Disinfection and Sterilization: Current Issues and Future Perspectives

William A. Rutala, Ph.D., M.P.H., C.I.C
Director, Statewide Program for Infection Control and Epidemiology
and Professor of Medicine, University of North Carolina at Chapel Hill, NC, USA

Former Director, Hospital Epidemiology, Occupational Health and Safety, UNC Health Care, Chapel Hill, NC (1979-2017)
DISCLOSURES
2020-2021

• Consultations
  ■ PDI

• Honoraria
  ■ ASP, PDI

☐ Other
  ■ Kinnos
Disinfection and Sterilization: Current Issues and Future Perspectives

- Overview DS
- Sterilization-robustness
- HLD-What’s new endoscope reprocessing
- HLD-outpatient care
- HLD-Human papillomavirus
- LLD-Electrostatic sprayers
- LLD-Ultrasound probes
- LLD-sporicide in all discharge pt rooms
- LLD-new sporicide-HP
- Colorized disinfectant
- LLD-“no” touch room decontamination
- Emerging pathogens
  - SARS-CoV-2
  - CRE
  - C. auris
- Continuous room decontamination technologies
  - Continuously active disinfectant
Disinfection and Sterilization: Current Issues and Future Perspectives

- Overview DS
- Sterilization-robustness
- HLD-What’s new endoscope reprocessing
- HLD-outpatient care
- HLD-Human papillomavirus
- LLD-Electrostatic sprayers
- LLD-Ultrasound probes
- LLD-sporicide in all discharge pt rooms
- LLD-new sporicide-HP
- Colorized disinfectant
- LLD-“no” touch room decontamination
- Emerging pathogens
  - SARS-CoV-2
  - CRE
  - C.auris
- Continuous room decontamination technologies
  - Continuously active disinfectant
Update: May 2019

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)\(^3\)

\(^1\)Hospital Epidemiology
University of North Carolina Health Care System
Chapel Hill, NC 27514

\(^2\)Division of Infectious Diseases
University of North Carolina School of Medicine
Chapel Hill, NC 27599-7030
EH Spaulding believed that how an object will be disinfected depended on the object’s intended use.

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

- **CRITICAL** - objects which 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.
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

- 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
Sterilization of “Critical Objects”

Heat resistant
  • Steam sterilization
Heat sensitive
  • Ethylene oxide
  • Hydrogen peroxide gas plasma
  • Ozone and hydrogen peroxide
  • Vaporized hydrogen peroxide
EH Spaulding believed that how an object will be disinfected depended on the object’s intended use:

- **CRITICAL** - objects which 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.
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, >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
Semicritical Items

- Endoscopes
- Respiratory therapy equipment
- Anesthesia equipment
- Endocavitary probes
- Tonometers
- Laryngoscopy
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)

Most Susceptible

Enveloped Viruses (HIV, HSV, Flu)
## 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*
Evidence environment contributes

- Role-MRSA, VRE, *C. difficile*
- Surfaces are contaminated—~25%
- EIP survive days, weeks, months
- Contact with surfaces results in hand contamination; contaminated hands transmit EIP to patients
- Disinfection reduces contamination
- Disinfection (daily) reduces HAI s
- Rooms not adequately cleaned

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

- **CRITICAL** - objects which 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.
Clean/disinfect at least daily
(one-step cleaning and disinfection)
Exposure time $\geq 1$ 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>PA with HP, 4% HP, chlorine (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)
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*)

Most Susceptible
Enveloped Viruses (HIV, HSV, Flu)

LLD
## 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>100 ppm (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 with HP, 4% HP, 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)**
C. difficile spores
<table>
<thead>
<tr>
<th>Disinfectant, 1 min</th>
<th>MNV Log$_{10}$ Reduction</th>
<th>HNV Log$_{10}$ Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>70% Ethanol</td>
<td>&gt;4 (3.3 at 15sec)</td>
<td>2</td>
</tr>
<tr>
<td>70% Isopropyl alcohol</td>
<td>4.2</td>
<td>2.2</td>
</tr>
<tr>
<td>65% Ethanol + QUAT</td>
<td>&gt;2</td>
<td>3.6</td>
</tr>
<tr>
<td>79% Ethanol + QUAT</td>
<td>3.4</td>
<td>3.6</td>
</tr>
<tr>
<td>Chlorine (5,000ppm)</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Chlorine (24,000ppm)</td>
<td>2.4</td>
<td>4.3</td>
</tr>
<tr>
<td>Phenolic, QUAT, Ag, 3% H$_2$O$_2$</td>
<td>≤1</td>
<td>≤1 (2.1 QUAT)</td>
</tr>
<tr>
<td>0.5% Accel H$_2$O$_2$</td>
<td>3.9</td>
<td>2.8</td>
</tr>
</tbody>
</table>

Disinfection and Sterilization: Current Issues and Future Perspectives

- Overview DS
- Sterilization-robustness
- HLD-What’s new endoscope reprocessing
- HLD-outpatient care
- HLD-Human papillomavirus
- LLD-Electrostatic sprayers
- LLD-Ultrasound probes
- LLD-sporicide in all discharge pt rooms
- LLD-new sporicide-HP

- Colorized disinfectant
- LLD-“no” touch room decontamination
- Emerging pathogens
  - SARS-CoV-2
  - CRE
  - C.auris
- Continuous room decontamination technologies
  - Continuously active disinfectant
  - Visible light disinfection through LEDs
  - Low concentration hydrogen peroxide
Sterilization

Enormous Margin of Safety!

100 quadrillion \((10^{17})\) margin of safety

Sterilization kills 1 trillion spores, washer/disinfector removes or inactivates 10-100 million; ~100 microbes on surgical instruments
“Dirty” (non-cleaned) Instruments

Blood (wet) and Bacteria

Blood (dry) and Bacteria

Bacteria
<table>
<thead>
<tr>
<th>Test Organism</th>
<th>Method of Sterilization</th>
<th>Instruments &quot;Dirty&quot; (Undeaned) With or Without Blood&lt;sup&gt;b&lt;/sup&gt;</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&lt;sup&gt;5&lt;/sup&gt;</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dirty with blood (spores mixed with blood not sandwich)&lt;sup&gt;h&lt;/sup&gt;</td>
<td>~1.99×10&lt;sup&gt;5&lt;/sup&gt;</td>
<td>0/12 (0)</td>
</tr>
<tr>
<td></td>
<td>ETO</td>
<td>Dirty</td>
<td>~1.53×10&lt;sup&gt;5&lt;/sup&gt;</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dirty with blood</td>
<td>~2.35×10&lt;sup&gt;5&lt;/sup&gt;</td>
<td>0/11 (0)</td>
</tr>
<tr>
<td></td>
<td>HPGP</td>
<td>Dirty</td>
<td>~1.58×10&lt;sup&gt;5&lt;/sup&gt;</td>
<td>5/10 (50)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dirty with blood</td>
<td>~2.35×10&lt;sup&gt;5&lt;/sup&gt;</td>
<td>9/15 (60)</td>
</tr>
<tr>
<td><em>Mycobacterium terrae</em></td>
<td>Steam Sterilization</td>
<td>Dirty</td>
<td>~4.25×10&lt;sup&gt;6&lt;/sup&gt;</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td><em>P. aeruginosa</em></td>
<td>HPGP</td>
<td>Dirty</td>
<td>~1.81×10&lt;sup&gt;6&lt;/sup&gt;</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&lt;sup&gt;7&lt;/sup&gt;</td>
<td>6/10 (60)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dirty with blood</td>
<td>~4.08×10&lt;sup&gt;7&lt;/sup&gt;</td>
<td>9/10 (90)</td>
</tr>
<tr>
<td>MRSA</td>
<td>ETO</td>
<td>Dirty</td>
<td>~2.62×10&lt;sup&gt;8&lt;/sup&gt;</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dirty with blood</td>
<td>~1.72×10&lt;sup&gt;8&lt;/sup&gt;</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td></td>
<td>HPGP</td>
<td>Dirty</td>
<td>~1.10×10&lt;sup&gt;8&lt;/sup&gt;</td>
<td>4/10 (40)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dirty with blood</td>
<td>~1.27×10&lt;sup&gt;8&lt;/sup&gt;</td>
<td>4/10 (40)</td>
</tr>
<tr>
<td></td>
<td>Steam sterilization</td>
<td>Dirty</td>
<td>2.56×10&lt;sup&gt;6&lt;/sup&gt;</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dirty with blood</td>
<td>5.20×10&lt;sup&gt;5&lt;/sup&gt;</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td>VRE</td>
<td>ETO</td>
<td>Dirty</td>
<td>~2.27×10&lt;sup&gt;6&lt;/sup&gt;</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dirty with blood</td>
<td>~3.59×10&lt;sup&gt;6&lt;/sup&gt;</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td></td>
<td>HPGP</td>
<td>Dirty</td>
<td>~2.63×10&lt;sup&gt;6&lt;/sup&gt;</td>
<td>3/10 (30)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dirty with blood</td>
<td>~2.34×10&lt;sup&gt;6&lt;/sup&gt;</td>
<td>9/10 (90)</td>
</tr>
<tr>
<td></td>
<td>Steam sterilization</td>
<td>Dirty</td>
<td>1.90×10&lt;sup&gt;6&lt;/sup&gt;</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dirty with blood</td>
<td>2.72×10&lt;sup&gt;5&lt;/sup&gt;</td>
<td>0/10 (0)</td>
</tr>
</tbody>
</table>

