Infection Prevention in Ambulatory Care: Meeting CMS Conditions for Coverage

Cleaning, Disinfection and Sterilization in the Ambulatory Care Setting

Definitions

- Sterilization: complete elimination, destruction of all microbial life
- Disinfection: elimination of many or all pathogenic organisms with the exception of bacterial spores
- Cleaning: removal of all soil from objects/surfaces
- Decontamination: removal of all pathogenic microorganisms from objects to ensure they are safe to handle
Background

Each year in the U.S.,
27,000,000 surgical procedures
and 10,000,000 gastrointestinal
endoscopies are performed…
…failure to follow adequate
disinfection/sterilization on any of
these cases carries the risk of
infection transmission.

Risks in Invasive Procedures Both
Inside and Outside the Traditional OR

- Improper environment
- Inadequate sterilization and disinfection
  processes
  - Staff not trained
  - Antiquated equipment
  - Borrowed equipment
  - Improper use of equipment
  - Compromised cleaning procedures

CLEANING
Cleaning

- Defined as the physical removal of all visible soil, dust, and other foreign materials.
- Effective cleaning will reduce microbial contamination on environmental surfaces & equipment.
- Cleaning is the first and most important step before disinfection or sterilization can occur.

Presoaking

- Prevents soils & proteins from drying on the instruments
- Softens soils and assists with their removal
- Prevents biofilm development
- Presoaking the instruments should ideally occur immediately following the surgical procedure

Manual Cleaning

- Follows presoaking
- Instruments washed submerged under water to prevent potential exposure to microorganisms through aerosolization
- Staff must wear PPE including eye and face protection
- Some washers may allow you to eliminate manual cleaning all together
Factors in Effective Cleaning and Decontamination:

- Water quality
- Acceptable washing method
- Cleaning agent
- Proper rinsing and drying
- Proper storage
- Practices to prevent personal injury
- Layout of the processing area
- Staff training

Instrument Cleaning

- Soiled instruments may harbor bacteria and viruses
- Due to their construction, many instruments & devices have surfaces that are hard to reach during the cleaning process

Washer Disinfector

- Mechanically cleans instruments using a spray action called impingement
  - Impingement is the water force making contact with the instrument.
- Several cycle processes; final step is heated air drying
A Washer in Action

Ultrasonics for Delicate Instruments (e.g. eye instruments)

- Effectiveness is based on cavitation: sonic waves generate minute bubbles on instrument surface
- Bubbles then expand, become unstable, then collapse or implode
- Implosion generates very localized vacuum areas that literally dislodges/sucks off the soil

Enzymatic Detergents

- Detergents are defined as substances capable of dislodging, removing and dispersing solid or liquid soils from a surface being cleaned
- Enzymatic detergents usually consist of a detergent base with a neutral pH to which one or more enzymes and a surfactant is added
Spaulding Classification for Medical Devices

In 1972, Dr. Earl Spaulding developed a system for classifying medical instrumentation and equipment:

- **Critical** (high risk) devices enter sterile tissue or bloodstream – **STERILIZATION**
- **Semi-critical** – devices in contact with intact mucous membranes or skin that is not intact – **HIGH LEVEL DISINFECTION**
- **Non-critical** – devices touch intact skin – **LOW LEVEL DISINFECTION**

Disinfection and Sterilization Levels:

- **STERILE**
- **HIGH-LEVEL**
- **INTERMEDIATE-LEVEL**
- **LOW-LEVEL**
Selection of Disinfection Agents

- Based upon intended use
- Degree of disinfection required
- Spaulding's classification
- Capability to meet all requirements to use the disinfection agent safely and appropriately
- Turn around time

Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants

| Prions | Spores | Mycobacteria | Non-Enveloped Viruses | Fungi | Bacteria | Enveloped Viruses |

<table>
<thead>
<tr>
<th>Device classification</th>
<th>Examples</th>
<th>Spaulding process classification</th>
<th>EPA Product Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical (enters sterile tissue or vascular system)</td>
<td>Implants, scalpels, needles, other surg. Instruments</td>
<td>Sterilization- sporicidal chemical; prolonged contact</td>
<td>Sterilant/disinfecant</td>
</tr>
<tr>
<td>Semi critical (touches mucous membranes)</td>
<td>Flexible endoscopes, laryngoscopes, ET tubes, vaginal specula</td>
<td>High level disinfection- sporicidal chemical; short contact</td>
<td>Sterilant/disinfecant</td>
</tr>
<tr>
<td>Hydrotherapy tanks</td>
<td>Intermediate level disinfection</td>
<td>Hospital disinfectant with label claim for tuberculocidal/ HBV activity</td>
<td></td>
</tr>
<tr>
<td>Non critical (touches intact skin)</td>
<td>Stethoscopes, tabletops, bedrails, blood pressure cuffs</td>
<td>Low level disinfection</td>
<td>Hospital disinfectant without HBV/TB label claim</td>
</tr>
</tbody>
</table>
Question

