Disinfection and Sterilization
Current Issues, New Research and New Technology

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October 2024

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DISCLOSURES
2023-2024

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

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Disinfection and Sterilization:
Current Issues, New Research and New Technology

- Overview DS
- HLD to Sterilization
- HLD to Sterilization
  - Duo-single use, endcaps
  - Urologic endoscopes, no HLD
  - Low-temp sterilization
- HLD-Human papilloma
- LLD-Ultrasound probes
- LLD-Electrostatic sprayers-new data
- LLD-new sporicide-HP-new tech
- LLD-*C. difficile* tolerates chlorine?
- LLD-emerging pathogens
- LLD-shared medical equipment
- LLD-"no" touch room decontamination
- Continuous room decontamination
  - Far UVC

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CDC Guideline for Disinfection and Sterilization
Rutala, Weber, HICPAC. November 2008. www.cdc.gov

Accessible version: https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/index.html

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
Update: June 2024

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

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Chapel Hill, NC 27599-7030

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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**.

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Critical Medical/Surgical Devices

Rutala et al. ICHE 2014;35:883; Rutala et al. ICHE 2014;35:1068; Rutala et al. AJIC 2023;51:A3-A12

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

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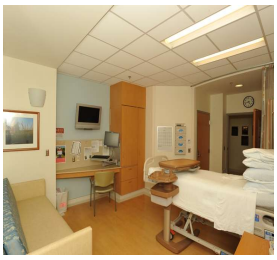
Noncritical Surfaces

Rutala et al. AJIC 2023;51:A3-A12 ; Weber, Kanamori, Rutala. Curr Op Infect Dis .2016.29:424-431



- Noncritical surfaces (environmental surfaces and noncritical medical equipment)
  - Transmission: direct and indirect
  - Control measures: low-level disinfection. Disinfection reduces contamination and HAIs
  - Risks: Contact with surfaces results in hand contamination and possible transmission to patients
  - Rooms not adequately cleaned

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Semicritical Medical Devices

Rutala et al. AJIC 2023;51:A3-A12; Rutala et al. AJIC 2016;44:e47

- Semicritical
  - Transmission: direct contact
  - Control measure: high-level disinfection
  - Endoscopes top ECRI list of 10 technology hazards, >150 outbreaks (GI, bronchoscopes)
    - No margin of safety
      - Microbial load, 10^{7}-10^{10}
      - Complexity
      - Biofilm
  - Other semicritical devices, rare outbreaks
    - ENT scopes, endocavitary probes (prostate, vaginal, TEE), laryngoscopes, cystoscopes
    - Reduced microbial load, less complex

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Reason for Endoscope-Related Outbreaks

Rutala et al. AJIC 2023;51:A97-A106 ; Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

- No margin of safety with endoscope reprocessing
- Microbial load
  - GI endoscopes contain 10^{7-10}
  - Cleaning results in 2-6 $\log_{10}$ reduction
  - High-level disinfection results in 4-6 $\log_{10}$ reduction
  - Results in a total 6-12 $\log_{10}$ reduction of microbes
  - Level of contamination after processing: 4 $\log_{10}$ or 10,000 (maximum contamination-10^{10}, minimal cleaning/HLD-10^{6})
- Complexity of endoscope and endoscope reprocessing
- Biofilms-could contribute to failure of endoscope reprocessing

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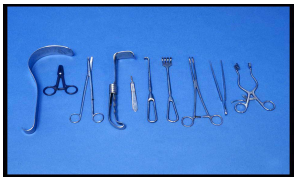
ENDOSCOPE REPROCESSING: CHALLENGES

Complex [elevator channel, long, narrow lumens]-10^{7-10} bacteria/endoscope

Surgical instruments-<10^{2} bacteria



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Transmission of Infection by Endoscopy

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

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

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More infections associated with endoscopes (and other semicritical items) than any other medical or surgical item in health care

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Infections/Outbreaks Associated with Semicritical Medical Devices

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[42–45]	0
Urologic instrumentation (eg, cystoscopes, ureteroscopes)	8[46–53]	0
Transrectal-ultrasound guided prostate probes	1[83]	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.

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What Is the Public Health Benefit?

Rutala et al. AJIC 2023;51:A96-A106

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

HLD (≥6 $\log_{10}$ reduction)

vs

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

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Endoscopes: Shift from Disinfection to Sterilization

Rutala, Weber. JAMA 2014. 312:1405-1406; Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643; Rutala, Weber. AJIC 2023;51:A96-A106

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,

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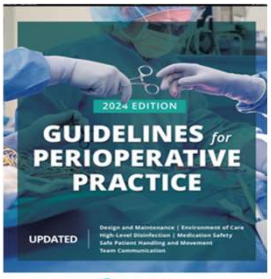
Sterilize reusable flexible endoscopes that are manufacturer validated for sterilization when possible. *[Recommendation]*



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With the infection risk that endoscopes present to the patient, sterilization is the preferred method of microbial inactivation and the only option for instruments to be used in "critical" uses entering sterile body cavities, tissues, or vascular spaces. Sterilization continues to be recommended for endoscopes. Terminal sterilization is also required for all endoscope accessories that penetrate the mucosa, such as biopsy forceps, sphincterotomes, etc. When sterilization is required, most endoscopes require low temperature sterilization. Compatibility with low-temperature sterilization processes varies with endoscope make and model. Compatible processes can include ethylene oxide (EO), hydrogen

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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.

CRITICAL - objects which enter normally sterile tissue (e.g., duodenoscope [duodenum], cystoscope [bladder], bronchoscope [lung]) 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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If guidelines recommend sterilization, why has sterilization of endoscopes not been implemented?

