Martin S. Favero Lectureship
Disinfection and Sterilization: Successes and Failures
William A. Rutala, Ph.D., M.P.H.
University of North Carolina (UNC) Health Care and
UNC at Chapel Hill, NC
Disclosure: Clorox, Advanced Sterilization Products

Successes
- Effective cleaning procedures
- Effective and robust high-temperature and low-temperature sterilization technology
- Effective new technologies
  - Low-level disinfection
  - High-level disinfection
  - Prions
- Know how to kill emerging pathogens

Successes

<table>
<thead>
<tr>
<th>Washer Disinfector</th>
<th>Removal/Inactivation of Inoculum (Exposed) on Instruments</th>
</tr>
</thead>
<tbody>
<tr>
<td>WD Conditions</td>
<td>Organism</td>
</tr>
<tr>
<td>Routine</td>
<td>MRSA</td>
</tr>
<tr>
<td>Routine</td>
<td>VRE</td>
</tr>
<tr>
<td>Routine</td>
<td>P aeruginosa</td>
</tr>
<tr>
<td>Routine</td>
<td>M terrae</td>
</tr>
<tr>
<td>Routine</td>
<td>GS spores</td>
</tr>
<tr>
<td>No Enz/Det</td>
<td>VRE</td>
</tr>
<tr>
<td>No Enz/Det</td>
<td>GS spores</td>
</tr>
</tbody>
</table>

Sterilization of “Critical Objects”
- Steam sterilization
- Hydrogen peroxide gas plasma
- Ethylene oxide
- Peracetic acid (0.2%)-chemical sterilization
- Ozone
- Vaporized hydrogen peroxide

High Level Disinfection of “Semicritical Objects”

<table>
<thead>
<tr>
<th>Exposure Time &gt; 12 m-30m (US), 20°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germicide</td>
</tr>
<tr>
<td>Glutaraldehyde</td>
</tr>
<tr>
<td>Ortho-phthalaldehyde (12 m)</td>
</tr>
<tr>
<td>Hydrogen peroxide</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
</tr>
<tr>
<td>Hypochlorite (free chlorine)*</td>
</tr>
<tr>
<td>Accelerated hydrogen peroxide</td>
</tr>
<tr>
<td>Glut and oxone (phenol)</td>
</tr>
</tbody>
</table>

*May cause cosmetic and functional damage; **Efficacy not verified
Low-Level Disinfection for “Noncritical” Objects

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

UD = Manufacturer’s recommended use dilution

Inactivation of Prions

Recent Studies

- Enzymatic cleaner (EC)-no effect
- Phenolic (Environ LpH), alkaline cleaner (AC), EC+HP-effective
- SDS/NaCl, AC, 0.2% PA, 5% SDS-effective (in vitro)
- Environ LpH-effective
- Fichet et al. JHI 2007;67:278. Gaseous HP-effective

Disinfection and Sterilization of Emerging Pathogens

- Hepatitis C virus
- Clostridium difficile
- Cryptosporidium
- Helicobacter pylori
- E.coli 0157:H7
- Human papilloma virus
- Antibiotic-resistant microbes (MDR-TB, VRE, MRSA)
- SARS Coronavirus, avian/swine influenza, norovirus
- Bioterrorism agents (anthrax, plague, smallpox)

Failures

- Compliance
  - High level disinfection
  - Low level disinfection
    - Suboptimal surface cleaning/disinfection practices
    - Disconnect between science and registration process
  - Flash Sterilization

Endoscope Channels

---

2
**Endoscope Reprocessing: Current Status of Cleaning and Disinfection**

- Guidelines
  - Centers for Disease Control and Prevention, 2008
  - Multi-Society Guideline, 11 professional organizations, 2003
  - Society of Gastroenterology Nurses and Associates, 2000
  - European Society of Gastrointestinal Endoscopy, 2000
  - British Society of Gastroenterology Endoscopy, 1998
  - Gastroenterological Society of Australia, 1999
  - Gastroenterological Nurses Society of Australia, 1999
  - American Society for Gastrointestinal Endoscopy, 1996
  - Association for Professional in Infection Control and Epidemiology, 2000

