Disinfection and Sterilization: Current Issues and New Technologies

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Disclosure: Advanced Sterilization Products and Clorox

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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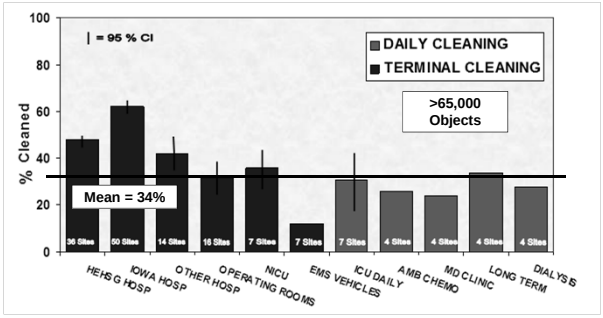
The Role of the Environment in Disease Transmission

- 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



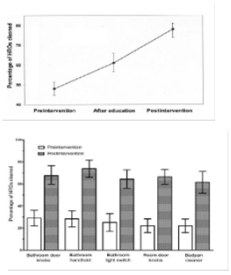
Thoroughness of Environmental Cleaning
Carling and coworkers, SHEA 2010



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

TABLE 1. UV-C Decontamination of Formica Surfaces in Patient Rooms Experimentally Contaminated with Methicillin-Resistant *Staphylococcus aureus* (MRSA), Vancomycin-Resistant *Enterococcus* (VRE), Multidrug-Resistant (MDR) *Acinetobacter baumannii*, and *Clostridium difficile* Spores

		UV-C line of sight						
		Total		Direct		Indirect		
Organism	Inoculum	No. of samples	Decontamination, $\log_{10}$ reduction, mean (95% CI)	No. of samples	Decontamination, $\log_{10}$ reduction, mean (95% CI)	No. of samples	Decontamination, $\log_{10}$ reduction, mean (95% CI)	*P*
MRSA	4.88 $\log_{10}$	50	3.94 (2.54–5.34)	10	4.31 (3.13–5.50)	40	3.85 (2.44–5.25)	.06
VRE	4.40 $\log_{10}$	47	3.46 (2.16–4.81)	15	3.90 (2.99–4.81)	32	3.25 (1.97–4.62)	.003
MDR *A. baumannii*	4.64 $\log_{10}$	47	3.88 (2.59–5.16)	10	4.21 (3.27–5.15)	37	3.79 (2.47–5.10)	.07
C. difficile spores	4.12 $\log_{10}$	45	2.79 (1.20–4.37)	10	4.04 (3.71–4.37)	35	2.43 (1.46–3.40)	<.001

Rutala WA, Gergen MF, Weber DJ. Infect Control Hosp Epidemiol 2010;31:1025-9

Effectiveness of UV Room Decontamination

Nerandzic et al. BMC Infect Dis 2010;8:197

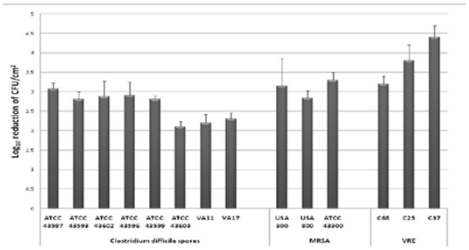


Figure 2 Mean reduction ($\log_{10}$ colony-forming units (CFU)/cm²) in recovery of multiple strains of *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus* (MRSA), and vancomycin-resistant *Enterococcus* (VRE) from laboratory bench top surfaces after the use of the Tru-D device. For each pathogen, the inoculum applied to the bench top was adjusted such that 10^5 to 10^6 CFU were recovered from the positive control specimens. The Tru-D device was operated at a reflected dose of 22,000 μW/cm² for ~45 minutes.

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)

Rutala WA, Weber DJ. ICHE (In press)

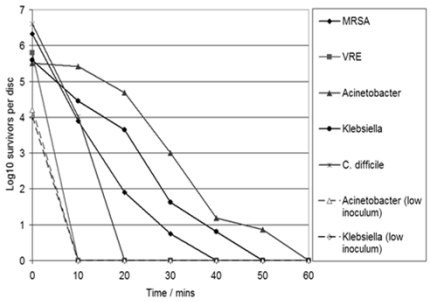
Hydrogen Peroxide (HP) Decontamination Systems

