
Updates on Disinfection and Sterilization

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disinfectionandsterilization.org

Updates on Disinfection and Sterilization

- Update on Disinfection and Sterilization
 - Principles
 - Environmental Hygiene
 - New Approaches to Room Decontamination
 - ◆ Ultraviolet
 - ◆ Hydrogen peroxide systems
 - Controlling the spread of *C. difficile* via the environment
 - Multi-Society Endoscope Reprocessing Guideline, 2011
 - Other issues (microfiber, monitoring temperature of HLD, wipes, Steris System 1E)

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Disinfection and Sterilization

WA Rutala, DJ Weber, and HICPAC, 2008. www.cdc.gov

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 (or non-germicidal detergent).



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Germany

Sterilization of “Critical Objects”

Steam sterilization

Hydrogen peroxide gas plasma

Ethylene oxide

Ozone

Vaporized hydrogen peroxide



High-Level Disinfection of “Semicritical Objects”

Exposure Time \geq 8m-45m (US), 20°C

Germicide	Concentration
Glutaraldehyde	$\geq 2.0\%$
Ortho-phthalaldehyde	$\geq 0.55\%$
Hydrogen peroxide*	7.5%
Hydrogen peroxide and peracetic acid*	1.0%/0.08%
Hydrogen peroxide and peracetic acid*	7.5%/0.23%
Hypochlorite (free chlorine)*	650-675 ppm
Accelerated hydrogen peroxide	2.0%
Glut and isopropanol	3.4%/26%
Glut and phenol/phenate**	1.21%/1.93%

*May cause cosmetic and functional damage; **efficacy not verified



Low-Level Disinfection for “Noncritical” Objects

Exposure time \geq 1 min

Germicide

Use Concentration

Ethyl or isopropyl alcohol

70-90%

Chlorine

100ppm (1:500 dilution)

Phenolic

UD

Iodophor

UD

Quaternary ammonium

UD

Accelerated hydrogen peroxide

0.5%

UD=Manufacturer's recommended use dilution

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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



Noncritical Items

Surface Disinfection-Noncritical Patient Care

WA Rutala, DJ Weber, and HICPAC, 2008. www.cdc.gov

- Disinfecting Noncritical Patient-Care Items
 - Process noncritical patient-care equipment with a EPA-registered disinfectant at the proper use dilution and a contact time of at least 1 min. *Category IB*
 - Ensure that the frequency for disinfecting noncritical patient-care surfaces be done minimally when visibly soiled and on a regular basis (such as after each patient use or once daily or once weekly). *Category II*

Environmental Surface Disinfection

WA Rutala, DJ Weber, and HICPAC, 2008. www.cdc.gov

- Disinfecting Environmental Surfaces in HCF
 - Disinfect (or clean) environmental surfaces on a regular basis (e.g., daily, three times per week), when spills occur, and when these surfaces are visibly soiled. *Category II*
 - Use a one-step process and a disinfectant for housekeeping purposes where: uncertainty exists as to the nature of the soil on the surfaces (blood vs dirt); or where uncertainty exists regarding the presence of multi-drug resistant organisms on such surfaces. *Category II*

Effective Surface Decontamination

Practice and Product

Effective Surface Decontamination

Practice and Product

TABLE 2
DISINFECTANT ACTIVITY AGAINST ANTIBIOTIC-SUSCEPTIBLE AND ANTIBIOTIC-RESISTANT BACTERIA

Product	Log ₁₀ Reductions							
	VSE		VRE		MSSA		MRSA	
	0.5 min	5 min	0.5 min	5 min	0.5 min	5 min	0.5 min	5 min
Vesphene Ilse	>4.3	>4.3	>4.8	>4.8	>5.1	>5.1	>4.6	>4.6
Clorox	>5.4	>5.4	>4.9	>4.9	>5.0	>5.0	>4.6	>4.6
Lysol Disinfectant	>4.3	>4.3	>4.8	>4.8	>5.1	>5.1	>4.6	>4.6
Lysol Antibacterial	>5.5	>5.5	>5.5	>5.5	>5.1	>5.1	>4.6	>4.6
Vinegar	0.1	5.3	1.0	3.7	+1.1	+0.9	+0.6	2.3

Abbreviations: MRSA, methicillin-resistant *Staphylococcus aureus*; MSSA, methicillin-susceptible *S aureus*; VRE, vancomycin-resistant *Enterococcus*; VSE, vancomycin-susceptible *Enterococcus*. Data represent mean of two trials (n=2). Values preceded by ">" represent the limit of detection of the assay. Assays were conducted at a temperature of 20°C and a relative humidity of 45%. Results were calculated as the log of Nd/No, where Nd is the titer of bacteria surviving after exposure and No is the titer of the control.

