Cleaning, Disinfection and Sterilization

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Objectives

- Determine how to select and use the best agents/systems for cleaning
- List important components in cleaning, disinfection, or sterilization
- Using Spaulding’s Classification of critical, semi-critical and non-critical, list the types of devices used in your facility
- Identify risks of failure to properly clean, disinfect, or sterilize equipment

Definitions

- Cleaning removes visible foreign material
- Sanitization reduces pathogenic organisms to relatively safe levels on inanimate objects

Definitions

- Decontamination removes pathogenic organisms and makes equipment safe for handling
- Sterilization destroys or eliminates all forms of microbial life
Definitions

- Disinfection is the elimination of pathogenic organisms with the exception of spores – Inanimate Objects
- Antisepsis reduces microorganisms on the skin or mucous membranes – Living Tissue

Infection Transmission

![Infection Transmission Diagram](image)

Regulatory Agencies

- Environmental Protection Agency (EPA)
  Oversees registration of sterilants and disinfectants
  [http://www.epa.gov](http://www.epa.gov)
- Food and Drug Administration (FDA)
  Monitors medical devices, food, & drugs
  [http://www.fda.gov/MedicalDevices/default.htm](http://www.fda.gov/MedicalDevices/default.htm)

Regulatory Agencies

- Occupational Safety and Health Administration (OSHA)
  Bloodborne Pathogens Rule
  29 CFR Part 1910.1030
Regulatory Agencies

- Centers for Medicare & Medicaid Services (CMS)
  - Enforces federal quality standards for various healthcare settings

Equipment & Environment

Pathogens may live on environmental surfaces

- Influenza: 4 hours
- Parainfluenza: 10 hours
- Rhinoviruses: 3 hours
- RSV: 7 hours
- VRE, VSE: 7 days
- MRSA, MSSA: 3 days
- C. difficile (spore form): months

Cleaning

- Environmental surfaces with an emphasis on surfaces in proximity to the patient and those that are frequently touched
- Clean first, then disinfect with an EPA-registered disinfectant
Cleaning

- Cleaners and disinfectants are used in accordance with the manufacturer’s instructions (e.g., dilution, storage, shelf-life, and contact time)

- Follow the manufacturer’s instructions for cleaning and maintaining noncritical equipment

Cleaning Principles

- Cleaning should be done from area of least soiling toward area of heaviest soiling

- Higher surfaces are to be cleaned before lower surfaces

Cleaning

- Regular cleaning of housekeeping surfaces (e.g., floors, walls, tabletops) is needed on a regular basis and clean up spills promptly

- Avoid dusting methods that disperse dust (e.g., feather dusting)

Cleaning “Don’ts”

- Do not use high-level disinfectants/liquid chemical sterilants for disinfection of either noncritical instruments and devices or any environmental surfaces; such use is counter to label instructions for these toxic chemicals
Cleaning “Don’ts”

- Do not perform disinfectant fogging in patient-care areas
- Avoid large surface cleaning methods that produce mists or aerosols

Minimum Expectations of Safe Care

- Written policies and procedures for routine cleaning and disinfection of environmental services, including identification of responsible personnel
- Staff receive job-specific training and competency validation at hire and when procedures/policies change

Minimum Expectations of Safe Care

- Training & equipment are available to ensure that HCP wear appropriate PPE to preclude exposure to infectious agents or chemicals
- PPE can include gloves, gowns, masks, and eye protection
Minimum Expectations of Safe Care

- Cleaning procedures are periodically monitored and assessed to ensure that they are consistently and correctly performed.
- The facility has a policy/procedure for decontamination of spills of blood or other body fluids.

Resource

Guidelines for Environmental Infection Control in Healthcare Facilities
http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf

Hierarchy of Resistance

- Prions
- Bacterial spores - Bacillus subtilis
- Mycobacteria - M. tuberculosis
- Nonlipid or small viruses – polio
- Fungi – Cryptococcus species
- Vegetative bacteria – P. aeruginosa
- Lipid or medium sized viruses – Herpes simplex

Least resistant

Spaulding Classification

EH Spaulding believed that how an object will be disinfected depended on the object’s intended use.

- Critical
- Semicritical
- Noncritical
Critical

- Objects which enter normally sterile tissue or the vascular system or through which blood flows must be **Sterile**

  - Surgical instruments
  - Cardiac catheters

Critical - Sterile

- All microorganisms and spores

  - High temperature – Steam
  - Low temperature – ETO or H2O2
  - Liquid chemical sterilants – H2O2, paracetic acid

Semicritical

- Objects that touch mucous membranes or non-intact skin require High Level Disinfection

  - Some endoscopes
  - Respiratory therapy equipment
  - Anesthesia equipment

Semicritical – High Level Disinfection

- Free of all microorganisms except high numbers of spores

  - Pasteurization
  - Liquid chemical sterilants
### Semicritical - Intermediate Disinfection

- Hydrotherapy tanks
- Hospital disinfectant with label claim for tuberculocidal activity