Comparison of HP Room Decontamination Systems

	Sterinis	Steris	Bioquell
Name	Aerosolized/dry mist HP	Vaporized HP	HP vapor
Active solution	5% HP, <50 ppm Ag cations	35% HP	35% HP
Application	Aerosol of active solution	Vapor, noncondensing	Vapor, condensing
Aeration	Passive decomposition	Active catalytic conversion	Active catalytic conversion
Sporicidal activity	~4-$\log_{10}$ reduction of *C. difficile in vitro* and incomplete inactivation *in site*	No data on *C. difficile*; inactivation of *G. stearothermophilus* BIs	>6-$\log_{10}$ reduction of *C. difficile in vitro* and complete inactivation *in situ*

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

HPV *in vitro* Efficacy



Otter and French. *J Clin Microbiol* 2009;47:205-207.

Hydrogen Peroxide Decontamination Systems

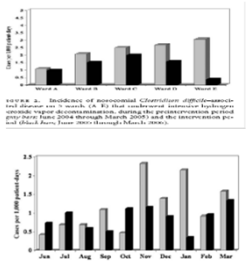
- Eterpi et al. Lett Appl Microbiol. 2011;52:150. Mycoplasma
- Ray et al. ICHE 2010;31:1236. MDR *Acinetobacter*
- Otter et al. Am J Infect Control 2010:38:754. MDR-GNR
- Otter, French. J Clin Microbiol 2009;47:205. Spores/bacteria
- Barbut et al. ICHE 2009;30:517. *C. difficile*
- Bartels MD et al. J Hosp Infect 2008;70:35. MRSA
- Boyce JM et al. ICHE 2008;29:723. *C. difficile*
- Shapey S et al. J Hosp Infect 2008;70:136. *C. difficile*

Hydrogen Peroxide Decontamination Systems

- Otter et al. J Hosp Infect 2007;67:182. MRSA, VRE, GNR
- Hardy KJ et al. J Hosp Infect 2007;66:360. MRSA
- Hall L et al. J Clin Microbiol 2007;45: 810. *M. tuberculosis*
- Bates CJ, Pearse R. J Hosp Infect 2005;61:364. *S. marcescens*
- Johnston MD et al. J Microbiol Methods 2005;60:403. *C. botulinum*
- French GL et al. J Hosp Infect 2004;57:31. MRSA
- Heckert RA et al. Appl Environ Microbiol 1997;63:3916. Viruses
- Klapes NA et al. Appl Environ Microbiol 1990;56;503. *Bacillus* spores/prototype HPV generator

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

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

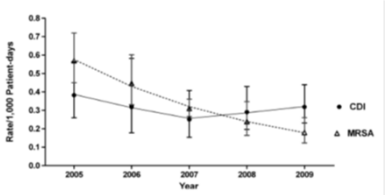
C. difficile
"The Perfect Storm" for Environmental Transmission

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

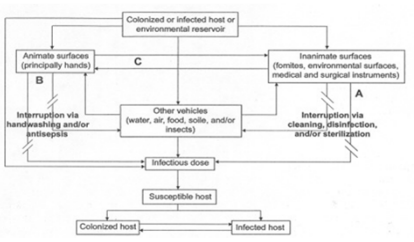
CDI Now the Most Common Healthcare-Associated Pathogen

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



Miller BA, et al. ICHE 2011;32:387-390

Transmission Mechanisms Involving the Surface Environment



Rutala WA, Weber DJ. In: "SHEA Practical Healthcare Epidemiology" (Lautenbach E, Woeltje KF, Malani PN, eds), 3rd ed, 2010.

