Disinfection and Sterilization:
What's New?

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DISCLOSURES

- **Consultation**
  - ASP (Advanced Sterilization Products)-2014, Clorox-2014, 2015
- **Honoraria** (2014, 2015)
  - 3M, ASP, Clorox
- **Grants**
  - CDC, CMS, Nanosonics

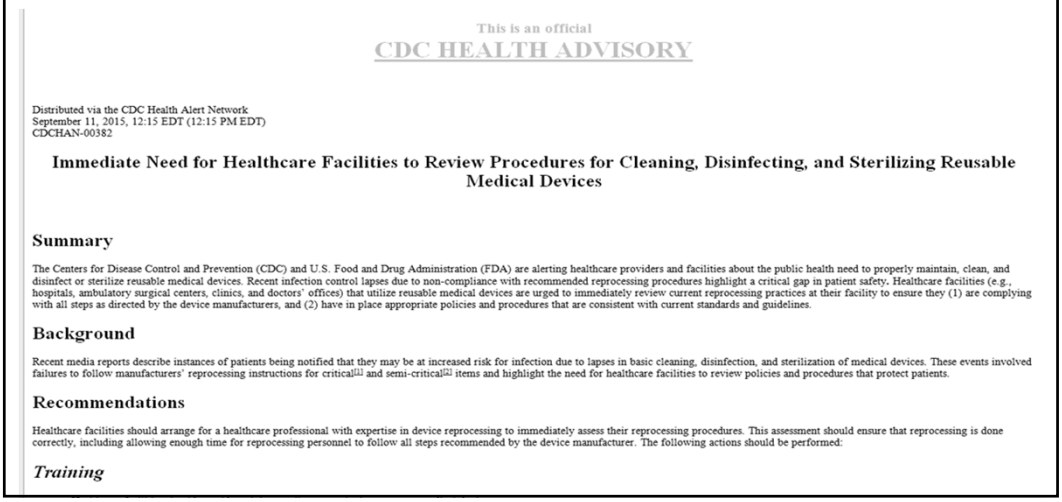
HLD and Sterilization: What's New?

- Sterilization
  - Biological indicators, emerging technologies, modified Spaulding classification
- High-Level Disinfection
  - Endoscope-related infections, channeled scopes, reuse of single-use items
- Low-Level Disinfection
  - Emerging pathogens, room decontamination methods

www.disinfectionandsterilization.org

Health Care Facilities Need to Immediately Medical Device Reprocessing Procedures

Train Staff, Audit Adherence to Steps, Provide Feedback on Adherence



This is an official

CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
September 11, 2015, 12:15 EDT (12:15 PM EDT)
CDCHAN-00382

Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

Summary

The Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) are alerting healthcare providers and facilities about the public health need to properly maintain, clean, and disinfect or sterilize reusable medical devices. Recent infection control lapses due to non-compliance with recommended reprocessing procedures highlight a critical gap in patient safety. Healthcare facilities (e.g., hospitals, ambulatory surgical centers, clinics, and doctors' offices) that utilize reusable medical devices are urged to immediately review current reprocessing practices at their facility to ensure they (1) are complying with all steps as directed by the device manufacturers, and (2) have in place appropriate policies and procedures that are consistent with current standards and guidelines.

Background

Recent media reports describe instances of patients being notified that they may be at increased risk for infection due to lapses in basic cleaning, disinfection, and sterilization of medical devices. These events involved failures to follow manufacturers' reprocessing instructions for critical[1] and semi-critical[2] items and highlight the need for healthcare facilities to review policies and procedures that protect patients.

Recommendations

Healthcare facilities should arrange for a healthcare professional with expertise in device reprocessing to immediately assess their reprocessing procedures. This assessment should ensure that reprocessing is done correctly, including allowing enough time for reprocessing personnel to follow all steps recommended by the device manufacturer. The following actions should be performed:

Training

Health Care Facilities Need to Immediately Medical Device Reprocessing Procedures

- Reprocessing lapses resulting in patient infections and exposures
- Healthcare facilities urged to immediately review current reprocessing practices to ensure comply with device manufacturer and guidelines
  - **Training (upon hire and at least annually), demonstrate and document competency**
  - **Audit should assess all reprocessing steps including cleaning, disinfectants (conc, contact time), sterilizer (chemical, biological indicators). Feedback from audits to personnel regarding adherence.**

CDC Guideline for Disinfection and Sterilization

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


Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

William A. Rutala, Ph.D., M.P.H.[1,2], David J. Weber, M.D., M.P.H.[1,2], and the Healthcare Infection Control Practices Advisory Committee (HICPAC)[3]

HLD and Sterilization:

What's New

- **Sterilization**
  - **Biological indicators, emerging technologies, modified Spaulding classification**
- **High-Level Disinfection**
  - **Endoscope-related infections, channeled scopes, reuse of single-use items**
- **Low-Level Disinfection**
  - **Emerging pathogens, room decontamination methods**

Sterilization of "Critical Objects"

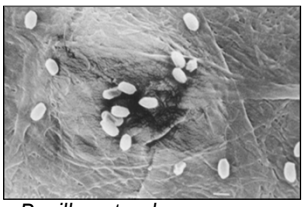
Steam sterilization
Hydrogen peroxide gas plasma
Ethylene oxide
Ozone
Vaporized hydrogen peroxide
Steam formaldehyde

Ozone and Hydrogen Peroxide

- **Sterizone VP4, 510(k) FDA clearance,TSO_3 Canada**
- **Sterilizer has a 4.4ft^3 chamber**
- Advantages/Disadvantages-not yet known

Biological Indicators

- **Select BIs that contain spores of** *Bacillus atrophaeus*
  - Rationale: BIs are the only sterilization process monitoring device that provides a direct measure of the lethality of the process



Bacillus atrophaeus

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

Rutala, Jones, Weber ICHE 1996. 17:423

Vol. 17 No. 7 INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY 423

COMPARISON OF A RAPID READOUT BIOLOGICAL INDICATOR FOR STEAM STERILIZATION WITH FOUR CONVENTIONAL BIOLOGICAL INDICATORS AND FIVE CHEMICAL INDICATORS

William A. Rutala, PhD, MPH; Suzanne M. Jones, MPH; David J. Weber, MD, MPH

Super Rapid Readout Biological Indicators
Commercially available

1491 BI (blue cap)
• Monitors 270°F and 275°F gravity –displacement steam sterilization cycles
• 30 minute result (from 1hour)

1492V BI (brown cap)
• Monitors 270°F and 275°F dynamic-air-removal (pre-vacuum) steam sterilization cycles
• 1 hour result (from 3 hours)

RECENT ENDOSCOPY-RELATED OUTBREAKS OF MRDO WITHOUT REPROCESSING BREACHES

MDRO	Scope	No.	Recovered From Scope	Molecular Link	Reference
P. aeruginosa (VIM-2)	Duodenoscope	22	Yes, under forceps elevator	Yes	Verfaillie CJ, 2015
E. coli (AmpC)	Duodenoscope	7	Yes (2 scopes)	Yes (PFGE)	Wendort, 2015
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Additional Outbreaks (not published; news media reports)

- UCLA, 2015, CRE, 179 patients exposed (2 deaths), 2 colonized duodenoscopes
- CMC, 2015, CRE, 18 patients exposed (7 infected), duodenoscopes
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- Wisconsin, 2013, CRE, (5 infected), duodenoscopes
- University of Pittsburgh, 2012, CRE, 9 patients, duodenoscopes

FDA Panel, May 2015, Recommended Sterilization of Duodenoscopes

(requires FDA-cleared technology that achieves a SAL 10^{-6} with duodenoscopes)

Disinfection and Sterilization

WA Rutala, DJ Weber, and HICPAC, 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).**

Disinfection and Sterilization

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

EH Spaulding believed that how an object will be disinfected depended on the object's intended use (modified).

