Disinfection and Sterilization
Current Issues, New Research and New Technology

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

2022

- **Consultations**
  - PDI (Professional Disposables International)
- **Honoraria**
  - PDI
- **Other**
  - Kinnos, Ideate Medical

Disinfection and Sterilization: Current Issues and New Technologies

- Overview DS
- HLD to Sterilization
- HLD to Sterilization-endo, new tech
- HLD to Sterilization
  - Duo-single use, endcaps
  - Urologic endoscopes, no HLD
- HLD-Human papilloma
- LLD-Ultrasound probes
- LLD-Electrostatic sprayers-new data
- LLD-new sporicide-HP-new tech
- LLD-sporicide in all discharge pt rooms
- LLD-emerging pathogens
- LLD-colorized disinfectant-new tech
- LLD-“no” touch room decontamination
- Continuous room decontamination technologies
  - Continuously active disinfectant-new technology

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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**.

Transition from HLD to Sterilization

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)

Infections/Outbreaks Associated with Semicritical Medical Devices

SES

Rutala, Weber. Am J Infect Control. Rutala WA, Weber DJ. Am J Infect Control. 2019 Jun;47S:A79-A89.

- HBV and HCV transmission during endoscopy and use of semicritical medical devices can occur, but it is rare (3)
- No articles related to possible transmission of HIV via medical device
- Greatest evidence of transmission associated with GI endoscopes/bronchoscopes(~130 outbreaks) likely due to microbial load and complexity.
- Several other semicritical medical devices are associated with infections related to inadequate reprocessing

Table 2
Infections and outbreaks associated with semicritical medical devices*

Instruments	# Outbreaks/ Infections	# Outbreaks/ Infections with bloodborne pathogens
Vaginal probes	0**	0
Nasal endoscopes	0	0
Hysteroscopes	0	0
Laryngoscopes	2[43-45]	0
Urologic instrumentation (eg, cystoscopes, ureteroscopes)	8[46-53]	0
Transrectal-ultrasound guided prostate probes	1[40]	0
Transesophageal echocardiogram	5[51,54-57]	0
Applanation tonometers	2[41,42]	
GI endoscopes/bronchoscopes	~130[7,8]	3 HBV[34]; HCV[35,36]

GI, gastrointestinal; *HBV*, hepatitis B virus; *HCV*, hepatitis C virus.
*These infections/outbreaks were found in the peer-review literature through PubMed and Google.
**Does not include outbreaks associated with contaminated ultrasound gel used with vaginal probes or transmission via health care personnel.

Slide 8

SES3 please confirm correct cite- it was listed as "in press"

Shenoy, Erica Seiguer,M.D.,Ph.D., 8/27/2021

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 bacteria)

vs

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

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).

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Future 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

- Optimize current LTST or new LTST proving SAL 10^{-6} achieved
- Disposable endoscopes (device innovations)
  - Partially-endcaps, decrease bacterial contamination after HLD
  - Fully-GI and bronchoscopes
- Steam sterilization for GI and other endoscopes
- Use of non-endoscopic methods to diagnose or treat disease
- Stop HLD for affected Storz urological endoscopes, transition to sterilization

New Endoscope Sterilization Technology

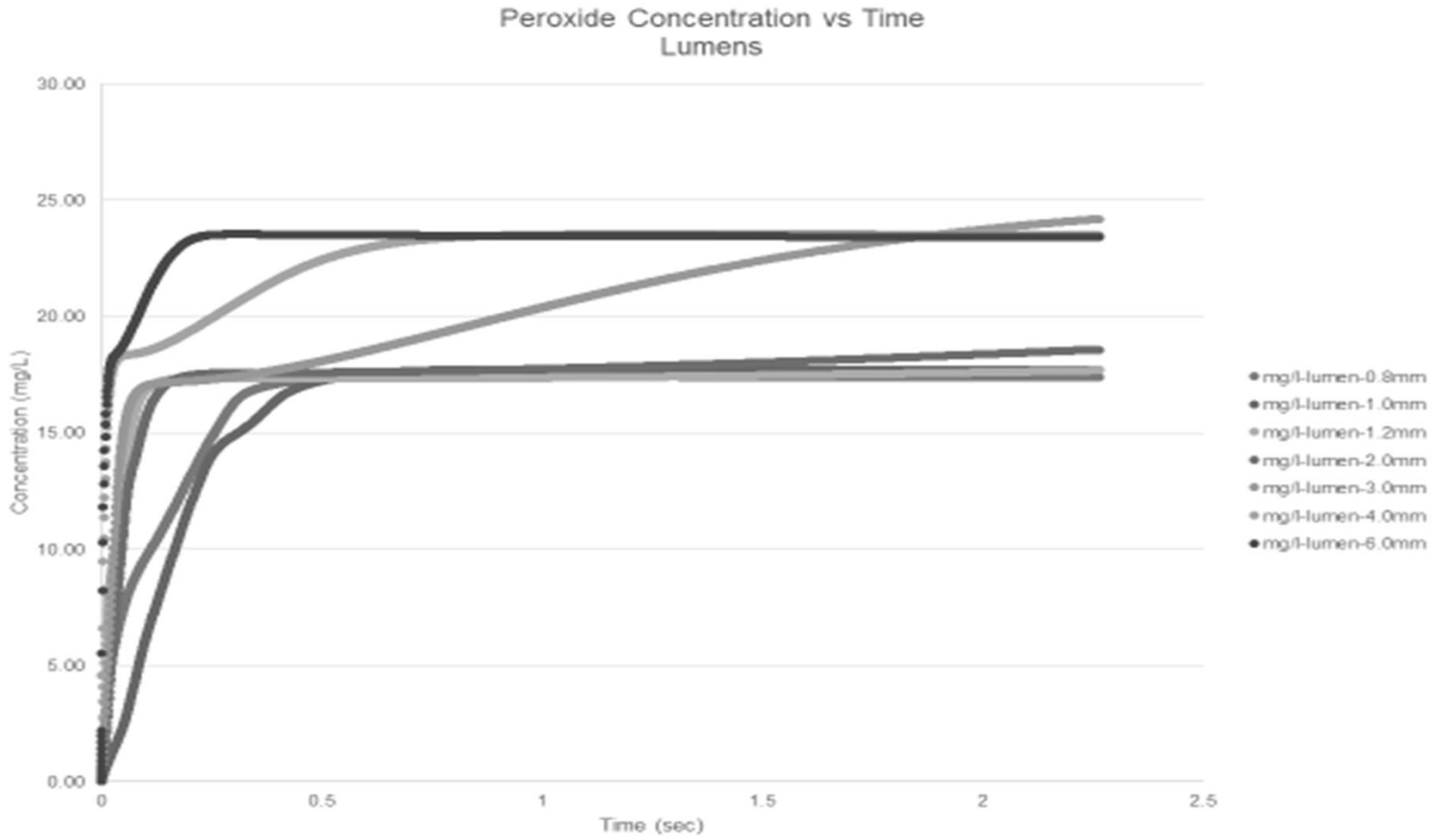
- New HP gas plasma sterilizer designed for the terminal sterilization of flexible endoscopes (will support sterilization of GI endoscopes and bronchoscopes/urologic endoscopes at initial release)
- Directs HP into the internal lumen channels of an endoscope
- Achieves the required concentration of VHP in channels up to 4m in <20s
- Footprint of automated endoscope reprocessor
- Uses lower concentration of HP with short exposure time, no damage
- Proprietary container facilitates sterile storage for 6 months
- Developer will seek FDA clearance in first-half of 2023

NEW STERILIZATION TECHNOLOGY



- Hydrogen Peroxide Gas Plasma sterilizer designed specifically for the terminal sterilization of flexible endoscopes
- Incorporates a proprietary vapor diffusion technology to direct Vaporized Hydrogen Peroxide (VHP) into the internal lumen channels of an endoscope
    - Utilizes a pressure differential in each internal endoscope channel to rapidly diffuse VHP to sterilize all endoscope channels
    - Achieves the required VHP efficacy concentration in all internal endoscope channels (up to 4 meters) in < 20 secs
    - Uses lower overall concentration of H_2O_2 with shorter exposure times, thereby eliminating potential damage to the endoscope
- Incorporates a proprietary sterilization container that interfaces with the sterilizer during the sterilization process and facilitates sterile storage (6 months) of the endoscope after processing
- Incorporates a proprietary pre-sterile single-use channel connector that is pressure activated. It seals during VHP transfer and then releases to allow sterilization of the mated connector interface
- Based on initial testing, we were able to sterilize an Olympus duodenoscope (TJF-Q160F) 125 times with no damage to the device

INTERNAL LUMEN H2O2 CONCENTRATONS (SURROGATE SCOPE - 3 METERS/7 CHANNELS)



DUODENOSCOPE ELEVATOR CHANNEL EFFICACY DATA

0.8mm ID X 1.6 M with 59% H202

Run	$[H_2O_2]_{Chamber}$ (mg/L)	Wire-BI Positives
1	19.2657	0
2	19.0984	0
3	19.8270	0
4	16.7001	0
5	20.9575	0
6	20.3405	0
7	19.2491	0
8	19.9215	0
9	21.5882	0
10	19.3935	0
11	23.1596	0
12	21.8425	0
13	22.0940	0
14	17.4122	0
15	23.1596	0
16	23.4499	0
17	20.4509	0
18	21.6296	0
19	20.4399	0
20	20.6036	0
21	21.4005	0
22	20.0804	0
23	20.2234	0
24**	N/A	N/A
25	13.6994	0
26	15.6713	0
27	18.7494	0
28	20.6106	0
29	19.7891	0
30	20.4717	0
31	19.7248	0
32	21.4151	0
33	18.4306	0
34	18.1938	0
35	20.6381	0
36	21.558	0
37	20.4089	0
38	19.4266	0
39	18.4615	0
40	19.8363	0
Average	**19.9839**	
SD	1.9128	

** PC did not record

Feasibility results: 0 positives/39 runs (SS wires inoculated with 10^6 *Geobacillus stearothermophilus* spores)

CAPABILITY TO TERMINALLY STERILIZE BROAD RANGE OF ENDOSCOPES

Name	Model	Total Length (mm)	Lumen Inner Diameter (mm)	# of Channels & Names	
Fuji Enteroscope	EN-580T	2300	1.2 – 3.2	4	1 Suction/Biopsy, 1 Air, 1 water, 1 Second Air
Olympus Duodenoscope	TJF-Q160F	1585	0.8	5	1 Suction/Biopsy, 1 Air, 1 water, 1 Second Air, 1 Elev. Wire
Olympus Gastrointestinal Videoscope	GIF-XTQ160	1400	6	5	1 Suction/Biopsy, 1 Air, 1 water, 1 Second Air, 1 Elev. Wire
Olympus Ultrasound Gastroscope	GF-UM160	1560	3.7	7	1 Suction/Biopsy, 1 Air, 1 water, 1 Second Air, 1 Elev. Wire, 1 Balloon Inflation, 1 Balloon Evacuation
Pentax Colonoscope	EC-38-i10L	2016	1.2-3.8	5	1 Suction/Biopsy, 1 Air, 1 water, 1 Second Air, 1 Aux. Water

- Boundary condition devices

7 channels, a lumen inner diameter of 0.8mm or larger x 1600mm and 1.2mm or larger x 4 meters

New Endoscope Sterilization Technology

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The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication

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Update as of April 4, 2022: The FDA provided new information supporting the transition to fully disposable duodenoscopes and those with disposable components as well as new information on completed postmarket surveillance studies (also known as 522 studies).

