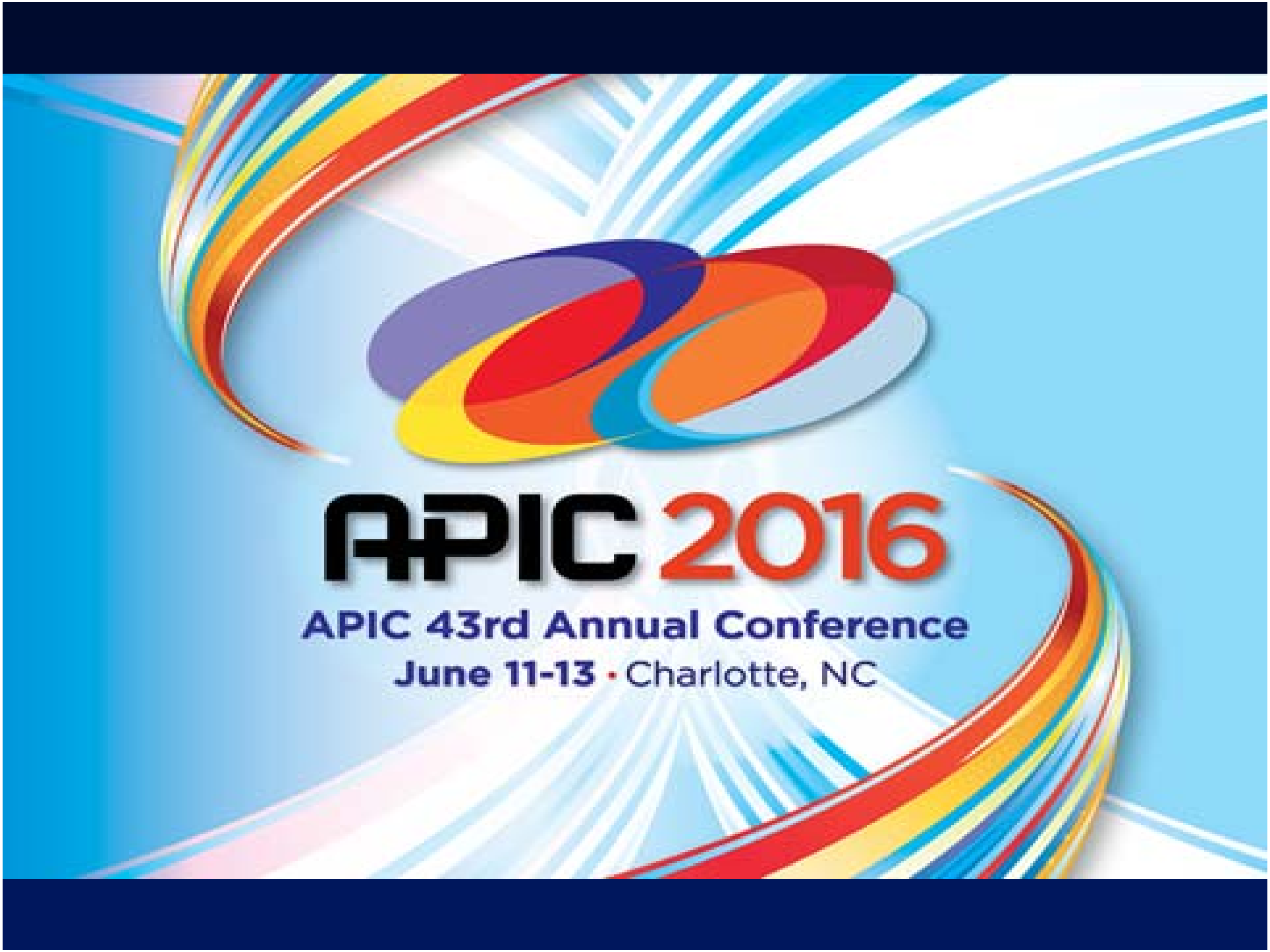

APIC 2016
APIC 43rd Annual Conference
June 11-13 · Charlotte, NC

Disinfection and Sterilization:
The Good, The Bad and The Ugly

William A. Rutala, PhD, MPH

Director, Hospital Epidemiology, Occupational Health and Safety at UNC Health Care; Research Professor of Medicine and Director, Statewide Program for Infection Control and Epidemiology at University of North Carolina School of Medicine at Chapel Hill, USA



Disinfection and Sterilization:

The Good, The Bad and The Ugly

www.disinfectionandsterilization.org

Our Responsibility to the Future

Prevent All Infectious Disease Transmission by Instruments and the Environment in 5 years

Via Research/Technology/Automation/Competency



DISCLOSURES

- Consultation
  - Clorox
- Honoraria
  - 3M
  - Clorox
- Grants to UNC or UNC Hospitals
  - CDC, CMS, Nanosonics


the good

Research and Technology/Automation
Five-Year Plan to Prevent Exposures/Infections

- Sterilization-highly effective
  - Huge margin of safety, modified Spaulding classification
- High-Level Disinfection-challenge #1
  - Eliminate endoscope-related infections, promote automation, research (scopes), sterilization
- Low-Level Disinfection-challenge #2
  - Eliminate environment as source of infection, “no touch” room decontamination methods; continuous room decontamination

Research and Technology/Automation
Five-Year Plan to Prevent Exposures/Infections

- Sterilization
  - Huge margin of safety, modified Spaulding classification
- High-Level Disinfection
  - Endoscope-related infections will promote automation, research (scopes), sterilization
- Low-Level Disinfection
  - No Touch room decontamination methods; continuous room decontamination



Sterilization
Enormous Margin of Safety!

100 quadrillion (10^{17}) margin of safety

Sterilization kills 1 trillion spores, washer/disinfector removes or inactivates 10-100 million; ~100 microbes on surgical instruments



Endoscopes top ECRI's list of 10 health technology hazards

Infections/infection risk not good but the solution is good!

Disinfection and Sterilization:

The Good, The Bad and The Ugly

First Challenge to Meet Goals

Prevent All Infectious Disease Transmission Associated with Endoscopy in 5 years

Via Research/Technology/Automation/Competency

High-Level Disinfection
No Margin of Safety

0 margin of safety

Microbial contamination 10^7-10^{10}: compliant with reprocessing guidelines 10,000 microbes after reprocessing:

maximum contamination, minimal cleaning (10^2)/HLD (10^4)

Transmission of Infection by Endoscopy

Kovaleva et al. Clin Microbiol Rev 2013. 26:231-254

Scope	Outbreaks	Micro (primary)	Pts Contaminated	Pts Infected	Cause (primary)
Upper GI	19	Pa, *H. pylori*, *Salmonella*	169	56	Cleaning/Dis-infection (C/D)
Sigmoid/Colonoscopy	5	*Salmonella*, HCV	14	6	Cleaning/Dis-infection
ERCP	23	*P. aeruginosa* (Pa)	152	89	C/D, water bottle, AER
Bronchoscopy	51	Pa, Mtb, Mycobacteria	778	98	C/D, AER, water
Totals	98		1113	249	

Based on outbreak data, if eliminated deficiencies associated with cleaning, disinfection, AER , contaminated water and drying would eliminate about 85% of the outbreaks.