CRITICAL - objects which directly or secondarily (i.e., via a mucous membrane such as duodenoscope) 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).

HLD and Sterilization:

What's New

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- Low-Level Disinfection
  - Emerging pathogens, room decontamination methods

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 except for high numbers of bacterial spores
  - NONCRITICAL - objects that touch only intact skin require low-level disinfection

High-Level Disinfection of "Semicritical Objects"

Exposure Time ≥ 8m-45m (US), 20°C

Germicide	Concentration
Glutaraldehyde	≥ 2.0%
Ortho-phthalaldehyde	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%
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

The Joint Commission surveyors will likely check on several high visibility items during your next survey

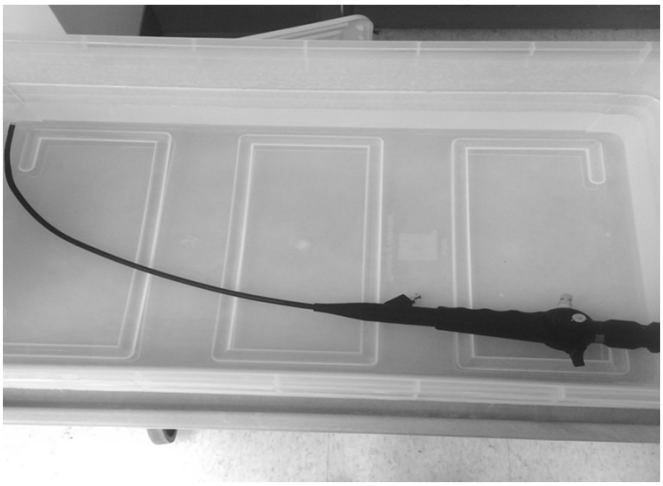
Reprocessing duodenoscopes

Reprocessing Channeled Endoscopes

Cystoscopes, Ureteroscopes, Hysteroscopes

Reprocessing Channeled Endoscopes

Cystoscope- "completely immerse" in HLD (J Urology 2008.180:588)

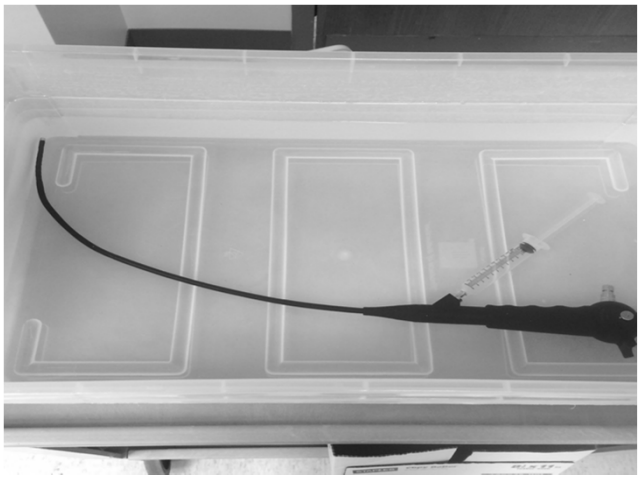


Reprocessing Channeled Endoscopes

Cystoscope-air pressure in channel stronger than fluid pressure at fluid-air interface

Reprocessing Channeled Endoscopes

Cystoscope-HLD perfused through lumen with syringe (luer locks onto port and syringe filled and emptied until no air exits the scope nor air in barrel of syringe-syringe and lumen filled with HLD)



Reprocessing Channeled Endoscopes

Rutala, Gergen, Bringhurst, Weber. ICHE. In press

Exposure Method	VRE Contamination Before HLD (glutaraldehyde)	VRE Contamination After HLD
Passive HLD (immersed, not perfused)	$3.6x10^8$ $2.0x10^8$ $1.1x10^8$	$7.5x10^8$ $1.0x10^8$ $6.8x10^7$
Active HLD (perfused HLD into channel with syringe)	$8.4x10^7$ $1.5x10^8$ $2.8x10^8$	1 CFU 0 0

- Pathogens must have exposure to HLD for inactivation
- Immerse channeled flexible scope into HLD will not inactivate channel pathogens
- Completely immerse the endoscope in HLD and ensure all channels are perfused
- Air pressure in channel stronger than fluid pressure at fluid-air interface

Reprocessing Channeled Endoscopes

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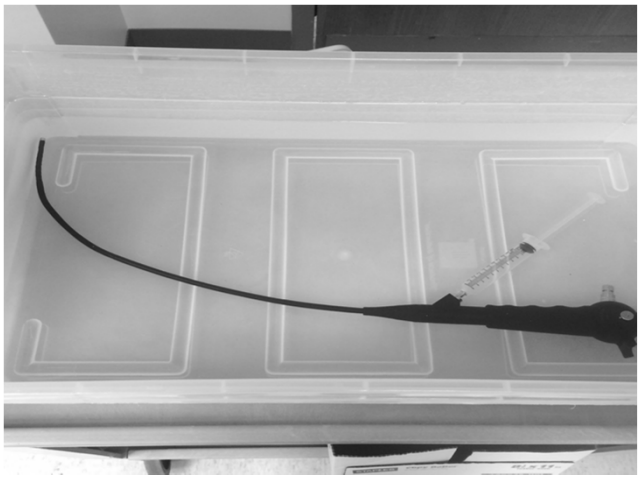

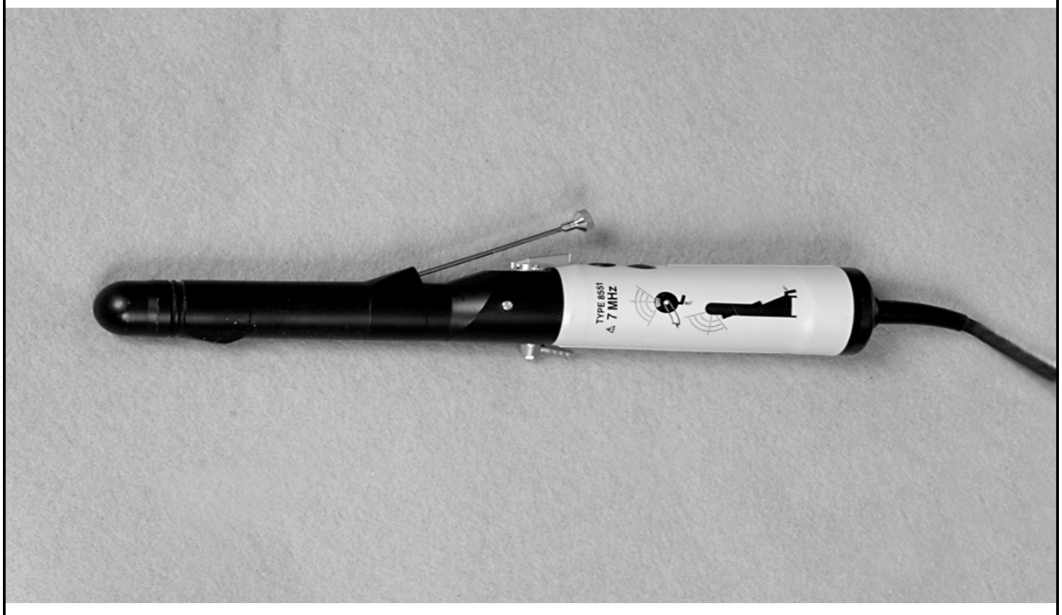

Do Not Reuse Single-Use Devices

- **Federal judge convicted a urologist who reused needle guides meant for single use during prostate procedures (Sept 2014)**
- **Third party reprocessor OK**
- **Criminal prosecution (based on conspiracy to commit adulteration)**