In general, sterilization technology for flexible endoscopes not available until now

(not-FDA cleared)

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Endoscopes: Shift from Disinfection to Sterilization

Rutala, Weber. JAMA 2014. 312:1405-1406; Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643; Rutala, Weber. AJIC 2023;51:A96-A106

- Until now, limited endoscope sterilization technology available to make transition
- FDA-cleared scope sterilization technology available today:
  - ETO-Anderson Products, EOGas4, FDA cleared "for terminal sterilization of duodenoscopes and colonoscopes, with a maximum lumen length of 3530 mm (11.6 feet) and minimum lumen diameter of 1.2mm…" https://www.sterility.com/eogas-4-receives-fda-clearance-for-duodenoscopes/ https://www.sterility.com/eo-gold-standard-endoscope-reprocessing/
  - ASP-Sterrad 100NX. The ULTRA GI™ cycle designed to reprocess Pentax duodenoscope. https://www.asp.com/en-gb/media/Advanced-Sterilization-Products-Announces-FDA-Clearance-Revolutionary-Sterilization-Cycle-Duodenoscopes

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Endoscopes: Shift from Disinfection to Sterilization

Rutala, Weber. JAMA 2014. 312:1405-1406; Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643; Rutala, Weber. AJIC 2023;51:A96-A106

- Until now, limited endoscope sterilization technology to make transition
- FDA-cleared scope sterilization technology available today:
  - ETO-Anderson Products, EOGas4.
  - ASP-Sterrad 100NX. The ULTRA GI™ cycle designed to reprocess Pentax duodenoscope.
  - Ideate Medical-SteroScope FDA-cleared claims:
    - Terminal sterilization of cleaned reusable flexible endoscopes with up to 8 internal lumens with lumen dimensions of:
      - ID of 1.0 mm or larger and a length of 3580 mm or shorter and
      - ID of 1.2 mm or larger and a length of 4095 mm or shorter
-

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Endoscopes: Shift from Disinfection to Sterilization

Rutala, Weber. JAMA 2014. 312:1405-1406; Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643; Rutala, Weber. AJIC 2023;51:A96-A106

- Until now, limited endoscope sterilization technology to make transition
- Other options:
  - Single use, sterile (fully disposable) duodenoscopes, bronchoscopes
  - Innovative designs with disposable components (e.g., endcaps)
  - Use of non-endoscope methods to diagnosis or treat disease (e.g., capsule endoscopy, stool or blood tests to detect GI cancer, stool DNA test)

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

Duodenoscopes with disposable endcap

Sterile, single-use duodenoscope for ERCP

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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

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Why Shift from HLD to Sterilization

Rutala, Weber. AJIC 2023;51:A96-A106

Many reasons sterilization is superior to standard HLD in reducing the risk of microbial contamination and infection to include:

- Evidence-based recommendation
- No margin of safety associated with high-level
- Sterilization can improve outcomes as it can be validated and provides a SAL
- Some high-level disinfectants are relatively resistant to NTM and outbreaks
- Compliant with Spaulding classification scheme
- HLD is a complex process and prone to errors and challenges
- High-level disinfected items are unpackaged and can become recontaminated

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Why Shift from HLD to Sterilization

Rutala, Weber. AJIC 2023;51:A96-A106

Many reasons sterilization is superior to standard HLD in reducing the risk of microbial contamination and infection to include:

- Environmental contamination during drying, handling and storage
- No toxicity or anaphylactic reaction
- Liability arising from an unquantifiable process that results in uncertainty
- Evidence emerging about biofilm resistance to high-level disinfectants
- Transition to sterilization would ensure the process is validated and monitored
- A shift from HLD to sterilization would provide a safety margin
- National/international guidelines recommend sterilization for lumened endoscopic devices

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Why Shift from HLD to Sterilization

Rutala Weber, JAMA 2014; 312:1405-1406; Rutala, Weber. AJIC 2023;51:A96-A106

- National/international guidelines recommend sterilization for lumened endoscopic devices (AORN; AAMI)
- FDA has recommended sterilization for bronchoscopes rather than HLD when feasible (FDA, 2021)
- FDA has recommended sterilization for duodenoscopes (FDA Panel, 2015)
- FDA has precluded use of HLD for certain urologic endoscopes due to HLD failure…FDA recommends sterilization (FDA, 2022)
- FDA has promoted innovation to enhance safety (e.g., use of fully disposable, sterile duodenoscopes) (FDA, 2022)

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Does FDA Favor Innovative Designs and Sterilization to Enhance Safety?

Yes, based on recent FDA safety communications

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Flexible Bronchoscopes and Updated Recommendations for Reprocessing: FDA Safety Communication

June 2021

Recommendations for Health Care Facilities and Staff

The FDA is reminding health care facilities and staff responsible for reprocessing bronchoscopes and their accessories about the importance of carefully following the manufacturer's reprocessing instructions. Additionally, the FDA recommends the following:

- Consider using sterilization instead of high-level disinfection when feasible, because sterilization has a greater safety margin than high-level disinfection. Steps should include precleaning, leak testing, cleaning, and sterilization.

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Sterilize Karl Storz Urological Endoscopes

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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.

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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.
- FDA stated not to 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

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Sterilize Karl Storz Urological Endoscopes

https://www.https://www.fda.gov/medical-devices/letters-health-care-providers/update-change-reprocessing-methods-certain-karl-storz-urological-endoscopes-letter-health-care

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

STORZ
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

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Sterilize Karl Storz Urological Endoscopes

https://www.fda.gov/medical-devices/letters-health-care-providers/update-change-reprocessing-methods-certain-karl-storz-urological-endoscopes-letter-health-care

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

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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).

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Characteristics of Disposable Duodenoscopes

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

Table 2. Characteristics of disposable duodenoscopes.

