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Cleaning, Disinfection, Sterilization of Medical Devices and Equipment

Published: June 2024

Long-Term Care Certification in Infection Prevention (LTC-CIP) Preparation Series

Sources

- Content of this module was informed by and used with permission from the Association for Professionals in Infection Control and Epidemiology resources:
  - APIC LTC-CIP™ Learning System
  - APIC Text Online

Association for Professionals in Infection Control and Epidemiology (APIC). APIC LTC-CIP™ learning system, book 1. Washington, DC: APIC; 2023.

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Exam Content

1. Long-Term Care Settings (15 items)
2. Management and Communication of the Infection Prevention Program (16 items)
3. Identification of Infectious Diseases (18 items)
4. Surveillance and Epidemiologic Investigation (24 items)
5. Prevention and Control of Infectious and Communicable Diseases (24 items)
6. Environment of Care (18 items)
7. **Cleaning, Disinfection, Sterilization of Medical Devices and Equipment (15 items)**
8. Antimicrobial Stewardship (11 items)
9. Employee/Occupational Health (9 items)

Learning Objectives

In this review session, the main topics that will be covered are:

1. Describing cleaning, disinfection and sterilization methods.
2. Identifying requirements and methods for medical equipment and devices based on their intended use.
3. Discussing the management of single-use devices.

What are Cleaning, Disinfection, and Sterilization of Medical Devices and Equipment?

What are Reprocessing, Cleaning, Disinfection, and Sterilization?

- **Reprocessing** is the steps performed to prepare medical devices and equipment for use, including cleaning, disinfection and sterilization.
- **Cleaning** is the removal of foreign material such as soil and organic material from objects. It must be performed prior to disinfection and sterilization.
- **Disinfection** is the thermal or chemical destruction of microbes. The process destroys most pathogens, but not all (e.g., bacterial spores).
- **Sterilization** results in sterility, which is when no live microorganisms remain (including spores).

The Infection Preventionists (IPs) Responsibility in Reprocessing

- Support the establishment of written policies and procedures for cleaning methods in collaboration with an interdisciplinary team (e.g., infection prevention and control (IPAC), environmental services (EVS), nursing, facility maintenance and food services staff).
- Provide recommendations on reprocessing procedures and schedules.
- Provide ongoing consultation on product selection (e.g., cleaning equipment and agents), and participate in quality improvement activities.
- Provide education to those responsible for reprocessing and other health care workers (HCWs) as needed

Policies and Procedures for Cleaning, Disinfection, and Sterilization

- These policies and procedures should include the following:
  - Clearly defined roles and responsibilities
  - Cleaning, disinfection and sterilization schedules
  - Storage of clean, disinfected, and sterile supplies
  - Following Manufacturer's Instructions For Use (MIFUs), including ensuring wet-contact time for all disinfectants is followed

What Should Cleaning, Disinfection, and Sterilization Policies and Procedures Include? (1/3)

- Information about the different products that may be used, including a list of approved cleaning and disinfecting products, as well as ensuring material safety data sheets for all products is available to all staff
- Cleaning all items immediately after use and when visibly soiled, followed by disinfection with facility- and Environmental Protection Agency- (EPA) approved hospital-grade disinfectant (or sterilization as required)
- Cleaning surfaces as soon as feasible
- Selection of reprocessing method for devices and equipment that are shared between residents based on the intended use
- Clear identification of reusable equipment after cleaning and disinfection (e.g., using a tag or cover with a plastic bag)

What Should Cleaning, Disinfection, and Sterilization Policies and Procedures Include? (2/3)

- Description of processes for monitoring and evaluating cleaning and disinfection procedures
- Using dedicated or disposable scissors; where not possible, ensure they are cleaned and disinfected between residents
- Opened, but unused sterile supplies are considered contaminated and need reprocessing or disposal.
- Where reprocessing is out-sourced:
  - The IP should verify all aspects of reprocessing are being followed appropriately
  - Management of reusable items that are sent off-site for reprocessing, including separation using sealable, leak- and puncture-proof containers for any devices with sharp edges

What Should Cleaning, Disinfection, and Sterilization Policies and Procedures Include? (3/3)

