Disinfection and Sterilization: What’s New?

William A. Rutala, PhD, MPH
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

DISCLOSURES

• Consultation
• Honoraria (2014, 2015)
  ■ 3M, ASP, Clorox
• Grants
  ■ CDC, CMS, Nanosonics
HLD and Sterilization: What’s New?

- **Sterilization**
  - Biological indicators, emerging technologies, modified Spaulding classification

- **High-Level Disinfection**
  - Endoscope-related infections, channeled scopes, reuse of single-use items

- **Low-Level Disinfection**
  - Emerging pathogens, room decontamination methods

www.disinfectionandsterilization.org
Health Care Facilities Need to Immediately Medical Device Reprocessing Procedures

Train Staff, Audit Adherence to Steps, Provide Feedback on Adherence

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 the 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 events, including a recent death, appear to underscore that inconsistent reprocessing practices highlight a critical gap in patient safety. Healthcare facilities must implement procedures that ensure compliance with device manufacturer and guideline recommendations. It is critical that (1) all steps as directed by the device manufacturer be completed, and (2) personnel receive appropriate training and procedural feedback to ensure adherence.

Background

Recent media reports describe instances of patients being infected that may be due to equipment failure to properly clean, disinfect, or sterilize medical devices. These events involve failure to follow manufacturer’s reprocessing instructions for critical and semi-critical 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

• Reprocessing lapses resulting in patient infections and exposures
• Healthcare facilities urged to immediately review current reprocessing practices to ensure compliance 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.
CDC Guideline for Disinfection and Sterilization

HLD and Sterilization:
What’s New

- Sterilization
  - Biological indicators, emerging technologies, modified Spaulding classification

- High-Level Disinfection
  - Endoscope-related infections, channeled scopes, reuse of single-use items

- Low-Level Disinfection
  - Emerging pathogens, room decontamination methods
Sterilization of “Critical Objects”

- Steam sterilization
- Hydrogen peroxide gas plasma
- Ethylene oxide
- Ozone
- Vaporized hydrogen peroxide
- Steam formaldehyde

Ozone and Hydrogen Peroxide

- Sterizone VP4, 510(k) FDA clearance, TSO₃ Canada
- Sterilizer has a 4.4ft³ chamber
- Advantages/Disadvantages-not yet known
Biological Indicators

- Select BIs that contain spores of *Bacillus atrophaeus*
- Rationale: BIs are the only sterilization process monitoring device that provides a direct measure of the lethality of the process

Rapid Readout BIs for Steam Now Require a 1-3h Readout Compared to 24-48h
Super Rapid Readout Biological Indicators
Commercially available

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

1492V BI (brown cap)
- Monitors 270°F and 275°F dynamic-air-removal (pre-vacuum) steam sterilization cycles
- 1 hour result (from 3 hours)

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>
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<tbody>
<tr>
<td><em>P. aeruginosa</em> (VIM-2)</td>
<td>Duodenoscope</td>
<td>22</td>
<td>Yes, under forceps elevator</td>
<td>Yes</td>
<td>Verfaillie CJ, 2015</td>
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<tr>
<td><em>E. coli</em> (AmpC)</td>
<td>Duodenoscope</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>Duodenoscope</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>Duodenoscope</td>
<td>39</td>
<td>Yes</td>
<td>Yes (PFGE)</td>
<td>Epstein L, 2014</td>
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</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
FDA Panel, May 2015, Recommended Sterilization of Duodenoscopes (requires FDA-cleared technology that achieves a SAL 10^{-6} with duodenoscopes)

Disinfection and Sterilization


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 (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) 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).

