Disinfection and Sterilization:
Current Issues and Future Perspectives

William A. Rutala, Ph.D., M.P.H., C.I.C

Director, Statewide Program for Infection Control and Epidemiology and Professor of Medicine, University of North Carolina at Chapel Hill, NC, USA

Former Director, Hospital Epidemiology, Occupational Health and Safety, UNC Health Care, Chapel Hill, NC (1979-2017)

DISCLOSURES

2020-2021

- **Consultations**
  - PDI
- **Honoraria**
  - ASP, PDI
- **Other**
  - Kinnos

Disinfection and Sterilization: Current Issues and Future Perspectives

- Overview DS
- Sterilization-robustness
- HLD-What's new endoscope reprocessing
- HLD-outpatient care
- HLD-Human papillomavirus
- LLD-Electrostatic sprayers
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- Colorized disinfectant
- LLD-"no" touch room decontamination
- Emerging pathogens
  - SARS-CoV-2
  - CRE
  - *C.auris*
- Continuous room decontamination technologies
  - Continuously active disinfectant

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CDC Guideline for Disinfection and Sterilization

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

Accessible version: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

Update: May 2019

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]

[1]Hospital Epidemiology
University of North Carolina Health Care System
Chapel Hill, NC 27514

[2]Division of Infectious Diseases
University of North Carolina School of Medicine
Chapel Hill, NC 27599-7030

Disinfection and Sterilization

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

CRITICAL - objects which enter normally sterile tissue or the vascular system or through which blood flows should be **sterile.**

SEMICRITICAL - objects that touch mucous membranes or skin that is not intact require a disinfection process (**high-level disinfection[HLD]**) that kills all microorganisms but high numbers of bacterial spores.

NONCRITICAL -objects that touch only intact skin require **low-level disinfection**.

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Critical Medical/Surgical Devices

Rutala et al. ICHE 2014;35:883; Rutala et al. ICHE 2014;35:1068; Rutala et al. AJIC 2016;44:e47

- Critical
  - Transmission: direct contact
  - Control measure: sterilization
  - Surgical instruments
    - Enormous margin of safety, rare outbreaks
    - ~85% of surgical instruments <100 microbes
    - Washer/disinfector removes or inactivates 10-100 million
    - Sterilization kills 1 trillion spores

Sterilization of "Critical Objects"

Rutala, Weber, HICPAC. November 2008. www.cdc.gov; Rutala et al. AJIC 2019;47:A3-A9

Heat resistant

- Steam sterilization

Heat sensitive

- Ethylene oxide
- Hydrogen peroxide gas plasma
- Ozone and hydrogen peroxide
- Vaporized hydrogen peroxide

DISINFECTION AND STERILIZATION

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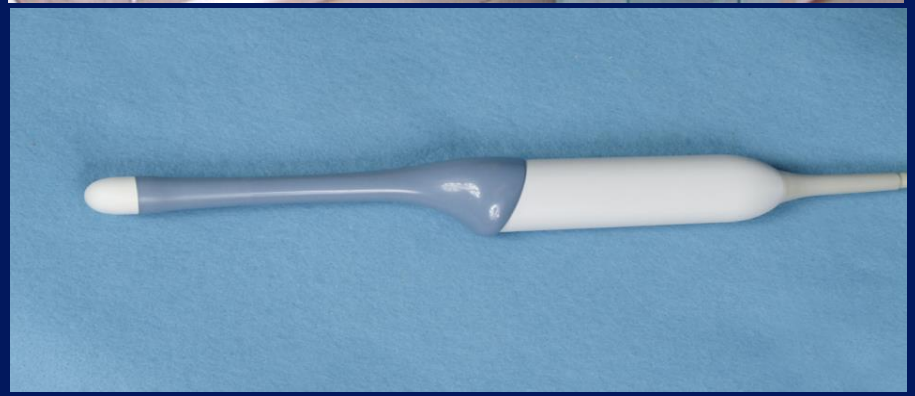
Semicritical Medical Devices

Rutala et al. AJIC 2016;44:e47



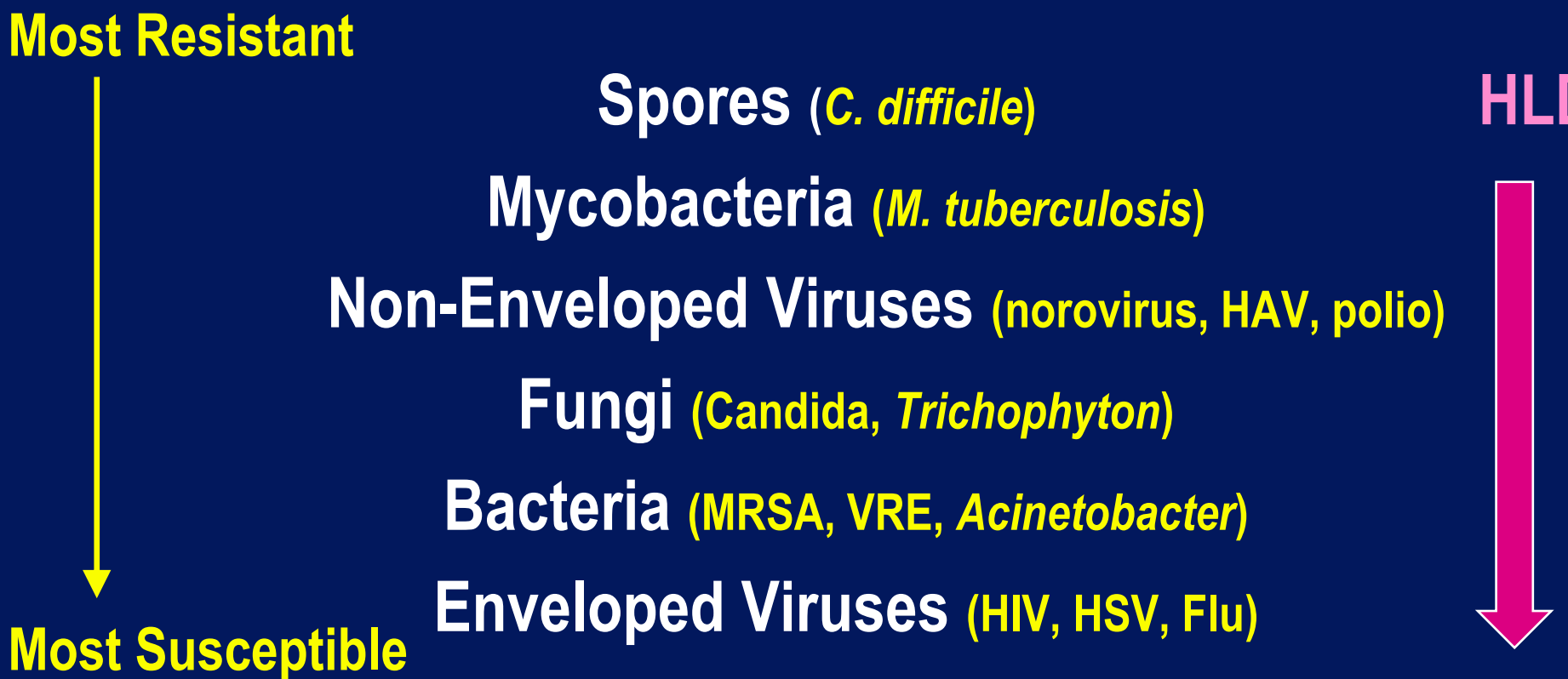
- Semicritical
  - Transmission: direct contact
  - Control measure: high-level disinfection
  - Endoscopes top ECRI list of 10 technology hazards, >130 outbreaks (GI, bronchoscopes)
    - 0 margin of safety
      - Microbial load, 10^7-10^{10}
      - Complexity
      - Biofilm
  - Other semicritical devices, rare outbreaks
    - ENT scopes, endocavitary probes (prostate, vaginal, TEE), laryngoscopes, cystoscopes
    - Reduced microbial load, less complex

Semicritical Items

- Endoscopes
- Respiratory therapy equipment
- Anesthesia equipment
- Endocavitary probes
- Tonometers
- Laryngoscopes

Microbiological Disinfectant Hierarchy

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



High-Level Disinfection of "Semicritical Objects"

Rutala, Weber. AJIC 2019;47:A3-A9

Germicide	Exposure Time ≥ 8m-45m (US), 20°C 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

Environmental Contamination Leads to HAIs

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

Evidence environment contributes

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

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Clean/disinfect at least daily (one-step cleaning and disinfection)

LOW-LEVEL DISINFECTION FOR NONCRITICAL EQUIPMENT AND SURFACES

Rutala, Weber. Infect Control Hosp Epidemiol. 2014;35:855-865; Rutala, Weber. AJIC 2019;47:A3-A9

Exposure time ≥ 1 min

Germicide	Use Concentration
Ethyl or isopropyl alcohol	70-90%
Chlorine	100ppm (1:500 dilution)
Phenolic	UD
Iodophor	UD
Quaternary ammonium (QUAT)	UD
QUAT with alcohol	RTU
Improved hydrogen peroxide (HP)	0.5%, 1.4%
PA with HP, 4% HP, chlorine (*C. difficile*)	UD

UD=Manufacturer's recommended use dilution; others in development/testing-electrolyzed water; polymeric guanidine; cold-air atmospheric pressure plasma (Boyce Antimicrob Res IC 2016. 5:10)

Microbiological Disinfectant Hierarchy

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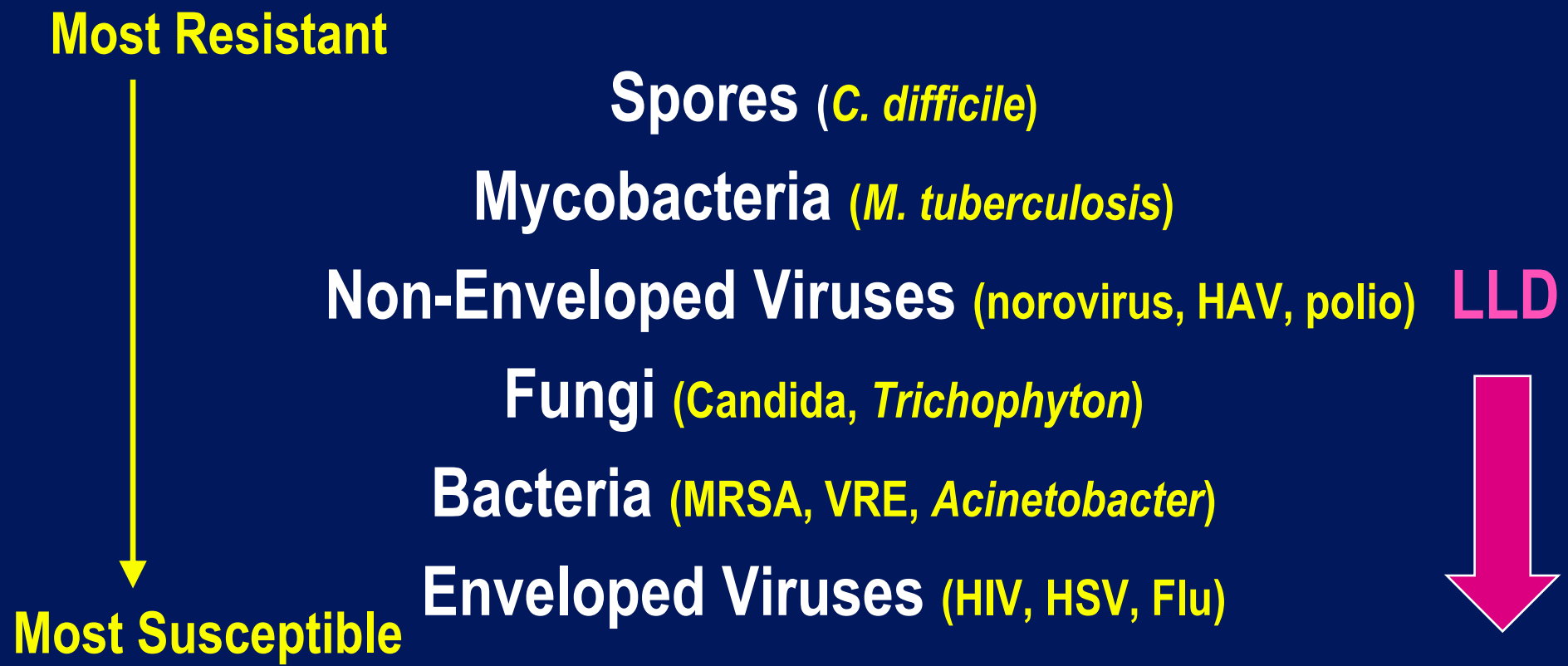

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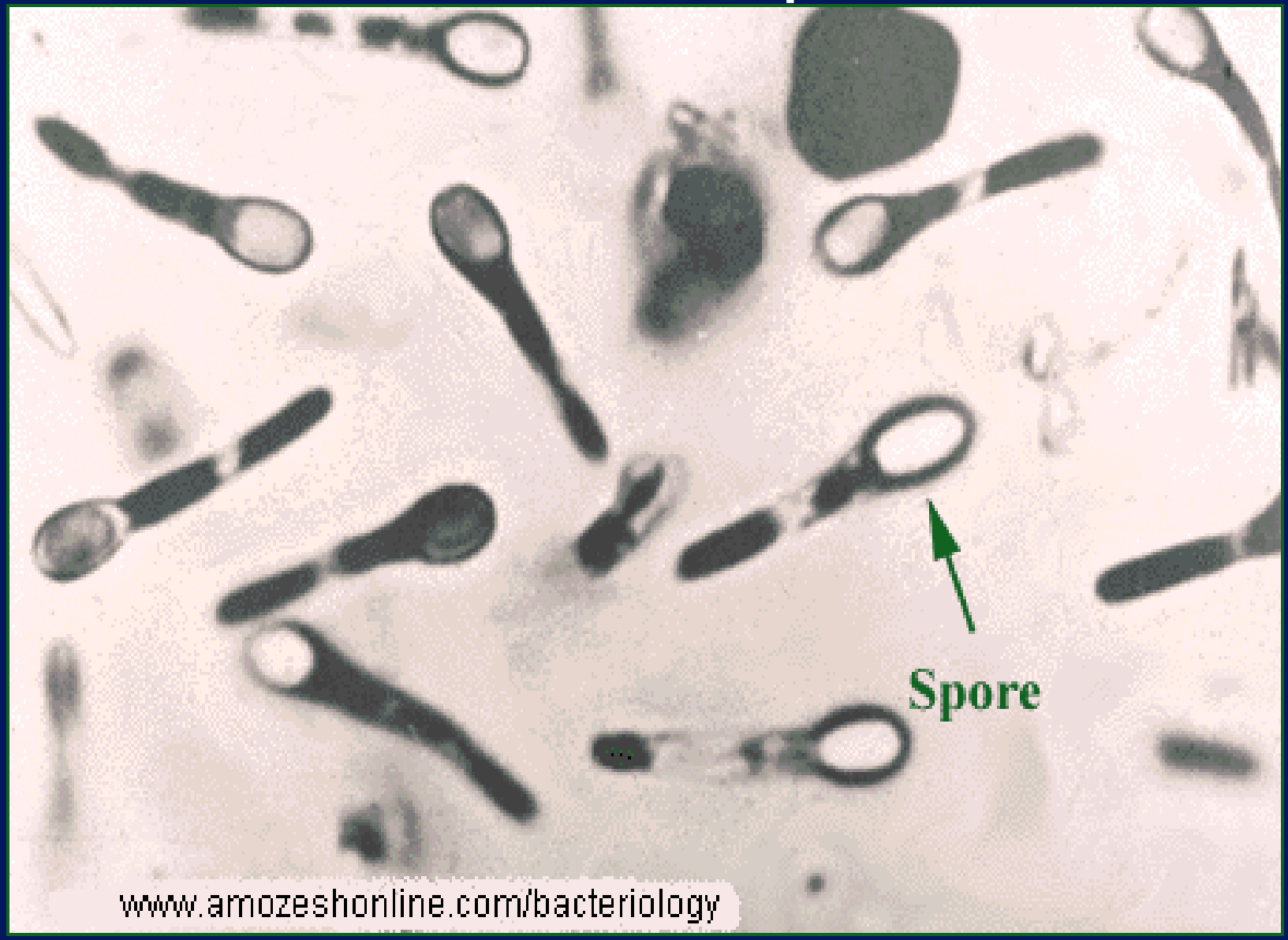
C. difficile spores



INACTIVATION OF MURINE AND HUMAN NOROVIRUES

Disinfectant, 1 min	MNV Log_{10} Reduction	HNV Log_{10} Reduction
70% Ethanol	>4 (3.3 at 15sec)	2
70% Isopropyl alcohol	4.2	2.2
65% Ethanol + QUAT	>2	3.6
79% Ethanol + QUAT	3.4	3.6
Chlorine (5,000ppm)	4	3
Chlorine (24,000ppm)	2.4	4.3
Phenolic, QUAT, Ag, 3% H_20_2	≤1	≤1 (2.1 QUAT)
0.5% Accel H_20_2	3.9	2.8

Rutala WA, Folan MP, Tallon LA, Lyman WH, Park GW, Sobsey MD, Weber DJ. 2007

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- Continuous room decontamination technologies
  - Continuously active disinfectant
  - Visible light disinfection through LEDs
  - Low concentration hydrogen peroxide

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

“Dirty” (non-cleaned) Instruments

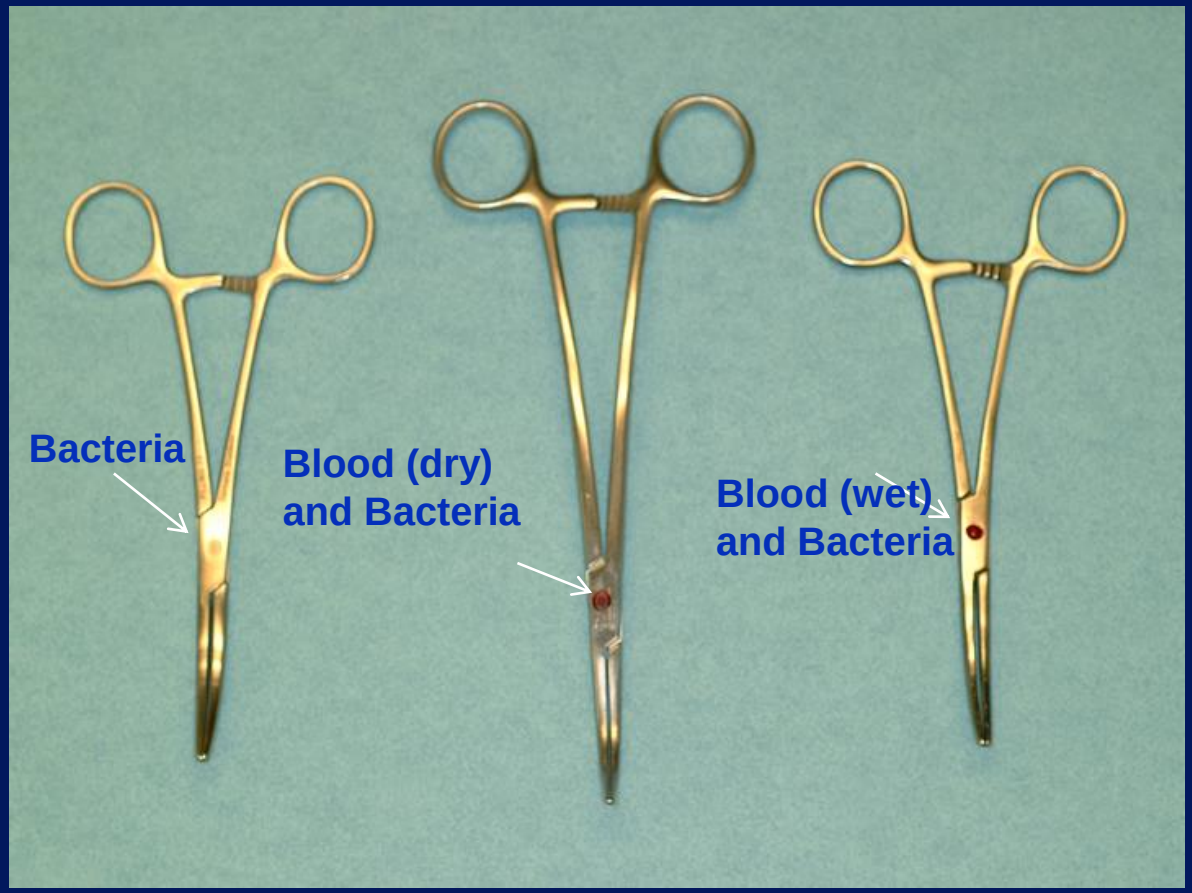

Table 1. Effectiveness of the Microbicidal Activity of Sterilization Technologies in the Presence of Blood on "Dirty" Instruments[a]