Note. ETO, ethylene oxide. <sup>b</sup>Study conditions not stated. <sup>h</sup>Sandwich consists of experiment was done.
# 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>~ 1.56x10(^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>~ 1.99x10(^5)</td>
<td>0/12 (0)</td>
</tr>
<tr>
<td><strong>Mycobacterium terrae</strong></td>
<td>Steam Sterilization</td>
<td>Dirty</td>
<td>~ 4.25x10(^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.
Disinfection and Sterilization: Current Issues and Future Perspectives

- Overview DS
- Sterilization-robustness
- HLD-What’s new endoscope reprocessing
- HLD-outpatient care
- HLD-Human papillomavirus
- LLD-Electrostatic sprayers
- LLD-Ultrasound probes
- LLD-sporicide in all discharge pt rooms

- LLD-new sporicide-HP
- Colorized disinfectant
- LLD-“no” touch room decontamination
- Emerging pathogens
  - SARS-CoV-2
  - CRE
  - C.auris

- Continuous room decontamination technologies
  - Continuously active disinfectant
# Infections/Outbreaks Associated with Semicritical Medical Devices


<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>
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: 4 log$_{10}$ (maximum contamination, minimal cleaning/HLD)

- Complexity of endoscope and endoscope reprocessing

- Biofilms—could contribute to failure of endoscope reprocessing
ENDOSCOPE REPROCESSING: CHALLENGES

Complex [elevator channel]-$10^7$-$10^9$ 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
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.

### 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 manufacture specific cleaning for duodenoscope elevator mechanisms, echoendoscopes, & double channel endoscopes.

### 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)

### HLD
- Test and monitor the disinfectant according to manufacture instructions.
- Completely immerse the endoscope in a basin of high-level disinfectant.

### Drying & Storage
- Flush all channels with 70% to 90% ethyl or isopropyl alcohol.
- Purge all channels with filtered compressed air.
- Use a system to identify which endoscope has been reprocessed (i.e. tagging)
- Use storage cabinets that can be cleaned and disinfected with EPA registered high level disinfectant.

### HLD Process
- Thoroughly rinse the endoscope and all removable parts with clean water.
- Remove damaged endoscope from service for repair or disposal

### Purge & Drying
- Purge water from all channels using forced air and dry exterior using lint free cloth
- Purge all channels with air before removing the endoscope from the high-level disinfectant
- Thoroughly rinse the endoscope and all removable parts with clean water.
## Complexity of Endoscope Reprocessing

**Pre-Cleaning**
- Wipe insertion tube with detergent solution
- Suction detergent solution through endoscope until visibly clear
- Flush and manipulate the forcep 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.
- Remove endoscope from service if leak is identified for repair or disposal.

**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 manufacture 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
- Repeat manual cleaning as needed
- Remove damaged endoscope from service for repair or disposal
- Purge all channels with air before removing the endoscope from the high-level disinfectant
- 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

**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
- Use a system to identify which endoscope has been reprocessed (i.e. tagging)
- 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 Manually
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 Manually


<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
Bacteria will survive if the elevator lever was improperly positioned (in horizontal position instead of $45^\circ$) in AER.

- *E. faecalis* (7 log inoculum, 2-6 log recovered) and *E. coli* (0-3 log) survived disinfection of sealed and unsealed elevator wire channel duodenoscopes in 2 different AERs.

- Ensure proper lever position when placed in AERs with PA.
Endoscopy Reprocessing Methods

A Prospective Study on the Impact of Human Factors and Automation

ABSTRACT

The main cause of endoscopy-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 multisite, 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 1.4% 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 reproprocessors (p = .001). Enhanced training and accountability, combined with increased automation, may ensure guideline adherence and patient safety while improving employee satisfaction and health.
Perform 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 (%)</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>
Automated Endoscopy Reprocessors

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

Robert A. Weinstein, MD
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 $(10^4)$
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
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.

HLD ($\geq 6 \text{ log}_{10}$ reduction) vs

Sterilization ($12 \text{ log}_{10}$ reduction=SAL $10^{-6}$)
What Should We Do Now?
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?
Double HLD demonstrated no benefit over single HLD; no significant differences observed.

**TABLE 2. Summary of culture positivity rates in the 2 study arms**

<table>
<thead>
<tr>
<th></th>
<th>Double HLD</th>
<th>Single HLD</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ali cultures</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of specimens</td>
<td>3052</td>
<td>2798</td>
<td></td>
</tr>
<tr>
<td>Any growth</td>
<td>127 (4.2)</td>
<td>108 (3.9)</td>
<td>.60 (.64)</td>
</tr>
<tr>
<td>Growth of high-concern pathogens</td>
<td>3 (.1)</td>
<td>5 (.2)</td>
<td>.49 (.43)</td>
</tr>
<tr>
<td><strong>Encounter-based</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of encounters</td>
<td>1526</td>
<td>1399</td>
<td></td>
</tr>
<tr>
<td>Any growth</td>
<td>122 (4.0)</td>
<td>102 (7.3)</td>
<td>.52 (.54)</td>
</tr>
<tr>
<td>Growth of high-concern pathogens</td>
<td>3 (.2)</td>
<td>5 (.4)</td>
<td>.49 (.43)</td>
</tr>
</tbody>
</table>
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.
Where are we?
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).
Future/Novel Approaches to Endoscope Reprocessing to Improve Patient Safety

- Antimicrobial detergents - reduce microbial contamination
- **Automated Endoscope Reprocessing** - HLD should be provided in an approved AER (manual-1.4% compliance vs 75.4% using AER)
- Endoscope sterilization - materials compatibility, throughput
- Disposable endoscopes (device innovations)
  - Partially (endcap) - does it decrease bacterial contamination after HLD
  - Fully-GI and bronchoscopes; cost, scope performance
- Use of non-endoscopic methods to diagnose or treat disease
- Assessment tool that is predictive of microbial contamination or infection risks
# Characteristics of Disposable Duodenoscopes

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

<table>
<thead>
<tr>
<th>Table 2: Characteristics of disposable duodenoscopes.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Disposable component</strong></td>
</tr>
<tr>
<td><strong>Field of view (degrees)</strong></td>
</tr>
<tr>
<td><strong>Depth of view (mm)</strong></td>
</tr>
<tr>
<td><strong>Working length (mm)</strong></td>
</tr>
<tr>
<td><strong>Instrument channel (mm)</strong></td>
</tr>
<tr>
<td><strong>Insertion tube diameter (mm)</strong></td>
</tr>
<tr>
<td><strong>Distal end diameter (mm)</strong></td>
</tr>
<tr>
<td><strong>Distal end with end-cap (mm)</strong></td>
</tr>
</tbody>
</table>
Implementing these advances will allow us to prevent endoscope-related infections
Disinfection and Sterilization: Current Issues and Future Perspectives

