High-Level Disinfection, Sterilization and Disinfection

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DISCLOSURES
2020-2021

• Consultations
  ■ Professional Disposables International (PDI)

• Honoraria
  ■ PDI
www.disinfectionandsterilization.org
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): 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 and environmental surfaces
• 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.1,2, David J. Weber, M.D., M.P.H.1,2, and the Healthcare Infection Control Practices Advisory Committee (HICPAC)3
Medical/Surgical Devices

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

• Critical
  • Transmission: direct contact
  • Control measure: sterilization
  • Surgical instruments
    • Enormous margin of safety, rare outbreaks
    • ~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, rare 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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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
Sterilization of “Critical Objects”

Heat resistant
• Steam sterilization
Heat sensitive
• Ethylene oxide
• Hydrogen peroxide gas plasma
• Ozone and hydrogen peroxide
• Vaporized hydrogen peroxide
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.
Microbial Load on Surgical Instruments

Surgical instruments-<10^2 bacteria
## 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>2.6x10⁷</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td>VRE</td>
<td>2.6x10⁷</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td><em>P. aeruginosa</em></td>
<td>2.1x10⁷</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td><em>M. terrae</em></td>
<td>1.4x10⁸</td>
<td>7.8</td>
<td>2/8</td>
</tr>
<tr>
<td>Routine</td>
<td>GS spores</td>
<td>5.3x10⁶</td>
<td>4.8</td>
<td>11/14</td>
</tr>
<tr>
<td>No Enz/Det</td>
<td>VRE</td>
<td>2.5x10⁷</td>
<td>Complete</td>
<td>0/10</td>
</tr>
<tr>
<td>No Enz/Det</td>
<td>GS spores</td>
<td>8.3x10⁶</td>
<td>5.5</td>
<td>8/10</td>
</tr>
</tbody>
</table>
Washer/disinfectors are very effective in removing/inactivating microorganisms from instruments.
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 132ºC in Pre vacuum 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

• 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
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
## Sterility Indicators Table

<table>
<thead>
<tr>
<th></th>
<th>Before Exposure</th>
<th>After Exposure (Sterile)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Steam Autoclave</strong></td>
<td>(Do not use)</td>
<td>(Ok if package is intact)</td>
</tr>
<tr>
<td>Tape</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Strip</strong></td>
<td><strong>STRATE-LINE™ sterilization mark</strong></td>
<td></td>
</tr>
<tr>
<td>Peel Pack</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ethylene Oxide (ETO, gas)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tape</td>
<td></td>
<td></td>
</tr>
</tbody>
</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
Biological Monitors

• 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


**Comparison of a Rapid Readout Biological Indicator for Steam Sterilization with Four Conventional Biological Indicators and Five Chemical Indicators**

William A. Rutala, PhD, MPH; Suzanne M. Jones, MPH; David J. Weber, MD, MPH
Super Rapid Readout Biological Indicators
Commercially available

1491 BI (blue cap)
• Monitors 270°F and 275°F gravity –displacement steam sterilization cycles
• 30-minute result (from 1 hour)

1492V BI (brown cap)
• Monitors 270°F and 275°F dynamic-air-removal (pre-vacuum) steam sterilization cycles
• 24 min (from 1 hour [3 hours])
Rapid Readout Biological Indicator for Steam (24-30m), 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

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• 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
### Infections/Outbreaks Associated with Semicritical Medical Devices

*Rutala, Weber, AJIC 2019;47:A79-A89*

<table>
<thead>
<tr>
<th>Medical Device</th>
<th>No. Outbreaks/Infections</th>
<th>No. Outbreaks/Infections with Bloodborne Pathogens</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal Probes</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Ear-Nose-Throat Endoscopes</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Urologic instruments (e.g. cystoscopes)</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Hysteroscopes</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Laryngoscopes</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Transrectal ultrasound guided prostate</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Applanation tonometers</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>TEE-Transesophageal echocardiogram</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>GI Endoscopes/Bronchoscopes</td>
<td>~130</td>
<td>3 (HBV-1 GI; HCV-2 GI; HIV-0)</td>
</tr>
</tbody>
</table>
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>&gt; 2.0%</td>
</tr>
<tr>
<td>Ortho-phthalaldehyde</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>Accelerated hydrogen peroxide</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 Susceptible

Enveloped Viruses (HIV, HSV, Flu)

Bacteria (MRSA, VRE, Acinetobacter)

Fungi (Candida, Trichophyton)

Non-Enveloped Viruses (norovirus, HAV, polio)

Mycobacteria (M. tuberculosis)

Spores (C. difficile)

