Disinfection and Sterilization
Current Issues, New Research and New Technology

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

DISCLOSURES

2022-2023

- **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[31,54-57]	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 (ETO, VHP, HP plus ozone) 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
- Use of non-endoscopic methods to diagnose or treat disease
- Stop HLD for affected Storz urological endoscopes, transition to sterilization

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

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 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

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

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

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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

Effect of Disposable Elevator Cap Duodenoscopes on Microbial Contamination

Forber et al. JAMA IM 2023;183:191-200

Microbial contamination detected in 11.2% of standard duodenoscopes and 3.8% of disposable elevator cap duodenoscopes without affecting technical performance and safety of ERCP

Table 2. Primary and Secondary Study Outcomes

Outcome	Disposable elevator cap duodenoscope			Standard duodenoscope			*P* value
	No. (%)	Scope ID	Occurrences/ cases performed	No. (%)	Scope ID	Occurrences/ cases performed	
Microbiology outcomes							
No.	208	NA	NA	214	NA	NA	NA
Persistent microbial contamination[a]							
Yes	8 (3.8)	NA	NA	24 (11.2)	NA	NA	.004
No	200 (96.2)	NA	NA	190 (88.8)	NA	NA	

WARNING LETTER

Olympus Medical Systems Corp.

MARCS-CMS 654013 — MARCH 15, 2023

- Issue: cap falling off the scope in the patient
- “Since November 2020, Olympus Medical has received approximately 160 complaints describing the ‘distal end cover’ code number MAJ-2315 has ‘dropped off’”
- Some patients suffered injuries, although no deaths were cited
- No similar problem identified yet for Pentax and Fujifilm

Sterilize Karl Storz Urological Endoscopes

www.fda.gov

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

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

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

KARL STORZ — ENDOSKOPE

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

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

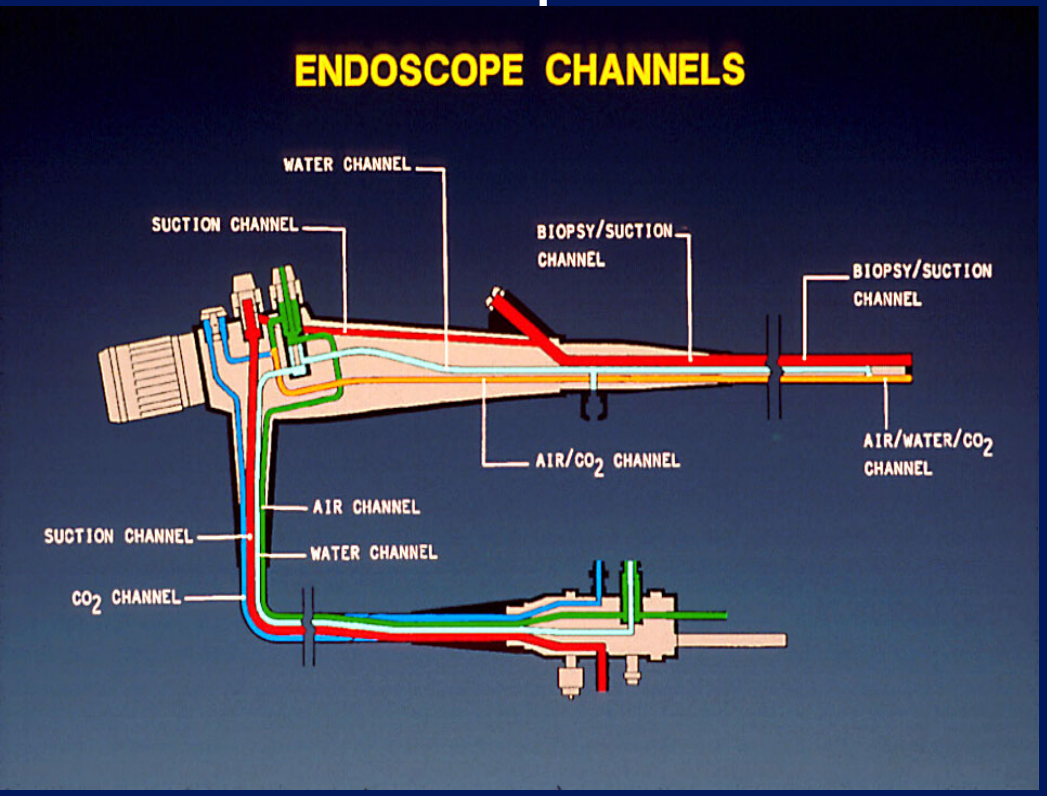
Supplemental Measures for Endoscope Reprocessing

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 significant benefit compared with single HLD in reducing bacterial contamination rates for duodenoscopes (16.1% v 9.2%)
- 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-2021
- Must educate/comply but confident will not prevent all infections and patient exposures due to microbial load and instrument complexity

Efficacy of Microbiologic Surveillance in Detecting Bacterial Contamination in Processed Endoscopes

Day et al. Gastro Endosc 2021;93:11-35; Olafsdottir et al. AJIC 2018;46:697-705

- Microbiologic testing not advised per US standards
- Surveillance as a QA measure advised by some international organizations
- ATP proposed as alternative but not widely applied
- ATP testing does not correlate well with microbiological cultures after HLD of duodenoscopes and should not be recommended as a surrogate for terminal cultures
- ATP testing might have a role as a quality assurance test after the manual cleaning stage and for training endoscope reprocessing staff

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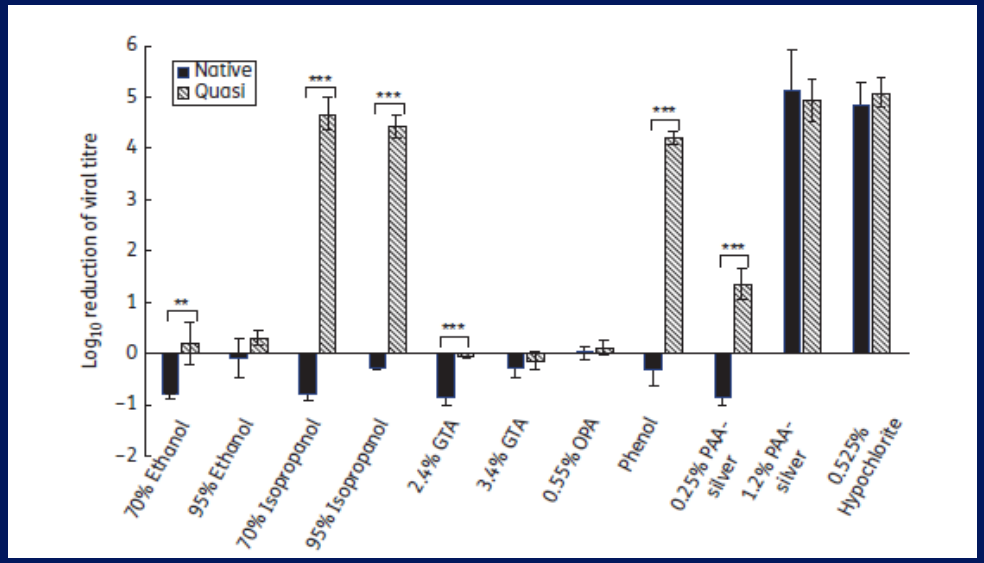
Human Papillomavirus

