DISINFECTION AND STERILIZATION:
CURRENT ISSUES AND NEW TECHNIQUES,
THE US VIEW

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DISCLOSURES

- Speaker’s bureau
  - Johnson and Johnson
  - Clorox

- Special thanks to Dr. William Rutala for slides
Disinfection and Sterilization: Current Issues and New Technologies

- Spaulding classification
- Recommended sterilants and disinfectants, CDC/HICPAC
  - Critical devices
  - Semicritical device
  - Non-critical devices
- Endoscopes continue to be the highest risk devices used in hospitals
  - New guidelines for cleaning and disinfection
- Improving room cleaning and disinfection
  - Room decontamination-UV and HPV
  - Self disinfecting surfaces
DISINFECTION AND STERILIZATION IN HEALTHCARE FACILITIES

Overview

- Last Centers for Disease Control and Prevention guideline in 1985
- Current Guidelines: 274 pages (>130 pages preamble, 21 pages recommendations, glossary of terms, tables/figures, >1100 references)
- Evidence-based guideline
- Cleared by HICPAC February 2003; delayed by FDA
- Published in November 2008

Rutala WA, Weber DJ, HICPAC
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**.
Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants

Most Resistant

- Prions
- Spores
- Mycobacteria
- Non-Enveloped Viruses
- Fungi
- Bacteria
- Enveloped Viruses

Least Resistant
## Processing “Critical” Patient Care Objects

<table>
<thead>
<tr>
<th>Classification:</th>
<th>Critical objects enter normally sterile tissue or vascular system, or through which blood flows</th>
</tr>
</thead>
<tbody>
<tr>
<td>Object:</td>
<td>Sterility</td>
</tr>
<tr>
<td>Level germicidal action:</td>
<td>Kill all microorganisms, including bacterial spores</td>
</tr>
<tr>
<td>Examples:</td>
<td>Surgical instruments and devices; cardiac catheters; implants; etc</td>
</tr>
<tr>
<td>Method:</td>
<td>Steam, gas, hydrogen peroxide plasma, ozone, HPV or chemical sterilization</td>
</tr>
</tbody>
</table>
“Ideal” Sterilization Method

- Highly efficacious
- Rapidly active
- Strong penetrability
- Materials compatibility
- Non-toxic
- Organic material resistance
- Adaptability
- Monitoring capability
- Cost-effective

Schneider PM. Tappi J. 1994;77:115-119
Sterilization of “Critical Objects”

- Steam sterilization
- Ethylene oxide
- Hydrogen peroxide gas plasma
- Peracetic acid (0.2%)-chemical sterilization?
- Ozone
- Vaporized hydrogen peroxide
- Steam formaldehyde
Ethylene Oxide (ETO)

■ Advantages
  ● Very effective at killing microorganisms
  ● Penetrates medical packaging and many plastics
  ● Compatible with most medical materials
  ● Cycle easy to control and monitor

■ Disadvantages
  ● Some states (CA, NY, TX) require ETO emission reduction of 90-99.9%
  ● CFC (inert gas that eliminates explosion hazard) banned after 1995
  ● Potential hazard to patients and staff
  ● Lengthy cycle/aeration time
Hydrogen Peroxide Gas Plasma Sterilization (Sterrad System)

Advantages
- Safe for the environment and health care worker; it leaves no toxic residuals
- Fast - cycle time is 28-52 min and no aeration necessary
- Used for heat and moisture sensitive items since process temperature 50°C
- Simple to operate, install, and monitor
- Compatible with most medical devices

Disadvantages
- Cellulose (paper), linens and liquids cannot be processed
- Sterilization chamber is small, about 3.5ft³ to 7.3ft³
- STERRAD booster may required to process long narrow lumen (see manufacturer’s recommendations); expanded claims with NX
- Requires synthetic packaging (polypropylene) and special container tray
Ozone

**Advantages**
- Used for moisture and heat-sensitive items
- Ozone generated from oxygen and water (oxidizing)
- No aeration because no toxic by-products
- FDA cleared for metal and plastic surgical instruments, including some instruments with lumens

