Disinfection and Sterilization: Current Issues and New Technologies

William A. Rutala, PhD, MPH
Director, Hospital Epidemiology, Occupational Health and Safety;
Professor of Medicine and Director, Statewide Program for
Infection Control and Epidemiology
University of North Carolina at Chapel Hill, USA

Disclosure

This presentation reflects the techniques, approaches and opinions of the individual presenter. This Advanced Sterilization Products ("ASP") sponsored presentation is not intended to be used as a training guide. Before using any medical device, review all relevant package inserts with particular attention to the indications, contraindications, warnings and precautions, and steps for use of the device(s).

I am compensated by and presenting on behalf of ASP, and must present information in accordance with applicable FDA requirements.

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Disinfection and Sterilization: Current Issues and New Technologies

- Current Issues and New Technologies
 - Sterilization of critical items
 - High-level disinfection for semi-critical items
 - Low-level disinfection of non-critical items

DISINFECTION AND STERILIZATION

- 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

DISINFECTION AND STERILIZATION

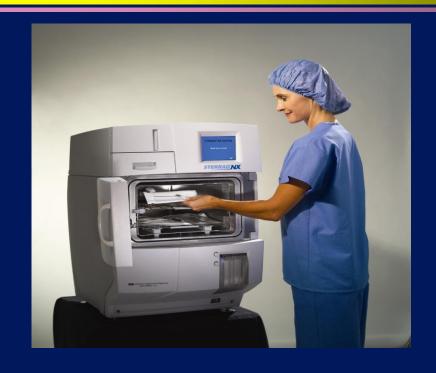
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Disinfection and Sterilization: Current Issues and New Technologies

- Current Issues and New Technologies
 - Sterilization of critical items
 - ◆Low-temperature sterilization technology
 - ◆Biological indicators
 - High-level disinfection for semi-critical items
 - Low-level disinfection of non-critical items

Low Temperature Sterilization Technology

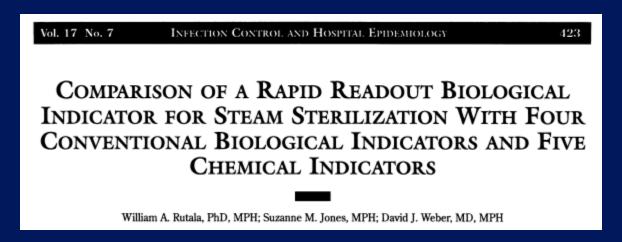




Newer Trends in Sterilization of Patient Equipment

- Alternatives to ETO-CFC
 ETO-CO₂, ETO-HCFC, 100% ETO
- New Low Temperature Sterilization Technology
 Hydrogen Peroxide Gas Plasma-most common
 Vaporized hydrogen peroxide-limited clinical use
 Ozone and hydrogen peroxide-not FDA cleared
 Nitrogen dioxide-not FDA cleared

Rapid Readout Bls for Steam Now Require a 1-3h Readout Compared to 24-48h





Attest™ Super Rapid Readout Biological Indicators Commercially available in early 2013



1491 BI (blue cap)

- Monitors 270°F and 275°F gravity –displacement steam sterilization cycles
- 30 minute result (from 1 hour)



1492V BI (brown cap)

- Monitors 270°F and 275°F dynamic-air-removal (pre-vacuum) steam sterilization cycles
- 1 hour result (from 3 hours)

Super Rapid Readout Biological Indicators and Challenge Packs

Rapid Attest technology has been optimized to produce a readout in 30-6-minutes. This technology will be commercialized in early 2013.