- 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

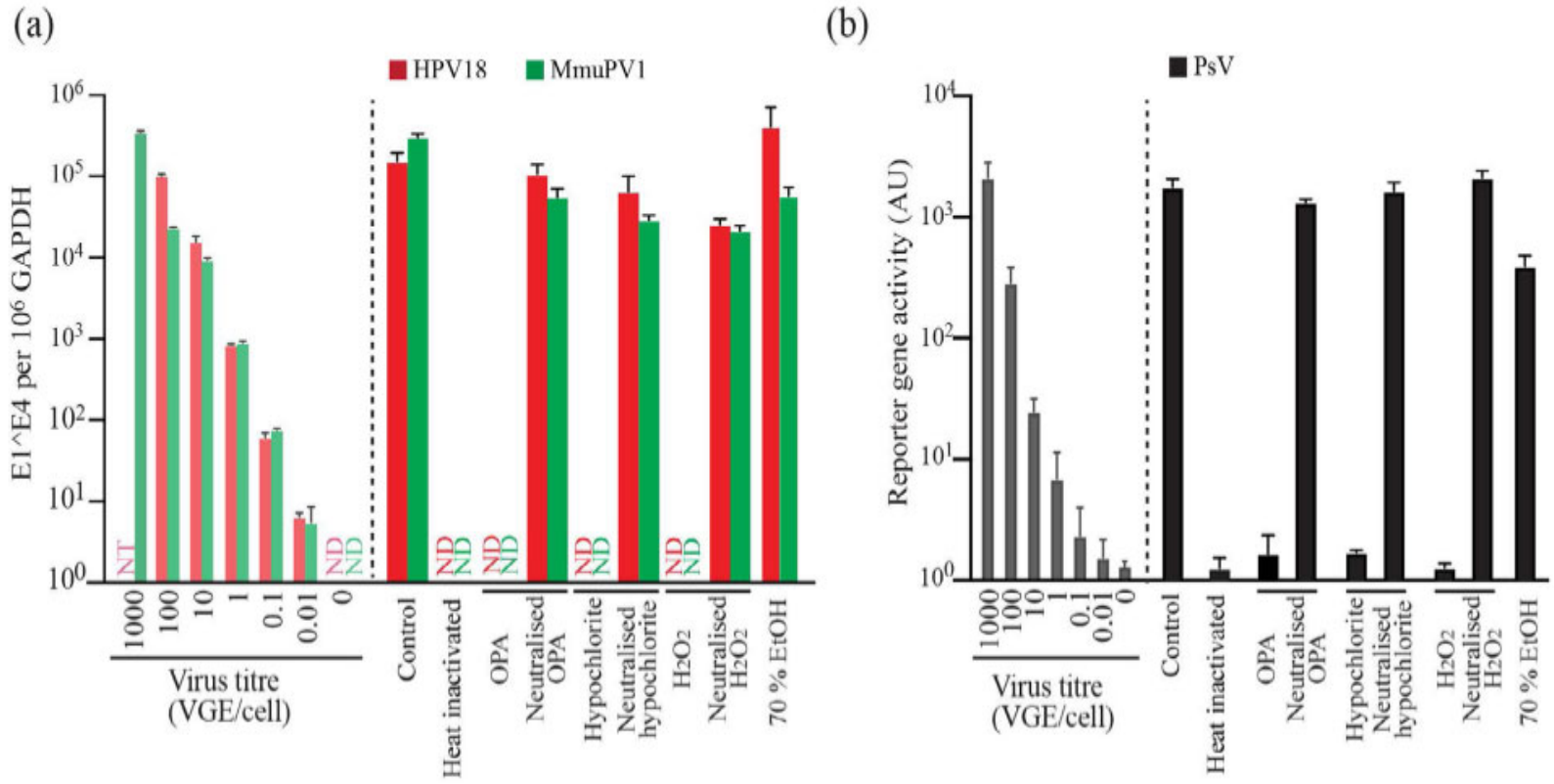


Fig. 5. Evaluation of disinfectant efficacy using in vitro infection assay

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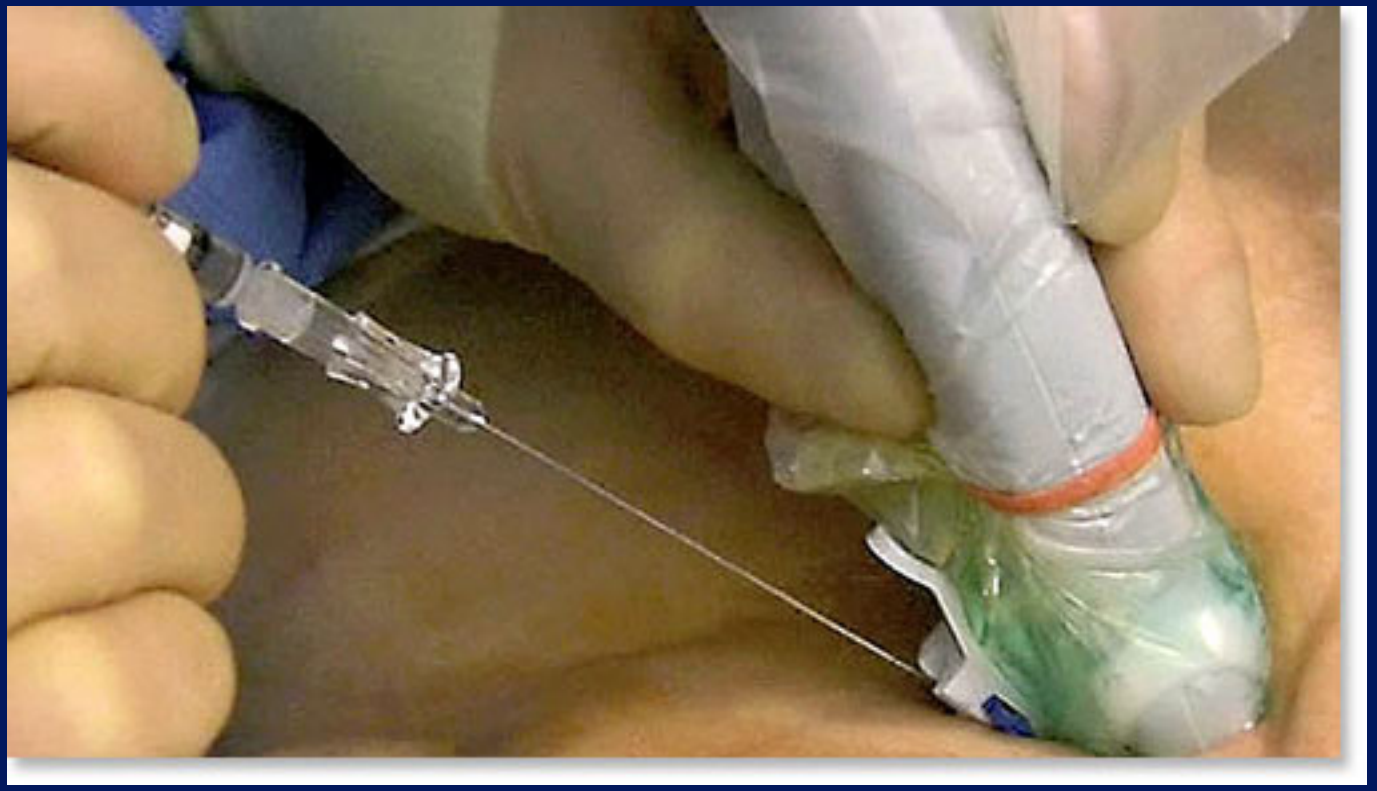
Do ultrasound transducers used for placing peripheral or central venous access devices require HLD/sterilization?



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.
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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

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Abstract

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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

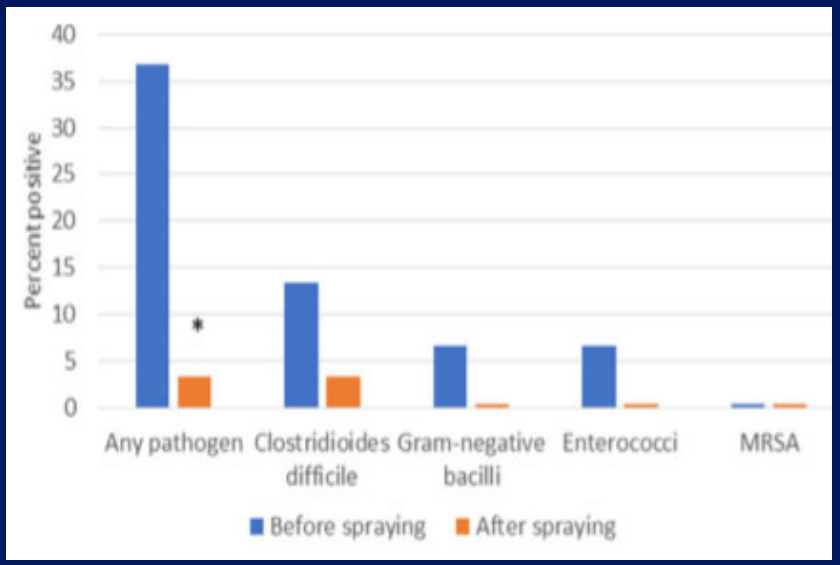
Cadnum et al. AJIC 2020

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

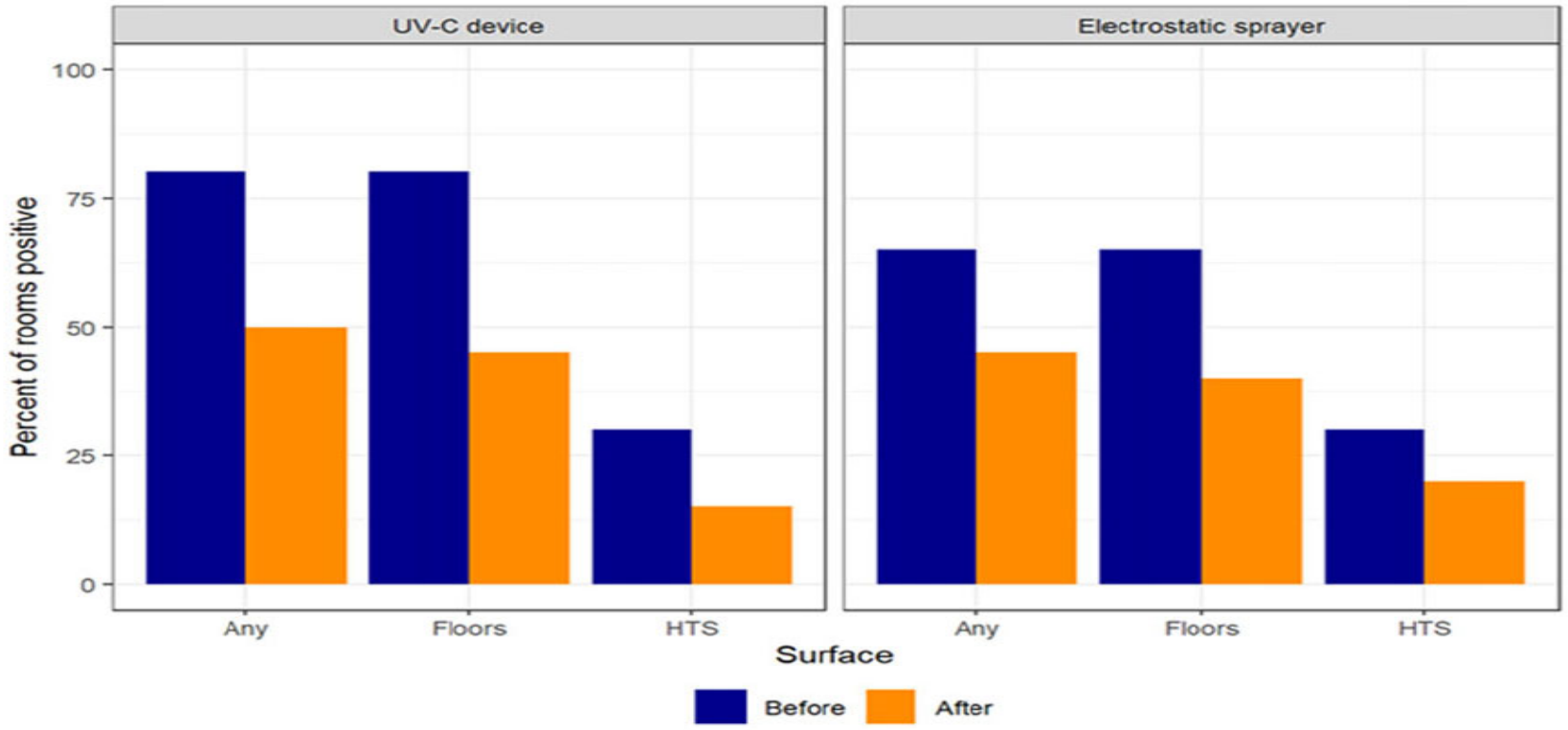


Fig. 1. Percentages of rooms with positive cultures for 1 or more healthcare-associated pathogens before versus after treatment with the ultraviolet-C (UV-C) light device or the electrostatic sprayer. Note. HTS, high-touch surface.

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)

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

Novel Hydrogen Peroxide Sporicide

Cadnum et al. AJIC 2021

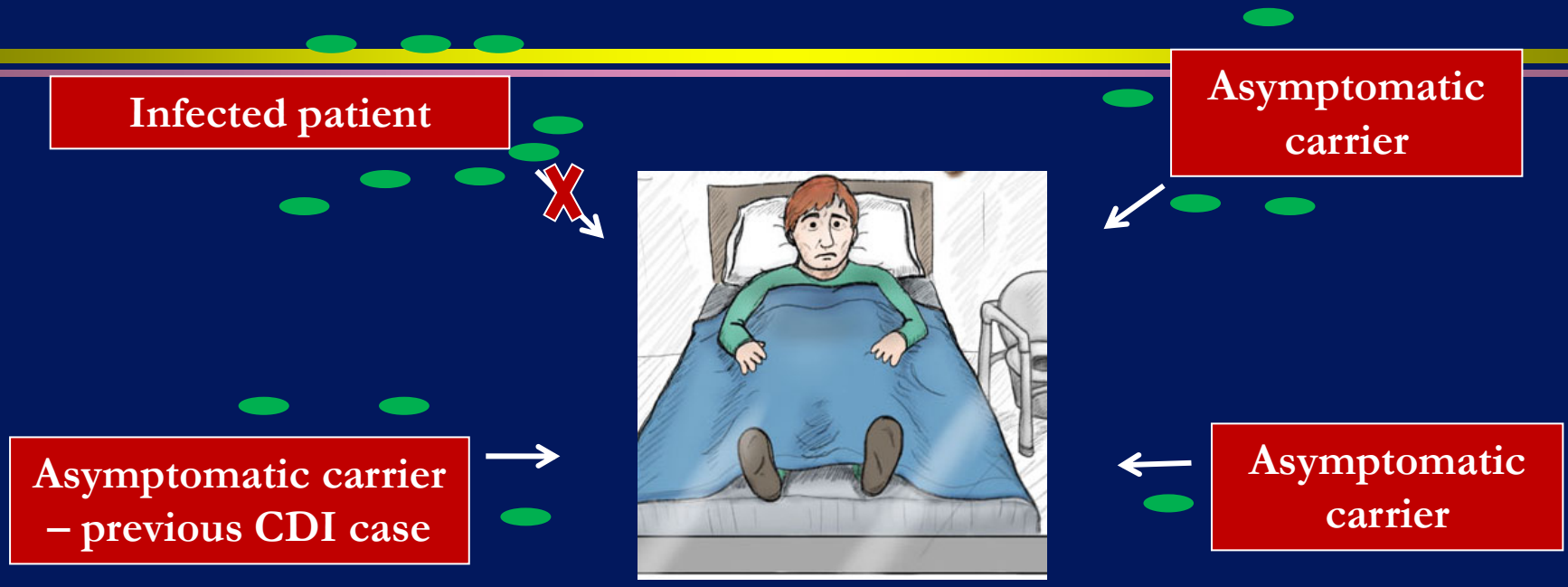
A novel 4% HP was effective against MRSA, CRE, *C. difficile* spores and *C. auris.* HP may be a useful addition to the sporicidal products available in healthcare.