**Disadvantages**
- Sterilization chamber small, 4ft³
- Limited use (material compatibility/penetrability/organic material resistance?) and limited microbicidal efficacy data
V-PRO™1, Vaporized Hydrogen Peroxide

- Advantages
  - Safe for the environment and health care worker; it leaves no toxic residuals
  - Fast - cycle time is 55 min and no aeration necessary
  - Used for heat and moisture sensitive items (metal and nonmetal devices)

- Disadvantages
  - Sterilization chamber is small, about 4.8ft³
  - Medical devices restrictions based on lumen internal diameter and length-see manufacturer’s recommendations, e.g., SS lumen 1mm diameter, 125mm length
  - Not used for liquid, linens, powders, or any cellulose materials
  - Requires synthetic packaging (polypropylene)
  - Limited use and limited comparative microbicidal efficacy data
Chemical Sterilization of “Critical Objects”

- Glutaraldehyde (>2.0%)
- Hydrogen peroxide-HP (7.5%)
- Peracetic acid-PA (0.2%)
- HP (1.0%) and PA (0.08%)
- HP (7.5%) and PA (0.23%)
- Glut (1.12%) and Phenol/phenate (1.93%)

Exposure time per manufacturers’ recommendations
### Processing “Semicritical” Patient Care Objects

<table>
<thead>
<tr>
<th>Classification:</th>
<th>Semicritical objects come in contact with mucous membranes or skin that is not intact.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Object:</td>
<td>Free of all microorganisms except high numbers of bacterial spores.</td>
</tr>
<tr>
<td>Level germicidal action:</td>
<td>Kills all microorganisms except high numbers of bacterial spores.</td>
</tr>
<tr>
<td>Examples:</td>
<td>Endoscopes, respiratory therapy and anesthesia equipment, thermometers, tonometers, endocavity probes, diaphragm fitting rings, etc.</td>
</tr>
<tr>
<td>Method:</td>
<td>High-level disinfection</td>
</tr>
</tbody>
</table>
# High Level Disinfection of “Semicritical Objects”

Exposure Time > 8m-30m (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 (12 m US)</td>
<td>0.55%</td>
</tr>
<tr>
<td>Hydrogen peroxide*</td>
<td>7.5%</td>
</tr>
<tr>
<td>Accelerated hydrogen peroxide</td>
<td>2.0%</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>&gt; 7.35%/&gt;0.23%</td>
</tr>
<tr>
<td>Hypochlorite (free chlorine)*</td>
<td>650-675 ppm</td>
</tr>
<tr>
<td>Glut and phenol/phenate</td>
<td>1.21%/1.93%</td>
</tr>
<tr>
<td>Glut and alcohol</td>
<td>3.4%/26% IPA</td>
</tr>
</tbody>
</table>

*May cause cosmetic and functional damage
Resert™ XL HLD

- High Level Disinfectant
- 2% hydrogen peroxide
  - pH stabilizers
  - Chelating agents
  - Corrosion inhibitors
- Efficacy (claims need verification)
  - Sporicidal, virucidal, bactericidal, tuberculocidal, fungicidal
- HLD: 8 mins at 20°C
- Odorless, non-staining, ready-to-use
- No special shipping or venting requirements
- Manual or automated applications
- 12-month shelf life, 14 days reuse
- Material compatibility/organic material resistance?

*The Accelerated Hydrogen Peroxide technology and logo are the property of Virox Technologies, Inc. Modified from G McDonnell. AJIC 2006;34:571*
ENDOSCOPES

- Gastrointestinal endoscopy
  - >70 outbreaks (>6000 patients exposed, >400 patients contaminated)
  - 70% agents *Salmonella* sp. and *P. aeruginosa*
  - Clinical spectrum ranged from colonization to death (~2%)

- Bronchoscopy
  - >50 outbreaks (>2000 patients exposed, >750 patients contaminated)
  - *M. tuberculosis*, atypical *Mycobacteria*, *P. aeruginosa*
  - Pseudo-outbreaks more common than outbreaks