Test Organism	Method of Sterilization	Instruments "Dirty" (Uncleaned) With or Without Blood[b]	Instrument Quantitation (Mean)	No. of Positives/ No. of Runs (% Positive)
Geobacillus stearothermophilus (spores)	Steam Sterilization	Dirty	~ 1.56×10^5	0/10 (0)
		Dirty with blood (spores mixed with blood not sandwich[b])	~1.99×10^5	0/12 (0)
	ETO	Dirty	~1.53×10^5	0/10 (0)
		Dirty with blood	~2.35×10^5	0/11 (0)
	HPGP	Dirty	~1.58×10^5	5/10 (50)
		Dirty with blood	~2.35×10^5	9/15 (60)
Mycobacterium terrae	Steam Sterilization	Dirty	~4.25×10^6	0/10 (0)
P. aeruginosa	HPGP	Dirty	~1.81×106	3/15 (20)
Bacillus atrophaeus (spores)	ETO	Dirty	~ 2.30×10^7	6/10 (60)
		Dirty with blood	~4.08×10^7	9/10 (90)
MRSA	ETO	Dirty	~2.62×10^6	0/10 (0)
		Dirty with blood	~1.72×10^6	0/10 (0)
	HPGP	Dirty	~1.10×10^6	4/10 (40)
		Dirty with blood	~1.27×10^6	4/10 (40)
	Steam sterilization	Dirty	2.56×10^6	0/10 (0)
		Dirty with blood	5.20×10^5	0/10 (0)
VRE	ETO	Dirty	~2.27×10^6	0/10 (0)
		Dirty with blood	~3.59×10^6	0/10 (0)
	HPGP	Dirty	~2.63×10^6	3/10 (30)
		Dirty with blood	~2.34×10^6	9/10 (90)
	Steam sterilization	Dirty	1.90×10^6	0/10 (0)
		Dirty with blood	2.72×10^5	0/10 (0)

Note. ETO, ethylene
[a]Study conditions no
[b]Sandwich consists
experiment was don

rmophilus

Effectiveness of the Microbicidal Activity of Steam Sterilization in the Presence of Blood on "Dirty" Instruments

Rutala et al. Infect Cont Hosp Epidemiol 2021 https://doi.org/10.1017/ice.2021.202

Test Organism	Method of Sterilization	Instruments "dirty" (non-cleaned) with or without blood[2]	Instrument Quantitation (Mean)	% Positive
Geobacillus stearothermophilus (spores)	Steam Sterilization	Dirty	~ 1.56×10^5	0/10 (0)
		Dirty with blood (spores mixed with blood not sandwich[2])	~ 1.99×10^5	0/12 (0)
Mycobacterium terrae	Steam Sterilization	Dirty	~ 4.25×10^6	0/10 (0)

[1]Study conditions not representative of practice or manufacturer's recommendations.

[2]Sandwich consists of "dirty" or non-cleaned instrument, then an inoculum of spores or vegetative bacteria, and lastly overlaid with blood after inoculum dry. One *G. stearothermophilus* experiment was done with the spores mixed with the inoculum and then placed on the dirty instrument.

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Infections/Outbreaks Associated with Semicritical Medical Devices

Rutala, Weber, AJIC 2019;47:A79-A89

Medical Device	No. Outbreaks/Infections	No. Outbreaks/Infections with Bloodborne Pathogens
Vaginal Probes	0	0
Ear-Nose-Throat Endoscopes	0	0
Urologic instruments (e.g. cystoscopes)	8	0
Hysteroscopes	0	0
Laryngoscopes	2	0
Transrectal ultrasound guided prostate	1	0
Applanation tonometers	2	0
TEE-Transesophageal echocardiogram	5	0
GI Endoscopes/Bronchoscopes	~130	3 (HBV-1 GI; HCV-2 GI; HIV-0)

Reason for Endoscope-Related Outbreaks

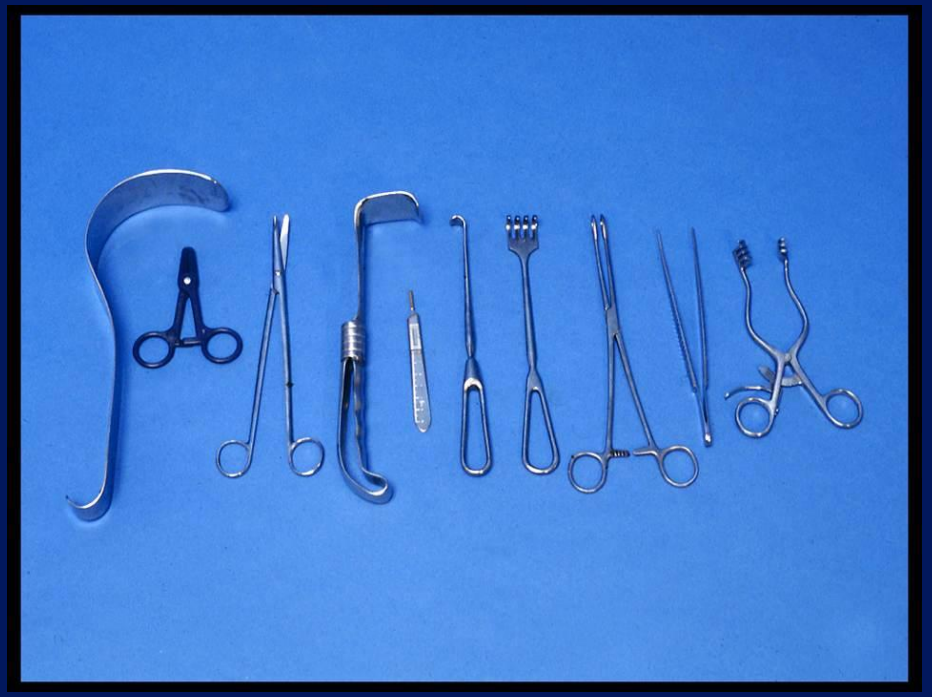
Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

- Margin of safety with endoscope reprocessing minimal or non-existent
- Microbial load
  - GI endoscopes contain 10^{7-10}
  - 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
- Biofilms-could contribute to failure of endoscope reprocessing

ENDOSCOPE REPROCESSING: CHALLENGES

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

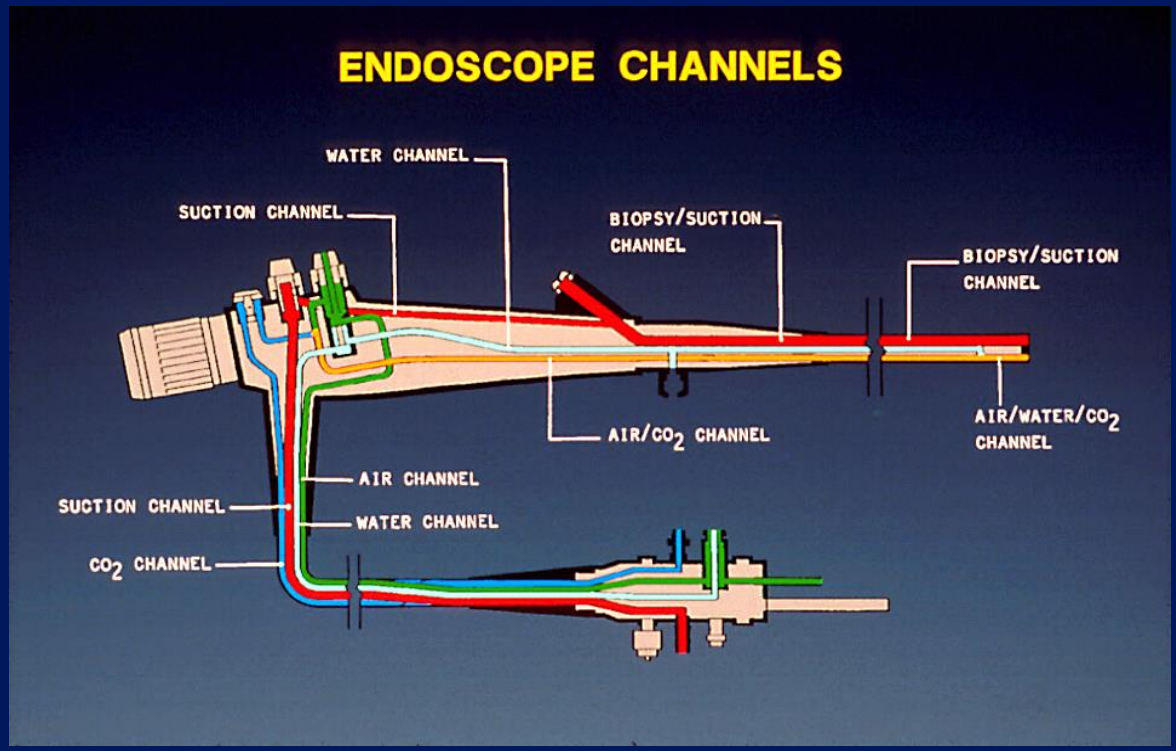
Surgical instruments-<10^{2} bacteria



FEATURES OF ENDOSCOPES THAT PREDISPOSE TO DISINFECTION FAILURES

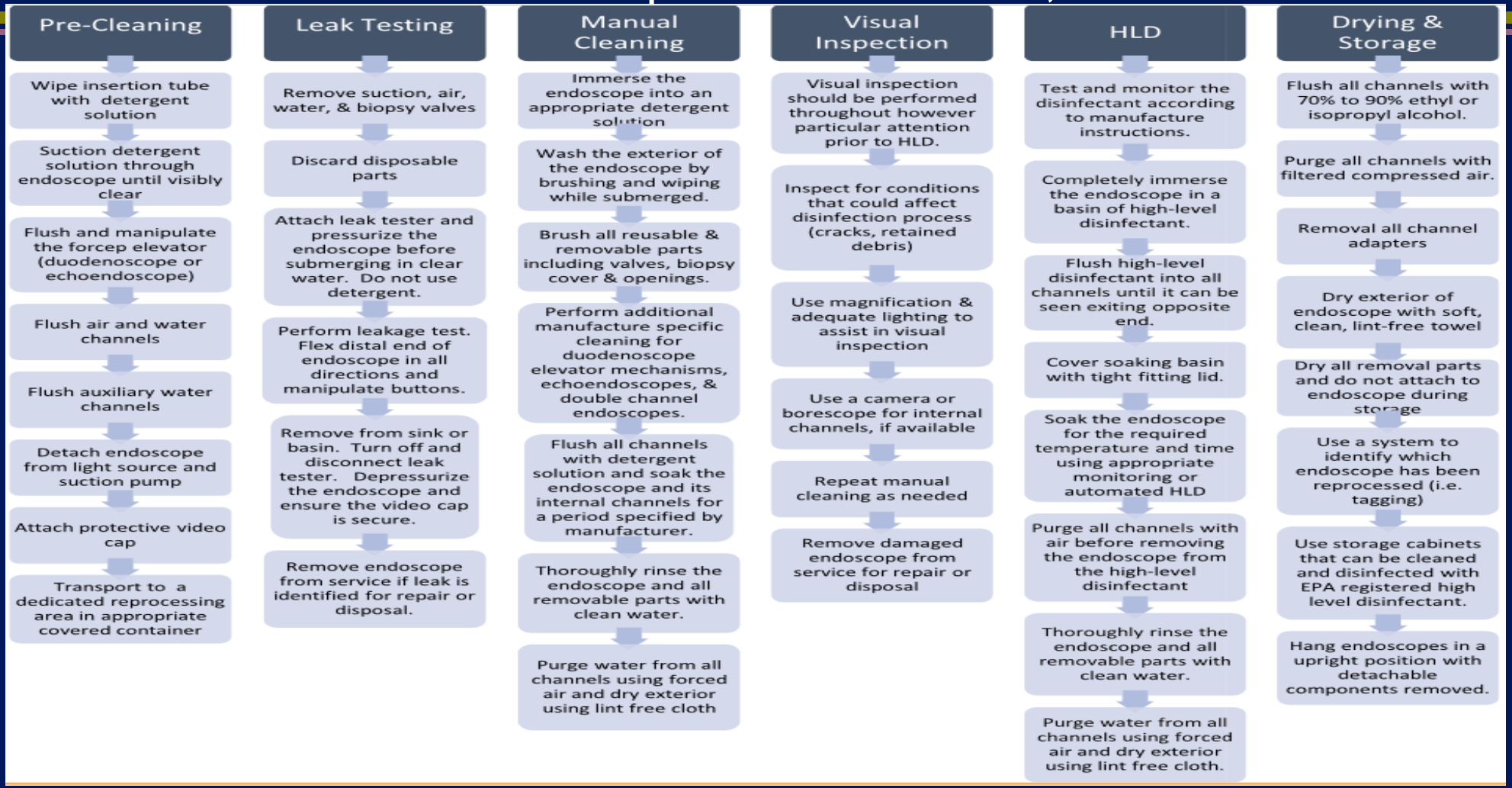
Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

- Heat labile
- Long, narrow lumens (3.5ft, 1-3mm)
- Right angle bends
- Rough or pitted surfaces
- Springs and valves
- Damaged channels may impede microbial exposure to HLD
- Heavily contaminated with pathogens, $10^{7\text{-}10}$
- Cleaning (2-6 $\log_{10}$ reduction) and HLD (4-6 $\log_{10}$ reduction) essential for patient safe instrument



Complexity of Endoscope Reprocessing

Chua et al. Techniq Innov Gastro Endo 2021;23:190



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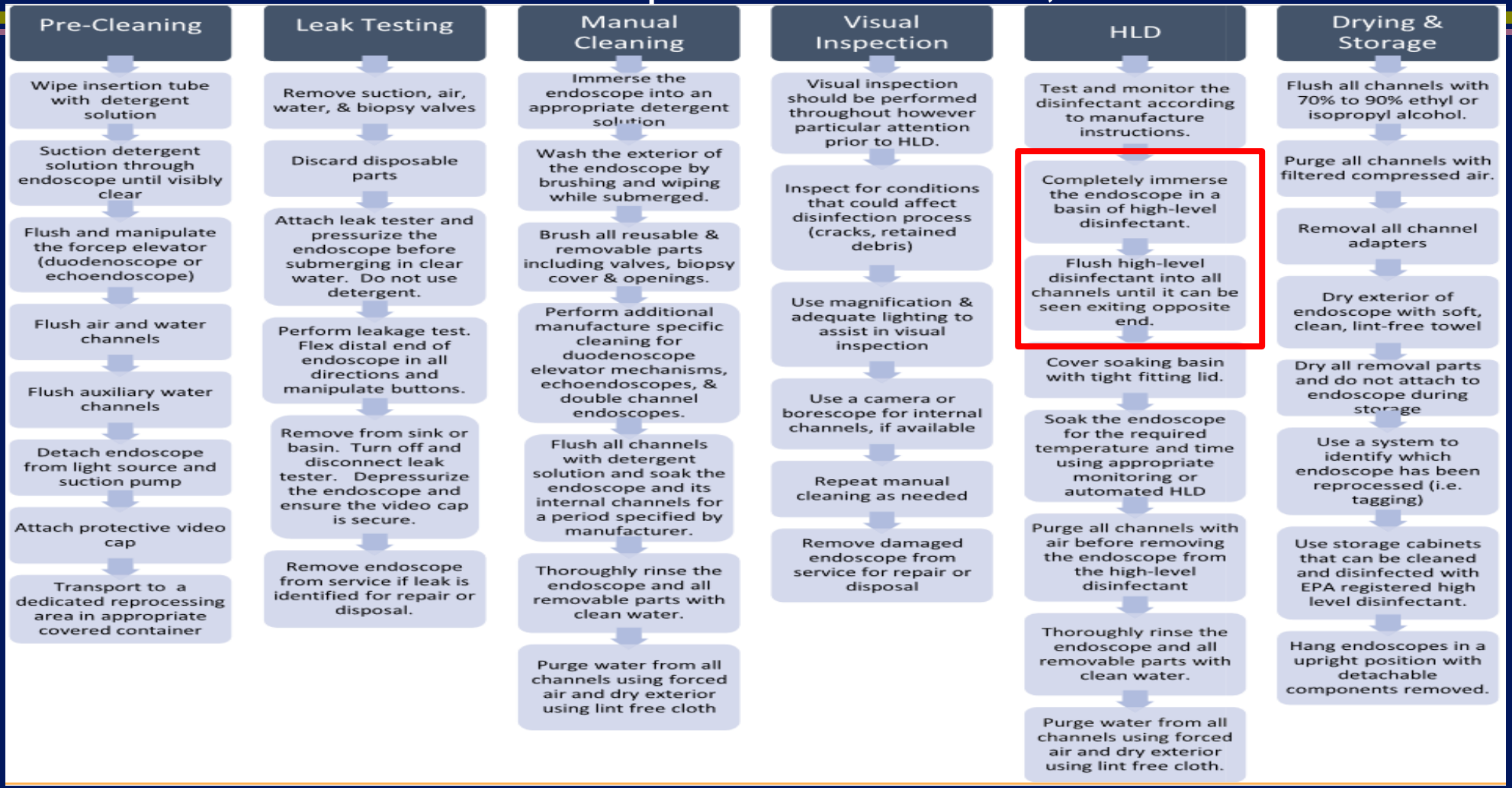
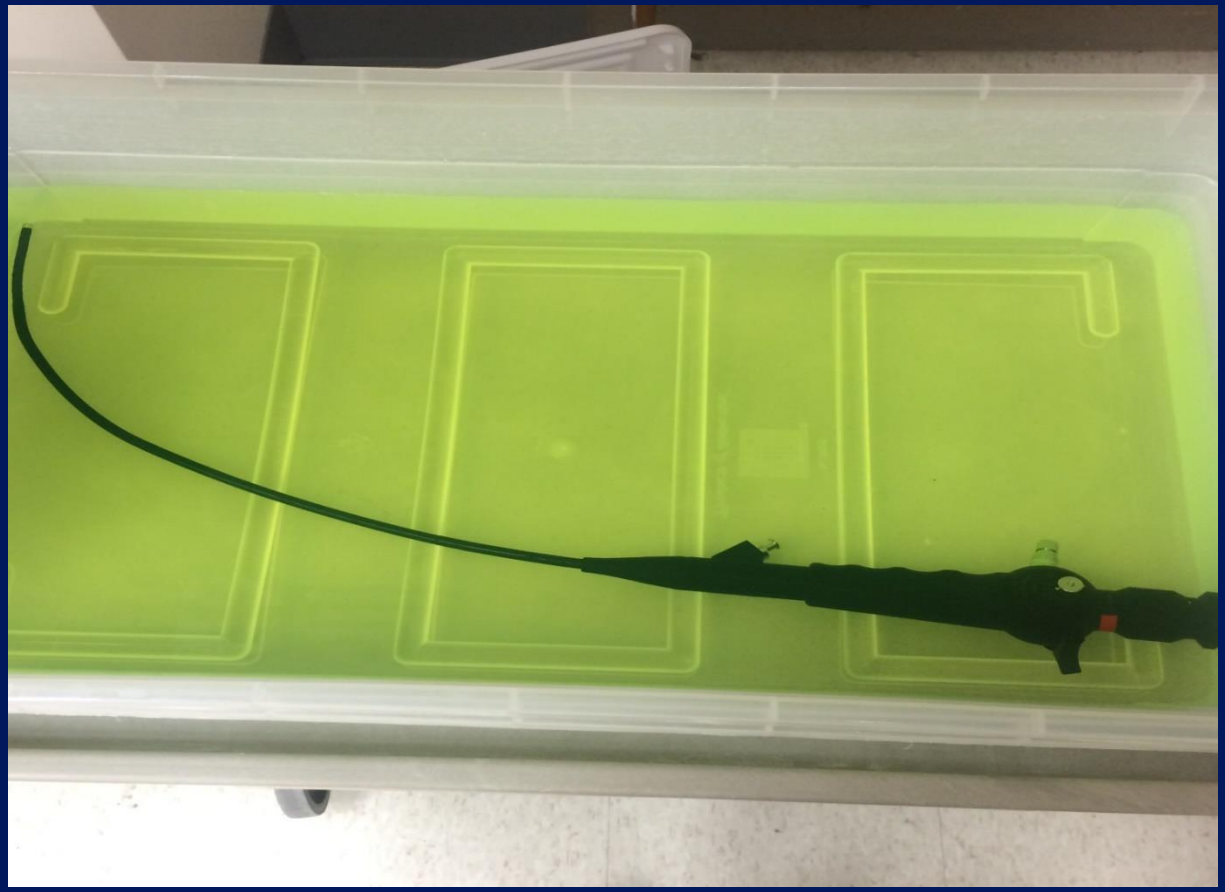


