High-Level Disinfection, Sterilization and Disinfection

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DISCLOSURES
2022

• Consultations
  ■ Professional Disposables International (PDI)

• Honoraria
  ■ PDI

• Other
  ■ Ideate Medical, Kinnos
Sources of Healthcare-Associated Pathogens

- Endogenous flora (SSI, UTI, CLABSI): ~40-60%
- Exogenous: ~20-40% (e.g., cross-infection via contaminated hands [staff, visitors])
- Other (environment): \( \leq 20\% \)
  - Medical devices
  - Contact with environmental surfaces (direct and indirect contact)
Sterilization and Disinfection

- Describe the Spaulding classification scheme for disinfection of patient care items
- Describe available methods for sterilization and types of indicators used to ensure the process was effective
- Understand the advantages and disadvantages of the various disinfectants and mechanical processes used to disinfect medical equipment
- Outline the controversies surrounding the reprocessing of endoscopes and disinfection of other complex medical instruments
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William A. Rutala, Ph.D., M.P.H.\textsuperscript{1,2}, David J. Weber, M.D., M.P.H.\textsuperscript{1,2}, and the Healthcare Infection Control Practices Advisory Committee (HICPAC)\textsuperscript{3}
EH Spaulding believed that how an object will be disinfected depended on the object’s intended use (developed 1968).

**CRITICAL**-medical/surgical devices which enter normally sterile tissue or the vascular system or through which blood flows should be sterile.

**SEMICRITICAL**-medical devices that touch mucous membranes or skin that is not intact require a disinfection process (high-level disinfection [HLD]) that kills all microorganisms but high numbers of bacterial spores.

**NONCRITICAL**-medical devices/environmental surfaces that touch only intact skin require low-level disinfection.
Critical Medical/Surgical Devices
Rutala et al. ICHE 2014;35:883; Rutala et al. ICHE 2014;35:1068; Rutala et al. AJIC 2019;47:A3-A9

- Critical
  - Transmission: direct contact
  - Control measure: sterilization
  - Surgical instruments
    - Enormous margin of safety, rare outbreaks, if ever
    - ~85% of surgical instruments <100 microbes
    - Washer/disinfector removes or inactivates 10-100 million
    - Sterilization kills 1 trillion spores
Semicritical Medical Devices

- Semicritical
  - Transmission: direct contact
  - Control measure: high-level disinfection
  - Endoscopes top ECRI list of 10 technology hazards, >130 outbreaks (GI, bronchoscopes)
    - 0 margin of safety
    - Microbial load, $10^7$-$10^{10}$
    - Complexity
    - Biofilm
  - Other semicritical devices, occasional outbreaks
    - ENT scopes, endocavitary probes (prostate, vaginal, TEE), laryngoscopes, cystoscopes
    - Reduced microbial load, less complex
Noncritical Environmental Surfaces and Medical Devices


- Noncritical environmental surfaces and medical devices
- Transmission: secondary transmission by contaminating hands/gloves via contact with the environment and transfer to patient
- Control measures: hand hygiene and low-level disinfection
- Noncritical devices (stethoscopes, blood pressure cuffs, wound vacuum), rare outbreaks
Sterilization and Disinfection

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• Describe available methods for sterilization and types of indicators used to ensure the process was effective
• Understand the advantages and disadvantages of the various disinfectants and mechanical processes used to disinfect medical equipment and environmental surfaces
• Outline the controversies surrounding the reprocessing of endoscopes and disinfection of other complex medical instruments
Critical Items
Sterilization

The complete elimination or destruction of all forms of microbial life and is accomplished in healthcare facilities by either physical or chemical processes.
Heat resistant
• Steam sterilization

Heat sensitive
• Ethylene oxide
• Hydrogen peroxide gas plasma
• Ozone and hydrogen peroxide
• Vaporized hydrogen peroxide
Pre-Cleaning

• Ideally, instruments should arrive in Central Processing free on visible contamination
• Wipe instruments clean and keep lumens flushed throughout surgery. Soiled instruments that will not be reused should be allowed to soak in a basin of sterile water for the remainder of the procedures
• Many hospitals spray instruments with an enzymatic solution
• Keep instruments moist (e.g., damp towel) as it prevents hardening
Microbial Load on Surgical Instruments

Surgical instruments-<10^2 bacteria
Cleaning

- Items must be cleaned using water with detergents or enzymatic cleaners before processing.
- Cleaning reduces the bioburden and removes foreign material (organic residue and inorganic salts) that interferes with the sterilization process.
- Cleaning and decontamination should be done as soon as possible after the items have been used as soiled materials become dried onto the instruments.
Washer/Disinfector

- Five Chambers
  - Pre-wash: water/enzymatic is circulated over the load for 1 min
  - Wash: detergent wash solution (150°F) is sprayed over the load for 4 min
  - Ultrasonic cleaning: basket is lowered into ultrasonic cleaning tank with detergent for 4 min
  - Thermal and lubricant rinse: hot water (180°F) is sprayed over the load for 1 min; instrument milk lubricant is added to the water and is sprayed over the load
  - Drying: blower starts for 4 min and temperature in drying chamber 180°F
# Washer/Disinfector

## Removal/Inactivation of Inoculum (Exposed) on Instruments


<table>
<thead>
<tr>
<th>WD Conditions</th>
<th>Organism</th>
<th>Inoculum</th>
<th>Log Reduction</th>
<th>Positives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine</td>
<td>MRSA</td>
<td>2.6x10^7</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td>VRE</td>
<td>2.6x10^7</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td><em>P. aeruginosa</em></td>
<td>2.1x10^7</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td><em>M. terrae</em></td>
<td>1.4x10^8</td>
<td>7.8</td>
<td>2/8</td>
</tr>
<tr>
<td>Routine</td>
<td>GS spores</td>
<td>5.3x10^6</td>
<td>4.8</td>
<td>11/14</td>
</tr>
<tr>
<td>No Enz/Det</td>
<td>VRE</td>
<td>2.5x10^7</td>
<td>Complete</td>
<td>0/10</td>
</tr>
<tr>
<td>No Enz/Det</td>
<td>GS spores</td>
<td>8.3x10^6</td>
<td>5.5</td>
<td>8/10</td>
</tr>
</tbody>
</table>
Washer/disinfectors are very effective in removing/inactivating microorganisms from instruments
Cleaning Indicators for Washers

- Monitor the automated washer and instrument cleaning chemistry functionality
- Complete soil removal of the dried test soil pattern is a “pass”
- Indicator includes proteins, lipids, and polysaccharides to mimic common challenging test soils
Steam Sterilization
Rutala, Weber AJIC 2019;47:A3-A9

• Advantages
  ■ Non-toxic
  ■ Cycle easy to control and monitor
  ■ Inexpensive
  ■ Rapidly microbicidal
  ■ Least affected by organic/inorganic soils
  ■ Rapid cycle time
  ■ Penetrates medical packing, device lumens

• Disadvantages
  ■ Deleterious for heat labile instruments
  ■ Potential for burns
## Minimum Steam Sterilization Times

