Current Issues in Disinfection and Sterilization

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Disclosure

This educational activity is brought to you, in part, by Advanced Sterilization Products (ASP) and Ethicon. The speaker receives an honorarium from ASP and Ethicon and must present information in compliance with FDA requirements applicable to ASP.

Current Issues in Disinfection and Sterilization

- Current Issues
  - Environmental Hygiene
  - New Approaches to Room Decontamination
    - Ultraviolet
    - Hydrogen peroxide vapor/aerosol
  - Citations-TJC and CMS
    - 20m/20ºC glutaraldehyde
    - ≥ 1 minute surface disinfection
  - Multi-Society Endoscope Reprocessing Guideline, 2011

disinfectionandsterilization.org

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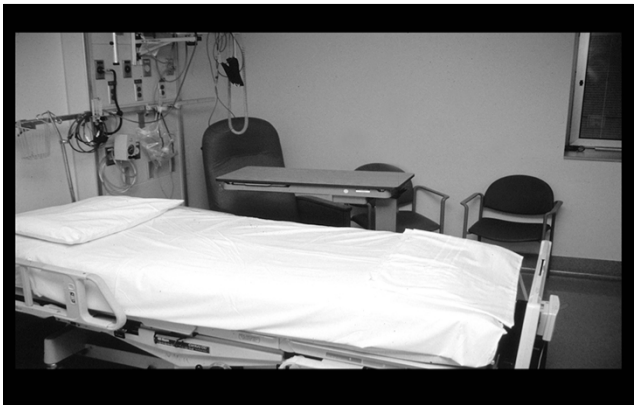


The Role of the Environment in Disease Transmission

- 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

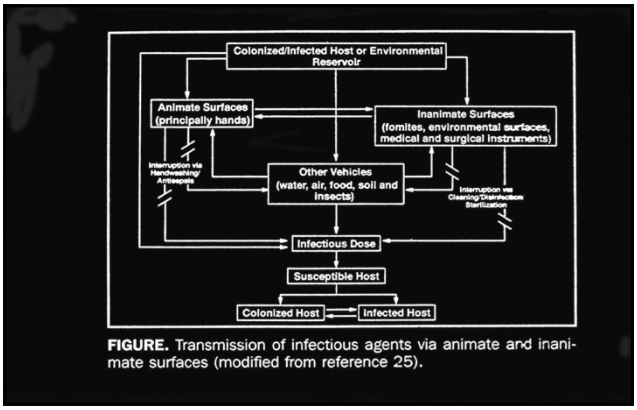


FIGURE. Transmission of infectious agents via animate and inanimate surfaces (modified from reference 25).

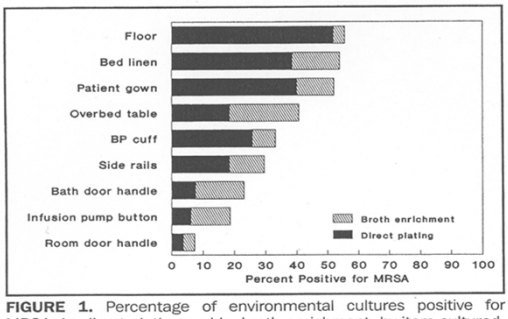


FIGURE 1. Percentage of environmental cultures positive for MRSA, by direct plating and by broth enrichment, by item cultured.

Hand contamination was equally likely after contact with touched environmental surfaces as skin sites

Stiefel et al. ICHE 2011;32:185

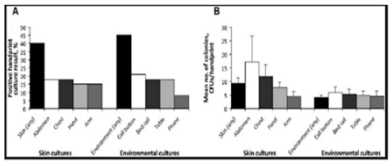
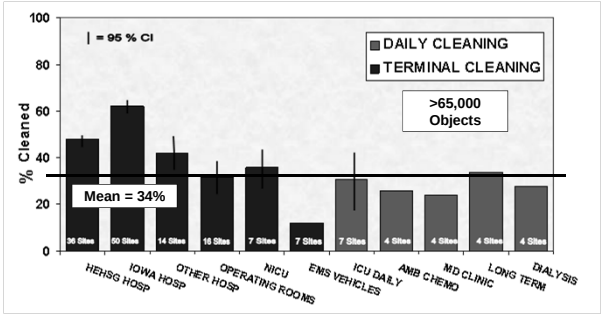