- Ensuring staff have, and use, appropriate personal proactive equipment (PPE) for the task
- Ensuring there is access to eye-wash stations where chemicals are used or prepared
- A service, maintenance and replacement schedule for all equipment in the long-term care home (LTCH), including reprocessing equipment (e.g., mechanical cleaners) if any are present.
- A schedule for the cleaning and disinfection of tools used for reprocessing (e.g., reusable cleaning cloths, brushes)
- Assigned responsibility for replacing cleaning solutions, and when this should be done
- A clear reporting structure for reporting damaged or faulty equipment
- Maintenance schedule for resident care equipment
- Who is responsible for cleaning different items (e.g., EVS or a nurse)
- Ensuring tape on equipment is not overused, as equipment with tape residue cannot be considered clean
- Disposable items can be discarded per policy or regulation

Selecting Products

Cleaning, Disinfection and Sterilization Product Selection (1/2)

- Considerations when selecting products include ease of use, efficacy, acceptability, safety and cost
- The IP should maintain a record of all cleaning and disinfecting agents used. The record should include:
  - What products are used?
  - What are the MIFUs?
  - Which products require preparation and what is the process for preparation?
  - When are the specific products being used?
  - Who uses the products?
  - Where are the products used?
  - How are the products stored?
  - What are the manufacturer's contact details?
  - Who is the distributor?

Cleaning, Disinfection and Sterilization Product Selection (2/2)

- Selected EPA-Registered Disinfectants Lists
  - Identifies antimicrobial products based on the common pathogens for which they are effective
  - IPs should be familiar with the EPA sticker (indicating the product is EPA-approved) and the selected EPA-registered disinfectants list so they can advise EVS and setting administration on the most appropriate product to purchase
- ICPs must ensure EVS staff are aware of when to use each product, and if a 1-step cleaning and disinfecting agent is used, it must be approved for this purpose
- Other considerations when selecting products:
  - **Kill Claims** – provides information about which organisms the product will kill (inactivate)
  - **Contact Time** – amount of time a disinfectant needs in order to be effective (also called dwell or wet time)
  - **Hazard Information** – describes potential hazards posed by products use
- Train staff to use new products/devices before they are put into use

Cleaning

What is Cleaning, Why Clean, and How to Clean?

- Proper disinfection or sterilization of items cannot occur unless they are cleaned first
- Cleaning is the physical removal of dirt, body fluids, or other organic matter from a surface or piece of equipment, and is the first step before disinfection or sterilization
- Why clean?
  - Reduce bioburden and remove foreign material, preventing it from drying/baking onto instruments, and preventing it from interfering with the effectiveness of disinfection/sterilization
- How to clean?
  - Cleaning is accomplished via a combination of water, friction, and detergents +/- enzymatic agents
    - Detergents are cleaning products that can emulsify oil and suspend soil
    - Enzymatic cleaners contain protease enzymes that can break down proteins (e.g., blood, body fluids, excretions and secretions)
  - Cleaning can be done manually/mechanically

Manual versus Mechanical Cleaning

- When using either manual or mechanical cleaning, instruments should be disassembled, and:
  - Cleaned manually in the ‘open’ position, if cleaning manually
  - Left in the ‘open’ position during mechanical cleaning, if cleaning mechanically
- Manual cleaning:
  - When a mechanical washer is unavailable, or for fragile or difficult to clean instruments
  - Clean using friction and fluids under pressure
- Mechanical cleaning:
  - E.g., ultrasonic cleaners, washer-decontaminators, washer-disinfectors, washer-sterilizers
  - Avoid stacking instruments/over-loading

Additional Cleaning Considerations

- Cleaning should happen as soon as possible following use to prevent soiled materials from drying or baking onto instruments or surfaces.
  - When soiled materials dry on instruments or surfaces, cleaning becomes harder, and disinfection and sterilization less effective.

Discussion/Knowledge Check

Disinfection

What is Disinfection?