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Disinfection and Sterilization: Current Issues and New Technologies

- Current Issues and New Technologies
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 - High-level disinfection for semi-critical items
 - ◆New high-level disinfectants
 - ◆ Reprocessing endoscopes-manual and automated
 - Low-level disinfection of non-critical items

High-Level Disinfection of "Semicritical Objects"

Exposure Time ≥ 8m-45m (US), 20°C

Germicide	Concentration
Glutaraldehyde	> 2.0%
Ortho-phthalaldehyde	
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%
Peracetic acid	0.2%
Glut and isopropanol	3.4%/26%
Glut and phenol/phenate**	1.21%/1.93%

^{*}May cause cosmetic and functional damage; **efficacy not verified

Semicritical Equipment

- Reprocessing semicritical items has been shown to have a narrow margin of safety
- Generally, the narrow margin of safety attributed to high microbial load and complex instruments with lumens
- Any deviation from the recommended reprocessing protocol can lead to the survival of microorganisms and an increased risk of infection
- Problems encountered with reprocessing semicritical equipment often related to improper cleaning

Reprocessing Semicritical Items

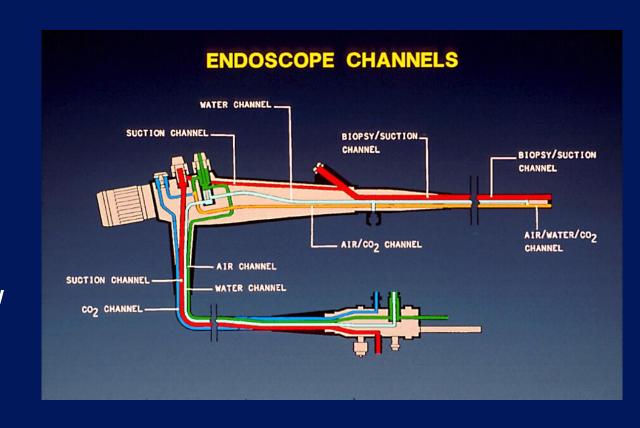
- New Developments in Reprocessing
 - Endoscopes
 - Laryngoscopes
 - Infrared coagulation device
 - Nasopharyngoscopes
 - Endocavitary probe
 - Prostate biopsy probes
 - Tonometers

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FEATURES OF ENDOSCOPES THAT PREDISPOSE TO DISINFECTION FAILURES

- Require low temperature disinfection
- Long narrow lumens
- Right angle turns
- Blind lumens
- May be heavily contaminated with pathogens
- Use of AERs has led to a new set of problems



Endoscope Reprocessing Methods

Ofstead, Wetzler, Snyder, Horton, Gastro Nursing 2010; 33:204



Cori L. Oferead, MSPH Harry P. Wetzler, MD, MSPH Alycea K. Snyder, BA Rebecca A. Hotton, DPT

Endoscope Reprocessing Methods

A Prospective Study on the Impact of Human Factors and Automation

ABSTRACT

The main cause of endoscopy-associated infections is failure to adhere to reprocessing guidelines. More information about factors impacting compliance is needed to support the development of effective inferventions. The purpose of this multisite, observational study was to evaluate reprocessing practices, employee perceptions, and occupational health issues. Data were collected utilizing interviews, surveys, and direct observation. Written reprocessing policies and procedures were in place at all five sites, and employees affirmed the importance of most recommended steps. Nevertheless, observers documented guideline adherence, with only 1.4% of endoscopes reprocessed using manual cleaning methods with automated high-level distriction versus 75.4% of those reprocessed using an automated endoscope deener and reprocessor. The majority reported health problems (i.e., pain, decreased flexibility, numbness, or ingling). Physical discomfort was associated with time spent reprocessors (p = .041). Discomfort diminished after installation of automated endoscope cleaners and reprocessors (p = .001). Enhanced training and accountability, combined with increased automation, may ensure guideline adherence and patient safety while improving amployee satisfaction and health.

