Disinfection and Sterilization: The Good, The Bad and The Ugly

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Director, Hospital Epidemiology, Occupational Health and Safety at UNC Health Care; Research Professor of Medicine and Director, Statewide Program for Infection Control and Epidemiology at University of North Carolina School of Medicine at Chapel Hill, USA
Our Responsibility to the Future

Prevent All Infectious Disease Transmission by Instruments and the Environment in 5 years

Via Research/Technology/Automation/Competency
DISCLOSURES

- Consultation
  - Clorox

- Honoraria
  - 3M
  - Clorox

- Grants to UNC or UNC Hospitals
  - CDC, CMS, Nanosonics
Research and Technology/Automation
Five-Year Plan to Prevent Exposures/Infections

- Sterilization-highly effective
  - Huge margin of safety, modified Spaulding classification

- High-Level Disinfection-challenge #1
  - Eliminate endoscope-related infections, promote automation, research (scopes), sterilization

- Low-Level Disinfection-challenge #2
  - Eliminate environment as source of infection, “no touch” room decontamination methods; continuous room decontamination
Research and Technology/Automation
Five-Year Plan to Prevent Exposures/Infections

- **Sterilization**
  - Huge margin of safety, modified Spaulding classification

- **High-Level Disinfection**
  - Endoscope-related infections will promote automation, research (scopes), sterilization

- **Low-Level Disinfection**
  - No Touch room decontamination methods; continuous room decontamination
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
Endoscopes top ECRI’s list of 10 health technology hazards

Infections/infection risk not good but the solution is good!
First Challenge to Meet Goals

Prevent All Infectious Disease Transmission Associated with Endoscopy in 5 years
Via Research/Technology/Automation/Competency
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 ($10^4$)
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/Colonscopy</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, Mtib, Mycobacteria</td>
<td>778</td>
<td>98</td>
<td>C/D, AER, water</td>
</tr>
<tr>
<td>Totals</td>
<td>98</td>
<td>1113</td>
<td>249</td>
<td></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

<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>Duod.</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>Duod.</td>
<td>7</td>
<td>Yes (2 scopes)</td>
<td>Yes (PFGE)</td>
<td>Wendort, 2015</td>
</tr>
<tr>
<td><em>K. pneumoniae</em> (OXA)</td>
<td>Duod.</td>
<td>5</td>
<td>No</td>
<td></td>
<td>Kola A, 2015</td>
</tr>
<tr>
<td><em>E. coli</em> (NDM-CRE)</td>
<td>Duod.</td>
<td>39</td>
<td>Yes</td>
<td>Yes (PFGE)</td>
<td>Epstein L, 2014</td>
</tr>
</tbody>
</table>

**Additional Outbreaks (not published; news media reports):**
- UCLA, 2015, CRE, 179 patients exposed (2 deaths), 2 colonized duodenoscopes
- CMC, 2015, CRE, 18 patients exposed (7 infected), duodenoscopes
- Cedars-Sinai, 2015, CRE, 67 patients exposed (4 infected), duodenoscopes
- Wisconsin, 2013, CRE, (5 infected), duodenoscopes
- University of Pittsburgh, 2012, CRE, 9 patients, duodenoscopes
Endemic Transmission of Infections Associated with GI Endoscopes Likely Go Unrecognized

- Inadequate surveillance of outpatient procedures for healthcare-associated infections
- Long lag time between colonization and infection
- Low frequency of infection
- Pathogens “usual” enteric flora
- Risk of some procedures might be lower than others (colonoscopy versus ERCP where normally sterile areas are contaminated in the latter)

CRE and ESBLs
Endoscopy Reprocessing

Microbial Load/Complex Instruments

New Guidelines

- Multi-society guideline (in prep)
- AORN-2016
- AAMI-2015
- SGNA-2015
- Must educate/comply but confident will not prevent all infections and patient exposures due to microbial load and instrument complexity
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.³ 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.¹

In this issue of JAMA, Epstein and colleagues² 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.³⁴ High-level disinfection achieves complete elimination of all microorganisms, except for small numbers of bacterial spores. Because flexible gastrointestinal endoscopic instruments are heat lable, only high-level disinfection with chemical agents or low-temperature sterilization technologies are possible.³ 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.³⁵ However, until now,
FDA Panel, May 2015, Recommended Sterilization of Duodenoscopes (requires FDA-cleared sterilization technology that achieves a SAL $10^{-6}$ with duodenoscopes—not yet available)
EH Spaulding believed that how an object will be disinfected depended on the object’s intended use (developed 1968).