---

**HLD and Sterilization: What’s New**

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  - Endoscope-related infections, channeled scopes, reuse of single-use items

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  - Emerging pathogens, room decontamination methods
DISINFECTION AND STERILIZATION

- 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 except for high numbers of bacterial spores
  - NONCRITICAL - objects that touch only intact skin require low-level disinfection

### High-Level Disinfection of “Semicritical Objects”

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

*May cause cosmetic and functional damage; **efficacy not verified
The Joint Commission surveyors will likely check on several high visibility items during your next survey

Reprocessing duodenoscopes

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

Reprocessing Channeled Endoscopes
Cystoscope-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 the scope nor air in barrel of syringe-syringe and lumen filled with HLD)

Exposure Method | VRE Contamination Before HLD (glutaraldehyde) | VRE Contamination After HLD
--- | --- | ---
Passive HLD (immersed, not perfused) | 3.6x10^8, 2.0x10^8, 1.1x10^8 | 7.5x10^6, 1.0x10^6, 6.8x10^5

Active HLD (perfused HLD into channel with syringe) | 8.4x10^7, 1.5x10^8, 2.8x10^8 | 1 CFU, 0, 0

• Pathogens must have exposure to HLD for inactivation
• Immerse channeled flexible scope into HLD will not inactivate channel pathogens
• Completely immerse the endoscope in HLD and ensure all channels are perfused
• Air pressure in channel stronger than fluid pressure at fluid-air interface

Reprocessing Channeled Endoscopes

Rutala, Gergen, Bringhurst, Weber. ICHE. In press
Reprocessing Channeled Endoscopes
Cystoscope-HLD perfused through lumen with syringe (luer locks onto port and syringe filled and emptied until no air exits the scope nor air in barrel of syringe-syringe and lumen filled with HLD)
Do Not Reuse Single-Use Devices

- Federal judge convicted a urologist who reused needle guides meant for single use during prostate procedures (Sept 2014)
- Third party reprocessor OK
- Criminal prosecution (based on conspiracy to commit adulteration)

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Endemic Transmission of Infections Associated with GI Endoscopes May 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)

Reason for Endoscope-Related Outbreaks

- Margin of safety with endoscope reprocessing minimal or non-existent for two reasons:
  - Microbial load
    - GI endoscopes contain $10^{7-10}$
    - Cleaning results in 2-6 log$_{10}$ reduction
    - High-level disinfection results in 4-6 log$_{10}$ reduction
    - Results in a total 6-12 log$_{10}$ reduction of microbes
    - Level of contamination after processing: 4 log$_{10}$ (maximum contamination, minimal cleaning/HLD)
  - Complexity of endoscope and endoscope reprocessing

ENDOSCOPE REPROCESSING: CHALLENGES

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

Surgical instruments-<10^2 bacteria

NDM-Producing *E. coli* Associated ERCP

NDM-producing *E. coli* recovered from elevator channel (elevator channel orients catheters, guide wires and accessories into the endoscope visual field; crevices difficult to access with cleaning brush and may impede effective reprocessing or killing CRE)
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, $10^7-10$
- 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 $10^7$-$10^9$
  ◆ Cleaning results in 2-6 log$_{10}$ reduction
  ◆ High-level disinfection results in 4-6 log$_{10}$ reduction
  ◆ Results in a total 6-12 log$_{10}$ reduction of microbes
  ◆ Level of contamination after processing: 4log$_{10}$ (maximum contamination, minimal cleaning/HLD)
• Complexity of endoscope
• Biofilms-unclear if contribute to failure of endoscope reprocessing

BIOFILMS
(Multi-layered bacteria plus exopolysaccharides that cement cell to surface; develop in wet environments; if reprocessing performed promptly after use and endoscope dry the opportunity for biofilm formation is minimal)
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
Current Enhanced Methods for Reprocessing Duodenoscopes

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

Summary of Advantages and Disadvantages of HLD and Sterilization Enhancements for Reprocessing Duodenoscopes

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<th>Method</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
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| HLD with ETO, Microbiologic surveillance | • Major endoscope manufacturer offers ETO as sterilization option  
• Should be used after standard high-level disinfection  
• Some data demonstrate reduced infection risk with HLD followed by ETO  
• Single-dose cartridge and negative-pressure chamber minimizes the potential for gas leak and ETO exposure  
• Simple to operate and monitor  
• Compatible with most medical materials       | • Requires aeration time to remove ETO residue  
• Only 20% of US hospitals have ETO on-site  
• Lengthy cycle/aeration time  
• No microbicidal efficacy data proving SAL 10⁶ achieved  
• Studies question microbicidal activity in presence of organic matter/salt  
• ETO is toxic, a carcinogen, flammable  
• May damage endoscope |
### Summary of Advantages and Disadvantages of HLD and Sterilization Enhancements for Reprocessing Duodenoscopes


