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Infection Prevention and Control (IPAC) Orientation for IPAC Leads in Long-Term care:

Reprocessing of Medical Equipment and Devices

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Learning Objectives

By the end of this module you will be able to:

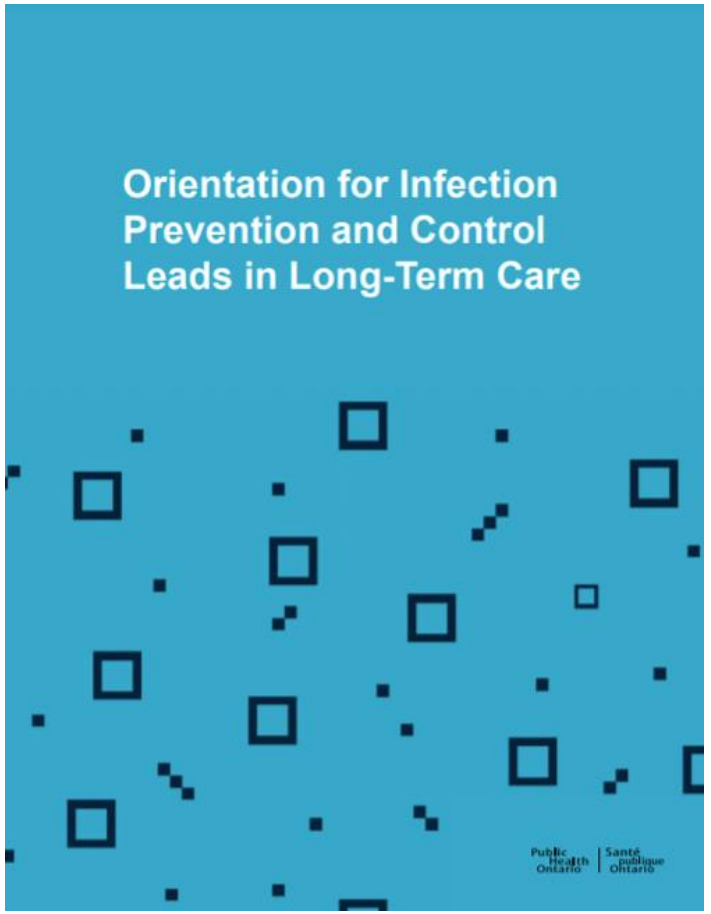
- Explain key principles for reprocessing medical devices/equipment.
- Apply Spaulding's classification of medical devices to determine the level of reprocessing necessary.
- Describe quality control measures for safe and effective reprocessing.

Agenda

Item	Time	Topic
1	5 (minutes)	Welcome and introductions
2	5 (minutes)	Introduction to the Checklist: IPAC Orientation for Infection Control Leads in LTC
3	35 (minutes)	Reprocessing
4	10 (minutes)	Questions and Answers
5	5 (minutes)	Wrap-up and next steps

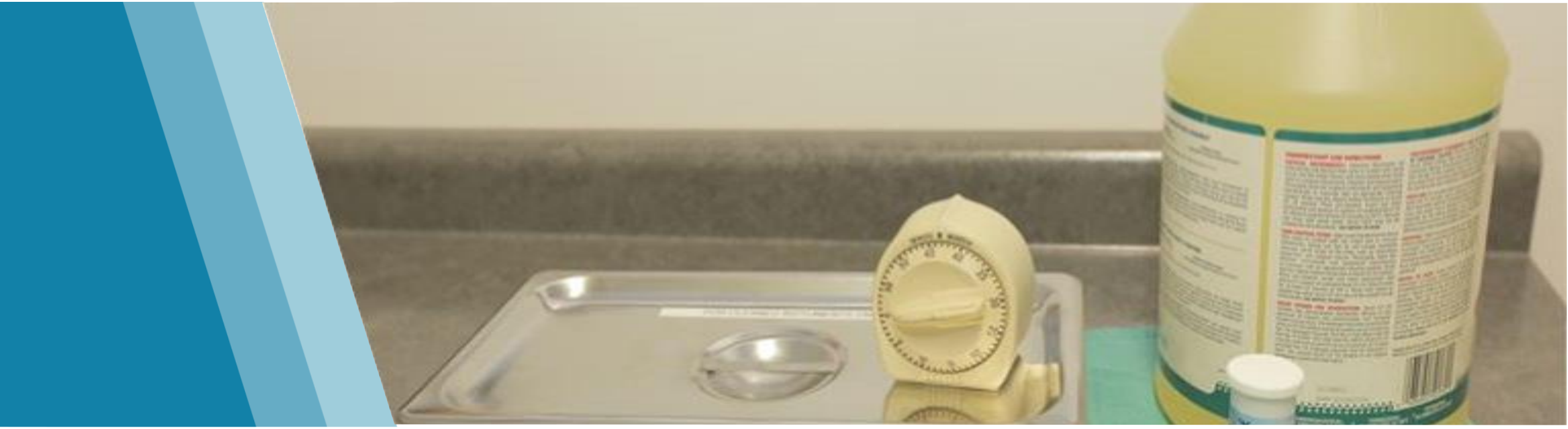
Checklist for IPAC Orientation for IPAC Leads in Long-Term Care