FEATURES OF ENDOSCOPES THAT IMPAIR CLEANING AND DISINFECTION

- Usually heat sensitive
- Long narrow lumens
- Cross-connections
- Mated surfaces
- Sharp angles
- Springs and valves
- Occluded dead ends
- Absorbent material
- Rough or pitted surfaces
<table>
<thead>
<tr>
<th>Type of intervention</th>
<th>United States No. of outbreaks</th>
<th>United States No. of patients exposed</th>
<th>Other countries No. of outbreaks</th>
<th>Other countries No. of patients exposed</th>
<th>Total No. of outbreaks</th>
<th>Total No. of patients exposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bronchoscopy</td>
<td>15</td>
<td>4001</td>
<td>12</td>
<td>1969</td>
<td>27</td>
<td>5970</td>
</tr>
<tr>
<td>Cystoscopy</td>
<td>2</td>
<td>773</td>
<td>1</td>
<td>152</td>
<td>3</td>
<td>925</td>
</tr>
<tr>
<td>ERCP</td>
<td>4</td>
<td>554</td>
<td>7</td>
<td>2432</td>
<td>11</td>
<td>2986</td>
</tr>
<tr>
<td>Lower GI endoscopy</td>
<td>4</td>
<td>4179</td>
<td>6</td>
<td>748</td>
<td>10</td>
<td>4927</td>
</tr>
<tr>
<td>Upper GI endoscopy</td>
<td>3</td>
<td>1130</td>
<td>6</td>
<td>689</td>
<td>9</td>
<td>1819</td>
</tr>
<tr>
<td>GI endoscopy, several*</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>4841</td>
<td>3</td>
<td>4841</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>28</strong></td>
<td><strong>10637</strong></td>
<td><strong>35</strong></td>
<td><strong>10831</strong></td>
<td><strong>63</strong></td>
<td><strong>21468</strong></td>
</tr>
<tr>
<td>Reference</td>
<td>Publication year</td>
<td>Microorganism</td>
<td>Outbreak or pseudo-outbreak?</td>
<td>Isolates</td>
<td>Infections</td>
<td>Deaths</td>
</tr>
<tr>
<td>-------------------</td>
<td>-----------------</td>
<td>--------------------------------</td>
<td>------------------------------</td>
<td>----------</td>
<td>------------</td>
<td>--------</td>
</tr>
<tr>
<td>Cosgrove et al(^{19})</td>
<td>2012</td>
<td><em>Pseudomonas sp.</em>, <em>Stenotrophomonas</em></td>
<td>Pseudo-outbreak</td>
<td>16</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Rosengarten et al(^{14})</td>
<td>2010</td>
<td><em>Burkholderia cepacia</em></td>
<td>Pseudo-outbreak</td>
<td>3</td>
<td>0</td>
<td>0</td>
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<tr>
<td>CDC(^{1})</td>
<td>2009</td>
<td><em>Legionella pneumophila</em></td>
<td>Pseudo-outbreak</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Schuetz et al(^{17})</td>
<td>2009</td>
<td><em>L. pneumophila</em></td>
<td>Pseudo-outbreak</td>
<td>13</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Chronocon et al(^{18})</td>
<td>2009</td>
<td><em>Mycobacterium chelonae</em></td>
<td>Pseudo-outbreak</td>
<td>9</td>
<td>0</td>
<td>0</td>
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<tr>
<td>DiazGranados et al(^{16})</td>
<td>2009</td>
<td><em>Pseudomonas aeruginosa</em></td>
<td>Both</td>
<td>12</td>
<td>2</td>
<td>0</td>
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<tr>
<td>Schaffer et al(^{16})</td>
<td>2008</td>
<td><em>Fusarium solani</em></td>
<td>Pseudo-outbreak</td>
<td>4</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Shimono et al(^{17})</td>