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| HLD only (not listed as an enhanced method for reprocessing endoscope) | • HLD inactivate MDR organisms including CREs  
• Current standard of care  
• Wide availability | • Based on recent ERCP outbreaks, infection risk related to device complexity and microbial load  
• No enhancement to reduce infection risk associated with ERCP scopes  
• Some HLD (e.g., aldehydes) may cross-link proteins |
| HLD, ATP only (not listed as an enhanced method for reprocessing endoscope) | • HLD inactivate MDR organisms including CREs  
• Real-time monitoring tool  
• Simple to conduct  
• Detects organic residue | • Based on recent ERCP outbreaks, infection risk related to device complexity and microbial load  
• No data demonstrating reduced infection risk  
• Does not detect microbial contamination  
• ATP not validated as risk factor for patient-to-patient transmission  
• Unknown cut-off level to assure safety |
UNC Hospitals
Interim Response to ERCP Outbreaks

- Ensure endoscopes are reprocessed in compliance with national guidelines (CDC, ASGE, etc)
- Evaluate CRE culture-positive patients for ERCP exposure
- In the short term, enhance reprocessing of ERCP scopes; reprocess ERCP scopes by HLD followed for ETO sterilization
- Microbiologic surveillance, 5-10% of scopes monthly
- When new recommendations are available from ASGE, CDC, FDA, etc. comply

Current Enhanced Methods for Reprocessing Duodenoscopes

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
To protect the public health we (FDA, industry, professional organizations) must shift duodenoscope reprocessing from HLD to sterilization.

GI Endoscopes: Shift from Disinfection to Sterilization

Gastrointestinal Endoscopes
A Need to Shift From Disinfection to Sterilization?
William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

More than 10 million gastrointestinal endoscopic procedures are performed annually in the United States for diagnostic purposes, therapeutic interventions, or both.1 Because gastrointestinal endoscopes contact mucosal surfaces, use of a contaminated endoscope may lead to patient-to-patient transmission of potential pathogens with a subsequent risk of infection.2

In this issue of JAMA, Epstein and colleagues3 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 6-month period, 9 nosocomial infections were identified, and 2 deaths were linked to the outbreak.4

First, endoscopes are semicritical devices, which contact mucus membranes or nonintact skin, and require at least high-level disinfection.5,6 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.7 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.8,9 However, until now,
Potential future methods to prevent GI-endoscope-related infections?

Potential Future Methods to Prevent GI-Endoscope Related Outbreaks

- Steam sterilization of GI endoscopes
- New (or optimize) low temperature sterilization methods proving SAL $10^{-6}$ achieved
- Disposable sterile GI endoscopes
- Improved GI endoscope design (to reduce or eliminate challenges listed earlier)
- Use of non-endoscope methods to diagnosis or treat disease (e.g., capsule endoscopy, blood tests to detect GI cancer, stool DNA test)
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

What Is the Public Health Benefit?
No ERCP-Related Infections

Margin of Safety—currently nonexistent; sterilization will provide a safety margin (~6 log₁₀). To prevent infections, all duodenoscopes should be devoid of microbial contamination.