- According to the Spaulding Classification system, a larynscope blade should be disinfected by the following method:
  - A. Cleaning followed by HLD
  - B. Cleaning followed by chlorexidine for 20 min.
  - C. Cleaning followed by ultrasonic washer
  - D. Alcohol disinfection

Low Level Disinfection

- Kills most bacteria, some viruses, some fungi
- Appropriate for non critical medical devices and environmental surfaces
- Quaternary ammonium compounds (Quats) are low level disinfectants
  - Many quats are effective against TB and Hepatitis B
  - Ok for use on blood spills and in OR environment

Intermediate Level Disinfectants

- Kills Mycobacterium tuberculosis, vegetative bacteria (e.g. Staphylococcus aureus), most viruses & fungi
- Most phenolic disinfectants are classified as intermediate level
- Appropriate for hard surfaces, floors, non-critical medical devices
- Phenolic disinfectants are used cautiously in the Nursery
Question

Which chemical agent should be used in an area where blood might be on the floor?
A. Alcohol
B. Halogen
C. Bleach

High-Level Disinfection

• A process (usually liquid chemicals or wet pasteurization) that eliminates:
  – many or all pathogenic microorganisms on inanimate objects
  – except large numbers of bacterial spores
  – short exposure times (<30 minutes)

Agents for Chemical High-Level Disinfection

Use for temperature sensitive devices
• Glutaraldehyde (≥ 2.0%)
• Hydrogen peroxide-HP (7.5%)
• Peracetic acid-PA (0.2%)
• HP (1.0%) and PA (0.08%)
• HP (7.5%) and PA (0.23%)
• Glutaraldehyde (1.12%) and Phenol/phenate (1.93%)
• Ortho-phthalaldehyde – OPA (0.55%)
High-Level Disinfection

• Glutaraldehyde and Ortho-phthaldehyde – OPA
  - Various formulations
  - Ready to use or requires activation (mixing)
  - 14, 28 and 72 day formulations
  - Must use test strips to assess concentration prior to each use
  - Minimum Effective Concentration (MEC) specific to each product.
  - Product must be rinsed thoroughly
  - sterile or potable water (dependent upon intended use of instrument)
  - Maintain Log
  - Must be neutralized for disposal

---

**High Level Disinfectant Log**

<table>
<thead>
<tr>
<th>Tray</th>
<th>Equipment</th>
<th>Date Processed</th>
<th>Solution Expiration Date</th>
<th>Test Strip Expiration Date</th>
<th>MEC Test Result</th>
<th>Test Strip Result (+ Pass or - Fail)</th>
<th>Solution Temperature (if using an automated endoscope reprocessor)</th>
<th>Initials</th>
</tr>
</thead>
</table>

**IMPORTANT!**
Solution must be discarded by expiration date
EVEN when MEC test Passes

**Test Strip Example**

- Fail
- Pass

---

**STERILIZATION**
Chemical Sterilants

- Chemicals used to destroy all forms of:
  - Microbiological life
  - Fungal and bacterial spores
  - Prolonged exposure times (6-10 hours)

High-level disinfectants when used as a sterilant may not convey the same level of sterility assurance as other methods (sterilizers).

Agents for Chemical High-Level Disinfection or Sterilization

Use for temperature sensitive devices
- Glutaraldehyde (≥ 2.0%)
- Hydrogen peroxide-HP (7.5%)
- Peracetic acid-PA (0.2%)
- HP (1.0%) and PA (0.08%)
- HP (7.5%) and PA (0.23%)
- Glutaraldehyde (1.12%) and Phenol/phenate (1.93%)
- Ortho-phthaldehyde – OPA (0.55%)
**Types of Sterilizers**

**Thermal (Heat)**
- Moist (Tabletop, Gravity, & High Speed Vacuum)
- Dry Chemical
- ETO
- HLD Chemicals
- Ozone
- Radiation

*Example of a tabletop steam autoclave.*

**Steam Gravity Sterilization**
- Low cost, quick turnover, no toxic chemicals, accommodates large loads
- Steam enters the chamber by gravity & displaces air (so steam can penetrate load)
- Takes longer for steam to reach required temperature
- 4 key parameters; steam, pressure, temperature, time

*Example of a tabletop steam autoclave.*

**Steam Pre-vacuum Sterilization or High Speed Vacuum**
- Low cost, quick turnover, no toxic chemicals, accommodates large loads
- Air is removed (so steam can penetrate load) by a pump before steam at an elevated temperature is rapidly introduced

*Example of an Electronic High Speed pre-and post-vacuum autoclave.*
Flash Sterilization

- **Definition:**
  - AAMI: “process designed for the steam sterilization of patient care items for immediate use”
  - AORN: “should be used only when there is insufficient time to sterilize the item by the preferred wrapped or container method”

- Not recommended outside of the ambulatory surgical center where it can be used in a controlled manner

- Should never be used as a substitute for sufficient inventory

---

Flash Sterilization

- What is flash sterilization?
- Why use flash sterilization?
- What is the main problem with flash sterilization?
- What can be done to prevent recontamination?
- Why not use muslin on non-woven wrap in the flash sterilizer?
- Are there any containers for flash sterilization which prevent recontamination?