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

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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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Why Shift from HLD to Sterilization

Summary

- Endoscopes associated with more infections than any other medical or surgical instrument in health care
- No margin of safety associated with HLD due to high microbial load, complexity
- Recommendation to sterilize is evidenced-based
- Professional organizations (e.g., AAMI and AORN) recommend sterilization
- Based on safety communications, FDA favors innovative designs and sterilization for endoscopes
- Sterilization offers many potential benefits (e.g., validated, endoscope free from microbes, sterility assurance level, improved patient outcomes, reduced toxicity, instrument compatibility, reduced liability)
- Endoscope sterilization is a paradigm shift that enhances patient safety and efficacy

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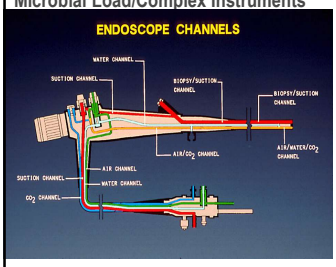
Endoscope Reprocessing

Microbial Load/Complex Instruments



New Guidelines

- Multi-society guideline-2021
- AAMI, ST91-2021
- SGNA-2018
- AORN-2024
- **Must educate/comply but confident will not prevent all infections and patient exposures due to microbial load and instrument complexity**

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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**

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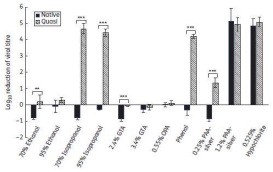
ENDOSCOPE REPROCESSING: CHALLENGES

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)**



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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

43

HLD Inactivate Papillomavirus

Egawa et al. EBioMedicine 2021;63

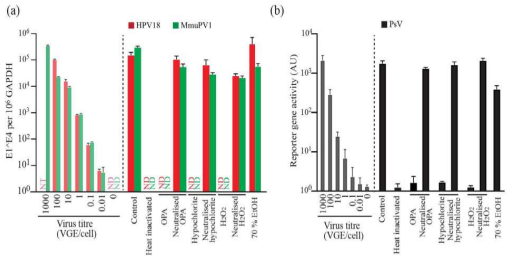

Fig. 5. Evaluation of disinfectant efficacy using in vitro infection assay
(a, b) Measurement of viral infectivity (E1^E4 viral gene transcripts or reporter gene activity shown as Mean and SD) of HPV18, MmuPV1 and PsV in HaCaT cells following incubation with viruses treated with disinfectants or their 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?

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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.

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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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Ultrasound-Guided Percutaneous Procedures Safely Performed in Conjunction with LLD
Co-signed by 20 Professional Organizations
2021 American Institute of Ultrasound in Medicine | J Ultrasound Med 2021; 40:895–897

Disinfection of Ultrasound Transducers Used for Percutaneous Procedures

Intersocietal Position Statement

We, the undersigned organizations, wish to address the issue of disinfection of transcutaneous ultrasound transducers used for percutaneous procedures or for the purpose of monitoring other invasive procedures.

Current guidelines from multiple clinical societies have endorsed the use of low-level disinfection (LLD) for transcutaneous ultrasound transducer cleaning and disinfection used for guidance of percutaneous procedures.[1–3] Some organizations are not congruent regarding their recommendations for disinfection.[1, 4–7] In some cases, guidelines that address endocavity transducers are being misapplied to percutaneous and vascular-access applications. The Spaulding classification[8] is meant for *intended* uses, and some of the above guidelines reclassify *intended non-critical applications* as semicritical.[6–7] Recommendations for high-level disinfection (HLD) of sheathed probes used for percutaneous procedures are

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Disinfection and Sterilization:
Current Issues, New Research and New Technology

- Overview DS
- HLD to Sterilization
- HLD to Sterilization
  - Duo-single use, endcaps
  - Urologic endoscopes, no HLD
  - Low-temp sterilization
- HLD-Human papilloma
- LLD-Ultrasound probes
- LLD-Electrostatic sprayers-new data
- LLD-new sporicide-HP-new tech
- LLD-*C. difficile* tolerates chlorine?
- LLD-emerging pathogens
- LLD-shared medical equipment
- LLD-"no" touch room decontamination
- Continuous room decontamination
  - Far UVC

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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,*]

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.

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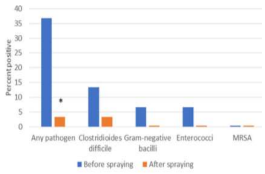
Efficacy of Disinfectant Electrostatic Spray (positive charged droplets attracted to negatively charged surfaces or microbes) in Reducing Pathogen Contamination

Cadnum et al. AJIC 2020

Picture of electrostatic sprayer
(0.25% sodium hypochlorite)

Efficacy of disinfectant spray
(waiting room chairs)



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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

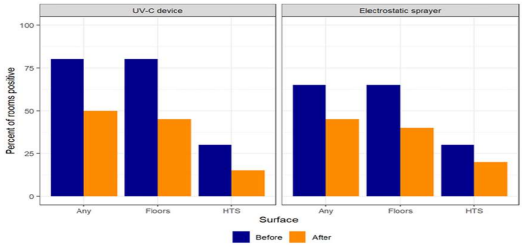

Fig. 1. Percentages of rooms with positive cultures for 1 or more healthcare-associated pathogens before versus after treatment with the ultraviolet-C (UV-C) light device or the electrostatic sprayer. Note. HTS, high-touch surface.