**Time at 132°C in Prevacuum Sterilizer**


<table>
<thead>
<tr>
<th>Item</th>
<th>Minimum exposure</th>
<th>Minimum drying time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped instruments</td>
<td>4 min</td>
<td>30 min</td>
</tr>
<tr>
<td>Textile packs</td>
<td>4 min</td>
<td>5 min</td>
</tr>
</tbody>
</table>
Immediate Use Steam Sterilization

• “Flash” originally defined as sterilization of an unwrapped object at 132°C for 3 min at 27-28 lbs pressure in gravity
• “Flash” used for items that must be used immediately and sterilized unpackaged (not sterile once removed from sterilizer)
• “Flash” is an antiquated term and replaced by “immediate use steam sterilization”
• The same critical reprocessing steps (such as cleaning, decontaminating, and transporting) must be followed
Immediate Use Steam Sterilization

- “Immediate Use” is defined as the shortest possible time between a sterilized item’s removal from sterilizer and aseptic transfer to sterile field; now same time-temp (132°C, 4min)
- A sterilized item intended for immediate use is not stored for future use.
- Sterilization process monitoring is essential
- Instruments inventories should be adequate to meet surgical volumes and permit the time to complete all critical elements of reprocessing
Sterilization of “Critical Objects”


Heat resistant
- Steam sterilization

Heat sensitive
- Ethylene oxide
- Hydrogen peroxide gas plasma
- Ozone and hydrogen peroxide
- Vaporized hydrogen peroxide
### Evaluation of Microbicidal Activities of Sterilization Technologies in Salt and Serum


<table>
<thead>
<tr>
<th>Organism</th>
<th>Mean Inoculating Suspension/mL</th>
<th>Mean Carrier Quantitation (Day of Run)</th>
<th>Mean Carrier Quantification (24 h ETO)</th>
<th>% Failure (Carriers Positive/Carriers Tested)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Steam</td>
</tr>
<tr>
<td>Vegetative cells</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em></td>
<td>$8.1 \times 10^6$</td>
<td>$2.0 \times 10^6$</td>
<td>$3.5 \times 10^4$</td>
<td>0 (0/30)</td>
</tr>
<tr>
<td><em>Escherichia coli</em></td>
<td>$1.1 \times 10^6$</td>
<td>$3.4 \times 10^6$</td>
<td>$5.1 \times 10^5$</td>
<td>0 (0/30)</td>
</tr>
<tr>
<td>Vanomycin-resistant enterococci</td>
<td>$5.9 \times 10^6$</td>
<td>$2.8 \times 10^6$</td>
<td>$2.8 \times 10^6$</td>
<td>0 (0/30)</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>$4.8 \times 10^6$</td>
<td>$2.3 \times 10^6$</td>
<td>$2.5 \times 10^6$</td>
<td>0 (0/30)</td>
</tr>
<tr>
<td><em>Mycobacterium terrae</em></td>
<td>$1.4 \times 10^6$</td>
<td>$5.2 \times 10^4$</td>
<td>$3.2 \times 10^5$</td>
<td>0 (0/20)</td>
</tr>
<tr>
<td>Vegetative cells, total</td>
<td></td>
<td></td>
<td></td>
<td>0 (0/140)</td>
</tr>
<tr>
<td><em>Bacillus atrophaeus</em> spores</td>
<td>$1.5 \times 10^7$</td>
<td>$1.2 \times 10^5$</td>
<td>$1.3 \times 10^5$</td>
<td>0 (0/30)</td>
</tr>
<tr>
<td><em>Geobacillus stearothermophilus</em> spores</td>
<td>$5.4 \times 10^6$</td>
<td>$5.1 \times 10^4$</td>
<td>$6.0 \times 10^4$</td>
<td>0 (0/30)</td>
</tr>
<tr>
<td><em>Clostridiales difficile</em> spores</td>
<td>$1.3 \times 10^7$</td>
<td>$4.4 \times 10^4$</td>
<td>$4.2 \times 10^4$</td>
<td>0 (0/20)</td>
</tr>
<tr>
<td>Spore total</td>
<td></td>
<td></td>
<td></td>
<td>0 (0/80)</td>
</tr>
<tr>
<td>Overall total</td>
<td>0 (0/220)</td>
<td>2 (6/310)</td>
<td>2 (5/270)</td>
<td>76 (206/270)</td>
</tr>
</tbody>
</table>

Note: ETO, ethylene oxide; HPGP, hydrogen peroxide gas plasma; FCS, fetal calf serum; ND, not done.

*To simulate inadequate cleaning, the inoculum for the vegetative bacteria contained 1% FCS and 0.66% salt but 10% FCS and 0.20% salt for the spores *B. atrophaeus* and *G. stearothermophilus* and 10% FCS and 0.52% salt *C. difficile* spores.

*Runs with ETO and HPGP failure of vegetative bacteria had higher carrier quantitation (day of run) than the mean carrier quantitation for the other runs and that organism (ie, $4.07 \times 10^6$ vs $2.54 \times 10^6$ for VRE; $8.39 \times 10^4$ vs $2.40 \times 10^4$ for *E. coli*).
“Dirty” (non-cleaned) Instruments

Bacteria

Blood (dry) and Bacteria

Blood (wet) and Bacteria
Steam sterilization is the most effective sterilization technology with the largest margin of safety, followed by ETO and hydrogen peroxide gas plasma.

<table>
<thead>
<tr>
<th>Test Organism</th>
<th>Method of Sterilization</th>
<th>Instrument “Dirty” (Uncleaned) With or Without Blood</th>
<th>Instrument Quantitation (Mean)</th>
<th>No. of Positives/No. of Runs (% Positive)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Geobacillus stearothermophilus</em> (spores)</td>
<td>Steam Sterilization</td>
<td>Dirty</td>
<td>~1.56 × 10^5</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dirty with blood (spores mixed with blood not sandwich)</td>
<td>~1.99 × 10^5</td>
<td>0/12 (0)</td>
</tr>
<tr>
<td>ETO</td>
<td>Dirty</td>
<td>~1.53 × 10^5</td>
<td>0/10 (0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dirty with blood</td>
<td>~2.35 × 10^5</td>
<td>0/11 (0)</td>
<td></td>
</tr>
<tr>
<td>HPGP</td>
<td>Dirty</td>
<td>~1.58 × 10^5</td>
<td>5/10 (50)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dirty with blood</td>
<td>~2.35 × 10^5</td>
<td>9/15 (60)</td>
<td></td>
</tr>
<tr>
<td><em>Mycobacterium terrae</em></td>
<td>Steam Sterilization</td>
<td>Dirty</td>
<td>~4.25 × 10^6</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td><em>P. aeruginosa</em></td>
<td>HPGP</td>
<td>Dirty</td>
<td>~1.81 × 10^6</td>
<td>3/15 (20)</td>
</tr>
<tr>
<td><em>Bacillus atrophaeus</em> (spores)</td>
<td>ETO</td>
<td>Dirty</td>
<td>~2.30 × 10^7</td>
<td>6/10 (60)</td>
</tr>
<tr>
<td></td>
<td>Dirty with blood</td>
<td>~4.08 × 10^7</td>
<td>9/10 (90)</td>
<td></td>
</tr>
<tr>
<td>MRSA</td>
<td>ETO</td>
<td>Dirty</td>
<td>~2.62 × 10^6</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td></td>
<td>Dirty with blood</td>
<td>~1.72 × 10^6</td>
<td>0/10 (0)</td>
<td></td>
</tr>
<tr>
<td>HPGP</td>
<td>Dirty</td>
<td>~1.10 × 10^6</td>
<td>4/10 (40)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dirty with blood</td>
<td>~1.27 × 10^6</td>
<td>4/10 (40)</td>
<td></td>
</tr>
<tr>
<td>Steam sterilization</td>
<td>Dirty</td>
<td>2.56 × 10^6</td>
<td>0/10 (0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dirty with blood</td>
<td>~5.20 × 10^8</td>
<td>0/10 (0)</td>
<td></td>
</tr>
<tr>
<td>VRE</td>
<td>ETO</td>
<td>Dirty</td>
<td>~2.27 × 10^6</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td></td>
<td>Dirty with blood</td>
<td>~3.59 × 10^6</td>
<td>0/10 (0)</td>
<td></td>
</tr>
<tr>
<td>HPGP</td>
<td>Dirty</td>
<td>~2.63 × 10^6</td>
<td>3/10 (30)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dirty with blood</td>
<td>~2.34 × 10^6</td>
<td>9/10 (90)</td>
<td></td>
</tr>
<tr>
<td>Steam sterilization</td>
<td>Dirty</td>
<td>1.90 × 10^6</td>
<td>0/10 (0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dirty with blood</td>
<td>2.72 × 10^5</td>
<td>0/10 (0)</td>
<td></td>
</tr>
</tbody>
</table>