Transition to Innovative Duodenoscope Designs-Disposable Endcaps or Fully Disposable Duodenoscopes

Use Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication

Share Tweet Linkedin Email Print

Date Issued: April 5, 2022

The U.S. Food and Drug Administration (FDA) is updating the April 2020 Safety Communication to provide new information supporting the transition to fully disposable duodenoscopes and those with disposable components as well as new information on completed postmarket surveillance studies (also known as 522 studies).

Given the cleaning concerns and contamination data with fixed endcap duodenoscopes and the increasing availability of duodenoscope models that facilitate or eliminate the need for reprocessing, hospitals and endoscopy facilities should complete transition to innovative duodenoscope designs that include disposable components such as disposable endcaps, or to fully disposable duodenoscopes. The use of a removable component to facilitate cleaning leads to significantly less contamination; interim results from one

FDA Cleared at least 6 Duodenoscopes with Disposable Components or Fully Disposable

Fully Disposable:

- Ambu Innovation GmbH, Duodenoscope model aScope Duodeno (fully disposable duodenoscope cleared under K201098)
- Boston Scientific Corporation, EXALT Model D Single-Use Duodenoscope (fully disposable duodenoscope cleared under K193202)

Disposable Components:

- Fujifilm Corporation, Duodenoscope model ED-580XT (disposable endcap duodenoscope cleared under K181745)
- Olympus Medical Systems, Evis Exera III Duodenovideoscope Olympus TJF-Q190V (disposable endcap duodenoscope cleared under K193182)
- Pentax Medical, Duodenoscope model ED34-i10T2 (disposable elevator duodenoscope cleared under K192245 and K210710)
- Pentax Medical, Duodenoscope model ED32-i10 (disposable elevator duodenoscope cleared under K202365)

No Longer Marketed:

- Pentax Medical, Duodenoscope model ED34-i10T (disposable endcap duodenoscope cleared under K163614 and K181522)

Transition to Innovative Duodenoscope Designs-Disposable Endcaps or Fully Disposable Duodenoscopes

Duodenoscopes with disposable endcap



Sterile, single-use duodenoscope for ERCP



Transition to Innovative Duodenoscope Designs-Disposable Endcaps or Fully Disposable Duodenoscopes: Why?

www.fda.gov

- Best solution to reducing the risk of disease transmission by duodenoscopes is through innovative device design that make reprocessing easier, more effective, or unnecessary.
- Postmarket surveillance studies on fixed endcap design indicate that as high as 6.6% (56/850) of samples tested positive with high concern organisms (e.g., *E. coli*, *Pa*). Interim results with removable components show 0.5% (2/417) tested positive with high concern organisms
- As a result, Pentax and Olympus are withdrawing their fixed endcap duodenoscopes from the market, and Fujifilm has completed withdrawal

Sterilize Karl Storz Urological Endoscopes

www.fda.gov

UPDATE: Change in Reprocessing Methods with Certain Karl Storz Urological Endoscopes – Letter to Health Care Providers

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April 4, 2022

As the U.S. Food and Drug Administration (FDA) continues to evaluate the risk of patient infections and contamination issues associated with reprocessed urological endoscopes, the FDA is aware that the current reprocessing instructions for certain urological endoscopes manufactured by Karl Storz are inadequate and are being changed updated by Karl Storz. The affected urological endoscopes include cystoscopes, ureteroscopes, cystourethroscopes and ureterorenoscopes, used for viewing and accessing the urinary tract.

In April 2021, the FDA communicated about reported patient infections and possible contamination issues with reprocessed urological endoscopes. At the FDA's request, Karl Storz conducted reprocessing validation testing on a sample of flexible urological endoscopes and identified reprocessing failures following high-level disinfection. Inadequate reprocessing of urological endoscopes may increase the risk of patient infection.

Sterilize Karl Storz Urological Endoscopes

www.fda.gov

- At FDA request, Karl Storz conducted reprocessing validation testing on a sample of flexible urological endoscopes and identified reprocessing failures following HLD.
- Do not use HLD methods or liquid chemical sterilization to reprocess affected urological endoscopes (HLD not achieved for affected products)
- Sterilize affected urological endoscopes after each use by using sterilization methods recommended in MIFU
- Do not use affected urological endoscopes if you do not have access to an appropriate sterilization method

Sterilize Karl Storz Urological Endoscopes

https://www.karlstorz.com/cps/rde/xbcr/karlstorz_assets/ASSETS/3680244.pdf

STORZ
KARL STORZ — ENDOSKOPE

ENDOSCOPES FOR MEDICINE AND TECHNICAL SCIENCE
INSTRUMENTS FOR OTO-RHINO-LARYNGOLOGY

Rev 1: April 2022

FSN Ref: 22-0002

Date: April 1, 2022

Urgent Medical Device Recall Notice
Certain KARL STORZ Flexible Endoscopes for Urological Use

For Attention of: Representatives for medical product safety, users, operators, importers, distributors

Commercial name(s):	See Appendix
Device Model/Catalogue/part numbers :	See Appendix
Affected serial numbers:	All serial numbers of devices listed
FSN Type:	New FSN, Ref.: 22-0002

Sterilize Karl Storz Urological Endoscopes

https://www.karlstorz.com/cps/rde/xbcr/karlstorz_assets/ASSETS/3680244.pdf

STORZ
KARL STORZ — ENDOSKOPE

APPENDIX
Affected Endoscopes and Reprocessing Methods

X = Method Not Acceptable and ✓ = Method Acceptable

Scope Base Part Number	Scope Kit Number	Product Description	Current IFU	Affected Reprocessing Methods	
				All High-Level Disinfection	Liquid Chemical Sterilization (STERIS System 1E)
11272C1	N/A	Flexible Cysto-Urethroscope Fiberscope	Z18449US-BD (08-2018)	X	X
11272C2	11272CK2	Flexible Cystoscope	Z18449US-BD (08-2018)	X	X
11272CU1	11272CUK1	Flexible Cystoscope	Z18449US-BD (08-2018)	X	X
11272V	N/A	Flexible CMOS Video Cysto Urethroscope	Z18446US-BE (01/2020)	X	X
11272VA	11272VAK	Flexible CMOS Video Cysto Urethroscope	Z18446US-BE (01/2020)	X	X
11272VH-TL	11272VHK-TL	HD-VIEW Flexible HD Cysto-Urethroscope	Z23875US-BC (10-2021)	X	X
11272VHU-TL	11272VHUK-TL	HD-VIEW Flexible HD Cysto-Urethroscope	Z23875US-BC (10-2021)	X	X
11272VN	11272VNK	Flexible Video Urethro Cystoscope	Z18442US-BD (08/2018)	X	X
11272VNU	11272VNUK	Flexible Video Urethro Cystoscope	Z18442US-BD (08/2018)	X	X
11272VU	11272VUK	Flexible CMOS Video Cysto Urethroscope	Z18446US-BE (01/2020)	X	X
11272VUA	11272VUAK	Flexible CMOS Video Cysto Urethroscope	Z18446US-BE (01/2020)	X	X
11272VUE	11272VUEK	Flexible Video Cysto-Urethroscope	96136031USCA V1.1 (04/2021)	X	X

Did supplemental measures work?

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

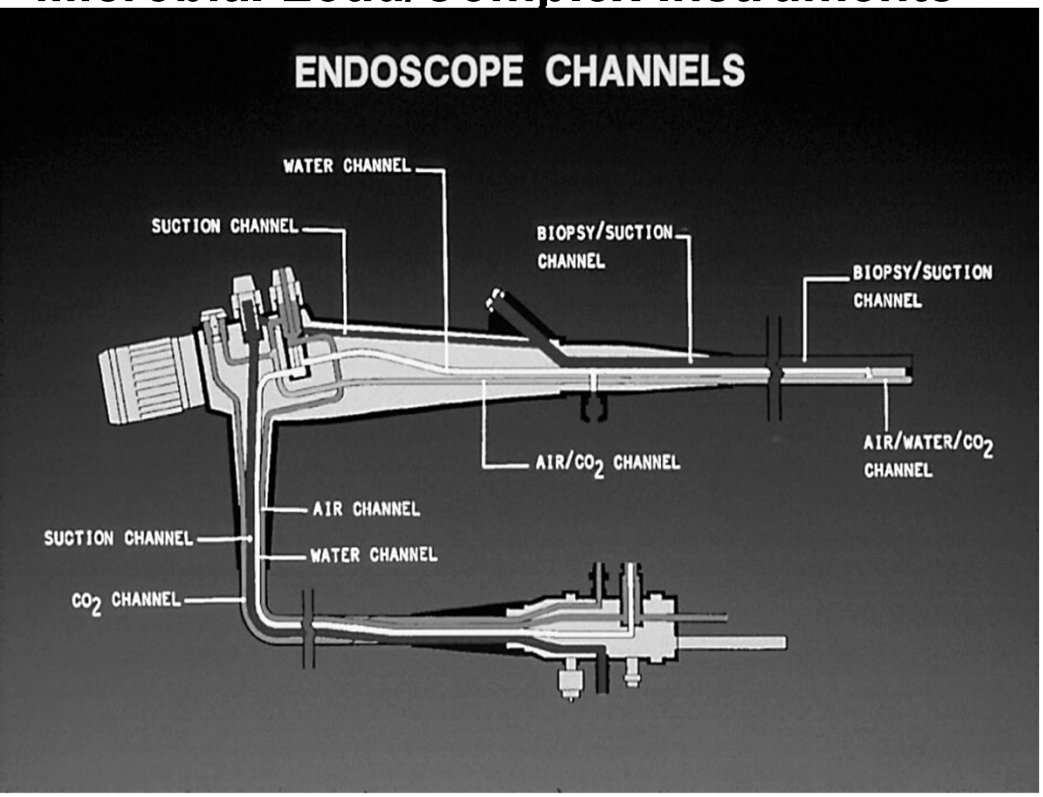
Supplemental Measures for Endoscope Reprocessing

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

Endoscope Reprocessing

Microbial Load/Complex Instruments



New Guidelines

- Multi-society guideline-2021
- AAMI, ST91-2021
- SGNA-2021
- AORN-2016
- Must educate/comply but confident will not prevent all infections and patient exposures due to microbial load and instrument complexity

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

- Optimize current LTST or new LTST proving SAL 10^{-6} achieved
- Disposable endoscopes (device innovations)
  - Partially-endcaps, decrease bacterial contamination after HLD
  - Fully-GI and bronchoscopes; cost, scope performance
- Steam sterilization for GI and other endoscopes
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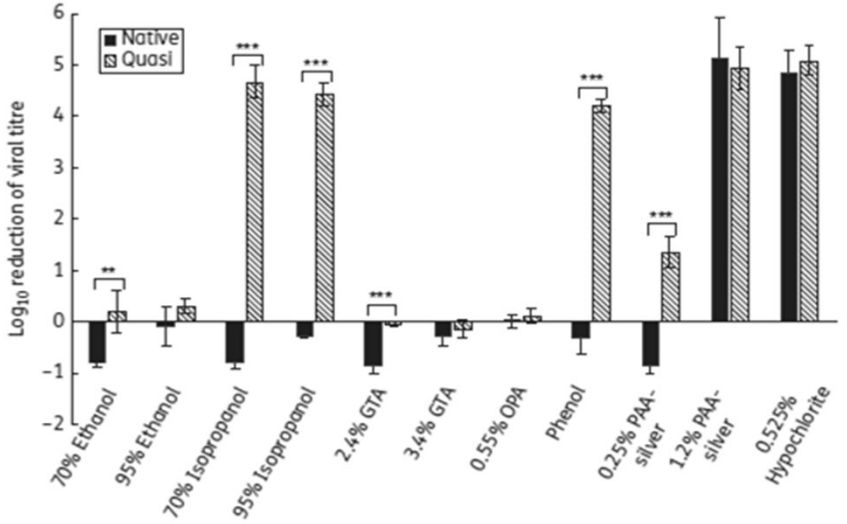
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Human Papillomavirus