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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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Disinfection and Sterilization:
Current Issues, New Research and New Technology

- Overview DS
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  - Duo-single use, endcaps
  - Urologic endoscopes, no HLD
  - Low-temp sterilization
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- LLD-Electrostatic sprayers-new data
- LLD-new sporicide-HP-new tech
- LLD-*C. difficile* tolerates chlorine?
- LLD-emerging pathogens
- LLD-shared medical equipment
- LLD-"no" touch room decontamination
- Continuous room decontamination
  - Far UVC

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Novel Hydrogen Peroxide Sporicide

Cadnum et al. AJIC 2021

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

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

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

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MICROBIOLOGY

RESEARCH ARTICLE

Ahmed and Joshi, *Microbiology* 2023;169:001418

DOI 10.1099/mic.0.001418

MICROBIOLOGY SOCIETY

ACCESS

Clostridioides difficile spores tolerate disinfection with sodium hypochlorite disinfectant and remain viable within surgical scrubs and gown fabrics

Humaira Ahmed[1] and Lovleen Tina Joshi[2,*]

Abstract

Clostridioides difficile is the most common cause of antibiotic-associated diarrhoea globally. Its spores have been implicated in the prevalence of *C. difficile* infection due to their resistance and transmission ability between surfaces. Currently, disinfectants such as chlorine-releasing agents (CRAs) and hydrogen peroxide are used to decontaminate and reduce the incidence of infections in clinical environments. Our previous research demonstrated the ability of *C. difficile* spores to survive exposure to recommended concentrations of sodium dichloroisocyanurate in liquid form and within personal protective fabrics such as surgical gowns; however, the present study examined the spore response to clinical in-use concentrations of sodium hypochlorite. Spores were exposed to a 10 min contact time of 1000, 5000 and 10 000 p.p.m. sodium hypochlorite, and spore recovery was determined. To understand whether biocide-exposed spores transmitted across clinical surfaces *in vitro*, biocide-exposed spores were spiked onto surgical scrubs and patient gowns and recovery was determined by a plate transfer assay. Scanning electron microscopy was used to establish if there were any morphological changes to the outer spore coat. The results revealed that viable biocide-exposed *C. difficile* spores can be recovered from surgical scrubs and patient gowns, with no observable changes to spore morphology, highlighting the potential of these fabrics as vectors of spore transmission. This study demonstrates that alternative strategies should be urgently sought to disinfect *C. difficile* spores to break the chain of transmission in clinical environments.

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C. difficile Spores Tolerate Chlorine

Ahmed H, Joshi LT. Microbiol 2023;169:001418

- Articles-lay press
  - Chlorine disinfectant is not more effective than water at killing off hospital superbug, new study shows November 2023 Phys Org
  - Chlorine-based cleaner ineffective against C diff, study finds November 2023. News Brief. CIDRAP
  - Chemical used to kill superbug in US hospitals no more effective than water. November 2023 Newsweek Health
  - Bleach is no more effective than water at killing off common superbug, scientists have found. November 2023. Euronews

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C. difficile Spores Tolerate Chlorine

Ahmed H, Joshi LT. Microbiol 2023;169:001418

- *C. difficile* most common cause of antibiotic-associate diarrhea
- Spores implicated in the prevalence of *C. difficile* due to their resistance and transmission ability between surfaces
- Disinfectants such as chlorine-releasing agents, PA and HP are used to decontaminate surfaces and reduce the incidence of infections in clinical environments
- Ahmed, Joshi data demonstrated the ability of *C. difficile* spores to survive exposure to recommended concentrations of sodium dichloroisocyanurate

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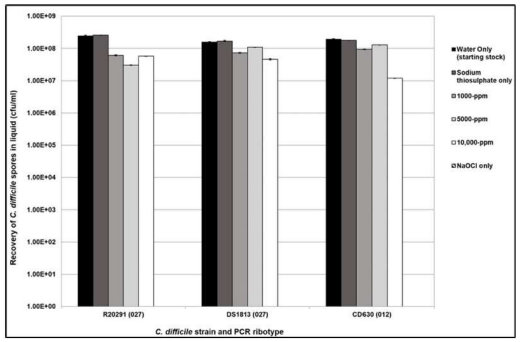

Fig. 1. Recovery of purified *C. difficile* spores following exposure to NaOCl at 1000, 5000 and 10 000 p.p.m. in liquid for 10 min. The spore inoculum was at 10^9 c.f.u. ml^{-1}. The inoculum was used as the positive control (water only) and was also suspended in sodium thiosulphate to ensure no cross-reactivity. Plots represent means±SEM ($n=3$).

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MICROBIOLOGY

LETTER

Cadnum *et al.*, *Microbiology* 2024;170:001436

DOI 10.1099/mic.0.001436

MICROBIOLOGY SOCIETY

ACCESS

Comment on the effectiveness of sodium hypochlorite against *Clostridioides difficile* spores

Jennifer L. Cadnum[1], Claire E. Kaple[2], William A. Rutala[3] and Curtis J. Donskey[4,5,*]

Dear Editor,

Sodium hypochlorite and other chlorine-releasing disinfectants have been a mainstay of efforts to prevent transmission of *Clostridioides difficile* for decades [1]. Many chlorine-releasing products are registered by the United States Environmental Protection Agency (EPA) for use against *C. difficile* spores based on required laboratory testing data [2]. However, Ahmed and Joshi [3] recently reported that spores from three strains of *C. difficile* were minimally reduced after a 10 min exposure to sodium hypochlorite, although the preparation tested was not an EPA-registered sporicidal product and a standardized test protocol was not used [2]. This report and two other recent publications have raised concern that strains of *C. difficile* with reduced susceptibility to chlorine-releasing disinfects may be emerging [4, 5]. To address this concern, there is an urgent need to test the effectiveness of EPA-registered chlorine-releasing agents against the isolates reported to have reduced susceptibility using a standard test protocol.