Note: ETO, ethylene; *Study conditions not met, experiment was done under different conditions.

*Sandwich consists of...
### Effectiveness of the Microbicidal Activity of Steam Sterilization in the Presence of Blood on “Dirty” Instruments


<table>
<thead>
<tr>
<th>Test Organism</th>
<th>Method of Sterilization</th>
<th>Instruments “dirty” (non-cleaned) with or without blood(^2)</th>
<th>Instrument Quantitation (Mean)</th>
<th>% Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Geobacillus stearothermophilus</strong> (spores)</td>
<td>Steam Sterilization</td>
<td>Dirty</td>
<td>~1.56 \times 10^5</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dirty with blood (spores mixed with blood not sandwich(^2))</td>
<td>~1.99 \times 10^5</td>
<td>0/12 (0)</td>
</tr>
<tr>
<td><strong>Mycobacterium terrae</strong></td>
<td>Steam Sterilization</td>
<td>Dirty</td>
<td>~4.25 \times 10^6</td>
<td>0/10 (0)</td>
</tr>
</tbody>
</table>

\(^1\)Study conditions not representative of practice or manufacturer’s recommendations.

\(^2\)Sandwich consists of “dirty” or non-cleaned instrument, then an inoculum of spores or vegetative bacteria, and lastly overlaid with blood after inoculum dry. One *G. stearothermophilus* experiment was done with the spores mixed with the inoculum and then placed on the dirty instrument.
Conclusions

- All sterilization processes effective in killing spores
- Cleaning removes salts and proteins and must precede sterilization
- Failure to clean or ensure exposure of microorganisms to sterilant (e.g. connectors) could affect effectiveness of sterilization process
Sterilization Practices
Sterilization monitored routinely by combination of physical, chemical, and biological parameters

- **Physical** - cycle time, temperature, pressure
- **Chemical** - heat or chemical sensitive inks that change color when germicidal-related parameters present
- **Biological** - *Bacillus* spores that directly measure sterilization
Objectives of Monitoring the Sterilization Process

• Assures probability of absence of all living organisms on medical devices being processed
• Detect failures as soon as possible
• Removes medical device involved in failures before patient use
Sterilizer Receipt

Load: 01/34-54-3
Printout: 01/34-54-3

Condition: B: 01/34-54
Exhaust: B: 01/34-54
Total Cycle: B: 01/34-54

Temp. Min = 271.9°F
Temp. Max = 272.4°F

Control Temp = 272°F
Steril. Time = 45 Min
Dry Time = 45 Min
Sterilization Monitoring

Sterilization monitored routinely by combination of physical, chemical, and biological parameters

- **Physical** - cycle time, temperature, pressure
- **Chemical** - heat or chemical sensitive inks that change color when germicidal-related parameters present
- **Biological** - *Bacillus* spores that directly measure sterilization
Six Classes of Indicators Are Recognized by International Organization of Standards (ISO)

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 1</td>
<td>Process indicators are attached to or printed on the outside of all packs to discern which packages have been processed from those that have not been processed in a sterilizer.</td>
</tr>
<tr>
<td>Class 2</td>
<td>Bowie-Dick test is used to reveal the pass/fail rate in dynamic air removal steam sterilizers. This Class 2 chemical indicator should be used in an empty chamber daily, preferably before any loads are processed at the beginning of the day.</td>
</tr>
<tr>
<td>Class 3</td>
<td>Single parameter indicator is placed inside each package and provides data on time or temperature, revealing if one of these sterilization parameters has been met during a cycle.</td>
</tr>
<tr>
<td>Class 4</td>
<td>Multiparameter indicators react to two or more sterilization parameters, such as time and temperature or time and pressure.</td>
</tr>
<tr>
<td>Class 5</td>
<td>React to all critical parameters of sterilization cycle over a range of temperatures; performance must equal that of the biological indicators.</td>
</tr>
<tr>
<td>Class 6</td>
<td>Cycle specific; react to all critical parameters for a specified sterilization level; used at the pack/tray level.</td>
</tr>
</tbody>
</table>
## Sterility Indicators Table

<table>
<thead>
<tr>
<th>Steam Autoclave</th>
<th>After Exposure (Sterile)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Do not use)</td>
<td>(Ok if package is intact)</td>
</tr>
<tr>
<td>Tape</td>
<td></td>
</tr>
<tr>
<td>Strips</td>
<td></td>
</tr>
<tr>
<td><strong>STRATE-LINE™ sterilization mark</strong></td>
<td></td>
</tr>
<tr>
<td>Peel Pack</td>
<td></td>
</tr>
</tbody>
</table>

**Ethylene Oxide (ETO, gas)**

<table>
<thead>
<tr>
<th>Tape</th>
<th></th>
</tr>
</thead>
</table>
Biological Indicators

• Select BIs that contain spores of *Bacillus atrophaeus*

• Rationale: BIs are the only sterilization process monitoring device that provides a direct measure of the lethality of the process
• Steam - *Geobacillus stearothermophilus*
• Dry heat - *B. atrophaeus (formerly B. subtilis)*
• ETO - *B. atrophaeus*
• New low temperature sterilization technologies
  • HP gas plasma - *G. stearothermophilus*
  • HP/Ozone - *G. stearothermophilus*
Rapid Readout BIs for Steam Now Require a 1-3h Readout Compared to 24-48h

Super Rapid Readout Biological Indicators
Commercially available

1491 BI (blue cap)
• Monitors 270°F and 275°F gravity –displacement steam sterilization cycles
• 24-minute result

1492V BI (brown cap)
• Monitors 270°F and 275°F dynamic-air-removal (pre-vacuum) steam sterilization cycles
• 24-minute result
Rapid Readout Biological Indicator for Steam (24m), ETO (4hr) and HP Sterilizers (variable)
Vaporized Hydrogen Peroxide (VHP) Biological Indicator Options (*all G. stearothermophilus*)

Refer to BI manufacturer’s IFU for cycles the BI is cleared for

<table>
<thead>
<tr>
<th>VHP read out time</th>
<th>Number of cleared biological indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 hours</td>
<td>2</td>
</tr>
<tr>
<td>2 hours</td>
<td>1</td>
</tr>
<tr>
<td>30 minutes</td>
<td>1</td>
</tr>
<tr>
<td>24 minutes</td>
<td>1</td>
</tr>
<tr>
<td>20 minutes</td>
<td>1</td>
</tr>
<tr>
<td>15 minutes</td>
<td>1</td>
</tr>
</tbody>
</table>
Recommendations
Monitoring of Sterilizers

• Monitor each load with physical and chemical (internal and external) indicators.