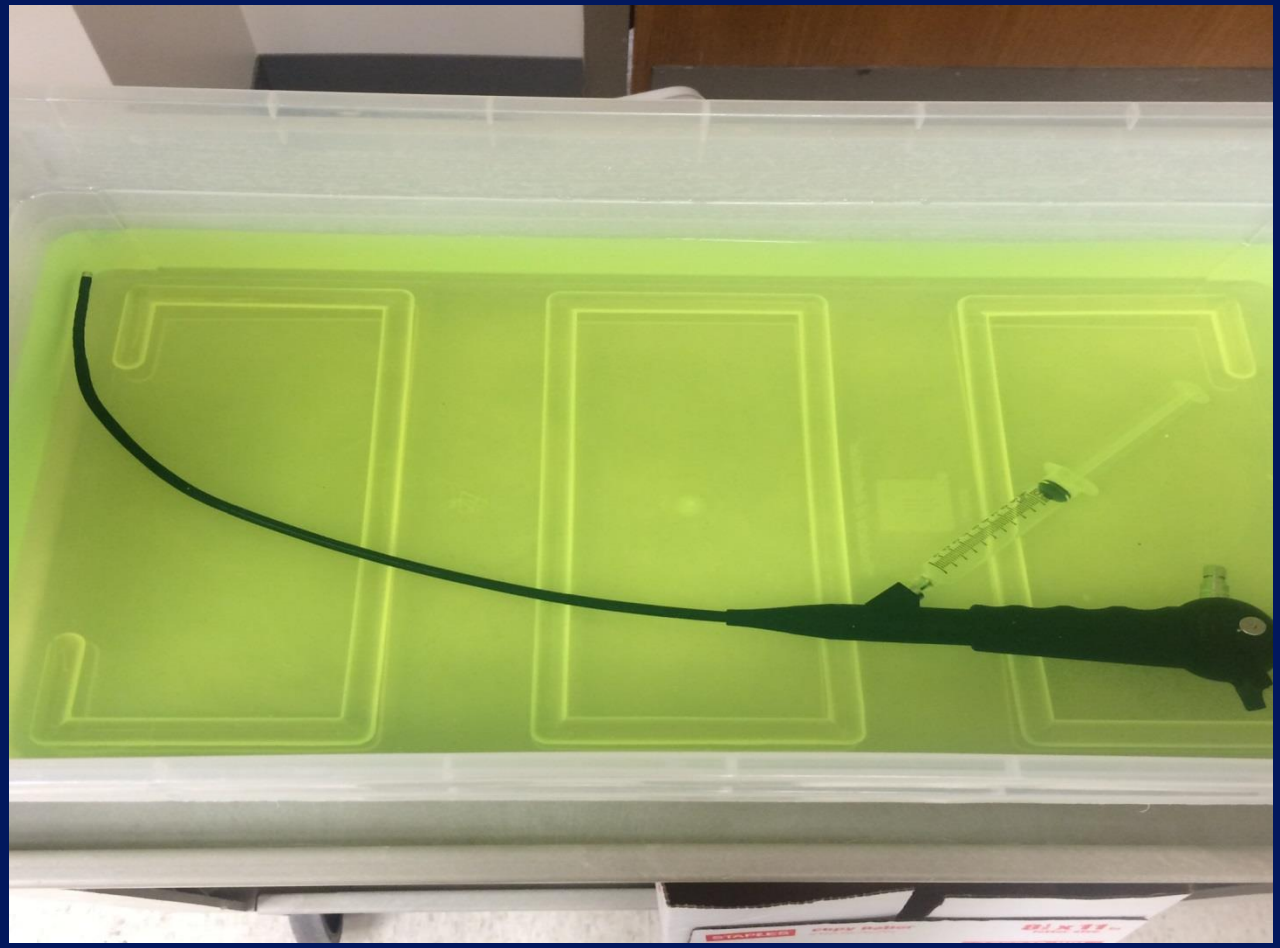
Reprocessing Channeled Endoscopes Manually

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



Reprocessing Channeled Endoscopes Manually

Cystoscope-HLD perfused through lumen with syringe (luer locks onto port and syringe and lumen filled with HLD)



Reprocessing Channeled Endoscopes Manually

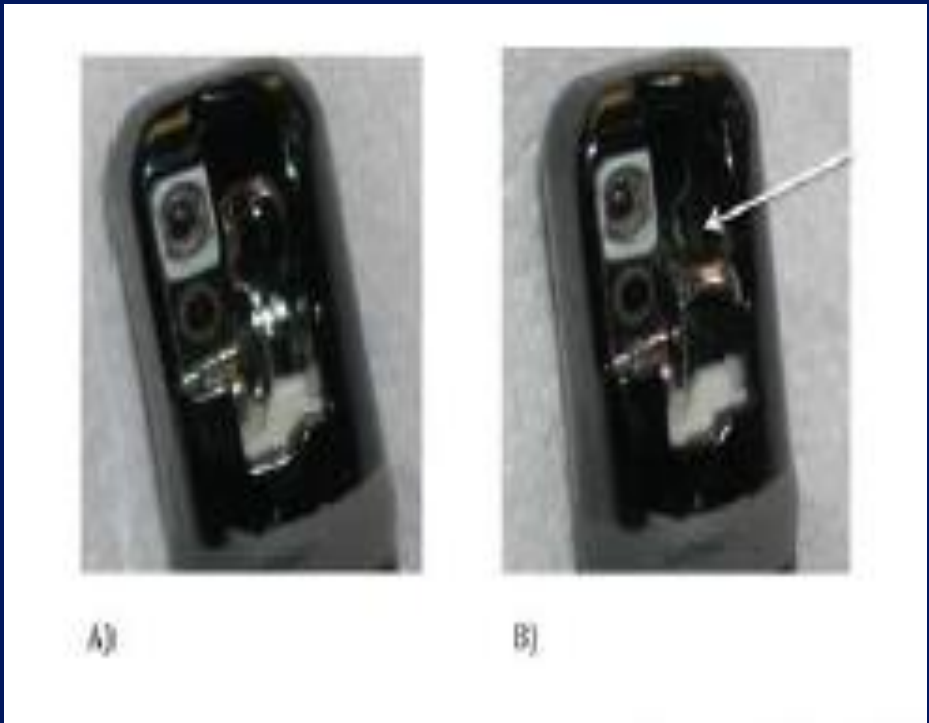
Rutala, Gergen, Bringhurst, Weber. ICHE. 2016;37:228-231

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

Duodenoscope Lever Position

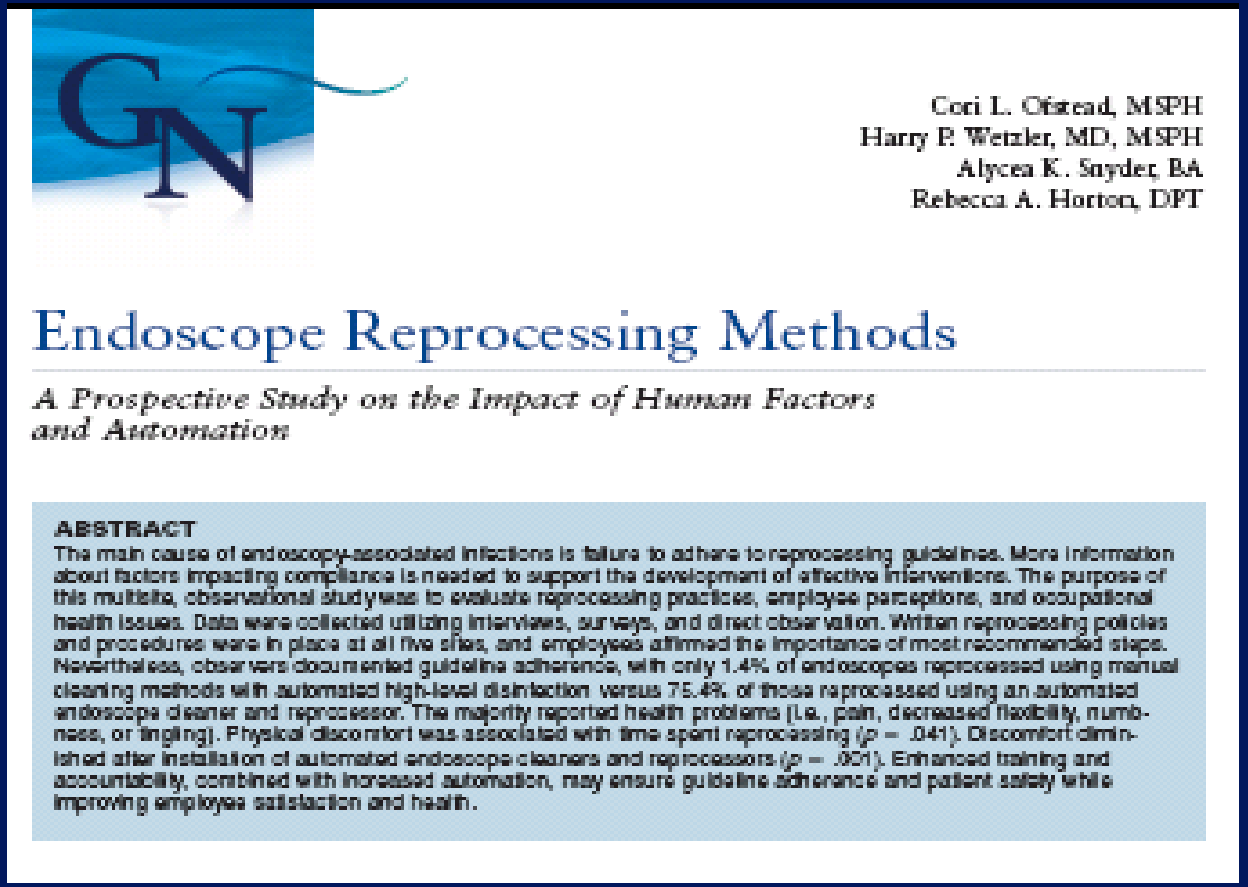
Alfa et al. AJIC 2018;46:73-75



- Bacteria will survive if the elevator lever was improperly positioned (in horizontal position instead of 45^{o}) in AER
- *E. faecalis* (7 log inoculum, 2-6 log recovered) and *E. coli* (0-3 log) survived disinfection of sealed and unsealed elevator wire channel duodenoscopes in 2 different AERs
- Ensure proper lever position when placed in AERs with PA

Endoscope Reprocessing Methods

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



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

Endoscope Reprocessing Methods

A Prospective Study on the Impact of Human Factors and Automation

ABSTRACT

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

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

AERs automate and standardize endoscope reprocessing steps

“Given the choice of improving technology or improving human behavior, technology is the better choice”

Robert A. Weinstein, MD

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)

Evidence-Based Recommendation for Sterilization of Endoscopes

(FDA Panel Recommendation for Duodenoscopes, May 2015; more peer-reviewed publications (>150) for the need for shifting from disinfection to sterilization than any other recommendation of AAMI, CDC [HICPAC], SHEA, APIC, SGNA, ASGE)

>130 plus endoscope-related outbreaks

GI endoscope contamination rates of 20-40% after HLD

Scope commonly have disruptive/irregular surfaces

>50,000 patient exposures involving HLD

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,

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})

What Should We Do Now?

Supplemental Measures to Reduce Infection Risk

Rutala WA, Weber DJ. ICHE 2015;36:643-648; Rutala et al. AJIC 2019:47:A62

Hospitals performing ERCPs should do one of the following; FDA adopted these recommendations

- **Ethylene oxide sterilization** after high level disinfection with periodic microbiologic surveillance
- **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

Did supplemental measures work?

Randomized Trial of Single versus Double HLD of Duodenoscopes

Bartles et al Gastro Endos 2018;88:306

Double HLD demonstrated no benefit over single HLD; no significant differences observed

TABLE 2. Summary of culture positivity rates in the 2 study arms

	Double HLD	Single HLD	*P* value*
	All cultures		
Specimen-based			
No. of specimens	3052	2798	
Any growth	127 (4.2)	108 (3.9)	.60 (.64)
Growth of high-concern pathogens	3 (.1)	5 (.2)	.49 (.43)
Encounter-based			
No. of encounters	1526	1399	
Any growth	122 (8.0)	102 (7.3)	.52 (.54)
Growth of high-concern pathogens	3 (.2)	5 (.4)	.49 (.43)

Supplemental Measures for Endoscope Reprocessing

Day et al. Gastro Endosc 2021;93:11-35; Gromski et al. Gastro Endosc 2021;93:927; Synder et al. Gastroenterology 2017;153:1018; Bartles et al Gastro Endos 2018;88:306

- In a nonoutbreak setting, repeat HLD has no additional benefit compared with single HLD in reducing bacterial contamination rates for duodenoscopes
- In nonoutbreak setting, limited data suggest that ETO sterilization does not reduce bacterial contamination rates in duodenoscopes compared with single HLD
- No significant difference of positive cultures when comparing double HLD (8) with duodenoscopes undergoing liquid chemical sterilant (9).
- The use of ETO sterilization on duodenoscopes during infectious outbreaks has been associated with terminating these outbreaks and such a modality should be considered in selected settings and patient populations
- However, many barriers to widespread use of ETO including cost, only 20% hospital use ETO (availability), possible damage to scopes, exposure of staff to ETO, exposure/turnaround time

Where are we?

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 (proposed clarification).

CRITICAL - objects which directly or indirectly/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).

Future/Novel Approaches to Endoscope Reprocessing to Improve Patient Safety

Rutala et al. AJIC 2019:47:A62; Chua et al. Techniq Innov Gastro Endo 2021;23:190

- Antimicrobial detergents-reduce microbial contamination
- Automated Endoscope Reprocessing-HLD should be provided in an approved AER (manual-1.4% compliance vs 75.4% using AER)
- Endoscope sterilization-materials compatibility, throughput
- Disposable endoscopes (device innovations)
  - Partially (endcap)-does it decrease bacterial contamination after HLD
  - Fully-GI and bronchoscopes; cost, scope performance
- Use of non-endoscopic methods to diagnose or treat disease
- Assessment tool that is predictive of microbial contamination or infection risks

Characteristics of Disposable Duodenoscopes

Chua et al. Techniq Innov Gastro Endo 2021;23:190

Table 2. Characteristics of disposable duodenoscopes.

	EvisExera III TJF-Q190V (Olympus)	ED34-i10T (Pentax)	ED34-i10T2 (Pentax)	ED-580XT (Fujifilm)	EXALT Model D (Boston Scientific)	aScopeDuodeno (Ambu)
Disposable component	Endcap	Endcap	Endcap	Endcap	Entire endoscope	Entire endoscope
Field of view (degrees)	100	100	100	100	108	130
Depth of view (mm)	5-60	4-60	4-60	4-60	5-60	Not available
Working length (mm)	1240	1250	1250	1250	1240	1240
Instrument channel (mm)	4.2	4.2	4.2	4.2	4.2	4.2
Insertion tube diameter (mm)	11.3	11.6	11.6	11.3	11.3	11.3
Distal end diameter (mm)	13.5	13	13	13.1	15.1	13.7
Distal end with endcap (mm)	13.5	13.8	13.4	14.9	15.1	13.7

Implementing these advances will allow us to prevent endoscope-related infections

Disinfection and Sterilization: Current Issues and Future Perspectives

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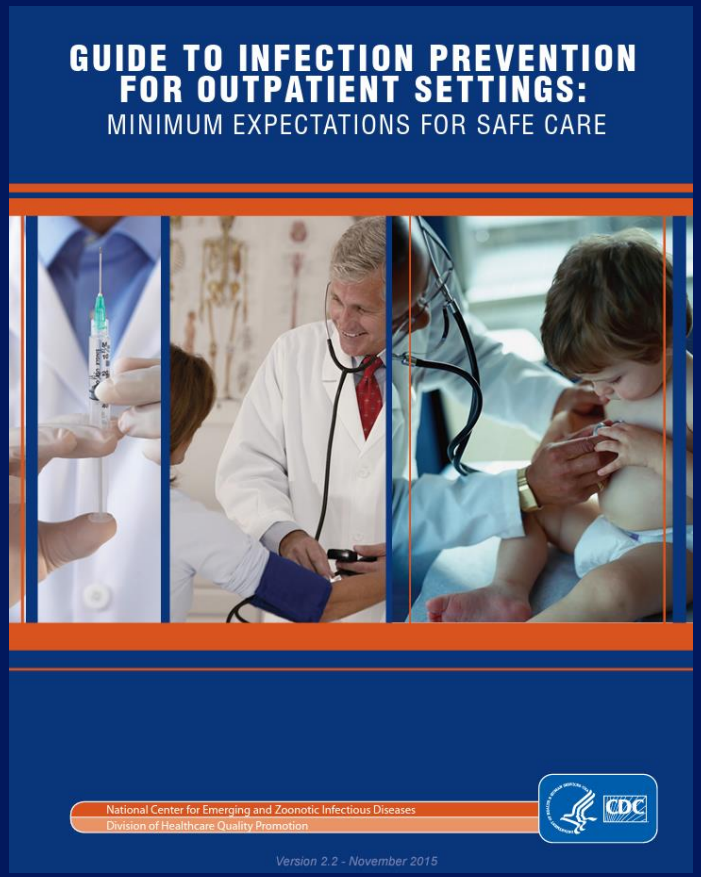
US Outpatient Surgery/Procedures Passes Inpatient Surgery/Procedure

Outpatient Care in the US

- From 2005 to 2015, visits to outpatient facilities increased by 14%
- Hospitals increased their capital investments in outpatient facilities such as specialized outpatient clinics, primary care clinics, etc.
- AHA surveyed ~6,000 hospitals and in 2017, these hospitals recorded a total of 880 million outpatient visits
- Many outpatient care facilities reprocess reusable critical and/or semicritical
- The items present an infection risk if not properly reprocessed

Expectations for Ambulatory Care



- Facilities should ensure that reusable medical devices are cleaned and reprocessed prior to use on another patient
- Reusable medical devices must be cleaned and reprocessed and maintained according to manufacturers instructions.
- Assign responsibilities for reprocessing medical devices to HCP with appropriate training
  - Maintain copies of the manufacturer's instructions for reprocessing of devices at the facilities; post instructions where reprocessing is performed
  - Hands-on training on proper selection and use of PPE and recommended steps for reprocessing assigned devices should be provided upon hire, annually, and when new devices are introduced or policies/procedures change
    - HCP should be required to demonstrate competency with reprocessing procedures
- Assure HCP have access to and wear appropriate PPE when handling and reprocessing contaminated medical equipment

https://www.cdc.gov/hai/pdfs/guidelines/ambulatory-carechecklist_508_11_2015.pdf

HLD and Sterilization in Outpatient Care

Rutala, Weber, AJIC 2019;47:A79-A89; J. Bringhurst. AJIC. 2019;47:A58-A61

- Because semicritical equipment has been associated with reprocessing errors, essential control measures instituted to prevent patient exposures
- Infection control rounds or audits should be conducted at least annually in all clinical areas that reproves critical and semicritical devices to ensure adherence to reprocessing guidelines, MIFU, and/or institutional policies
- Results provided to unit managers and deficiencies corrected and corrective measures documented within 30 days
- Patient safety issues (e.g., wrong contact time, temperature, HLD concentration) require immediate correction

HICPAC Audit Tool

https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html

HICPAC Sample Audit Tool: Reprocessing Flexible Endoscopes

Purpose: Facilities can use this sample Audit Tool document as a template to develop their own audit tool specific to their endoscopes and evidence-based reprocessing practices. This sample tool is designed to be used in conjunction with the Competency Verification Tool. Facilities are encouraged to use these tools together to verify competency and audit current practice as well as to ensure that their practices are consistent with "Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee."