FIGURE 1. Frequency of acquisition of methicillin-resistant *Staphylococcus aureus* (MRSA) on gloved hands after contact with skin and environmental sites (*A*) and the mean number of MRSA colonies acquired on hands (*B*). Error bars show standard errors.

Target Enhanced

Thoroughness of Environmental Cleaning

Carling and coworkers, SHEA 2010



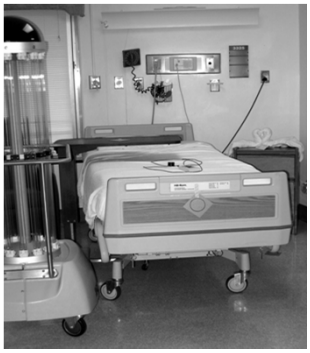
Risk of Acquiring MRSA, VRE, and *C. difficile* from Prior Room Occupants

- 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

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

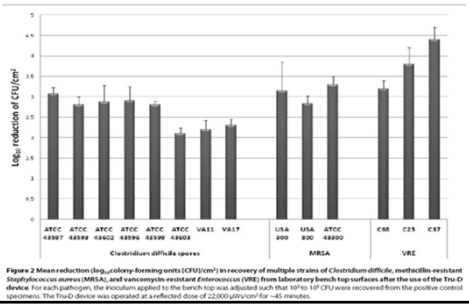


Figure 2 Mean reduction ($\log_{10}$ colony-forming units [CFU]/cm²) in recovery of multiple strains of *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus* (MRSA), and vancomycin-resistant *Enterococcus* (VRE) from laboratory bench top surfaces after the use of the Tru-D device. For 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.

Hydrogen Peroxide Vapor/Aerosol Decontamination

Hydrogen Peroxide Vapor/Aerosol Decontamination

- Sterinis
  - Fine mist by aerosolizing solution of 5% HP, <50 ppm silver
- Steris
  - Vaporized HP from 35% HP
- Bioquell
  - HP vapor from 35% HP

Hydrogen Peroxide Vapor/Aerosol Decontamination

- 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 Vapor/Aerosol Decontamination

- 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

Decontamination with Hydrogen Peroxide Vapor

Boyce et al: ICHE 2008;29:723

- 5 wards with a high incidence of *C. difficile*
- HPV was injected into sealed wards and individual patient rooms using generators until approx 1 micron film of HP was achieved on the surface
- 11/43 (25.6%) surface samples yielded *C. difficile* compared to 0/27 (0%) after HPV decontamination
- The incidence of nosocomial CDAD was significantly lower during the intervention period
- Conclusion: HPV was efficacious in eradicating *C. difficile* from contaminated surfaces

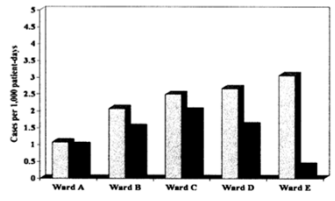


FIGURE 2. Incidence of nosocomial *Clostridium difficile*–associated disease on 5 wards (A–E) that underwent intensive hydrogen peroxide vapor decontamination, during the preintervention period (*gray bars;* June 2004 through March 2005) and the intervention period (*black bars;* June 2005 through March 2006).