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

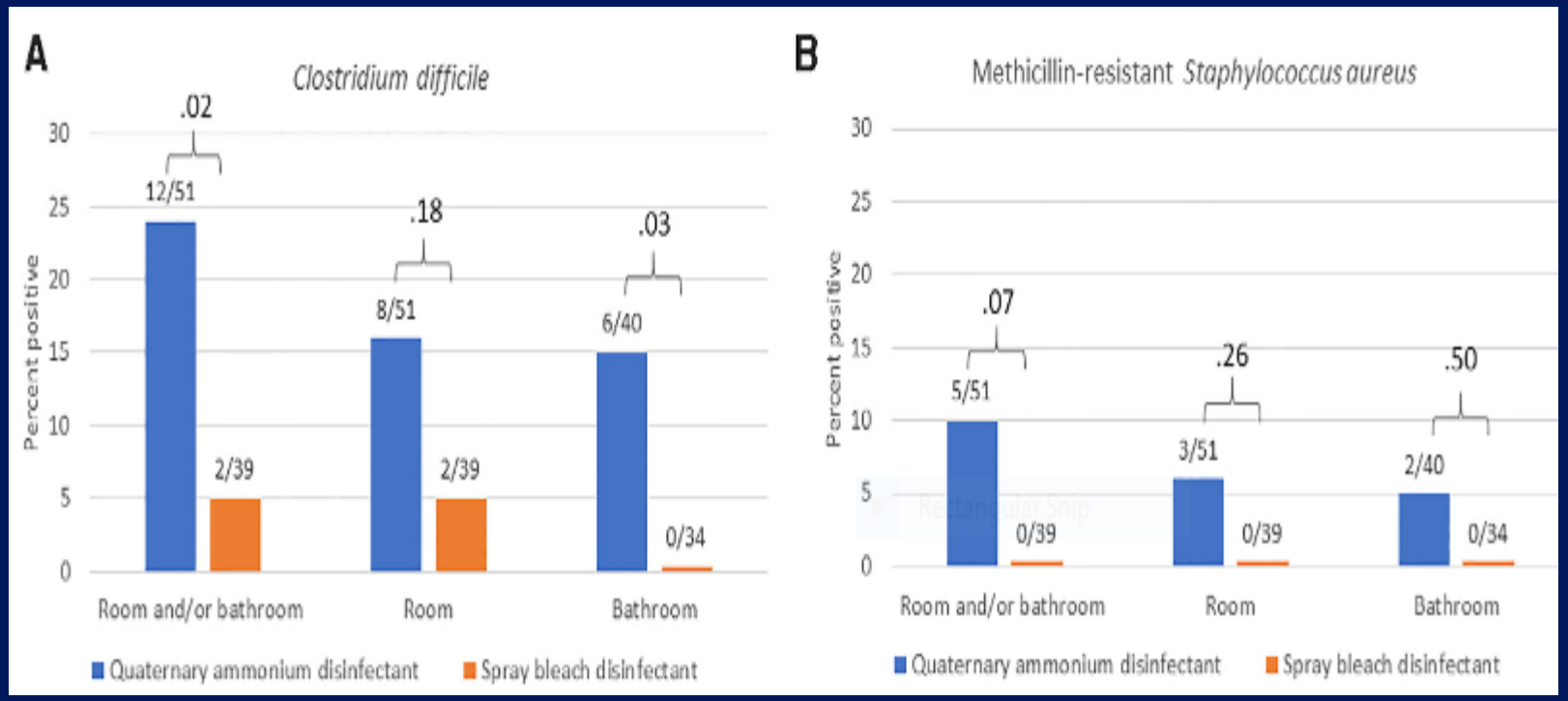
(courtesy Dr. Donskey)



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

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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

CRE: FREQUENCY OF ENVIRONMENTAL CONTAMINATION AND SURVIVAL OVER TIME

TABLE 1. Contamination on Surfaces in Rooms Housing a Patient with CRE

Room Site Cultured (No.)	CRE Positive, No. (%)[a]	CRE, mean CFU (range)[b]
Bed rail (15)	2 (13.3)	45 (43–47)
Overbed table (15)	1 (6.7)	3
Chair #1 arm (12)	0 (0.0)	...
Sink (15)	2 (13.3)	14.5 (11–18)
Toilet (11)	2 (18.2)	7 (4–10)
Bathroom floor (10)	1 (10.0)	5
Supply cart (11)	1 (9.1)	2
Linen hamper (12)	0 (0.0)	...
Mobile computer (3)	0 (0.0)	...
Chair #2 arm (3)	0 (0.0)	...
Bedside table (3)	0 (0.0)	...
Toilet cabinet (4)	0 (0.0)	...
Floor outside toilet cabinet (4)	1 (25.0)	2
Ventilator counter (1)	0 (0.0)	...
Total (119)[c]	10 (8.4)	5.1 (2–47)

CFU, colony forming units; CRE, carbapenem-resistant *Enterobacteriaceae*.
[a]Considered positive if ≥1 of the 5 Rodac plates had positive growth (ie, area sampled = 120 cm^2).
[b]Mean and range calculated only for CRE culture positive sites.
[c]For one site cultured, technical difficulties prevented assessing growth. Thus total was 119 sites instead of 120 sites.

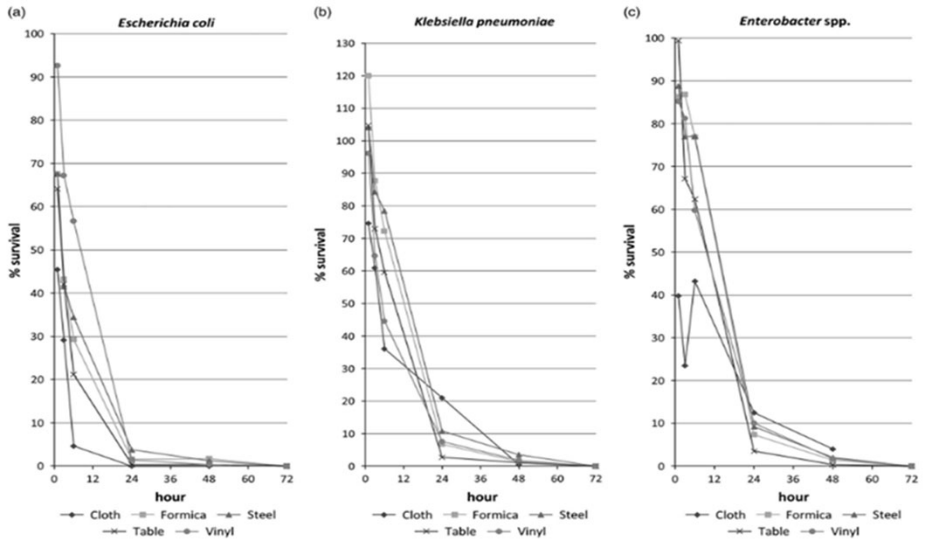

FIGURE 1. a. Survival of Carbapenem-Resistant *Escherichia coli* on 5 Different Environmental Surfaces. b. Survival of Carbapenem-Resistant *Klebsiella pneumoniae* on 5 Different Environmental Surfaces. c. Survival of Carbapenem-Resistant *Enterobacter* spp. on 5 Different Environmental Surfaces

Weber DJ, Rutala WA, et al. ICHE 2015;36:590-593

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

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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

>3-$\log_{10}$ reduction (CRE, 1min, 5% FCS, QTC)

- 0.20% peracetic acid
- 2.4% glutaraldehyde
- 0.5% Quat, 55% isopropyl alcohol
- 58% ethanol, 0.1% Quat
- 28.7% isopropanol, 0.06% p-tertiary amylphenol
- ~5,250ppm chlorine
- 70% isopropanol
- 70% ethanol (hand rub)
- O.65% hydrogen peroxide, 0.15% peroxyacetic acid
- Accelerated hydrogen peroxide; 1.4% and 2.0%
- Quat; 0.085% QACs (not *K. pneumoniae*)

Kanamori H, Rutala WA, et al. AAC 2018;62:e00318-18

CANDIDA AURIS: AN OVERVIEW, CDC

- *Candida auris* is an emerging fungus that presents a serious global health threat for the following reasons:
  - *C. auris* is spreading geographically and increasing in incidence.
  - From 2019 to 2021, 17 states reported their first *C. auris* case and cases resistant to antifungal drugs tripled…now 35 states
  - *C. auris* may colonize patients for months to years (no method of decolonization). Infection (usually candidemia) has a high mortality (~60%).
  - It is often multidrug-resistant (e.g., echinocandins, triazoles, polyene [amphotericin B]). Some strains are resistant to all three available classes of antifungals.
  - It is difficult to identify with standard laboratory methods, and it can be misidentified in labs without specific technology. Misidentification may lead to inappropriate management.
  - It has caused multiple outbreaks in healthcare settings. For this reason, it is important to quickly identify *C. auris* in a hospitalized patient so that healthcare facilities can take special precautions to stop its spread.
- May 11, 2021: Updated tracking *C. auris* to include historical and current U.S. interactive maps and downloadable datasets
- July 19, 2021: Environmental Protection Agency (EPA) has created List P, a list of EPA-registered disinfectants effective against *C. auris*
- Current needs: (1) rapid diagnostics; (2) new drugs; (3) decolonization methods; (4) registered, easy to use and effective disinfectants; (5) other tools or protocols for treatment and prevention

https://www.cdc.gov/fungal/candida-auris/index.html
https://www.cdc.gov/fungal/candida-auris/researchers-and-industry-professionals.html

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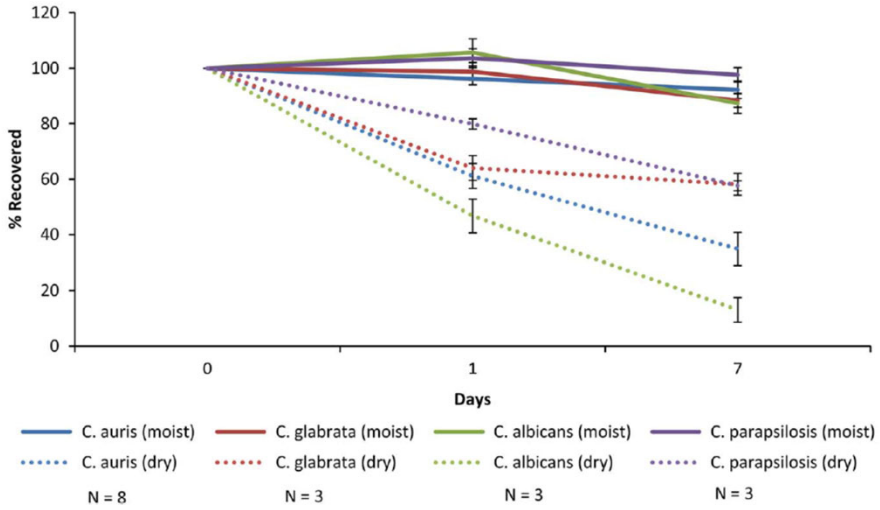
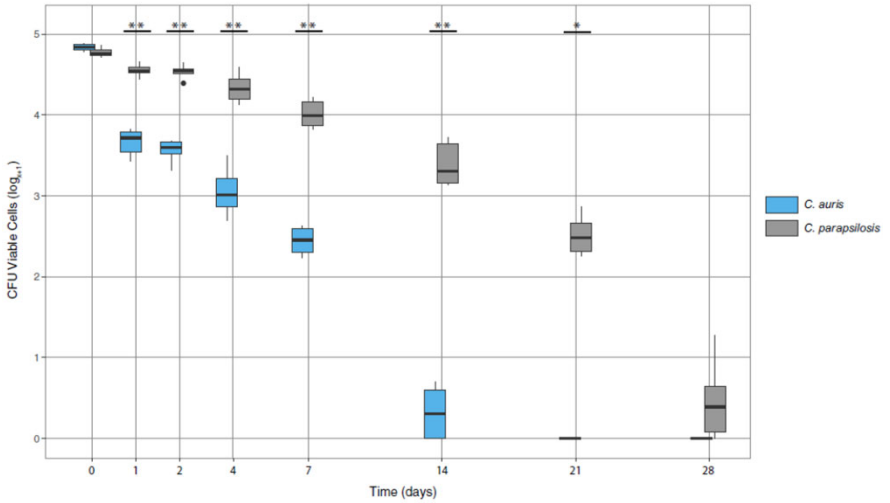
ENVIRONMENTAL SURVIVAL OF *CANDIDA AURIS*

Persists for 7 days on moist or dry surfaces





Piedrahita C, et al. ICHE 2017;38:1107-1109

Welsh RM, et al. J Clin Microbiol 2017;55:2996-3005

Susceptibility of *C. auris* and *C. albicans* to 21 germicides used in healthcare facilities

- Goal: Assess susceptibility of *C. auris* to germicides
- Methods: Disc-based quantitative carrier testing
- Results: All of the FDA-cleared high-level disinfectants have a registration claim >1 minute (e.g., 8–45 minutes). In summary, with the exception of a water-based QAC and a 1:50 dilution of sodium hypochlorite, our data demonstrate that most disinfectants (10 of 13, 77%) used in healthcare facilities are effective (>3-$\log_{10}$ reduction) against *C. auris*.