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
K. pneumoniae (OXA)	Duodenoscope	5	No		Kola A, 2015
E. coli (NDM-CRE)	Duodenoscope	39	Yes	Yes (PFGE)	Epstein L, 2014

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
- Cedars-Sinai, 2015, CRE, 67 patients exposed (4 infected), duodenoscopes
- Wisconsin, 2013, CRE, (5 infected), duodenoscopes
- University of Pittsburgh, 2012, CRE, 9 patients, duodenoscopes

Endemic Transmission of Infections Associated with GI Endoscopes Likely Go Unrecognized

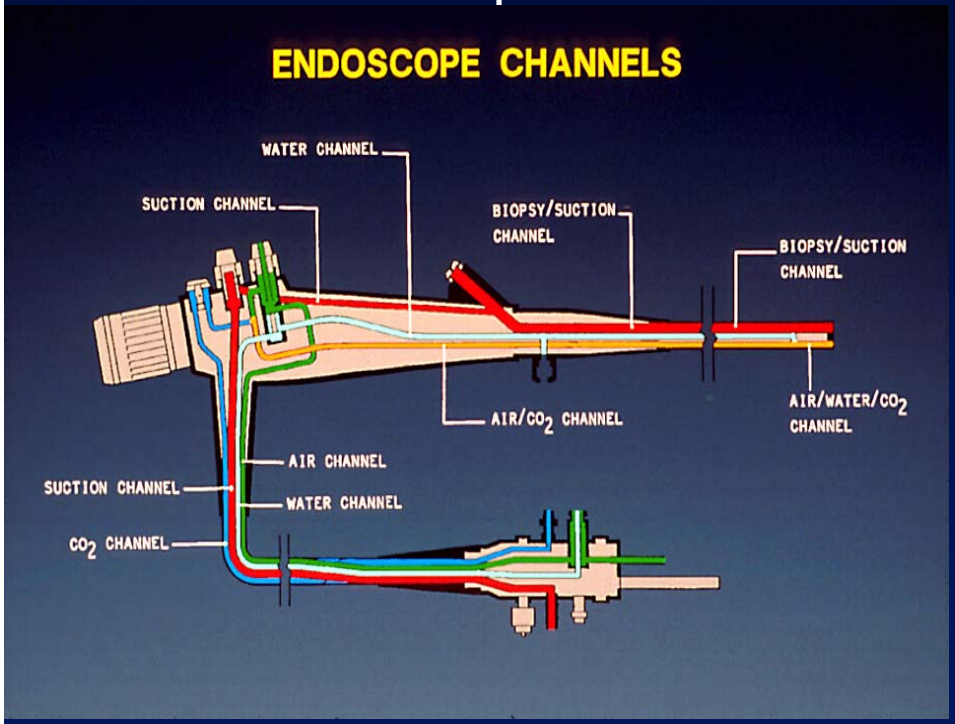
Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643



- 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)

Endoscope Reprocessing

Microbial Load/Complex Instruments



New Guidelines

- Multi-society guideline (in prep)
- AORN-2016
- AAMI-2015
- SGNA-2015
- Must educate/comply but confident will not prevent all infections and patient exposures due to microbial load and instrument complexity

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,

FDA Panel, May 2015, Recommended Sterilization of Duodenoscopes

(requires FDA-cleared sterilization technology that achieves a SAL 10^{-6} with duodenoscopes- not yet available)

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 (developed 1968).

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

Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643.

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, cystoscope, bronchoscope) 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).

Technology Will Be Developed to Sterilize Endoscopes or Use a Sterile, Disposable GI Scopes



Research and Technology/Automation
Five-Year Plan to Prevent Exposures/Infections

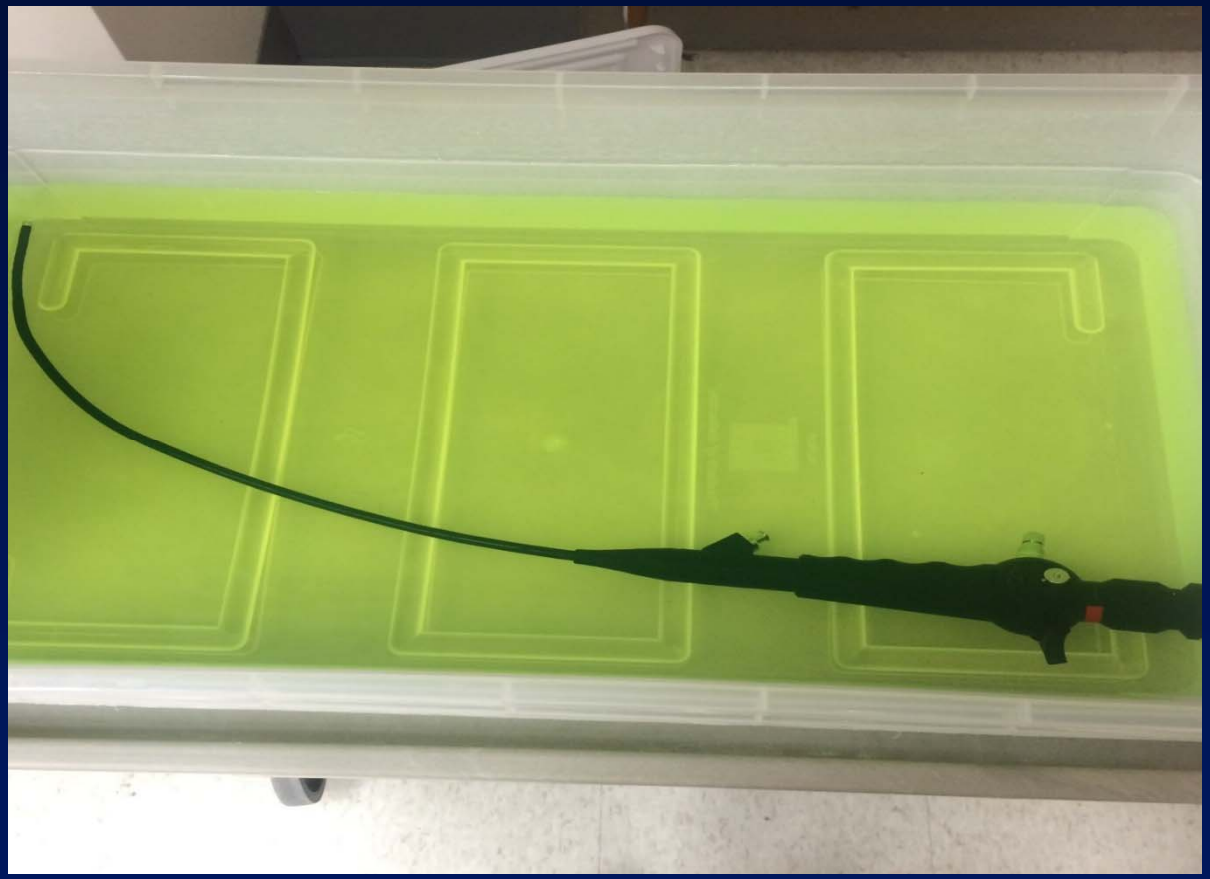
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  - No Touch room decontamination methods; continuous room decontamination

Research and Technology/Automation



Reprocessing Channeled Endoscopes

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



Reprocessing Channeled Endoscopes

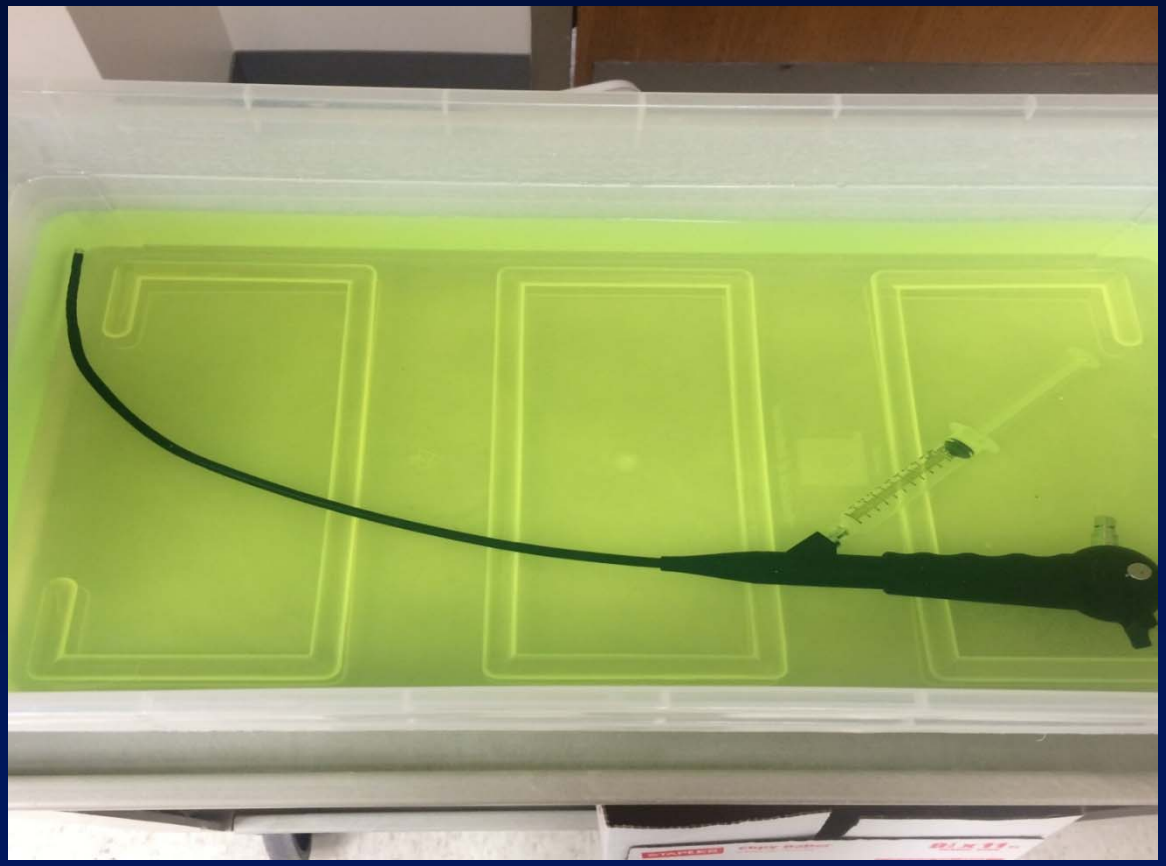
Rutala, Gergen, Bringhurst, Weber. ICHE. 2016;37:228-231