**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 (or non-germicidal detergent).
EH Spaulding believed that how an object will be disinfected depended on the object’s intended use (modified).

**CRITICAL** - objects which directly or 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).
Technology Will Be Developed to Sterilize Endoscopes or Use a Sterile, Disposable GI Scopes
Research and Technology/Automation
Five-Year Plan to Prevent Exposures/Infections

- **Sterilization**
  - Huge margin of safety, modified Spaulding classification

- **High-Level Disinfection**
  - Endoscope-related infections will promote automation, research (scopes), sterilization

- **Low-Level Disinfection**
  - No Touch room decontamination methods; continuous room decontamination
Research and Technology/Automation
Reprocessing Channeled Endoscopes

Cystoscope- “completely immerse” in HLD (J Urology 2008.180:588)
Reprocessing Channeled Endoscopes

<table>
<thead>
<tr>
<th>Exposure Method</th>
<th>CRE (<em>K. pneumoniae</em>) Inoculum before HLD (glutaraldehyde)</th>
<th>CRE (<em>K. pneumoniae</em>) 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
Reprocessing Channeled Endoscopes

Cystoscope-HLD perfused through lumen with syringe (luer locks onto port and syringe filled and emptied until no air exits in the scope nor air in barrel of syringe-syringe and lumen filled with HLD)
Technology and Automation

Given the choice of changing human behavior (e.g., improving aseptic technique) or designing a better device, the device will always be more successful... Robert A. Weinstein
Performed all 12 steps with only 1.4% of endoscopes using manual versus 75.4% of those processed using AER.

<table>
<thead>
<tr>
<th>Observed Activity</th>
<th>Steps Completed (%) (n = 69)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leak test performed in clear water</td>
<td>77</td>
</tr>
<tr>
<td>Disassemble endoscope completely</td>
<td>100</td>
</tr>
<tr>
<td>Brush all endoscope channels and components</td>
<td>43</td>
</tr>
<tr>
<td>Immerse endoscope completely in detergent</td>
<td>99</td>
</tr>
<tr>
<td>Immerse components completely in detergent</td>
<td>99</td>
</tr>
<tr>
<td>Flush endoscope with detergent</td>
<td>99</td>
</tr>
<tr>
<td>Rinse endoscope with water</td>
<td>96</td>
</tr>
<tr>
<td>Purge endoscope with air</td>
<td>84</td>
</tr>
<tr>
<td>Load and complete automated cycle for high-level disinfection</td>
<td>100</td>
</tr>
<tr>
<td>Flush endoscope with alcohol</td>
<td>86</td>
</tr>
<tr>
<td>Use forced air to dry endoscope</td>
<td>45</td>
</tr>
<tr>
<td>Wipe down external surfaces before hanging to dry</td>
<td>90</td>
</tr>
</tbody>
</table>
Automated Endoscope Reprocessors
Hydrogen Peroxide Mist
(uses HP mist to achieve HLD in 7m)
Effectiveness of HP Mist System in Inactivating Healthcare Pathogens on Probes

Rutala, Gergen, Sickbert-Bennett. ICHE 2016;37:613-614

- Automated, closed system that uses HP mist for HLD of ultrasound probes
- $>10^6$ pathogens inoculated onto probe at 2-3 sites
- Inactivated bacteria and good but not complete kill of mycobacteria, spores
- Alternative to high-level disinfection by high-level disinfectants

<table>
<thead>
<tr>
<th>Table 1. Proportion of Surface and Endocavitary Probes Positive After of an Organic Challenge*</th>
<th>System Processing According to the Presence or Absence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Probes with Mycobacterium terrae, No./Total (mean log$_{10}$ reduction and 95% CI)</td>
</tr>
<tr>
<td>5% Fetal Calf Serum-FCS</td>
<td>Probes with vancomycin-resistant <em>Enterococcus</em> (VRE), No./Total</td>
</tr>
<tr>
<td>Present</td>
<td>0/7</td>
</tr>
<tr>
<td>Absent</td>
<td>0/6</td>
</tr>
</tbody>
</table>
Research and Technology/Automation
Five-Year Plan to Prevent Exposures/Infections