Auditor: _____ **Date:** _____

Audit Item	Yes	No	Comments/Action
Precleaning			
Precleans the flexible endoscope at the point of use.			
Discards the cleaning solution and cloth after use.			
Transporting			
Transports the contaminated endoscope and accessories to the endoscopy processing room as soon as possible after use.			
Ensures the container or cart is labeled with a biohazard legend.			
Leak Testing			
Performs leak testing before manual cleaning if indicated.			
Manual Cleaning			
Uses a freshly prepared cleaning solution and does not add additional products to the water unless recommended by the manufacturer.			
Completely submerges the endoscope and accessories.			
Cleans exterior surfaces of the endoscope with a soft, lint-free cloth or sponge.			
Cleans all accessible channels and the end of the endoscope with a cleaning brush of the length, width, and material recommended by the endoscope manufacturer.			
Uses a clean brush for each endoscope cleaning.			
If the endoscope has an elevator, raises and lowers the elevator throughout the manual cleaning process.			
Brushes the accessible channels until no debris appears on the brush.			
Removes debris before retracting the brush back through the endoscope.			
Flushes the channels of the endoscope with the cleaning solution.			
Manually actuates the valves during the cleaning process.			
Flushes and rinses exterior surfaces and internal channels with water until all cleaning solution and residual debris is removed.			
Dries exterior surfaces and removable parts of the endoscope and purges all channels with air.			
Reprocesses reusable parts, accessories, and cleaning implements according to the manufacturer's instructions for use (IFU).			
Disposes of single-use parts, accessories, and cleaning implements.			

Audit Item	Yes	No	Comments/Action
Inspection			
Inspects and evaluates endoscopes and accessories for • cleanliness			
• missing parts			
• clarity of lenses			
• integrity of seals and gaskets			
• physical or chemical damage			
• moisture			
• function			
Uses additional illumination and magnification for inspection, as needed.			
High-level Disinfection or Sterilization			
Manually cleans the endoscope and accessories before mechanical or manual high-level disinfection or sterilization.			
Mechanical methods Checks the expiration date of the high-level disinfectant or liquid chemical sterilant before each use.			
Uses a test strip or other FDA-cleared testing device specific to the disinfectant or liquid chemical sterilant and minimum effective concentration of the active ingredient for monitoring solution potency before each use.			
Positions endoscopes and accessories within the mechanical processor to ensure contact of the processing solutions with all surfaces of the endoscope.			
Connects the endoscope to the mechanical processor correctly.			
Verifies mechanical processing cycles are completed as programmed.			
Manual methods Checks the expiration date of the high-level disinfectant before each use.			
Uses a test strip or other FDA-cleared testing device specific to the disinfectant and minimum effective concentration of the active ingredient for monitoring solution potency before each use.			
Flushes and fills lumens and ports with the high-level disinfectant.			
Completely immerses the endoscope in the high-level disinfectant solution for the designated time according to the device and high-level disinfectant solution manufacturer's IFU.			
Rinses the endoscope with water that meets the manufacturer's specification or as recommended by professional organizations after disinfection.			
May be required for both mechanical and manual methods Flushes lumens using 70% to 90% ethyl or isopropyl alcohol according to the endoscope manufacturer's IFU.			
Dries exterior surfaces and removable parts of the endoscope and purges all channels with air.			

Audit Item	Yes	No	Comments/Action
Sterilization Packages and sterilizes endoscopic accessories that enter sterile tissue or the vascular system per the health care facility's policy and procedure.			
Storage			
Wears clean gloves when transporting the endoscope to and from the storage cabinet.			
Based on the cabinet design, stores flexible endoscopes horizontally or hangs them vertically so they do not coil or touch the floor of the cabinet.			
Stores the flexible endoscope with all valves open and removable parts detached.			
Stores sterile items in a sterile storage area.			
Records			
Processing records include • date and time			
• identity of endoscope and endoscope accessories			
• method and verification of cleaning and results of cleaning verification testing			
• number or identifier of the mechanical processor or sterilizer and results of process efficacy testing			
• identity of the persons performing the processing			
• lot numbers of the processing solutions			
• disposition of defective items or equipment			
• maintenance of water systems, endoscopes and endoscope accessories, and processing equipment			
Procedural records include • date and time			
• identity of the patient			
• procedure			
• identity of the licensed independent practitioner performing the procedure			
• identity of the endoscope and endoscope accessories used			

Available from: https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html

Challenges in Outpatient Settings

Rutala, Weber, AJIC 2019;47:A79-A89; J. Bringhurst. AJIC. 2019;47:A58-A61

- Technical/Reprocessing Issues
  - Complex instruments
- Other Challenges
  - Physical plant (sinks, no sinks, clean-to-dirty…goal-safer/better)
  - Training, education, validation, standardization
    - Training/education- in person, on-line, frequency, measuring competency
    - Validation (validated by manufacturer of AER, device have lumens, correct adapters/hookups, chemicals, enzymatics, temperature, soak time, test strips (readout time, controls)
  - Presence of infection prevention

Challenges in Outpatient Settings: Space

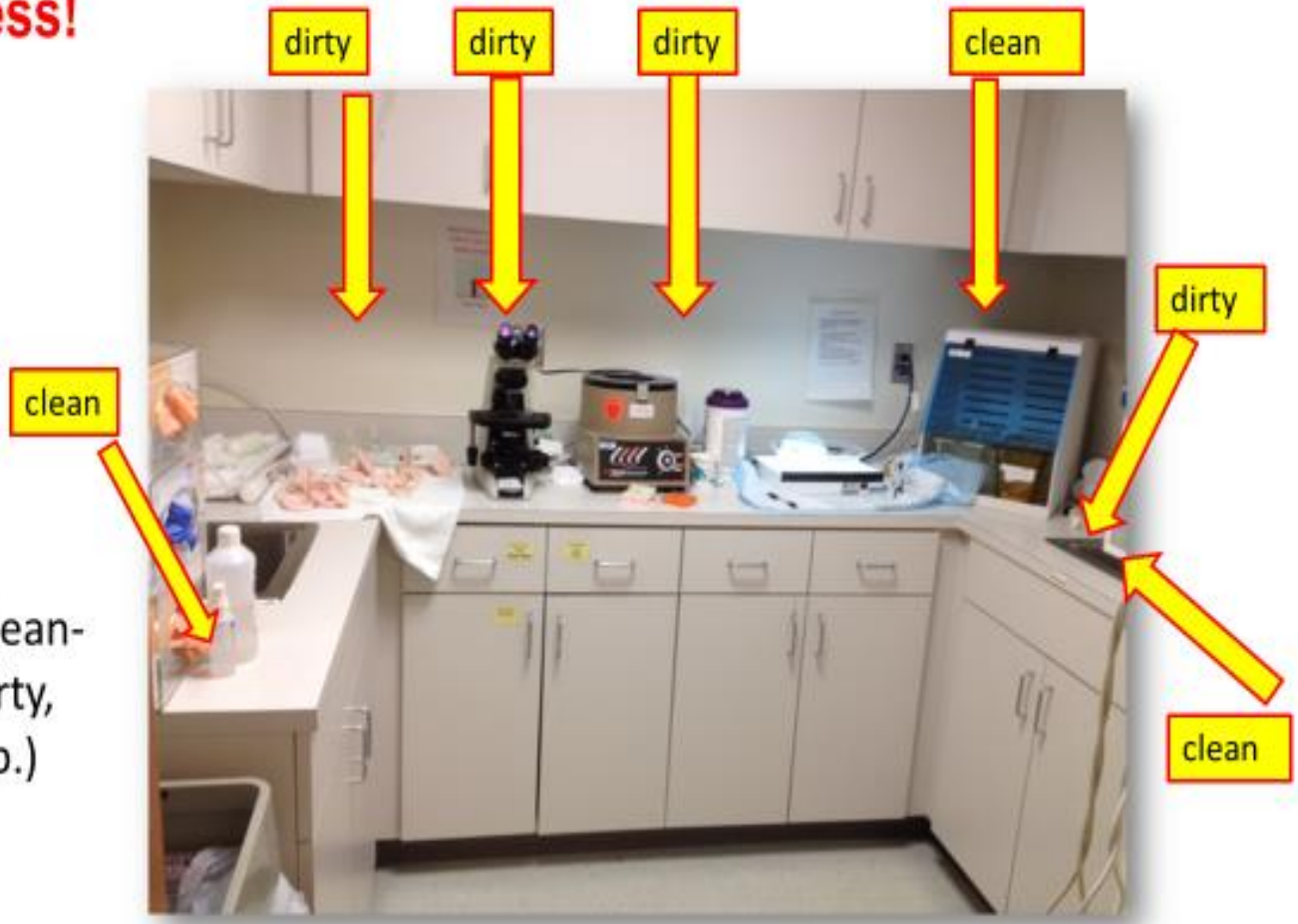
J Bringhurst AJIC 2019:47:A58-61

- Instrument reprocessing (e.g., endoscopes) should not be performed in patient care areas
  - Instrument reprocessing contaminates the area
  - Reprocessing area should be divided into distinct work areas when ever feasible: receiving, cleaning and decontamination, preparation, HLD/sterilization; and storage (manner that prevents recontamination)
  - Establish a dirty-to-clean flow in the area

Before Infection Prevention Assistance…a Mess!

Critical: rooms must have a dirty-to-clean flow *to the best of our ability to make it so.*

(This is a "clean-to-dirty-to-clean-to-dirty-to-dirty-to-dirty, dirty, dirty, dirty-to-clean" set up.)



Courtesy of Judie Bringhurst

After Infection Prevention Assistance – it's all rainbows and unicorns!

They decluttered and established a "dirty-to-clean" flow (mostly).

Infection Prevention helped them figure this out.

Courtesy of Judie Bringhurst

Inadequate Cleaning: Blood on Scope

Two Probes in One Cannister

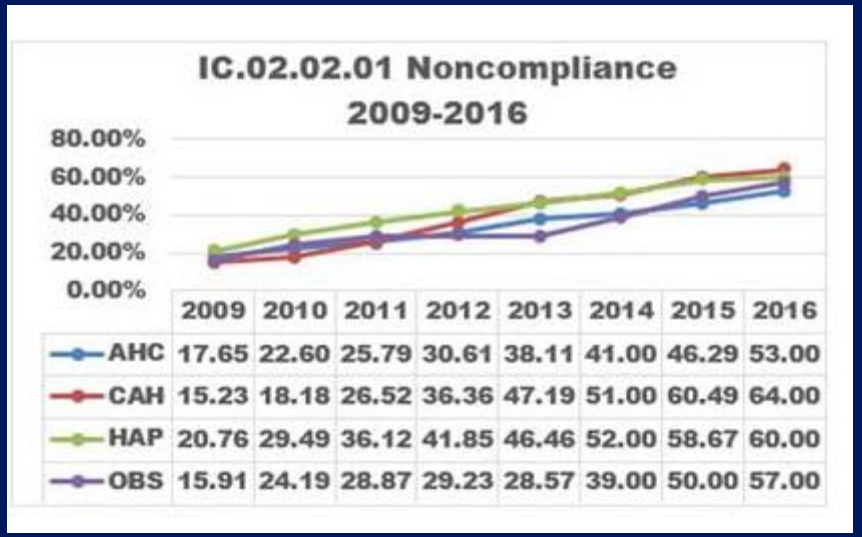
Challenges in Outpatient Settings: Education/Training/Competency

J. Bringhurst. AJIC. 2019;47:A58-A61

- Education can take many forms
  - In person, on-line, directly observed
  - Interval
  - Measurement of competency
- At UNC Hospitals, to optimize training for persons reprocessing semicritical items
  - All persons performing HLD must attend a 3-hour HLD workshop, which is designed and delivered by infection prevention.
  - A 1-hour refresher HLD class is mandatory every 365 days
  - Results from onsite infection prevention reprocessing surveys were used to guide the curriculum
  - The workshop is not a "train-the-trainer" nor is it an online module. It is conducted by an IP, face-to-face

Joint Commission: High Levels of Non-Compliance with Standards

- From 2013-2016, immediate threat to life (ITL) declarations directly related to improperly sterilized or HLD equipment increased significantly
- In 2016, 74 percent of all ITLs were related to improperly sterilized or HLD equipment



	2009	2010	2011	2012	2013	2014	2015	2016
AHC	17.65	22.60	25.79	30.61	38.11	41.00	46.29	53.00
CAH	15.23	18.18	26.52	36.36	47.19	51.00	60.49	64.00
HAP	20.76	29.49	36.12	41.85	46.46	52.00	58.67	60.00
OBS	15.91	24.19	28.87	29.23	28.57	39.00	50.00	57.00

The Joint Commission. Quick Safety 33: Improperly sterilized or HLD equipment – a growing problem; https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/quick-safety-issue-33-improperly-sterilized-or-hld-equipment--a-growing-problem/improperly-sterilized-or-hld-equipment--a-growing-problem/

Findings from Non-Complying Organizations

- The mistaken belief that the risk of passing bloodborne pathogens or bacterial agents to patients is low or nonexistent
- Staff lack the knowledge or training required to properly sterilize or HLD equipment.
- Staff don't have access to or lack knowledge of evidence-based guidelines.
- Lack of leadership oversight.
- Sterilization or HLD of equipment becomes a low priority within the organization.
- Lack of a culture of safety that supports the reporting of safety risks.
- Processes for sterilization or HLD are not followed (i.e., staff take shortcuts).
- The time frames for proper sterilization or HLD of equipment are not followed.
- There is no dedicated staff person to oversee the proper sterilization or HLD of equipment.
- Facility design or space issues prevent proper sterilization or HLD of equipment (e.g., processing takes place in a small room that also is used for storage).
- Lack of monitoring or documentation of sterilization or HLD of equipment, which makes it difficult to track the use of equipment on a specific patient, complicating the patient notification process when an outbreak occurs.
- Equipment is spread throughout the facility and may be processed or stored in numerous locations, making it difficult to track the equipment for documentation purposes.

The Joint Commission. Quick Safety 33: Improperly sterilized or HLD equipment – a growing problem; https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/quick-safety-issue-33-improperly-sterilized-or-hld-equipment--a-growing-problem/improperly-sterilized-or-hld-equipment--a-growing-problem/

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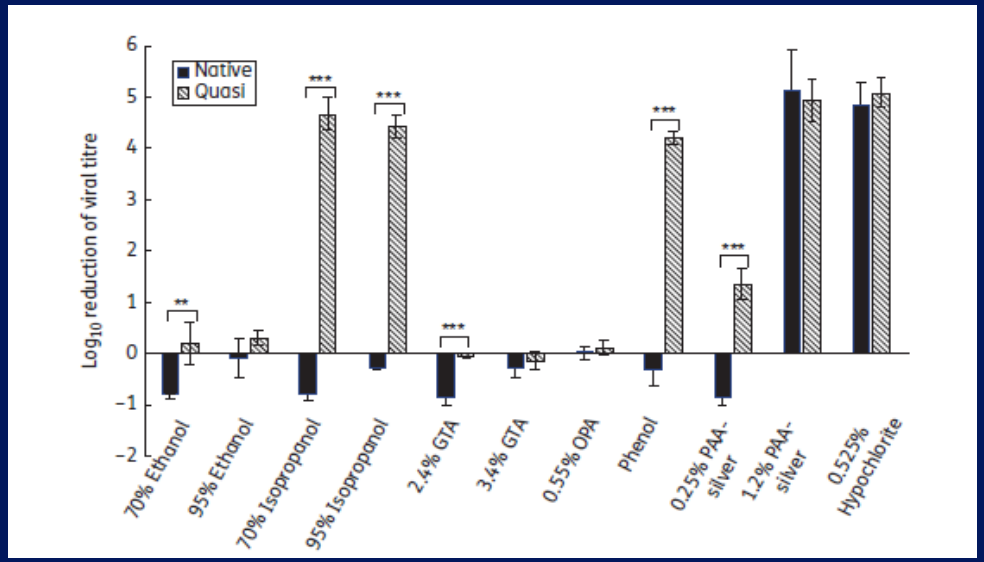
  - CRE
  - *C.auris*
- Continuous room decontamination technologies
  - Continuously active disinfectant

Human Papillomavirus

- Human Papillomavirus (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 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 (OPA, glut), no effect on HPV
- Finding inconsistent with other small, non-enveloped viruses such as polio and parvovirus
- 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)



Human Papillomavirus

- Two recently published studies identified methodological artifacts (did not use refined virus) and question the validity of the results.
  - Ozbun et al. EBioMedicine 2021;63:103165. Showed OPA treatment inactivated refined HPV 31 raft virus, xenograft-derived HPV 11, recombinant quasivirus HPV 11, HPV 16 and HPV 31
  - Egawa et al. EBioMedicine 2021; 63:103177. Showed that refined raft-derived HPV18 and HPV pseudovirus and mouse papilloma virus were inactivated
- Based of findings by Ozbun and Egawa, we believe that aldehydes are effective against HPV

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Am J Infect Control. 2020 Aug; 48(8): 951–954.
Published online 2020 Jun 6. doi: 10.1016/j.ajic.2020.06.002
PMCID: PMC7275188
PMID: 32522608

Evaluation of an electrostatic spray disinfectant technology for rapid decontamination of portable equipment and large open areas in the era of SARS-CoV-2

Jennifer L. Cadnum, BS,[a] Annette L. Jencson, CIC,[a] Scott H. Livingston, MD,[b] Daniel F. Li, BS,[a] Sarah N. Redmond, BS,[b] Basya Pearlmutter, BS,[a] Brigid M. Wilson, PhD,[c] and Curtis J. Donskey, MD[b,c,*]

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Abstract

Go to:

In the setting of the coronavirus disease 2019 pandemic, efficient methods are needed to decontaminate shared portable devices and large open areas such as waiting rooms. We found that wheelchairs, portable equipment, and waiting room chairs were frequently contaminated with potential pathogens. After minimal manual precleaning of areas with visible soiling, application of a dilute sodium hypochlorite disinfectant using an electrostatic sprayer provided rapid and effective decontamination and eliminated the benign virus bacteriophage MS2 from inoculated surfaces.

