactivates the disinfectant or sterilant – doesn’t work!
- Disinfectants overloaded with soil can become contaminated → source for transmission of microorganisms
Disinfection

“Failure to use disinfection products or processes appropriately has repeatedly been associated with the transmission of healthcare associated infections”

Health Canada. Hand Washing, Cleaning, Disinfection and Sterilization. CCDR. 1998; 24S8

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Disinfection

- All disinfectants must have a Drug Identification Number (DIN) from Health Canada (Public Health Agency of Canada)(Therapeutic Drugs Directorate)

Link to learn more about “DIN numbers”:

Compatibility

• Chemicals must be compatible with product
• Cleaners and disinfectants must be compatible
• Follow manufacturer’s directions
• Log/document

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REPROCESSING STEPS
Step 1: Pre Clean

- Policies and procedures for all reprocessing steps
- Remove visible soil at point of use
- Soak/pre-treat with enzymatic cleaner in approved container/transport device
Step 2: Inspection, Disassembly, Sorting and Soaking

- Disassemble and inspect instrument as required
- Sort instruments in sets
- Soak in approved enzymatic cleaner
Step 3: Cleaning: Manual or Mechanical

- Manually clean instrument
- Clean lumens with brush/cloth
- Flush
- Rinse
- Inspect instrument
- Follow with mechanical cleaning if available (ultrasonic cleaner)
Step 4: Rinsing and Drying

- Rinse with sterile water
- Air dry or with lint-free towel or compressed filtered air for lumens

Image source: Just In Time Productions
Step 5: High level Disinfection or Chemical Sterilization

High Level Disinfection:

• Soak in approved and properly mixed HLD or chemo sterilant
• Monitoring, auditing and documentation required
• Rinse with sterile water x 3 and dry
• Recall procedure for sterilization failure
Step 5: High level Disinfection or Chemical Sterilization

<table>
<thead>
<tr>
<th>Criterion</th>
<th>HLD</th>
<th>Sterilant</th>
</tr>
</thead>
<tbody>
<tr>
<td>The product information clearly indicates the following:</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>- the product's intended use</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>- a quantitative statement of active ingredient(s)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>- the area and site of use</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>- specific directions for use, including the specific types of surfaces/instruments to be cleaned/disinfected</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>- the dilution or activation procedure(s) required, if any</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>- the mode of application</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>- minimum contact time with the item(s) to be cleaned/disinfected/sterilized</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>- cleaning and disinfection procedures</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>- the temperature for use</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>- the re-use period (e.g., 14 days, 21 days)</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

The product meets high-level disinfectant criteria:

| Bactericidal – effective against vegetative bacterial strains by > 5 log10 reduction | ✓ | ✓ |
| General Virucidal – effective against Saliv (Type 1 polio) strain by >2 log10 reduction | ✓ | ✓ |
| Virucidal – effective against targeted viruses by >3 log10 reduction | ✓ | ✓ |
| Fungicidal – effective against Trichophyton mentagrophytes by >4 log10 reduction | ✓ | ✓ |
| Tuberculocidal – effective against Mycobacterium furus by M6 log10 reduction for a high-level disinfectant claim (>4 log10 reduction for an intermediate disinfectant claim) | ✓ | ✓ |

The product meets sporicidal criteria:

| Bactericidal – effective against vegetative bacterial strains by > 5 log10 reduction | ✓ | ✓ |
| General Virucidal – effective against Saliv (Type 1 polio) strain by >2 log10 reduction | ✓ | ✓ |
| Virucidal – effective against targeted viruses by >3 log10 reduction | ✓ | ✓ |
| Fungicidal – effective against Trichophyton mentagrophytes by >4 log10 reduction | ✓ | ✓ |
| Tuberculocidal – effective against Mycobacterium furus by M6 log10 reduction for a high-level disinfectant claim (>4 log10 reduction for an intermediate disinfectant claim) | ✓ | ✓ |
| Sporicidal – effective against Clostridium sporogenes and Bacillus subtilis outbred by >6 log10 reduction | ✓ | ✓ |

The product is compatible with BOTH the equipment/surface’s manufacturer’s instructions and with the scaling products being used to disinfect/sterilize the equipment/surface.
Step 5

Steam Sterilization:

• Inspect, lubricate and reassemble as required

• Wrapping and documentation

• Apply biological and chemical sterilization monitors

• Monitoring, auditing and documentation on reprocessing steps and sterilizer required

