Cleaning, Disinfection, and Sterilization News

APIC- MN ANNUAL CONFERENCE 2015

KAREN K HOFFMANN RN MS CIC FSHEA
UNIVERSITY OF NORTH CAROLINA
CHAPEL HILL
SCHOOL OF MEDICINE

DISCLOSURES

- Carefusion, honoraria
- AMA Foundation, consultant
- APIC Board of Directors
- CMS, consultant/contractor
DISCLAIMERS

- The information provided in this presentation is only intended to be general summary information.
- It is not intended to take the place of statute, regulations or official CMS policy.

OBJECTIVES

- 1. Assess new technologies for cleaning and disinfection.
- 2. List new practices for reprocessing critical and semi-critical equipment.
- 3. Review the GI endoscope outbreaks and revised reprocessing strategies.
CDC HICPAC Guidelines for 
Disinfection and Sterilization, 2008

Acknowledgement to Dr. Bill Rutala for slides!

Spaulding Disinfection and Classification System

- **Low-Level Disinfection**
  - Emerging pathogens, Ultrasound gels, improved room decontamination

- **High-Level Disinfection**
  - Endoscope-related infections, channeled scopes, Point of Care Instrument HLD systems

- **Sterilization**
  - Biological indicators, emerging technologies, modified Spaulding classification
Patient Environment
25 to 30% of surfaces contaminated with MDROS in rooms of patients on Contact Precautions

Environmental Contamination Associated With Hand Contamination

- HCP contaminates hands as often and as much as when touching the patient as when touching the environment.
- Contaminated HCP hands transfer to other patients leads to increased HAIs.
- All “touchable” (hand contact) surfaces should be wiped with a disinfectant
Most Prevalent Pathogens Causing HAIS

- **Staphylococcus aureus** (15.6%)
- **E. coli** (11.5%)
- Coagulase-negative *Staphylococcus* (CoNS) (11.4%)
- **Klebsiella** (8.0%)
- **Pseudomonas aeruginosa** (7.5%)
- **Enterococcus faecalis** (6.8%)
- **Candida albicans** (5.3%)
- **Enterobacter** spp. (4.7%)
- Other *Candida* spp. (4.2%)
- **Enterococcus faecium** (4.1%)
- **Enterococcus** spp. (3.0%)
- **Proteus** spp. (2.5%)
- **Serratia** spp. (2.1%)
- **Acinetobacter baumannii** (1.8%)

Modify Disinfectant Used
- **C. difficile** spores—over the past decade, incidence of *C. difficile* increasing and now most common in some hospitals
- Norovirus

Low Level Disinfection for “Noncritical” Objects

**Exposure time <10 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>Improved hydrogen peroxide</td>
<td>0.5%, 1.4%</td>
</tr>
<tr>
<td>Quaternary ammonium</td>
<td>UD</td>
</tr>
</tbody>
</table>

UD=Manufacturer’s recommended use dilution
Environmental Disinfection Interventions

- Cleaning product substitutions
- Improvements in the effectiveness of cleaning and disinfection practices
  - Education
  - Audit and feedback
    - Addition of housekeeping or specialized cleaning staff
- Automated technologies
- Conclusion: Improvements in environmental disinfection may prevent transmission of pathogens and reduce HAIs
Alfa et al. AJIC 2015;43:141-146

Conclusion: Daily use of disinfectant applied to environmental surfaces with an 80% compliance was superior to a cleaner because it resulted in significantly reduced rates of HAIs caused by C. difficile, MRSA, VRE.

Daily disinfection OF High-Touch Surfaces
Kundrapu et al. ICHE 2012;33:1039

Daily disinfection of high-touch surfaces (vs cleaned when soiled) with sporidical disinfectant 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.
**Wipes for Healthcare**

Wipes should have sufficient wetness to achieve the IFU disinfection contact time (e.g. >1 minute). Used only for recommended area.

**Transfer of Pathogens by Wipes**

- Wipes should have sufficient wetness to achieve the IFU disinfection contact time (e.g. >1 minute). Used only for recommended area.