Persistence of Clinically Relevant Bacteria of Dry Inanimate Surfaces

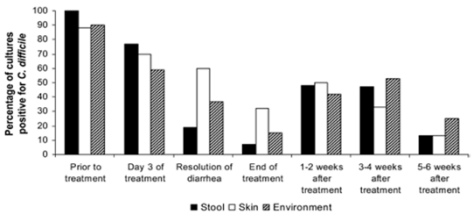
Type of bacterium	Duration of persistence (range)
Acinetobacter spp.	3 days to 5 months
Bordetella pertussis	3 – 5 days
Campylobacter jejuni	up to 6 days
Clostridium difficile (spores)	5 months
Chlamydia pneumoniae, *C. trachomatis*	≥ 30 hours
Chlamydia psittaci	15 days
Corynebacterium diphtheriae	7 days – 6 months
Corynebacterium pseudotuberculosis	1–8 days
Escherichia coli	1.5 hours – 16 months
Enterococcus spp. including VRE and VSE	5 days – 4 months
Haemophilus influenzae	12 days
Helicobacter pylori	≤ 90 minutes
Klebsiella spp.	2 hours to > 30 months
Listeria spp.	1 day – months
Mycobacterium bovis	> 2 months
Mycobacterium tuberculosis	1 day – 4 months
Neisseria gonorrhoeae	1 – 3 days
Proteus vulgaris	1 – 2 days
Pseudomonas aeruginosa	6 hours – 16 months; on dry floor: 5 weeks
Salmonella typhi	6 hours – 4 weeks
Salmonella typhimurium	10 days – 4.2 years
Salmonella spp.	1 day
Serratia marascens	3 days – 2 months; on dry floor: 5 weeks
Shigella spp.	2 days – 5 months
Staphylococcus aureus, including MRSA	7 days – 7 months
Streptococcus pneumoniae	1 – 20 days
Streptococcus pyogenes	3 days – 6.5 months
Vibrio cholerae	1 – 7 days

Kramer A, et al. BMC Infect Dis 2006;6:130

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% (14/489) in areas with no known cases. (Fekety et al. AJM 1981;70:907)**

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



Skin (chest and abdomen) and environment (bed rail, bedside table, call button, toilet seat)
Sethi AK, et al. ICHE 2010;31:21-27

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**
  - **↑ environmental contamination ↑ hand contamination**

Samore MH, et al. Am J Med 1996;100:32-40

Frequency of Cultures Positive for *Clostridium difficile* From Different Environmental Sites Within the Hospital Room

Site	All Rooms: No. Positive/ No. Tested (%)	Double Rooms: Index Side (%)	Double Rooms: Roommate Side (%)
Floor	15/31 (48)	NA	NA
Commode	7/17 (41)	NA	NA
Windowsill	6/16 (38)	NA	NA
Toilet	15/45 (33)	NA	NA
Buzzer	11/57 (19)	6/19 (32)	1/17 (6)
Bedsheets	12/56 (21)	4/20 (20)	2/14 (14)
Bedrails	15/81 (18)	7/26 (27)	2/25 (8)
Totals	81/303 (27)	17/65 (26)*	5/56 (9)

*$P = 0.02$ by Fisher's exact test, index side versus roommate side.
NA = not applicable.

Correlation Between Proportion of Positive Environmental Sites and Isolation of *Clostridium difficile* From Hands of Hospital Personnel

Environmental Sites Positive (%)	No. of Index Cases With Environmental Sites and Personnel Cultured	No. of Positive Personnel/ No. of Personnel Cultured (%)
0	12	0/25
1–25	5	0/11
26–50	5	1/12 (8)
≥50	6	9/25 (36)*

*Chi-square test for linear trend in proportions: $P < 0.01$.

Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants

Most Resistant

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

Most Susceptible

Disinfectants

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

- Vesphene (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- (Lancet 2000;356:1324)
- Novaplus (10% povidone iodine)
- Accel (0.5% hydrogen peroxide)

Rutala W, Weber D, et al. Unpublished results 2006

Disinfectants and Antiseptics

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

- ~4 $\log_{10}$ reduction (5 *C. difficile* strains including BI-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

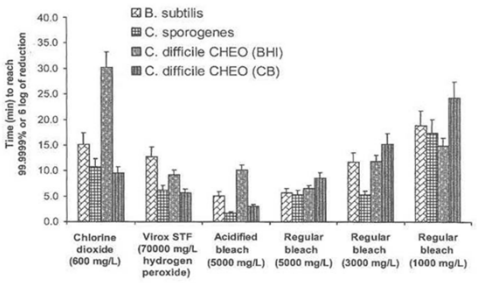


Fig 1. Times required for the microbicides to inactivate ≥6 $\log_{10}$ (99.9999%) of the spores tested.

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

- Use of chlorine (500 [79%reduction]-1600 ppm [98%]) decreased surface contamination and the outbreak ended. Mean CFU/positive culture in outbreak 5.1, reduced to 2.0 with chlorine. Kaatz et al. Am J Epid 1988;127:1289.
- 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.

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

- 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.

Environmental Surface Disinfection

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

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?)

New Approaches to Room Decontamination





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 (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"

How Do Hospitals Avoid Citations?