Endoscope Reprocessing Methods

Ofstead, Wetzler, Snyder, Horton, Gastro Nursing 2010; 33:204

Performed all 12 steps for 1.4% (1/69) endoscopes using manual and 75.4% (86/114) endoscopes

using AER

TABLE 3. Documented Completion of Steps During Manual Cleaning With High-Level Disinfection Reprocessing				
Observed Activity	Steps Completed (%) (n = 69)			
Leak test performed in clear water	77			
Disassemble endoscope completely	100			
Brush all endoscope channels and components	43			
completely in detergent	99			
immerse companents completely in delergent	99			
Flush endoscope with detergent	99			
Filmse en doscope with water	96			
Furge endoscope with air	84			
Load and complete automated cycle for high-level disinfection	100			
Flush endoscope with aloch of	86			
Use forced air to dry endoscope	45			
Wipe down external surfaces before hanging to dry	90			

Effectiveness of Endoscope Reprocessing Infect Control Hosp Epidemiol 2013;34:309

- Practice of reprocessing endoscopes and effectiveness evaluated in 37 services (Brazil)
 - Contamination of at least 1 scope identified in 34 (92%) of 37 services
 - Bacteria, fungi and/or mycobacteria isolated from 84.6% (33/39) of the colonoscopes (110-32,000CFU/ml) and from 80.6% (50/62) of the gastroscopes (100-33,000CFU/ml)
 - Not all services followed guidelines; patients were exposed to diverse pathogens

Automated Endoscope Reprocessors (AER)

- Manual cleaning of endoscopes is prone to error. AERs can enhance efficiency and reliability of HLD by replacing some manual reprocessing steps
- AER Advantages: automate and standardize reprocessing steps, reduce personnel exposure to chemicals, filtered tap water
- AER Disadvantages: failure of AERs linked to outbreaks, does not eliminate precleaning (until now-EvoTech) BMC Infect Dis 2010;10:200
- Problems: incompatible AER (side-viewing duodenoscope); biofilm buildup; contaminated AER; inadequate channel connectors; used wrong set-up or connector MMWR 1999;48:557
- Must ensure exposure of internal surfaces with HLD/sterilant

Automated Endoscope Reprocessors with Cleaning Claim



Product Definition:

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

MULTISOCIETY GUIDELINE ON REPROCESSING GI ENDOSCOPES, 2011

Petersen et al. ICHE. 2011;32:527

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 have been associated with failure to follow established cleaning and disinfection/sterilization guidelines or use of defective equipment. Despite the strong published data regarding the safety of endoscope reprocessing, concern over the potential

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 expanded details related to critical reprocessing steps (including cleaning and drying), reprocessing issues for various endoscope attachments such as flushing catheters, discussion of risks related to selected periprocedural practices including

ENDOSCOPE REPROCESSING

Multi-Society Guideline on Endoscope Reprocessing, 2011

- PRECLEAN-point-of-use (bedside) remove debris by wiping exterior and aspiration of detergent through air/water and biopsy channels
- CLEAN-mechanically cleaned with water and enzymatic cleaner
- HLD/STERILIZE-immerse scope and perfuse HLD/sterilant through all channels for exposure time (>2% glut at 20m at 20°C). If AER used, review model-specific reprocessing protocols from both the endoscope and AER manufacturer
- RINSE-scope and channels rinsed with sterile water, filtered water, or tap water. Flush channels with alcohol and dry
- DRY-use forced air to dry insertion tube and channels
- STORE-hang in vertical position to facilitate drying; stored in a manner to protect from contamination

Disinfection and Sterilization: Current Issues and New Technologies

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 - High-level disinfection for semi-critical items
 - Low-level disinfection of non-critical items
 - ◆ New low-level disinfectants (improved hydrogen peroxide)
 - ◆Surface disinfection
 - ◆Transmission via environmental surfaces
 - ◆Inactivation of *C. difficile*

DISINFECTION AND STERILIZATION

Rutala, Weber, HICPAC. 2008. www.cdc.gov

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LOW-LEVEL DISINFECTION FOR NONCRITICAL EQUIPMENT AND SURFACES

Exposure time > 1 min

Germicide Use Concentration

Ethyl or isopropyl alcohol 70-90%

Chlorine 100ppm (1:500 dilution)