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Effectiveness of Chlorine Against *C. difficile* Spores

Cadnum, Kaple, Rutala, Donskey. Microbiology 2024

- Using a standard quantitative disc carrier test method to test the efficacy of an EPA-registered sporicidal disinfectant against *C. difficile* spores
- Tested 3 *C. difficile* isolates: strain recommended by EPA (ATCC 43598); a clinical ribotype 027 strain; and one strain tested by Ahmed (R20291)
- Chlorine conc tested of 500, 1000, 5000, 7850, and 10,000ppm
- Exposure times of 1, 5, and 10min in three separate experiments

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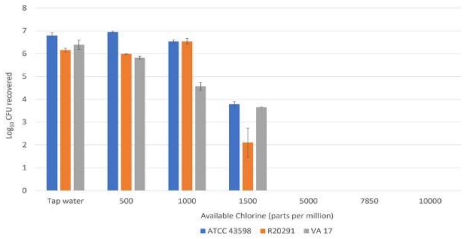
Effectiveness of Chlorine Against *C. difficile* Spores

Cadnum, Kaple, Rutala, Donskey. Microbiology 2024

- 10-minute exposure, ≥6 $\log_{10}$ reduction at 5,000 and 10,000ppm



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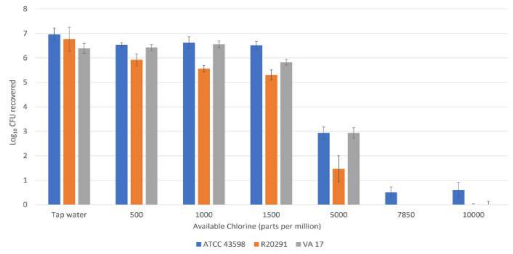
Effectiveness of Chlorine Against *C. difficile* Spores

Cadnum, Kaple, Rutala, Donskey. Microbiology 2024

- 5-minute exposure, ≥6 $\log_{10}$ reduction at 7,850 and 10,000ppm



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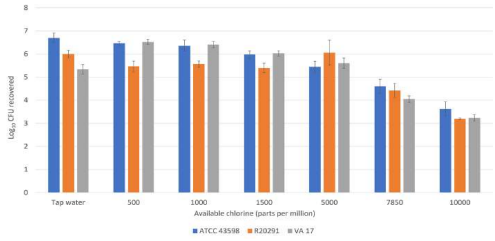
Effectiveness of Chlorine Against *C. difficile* Spores

Cadnum, Kaple, Rutala, Donskey. Microbiology 2024

- 1 minute exposure time, limited efficacy



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Innovative Disinfection Strategies

Summary

- Continuous room decontamination
  - Far UV 222 nm, MRSA reduced by ≥3 $\log_{10}$ at 6 of 8 sites
  - Motion detectors-use to deliver UVC when people are not present
- Sodium hypochlorite effective against *C. difficile* spores
  - 5- and 10-minute exposure, ≥6 $\log_{10}$ reduction at 7,850 and 10,000ppm
- Enhanced disinfection of shared medical equipment reduced HAIs
  - An additional 3h per workday for dedicated CD of shared medical equipment by 21 dedicated CD staff

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C. difficile Spores Tolerate Chlorine

Ahmed H, Joshi LT. Microbiol 2023;169:001418

- *C. difficile* most common cause of antibiotic-associate diarrhea
- Spores implicated in the prevalence of *C. difficile* due to their resistance and transmission ability between surfaces
- Disinfectants such as chlorine-releasing agents, PA and HP are used to decontaminate surfaces and reduce the incidence of infections in clinical environments
- Ahmed, Joshi data demonstrated the ability of *C. difficile* spores to survive exposure to recommended concentrations of sodium dichloroisocyanurate

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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

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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*)

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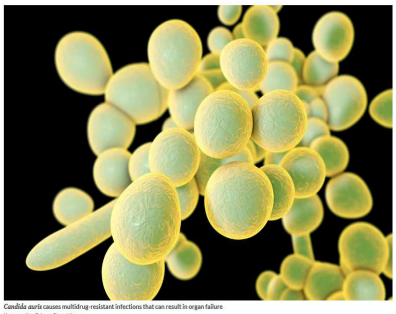
Deadly, drug-resistant Candida yeast infection spreads in the US



Candida auris causes multidrug-resistant infections that can result in organ failure
Kateryna Kon/Science Photo Library

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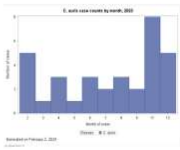
CANDIDA AURIS

- *Candid auris*, an emerging fungal infection: Spreading geographically and increasing in incidence; Cases detected in NC; 3 patients provided care at UNC-MC
- Concerns: May colonize patients for months to years; infections have high mortality (~60%); often multidrug-resistant; difficult to identify with standard lab methods; multiple outbreaks in healthcare settings
- Risks for infection: Prolonged ICU stay, immuno-compromising conditions, broad-spectrum antibiotics, renal failure, diabetes, indwelling medical devices
- Transmission: Direct and indirect contact; environmental contamination common; prolonged survival
- Risk of infection to healthcare personnel is low
- Isolation precautions: Enteric contact
- PPE: Gloves, gowns
- July 19, 2021: Environmental Protection Agency (EPA) has created List P, a list of EPA-registered disinfectants effective against *C. auris*

CDC, data till 12/22
NC, data till 2/24



31 cases *C. auris* in NC 2023

67% Hispanic
Mean age=45 years

Preliminary data- subject to change

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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

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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	2.8	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, Rechanicsville, VA	70% isopropyl alcohol	Undiluted	Antiseptic/Disinfectant	3.8	4.1
Solution of hydrogen peroxide 3% USP	Medichoice, Rechanicsville, VA	3% hydrogen peroxide	Undiluted	Antiseptic	1.4	1.8
Austin's A-L bleach 1:10	James Austin Co, Mars, PA	5.25% sodium hypochlorite (~4,150-4,726 ppm)	1:10 dilution	Disinfectant	4.1	4.0
Austin's A-L 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	0.09% 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[e]	Disinfectant	3.9	4.1
Prime Sani-Cloth wipe	PDI, Orangeburg, NY	28.7% isopropyl alcohol, 27.3% ethyl alcohol, 0.61% QAC[c]	Undiluted[e]	Disinfectant	4.1	4.1

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

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

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

- 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

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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."