- **Sterilization**
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  - Endoscope-related infections will promote automation, research (scopes), sterilization

- **Low-Level Disinfection**
  - Eliminate environmental as source of HA pathogens; No Touch room decontamination; continuous room decontamination
Research and Technology/Automation
Disinfection and Sterilization:
The Good, The Bad and The Ugly

Second Challenge to Meet Goals
Prevent All Infectious Disease Transmission Associated with the Environment in 5 years
Via Research/Technology/Automation/Competency
Environmental Contamination Leads to HAIs


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

• Results in the newly admitted patient having an increased risk of acquiring that pathogen by 39-353%

• For example, increased risk for *C. difficile* is 235% (11.0% vs 4.6%)
Acquisition of MRSA on Hands After Contact with Environment Surfaces
Acquisition of MRSA on Hands/Gloves After Contact with Contaminated Equipment
Transfer of MRSA from Patient or Environment to IV Device and Transmission of Pathogen
Acquisition of *C. difficile* on Patient Hands after Contact with Environmental Sites and Then Inoculation of Mouth
Thoroughness of Environmental Cleaning
Carling P. AJIC 2013;41:S20-S25

Mean = 32%

>110,000 Objects

Mean = 32%
Monitoring the Effectiveness of Cleaning
Cooper et al. AJIC 2007;35:338

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

No Touch

(supplements but do not replace surface cleaning/disinfection)
NEW “NO TOUCH” APPROACHES TO ROOM DECONTAMINATION
Supplement Surface Disinfection
## HYDROGEN PEROXIDE FOR DECONTAMINATION OF THE HOSPITAL ENVIRONMENT


<table>
<thead>
<tr>
<th>Author, Year</th>
<th>HP System</th>
<th>Pathogen</th>
<th>Before HPV</th>
<th>After HPV</th>
<th>% Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>French, 2004</td>
<td>VHP</td>
<td>MRSA</td>
<td>61/85-72%</td>
<td>1/85-1%</td>
<td>98</td>
</tr>
<tr>
<td>Bates, 2005</td>
<td>VHP</td>
<td>Serratia</td>
<td>2/42-5%</td>
<td>0/24-0%</td>
<td>100</td>
</tr>
<tr>
<td>Jeanes, 2005</td>
<td>VHP</td>
<td>MRSA</td>
<td>10/28-36%</td>
<td>0/50-0%</td>
<td>100</td>
</tr>
<tr>
<td>Hardy, 2007</td>
<td>VHP</td>
<td>MRSA</td>
<td>7/29-24%</td>
<td>0/29-0%</td>
<td>100</td>
</tr>
<tr>
<td>Dryden, 2007</td>
<td>VHP</td>
<td>MRSA</td>
<td>8/29-28%</td>
<td>1/29-3%</td>
<td>88</td>
</tr>
<tr>
<td>Otter, 2007</td>
<td>VHP</td>
<td>MRSA</td>
<td>18/30-60%</td>
<td>1/30-3%</td>
<td>95</td>
</tr>
<tr>
<td>Boyce, 2008</td>
<td>VHP</td>
<td>C. difficile</td>
<td>11/43-26%</td>
<td>0/37-0%</td>
<td>100</td>
</tr>
<tr>
<td>Bartels, 2008</td>
<td>HP dry mist</td>
<td>MRSA</td>
<td>4/14-29%</td>
<td>0/14-0%</td>
<td>100</td>
</tr>
<tr>
<td>Shapey, 2008</td>
<td>HP dry mist</td>
<td>C. difficile</td>
<td>48/203-24%</td>
<td>7/203-3%</td>
<td>88</td>
</tr>
<tr>
<td>Barbut, 2009</td>
<td>HP dry mist</td>
<td>C. difficile</td>
<td>34/180-19%</td>
<td>4/180-2%</td>
<td>88</td>
</tr>
<tr>
<td>Otter, 2010</td>
<td>VHP</td>
<td>GNR</td>
<td>10/21-48%</td>
<td>0/63-0%</td>
<td>100</td>
</tr>
</tbody>
</table>
Clinical Trials Using HP for Terminal Room Disinfection to Reduce HAIs

