Disinfection and Sterilization: Current Issues and New Technologies

Current Issues and New Technologies
- Environmental Hygiene
- New Approaches to Room Decontamination
  - Ultraviolet
  - Hydrogen peroxide systems
- Controlling the spread of C. difficile via the environment
- Citations: TJC and CMS
  - > 1 minute surface disinfection
  - 20m/20°C glutaraldehyde
- Multi-Society Endoscope Reprocessing Guideline, 2011
- Other issues (monitoring temperature of HLD, wipes, Steris System 1E)

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The Role of the Environment in Disease Transmission

- Over the past decade there has been a growing appreciation that environmental contamination makes a contribution to HAI with MRSA, VRE, and C. difficile
- Surface disinfection practices are currently not effective in eliminating environmental contamination
- Inadequate terminal cleaning of rooms occupied by patients with MDR pathogens places the next patients in these rooms at increased risk of acquiring these organisms
- Improved methods of disinfecting the hospital environment are needed
Target Enhanced

Terminal Room Cleaning: Demonstration of Improved Cleaning
- Evaluated cleaning before and after an intervention to improve cleaning
- 36 US acute care hospitals
- Assessed cleaning using a fluorescent dye
- Interventions
  - Increased education of environmental service workers
  - Feedback to environmental service workers
  - Improvement in thoroughness of room decontamination (?)
  Carling PC, et al. ICHE 2008;29:1035-41

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). Huang et al. 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. Drees et al. Clin Infect Dis 2008;46:678.
- Prior room occupant with CDAD is a significant risk for CDAD acquisition. Shaughnessy et al. ICHE 2011;32:201

Novel Methods of Room Decontamination
- No touch methods (supplement, do not replace, standard cleaning and disinfection)
  - Ultraviolet light
  - Hydrogen peroxide (HP) systems
    - 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 (proposed)
    - Silver or silver ion impregnated
    - Copper
    - Sharklet pattern

New Approaches to Room Decontamination
Ultraviolet Irradiation

Effectiveness of UV Room Decontamination


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)

Hydrogen Peroxide (HP) Decontamination Systems

Rutala WA, Weber DJ. ICHE (in press)
Comparison of HP Room Decontamination Systems

<table>
<thead>
<tr>
<th>Sterilis</th>
<th>Steris</th>
<th>Bioquell</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Aerosolized mist HP</td>
<td>Vaporized HP</td>
</tr>
<tr>
<td>Active solution</td>
<td>5% HP, &lt;50 ppm Ag cations</td>
<td>35% HP</td>
</tr>
<tr>
<td>Application</td>
<td>Aerosol of active solution</td>
<td>Vapor, noncondensing</td>
</tr>
<tr>
<td>Aeration</td>
<td>Passive decomposition</td>
<td>Active catalytic conversion</td>
</tr>
<tr>
<td>Sporicidal activity</td>
<td>~4-log reduction of C. difficile in vitro and incomplete inactivation in situ</td>
<td>No data on C. difficile inactivation of G. stearothermophilus Bio II</td>
</tr>
</tbody>
</table>

Otter JA, Yezli S. J Hosp Infect 2011;77:76-92

Hydrogen Peroxide Decontamination Systems

- Ray et al. ICHE 2010;31:1236. MDR Acinetobacter
- Barbut et al. ICHE 2009;30:517. C. difficile
- Bartels MD et al. J Hosp Infect 2008;70:35. MRSA
- Boyce JM et al. ICHE 2008;29:723. C. difficile

- 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

HPV in vitro Efficacy

HP System 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)

Rutala WA, Weber DJ. ICHE (in press)
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Controlling the Spread of C. difficile via the Environment

C. difficile

“The Perfect Storm” for Environmental Transmission

- Microbial factors that facilitate environmental transmission
  - Ability to survive in the environment for hours to days
  - Ability to remain virulent after environmental exposure
  - Low inoculating dose
  - Deposition on surfaces frequently touched by HCP must occur
  - Ability to colonize patients
  - Transmission directly or via the contaminated hands of HCP
  - Relative resistance to antiseptics
  - Relative resistance to disinfectants