### Noncritical

Objects that only touch intact skin require Low Level Disinfection

- Bedpans
- Blood pressure cuffs
- Bed rails
- Environmental surfaces

### Noncritical – Low Level Disinfection

Free of all vegetative bacteria & some fungi and viruses

- EPA registered hospital grade disinfectant
  - Chlorine base
  - Phenolics
  - Quaternary ammonium
  - 70-90% alcohol

### Single Use Devices (SUDs)

- Labeled by the manufacturer for a single use, “Single Use only”
- Do not have reprocessing instructions
- May not be reprocessed for reuse except by entities which have complied with FDA regulatory requirements
Single Use Devices (SUD)

- Hospitals that reprocess a SUD are regulated the same as the original equipment manufacturer
- To reprocess must be FDA 510(k) status

Minimum Expectations of Safe Care

- Policies and procedures to ensure that reusable medical devices are cleaned and reprocessed appropriately prior to use on another patient
- Includes a clear delineation of responsibility among HCP

Minimum Expectations of Safe Care

- Policies, procedures, and manufacturer reprocessing instructions for reusable medical devices are available in the reprocessing area
- Staff appropriately trained and competencies are regularly documented (at least annually & when new equipment is introduced)

Minimum Expectations of Safe Care

- Training and equipment are available to ensure that staff wear appropriate PPE
Resources

- Guideline for Disinfection and Sterilization in Healthcare Facilities
- FDA - Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals, 2000

Space Requirements

- Dedicated area for cleaning of equipment
- Dedicated area for sterilization
- Adequate plumbing and utilities
- Appropriate air exchanges & pressure relationships to adjacent areas
- Storage for sterile items

6 Steps for Instrument Processing

- Cleaning
- Inspection
- Packaging
- Sterilization
- Storage & Delivery
- Quality Assurance

Cleaning

- Wear appropriate Personal Protective Equipment (PPE)
- Surgical instruments should be presoaked or rinsed and disassembled when applicable
- Use of manual or mechanical cleaners (ultrasonics or washers)
Cleaning

- Clean using water with a neutral pH detergent or enzymatic cleaner
- Scrub while submerged to prevent aerosolization of blood & body fluids
- Thoroughly rinse with tap water
  
  If it isn’t clean it will never be sterile

Inspection

- Inspect for residual debris or damage
- Check for proper function and lubricate
- Allow instruments to dry

Packaging

- Should be done in a clean and low contamination area
- Choose correct package for the sterilization method and size of the item

Packaging

- Paper/plastic pouches
- Wrapped sets
- Rigid containers

AAMI - Use approved wrappers or rigid containers
FDA – Follow manufacturer’s directions
Sterilization

- Steam
- Ethylene oxide (ETO)
- Hydrogen peroxide gas plasma
- Peracetic acid

Steam Sterilization

- Gravity displacement
- Prevacuum – Use Bowie Dick Test

Steam Sterilization

- Read and follow manufacturer’s operation manual
- Maintain a preventive maintenance manual
Storage and Delivery

- Store to reduce potential for contamination
- Avoid high traffic areas
- Store 8-10 inches from floor
- Store 18 inches from fire sprinkler
- Solid bottom shelf
- Dust cover seldom used supplies

Storage and Delivery

- No rubber bands
- Closed cabinets
- Temperature and humidity control
- Store 2 inches from outside wall
- Inspect before distributing

Quality Assurance

- Physical
- Chemical
- Biological

Quality Assurance

Physical – cycle time, temperature, and pressure (steam)
- Verify prior to unloading the sterilizer
- Record for every cycle
Quality Assurance

Chemical – change color or show movement to verify sterilization parameters are met

- Should be on the outside & inside of packages
- Specific to the type of sterilization process

Integrators

- Chemical indicator
- Approved by the FDA – measures more than one parameter of sterilization (temperature, steam penetration, pressure time)
- Biological indicator must be used

Steam Quality Assurance

Biological – bacterial spore that provides highest level of sterility assurance

- Steam sterilizers use weekly, preferably daily
- Use a biological indicator for every implant
- Place on bottom shelf directly above the drain

Failed Biological Indicator (BI)

- Immediately take sterilizer out of service
- Notify physician and Infection Control
- Verify integrity of BI
- Verify mechanical indicator (print out)
- Verify correct cycle selection
- Verify plant operation
Failed Biological Indicator (BI)
- Recall procedure
- Correct errors and retest
- Repeat BI for three consecutive runs with negative results before putting sterilizer back in service

Sterility Assurance
- Event related sterility
- Inspect package before use and do not use if:
  - package is wet or crushed
  - Item is dirty
  - Seal is broken
  - Package has been dropped to the floor

Sterility Assurance
- Check for an expiration date
- If expiration date passed then discard