Phenolic UD

lodophor UD

Quaternary ammonium UD

Improved hydrogen peroxide (HP) 0.5%, 1.4%

UD=Manufacturer's recommended use dilution

IMPROVED HYDROGEN PEROXIDE (HP) SURFACE DISINFECTANT

- Advantages
 - 30 sec -1 min bactericidal and virucidal claim (fastest non-bleach contact time)
 - 5 min mycobactericidal claim
 - Safe for workers (lowest EPA toxicity category, IV)
 - Benign for the environment; noncorrosive; surface compatible
 - One step cleaner-disinfectant
 - No harsh chemical odor
 - EPA registered (0.5% RTU, 1.4% RTU, wet wipe)
- Disadvantages
 - More expensive than QUAT

BACTERICIDAL ACTIVITY OF DISINFECTANTS (log₁₀ reduction) WITH A CONTACT TIME OF 1m WITH/WITHOUT FCS. Rutala et al. ICHE. In press

Improved hydrogen peroxide is significantly superior to standard HP at same concentration and superior or similar to the QUAT tested

Organism	Oxivir-0.5%	0.5% HP	Clorox HC HP Cleaner-Dis 1.4%	1.4% HP	3.0% HP	QUAT
MRSA	>6.6	<4.0	>6.5	<4.0	<4.0	5.5
VRE	>6.3	<3.6	>6.1	<3.6	<3.6	4.6
MDR-Ab	>6.8	<4.3	>6.7	<4.3	<4.3	>6.8
MRSA, FCS	>6.7	NT	>6.7	NT	<4.2	<4.2
VRE, FCS	>6.3	NT	>6.3	NT	<3.8	<3.8
MDR-Ab, FCS	>6.6	NT	>6.6	NT	<4.1	>6.6

Wipes Cotton, Disposable, Microfiber

Wipe should have sufficient wetness to achieve the disinfectant contact time. Discontinue use of a disposable wipe if it no longer leaves the surface visibly

wet for ≥ 1 m



Low Level disinfectants Non-critical surfaces and Objects

- Quaternary ammonium
- Chlorine
- Improved hydrogen peroxide
- Phenolic

Surface Disinfection

- Wipe all "touchable" or "hand contact" surfaces with sufficient wetness to achieve the disinfectant contact time (> 1 minute).
- Daily disinfection of surfaces (vs cleaned when soiled)
 with disinfectant in rooms of patients with CDI and
 MRSA reduced acquisition of pathogens on hands after
 contact with surfaces and of hands caring for the patient

SURFACE DISINFECTION

Effectiveness of Different Methods, Rutala et al. 2012

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

Daily Disinfection of High-Touch Surfaces

Kundrapu et al. ICHE 2012;33:1039

Daily disinfection of high-touch surfaces (vs cleaned when soiled) with sporicidal disinfectant in rooms of patients with CDI and MRSA reduced acquisition of pathogens on hands after contact with surfaces and of hands caring for the patient

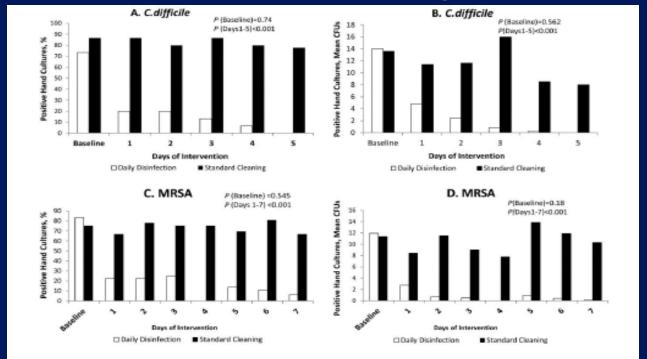


FIGURE 1. Effect of daily disinfection of high-touch environmental surfaces on acquisition of Clostridium difficile and methicillin-resistant Staphylococcus aureus (MRSA) on gloved hands of investigators after contact with the surfaces. A Percentage of positive C. difficile cultures; B, mean number of C. difficile colony-forming units acquired; C, percentage of positive MRSA cultures; D, mean number of MRSA colony-forming units acquired.