Summary

- MRSA, VRE, *C. difficile*, MDR-*Acinetobacter* comprise a growing reservoir of epidemiologically important pathogens that have an environmental mode of transmission
- UV and HP vapor/aerosol have been demonstrated to be effective against various HA pathogens (including *C. difficile* spores) and offer an option for room decontamination
- Since contamination of surfaces is common, even after surface disinfection, this technology should be considered in selected patient rooms and care areas when the environmental mode of transmission is significant

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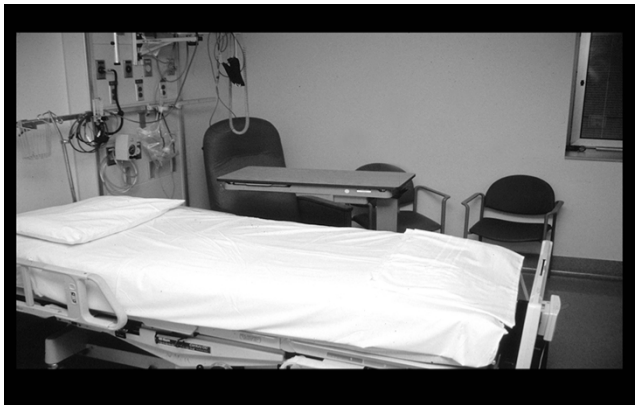

Surface Disinfection

- 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)

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Risk-Assessment Worksheet

Issue: Off-label use of one minute contact times for low-level surface disinfectants used on nonoritical 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 nonoritical 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 (e.g., MRSA, VRE, CDVS) with a contact time of ≤1 minute. 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 on the 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 1 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 (36%). 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.

High-Level Disinfection

20ºC at 20 minutes

SHEA Position Paper

Multi-society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes

Douglas B. Nelson, MD; William R. Jarvis, MD; William A. Rutala, PhD; Amy E. Foxx-Orenstein, DO; Gerald Isenberg, MD; Georgia P. Dash, RN, MS, CIC; Carla J. Alvarado, MS, CIC; Marilee Ball, RN, MHA, CGRN; Joyce Griffin-Sobel, RN, PhD, ADCN, APN; Carol Petersen, RN, BSN, MAOM, CNOR; Kay A. Ball, RN, BSN, MSA, CNOR, FAAN; Jerry Henderson; Rachel L. Stricof, MPH

The beneficial role of gastrointestinal 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 episodes

physician and nursing organizations, infection control organizations, federal and state agencies, and industry leaders presented and discussed the latest information on this subject. A consensus panel on the second day reviewed the data presented at the conference to recommend evidence-based guidelines for reprocessing gastrointestinal endoscopes.

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[1] 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

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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
    - Without full data reprocessing within this interval may be advisable for certain situations (endoscope entry to otherwise sterile regions such as biliary tree, pancreas)

Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- Unresolved Issues
  - Optimal frequencies for replacement of: clean water bottles and tubing for insufflation of air and lens wash water, and waste vacuum canisters and suction tubing
    - Concern related to potential for backflow from a soiled endoscope against the direction of forced fluid and air passage into clean air/water source or from tubing/canister against a vacuum into clean instruments
  - Microbiologic surveillance testing after reprocessing
    - Detection of non-environmental pathogens indicator of faulty reprocessing equipment, inadequate solution, or failed human process

Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- Relatively new technologies for HLD
  - EvoTech
  - OER-Pro
- Endoscope durability and longevity
  - No published data regarding materials durability and potential for reduced function or reduced ability to attain HLD

EVOTECH w/Cleaning Claim

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

Automatic Endoscope Reprocessors

- EvoTech-integrates cleaning (FDA-cleared claim) and high-level disinfection. Automated cleaning comparable to manual cleaning. All residual data for cleaning of the internal channels as well as external insertion tube surfaces were below the limit of <6.4ug/cm^2 of protein and <1.8ug/cm^2 of hemoglobin. Data demonstrate that the soil and microbial removal effected by EvoTech cleaning phase was equivalent to that achieved by manual cleaning. BMC Infect Dis 2010;10:200

Current Issues in Disinfection and Sterilization 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 patients in these rooms at increased risk of acquiring these organisms
- UV and HP aerosol/vapor 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

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Thank you

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- 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
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