Rutala WA, Barbee SL, Aguiar NC, Sobsey MD, Weber DJ. Antimicrobial Activity of Home Disinfectants and Natural Products Against Potential Human Pathogens. *Infection Control and Hospital Epidemiology* 2000;21:33-38.

Effective Surface Decontamination

Practice and Product

Monitor the Effectiveness of Cleaning

Cooper et al. AJIC 2007;35:338

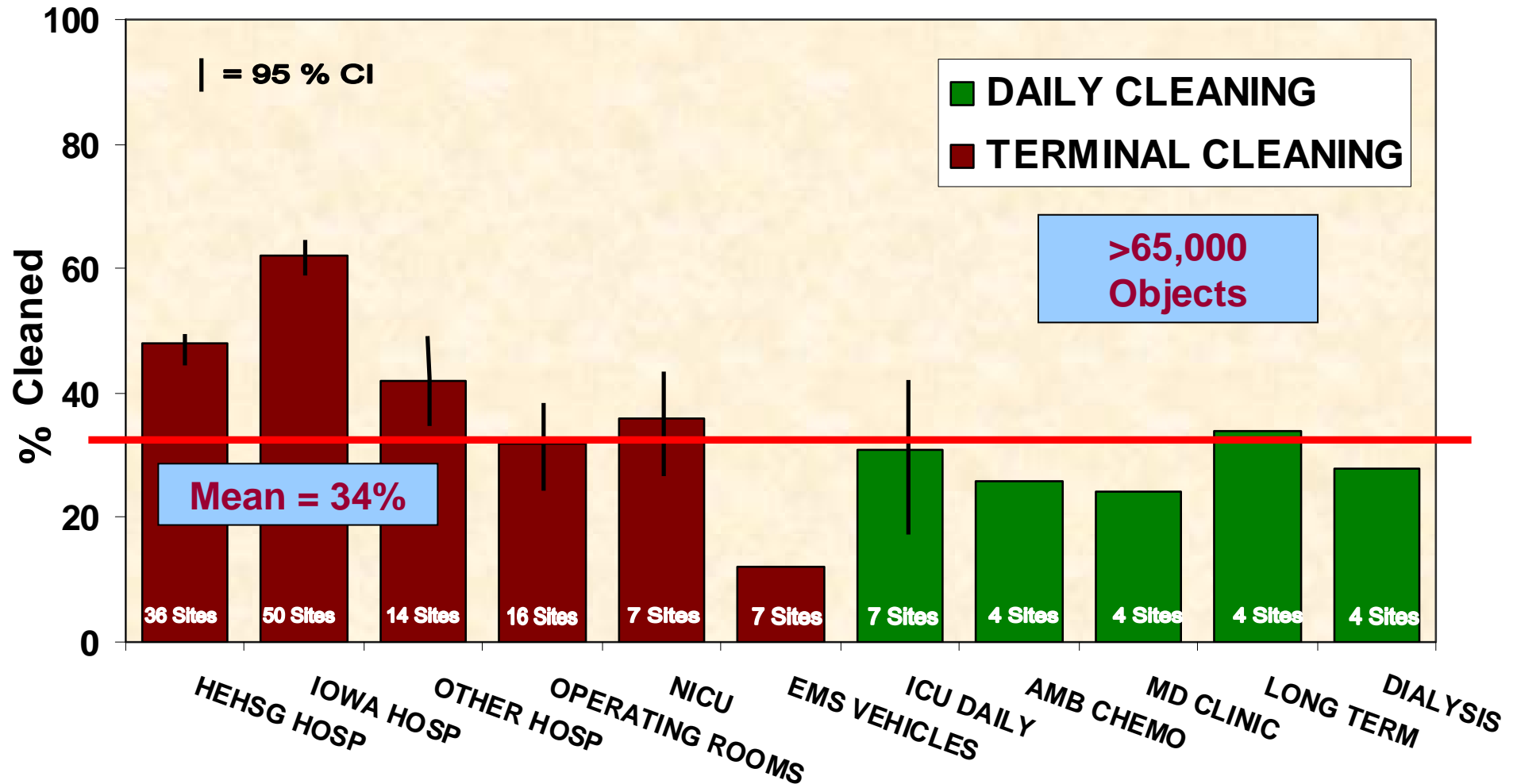
- Visual assessment-not a reliable indicator of surface cleanliness
- ATP bioluminescence-all types of living organisms contain the energy molecule, ATP (each unit has own reading scale)
- Microbiological methods-<2.5CFUs/cm²-pass; can be costly and pathogen specific
- Fluorescent marker