• Use biological indicators to monitor effectiveness of sterilizers at least weekly with spores intended for the type of sterilizer.

• Use biological indicators for every load containing implantable items
Recommendations
Monitoring of Sterilizers

- Following a single positive biological indicator used with a method other than steam, treat as non-sterile all items that have been processed in that sterilizer, dating back to last negative biological indicator.

- Following a positive biological indicator with steam sterilization, objects, other than implantable objects, do not need to be recalled because of a single positive spore test unless the sterilizer or procedure is defective or inappropriate cycle settings. If additional spore tests remain positive, consider the items nonsterile and recall and reprocess the items from the suspect load.
Recommendations
Methods of Sterilization

• Steam is preferred for critical items not damaged by heat
• Follow the operating parameters recommended by the manufacturer
• Use low temperature sterilization technologies for reprocessing critical items damaged by heat
• Use immediately critical items that have been sterilized by peracetic acid immersion process (no long term storage)
Sterilization and Disinfection

• Describe the Spaulding classification scheme for disinfection of patient care items
• Describe available methods for sterilization and types of indicators used to ensure the process was effective
• Understand the advantages and disadvantages of the various disinfectants and mechanical processes used to disinfect medical equipment and environmental surfaces
• Outline the controversies surrounding the reprocessing of endoscopes and disinfection of other complex medical instruments
Semicritical Medical Devices
Rutala et al. AJIC 2019;47:A3-A9

- **Semicritical**
  - Transmission: direct contact
  - Control measure: high-level disinfection
  - Endoscopes top ECRI list of 10 technology hazards, >130 outbreaks (GI, bronchoscopes)
    - 0 margin of safety
    - Microbial load, $10^7$-$10^{10}$
    - Complexity
    - Biofilm
  - Other semicritical devices, rare outbreaks
    - ENT scopes, endocavitary probes (prostate, vaginal, TEE), laryngoscopes, cystoscopes
    - Reduced microbial load, less complex
**High-Level Disinfection of “Semicritical Objects”**

Rutala, Weber. AJIC 2019;47:A3-A9

**Exposure Time > 8m-45m (US), 20°C**

<table>
<thead>
<tr>
<th>Germicide</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde</td>
<td>≥ 2.0%</td>
</tr>
<tr>
<td><strong>Ortho-phthalaldehyde</strong></td>
<td>0.55%</td>
</tr>
<tr>
<td>Hydrogen peroxide*</td>
<td>7.5%</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
<td>1.0%/0.08%</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
<td>7.5%/0.23%</td>
</tr>
<tr>
<td>Hypochlorite (free chlorine)*</td>
<td>650-675 ppm</td>
</tr>
<tr>
<td><strong>Accelerated hydrogen peroxide</strong></td>
<td>2.0%</td>
</tr>
<tr>
<td>Peracetic acid</td>
<td>0.2%</td>
</tr>
<tr>
<td>Glut and isopropanol</td>
<td>3.4%/26%</td>
</tr>
<tr>
<td>Glut and phenol/phenate**</td>
<td>1.21%/1.93%</td>
</tr>
</tbody>
</table>

*May cause cosmetic and functional damage; **efficacy not verified
Microbiological Disinfectant Hierarchy
Rutala WA, Weber DJ, HICPAC. www.cdc.gov

Most Resistant

Spores (C. difficile)

Mycobacteria (M. tuberculosis)

Non-Enveloped Viruses (norovirus, HAV, polio)

Fungi (Candida, Trichophyton)

Bacteria (MRSA, VRE, Acinetobacter)

Enveloped Viruses (HIV, HSV, Flu)

Most Susceptible
HBV and HCV transmission during endoscopy and use of semicritical medical devices can occur, but it is rare (3).

No articles related to possible transmission of HIV via medical device.

Greatest evidence of transmission associated with GI endoscopes/bronchoscopes (~130 outbreaks) likely due to microbial load and complexity.

Several other semicritical medical devices are associated with infections related to inadequate reprocessing.
# Comparison of Glutaraldehyde and OPA

Rutala, Weber. AJIC 2019;47:A3-A9

<table>
<thead>
<tr>
<th>Glutaraldehyde</th>
<th>OPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;2.0%</td>
<td>0.55%</td>
</tr>
<tr>
<td>HLD: 45 min at 25ºC</td>
<td>HLD: 12 min at 20ºC</td>
</tr>
<tr>
<td>Needs activator</td>
<td>No activator needed</td>
</tr>
<tr>
<td>14-day use life, 2-year shelf life</td>
<td>14-day use life, 2-year shelf life</td>
</tr>
<tr>
<td>ACGIH ceiling limit, 0.05ppm</td>
<td>No ACGIH or OSHA limit</td>
</tr>
<tr>
<td>Strong odor</td>
<td>Weak odor</td>
</tr>
<tr>
<td>MEC, 1.5%</td>
<td>MEC, 0.3%</td>
</tr>
<tr>
<td>Cost - $10/gallon</td>
<td>Cost - $30/gallon</td>
</tr>
<tr>
<td>Disadv-slow mycobactericidal activity</td>
<td>Disadv-Anaphylactic rxn w/ repeated exposure through cysto</td>
</tr>
</tbody>
</table>
Improved Hydrogen Peroxide
Rutala, Weber. AJIC 2019;47:A3-A9

• Advantages
  ■ No activation required
  ■ Enhanced removal of organisms
  ■ No disposal issues
  ■ No odor or irritation issues
  ■ No special venting requirements
  ■ Does not coagulate blood or fix tissues to surfaces
  ■ Use studies published
  ■ 8-min at 20°C HLD claim

• Disadvantages
  ■ Material compatibility concerns for brass, zinc, copper, and nickel/silver plating (cosmetic and functional damage)
  ■ Eye damage with contact
Peracetic Acid
Rutala, Weber. AJIC 2019;47:A3-A9

• Advantages
  ■ Enhanced removal of organisms
  ■ Single-use system eliminates need for concentration testing
  ■ Compatible with many materials and instruments
  ■ Does not coagulate blood or fix tissues to surfaces
  ■ Rapidly sporicidal

• Disadvantages
  ■ Used for immersible instruments only
  ■ More expensive than many HLD
  ■ Eye damage with contact
  ■ Potential material incompatibility (e.g., aluminum anodized coating becomes dull)
Sterilization and Disinfection

- Describe the Spaulding classification scheme for disinfection of patient care items
- Describe available methods for sterilization and types of indicators used to ensure the process was effective
- Understand the advantages and disadvantages of the various disinfectants and mechanical processes used to disinfect medical equipment and environmental surfaces
- Outline the controversies surrounding the reprocessing of endoscopes and disinfection of other complex medical instruments
Reprocessing Medical Devices: The Good, The Bad and The Ugly
Based on outbreak data, if eliminated deficiencies associated with cleaning, disinfection, AER, contaminated water and drying would eliminate about 85% of the outbreaks.