RECENT ENDOSCOPY-RELATED OUTBREAKS OF MRDO WITHOUT REPROCESSING BREACHES

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Endemic Transmission of Infections Associated with GI Endoscopes May Go Unrecognized

- **Inadequate surveillance of outpatient procedures for healthcare-associated infections**
- **Long lag time between colonization and infection**
- **Low frequency of infection**
- **Pathogens "usual" enteric flora**
- **Risk of some procedures might be lower than others (colonoscopy versus ERCP where normally sterile areas are contaminated in the latter)**

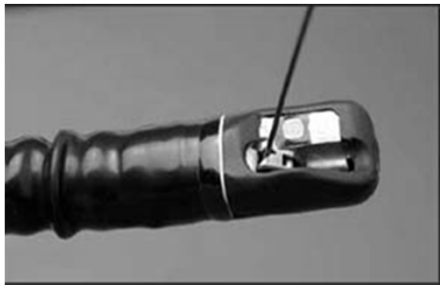
Reason for Endoscope-Related Outbreaks

Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

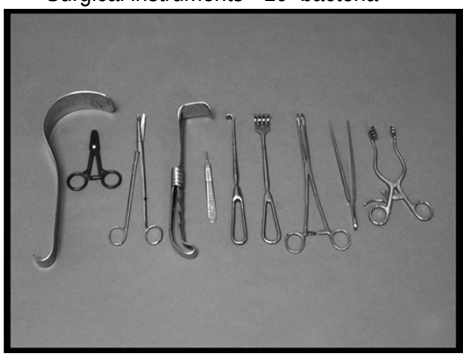
- Margin of safety with endoscope reprocessing minimal or non-existent for two reasons:
- Microbial load
  - **GI endoscopes contain 10^{7-10}**
  - **Cleaning results in 2-6 $\log_{10}$ reduction**
  - **High-level disinfection results in 4-6 $\log_{10}$ reduction**
  - **Results in a total 6-12 $\log_{10}$ reduction of microbes**
  - **Level of contamination after processing: 4 $\log_{10}$ (maximum contamination, minimal cleaning/HLD)**
- Complexity of endoscope and endoscope reprocessing

ENDOSCOPE REPROCESSING: CHALLENGES

Complex [elevator channel]-10^{7-10} bacteria



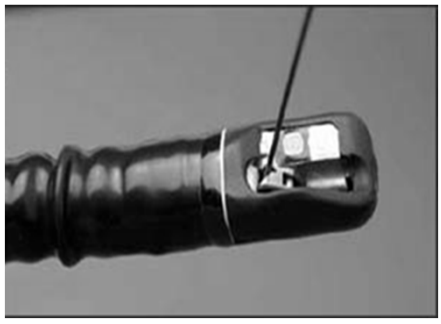
Surgical instruments-$<10^{2}$ bacteria



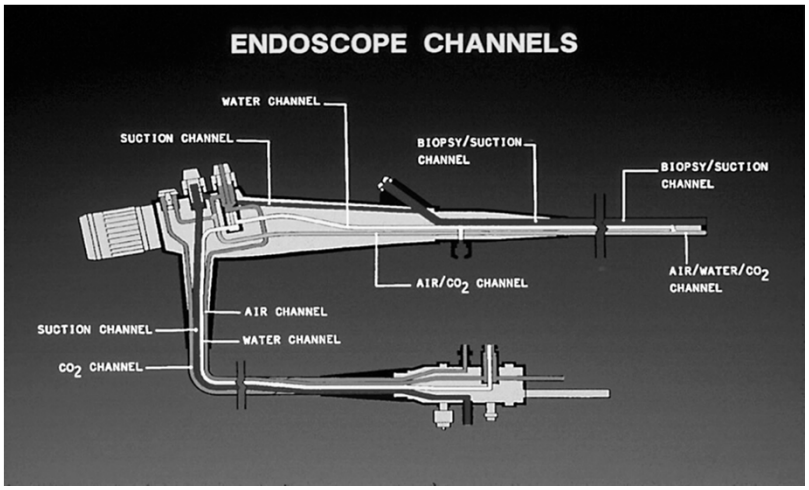
ENDOSCOPE REPROCESSING: CHALLENGES
NDM-Producing *E. coli* Associated ERCP

MMWR 2014;62:1051; Epstein et al. JAMA 2014;312:1447-1455

NDM-producing E.coli recovered from elevator channel (elevator channel orients catheters, guide wires and accessories into the endoscope visual field; crevices difficult to access with cleaning brush and may impede effective reprocessing or killing CRE)



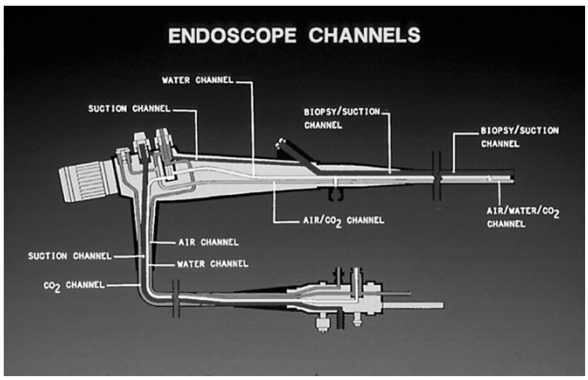
ENDOSCOPE REPROCESSING



FEATURES OF ENDOSCOPES THAT PREDISPOSE TO DISINFECTION FAILURES

Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

- **Heat labile**
- **Long, narrow lumens**
- **Right angle bends**
- **Rough or pitted surfaces**
- **Springs and valves**
- **Damaged channels may impede microbial exposure to HLD**
- **Heavily contaminated with pathogens, 10^{7-10}**
- **Cleaning (4-6 log_{10} reduction) and HLD (4-6 log_{10} reduction) essential for patient safe instrument**



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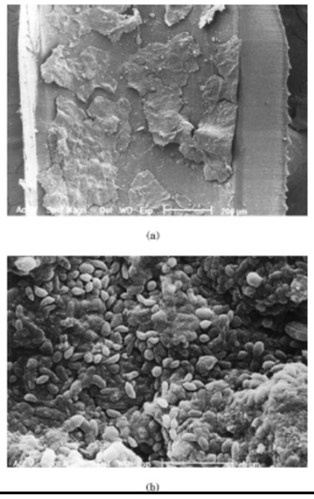
  - Cleaning results in 2-6 $\log_{10}$ reduction
  - High-level disinfection results in 4-6 $\log_{10}$ reduction
  - Results in a total 6-12 $\log_{10}$ reduction of microbes
  - Level of contamination after processing: $4\log_{10}$ (maximum contamination, minimal cleaning/HLD)
- Complexity of endoscope
- Biofilms-unclear if contribute to failure of endoscope reprocessing

BIOFILMS

(Multi-layered bacteria plus exopolysaccharides that cement cell to surface; develop in wet environments; if reprocessing performed promptly after use and endoscope dry the opportunity for biofilm formation is minimal)



(a)

(b)

What Should We Do Now?

How Can We Prevent ERCP-Related Infections?

Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

- No single, simple and proven technology or prevention strategy that hospitals can use to guarantee patient safety
- Of course, must continue to emphasize the enforcement of evidenced-based practices, including equipment maintenance and routine audits with at least yearly competency testing of reprocessing staff
- Must do more or additional outbreaks will continue

Current Enhanced Methods for Reprocessing Duodenoscopes

Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

Hospitals performing ERCPs should do one of the following (priority ranked). Doing nothing is not an option:

- **Ethylene oxide sterilization after high level disinfection with periodic microbiologic surveillance (UNC Hospitals)**
- **Double high-level disinfection with periodic microbiologic surveillance**
- **High-level disinfection with scope quarantine until negative culture**
- **Liquid chemical sterilant processing system using peracetic acid (rinsed with extensively treated potable water) with periodic microbiologic surveillance**
- **High-level disinfection with periodic microbiologic surveillance**

Summary of Advantages and Disadvantages of HLD and Sterilization Enhancements for Reprocessing Duodenoscopes

Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

Method	Advantages	Disadvantages
HLD with ETO, Microbiologic surveillance	• Major endoscope manufacturer offers ETO as sterilization option • Should be used after standard high-level disinfection • Some data demonstrate reduced infection risk with HLD followed by ETO • Single-dose cartridge and negative-pressure chamber minimizes the potential for gas leak and ETO exposure • Simple to operate and monitor • Compatible with most medical materials	• Requires aeration time to remove ETO residue • Only 20% of US hospitals have ETO on-site • Lengthy cycle/aeration time • No microbicidal efficacy data proving SAL 10^{-6} achieved • Studies question microbicidal activity in presence of organic matter/salt • ETO is toxic, a carcinogen, flammable • May damage endoscope

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Method	Advantages	Disadvantages
HLD only (not listed as an enhanced method for reprocessing endoscope)	• **HLD inactivate MDR organisms including CREs** • Current standard of care • Wide availability	• **Based on recent ERCP outbreaks, infection risk related to device complexity and microbial load** • **No enhancement to reduce infection risk associated with ERCP scopes** • Some HLD (e.g., aldehydes) may cross-link proteins

Summary of Advantages and Disadvantages of HLD and Sterilization Enhancements for Reprocessing Duodenoscopes

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Method	Advantages	Disadvantages
HLD, ATP only (not listed as an enhanced method for reprocessing endoscope)	• HLD inactivate MDR organisms including CREs • **Real-time monitoring tool** • **Simple to conduct** • **Detects organic residue**	• Based on recent ERCP outbreaks, **infection risk related to device complexity and microbial load** • **No data demonstrating reduced infection risk** • **Does not detect microbial contamination** • **ATP not validated as risk factor for patient-to-patient transmission** • **Unknown cut-off level to assure safety**

UNC Hospitals
Interim Response to ERCP Outbreaks

- Ensure endoscopes are reprocessed in compliance with national guidelines (CDC, ASGE, etc)
- Evaluate CRE culture-positive patients for ERCP exposure
- In the short term, **enhance reprocessing of ERCP scopes; reprocess ERCP scopes by HLD followed for ETO sterilization**
- Microbiologic surveillance, 5-10% of scopes monthly
- When new recommendations are available from ASGE, CDC, FDA, etc. comply

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To protect the public health we (FDA, industry, professional organizations) must shift duodenoscope reprocessing from HLD to sterilization..

GI Endoscopes: Shift from Disinfection to Sterilization

Rutala, Weber. JAMA 2014. 312:1405-1406

EDITORIAL

Editorials represent the opinions of the authors and *JAMA* and not those of the American Medical Association.

Gastrointestinal Endoscopes
A Need to Shift From Disinfection to Sterilization?

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

More than 10 million gastrointestinal endoscopic procedures are performed annually in the United States for diagnostic purposes, therapeutic interventions, or both.[1] Because gastrointestinal endoscopes contact mucosal surfaces, use of a contaminated endoscope may lead to patient-to-patient transmission of potential pathogens with a subsequent risk of infection.[1]

In this issue of *JAMA*, Epstein and colleagues[2] report findings from their investigation of a cluster of New Delhi metallo-β-lactamase (NDM)-producing *Escherichia coli* associated with gastrointestinal endoscopy that occurred from March 2013 to July 2013 in a single hospital in northeastern Illinois. During the 5-month period, 9 pa-

Related article page 1447

First, endoscopes are semicritical devices, which contact mucous membranes or nonintact skin, and require at least high-level disinfection.[3,4] High-level disinfection achieves complete elimination of all microorganisms, except for small numbers of bacterial spores. Because flexible gastrointestinal endoscopic instruments are heat labile, only high-level disinfection with chemical agents or low-temperature sterilization technologies are possible.[3] However, no low-temperature sterilization technology is US Food and Drug Administration (FDA)-cleared for gastrointestinal endoscopes such as duodenoscopes.

Second, more health care–associated outbreaks and clusters of infection have been linked to contaminated endoscopes than to any other medical device.[3,5] However, until now,

Potential future methods to prevent GI-endoscope-related infections?

Potential Future Methods to Prevent GI-Endoscope Related Outbreaks

Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

- Steam sterilization of GI endoscopes
- New (or optimize) low temperature sterilization methods proving SAL 10^{-6} achieved
- Disposable sterile GI endoscopes
- Improved GI endoscope design (to reduce or eliminate challenges listed earlier)
- Use of non-endoscope methods to diagnosis or treat disease (e.g., capsule endoscopy, blood tests to detect GI cancer, stool DNA test)

Some Potential Sterilization Technologies for Duodenoscopes

Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

- **Optimize existing low-temperature sterilization technology**
  - **Hydrogen peroxide gas plasma**
  - **Vaporized hydrogen peroxide**
  - **Ethylene oxide**
- **Potential new low-temperature sterilization technology**
  - **Ozone plus hydrogen peroxide vapor**
  - **Nitrogen dioxide**
  - **Supercritical CO_2**
  - **Peracetic acid vapor**
- **Steam sterilization for heat-resistant endoscopes**

What Is the Public Health Benefit?
No ERCP-Related Infections

Margin of Safety-currently nonexistent; sterilization will provide a safety margin (~6 $\log_{10}$). To prevent infections, all duodenoscopes should be devoid of microbial contamination.

HLD (6 $\log_{10}$ reduction)

vs

Sterilization (12 $\log_{10}$ reduction=SAL 10^{-6})

FDA Panel, May 2015, Recommended Sterilization of Duodenoscopes

HLD and Sterilization:
What's New

- Sterilization
  - Biological indicators, emerging technologies, modified Spaulding classification
- High-Level Disinfection
  - Endoscope-related infections, channeled scopes, reuse of single-use items
- Low-Level Disinfection
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ENVIRONMENTAL CONTAMINATION LEADS TO HAIs

- 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/equipment

KEY PATHOGENS WHERE ENVIRONMENTIAL SURFACES PLAY A ROLE IN TRANSMISSION

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

ENVIRONMENTAL CONTAMINATION ENDEMIC AND EPIDEMIC MRSA

	Outbreak	Endemic				Site estimated mean§
	Rampling et al[37]*	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

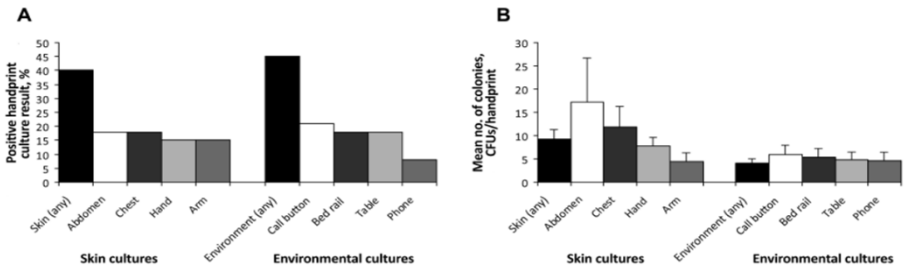
ENVIRONMENTAL SURVIVAL OF KEY PATHOGENS ON HOSPITAL SURFACES

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

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

EVALUATION OF HOSPITAL ROOM ASSIGNMENT AND ACQUISITION OF CDI

- **Study design: Retrospective cohort analysis, 2005-2006**
- **Setting: Medical ICU at a tertiary care hospital**
- **Methods: All patients evaluated for diagnosis of CDI 48 hours after ICU admission and within 30 days after ICU discharge**
- **Results (acquisition of CDI)**
  - **Admission to room previously occupied by CDI = 11.0%**
  - **Admission to room not previously occupied by CDI = 4.6% (p=0.002)**