Exposure Method	CRE (*K. pneumoniae*) Inoculum before HLD (glutaraldehyde)	CRE (K. pneumoniae) Contamination after HLD
Passive HLD (immersed, not perfused)	$3.2x10^8$ $1.9x10^9$ $4.1x10^8$	$3.1x10^8$ $4.6x10^8$ $1.0x10^8$
Active HLD (perfused HLD into channel with syringe)	$3.0x10^8$ $9.2x10^8$ $8.4x10^8$	0 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 (e.g., hysteroscopes, cystoscopes) are perfused
- 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 in the scope nor air in barrel of syringe-syringe and lumen filled with HLD)



Technology and Automation

Given the choice of changing human behavior (e.g., improving aseptic technique) or designing a better device, the device will always be more successful… Robert A. Weinstein



Endoscope Reprocessing Methods

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

Performed all 12 steps with only 1.4% of endoscopes using manual versus 75.4% of those processed 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
Immerse endoscope completely in detergent	99
Immerse components completely in detergent	99
Flush endoscope with detergent	99
Rinse endoscope with water	96
Purge endoscope with air	84
Load and complete automated cycle for high-level disinfection	100
Flush endoscope with alcohol	86
Use forced air to dry endoscope	45
Wipe down external surfaces before hanging to dry	90

Automated Endoscope Reprocessors







Hydrogen Peroxide Mist
(uses HP mist to achieve HLD in 7m)





Effectiveness of HP Mist System in Inactivating Healthcare Pathogens on Probes

Rutala, Gergen, Sickbert-Bennett. ICHE 2016;37:613-614

TABLE 1. Proportion of Surface and Endocavitary Probes Positive After System Processing According to the Presence or Absence of an Organic Challenge*

5% Fetal Calf Serum-FCS	Probes with vancomycin-Resistant *Enterococcus* (VRE), No./Total	Probes with CR *Klebsiella pneumoniae*, No./Total	Probes with *Mycobacterium terrae*, No./Total (mean $\log_{10}$ reduction and 95% CI)	Probes with *Clostridium difficile* spores, No./Total (mean $\log_{10}$ reductions and 95% CI)
Present	0/7	0/6	4/9 (5.19 [4.61–5.76])	3/6 (5.12 [4.42–5.83])
Absent	0/6	0/6	1/6 (4.62 [4.07–5.17])	1/9 (6.23 [6.02–6.43])

- Automated, closed system that uses HP mist for HLD of ultrasound probes
- >10^6 pathogens inoculated onto probe at 2-3 sites
- Inactivated bacteria and good but not complete kill of mycobacteria, spores
- Alternative to high-level disinfection by high-level disinfectants

Research and Technology/Automation
Five-Year Plan to Prevent Exposures/Infections

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Research and Technology/Automation

Disinfection and Sterilization:

The Good, The Bad and The Ugly

Second Challenge to Meet Goals

Prevent All Infectious Disease Transmission Associated with the Environment in 5 years

Via Research/Technology/Automation/Competency

Environmental Contamination Leads to HAIs

Weber, Kanamori, Rutala. Curr Op Infect Dis .2016. In press.



- Evidence environment contributes
- Role-MRSA, VRE, *C. difficile*
- Surfaces are contaminated-~25%
- EIP survive days, weeks, months
- Contact with surfaces results in hand contamination
- Disinfection reduces contamination
- Disinfection (daily) reduces HAIs
- Rooms not adequately cleaned

Admission to Room Previously Occupied by Patient C/I with Epidemiologically Important Pathogen



- Results in the newly admitted patient having an increased risk of acquiring that pathogen by 39-353%
- For example, increased risk for *C. difficile* is 235% (11.0% vs 4.6%)

Acquisition of MRSA on Hands After Contact with Environment Surfaces



Acquisition of MRSA on Hands/Gloves After Contact with Contaminated Equipment



Transfer of MRSA from Patient or Environment to IV Device and Transmission of Pathogen

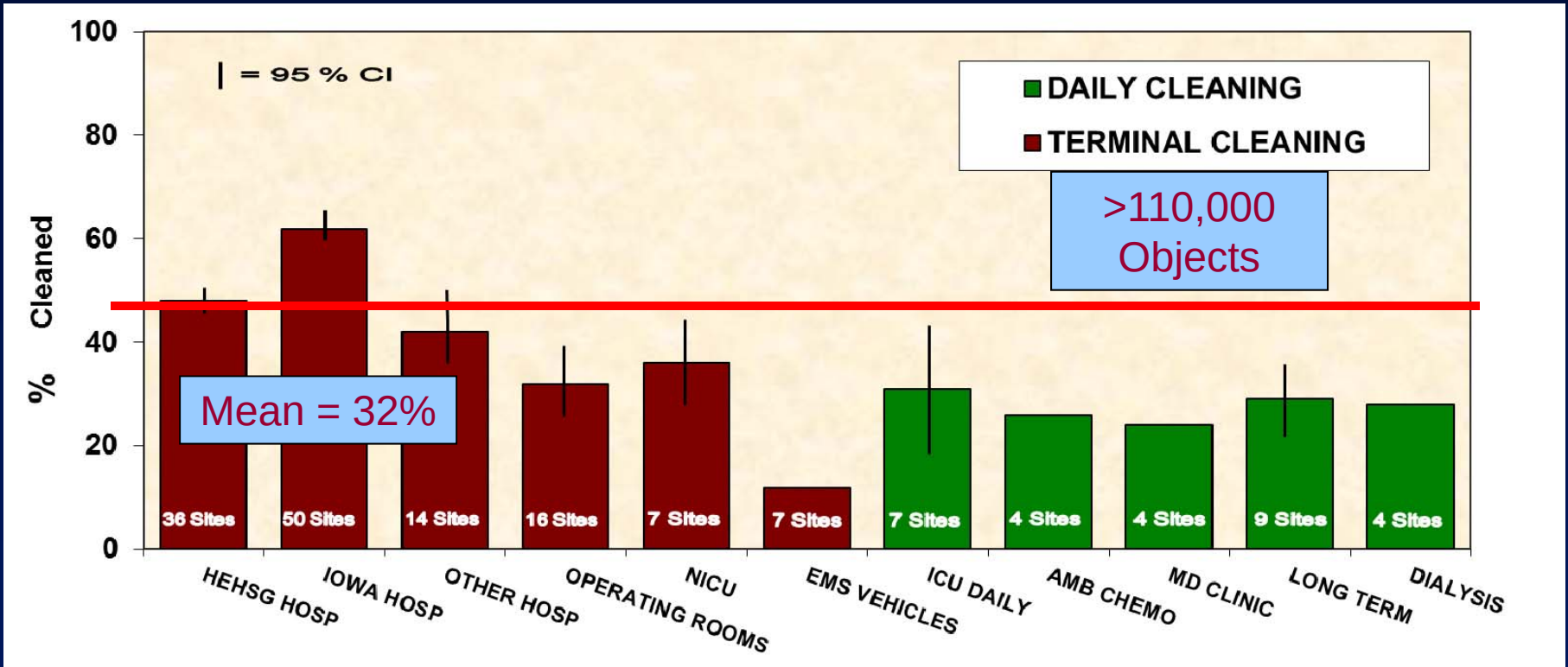


Acquisition of *C. difficile* on Patient Hands after Contact with Environmental Sites and Then Inoculation of Mouth



Thoroughness of Environmental Cleaning

Carling P. AJIC 2013;41:S20-S25



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/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)

These interventions not enough to achieve consistent and high rates of cleaning/disinfection

No Touch

(supplements but do not replace surface cleaning/disinfection)

NEW "NO TOUCH" APPROACHES TO ROOM DECONTAMINATION

Supplement Surface Disinfection

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







HYDROGEN PEROXIDE 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%	7/203-3%	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

Clinical Trials Using HP for Terminal Room Disinfection to Reduce HAIs

Weber, Rutala et al. Am J Infect Control. 2016;44:e53-e62

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
Horn, 2015	Before-After	CDI, VRE, ESBL GNR	Yes

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

Clinical Trials Using UV for Terminal Room Decontamination to Reduce HAIs

Weber, Rutala et al. Am J Infect Control. 2016;44:e77-e84.