- Detergent/Nonsporicidal wipes transfer or spread microbes/spores to adjacent surfaces; disinfectants inactivate microbe
  
  Cadnum et al. ICHE 2013;34:441-2

- Pathogen transfer and high variability in pathogen removal by detergent wipes. Seven detergent wipes tested for ability to remove and transfer *S aureus*, *Acinetobacter baumanii*, and *C difficile* using 3 stage process.
  
  Ramm and Maillard et al. AJIC 2015;43724-8
Thoroughness of Environmental Cleaning

MONITORING THE EFFECTIVENESS
OF CLEANING

- 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)

Cooper et al. AJIC 2007;35:338
TECHNOLOGIES TO IMPROVE DISINFECTION OF ENVIRONMENTAL SURFACES

- New surface disinfectants
  - Improved hydrogen peroxide
- “No touch” terminal disinfection
  - UV light: UV-C or pulsed xenon
  - Hydrogen peroxide systems: Vapor or aerosol
  - Portable devices: Continuous UV systems
- “Self disinfecting” surfaces
  - Heavy metal surface coatings: Silver, copper

Hospital Privacy Curtains

- Pre-and post-intervention study; sampled curtain, sprayed “grab area” 3x from 6-8” with 1.4% IHP and allowed 2 minute contact; sampled curtain.
### Decontamination of Curtains with Activated HP

**Rutala WA, et. al, AJIC. 2014;42:426-428**

<table>
<thead>
<tr>
<th>CP for</th>
<th>Before Disinfection CFU/5 Rodac (#Path)</th>
<th>After Disinfection CFU/5 Rodac (#Path)</th>
<th>% Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRSA</td>
<td>330 (10 MRSA)</td>
<td>21* (0 MRSA)</td>
<td>93.6%</td>
</tr>
<tr>
<td>MRSA</td>
<td>186 (24 VRE)</td>
<td>4* (0 VRE)</td>
<td>97.9%</td>
</tr>
<tr>
<td>MRSA</td>
<td>108 (10 VRE)</td>
<td>2* (0 VRE)</td>
<td>98.2%</td>
</tr>
<tr>
<td>VRE</td>
<td>75 (4 VRE)</td>
<td>0 (0 VRE)</td>
<td>100%</td>
</tr>
<tr>
<td>VRE</td>
<td>68 (2 MRSA)</td>
<td>2* (0 MRSA)</td>
<td>97.1%</td>
</tr>
<tr>
<td>VRE</td>
<td>98 (40 VRE)</td>
<td>1* (0 VRE)</td>
<td>99.0%</td>
</tr>
<tr>
<td>MRSA</td>
<td>618 (341 MRSA)</td>
<td>1* (0 MRSA)</td>
<td>99.8%</td>
</tr>
<tr>
<td>MRSA</td>
<td>55 (1 VRE)</td>
<td>0 (0 MRSA)</td>
<td>100%</td>
</tr>
<tr>
<td>MRSA, VRE</td>
<td>320 (0 MRSA, 0 VRE)</td>
<td>1* (0 MRSA, 0 VRE)</td>
<td>99.7%</td>
</tr>
<tr>
<td>MRSA</td>
<td>288 (0 MRSA)</td>
<td>1* (0 MRSA)</td>
<td>99.7%</td>
</tr>
<tr>
<td>Mean</td>
<td>2146/10=215 (432/10=44)</td>
<td>33*/10=3 (0)</td>
<td>98.5%</td>
</tr>
</tbody>
</table>

### Effectiveness of UV-C Room Decontamination (inoculated surfaces)

<table>
<thead>
<tr>
<th>Pathogens</th>
<th>Dose</th>
<th>Mean log&lt;sub&gt;10&lt;/sub&gt; Reduction Line of Sight</th>
<th>Mean log&lt;sub&gt;10&lt;/sub&gt; 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>Nerandzc 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>Nerandzc M, et al.²</td>
</tr>
<tr>
<td>C. difficile</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>3.5-4.0</td>
<td>1.7-4.0</td>
<td>39-40 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</td>
<td>overall</td>
<td>73 min</td>
<td>Havili N et al³</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 al⁵</td>
</tr>
</tbody>
</table>