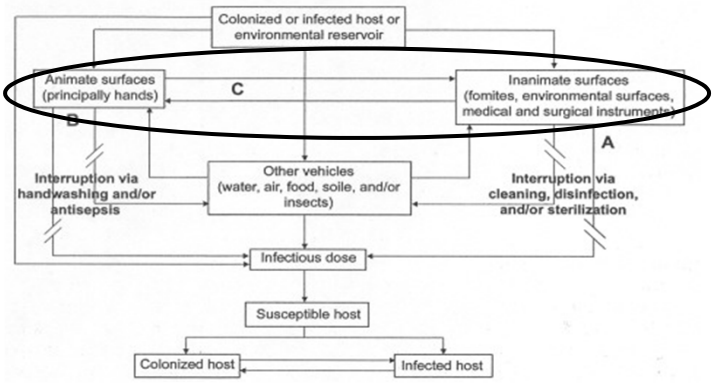
Shaughnessy MK, et al. ICHE 2011;32:201-206

TABLE 3. Multivariate Analysis of Risk Factors for Acquisition of *Clostridium difficile* Infection (CDI)

Risk factor	HR (95% CI)	P
Prior room occupant with CDI	2.35 (1.21–4.54)	.01
Greater age	1.00 (0.99–1.01)	.71
Higher APACHE III score	1.00 (1.00–1.01)	.06
Proton pump inhibitor use	1.11 (0.44–2.78)	.83
Antibiotic exposure		
Norfloxacin	0.38 (0.05–2.72)	.33
Levofloxacin	1.08 (0.67–1.73)	.75
Ciprofloxacin	0.49 (0.15–1.67)	.23
Fluoroquinolones	1.17 (0.72–1.91)	.53
Clindamycin	0.45 (0.14–1.42)	.17
Third- or fourth-generation cephalosporins	1.17 (0.76–1.79)	.48
Carbapenems	1.05 (0.63–1.75)	.84
Piperacillin-tazobactam	1.31 (0.82–2.10)	.27
Other penicillin	0.47 (0.23–0.98)	.04
Metronidazole	1.31 (0.83–2.07)	.24
Vancomycin		
Oral	1.38 (0.32–5.89)	.67
Intravenous	1.55 (0.88–2.73)	.13
Aminoglycosides	1.27 (0.78–2.06)	.35
Multiple (≥3 antibiotic classes)	1.28 (0.75–2.21)	.37

NOTE. APACHE, Acute Physiology and Chronic Health Evaluation; CI, confidence interval; HR, hazard ratio.

TRANSMISSION MECHANISMS INVOLVING THE SURFACE ENVIRONMENT

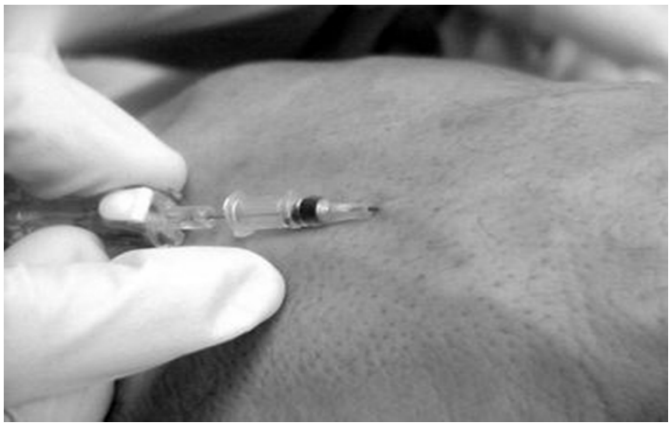


Rutala WA, Weber DJ. In:"SHEA Practical Healthcare Epidemiology" (Lautenbach E, Woeltje KF, Malani PN, eds), 3rd ed, 2010.

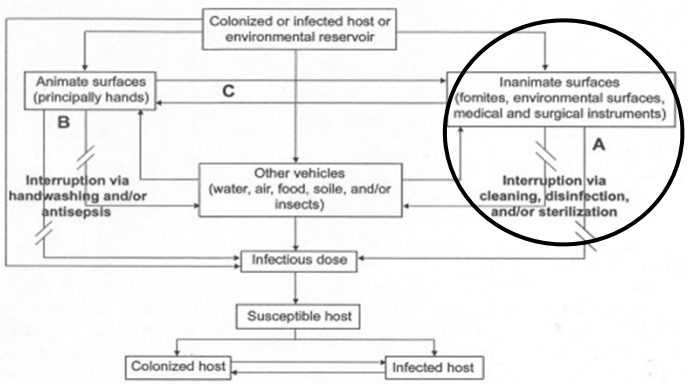
ACQUISITION OF MRSA ON HANDS AFTER CONTACT WITH ENVIRONMENTAL SITES

ACQUISITION OF MRSA ON HANDS/GLOVES AFTER CONTACT WITH CONTAMINATED EQUIPMENT

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

ALL "TOUCHABLE" (HAND CONTACT) SURFACES SHOULD BE WIPED WITH DISINFECTANT

"High touch" objects only recently defined (no significant differences in microbial contamination of different surfaces) and "high risk" objects not epidemiologically defined.

Effective Surface Decontamination

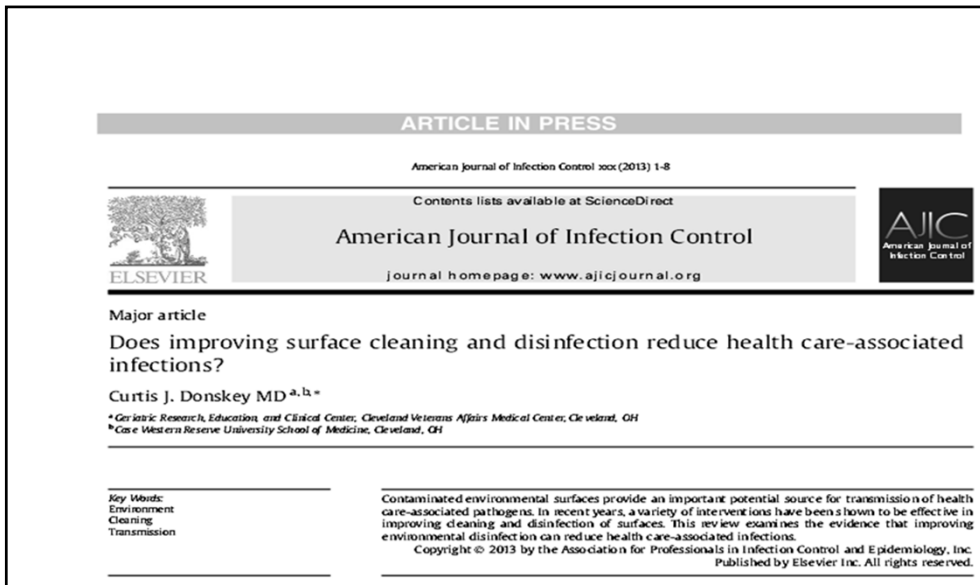
Product and Practice = Perfection

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
Iodophor	UD
Quaternary ammonium	UD
Improved hydrogen peroxide	0.5%, 1.4%

UD=Manufacturer's recommended use dilution



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American Journal of Infection Control xxx (2013) 1-8

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major article

Does improving surface cleaning and disinfection reduce health care-associated infections?

