Sterilization and Disinfection

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DISCLOSURES
2017-2018

• Consultations
  ■ ASP (Advanced Sterilization Products), PDI

• Honoraria
  ■ PDI, Kennall

• Scientific Advisory Board
  ■ Kinnos

• Grants
  ■ CDC, CMS
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 chemical agents 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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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 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 2016;44:e47

- 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

Rutala et al. AJIC 2016;44:e47

- Semicritical
  - Transmission: direct contact
  - Control measure: high-level disinfection
  - Endoscopes top ECRI list of 10 technology hazards, >100 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 Medical Devices
Rutala et al. AJIC 2016;44:e1; Rutala, Weber. Env Issues NI, Farber 1987

- Noncritical 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 chemical agents and mechanical processes used to disinfect medical equipment
- Outline the controversies surrounding the reprocessing of endoscopes and disinfection of other complex medical instruments
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”

- Steam sterilization
- Hydrogen peroxide gas plasma
- Ethylene oxide
- 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>$2.6 \times 10^7$</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td>VRE</td>
<td>$2.6 \times 10^7$</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td>$P. \ aeruginosa$</td>
<td>$2.1 \times 10^7$</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td>$M. \ terrae$</td>
<td>$1.4 \times 10^8$</td>
<td>7.8</td>
<td>2/8</td>
</tr>
<tr>
<td>Routine</td>
<td>GS spores</td>
<td>$5.3 \times 10^6$</td>
<td>4.8</td>
<td>11/14</td>
</tr>
<tr>
<td>No Enz/Det</td>
<td>VRE</td>
<td>$2.5 \times 10^7$</td>
<td>Complete</td>
<td>0/10</td>
</tr>
<tr>
<td>No Enz/Det</td>
<td>GS spores</td>
<td>$8.3 \times 10^6$</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 2016;44:e1-e6

● 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>

- Alternatives to ETO-CFC
  - ETO-CO$_2$, ETO-HCFC, 100% ETO
- New Low Temperature Sterilization Technology
  - Hydrogen Peroxide Gas Plasma
  - Ozone and hydrogen peroxide
  - Vaporized Hydrogen Peroxide
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 cannot be packaged, sterilized and stored before use
- “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.
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
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
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
<table>
<thead>
<tr>
<th></th>
<th>Before Exposure (Do not use)</th>
<th>After Exposure (Sterile) (Ok if package is intact)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Steam Autoclave</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tape</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strip</td>
<td>STRATE-LINE™ sterilization</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>
<tr>
<td>Strip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peel Pack</td>
<td>MEDLI-PLUS™ SELF SEAL POUCH</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 1/2&quot; x 5 1/2&quot; Terra Gold</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Brown in Gas</td>
<td></td>
</tr>
<tr>
<td></td>
<td>READ INSTR.</td>
<td></td>
</tr>
<tr>
<td><strong>Sterrad</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tape</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strip</td>
<td>STERRAD Chemical Indicator</td>
<td></td>
</tr>
<tr>
<td></td>
<td>REF 14100</td>
<td></td>
</tr>
<tr>
<td></td>
<td>USE in STERRAD Sterilizer only</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bar when exposed to H2O during processing in the STERRAD Sterilizer</td>
<td></td>
</tr>
<tr>
<td><strong>Steris</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6/23/97</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*
  - Ozone and HP - *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
Commerically 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
• 1 hour result (from 3 hours)
30m or 24m Biological Indicator for HP Sterilizers
Recommendations
Monitoring of Sterilizers

- Monitor each load with mechanical 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.
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)
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Rutala et al. AJIC 2016;44:e47

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Semicritical Items

- Endoscopes
- Respiratory therapy equipment
- Anesthesia equipment
- Endocavitary probes
- Tonometers
- Laryngoscopes
# High-Level Disinfection of “Semicritical Objects”

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
Comparison of Glutaraldehyde and OPA


>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

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
Improved Hydrogen Peroxide


● 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
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, <em>H. pylori</em>, 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><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>

Based on outbreak data, if eliminated deficiencies associated with cleaning, disinfection, AER, contaminated water and drying would eliminate about 85% of the outbreaks.
## Recent Endoscopy-Related Outbreaks of MRDO Without Reprocessing Breaches