¹ICHE 2010;31:1025; ²BMC 2010;10:197; ³ICHE 2011;32:737; ⁴JHI 2013;84:323; ⁵ICHE 2012;33:507-12; ⁶ICHE 2013;34:469; ⁷μW/cm²; min = minutes; NA = not available.
Ultraviolet UV Light Disinfection Studies

1. UV robot killed *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant Enterococcus on hospital room surfaces (ICHE).


3. UV light disinfection used on PPE, while HCW was still wearing it, to reduce the risk of possible contamination while taking off the PPE, (AJIC).

4. Continuous UV-C disinfection robots observed more effective than pulsed xenon devices (study funded by the U.S. Veterans Administration).

5. UV cleaned hospital equal to manual cleaning, (from the Texas A&M Health Science Center in Round Rock).

Last year in a different study, same researcher also found that manual cleaning plus UV light killed 99 percent of MRSA bacteria.

“No touch technologies”
Ultraviolet (UV) Robotic Light Systems

Epicenter study on UV robot HAI effectiveness

*Coming soon!*
Hydrogen Peroxide Vapor Disinfection System

Must improve thoroughness of cleaning/disinfection on a daily basis and also, evaluate new technologies
Visible Light Disinfection System
Rutala and Weber (unpublished) 2015

- Uses blue-violet range of light of visible light in the 400-450nm region through LEDs: continuous
- Initiates a photoreaction with porphyrins in microbes which yield reactive oxygen
- In preliminary studies have observed significant reductions with bacteria.

Copper Destroys Human Norovirus – Fast

- Copper has known antimicrobial activity (first study on human norovirus)
- Methodology: tested on virus-like particles (the shells of viruses), which have the same surface properties as infectious virus.
- Results: “A variety of copper surfaces had a major impact on the virus in 10 minutes, whereas the virus was very stable on stainless steel surfaces.”
- Conclusion: cycle of virus destruction begins when copper ions generate free radicals from water and oxygen, and sometimes from certain sulfur-containing amino acids. Free radicals react energetically with molecules such as DNA and proteins, damaging and often destroying them.
- Hospital ICU replaced other materials in high touch surfaces with copper reduced the overall HAI rate by half.

Jaykus, Applied and Environmental Microbiology, a journal of the American Society for Microbiology, May 2015
http://www.sciencedaily.com/releases/2015/08/150810172808.htm
## 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 (CJD)</td>
<td>LLD effective on green, HLD disinfection = blue, Special sterilization for C difficile and Prions</td>
</tr>
<tr>
<td>Bacterial spores (<em>C. difficile</em>)</td>
<td></td>
</tr>
<tr>
<td>Protozoal oocysts</td>
<td></td>
</tr>
<tr>
<td>Helminth eggs</td>
<td></td>
</tr>
<tr>
<td>Mycobacteria</td>
<td></td>
</tr>
<tr>
<td>Small, non-enveloped viruses (EV-D68, norovirus, papillomavirus)</td>
<td></td>
</tr>
<tr>
<td>Protozoal cysts</td>
<td></td>
</tr>
<tr>
<td>Fungal spores</td>
<td></td>
</tr>
<tr>
<td>Gram-negative bacilli (e.g. <em>Acinetobacter</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 (coronavirus, MERS)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Disinfection of Prions

**Management of Neurosurgical Instruments Exposed to CJD**

Conventional sterilization/disinfection inadequate for prions. Need special prion reprocessing (critical/semi device contaminated with high risk tissue (eyes, brain, spinal) from a high-risk patient.