---

**TRANSMISSION OF INFECTION**

- Gastrointestinal endoscopy
  - >300 infections transmitted
  - 70% agents Salmonella sp. and P. aeruginosa
  - Clinical spectrum ranged from colonization to death (~4%)
- Bronchoscopy
  - 90 infections transmitted
  - M. tuberculosis, atypical Mycobacteria, P. aeruginosa


---

**Disinfection and Sterilization New Systems and Technologies**

- New technology that eliminates risk (AERs) or improved compliance
- Elimination of high-level disinfection
  - Improve low-temperature sterilization process so all semicritical items can be sterilized (no restrictions, simple and inexpensive)
  - Develop semicritical items that can be steam sterilized
  - Develop disposable semicritical items (e.g., endoscopes)

---

**Endoscope Reprocessing, Worldwide**

- Worldwide, endoscopy reprocessing varies greatly
  - India, of 133 endoscopy centers, only 1/3 performed even a minimum disinfection (1% glut for 2 min)
  - Brazil, "a high standard … occurs only exceptionally"
  - Western Europe, >30% did not adequately disinfect
  - Japan, found "exceedingly poor" disinfection protocols
  - US, 25% of endoscopes revealed >100,000 bacteria

---

**EVOTECH w/Cleaning Claim**

- **Product Definition**
  - 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)
Reliance™ EPS
Endoscope Processing System

Disinfection and Sterilization
New Systems and Technologies

- New technology that eliminates risk (AERs) or improved compliance
- Elimination of high-level disinfection
  - Improve low-temperature sterilization process so all semicritical items can be sterilized (no restrictions, simple and inexpensive)
  - Develop semicritical items that can be steam sterilized
  - Develop disposable semicritical items (e.g., endoscopes)

Risk of Acquiring MRSA, VRE, and C. difficile from Prior Room Occupants

- Admission to a room previously occupied by an MRSA-positive patient or VRE-positive patient significantly increased the odds of acquisition for MRSA and VRE (although this route is a minor contributor to overall transmission). Arch Intern Med 2006;166:1945.
- Prior environmental contamination, whether measured via environmental cultures or prior room occupancy by VRE-colonized patients, increases the risk of acquisition of VRE. Clin Infect Dis 2008;46:678.
- Prior room occupant with CDAD is a significant risk for CDAD acquisition. ICACC (K-4194) 2008. Shaughnessy et al.

Role of the Environment in Transmission

Pathogens implicated in transmission via contaminated noncritical surfaces (survival in the environment and recovered from the environment)

- Bacteria
  - Oxacillin-resistant Staphylococcus aureus
  - Vancomycin-resistant Enterococcus spp.
  - Clostridium difficile
  - Acinetobacter and P. aeruginosa
- Viruses
  - Rotavirus
  - Norovirus
  - SARS coronavirus

Environmental Contamination MRSA

- 27% of 350 surfaces sampled in the rooms of affected patients were contaminated with MRSA. When patients had MRSA in a wound or urine, 36% of surfaces were contaminated. Boyce et al. ICHE 1997;18:622.
- 74% of 359 swabs taken before cleaning yielded MRSA. French et al. J Hosp Infect 2004;57:31

The Inanimate Environment Can Facilitate Transmission

**C. difficile Environmental Contamination**

- Frequency of sites found contaminated: 10% -> 50% from 13 studies-stethoscopes, bed frames/rails, call buttons, sinks, hospital charts, toys, floors, window sills, commodes, toilets, bedsheets, scales, blood pressure cuffs, phones, door handles, electronic thermometers, flow-control devices for IV catheter, feeding tube equipment, bedpan hoppers
- C. difficile spore load is low; 7 studies assessed the spore load and most found <10 colonies on surfaces found to be contaminated. Two studies reported >100; one reported a range of "1->200" and one study sampled several sites with a sponge and found 1,300 colonies C. difficile.