- Overview DS
- Sterilization-robustness
- HLD-What’s new endoscope reprocessing
- HLD-outpatient care
- HLD-Human papillomavirus
- LLD-Electrostatic sprayers
- LLD-Ultrasound probes
- LLD-sporicide in all discharge pt rooms

- LLD-new sporicide-HP
- Colorized disinfectant
- LLD-“no” touch room decontamination
- Emerging pathogens
  - SARS-CoV-2
  - CRE
  - C.auris
- Continuous room decontamination technologies
  - Continuously active disinfectant
US Outpatient Surgery/Procedures Passes Inpatient Surgery/Procedure
Outpatient Care in the US

- From 2005 to 2015, visits to outpatient facilities increased by 14%.
- Hospitals increased their capital investments in outpatient facilities such as specialized outpatient clinics, primary care clinics, etc.
- AHA surveyed ~6,000 hospitals and in 2017, these hospitals recorded a total of 880 million outpatient visits.
- Many outpatient care facilities reprocess reusable critical and/or semicritical.
- The items present an infection risk if not properly reprocessed.
Expectations for Ambulatory Care

- Facilities should ensure that reusable medical devices are cleaned and reprocessed prior to use on another patient.
- Reusable medical devices must be cleaned and reprocessed and maintained according to manufacturers' instructions.
- Assign responsibilities for reprocessing medical devices to HCP with appropriate training.
  - Maintain copies of the manufacturer’s instructions for reprocessing of devices at the facilities; post instructions where reprocessing is performed.
  - Hands-on training on proper selection and use of PPE and recommended steps for reprocessing assigned devices should be provided upon hire, annually, and when new devices are introduced or policies/procedures change.
    - HCP should be required to demonstrate competency with reprocessing procedures.
- Assure HCP have access to and wear appropriate PPE when handling and reprocessing contaminated medical equipment.

Because semicritical equipment has been associated with reprocessing errors, essential control measures instituted to prevent patient exposures.

Infection control rounds or audits should be conducted at least annually in all clinical areas that reproves critical and semicritical devices to ensure adherence to reprocessing guidelines, MIFU, and/or institutional policies.

Results provided to unit managers and deficiencies corrected and corrective measures documented within 30 days.

Patient safety issues (e.g., wrong contact time, temperature, HLD concentration) require immediate correction.
HICPAC Audit Tool

https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html

HICPAC Sample Audit Tool: Reprocessing Flexible Endoscopes

Audit Form

Audit Item | Yes | No | Comments/Action
--- | --- | --- | ---
Precise the flexible endoscope at the point of use. | | | 
Disinfect the cleaning solution and clothes after use. | | | 
Ensure the container or cart is labeled with a biohazard legend. | | | 
Perform kit testing before manual cleaning if indicated. | | | 
Clean exterior surfaces of the endoscope with a soft, lint-free cloth or sponge. | | | 
Clean all accessible channels and the end of the endoscope with a cleaning brush of the length, width, and material recommended by the endoscope manufacturer. | | | 
If the endoscope has an elevator, raise and lower the elevator throughout the manual cleaning process. | | | 
Remove debris before retracting the brush back through the endoscope. | | | 
Floater the channels of the endoscope with the cleaning solution. | | | 
Identify the manufacturer's instructions for use (IFU). | | | 
Aptly evaluate the values during the cleaning process. | | | 
Flush and rinse exterior surface and internal channels with water until all cleaning solution and residual debris is removed. | | | 
Gather exterior surfaces and removable parts of the endoscope and garbage all channels with air. | | | 
Reassemble reusable parts, accessories, and cleaning implements according to the manufacturer's instructions for use (IFU). | | | 
Dispose of single-use parts, accessories, and cleaning implements. | | | 


Adapted with permission from Guideline Essentials. Copyright © 2016, GOWIN, Inc. 2176 S. Parker Road, Suite 800, Denver, CO 80237. All rights reserved.
Technical/Reprocessing Issues
- Complex instruments

Other Challenges
- Physical plant (sinks, no sinks, clean-to-dirty…goal-safer/better)
- Training, education, validation, standardization
  - Training/education: in person, on-line, frequency, measuring competency
  - Validation: (validated by manufacturer of AER, device have lumens, correct adapters/hookups, chemicals, enzymatics, temperature, soak time, test strips (readout time, controls)
- Presence of infection prevention
Challenges in Outpatient Settings: Space

- Instrument reprocessing (e.g., endoscopes) should not be performed in patient care areas
  - Instrument reprocessing contaminates the area
  - Reprocessing area should be divided into distinct work areas when ever feasible: receiving, cleaning and decontamination, preparation, HLD/sterilization; and storage (manner that prevents recontamination)
  - Establish a dirty-to-clean flow in the area
Before Infection Prevention Assistance... a Mess!

Critical: rooms must have a dirty-to-clean flow to the best of our ability to make it so.

(This is a “clean-to-dirty-to-clean-to-dirty-to-dirty-to-dirty, dirty, dirty, dirty-to-clean” set up.)

Courtesy of Judie Bringhurst
After Infection Prevention Assistance – it’s all rainbows and unicorns!

They decluttered and established a “dirty-to-clean” flow (mostly).

Infection Prevention helped them figure this out.
Inadequate Cleaning: Blood on Scope
Two Probes in One Cannister
Education can take many forms

- In person, on-line, directly observed
- Interval
- Measurement of competency

At UNC Hospitals, to optimize training for persons reprocessing semicritical items

- All persons performing HLD must attend a 3-hour HLD workshop, which is designed and delivered by infection prevention.
- A 1-hour refresher HLD class is mandatory every 365 days
- Results from onsite infection prevention reprocessing surveys were used to guide the curriculum
- The workshop is not a “train-the-trainer” nor is it an online module. It is conducted by an IP, face-to-face
From 2013-2016, immediate threat to life (ITL) declarations directly related to improperly sterilized or HLD equipment increased significantly.

In 2016, 74 percent of all ITLs were related to improperly sterilized or HLD equipment.

Findings from Non-Complying Organizations

- The mistaken belief that the risk of passing bloodborne pathogens or bacterial agents to patients is low or nonexistent
- Staff lack the knowledge or training required to properly sterilize or HLD equipment.
- Staff don’t have access to or lack knowledge of evidence-based guidelines.
- Lack of leadership oversight.
- Sterilization or HLD of equipment becomes a low priority within the organization.
- Lack of a culture of safety that supports the reporting of safety risks.
- Processes for sterilization or HLD are not followed (i.e., staff take shortcuts).
- The time frames for proper sterilization or HLD of equipment are not followed.
- There is no dedicated staff person to oversee the proper sterilization or HLD of equipment.
- Facility design or space issues prevent proper sterilization or HLD of equipment (e.g., processing takes place in a small room that also is used for storage).
- Lack of monitoring or documentation of sterilization or HLD of equipment, which makes it difficult to track the use of equipment on a specific patient, complicating the patient notification process when an outbreak occurs.
- Equipment is spread throughout the facility and may be processed or stored in numerous locations, making it difficult to track the equipment for documentation purposes.

Disinfection and Sterilization: Current Issues and Future Perspectives

- Overview DS
- Sterilization-robustness
- HLD-What’s new endoscope reprocessing
- HLD-outpatient care
- HLD-Human papillomavirus
- LLD-Electrostatic sprayers
- LLD-Ultrasound probes
- LLD-sporicide in all discharge pt rooms
- LLD-new sporicide-HP
- Colorized disinfectant
- LLD-“no” touch room decontamination
- Emerging pathogens
  - SARS-CoV-2
  - CRE
  - C.auris
- Continuous room decontamination technologies
  - Continuously active disinfectant
Human Papillomavirus

- Human Papillomavirus (HPV)
  - HPV is transmitted through sexual contact
  - Medical devices can become contaminated
  - If adequate disinfection of devices does not occur, the next patient may be at risk for HPV infection
  - Based on one publication, there are currently no FDA-cleared HLDs that are effective against HPV
Most common STD

In one study, FDA-cleared HLD (OPA, glut), no effect on HPV

Finding inconsistent with other small, non-enveloped viruses such as polio and parvovirus

Further investigation needed: test methods unclear; glycine; organic matter; comparison virus

Conversation with CDC: validate and use HLD consistent with FDA-cleared instructions (no alterations)
Two recently published studies identified methodological artifacts (did not use refined virus) and question the validity of the results.