Wipes Cotton, Disposable, Microfiber



Blood Pressure Cuff Non-Critical Patient Care Item





DECREASING ORDER OF RESISTANCE OF MICROORGANISMS TO DISINFECTANTS/STERILANTS

Most Resistant Prions Spores (C. difficile) Mycobacteria Non-Enveloped Viruses (norovirus) Fungi Bacteria (MRSA, VRE, Acinetobacter) **Enveloped Viruses** Most Susceptible

DISINFECTANTS AND ANTISEPSIS

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

- ~4 log₁₀ reduction (3 *C. difficile* strains including BI-9)
 - Bleach, 1:10, ~6,000 ppm chlorine (but not 1:50)
 - Chlorine, ~19,100 ppm chlorine
 - Chlorine, ~25,000 ppm chlorine
 - 0.35% peracetic acid
 - 2.4% glutaraldehyde
 - OPA, 0.55% OPA
 - 2.65% glutaraldehyde
 - 3.4% glutaraldehyde and 26% alcohol

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KEY PATHOGENS WHERE ENVIRONMENTIAL SURFACES PLAY A ROLE IN TRANSMISSION

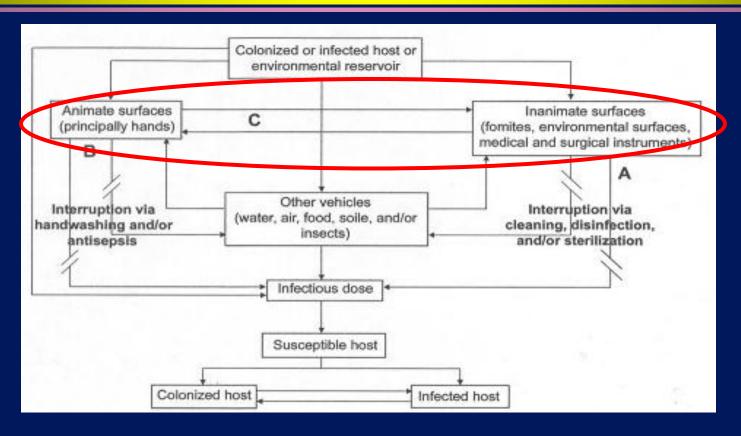
- MRSA
- VRE
- Acinetobacter spp.
- Clostridium difficile
- Norovirus
- Rotavirus
- SARS

ENVIRONMENTAL CONTAMINATION LEADS TO HAIS

Weber, Rutala, Miller et al. AJIC 2010;38:S25

- Microbial persistence in the environment
- Frequent environmental contamination
- HCW hand contamination with the environment
- Prior room occupant with MRSA, VRE, CDI is a significant risk for acquisition of these pathogens.

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.

ENVIRONMENTAL SURVIVAL OF KEY PATHOGENS ON HOSPITAL SURFACES

Pathogen	Survival Time		
S. aureus (including MRSA)	7 days to >12 months		
Enterococcus spp. (including VRE)	5 days to >46 months		
Acinetobacter spp.	3 days to 11 months		
Clostridium difficile (spores)	>5 months		
Norovirus (and feline calicivirus)	8 hours to >2 weeks		
Pseudomonas aeruginosa	6 hours to 16 months		
Klebsiella spp.	2 hours to >30 months		

Adapted from Hota B, et al. Clin Infect Dis 2004;39:1182-9 and Kramer A, et al. BMC Infectious Diseases 2006;6:130