<td>2008</td>
<td><em>P. aeruginosa</em></td>
<td>Outbreak</td>
<td>7</td>
<td>7</td>
<td>0</td>
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<tr>
<td>Ahn et al(^{18})</td>
<td>2007</td>
<td><em>Stenotrophomonas maltophilia</em></td>
<td>Pseudo-outbreak</td>
<td>7</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Bou et al(^{14})</td>
<td>2006</td>
<td><em>P. aeruginosa</em></td>
<td>Both</td>
<td>10</td>
<td>10</td>
<td>0</td>
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<tr>
<td>Corne et al(^{16})</td>
<td>2005</td>
<td><em>P. aeruginosa</em></td>
<td>Both</td>
<td>16</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Cêtre et al(^{11})</td>
<td>2005</td>
<td>Enteric GNR</td>
<td>Both</td>
<td>117</td>
<td>2</td>
<td>0</td>
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<tr>
<td>Larson et al(^{22})</td>
<td>2003</td>
<td><em>Mycobacterium tuberculosis</em></td>
<td>Pseudo-outbreak</td>
<td>3</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Singh et al(^{23})</td>
<td>2003</td>
<td><em>Trichosporon mucides</em></td>
<td>Pseudo-outbreak</td>
<td>6</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Silva et al(^{44})</td>
<td>2003</td>
<td><em>P. aeruginosa</em>, <em>Serratia marcescens</em></td>
<td>Pseudo-outbreak</td>
<td>41</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Srinivasan et al(^{25})</td>
<td>2003</td>
<td><em>P. aeruginosa</em></td>
<td>Outbreak</td>
<td>97</td>
<td>48</td>
<td>35</td>
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<tr>
<td>Kirschke et al(^{26})</td>
<td>2003</td>
<td><em>P. aeruginosa</em></td>
<td>Both</td>
<td>20</td>
<td>1</td>
<td>0</td>
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<tr>
<td>Ramsey et al(^{17})</td>
<td>2002</td>
<td><em>M. tuberculosis</em></td>
<td>Pseudo-outbreak</td>
<td>10</td>
<td>4</td>
<td>0</td>
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<tr>
<td>Rossetti et al(^{18})</td>
<td>2002</td>
<td><em>Mycobacterium gordonae</em></td>
<td>Pseudo-outbreak</td>
<td>16</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Kresel and Kidd(^{29})</td>
<td>2001</td>
<td><em>M. chelonae</em>, <em>Methylobacterium mesophilicum</em></td>
<td>Pseudo-outbreak</td>
<td>20</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Sorin et al(^{30})</td>
<td>2001</td>
<td><em>P. aeruginosa</em></td>
<td>Both</td>
<td>18</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Kramer et al(^{31})</td>
<td>2001</td>
<td><em>P. aeruginosa</em></td>
<td>Both</td>
<td>18</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Wilson et al(^{25})</td>
<td>2000</td>
<td><em>Aureobasidium sp.</em></td>
<td>Pseudo-outbreak</td>
<td>10</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gillespie et al(^{33})</td>
<td>2000</td>
<td><em>M. chelonae</em></td>
<td>Pseudo-outbreak</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Schelenz and French(^{24})</td>
<td>2000</td>
<td><em>P. aeruginosa</em></td>
<td>Unknown</td>
<td>8</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Note:** AER, automated endoscope reprocessor; GNR, gram-negative rods.
DISINFECTION OF ENDOSCOPES