- Ozbun et al. EBioMedicine 2021;63:103165. Showed OPA treatment inactivated refined HPV 31 raft virus, xenograft-derived HPV 11, recombinant quasivirus HPV 11, HPV 16 and HPV 31
- Egawa et al. EBioMedicine 2021; 63:103177. Showed that refined raft-derived HPV18 and HPV pseudovirus and mouse papilloma virus were inactivated

Based on findings by Ozbun and Egawa, we believe that aldehydes are effective against HPV.
Disinfection and Sterilization: Current Issues and Future Perspectives

- Overview DS
- Sterilization-robustness
- HLD-What’s new endoscope reprocessing
- HLD-outpatient care
- HLD-Human papillomavirus
- LLD-Electrostatic sprayers
- LLD-Ultrasound probes
- LLD-sporicide in all discharge pt rooms
- LLD-new sporicide-HP
- Colorized disinfectant
- LLD-“no” touch room decontamination
- Emerging pathogens
  - SARS-CoV-2
  - CRE
  - C.auris
- Continuous room decontamination technologies
  - Continuously active disinfectant
Evaluation of an electrostatic spray disinfectant technology for rapid decontamination of portable equipment and large open areas in the era of SARS-CoV-2

Jennifer L. Cadnum, BS,a Annette L. Jencson, CIC,a Scott H. Livingston, MD,b Daniel F. Li, BS,a Sarah N. Redmond, BS,b Basya Pearlmutter, BS,a Brigid M. Wilson, PhD,c and Curtis J. Donskey, MDb,c,*

Abstract

In the setting of the coronavirus disease 2019 pandemic, efficient methods are needed to decontaminate shared portable devices and large open areas such as waiting rooms. We found that wheelchairs, portable equipment, and waiting room chairs were frequently contaminated with potential pathogens. After minimal manual precleaning of areas with visible soiling, application of a dilute sodium hypochlorite disinfectant using an electrostatic sprayer provided rapid and effective decontamination and eliminated the benign virus bacteriophage MS2 from inoculated surfaces.
Efficacy of Disinfectant Electrostatic Spray (positive charged droplets attracted to negatively charged surfaces or microbes) in Reducing Pathogen Contamination

Cadnum et al. AJIC 2020

Picture of electrostatic sprayer (0.25% sodium hypochlorite)

Efficacy of disinfectant spray (waiting room chairs)

![Graph showing efficacy of disinfectant spray](chart.png)
Summary of Electrostatic Sprayer Issues Include

- Optimal droplet size is between 40-70u; what is the droplet size of the proposed unit
- Spray patterns vary tremendously across vendors and even across products from a single vendor
- EPA demands that all surfaces being disinfected be thoroughly wetted for the contact time of the specific disinfectant
- Person applying the disinfectant may need to wear full PPE because of inhalation concerns
- Electrostatic sprayer does not replace the initial cleaning and disinfecting that EVS performs
- Cadnum/Donskey study used sporicidal disinfectant alone with no pre-cleaning or wiping
- Electrostatic sprayers might be most useful for items and areas that are not amenable to standard cleaning and disinfection (Cadnum/Donskey)
- Effectiveness on soft surfaces?
- Considerations for purchase include: coverage requirements, weight of loaded device; ease of handling; effective distance; particulate size; and disinfectant safety
- Electrostatic sprayers are promoted as a “get in” and “get out” time saving technology
- How many seconds per square foot with a sprayer to properly treat the surface
- Equipment can be easily misused (must prevent misuse and consider sprayer, time allotted to perform, disinfectant, surface [soft v hard], space/area to disinfect, level of cleaning prior to application, user training)
Disinfection and Sterilization: Current Issues and Future Perspectives

- Overview DS
- Sterilization-robustness
- HLD-What’s new endoscope reprocessing
- HLD-outpatient care
- HLD-Human papillomavirus
- LLD-Electrostatic sprayers
- LLD-Ultrasound probes
- LLD-sporicide in all discharge pt rooms

- LLD-new sporicide-HP
- Colorized disinfectant
- LLD-“no” touch room decontamination
- Emerging pathogens
  - SARS-CoV-2
  - CRE
  - C.auris
- Continuous room decontamination technologies
  - Continuously active disinfectant
Do ultrasound transducers used for placing peripheral or central venous access devices require HLD/sterilization?
Transducer Disinfection for Insertion of Peripheral and Central Catheters
Association of Vascular Access Guideline. June 2018; AIUM 2017

- “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.
All clinicians involved in ultrasound guidance should undergo comprehensive training on disinfection of the ultrasound 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.

Some publications have interpreted CDC and AIUM recommendations differently (AJIC 2018:46:913-920): ultrasound guided CVC insertion (critical-sterilize or HLD with sterile sheath and sterile gel); scan across unhealthy skin (semicritical-HLD and use with clean sheath and clean gel)
Disinfection and Sterilization: Current Issues and Future Perspectives

- Overview DS
- Sterilization-robustness
- HLD-What’s new endoscope reprocessing
- HLD-outpatient care
- HLD-Human papillomavirus
- LLD-Electrostatic sprayers
- LLD-Ultrasound probes
- LLD-sporicide in all discharge patient rooms
- LLD-new sporicide-HP
- Colorized disinfectant
- LLD-“no” touch room decontamination
- Emerging pathogens
  - SARS-CoV-2
  - CRE
  - C.auris
- Continuous room decontamination technologies
  - Continuously active disinfectant
Asymptomatic carriers contribute to C. difficile transmission

1. Curry SR. Clin Infect Dis 2013 (29% of hospital-associated CDI cases linked to carriers by MLVA); 2. Blixt T. Gastroenterol 2017;152:1031 (exposure to carriers increased CDI risk); 3. Longtin Y. JAMA Int Med 2016 (screening for and isolating carriers reduced CDI by 63%); 4. Samore MH. Am J Med 1996;100:32 (only 1% of cases linked to asymptomatic carriers - roommates and adjacent rooms - by PFGE/REA); 5. Eyre DW. PLOS One 2013;8:e78445 (18 carriers: no links to subsequent CDI cases); 6. Lisenmyer K. Clin Infect Dis 2018 (screening and isolation of carriers associated with control of a ward outbreak); 7. Paquet-Bolduc B. Clin Infect Dis 2018 (unit-wide screening and isolation of carriers not associated with shorter outbreak durations vs historical controls); 8. Donskey CJ. Infect Control Hosp Epidemiol 2018 (14% of healthcare-associated CDI cases linked to LTCF asymptomatic carriers); 9. Kong LY. Clin Infect Dis 2018 (23% of healthcare-associated CDI linked to carriers vs 42% to CDI cases and 35% to carriers or cases).
Interventions focused on CDI rooms

Sporicidal disinfection only in CDI rooms

CDI rooms

Non-CDI rooms

Interventions addressing CDI cases and asymptomatic carriers

Sporicidal disinfection in CDI and non-CDI rooms

*C. difficile* slides courtesy Dr. Donskey
The percentage of rooms contaminated with *C. difficile* was significantly reduced during the period with a sporicidal product was used 5% vs 24%. Results suggest sporicidal disinfectant in all postdischarge rooms could potentially be beneficial in reducing the risk for *C. difficile* transmission from contaminated surfaces.
Disinfection and Sterilization: Current Issues and Future Perspectives

- Overview DS
- Sterilization-robustness
- HLD-What’s new endoscope reprocessing
- HLD-outpatient care
- HLD-Human papillomavirus
- LLD-Electrostatic sprayers
- LLD-Ultrasound probes
- LLD-sporicide in all discharge pt rooms
- LLD-new sporicide-HP
- Colorized disinfectant
- LLD-“no” touch room decontamination
- Emerging pathogens
  - SARS-CoV-2
  - CRE
  - C.auris
- Continuous room decontamination technologies
  - Continuously active disinfectant
A novel 4% HP was effective against MRSA, CRE, *C. difficile* spores and *C. auris*. HP may be a useful addition to the sporicidal products available in healthcare.