HLD (6 log₁₀ reduction)
vs
Sterilization (12 log₁₀ reduction=SAL 10⁻⁶)
FDA Panel, May 2015, Recommended Sterilization of Duodenoscopes

HLD and Sterilization: What’s New

- Sterilization
  - Biological indicators, emerging technologies, modified Spaulding classification

- High-Level Disinfection
  - Endoscope-related infections, channeled scopes, reuse of single-use items

- Low-Level Disinfection
  - Emerging pathogens, improved room decontamination methods
ENVIRONMENTAL CONTAMINATION LEADS TO HAI

- There is increasing evidence to support the contribution of the environment to disease transmission
- This supports comprehensive disinfecting regimens (goal is not sterilization) to reduce the risk of acquiring a pathogen from the healthcare environment/equipment
KEY PATHOGENS WHERE ENVIRONMENTAL SURFACES PLAY A ROLE IN TRANSMISSION

- MRSA
- VRE
- *Acinetobacter* spp.
- *Clostridium difficile*
- Norovirus
- Rotavirus
- SARS

ENVIRONMENTAL CONTAMINATION ENDEMIC AND EPIDEMIC MRSA

<table>
<thead>
<tr>
<th>Site</th>
<th>Endemic</th>
<th>Outbreak</th>
</tr>
</thead>
<tbody>
<tr>
<td>Door</td>
<td>4%</td>
<td>44%</td>
</tr>
<tr>
<td>Window</td>
<td>12%</td>
<td>32%</td>
</tr>
<tr>
<td>Chair</td>
<td>19%</td>
<td>59%</td>
</tr>
<tr>
<td>Table</td>
<td>23%</td>
<td>36%</td>
</tr>
<tr>
<td>Bed</td>
<td>27%</td>
<td>19%</td>
</tr>
</tbody>
</table>

## Environmental Survival of Key Pathogens on Hospital Surfaces

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Survival Time</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>S. aureus</em> (including MRSA)</td>
<td>7 days to &gt;12 months</td>
</tr>
<tr>
<td><em>Enterococcus</em> spp. (including VRE)</td>
<td>5 days to &gt;46 months</td>
</tr>
<tr>
<td><em>Acinetobacter</em> spp.</td>
<td>3 days to 11 months</td>
</tr>
<tr>
<td><em>Clostridium difficile</em> (spores)</td>
<td>&gt;5 months</td>
</tr>
<tr>
<td>Norovirus (and feline calicivirus)</td>
<td>8 hours to &gt;2 weeks</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em></td>
<td>6 hours to 16 months</td>
</tr>
<tr>
<td><em>Klebsiella</em> spp.</td>
<td>2 hours to &gt;30 months</td>
</tr>
</tbody>
</table>


## Frequency of Acquisition of MRSA on Gloved Hands After Contact with Skin and Environmental Sites

No significant difference on contamination rates of gloved hands after contact with skin or environmental surfaces (40% vs 45%; p=0.59)

EVALUATION OF HOSPITAL ROOM ASSIGNMENT AND ACQUISITION OF CDI

- Study design: Retrospective cohort analysis, 2005-2006
- Setting: Medical ICU at a tertiary care hospital
- Methods: All patients evaluated for diagnosis of CDI 48 hours after ICU admission and within 30 days after ICU discharge
- Results (acquisition of CDI)
  - Admission to room previously occupied by CDI = 11.0%
  - Admission to room not previously occupied by CDI = 4.6% (p=0.002)

Shaughnessy MK, et al. ICHE 2011;32:201-206

TRANSMISSION MECHANISMS INVOLVING THE SURFACE ENVIRONMENT

ACQUISITION OF MRSA ON HANDS AFTER CONTACT WITH ENVIRONMENTAL SITES

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


TRANSMISSION MECHANISMS INVOLVING THE SURFACE ENVIRONMENT

ACQUISITION OF *C. difficile* ON PATIENT HANDS AFTER CONTACT WITH ENVIRONMENTAL SITES AND THEN INOCULATION OF MOUTH

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

ALL “TOUCHABLE” (HAND CONTACT) SURFACES SHOULD BE WIPED WITH DISINFECTANT
Effective Surface Decontamination

Product and Practice = Perfection

LOW-LEVEL DISINFECTION FOR NONCRITICAL EQUIPMENT AND SURFACES

**Exposure time > 1 min**

<table>
<thead>
<tr>
<th>Germicide</th>
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<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</td>
<td>UD</td>
</tr>
<tr>
<td>Improved hydrogen peroxide</td>
<td>0.5%, 1.4%</td>
</tr>
</tbody>
</table>