---

**Practice or Product**

**Patient Area Cleaning/Disinfecting**

PC Carling et al, ICHE 2008;29:1 and ICHE 2008;29:1035

- Monitor cleaning performance using an invisible fluorescent targeting method. Rooms (14 high-touch objects) were marked and evaluated after terminal cleaning.
- Results: 1,605 rooms and 20,646 objects were evaluated in 36 hospitals. Mean proportion of objects cleaned was 48%. Following education and process improvement feedback, cleaning improved to 77%
- Conclusion: Substantial opportunity for improving terminal cleaning/disinfecting activities.

---

**Practice* NOT Product**

*surfaces not wiped

---

**Table. Rates of Cleaning for 14 Types of High-Risk Objects**

<table>
<thead>
<tr>
<th>Object</th>
<th>Percentage cleaned</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sink</td>
<td>82 ± 12</td>
<td>77-88</td>
</tr>
<tr>
<td>Toilet seat</td>
<td>76 ± 18</td>
<td>69-84</td>
</tr>
<tr>
<td>Tray table</td>
<td>77 ± 15</td>
<td>71-84</td>
</tr>
<tr>
<td>Bedside table</td>
<td>64 ± 22</td>
<td>58-72</td>
</tr>
<tr>
<td>Toilet handle</td>
<td>66 ± 22</td>
<td>50-69</td>
</tr>
<tr>
<td>Side rail</td>
<td>60 ± 21</td>
<td>51-69</td>
</tr>
<tr>
<td>Call box</td>
<td>50 ± 19</td>
<td>42-58</td>
</tr>
<tr>
<td>Telephone</td>
<td>49 ± 16</td>
<td>42-56</td>
</tr>
<tr>
<td>Chair</td>
<td>48 ± 28</td>
<td>35-61</td>
</tr>
<tr>
<td>Toilet door knobs</td>
<td>28 ± 22</td>
<td>18-37</td>
</tr>
<tr>
<td>Toilet hand hold</td>
<td>28 ± 23</td>
<td>18-38</td>
</tr>
<tr>
<td>Bedpan cleaner</td>
<td>25 ± 18</td>
<td>17-33</td>
</tr>
<tr>
<td>Room door knobs</td>
<td>23 ± 19</td>
<td>15-31</td>
</tr>
<tr>
<td>Bathroom light switch</td>
<td>20 ± 21</td>
<td>13-30</td>
</tr>
</tbody>
</table>

**Note.** CI, confidence interval.

Mean proportion of surfaces disinfected at terminal cleaning is ~50%
Risk of Acquiring MRSA, VRE, and *C. difficile* from Prior Room Occupants

- Admission to a room previously occupied by an MRSA-positive patient or VRE-positive patient significantly increased the odds of acquisition for MRSA and VRE (although this route is a minor contributor to overall transmission). Arch Intern Med 2006;166:1945.
- Prior environmental contamination, whether measured via environmental cultures or prior room occupancy by VRE-colonized patients, increases the risk of acquisition of VRE. Clin Infect Dis 2008;46:678.
- Prior room occupant with CDAD is a significant risk for CDAD acquisition. ICACC (K-4194) 2008. Shaughnessy et al.