Efficacy of Disinfectant Electrostatic Spray (positive charged droplets attracted to negatively charged surfaces or microbes) in Reducing Pathogen Contamination

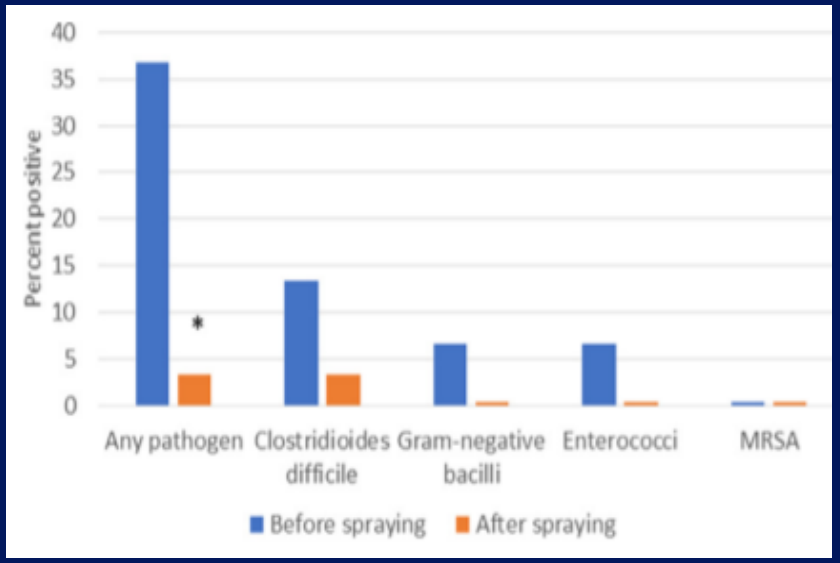
Cadnum et al. AJIC 2020

Picture of electrostatic sprayer

(0.25% sodium hypochlorite)

Efficacy of disinfectant spray

(waiting room chairs)



Summary of Electrostatic Sprayer Issues Include

- Optimal droplet size is between 40-70u; what is the droplet size of the proposed unit
- Spray patterns vary tremendously across vendors and even across products from a single vendor
- EPA demands that all surfaces being disinfected be thoroughly wetted for the contact time of the specific disinfectant
- Person applying the disinfectant may need to wear full PPE because of inhalation concerns
- Electrostatic sprayer does not replace the initial cleaning and disinfecting that EVS performs
- Cadnum/Donskey study used sporicidal disinfectant alone with no pre-cleaning or wiping
- Electrostatic sprayers might be most useful for items and areas that are not amenable to standard cleaning and disinfection (Cadnum/Donskey)
- Effectiveness on soft surfaces?
- Considerations for purchase include: coverage requirements, weight of loaded device; ease of handling; effective distance; particulate size; and disinfectant safety
- Electrostatic sprayers are promoted as a “get in” and “get out” time saving technology
- How many seconds per square foot with a sprayer to properly treat the surface
- Equipment can be easily misused (must prevent misuse and consider sprayer, time allotted to perform, disinfectant, surface [soft v hard], space/area to disinfect, level of cleaning prior to application, user training)

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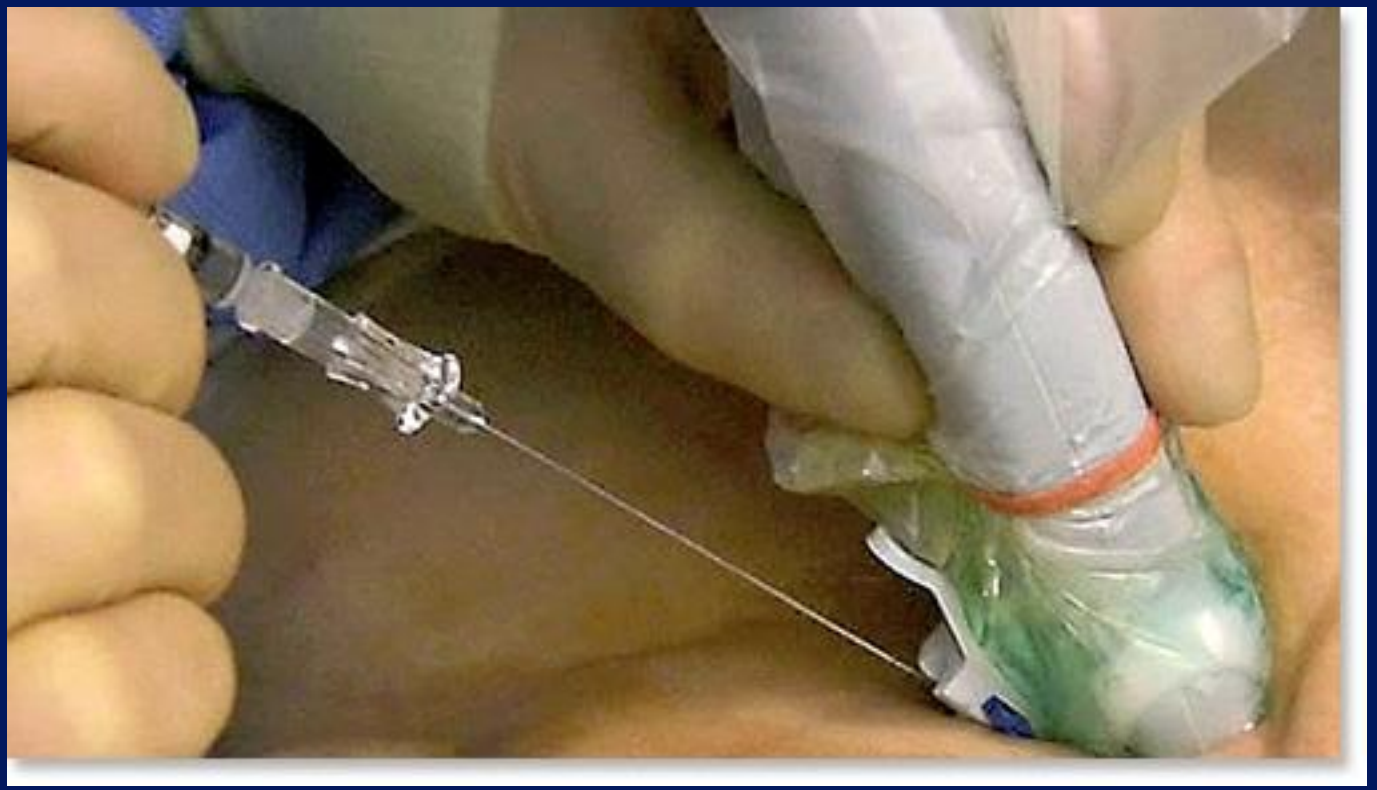
Do ultrasound transducers used for placing peripheral or central venous access devices require HLD/sterilization?



Transducer Disinfection for Insertion of Peripheral and Central Catheters

Association of Vascular Access Guideline. June 2018; AIUM 2017

- "All transducers/probes used for peripheral VAD insertion will undergo, at a minimum, low-level disinfection…." Clean (step 1) the probe prior to disinfection (step 2).
- "During assessment, consider using a single-use condom or commercially manufactured transducer sheath (excluded: transparent dressing, gloves) during all use where there is the possibility of contact with blood/body fluids or non-intact skin"
- "Perform ALL ultrasound guided vascular access device insertions (PIV, Midline, PICC, CVC, arterial line) with the use of a sterile sheath and single-use sterile gel".
  - After the procedure, the used sheath should be inspected for tears and the transducer inspected for potential compromise
  - Once inspected, the probe should be cleaned and then disinfected.

Transducer Disinfection for Insertion of Peripheral and Central Catheters

Association of Vascular Access (AVA) Guideline. June 2018; AIUM 2017

- All clinicians involved in ultrasound guidance should undergo comprehensive training on disinfection of the ultrasound transducers
- The AVA recommendations are similar to guidelines from the American Institute for Ultrasound in Medicine (AIUM): that is, internal probes-HLD; "interventional percutaneous procedure probes that are used for percutaneous needle or catheter placement…should be cleaned using LLD and be used in conjunction with a single-use sterile probe cover", if probe cover compromised HLD the probe.
- Some publications have interpreted CDC and AIUM recommendations differently (AJIC 2018:46:913-920): ultrasound guided CVC insertion (critical-sterilize or HLD with sterile sheath and sterile gel); scan across unhealthy skin (semicritical-HLD and use with clean sheath and clean gel)

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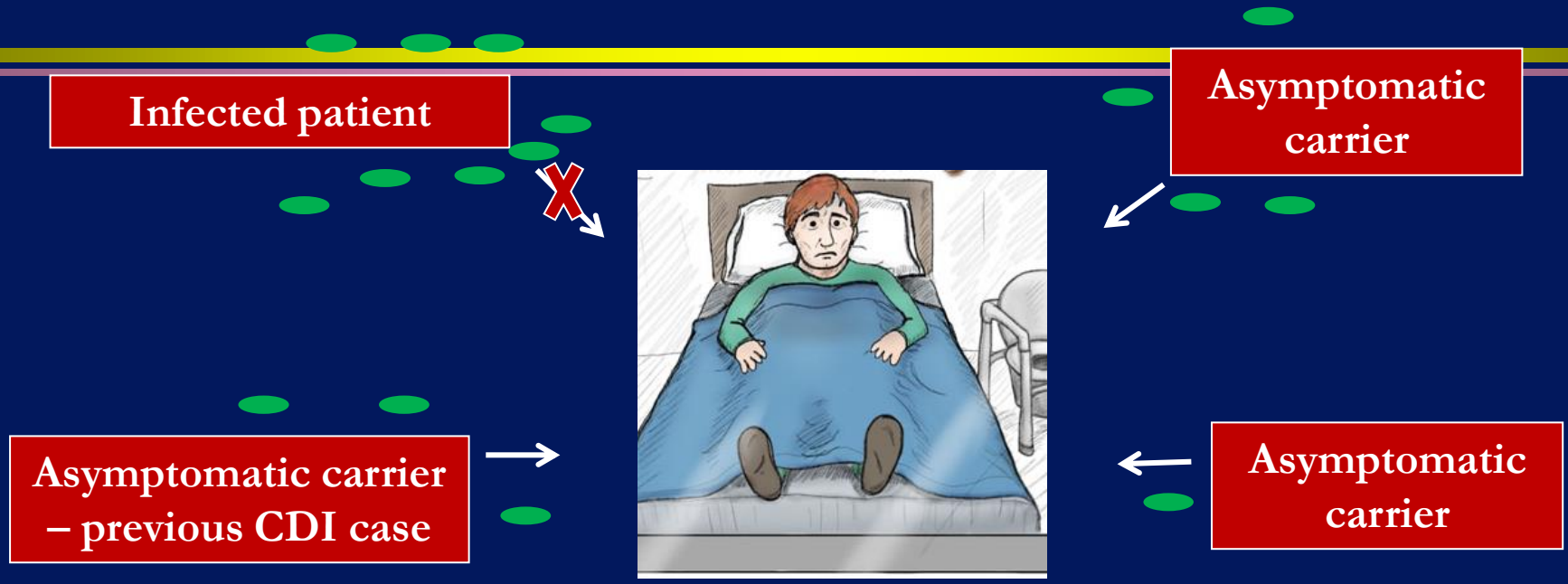
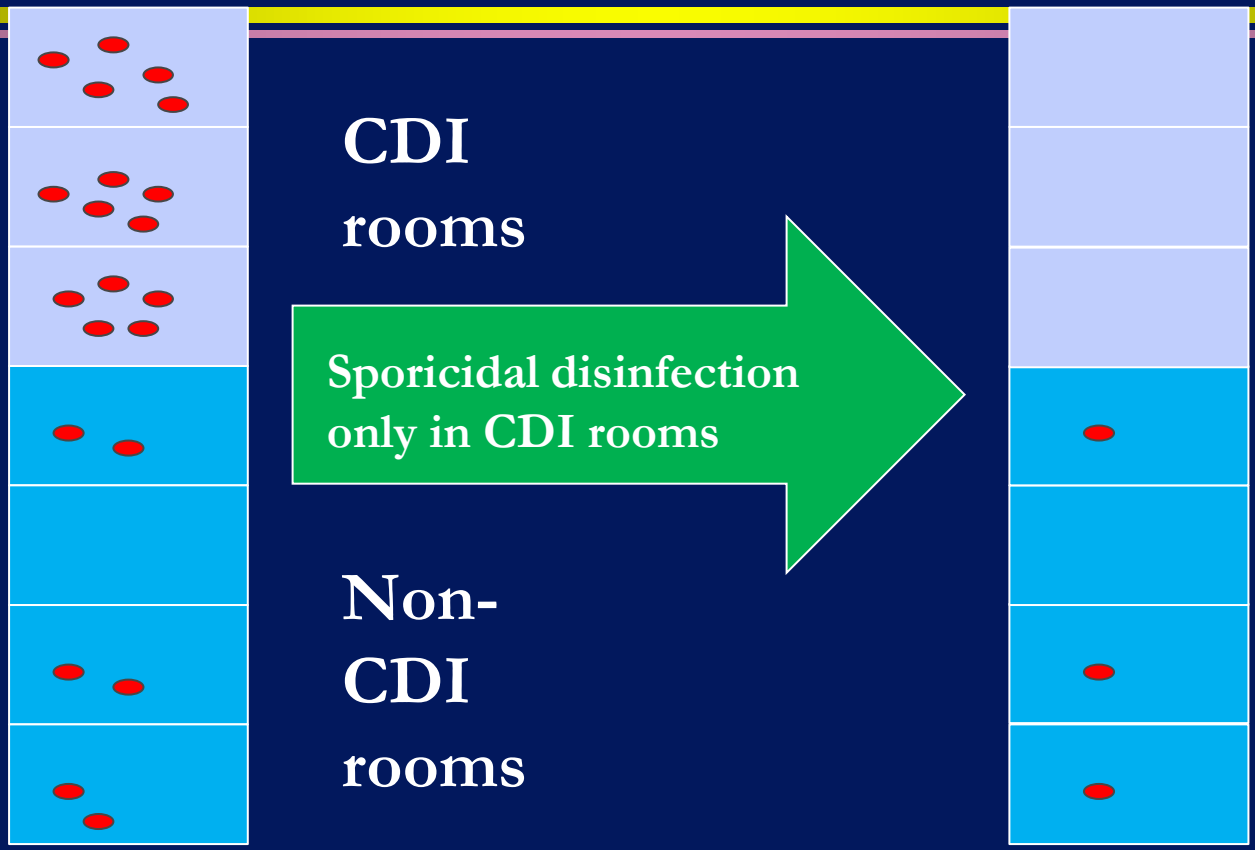
- Continuous room decontamination technologies
  - Continuously active disinfectant

Asymptomatic carriers contribute to *C. difficile* transmission



1. Curry SR. Clin Infect Dis 2013 (29% of hospital-associated CDI cases linked to carriers by MLVA); 2. Blixt T. Gastroenterol 2017;152:1031 (exposure to carriers increased CDI risk); 3. Longtin Y. JAMA Int Med 2016 (screening for and isolating carriers reduced CDI by 63%); 4. Samore MH. Am J Med 1996;100:32 (only 1% of cases linked to asymptomatic carriers - roommates and adjacent rooms - by PFGE/REA); 5. Eyre DW. PLOS One 2013;8:e78445 (18 carriers: no links to subsequent CDI cases); 6. Lisenmyer K. Clin Infect Dis 2018 (screening and isolation of carriers associated with control of a ward outbreak); 7. Paquet-Bolduc B. Clin Infect Dis 2018 (unit-wide screening and isolation of carriers not associated with shorter outbreak durations vs historical controls); 8. Donskey CJ. Infect Control Hosp Epidemiol 2018 (14% of healthcare-associated CDI cases linked to LTCF asymptomatic carriers); 9. Kong LY. Clin Infect Dis 2018 (23% of healthcare-associated CDI linked to carriers vs 42% to CDI

Interventions focused on CDI rooms



Curry SR, et al. Clin Infect Dis 2013;57:1094-102; Kong LY, et al. Clin Infect Dis 2018; Longtin Y, et al. JAMA Intern Med 2016;

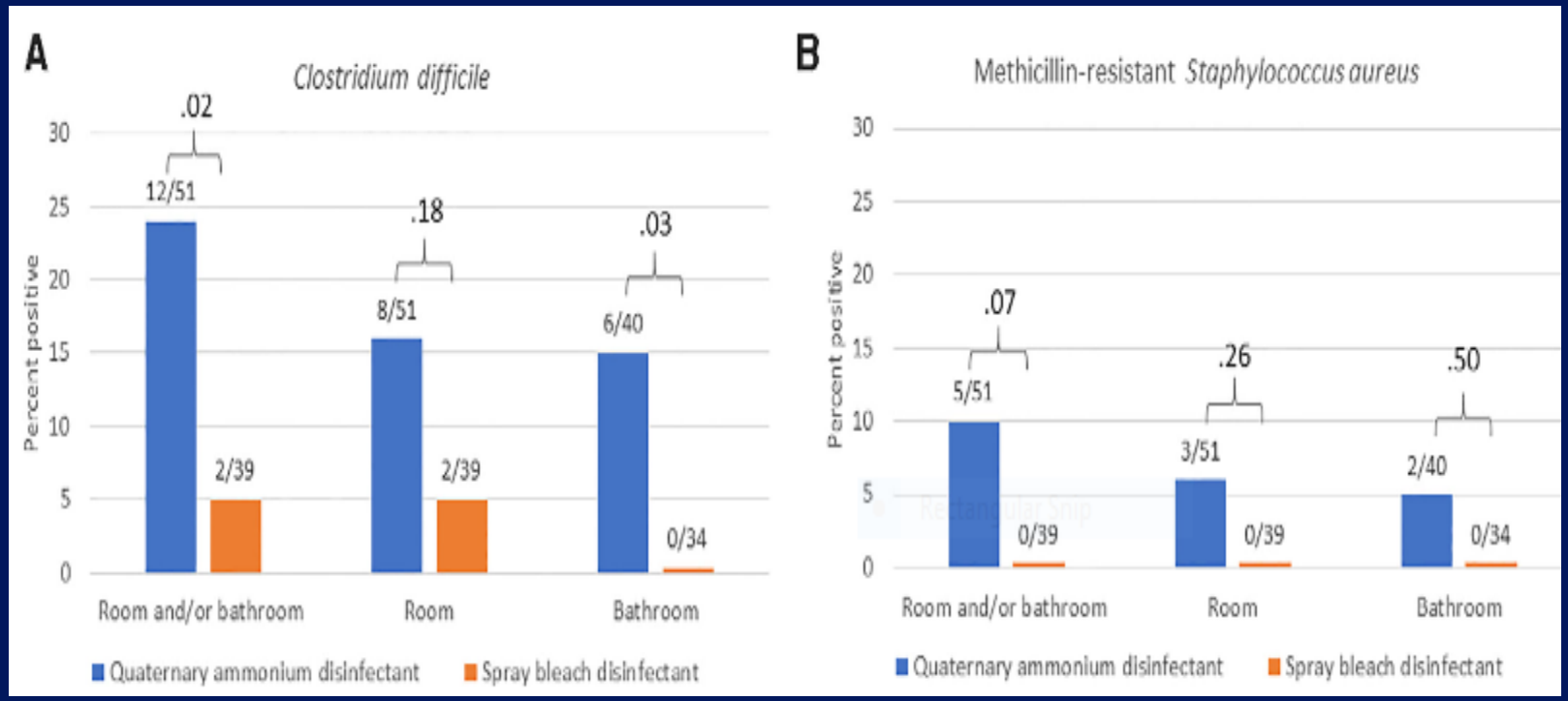
Interventions addressing CDI cases and asymptomatic carriers

C. difficile slides courtesy Dr. Donskey

Use of Sporicidal Disinfectant on *C. difficile* spore Contamination in non-*C. difficile* Infection Rooms

Wong et al. AJIC. 2019:47:843-845

The percentage of rooms contaminated with *C. difficile* was significantly reduced during the period with a sporicidal product was used 5% vs 24%. Results suggest sporicidal disinfectant in all postdischarge rooms could potentially be beneficial in reducing the risk *for C. difficile* transmission from contaminated surfaces



Disinfection and Sterilization: Current Issues and Future Perspectives

- Overview DS
- Sterilization-robustness
- HLD-What's new endoscope reprocessing
- HLD-outpatient care
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Novel Hydrogen Peroxide Sporicide

Cadnum et al. AJIC 2021

A novel 4% HP was effective against MRSA, CRE, *C. difficile* spores and *C. auris.* HP may be a useful addition to the sporicidal products available in healthcare.