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

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

- 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

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About List N: Disinfectants for Coronavirus (COVID-19)

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.

Learn more about the efficacy of disinfectants on strains and variants of coronavirus.

Click Here to Find a Product to Kill Coronavirus (COVID-19)

- Infographic: Best cleaning and disinfecting practices during the COVID-19 pandemic
- Video: Using the List N Tool to find a disinfectant
- Infographic: Tips on using the List N Tool to find a disinfectant
- Infographic: How to use disinfectants safely and effectively - IMPORTANT, PLEASE READ
- Use our advanced search option to find a product

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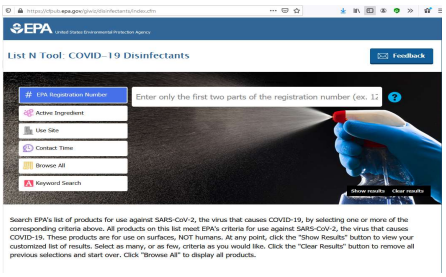
List N Tool: COVID-19 Disinfectants

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



78

List N: COVID-19 Disinfectants
Active Ingredients Include

- Ethyl alcohol (ethanol)
- Hydrogen peroxide
- Hypochlorous acid/chlorine
- Isopropyl alcohol
- Peracetic acid
- Phenolic
- Quaternary ammonium

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Enhanced Disinfection Reduces HAIs

Browne et al. Lancet. 2024

80

Investigating the effect of enhanced cleaning and disinfection of shared medical equipment on health-care-associated infections in Australia (CLEEN): a stepped-wedge, cluster randomised, controlled trial

Katrina Browne, Nicole M White, Philip L Russo, Allen C Cheng, Andrew J Stewardson, Georgia Mattarson, Peta E Tehan, Kirsty Graham, Maham Amin, Maria Northcote, Martin Kiernan, Jennie King, David Brain, Brett G Mitchell

Summary

Background There is a paucity of high-quality evidence based on clinical endpoints for routine cleaning of shared medical equipment. We assessed the effect of enhanced cleaning and disinfection of shared medical equipment on health-care-associated infections (HAIs) in hospitalised patients.

Methods We conducted a stepped-wedge, cluster randomised, controlled trial in ten wards of a single hospital located

Lancet Infect Dis 2024
Published Online August 13, 2024
https://doi.org/10.1016/S1473-3099(24)00399-2

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Enhanced Disinfection of Shared Medical Equipment Reduces HAIs

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

- Cluster randomized, controlled trial in ten ward, single hospital in Australia
- Each cluster, 2 randomly allocated wards (March-November 2023)
- Control phase no change to CD (no requirement for cleaning staff; responsibility of HCWs to CD after use)
- Intervention phase, CD bundle included additional 3h per weekday for dedicated CD of noncritical, shared medical equipment (BP, pumps, infusion drip stands) by 21 dedicated CD staff
- Primary outcome HAIs as assessed by fortnightly point prevalence survey

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Enhanced Disinfection of Shared Medical Equipment Reduces HAIs

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Enhanced CD of Shared Medical Equipment

- Clinell universal and sporicidal wipes
- Dual detergent-disinfectant wipes, GAMA Healthcare
- 1-h training session with 21 dedicated cleaning staff
- Cleaning thoroughness <50% refresher training
- Fluorescent marker gel, randomized list of 12 items for each audit
- 1786 shared equip audited. CD increased from ≥18% to ≥57%
- No policy changes, such as screening, isolation or outbreaks
- Hand hygiene compliance, colonization pressure-no change

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Enhanced Cleaning/Disinfection (CD) of Shared Medical Equipment

- Intervention reduced HAIs

	Control			Intervention		
	Patients	HAIs	HAI prevalence, % (95% CI)	Patients	HAIs	HAI prevalence, % (95% CI)
1	189	23	12·2% (7·5–16·8)	359	37	10·3% (7·1–13·5)
2	276	58	21·0% (16·2–25·8)	275	32	11·6% (7·9–15·4)
3	82	9	11·0% (4·2–17·7)	393	36	9·2% (6·3–12·0)
4*	314	37	11·8% (8·2–15·4)	278	29	10·4% (6·8–14·0)
5	161	24	14·9% (9·4–20·4)	314	48	15·3% (11·3–19·3)
6	401	60	15·0% (11·5–18·5)	73	11	15·1% (6·9–23·2)
7	91	18	19·8% (11·6–28·0)	430	44	10·2% (7·4–13·1)
8	340	54	15·9% (12·0–19·8)	65	12	18·5% (9·0–27·9)
9	321	96	29·9% (24·9–34·9)	160	32	20·0% (13·8–26·2)
10	322	54	16·8% (12·7–20·9)	161	20	12·4% (7·3–17·5)
All wards	2497†	433	17·3% (15·9–18·8)	2508	301	12·0% (10·7–13·3)

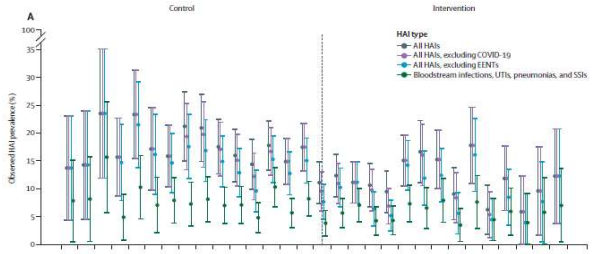
HAI=health-care-associated infection. *Ward 4 was relocated in the last week of the study to a new area in the hospital. The ward and patients on the ward were excluded from the final 2 weeks of the study. †Three patients had two separate admissions each, and are therefore counted twice here.