Curtis J. Donskey MD [a,b,*]

[a] Geriatric Research, Education, and Clinical Center, Cleveland Veterans Affairs Medical Center, Cleveland, OH
[b] Case Western Reserve University School of Medicine, Cleveland, OH

Key Words:
Environment
Cleaning
Transmission

Contaminated environmental surfaces provide an important potential source for transmission of health care-associated pathogens. In recent years, a variety of interventions have been shown to be effective in improving cleaning and disinfection of surfaces. This review examines the evidence that improving environmental disinfection can reduce health care-associated infections.

Does Improving Surface Cleaning and Disinfection Reduce Healthcare-Associated Infections?

Donskey CJ. AJIC 2013;41:S12-S19

"As reviewed here, during the past decade a growing body of evidence has accumulated suggesting that improvements in environmental disinfection may prevent transmission of pathogens and reduce HAIs. Although, the quality of much of the evidence remains suboptimal, a number of high-quality investigations now support environmental disinfection as a control strategy"

Alfa et al. AJIC 2015;43:141-146

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major article

Use of a daily disinfectant cleaner instead of a daily cleaner reduced hospital-acquired infection rates

Michelle J. Alfa PhD [a,b,*], Evelyn Lo MD [b,c], Nancy Olson BSc [a], Michelle MacRae [c], Louise Buelow-Smith RN [c]

[a] St Boniface Research Centre, Winnipeg, MB, Canada
[b] Department of Medical Microbiology, University of Manitoba, Winnipeg, MB, Canada
[c] St Boniface Hospital, Winnipeg, MB, Canada

Key Words:
Methicillin-resistant *Staphylococcus aureus*
Vancomycin-resistant enterococci
Clostridium difficile
Housekeeping
Environmental cleaning

Background: Documenting effective approaches to eliminate environmental reservoirs and reduce the spread of hospital-acquired infections (HAIs) has been difficult. This was a prospective study to determine if hospital-wide implementation of a disinfectant cleaner in a disposable wipe system to replace a cleaner alone could reduce HAIs over 1 year when housekeeping compliance was ≥80%.
Methods: In this interrupted time series study, a ready-to-use accelerated hydrogen peroxide disinfectant cleaner in a disposable wipe container system (DCW) was used once per day for all high-touch surfaces in patient care rooms (including isolation rooms) to replace a cleaner only. The HAI rates for methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), and *Clostridium difficile* were stratified by housekeeping cleaning compliance (assessed using ultraviolet-visible marker monitoring).
Results: When cleaning compliance was ≥80%, there was a significant reduction in cases/10,000 patient days for MRSA ($P = .0071$), VRE ($P < .0001$), and *C difficile* ($P = .0005$). For any cleaning compliance level there was still a significant reduction in the cases/10,000 patient days for VRE ($P = .0358$).
Conclusion: Our study data showed that daily use of the DCW applied to patient care high-touch environmental surfaces with a minimum of 80% cleaning compliance was superior to a cleaner alone because it resulted in significantly reduced rates of HAIs caused by *C difficile*, MRSA, and VRE.

Use of a Daily Disinfectant Cleaner Instead of a Daily Cleaner Reduced HAI Rates

Alfa et al. AJIC 2015.43:141-146

- **Method: Improved hydrogen peroxide disposable wipe was used once per day for all high-touch surfaces to replace cleaner**
- **Result: When cleaning compliance was ≥ 80%, there was a significant reduction in cases/10,000 patient days for MRSA, VRE and *C. difficile***
- **Conclusion: Daily use of disinfectant applied to environmental surfaces with a 80% compliance was superior to a cleaner because it resulted in significantly reduced rates of HAIs caused by *C. difficile*, MRSA, VRE**

It appears that not only is disinfectant use important but how often is important

Daily disinfection vs clean when soiled

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 (PA) 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

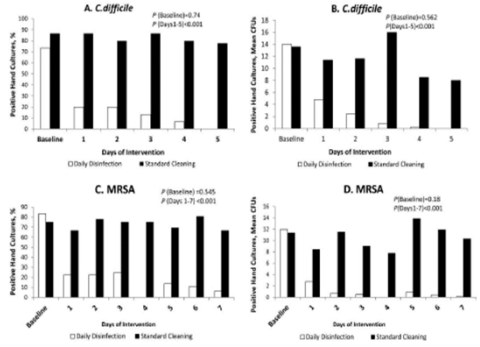


FIGURE 1. Effect of daily disinfection of high-touch environmental surfaces on acquisition of *Clostridium difficile* and methicillin-resistant *Staphylococcus aureus* (MRSA) on gloved hands of investigators after contact with the surfaces. *A*, Percentage of positive *C. difficile* cultures; *B*, mean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

Effective Surface Decontamination

Product and Practice = Perfection

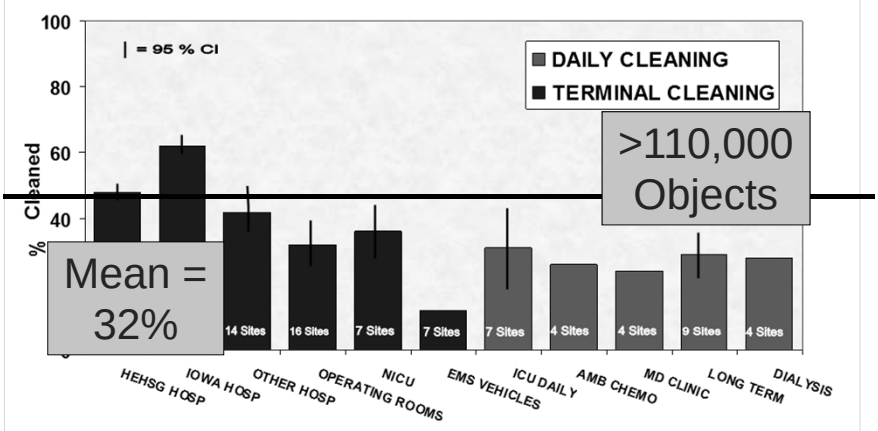
Wipes

Cotton, Disposable, Microfiber, Cellulose-Based, Nonwoven Spunlace

Wipe should have sufficient wetness to achieve the disinfectant contact time (e.g. >1 minute)

Thoroughness of Environmental Cleaning

Carling P. AJIC 2013;41:S20-S25



Mean proportion of surfaces disinfected at terminal cleaning is 32%

Terminal cleaning methods ineffective (products effective practices deficient [surfaces not wiped]) in eliminating epidemiologically important pathogens

MONITORING THE EFFECTIVENESS OF CLEANING

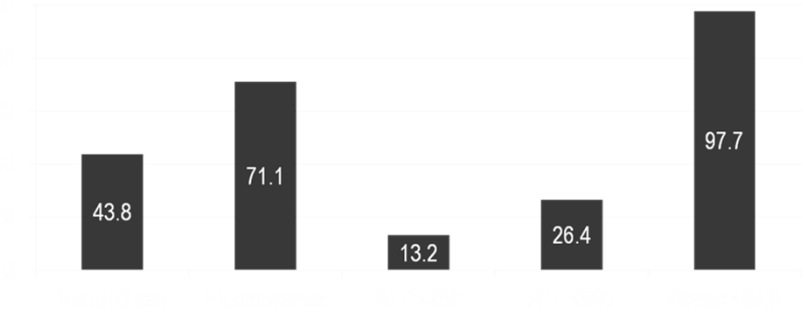
Cooper et al. AJIC 2007;35:338; Carling P AJIC 2013;41:S20-S25

- 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/cm^2-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 IP unbeknown to EVS, after EVS cleaning, markings are reassessed)

Percentage of Surfaces Clean by Different Measurement Methods

Rutala, Gergen, Sickbert-Bennett, Huslage, Weber. 2013

Fluorescent marker is a useful tool in determining how thoroughly a surface is wiped and mimics the microbiological data better than ATP



ALL "TOUCHABLE" (HAND CONTACT) SURFACES SHOULD BE WIPED WITH DISINFECTANT

"High touch" objects only recently defined (no significant differences in microbial contamination of different surfaces) and "high risk" objects not epidemiologically defined.