Image source: Just In Time Productions
Step 6: Storage

- Sterility is event-related
- Store and transport in a manner that avoids contamination or damage
- Store in a designated area on approved shelving

Image source: Just In Time Productions
Other Considerations: 1. Policies and Procedures

- Responsibilities of management and staff
- Qualifications, education and training for staff IPAC activities
- Worker health and safety
- Preventive maintenance
- Written protocols for each process
- Annual review and updating as required

- Documentation and maintenance of records
- Audits
- Incidents reporting and follow-up
- Requirements for internal or external subcontractors
- Recall procedures

Image source: Just In Time Productions
Other considerations: 2. The Reprocessing Area

- Adequate space
- Segregated away from client and clean areas
- Distinctly separate from areas where clean/disinfected/sterile devices/equipment are handled/stored
- Restricted access from other areas and one-way movement by staff
- Must have ready access to hand hygiene facilities
- Surfaces that can be easily cleaned

- Slip-proof flooring
- Eye wash station
- Decontamination sinks must meet requirements
- Air changes, temperature and humidity
- Airflow
- Quality of water supply
- Written contingency plans
An example of reprocessing area set-up

Workflow from dirty to clean
Other Considerations: 3. Staff Training

- Supervisory and all staff doing reprocessing shall be qualified through education in a formally recognized course for reprocessing
- Process to assess competency and continued education
- Appropriate PPE
- Appropriate immunizations (hep B)
Other Considerations: 4. Sterilizer Requirements

- Must meet PHAC standards as a sterilizer(www.mdall.ca)
- Must have print out for time, temperature and pressure
- Must have time, temperature and pressure indicators
- Instruments are able to be wrapped/packaged
- Must have sterilizer operating, maintenance and inspection instructions available
Other Considerations: Sterilizer Requirements cont’d

- Must have sterilizer operating, maintenance and inspection instructions available
- Documentation on regular maintenance must be maintained
Other Considerations: Sterilizer Requirements cont’d

- Must have installation and service instructions available
- Must have provisions available for staff in-service from supplier
- Steam quality must be met
- Must meet proper electrical supply and ventilation requirements

Image source: Just In Time Productions
Courses and Education:

<table>
<thead>
<tr>
<th>Program Areas</th>
<th>CSAO</th>
<th>Algonquin College*</th>
<th>Centennial College*</th>
<th>Fanshawe College</th>
<th>OHA</th>
<th>CSA**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class room course</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distance/online course</td>
<td></td>
<td>√</td>
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<tr>
<td>Individual courses/conferences</td>
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<tr>
<td>Certification exam</td>
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<tr>
<td>Costs</td>
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<td>$2200</td>
<td>$2100</td>
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<td>variable</td>
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<tr>
<td>Costs</td>
<td>$747.95</td>
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<td></td>
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RICN Reprocessing Project Focus Group
RICN Reprocessing Project

- Survey – Fall 2012
- Focus Group – January 2013
- First steps:
  - Training manual
    - Sample policies and procedures
  - Educational manual
LTC Scenario

• Ear irrigation syringe
  • Metal
  • Parts/disassembly required

• Who owns cleaning it?
• How?
• Move to single-use?
• What about other equipment?
Example: Ear cleaning equipment, ear curettes, otoscope tips:

<table>
<thead>
<tr>
<th>Level or processing/ Reprocessing</th>
<th>Classification of Equipment/ Device</th>
<th>Examples of equipment/ Devices</th>
<th>Products</th>
</tr>
</thead>
</table>
| High level disinfection           | Semi-critical equipment/ device    | ....Respiratory therapy equipment, ear syringe nozzles, CPR face masks, ....Ear cleaning equipment, ear curettes, otoscope tips... | 2% Glutaraldehyde (20 minutes at 20°C)  
6% Hydrogen peroxide (30 minutes)  
0.55% Orthophthalaldehyde (OPA) (10 minutes at 20°C)  
Pasteurization (30 minutes at 71°C)  
7% Accelerated hydrogen peroxide (20 minutes)  
0.2% Peracetic acid (30-45 minutes) |
Bottom line

• Clean first, then disinfect or sterilize
• Dispose single use
• Use client’s own equipment – clean after use
• Multi-use equipment – clean and disinfect/sterilize after every use
• Reprocess as per PIDAC best practice guidelines
• Start now to catalogue all your medical equipment/devices and learn more about CDS!

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Questions?