---

Flash Sterilization

Acceptable only for items:

- AAMI guidelines for implants
- AORN guidelines for implants
- Single instruments only (not trays)
- Urgently needed
- Cleaned well
- Used close to point of sterilization
- Adequately covered or protected from contamination
Flash Sterilization

Considerations:
• Risk of pt. burns from hot instruments
• Recomination of instruments during transport
• Keep logs of all flashing (process surveillance)
• Monitor number of times used, what procedures, and why – use as dept PI
• Monitor staff training and performance

Dry Heat Sterilization

• Gravity
• Mechanical Convection – more efficient and temperature is more uniform

Low Temperature Sterilization

Ethylene oxide (EtO);
• Used for heat & moisture sensitive devices
• Lengthy aeration time must follow each cycle to allow removal of harmful residuals before opening chamber doors
• EtO is associated with human tumors
• Alarms, ventilation, and training of staff promote safe use of this agent
Sterilizer that uses Paracetic Acid

Sterilizer that uses Hydrogen Peroxide
Gas Plasma
Quality Assurance for Steam Sterilization

- Critical Parameters for each load must be met
  - Steam
  - Adequate temperature
  - Pressure
  - Time

Influencing Factors on Disinfection & Sterilization

- Cleaning of the object
- Organic and inorganic load present
- Type and level of microbial contamination
- Concentration of and exposure time to disinfectant/sterilant
- Nature of the object
- Temperature and relative humidity
- Improper packaging or overloading the sterilizer chamber can form air pockets that prohibit items from being sterilized

Sterilization Monitoring: Biological Indicators (BI)

- Closest to being the ideal monitor & measure of effectiveness by challenging the sterilization process against the resistant spore (Bacillus spores)
- Use BI daily if sterilizer is used frequently
- Also, use a BI for every implant & EtO run
- Procedures: include positive tests-who to notify, instruments used?, IC Communication report
**Sterilization Monitoring:**
**Biological Indicators (BI)**

**Steps for use**
- Write sterilizer information, load and date on indicator
- Place in a package in the area most difficult to sterilize
- Run sterilizer
- Check chemical indicator for color change
- Remove and place in incubator (must crush capsule to activate upon placing in incubator)
- Place a control (indicator that has not been processed) into incubator
- Run incubator

**Biological Indicators (BI)**

- Remove at regular intervals and compare results for color change
- Length varies with the product; rapid readout 1-3 hours, or 24 hours
- Read and record results
- Positive test = sterilization process has failed due to improperly processed load, failure to meet temperature or exposure parameters, mechanical problems, etc.

**Documentation:** Note the Control is positive but the Biological is negative
Positive BIs

- Remove sterilizer from service until problem is resolved
- Check sterilizer records or logs to see if all other critical parameters were met
- Repeat the BI in 3 separate loads
  - If all are negative and critical parameters are met place it back into use
  - If one or more continue to be positive
    - Have machine serviced
    - Repeat BI using a different manufacturer or lot of indicators

Sterilization Monitoring: Chemical Indicators (CI)

- The CI is a temperature indicator that signals the item has been exposed to sterilization process
- A CI is affixed to outside of package & used with every load
- An indicator is also placed inside the pack to verify steam penetration

Chemical Indicator placed in the tray prior to sterilization
Examples of Bowie Dick Tests

Sterilization Monitoring: Mechanical Indicators

- Cycle time, temperature, & pressure is displayed on the sterilizer gauges with each instrument load
- Printout or graph documents these indicators

Class V Integrators

- Reacts to more than one of the critical parameters
- Provides a high level of quality assurance
- Must be used with a Biological Indicator
- Class 6 Integrators are new : AAMI updating standards ST79 in Aug. 2009
Minimum Effective Concentration (MEC) Test Strips for HLD/ Sterilants

- Dilution of chemical occurs during routine use
- Test strips for monitoring the MEC; testing frequency depends on frequency of use of chemical e.g. use daily, then test daily
- Do not use test strips beyond expiration date
- Test & document when opening a new bottle; refer to manufacturer’s protocol

Time-Related vs. Event-Related Sterilization

- Historically, time-related sterile items had an expiration date...yet items don’t suddenly convert from sterile to non-sterile
- Event-related sterilization states the product does not have an expiration date providing the package integrity is intact (e.g. wrapping intact, package is not wet, etc.)