NEW "NO TOUCH" APPROACHES TO ROOM DECONTAMINATION

Supplement Surface Disinfection

Rutala, Weber. Infect Control Hosp Epidemiol. 2013;41:S36-S41

EFFECTIVENESS OF UV-C FOR ROOM DECONTAMINATION (Inoculated Surfaces)

Pathogens	Dose*	Mean log_{10} Reduction Line of Sight	Mean log_{10} Reduction Shadow	Time	Reference
MRSA, VRE, MDR-A	**12,000**	**3.90-4.31**	**3.25-3.85**	**~15 min**	**Rutala W, et al.[1]**
C. difficile	**36,000**	**4.04**	**2.43**	**~50 min**	**Rutala W, et al.[1]**
MRSA, VRE	**12,000**	**>2-3**	**NA**	**~20 min**	**Nerandzic M, et al.[2]**
C. difficile	**22,000**	**>2-3**	**NA**	**~45 min**	**Nerandzic M, et al.[2]**
C. difficle	**22,000**	**2.3**	**overall**	**67.8 min**	**Boyce J, et al.[3]**
MRSA, VRE, MDR-A, *Asp*	**12,000**	**3.-5->4.0**	**1.7->4.0**	**30-40 min**	**Mahida N, et al.[4]**
MRSA, VRE, MDR-A, *Asp*	**22,000**	**≥4.0***	**1.0-3.5**	**60-90 min**	**Mahida N, et al.[4]**
C. difficile, G. stear **spore**	**22,000**	**2.2**	**overall**	**73 min**	**Havill N et al[5]**
VRE, MRSA, MDR-A	**12,000**	**1.61**	**1.18**	**25 min**	**Anderson et al[6]**

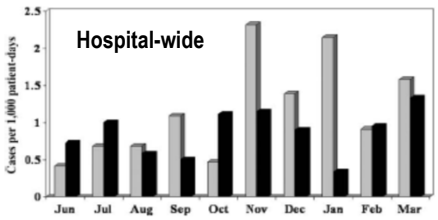
[1]ICHE 2010;31:1025; [2]BMC 2010;10:197; [3]ICHE 2011;32:737; [4]JHI 2013;84:323l [5]ICHE 2012;33:507-12 [6]ICHE 2013;34:466
* $\mu Ws/cm^2$; min = minutes; NA = not available

HP for Decontamination of the Hospital Environment
Falagas et al. J Hosp Infect. 2011;78:171

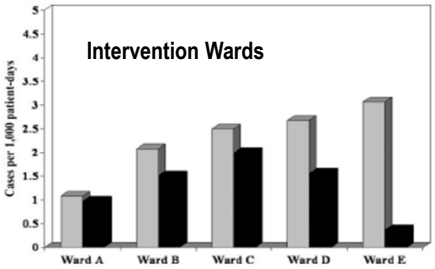
Author, Year	HP System	Pathogen	Before HPV	After HPV	% Reduction
French, 2004	VHP	MRSA	61/85-72%	1/85-1%	98
Bates, 2005	VHP	*Serratia*	2/42-5%	0/24-0%	100
Jeanes, 2005	VHP	MRSA	10/28-36%	0/50-0%	100
Hardy, 2007	VHP	MRSA	7/29-24%	0/29-0%	100
Dryden, 2007	VHP	MRSA	8/29-28%	1/29-3%	88
Otter, 2007	VHP	MRSA	18/30-60%	1/30-3%	95
Boyce, 2008	VHP	*C. difficile*	11/43-26%	0/37-0%	100
Bartels, 2008	HP dry mist	MRSA	4/14-29%	0/14-0%	100
Shapey, 2008	HP dry mist	*C. difficile*	48/203-24%; 7	7/203-3%; 0.4	88
Barbut, 2009	HP dry mist	*C. difficile*	34/180-19%	4/180-2%	88
Otter, 2010	VHP	GNR	10/21-48%	0/63-0%	100

IMPACT OF HPV ROOM DECONTAMINATON ON *C. difficile* TRANSMISSION

Incidence CDI: VHP Pre-intervention (grey) vs Intervention period (black)



Pre-intervention CDAD = 1.89 cases/1000 Pt-d
Intervention CDAD = 0.88 cases/1000 Pt-d
Nov 2004 through March 2005



Pre-intervention CDAD = 2.28 cases/1000 Pt-d
Intervention CDAD = 1.28 cases/1000 Pt-d
Boyce JM, et al. ICHE 2008;29:723-9

Clinical Trials Using HP for Terminal Room Disinfection to Reduce HAIs

Weber, Rutala et al. Am J Infect Control, In press

Author, Year	Design	Pathogen	Reduction in HAIs
Boyce, 2008	Before-After	CDI	Yes
Cooper, 2011	Before-After	CDI	Decrease cases (incidence not stated)
Passaretti, 2013	Prospective cohort	MRSA, VRE, CDI	Yes, in all MDROs
Manian, 2013	Before-After	CDI	Yes
Mitchell, 2014	Before-After	MRSA	Yes

Clinical Trials Using UV for Terminal Room Disinfection to Reduce HAIs

Weber, Rutala et al. Am J Infect Control, In press

Author, Year	Design	Pathogens	Reduction in HAIs
Levin, 2013	Before-After, Pulsed Xenon	CDI	Yes
Hass, 2014	Before-After, Pulsed Xenon	CDI, MRSA, VRE, MDRO-GNR	Yes
Miller, 2015	Before-After, Pulsed Xenon	CDI	Yes
Nagaraja, 2015	Before-After, Pulsed Xenon	CDI	Yes (p=0.06)
Pegues, 2015	Before-After, Optimum	CDI	Yes
Anderson, 2015	Randomized-controlled trial, Tru-D	MRSA, VRE, CDI	Yes

This technology should be used (capital equipment budget) for terminal room disinfection (e.g., after discharge of patients under CP, during outbreaks).

Selection of a UV or HP Device

Weber, Rutala et al. Am J Infect Control, In press

- Since different UV and hydrogen peroxide systems vary substantially, infection preventionists should review the peer-reviewed literature and choose only devices with demonstrated bactericidal capability as assessed by carrier tests and/or the ability to disinfect actual patient rooms
- Ultimately, one would select a device that has demonstrated bactericidal capability and the ability to reduce HAIs

Must improve thoroughness of cleaning/disinfection daily basis also, evaluate new technologies

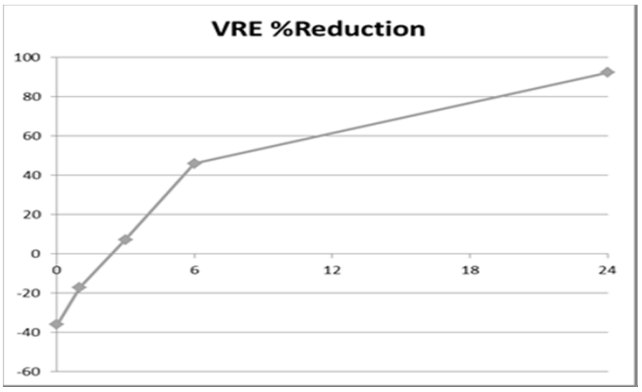
Visible Light Disinfection System

Rutala, Gergen, Kanamori, Sickbert-Bennett, Weber. 2015

- **Uses blue-violet range of visible light in 400-450nm region through light emitting diodes (LEDs); continuous**
- **Initiates a photoreaction with porphyrins in microbes which yield reactive oxygen**
- **In preliminary studies have observed significant reductions with some microbes**