- 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 original 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

HLD Inactivate Papillomavirus

Egawa et al. EBioMedicine 2021;63

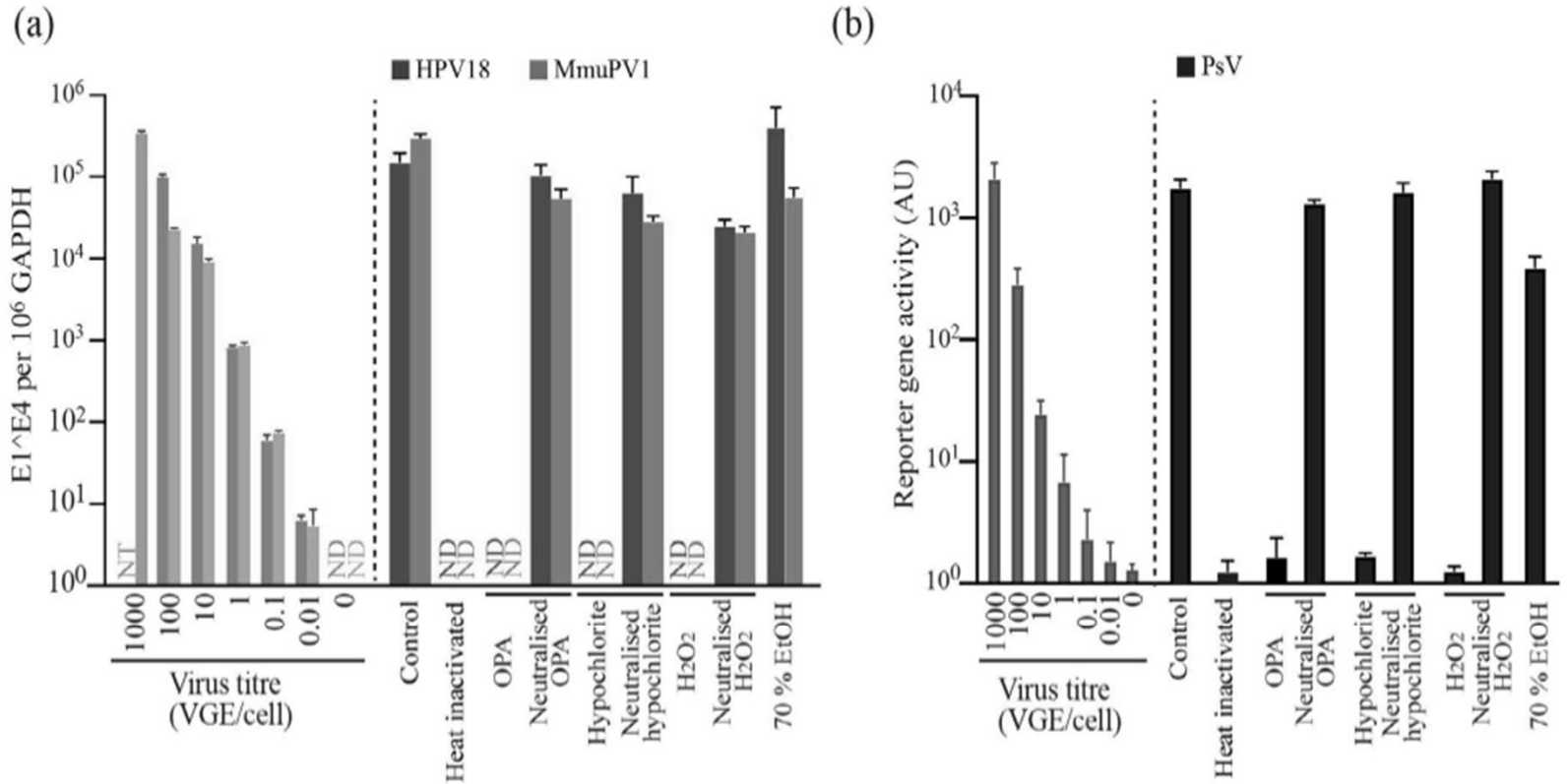


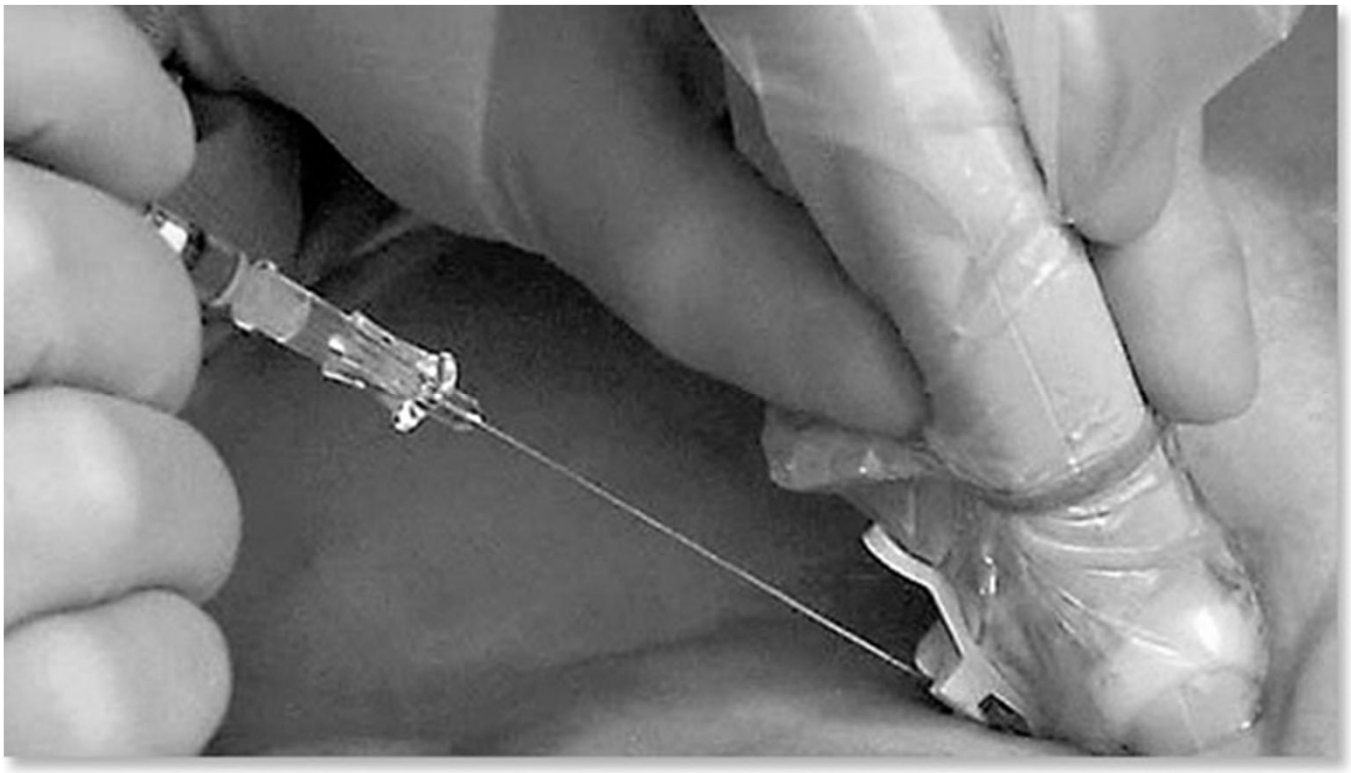
Fig. 5. Evaluation of disinfectant efficacy using in vitro infection assay

(a, b) Measurement of viral infectivity (E1^E4 viral gene transcripts or reporter gene activity shown as Mean and SD) of HPV18, MmuPV1 and PsV in HaCaT cells following incubation with viruses treated with disinfectants or their neutralised equivalent (except 70% ethanol). AU, arbitrary unit; ND, not detected. Data were obtained with biological triplicates and shown as Mean and SD.

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- HLD to Sterilization-endo, new tech
- HLD to Sterilization
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- Continuous room decontamination technologies
  - Continuously active disinfectant-new technology

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 [vaginal]-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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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

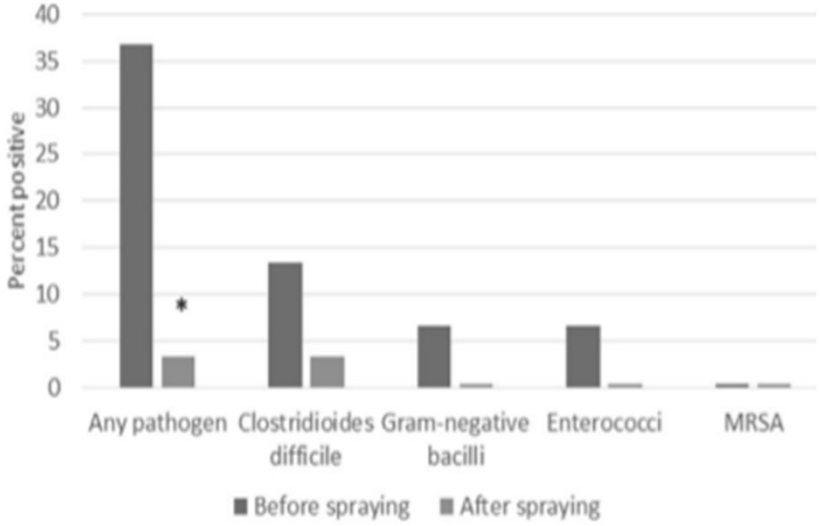
Picture of electrostatic sprayer

(0.25% sodium hypochlorite)



Efficacy of disinfectant spray

(waiting room chairs)



UVC vs Electrostatic Sprayer (0.25% NaOCl) for Adjunctive Room Decontamination

Carlisle MG, Rutala WA…Donskey CJ. ICHE. 2022. doi:10.1017/ice.2022.132

ES Sprayer and UVC similarly effective in reducing pathogen contamination on floors and high-tech surfaces