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY  JUNE 2011, VOL. 32, NO. 6

ASGE-SHEA GUIDELINE

Multisociety Guideline on Reprocessing Flexible GI Endoscopes: 2011

Bret T. Petersen, MD, FASGE; Jennifer Chennat, MD; Jonathan Cohen, MD, FASGE; Peter B. Cotton, MD, FASGE; David A. Greenwald, MD, FASGE; Thomas E. Kowalski, MD; Mary L. Krinsky, DO; Walter G. Park, MD; Irving M. Pike, MD, FASGE; Joseph Romagnuolo, MD, FASGE; for the ASGE Quality Assurance in Endoscopy Committee; and William A. Rutala, PhD, MPH; for the Society for Healthcare Epidemiology of America
Since 2003, changes in
- High-level disinfectants
- Automated endoscope reprocessors
- Endoscopes
- Endoscopic accessories

However, efficacy of decontamination and high-level disinfection is unchanged and the principles guiding both remain valid

Additional outbreaks of infection related to suboptimal infection prevention practices during endoscopy or lapses in endoscope reprocessing (unfamiliarity with endoscope channels, accessories, attachments; gaps in infection prevention at ASC)
Transmission categorized as:

- Non-endoscopic and related to care of intravenous lines and administration of anesthesia or other medications
  - Multidose vials
  - Reuse of needles and syringes
  - Intravenous sedation tubing
- Endoscopic and related to endoscope and accessories
  - Failure to sterilize biopsy forceps between patients
  - Lapses in reprocessing tubing used in channel irrigation
Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- Unresolved Issues
  - Interval of storage after which endoscopes should be reprocessed before use
    - Data suggest that contamination during storage for intervals of 7-14 days is negligible, unassociated with duration, occurs on exterior of instruments and involves only common skin organisms
    - Data are insufficient to proffer a maximal outer duration for use of appropriately cleaned, reprocessed, dried and stored endoscopes
  - Microbiologic surveillance testing after reprocessing
    - Detection of non-environmental pathogens indicator of faulty reprocessing equipment, inadequate solution, or failed human process
Unresolved Issues

- Optimal frequencies for replacement of: clean water bottles and tubing for insufflation of air and lens wash water, and waste vacuum canisters and suction tubing
  - Concern related to potential for backflow from a soiled endoscope against the direction of forced fluid and air passage into clean air/water source or from tubing/canister against a vacuum into clean instruments
- Microbiologic surveillance testing after reprocessing
  - Detection of non-environmental pathogens indicator of faulty reprocessing equipment, inadequate solution, or failed human process
ENDOSCOPE DISINFECTION

- CLEAN-mechanically cleaned with water and enzymatic cleaner
- HLD/STERILIZE-immerse scope and perfuse HLD/sterilant through all channels for at least 12 min
- RINSE-scope and channels rinsed with sterile water, filtered water, or tap water followed by alcohol
- DRY-use forced air to dry insertion tube and channels
- STORE-prevent recontamination
CLEANING OF ENDOSCOPES

- Mechanical cleaning machines-automated equipment may increase productivity, improve cleaning effectiveness, and decrease worker exposure
  - Utensil washer-sanitizer
  - Ultrasonic cleaner
  - Washer sterilizer
  - Dishwasher
  - Washer disinfecter
- Manual
<table>
<thead>
<tr>
<th>Disinfection step</th>
<th>Reason for disinfection step</th>
<th>Mechanism for failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleaning</td>
<td>Remove bioburden</td>
<td>Inadequate policies;</td>
</tr>
<tr>
<td></td>
<td>Remove substances that might interfere with disinfection: blood, salt, protein</td>
<td>Inadequate training or supervision; failure to clean immediately (i.e., allowing body fluids to dry);</td>
</tr>
<tr>
<td></td>
<td></td>
<td>failure to brush all channels; damaged internal channel(s); poorly mated internal components</td>
</tr>
<tr>
<td>Appropriate disinfectant</td>
<td>Inactivation of contaminating microbes</td>
<td>Ineffective disinfectant (e.g., iodides); inadequate concentration; inadequate duration; inadequate temperature</td>
</tr>
<tr>
<td>Contact between disinfectant</td>
<td>Requirement for killing</td>
<td>AER: failure to use channel connectors; AER: wrong channel connectors; occluded lumen; torn or damaged lumen</td>
</tr>
<tr>
<td>and contaminating microbes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rinse</td>
<td>Remove potentially toxic chemicals (e.g., glutaraldehyde, hydrogen peroxide)</td>
<td>Mucous membrane damage to subsequent patient (e.g., colitis); contaminated rinse water</td>
</tr>
<tr>
<td>Prevention of recontamination</td>
<td>Prevent contamination with environmental microbes</td>
<td>Tap water rinse without subsequent alcohol rinse;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>failure to air-dry endoscope; contaminated AER; reassembly of valves before storage; placement of endoscope in contaminated container; storage in coiled position (rather than hanging straight)</td>
</tr>
</tbody>
</table>
Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- Relatively new technologies for HLD
  - EvoTech
  - OER-Pro

- Endoscope durability and longevity
  - No published data regarding materials durability and potential for reduced function or reduced ability to attain HLD
EVOTECH w/Cleaning Claim