Table 2: Unadjusted prevalence of HAIs in control and intervention phases by ward

85

Enhanced CD of Shared Medical Equipment

- HAIs in intervention and control phase



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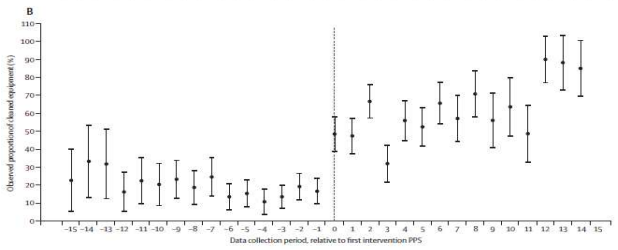
Enhanced CD of Shared Medical Equipment

- Proportion of cleaned equipment in intervention and control phase



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Enhanced CD of Shared Medical Equipment

- The prevalence of HAIs was reduced from 14.9% to 9.8% when CD of shared equipment was initiated
- Supports the role of CD shared medical equipment as a key intervention strategy
- Might be due to reduced burden of infectious pathogens

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Disinfection and Sterilization:
Current Issues, New Research and New Technology

- Overview DS
- HLD to Sterilization
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  - Duo-single use, endcaps
  - Urologic endoscopes, no HLD
  - Low-temp sterilization
- HLD-Human papilloma
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- LLD-new sporicide-HP-new tech
- LLD-*C. difficile* tolerates chlorine?
- LLD-emerging pathogens
- LLD-shared medical equipment
- LLD-"no" touch room decontamination
- Continuous room decontamination
  - Far UVC

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

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

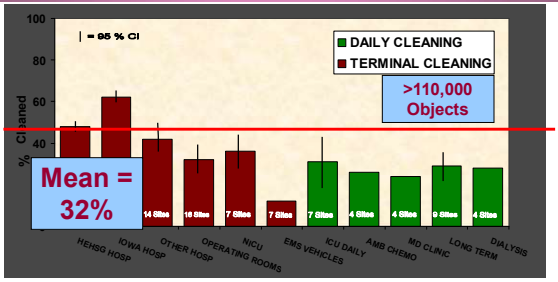
A Bundle Approach to Surface Disinfection

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

90

Thoroughness of Environmental Cleaning

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



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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%)
- 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)

92

"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.

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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.

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This technology ("no touch"-microbicidal and ideally, HAI reduction per peer-reviewed literature) should be used (capital equipment budget) for terminal room disinfection (e.g., after discharge of patients on Contact Precautions).

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- Continuous room decontamination
  - Far UVC

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Continuous Room Decontamination Technology

- Advantages
  - Allows continued disinfection
  - May eliminate the problem of suboptimal CD and 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

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Continuous Room Decontamination Technologies for Disinfection of the Healthcare Environment

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

- Visible light disinfection through LEDs
- Dry/dilute hydrogen peroxide; 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

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Antimicrobial Stewardship & Healthcare Epidemiology (2024), **4**, e123, 1–3
doi:10.1017/ash.2024.388

SHEA

Concise Communication

A novel approach for safe and automated implementation of far ultraviolet-C light decontamination in clinical areas

Samir Memic BS[1,2], Jennifer L. Cadnum BS[2], Andrew Osborne BS[3], William A. Rutala PhD[4,5] and Curtis J. Donskey MD[3,6]

[1]Department of Systems Biology, Case Western Reserve University School of Medicine, Cleveland, OH, USA, [2]Research Service, Louis Stokes Cleveland VA Medical Center, Cleveland, OH, USA, [3]Department of Medicine, Case Western Reserve University School of Medicine, Cleveland, OH, USA, [4]Statewide Program for Infection Control and Epidemiology, University of North Carolina School (UNC) of Medicine, Chapel Hill, NC, USA, [5]Division of Infectious Diseases, UNC School of Medicine, Chapel Hill, NC, USA and [6]Geriatric Research, Education, and Clinical Center, Louis Stokes Cleveland VA Medical Center, Cleveland, OH, USA

Abstract

A novel wall-mounted far ultraviolet-C (UV-C) light technology providing automated delivery of far UV-C only when people are not present reduced methicillin-resistant *Staphylococcus aureus* in a patient room and equipment room. The safety feature that discontinues far UV-C output when people are detected was effective in preventing far UV-C exposure.

(Received 7 February 2024; accepted 30 May 2024)

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Far UV-C 222

Continuous decontamination of air and surfaces

- Filters block >230nm
- Placed on wall
- Kill microbes (3 $\log_{10}$ reduction in 45m) in air and on surfaces when within 2-3m
- Safe for occupied areas
- Long-term safety needs to be investigated
- Proposed as continuous, safe decontamination for air and surface contamination in occupied spaces

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Far Ultraviolet-C

Memic et al. Antimicrob Steward Healthcare Epidemiol. 2024

- December 2021. ACGIH increased Threshold Limit Values for the amount of 222nm Far UVC exposure from 23 to 161mJ/cm^2 for the eyes and 479mJ/cm^2 for skin
- However, safety evaluations have involved animal or *in vitro* skin models with only preliminary reports in exposed humans
- One safer use of UVC technologies in clinical areas could be addition of motion detectors with discontinuation of Far UVC delivery when motion is detected
- Device programmed to discontinue Far UVC when people detected and resume delivery when moved outside area the area of exposure

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Far Ultraviolet-C

Memic et al. Antimicrob Steward Healthcare Epidemiol. 2024

Figure 1. Picture of the wall-mounted device showing the 3 krypton-chloride excimer lamps and adjustable arm that can be used to adjust the position of the lamps.