Author, Year	Design	Pathogens	Reduction in HAIs
Levin, 2013	Before-After	CDI	Yes
Hass, 2014	Before-After	CDI, MRSA, VRE, MDRO-GNR	Yes
Miller, 2015	Before-After	CDI	Yes
Nagaraja, 2015	Before-After	CDI	Yes (p=0.06)
Pegues, 2015	Before-After	CDI	Yes
Anderson, 2015	Randomized-controlled trial	MRSA, VRE, CDI	Yes
Vianna, 2016	Before-After	CDI, MRSA, VRE	Yes

The Benefits of Enhanced Terminal Room (BETR) Disinfection Study: Duke/UNC Epicenter

Anderson et al, 2015, ID Week

A Pragmatic, Prospective, Cluster Randomized, Multicenter Crossover Study with 2x2 Factorial Design to Evaluate the Impact of Enhanced Terminal Room Disinfection on Acquisition and Infection Caused by Multidrug-Resistant Organisms

2x2 Factorial Design

	No UV Light	UV Light
Quat*	A	B
Bleach	C	D

**NOTE: Bleach always used in rooms of patients with suspected or confirmed C. difficile*

Rooms of Patients on Contact Precautions Decontaminated with Standard or Enhanced Methods and "Exposed" Patient Monitored for Target MDRO

Patient in "Seed Room"



Terminal Clean

"Exposed Patient"



Documented infection or colonization with

MRSA

VRE

C. difficile

MDR-Acinetobacter

In room ≥ 24 hours

Exposure days = Time spent in "seed room"

Clinical Incidence of All Target MDROs Following the Use of Four Strategies for Terminal Room Disinfection

Study Phase Strategy	A Quat	B Quat/UV	C Bleach	D Bleach/UV
All target MDROs				
n/exposure days	115/22,426	76/22,389	101/24,261	131/28,757
Cumulative rate	51.3	33.9	41.6	45.6
Average rate ± STD	46.1±27.9	28.7±20.5	41.1±16.6	39.2±20.9
RR (95% CI) p-value	*ref*	0.70 (0.50-0.98) 0.036	0.85 (0.69-1.04) 0.12	0.91 (0.76-1.09) 0.30

Conclusion: Enhanced terminal room disinfection strategies decreased the clinical incidence of target MDROs by 10-30%

Relationship Between Reduced Environmental Contamination and Reduction of HAIs

Rutala, Kanamori, Gergen et al. 2016

Intervention	MDR-*Acinetobacter*	*C. difficile*	MRSA	VRE	EIP*
Quat	8.95	3.76	8.52	39.6	60.8
Quat/UV	0.17	2.86	0.11	0.21	3.4
Bleach	0.39	4.48	4.39	2.43	11.7
Bleach/UV	0.25	3.25	0.85	1.90	6.3

*EIP-epidemiologically-important pathogens (mean CFU/room/125cm^2) by intervention and contamination in patient rooms.

All enhanced disinfection technologies were significantly superior to Quat alone In reducing EIPs. Comparing the best strategy with the worst strategy (i.e., Quat vs Quat/UV) revealed that a reduction of 94% in EIP (60.8 vs 3.4) led to a 35% decrease in colonization/infection (2.3% vs 1.5%). Our data demonstrated that a decrease in room contamination was associated with a decrease in patient colonization/infection.

This technology ("no touch"-UV/HP) should be used (capital equipment budget) for terminal room disinfection (e.g., after discharge of patients on Contact Precautions).

Selection of a UV or HP Device

Weber, Rutala et al. Am J Infect Control. 2016;44:e77-e84.

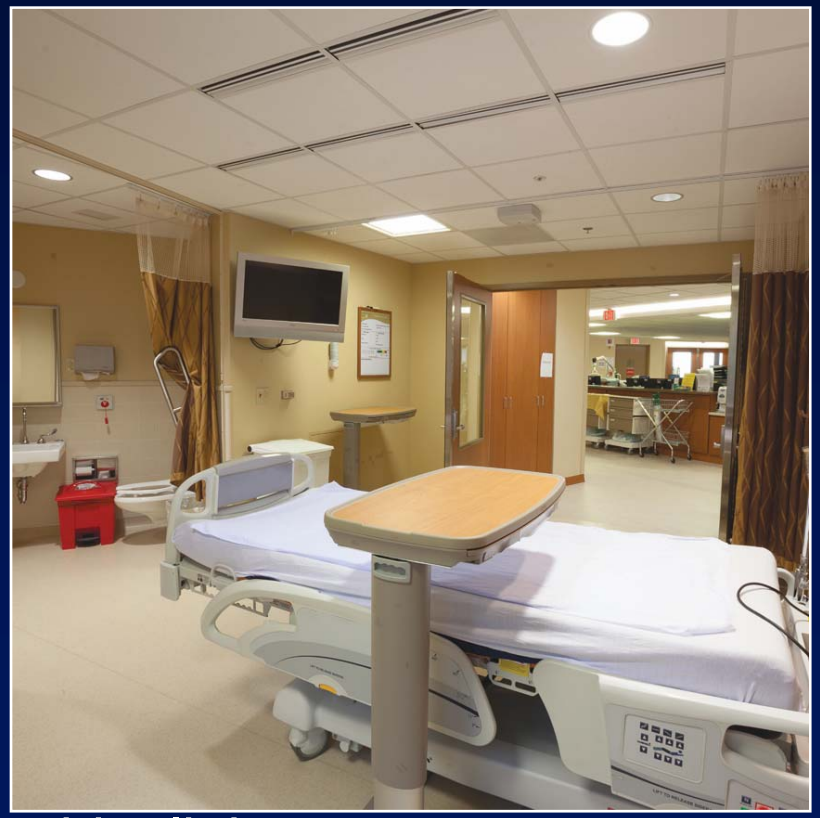
- Since different UV and hydrogen peroxide systems vary substantially, infection preventionists should review the peer-reviewed literature and choose only devices with demonstrated bactericidal capability as assessed by carrier tests and/or the ability to disinfect actual patient rooms
- Ideally, one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

To eliminate environmental contribution to HAIs, must also improve thoroughness of cleaning/disinfection daily basis also, evaluate new technologies

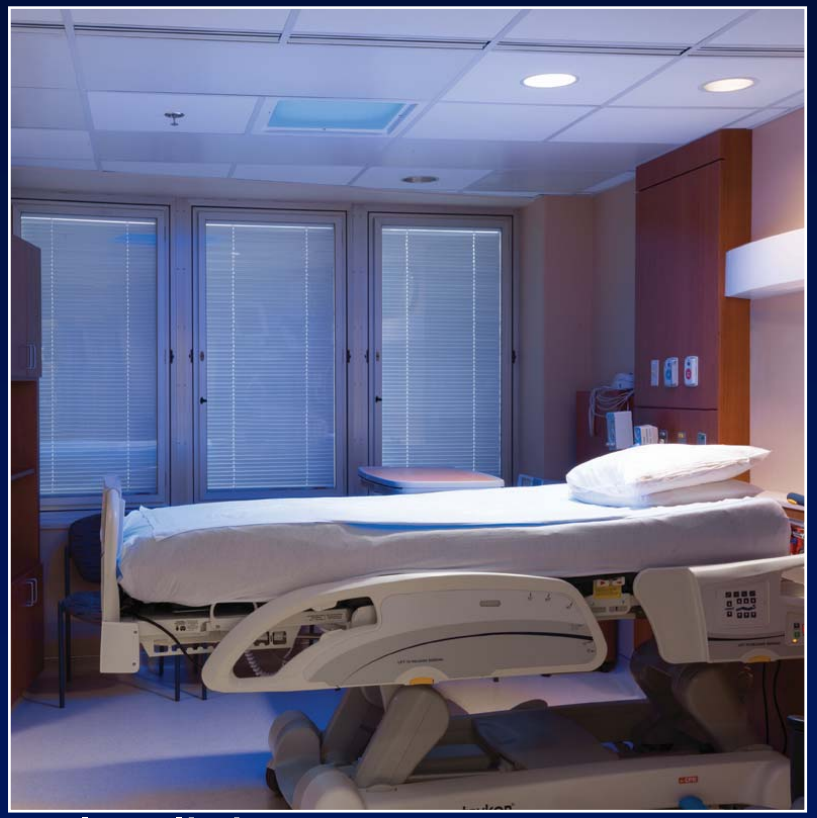
Hygienically clean (not sterile)-free of pathogens in sufficient numbers to prevent human disease