- Integrated double-bay AER
- Eliminates manual cleaning
- Uses New High-Level Disinfectant (HLD) with IP protection
- Single-shot HLD
- Automated testing of endoscope channels and minimum effective concentration of HLD
- Incorporates additional features (LAN, LCD display)
- Eliminates soil and microbes equivalent to optimal manual cleaning. BMC ID 2010; 10:200
## Processing “Noncritical” Patient Care Objects

<table>
<thead>
<tr>
<th>Classification</th>
<th>Noncritical objects will not come in contact with mucous membranes or skin that is not intact.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Object</td>
<td>Can be expected to be contaminated with some microorganisms.</td>
</tr>
<tr>
<td>Level germicidal action</td>
<td>Kill vegetative bacteria, fungi and lipid viruses.</td>
</tr>
<tr>
<td>Examples</td>
<td>Bedpans; crutches; bed rails; EKG leads; bedside tables; walls, floors and furniture.</td>
</tr>
<tr>
<td>Method</td>
<td>Low-level disinfection</td>
</tr>
</tbody>
</table>
## Low-Level Disinfection for “Noncritical” Objects

Exposure time $> 1$ min

<table>
<thead>
<tr>
<th>Germicide</th>
<th>Use Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl or isopropyl alcohol</td>
<td>70-90%</td>
</tr>
<tr>
<td>Chlorine</td>
<td>100ppm (1:500 dilution)</td>
</tr>
<tr>
<td>Phenolic</td>
<td>UD</td>
</tr>
<tr>
<td>Iodophor</td>
<td>UD</td>
</tr>
<tr>
<td>Quaternary ammonium</td>
<td>UD</td>
</tr>
<tr>
<td>Accelerated hydrogen peroxide</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

UD=Manufacturer’s recommended use dilution
NOVEL METHODS OF ROOM DISINFECTION

- No touch methods
  - Ultraviolet light
  - Hydrogen peroxide (HP)
    - Sterinis: Fine mist by aerosolizing solution of 5% HP, <50 ppm silver
    - Steris: Vaporized HP from 35% HP
    - Bioquell: HP vapor from 35% HP

- Self disinfecting surfaces
  - Copper
  - Silver or silver ion impregnated
  - Sharklet pattern
  - Light activated antimicrobial coatings

- Accelerated hydrogen peroxide
Novel Methods of Room Disinfection
# COMPARISON OF ROOM DECONTAMINATION SYSTEMS THAT USE UV IRRADATION AND HYDROGEN PEROXIDE (HP)

<table>
<thead>
<tr>
<th>Sterinis</th>
<th>Steris</th>
<th>Bioquell</th>
<th>Tru-D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbreviation</td>
<td>DMHP (dry mist HP)</td>
<td>VHP (vaporized HP)</td>
<td>HPV (HP vapor)</td>
</tr>
<tr>
<td>Active agent</td>
<td>Stenusil (5% HP, &lt;50 ppm silver cations)</td>
<td>Vaprox (35% HP)</td>
<td>35% HP</td>
</tr>
<tr>
<td>Application</td>
<td>Aerosol of active solution</td>
<td>Vapor, noncondensing</td>
<td>Vapor, condensing</td>
</tr>
<tr>
<td>Aeration (removal of active agent from enclosure)</td>
<td>Passive decomposition</td>
<td>Active catalytic conversion</td>
<td>Active catalytic conversion</td>
</tr>
<tr>
<td>Sporicidal efficacy</td>
<td>Single cycle does not inactivate Bacillus atrophaeus BIs; ~4-log$_{10}$ reduction in Clostridium difficile$^a$ and incomplete inactivation in situ</td>
<td>Inactivation of Geobacillus stearothermophillus BIs</td>
<td>Inactivation of G. stearothermophilus BIs; &gt;6-log$_{10}$ reduction in C. difficile$^a$ in vitro and complete inactivation in situ</td>
</tr>
<tr>
<td>Evidence of clinical impact</td>
<td>None published</td>
<td>None published</td>
<td>Significant reduction in the incidence of C. difficile</td>
</tr>
</tbody>
</table>