Table. Mean (Standard error) $\log_{10}$ reductions in healthcare-associated pathogens using a quantitative carrier test with a 1-minute exposure time

Disinfectant	*C. difficile*	MRSA	CRE (*E. coli*)	*Candida auris* (N=2)
Sani-HyPerCide	4.7 (0.08)	≥6.4 (0)	≥5.6 (0)	>5.1 (0)
Clorox germicidal bleach	≥6.7 (0)	≥6.4 (0)	≥5.6 (0)	≥6.1 (0)
OxyCide	≥5.0 (0)	≥5.48 (0)	≥5.6 (0)	≥5.1 (0)
Oxivir 1	2.6 (0.3)	≥6.5 (0)	6.2 (0.3)	≥5.1 (0)

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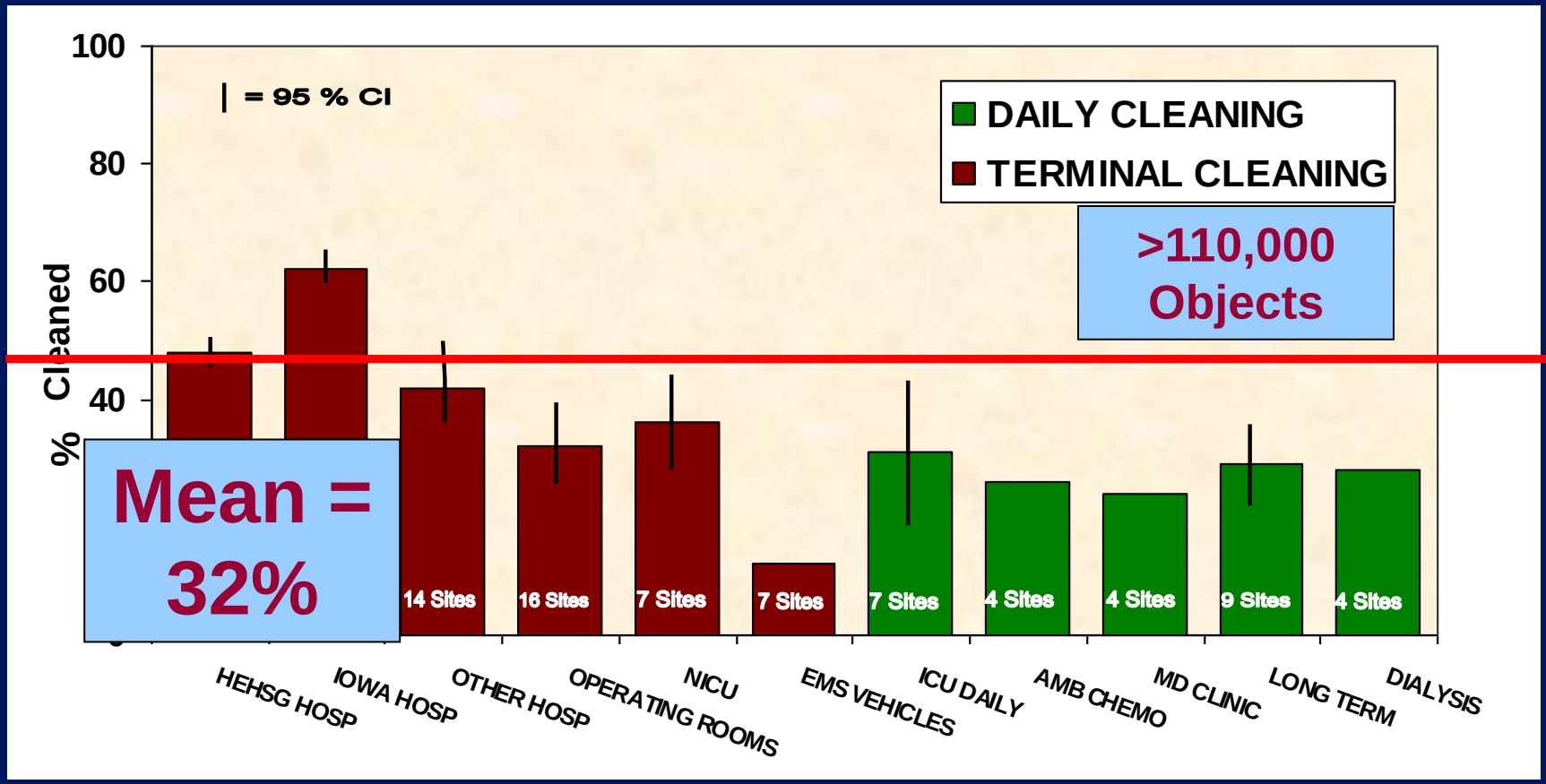
Effective Surface Decontamination

Product and Practice = Perfection

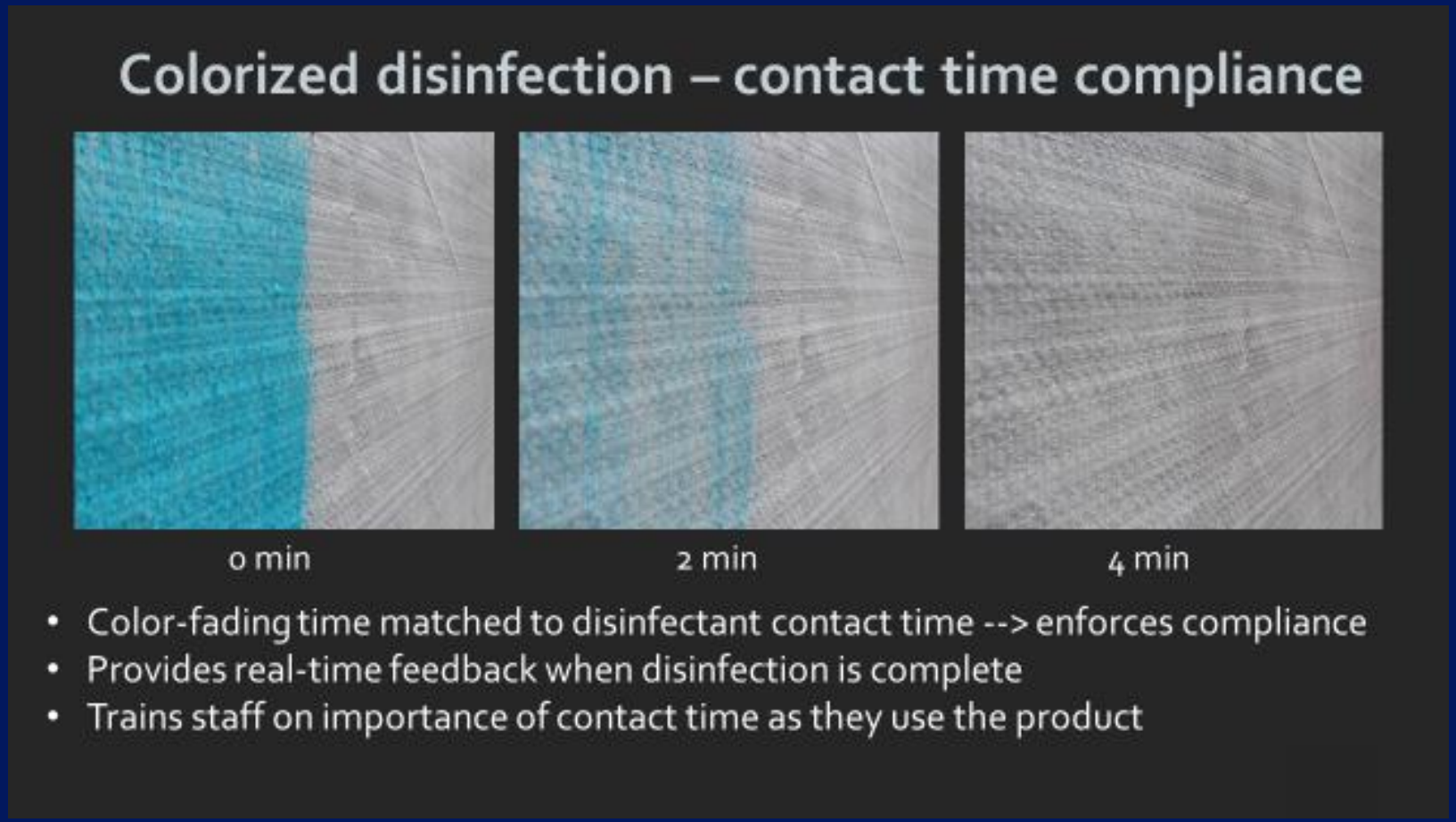
Thoroughness of Environmental Cleaning

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



Future May Have Methods to Ensure Thoroughness Such as Colorized Disinfectant

Kang et al. J Hosp Infect 2017



Kinnos slides courtesy of Kevin Tyan and Rachael Sparks

Colorized disinfection – empowers behavior change to improve coverage

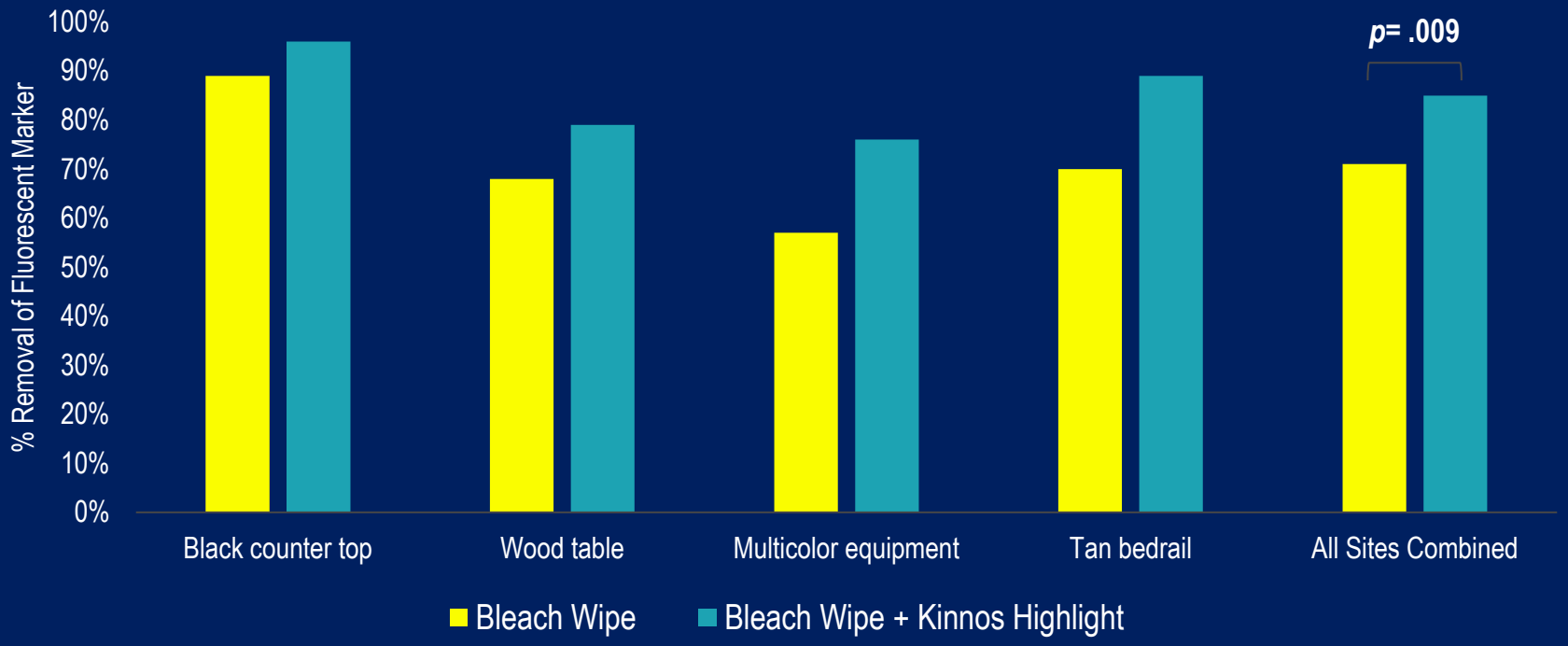
Regular disinfectant wipes

Colorized wipes

- Increased visibility when disinfecting surfaces, fewer missed spots
- Real-time quality control that allows staff to monitor thoroughness of cleaning

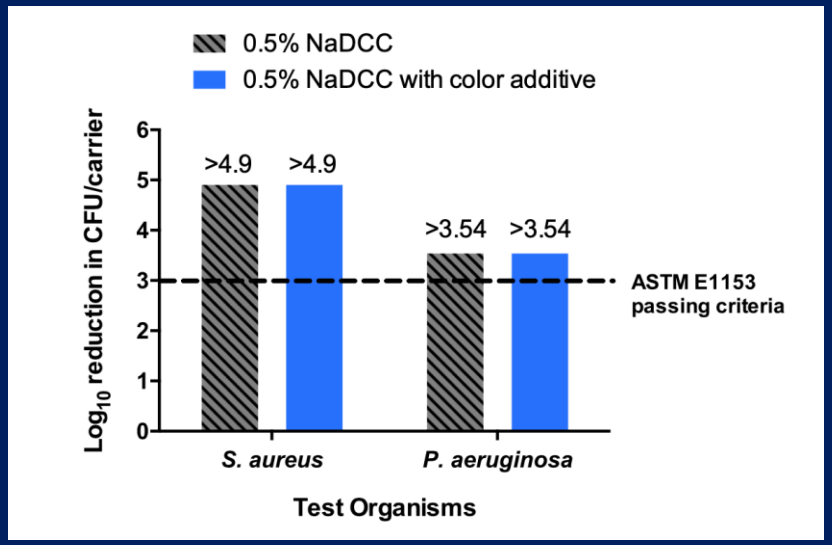
Highlight® increases cleaning efficacy by 29%

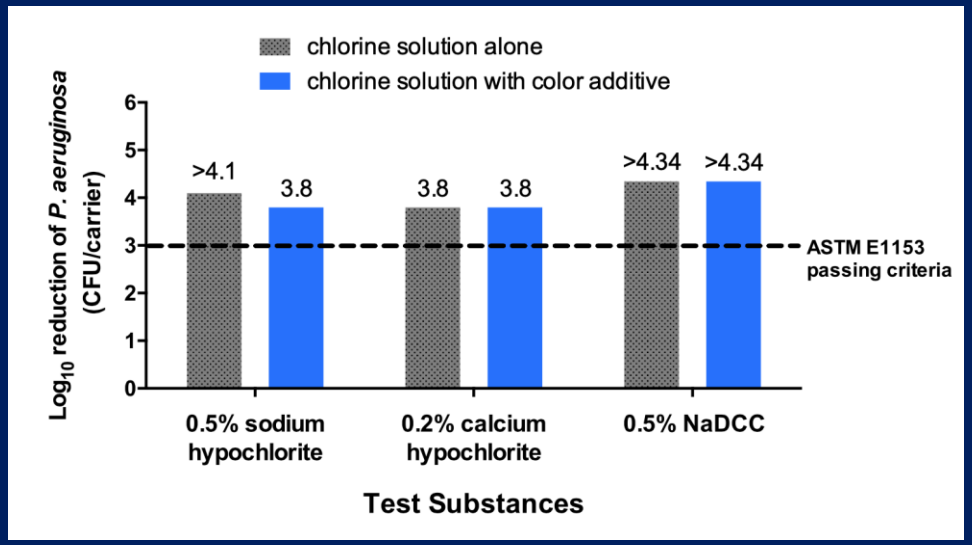
Cleveland VA Medical Center found Highlight® to quantifiably improve thoroughness of cleaning



Manuscript in preparation.

Efficacy and skin toxicity testing of Highlight®

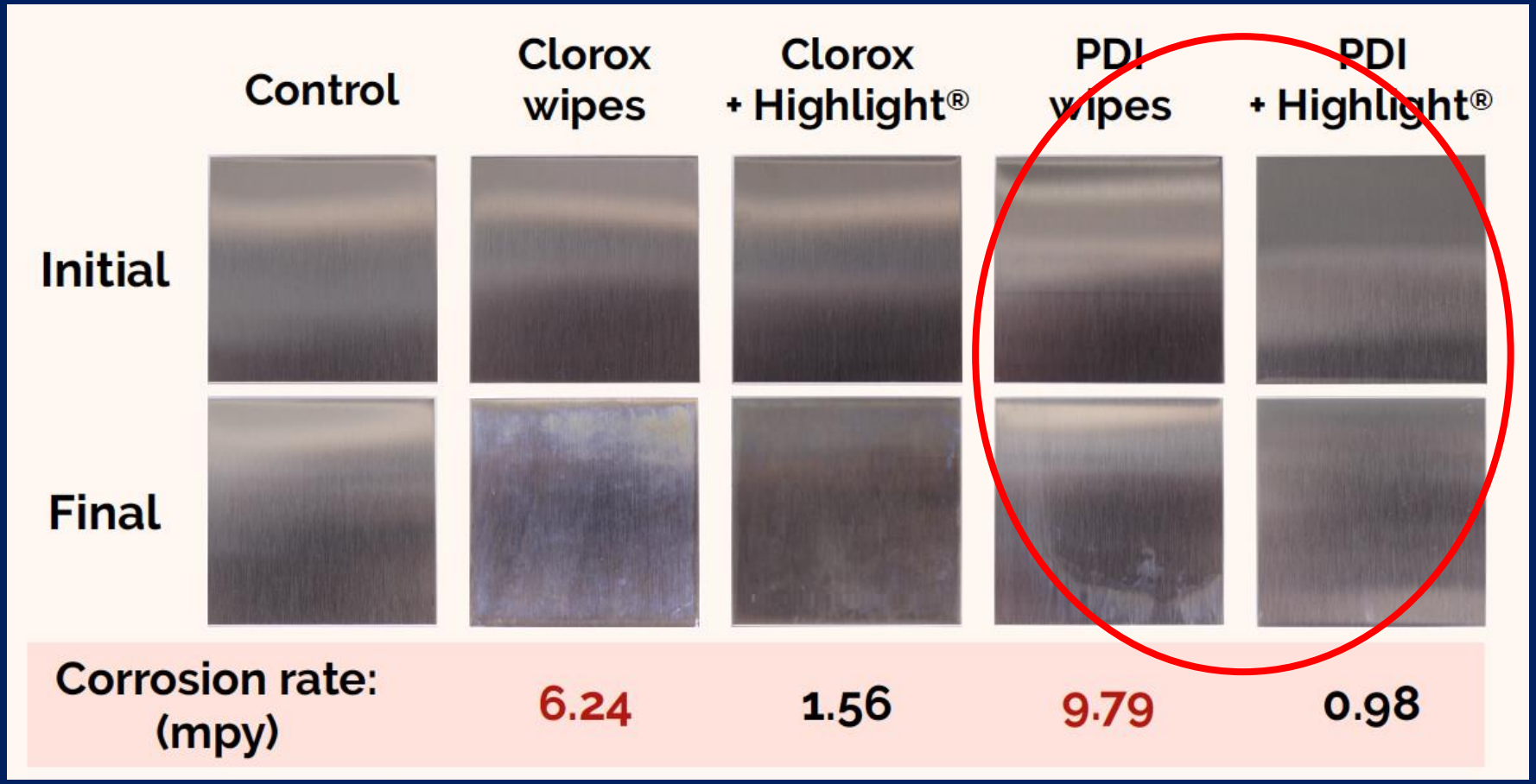




- 3rd party testing: Highlight® is a non-irritant and does not reduce efficacy of disinfectant

Tyan KS, Kang J, Jin K, Kyle AM. *Am J Infect Control*. 2018;46:1254-61.

Highlight® reduces bleach corrosiveness



Bleach wipes alone caused severe corrosion (> 5 mils per year [mpy], 1 normal) while the addition of Highlight® both significantly reduced corrosion rate (< 2 mpy) and prevented discoloration of the metal.

Tyan K, Jin K, Kang J. *J Hosp Infect*. 2018;S0195-6701(18)30491-2.

Lids fit onto bleach wipe cannisters

(feeds wipe out for the user and retracts them to prevent dry-out when not in use)

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Best Practices in Disinfection of Noncritical Surfaces in the Healthcare Setting: A Bundle Approach

NL Havill AJIC 2013;41:S26-30; Rutala, Weber. AJIC 2019

A Bundle Approach to Surface Disinfection

- Develop policies and procedures
- Select cleaning and disinfecting products
- Educate staff-environmental services and nursing
- Monitor compliance (thoroughness of cleaning, product use) and feedback
- Implement “no touch” room decontamination technology and monitor compliance (and new strategies)

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%; Shaughnessy et al. ICHE 2011;32:201)
- Exposure to contaminated rooms confers a 5-6 fold increase in odds of infection, hospitals must adopt proven methods for reducing environmental contamination (Cohen et al. ICHE. 2018;39:541-546)

These interventions (effective surface disinfection, thoroughness indicators) not enough to achieve consistent and high rates of cleaning/disinfection

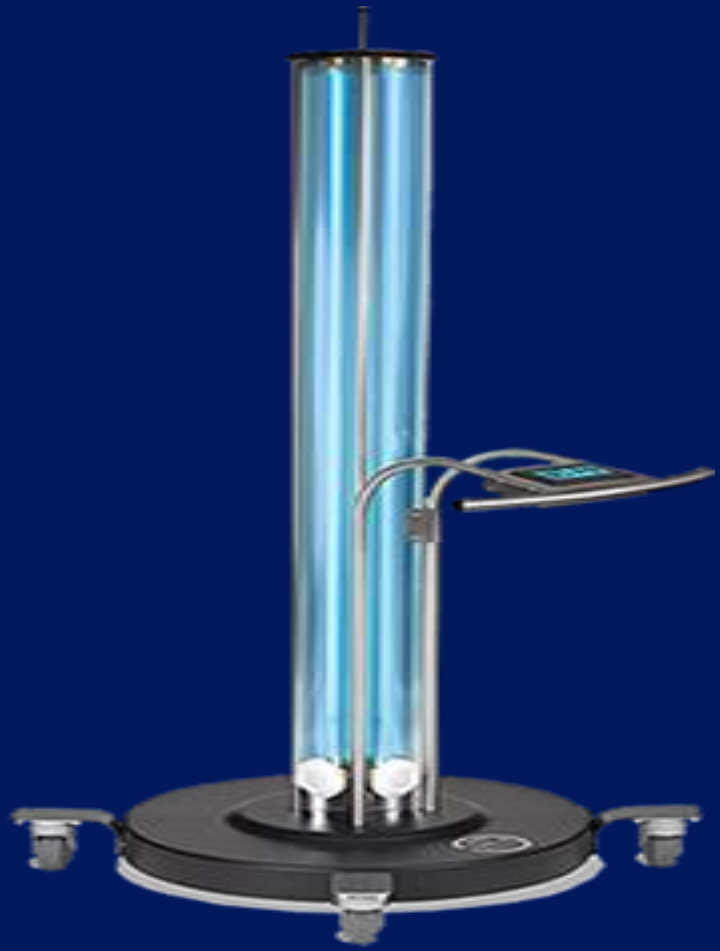
No Touch

(supplements but do not replace surface cleaning/disinfection)

"NO TOUCH" APPROACHES TO ROOM DECONTAMINATION

(UV/VHP~20 microbicidal studies, 12 HAI reduction studies; will not discuss technology with limited data)

Weber, Kanamori, Rutala. Curr Op Infect Dis 2016;29:424-431; Weber, Rutala et al. AJIC; 2016:44: e77-e84; Anderson et al. Lancet 2017;389:805-14; Anderson et al. Lancet Infect Dis 2018;June 2018.