- Disinfection is the process where many pathogenic microbes (except bacterial spores) are eliminated from surfaces/items
- Disinfection involves either liquid chemicals or wet pasteurization
- Factors that affect disinfection:
  - Any organic material still present after cleaning
  - Temperatures, concentrations, exposure times, and solution pH being used
  - Physical nature of the item (e.g., hard to reach areas)
  - Biofilms
- Disinfection is not sporicidal
  - Some disinfectants can kill spores if surfaces receive prolonged exposure to certain chemical sterilants (3 to 12 hours), though this is dependent on the level of contamination

Levels of Disinfection

- **Low level disinfection** – destroys vegetative bacteria, some fungi and viruses (not mycobacteria or spores)
- **Intermediate level disinfection** – destroys vegetative bacteria, mycobacteria, most viruses, most fungi (not bacterial spores)
- **High level disinfection** – destroys all microorganisms (some spores may remain)

Considerations for Selecting Disinfecting Agents (1/2)

- Factors to consider when choosing chemical disinfectants
  - Positive factors may include:
    - Cost effective
    - No odor/irritation issues
    - Non-staining
    - No special venting requirement
  - Negative factors may include:
    - Material incompatibility
    - Respiratory irritation, skin or eye damage
    - Long contact time (impractical)

Considerations for Selecting Disinfecting Agents (2/2)

- Disinfectants are not interchangeable, and multiple factors can impact the disinfectant process, including:
  - the effectiveness against certain organisms
  - varying contact times
  - initial level of cleanliness
  - disinfectant resistance
- MIFUs for disinfectant products must always be followed, in addition to following all safety precautions (e.g., wearing PPE and preparing solutions in well-ventilated areas).
- Settings should only use EPA-approved, hospital-grade disinfectants.

Disinfection – Types of Disinfecting Agents

Type of Agent	Pros	Cons
Alcohols	• Effective and rapid bacteriocide • Inexpensive • Minimal odor • No residue • Non-staining • Non-toxic • Non-allergenic	• Non-sporicidal • Cannot penetrate proteinaceous materials • Can damage rubber, plastic tubing, glass and plastic coatings • Flammable • NOT registered with EPA
Chlorine (and compounds)	• Broad spectrum of activity • No toxic residue • Unaffected by water hardness • Inexpensive • Fast-acting • Effective against biofilms and surface organisms • Deodorizing • Easy to use • Minimal residue	• Corrosive (metals) • Can irritate skin and eyes with prolonged exposure • Burns if ingested/inhaled • Some organic matter can render it inactive • Can bleach fabrics/materials • Questionable use as sporicidal
Formaldehyde	• Effective bacteriocide, tuberculocide, fungicide, virucide and sporicide • Quick neutralization • Active in presence of organic matter • Relatively inexpensive and available • EPA registered	• Potential carcinogen • Fatal if ingested • Can cause respiratory problems and skin irritation after prolonged exposure

Disinfection – Types of Disinfecting Agents

Type of Agent	Pros	Cons
Glutaraldehyde	• Relatively inexpensive • Compatible with wide range of materials • Active in presence of organic matter • Nonflammable	• Activation required • Respiratory irritation from vapour • Strong, unpleasant odor • Slow activity (10 minute contact time) • Can cause contact dermatitis • Coagulates blood • Limited-shelf life once prepared • Rinsing required to remove residue
Hydrogen Peroxide	• No activation required • Minimal odor and irritation • Easy disposal • Does not coagulate blood • Stable when properly stored • Wide range of uses	• Requires thorough cleaning before and after use • Can cause chemical irritation (with contact) • Requires careful solution monitoring
Iodophors	• Disinfectant and antiseptic • Effective against blood • Relatively nontoxic with minimal to no irritation • Non-staining • Safe and convenient • Stable storage	• Activation requires dilution • Can damage silicon products • Can be expensive