Table. Mean (Standard error) $\log_{10}$ reductions in healthcare-associated pathogens using a quantitative carrier test with a 1-minute exposure time

<table>
<thead>
<tr>
<th>Disinfectant</th>
<th><em>C. difficile</em></th>
<th>MRSA</th>
<th>CRE (<em>E. coli</em>)</th>
<th><em>Candida auris</em> (N=2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sani-HyPerCide</td>
<td>4.7 (0.08)</td>
<td>≥6.4 (0)</td>
<td>≥5.6 (0)</td>
<td>&gt;5.1 (0)</td>
</tr>
<tr>
<td>Clorox germicidal</td>
<td>≥6.7 (0)</td>
<td>≥6.4 (0)</td>
<td>≥5.6 (0)</td>
<td>≥6.1 (0)</td>
</tr>
<tr>
<td>bleach</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OxyCide</td>
<td>≥5.0 (0)</td>
<td>≥5.48 (0)</td>
<td>≥5.6 (0)</td>
<td>≥5.1 (0)</td>
</tr>
<tr>
<td>Oxivir 1</td>
<td>2.6 (0.3)</td>
<td>≥6.5 (0)</td>
<td>6.2 (0.3)</td>
<td>≥5.1 (0)</td>
</tr>
</tbody>
</table>
Disinfection and Sterilization: Current Issues and Future Perspectives

- Overview DS
- Sterilization-robustness
- HLD-What’s new endoscope reprocessing
- HLD-outpatient care
- HLD-Human papillomavirus
- LLD-Electrostatic sprayers
- LLD-Ultrasound probes
- LLD-sporicide in all discharge pt rooms

- LLD-new sporicide-HP
- Colorized disinfectant
- LLD-“no” touch room decontamination
- Emerging pathogens
  - SARS-CoV-2
  - CRE
  - C.auris
- Continuous room decontamination technologies
  - Continuously active disinfectant
Effective Surface Decontamination

Product and Practice = Perfection
Thoroughness of Environmental Cleaning

Carling et al. ECCMID, Milan, Italy, May 2011

Mean = 32%

DAILY CLEANING
TERMINAL CLEANING

>110,000 Objects

| 95% CI |

Mean = 32%

Objects
Future May Have Methods to Ensure Thoroughness Such as Colorized Disinfectant

Kang et al. J Hosp Infect 2017

Colorized disinfection – contact time compliance

- Color-fading time matched to disinfectant contact time --> enforces compliance
- Provides real-time feedback when disinfection is complete
- Trains staff on importance of contact time as they use the product

Kinnos slides courtesy of Kevin Tyan and Rachael Sparks
Colorized disinfection – empowers behavior change to improve coverage

- Increased visibility when disinfecting surfaces, fewer missed spots
- Real-time quality control that allows staff to monitor thoroughness of cleaning
Highlight® increases cleaning efficacy by 29%

Cleveland VA Medical Center found Highlight® to quantifiably improve thoroughness of cleaning.

Manuscript in preparation.
Efficacy and skin toxicity testing of Highlight®

• 3rd party testing: Highlight® is a non-irritant and does not reduce efficacy of disinfectant

Highlight® reduces bleach corrosiveness

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Clorox wipes</th>
<th>Clorox + Highlight®</th>
<th>PDI wipes</th>
<th>PDI + Highlight®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrosion rate (mpy)</td>
<td>6.24</td>
<td>1.56</td>
<td>9.79</td>
<td>0.98</td>
<td></td>
</tr>
</tbody>
</table>

Bleach wipes alone caused severe corrosion (> 5 mils per year [mpy], 1 normal) while the addition of Highlight® both significantly reduced corrosion rate (< 2 mpy) and prevented discoloration of the metal.

Lids fit onto bleach wipe cannisters
(feeds wipe out for the user and retracts them to prevent dry-out when not in use)
Disinfection and Sterilization: Current Issues and Future Perspectives

- Overview DS
- Sterilization-robustness
- HLD-What’s new endoscope reprocessing
- HLD-outpatient care
- HLD-Human papillomavirus
- LLD-Electrostatic sprayers
- LLD-Ultrasound probes
- LLD-sporicide in all discharge pt rooms
- LLD-new sporicide-HP
- Colorized disinfectant
- LLD-“no” touch room decontamination
- Emerging pathogens
  - SARS-CoV-2
  - CRE
  - C. auris
- Continuous room decontamination technologies
  - Continuously active disinfectant
Best Practices in Disinfection of Noncritical Surfaces in the Healthcare Setting: A Bundle Approach

NL Havill AJIC 2013;41:S26-30; Rutala, Weber. AJIC 2019

A Bundle Approach to Surface Disinfection

- Develop policies and procedures
- Select cleaning and disinfecting products
- Educate staff-environmental services and nursing
- Monitor compliance (thoroughness of cleaning, product use) and feedback
- Implement “no touch” room decontamination technology and monitor compliance (and new strategies)
Admission to Room Previously Occupied by Patient C/I with Epidemiologically Important 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%; Shaughnessy et al. ICHE 2011;32:201)

• Exposure to contaminated rooms confers a 5-6 fold increase in odds of infection, hospitals must adopt proven methods for reducing environmental contamination (Cohen et al. ICHE. 2018;39:541-546)
These interventions (effective surface disinfection, thoroughness indicators) not enough to achieve consistent and high rates of cleaning/disinfection

No Touch
(supplements but do not replace surface cleaning/disinfection)
“NO TOUCH” APPROACHES TO ROOM DECONTAMINATION
(UV/VHP~20 microbicidal studies, 12 HAI reduction studies; will not discuss technology with limited data)
Enhanced Disinfection Leading to Reduction of Microbial Contamination and a Decrease in Patient Col/Infection

Anderson et al. Lancet 2017;289:805; Rutala et al. ICHE 2018;39:1118

<table>
<thead>
<tr>
<th></th>
<th>Standard Method</th>
<th>Enhanced method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quat</td>
<td>Quat/UV</td>
</tr>
<tr>
<td>EIP (mean CFU per room)¹</td>
<td>60.8</td>
<td>3.4</td>
</tr>
<tr>
<td>Reduction (%)</td>
<td></td>
<td>94</td>
</tr>
<tr>
<td>Colonization/Infection (rate)²</td>
<td>2.3</td>
<td>1.5</td>
</tr>
<tr>
<td>Reduction (%)</td>
<td></td>
<td>35</td>
</tr>
</tbody>
</table>

All enhanced disinfection technologies were significantly superior to Quat alone in reducing EIPs. Comparing the best strategy with the worst strategy (i.e., Quat vs Quat/UV) revealed that a reduction of 94% in EIP (60.8 vs 3.4) led to a 35% decrease in colonization/infection (2.3% vs 1.5%). Our data demonstrated that a decrease in room contamination was associated with a decrease in patient colonization/infection. First study which quantitatively described the entire pathway whereby improved disinfection decreases microbial contamination which in-turn reduced patient colonization/infection.
This technology ("no touch"-e.g., UV/HP) should be used (capital equipment budget) for terminal room disinfection (e.g., after discharge of patients on Contact Precautions).
Disinfection and Sterilization: Current Issues and Future Perspectives

- Overview DS
- Sterilization-robustness
- HLD-What’s new endoscope reprocessing
- HLD-outpatient care
- HLD-Human papillomavirus
- LLD-Electrostatic sprayers
- LLD-Ultrasound probes
- LLD-sporicide in all discharge pt rooms
- LLD-new sporicide-HP
- Colorized disinfectant
- LLD-“no” touch room decontamination
- Emerging pathogens
  - SARS-CoV-2
  - CRE
  - C. auris
- Continuous room decontamination technologies
  - Continuously active disinfectant
Centers for Disease Control & Prevention says the virus spreads from person to person mainly through respiratory droplets from coughing, sneezing or talking in close proximity to each other, but the CDC has also said it may be possible for a person to get COVID-19 by touching a surface or object that has the virus on it and then touching their own mouth, nose or possibly their eyes. CDC clarified while it is still possible that a person can catch it from touching a contaminated surface, it’s “not thought to be the main way the virus spreads.”
Transmission of SARS-CoV-2