Visible Light Disinfection in a Patient Room

(automatic switching between modes performed by wall-mounted controls)



White light



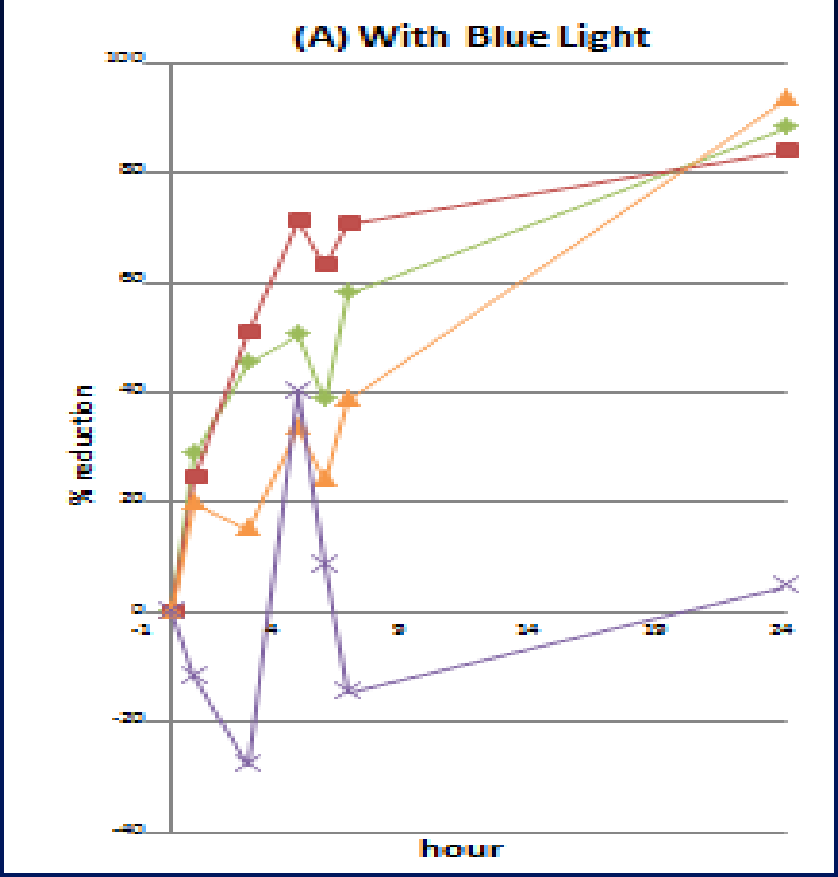
Blue light-increase irradiance, increase kill

Antimicrobial Activity of a Continuous Visible Light Disinfection System

- Visible Light Disinfection uses the blue-violet range of visible light in the 400-450nm region generated through light-emitting diodes (LEDs)
- Initiates a photoreaction with endogenous porphyrin found in microorganisms which yield production of reactive oxygen species inside microorganisms, leading to microbial death
- Overhead illumination systems can be replaced with Visible Light Disinfection counterparts

Percent Reduction of Epidemiologically-Important Pathogens with a Visible Light Disinfection System

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



- MRSA, VRE, and MDR-*Acinetobacter* were greatly reduced on Formica surfaces (>80% at 24h, 20-50% in 3h)
- This technology could be considered for several healthcare decontamination applications (e.g., ORs)

Antimicrobial Activity of a Continuous Visible Light Disinfection System

- Advantages
  - Decontamination can be accomplished 24/7 (lights must be on)
  - Patients and staff do not have to leave the room during decontamination
  - Biocidal activity against a range of HA pathogens
  - Room surfaces and equipment decontaminated
  - Residual free, and no known safety or health concerns
- Disadvantages
  - Has not been demonstrated to reduce HAIs in clinical trials
  - Kills in hours not minutes
  - Capital equipment costs are substantial

Research and Technology/Automation
Five-Year Plan to Prevent Exposures/Infections

- New Continuous Room Decontamination
  - Dilute hydrogen peroxide, persistent antimicrobials
- Microbiome (collaboration with Duke UMC)
  - Microbiome (collective genomes of all microorganisms that reside) on surgical instruments and environmental surfaces
    - Measure microbiome changes with exposure to disinfection and sterilization practices
    - Improve knowledge on the reservoir and transmission of pathogens
- New Germicides
  - New sporicidal products that kill *C. difficile* spores in 2 minutes; broad surface compatibility (no residue); low odor


the bad



Non-Compliance

Human errors, omissions (equipment failures, system problems)-patient infections and exposures

Endoscope Reprocessing Methods

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

Performed all 12 steps with only 1.4% of endoscopes using manual versus 75.4% of those processed using AER

TABLE 3. Documented Completion of Steps During Manual Cleaning With High-Level Disinfection Reprocessing

Observed Activity	Steps Completed (%) (n = 69)
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Load and complete automated cycle for high-level disinfection	100
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Use forced air to dry endoscope	45
Wipe down external surfaces before hanging to dry	90

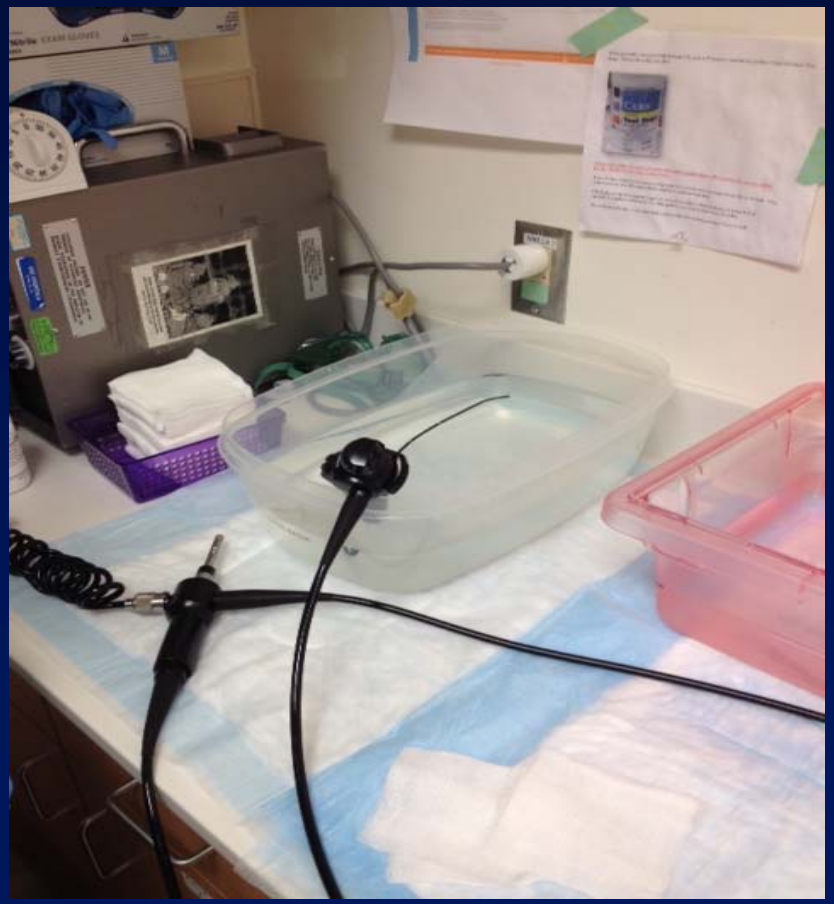
Two Probes in One Cannister



Inadequate Cleaning: Blood on Scope



Incomplete immersion: Only Tip



Health Care Facilities Need to Immediately Review 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.**


Ambulatory Care Center
NYU Langone
MEDICAL CENTER
Ambulatory Care Center
240 East 38th Street
NYU Langone
Ambulatory Care Center
240

Safe Injection Practices

Reprocessing Semicritical Items

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

Reprocessing endoscopes and other semicritical items

Competency and Compliance with Evidence-Based D/S Guidelines



Education/Training/Competency



Judie Bringhurst



High Level Disinfection (HLD) Certificate Class

Class size is limited to 24 students



When: Tuesday, July 7, 2015
9am – noon

Where: On Campus
MacNider 18
Chapel Hill

At this class you will:

- Learn how to high-level disinfect semi-critical devices
- Understand your responsibilities related to HLD
- Learn the pitfalls of inadequate high-level disinfection
- Learn about OSHA regulations related to high level disinfectants
- *Earn 3 nursing contact hours!*



Faculty:
Judie Bringhurst, MSN, RN, CIC

Registration:
By email **ONLY** please. Email your **name**, your **clinic** name, and your **phone number** to Judie Bringhurst, Hospital Epidemiology: jbringhu@unch.unc.edu You will receive confirmation of your registration by return email.