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Design</th>
<th>Pathogen</th>
<th>Reduction in HAIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boyce, 2008</td>
<td>Before-After</td>
<td>CDI</td>
<td>Yes</td>
</tr>
<tr>
<td>Cooper, 2011</td>
<td>Before-After</td>
<td>CDI</td>
<td>Decrease cases (incidence not stated)</td>
</tr>
<tr>
<td>Passaretti, 2013</td>
<td>Prospective cohort</td>
<td>MRSA, VRE, CDI</td>
<td>Yes, in all MDROs</td>
</tr>
<tr>
<td>Manian, 2013</td>
<td>Before-After</td>
<td>CDI</td>
<td>Yes</td>
</tr>
<tr>
<td>Mitchell, 2014</td>
<td>Before-After</td>
<td>MRSA</td>
<td>Yes</td>
</tr>
<tr>
<td>Horn, 2015</td>
<td>Before-After</td>
<td>CDI, VRE, ESBL GNR</td>
<td>Yes</td>
</tr>
</tbody>
</table>
EFFECTIVENESS OF UV-C FOR ROOM DECONTAMINATION (Inoculated Surfaces)

<table>
<thead>
<tr>
<th>Pathogens</th>
<th>Dose*</th>
<th>Mean log$_{10}$ Reduction Line of Sight</th>
<th>Mean log$_{10}$ Reduction Shadow</th>
<th>Time</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRSA, VRE, MDR-A</td>
<td>12,000</td>
<td>3.90-4.31</td>
<td>3.25-3.85</td>
<td>~15 min</td>
<td>Rutala W, et al.¹</td>
</tr>
<tr>
<td>C. difficile</td>
<td>36,000</td>
<td>4.04</td>
<td>2.43</td>
<td>~50 min</td>
<td>Rutala W, et al.¹</td>
</tr>
<tr>
<td>MRSA, VRE</td>
<td>12,000</td>
<td>&gt;2-3</td>
<td>NA</td>
<td>~20 min</td>
<td>Nerandzic M, et al.²</td>
</tr>
<tr>
<td>C. difficile</td>
<td>22,000</td>
<td>&gt;2-3</td>
<td>NA</td>
<td>~45 min</td>
<td>Nerandzic M, et al.²</td>
</tr>
<tr>
<td>C. difficile</td>
<td>22,000</td>
<td>2.3 overall</td>
<td>67.8 min</td>
<td></td>
<td>Boyce J, et al.³</td>
</tr>
<tr>
<td>MRSA, VRE, MDR-A, Asp</td>
<td>12,000</td>
<td>3.5-&gt;4.0</td>
<td>1.7-&gt;4.0</td>
<td>30-40 min</td>
<td>Mahida N, et al.⁴</td>
</tr>
<tr>
<td>MRSA, VRE, MDR-A, Asp</td>
<td>22,000</td>
<td>&gt;4.0*</td>
<td>1.0-3.5</td>
<td>60-90 min</td>
<td>Mahida N, et al.⁴</td>
</tr>
<tr>
<td>C. difficile, G. stear spore</td>
<td>22,000</td>
<td>2.2 overall</td>
<td>73 min</td>
<td></td>
<td>Havill N et al⁵</td>
</tr>
<tr>
<td>VRE, MRSA, MDR-A</td>
<td>12,000</td>
<td>1.61</td>
<td>1.18</td>
<td>25 min</td>
<td>Anderson et al⁶</td>
</tr>
</tbody>
</table>


* μWs/cm²; min = minutes; NA = not available
Clinical Trials Using UV for Terminal Room Decontamination to Reduce HAIs

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Design</th>
<th>Pathogens</th>
<th>Reduction in HAIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levin, 2013</td>
<td>Before-After</td>
<td>CDI</td>
<td>Yes</td>
</tr>
<tr>
<td>Hass, 2014</td>
<td>Before-After</td>
<td>CDI, MRSA, VRE, MDRO-GNR</td>
<td>Yes</td>
</tr>
<tr>
<td>Miller, 2015</td>
<td>Before-After</td>
<td>CDI</td>
<td>Yes</td>
</tr>
<tr>
<td>Nagaraja, 2015</td>
<td>Before-After</td>
<td>CDI</td>
<td>Yes (p=0.06)</td>
</tr>
<tr>
<td>Pegues, 2015</td>
<td>Before-After</td>
<td>CDI</td>
<td>Yes</td>
</tr>
<tr>
<td>Anderson, 2015</td>
<td>Randomized-controlled trial</td>
<td>MRSA, VRE, CDI</td>
<td>Yes</td>
</tr>
<tr>
<td>Vianna, 2016</td>
<td>Before-After</td>
<td>CDI, MRSA, VRE</td>
<td>Yes</td>
</tr>
</tbody>
</table>
The Benefits of Enhanced Terminal Room (BETR) Disinfection Study: Duke/UNC Epicenter
Anderson et al, 2015, ID Week