- PHO has developed a new webpage that will contain the Checklist and the series of presentations
- The Checklist and the series of presentations will help build your IPAC knowledge.



Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario). Orientation for infection prevention and control leads in long-term care [Internet]. Toronto, ON: Queen's Printer for Ontario; 2022 [cited 2022 May 12]. Available from: https://www.publichealthontario.ca/-/media/Documents/I/2022/ipac-leads-orientation-long-term-care.pdf?sc_lang=en.

Reprocessing of Medical Equipment and Devices



Reprocessing Standards

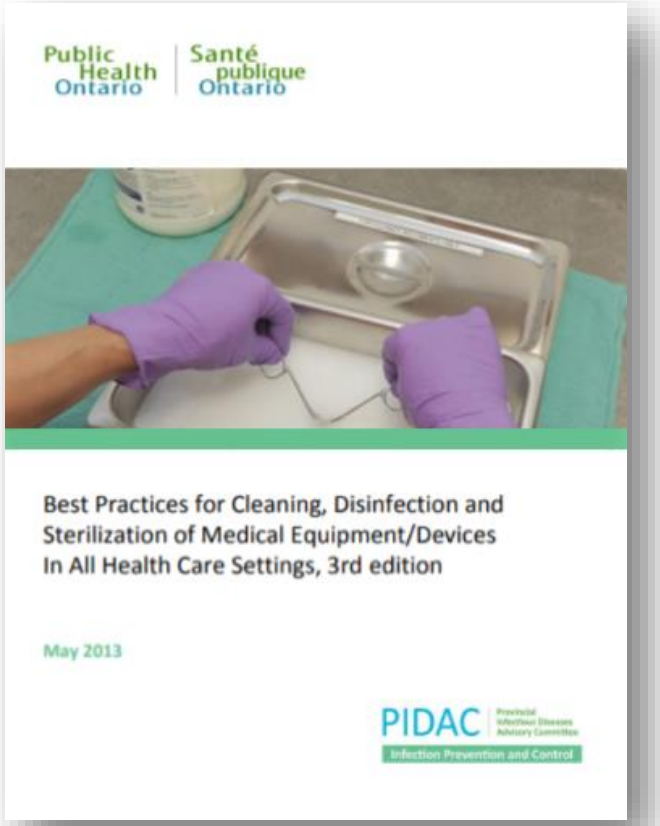
- All reusable equipment must be reprocessed according to the manufacturer's instructions for use (MIFUs), standards, guidelines, and organizational policies and procedures, regardless of care setting
- MIFUs are the minimum and reprocessing must meet best practice standards and guidelines.

Goals of Safe Reprocessing of Medical Equipment /Devices

1. preventing transmission of microorganisms to personnel and clients/patients/residents and;
2. minimizing damage to medical equipment/devices from foreign material (e.g., blood, body fluids, saline, and medications) or inappropriate handling.

Ontario Agency for Health Protection and Promotion (Public Health Ontario), Provincial Infectious Diseases Advisory Committee. Best practices for cleaning, disinfection and sterilization of medical equipment/devices in all health care settings. 3rd ed. Toronto, ON: Queen's Printer for Ontario; 2013. Available from: https://www.publichealthontario.ca/-/media/documents/b/2013/bp-cleaning-disinfection-sterilization-hcs.pdf?sc_lang=en.