Most Resistant

HLD
Comparison of Glutaraldehyde and OPA
Rutala, Weber. AJIC 2019;47:A3-A9

>2.0% Glutaraldehyde
• HLD: 45 min at 25°C
• Needs activator
• 14-day use life, 2-year shelf life
• ACGIH ceiling limit, 0.05ppm
• Strong odor
• MEC, 1.5%
• Cost - $10/gallon
• Disadv-slow mycobactericidal acttivity

0.55% Ortho-phthalaldehyde
• HLD: 12 min at 20°C
• No activator needed
• 14-day use life, 2-year shelf life
• No ACGIH or OSHA limit
• Weak odor
• MEC, 0.3%
• Cost - $30/gallon
• Disadv-Anaphylactic rxn w/ repeated exposure through cysto
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

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Reprocessing Medical Devices: The Good, The Bad and The Ugly
Transmission of Infection by Endoscopy

<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, H. pylori, Salmonella</td>
<td>169</td>
<td>56</td>
<td>Cleaning/Disinfection (C/D)</td>
</tr>
<tr>
<td>Sigmoid-Colonoscopy</td>
<td>5</td>
<td>Salmonella, HCV</td>
<td>14</td>
<td>6</td>
<td>Cleaning/Disinfection</td>
</tr>
<tr>
<td>ERCP</td>
<td>23</td>
<td>P. aeruginosa (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>

Based on outbreak data, if eliminated deficiencies associated with cleaning, disinfection, AER, contaminated water and drying would eliminate about 85% of the outbreaks.
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>mcr-1</td>
<td>2</td>
<td>No</td>
<td>No</td>
<td>Yes-WGS</td>
<td>Shency et al., 2018</td>
</tr>
<tr>
<td><em>K pneumoniae</em></td>
<td>blaoxa-232</td>
<td>15 (8)</td>
<td>No</td>
<td>No</td>
<td>Yes-PCR</td>
<td>Kim et al., 2016</td>
</tr>
<tr>
<td><em>Escherichia coli</em> (AmpC)</td>
<td>blacmy-2</td>
<td>35</td>
<td>No</td>
<td>Yes (2)</td>
<td>Yes-PCR, PFGE</td>
<td>Wendorf et al., 2015</td>
</tr>
<tr>
<td><em>K pneumoniae</em></td>
<td>blaoxa-48</td>
<td>12</td>
<td>Yes</td>
<td>No</td>
<td>Yes-PCR, PFGE</td>
<td>Kola et al., 2015</td>
</tr>
<tr>
<td><em>K pneumoniae</em></td>
<td>blakpc</td>
<td>34?</td>
<td>No</td>
<td>Yes (3)</td>
<td>Yes-PCR, PFGE, MLST, WGS</td>
<td>Marsh et al., 2015</td>
</tr>
<tr>
<td><em>E coli</em></td>
<td>blanmd</td>
<td>39</td>
<td>Yes</td>
<td>Yes (1)</td>
<td>Yes-PCR, PFGE</td>
<td>Epstein et al., 2014</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em></td>
<td>blavim-2</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., 2015</td>
</tr>
<tr>
<td><em>E coli</em></td>
<td>blanmd-1</td>
<td>3 (3)</td>
<td>No</td>
<td>No</td>
<td>Unknown</td>
<td>Smith et al., 2015</td>
</tr>
<tr>
<td><em>K pneumoniae</em></td>
<td>blakpc, blashv-12</td>
<td>13</td>
<td>Yes</td>
<td>Yes (2)</td>
<td>Yes-PCR, PFGE, MLST</td>
<td>Carbone et al., 2010</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 $\log_{10}$ ($10^7$-$10^9$)
  ◆ 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]-$10^7$-$10$ bacteria/endoscope

Surgical instruments-$<10^2$ bacteria
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
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>Brush all endoscope channels and components</td>
<td>43</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>
Margin of safety with endoscope reprocessing minimal or non-existent

Microbial load
- GI endoscopes contain $10^7-10$
- 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: 4log$_{10}$ (maximum contamination, minimal cleaning/HLD)

Complexity of endoscope and endoscope reprocessing

Biofilms—may contribute to failure of endoscope reprocessing
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

Direction of Fluid Flow:
- Continuously 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*

Rectangular Snip

~10 - 50μm thick

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?
GI Endoscopes: Shift from Disinfection to Sterilization

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.1 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.3

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...
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
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.