- Droplet (< 6 feet)
- Direct-person-to-person via respiratory aerosols
- Indirect (via the contaminated environment); not main route
- Asymptomatic (infection transmission demonstrated)
- Pre-symptomatic—highly likely
Role of Healthcare Surface Environment in SARS-CoV-2 Transmission

- Survival on environmental surfaces
  - Hours to days (SARS-CoV-2)
  - Depends on experimental conditions such as viral titer ($10^7$ higher than real life) and volume of virus applied to surface, suspending medium, temperature, relative humidity and surface substrates
  - Human coronavirus 229E persist on surface materials at RT for at least 5 days
  - SARS-CoV-2 can be viable on surfaces for 3 days (plastic, stainless steel ~2-3 days, cardboard ~24h)
  - Suggest transmission of SARS-CoV-2 may occur
Contamination of SARS-CoV-2 RNA by PCR on environmental surfaces and medical devices have been documented. Rate varies from 0-75% (median 12.1%).
# Role of Healthcare Surface Environment in SARS-CoV-2 Transmission

Kanamori, Weber, Rutala, Clin Infect Dis, [https://doi.org/10.1093/cid/ciaa1467](https://doi.org/10.1093/cid/ciaa1467), 28 September 2020

<table>
<thead>
<tr>
<th>SARS-CoV-2 RNA</th>
<th>Sink</th>
<th>BP monitor</th>
<th>Infusion pump</th>
<th>Keyboard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bed rail</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bedside table</td>
<td>Floor</td>
<td>ECG monitor</td>
<td>Fluid stand</td>
<td>Phone</td>
</tr>
<tr>
<td>Chair</td>
<td>Toilet seat</td>
<td>Oxygen regulator</td>
<td>Hand sanitizer</td>
<td>Computer mouse</td>
</tr>
<tr>
<td>Doorknob</td>
<td>Toilet bowl</td>
<td>Oxygen mask</td>
<td>Trash can</td>
<td>Door</td>
</tr>
<tr>
<td>Light switches</td>
<td>Stethoscope</td>
<td>CT scanner</td>
<td>Self-service printer</td>
<td>Glass window</td>
</tr>
<tr>
<td>Call button</td>
<td>Pulse oximetry</td>
<td>Ventilator</td>
<td>Desktop</td>
<td>PPE storage area</td>
</tr>
<tr>
<td>Centrifuge</td>
<td>Biosafety cabinet</td>
<td>Infant bed</td>
<td>Air outlet</td>
<td>Ambu bag</td>
</tr>
<tr>
<td>TV remote</td>
<td>Bed sheet</td>
<td>Urinary catheters</td>
<td>TV</td>
<td>Beepers</td>
</tr>
<tr>
<td>Elevator buttons</td>
<td>Ventilator tubing</td>
<td>Glove boxes</td>
<td>Touch screen</td>
<td>All surfaces in nurse’s station</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Detection of SARS-CoV-2 RNA does not represent the presence of viable virus. Further, even the detection of viable virus, does not mean an infectious dose of SARS-CoV-2 is present. Infectious dose for SARS-CoV-1 estimated to be 280 viral particles to cause disease in 50% of the population.
Do established infection prevention measures prevent spread of SARS-CoV-2 to the hospital environment beyond the patient room?

Jerry et al. J Hosp Infection 2020

Contamination rate: patient room-42% (11/26); nurse’s station-3%; post terminal clean-4% (1/25)

<table>
<thead>
<tr>
<th>Sites of swabs/air samples and results</th>
<th>Sample location</th>
<th>Grand total</th>
<th>Detected</th>
<th>Not detected</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>COVID-19 patient’s room</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bed rail</td>
<td>6</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Bedside table</td>
<td>6</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Call bell</td>
<td>4</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Patient chair-arm</td>
<td>4</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Remote for bed</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Toilet door handle</td>
<td>4</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>26</td>
<td>11</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>Nurses’ station COVID-19 cohort ward</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Desk</td>
<td>10</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Keyboard</td>
<td>10</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Telephone</td>
<td>10</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>30</td>
<td>1</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>Patient room post-terminal clean</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bed rail</td>
<td>5</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Bedside table</td>
<td>5</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Call bell</td>
<td>5</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Patient chair-arm</td>
<td>5</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Toilet door handle</td>
<td>5</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>25</td>
<td>1</td>
<td>24</td>
</tr>
</tbody>
</table>
Viable SARS-CoV-2 on Surfaces
Environmental Contamination in COVID-19 Rooms with Severe Pneumonia

Ahn et al. J Hosp Infec 2020;106:570

Pt 1 and 2-2/48-4% (closed suction to ventilator) pt 3-13/28-46% (high-flow oxygen therapy via nasal cannula, non-invasive ventilation). Found viable virus (7/28-25%) only on surfaces within droplet distance. All air samples negative.
Found viable virus only on surface within droplet distance.
# Inactivation of Coronavirus