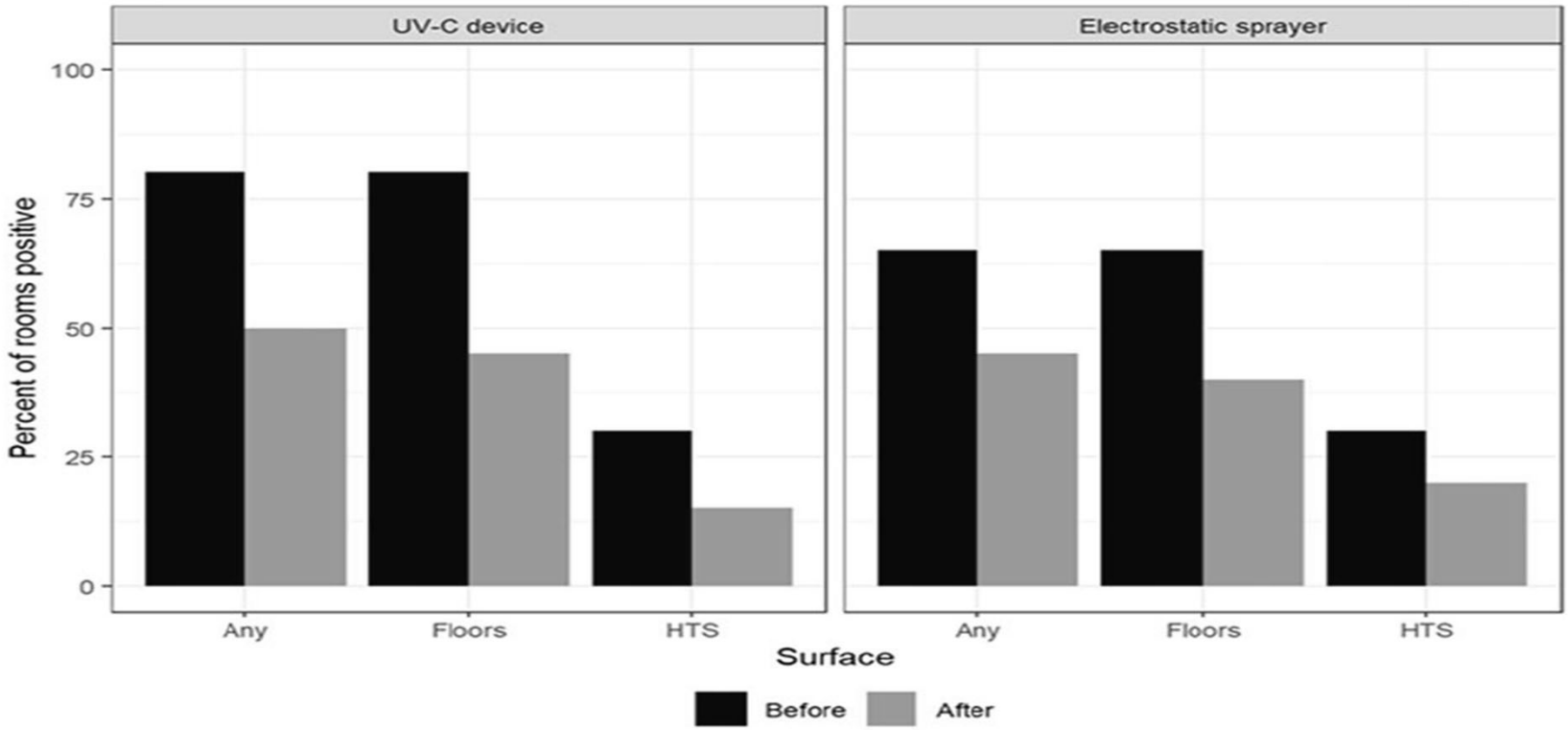


Fig. 1. Percentages of rooms with positive cultures for 1 or more healthcare-associated pathogens before versus after treatment with the ultraviolet-C (UV-C) light device or the electrostatic sprayer. Note. HTS, high-touch surface.

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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Novel Hydrogen Peroxide Sporicide

Cadnum et al. AJIC 2021

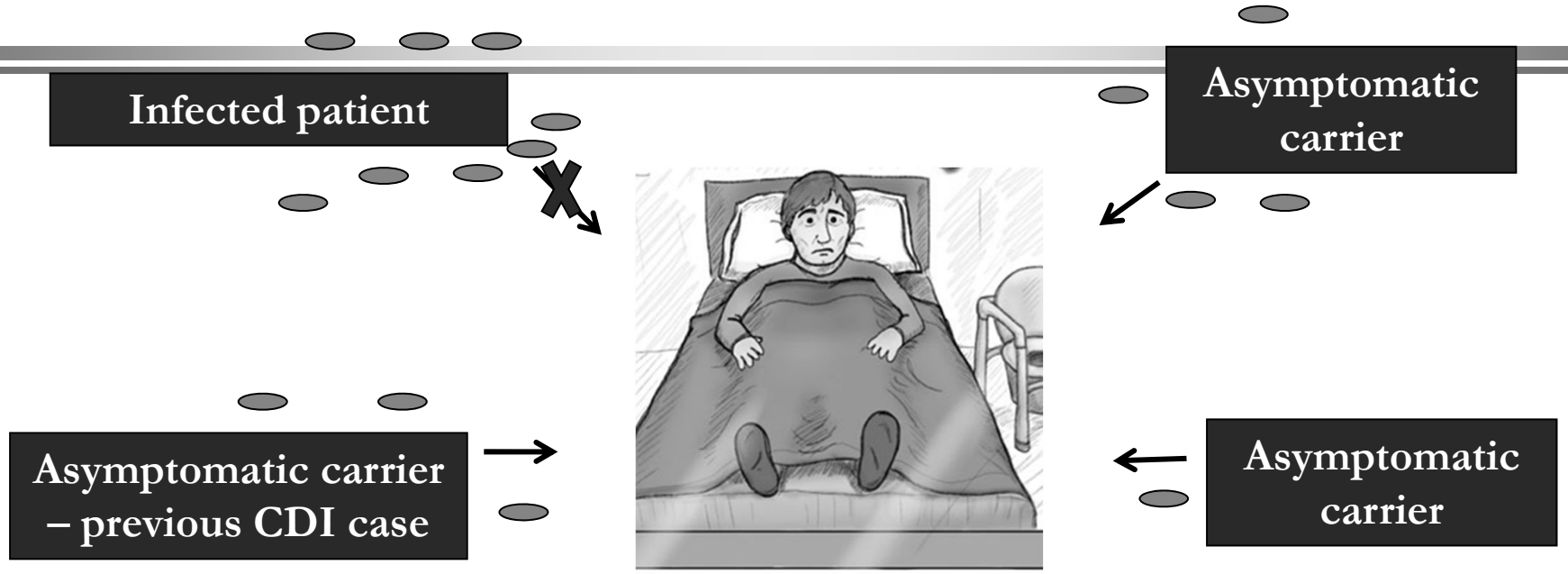
A novel 4% HP was effective against MRSA, CRE, *C. difficile* spores and *C. auris.* HP may be a useful addition to the sporicidal products available in healthcare.

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)

Asymptomatic carriers contribute to room contamination and *C. difficile* transmission

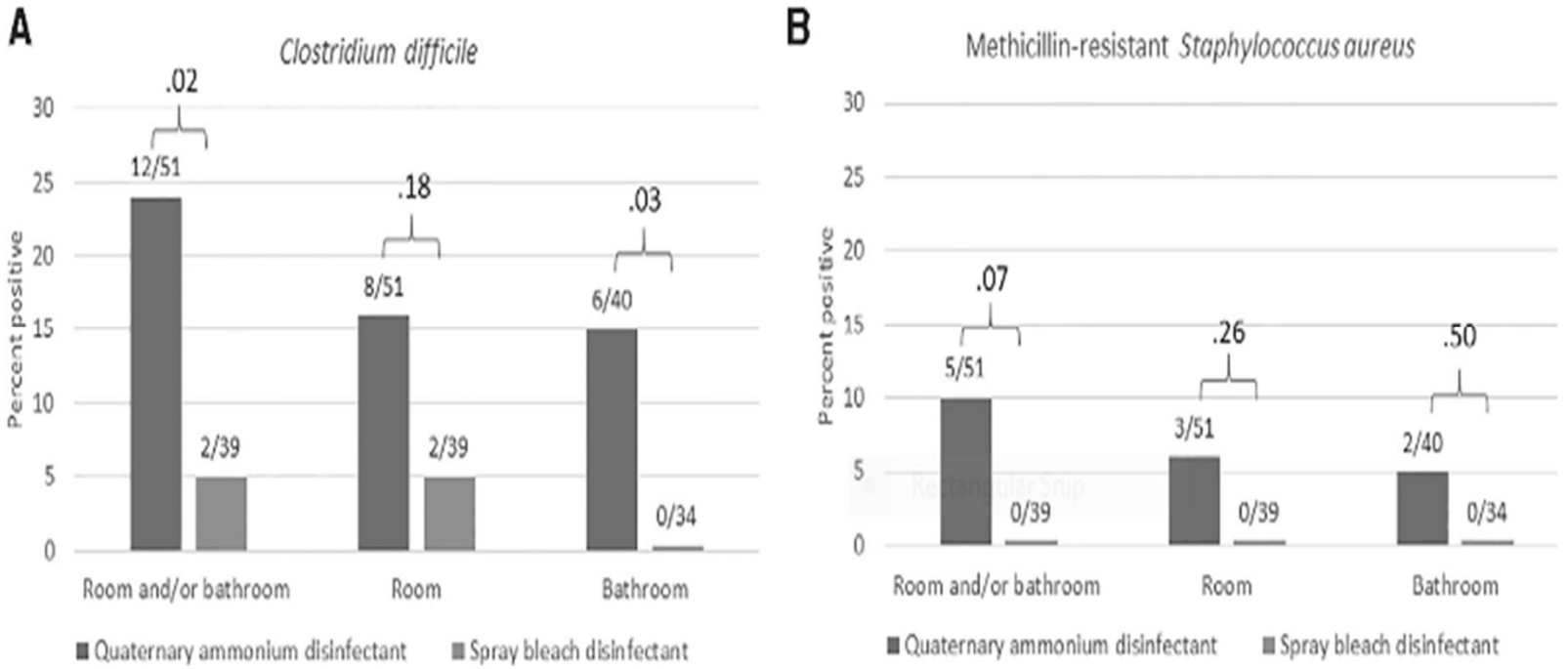
(courtesy Dr. Donskey)



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



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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.

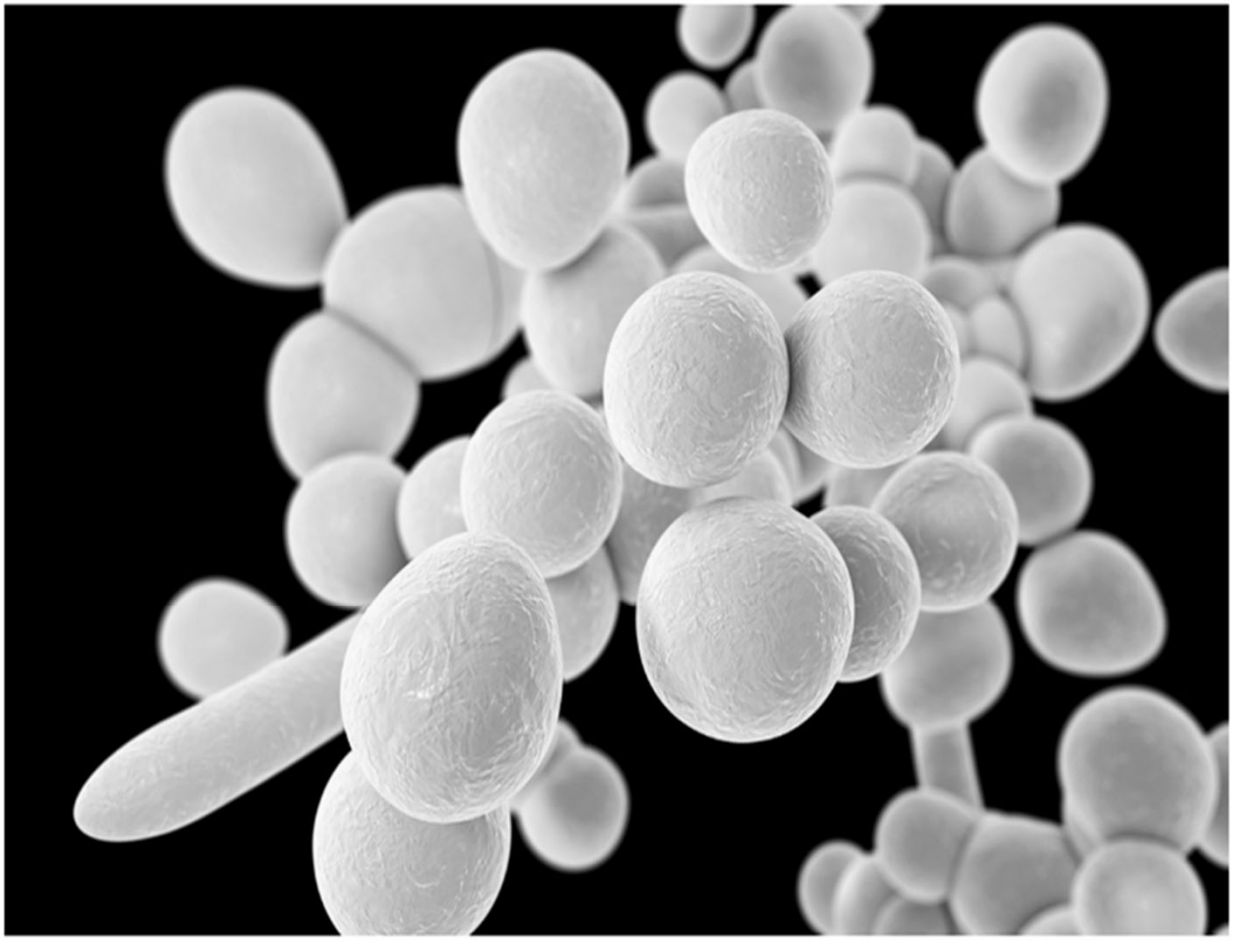
KEYWORDS carbapenem-resistant *Enterobacteriaceae*, *Klebsiella pneumoniae* carbapenemase, colistin-resistant *Enterobacteriaceae*, *mcr-1*, germicides, disinfectants, antiseptics, efficacy