Target Enhanced



Thoroughness of Environmental Cleaning

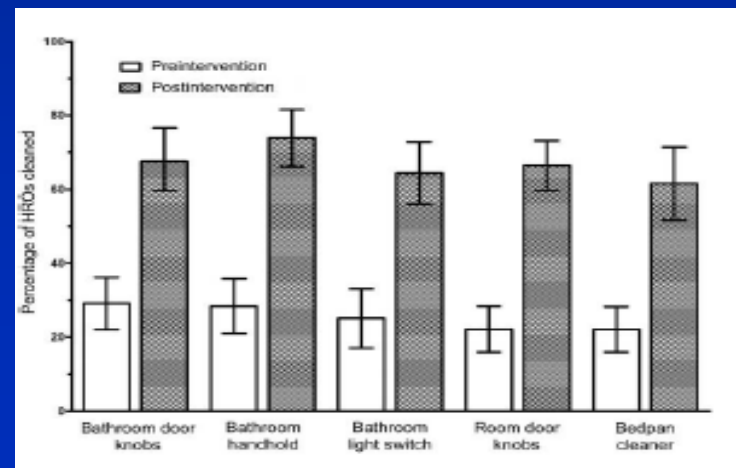
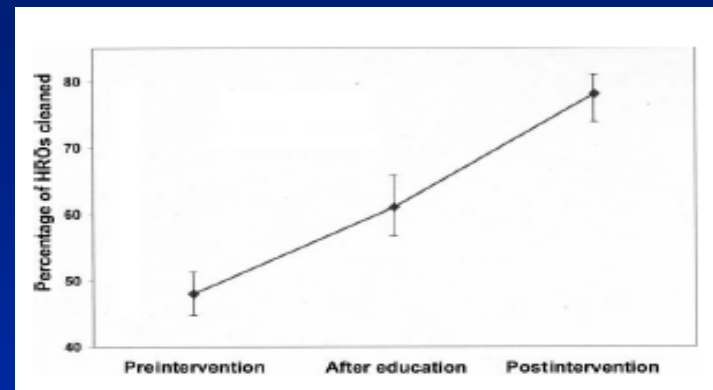
Carling and coworkers, SHEA 2010



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



Practice* NOT Product

*surfaces not wiped

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

UV Room Decontamination

(Rutala, Gergen, Weber, ICHE. 2010:31:1025-1029)

- 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 total dosing/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 ($36,000\mu\text{Ws}/\text{cm}^2$ for spore, $12,000\mu\text{Ws}/\text{cm}^2$ for bacteria), will power-down and audibly notify the operator
- Reduces colony counts of pathogens by >99.9% within 20 minutes



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)	<i>P</i>
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 <i>A. baumannii</i>	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
<i>C. difficile</i> 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