Disinfection – Types of Disinfecting Agents

Type of Agent	Pros	Cons
Ortho-phthalaldehyde (OPA)	• No activation required • Fast-acting high level disinfectant • Minimal odor • Does not coagulate blood	• Can stain skin • Expensive • Eye irritation (with contact) • Slow sporicidal activity • Requires meticulous rinsing post-use
Peracetic Acid	• No activation required • Minimal odor and irritation • Fast-acting (30-45 min) sterilizing and sporicidal • Low temp liquid immersion (50-55°C) • Standardized for ease of use	• Some material incompatibility • Immersible instruments only • Expensive • Can damage skin and eyes (with contact)
Phenolics	• Wide spectrum of activity • Good for environmental surfaces and noncritical devices • Can be used to pre-clean critical/semicritical devices	• Relatively poor sporicide • Easily absorbed and can cause irritation • Unpleasant odor • Inactivated by organic matter • Can be expensive

Disinfection – Types of Disinfecting Agents

Type of Agent	Pros	Cons
Quaternary ammonium compounds (quats)	• Less toxic than bleach or phenolics • Minimal odor • Non-toxic and non-allergenic • Easy to prepare and use • Inexpensive	• Potential for skin and respiratory irritation at higher concentrations • Non-sporicidal • Incompatible with soaps • Interference by organic matter
Steam	• Nontoxic (to staff, residents, and the environment) • Easy to control/monitor • Rapid microbiocidal • Least affected by organic/inorganic soils • Can penetrate some medical packaging	• Potential for burns • Inappropriate for heat-sensitive items • Moisture post-use (which may lead to rust in instruments)

Emerging Technologies

- Innovations in cleaning and disinfecting technology are being adopted in health care settings, including LTCHs.
- Emerging technologies that may be used in LTCHs include:
  - **Ultraviolet (UV) irradiation** – used for the control of a variety of pathogens including control of *Legionella* in water, as well as the disinfection of air, surfaces and instruments. UV is less effective against spores and is mostly used in the destruction of airborne organisms and the inactivation of microorganisms on surfaces. The efficacy is a function of many parameters, including exposure time and distance of light from object.
  - **Antimicrobial-coated surfaces** – EPA has approved copper surfaces in medical settings since 2008. Several other heavy-metals have well-demonstrated antimicrobial properties, and these surfaces provide continuous environmental disinfection on the surfaces they cover.
  - **Hydrogen peroxide (HP) vaporization/aerosolization** – hydrogen peroxide is effective against certain pathogens (e.g., MRSA, TB, *C. diff*). HP spray is being used more frequently in room and furniture decontamination but requires a longer application time than other methods.

Biofilms: Disinfection Challenges

- Biofilms are a thick matrix of cells and extracellular materials which can form on surfaces immersed in liquids, resulting in a continuous source of contamination.
- Biofilms can protect microbes from cleaning and disinfection.
- In LTCHs biofilms may form on contact lenses, pacemakers, urinary catheters, or many other medical devices, as well as showers, baths, and sinks when these are not cleaned properly.
- When biofilms are found in channels, grooves or hinges of devices, they are especially difficult to remove.

Biofilms: Prevention and Removal

- Bacteria and fungi (e.g., *Candida* sp.) protected by biofilms have been associated with hospital acquired infections, and biofilms pose a serious threat to immunocompromised residents.
- Biofilm prevention/management should be included in a setting's cleaning and disinfection policies.
- No enzymatic detergents have been approved for the degradation of biofilms, though chlorine and monochlorine disinfecting agents are currently the most effective agents at inactivating biofilm bacteria.
- The best way to prevent biofilms in devices is to promptly and correctly clean and disinfect these per MIFUs.
  - High-level disinfection and sterilization are most effective.