<table>
<thead>
<tr>
<th>Scope</th>
<th>Outbreaks</th>
<th>Micro (primary)</th>
<th>Pts Contaminated</th>
<th>Pts Infected</th>
<th>Cause (primary)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper GI</td>
<td>19</td>
<td>Pa, <em>H. pylori</em>, <em>Salmonella</em></td>
<td>169</td>
<td>56</td>
<td>Cleaning/Disinfection (C/D)</td>
</tr>
<tr>
<td>Sigmoid/Colonoscopy</td>
<td>5</td>
<td><em>Salmonella</em>, HCV</td>
<td>14</td>
<td>6</td>
<td>Cleaning/Disinfection</td>
</tr>
<tr>
<td>ERCP</td>
<td>23</td>
<td><em>P. aeruginosa</em> (Pa)</td>
<td>152</td>
<td>89</td>
<td>C/D, water bottle, AER</td>
</tr>
<tr>
<td>Bronchoscopy</td>
<td>51</td>
<td>Pa, Mtb, Mycobacteria</td>
<td>778</td>
<td>98</td>
<td>C/D, AER, water</td>
</tr>
<tr>
<td>Totals</td>
<td>98</td>
<td></td>
<td>1113</td>
<td>249</td>
<td></td>
</tr>
</tbody>
</table>
## Duodenoscope-Related Outbreaks of CRE and Other MDROs Without Reprocessing Breaches

Rutala et al. AJIC 2019;47:A62-A66

<table>
<thead>
<tr>
<th>MDRO</th>
<th>Resistance gene</th>
<th>No. of patients (infected)</th>
<th>Propagated outbreak</th>
<th>Positive scope(s)</th>
<th>Molecular link</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Klebsiella pneumoniae</em></td>
<td><em>mcr-1</em></td>
<td>2</td>
<td>No</td>
<td>No</td>
<td>Yes-WGS</td>
<td>Shencoy et al, 2018²¹</td>
</tr>
<tr>
<td><em>K pneumoniae</em></td>
<td><em>bla</em>₉₉₂-2₃₂</td>
<td>15 (8)</td>
<td>No</td>
<td>No</td>
<td>Yes-PCR</td>
<td>Kim et al, 2016¹⁹</td>
</tr>
<tr>
<td><em>Escherichia coli</em> (AmpC)</td>
<td><em>bla</em>₉₉₂-₉</td>
<td>35</td>
<td>No</td>
<td>Yes (2)</td>
<td>Yes-PCR, PFGE</td>
<td>Wendendorf et al, 2015¹⁶</td>
</tr>
<tr>
<td><em>K pneumoniae</em></td>
<td><em>bla</em>₉₉₉-₉₈</td>
<td>12</td>
<td>Yes</td>
<td>No</td>
<td>Yes-PCR, PFGE</td>
<td>Kola et al, 2015²³</td>
</tr>
<tr>
<td><em>K pneumoniae</em></td>
<td><em>bla</em>KPC</td>
<td>34?</td>
<td>No</td>
<td>Yes (3)</td>
<td>Yes-PCR, PFGE, MLST, WGS</td>
<td>Marsh et al, 2015²²</td>
</tr>
<tr>
<td><em>E coli</em></td>
<td><em>bla</em>₁₉₉</td>
<td>39</td>
<td>Yes</td>
<td>Yes (1)</td>
<td>Yes-PCR, PFGE</td>
<td>Epstein et al, 2014¹⁷</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em></td>
<td><em>bla</em>₁₉₉</td>
<td>22</td>
<td>Yes</td>
<td>Yes (1)</td>
<td>Yes-PCR*, PFGE, repetitive-sequence-based PCR typing</td>
<td>Verfaillie et al, 2015²⁴</td>
</tr>
<tr>
<td><em>E coli</em></td>
<td><em>bla</em>₁₉₉-₁</td>
<td>3 (3)</td>
<td>No</td>
<td>No</td>
<td>Unknown</td>
<td>Smith et al, 2015²⁰</td>
</tr>
<tr>
<td><em>K pneumoniae</em></td>
<td><em>bla</em>KPC, <em>bla</em>₁₉₉</td>
<td>13</td>
<td>Yes</td>
<td>Yes (2)</td>
<td>Yes-PCR, PFGE, MLST</td>
<td>Carbone et al, 2010¹⁸</td>
</tr>
</tbody>
</table>

CRE, carbapenem-resistant *Enterobacteriaceae*; MDRO, multidrug-resistant organism; MLST, multilocus sequence typing; PCR, polymerase chain reaction; PFGE, pulsed-field gel electrophoresis; WGS, whole-genome sequencing.

*PCR for resistance gene.
Reason for Endoscope-Related Outbreaks


• Margin of safety with endoscope reprocessing minimal or non-existent

• Microbial load
  - GI endoscopes contain $7-10 \log_{10} (10^{7-10})$
  - Cleaning results in $2-6 \log_{10}$ reduction
  - High-level disinfection results in $4-6 \log_{10}$ reduction
  - Results in a total $6-12 \log_{10}$ reduction of microbes
  - Level of contamination after processing: $4 \log_{10}$ (maximum contamination, minimal cleaning/HLD)

• Complexity of endoscope and endoscope reprocessing
• Biofilms-may contribute to failure of endoscope reprocessing
ENDOSCOPE REPROCESSING: CHALLENGES

Complex [elevator channel]-10^7-10^10 bacteria/endoscope

Surgical instruments-<10^2 bacteria
Reason for Endoscope-Related Outbreaks

• Margin of safety with endoscope reprocessing minimal or non-existent

• Microbial load
  ◆ GI endoscopes contain $10^7$-$10$^10
  ◆ Cleaning results in 2-6 log$_{10}$ reduction
  ◆ High-level disinfection results in 4-6 log$_{10}$ reduction
  ◆ Results in a total 6-12 log$_{10}$ reduction of microbes
  ◆ Level of contamination after processing: 4log$_{10}$ (maximum contamination, minimal cleaning/HLD)

• Complexity of endoscope and endoscope reprocessing

• Biofilms—may contribute to failure of endoscope reprocessing
FEATURES OF ENDOSCOPES THAT PREDISPOSE TO DISINFECTION FAILURES


- Heat labile
- Long, narrow lumens (3.5ft, 1-3mm)
- Right angle bends
- Rough or pitted surfaces
- Springs and valves
- Damaged channels may impede microbial exposure to HLD
- Heavily contaminated with pathogens, $10^7-10^{10}$
- Cleaning ($2-6 \log_{10}$ reduction) and HLD ($4-6 \log_{10}$ reduction) essential for patient safe instrument
ENDOSCOPE REPROCESSING
CDC 2008: Multi-Society Guideline on Endoscope Reprocessing, 2017