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 2018

- ≥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, 2019

- ≤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

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, In press

- 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."

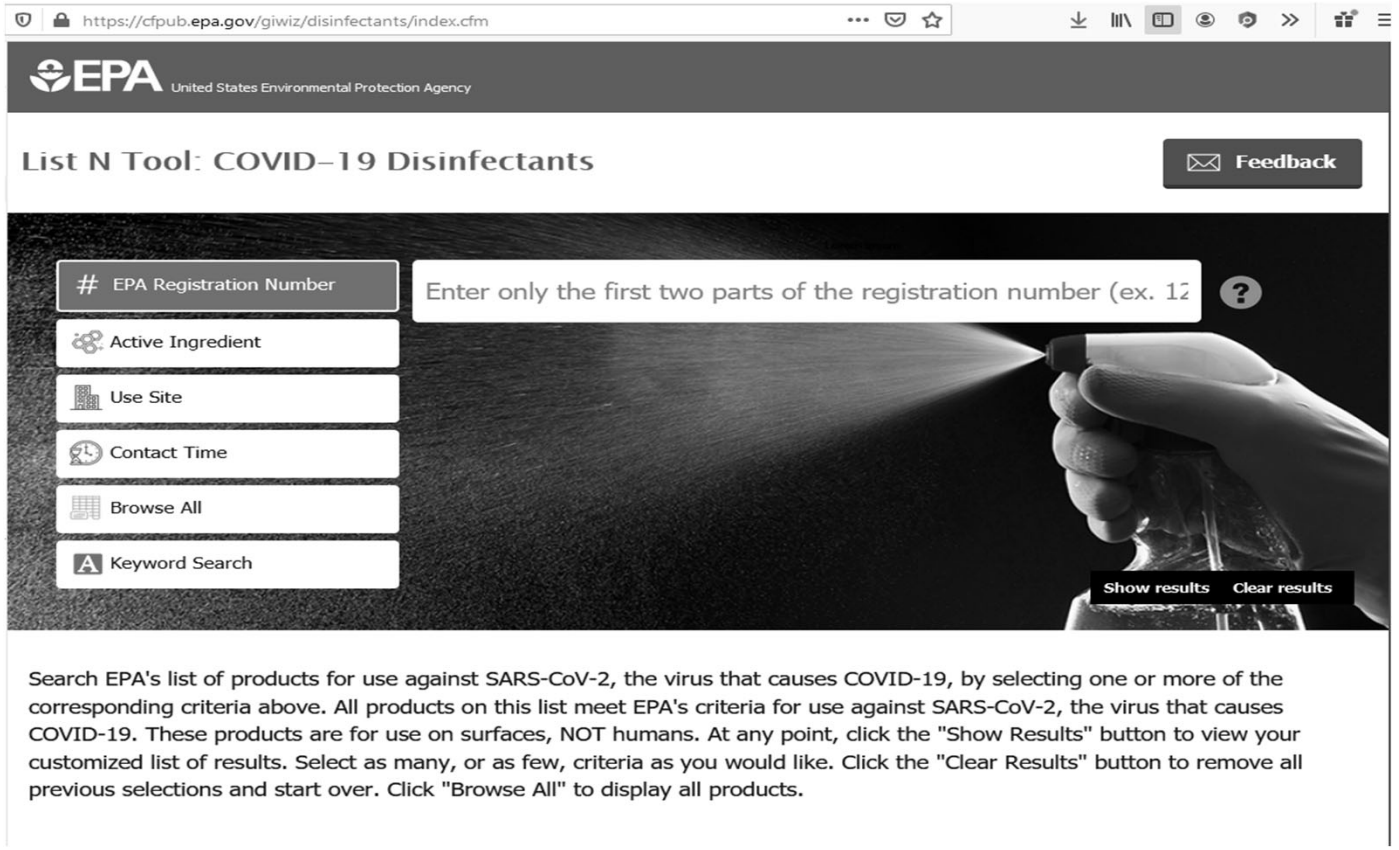
Role of Healthcare Surface Environment in SARS-CoV-2 Transmission

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

- 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

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
- Hypochlorous acid
- Isopropyl alcohol
- Peracetic acid
- Phenolic
- Quaternary ammonium

Disinfection and Sterilization: Current Issues and New Technologies

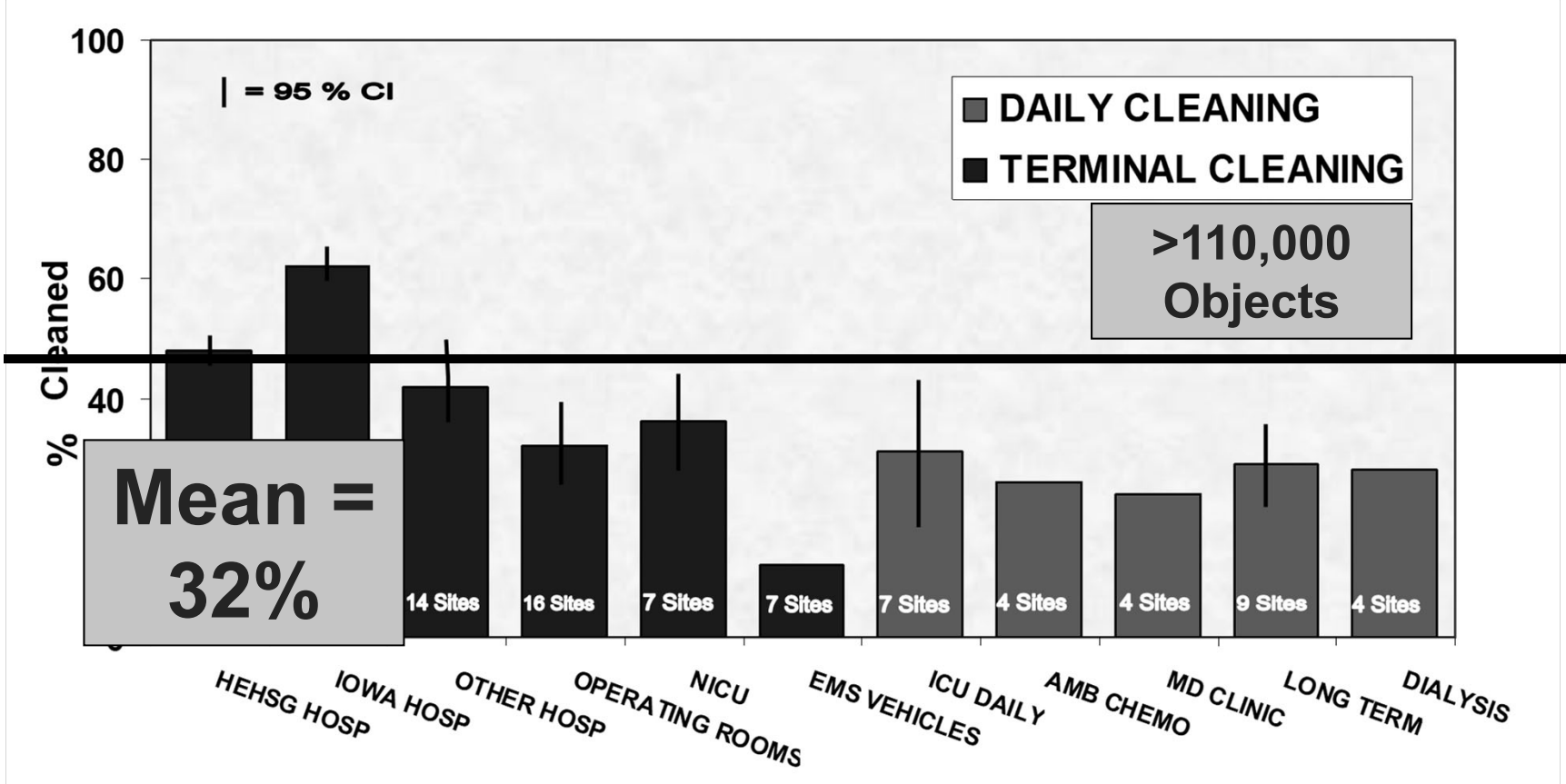
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Effective Surface Decontamination