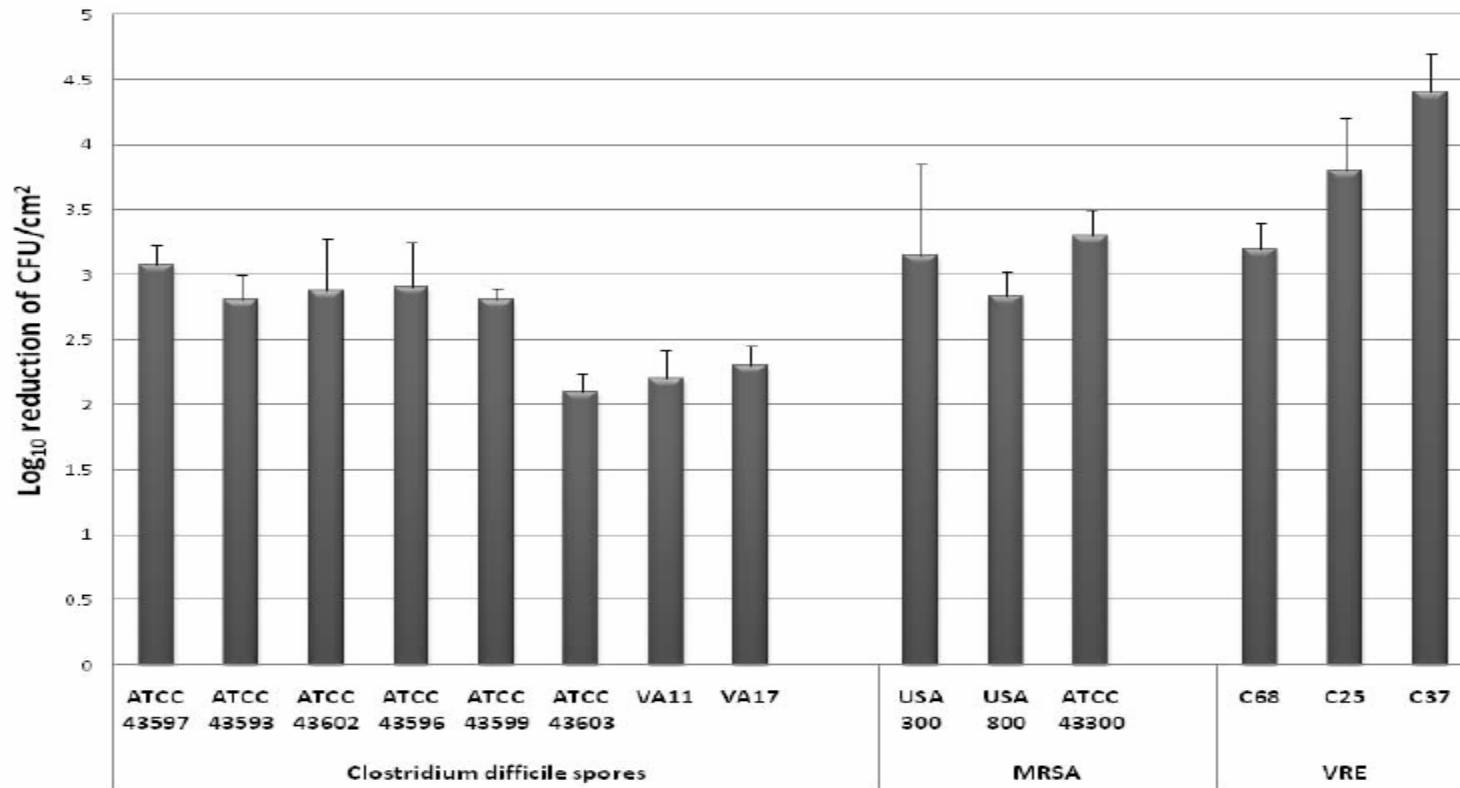


Figure 2 Mean reduction (\log_{10} colony-forming units [CFU]/cm²) in recovery of multiple strains of *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus* (MRSA), and vancomycin-resistant *Enterococcus* (VRE) from laboratory bench top surfaces after the use of the Tru-D device. For each pathogen, the inoculum applied to the bench top was adjusted such that 10^3 to 10^5 CFU were recovered from the positive control specimens. The Tru-D device was operated at a reflected dose of 22,000 $\mu\text{Ws}/\text{cm}^2$ 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)

VHP



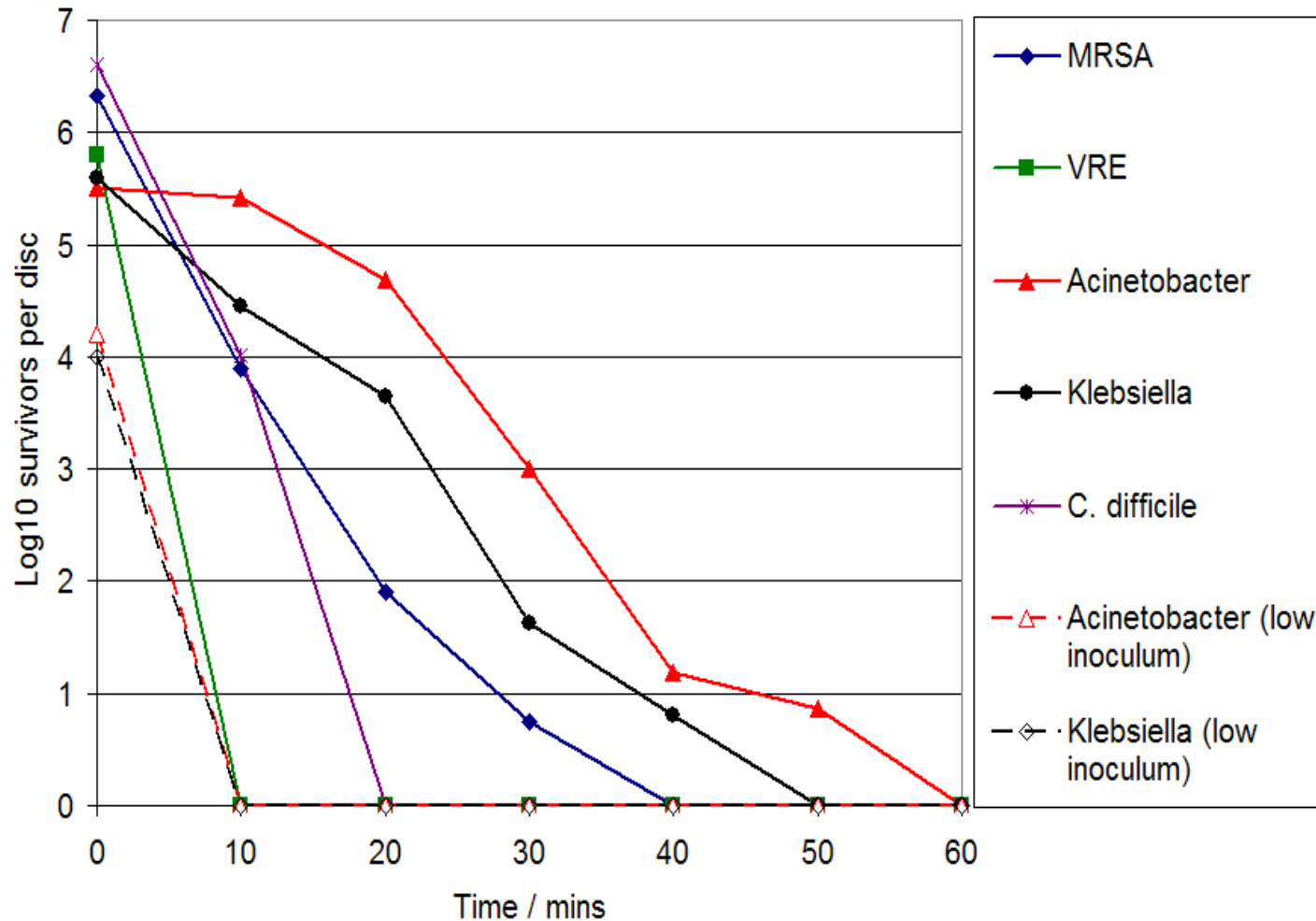
Hydrogen Peroxide (HP) Decontamination Systems