A Pragmatic, Prospective, Cluster Randomized, Multicenter Crossover Study with 2x2 Factorial Design to Evaluate the Impact of Enhanced Terminal Room Disinfection on Acquisition and Infection Caused by Multidrug-Resistant Organisms
**2x2 Factorial Design**

<table>
<thead>
<tr>
<th></th>
<th>No UV Light</th>
<th>UV Light</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quat*</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>Bleach</td>
<td>C</td>
<td>D</td>
</tr>
</tbody>
</table>

*NOTE: Bleach always used in rooms of patients with suspected or confirmed C. difficile*
Rooms of Patients on Contact Precautions Decontaminated with Standard or Enhanced Methods and “Exposed” Patient Monitored for Target MDRO

Patient in “Seed Room”

Documented infection or colonization with
- MRSA
- VRE
- *C. difficile*
- MDR-Acinetobacter

“Exposed Patient”

In room $\geq 24$ hours

Exposure days = Time spent in “seed room”

Terminal Clean
# Clinical Incidence of All Target MDROs Following the Use of Four Strategies for Terminal Room Disinfection

<table>
<thead>
<tr>
<th>Study Phase Strategy</th>
<th>A Quat</th>
<th>B Quat/UV</th>
<th>C Bleach</th>
<th>D Bleach/UV</th>
</tr>
</thead>
<tbody>
<tr>
<td>All target MDROs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n/exposure days</td>
<td>115/22,426</td>
<td>76/22,389</td>
<td>101/24,261</td>
<td>131/28,757</td>
</tr>
<tr>
<td>Cumulative rate</td>
<td>51.3</td>
<td>33.9</td>
<td>41.6</td>
<td>45.6</td>
</tr>
<tr>
<td>Average rate ± STD</td>
<td>46.1 ± 27.9</td>
<td>28.7 ± 20.5</td>
<td>41.1 ± 16.6</td>
<td>39.2 ± 20.9</td>
</tr>
<tr>
<td>RR (95% CI) p-value</td>
<td>ref</td>
<td>0.70 (0.50-0.98) 0.036</td>
<td>0.85 (0.69-1.04) 0.12</td>
<td>0.91 (0.76-1.09) 0.30</td>
</tr>
</tbody>
</table>

**Conclusion:** Enhanced terminal room disinfection strategies decreased the clinical incidence of target MDROs by 10-30%
### Relationship Between Reduced Environmental Contamination and Reduction of HAIs

**Rutala, Kanamori, Gergen et al. 2016**

<table>
<thead>
<tr>
<th>Intervention</th>
<th>MDR-\textit{Acinetobacter}</th>
<th>\textit{C. difficile}</th>
<th>MRSA</th>
<th>VRE</th>
<th>EIP*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quat</td>
<td>8.95</td>
<td>3.76</td>
<td>8.52</td>
<td>39.6</td>
<td>60.8</td>
</tr>
<tr>
<td>Quat/UV</td>
<td>0.17</td>
<td>2.86</td>
<td>0.11</td>
<td>0.21</td>
<td>3.4</td>
</tr>
<tr>
<td>Bleach</td>
<td>0.39</td>
<td>4.48</td>
<td>4.39</td>
<td>2.43</td>
<td>11.7</td>
</tr>
<tr>
<td>Bleach/UV</td>
<td>0.25</td>
<td>3.25</td>
<td>0.85</td>
<td>1.90</td>
<td>6.3</td>
</tr>
</tbody>
</table>

*EIP*-epidemiologically-important pathogens (mean CFU/room/125cm$^2$) by intervention and contamination in patient rooms.

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.
This technology ("no touch"-UV/HP) should be used (capital equipment budget) for terminal room disinfection (e.g., after discharge of patients on Contact Precautions).
Selection of a UV or HP Device

• Since different UV and hydrogen peroxide systems vary substantially, infection preventionists should review the peer-reviewed literature and choose only devices with demonstrated bactericidal capability as assessed by carrier tests and/or the ability to disinfect actual patient rooms.