CDI Now the Most Common Healthcare-Associated Pathogen

- Analysis of 10 community hospitals, 2005-2009, in the Duke DICON system

Transmission Mechanisms Involving the Surface Environment

Persistence of Clinically Relevant Bacteria of Dry Inanimate Surfaces


Environmental Contamination with C. difficile

- 25% (117/466) of cultures positive (<10 CFU) for C. difficile. >90% of sites positive with incontinent patients. (Samore et al. AJM 1996;100:32)
- 31.4% of environmental cultures positive for C. difficile. (Kaatz et al. AJE 1988;127:1289)
- 9.3% (85/910) of environmental cultures positive (floors, toilets, toilet seats) for C. difficile. (Kim et al. JID 1981;143:42)
- 29% (62/216) environmental samples were positive for C. difficile. 29% (11/38) positive cultures in rooms occupied by asymptomatic patients and 49% (44/90) in rooms with patients who had CDAD. (NEJM 1989;320:204)
- 10% (110/1086) environmental samples were positive for C. difficile in case-associated areas and 2.5% (144/689) in areas with no known cases. (Fekety et al. AJM 1991;70:907)

Percent of Stool, Skin and Environment Cultures Positive for C. difficile

- 25% (117/466) of cultures positive (<10 CFU) for C. difficile. >90% of sites positive with incontinent patients. (Samore et al. AJM 1996;100:32)
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Frequency of Environmental Contamination and Relation to Hand Contamination

- Study design: Prospective study, 1992
- Setting: Tertiary care hospital
- Methods: All patients with CDI assessed with environmental cultures
- Results
  - Environmental contamination frequently found (25% of sites) but higher if patients incontinent (>90%)
  - Level of contamination low (<10 colonies per plate)
  - Also contaminated: BP cuff, electronic thermometer, IV accurate control device and oximeter

Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants

Most Resistant
- Prions
- Spores (C. difficile)
- Mycobacteria
- Non-Enveloped Viruses
- Fungi
- Bacteria

Most Susceptible
- Enveloped Viruses

Disinfectants
No measurable activity (1 C. difficile strain, J9; spores at 20 min)

- Vesphe (phenolic)
- 70% isopropyl alcohol
- 95% ethanol
- 3% hydrogen peroxide
- Clorox disinfecting spray (65% ethanol, 0.6% QUAT)
- Lysol II disinfecting spray (79% ethanol, 0.1% QUAT)
- TBQ (0.06% QUAT); QUAT may increase sporulation capacity
- Novaplus (10% povidone iodine)
- Accel (0.5% hydrogen peroxide)


Disinfectants and Antiseptics
C. difficile spores at 10 and 20 min, Rutala et al, 2006

- ~4 log_{10} reduction (5 C. difficile strains including Bl-9)
  - Clorox, 1:10, ~6,000 ppm chlorine (but not 1:50, ~1,200 ppm)
  - Clorox Clean-up, ~19,100 ppm chlorine
  - Tilex, ~25,000 ppm chlorine
  - Steris 20 sterilant, 0.2% peracetic acid
  - Cidex, 2.4% glutaraldehyde
  - Cidex-OPA, 0.55% OPA
  - Wavicide, 2.65% glutaraldehyde
  - Aldahol, 3.4% glutaraldehyde and 26% alcohol
Effect of Hypochlorite on Environmental Contamination and Incidence of *C. difficile*

- In an intervention study, the incidence of CDAD for bone marrow transplant patients decreased significantly, from 8.6 to 3.3 cases per 1000 patient days after the environmental disinfection was switched from QUAT to 1:10 hypochlorite solution in the rooms of patients with CDAD. No reduction in CDAD rates was seen among NS-ICU and medicine patients for whom baseline rates were 3.0 and 1.3 cases per 1000-patient days. Mayfield et al. Clin Inf Dis 2000;31:995.