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 <i>C. difficile</i> <i>in vitro</i> and incomplete inactivation <i>in situ</i>	No data on <i>C. difficile</i> ; inactivation of <i>G. stearothersophilus</i> BIs	>6-log ₁₀ reduction of <i>C. difficile</i> <i>in vitro</i> and complete inactivation <i>in situ</i>

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

HPV *in vitro* Efficacy



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*

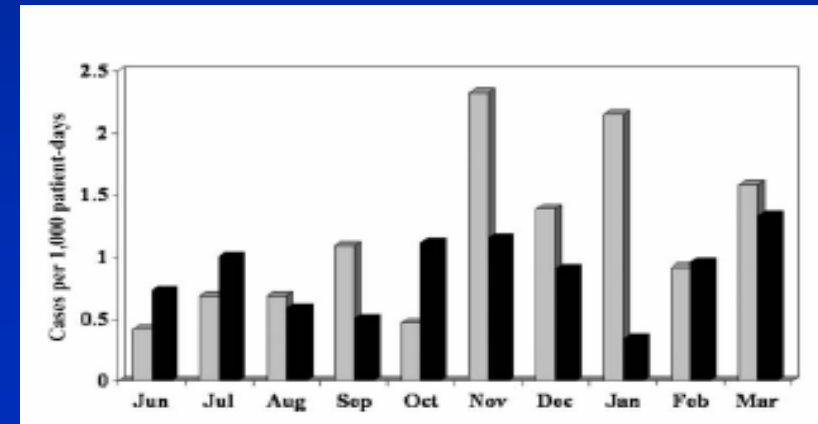
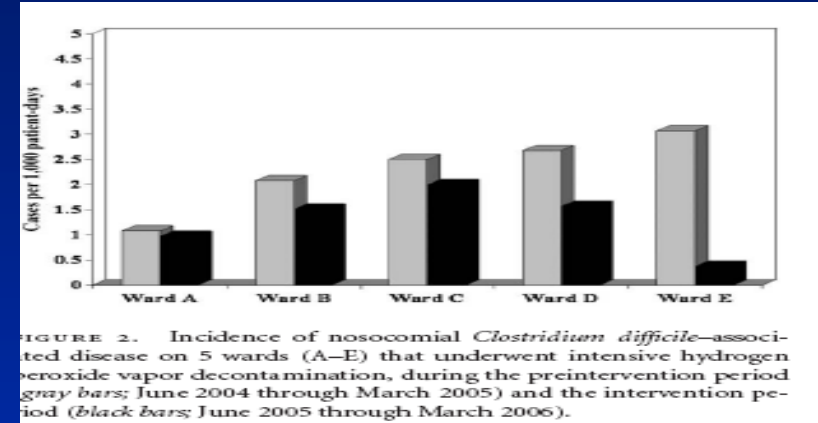
Hydrogen Peroxide Decontamination Systems