Staff Education

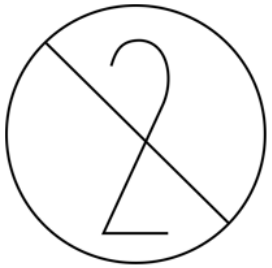


- "All staff involved in reprocessing of medical equipment/devices must be supervised and shall be qualified through education in a formally recognized course for sterilization technology, training and experience in the functions they perform."(p. 21)
- It is important to determine which staff will carry this responsibility and make sure they are appropriately trained.

Ontario Agency for Health Protection and Promotion (Public Health Ontario), Provincial Infectious Diseases Advisory Committee. Best practices for cleaning, disinfection and sterilization of medical equipment/devices in all health care settings. 3rd ed. Toronto, ON: Queen's Printer for Ontario; 2013. Available from: https://www.publichealthontario.ca/-/media/documents/b/2013/bp-cleaning-disinfection-sterilization-hcs.pdf?sc_lang=en.

Considerations for Reprocessing: Single-use vs. Multi-use Medical Devices

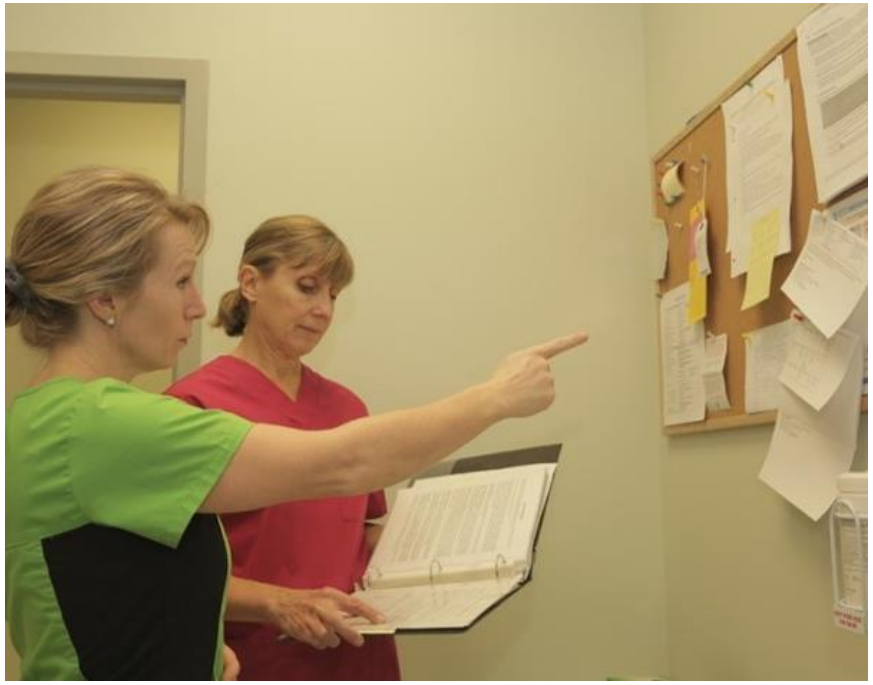
Single-use medical equipment/devices are usually labelled by the manufacturer with this symbol:



- Devices labelled as single-use by the manufacturer will not have instructions for reprocessing.
- Must be disposed of after use
- When comparing costs between single-use vs. multi use consider:
  - Staff time
  - Staff education
  - Equipment
  - Risk

Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario), Provincial Infectious Diseases Advisory Committee. Best practices for cleaning, disinfection and sterilization of medical equipment/devices in all health care settings. 3rd ed. Toronto, ON: Queen's Printer for Ontario; 2013. Available from: https://www.publichealthontario.ca/-/media/documents/b/2013/bp-cleaning-disinfection-sterilization-hcs.pdf?sc_lang=en.

Manufacturer's Instructions



- Need to be available to staff responsible for reprocessing
- Considered to be the minimum standard.
- Should be periodically checked to ensure there have been no changes
- Ensure that items you are reprocessing are not labelled single-use

Policies and Procedures Requirements

- Should follow current Public Health Agency of Canada (PHAC), Health Canada, Canadian Standards Association (CSA) standards, and PIDAC best practices.
- Should be reviewed by someone with infection prevention and control (IPAC) expertise.
- Should be reviewed annually or when there is a change in equipment or a process.
- Should be available in areas where reprocessing takes place.