- PRECLEAN-point-of-use (bedside) remove debris by wiping exterior and aspiration of detergent through air/water and biopsy channels; leak test
- CLEAN-mechanically cleaned with water and enzymatic cleaner
- HLD/STERILIZE-immersse scope and perfuse HLD/sterilant through all channels for exposure time (>2% glut at 20m at 20°C). If AER used, review model-specific reprocessing protocols from both the endoscope and AER manufacturer
- RINSE-scope and channels rinsed with sterile water, filtered water, or tap water. Flush channels with alcohol and dry
- DRY-use forced air to dry insertion tube and channels
- STORE-hang in vertical position to facilitate drying; stored in a manner to protect from contamination
### Complexity of Endoscope Reprocessing

**Chua et al. Techniq Innov Gastro Endo 2021;23:190**

<table>
<thead>
<tr>
<th>Pre-Cleaning</th>
<th>Leak Testing</th>
<th>Manual Cleaning</th>
<th>Visual Inspection</th>
<th>HLD</th>
<th>Drying &amp; Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wipe insertion tube with detergent solution</td>
<td>Remove suction, air, water, &amp; biopsy valves</td>
<td>Immerse the endoscope into an appropriate detergent solution</td>
<td>Visual inspection should be performed throughout however particular attention prior to HLD.</td>
<td>Test and monitor the disinfectant according to manufacture instructions.</td>
<td>Flush all channels with 70% to 90% ethyl or isopropyl alcohol.</td>
</tr>
<tr>
<td>Suction detergent solution through endoscope until visibly clear</td>
<td>Discard disposable parts</td>
<td>Wash the exterior of the endoscope by brushing and wiping while submerged.</td>
<td>Inspect for conditions that could affect disinfection process (cracks, retained debris)</td>
<td>Completely immerse the endoscope in a basin of high-level disinfectant.</td>
<td>Purge all channels with filtered compressed air.</td>
</tr>
<tr>
<td>Flush and manipulate the forcep elevator (duodenoscope or echoendoscope)</td>
<td>Attach leak tester and pressurize the endoscope before submerging in clear water. Do not use detergent.</td>
<td>Brush all reusable &amp; removable parts including valves, biopsy cover &amp; openings.</td>
<td>Use magnification &amp; adequate lighting to assist in visual inspection</td>
<td>Flush high-level disinfectant into all channels until it can be seen exiting opposite end</td>
<td>Removal all channel adapters.</td>
</tr>
<tr>
<td>Flush air and water channels</td>
<td>Perform leakage test. Flex distal end of endoscope in all directions and manipulate buttons.</td>
<td>Perform additional manufacture specific cleaning for duodenoscope elevator mechanisms, echoendoscopes, &amp; double channel endoscopes.</td>
<td>Use a camera or borescope for internal channels, if available</td>
<td>Cover soaking basin with tight fitting lid.</td>
<td>Dry exterior of endoscope with soft, clean, lint-free towel.</td>
</tr>
<tr>
<td>Flush auxiliary water channels</td>
<td>Remove from sink or basin. Turn off and disconnect leak tester. Depressurize the endoscope and ensure the video cap is secure.</td>
<td>Flush all channels with detergent solution and soak the endoscope and its internal channels for a period specified by manufacturer.</td>
<td>Use a camera or borescope for repair or disposal</td>
<td>Soak the endoscope for the required temperature and time using appropriate monitoring or automated HLD</td>
<td>Dry all removal parts and do not attach to endoscope during storage.</td>
</tr>
<tr>
<td>Detach endoscope from light source and suction pump</td>
<td>Remove endoscope from service if leak is identified for repair or disposal.</td>
<td>Thoroughly rinse the endoscope and all removable parts with clean water.</td>
<td>Repeat manual cleaning as needed</td>
<td>Purge all channels with air before removing the endoscope from the high-level disinfectant</td>
<td>Use a system to identify which endoscope has been reprocessed (i.e. tagging)</td>
</tr>
<tr>
<td>Attach protective video cap</td>
<td></td>
<td>Purge water from all channels using forced air and dry exterior using lint free cloth</td>
<td>Remove damaged endoscope from service for repair or disposal</td>
<td>Thoroughly rinse the endoscope and all removable parts with clean water.</td>
<td>Use storage cabinets that can be cleaned and disinfected with EPA registered high level disinfectant.</td>
</tr>
<tr>
<td>Transport to a dedicated reprocessing area in appropriate covered container</td>
<td></td>
<td>Purge water from all channels using forced air and dry exterior using lint free cloth</td>
<td></td>
<td>Purge water from all channels using forced air and dry exterior using lint free cloth.</td>
<td>Hang endoscopes in an upright position with detachable components removed.</td>
</tr>
</tbody>
</table>
Complexity of Endoscope Reprocessing

Chua et al. Techniq Innov Gastro Endo 2021;23:190

Pre-Cleaning
- Wipe insertion tube with detergent solution
- Suction detergent solution through endoscope until visibly clear
- Flush and manipulate the forceps elevator (duodenoscope or echoendoscope)
- Flush air and water channels
- Flush auxiliary water channels
- Detach endoscope from light source and suction pump
- Attach protective video cap
- Transport to a dedicated reprocessing area in appropriate covered container

Leak Testing
- Remove suction, air, water, & biopsy valves
- Discard disposable parts
- Attach leak tester and pressurize the endoscope before submerging in clear water. Do not use detergent.
- Perform leakage test. Flex distal end of endoscope in all directions and manipulate buttons.
- Remove from sink or basin. Turn off and disconnect leak tester. Depressurize the endoscope and ensure the video cap is secure.

Manual Cleaning
- Immerse the endoscope into an appropriate detergent solution
- Wash the exterior of the endoscope by brushing and wiping while submerged.
- Brush all reusable & removable parts including valves, biopsy cover & openings.
- Perform additional manufacturer-specific cleaning for duodenoscope elevator mechanisms, echoendoscopes, & double channel endoscopes.
- Flush all channels with detergent solution and soak the endoscope and its internal channels for a period specified by manufacturer.
- Thoroughly rinse the endoscope and all removable parts with clean water.
- Purge water from all channels using forced air and dry exterior using lint free cloth

Visual Inspection
- Visual inspection should be performed throughout however particular attention prior to HLD.
- Inspect for conditions that could affect disinfection process (cracks, retained debris)
- Use magnification & adequate lighting to assist in visual inspection
- Use a camera or borescope for internal channels, if available

HLD
- Test and monitor the disinfectant according to manufacture instructions.
- Completely immerse the endoscope in a basin of high-level disinfectant.
- Flush high-level disinfectant into all channels until it can be seen exiting opposite end.
- Cover soaking basin with tight fitting lid.
- Soak the endoscope for the required temperature and time using appropriate monitoring or automated HLD
- Repeat manual cleaning as needed
- Remove damaged endoscope from service for repair or disposal