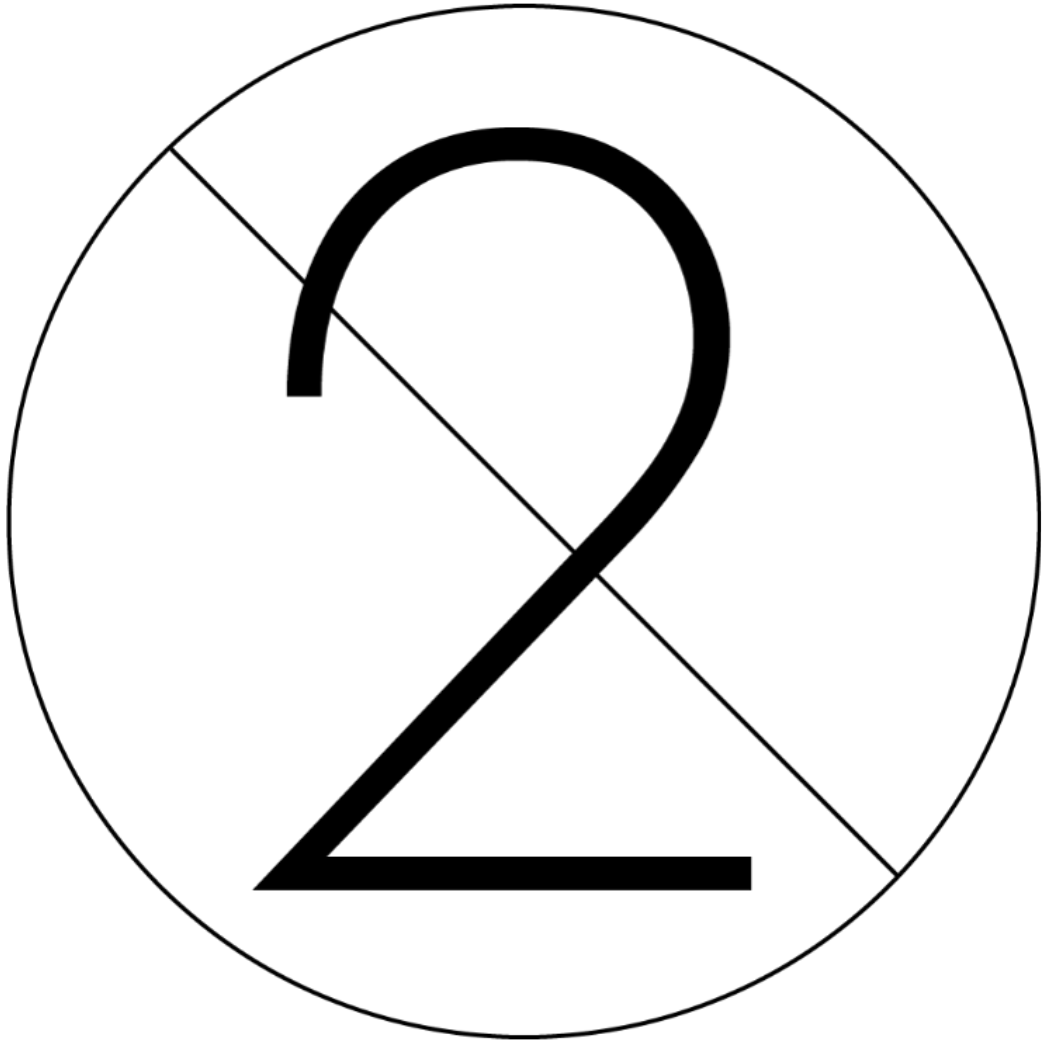
Sterilization

What is Sterilization and what do LTCHs need to know?

- Process by which all forms of microbial life are destroyed or eliminated
- Achieved via physical or chemical methods
  - Common agents used in healthcare include steam under pressure, dry heat, ethylene oxide gas, hydrogen peroxide gas plasma, and liquid chemicals
- Sterilization does not happen frequently in LTCHs, often due to lack of proper infrastructure, however, it is important that LTCHs know:
  - How to store, transport, distribute and use sterilized products
  - Which items are required to be sterile prior to use (e.g., indwelling devices and wound dressings) and which items require sterilization after use (e.g. scalpel used in abscess drainage)
  - That sterilization is performed appropriately if being outsourced

Sterile Storage

- All staff who are involved in sterilization, or the handling and storage of sterile equipment, should be educated and trained on storing and handling medical equipment and supplies.
- The training program should cover:
  - **Storage** – store sterile products in a clean, climate-controlled utility room
    - Sterile products should be stored at least 3 feet from sinks, 8 – 10 inches from the floor, 18 inches to the ceiling, and at least 2 inches from outside walls.
  - **Stock rotation** – rotating stock ensures sterile products with expiry dates are used in a timely manner
  - **Organization** – store sterile products in dedicated areas, shelves, carts or cabinets (these are ideally closed) that remain uncompromised



Single-Use Devices

Repurposing/Reprocessing Single-Use Devices

- A single-use device (SUD) is intended for a single use on a single resident during a single procedure.
- After using a SUD it needs to be disposed of.
- Reprocessing of SUDs raises several ethical, regulatory, medical, legal and economic issues.
- Reprocessing of SUDs is regulated by the US Food and Drug Administration (FDA) , and is restricted to hospitals with capabilities to properly reprocess the devices, as well as third-party reprocessors who meet FDA standards.