Germicide name	Manufacturer, Location	Active Ingredient	Formulation Tested	Classification	*C. auris*[a]	*C. albicans*[a]
Purell Advanced instant hand sanitizer	GOJO, Akron, OH	70% ethanol	Undiluted	Antiseptic	4.0	2.5
Betadine solution	Purdue Products, Stamford, CT	10% povidone–iodine/1% iodine	Undiluted	Antiseptic	2.5	2.3
Medicated Soft 'N Sure	Steris, St. Louis, MO	0.5% triclosan	Undiluted	Antiseptic/Handwash	1.4	1.7
Soft Care Defend	Diversey, Charlotte, NC	1% chloroxylenol	Undiluted	Antiseptic/Handwash	2.8	3.9
Avagard	3M, St Paul, MN	1% chlorhexidine gluconate solution, 61% ethyl alcohol	Undiluted	Antiseptic/Surgical hand scrub	2.0	1.9
Scrub-Stat 2%	Ecolab, St Paul, MN	2% chlorhexidine gluconate solution	Undiluted	Antiseptic/Surgical hand scrub/handwash	1.6	2.8
Scrub-Stat 4%	Ecolab, St Paul, MN	4% chlorhexidine gluconate solution	Undiluted	Antiseptic/Surgical hand scrub/handwash	1.9	3.5
Isopropyl rubbing alcohol 70% USP	Medichoice, Mechanicsville, VA	70% isopropyl alcohol	Undiluted	Antiseptic/Disinfectant	3.8	4.1
Solution of hydrogen peroxide 3% USP	Medichoice, Mechanicsville, VA	3% hydrogen peroxide	Undiluted	Antiseptic	1.4	1.8
Austin's A-1 bleach 1:10	James Austin Co, Mars, PA	5.25% sodium hypochlorite (~6,100–6,700 ppm)	1:10 dilution	Disinfectant	4.1	4.0
Austin's A-1 bleach 1:50	James Austin Co, Mars, PA	5.25% sodium hypochlorite (~1,245 ppm)	1:50 dilution	Disinfectant	1.6	1.5
Vesphene IIse	Steris, St Louis, MO	9.09% o-phenylphenol, 7.66% p-tertiary amylphenol	1:128 dilution	Disinfectant	4.1	3.6
Hydrogen peroxide cleaner disinfectant	Clorox, Oakland, CA	1.4% hydrogen peroxide	Undiluted	Disinfectant	4.1	4.1
Lysol disinfectant spray	Reckitt Benckiser, Parsippany, NJ	58% ethanol, 0.1% QAC[b]	Undiluted	Disinfectant	3.8	4.1
A-456 II disinfectant cleaner	Ecolab, St Paul, MN	21.7% QAC[c]	1:256 dilution	Disinfectant	1.7	1.5
Super Sani-Cloth wipe	PDI, Orangeburg, NY	55% isopropyl alcohol, 0.5% QAC[d]	Undiluted[f]	Disinfectant	3.9	4.1
Prime Sani-Cloth wipe	PDI, Orangeburg, NY	28.7% isopropyl alcohol, 27.3% ethyl alcohol, 0.61% QAC[e]	Undiluted[f]	Disinfectant	4.1	4.1

Rutala WA, et al. ICHE 2019;40:380-382

List P: Antimicrobial Products Registered with EPA for Claims Against *Candida auris* (contact times, product dependent)

- Sodium Hypochlorite (1-3 min)
- Hydrogen peroxide and peracetic acid (1-3 min)
- Hydrogen Peroxide, Peracetic Acid and Octoanoic Acid (4 min)
- Dodecylbenzenesulfonic acid (1-1.25 min)
- Isopropyl Alcohol and Quaternary Ammonium Compound (1 min)
- Isopropyl Alcohol, DDAC and ADBAC (2 min)
- Hydrogen Peroxide (1-5 min)
- Quaternary Ammonium Compounds (10 min)
- Sodium dichloro-s-triazinetrione (2 min)
- Ethanol, Isopropyl Alcohol and DDAC (1 min)
- Isopropyl Alcohol and Quaternary Ammonium Compounds (2 min)

Caveats

- List P displays 30 approved products
- All products are ONLY approved for "hard non-porous surfaces"
- Contact times vary by class and specific product
- Products include sprays, wipes and liquids
- Some products are ready to use; others may require dilution
- Per CDC, if products on List P are not accessible or otherwise suitable, interim guidance permits use of an EPA-registered disinfectant active against *C. difficile* (List K)
- Follow manufacturer's use recommendations

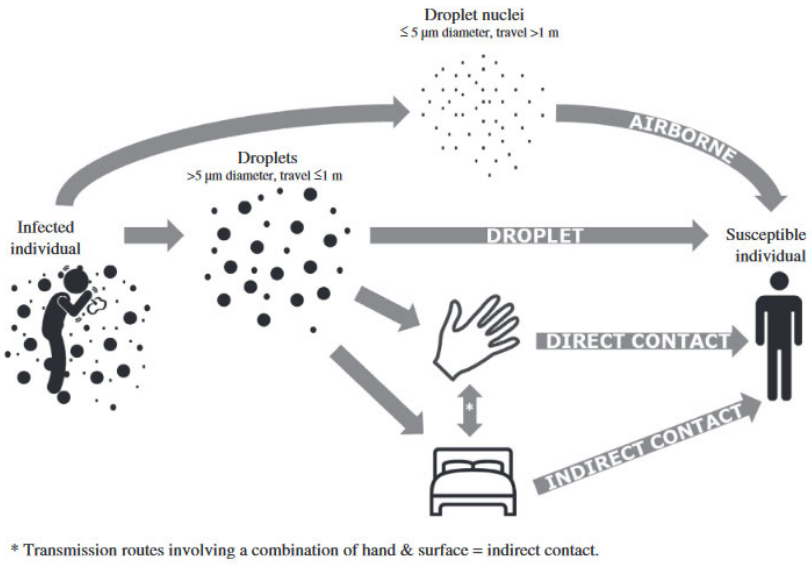
https://www.epa.gov/pesticide-registration/list-p-antimicrobial-products-registered-epa-claims-against-candida-auris
https://www.cdc.gov/fungal/candida-auris/c-auris-infection-control.html

SUSCEPTIBILITY OF *C. auris* TO UV

- UV-C efficacy assessed against MRSA, *C. auris*, *Candida* sp., and MRSA[1]
  - *C. auris* less susceptible to UV-C than MRSA; similar but slight less susceptible than *C. difficile*
  - Increasing exposure time (10 to 20 to 30 min) resulted in enhanced killing; at 20 min, >4.5 $\log_{10}$; at 30 min >6 $\log_{10}$
- Pulsed xenon efficacy assess against *C. auris*[2]
  - 99.4% reduction in *C. auris* CFU after 5min at 1m and 99.6% after 10min at 2m
- Killing of *C. auris* by UV-C: Importance of exposure time and distance[3]
  - Maximal effect of *C. auris* killing found at 30min exposure at 2m (maximal killing, >5 $\log_{10}$). With half the time or twice the distance, efficacy diminished to ~10 and ~50-fold, respectively. At suboptimal exposure times and distance, strains from Japan/Korea more sensitive to UV-C killing than from Venezuela, Spain and India.
- Clade-specific variation in susceptibility of *C. auris* to UV-C[4]
  - Increased susceptibility of *C. auris* belonging to clades I, II and IV with increasing UV exposure time. *C. auris* isolates susceptible to UV-C were mostly nonaggregating, but the isolates that were more resistant to UV exposure formed aggregates.
- Efficacy of relatively low-cost UV-C devices against *C. auris*[5]
  - Some low-cost devices provided effective decontamination. *C. auris* from clades III and IV were less susceptible that from clades I and II.
- Inactivation of C. *auris* by UV-C[6]
  - With an organic load (FCS), *C. auris* reduction ($\log_{10}$) were; 4.57 direct line of sight, 2.41 indirect line of sight
- UV-C disinfection using a robot for routine cleaning[7]
  - UV-C inhibited growth of *C. auris* in the lag phase, but not in the presence of rim shadows; *C. auris* not effectively killed by standard UV cycle

[1]Cadnum JL, et al. ICHE 2018;39:94; [2]Maslo C, et al. BMC ID 2019;19:540; 3 de Groot T, et al. Mycoses 2019;62:408; [4]Chatterjee P, et al. ICHE 2020;41: 1384; [5]Pearlmutter BS, et al. ICHE 2021, 1-5; [6]Rutala WA, et al. ICHE 2021, 1-3; 7 Astrid F, et al. Antimicrob Resist Infect Control 2021;10:84

TRANSMISSION OF SARS CoV-2



Otter JA, et al. J Hosp Infect 2016;92:235-50

- Aerosol/Droplet (≤6 feet) most important mode of transmission
- Aerosol (>6 feet) demonstrated indoor with directional airflow and poor ventilation (less important than short distance transmission)
- Other modes: Direct contact and indirect (via the contaminated environment)
  - Elevator button in an apartment building (less likely aerosol remaining in elevator) (Xie C, et al. BMC Public Health 2020;5 August)
  - Elevator buttons or restroom taps in a mall (Cai J, et al. Emerg Infect Dis 2020;26:1343-1345)
  - Toilet on aircraft (Bae SH, et al. Emerg Infect Dis 2020;26:Nov.)
- Pre-symptomatic (i.e., up to 48 hours before person develops symptoms) and asymptomatic transmission well documented – important in maintaining pandemic
- Transmission via blood not demonstrated; via stool (very rare; two outbreaks linked to plumbing)
- **Prevention - In hospital, adhere to Universal Pandemic Precautions**

Table 1: Inactivation of viruses by different types of physical disinfectants.

Disinfection	Concentration	Virus	Strain isolate	Retention time	Reduction of viral infectivity (log_{10})	Reference
UVC (254 nm)	Dose of 3 J/m^2	SARS-CoV-2	Isolate FFM-1	11–34 min	1.0	[9]
UVC (254 nm)	Dose of 7 J/m^2	SARS-CoV-2	Isolate FFM-1	11–34 min	2.0	[9]
UVC (254 nm)	Dose of 28 J/m^2	SARS-CoV-2	Isolate FFM-1	11–34 min	3.0	[9]
UVC (254 nm)	Dose of 140 J/m^2	SARS-CoV-2	Isolate FFM-1	11–34 min	6.0	[9]
UVC (254 nm)	Dose of 6.9 J/m^2	SARS-CoV-2	—	2 h	1.0	[10]
UVB (300 nm)	Dose of 1400 J/m^2	Vaccinia virus	—	2 h	2.0	[11]
UVC (254 nm)	Dose of 0.2 J/cm^2	SARS-CoV-2	Frankfurt 1	—	≥3.4	[12]
UVC (254 nm)	Dose of 0.2 J/cm^2	CCHFV	Afg09-2990	—	≥2.2	[12]
UVC (254 nm)	Dose of 0.2 J/cm^2	NiV	Malaysia	—	≥4.3	[12]
UVC (222 nm)	Dose of 0.56 mJ/cm^2	HCoV	229E	—	1.0	[13]
UVC (222 nm)	Dose of 0.39 mJ/cm^2	HCoV	OC43	—	1.0	[13]
Pulsed-xenon ultraviolet light	—	SARS-CoV-2	USA-WA1/2020	2 min	>4.54	[14]
Visible light plus MB (plasma units)	120 J/cm^2	MERS-CoV	EMC/2012	—	≥3.3	[12]
Visible light plus MB (plasma units)	120 J/cm^2	EBOV	Mayinga-76	—	≥4.6	[12]
Gamma irradiation	1 mrad	SARS-CoV-1	Strain Tor 2	5 s	>4.0	[15]
Dry heat	90°C	Poliovirus	Strain Sabin	1 min	>4.6	[16]
Dry heat	90°C	Adenovirus	Type 5	1 min	3.9	[16]
Dry heat	60°C	CCV	SP-80 strain	1 min	1.56	[17]
Dry heat	60°C	MHV	RV-13 strain	1 min	2.87	[17]
Dry heat	80°C	CCV	SP-80 strain	1 min	>4.04	[17]
Dry heat	80°C	MHV	RV-13 strain	1 min	>3.88	[17]
Dry heat	56°C	SARS-CoV	Isolate FFM-1	30 min	≥5.01	[18]
Dry heat	60°C	SARS-CoV	Isolate FFM-1	30 min	≥5.01	[18]
Dry heat	4°C	PEDV	Strain CV777	120 min	0.0	[19]
Dry heat	40°C	PEDV	Strain CV777	120 min	1.0	[19]
Dry heat	56°C	PEDV	Strain CV777	10 min	1.0–1.7	[20]
Dry heat	56°C	MERS-CoV	MERS-CoV strain Hu/France-FRA2_130569/2013 (FRA2)	30 s	0.1–0.9	[21]
Dry heat	56°C	CCV	Strain S378	30 min	≥5.01	[22]
Moist heat	90°C	Poliovirus	Strain Sabin	1 min	>5.0	[18]
Moist heat	90°C	Adenovirus	Type 5	1 min	>4.1	[18]

CCHFV: Crimean-Congo haemorrhagic fever virus; NiV: Nipah virus; EBOV: Ebola virus; MB: methylene blue; SARS: severe acute respiratory syndrome; MERS: Middle East respiratory syndrome; MHV: mouse hepatitis virus; CCV: canine coronavirus; HCoV: human coronavirus; TGEV: transmissible gastroenteritis virus; PEDV: porcine epidemic diarrhoea virus.

Table 2: Inactivation of viruses by different types of chemical disinfectants.