Product and Practice = Perfection

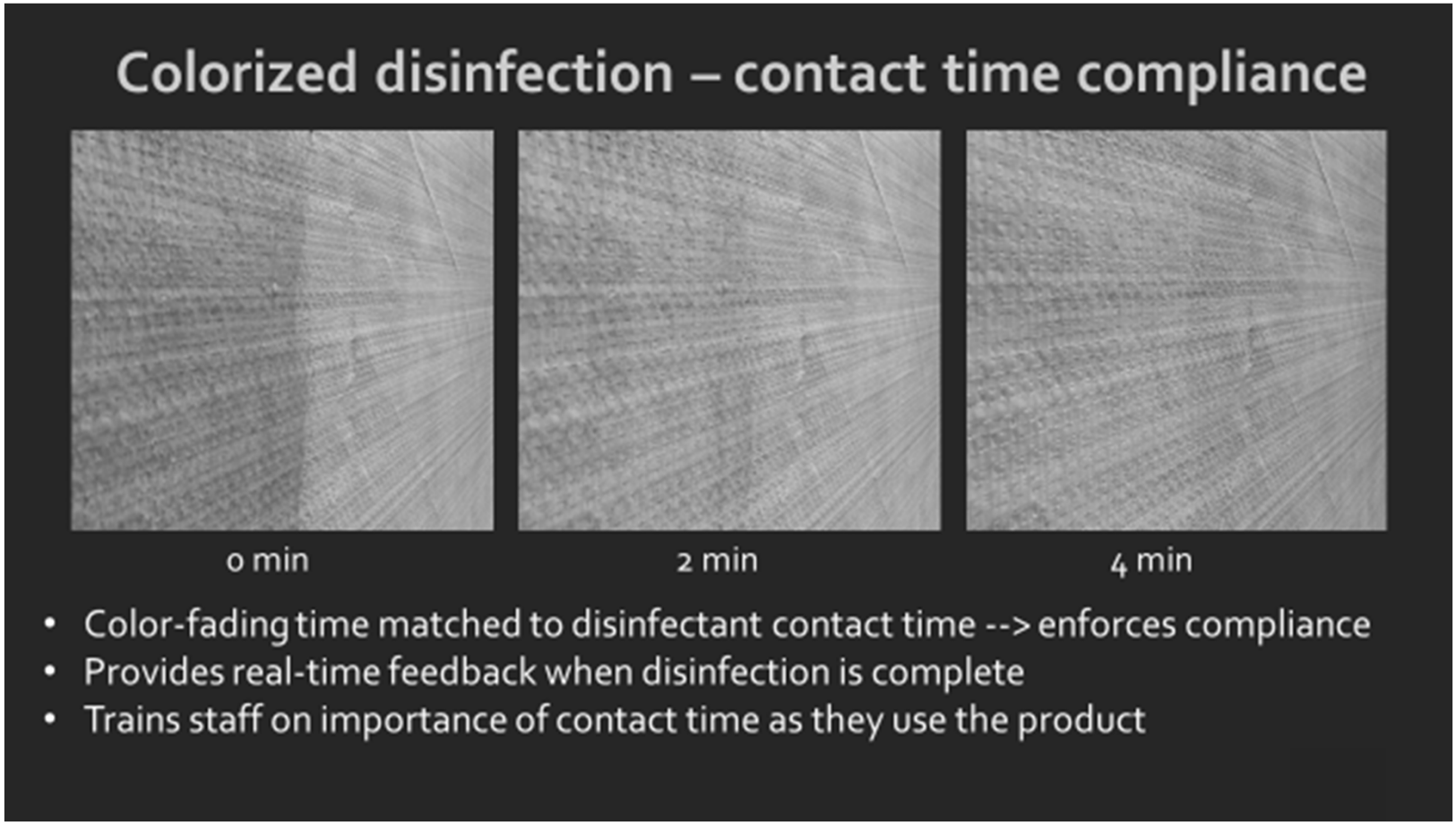
Thoroughness of Environmental Cleaning

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



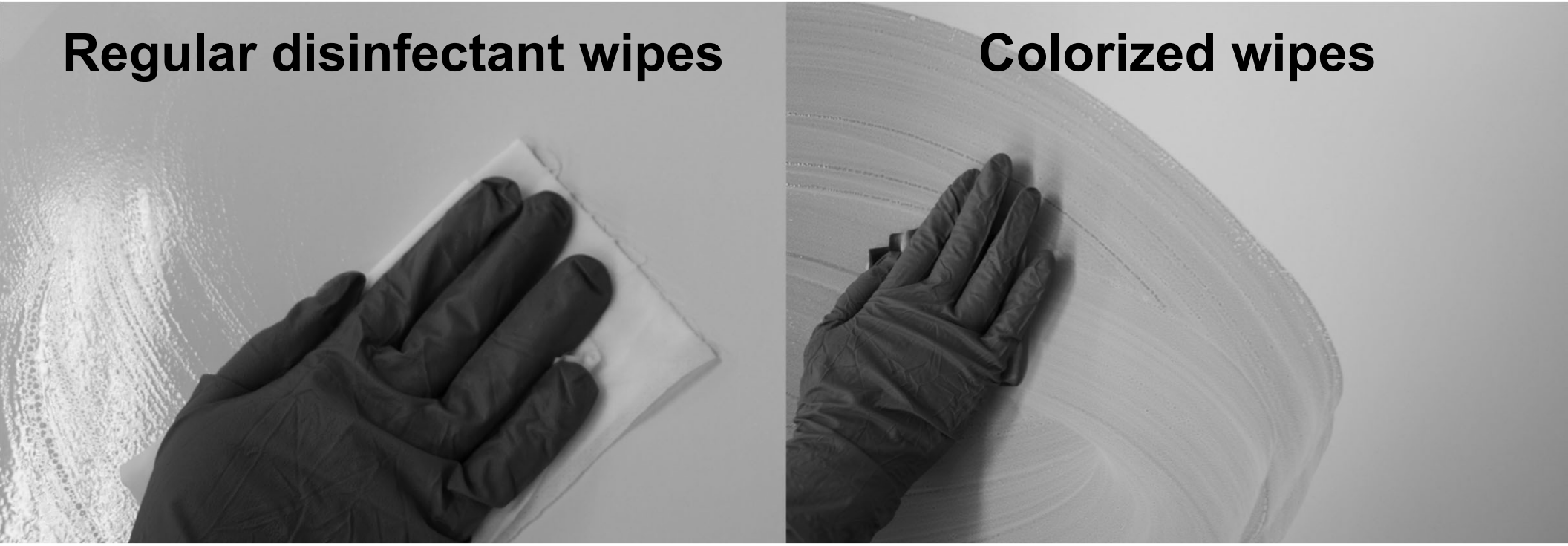
Methods to Ensure Thoroughness Such as Colorized Disinfectant

Kang et al. J Hosp Infect 2017



Courtesy of Kevin Tyan and Rachael Sparks

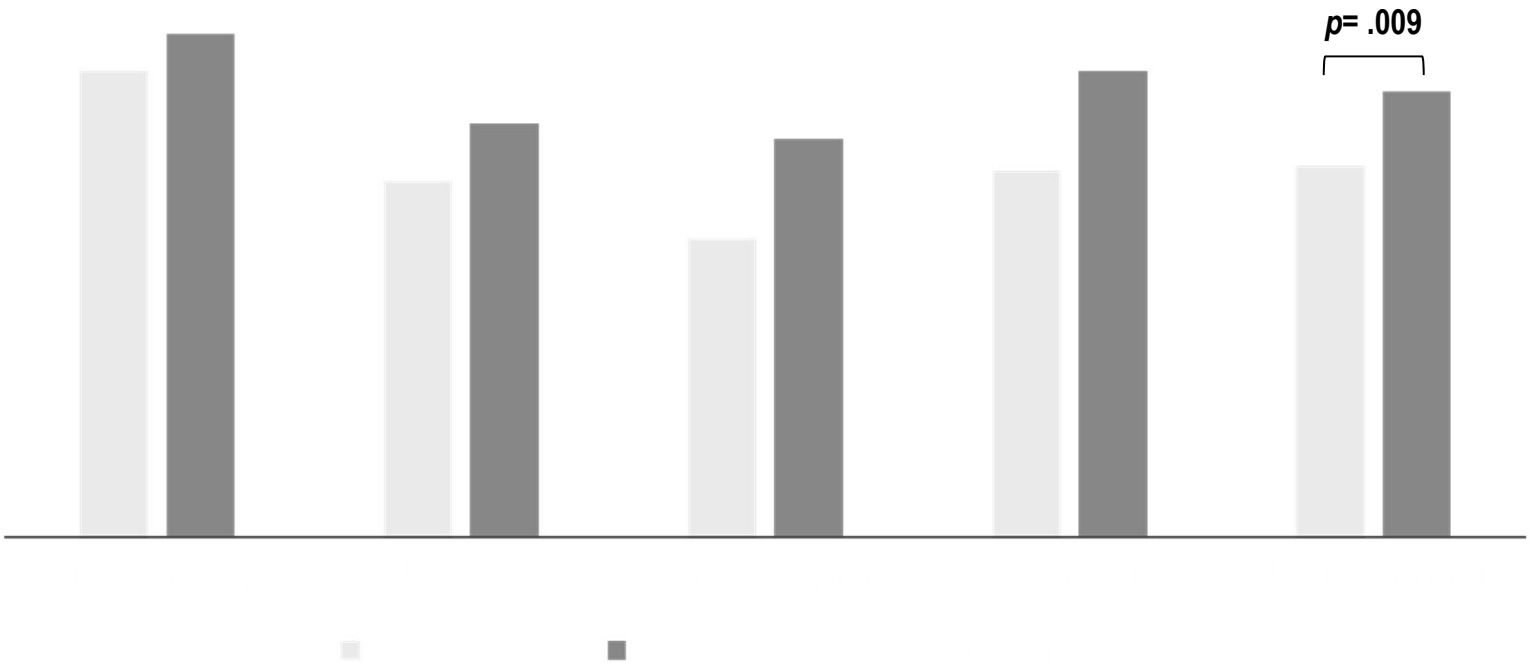
Colorized disinfection – empowers behavior change to improve coverage



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

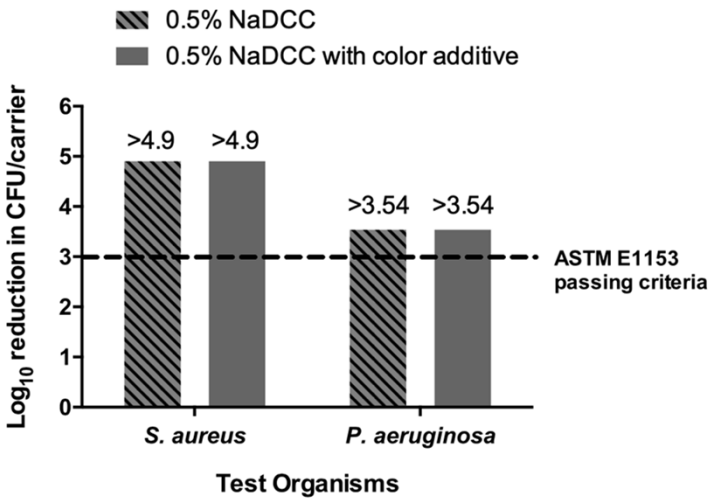
Colorized disinfectant increases cleaning efficacy by 29%

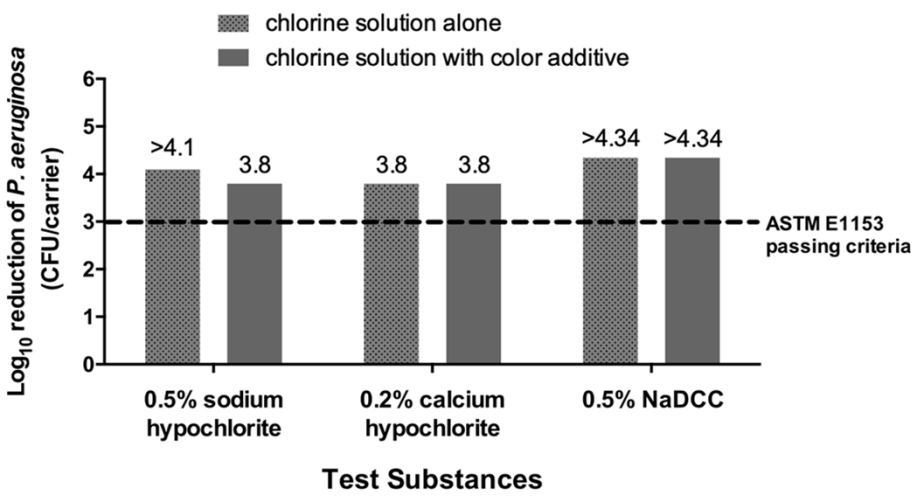
Cleveland VA Medical Center found colorized disinfectant to quantifiably improve thoroughness of cleaning



Manuscript in preparation.