Drying & Storage
- Flush all channels with 70% to 90% ethyl or isopropyl alcohol.
- Purge all channels with filtered compressed air.
- Removal all channel adapters
- Dry exterior of endoscope with soft, clean, lint-free towel
- Dry all removal parts and do not attach to endoscope during storage
- Use storage cabinets that can be cleaned and disinfected with EPA registered high level disinfectant.
- Hang endoscopes in an upright position with detachable components removed.
Reprocessing Channeled Endoscopes
Cystoscope- “completely immerse” in HLD (J Urology 2008.180:588)
Reprocessing Channeled Endoscopes Manually

Cystoscope-HLD perfused through lumen with syringe (luer locks onto port and syringe and lumen filled with HLD)
Reprocessing Channeled Endoscopes

Exposure Method | CRE (K. pneumoniae) Inoculum before HLD (glutaraldehyde) | CRE (K. pneumoniae) Contamination after HLD
---|---|---
Passive HLD (immersed, not perfused) | 3.2x10^8 1.9x10^9 4.1x10^8 | 3.1x10^8 4.6x10^8 1.0x10^8
Active HLD (perfused HLD into channel with syringe) | 3.0x10^8 9.2x10^8 8.4x10^8 | 0 0 0

- Pathogens must have exposure to HLD for inactivation
- Immerse channeled flexible scope into HLD will not inactivate channel pathogens
- Completely immerse the endoscope in HLD and ensure all channels (e.g., hysteroscopes, cystoscopes) are perfused
- Air pressure in channel stronger than fluid pressure at fluid-air interface
Endoscope Reprocessing Methods

Cori L. Ofstead, MSPH
Harry P. Wetzler, MD, MSPH
Alycea K. Snyder, BA
Rebecca A. Horton, DPT

Endoscope Reprocessing Methods
A Prospective Study on the Impact of Human Factors and Automation

ABSTRACT
The main cause of endoscope-associated infections is failure to adhere to reprocessing guidelines. More information about factors impacting compliance is needed to support the development of effective interventions. The purpose of this multi-site, observational study was to evaluate reprocessing practices, employee perceptions, and occupational health issues. Data were collected utilizing interviews, surveys, and direct observation. Written reprocessing policies and procedures were in place at all five sites, and employees affirmed the importance of most recommended steps. Nevertheless, observers documented guideline adherence, with only 14% of endoscopes reprocessed using manual cleaning methods with automated high-level disinfection versus 75.4% of those reprocessed using an automated endoscope cleaner and reprocessor. The majority reported health problems (i.e., pain, decreased flexibility, numbness, or tingling). Physical discomfort was associated with time spent reprocessing (p = .041). Discomfort diminished after installation of automated endoscope cleaners and reprocers (p = .001). Enhanced training and accountability, combined with increased automation, may ensure guideline adherence and patient safety while improving employee satisfaction and health.
Performed all 12 steps with only 1.4% of endoscopes using manual versus 75.4% of those processed using AER

<table>
<thead>
<tr>
<th>Observed Activity</th>
<th>Steps Completed (%) (n = 69)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leak test performed in clear water</td>
<td>77</td>
</tr>
<tr>
<td>Disassemble endoscope completely</td>
<td>100</td>
</tr>
<tr>
<td><strong>Brush all endoscope channels and components</strong></td>
<td><strong>43</strong></td>
</tr>
<tr>
<td>Immerse endoscope completely in detergent</td>
<td>99</td>
</tr>
<tr>
<td>Immerse components completely in detergent</td>
<td>99</td>
</tr>
<tr>
<td>Flush endoscope with detergent</td>
<td>99</td>
</tr>
<tr>
<td>Rinse endoscope with water</td>
<td>96</td>
</tr>
<tr>
<td>Purge endoscope with air</td>
<td>84</td>
</tr>
<tr>
<td>Load and complete automated cycle for high-level disinfection</td>
<td>100</td>
</tr>
<tr>
<td>Flush endoscope with alcohol</td>
<td>86</td>
</tr>
<tr>
<td>Use forced air to dry endoscope</td>
<td>45</td>
</tr>
<tr>
<td>Wipe down external surfaces before hanging to dry</td>
<td>90</td>
</tr>
</tbody>
</table>
Automated Endoscope Reprocessors

AERs automate and standardize endoscope reprocessing steps
“Given the choice of improving technology or improving human behavior, technology is the better choice”

Robert A. Weinstein, MD
Biofilms on Instruments and Environmental Surfaces
Alfa, AJIC 2019;47:A39-A45

• Three types of biofilm
  ■ Traditional hydrated biofilm (water content 90%)
  ■ Build-up biofilm—may contribute to failure of endoscope reprocessing
  ■ Dry surface biofilm—heterogenous accumulation of organisms and other material in a dry matrix (water content 61%)
    ◆ Raises questions about the inactivation of microbes with a dry surface biofilm by currently used cleaning/disinfecting methods
Figure 1 Comparison of traditional to cyclic build-up biofilm

<table>
<thead>
<tr>
<th>Stage 1</th>
<th>Stage 2</th>
<th>Stage 3</th>
</tr>
</thead>
</table>

**Direction of Fluid Flow:**
Continuous bathed in Fluid

Biofilm

Continuous Hydration
~300 - 500μm thick

**Cyclic Build-up Biofilm**
Cycle 1 → Cycle 2 → Cycle 50

Build-up Biofilm; layers of dried organic matrix with embedded organisms

Cycle:
- post-patient: hydrated
- cleaning: hydrated
- disinfection: hydrated
- storage: dry

~10 - 50μm thick

High-Level Disinfection
No Margin of Safety

0 margin of safety

Microbial contamination $10^7$-$10^{10}$: compliant with reprocessing guidelines. 10,000 microbes after reprocessing:

maximum contamination, minimal cleaning ($10^2$)/HLD ($10^4$)
If the margin of safety is so small that perfection is required, then the design is too complex and the process is too unforgiving to be practical in a real-world setting.
What Should We Do Now?
Gastrointestinal Endoscopes
A Need to Shift From Disinfection to Sterilization?

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

More than 10 million gastrointestinal endoscopic procedures are performed annually in the United States for diagnostic purposes, therapeutic interventions, or both. Because gastrointestinal endoscopes contact mucosal surfaces, use of a contaminated endoscope may lead to patient-to-patient transmission of potential pathogens with a subsequent risk of infection. In this issue of JAMA, Epstein and colleagues report findings from their investigation of a cluster of New Delhi metallo-β-lactamase (NDM)-producing Escherichia coli associated with gastrointestinal endoscopy that occurred from March 2013 to July 2013 in a single hospital in northeastern Illinois. During the 5-month period, 9 pa-

First, endoscopes are semicritical devices, which contact mucous membranes or nonintact skin, and require at least high-level disinfection. High-level disinfection achieves complete elimination of all microorganisms, except for small numbers of bacterial spores. Because flexible gastrointestinal endoscopic instruments are heat labile, only high-level disinfection with chemical agents or low-temperature sterilization technologies are possible. However, no low-temperature sterilization technology is US Food and Drug Administration (FDA)–cleared for gastrointestinal endoscopes such as duodenoscopes.