Enhanced Disinfection Leading to Reduction of Microbial Contamination and a Decrease in Patient Col/Infection

Anderson et al. Lancet 2017;289:805; Rutala et al. ICHE 2018;39:1118

	Standard Method	Enhanced method		
	Quat	Quat/UV	Bleach	Bleach/UV
EIP (mean CFU per room)[a]	60.8	3.4	11.7	6.3
Reduction (%)		94	81	90
Colonization/Infection (rate)[a]	2.3	1.5	1.9	2.2
Reduction (%)		35	17	4

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. First study which quantitatively described the entire pathway whereby improved disinfection decreases microbial contamination which in-turn reduced patient colonization/infection.

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

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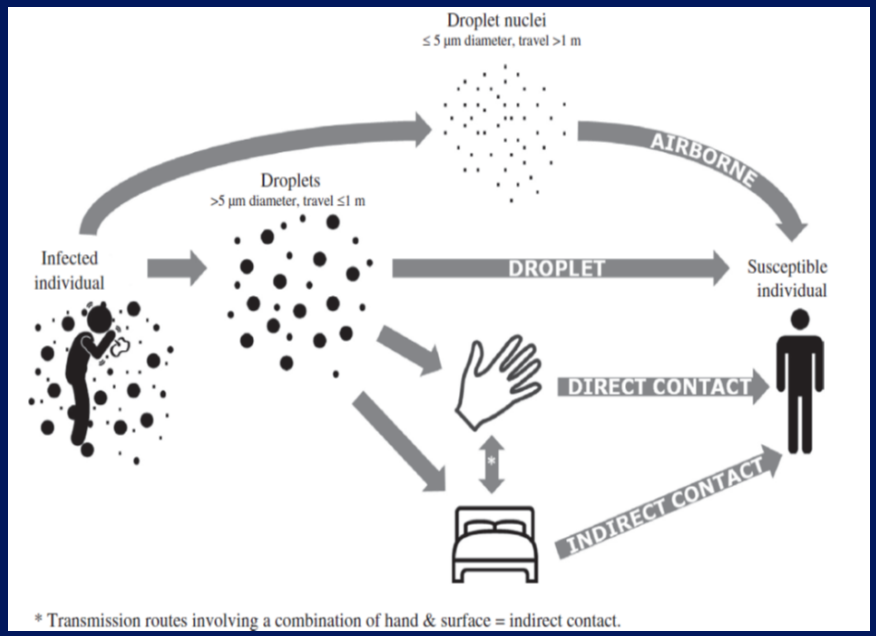
Role of Healthcare Surface Environment in SARS-CoV-2 Transmission

Kanamori, Weber, Rutala, Clin Infect Dis, https://doi.org/10.1093/cid/ciaa1467, 28 September 2020

- Centers for Disease Control & Prevention says the virus spreads from person to person mainly through respiratory droplets from coughing, sneezing or talking in close proximity to each other, but the CDC has also said it may be possible for a person to get COVID-19 by touching a surface or object that has the virus on it and then touching their own mouth, nose or possibly their eyes. CDC clarified while it is still possible that a person can catch it from touching a contaminated surface, it's "not thought to be the main way the virus spreads."

Transmission of SARS-CoV-2



- Droplet (< 6 feet)
- Direct-person-to-person via respiratory aerosols
- Indirect (via the contaminated environment); not main route
- Asymptomatic (infection transmission demonstrated)
- Pre-symptomatic-highly likely

Role of Healthcare Surface Environment in SARS-CoV-2 Transmission

Kanamori, Weber, Rutala, Clin Infect Dis, https://doi.org/10.1093/cid/ciaa1467, 28 September 2020

- Survival on environmental surfaces
  - Hours to days (SARS-CoV-2)
  - Depends on experimental conditions such as viral titer (10^7 higher than real life) and volume of virus applied to surface, suspending medium, temperature, relative humidity and surface substrates
  - Human coronavirus 229E persist on surface materials at RT for at least 5 days
  - SARS-CoV-2 can be viable on surfaces for 3 days (plastic, stainless steel ~2-3 days, cardboard ~24h)
  - Suggest transmission of SARS-CoV-2 may occur

Role of Healthcare Surface Environment in SARS-CoV-2 Transmission

Kanamori, Weber, Rutala, Clin Infect Dis, https://doi.org/10.1093/cid/ciaa1467, 28 September 2020

Contamination of SARS-CoV-2 RNA by PCR on environmental surfaces and medical devices have been documented. Rate varies from 0-75% (median 12.1%).

Role of Healthcare Surface Environment in SARS-CoV-2 Transmission

Kanamori, Weber, Rutala, Clin Infect Dis, https://doi.org/10.1093/cid/ciaa1467, 28 September 2020

SARS-CoV-2 RNA				
Bed rail	Sink	BP monitor	Infusion pump	Keyboard
Bedside table	Floor	ECG monitor	Fluid stand	Phone
Chair	Toilet seat	Oxygen regulator	Hand sanitizer	Computer mouse
Doorknob	Toilet bowl	Oxygen mask	Trash can	Door
Light switches	Stethoscope	CT scanner	Self-service printer	Glass window
Call button	Pulse oximetry	Ventilator	Desktop	PPE storage area
Centrifuge	Biosafety cabinet	Infant bed	Air outlet	Ambu bag
TV remote	Bed sheet	Urinary catheters	TV	Beepers
Elevator buttons	Ventilator tubing	Glove boxes	Touch screen	All surfaces in nurse's station

Role of Healthcare Surface Environment in SARS-CoV-2 Transmission

Kanamori, Weber, Rutala, Clin Infect Dis, https://doi.org/10.1093/cid/ciaa1467, 28 September 2020

Detection of SARS-CoV-2 RNA does not represent the presence of viable virus. Further, even the detection of viable virus, does not mean an infectious dose of SARS-CoV-2 is present. Infectious dose for SARS-CoV-1 estimated to be 280 viral particles to cause disease in 50% of the population.

Do established infection prevention measures prevent spread of SARS-CoV-2 to the hospital environment beyond the patient room?

Jerry et al. J Hosp Infection 2020

Contamination rate: patient room-42% (11/26); nurse's station-3%; post terminal clean-4% (1/25)

Sites of swabs/air samples and results

Sample location	Grand total	Detected	Not detected
COVID-19 patient's room			
Bed rail	6	4	2
Bedside table	6	3	3
Call bell	4	1	3
Patient chair-arm	4	1	3
Remote for bed	2	2	0
Toilet door handle	4	0	4
Total	26	11	15
Nurses' station COVID-19 cohort ward			
Desk	10	0	10
Keyboard	10	0	10
Telephone	10	1	9
Total	30	1	29
Patient room post-terminal clean			
Bed rail	5	0	5
Bedside table	5	0	5
Call bell	5	1	4
Patient chair-arm	5	0	5
Toilet door handle	5	0	5
Total	25	1	24

Viable SARS-CoV-2 on Surfaces

Environmental Contamination in COVID-19 Rooms with Severe Pneumonia

Ahn et al. J Hospi Infect 2020;106:570

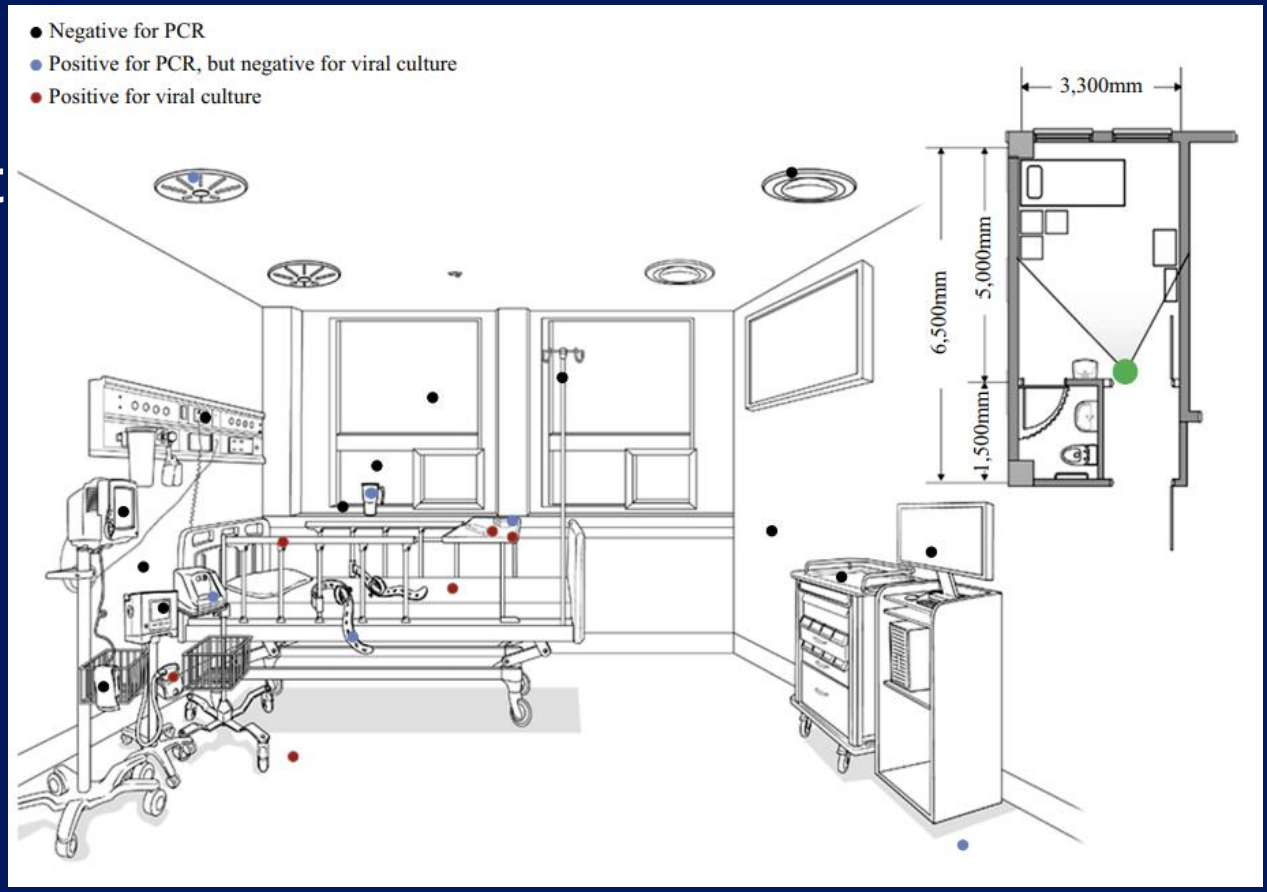
Pt 1 and 2-2/48-4% (closed suction to ventilator) pt 3-13/28-46% (high-flow oxygen therapy via nasal cannula, non-invasive ventilation). Found viable virus (7/28-25%) only on surfaces within droplet distance. All air samples negative.

Sample	Patient 1				Patient 2				Patient 3			
	PCR	C_T value		Culture	PCR	C_T value		Culture	PCR	C_T value		Culture
		E gene	RdRp			E gene	RdRp			E gene	RdRp	
Air	−			ND	−			ND	−			ND
Air outlet fan	−			ND	−			ND	+	33.93	34.99	−
Air inlet fan	−			ND	−			ND	−			ND
Nasal prong/endotracheal tube	+	30.95	31.36	+	+	32.33	33.02	−	+	31.78	34.28	+
Intravenous pole	−			ND	−			ND	−			ND
Computer	−			ND	−			ND	−			ND
Medication cart	−			ND	−			ND	−			ND
Window	−			ND	−			ND	U	U	U	−
Window frame	−			ND	−			ND	−	34.23	36.04	−
Blind curtain	−			ND	−			ND	−			ND
Wall 1	−			ND	−			ND	−			ND
Wall 2	−			ND	−			ND	−			ND
Floor near the patient[a]	−			ND	−			ND	+	30.38	33.07	+
Floor far from the patient[b]	−			ND	−			ND	+	31.97	34.28	−
Bed rails	−			ND	−			ND	+	30.22	30.13	+
Bedsheet	−			ND	−			ND	+	31.54	31.99	+
Pillows	−			ND	−			ND	ND			ND
Faucet handle	−			ND	−			ND	ND			ND
Door knob	−			ND	−			ND	−			ND
Call button	−			ND	−			ND	−			ND
Restraint	−			ND	−			ND	+	34.08	35.18	−
Blood pressure cuff	−			ND	−			ND	−			ND
Ambu mask/NIV mask	−			ND	−			ND	+	28.85	28.94	+
Ventilator	−			ND	−			ND	−			ND
Patient monitor	−			ND	−			ND	−			ND
Bedside table	ND			ND	ND			ND	U	33.09	U	+
High-flow oxygen generator	ND			ND	ND			ND	+	30.56	33.12	−
Telephone	ND			ND	ND			ND	+	31.39	33.42	−
Remote controller	ND			ND	ND			ND	+	29.48	29.66	+
Thermometer	ND			ND	ND			ND	+	31.56	32.13	−
Cup	ND			ND	ND			ND	+	32.32	33.55	−

Environmental Contamination in COVID-19 Rooms with Severe Pneumonia

Ahn et al. J Hospi Infect 2020;106:570

Found viable virus only on surface within droplet distance.



Inactivation of Coronavirus

Kampf G. J Hosp Infect 2020

Table II. Inactivation of coronaviruses by different types of biocidal agents in suspension tests.

Biocidal agent	Concentration	Virus	Strain / isolate	Exposure time	Reduction of viral infectivity (log_{10})	Reference
Ethanol	95%	SARS-CoV	Isolate FFM-1	30 s	≥ 5.5	[29]
	85%	SARS-CoV	Isolate FFM-1	30 s	≥ 5.5	[29]
	80%	SARS-CoV	Isolate FFM-1	30 s	≥ 4.3	[29]
	80%	MERS-CoV	Strain EMC	30 s	> 4.0	[14]
	78%	SARS-CoV	Isolate FFM-1	30 s	≥ 5.0	[28]
	70%	MHV	Strains MHV-2 and MHV-N	10 min	> 3.9	[30]
	70%	CCV	Strain I-71	10 min	> 3.3	[30]
2-Propanol	100%	SARS-CoV	Isolate FFM-1	30 s	≥ 3.3	[28]
	75%	SARS-CoV	Isolate FFM-1	30 s	≥ 4.0	[14]
	75%	MERS-CoV	Strain EMC	30 s	≥ 4.0	[14]
	70%	SARS-CoV	Isolate FFM-1	30 s	≥ 3.3	[28]
	50%	MHV	Strains MHV-2 and MHV-N	10 min	> 3.7	[30]
	50%	CCV	Strain I-71	10 min	> 3.7	[30]
2-Propanol and 1-propanol	45% and 30%	SARS-CoV	Isolate FFM-1	30 s	≥ 4.3	[29]
		SARS-CoV	Isolate FFM-1	30 s	≥ 2.8	[28]
Benzalkonium chloride	0.2%	HCoV	ATCC VR-759 (strain OC43)	10 min	0.0	[31]
	0.05%	MHV	Strains MHV-2 and MHV-N	10 min	> 3.7	[30]
	0.05%	CCV	Strain I-71	10 min	> 3.7	[30]
	0.00175%	CCV	Strain S378	3 d	3.0	[32]
Didecyldimethyl ammonium chloride	0.0025%	CCV	Strain S378	3 d	> 4.0	[32]
Chlorhexidine digluconate	0.02%	MHV	Strains MHV-2 and MHV-N	10 min	0.7 – 0.8	[30]
	0.02%	CCV	Strain I-71	10 min	0.3	[30]
Sodium hypochlorite	0.21%	MHV	Strain MHV-1	30 s	≥ 4.0	[33]
	0.01%	MHV	Strains MHV-2 and MHV-N	10 min	2.3 – 2.8	[30]
	0.01%	CCV	Strain I-71	10 min	1.1	[30]
	0.001%	MHV	Strains MHV-2 and MHV-N	10 min	0.3 – 0.6	[30]
	0.001%	CCV	Strain I-71	10 min	0.9	[30]
Hydrogen peroxide	0.5%	HCoV	Strain 229E	1 min	> 4.0	[34]
Formaldehyde	1%	SARS-CoV	Isolate FFM-1	2 min	> 3.0	[28]

Role of Healthcare Surface Environment in SARS-CoV-2 Transmission

Kanamori, Weber, Rutala, Clin Infect Dis, In press

- CDC recommends that an EPA-registered disinfectant on the EPA's List N that has qualified under the emerging pathogen program for use against SARS-CoV-2 be chosen for the COVID-19 patient care.
- List N has >450 entries and 32 different active ingredients

Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants

Rutala, Weber, CDC DS Guideline 2008. www.cdc.gov

Most Resistant

Most Susceptible

Prions

Spores (*C. difficile*)

Mycobacteria

Non-Enveloped Viruses (norovirus, adeno)

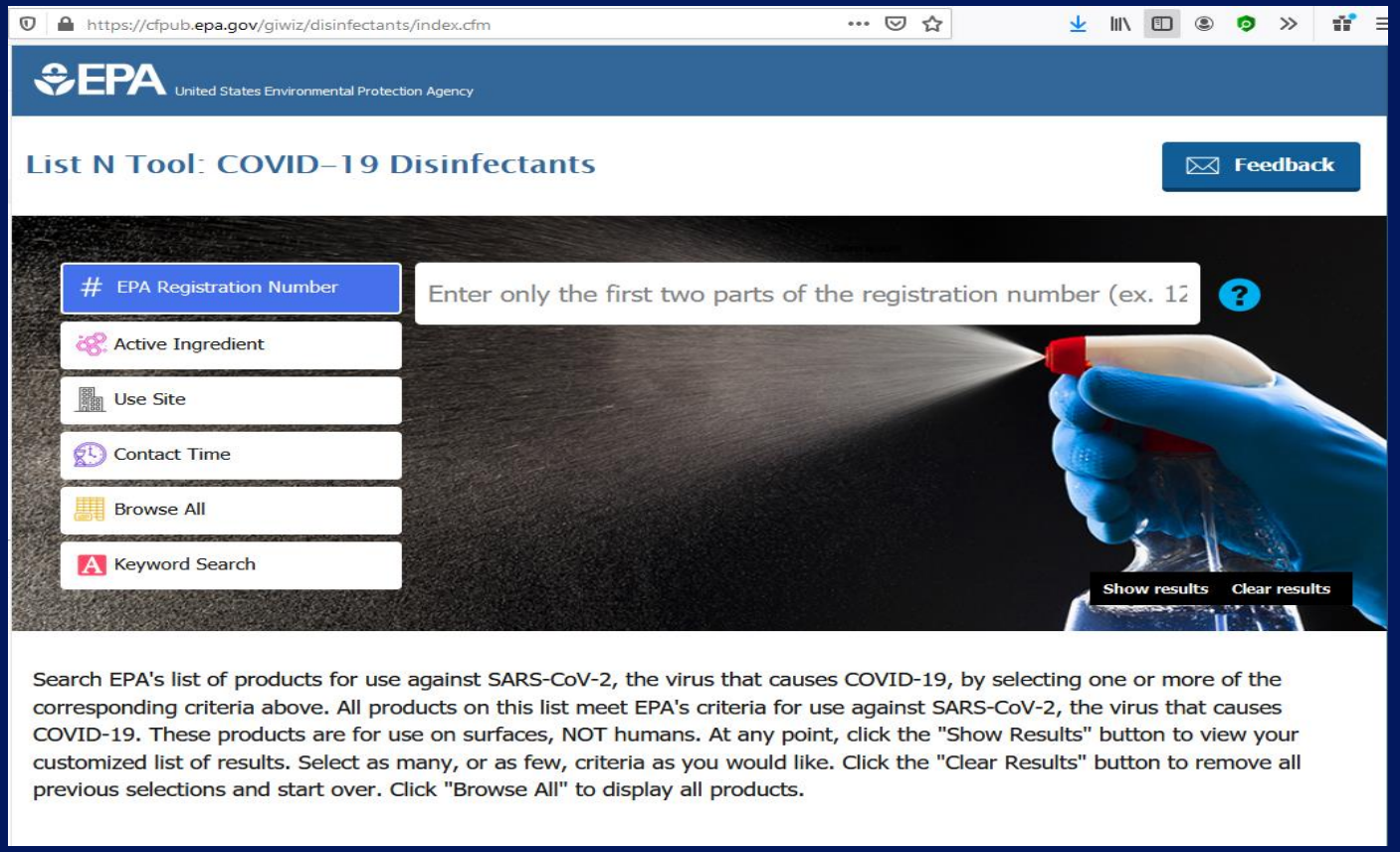
Fungi

Bacteria (MRSA, VRE, *Acinetobacter*)

Enveloped Viruses (SARS-CoV-2)

List N Tool: COVID-19 Disinfectants

https://cfpub.epa.gov/giwiz/disinfectants/index.cfm



List N Tool: COVID-19 Disinfectants

32 Active Ingredients

- Ethyl alcohol
- Hydrogen peroxide
- Hypochlorite
- Isopropyl alcohol
- Peracetic acid
- Phenolic
- Quaternary ammonium

AMERICAN SOCIETY FOR MICROBIOLOGY | Antimicrobial Agents and Chemotherapy®

EXPERIMENTAL THERAPEUTICS

Germicidal Activity against Carbapenem/Colistin-Resistant *Enterobacteriaceae* Using a Quantitative Carrier Test Method

Hajime Kanamori,[a,b] William A. Rutala,[a,b] Maria F. Gergen,[a] Emily E. Sickbert-Bennett,[a,b] David J. Weber[a,b]

[a]Department of Hospital Epidemiology, University of North Carolina Health Care, Chapel Hill, North Carolina, USA

[b]Division of Infectious Diseases, University of North Carolina School of Medicine, Chapel Hill, North Carolina, USA

ABSTRACT Susceptibility to germicides for carbapenem/colistin-resistant *Enterobacteriaceae* is poorly described. We investigated the efficacy of multiple germicides against these emerging antibiotic-resistant pathogens using the disc-based quantitative carrier test method that can produce results more similar to those encountered in health care settings than a suspension test. Our study results demonstrated that germicides commonly used in health care facilities likely will be effective against carbapenem/colistin-resistant *Enterobacteriaceae* when used appropriately in health care facilities.