UV ROOM DECONTAMINATION: ADVANTAGES AND DISADVANTAGES

■ Advantages
  ● Reliable biocidal activity against a wide range of pathogens
  ● Surfaces and equipment decontaminated
  ● Room decontamination is rapid (~15 min) for vegetative bacteria
  ● HVAC system does not need to be disabled and room does not need to be sealed
  ● UV is residual free and does not give rise to health and safety concerns
  ● No consumable products so operating costs are low (key cost = acquisition)

■ Disadvantages
  ● No studies evaluating whether use reduces HAIs
  ● Can only be done for terminal disinfection (i.e., not daily cleaning)
  ● All patients and staff must be removed from room
  ● Substantial capital equipment costs
  ● Does not remove dust and stains which are important to patients/visitors
  ● Sensitive use parameters (e.g., UV dose delivered)

**EFFECTIVENESS OF UV ROOM DECONTAMINATION**

<table>
<thead>
<tr>
<th>Organism</th>
<th>Inoculum</th>
<th>No. of samples</th>
<th>Decontamination, log_{10} reduction, mean (95% CI)</th>
<th>UV-C line of sight</th>
<th>Direct</th>
<th>Indirect</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Total</td>
<td></td>
<td>No. of samples</td>
<td>Decontamination, log_{10} reduction, mean (95% CI)</td>
</tr>
<tr>
<td>MRSA</td>
<td>4.88 log_{10}</td>
<td>50</td>
<td>3.94 (2.54–5.34)</td>
<td></td>
<td>10</td>
<td>4.31 (3.13–5.50)</td>
</tr>
<tr>
<td>VRE</td>
<td>4.40 log_{10}</td>
<td>47</td>
<td>3.46 (2.16–4.81)</td>
<td></td>
<td>15</td>
<td>3.90 (2.99–4.81)</td>
</tr>
<tr>
<td>MDR A. baumannii</td>
<td>4.64 log_{10}</td>
<td>47</td>
<td>3.88 (2.59–5.16)</td>
<td></td>
<td>10</td>
<td>4.21 (3.27–5.15)</td>
</tr>
<tr>
<td>C. difficile spores</td>
<td>4.12 log_{10}</td>
<td>45</td>
<td>2.79 (1.20–4.37)</td>
<td></td>
<td>10</td>
<td>4.04 (3.71–4.37)</td>
</tr>
</tbody>
</table>

Rutala WA, Gergen MF, Weber DJ. ICHE 2010;31:1025-9
EFFECTIVENESS OF UV ROOM DECONTAMINATION

Figure 4: Mean number of colony-forming units (CFU) of *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus* (MRSA), and vancomycin-resistant *Enterococcus* (VRE) recovered from contaminated surfaces in hospital rooms before and after disinfection with the Tru-D device. Two hundred sixty-one total surfaces from 66 rooms were cultured, including call lights, bedside tables, telephones, and bed rails.

HP ROOM DECONTAMINATION: ADVANTAGES AND DISADVANTAGES

Advantages
- Reliable biocidal activity against a wide range of pathogens
- Surfaces and equipment decontaminated
- Demonstrated to decrease disease incidence (C. difficile)
- Residual free and does not give rise to health and safety concerns (aeration units convert HPV into oxygen and water)
- Useful for disinfecting complex equipment and furniture

Disadvantages
- Can only be done for terminal disinfection (i.e., not daily cleaning)
- All patients and staff must be removed from room
- Decontamination takes approximately 3-5 hours
- HVAC system must be disabled and the room sealed with tape
- Substantial capital equipment costs
- Does not remove dust and stains which are important to patients/visitors
- Sensitive use parameters (e.g., HP concentration 280 ppm)

Rutala WA, Weber DJ. ICHE (In press)
HPV in vitro Efficacy

Room Decontamination With HPV

Study design
- Before and after study of HPV

Outcome
- *C. difficile* incidence

Results
- HPV decreased environmental contamination with *C. difficile* (p<0.001), rates on high incidence floors from 2.28 to 1.28 cases per 1,000 pt-days (p=0.047), and throughout the hospital from 1.36 to 0.84 cases per 1,000 pt days (p=0.26)