- 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

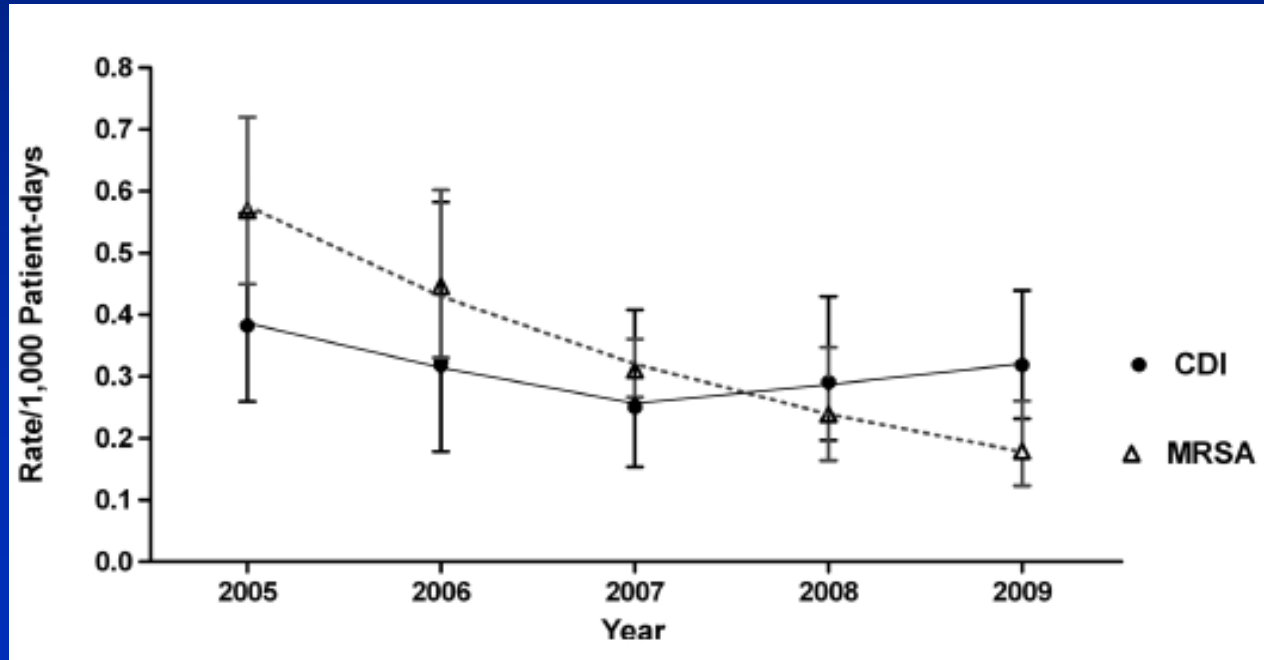
“The Perfect Storm” for Environmental Transmission