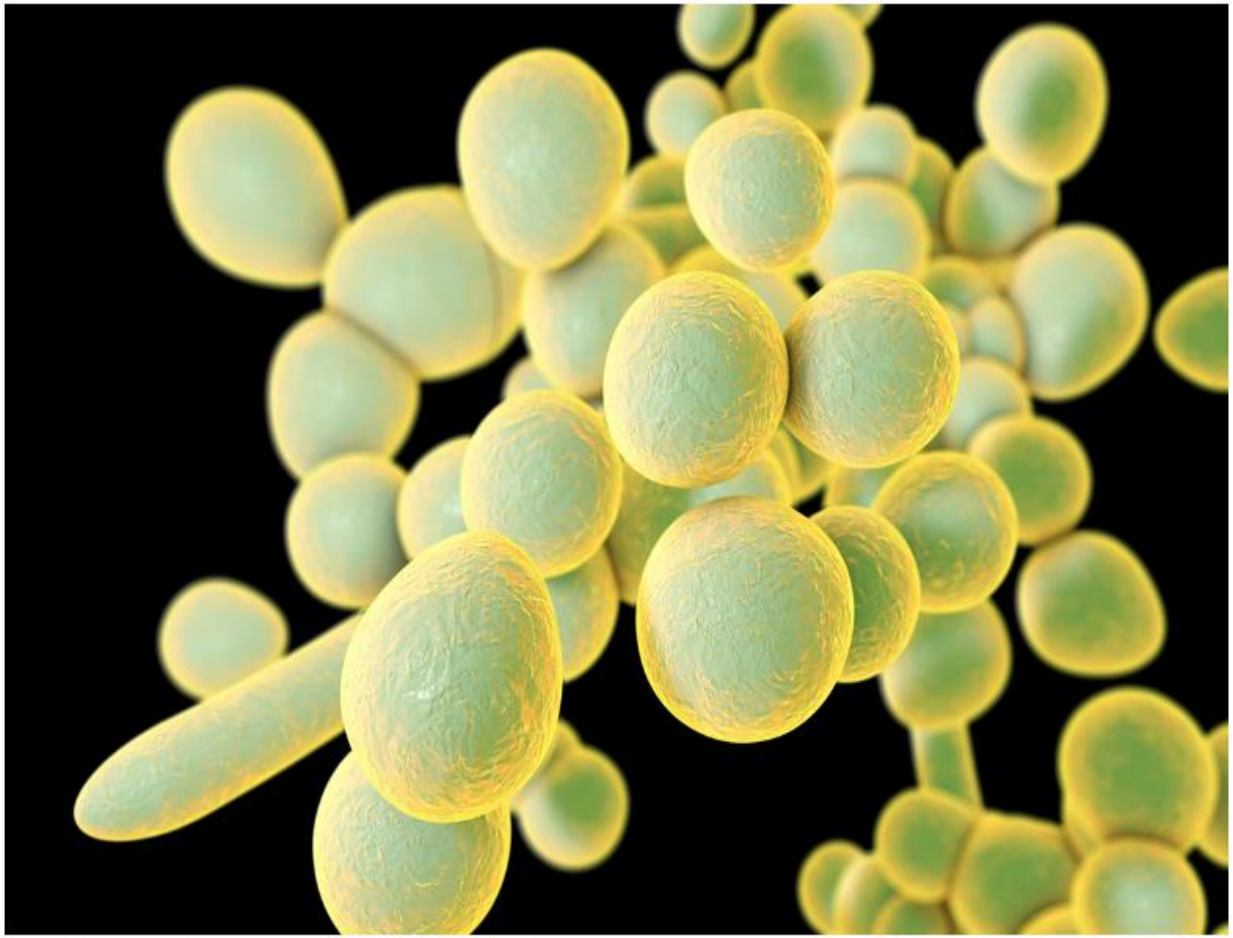
KEYWORDS carbapenem-resistant *Enterobacteriaceae*, *Klebsiella pneumoniae* carbapenemase, colistin-resistant *Enterobacteriaceae*, *mcr-1*, germicides, disinfectants, antiseptics, efficacy

Efficacy of Disinfectants and Antiseptics against Carbapenem-Resistant *Enterobacteriaceae*

Rutala, Kanamori, Gergen, Sickbert-Bennett, Weber, 2017 ID Week;
Kanamori et al Antimicrob. Agents Chemother 2018.

- ≥3 $\log_{10}$ reduction (CRE, 1m, 5% FCS, QCT)
  - 0.20% peracetic acid
  - 2.4% glutaraldehyde
  - 0.5% Quat, 55% isopropyl alcohol
  - 58% ethanol, 0.1% QUAT
  - 28.7% isopropyl alcohol, 27.3% ethyl alcohol, 0.61% QAC
  - 0.07% o-phenylphenol, 0.06% p-tertiary amylphenol
  - ~5,250 ppm chlorine
  - 70% isopropyl alcohol
  - Ethanol hand rub (70% ethanol)
  - 0.65% hydrogen peroxide, 0.15% peroxyacetic acid
  - Accelerated hydrogen peroxide, 1.4% and 2.0%
  - Quat, (0.085% QACs; not *K. pneumoniae*)

Deadly, drug-resistant Candida yeast infection spreads in the US



Candida auris causes multidrug-resistant infections that can result in organ failure

Kateryna Kon/Science Photo Library

Candida auris

Cadnum et al . ICHE 2017;38:1240-1243

- *Candida auris* is a globally emerging pathogen that is often resistant to multiple antifungal agents
- In several reports, *C. auris* has been recovered from the hospital environment
- CDC has recommended daily and post-discharge disinfection of surfaces in rooms of patients with *C. auris* infection.
- No hospital disinfectants are registered for use specifically against *C. auris*, and its susceptibility to germicides in not known

Efficacy of Disinfectants and Antiseptics against *Candida auris*

Rutala, Kanamori, Gergen, Sickbert-Bennett, Weber, ICHE 2019;40:380

- ≥3 $\log_{10}$ reduction (*C. auris*, 1m, 5% FCS, QCT)
  - 0.20% peracetic acid
  - 2.4% glutaraldehyde
  - 0.65% hydrogen peroxide, 0.14% peroxyacetic acid
  - 0.5% Quat, 55% isopropyl alcohol
  - Disinfecting spray (58% ethanol, 0.1% QUAT)
  - 28.7% isopropyl alcohol, 27.3% ethyl alcohol, 0.61% QAC
  - 0.07% o-phenylphenol, 0.06% p-tertiary amylphenol
  - 70% isopropyl alcohol
  - ~5,250 ppm chlorine
  - Ethanol hand rub (70% ethanol)
  - Accelerated hydrogen peroxide, 1.4%
  - Accelerated hydrogen peroxide, 2%

Efficacy of Disinfectants and Antiseptics against *Candida auris*

Rutala, Kanamori, Gergen, Sickbert-Bennett, Weber, ICHE 2019;40:380

- ≤3 $\log_{10}$ (most <2 $\log_{10}$) reduction (*C. auris*, 1m, 5% FCS, QCT)
  - 0.55% OPA
  - 3% hydrogen peroxide
  - Quat, (0.085% QACs)
  - 10% povidone-iodine
  - ~1,050 ppm chlorine
  - 2% Chlorhexidine gluconate-CHG
  - 4% CHG
  - 0.5% triclosan
  - 1% CHG, 61% ethyl alcohol
  - 1% chloroxylenol

Disinfection and Sterilization: Current Issues and Future Perspectives

- Overview DS
- Sterilization-robustness
- HLD-What's new endoscope reprocessing
- HLD-outpatient care
- HLD-Human papillomavirus
- LLD-Electrostatic sprayers
- LLD-Ultrasound probes
- LLD-sporicide in all discharge pt rooms
- LLD-new sporicide-HP
- Colorized disinfectant
- LLD-"no" touch room decontamination
- Emerging pathogens
  - SARS-CoV-2
  - CRE
  - *C.auris*
- Continuous room decontamination technologies
  - Continuously active disinfectant

Continuous Room Decontamination Technologies for Disinfection of the Healthcare Environment

Weber, Rutala et al. AJIC. 2019;47:A72; Rutala et al. ICHE 2019

- Visible light disinfection through LEDs
- Dry/dilute hydrogen peroxide
- Self-disinfecting surfaces (e.g., copper)
- Far UV 222 nm
- Bipolar ionization
- Multijet cold air plasma
- Continuously active disinfectant (CAD) or persistent disinfectant that provides continuous disinfection action
  - Allows continued disinfection and may eliminate the problem of recontamination
  - Patients, staff and visitors can remain in the room

Microbial Assessment of Recontamination with *Acinetobacter* in Patient Room Environment in Burn Units

Rutala et al. AJIC. 2020; 48 Suppl;S20

- Purpose: assess how much environmental sites (e.g., chair, bedrail, overbed table, stock cabinet, IV pump, etc.) become recontaminated with *Acinetobacter* over time after cleaning/disinfection.
- Results:
- At baseline all environmental sites sampled except overbed table were contaminated with *Acinetobacter*.
- No *Acinetobacter* were detected except bed rail just after cleaning/disinfection.
- First time to recontamination with *Acinetobacter* was 3 hours at chair, 2 hours at overbed table, 3 hours at stock cabinet, and 2 hours at IV pump. No recontamination was observed at the monitor.
- The level of *Acinetobacter* contamination on surfaces was occasionally high (e.g., when a stock cabinet was sampled at 5 hours, 75 of 96 CFU were *Acinetobacter*).
- The amount of recontamination with aerobes and *Acinetobacter* on some surfaces tended to increase over time.

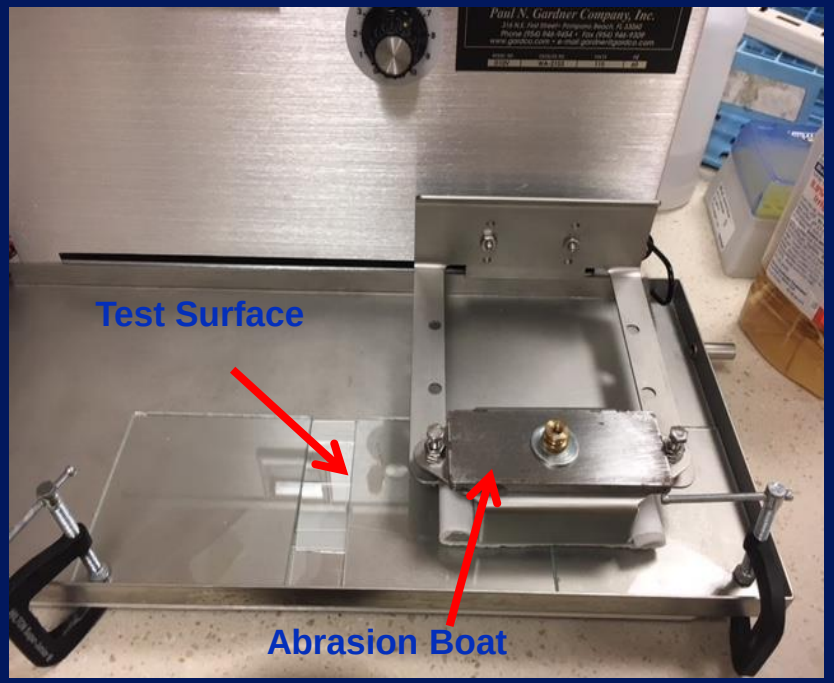
Surfaces should be hygienically clean (not sterile)-free of pathogens in sufficient numbers to prevent human disease

Evaluation of a Continuously Active Disinfectant

"EPA Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residuals on Hard, Non-Porous Surfaces"

Rutala et al. ICHE, In press, 2021; Rutala et al. ICHE 2019;40:1284

- Test surface inoculated (10^5), treated with test disinfectant, allowed to dry.
- Surface will undergo "wears" (abraded under alternating wet and dry conditions [24 passes, 12 cycles]) and 6 re-inoculations ($10^{\geq 3.75}$, 30min dry) over 48hr
- At the end of the study and at least 48 hours later, the ability of the test surface to kill microbes (99.9%) within 1 min is measured using the last inoculation (10^6)



Efficacy of a Continuously Active Disinfectant Against Healthcare Pathogens

Rutala WA et al. ICHE 2019;40:1284; Redmond et al. ICHE 2021, https://doi.org/10.1017/ice.2021.66

4-5 log_{10} reduction in 5 min over 24hr for most pathogens; ~99% reduction with *Klebsiella* and CRE *Enterobacter*. Redmond et al. found 5 log_{10} reduction for CRE *Enterobacter, K. pneumoniae*, MRSA, VRE, and *C. auris*

Test Pathogen	Mean Log_{10} Reduction , 95% CI n=4
*S.aureus**	4.4 (3.9, 5.0)
S.aureus (formica)	4.1 (3.8, 4.4)
S.aureus (stainless steel)	5.5 (5.2, 5.9)
VRE	≥4.5
E.coli	4.8 (4.6, 5.0)
Enterobacter sp.	4.1 (3.5, 4.6)
Candida auris	≥5.0
K pneumoniae	1.5 (1.4, 1.6)
CRE *E.coli*	3.0 (2.6, 3.4)
CRE *Enterobacter*	2.0 (1.6, 2.4)
CRE *K pneumoniae*	2.1 (1.8, 2.4)

Comparison of CAD with Three Disinfectants Using EPA Method and *S. aureus*

Rutala WA, Gergen M, Sickbert-Bennett E, Anderson D, Weber D. ICHE 2019;40:1284

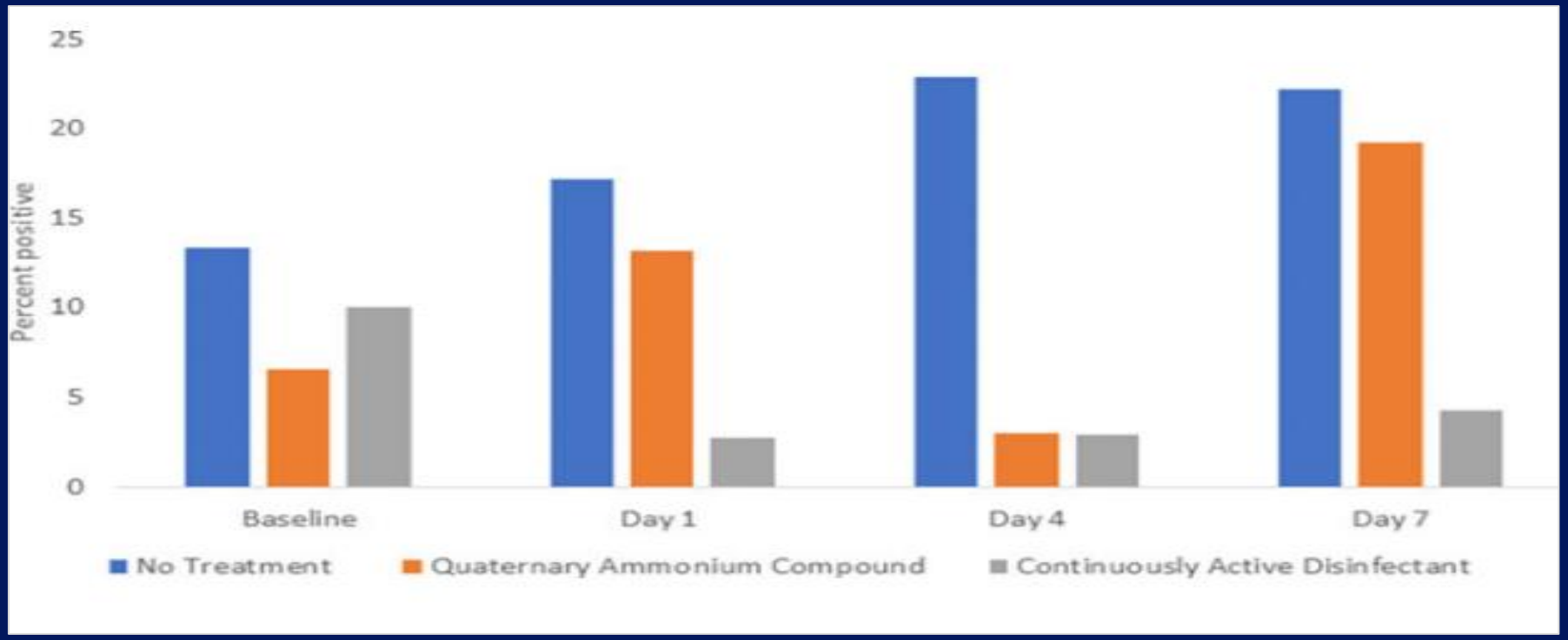
Test Disinfectant	Mean Log_{10} Reduction
Continuously Active Disinfectant	4.4
Quat-Alcohol	0.9
Improved hydrogen peroxide	0.2
Chlorine	0.1

Efficacy of Continuously Active Disinfectant for Portable Medical Equipment

Redmond et al. ICHE 2021, https://doi.org/10.1017/ice.2021.66

Comparison of *S. aureus* and enterococci recovered from PME at baseline, 1, 4, 7days

The percentage of sites positive for *S. aureus* and/or enterococci was significantly reduced on days 1-7 in the continuously active group (3 of 93, 3%) versus both the no treatment group (20 of 97, 21%) and the Quat group (11 of 97, 11%)



Will the continuously active disinfectant kill viruses like coronaviruses?

Efficacy of a Continuously Active Disinfectant Against a Human Coronavirus, 229E, Evaluated after 48 hours

Rutala WA et al. ICHE, In press

A novel disinfectant studied using an EPA protocol (wears/re-inoculations) demonstrated excellent continuous antiviral activity (i.e., >4.5-log_{10} reduction) in 1 minute after 48 hours for a human coronavirus, 229E

Carrier Treatment with Wears and Re-inoculations	Contact Time	Mean Viral Recovery Titer per Carrier (log_{10})	Log_{10} Reduction
Control (sterile water, n=3)	1 minute	6.00 ± 0.25	N.A.
Test disinfectant (n=3)	1 minute	≤ 1.50 ± 0.00	>4.50

Efficacy of a Continuously Active Disinfectant

Summary

A continuously active disinfectant may reduce or eliminate the problem of recontamination and the role of contaminated environmental surfaces and equipment in transmission of healthcare pathogens including SARS-CoV-2.

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THANK YOU!

www.disinfectionandsterilization.org

Environmental Disinfection in Healthcare Facilities

- Continuously active disinfectants reduces bioburden
- Whether a CAD translates in a reduction of HAIs remains to be determined
- Continuously active disinfectants should not alter the frequency of cleaning and disinfection as one of the purposes of routine cleaning and disinfection is to remove dirt and debris in addition to the reduction of microbial contamination