Second, more health care–associated outbreaks and clusters of infection have been linked to contaminated endoscopes than to any other medical device. However, until now,
What Is the Public Health Benefit?
No ERCP-Related Infections

Margin of Safety—currently nonexistent; sterilization will provide a safety margin (~6 log\(_{10}\)). To prevent infections, all duodenoscopes should be devoid of microbial contamination.

\[
\text{HLD (6 log}_{10}\text{ reduction)} \quad \text{vs} \quad \text{Sterilization (12 log}_{10}\text{ reduction=SAL 10}^{-6})
\]
EH Spaulding believed that how an object will be disinfected depended on the object’s intended use (proposed clarification).

CRITICAL - objects which directly or indirectly/secondarily (i.e., via a mucous membrane such as duodenoscope, cystoscope, bronchoscope) enter normally sterile tissue or the vascular system or through which blood flows should be sterile.

SEMICRITICAL - objects that touch mucous membranes or skin that is not intact require a disinfection process (high-level disinfection [HLD]) that kills all microorganisms but high numbers of bacterial spores.

NONCRITICAL - objects that touch only intact skin require low-level disinfection (or non-germicidal detergent).
Evidence-Based Recommendation for Sterilization of Endoscopes

(FDA Panel Recommendation for Duodenoscopes, May 2015; more peer-reviewed publications (>150) for the need for shifting from disinfection to sterilization than any other recommendation of AAMI, CDC [HICPAC], SHEA, APIC, SGNA, ASGE)

>130 plus endoscope-related outbreaks
GI endoscope contamination rates of 20-40% after HLD
Scope commonly have disruptive/irregular surfaces
>50,000 patient exposures involving HLD
Supplemental Measures to Reduce Infection Risk


Hospitals performing ERCPs should do one of the following; FDA adopted these recommendations

- **Ethylene oxide sterilization** after high level disinfection with periodic microbiologic surveillance
- **Double high-level disinfection** with periodic microbiologic surveillance
- High-level disinfection with scope quarantine until negative culture
- **Liquid chemical sterilant** processing system using peracetic acid (rinsed with extensively treated potable water) with periodic microbiologic surveillance
- High-level disinfection with periodic microbiologic surveillance
Did supplemental measures work?
Supplemental Measures for Endoscope Reprocessing


- In a nonoutbreak setting, repeat HLD has no additional benefit compared with single HLD in reducing bacterial contamination rates for duodenoscopes.
- In nonoutbreak setting, limited data suggest that ETO sterilization does not reduce bacterial contamination rates in duodenoscopes compared with single HLD.
- No significant difference of positive cultures when comparing double HLD (8) with duodenoscopes undergoing liquid chemical sterilant (9).
- The use of ETO sterilization on duodenoscopes during infectious outbreaks has been associated with terminating these outbreaks and such a modality should be considered in selected settings and patient populations.
- However, many barriers to widespread use of ETO including cost, only 20% hospital use ETO (availability), possible damage to scopes, exposure of staff to ETO, exposure/turnaround time.
Gastrointestinal Endoscopes
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Do ultrasound transducers used for placing peripheral or central venous access devices require HLD/sterilization?
“All transducers/probes used for peripheral VAD insertion will undergo, at a minimum, low-level disinfection…. Clean (step 1) the probe prior to disinfection (step 2).

During assessment, consider using a single-use condom or commercially manufactured transducer sheath (excluded: transparent dressing, gloves) during all use where there is the possibility of contact with blood/body fluids or non-intact skin”

“Perform ALL ultrasound guided vascular access device insertions (PIV, Midline, PICC, CVC, arterial line) with the use of a sterile sheath and single-use sterile gel”.

After the procedure, the used sheath should be inspected for tears and the transducer inspected for potential compromise

Once inspected, the probe should be cleaned and then disinfected.
Transducer Disinfection for Insertion of Peripheral and Central Catheters


- All clinicians involved in ultrasound guidance should undergo comprehensive training on disinfection of the US transducers.
- The AVA recommendations are similar to guidelines from the American Institute for Ultrasound in Medicine (AIUM): that is, internal probes-HLD; “interventional percutaneous procedure probes that are used for percutaneous needle or catheter placement…should be cleaned using LLD and be used in conjunction with a single-use sterile probe cover”, if probe cover compromised HLD the probe.
Semicritical/Critical Reprocessing Failures

- Examples of failures
  - Use Quat/Alcohol wipe rather than HLD (ENT, vaginal probes)
  - Failure to monitor concentration of HLD
  - Staff did not flush and brush all channels
  - Channels not perfused with HLD (cystoscopes)
  - Time and/or temperature on AER was wrong
  - Steam cycle at 0 minutes rather than 4 minutes (132°C)
How to Assess Risk of Disease Transmission to Patients When There Is a Failure to Follow Recommended Disinfection and Sterilization Guidelines

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

BACKGROUND. Disinfection and sterilization are critical components of infection control. Unfortunately, breaches of disinfection and sterilization guidelines are not uncommon.

OBJECTIVE. To describe a method for evaluating a potential breach of guidelines for high-level disinfection and sterilization of medical devices.

METHODS. The appropriate scientific literature was reviewed to determine the frequency of failures of compliance. A risk assessment model was constructed.

RESULTS. A 14-step protocol was constructed to aid infection control professionals in the evaluation of potential disinfection and sterilization failures. In addition, a model is presented for aiding in determining how patients should be notified of the potential adverse event. Sample statements and letters are provided for communicating with the public and individual patients.

CONCLUSION. Use of a protocol can guide an institution in managing potential disinfection and sterilization failures.

Infect Control Hosp Epidemiol 2007; 28:146-155

In the United States in 1996, there were approximately 46,500,000 surgical procedures and a much larger number of infection failure on record involved the distribution of an inactive lot of glutaraldehyde disinfectant solution that had
Failure to Follow Disinfection and Sterilization Principles

• What do you do?
  ■ Follow the 14 steps at website www.disinfectionandsterilization.org (confirm failure, embargo improperly D/S items, investigate the cause, etc)
  ■ The steps provide a general outline, but each event is unique and you must be flexible and adaptable
  ■ Communication among key stakeholders is very important
  ■ Ethical to notify patients if there is a risk—should be upfront and factual
  ■ Train staff and access processes/practices to minimize recurrence
  ■ These are stressful events (patients and staff) but the goal is to assess failure and protect patients rather than assessing blame
Sterilization and Disinfection

• Describe the Spaulding classification scheme for disinfection of patient care items
• Describe available methods for sterilization and types of indicators used to ensure the process was effective
• Understand the advantages and disadvantages of the various disinfectants and mechanical processes used to disinfect medical equipment and environmental surfaces
• Outline the controversies surrounding the reprocessing of endoscopes and disinfection of other complex medical instruments
High-Level Disinfection, Sterilization and Disinfection
Summary

- Disinfection and sterilization technologies and practices (e.g., monitoring cleaning) must be followed to prevent exposure to pathogens that may lead to infection.
- Endoscope represent a nosocomial hazard. Urgent need to understand the gaps in endoscope reprocessing. Reprocessing guidelines must be followed to prevent exposure to pathogens that may lead to infection. Endoscopes have narrow margin of safety and manufacturers should be encouraged to develop practical sterilization technology.
THANK YOU!

www.disinfectionandsterilization.org