Quality Improvement

Monitoring the Effectiveness of Cleaning

Cooper et al. AJIC 2007;35:338

- Visual assessment—not a reliable indicator of surface cleanliness
- ATP bioluminescence—measures organic debris (each unit has own reading scale)
- Microbiological methods—<2.5CFUs/cm²—pass; can be costly and pathogen specific
- Fluorescent marker

Fluorescent Marker

- A mixture of several glues, soaps, and a target dye (Carling, 2009)
  - Dries rapidly
  - Simple
  - Easily removed by wetted cloth
  - Environmentally stable
  - Rapid
  - Unfortunately, not readily available (Carling and Sodexho)

Rates of Cleaning for High-Risk Objects

Room Decontamination Units

MRSA, VRE, *C. difficile*

- Hydrogen peroxide vapor
- Hydrogen peroxide gas
- UV
Hydrogen Peroxide Vapor Decontamination
- Bartels MD et al. J Hosp Infect 2008;70:35. MRSA/Sterinis
- Boyce JM et al. ICHE 2008;29:7. C. difficile/Bioquell

UV Room Decontamination
- Fully automated, self calibrates, activated by hand-held remote
- Room ventilation does not need to be modified
- Uses UV-C (254 nm range) to decontaminate surfaces
- Measures UV reflected from walls, ceilings, floors or other treated areas and calculates the operation time to deliver the programmed lethal dose for pathogens.
- UV sensors determines and targets highly-shadowed areas to deliver measured dose of UV energy
- After UV dose delivered, will power-down and audibly notify the operator
- Reduces colony counts of pathogens by >99.9% within 20 minutes

UV Room Decontamination with UV
(Rutala, Gergen, Weber, 2009, Unpublished Results)

<table>
<thead>
<tr>
<th>Organism</th>
<th>Dose Reading (time)</th>
<th>Log_{10} Reduction (10 sites, 5 replicates)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRSA</td>
<td>~470 mj/cm^2 (~15m)</td>
<td>3.91</td>
</tr>
<tr>
<td>VRE</td>
<td>~660 mj/cm^2 (~15m)</td>
<td>3.36</td>
</tr>
<tr>
<td>Acinetobacter</td>
<td>~630 mj/cm^2 (~14m)</td>
<td>3.77</td>
</tr>
<tr>
<td>C. difficile</td>
<td>~2120 mj/cm^2 (~50m)</td>
<td>2.67</td>
</tr>
</tbody>
</table>

Room Decontamination with UV

Contact Time for Surface Disinfection
- CDC guidelines recommends a 1 minute contact time for noncritical surfaces/items. If user selects exposure conditions that differ from label, the user assumes liability and subject to FIFRA.
- Labels on most products registered by EPA specifies a contact time of 10 minutes (some have times of 1-3 minutes)
- Such a long contact time is impractical because dry time 1-3 minutes
- Multiple investigators demonstrated the effectiveness of these disinfectants against bacteria, yeasts, viruses-remedy disconnect

Failures
- Compliance
  - High level disinfection
  - Low level disinfection
    - Suboptimal surface cleaning/disinfection practices
    - Disconnect between science and registration process
- Flash Sterilization
### Flash Sterilization

#### What is the definition?
- In 1942, Underwood defined flash sterilization as 3 minutes at 250°F for instruments when there is an “extreme emergency”.
- In 1969, Perkins redefined flash sterilization to the current definition of an unwrapped item at 270°F for 3 minutes in a gravity sterilizer.

### Flash Sterilization

#### AORN, CDC Guidelines
- Flash sterilization used for items that must be used immediately
- Acceptable for processing items that cannot be packaged, sterilized and stored before use
- Because of the potential for serious infections, implanted surgical devices should not be flash sterilized unless unavoidable (e.g., orthopedic screws)
- Do not use flash sterilization for reasons of convenience, as an alternative to purchasing additional instrument sets, or to save time

### Successes
- Effective cleaning procedures
- Effective and robust high-temperature and low-temperature sterilization technology
- Effective new technologies
  - Low-level disinfection
  - High-level disinfection
  - Prions
- Know how to kill emerging pathogens

### Failures
- Compliance
  - High level disinfection
  - Low level disinfection
  - Suboptimal surface cleaning/disinfection practices
  - Disconnect between science and registration process
- Flash Sterilization
Thank you

Martin S. Favero Lectureship, 2009