Microbial factors that facilitate environmental transmission

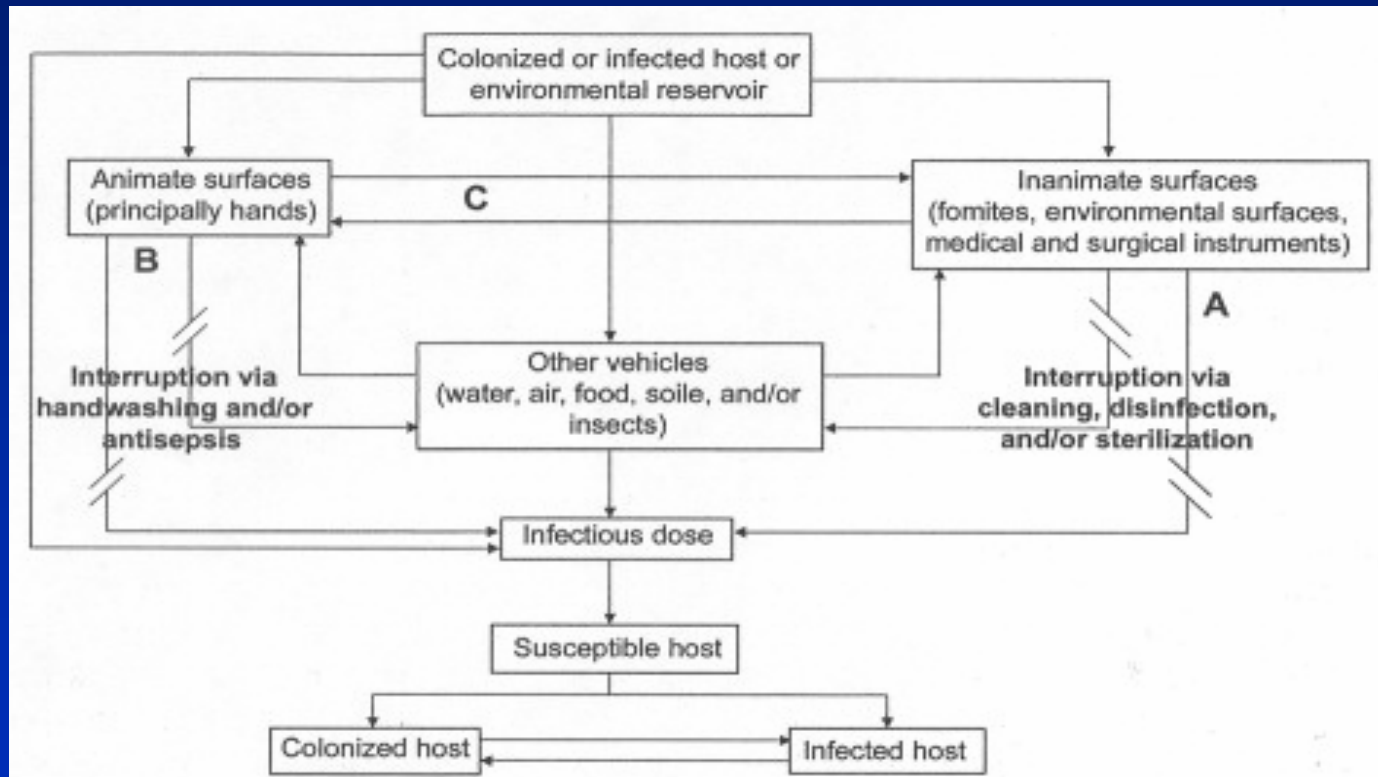
- Ability to **survive** in the environment for hours to days
- Ability to **remain virulent** after environmental exposure
- Low inoculating dose
- **Deposition on surfaces** frequently touched by HCP must occur
- Ability to colonize patients
- **Transmission directly or via the contaminated hands of 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



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.

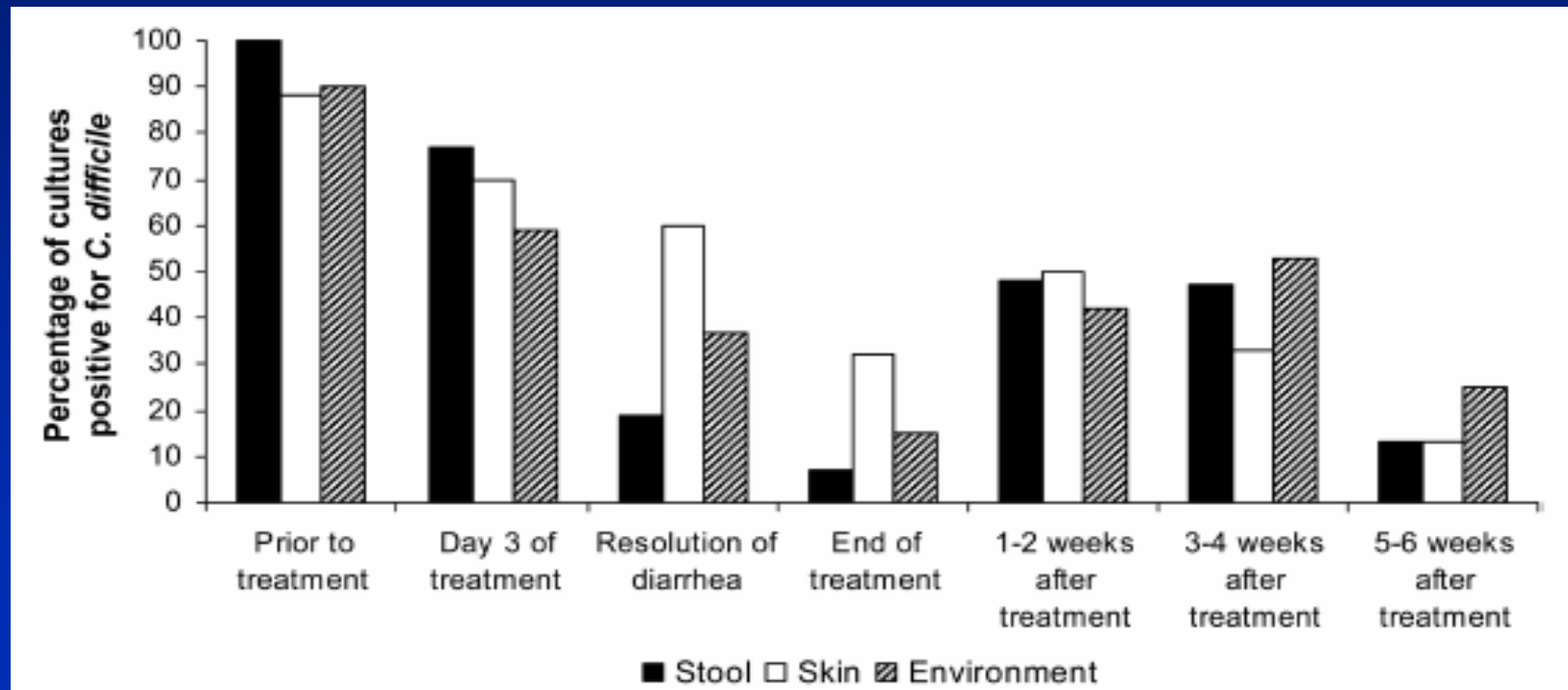
Persistence of Clinically Relevant Bacteria of Dry Inanimate Surfaces