Disinfection	Concentration	Virus	Strain isolate	Contact time	Reduction of viral infectivity (log_{10})	Reference
Ethanol	95%	SARS-CoV	Isolate FFM-1	30 s	≥5.5	[23]
Ethanol	80%	MERS-CoV	Strain EMC	30 s	>4.0	[24]
Ethanol	70%	Poliovirus	Strain Sabin	1 min	2.1	[16]
Ethanol	70%	Adenovirus	Type 5	1 min	2.4	[16]
2-Propanol	100%	SARS-CoV-2	Isolate FFM-1	30 s	≥3.31	[23]
2-Propanol	70%	SARS-CoV-2	Isolate FFM-1	30 s	≥3.31	[23]
Desderman (78% ethanol)	78%	SARS-CoV-2	Isolate FFM-1	30 s	≥5.01	[23]
Sterillium (45% 2-propanol and 30% 1-propanol)	45% and 30%	SARS-CoV-2	Isolate FFM-1	30 s	≥2.78	[23]
Hydrogen peroxide	Vapor of unknown concentration	TGEV	Purdue strain type 1	2-3 h	4.9–5.3	[25]
Hydrogen peroxide	0.5%	HCoV	Strain 229E	1 min	>4.0	[26]
Hydrogen peroxide	0.5%	Influenza A virus	PR-8	1 min	>4.75	[26]
Hydrogen peroxide	0.5%	HCoV	Type 37	1 min	>4.25	[26]
Benzalkonium chloride	0.04%	HCoV	Strain 229E	1 min	<3.0	[27]
Didecyldimethylammonium chloride	0.0025%	CCV	Strain S378	3 d	>4.0	[28]
Sodium hypochlorite	2500 ppm	Poliovirus	Strain Sabin	10 min	4.5	[16]
Sodium hypochlorite	2500 ppm	Adenovirus	Type 5	10 min	ND	[16]
Sodium hypochlorite	10 ppm	CCV	SP-80 strain	10 min	0.9	[17]
Sodium hypochlorite	100 ppm	CCV	SP-80 strain	10 min	1.05	[17]
Sodium hypochlorite	0.5–0.6%	Ebola virus	—	10 min	1.1	[29]
Sodium hypochlorite	0.5%	HIV	—	1 min	≥7	[29]
Formaldehyde	0.7%	SARS-CoV	Isolate FFM-1	2 min	>3.01	[18]
Formaldehyde	1%	SARS-CoV	Isolate FFM-1	2 min	>3.01	[18]
Glutaraldehyde	0.5%	SARS-CoV	Isolate FFM-1	2 min	>4.01	[18]
Glutaraldehyde	2%	HCoV	Strain 229E	1 min	>3.0	[27]
Glucoprotamin	26%	SARS-CoV	Isolate FFM-1	2 min	>1.68	[27]
Magnesium monoperphthalate	0.5%	SARS-CoV	Isolate FFM-1	30 min	>4.5	[27]
PVP-I surgical scrub (7.5 g/L available iodine)	7.5 g/L	MERS-CoV	Isolate HCoV-EMC/2012	15 s	4.64	[30]
PVP-I skin cleanser (4 g/L available iodine)	4 g/L	MERS-CoV	Isolate HCoV-EMC/2012	15 s	4.97	[30]
PVP-I gargle and mouthwash (1 g/L available iodine)	1 g/L	MERS-CoV	Isolate HCoV-EMC/2012	15 s	4.30	[30]
Povidone-iodine	0.23%	SARS-CoV	Isolate FFM-1	15 s	4.60	[4]
Povidone-iodine	0.23%	MERS-CoV	Isolate HCoV-EMC/2012	15 s	4.40	[4]
Povidone-iodine	0.23%	Influenza virus A	H1N1	15 s	5.67	[4]

ND: not done; SARS: severe acute respiratory syndrome; MERS: Middle East respiratory syndrome; MHV: mouse hepatitis virus; CCV: canine coronavirus; HCoV: human coronavirus; TGEV: transmissible gastroenteritis virus.

SARS-CoV-2: CONCLUSIONS

- SARS-CoV-2 can survive on various surfaces for minutes to hours
- SARS-CoV-2 mRNA can often be detected on hospital rooms surfaces; viable SARS-CoV-2 is infrequently detected
- Coronaviruses can be efficiently inactivated by physical and chemical disinfectants at different concentrations (70, 80, 85, and 95%) of isopropanol (70 and 80%) in less than or equal to 60 s and 0.5% hydrogen peroxide or 0.1% sodium hypochlorite within 1 minute. Additionally, glutaraldehyde (0.5-2%), formaldehyde (0.7-1%), and povidone-iodine (0.1-0.75%) could readily inactivate coronaviruses. Moreover, dry heat at 56°C, ultraviolet light dose of 0.2 to 140 J/cm2, and gamma irradiation could effectively inactivate coronavirus.
- EPA cleared disinfectants (List N) - EPA expects products on List N to kill all strains and variants of the coronavirus SARS-CoV-2 (COVID-19) when used according to the label directions. See: https://www.epa.gov/coronavirus/about-list-n-disinfectants-coronavirus-covid-19-0.
  - Minimum contact time reported among similar products (contact times varies among products; review MFU): Hydrogen peroxide/oxtanoic acid/peracetic acid, 0.25 min; Quaternary ammonium/isopropanol, 0.5 min; Hydrogen peroxide, 0.5 min; Sodium hypochlorite, 0.5 min; Hydrogen peroxide/peracetic acid, 1 min; Isopropanol, 1 min; Quaternary ammonium compounds, 1 min; Phenolic, 3 min
- SARS-CoV-2 highly susceptible to UV-C

Fadaei A. ScientificWorldJournal 2021;Oct 25:9342748

UNC SCHOOL OF MEDICINE

Disinfection and Sterilization: Current Issues and New Technologies

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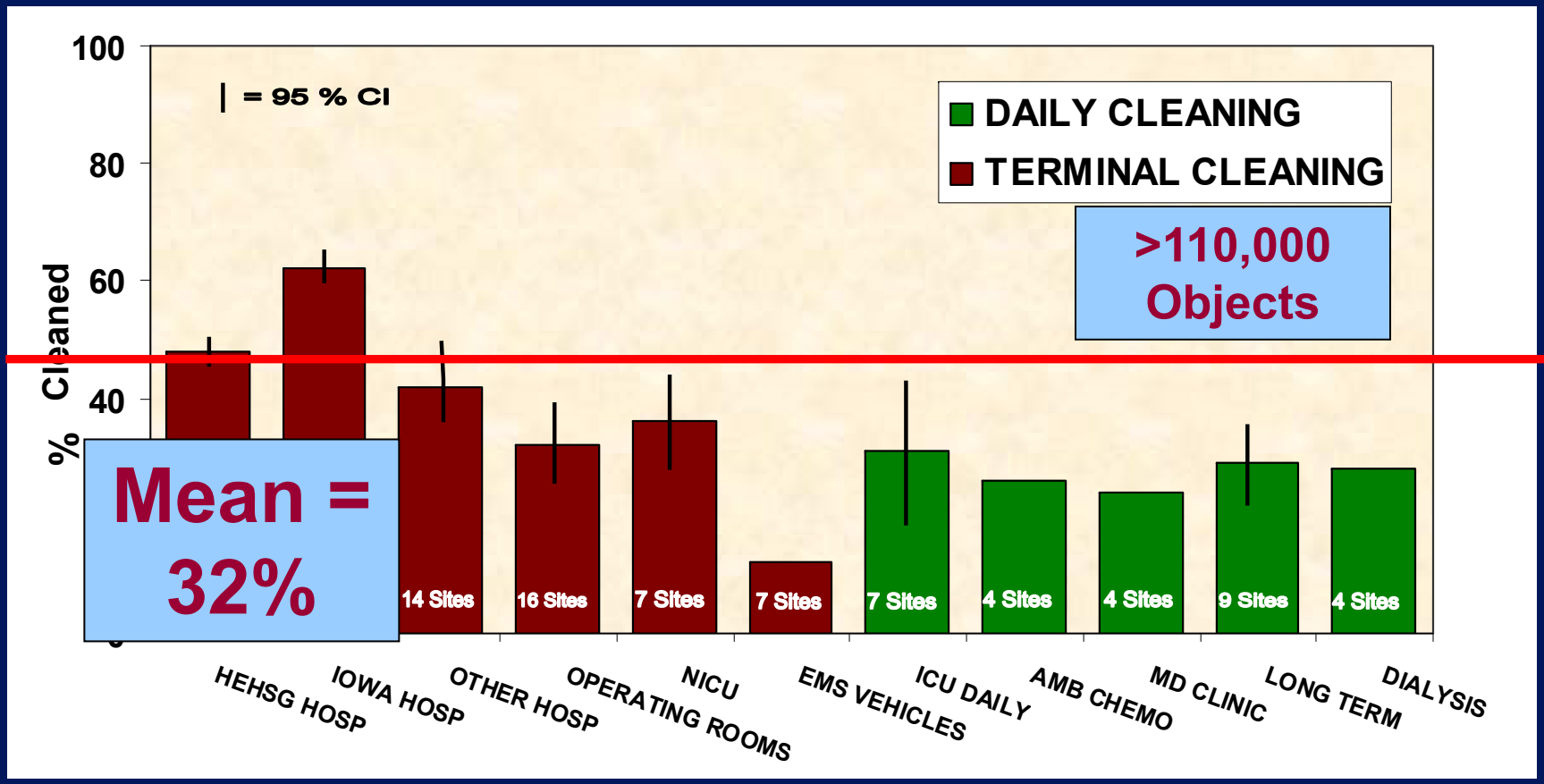
Effective Surface Decontamination

Product and Practice = Perfection

Thoroughness of Environmental Cleaning

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



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Major Article

Evaluation of daily environmental cleaning and disinfection practices in veterans affairs acute and long-term care facilities: A mixed methods study

L. McKinley RN, PhD [a,*], C.C. Goedken MPH [b], E. Balkenende MPH [b,c], G. Clore MPH [b,c], Sherlock S. Hockett MAA [b,c], R. Bartel MA [d], S. Bradley MD [e,f], J. Judd MBA [g,h], Goedken Lyons BHS, MPH [e,f], C. Rock MD, MS [i], M. Rubin MD, PhD [g,h], C. Shaughnessy BS [a], H.S. Reisinger PhD [b,c], E. Perencevich MD, MS [b,c], N. Safdar MD, PhD [a,j]

Descriptive Characteristics of Environmental CD by 62 Room Observations

McKinley et al. AJIC.2023;51:205-213

- Semiprivate pt rooms and surfaces close to patient barriers to CD

Acute Care=35 LTC=27 Total=62

Disinfectant application method			
• Spray bottle	4 (11%)	8 (30%)	12 (19%)
• Wet cloth	29 (83%)	18 (67%)	47 (76%)
Number of cleaning wipes used			
• >3	5 (14%)	5 (19%)	10 (16%)
• 2-3	18 (51%)	7 (26%)	25 (40%)
• 0-1	10 (29%)	14 (52%)	24 (39%)
Mop method			
• Dry	1 (3%)	2 (7%)	3 (5%)
• Wet	30 (86%)	24 (89%)	54 (87%)
Mop material			
• Reusable cotton	23 (66%)	0 (0%)	23 (37%)
• Microfiber	10 (29%)	27 (100%)	37 (60%)
• Disposable synthetic	0 (0%)	0 (0%)	0 (0%)
Cleaning wipe material			
• Reusable cotton	0 (0%)	0 (0%)	0 (0%)
• Microfiber	10 (29%)	27 (100%)	37 (60%)
• Disposable synthetic	0 (0%)	0 (0%)	0 (0%)
Bedroom disinfectant			
• Quaternary ammonium	33 (94%)	27 (100%)	60 (97%)
• Sodium hypochlorite	0 (0%)	0 (0%)	0 (0%)
Bathroom disinfectant			
• Quaternary ammonium	29 (83%)	21 (78%)	50 (81%)
• Sodium hypochlorite	1 (3%)	0 (0%)	1 (2%)
• Quaternary plus Bleach	3 (9%)	6 (22%)	9 (15%)
Hand Hygiene upon room entry			
• Yes	14 (20%)	12 (44%)	26 (42%)
• No	21 (80%)	15 (56%)	36 (58%)

Observed Environmental Surface Cleaning and Disinfection (CD) in AC and LTC

McKinley et al. AJIC.2023;51:205-213

Observed surface CD was 33.6% for all environmental surfaces and 60% for high-touch surfaces. Must improve CD compliance by standardized CD/monitoring

Table 2

Frequency of observed environmental surface cleaning rates by surface observation (N = 3602)