Visible Light Disinfection System

Rutala, Gergen, Kanamori, Sickbert-Bennett, Weber. 2015



Norovirus, *C. difficile* spores, MERS-CoV, Enterovirus D68, Ebola, MDR organisms such carbapenemase-producing *Enterobacteriaceae* (CRE)
In general, emerging pathogens are susceptible to currently available disinfectants. However, some pathogens need additional information (e.g., HPV) or must modify disinfection/sterilization practices (e.g., *C. difficile* spores, prions)

Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants

Most Resistant

Most Susceptible

Prions
Bacterial spores (*C. difficile*)
Mycobacteria
Small, non-enveloped viruses (EV-D68)
Fungal spores
Gram-negative bacilli (*Acinetobacter,* CRE)
Vegetative fungi and algae
Large, non-enveloped viruses
Gram-positive bacteria (MRSA, VRE)
Enveloped viruses (Ebola, MERS-CoV)

LLD-kill microbes in "green"; HLD kill microbes in "blue"-HPV?

C. difficile Spores
EPA-Registered Products

- List K: EPA's Registered Antimicrobials Products Effective Against *C. difficile* spores, April 2014
- http://www.epa.gov/oppad001/list_k_clostridium.pdf
- 34 registered products; most chlorine-based, some HP/PA-based, PA with silver

SHEA Prion Guideline

Rutala, Weber. Infect Control Hosp Epidemiol 2010;31:107

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY FEBRUARY 2010, VOL. 31, NO. 2

SHEA GUIDELINE

Guideline for Disinfection and Sterilization of Prion-Contaminated Medical Instruments

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

EPIDEMIOLOGY OF THE CREUTZFELDT-JAKOB DISEASE PRION

Creutzfeldt-Jakob disease (CJD) is a degenerative neurologic disorder of humans with an incidence in the United States of approximately 1 case per million population per year.[1-5]

tains. To date, no evidence for transmission of chronic wasting disease of deer and elk to humans has been identified.[7-10]

TRANSMISSION OF CJD VIA MEDICAL DEVICES

Management of Neurosurgical Instruments and Patients Exposed to CJD

- Conventional sterilization/disinfection inadequate for prions. Need special prion reprocessing (critical/semi device contaminated with high risk tissue from high-risk patient)
- Belay et al. ICHE 2014;34:1272. Decontamination options combine chemical and SS-1) immerse in 1N NaOH and heat in gravity at ≥121C for 30m in appropriate container; 2) immerse in 1N NaOH or NaOCl 20,000ppm 1h then transfer into water and autoclave at ≥121C for 1h; 3) immerse in 1N NaOH or NaOCl 20,000ppm 1h, rinse with water, transfer to pan and autoclave at 121C (gravity) or 134C (porous) for 1 hour. Clean and sterilize by conventional means.
- Thomas et al. J Clin Neurosci 2013;20:1207. Reviews prevention strategies
- McDonnell et al. J Hosp Infect. 2013;85:268. Investigates the combination of cleaning, disinfection and/or sterilization on prions
- Rutala, Weber. ICHE 2010;31:107. SHEA Guideline-134C for 18m in prevacuum or NaOH/autoclave (such as CDC option 2)

ENDOSCOPE/ENDOCAVITARY PROBES REPROCESSING: CHALLENGES
Susceptibility of Human Papillomavirus
J Meyers et al. J Antimicrob Chemother, Epub Feb 2014

- Most common STD
- In one study, FDA-cleared HLD no effect on HPV
- Finding inconsistent with other small, non-enveloped viruses such as polio, rhino, echo
- Further investigation needed: test methods unclear; glycine; organic matter; comparison virus
- Conversation with CDC: validate and use HLD consistent with FDA-cleared instructions (no alterations)

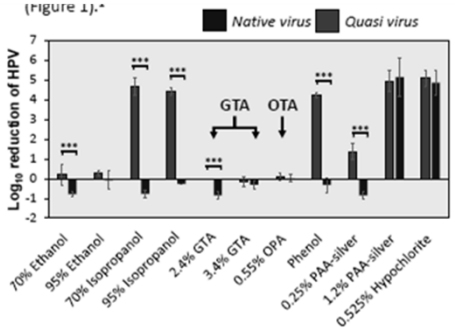


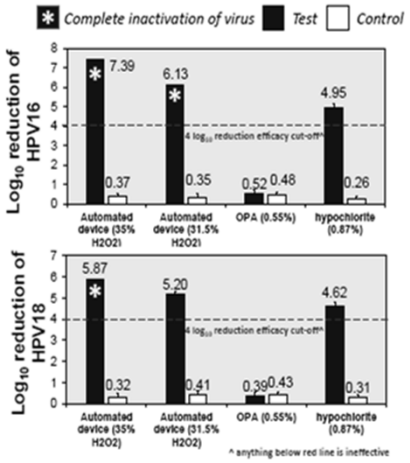
Figure 1: Susceptibility of HPV virions to clinical disinfectants. Both authentic virus and quasivirus were incubated with the indicated disinfectants for a contact time of 45 min. Disinfectants were neutralized and the virus was added to HaCaT cells for infection. Data shown are the averages of at least five independent experiments, with errors shown as the standard deviations of all experiments. **P<0.01; ***P<0.001.

Hydrogen Peroxide Mist

(uses HP mist to achieve HLD in 7m-no independent efficacy data)

Efficacy of HP Mist Against HPV

Meyers C et al. SHEA Poster, 2015



- **HLD widely used to reprocess semicritical items including endocavitary probes**
- **Tested OPA, hypochlorite and HP mist**
- **HP mist system and hypochlorite >4 log_{10} reduction, OPA achieved <1 log_{10} reduction**

Effectiveness of HP Mist System in Inactivating Healthcare Pathogens

Rutala, Gergen, Sickbert-Bennett, Weber 2015

- Designed to provide HLD of ultrasound probes
- Automated, closed system that uses hydrogen peroxide mist
- >10^6 pathogens inoculated onto probe at 2-3 sites
- Inactivated bacteria and good but not complete kill of mycobacteria, spores

5% FCS	VRE	CRE-Kp	*M. terrae*	*C. difficile* spores
Present	0/7	0/6	4/9	3/6
Absent	0/6	ND	1/6	1/9

HLD and Sterilization:

What's New

- Sterilization
  - Biological indicators, emerging technologies, modified Spaulding classification
- High-Level Disinfection
  - Endoscope-related infections, channeled scopes, laryngoscopes, reuse of single-use items
- Low-Level Disinfection
  - Emerging pathogens, room decontamination methods

Disinfection and Sterilization: What's New

- New D/S technologies (new disinfectants, BIs) and practices (e.g., perfused channel scopes with HLD) could reduce risk of infection.
- Endoscope represent a nosocomial hazard. Endoscopes have narrow margin of safety due to complexity and microbial load. Comply with reprocessing guidelines and implement enhanced method for duodenoscopes.
- Do not reuse single-use devices
- Implement "no touch" technologies such as UV for terminal room decontamination of Contact Precaution patient rooms
- In general, emerging pathogens are susceptible to currently available disinfectants. However, some pathogens need additional information or modify D/S practices (e.g., prions, *C. difficile* spores, HPV).

THANK YOU!
www.disinfectionandsterilization.org

Calvin the Owl

Halloween, 2015