- HLD (6 log$_{10}$ reduction)
- vs
- Sterilization (12 log$_{10}$ reduction=SAL 10$^{-6}$)
Reprocessing Channeled Endoscopes
Cystoscope-HLD perfused through lumen with syringe (luer locks onto port and syringe filled and emptied until no air exits the scope nor air in barrel of syringe-syringe and lumen filled with HLD)
Reprocessing Channeled Endoscopes

<table>
<thead>
<tr>
<th>Exposure Method</th>
<th>CRE (K. pneumoniae) Inoculum before HLD (glutaraldehyde)</th>
<th>CRE (K. pneumoniae) Contamination after HLD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passive HLD (immersed, not perfused)</td>
<td>3.2x10^8 1.9x10^9 4.1x10^8</td>
<td>3.1x10^8 4.6x10^8 1.0x10^8</td>
</tr>
<tr>
<td>Active HLD (perfused HLD into channel with syringe)</td>
<td>3.0x10^8 9.2x10^8 8.4x10^8</td>
<td>0 0 0</td>
</tr>
</tbody>
</table>

- 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
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.

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
What do you do?

- Follow the 14 steps at website 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
Noncritical Environmental Surfaces and Medical Devices

Rutala et al. AJIC 2016;44:e1; Rutala, Weber. Env Issues NI, Farber 1987

- 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
Evidence environment contributes
- Role-MRSA, VRE, *C. difficile*
- Surfaces are contaminated~25%
- EIP survive days, weeks, months
- Contact with surfaces results in hand contamination
- Disinfection reduces contamination
- Disinfection (daily) reduces HAIs
- Rooms not adequately cleaned
Admission to Room Previously Occupied by Patient C/I with Epidemiologically Important Pathogen


- Results in the newly admitted patient having an increased risk of acquiring that pathogen by 39-353%
- For example, increased risk for *C. difficile* is 235% (11.0% vs 4.6%)
Acquisition of EIP on Hands of Healthcare Providers after Contact with Contaminated Environmental Sites and Transfer to Other Patients
Acquisition of EIP on Hands of Patient after Contact with Contaminated Environmental Sites and Transfers EIP to Eyes/Nose/Mouth
ALL “TOUCHABLE” (HAND CONTACT) SURFACES SHOULD BE WIPED DAILY WITH DISINFECTANT

“High touch” objects only recently defined (no significant differences in microbial contamination of different surfaces) and “high risk” objects not epidemiologically defined.
Effective Surface Decontamination

Product and Practice = Perfection
## LOW-LEVEL DISINFECTION FOR NONCRITICAL EQUIPMENT AND SURFACES


<table>
<thead>
<tr>
<th>Germicide</th>
<th>Use Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl or isopropyl alcohol</td>
<td>70-90%</td>
</tr>
<tr>
<td>Chlorine</td>
<td>100ppm (1:500 dilution)</td>
</tr>
<tr>
<td>Phenolic</td>
<td>UD</td>
</tr>
<tr>
<td>Iodophor</td>
<td>UD</td>
</tr>
<tr>
<td>Quaternary ammonium (QUAT)</td>
<td>UD</td>
</tr>
<tr>
<td>QUAT with alcohol</td>
<td>RTU</td>
</tr>
<tr>
<td>Improved hydrogen peroxide (HP)</td>
<td>0.5%, 1.4%</td>
</tr>
<tr>
<td>PA/HP or chlorine (C. difficile spores)</td>
<td>UD</td>
</tr>
</tbody>
</table>

**UD** = Manufacturer's recommended use dilution; others in development/testing-electrolyzed water; polymeric guanidine; cold-air atmospheric pressure plasma (Boyce Antimicrob Res IC 2016. 5:10)
Thoroughness of Environmental Cleaning
Carling P. AJIC 2013;41:S20-S25

Mean = 32%

Objects

DAILY CLEANING
TERMIAL CLEANING

HEHSG HOSP
IOWA HOSP
OTHER HOSP
OPERATING ROOMS
NICU
EMS VEHICLES
ICU DAILY
AMB CHEMO
MD CLINIC
LONG TERM
DIALYSIS

>110,000

95% CI
MONITORING THE EFFECTIVENESS OF CLEANING
Cooper et al. AJIC 2007;35:338

- Visual assessment-not a reliable indicator of surface cleanliness
- **ATP bioluminescence**-measures organic debris (each unit has own reading scale, <250-500 RLU)
- Microbiological methods-<2.5CFUs/cm²-pass; can be costly and pathogen specific
- Fluorescent marker-transparent, easily cleaned, environmentally stable marking solution that fluoresces when exposed to an ultraviolet light (applied by IP unbeknown to EVS, after EVS cleaning, markings are reassessed)
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.

- Endoscopy represent a nosocomial hazard. Urgent need to understand the gaps in endoscopy 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.

- The contaminated surface environment in hospital rooms is important in the transmission of healthcare-associated pathogens (MRSA, VRE, *C. difficile*, *Acinetobacter*). Thoroughness of cleaning should be monitored.
THANK YOU!
www.disinfectionandsterilization.org