Determining the Level of Reprocessing to Use

Spaulding's Classification Tool for Medical Devices

Classification	Definition	Level of Processing/Reprocessing	Examples
Critical equipment/device	Equipment/device that enters sterile tissues, including the vascular system	Cleaning followed by Sterilization.	Surgical instruments Implants Biopsy instruments Foot care equipment Eye and dental equipment
Semi critical equipment/device	Equipment/device that comes in contact with non intact skin or mucous membranes but do not penetrate them	Cleaning followed by High-Level Disinfection (as a minimum) Sterilization is preferred	Respiratory therapy equipment Anaesthesia equipment Tonometer
Noncritical equipment/device	Equipment/device that touches only intact skin and not mucous membranes or do not directly touch the client/patient/ resident	Cleaning followed by Low-Level Disinfection (in some cases, cleaning alone is acceptable)	ECG machines Oximeters Bedpans, urinals, commodes

Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario), Provincial Infectious Diseases Advisory Committee. Best practices for cleaning, disinfection and sterilization of medical equipment/devices in all health care settings. 3rd ed. Toronto, ON: Queen's Printer for Ontario; 2013. Available from: https://www.publichealthontario.ca/-/media/documents/b/2013/bp-cleaning-disinfection-sterilization-hcs.pdf?sc_lang=en.

Critical Medical Devices

Critical medical devices are those that enter sterile parts of the body

Example: Foot Care Equipment

1. Pre-cleaned
2. Cleaned
3. Sterilization

outcome:
sterilized

Outsourcing Medical Equipment Reprocessing

- If using outside companies to reprocess your equipment verify:
  - Compliance with best practices and standards
  - Adequate training of staff responsible for reprocessing
  - Quality control measures in place
  - On-site storage requirements of dirty equipment

Semi-Critical Medical Devices

Semi-critical medical devices are those that come into contact with non-intact skin or mucous membranes, but do not penetrate them

Example: Fingernail clippers used on multiple residents

1. Pre-cleaned
2. Cleaned
3. High level disinfection

Outcome: Disinfected

Semi-Critical Devices: High-level disinfection (1/3)

- Eliminates vegetative bacteria, enveloped viruses, fungi, mycobacteria, and non-enveloped viruses.
- Can be achieved through liquid chemicals or pasteurization.
  - Chemical – suitable for instruments
- The process must be monitored for efficacy, carefully documented, and audited periodically.
  - Chemical – concentration verified using test strips

Ontario Agency for Health Protection and Promotion (Public Health Ontario), Provincial Infectious Diseases Advisory Committee. Best practices for cleaning, disinfection and sterilization of medical equipment/devices in all health care settings. 3rd ed. Toronto, ON: Queen's Printer for Ontario; 2013. Available from: https://www.publichealthontario.ca/-/media/documents/b/2013/bp-cleaning-disinfection-sterilization-hcs.pdf?sc_lang=en.

Semi-critical Devices: High-level Disinfection (2/3)

Liquid chemicals used for high-level disinfection must:

- Have a drug identification number (DIN).
  - For more information on DINs refer to Health Canada's website.
  - Be compatible with items being disinfected and with cleaning agent(s).
- Be diluted properly if required.
- Remain in contact with the medical device for the required period of time and rinsed appropriately.

Health Canada. Drug Identification Number (DIN) [Internet]. Ottawa, ON: Government of Canada; 2022 [modified 2022 Jan 14; cited 2022 Jun 09]. Available from: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/dinfs_fd-eng.php.

Semi-critical Devices: High-level Disinfection (3/3)

Chemical test strips should:

- Be used to determine whether an effective concentration of active ingredients is present.
- Test the disinfectant in use daily and follow the manufacturer's instructions
- Be checked each time a new package/bottle is opened to verify they are accurate, using positive and negative controls.
- Not be used to justify using a chemical beyond its expiry date.

Ontario Agency for Health Protection and Promotion (Public Health Ontario), Provincial Infectious Diseases Advisory Committee. Best practices for cleaning, disinfection and sterilization of medical equipment/devices in all health care settings. 3rd ed. Toronto, ON: Queen's Printer for Ontario; 2013. Available from: https://www.publichealthontario.ca/-/media/documents/b/2013/bp-cleaning-disinfection-sterilization-hcs.pdf?sc_lang=en.