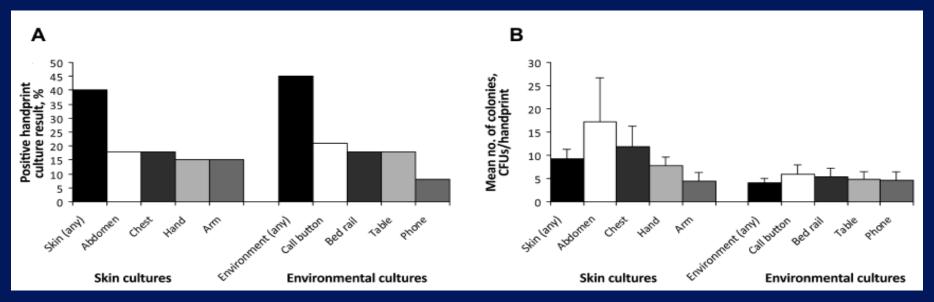
ENVIRONMENTAL CONTAMINATION ENDEMIC AND EPIDEMIC MRSA

	Outbreak	Endemic				Site estimated mean§
	Rampling et al ²⁷ *	Boyce et al ⁴⁸ *	Sexton et al ⁵¹ †	Lemmen et al ⁵⁰ *‡	French et al ^{64*}	
Floor	9%	50-55%	44-60%	24%		34.5%
Bed linen		38-54%	44%	34%		41%
Patient gown		40-53%		34%		40.5%
Overbed table		18-42%	64-67%	24%		40%
Blood pressure cuff	13%	25-33%				21%
Bed or siderails	5%	1-30%	44-60%	21%	43%	27%
Bathroom door handle		8–24%		12%¶		14%
Infusion pump button	13%	7–18%		30%		19%
Room door handle	11%	4–8%		23%	59%	21.5%
Furniture	11%		44-59%	19%		27%
Flat surfaces	7%		32-38%			21.5%
Sink taps or basin fitting				14%	33%	23.5%
Average quoted**	11%	27%	49%	25%	74%	37%

Dancer SJ et al. Lancet ID 2008;8(2):101-13

FREQUENCY OF ACQUISITION OF MRSA ON GLOVED HANDS AFTER CONTACT WITH SKIN AND ENVIRONMENTAL SITES

No significant difference on contamination rates of gloved hands after contact with skin or environmental surfaces (40% vs 45%; p=0.59)