35% of 1128 environmental cultures were positive for *C. difficile*. To determine how best to decontaminate, a cross-over study conducted. There was a significant decrease of *C. difficile* on one of two medicine wards (8.9 to 5.3 per 100 admissions) using hypochlorite (1,000 ppm) vs. detergent. Wilcox et al. J Hosp Infect 2003;54:109.

There was a 48% reduction (0.85 to 0.45/1000 patient days) in the prevalence density of *C. difficile* after the bleaching intervention (thorough, all-surface terminal bleach cleaning program in the rooms of patients with CDI). Hacek et al. Am J Infect Control 2010;38:350-3.

Effect of Hypochlorite on Environmental Contamination and Incidence of *C. difficile*

Environmental Surface Disinfection

Products-5000-6000ppm chlorine effective or other products with *C. difficile* claims

New Approaches to Room Decontamination

Controlling the Spread of *C. difficile* via the Environment

Practice-ensure thoroughness of disinfection
Products-5000-6000ppm chlorine effective or other products with *C. difficile* claims
When-with increased rates of *C. difficile* (all CDI rooms?)
Disinfection and Sterilization: Current Issues and New Technologies

- Current Issues and New Technologies
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      - ≥ 1 minute surface disinfection
      - 20m/20°C glutaraldehyde
    - Multi-Society Endoscope Reprocessing Guideline, 2011
    - Other issues (wipes, Steris System 1E)

Surface Disinfection

- Exposure Time
  - CMS surveyors (CA) and TJC have been paying closer attention to cleaning the environment, including assurance that hospitals are following manufacturer’s directions for disinfectant contact time
  - Hospital cited for using a shorter contact time than manufacturer’s label claim and appealed based upon published peer-reviewed literature supporting shorter exposure times
  - Appeal denied

Surface Disinfection

- Exposure Time
  - CDC guideline recommends a contact time of at least 1 minute
  - In order to get EPA clearance of the CDC Guideline it was necessary to insert two sentences. “By law, all applicable label instructions on EPA-registered products must be followed. If the user selects exposure conditions that differ from those on the EPA-registered product label, the user assumes liability from any injuries resulting from off-label use and is potentially subject to enforcement action under FIFRA”

Risk Assessment

- Present best judgment for hospital when standards are unclear
- Demonstrates a clear thought process and understanding of why we do something a particular way
- Four steps
  - Review the requirements-regulations/guidelines
  - Review the literature
  - Review your own experience-any adverse events
  - Make you decision-the result of a thoughtful process

How Do Hospitals Avoid Citations?

Risk Assessment
**Surface Disinfection**

Contact Time ≥ 1 minute

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**Risk Assessment**

- Requirements: CDC guidelines, EPA label registration
- Review the literature: >15 scientific studies have demonstrated the efficacy of hospital disinfectants against HA pathogens with a contact time of 1 minute
- Review your own experience: no data that demonstrate improved infection prevention by a 10 minute contact time vs a 1 minute contact time and no HAIs attributed to noncritical items
- Make your decision: use of >1 minute for surface disinfection of noncritical environmental surfaces and patient care equipment (ensure all contaminated surfaces are wiped)

---

**Table 3. Sustained Efficacy of Disinfectants Applied in Keyboard Against Vancomycin-Resistant Enterococcal Species**

<table>
<thead>
<tr>
<th>Disinfectant</th>
<th>Challenge at 6 Hours</th>
<th>Challenge at 24 Hours</th>
<th>Challenge at 48 Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10-min Exposure</td>
<td>60-min Exposure</td>
<td>10-min Exposure</td>
</tr>
<tr>
<td></td>
<td>10-min Exposure</td>
<td>60-min Exposure</td>
<td></td>
</tr>
<tr>
<td>CarWipes</td>
<td>100.00</td>
<td>100.00</td>
<td>100.00</td>
</tr>
<tr>
<td>Chlorhexidine Wipes</td>
<td>100.00</td>
<td>100.00</td>
<td>100.00</td>
</tr>
<tr>
<td>Anti-Clot Plus</td>
<td>100.00</td>
<td>100.00</td>
<td>100.00</td>
</tr>
</tbody>
</table>

**NOTE**: Efficacy was calculated as the percentage difference in the number of colony-forming units on the treated keys, compared with the number of colony-forming units on the control keys. Challenge times are hours since disinfectant exposure.