Risk Assessment

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

Surface Disinfection

Contact Time ≥ 1 minute

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)

UNC HEALTH CARE

Risk-Assessment Worksheet

Issue: Off-label use of one minute contact times for low-level surface disinfectants used on noncritical environmental surfaces and noncritical patient care equipment

Assessment Date: March 15, 2011

Scoring: Low = 1 Moderate = 3 High = 5

Team Members: Bill Rutala, Vickie Brown, David Weber, Kirk Huslage, Becky Brooks, Tina Adams, Brenda Featherstone, Lisa Teal, Emily Sickbert-Bennett, Maria Gergen.

Meeting Actions: Team members evaluated the evidence and determined that off-label 1 minute contact times was sufficient to disinfect noncritical environmental surfaces and noncritical patient care equipment in a healthcare environment

Suggested Questions	Benefit	Risk
What is the impact on patient care delivery?	There are no data demonstrating an infection prevention benefit of a 10 minute contact time for surface disinfection. More than a dozen articles* demonstrate the ability of EPA-registered disinfectants to inactivate HA pathogens in a MINUTE or LESS! Additionally, data demonstrate that our surface disinfectant (QUAT) continues to have significant antimicrobial activity that extends beyond the wet time on a surface. That is, our surface disinfectant has sustained antimicrobial effectiveness (i.e., >6 hours) against HA pathogens when left to dry surface. Score - 5	There are no demonstrated risks to utilizing a 1 minute contact time for surface disinfection. No HAIs have ever been attributed to non-critical environmental surfaces and noncritical patient care equipment. Score – 1
How does the issue affect the staff?	In order to achieve a contact time of 10 minutes, as recommended by the labeling on many disinfectants, the disinfectant would need to be applied up to 5 times as the typical drying time of a	Requiring staff to follow label directions for actions with no proven benefit to employee or patient safety may serve to reduce efforts proven to improve patient outcomes.

PROOF | INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY APRIL 2006, VOL. 27, NO. 4

ORIGINAL ARTICLE

Bacterial Contamination of Keyboards: Efficacy and Functional Impact of Disinfectants

William A. Rutala, PhD, MPH; Matthew S. White; Maria F. Gergen, MT(ASCP); David J. Weber, MD, MPH

BACKGROUND. Computers are ubiquitous in the healthcare setting and have been shown to be contaminated with potentially pathogenic microorganisms. This study was performed to determine the degree of microbial contamination, the efficacy of different disinfectants, and the cosmetic and functional effects of the disinfectants on the computer keyboards.

METHODS. We assessed the effectiveness of 6 different disinfectants (1 each containing chlorine, alcohol, or phenol and 3 containing quaternary ammonium) against 3 test organisms (oxacillin-resistant *Staphylococcus aureus* [ORSA], *Pseudomonas aeruginosa*, and vancomycin-resistant *Enterococcus* species) inoculated onto study computer keyboards. We also assessed the computer keyboards for functional and cosmetic damage after disinfectant use.

RESULTS. Potential pathogens cultured from more than 50% of the computers included coagulase-negative staphylococci (100% of keyboards), diphtheroids (80%), *Micrococcus* species (72%), and *Bacillus* species (64%). Other pathogens cultured included ORSA (4% of keyboards), OSSA (4%), vancomycin-susceptible *Enterococcus* species (12%), and nonfermentative gram-negative rods (56%). All disinfectants, as well as the sterile water control, were effective at removing or inactivating more than 95% of the test bacteria. No functional or cosmetic damage to the computer keyboards was observed after 300 disinfection cycles.

CONCLUSIONS. Our data suggest that microbial contamination of keyboards is prevalent and that keyboards may be successfully decontaminated with disinfectants. Keyboards should be disinfected daily or when visibly soiled or if they become contaminated with blood.

Infect Control Hosp Epidemiol 2006; 27:000-000

TABLE 3. Sustained Efficacy of Disinfectants Applied to Keyboard Against Vancomycin-Resistant *Enterococcus* Species

	Efficacy of Disinfectant, by Time of Microbial Challenge and Duration of Disinfectant Exposure, %					
	Challenge at 6 Hours		Challenge at 24 Hours		Challenge at 48 Hours	
Disinfectant	10-min Exposure	60-min Exposure	10-min Exposure	60-min Exposure	10-min Exposure	60-min Exposure
Alcohol	3.05	5.67	12.58	3.31	10.89	5.59
CaviWipes	100.00	100.00	100.00	100.00	100.00	100.00
Clorox Disinfecting Wipes	100.00	100.00	100.00	100.00	100.00	100.00
Sani-Cloth Plus	100.00	100.00	100.00	100.00	100.00	100.00
Sterile water	0.00	0.28	9.69	0.00	0.00	9.09

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.