Stiefel U, et al. ICHE 2011;32:185-187

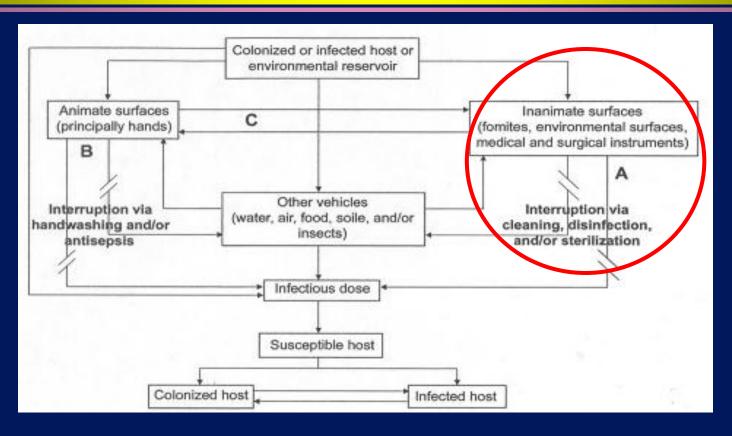
ACQUISITION OF MRSA ON HANDS AFTER CONTACT WITH ENVIRONMENTAL SITES



TRANSFER OF MRSA FROM PATIENT OR ENVIRONMENT TO IV DEVICE AND TRANSMISSON OF PATHOGEN



TRANSMISSION MECHANISMS INVOLVING THE SURFACE ENVIRONMENT



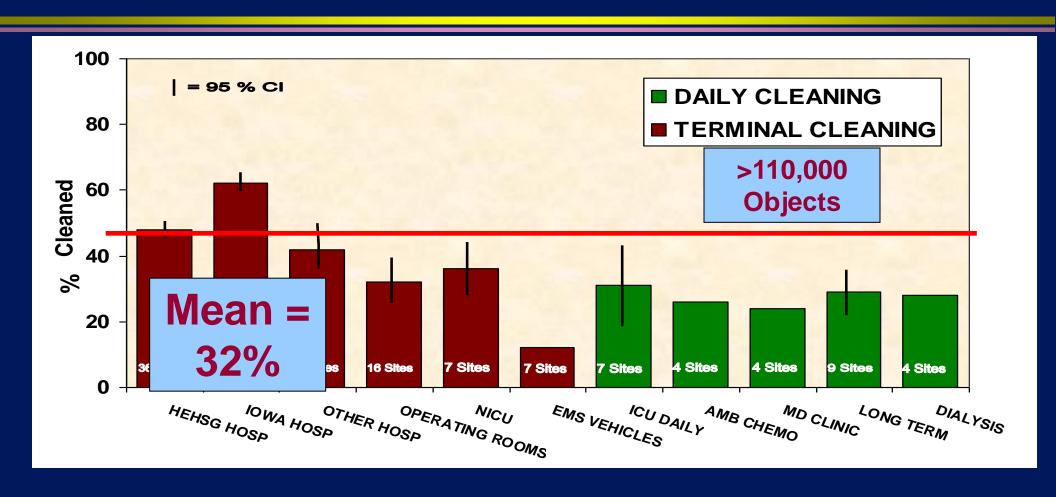
Rutala WA, Weber DJ. In: "SHEA Practical Healthcare Epidemiology" (Lautenbach E, Woeltje KF, Malani PN, eds), 3rd ed, 2010.

ACQUISITION OF *C. difficile* ON PATIENT HANDS AFTER CONTACT WITH ENVIRONMENTAL SITES AND THEN INOCULATION OF MOUTH



Thoroughness of Environmental Cleaning

Carling et al. ECCMID, Milan, Italy, May 2011



RELATIVE RISK OF PATHOGEN ACQUISITION IF PRIOR ROOM OCCUPANT INFECTED



^{*} Prior room occupant infected; ^Any room occupant in prior 2 weeks infected

ENVIRONMENTAL CONTAMINATION LEADS TO HAISSuboptimal Cleaning

- There is increasing evidence to support the contribution of the environment to disease transmission
- This supports comprehensive disinfecting regimens (goal is not sterilization) to reduce the risk of acquiring a pathogen from the healthcare environment

MONITORING THE EFFECTIVENESS OF CLEANING

Cooper et al. AJIC 2007;35:338

- Visual assessment-not a reliable indicator of surface cleanliness
- ATP bioluminescence-measures organic debris (each unit has own reading scale, <250-500 RLU)
- Microbiological methods-<2.5CFUs/cm²-pass; can be costly and pathogen specific
- Fluorescent marker-transparent, easily cleaned, environmentally stable marking solution that fluoresces when exposed to an ultraviolet light (applied by Infection Preventionist unbeknown to EVS, after EVS cleaning, markings are reassessed)

DAZO Solution (AKA – Goo)