Efficacy and skin toxicity testing of colorized disinfectant®

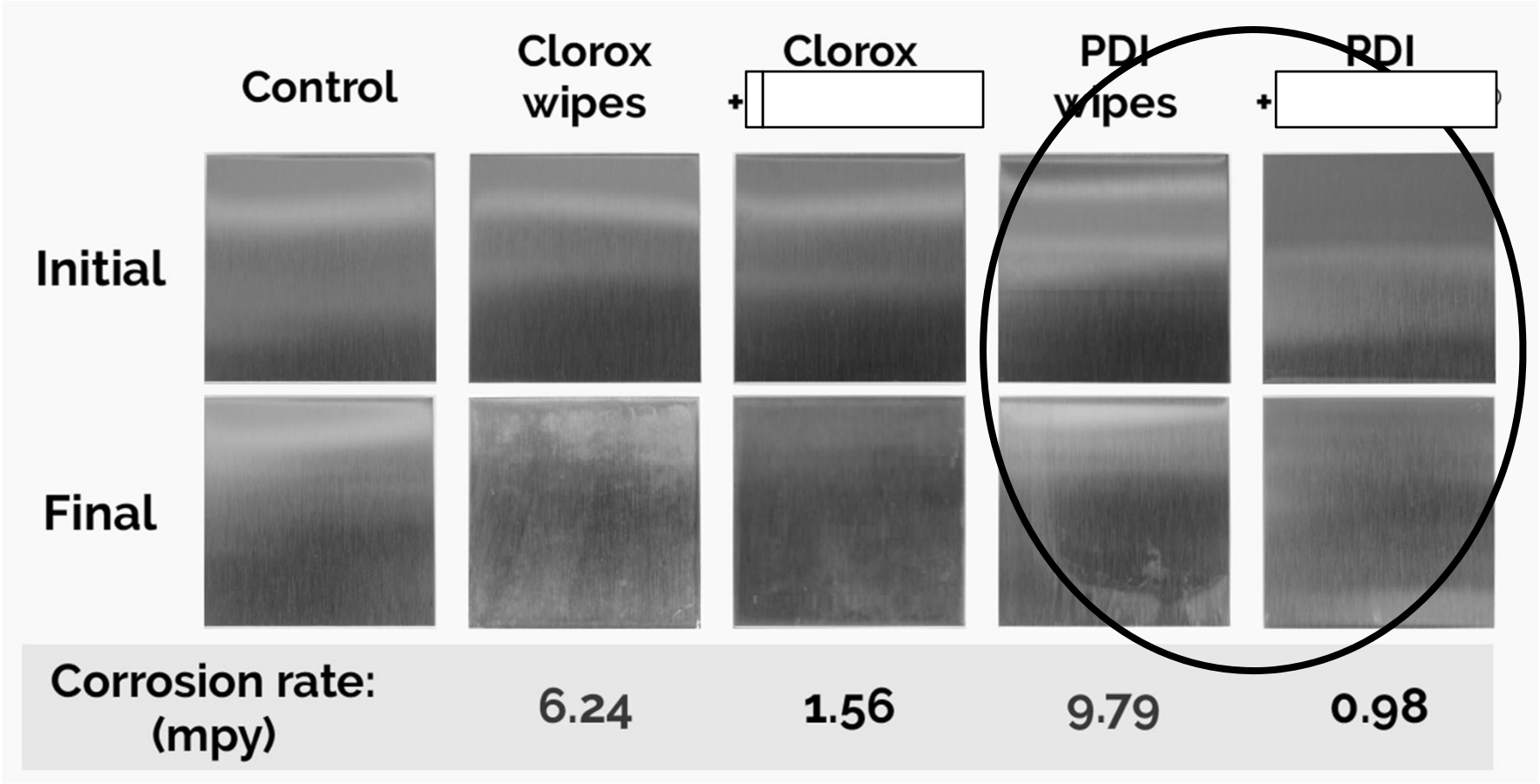




- 3rd party testing: Colorized disinfectant is a non-irritant and does not reduce efficacy of disinfectant

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

Colorized disinfectant reduces bleach corrosiveness



Bleach wipes alone caused severe corrosion (> 5 mils per year [mpy], 1 normal) while the addition of colorized disinfectant both significantly reduced corrosion rate (< 2 mils per year) 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 (Quat/Alc) wipe cannisters

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



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Environmental Contamination Leads to HAIs

- By contaminating hands/gloves via contact with the environment and transfer to patient or patient self inoculation
- Surfaces should be hygienically clean (not sterile)-free of pathogens in sufficient numbers to prevent human disease
- Two environmental surface concerns
  - Discharge/terminal-prevent infection to new patient in room
  - Daily room decontamination, suboptimal CD and recontamination

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

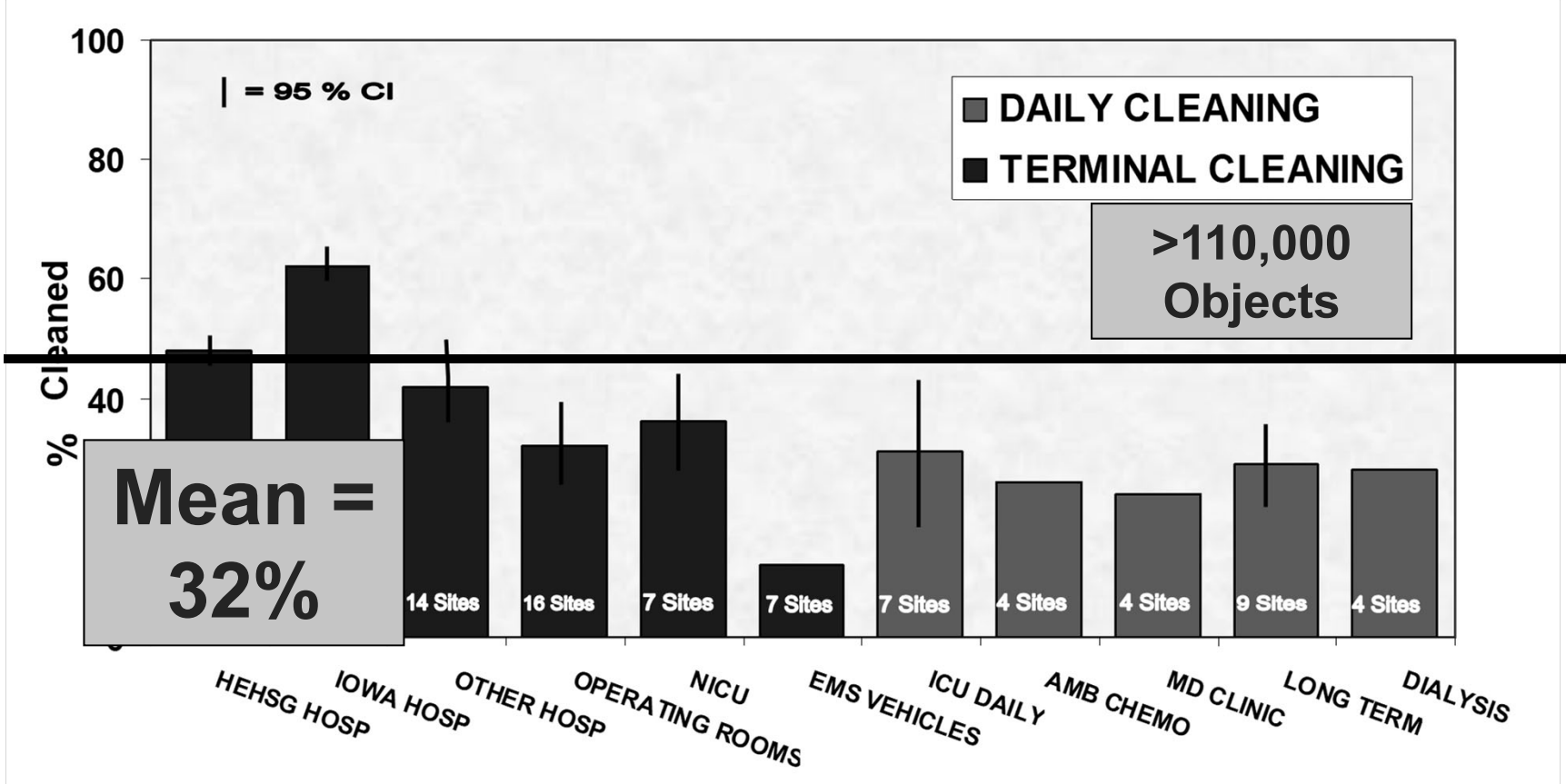
NL Havill AJIC 2013;41:S26-30; Rutala, Weber. AJIC 2019;47:A96-A105

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)

Thoroughness of Environmental Cleaning

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



Environmental Contamination Leads to HAIs

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“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.







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

Robert A. Weinstein, MD

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.

Environmental Contamination Leads to HAIs

- By contaminating hands/gloves via contact with the environment and transfer to patient or patient self inoculation
- Surface should be hygienically clean (not sterile)-free of pathogens in sufficient numbers to prevent human disease
- Two environmental surface concerns
  - Discharge/terminal-prevent infection to new patient in room
  - Daily room decontamination (referred to “trash and dash”) suboptimal C/D and recontamination

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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.

Rationale for Continuous Room Decontamination Methods

- Key issues in daily room disinfection and rationale for improving daily room disinfection (patients, staff, visitors can be in room during continuous decontamination)
  - Environmental contamination leads to HAIs
  - Suboptimal disinfection
  - Rapid recontamination of surface occurs after disinfection
  - EIP are present on environmental surfaces (via prevalence survey, after terminal disinfection)
  - All touchable surfaces are equally contaminated
  - Increased surface bioburden is associated with an increased rate of HAIs and decreasing the bioburden (terminal disinfection) reduces HAIs
- Need to evaluate continuous room disinfection

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

Continuous Room Decontamination Technologies for Disinfection of the Healthcare Environment

Weber, Rutala et al. AJIC. 2019;47:A72; Rutala et al. ICHE 2019; Weber D, Rutala W. AJIC 2013;41:S31

- Visible light disinfection through LEDs
- Dry/dilute hydrogen peroxide; hydroxyl radicals, free reactive oxygen
- Self-disinfecting surfaces (e.g., heavy metals-copper, silver)
- 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

Continuous Room Decontamination Technology

- Advantages
  - Allows continued disinfection (may eliminate the problem of recontamination)
  - Patients, staff and visitors can remain in the room
  - Does not require an ongoing behavior change or education of personnel
  - Self-sustaining once in place
  - Once purchased might have low maintenance cost
  - Technology does not give rise to health or safety concerns
  - No (limited) consumable products

Continuous Room Decontamination Technology

- Disadvantages
  - Room decontamination/biocidal activity is slow
  - Capital equipment costs are substantial
  - Does not remove dust, dirt, stains that are important to patients and visitors
  - Studies have not shown whether the use will decrease HAIs

Continuous Room Decontamination Technologies for Disinfection of the Healthcare Environment