• Ideally, one would select a device that has demonstrated bactericidal capability and the ability to reduce HAIs.
To eliminate environmental contribution to HAIs, must also improve thoroughness of cleaning/disinfection *daily basis* also, evaluate new technologies. Hygienically clean (not sterile)-free of pathogens in sufficient numbers to prevent human disease.
Visible Light Disinfection in a Patient Room

(automatic switching between modes performed by wall-mounted controls)

White light

Blue light—increase irradiance, increase kill
Antimicrobial Activity of a Continuous Visible Light Disinfection System

- Visible Light Disinfection uses the blue-violet range of visible light in the 400-450nm region generated through light-emitting diodes (LEDs)
- Initiates a photoreaction with endogenous porphyrin found in microorganisms which yield production of reactive oxygen species inside microorganisms, leading to microbial death
- Overhead illumination systems can be replaced with Visible Light Disinfection counterparts
Percent Reduction of Epidemiologically-Important Pathogens with a Visible Light Disinfection System
Rutala, Kanamori, Gergen, Sickbert-Bennett, Weber. 2015

- MRSA, VRE, and MDR-\textit{Acinetobacter} were greatly reduced on Formica surfaces (>80% at 24h, 20-50% in 3h)
- This technology could be considered for several healthcare decontamination applications (e.g., ORs)
Antimicrobial Activity of a Continuous Visible Light Disinfection System

• **Advantages**
  - Decontamination can be accomplished 24/7 (lights must be on)
  - Patients and staff do not have to leave the room during decontamination
  - Biocidal activity against a range of HA pathogens
  - Room surfaces and equipment decontaminated
  - Residual free, and no known safety or health concerns

• **Disadvantages**
  - Has not been demonstrated to reduce HAIs in clinical trials
  - Kills in hours not minutes
  - Capital equipment costs are substantial
Research and Technology/Automation
Five-Year Plan to Prevent Exposures/Infections

- New Continuous Room Decontamination
  - Dilute hydrogen peroxide, persistent antimicrobials
- Microbiome (collaboration with Duke UMC)
  - Microbiome (collective genomes of all microorganisms that reside) on surgical instruments and environmental surfaces
    - Measure microbiome changes with exposure to disinfection and sterilization practices
    - Improve knowledge on the reservoir and transmission of pathogens
- New Germicides
  - New sporicidal products that kill *C. difficile* spores in 2 minutes; broad surface compatibility (no residue); low odor
Non-Compliance

Human errors, omissions (equipment failures, system problems)-patient infections and exposures
Endoscope Reprocessing Methods
Ofstead, Wetzler, Snyder, Horton, Gastro Nursing 2010; 33:204

Performed all 12 steps with only 1.4% of endoscopes using manual versus 75.4% of those processed using AER

<table>
<thead>
<tr>
<th>Observed Activity</th>
<th>Steps Completed (%) (n = 69)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leak test performed in clear water</td>
<td>77</td>
</tr>
<tr>
<td>Disassemble endoscope completely</td>
<td>100</td>
</tr>
<tr>
<td><strong>Brush all endoscope channels and components</strong></td>
<td>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>
Two Probes in One Cannister
Inadequate Cleaning: Blood on Scope
Incomplete immersion: Only Tip
Health Care Facilities Need to Immediately Review Medical Device Reprocessing Procedures
Train Staff, Audit Adherence to Steps, Provide Feedback on Adherence

This is an official

CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
September 11, 2015, 12:15 EDT (12:15 PM EDT)
CDCN00382

Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

Summary

The Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) are alerting healthcare providers and facilities about the public health need to properly maintain, clean, and disinfect or sterilize reusable medical devices. Recent infection control lapses due to non-compliance with recommended reprocessing procedures highlight a critical gap in patient safety. Healthcare facilities (e.g., hospitals, ambulatory surgical centers, clinics, and doctors’ offices) that utilize reusable medical devices are urged to immediately review current reprocessing practices at their facility to ensure they (1) are complying with all steps as directed by the device manufacturers, and (2) have in place appropriate policies and procedures that are consistent with current standards and guidelines.