Kampf G. J Hosp Infect 2020

## Table II. Inactivation of coronaviruses by different types of biocidal agents in suspension tests.

<table>
<thead>
<tr>
<th>Biocidal agent</th>
<th>Concentration</th>
<th>Virus</th>
<th>Strain / isolate</th>
<th>Exposure time</th>
<th>Reduction of virus infectivity (log₁₀)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>95%</td>
<td>SARS-CoV</td>
<td>Isolate FFM-1</td>
<td>30 s</td>
<td>≥ 5.5</td>
<td>[29]</td>
</tr>
<tr>
<td></td>
<td>85%</td>
<td>SARS-CoV</td>
<td>Isolate FFM-1</td>
<td>30 s</td>
<td>≥ 5.5</td>
<td>[29]</td>
</tr>
<tr>
<td></td>
<td>80%</td>
<td>SARS-CoV</td>
<td>Isolate FFM-1</td>
<td>30 s</td>
<td>≥ 4.3</td>
<td>[29]</td>
</tr>
<tr>
<td></td>
<td>80%</td>
<td>MERS-CoV</td>
<td>Strain EMC</td>
<td>30 s</td>
<td>&gt; 4.0</td>
<td>[14]</td>
</tr>
<tr>
<td></td>
<td>78%</td>
<td>SARS-CoV</td>
<td>Isolate FFM-1</td>
<td>30 s</td>
<td>≥ 5.0</td>
<td>[28]</td>
</tr>
<tr>
<td></td>
<td>70%</td>
<td>MHV</td>
<td>Strains MHV-2 and MHV-N</td>
<td>10 min</td>
<td>&gt; 3.9</td>
<td>[30]</td>
</tr>
<tr>
<td>2-Propanol and 1-</td>
<td>100%</td>
<td>SARS-CoV</td>
<td>Isolate FFM-1</td>
<td>30 s</td>
<td>≥ 3.3</td>
<td>[28]</td>
</tr>
<tr>
<td>propanol 45% and 30%</td>
<td>75%</td>
<td>SARS-CoV</td>
<td>Isolate FFM-1</td>
<td>30 s</td>
<td>≥ 4.0</td>
<td>[14]</td>
</tr>
<tr>
<td></td>
<td>75%</td>
<td>MERS-CoV</td>
<td>Strain EMC</td>
<td>30 s</td>
<td>≥ 3.3</td>
<td>[28]</td>
</tr>
<tr>
<td></td>
<td>50%</td>
<td>SARS-CoV</td>
<td>Isolate FFM-1</td>
<td>30 s</td>
<td>≥ 3.3</td>
<td>[28]</td>
</tr>
<tr>
<td></td>
<td>50%</td>
<td>MHV</td>
<td>Strains MHV-2 and MHV-N</td>
<td>10 min</td>
<td>&gt; 3.7</td>
<td>[30]</td>
</tr>
<tr>
<td>2-Propanol and 1-</td>
<td>45%</td>
<td>SARS-CoV</td>
<td>Isolate FFM-1</td>
<td>30 s</td>
<td>≥ 2.8</td>
<td>[28]</td>
</tr>
<tr>
<td>propanol 3%</td>
<td>0.2%</td>
<td>HCoV</td>
<td>ATCC VR-759 (strain DC43)</td>
<td>10 min</td>
<td>0.0</td>
<td>[31]</td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>0.05%</td>
<td>MHV</td>
<td>Strains MHV-2 and MHV-N</td>
<td>10 min</td>
<td>&gt; 3.7</td>
<td>[30]</td>
</tr>
<tr>
<td></td>
<td>0.05%</td>
<td>CCV</td>
<td>Strain I-71</td>
<td>10 min</td>
<td>&gt; 3.7</td>
<td>[30]</td>
</tr>
<tr>
<td></td>
<td>3.0</td>
<td>CCV</td>
<td>Strain S378</td>
<td>3 d</td>
<td>&gt; 4.0</td>
<td>[32]</td>
</tr>
<tr>
<td>Didecyldimethylammonium chloride</td>
<td>0.0025%</td>
<td>CCV</td>
<td>Strain S378</td>
<td>3 d</td>
<td>&gt; 4.0</td>
<td>[32]</td>
</tr>
<tr>
<td>Chlorhexidine</td>
<td>0.02%</td>
<td>MHV</td>
<td>Strains MHV-2 and MHV-N</td>
<td>10 min</td>
<td>0.7 – 0.8</td>
<td>[30]</td>
</tr>
<tr>
<td>Digluconate</td>
<td>0.02%</td>
<td>CCV</td>
<td>Strain I-71</td>
<td>10 min</td>
<td>0.3</td>
<td>[30]</td>
</tr>
<tr>
<td>Sodium hypochlorite</td>
<td>0.21%</td>
<td>MHV</td>
<td>Strain MHV-1</td>
<td>30 s</td>
<td>≥ 4.0</td>
<td>[33]</td>
</tr>
<tr>
<td></td>
<td>0.01%</td>
<td>MHV</td>
<td>Strains MHV-2 and MHV-N</td>
<td>10 min</td>
<td>≥ 3.3</td>
<td>[30]</td>
</tr>
<tr>
<td></td>
<td>0.01%</td>
<td>CCV</td>
<td>Strain I-71</td>
<td>10 min</td>
<td>≥ 3.3</td>
<td>[30]</td>
</tr>
<tr>
<td></td>
<td>0.001%</td>
<td>CCV</td>
<td>Strain I-71</td>
<td>10 min</td>
<td>≥ 3.1</td>
<td>[30]</td>
</tr>
<tr>
<td>Hydrogen peroxide</td>
<td>0.5%</td>
<td>HCoV</td>
<td>Strain 229E</td>
<td>1 min</td>
<td>&gt; 4.0</td>
<td>[34]</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>1%</td>
<td>SARS-CoV</td>
<td>Isolate FFM-1</td>
<td>2 min</td>
<td>≥ 3.0</td>
<td>[28]</td>
</tr>
</tbody>
</table>
CDC recommends that an EPA-registered disinfectant on the EPA’s List N that has qualified under the emerging pathogen program for use against SARS-CoV-2 be chosen for the COVID-19 patient care.

List N has >450 entries and 32 different active ingredients.
Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants


Prions
Spores (C. difficile)
Mycobacteria
Non-Enveloped Viruses (norovirus, adeno)
Fungi
Bacteria (MRSA, VRE, Acinetobacter)
Enveloped Viruses (SARS-CoV-2)
List N Tool: COVID-19 Disinfectants

https://cfpub.epa.gov/giwiz/disinfectants/index.cfm

EPA's list of products for use against SARS-CoV-2, the virus that causes COVID-19, by selecting one or more of the corresponding criteria above. All products on this list meet EPA's criteria for use against SARS-CoV-2, the virus that causes COVID-19. These products are for use on surfaces, NOT humans. At any point, click the "Show Results" button to view your customized list of results. Select as many, or as few, criteria as you would like. Click the "Clear Results" button to remove all previous selections and start over. Click "Browse All" to display all products.
List N Tool: COVID-19 Disinfectants

32 Active Ingredients

- Ethyl alcohol
- Hydrogen peroxide
- Hypochlorite
- Isopropyl alcohol
- Peracetic acid
- Phenolic
- Quaternary ammonium
Germicidal Activity against Carbapenem/Colistin-Resistant Enterobacteriaceae Using a Quantitative Carrier Test Method

Hajime Kanamori, a,b William A. Rutala, a,b Maria F. Gergen, a Emily E. Sickbert-Bennett, a,b David J. Weber a,b

a Department of Hospital Epidemiology, University of North Carolina Health Care, Chapel Hill, North Carolina, USA
b Division of Infectious Diseases, University of North Carolina School of Medicine, Chapel Hill, North Carolina, USA

ABSTRACT Susceptibility to germicides for carbapenem/colistin-resistant Enterobacteriaceae is poorly described. We investigated the efficacy of multiple germicides against these emerging antibiotic-resistant pathogens using the disc-based quantitative carrier test method that can produce results more similar to those encountered in health care settings than a suspension test. Our study results demonstrated that germicides commonly used in health care facilities likely will be effective against carbapenem/colistin-resistant Enterobacteriaceae when used appropriately in health care facilities.

KEYWORDS carbapenem-resistant Enterobacteriaceae, Klebsiella pneumoniae carbenemase, colistin-resistant Enterobacteriaceae, mcr-1, germicides, disinfectants, antiseptics, efficacy
Efficacy of Disinfectants and Antiseptics against Carbapenem-Resistant Enterobacteriaceae


- $\geq 3 \log_{10}$ reduction (CRE, 1m, 5% FCS, QCT)
  - 0.20% peracetic acid
  - 2.4% glutaraldehyde
  - 0.5% Quat, 55% isopropyl alcohol
  - 58% ethanol, 0.1% QUAT
  - 28.7% isopropyl alcohol, 27.3% ethyl alcohol, 0.61% QAC
  - 0.07% o-phenylphenol, 0.06% p-tertiary amylphenol
  - ~5,250 ppm chlorine
  - 70% isopropyl alcohol
  - Ethanol hand rub (70% ethanol)
  - 0.65% hydrogen peroxide, 0.15% peroxyacetic acid
  - Accelerated hydrogen peroxide, 1.4% and 2.0%
  - Quat, (0.085% QACs; not K. pneumoniae)
Deadly, drug-resistant Candida yeast infection spreads in the US

*Candida auris* causes multidrug-resistant infections that can result in organ failure

Katerina Kon/Science Photo Library
Candida auris is a globally emerging pathogen that is often resistant to multiple antifungal agents.

In several reports, C. auris has been recovered from the hospital environment.

CDC has recommended daily and post-discharge disinfection of surfaces in rooms of patients with C. auris infection.