---

**Bacterial Contamination of Keyboards: Efficacy and Functional Impact of Disinfectants**

William A. Partid, MD, MPH; Beth M. White; Helen B. Gage, MD, MSc; David J. Vlahos, MD, MPH

Computers are ubiquitous in healthcare settings and have been shown to harbor and transmit potentially pathogenic microorganisms. This study evaluated the impact of different disinfection methods, such as alcohol-based hand sanitizer, chlorhexidine, and hydrogen peroxide mist, on the bacterial load of computers in a hospital setting. The study concluded that both alcohol-based hand sanitizer and chlorhexidine were effective in reducing bacterial loads on computer keyboards.

**Conclusions**: The data suggest that consistent contamination of keyboards is prevented and that keyboards may be reasonably decontaminated with disinfection with alcohol-based hand sanitizer or chlorhexidine.

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**ANC-061: A National Guideline**

**Multisociety Guideline on Reprocessing Flexible GI Endoscopes: 2011**

Bert T. Pittman, MD, FASC; Jennifer Choinier, MD; Jonathan Cohen, MD, FASC; Peter B. Conte, MD, FASC; David A. Greenson, MD, FASC; Thomas E. Kavalk, MD, Mary J. Landy, DO; Walter C. Park, MD; Irving M. Pikel, MD, FASC; Joseph Rasmussen, MD, FASC; for the American Society for Gastrointestinal Endoscopy; and William A. Roberts, MD, MPH, for the Society for Healthcare Epidemiology of America

The hospital's role in the reprocessing of GI endoscopes for the prevention, diagnosis, and treatment of gastrointestinal diseases and cancer is well-established. Many institutions have implemented reprocessing protocols that vary from institution to institution. This document provides a comprehensive guideline for the reprocessing of flexible GI endoscopes, including specific recommendations for pre-processing, cleaning, disinfection, sterilization, and post-processing steps. It also includes guidelines for the management of endoscopic equipment and supplies, as well as the implementation of quality control and infection prevention measures.
High-Level Disinfection

20°C at 20 minutes

Risk Assessment

- Requirements-CDC/Multi-Society guidelines, FDA label claims
- Review the literature—>40 scientific studies and professional organizations support the efficacy of 2% glutaraldehyde for 20 minutes at 20°C in conjunction with cleaning prior to HLD
- Review your own experience—no published studies of transmission of infection when current guidelines followed
- Make your decision—use >2% glutaraldehyde at 20°C at 20 minutes

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  - Other issues (monitoring the temperature of HLD, wipes, Steris System 1E)

Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- Since 2003, changes in
  - High-level disinfectants
  - Automated endoscope reproprocessors
  - 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 reproprocessing (unfamiliarity with endoscope channels, accessories, attachments; gaps in infection prevention at ASC)
Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- 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

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

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Monitoring Temperature of High-Level Disinfectant
Advanced Sterilization Products May 2011

- Regulatory and accrediting organizations have increased their scrutiny of HLD temperatures and often request objective evidence that reprocessing temperatures meet requirements
- In many cases, the ambient temperature of a reprocessing area is sufficient to ensure the minimum reprocessing temperature is maintained during HLD

Monitoring Temperature of High-Level Disinfectant
Advanced Sterilization Products May 2011

- In some cases, however, a reprocessing area may not be sufficiently warm to ensure a basin is above the required temperature, and in this case the solution should not be used until the temperature is sufficient
- In this case the solution must be warmed to the appropriate temperature before the processing begins
- The minimum temperature should be maintained or exceeded throughout the soaking time
- If a warmer is used, heat only to meet or to marginally exceed the minimum required temperature (do not overheat)
- Consider regularly monitoring the solution temperature
- Numerous heating systems are in the market that may be used to gently warm the HLD
- Asked all users at UNC Health Care to conduct daily temperature monitoring of HLD and record on the log along with MEC
Warming Pad and Rack