Non-critical Medical Devices: Low-level Disinfection

Equipment/device that touches only intact skin and not mucous membranes, or does not directly touch the resident

Example: Wheelchair

Cleaned followed by low-level disinfection

Outcome: Disinfected

Quality Control in Reprocessing

Quality Control Measures

- Each long-term care home should have a system in place to provide quality resident care through the provision of clean and disinfected or sterile equipment and medical devices.

Administrative Controls

- Polices and procedures
- Properly functioning equipment

Indicator Monitoring

- Sterilization is monitored by using physical, chemical and biological monitors
  - For more information on sterilization please see Additional IPAC Resources
- High-level disinfection is monitored by concentration and contact time, chemical test strips determine whether an effective concentration of active ingredients is present.

Continuous Improvement

- An audit of medical device reprocessing should be done in your organization.
- Important components of the audit should include:
  - Does the medical device reprocessing area meet standards?
  - What devices are being reprocessed?
  - Are there single use devices and are they being disposed of after one use?
  - Are you following the manufacturer's instruction for reprocessing?
  - How are you ensuring reprocessing is being done properly?

Documentation

- Record keeping for high level disinfection shall include but not limited to:
  - the identification of the equipment/device to be disinfected
  - date and time of the clinical procedure
  - concentration and contact time of the disinfectant used in each process

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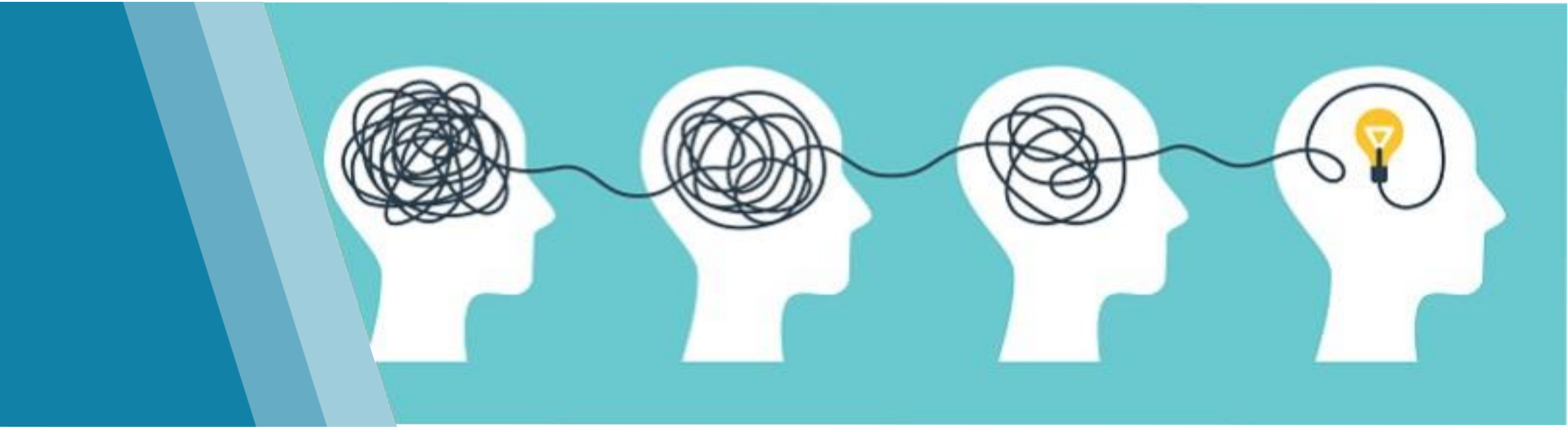
IPAC Resources

Continue to grow your knowledge and fill outstanding gaps with relevant sections from the following resources:

- PHO's Reprocessing webpage
  - Online Learning: Reprocessing in Community Health Care Settings
  - PHO & PIDAC: Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices in All Health Care Settings, 3rd ed.
  - PHO & PIDAC: Reprocessing Decision Chart
- CAN/CSA-Z314-18: Canadian medical device reprocessing

CSA Group. CAN/CSA-Z314-18: Canadian medical device reprocessing. Toronto, ON: CSA Group; 2018.

Questions and Answers



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