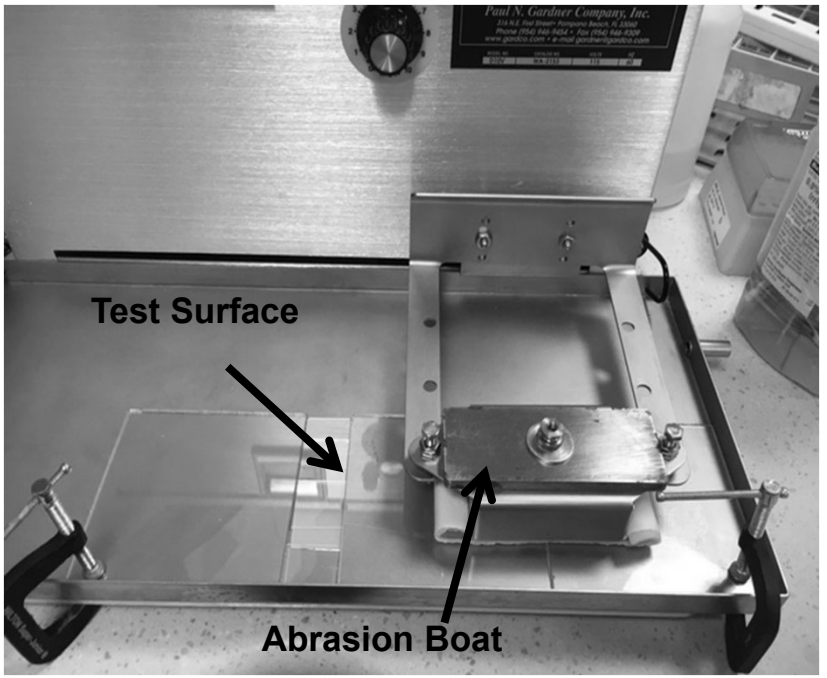
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Evaluation of a Continuously Active Disinfectant "EPA Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residuals on Hard, Non-Porous Surfaces"

Rutala et al. ICHE;2021: doi:10.1017/ice.2021.481; 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 HA 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*

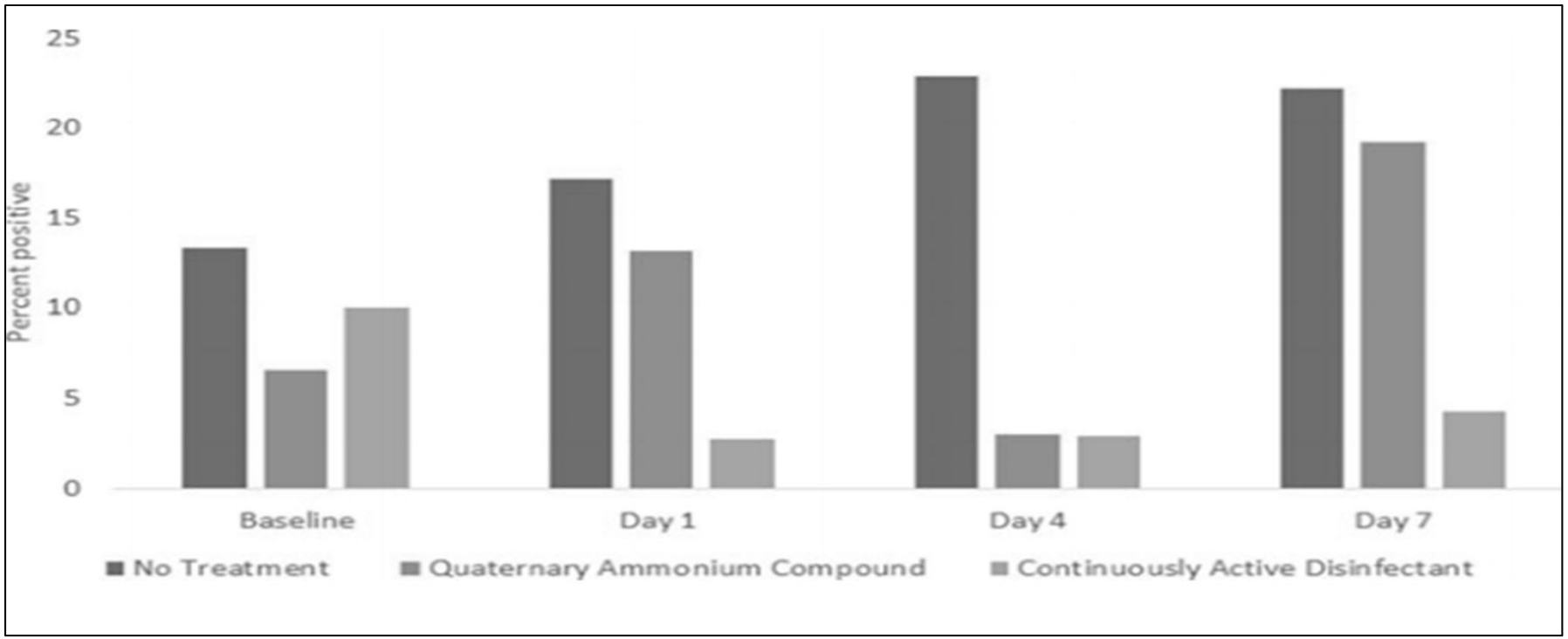
Rutala WA, Gergen M, Sickbert-Bennett E, Anderson D, Weber D. ICHE 2019

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 (PME)

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%)



Efficacy of a Continuously Active Disinfectant Against SARS-CoV-2 and Human Coronavirus, 229E, Evaluated after 48 hours

Rutala WA et al. ICHE, 2021 doi:10.1017/ice.2021.481

A novel disinfectant studied using an EPA protocol (wears/re-inoculations) demonstrated excellent continuous antiviral activity (i.e., >4-log_{10} reduction) in 1 minute after 48 hours for SARS-CoV-2 and human coronavirus, 229E

Table 1. Inactivation of SARS-CoV-2 and the Human Coronavirus 229E by a Continuously Active Disinfectant Following a 48-Hour Period of Wear and Abrasion Exposure

Carrier Treatment with Wears and Reinoculations	Contact Time	Mean Viral Recovery Titer per Carrier (Log_{10})	HCoV 229E Log_{10} Reduction	SARS-CoV-2 Log_{10} Reduction
Control (sterile ND water, n=3)	1 min	≥		NA
Continuously active disinfectant, n=3	1 min	≤ 1.50 ± 0.00	>4.50	>4.22

Note. NA, not available.

Efficacy of a Continuously Active Disinfectant

Summary

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

Disinfection and Sterilization: Current Issues and New Technologies

- Overview DS
- HLD to Sterilization
- HLD to Sterilization-endo, new tech
- HLD to Sterilization
  - Duo-single use, endcaps
  - Urologic endoscopes, no HLD
- HLD-Human papilloma
- LLD-Ultrasound probes
- LLD-Electrostatic sprayers-new data
- LLD-new sporicide-HP-new tech
- LLD-sporicide in all discharge pt rooms
- LLD-emerging pathogens
- LLD-colorized disinfectant-new tech
- LLD-“no” touch room decontamination
- Continuous room decontamination technologies
  - Continuously active disinfectant-new technology

Disinfection and Sterilization:
Current Issues and New Technologies

- Endoscope represent a nosocomial hazard. Urgent need to transition from HLD to sterilization. New technology (e.g., disposable endcaps, LT sterilization, disposable scopes) should reduce or eliminate infection risk.
- Implement evidence-based practices for surface disinfection (product, practice, train, improve compliance, “no touch”)
- Continuous room decontamination technology (e.g., continuously active disinfectants, >4 $\log_{10}$ reduction in 1-5 min) shows promise and could reduce the risk of infections associated with devices (portable equipment) and surfaces

THANK YOU!
www.disinfectionandsterilization.org



SHEA Guideline

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

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

SHEA GUIDELINE

Guideline for Disinfection and Sterilization of Prion-Contaminated Medical Instruments

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

EPIDEMIOLOGY OF THE CREUTZFELDT-JAKOB DISEASE PRION

Creutzfeldt-Jakob disease (CJD) is a degenerative neurologic disorder of humans with an incidence in the United States of approximately 1 case per million population per year.[1-3]

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

TRANSMISSION OF CJD VIA MEDICAL DEVICES

Epidemiology of CJD in the US

- Degenerative neurologic disorder with progressive dementia
- Incidence
  - One death/million population
  - No seasonal distribution, no geographic aggregation
  - Both genders equally affected
  - Age range 50-80+ years, average 67
- Long incubation disease (months-years)
- Rapid disease progression after onset (death within 6 mo)
- Resistant to conventional DS procedures

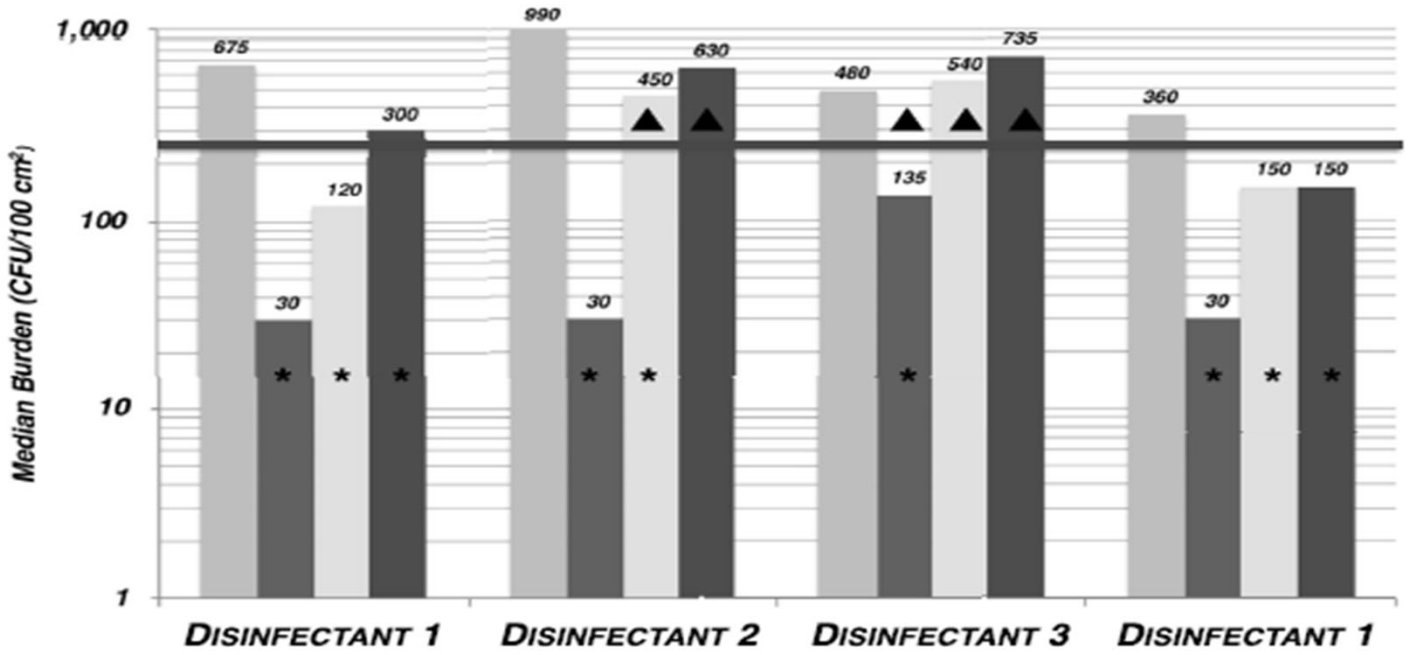
CJD: Disinfection and Sterilization
Conclusions

- Critical/Semicritical-devices contaminated with high-risk tissue from high-risk patients requires special prion reprocessing
  - 134°C for 18m (prevacuum)
  - 132°C for 60m (gravity)
  - NaOH and steam sterilization (e.g., 1N NaOH 1h, then 121°C 1h)

Evaluation of Three Disinfectants for Ability to Limit Establishment of Bioburden After Disinfection

Schmidt et al. Am J Infect Control 2019;47:732-4

The continuously active disinfectant was able to significantly reduce bioburden on bed rails, a critical touch surface.



Bioburden samples (bed rails) were collected before disinfection (gray) and at 1, 6, and 24 hours. Each disinfectant significantly controlled bioburden for the first hour. In comparison, the CAD (Disinfectant 1) was found superior for all time points compared to two other Quats.