1. Belay et al. ICHE 2014;34:1272. Decontamination options-1) immerse in 1N NaOH and heat in gravity at ≥121°C for 30m in appropriate container; 2) immerse in 1N NaOH or NaOCl 20,000ppm 1h then transfer into water and autoclave at ≥121°C for 1h; 3) immerse in 1N NaOH or NaOCl 20,000ppm 1h, rinse with water, transfer to pan and autoclave at 121°C (gravity) or 134°C (porous) for 1 hour. Clean and sterilize by conventional means.

2. Rutala, Weber. ICHE 2010;31:107. SHEA Guideline–134°C for 18m in prevacuum or NaOH/autoclave (such as CDC option 2)
Spaulding Classification System for 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 (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”

Exposure Time >8m-45m (US), 20°C

<table>
<thead>
<tr>
<th>Germicide</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde</td>
<td>&gt;2.0%</td>
</tr>
<tr>
<td>Ortho-phthalaldehyde</td>
<td>0.55%</td>
</tr>
<tr>
<td>Hydrogen peroxide*</td>
<td>7.5%</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
<td>1.0%/0.08%</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
<td>7.5%/0.23%</td>
</tr>
<tr>
<td>Hypochlorite (free chlorine)*</td>
<td>650-675 ppm</td>
</tr>
<tr>
<td>Accelerated hydrogen peroxide</td>
<td>2.0%</td>
</tr>
<tr>
<td>Peracetic acid</td>
<td>0.2%</td>
</tr>
<tr>
<td>Glut and isopropanol</td>
<td>3.4%/26%</td>
</tr>
<tr>
<td>Glut and phenol/phenate**</td>
<td>1.21%/1.93%</td>
</tr>
</tbody>
</table>

*May cause cosmetic and functional damage;
**efficacy not verified
Endocavitary Probes Reprocessing: Challenges
Susceptibility of Human Papillomavirus

- Most common STD
- 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 7 mins- no independent efficacy data)
Efficacy of HP Mist 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 HP Mist System in Inactivating Healthcare Pathogens
Rutala et al, (unpublished) 2015

- Designed to provide HLD of ultrasound probes
- Automated, closed system that uses HP mist
- >10^6 pathogens inoculated onto probes at 2-3 sites
- Inactivated bacteria and good but not complete kill of mycobacteria, spores.
Reprocessing Channeled Endoscopes
Cautionary Warning!

- Cystoscopes “must be completely immersed” in HLD (J Urology 2008. 108:588)

Reprocessing Channeled Endoscopes
Cautionary Warning!

- Cystoscope-air pressure in channel stronger than fluid pressure

- Must **actively perfuse** HLD through lumen via a syringe for all channeled endoscopes with leur-locks until all air is removed.
Reprocessing Channeled Endoscopes
Rutala et al, (unpublished) 2015

- 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 air-fluid interface.

<table>
<thead>
<tr>
<th>Exposure Method</th>
<th>VRE Contamination Before HLD (glutaraldehyde)</th>
<th>VRE Contamination After HLD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passive HLD</td>
<td>3.6x10⁴</td>
<td>7.5x10⁶</td>
</tr>
<tr>
<td>(immersed,</td>
<td>2.0x10⁴</td>
<td>1.0x10⁶</td>
</tr>
<tr>
<td>not perfused)</td>
<td>1.1x10⁴</td>
<td>6.8x10⁵</td>
</tr>
<tr>
<td>Active HLD</td>
<td>8.4x10⁷</td>
<td>1 CFU</td>
</tr>
<tr>
<td>(perfused</td>
<td>1.5x10⁶</td>
<td>0</td>
</tr>
<tr>
<td>HLD into</td>
<td>2.8x10⁶</td>
<td>0</td>
</tr>
<tr>
<td>channel with</td>
<td></td>
<td></td>
</tr>
<tr>
<td>syringe)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