Rutala WA et al. Submitted for publication

<table>
<thead>
<tr>
<th>MDRO</th>
<th>Scope</th>
<th>No.</th>
<th>Recovered From Scope</th>
<th>Molecular Link</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>P. aeruginosa</em> (VIM-2)</td>
<td>Duodenoscope</td>
<td>22</td>
<td>Yes, under forceps elevator</td>
<td>Yes</td>
<td>Verfaillie CJ, 2015</td>
</tr>
<tr>
<td><em>E. coli</em> (AmpC)</td>
<td>Duodenoscope</td>
<td>35</td>
<td>Yes (2 scopes)</td>
<td>Yes</td>
<td>Wendorf, 2015</td>
</tr>
<tr>
<td><em>K. pneumoniae</em> (OXA)</td>
<td>Duodenoscope</td>
<td>12</td>
<td>No</td>
<td>Yes</td>
<td>Kola A, 2015</td>
</tr>
<tr>
<td><em>E. coli</em> (NDM-CRE)</td>
<td>Duodenoscope</td>
<td>39</td>
<td>Yes</td>
<td>Yes</td>
<td>Epstein L, 2015</td>
</tr>
<tr>
<td><em>K. pneumoniae</em></td>
<td>Duodenoscope</td>
<td>15</td>
<td>No</td>
<td>Yes</td>
<td>Kim S, 2016</td>
</tr>
<tr>
<td><em>K. pneumoniae</em></td>
<td>Duodenoscope</td>
<td>34</td>
<td>Yes</td>
<td>Yes</td>
<td>Marsh J, 2015</td>
</tr>
<tr>
<td><em>E. coli</em></td>
<td>Duodenoscope</td>
<td>3</td>
<td>No</td>
<td>Unknown</td>
<td>Smith Z, 2015</td>
</tr>
<tr>
<td><em>K. pneumoniae</em></td>
<td>Duodenoscope</td>
<td>13</td>
<td>Yes</td>
<td>Yes</td>
<td>Carbonne A, 2010</td>
</tr>
</tbody>
</table>
Reason for Endoscope-Related Outbreaks


- 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: 4 log$_{10}$ (maximum contamination, minimal cleaning/HLD)
- Complexity of endoscope and endoscope reprocessing
- Biofilms-unclear if contribute to failure of endoscope reprocessing
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.

**Endoscope Reprocessing Methods**

Ofstead, Wetzler, Snyder, Horton, Gastro Nursing 2010; 33:204

<table>
<thead>
<tr>
<th>Observed Activity</th>
<th>Steps Completed (%)</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>
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- Biofilms-unclear if contribute to failure of endoscope reprocessing
BIOFILMS
(Multi-layered bacteria plus exopolysaccharides that cement cell to surface; develop in wet environments; if reprocessing performed promptly after use and endoscope dry the opportunity for biofilm formation is minimal; Pajkos et al. J Hosp Infect 2004;58:224)
## Microbial Surveillance of GI Endoscopes


<table>
<thead>
<tr>
<th>Characteristics of Sample</th>
<th>Action Level (TCU&gt;100/scope) or EIP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastroscope</td>
<td>26.6%</td>
</tr>
<tr>
<td>Colonoscope</td>
<td>33.7%</td>
</tr>
<tr>
<td>Duodenoscope</td>
<td>34.7%</td>
</tr>
<tr>
<td>Echo-endoscope</td>
<td>31.9%</td>
</tr>
<tr>
<td>AER</td>
<td>27.2%</td>
</tr>
<tr>
<td>Manual</td>
<td>39.3%</td>
</tr>
<tr>
<td>Age of endoscope &lt;2 years</td>
<td>18.9%</td>
</tr>
<tr>
<td>Age of endoscope &gt;2 years</td>
<td>38.8%</td>
</tr>
</tbody>
</table>
To protect the public health we (FDA, industry, professional organizations) must shift duodenoscope reprocessing from HLD 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. 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-

Related article page 1447
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=$10^{-6}$)
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


- 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

<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>
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
Rutala, Weber. ICHE 2007;28:146-155

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

- Noncritical medical devices
- Transmission: secondary transmission by contaminated 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
### Exposure time ≥ 1 min

<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>Peracetic acid with HP (C. difficile)</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)
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 chemical agents and mechanical processes used to disinfect medical equipment
- Outline the controversies surrounding the reprocessing of endoscopes and disinfection of other complex medical instruments
Sterilization and Disinfection
Summary

D/S guidelines must be followed to prevent exposure to pathogens that may lead to infection.
THANK YOU!
www.disinfectionandsterilization.org