UD=Manufacturer’s recommended use dilution
Does Improving Surface Cleaning and Disinfection Reduce Healthcare-Associated Infections?
Donskey CJ. AJIC 2013;41:S12-S19

“As reviewed here, during the past decade a growing body of evidence has accumulated suggesting that improvements in environmental disinfection may prevent transmission of pathogens and reduce HAIs. Although, the quality of much of the evidence remains suboptimal, a number of high-quality investigations now support environmental disinfection as a control strategy”
Use of a Daily Disinfectant Cleaner Instead of a Daily Cleaner Reduced HAI Rates

Alfa et al. AJIC 2015;43:141-146

- **Method:** Improved hydrogen peroxide disposable wipe was used once per day for all high-touch surfaces to replace cleaner.

- **Result:** When cleaning compliance was ≥ 80%, there was a significant reduction in cases/10,000 patient days for MRSA, VRE and *C. difficile*.

- **Conclusion:** Daily use of disinfectant applied to environmental surfaces with a 80% compliance was superior to a cleaner because it resulted in significantly reduced rates of HAIs caused by *C. difficile*, MRSA, VRE.
It appears that not only is disinfectant use important but how often is important

Daily disinfection vs clean when soiled

Daily Disinfection of High-Touch Surfaces
Kundrapu et al. ICHE 2012;33:1039

Daily disinfection of high-touch surfaces (vs cleaned when soiled) with sporicidal disinfectant (PA) in rooms of patients with CDI and MRSA reduced acquisition of pathogens on hands after contact with surfaces and of hands caring for the patient.
Effective Surface Decontamination

Product and Practice = Perfection

Wipes

Cotton, Disposable, Microfiber, Cellulose-Based, Nonwoven Spunlace

Wipe should have sufficient wetness to achieve the disinfectant contact time (e.g. >1 minute)
Thoroughness of Environmental Cleaning
Carling P. AJIC 2013;41:S20-S25

Mean proportion of surfaces disinfected at terminal cleaning is 32%

Terminal cleaning methods ineffective (products effective practices deficient [surfaces not wiped]) in eliminating epidemiologically important pathogens
MONITORING THE EFFECTIVENESS OF CLEANING
Cooper et al. AJIC 2007;35:338; Carling P AJIC 2013;41:S20-S25

- 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—<2.5 CFUs/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)

Percentage of Surfaces Clean by Different Measurement Methods
Rutala, Gergen, Sickbert-Bennett, Huslage, Weber. 2013

Fluorescent marker is a useful tool in determining how thoroughly a surface is wiped and mimics the microbiological data better than ATP
ALL “TOUCHABLE” (HAND CONTACT) SURFACES SHOULD BE WIPED WITH DISINFECTANT

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

NEW “NO TOUCH” APPROACHES TO ROOM DECONTAMINATION
Supplement Surface Disinfection
**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><em>C. difficile</em></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><em>C. difficile</em></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><em>C. difficile</em></td>
<td>22,000</td>
<td>2.3</td>
<td>overall</td>
<td>67.8 min</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><em>C. difficile</em>, <em>G. stear spore</em></td>
<td>22,000</td>
<td>2.2</td>
<td>overall</td>
<td>73 min</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

**HP 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><em>Serratia</em></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><em>C. difficile</em></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><em>C. difficile</em></td>
<td>48/203-24%; 7</td>
<td>7/203-3%; 0.4</td>
<td>88</td>
</tr>
<tr>
<td>Barbut, 2009</td>
<td>HP dry mist</td>
<td><em>C. difficile</em></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>
**IMPACT OF HPV ROOM DECONTAMINATION ON C. difficile TRANSMISSION**

Incidence CDI: VHP Pre-intervention (grey) vs Intervention period (black)

- **Hospital-wide**
  - Pre-intervention CDAD = 1.89 cases/1000 Pt-d
  - Intervention CDAD = 0.88 cases/1000 Pt-d
  - Nov 2004 through March 2005