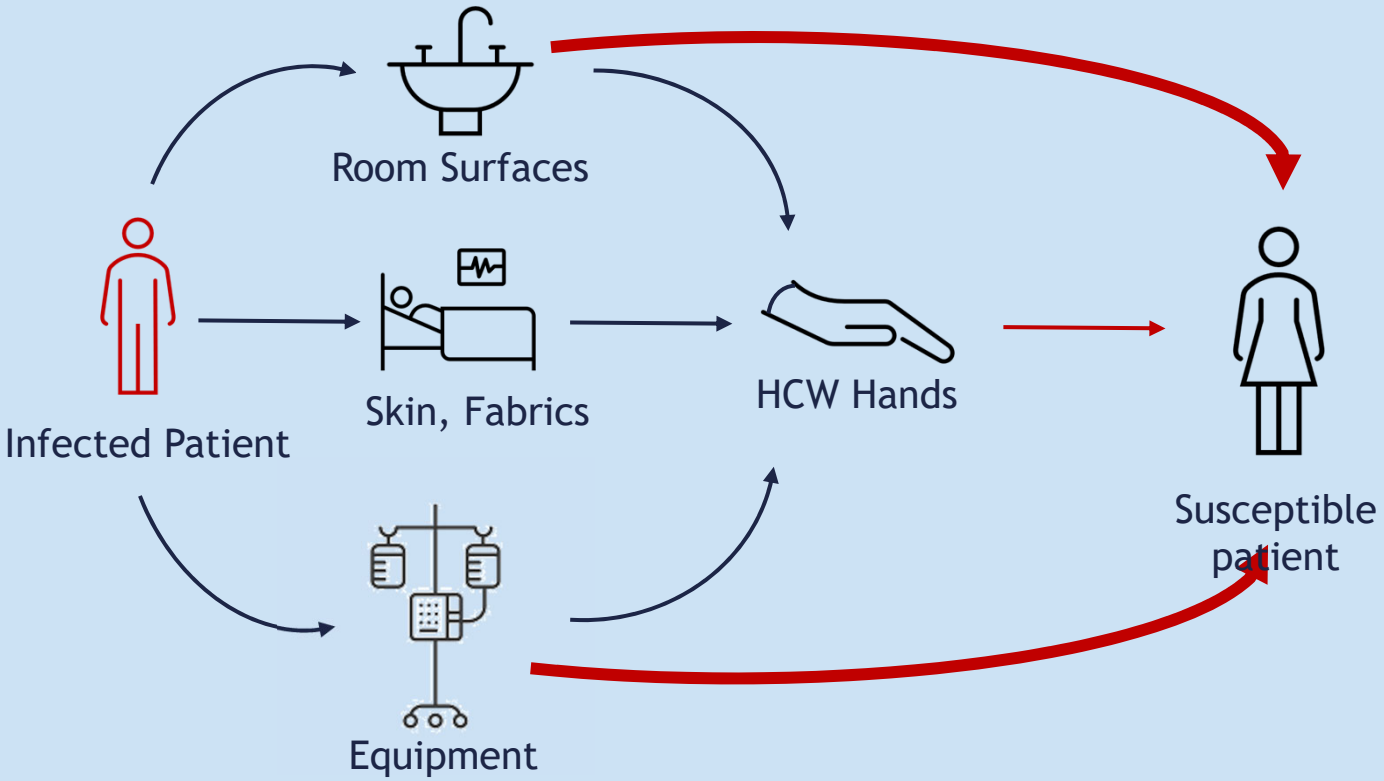
	ACMean (SD)	LTCMean (SD)	TotalMean (SD)
Cleaning rates – all surfaces	0.27 (0.09)	0.42 (0.11)	33.69 (1.26)
Cleaning rates – HTSs	0.69 (0.12)	0.49 (0.14)	60.17 (1.63)

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)
- 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)

Manual Cleaning and Disinfection is the Cornerstone of Infection Prevention



Isolation Precautions

Hand Hygiene

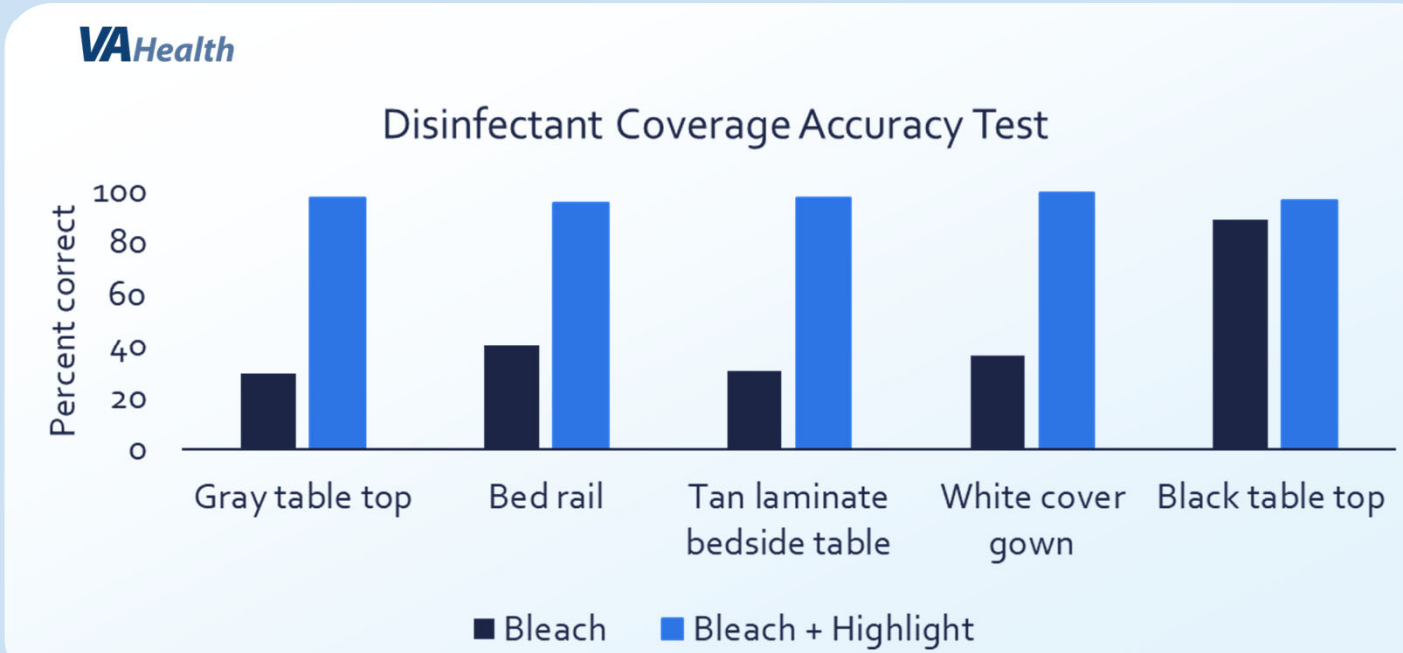
Manual Cleaning

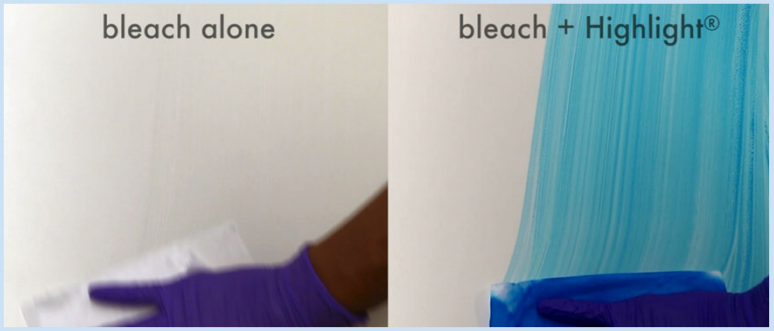
50% of critical surfaces are cleaned improperly

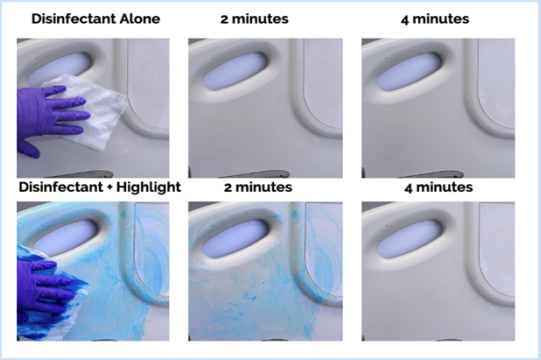
Am J Infect Control, 2013;41(5 Suppl):S12-9. | Crit Care Med. 2010;38(4):1054-9.

Status Quo is an Invisible Process

- Healthcare staff asked where disinfectant was applied 30 seconds after application
- Most staff **unable to correctly determine surface coverage** with disinfectant alone







Am J Infect Control. 2018. 46(1):119-121.

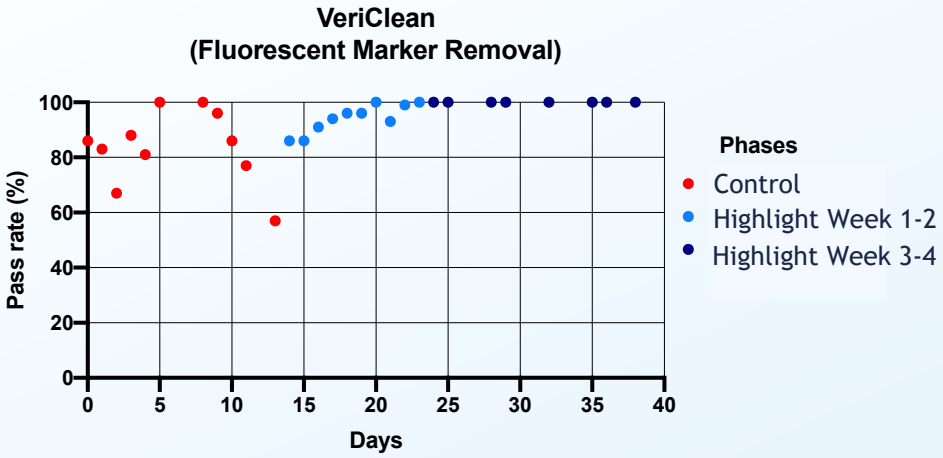
Highlight® Quantifiably Improves Thoroughness of Cleaning

Fluorescent Marker & ATP Score Improvements

Hackensack Meridian *Health*

+70%

Improvement compared to control



Keck Medicine of USC

+65-95%

Improvement in fluorescent marker scores compared to control

BOSTON MEDICAL CENTER
EXCEPTIONAL CARE. WITHOUT EXCEPTION.

5.7% → 0%

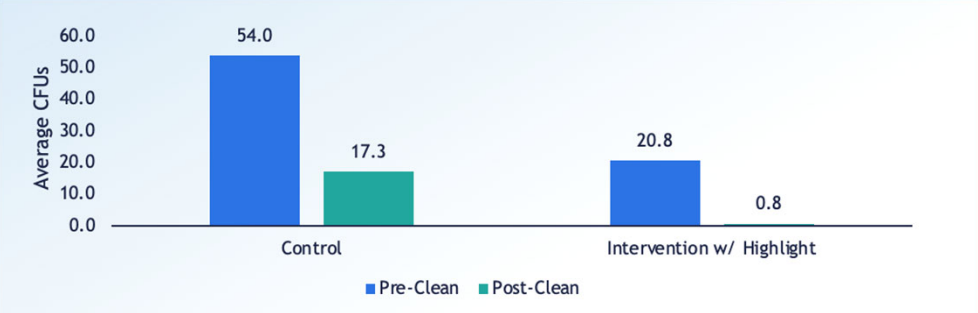
ATP failure rates before and after

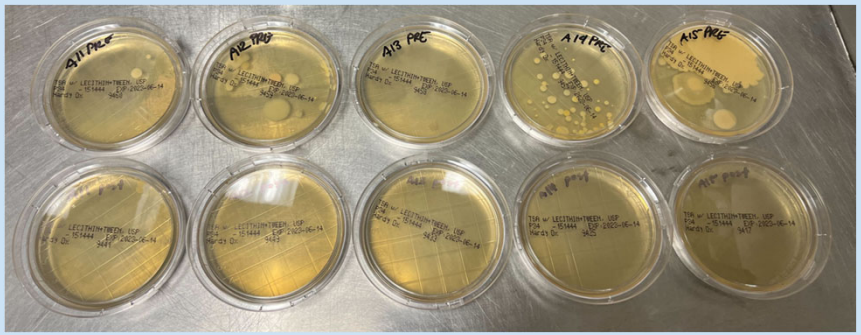
Peer-reviewed papers show consistent, statistically significant, and quantifiable improvements

Infect Control Hosp Epidemiol. 2019;40(2):256-258. | Am J Infect Control. 2021;S0196-6553(21)00738-0. | Manuscript accepted, pre-print.