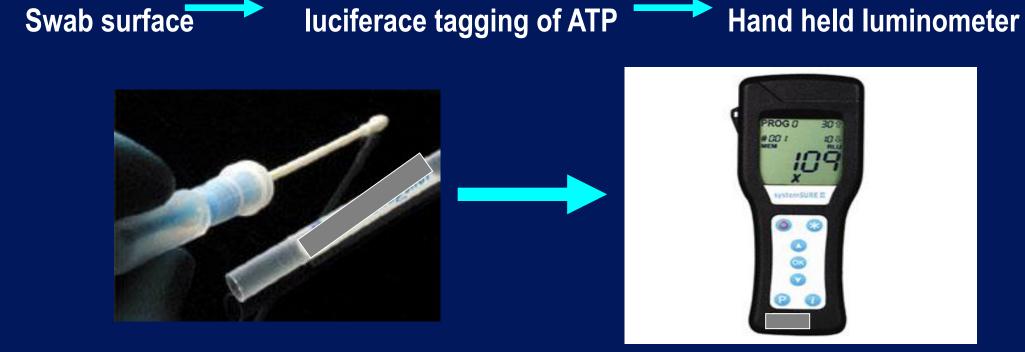
Target After Marking



Target Enhanced



SURFACE EVALUATION USING ATP BIOLUMINESCENCE



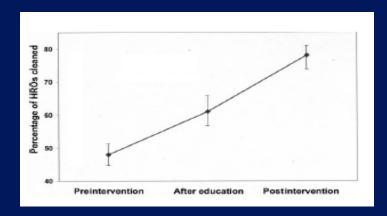
Used in the commercial food preparation industry to evaluate surface cleaning before reuse and as an educational tool for more than 30 years.

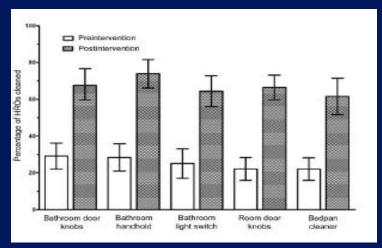
TERMINAL ROOM CLEANING: DEMONSTRATION OF IMPROVED CLEANING

- 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

†Regularly change "dotted" items to prevent targeting objects

Carling PC, et al. ICHE 2008;29:1035-41





NEW "NO TOUCH" APPROACHES TO ROOM DECONTAMINATION Supplement Surface DisinfectionRutala, Weber. Infect Control Hosp Epidemiol. 2011;32:743







ROOM DECONTAMINATION UNITS

Rutala, Weber. ICHE. 2011;32:743

UV and HP systems have been demonstrated to be effective against various healthcare-associated pathogens

TABLE 1. Comparison of Room Decontamination Systems That Use UV Irradiation and Hydrogen Peroxide (HP)							
	Sterinis	Steris	Bioquell	Tru-D			
Abbreviation	DMHP (dry mist HP)	VHP (vaporized HP)	HPV (HP vapor)	UV-C			
Active agent	Stenusil (5% HP, <50 ppm silver cations)	Vaprox (35% HP)	35% HP	UV-C irradiation at 254 nm			
Application	Aerosol of active solution	Vapor, noncondensing	Vapor, condensing	UV irradiation, direct and reflected			
Aeration (removal of active agent from	Passive decomposition	Active catalytic conversion	Active catalytic conversion	Not necessary			
enclosure)							
Sporicidal efficacy	Single cycle does not inacti- vate Bacillus atrophaeus BIs; ~4-log ₁₀ reduction in Clostridium difficile* and incomplete inactivation in situ	Inactivation of Geoba- cillus stearothermo- philus BIs	Inactivation of G. stearother- mophilus BIs; >6-log ₁₀ re- duction in C. difficile ^a in vitro and complete inacti- vation in situ	1.7–4-log ₁₀ reduction in <i>C. difficile</i> * in situ			
Evidence of clinical	None published	None published	Significant reduction in the	None published			
impact			incidence of C. aifficile				
NOTE. Adapted from Otter and Yezli. BIs, biological indicators; VRE, vancomycin-resistant Enterococcus. All C. difficile experiments were done with C. difficile spores.							

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Summary

- New sterilization, high-level disinfection and low-level disinfection technologies/practices/products are effective
- New technologies/practices/products integrated into guidelines/policies/practices can improve patient care
- Effective surface disinfection essential to eliminate the environment as a source for transmission of healthcareassociated pathogens.

THANK YOU!