- **Intervention Wards**
  - Pre-intervention CDAD = 2.28 cases/1000 Pt-d
  - Intervention CDAD = 1.28 cases/1000 Pt-d
  - Boyce JM, et al. ICHE 2008;29:723-9

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**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>
</tbody>
</table>
Clinical Trials Using UV for Terminal Room Disinfection 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, Pulsed Xenon</td>
<td>CDI</td>
<td>Yes</td>
</tr>
<tr>
<td>Hass, 2014</td>
<td>Before-After, Pulsed Xenon</td>
<td>CDI, MRSA, VRE, MDRO-GNR</td>
<td>Yes</td>
</tr>
<tr>
<td>Miller, 2015</td>
<td>Before-After, Pulsed Xenon</td>
<td>CDI</td>
<td>Yes</td>
</tr>
<tr>
<td>Nagaraja, 2015</td>
<td>Before-After, Pulsed Xenon</td>
<td>CDI</td>
<td>Yes (p=0.06)</td>
</tr>
<tr>
<td>Pegues, 2015</td>
<td>Before-After, Optimum</td>
<td>CDI</td>
<td>Yes</td>
</tr>
<tr>
<td>Anderson, 2015</td>
<td>Randomized-controlled trial, Tru-D</td>
<td>MRSA, VRE, CDI</td>
<td>Yes</td>
</tr>
</tbody>
</table>

This technology should be used (capital equipment budget) for terminal room disinfection (e.g., after discharge of patients under CP, during outbreaks).
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.
- Ultimately, one would select a device that has demonstrated bactericidal capability and the ability to reduce HAIs.

Must improve thoroughness of cleaning/disinfection daily basis also, evaluate new technologies.
Visible Light Disinfection System
Rutala, Gergen, Kanamori, Sickbert-Bennett, Weber. 2015

- Uses blue-violet range of visible light in 400-450nm region through light emitting diodes (LEDs); continuous
- Initiates a photoreaction with porphyrins in microbes which yield reactive oxygen
- In preliminary studies have observed significant reductions with some microbes
Norovirus, *C. difficile* spores, MERS-CoV, Enterovirus D68, Ebola, MDR organisms such as carbapenemase-producing *Enterobacteriaceae* (CRE)

In general, emerging pathogens are susceptible to currently available disinfectants. However, some pathogens need additional information (e.g., HPV) or must modify disinfection/sterilization practices (e.g., *C. difficile* spores, prions)

**Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants**

<table>
<thead>
<tr>
<th>Most Resistant</th>
<th>Most Susceptible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prions</td>
<td>LLD-kill microbes in “green”; HLD kill microbes in “blue”-HPV?</td>
</tr>
<tr>
<td>Bacterial spores (<em>C. difficile</em>)</td>
<td></td>
</tr>
<tr>
<td>Mycobacteria</td>
<td></td>
</tr>
<tr>
<td>Small, non-enveloped viruses (EV-D68)</td>
<td></td>
</tr>
<tr>
<td>Fungal spores</td>
<td></td>
</tr>
<tr>
<td>Gram-negative bacilli (<em>Acinetobacter, CRE</em>)</td>
<td></td>
</tr>
<tr>
<td>Vegetative fungi and algae</td>
<td></td>
</tr>
<tr>
<td>Large, non-enveloped viruses</td>
<td></td>
</tr>
<tr>
<td>Gram-positive bacteria (MRSA, VRE)</td>
<td></td>
</tr>
<tr>
<td>Enveloped viruses (Ebola, MERS-CoV)</td>
<td></td>
</tr>
</tbody>
</table>
**C. difficile Spores**

**EPA-Registered Products**

- List K: EPA’s Registered Antimicrobials Products Effective Against *C. difficile* spores, April 2014
- [http://www.epa.gov/oppad001/list_k_clostridium.pdf](http://www.epa.gov/oppad001/list_k_clostridium.pdf)
- 34 registered products; most chlorine-based, some HP/PA-based, PA with silver

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**SHEA Prion Guideline**


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(Guideline for Disinfection and Sterilization of Prion-Contaminated Medical Instruments)

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

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**Epidemiology of the Creutzfeldt-Jakob Disease Prion**

Creutzfeldt-Jakob disease (CJD) is a degenerative neurologic disorder of humans with an incidence in the United States of approximately 1 case per million population per year. To date, no evidence for transmission of chronic wasting disease of deer and elk to humans has been identified. Transmission of CJD via medical devices.