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

The beneficial role of GI endoscopy for the prevention, diagnosis, and treatment of many digestive diseases and cancer is well established. Like many sophisticated medical devices, the endoscope is a complex, reusable instrument that requires reprocessing before being used on subsequent patients. The most commonly used methods for reprocessing endoscopes result in high-level disinfection. To date, all published occurrences of pathogen transmission related to GI endoscopy spread gaps in infection prevention practices.[1] Given the ongoing occurrences of endoscopy-associated infections attributed to lapses in infection prevention, an update of the multisociety guideline is warranted.

This document provides an update of the previous guideline, with additional discussion of new or evolving reprocessing issues and updated literature citations, where appropriate. Specific additions or changes include review of

High-Level Disinfection

20ºC 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 20m at 20ºC 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 20ºC at 20 minutes

UNC HEALTH CARE

Risk-Assessment Worksheet

Issue:	Off-label use of >2% glutaraldehyde chemical germicide utilizing a 20-minute immersion at 20°C (20/20) after a standard cleaning protocol is sufficient to achieve high-level disinfection
Assessment Date:	March 18, 2011
Scoring:	Low = 1 Moderate = 3 High = 5
Team Members:	Bill Rutala, Vickie Brown, David Weber, Kirk Huslage, Becky Brooks, Tina Adams, Brenda Featherstone, Lisa Teal, Emily Sickbert-Bennett, Maria Gergen.
Meeting Actions:	Team members evaluated the evidence and determined that off-label use of a standard cleaning protocol in conjunction with a 20-minute, 20°C >2% glutaraldehyde immersion will achieve high-level disinfection.

Suggested Questions	Benefit	Risk
What is the impact on patient care delivery?	There are no data demonstrating benefit of utilizing an extended immersion time of 45-minutes at 25°C to achieve high-level disinfection. Numerous scientific studies and professional organizations[7] support the efficacy of >2% glutaraldehyde for 20-minutes at 20°C in conjunction with adequate cleaning prior to achieve high-level disinfection. Score - 5	There is no risk associated with the transmission of pathogens utilizing the 20/20 protocol, assuming adequate cleaning prior to disinfection. There are no published studies of transmission of infection when guidelines have been followed. Score – 1

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/20ºC glutaraldehyde**
  - **Multi-Society Endoscope Reprocessing Guideline, 2011**
  - **Other issues (monitoring the temperature of HLD, wipes, Steris System 1E)**

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Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- 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)

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

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

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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

Monitoring Temperature of High-Level Disinfectant

Advanced Sterilization Products May 2011

- 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



Pictured:

[redacted] Solution Tray w/ Cozy Warming Pad & Rack
Part Number: GM-1
Contact: 312.226.2473

Note: Do not use a heating mat on a countertop or surface that is heat sensitive or the surface may discolor or change shape. **Temperatures below the mat may reach 65 °C.**

Digital Temperature Heater Controller

(or any thermometer [±0.5°C] with a traceable calibration, eg, VWR Scientific Products or Lab Safety Supply)

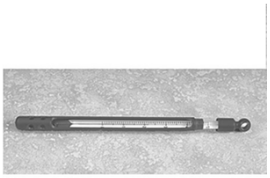


Pictured (Available from Amazon.com):

HC-810M: Finnex Digital Temperature Heater Controller (ASIN: B002TMTA7G)

Glass Thermometer

Spirit-Filled, 0-50°C



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Surface Disinfection

Effectiveness of Different Methods

Technique (with cotton)	MRSA Log_{10} Reduction (QUAT)
Saturated cloth	4.41
Spray (10s) and wipe	4.41
Spray, wipe, spray (1m), wipe	4.41
Spray	4.41
Spray, wipe, spray (until dry)	4.41
Disposable wipe with QUAT	4.55
Control: detergent	2.88

Wipes

Practice-ensure at least 1 minute wet time (coverage area can vary from ~5 to ~40 ft^2- 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.



Steris System 1E

FDA cleared April 2010

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

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
Summary

- 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

- Rutala WA (editor). Disinfection, Sterilization, and Antisepsis: Principles, Practices, Current Issues, New Research, and New Technology. Association for Professionals in Infection Control and Epidemiology, Washington, DC. 2010
- Rutala WA, Weber DJ, HICPAC. 2008. CDC guideline for disinfection and sterilization in healthcare facilities. www.cdc.gov