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

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 <i>Clostridium difficile</i> From Different Environmental Sites Within the Hospital Room			
Site	All Rooms	Double Rooms	
	No. Positive/ No. Tested (%)	Index Side (%)	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 <i>Clostridium difficile</i> 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)

Disinfectants and Antiseptics

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

- ~4 log₁₀ 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

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 at terminal clean)

New Approaches to Room Decontamination



Updates on Disinfection and Sterilization

- Update on Disinfection and Sterilization
 - Principles
 - Environmental Hygiene
 - New Approaches to Room Decontamination
 - ◆ Ultraviolet
 - ◆ Hydrogen peroxide systems
 - Controlling the spread of *C. difficile* via the environment
 - **Multi-Society Endoscope Reprocessing Guideline, 2011**
 - Other issues (microfiber, monitoring temperature of HLD, wipes, Steris System 1E)

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.¹⁰ 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

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*

Spach DH et al Ann Intern Med 1993; 118:117-128 and Weber DJ, Rutala WA Gastroint Dis 2002;87

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

Updates on Disinfection and Sterilization

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 - ◆ Hydrogen peroxide systems
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 - Multi-Society Endoscope Reprocessing Guideline, 2011
 - Other issues (microfiber, monitoring temperature of HLD, wipes, Steris System 1E)

Microfiber

Microfiber Cleaning

- Pad contains fibers (polyester and polyamide) that provide a cleaning surface 40 times greater than conventional string mops
- Proposed advantages: reduce chemical use and disposal (disinfectant solution not changed after every third room, clean microfiber per room [washing lifetime 500-1000x]); light (~5 lb less than string mop) and ergonomic; reduce cleaning times.
- Does the microfiber provide the same or better removal of microorganisms on surfaces?





Effectiveness of Microfiber Mop

- Test conditions with a EPA-registered disinfectant: compared routine mop and bucket; microfiber mop and bucket; microfiber mop and system bucket. Twenty-four replicates per condition.
- Conducted RODAC sampling before and after floor disinfection (5 samples per room)
- New disinfectant solution for each test condition
- Dry time varied from 2 (routine mop and bucket)-8 (microfiber mop and bucket) minutes

Effectiveness of Microfiber Mop

(Rutala, Gergen and Weber, Am J Infect Control, 2007;35:569)

Disinfectant-regular mop	95%
Disinfectant-microfiber system	95%
Disinfectant-microfiber mop and regular mop bucket	88%
Detergent-regular mop	68%
Detergent-microfiber system	95%
Detergent-microfiber mop and regular mop bucket	78%

Microfiber

Summary

- The microfiber system demonstrated superior microbial removal compared to cotton string mops when used with a detergent cleaner
- The use of a disinfectant did not improve the microbial elimination demonstrated by the microfiber system
- Use of a disinfectant did significantly improve microbial removal when a cotton string mop was used

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

Digital Temperature Heater Controller

(or any thermometer [$\pm 0.5^{\circ}\text{C}$] 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



Warming Pad and Rack



Pictured:

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.

Updates on Disinfection and Sterilization

- 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 (microfiber, monitoring temperature of HLD, wiper, Steris System 1E)



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 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.



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

Updates on Disinfection and Sterilization

Summary

- Surface disinfection practices are currently not effective in eliminating environmental contamination; must improve practices (checklist, monitoring, assignments)
- 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
- The microfiber system demonstrated superior microbial removal compared to cotton string mops when used with a detergent cleaner
- Unresolved issues in endoscope reprocessing but the principles guiding cleaning and high-level disinfection are unchanged

Updates on Disinfection and Sterilization

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

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

Thank you

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