Storage of Clean/Sterile supplies

- Store at least
  - 8-10 inches from the floor
  - 18 inches from the ceiling
- Solid bottom shelf
Reuse of Sterile, Single Use Medical Devices

- Manufacturers cite “single use only” on many of their products (e.g., cardiac catheterization catheters, orthopedic bits/blades, DVT sleeves, etc.)
- Re-use of these products can result in significant financial savings
- Concern with the risk of infection and injury when the devices are re-used
- Must consider regulatory, medical, ethical, legal, & economic issues before proceeding forward
- 3rd Party reprocessing acceptable when premarket requirements are met (FDA 501(k))
Cleaning/Disinfection in Radiology Setting

- Decontamination and care of equipment
  - Sterile catheters
  - Single use vs reusable patient care items
  - Disposable cover for probes
  - Cleaning and high level disinfection of probes – Manufacturer’s instructions
  - Use of closed flush and waste containment systems for angiography
  - Environmental cleaning

Cleaning/Disinfection in Endoscopy Setting

Key Infection Prevention Interventions for cleaning and processing endoscopes

- Keep the scope moist – enzymatic soak
- Transport in covered container
- Consistent and complete cleaning of all channels
- Manual cleaning includes
  - Valves
  - Channels
  - Connectors
  - All detachable parts
  - Brushes

Risks Inherent in the Endoscopy Setting

Key Infection Prevention Interventions for cleaning and processing endoscopes (cont.)

- Inspection
- Leak testing and scope inspection
- Processing: According to manufacturer
  - Chemical
  - Automated endoscope washer-disinfector
  - Use alcohol for final rinse
- Hang to dry in a vented or cabinet designed for hanging and storage of scopes (no coiling)
Cleaning/Disinfection in Endoscopy Setting

• Documentation
  – Patient name
  – Type of scope - Serial number
  – Date and time of processing
  – Enzymatic soak time if manual
  – Chemical indicator results
  – Machine – Bay Number
  – Soak time if manual
  – Attach read out if available

ENDOSCOPY REPROCESSING LOG
Today's Date: ______________________ Results Of Pre-Process Test:
Disinfectant: _______________________ Expiration Date Of Test Strips:_____________
Activation Date: ____________________

| Patient’s Name | Processed | Type | Time | Cleaning | Rinse | Alcohol | Purge | Initials | Test
|----------------|-----------|-----|------|----------|-------|---------|-------|----------|------
|                |           |     |      |          |       |         |       |          |      
|                |           |     |      |          |       |         |       |          |      
|                |           |     |      |          |       |         |       |          |      
|                |           |     |      |          |       |         |       |          |      

Question
To facilitate drying and to reduce microbial contamination and proliferation in an endoscope, you should:

A. blow dry with compressed air, rinse with tap water, and hang vertically to dry
B. blow compressed air through the channel and rinse with 70% ethyl or isopropyl alcohol
C. rinse with tap water and blow compressed air through the channels
D. rinse with alcohol, hang vertically to dry, and store in a case to keep clean
Vendor Equipment

- Vendor
  - Must wear appropriate attire
  - Name badge
  - Bring cleaning, disinfection instructions from manufacturer of device
- Equipment
  - Must be delivered to the processing department for cleaning and sterilization
  - Allow for adequate time for processing
  - Record “borrowed” equipment contents, vendor name, patient or case number involved, surgeon name, date and time

Summary: Variables Impacting the Disinfection/Sterilization Process

- Amount of microbes present
- Innate resistance of microorganisms; spores v. vegetative bacteria (e.g. Pseudomonas, Staphylococcus)
- Disinfection concentration/potency
- Physical/chemical factors (temperature, pH, humidity, water hardness)
- Soiling (feces, pus, blood, serum, etc.)
- Exposure duration to the germicide
- Biofilms; microbial mass attached to surfaces that are immersed in liquids
- Cleaning; manually, ultrasonic cleaner, washer-disinfector, washer-sterilizer with a detergent

SUMMARY

- When properly used, disinfection and sterilization can ensure the safe use of invasive and non-invasive medical devices.
- The method of disinfection and sterilization used depends on what the intended use of the medical device is.
- Meticulous cleaning should precede high-level disinfection and sterilization.
- Staff should know the current recommended guidelines and utilize them when developing/reviewing/revising related policies.
Resources

Guidelines:
• AORN - Association of periOperative Registered Nurses
  - www.aorn.org/
• (AAMI) Association for the Advancement of Medical Instrumentation
  - www.aami.org/
• CDC: Guidelines for Environmental Infection Control in Health-Care Facilities
  - http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm
• APIC web site: Practice Guidance section
  - www.apic.org

Disinfection and Sterilization Resource:

www.disinfectionandsterilization.org
Established by William A Rutala, PhD., M.P.H.

Any Questions?