US, Duodenoscope-Related Outbreaks of MDROs

10 Outbreaks secondary to duodenoscope between 2012 and 2014.

<table>
<thead>
<tr>
<th>MDRO</th>
<th>Scope</th>
<th>No.</th>
<th>Recovered From Scope</th>
<th>Molecular Link</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>P. aeruginosa</em> (VIM-2)</td>
<td>Duodenoscope</td>
<td>22</td>
<td>Yes, under forceps elevator</td>
<td>Yes</td>
<td>Verfaillie CJ, 2015</td>
</tr>
<tr>
<td><em>E. coli</em> (AmpC)</td>
<td>Duodenoscope</td>
<td>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>No</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>
</tr>
</tbody>
</table>

- For all outbreaks...No Breeches reported!
CMS CRE-ERCP Workgroup – S&C ALERT

Center for Medical Education & Medical Services
7300 Security Boulevard, Med Stop C3-28-66
Baltimore, Maryland 21244-5180

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C-45-XX Hospitals CAHs: ASCs

DATE: March XX, 2015
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group

SUBJECT: Alert Related to Outbreaks of Carbapenem-Resistant Enterobacteriaceae (CRE)

FDA issued a communication to follow manufacturer’s IFU for reprocessing and adhere to the MULTISOCIETY GUIDELINE ON REPROCESSING GI ENDOSCOPES, 2011
Petersen et al. ICHE. 2011;32:527

diabetes may impede effective cleaning.

Expectations for Reprocessing Duodenoscopes: Hospitals, critical access hospitals (CAHs), and ambulatory surgical centers (ASCs) are expected to meticulously follow the manufacturer’s instructions for reprocessing duodenoscopes, as well as adhere to the nationally recognized multisociety consensus guidelines developed by multiple expert organizations and issued in 2011.

Are Flexible Scopes Really Getting Clean?

Ofstead et al., AJIC, 2015 43;794-6

Microbial culture tests found viable organisms:
- 92% of the scopes after bedside cleaning,
- 46% after manual cleaning,
- 64% after HLD
- 9% after overnight storage.

Rapid-indicator tests (protein, carbohydrate, hemoglobin, or ATP) found contamination above benchmarks on all devices after bedside cleaning:
- 92% after manual cleaning,
- 73% after high-level disinfection,
- 82% after overnight storage.
Adenosine Triphosphate (ATP)

- Validated monitoring tool for assessing cleaning - detects organic residuals.
- Not good indicator of microbial contamination and not a validated method to assess risk of patient-to-patient transmission.
- ATP <200 RLU benchmark for clean, equates to <4 $\log_{10}$ CFUs/cm$^2$ or $10^6$ CFUs per endoscope.
- Endoscope assessed as clean using ATP could still have a significant microbial load (e.g. $10^6$).

Reasons for Endoscope-Related Outbreaks
Rutala et al, ICHE 2015;36:643-648

- Margin of safety with endoscope reprocessing minimal or non-existent for two reasons:
- Microbial load
  - GI endoscopes contain $10^7$-$10^9$
  - Cleaning results in 2-6 $\log_{10}$ reduction
  - HLD 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 endoscopes
Endoscopes Reprocessing: Challenges

Complex (elevator channel) $10^9$ bacteria
Surgical instruments $<10^2$ bacteria

Features of Endoscopes That Predispose To Disinfection Failures
Rutala et al, ICHP 2015;36:643-648

- 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, $10^7-10^8$
What We Need Now To Prevent ERCP-Related Infections?
Rutala and Weber et al, ICHE 2015;36:643-648

- No single simple proven technology or prevention strategy that hospitals can use to guarantee patient safety.
- Must continue to emphasize the enforcement of evidence-based practices, including equipment maintenance and routine audits with at least yearly competency testing of reprocessing staff.
- Must do more to prevent additional outbreaks

Current Enhanced Methods for Reprocessing Duodenoscopes
Rutala and Weber et al, ICHE 2015;36:643-648

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
- Double HLD with periodic microbiologic surveillance.
- HLD with scope quarantine until negative culture.
- Liquid chemical sterilant processing system using peracetic acid (rinsed with extensively treated potable water) with periodic microbiologic surveillance.
- HLD with periodic microbiologic surveillance
Invited experts, met in May 14 -15, 2015, Recommended sterilization of duodenoscopes which requires a FDA cleared technology

Sterilization (12 $\log_{10}$ reduction=SAL $10^{-6}$)
This is a safety margin of ($\sim 6 \log_{10}$)

HLD (6 $\log_{10}$ reduction)
Margin of safety with HLD – currently nonexistent!