Highlight® Quantifiably Reduces Microbial Bioburden

VALLEY PRESBYTERIAN HOSPITAL





	Average CFUs Pre-Clean		Average CFUs Post-Clean	% Post-Clean Plates w/ Growth	% Reduction in CFUs
Control	54.0	→	17.3	44.9%	68.0%
Intervention (w/ Highlight)	20.8	→	0.8	21.0%	96.2%

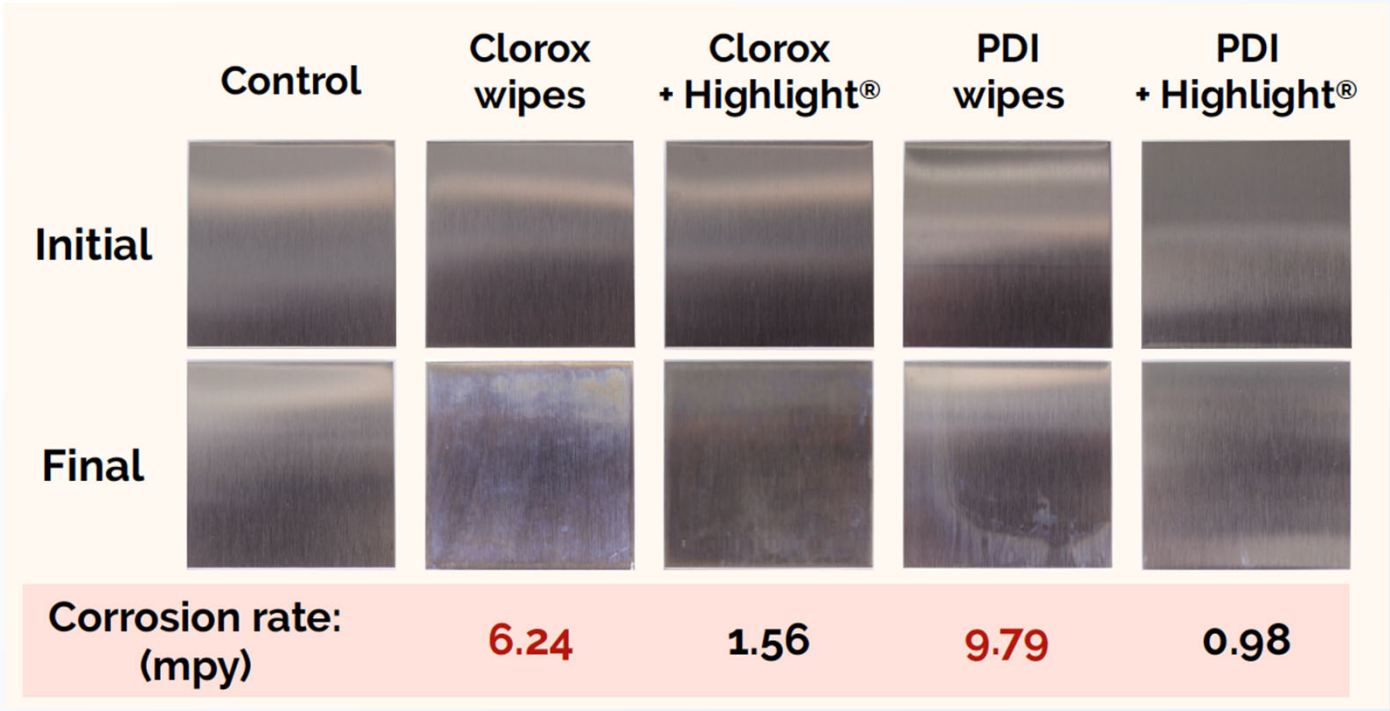
Comparing the post-clean bioburden (17.3 vs. 0.8 CFUs), Highlight:

- Reduced remaining contamination by **95%** ($p<0.01$)
- Also improved room turnover time efficiency by **17%**

Unpublished data.

Highlight® Reduces Corrosion Caused by Bleach

- Bleach wipes caused severe corrosion (>5 mpy) while Highlight® reduced corrosion rate (<2 mpy) and prevented discoloration of the metal
- Highlight® saves money by damaging surfaces less



J Hosp Infect . 2019 Oct;103(2):227-230.

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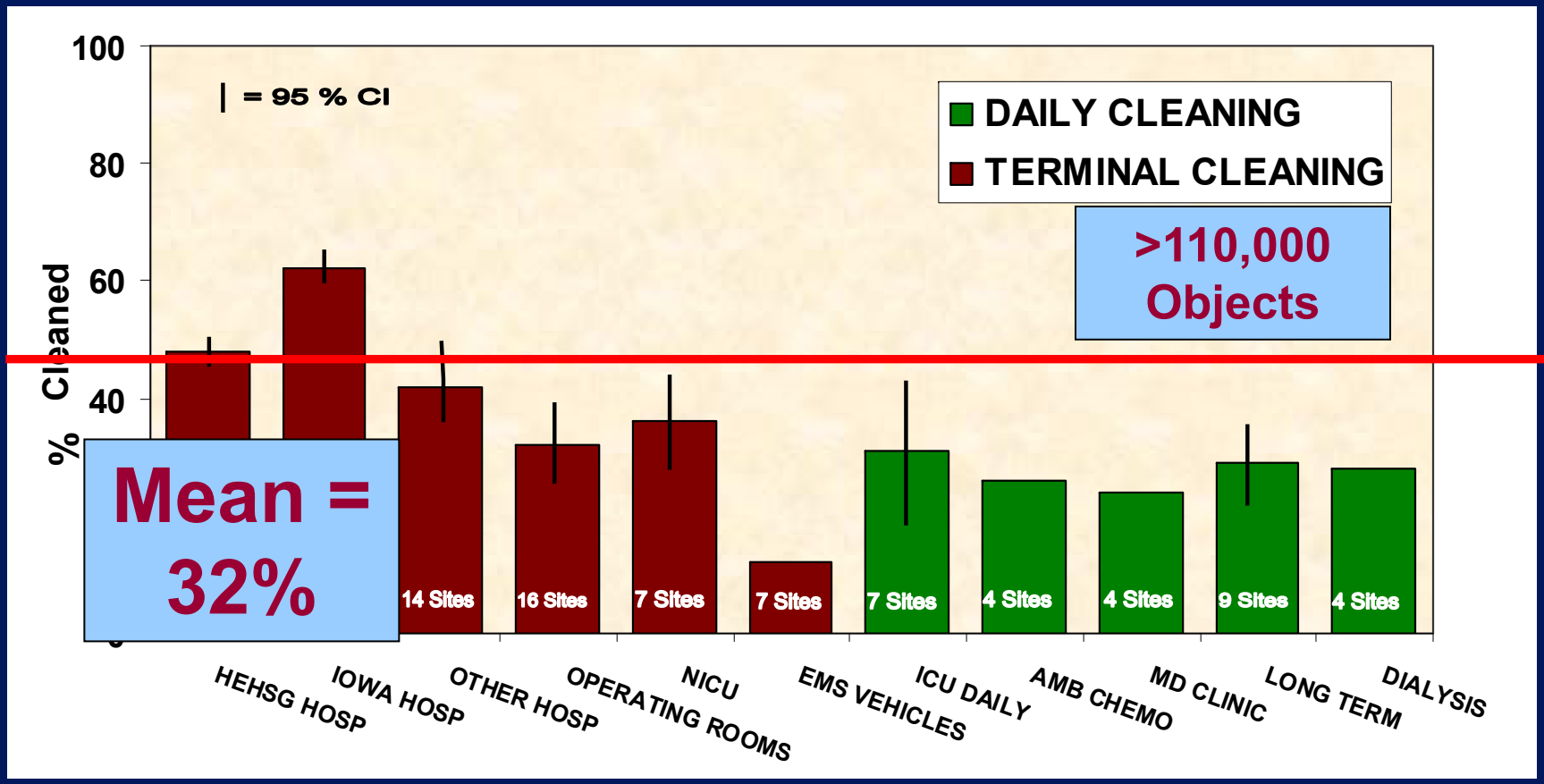
  - Continuously active disinfectant-new technology

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

Thoroughness of Environmental Cleaning

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



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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;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)

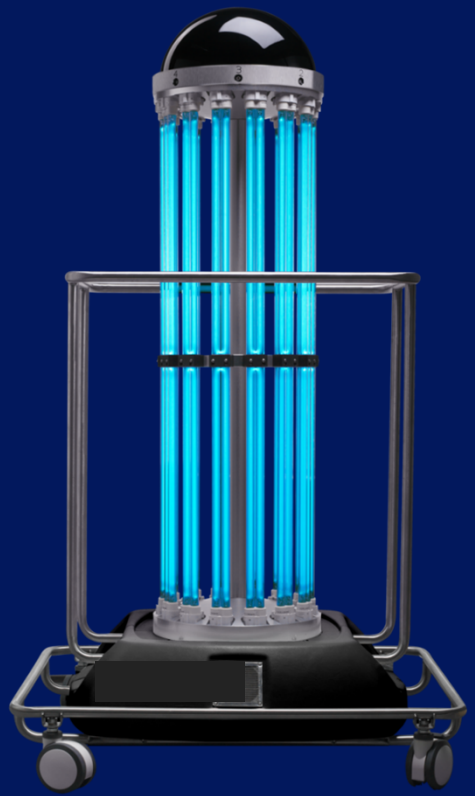
“Given the choice of improving technology or improving human behavior, technology is the better choice”

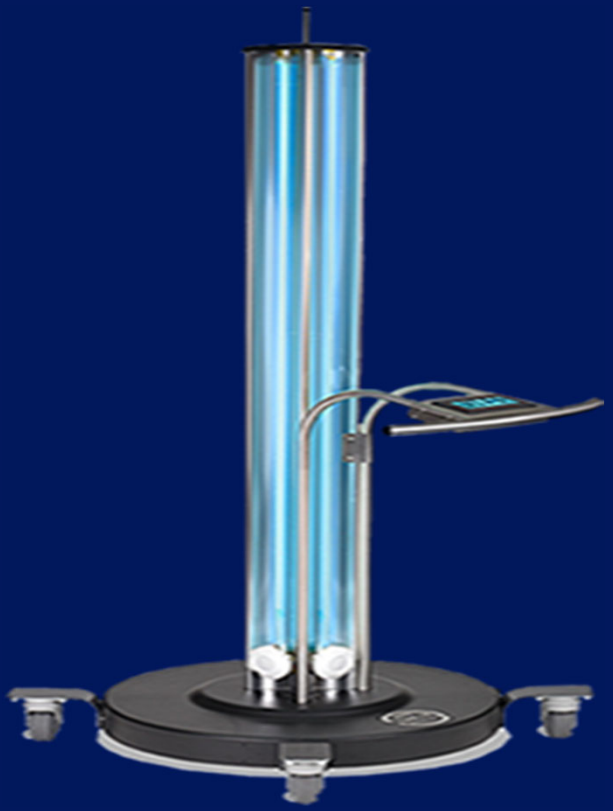
Robert A. Weinstein, MD

"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.

Environmental Contamination Leads to HAIs

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- Surface should be hygienically clean (not sterile)-free of pathogens in sufficient numbers to prevent human disease
- Two environmental surface concerns
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  - 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

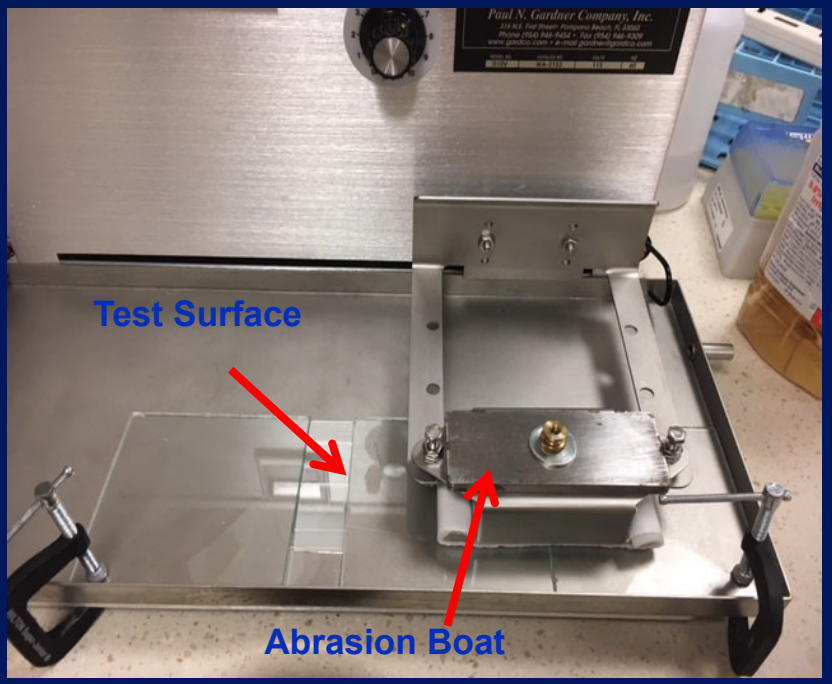
Weber, Rutala et al. AJIC. 2019;47:A72; Rutala et al. ICHE 2019; Weber D, Rutala W. AJIC 2013;41:S31