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**Transmission of CJD via Medical Devices**

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Management of Neurosurgical Instruments and Patients Exposed to CJD

- Conventional sterilization/disinfection inadequate for prions. Need special prion reprocessing (critical/semi device contaminated with high risk tissue from high-risk patient)
- Belay et al. ICHE 2014;34:1272. Decontamination options combine chemical and SS-1) immerse in 1N NaOH and heat in gravity at ≥121C for 30m in appropriate container; 2) immerse in 1N NaOH or NaOCl 20,000ppm 1h then transfer into water and autoclave at ≥121C for 1h; 3) immerse in 1N NaOH or NaOCl 20,000ppm 1h, rinse with water, transfer to pan and autoclave at 121C (gravity) or 134C (porous) for 1 hour. Clean and sterilize by conventional means.
- McDonnell et al. J Hosp Infect. 2013;85:268. Investigates the combination of cleaning, disinfection and/or sterilization on prions
- Rutala, Weber. ICHE 2010;31:107. SHEA Guideline-134C for 18m in prevacuum or NaOH/autoclave (such as CDC option 2)

ENDOSCOPE/ENDOCAVITARY PROBES REPROCESSING: CHALLENGES
Susceptibility of Human Papillomavirus

- 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)
Hydrogen Peroxide Mist
(uses HP mist to achieve HLD in 7m-no independent efficacy data)

Efficacy of HP Mist Against HPV
Meyers C et al. SHEA Poster, 2015

- 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 HP Mist System in Inactivating Healthcare Pathogens
Rutala, Gergen, Sickbert-Bennett, Weber 2015

- Designed to provide HLD of ultrasound probes
- Automated, closed system that uses hydrogen peroxide mist
- $>10^6$ pathogens inoculated onto probe at 2-3 sites
- Inactivated bacteria and good but not complete kill of mycobacteria, spores

<table>
<thead>
<tr>
<th>5% FCS</th>
<th>VRE</th>
<th>CRE-Kp</th>
<th>M. terrae</th>
<th>C. difficile spores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present</td>
<td>0/7</td>
<td>0/6</td>
<td>4/9</td>
<td>3/6</td>
</tr>
<tr>
<td>Absent</td>
<td>0/6</td>
<td>ND</td>
<td>1/6</td>
<td>1/9</td>
</tr>
</tbody>
</table>

HLD and Sterilization: What’s New

- Sterilization
  - Biological indicators, emerging technologies, modified Spaulding classification
- High-Level Disinfection
  - Endoscope-related infections, channeled scopes, laryngoscopes, reuse of single-use items
- Low-Level Disinfection
  - Emerging pathogens, room decontamination methods
## Disinfection and Sterilization: What’s New

- New D/S technologies (new disinfectants, BIs) and practices (e.g., perfused channel scopes with HLD) could reduce risk of infection.
- Endoscope represent a nosocomial hazard. Endoscopes have narrow margin of safety due to complexity and microbial load. Comply with reprocessing guidelines and implement enhanced method for duodenoscopes.
- Do not reuse single-use devices
- Implement “no touch” technologies such as UV for terminal room decontamination of Contact Precaution patient rooms
- In general, emerging pathogens are susceptible to currently available disinfectants. However, some pathogens need additional information or modify D/S practices (e.g., prions, *C. difficile* spores, HPV).

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**THANK YOU!**

[www.disinfectionandsterilization.org](http://www.disinfectionandsterilization.org)
Calvin the Owl
Halloween, 2015