Parking:
Staff without on-campus parking assignments may want to park in the visitor's parking deck on Manning Drive.

Managing Instrument (Semicritical and Critical) Reprocessing Competencies and Lists

- Managers should:
  - Keep list of HCP that reprocess semicritical or critical
  - List of instruments reprocessed in their unit/clinic
  - Ensure appropriate competencies in place upon hire and annually (also when new endoscopic models, new processing equipment/products)
  - Surveyors will want demonstration and observation and documentation
  - Documentation is the valid competency form
  - Must be completed by another HCP who also has a valid competency
  - Must be stored in employees' records

Compliance with Evidence-Based Guidelines

Compliance with Evidence-Based Guidelines

- Must work with our professional organizations (APIC, SHEA, SGNA) to promote compliance with evidence-based guidelines by surveyors not “consensus” guidelines or “commentaries”
- Requiring staff to perform functions with no proven benefit to patient or employee safety may serve to reduce efforts proven to improve patient outcomes
- Strategies should have evidence-based



- No endoscope outbreak or infection related to endoscopes touching
- Outbreaks and exposures related to cleaning, HLD (time, temperature, conc) deficiencies, competency
- Need validated real-time cleaning verification test that predicts microbial contamination/patient exposure (ideally infection risk)
- Cleaning assessment tools are not predictive of infection risks

Infection Risk to Patients

Human Papilloma Virus (HPV) and Endoscopes



Research and Technology

Five-Year Plan to Prevent Exposures/Infections

- Human Papilloma Virus (HPV)
  - HPV is transmitted through sexual contact
  - Medical devices can become contaminated
  - If adequate disinfection of devices does not occur, the next patient may be at risk for HPV infection
  - Based on one publication, there are currently no FDA-cleared HLDs that are effective against HPV

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)

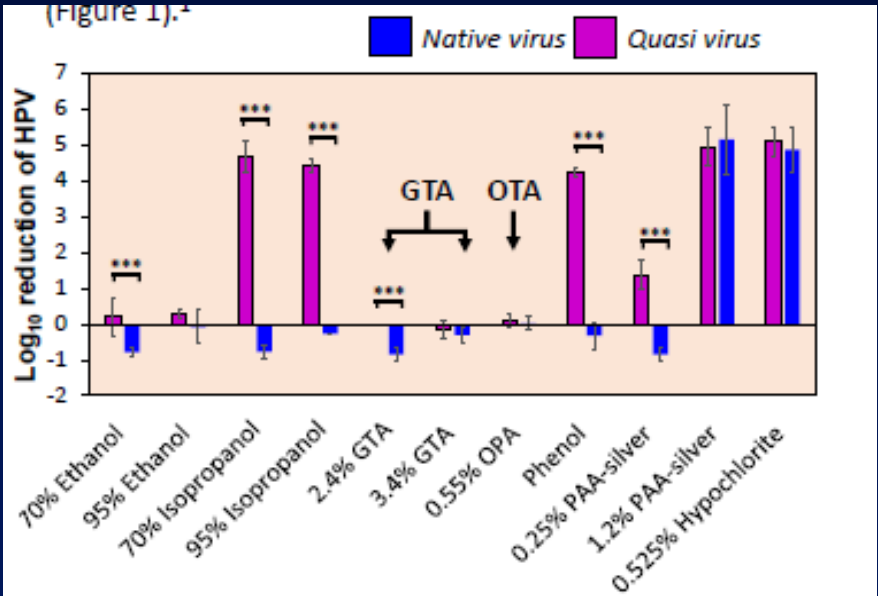
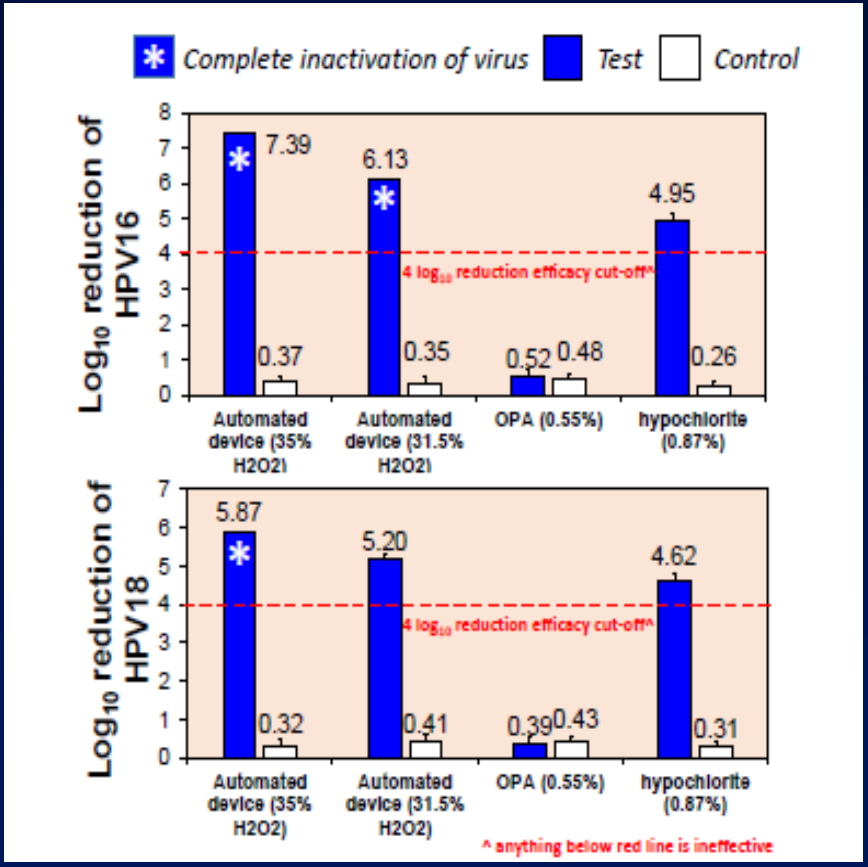


Figure 1: Susceptibility of HPV virions to clinical disinfectants. Both authentic virus and quasivirus were incubated with the indicated disinfectants for a contact time of 45 min. Disinfectants were neutralized and the virus was added to HaCaT cells for infection. Data shown are the averages of at least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