No hospital disinfectants are registered for use specifically against C. auris, and its susceptibility to germicides is not known.
Efficacy of Disinfectants and Antiseptics against *Candida auris*


- ≥3 \( \log_{10} \) reduction (*C. auris*, 1m, 5% FCS, QCT)
  - 0.20% peracetic acid
  - 2.4% glutaraldehyde
  - 0.65% hydrogen peroxide, 0.14% peroxycetic acid
  - 0.5% Quat, 55% isopropyl alcohol
  - Disinfecting spray (58% ethanol, 0.1% QUAT)
  - 28.7% isopropyl alcohol, 27.3% ethyl alcohol, 0.61% QAC
  - 0.07% o-phenylphenol, 0.06% p-tertiary amylphenol
  - 70% isopropyl alcohol
  - ~5,250 ppm chlorine
  - Ethanol hand rub (70% ethanol)
  - Accelerated hydrogen peroxide, 1.4%
  - Accelerated hydrogen peroxide, 2%
Efficacy of Disinfectants and Antiseptics against *Candida auris*


- $\leq 3 \log_{10}$ (most $< 2 \log_{10}$) reduction ($C. \text{ auris}$, 1m, 5% FCS, QCT)

- 0.55% OPA
- 3% hydrogen peroxide
- Quat, (0.085% QACs)
- 10% povidone-iodine
- ~1,050 ppm chlorine
- 2% Chlorhexidine gluconate-CHG
- 4% CHG
- 0.5% triclosan
- 1% CHG, 61% ethyl alcohol
- 1% chloroxylenol
Disinfection and Sterilization: Current Issues and Future Perspectives

- Overview DS
- Sterilization-robustness
- HLD-What’s new endoscope reprocessing
- HLD-outpatient care
- HLD-Human papillomavirus
- LLD-Electrostatic sprayers
- LLD-Ultrasound probes
- LLD-sporicide in all discharge pt rooms

- LLD-new sporicide-HP
- Colorized disinfectant
- LLD-“no” touch room decontamination
- Emerging pathogens
  - SARS-CoV-2
  - CRE
  - C. auris

- Continuous room decontamination technologies
  - Continuously active disinfectant
Continuous Room Decontamination Technologies for Disinfection of the Healthcare Environment

Weber, Rutala et al. AJIC. 2019;47:A72; Rutala et al. ICHE 2019

- Visible light disinfection through LEDs
- Dry/dilute hydrogen peroxide
- Self-disinfecting surfaces (e.g., copper)
- Far UV 222 nm
- Bipolar ionization
- Multijet cold air plasma
- **Continuously active disinfectant** (CAD) or persistent disinfectant that provides continuous disinfection action
  - Allows continued disinfection and may eliminate the problem of recontamination
  - Patients, staff and visitors can remain in the room
Microbial Assessment of Recontamination with *Acinetobacter* in Patient Room Environment in Burn Units

Rutala et al. AJIC. 2020; 48 Suppl;S20

- **Purpose:** assess how much environmental sites (e.g., chair, bedrail, overbed table, stock cabinet, IV pump, etc.) become recontaminated with *Acinetobacter* over time after cleaning/disinfection.

- **Results:**
  - At baseline all environmental sites sampled except overbed table were contaminated with *Acinetobacter*.
  - No *Acinetobacter* were detected except bed rail just after cleaning/disinfection.
  - First time to recontamination with *Acinetobacter* was 3 hours at chair, 2 hours at overbed table, 3 hours at stock cabinet, and 2 hours at IV pump. No recontamination was observed at the monitor.
  - The level of *Acinetobacter* contamination on surfaces was occasionally high (e.g., when a stock cabinet was sampled at 5 hours, 75 of 96 CFU were *Acinetobacter*).
  - The amount of recontamination with aerobes and *Acinetobacter* on some surfaces tended to increase over time.
Surfaces should be hygienically clean (not sterile)-free of pathogens in sufficient numbers to prevent human disease
Test surface inoculated \((10^5)\), treated with test disinfectant, allowed to dry.

Surface will undergo “wears” (abraded under alternating wet and dry conditions [24 passes, 12 cycles]) and 6 re-inoculations \((10^{\geq 3.75}, 30\text{min dry})\) over 48hr.

At the end of the study and at least 48 hours later, the ability of the test surface to kill microbes (99.9%) within 1 min is measured using the last inoculation \((10^6)\)
Efficacy of a Continuously Active Disinfectant Against Healthcare Pathogens


4-5 log\textsubscript{10} reduction in 5 min over 24hr for most pathogens; ~99% reduction with *Klebsiella* and CRE *Enterobacter*. Redmond et al. found 5 log\textsubscript{10} reduction for CRE *Enterobacter*, *K. pneumoniae*, MRSA, VRE, and *C. auris*

<table>
<thead>
<tr>
<th>Test Pathogen</th>
<th>Mean Log\textsubscript{10} Reduction , 95% CI n=4</th>
</tr>
</thead>
<tbody>
<tr>
<td>S.aureus*</td>
<td>4.4 (3.9, 5.0)</td>
</tr>
<tr>
<td>S.aureus (formica)</td>
<td>4.1 (3.8, 4.4)</td>
</tr>
<tr>
<td>S.aureus (stainless steel)</td>
<td>5.5 (5.2, 5.9)</td>
</tr>
<tr>
<td>VRE</td>
<td>≥4.5</td>
</tr>
<tr>
<td><em>E.coli</em></td>
<td>4.8 (4.6, 5.0)</td>
</tr>
<tr>
<td><em>Enterobacter sp.</em></td>
<td>4.1 (3.5, 4.6)</td>
</tr>
<tr>
<td><em>Candida auris</em></td>
<td>≥5.0</td>
</tr>
<tr>
<td><em>K pneumoniae</em></td>
<td>1.5 (1.4, 1.6)</td>
</tr>
<tr>
<td>CRE <em>E.coli</em></td>
<td>3.0 (2.6, 3.4)</td>
</tr>
<tr>
<td>CRE <em>Enterobacter</em></td>
<td>2.0 (1.6, 2.4)</td>
</tr>
<tr>
<td>CRE <em>K pneumoniae</em></td>
<td>2.1 (1.8, 2.4)</td>
</tr>
</tbody>
</table>
Comparison of CAD with Three Disinfectants Using EPA Method and *S. aureus*


<table>
<thead>
<tr>
<th>Test Disinfectant</th>
<th>Mean Log$_{10}$ Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuously Active Disinfectant</td>
<td>4.4</td>
</tr>
<tr>
<td>Quat-Alcohol</td>
<td>0.9</td>
</tr>
<tr>
<td>Improved hydrogen peroxide</td>
<td>0.2</td>
</tr>
<tr>
<td>Chlorine</td>
<td>0.1</td>
</tr>
</tbody>
</table>
Comparison of *S. aureus* and enterococci recovered from PME at baseline, 1, 4, 7 days
The percentage of sites positive for *S. aureus* and/or enterococci was significantly reduced on days 1-7 in the continuously active group (3 of 93, 3%) versus both the no treatment group (20 of 97, 21%) and the Quat group (11 of 97, 11%)
Will the continuously active disinfectant kill viruses like coronaviruses?
A novel disinfectant studied using an EPA protocol (wears/re-inoculations) demonstrated excellent continuous antiviral activity (i.e., >4.5-$\log_{10}$ reduction) in 1 minute after 48 hours for a human coronavirus, 229E.

<table>
<thead>
<tr>
<th>Carrier Treatment with Wears and Re-inoculations</th>
<th>Contact Time</th>
<th>Mean Viral Recovery Titer per Carrier ($\log_{10}$)</th>
<th>$\log_{10}$ Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control (sterile water, n=3)</td>
<td>1 minute</td>
<td>6.00 ± 0.25</td>
<td>N.A.</td>
</tr>
<tr>
<td>Test disinfectant (n=3)</td>
<td>1 minute</td>
<td>$\leq 1.50$ ± 0.00</td>
<td>&gt;4.50</td>
</tr>
</tbody>
</table>
A continuously active disinfectant may reduce or eliminate the problem of recontamination and the role of contaminated environmental surfaces and equipment in transmission of healthcare pathogens including SARS-CoV-2.
Disinfection and Sterilization: Current Issues and Future Perspectives

- Overview DS
- Sterilization-robustness
- HLD-What’s new endoscope reprocessing
- HLD-outpatient care
- HLD-Human papillomavirus
- LLD-Electrostatic sprayers
- LLD-Ultrasound probes
- LLD-sporicide in all discharge pt rooms
- LLD-new sporicide-HP
- LLD-“no” touch room decontamination
- Emerging pathogens
  - SARS-CoV-2
  - CRE
  - C.auris
- Continuous room decontamination technologies
  - Continuously active disinfectant
Environmental Disinfection in Healthcare Facilities

- Continuously active disinfectants reduces bioburden
- Whether a CAD translates in a reduction of HAIs remains to be determined
- Continuously active disinfectants should not alter the frequency of cleaning and disinfection as one of the purposes of routine cleaning and disinfection is to remove dirt and debris in addition to the reduction of microbial contamination