Background

Recent media reports describe instances of patients being notified that they may be at increased risk for infection due to lapses in basic cleaning, disinfection, and sterilization of medical devices. These events involved failures to follow manufacturers’ reprocessing instructions for critical[1][2] and semi-critical[1][2] items and highlight the need for healthcare facilities to review policies and procedures that protect patients.

Recommendations

Healthcare facilities should arrange for a healthcare professional with expertise in device reprocessing to immediately assess their reprocessing procedures. This assessment should ensure that reprocessing is done correctly, including allowing enough time for reprocessing personnel to follow all steps recommended by the device manufacturer. The following actions should be performed:

Training
Health Care Facilities Need to Immediately Medical Device Reprocessing Procedures

- Reprocessing lapses resulting in patient infections and exposures
- Healthcare facilities urged to immediately review current reprocessing practices to ensure comply with device manufacturer and guidelines
  - Training (upon hire and at least annually), demonstrate and document competency
  - Audit should assess all reprocessing steps including cleaning, disinfectants (conc, contact time), sterilizer (chemical, biological indicators). Feedback from audits to personnel regarding adherence.
Safe Injection Practices
Reprocessing Semicritical Items
The Joint Commission surveyors will likely check on several high visibility items during your next survey. Reprocessing endoscopes and other semicritical items.
Competency and Compliance with Evidence-Based D/S Guidelines
High Level Disinfection (HLD) Certificate Class

Class size is limited to 24 students

When: Tuesday, July 7, 2015
9am – noon

Where: On Campus
MacNider 18
Chapel Hill

At this class you will:
- Learn how to high-level disinfect semi-critical devices
- Understand your responsibilities related to HLD
- Learn the pitfalls of inadequate high-level disinfection
- Learn about OSHA regulations related to high level disinfectants
- Earn 3 nursing contact hours!

Faculty:
Judie Bringhurst, MSN, RN, CIC

Registration:
By email ONLY please. Email your name, your clinic name, and your phone number to Judie Bringhurst, Hospital Epidemiology: jbringhu@unch.unc.edu You will receive confirmation of your registration by return email.

Parking:
Staff without on-campus parking assignments may want to park in the visitor’s parking deck on Manning Drive.
Managing Instrument (Semicritical and Critical) Reprocessing Competencies and Lists

- Managers should:
  - Keep list of HCP that reprocess semicritical or critical
  - List of instruments reprocessed in their unit/clinic
  - Ensure appropriate competencies in place upon hire and annually (also when new endoscopic models, new processing equipment/products)
  - Surveyors will want demonstration and observation and documentation
  - Documentation is the valid competency form
  - Must be completed by another HCP who also has a valid competency
  - Must be stored in employees’ records
Compliance with Evidence-Based Guidelines
Compliance with Evidence-Based Guidelines

- Must work with our professional organizations (APIC, SHEA, SGNA) to promote compliance with evidence-based guidelines by surveyors not “consensus” guidelines or “commentaries”
- Requiring staff to perform functions with no proven benefit to patient or employee safety may serve to reduce efforts proven to improve patient outcomes
- Strategies should have evidence-based
• No endoscope outbreak or infection related to endoscopes touching
• Outbreaks and exposures related to cleaning, HLD (time, temperature, conc) deficiencies, competency
• Need validated real-time cleaning verification test that predicts microbial contamination/patient exposure (ideally infection risk)
• Cleaning assessment tools are not predictive of infection risks
Infection Risk to Patients
Human Papilloma Virus (HPV) and Endoscopes
Human Papilloma Virus (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 no effect on HPV

Finding inconsistent with other small, non-enveloped viruses such as polio, rhino, echo

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)
Efficacy of HP Mist Against HPV

• HLD widely used to reprocess semicritical items including endocavitary probes
• Tested OPA, hypochlorite and HP mist
• HP mist system and hypochlorite >4 log_{10} reduction, OPA achieved <1 log_{10} reduction
Effectiveness of Germicides Against HPV
(Dr. Carey Allen Moody, UNC and Duke UMC)

- Germicides
  - Aldehydes
    - Glutaraldehyde
    - Ortho-phthalaldehyde
  - Others
    - Phenolics
    - Ethanol
    - CHG-4%
    - Quats

- Germicides
  - Oxidizing agents
    - 1.5% and 2.0% accelerated HP
    - 0.525% sodium hypochlorite
    - 1% HP/0.08% peracetic acid
    - 0.2% peracetic acid, 55°C
    - 1000-1300ppm peracetic acid
What if HPV is Resistant to Aldehydes?