Efficacy of HP Mist Against HPV

Ryndock E et al. J Med Virol, 2016;88:1076-1080



- 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

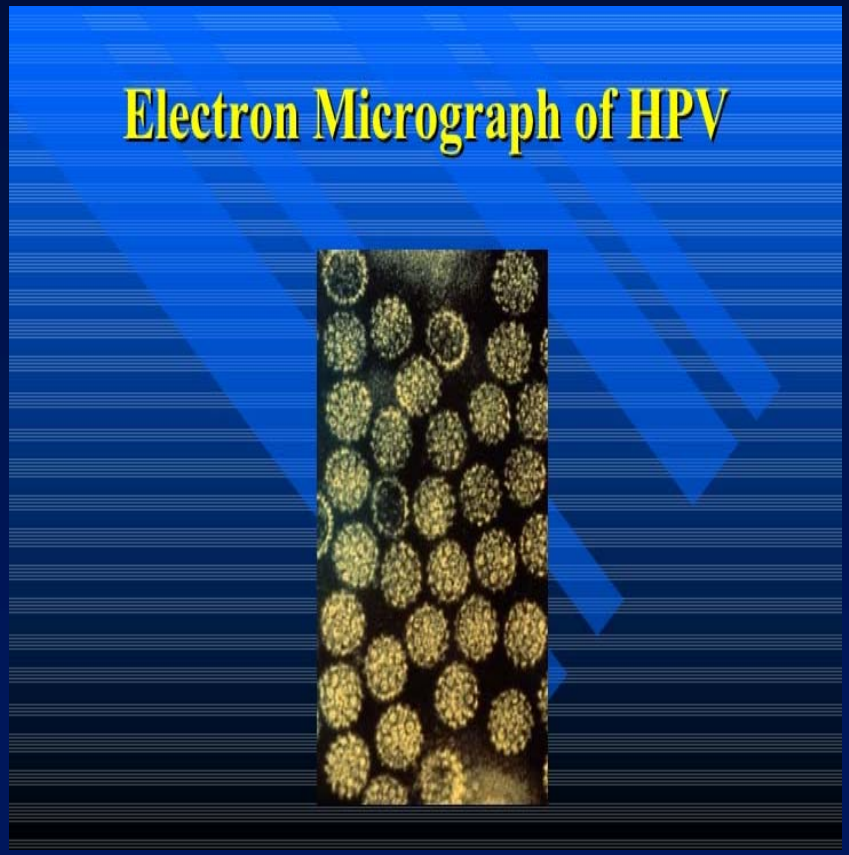
Effectiveness of Germicides Against HPV

(Dr. Carey Allen Moody, UNC and Duke UMC)

- Germicides
  - Aldehydes
    - Glutaraldehyde
    - Ortho-phthalaldehyde
  - Others
    - Phenolics
    - Ethanol
    - CHG-4%
    - Quats

- Germicides
  - Oxidizing agents
    - 1.5% and 2.0% accelerated HP
    - 0.525% sodium hypochlorite
    - 1% HP/0.08% peracetic acid
    - O.2% peracetic acid, 55^{o}C
    - 1000-1300ppm peracetic acid

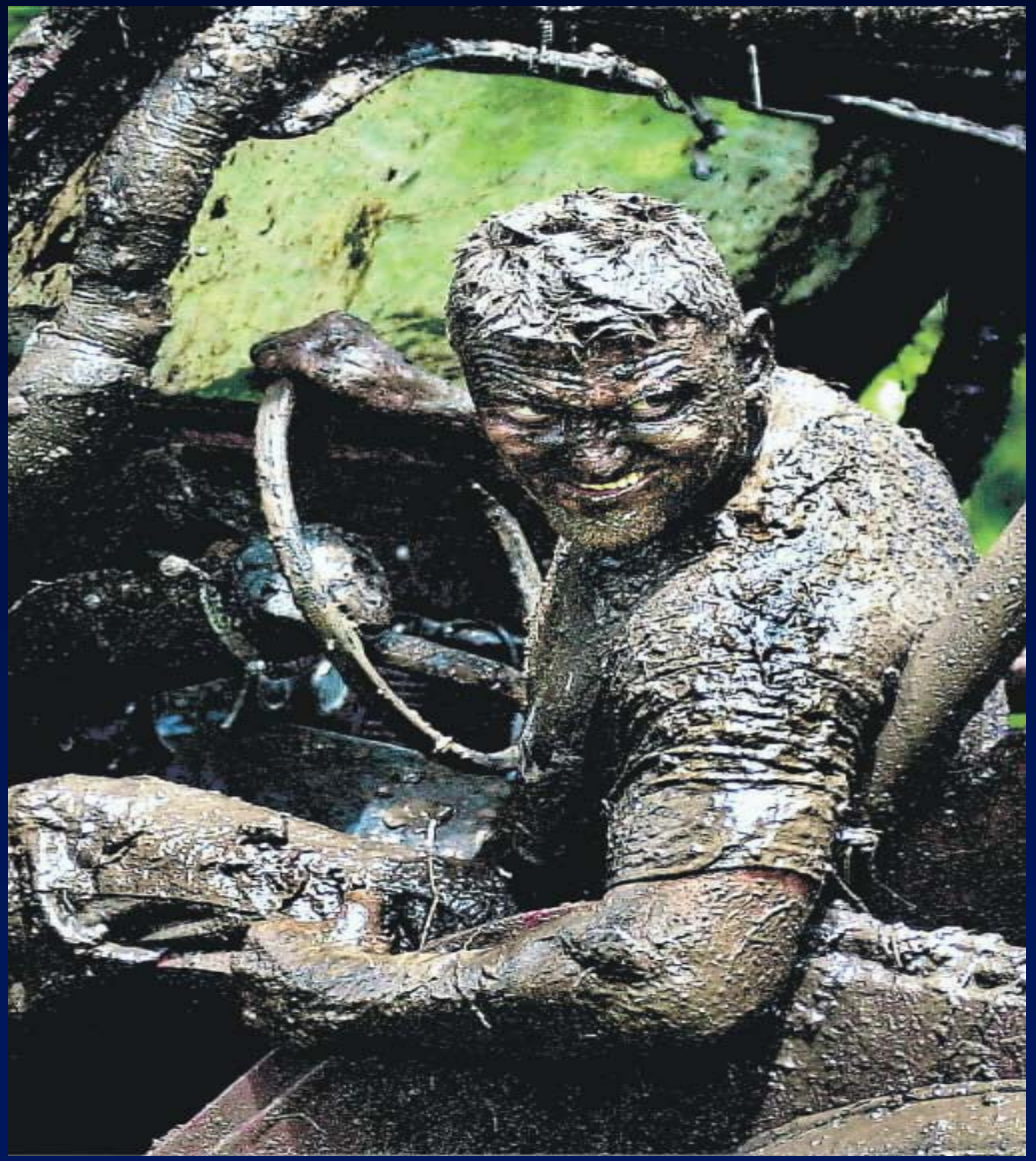
What if HPV is Resistant to Aldehydes?



- If unlike all other non-enveloped viruses that are susceptible to aldehydes
- Upset the Spaulding classification scheme (HLD kill all viruses)
- If only oxidizing agents kill HPV (transition to PA or HP alone or combination)

Endoscopes top ECRI's list of 10 health technology hazards

What does this off-road driver/vehicle have in common with endoscope? 10 Billion, complex