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 disinfectant process (HLD) that kills all microorganisms but high numbers of bacterial spores.
NONCRITICAL – objects that touch only intact skin require LLD (or non-germicidal detergent)
Sterilization of Critical Objects

- Steam sterilization
- Hydrogen peroxide gas plasma
- Ethylene oxide
- Ozone
- Vaporized hydrogen peroxide
- Steam formaldehyde
- New Ozone and Hydrogen Peroxide – Sterizone VP4 FDA cleared, Canada

SCG S&C Memo
Immediate Use Steam Sterilization (IUSS)

Change in terminology from flash to IUSS
Updated Standards for IUSS
IUSS cannot be used routinely. Must follow manufacturer’s IFU of the item, sterilizer and container.
Safety Communication Bacteria Found in Sonic Generic Ultrasound Gel

- In 2012, the FDA received a hospital report of 16 patients had developed colonization or infection with the bacteria *Pseudomonas aeruginosa*.
- Patients were examined with transesophageal ultrasound probes* using Other-Sonic Generic Ultrasound Transmission Gel.
- Upon investigation, the ultrasound gel found to be contaminated with the bacteria *Pseudomonas aeruginosa* and *Klebsiella oxytoca*.
  - [http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm)

CDC Recommendations Regarding All Ultrasound Transmission Gels

- Only unopened containers of ultrasound gel labeled as sterile should be used for an indication that requires sterile gel. Ultrasound gel products that are labeled as non-sterile or that are not labeled at all with respect to sterility are NOT sterile.
- Review your policies and clinical practice standards to ensure you are always using sterile ultrasound gel for those procedures that require it.
- Check the instructions for use, as well as hospital/facility policies, to determine if sterile ultrasound gel is needed for a particular procedure or if non-sterile ultrasound gel is recommended for procedures using ultrasound transducers.
  - coca@cdc.gov
CDC Recommendations Regarding All Ultrasound Transmission Gels

- Use sterile ultrasound gel as recommended in clinical practice standards for all sterile body site procedures and any invasive procedures using ultrasound-guided biopsy.

- Use sterile ultrasound gel for procedures with mucosal contact where biopsy is not planned but any possible added bioburden would be undesirable or mucosal trauma is likely (e.g., transesophageal echocardiography (TEE) procedures, transvaginal ultrasound procedures without biopsy, transrectal ultrasound procedures without biopsy).
  
  - coca@cdc.gov

Reporting Problems to the FDA

- Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

- If you suspect a problem with medical drugs or products, you should file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program.

- Healthcare personnel employed by facilities that are subject to the FDA’s user facility reporting requirements should follow the reporting procedures established by their facilities.

- Device manufacturers must comply with the Medical Device Reporting (MDR) regulations.
  
Disinfection and Sterilization: Current Issues and New Technologies

- New D/S technologies and disinfectants, and practices (e.g., curtain decontamination) could reduce risk of infection associated with devices and surfaces.
- Endoscope represent a nosocomial hazard. Urgent need to understand the gaps in endoscope reprocessing. Reprocessing guidelines must be followed to prevent exposure to pathogens that may lead to infection. Endoscopes have narrow margin of safety and manufacturers should be encouraged to develop practical sterilization technology.
- The contaminated surface environment in hospital rooms is important in the transmission of healthcare-associated pathogens (MRSA, VRE, C. difficile, Acinetobacter). Thoroughness of cleaning should be monitored (e.g., fluorescence).
- In general, emerging pathogens are susceptible to currently available disinfectants. However, some pathogens need additional information (e.g., HPV, prions).

Question and Answer Time
Thank you!