Flash (Immediate Use) Sterilization
- Utilization of a short sterilization cycle of a wrapped/contained load
- Make sure sterilizer has been cleared by FDA to run a short cycle and been validated by the manufacturer
- Maintain log on each load
<table>
<thead>
<tr>
<th>Flash (Immediate Use) Sterilization</th>
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</thead>
<tbody>
<tr>
<td>➢ Follow the device manufacturer’s written instructions</td>
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<tr>
<td>➢ Not to be used to make up for equipment shortages</td>
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<table>
<thead>
<tr>
<th>Steris System 1E</th>
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<tbody>
<tr>
<td>➢ Liquid chemical sterilant processing system (Peracetic acid)</td>
</tr>
<tr>
<td>➢ Devices are wet and unwrapped</td>
</tr>
<tr>
<td>➢ High level disinfection</td>
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<tr>
<td>➢ Safe for urological scopes</td>
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</tbody>
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<tr>
<th>Sterrad NX</th>
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<tr>
<td>➢ Hydrogen peroxide gas plasma</td>
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<tr>
<td>➢ Low temperature</td>
</tr>
<tr>
<td>➢ Use on heat stable, heat sensitive &amp; moisture sensitive instruments that have to be sterile</td>
</tr>
<tr>
<td>➢ Rapid cycle</td>
</tr>
<tr>
<td>➢ No fumes and no aeration required</td>
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<table>
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<th>Minimum Expectations of Safe Care</th>
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<tr>
<td>➢ All reusable critical instruments and devices are sterilized prior to reuse</td>
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<tr>
<td>➢ Routine maintenance for sterilization equipment is performed according to manufacturer instructions (confirm maintenance records are available)</td>
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Minimum Expectations of Safe Care

- Policies and procedures are in place outlining facility response (i.e., recall of device and risk assessment) in the event of a reprocessing error/failure

Universal Truths

- Running a cycle in a sterilizer does not automatically guarantee sterility
- If it was sterile – mishandling may contaminate it

Universal Truths

- Value of standard operating procedures (SOP’s) and knowledgeable staff following manufacturer’s guidelines provides the best sterility assurance
- If it isn’t clean it will never be sterile

High Level Disinfectants

- Glutaraldehyde (>2%)
- 0.55% Ortho-phthaldehyde (OPA)
- Follow manufacturer’s directions
- Wear PPE
Glutaraldehyde and OPA

- Use test strips to check minimum effective concentration (MEC)
- Check temperature with MEC check
- Maintain log

Completely submerge for the specified time & remove
Remove excess solution
Read results at specified time

Glutaraldehyde and OPA

- Maintain competency
- Adequate air exchanges
- Keep lid tightly closed on container

Scopes

- Follow manufacturer’s recommendations
- Wear PPE
- Preclean, always wipe outside immediately after use
- Transport the soiled scope
Scopes

- Perform leak test
- Clean thoroughly, disassemble, flush & brush all lumens
- Disinfect – Manual or Automated

Scopes

- Rinse thoroughly
- Flush channels with 70% isopropyl alcohol
- Dry
- Store – hang vertically

Minimum Expectations of Safe Care

- All reusable semicritical items receive at least high-level disinfection prior to reuse
- Has a system in place to identify which instrument (e.g., endoscope) was used on a patient via a log for each procedure

Minimum Expectations of Safe Care

- Routine maintenance for high-level disinfection equipment is performed according to manufacturer instructions; confirm maintenance records are available
Questions
Infection Prevention References and Resources for Ambulatory Care Settings

1. CDC HAI Prevention Guidance

2. CDC Outpatient Settings:

3. Hand Hygiene:

4. CDC Hand Hygiene web page with links to videos, posters etc.:

5. Injection Safety:

6. CDC Injection Safety web page where we have slide sets, FAQs, educational materials and references that you can use to give outbreak examples

7. Injection Safety Video – This has a series of vignettes and clinical scenarios that might be helpful:

8. Point of Care Devices (Blood glucose meters):
   a. CDC webpage – this has a lot of great info and links to info from CMS and FDA as well as a link to some FAQs that give info about cleaning/disinfection of meters and there are a ton of references that can be used for outbreak examples:
      http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

9. Disinfection/Sterilization:

10. Environmental Cleaning:

11. Healthcare Personnel Safety:

12. Personal Protective Equipment:
13. Proper Sterilization of Instruments is Essential to Patient Safety (example competency tool)
   http://www.apic.org/Content/NavigationMenu/Publications/InfectionConnection/Proper_Sterilization.htm

   http://www.asge.org/uploadedFiles/Publications_and_Products/Practice_Guidelines/Multisociety%20guideline%20on%20reprocessing%20flexible%20gastrointestinal.pdf

15. CDC Environmental Checklist for Monitoring Terminal Cleaning
   http://www.cdc.gov/HAI/toolkits/Environmental-Cleaning-Checklist-10-6-2010.pdf

16. International Association of Healthcare Central Service Materiel Management (IAHCSMM)
   http://www.iahcsmm.org/

17. Certification Board for Sterile Processing and Distribution
   http://www.sterileprocessing.org/cbspd.htm

18. Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care

    Environmental Cleaning Eval Worksheet
    http://www.cdc.gov/HAI/toolkits/Evaluating-Environmental-Cleaning.html

    http://www.aami.org

21. Disinfection & Sterilization established by William A. Rutala, Ph.D., M.P.H.
    http://www.disinfectionandsterilization.org

22. Outpatient Oncology Centers
    http://www.cdc.gov/cancer/preventinfections/providers.htm

23. Dialysis Guidelines