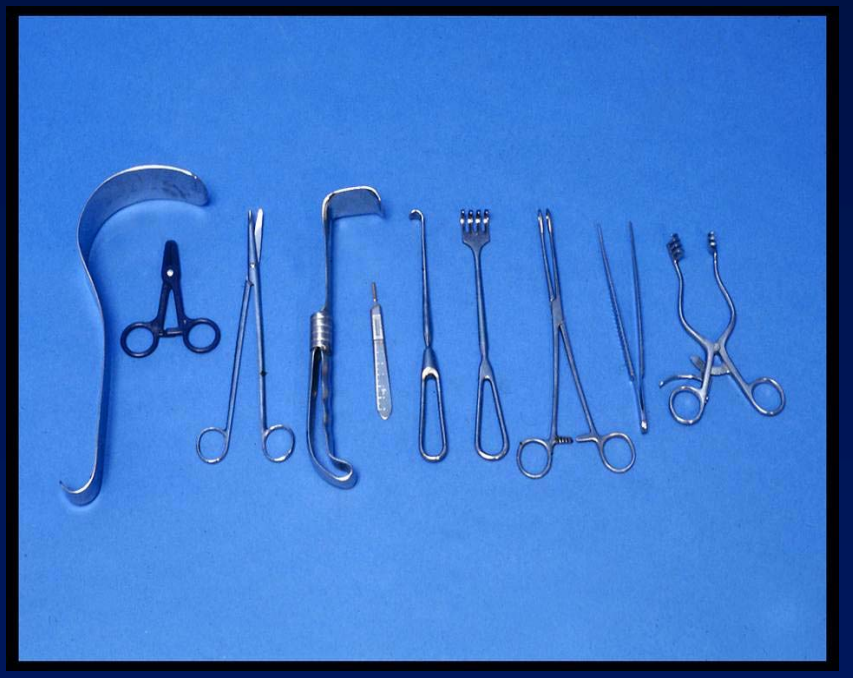
ENDOSCOPE REPROCESSING: CHALLENGES

Rutala, Weber Infect Control Hosp Epidemiol. 2015;36:643

Endoscope-10^7-10^{10}-crevices difficult to clean/disinfect



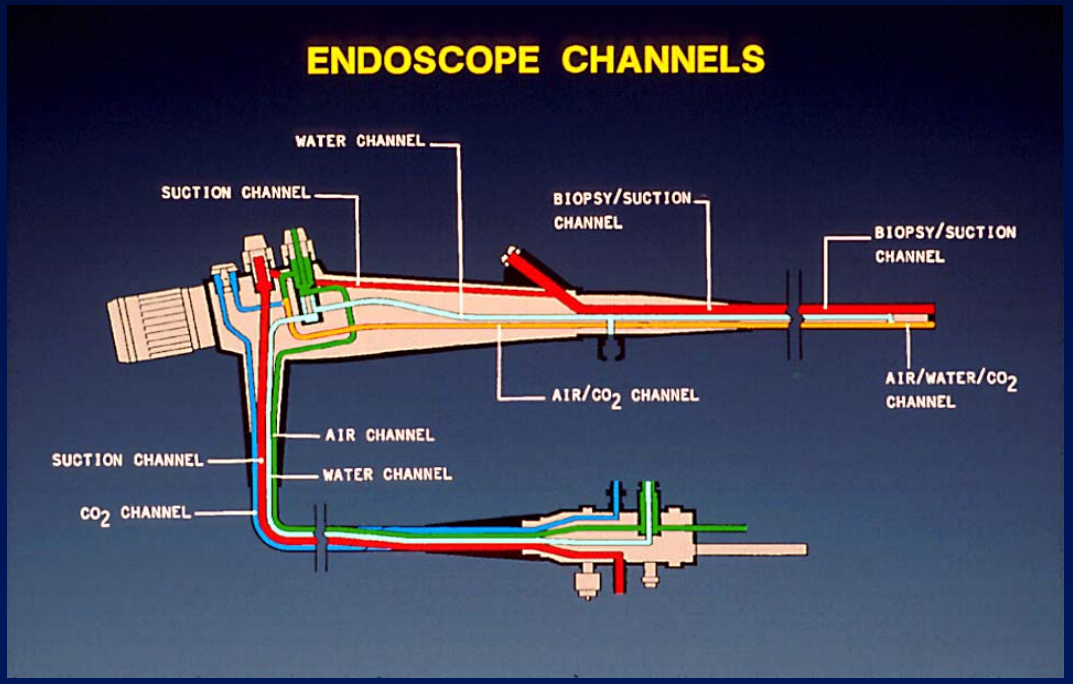
Surgical instruments-<10^2 bacteria



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



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
- Microbial load
  - GI endoscopes contain $10^{7\text{-}10}$
  - 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
- Biofilms-unclear if contribute to failure of endoscope reprocessing

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

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})

Disinfection and Sterilization

Rutala, Weber Am J Infect Control. 2016;44:e1-e7

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).

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

Technology Will Be Developed Sterilize Endoscopes or Use a Sterile, Disposable GI Scopes




THE
GOOD
THE
BAD
THE
UGLY

The Good



- Sterilization-highly effective
  - BIs, emerging technologies, sterilization endoscopes
- High-level disinfection
  - Endoscope-related infections will promote automation and sterilization
- Low-level disinfection
  - Eliminate environment as source- "No touch" room decontamination, new germicides, continuous room decontamination

The Bad



- Improve instrument reprocessing
  - Competency
  - Compliance with evidence-based guidelines
  - Research/Technology/ Automation

The Ugly



- Infection risks
  - Endoscopes
  - Human papilloma virus

Disinfection and Sterilization:
The Good, The Bad and The Ugly

Our Responsibility to the Future

Prevent All Infectious Disease Transmission by Instruments and the Environment in 5 years

Via Research/Technology/Automation/Competency

Five-Year Plan to Prevent Infections Associated with Instruments and Environment

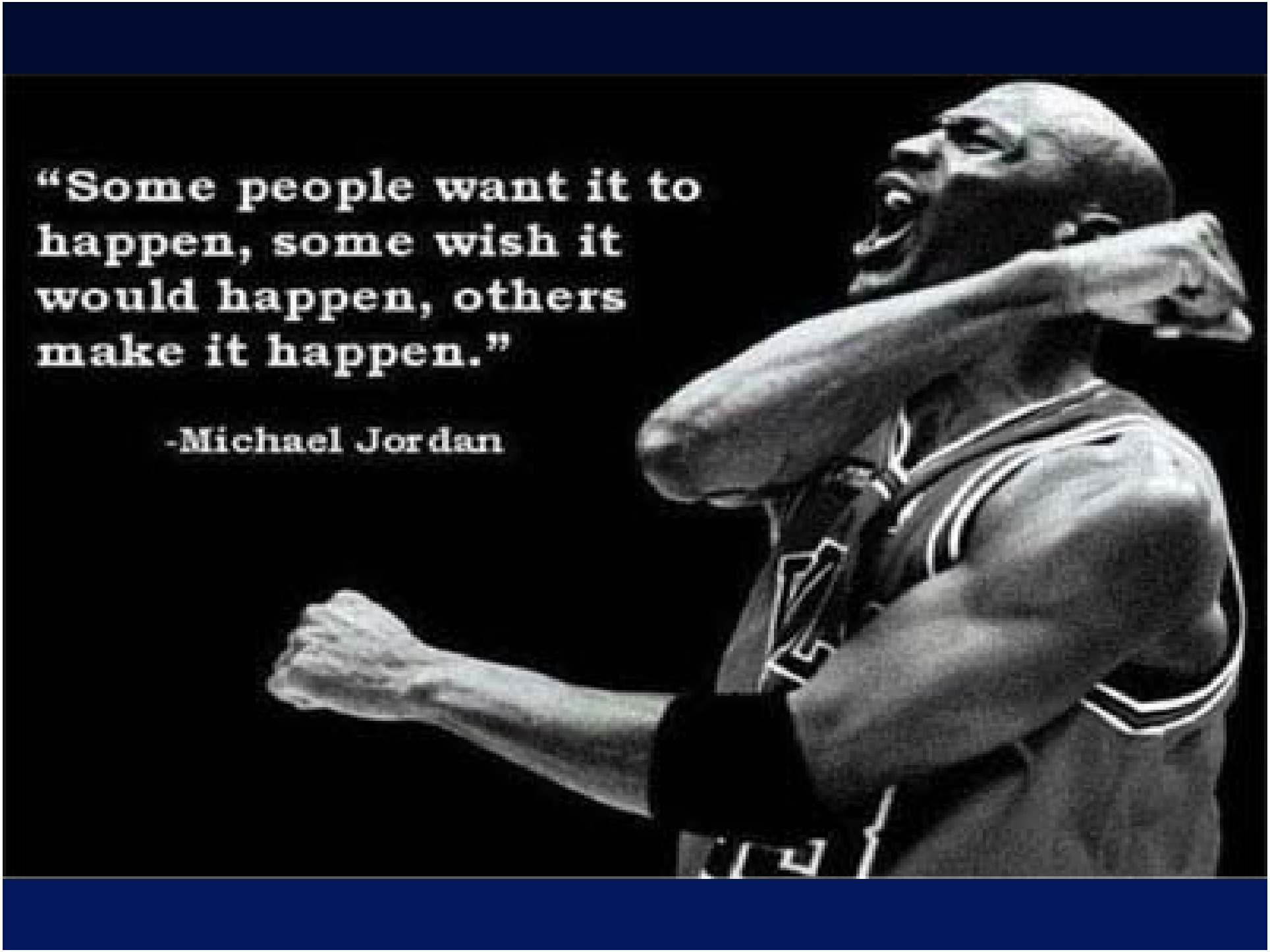
Research/Technology/Automation/Compliance

- Sterilization-highly effective
  - Comply with IFU/guidelines, competency, implement technologies/research
- High-Level Disinfection-no margin of safety
  - Transition to sterilization (margin of safety)-will require new technology, research (HPV) , automation and competency
- Low-Level Disinfection
  - Eliminate environment as source of HA pathogens by “no touch” room decontamination methods; continuous room decontamination; new surface disinfection technology

No Infections Associated with Instruments or the Environment

Set our goal, made a plan, we have a purpose, it is our passion that will make it happen!




"Some people want it to happen, some wish it would happen, others make it happen."
-Michael Jordan

THANK YOU!

www.disinfectionandsterilization.org



Spreading knowledge.

Preventing infection.



APIC

Association for Professionals in Infection Control and Epidemiology