- 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

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

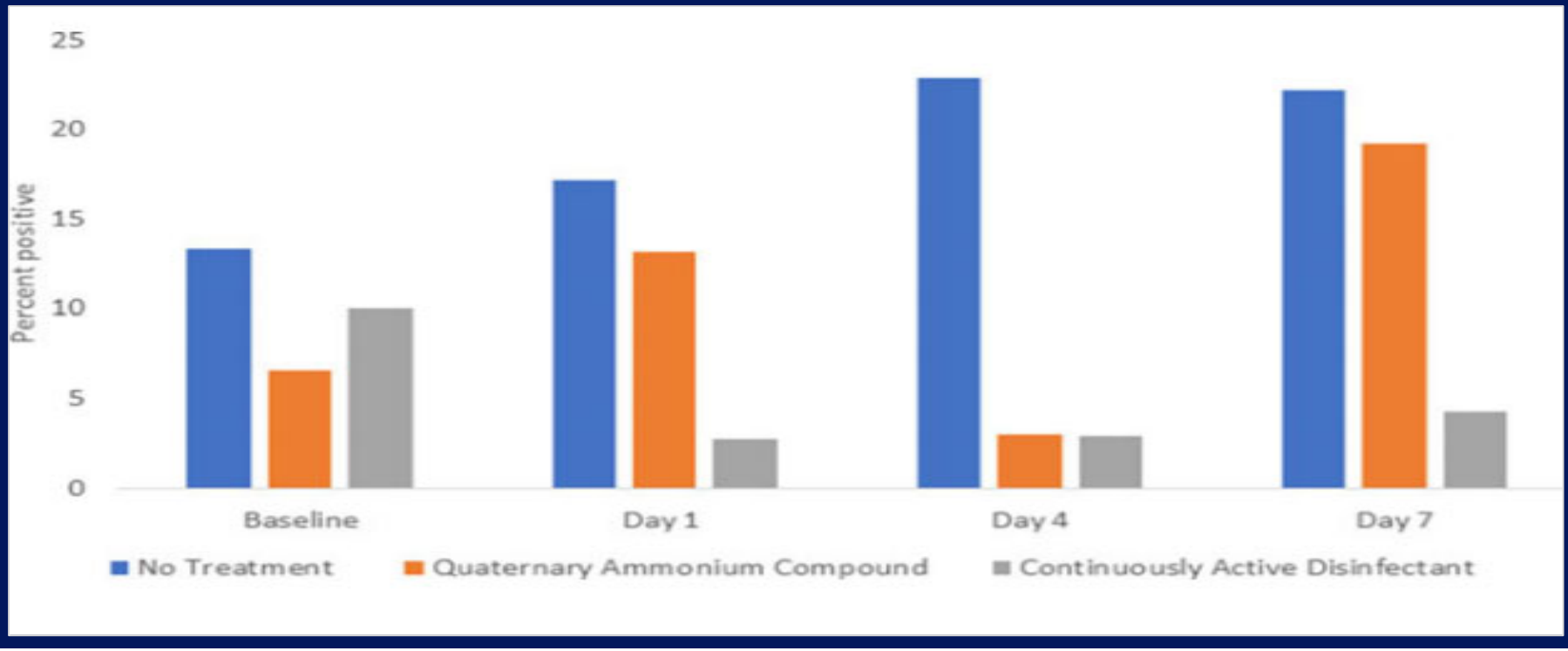
Test Disinfectant	Mean Log_{10} Reduction
Continuously Active Disinfectant	4.4
Quat-Alcohol	0.9
Improved hydrogen peroxide	0.2
Chlorine	0.1

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.

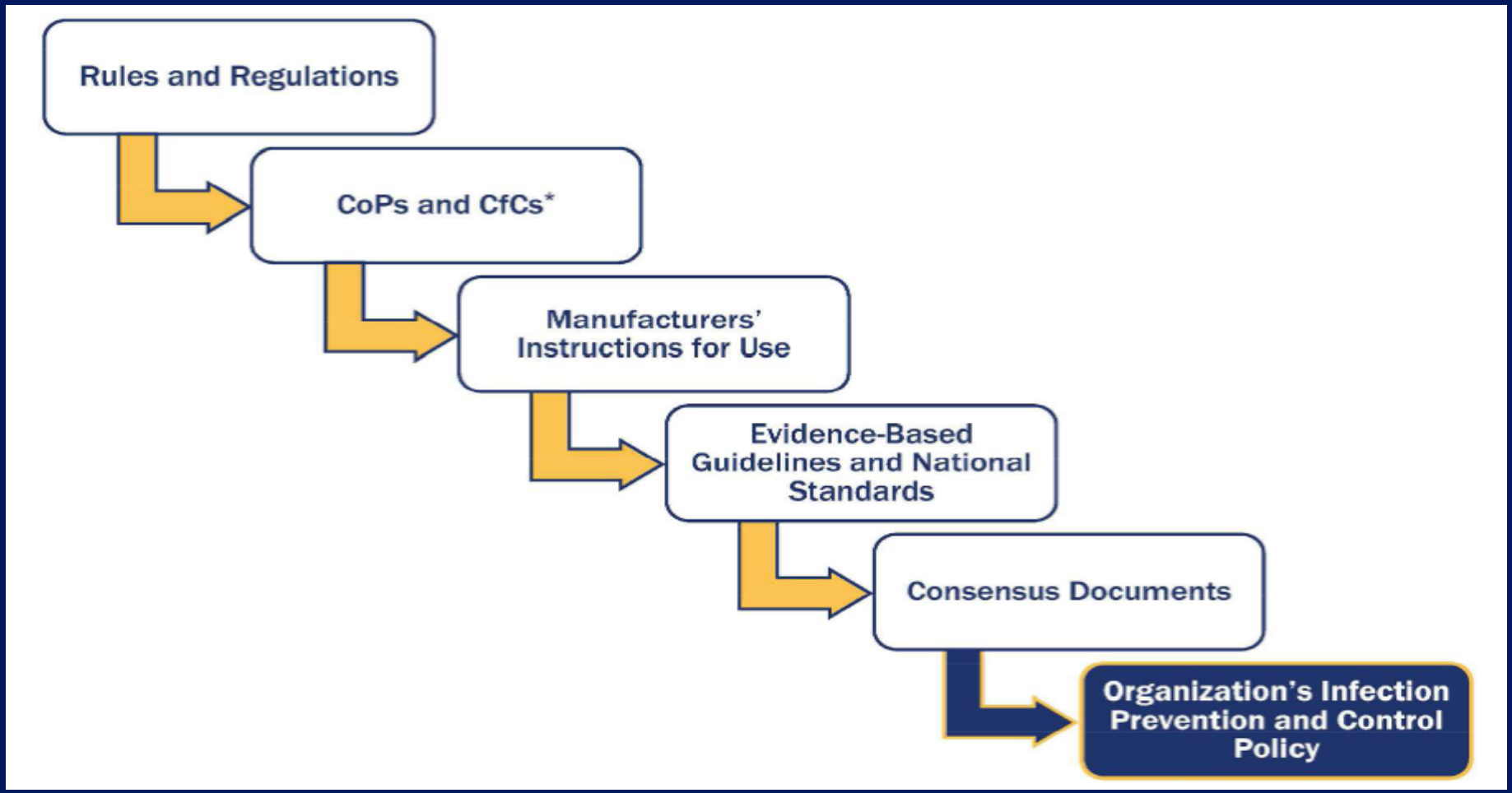
Disinfection and Sterilization: Current Issues and New Technologies

- 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”; emerging pathogens)
- 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
- Innovation strategies (e.g., sporicides and sporicide use, “no touch”, shift from HLD to sterilization, colorized disinfectants) are likely to improve thoroughness of cleaning and disinfection, and reduce risk associated with surface and devices

Hierarchy of Various References that Organization Needs to Include in Policies

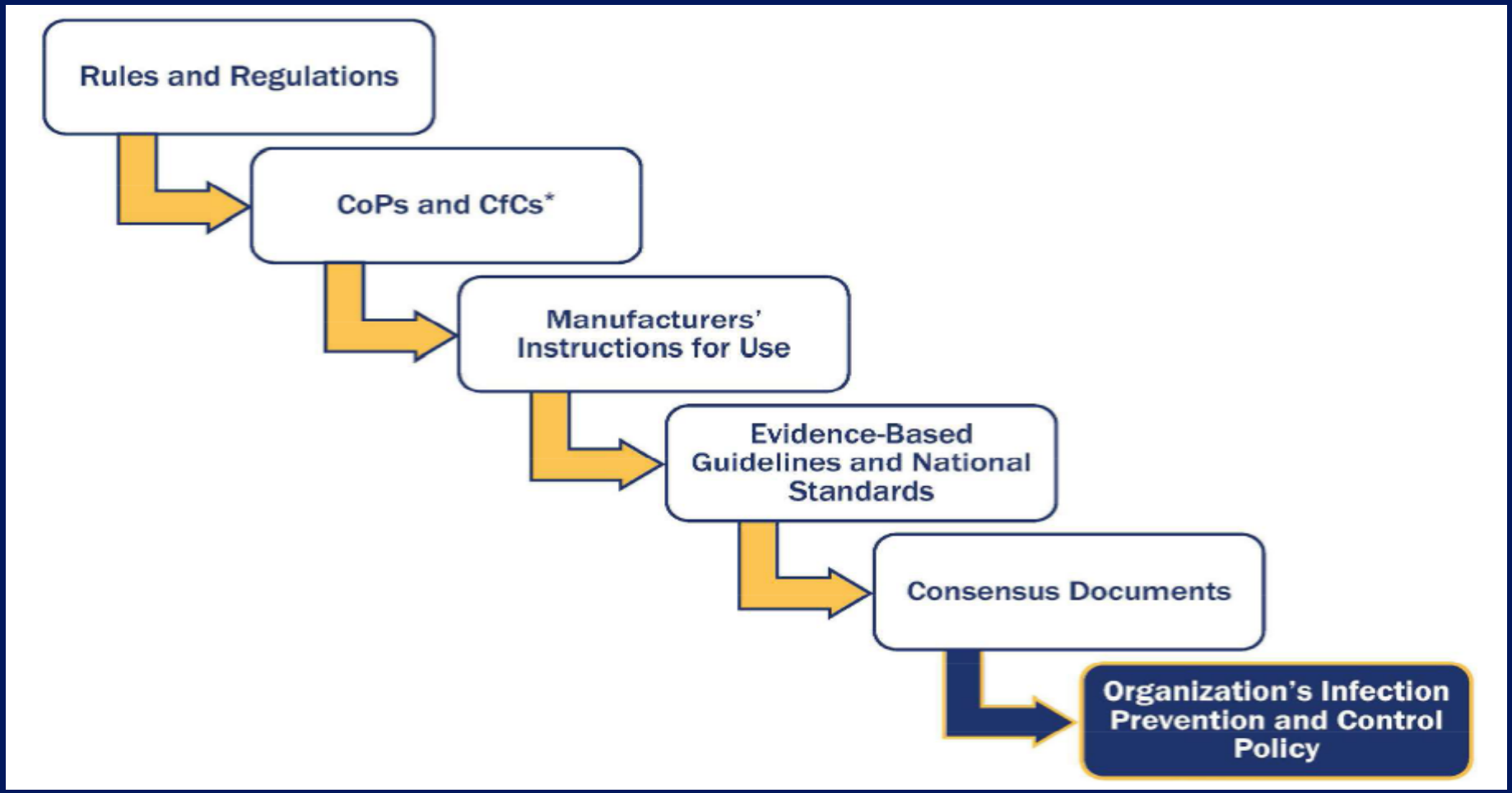


Clarifying Infection Control Policy Requirements-The Joint Commission

https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/infection-prevention-and-hai/ic-hierarchical-approach-to-scoring-standards-april-2019-perspectives.pdf

- JC standards and elements of performance written to allow each HCF determine methods and best practices
- TJC finding many HCF build policies on evidence-based guidelines alone
- TJC recommends HCF apply a hierarchical method to address the IC requirements
- The following graphic illustrates the hierarchy of various references organizations should use as they draft and/or revise their IC-related policies

Hierarchy of Various References that Organization Needs to Include in Policies



Clarifying IC Policy Requirements

(must comply with first three groups in illustration to comply with JC)

- Rules and regulations (e.g., BBP)
- CoPs and CfCs-CMS conditions of participation or conditions of coverage.
- Manufacturers Instructions for Use-deviation may result on biological, chemical or functional incompatibility
- Evidence-based guidelines (EBG) and National Standards. Organizations may choose to follow a variety of EBG
- Consensus Documents.

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