- If unlike all other non-enveloped viruses that are susceptible to aldehydes
- Upset the Spaulding classification scheme (HLD kill all viruses)
- If only oxidizing agents kill HPV (transition to PA or HP alone or combination)
Endoscopes top ECRI’s list of 10 health technology hazards
What does this off-road driver/vehicle have in common with endoscope? 10 Billion, complex
ENDOSCOPE REPROCESSING: CHALLENGES
Rutala, Weber Infect Control Hosp Epidemiol. 2015;36:643

Endoscope: $10^7$-$10^{10}$-crevices difficult to clean/disinfect

Surgical instruments: $<10^2$ bacteria
FEATURES OF ENDOSCOPES THAT PREDISPOSE TO DISINFECTION FAILURES


- Heat labile
- Long, narrow lumens
- 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 (4-6 $\log_{10}$ reduction) and HLD (4-6 $\log_{10}$ reduction) essential for patient safe instrument
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
- Biofilms—unclear if contribute to failure of endoscope reprocessing
What Should We Do Now?
How Can We Prevent ERCP-Related Infections?


• No single, simple and proven technology or prevention strategy that hospitals can use to guarantee patient safety

• Of course, must continue to emphasize the enforcement of evidenced-based practices, including equipment maintenance and routine audits with at least yearly competency testing of reprocessing staff

• Must do more or additional outbreaks will continue
Hospitals performing ERCPs should do one of the following (priority ranked); doing nothing is not an option:

- Ethylene oxide sterilization after high level disinfection with periodic microbiologic surveillance (UNC Hospitals)
- 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
What Is the Public Health Benefit?
No ERCP-Related Infections

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

HLD (6 log$_{10}$ reduction) vs Sterilization (12 log$_{10}$ reduction=SAL 10$^{-6}$)
EH Spaulding believed that how an object will be disinfected depended on the object’s intended use (modified).

**CRITICAL** - objects which directly or secondarily (i.e., via a mucous membrane such as duodenoscope) 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).
Some Potential Sterilization Technologies for Duodenoscopes

• **Optimize existing low-temperature sterilization technology**
  - Hydrogen peroxide gas plasma
  - Vaporized hydrogen peroxide
  - Ethylene oxide

• **Potential new low-temperature sterilization technology**
  - Ozone plus hydrogen peroxide vapor
  - Nitrogen dioxide
  - Supercritical CO2
  - Peracetic acid vapor

• **Steam sterilization for heat-resistant endoscopes**
Technology Will Be Developed to Sterilize Endoscopes or Use a Sterile, Disposable GI Scopes
The Good

- **Sterilization**- highly effective
  - **Bls, emerging technologies, sterilization endoscopes**

- **High-level disinfection**
  - Endoscope-related infections will promote automation and **sterilization**

- **Low-level disinfection**
  - **Eliminate environment as source**-
    - “No touch” room decontamination, new germicides, continuous room decontamination
The Bad

- Improve instrument reprocessing
  - Competency
  - Compliance with evidence-based guidelines
  - Research/Technology/Automation
The Ugly

- Infection risks
  - Endoscopes
  - Human papilloma virus
Disinfection and Sterilization:
The Good, The Bad and The Ugly

Our Responsibility to the Future
Prevent All Infectious Disease Transmission by Instruments and the Environment in 5 years
Via Research/Technology/Automation/Competency
Five-Year Plan to Prevent Infections Associated with Instruments and Environment

Research/Technology/Automation/Compliance

• Sterilization-highly effective
  ▪ Comply with IFU/guidelines, competency, implement technologies/research

• High-Level Disinfection-no margin of safety
  ▪ Transition to sterilization (margin of safety)-will require new technology, research (HPV), automation and competency

• Low-Level Disinfection
  ▪ Eliminate environment as source of HA pathogens by “no touch” room decontamination methods; continuous room decontamination; new surface disinfection technology
No Infections Associated with Instruments or the Environment

Set our goal, made a plan, we have a purpose, it is our passion that will make it happen!
“Some people want it to happen, some wish it would happen, others make it happen.”

-Michael Jordan
THANK YOU!

www.disinfectionandsterilization.org
Spreading knowledge. Preventing infection.

Association for Professionals in Infection Control and Epidemiology (APIC)