Digital Temperature Heater Controller
(or any thermometer [±0.5°C] with a traceable calibration, e.g., VWR Scientific Products or Lab Safety Supply)

Glass Thermometer
Spirit-Filled, 0-50°C

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Surface Disinfection
Effectiveness of Different Methods

<table>
<thead>
<tr>
<th>Technique (with cotton)</th>
<th>MRSA Log_{10} Reduction (QUAT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saturated cloth</td>
<td>4.41</td>
</tr>
<tr>
<td>Spray (10s) and wipe</td>
<td>4.41</td>
</tr>
<tr>
<td>Spray, wipe, spray (1m), wipe</td>
<td>4.41</td>
</tr>
<tr>
<td>Spray</td>
<td>4.41</td>
</tr>
<tr>
<td>Spray, wipe, spray (until dry)</td>
<td>4.41</td>
</tr>
<tr>
<td>Disposable wipe with QUAT</td>
<td>4.55</td>
</tr>
<tr>
<td>Control: detergent</td>
<td>2.88</td>
</tr>
</tbody>
</table>
**Wipes**

Practice—ensure at least 1 minute wet time (coverage area can vary from ~5 to ~40 ft²—wipe size and disinfectant)

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**Steris System 1**

SS1 had been used as a chemical sterilization process but in December 2009 FDA advised users to transition to other legally marketed technology.

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**Steris System 1E**

FDA cleared April 2010

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**UNC Health Care Policy-SS1E**

- UNC Health Care will eliminate the use of SS1 over the next several months (before February 2, 2012)
- We will use the replacement reprocessor, SS1E, for reprocessing semicritical items that require high-level disinfection
- As a general rule, the Steris System 1E will not be used to reprocess critical items unless the item cannot be sterilized by other legally marketed sterilization methods (e.g., SS, ETO, HP gas plasma, VHP, ozone) validated for that type of device

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**Steris System 1E**

- SS1E—liquid chemical sterilant processing system (LCSPS)
  - All LCSPS have the same limitation in that final devices emerge wet and unwrapped from the processor (not terminally sterilized)
  - The SS1E rinse water is not described as sterile
  - FDA consider steam sterilization, HP gas plasma, VHP, ETO, and ozone sterilizers (which the agency has cleared) to be fully validated terminal sterilizers which provide terminally sterilized products
Steris System 1E Example

If a hospital has a Sterrad HP gas plasma sterilizer and a Steris VHP sterilizer and a device which cannot be processed at high temperatures, but has been validated for reprocessing in the available Sterrad gas plasma and Steris VHP sterilizers as well as the SS1E, it should be processed in the available HP sterilizers rather than the SS1E. However, if a hospital has neither a HP gas plasma, VHP, ozone or ETO sterilizer, a SS1E might be the only available reprocessing choice.

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Disinfection and Sterilization: Current Issues and New Technology Summary

- Surface disinfection practices are currently not effective in eliminating environmental contamination
- Inadequate terminal cleaning of rooms occupied by patients with MDR pathogens places the next patient in these rooms at increased risk of acquiring these organisms
- UV and HP systems are effective and offer an option for room decontamination
- Hospitals cited for not following label claims for surface disinfectants (EPA) and HLD (FDA); consider risk assessment
- Unresolved issues in endoscope reprocessing but the principles guiding cleaning and high-level disinfection are unchanged

Disinfection and Sterilization: Current Issues and New Technology

- Control the spread of C. difficile in the environment by adherence to proper room cleaning, use of sporicidal agents (or UV/HP) in CDI rooms
- Consider monitoring the temperature of HLD
- When using pop-up wipes ensure a 1 minute wet time
- Steris System 1E should be used only for processing heat-sensitive semicritical and critical devices that are compatible with the sterilant and processing system and cannot be sterilized by other fully validated terminal sterilization methods for that device

Thank you
disinfectionandsterilization.org
References