Identifying the Required Level of Reprocessing

Spaulding Classification

- Divides medical equipment into 3 risk-based categories that are based on the intended use of the item
- Each category requires a different level of disinfection or sterilization
  - Critical
  - Semicritical
  - Noncritical
- All equipment in LTCHs must be cleaned/disinfected/sterilized according to Spaulding Classification.
- Noncritical items are the most frequently found items in LTCHs

Noncritical Equipment

- Many devices used in LTCHs are classified as noncritical.
- Noncritical items can be separated into 2 groups:
  - **Resident care items** include, but are not limited to, electric razors, bedpans, stethoscopes.
  - **Environmental surfaces** include, but are not limited to, bed rails, bedside tables, counters and floors.
- Noncritical **personal care items** such as toothbrushes are for single-resident use only and should not be shared due to the risk of pathogen transmission.
- If noncritical items are shared between residents they must be fully cleaned and low-level disinfected prior to being used on another resident.
- Ensure cleaning/disinfecting product is compatible with equipment.
- If contaminated with blood, clean and disinfect using EPA-approved products with Human Immunodeficiency Virus (HIV) or Hepatitis B virus (HBV) label claims.

Semicritical Equipment

- The semicritical devices and equipment found in LTCHs will be dependent on the level of care/services provided.
- Semicritical items are **not** frequently encountered in LTCH.
- Residents who require a procedure with a semicritical instrument would likely be transferred out for the procedure.
- Examples of semicritical devices include some dental and foot care instruments, for example.
  - These, and other semicritical devices require high-level disinfection or sterilization, which is not typically performed in LTCHs

Critical Equipment

- Most critical items are not encountered in LTCHs.
  - Examples of critical items include surgical instruments and implants.
- Most critical items are purchased sterile, but some require sterilization after purchase.
- Steam-sterilization is recommended when critical items are compatible.
- Critical items that are found in LTC include, but are not limited to, scalpels, lancets, and intravenous (IV) catheters.
- Urinary catheters are one of the most commonly used critical equipment in LTCHs, and must be sterile (these must be purchased sterile and never reprocessed; they must be disposed of after use).
- IPAC must ensure that relevant LTCH staff are knowledgeable about the storage, preparation and use of critical equipment.

Spaulding Classification

Classification	Definition	Level of Reprocessing	Effect
Critical	Equipment/device that enters sterile tissues, including the vascular system	Cleaning followed by sterilization	Destroys of all forms of microbial life including bacteria, viruses, spores and fungi
Semicritical	Equipment/device that comes in contact with non-intact skin or mucous membranes but do not penetrate them	Cleaning followed by minimum high level disinfection. Sterilization is preferred	Destroys vegetative bacteria, mycobacteria, fungi and enveloped and non-enveloped viruses, but not necessarily bacterial spores
Noncritical	Equipment/device that touches only intact skin and not mucous membranes or does not directly touch patient	Cleaning followed by low level disinfection	Kills most vegetative bacteria and some fungi as well as enveloped viruses. Do not kill mycobacteria or bacterial spores

Discussion/Knowledge Check

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References

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- Slides 25 – 28:
  - Adapted from: Association for Professionals in Infection Control and Epidemiology (APIC). Certification study guide. 6th ed. Washington, DC: APIC; 2015. Exhibit 5-17; p. 48-9.

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How to Cite this Presentation

Ontario Agency for Health Protection and Promotion (Public Health Ontario); Infection and Prevention Control Canada. Cleaning, disinfection, sterilization of medical devices and equipment. Toronto, ON: King’s Printer for Ontario; 2024.

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