Boyce JM, et al. ICHE 2008;29:723-729
EFFICACY OF HYPOCHLORITE VS HYDROGEN PEROXIDE DRY MIST

- Study design: Prospective randomized before-after study, 2007
- Setting: 2 French hospitals
- Methods: Disinfection: A=0.5% hypochlorite; B=HP-Ag cation dry-mist (Sterusil)
- Results
  - After disinfection 12% of samples from hypochlorite rooms and 2% from HP showed contamination (p<0.005)
- No measurement of cleaning thoroughness

SELF DISINFECTING SURFACES

Copper coated overbed table

Sharklet Pattern

Antimicrobial effects of silver

Triclosan pen
SELF DISINFECTING SURFACES

- Copper (Surfaces contaminated on copper objects)\(^1\)
  - VRE (1.8% → 0.2%)*; MSSA (4.6% → 1.3%)*; MRSA (3.7% → 2.3%), Coliforms (8.1% → 3.4%)*; *C. difficile* (0.4% → 1.4%) {* p<0.05}
  - Decrease (when significant, 1-2-log\(_{10}\))

- Silver\(^2\)
  - Silver (surfacine) active against *S. aureus*, VRE, *E. coli*, *Klebsiella*
  - Reduction 3-5-log\(_{10}\)

- Sharklet pattern\(^3\)
  - Sharklet pattern effective in decreasing growth of *S. aureus* on surfaces

- Light activated antimicrobial coating (methylene blue, gold nanoparticles)\(^4\)
  - Coating able to reduce MRSA 99.33% to 99.99%

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Disinfection and Sterilization of Emerging Pathogens

- Hepatitis C virus
- Norovirus
- Novel H1N1 influenza
- SARS Coronavirus
- *Helicobacter pylori*
- *E.coli 0157:H7*
- Bioterrorism agents (anthrax, plague, smallpox)
- Antibiotic-resistant microbes (MDR-TB, VRE, MRSA)
- *Clostridium difficile*
- *Cryptosporidium*
Disinfection and Sterilization of Emerging Pathogens

Standard disinfection and sterilization procedures for patient care equipment are adequate to sterilize or disinfect instruments or devices contaminated with blood and other body fluids from persons infected with emerging pathogens with the exception of prions.
Failure to Follow Disinfection and Sterilization Principles

- Method for assessing patient risk for adverse events
- Although exposure events are often unique, can approach the evaluation of potential failure using a standardized approach
- Propose a sequence of 14 steps that form a general approach to a possible failure of disinfection/sterilization (D/S)
- D/S failure could result in patient exposure to an infectious agent

Rutala, Weber ICHE 2007;28:146
1. Confirm disinfection or sterilization reprocessing failure
2. Impound any improperly disinfected/sterilized items
3. Do not use the questionable disinfection/sterilization unit (e.g., sterilizer, automated endoscope reprocessor) until proper functioning can be assured
4. Inform key stakeholders
5. Conduct a complete and thorough evaluation of the cause of the disinfection/sterilization failure
6. Prepare a line listing of potentially exposed patients
7. Assess whether disinfection/sterilization failure increases patient risk for infection
8. Inform expanded list of stakeholders of the reprocessing issue
9. Develop a hypothesis for the disinfection/sterilization failure and initiate corrective action
10. Develop a method to assess potential adverse patient events
11. Consider notification of state and federal authorities
12. Consider patient notification
13. Develop long-term follow-up plan
14. Perform after-action report

**Figure 1.** Protocol for exposure investigation after a failure of disinfection and sterilization procedures
CONCLUSIONS

- Rigorous adherence to disinfection/sterilization guideline necessary to prevent healthcare associated outbreaks
  - Cleaning must precede disinfection/sterilization
  - Must pay special attention to disinfection of endoscopes (associated with more outbreaks than any other medical device)
- Contaminated hospital surfaces important in transmission of several organisms: MRSA, VRE, *C. difficile*, *Acinetobacter*, norovirus
- Novel “no touch” methods may be useful in reducing surface contamination
- In the event of a possible disinfection/sterilization failure an organized method for evaluating risk may aid in assessing patient risk