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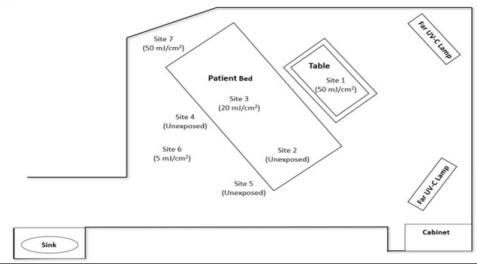
Far Ultraviolet-C

Memic et al. Antimicrob Steward Healthcare Epidemiol. 2024



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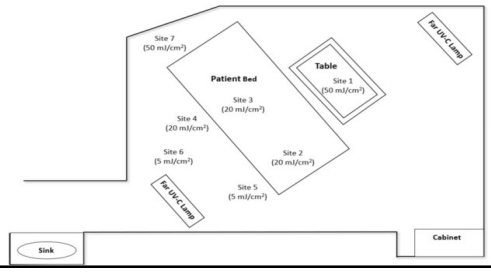
Far Ultraviolet-C

Memic et al. Antimicrob Steward Healthcare Epidemiol. 2024

- Far UVC placed at opposite sides of the room with the bed midway between the lamps. Doses of far UVC measured using colorimetric indicators are shown in parentheses.



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Far Ultraviolet-C

Memic et al. Antimicrob Steward Healthcare Epidemiol. 2024

- Testing conducted in unoccupied patient room
- Based on initial results, testing was conducted with 2 devices positioned at height of 2m at opposite ends of the room
- 45 minute continuous exposure chosen
- Quantitative disk carrier (SS) test method chosen (ASTM 2197)
- 5 sites chosen located 1.5-2m from the nearest device
- MRSA chosen as common HA pathogen

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Far Ultraviolet-C

Memic et al. Antimicrob Steward Healthcare Epidemiol. 2024

- Testing conducted in equipment room with two devices placed on opposite sides of the room
- A workstation-on-wheels, portable vital signs unit, and wheelchair were inoculated with 10^6 CFU MRSA
- Test sites ranged from 1.5 to 2.2m from the nearest device
- After 45 minute and 4 hours of exposure, sites were sampled
- Swabs processed to quantify MRSA
- Log_{10} reductions calculated compared to untreated control

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Far Ultraviolet-C

Memic et al. Antimicrob Steward Healthcare Epidemiol. 2024

- Pictures of a patient room with 2 Far UVC devices positioned in parallel along 1 wall

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Far Ultraviolet-C

Memic et al. Antimicrob Steward Healthcare Epidemiol. 2024

- Pictures of a patient room with 2 Far UVC devices positioned at opposite sides of the room on each side of the bed

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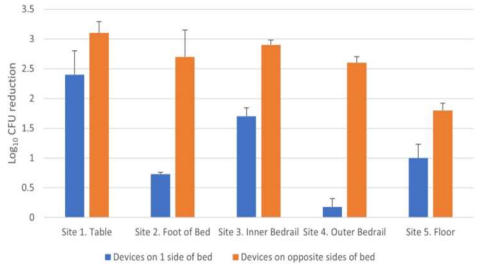
Far Ultraviolet-C

Memic et al. Antimicrob Steward Healthcare Epidemiol. 2024

- Reductions in MRSA after 45m of exposure



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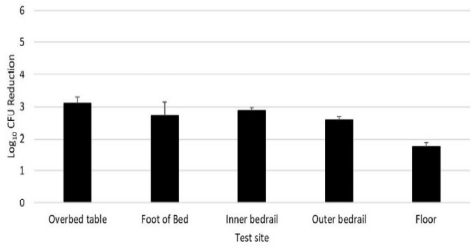
Far Ultraviolet-C

Memic et al. Antimicrob Steward Healthcare Epidemiol. 2024

- After 45 minutes of exposure, MRSA was reduced by ≥1.7 $\log_{10}$ at all sites.



110

Far Ultraviolet-C

Memic et al. Antimicrob Steward Healthcare Epidemiol. 2024

- Pictures of the equipment room with 2 Far UVC devices positioned at opposite sides of the room

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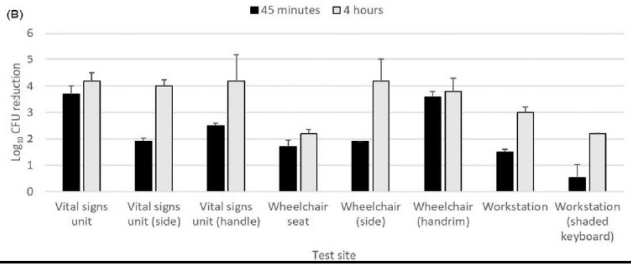
Far Ultraviolet-C

Memic et al. Antimicrob Steward Healthcare Epidemiol. 2024

- 45m exposure reduced MRSA by ≥1.6 $\log_{10}$ CFU at each site except a partially shaded keyboard of the workstation; after 4 hours exposure, MRSA was reduced by ≥3 $\log_{10}$ at 6 of 8 sites



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Far Ultraviolet-C

Memic et al. Antimicrob Steward Healthcare Epidemiol. 2024

- Wall-mounted technology modified to provide automated delivery of UVC only when people are not present was effective in reducing MRSA in patient rooms and equipment room
- >3 $\log_{10}$ reductions were achieved on 6 of 8 inoculated device sites after 4 hours of exposure
- Safety feature (motion detector) that discontinues Far UVC output when people in the room effective in preventing exposure to Far UVC light

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Far Ultraviolet-C

Memic et al. Antimicrob Steward Healthcare Epidemiol. 2024

- To determine if consistently detect people, person walked toward device from 20 angles. Illustration of area where a Far UVC device turned off upon entry of a person into vicinity of the device (shaded in grey). Colorimetric indicators worn by personnel indicated no detectable exposure to UVC.

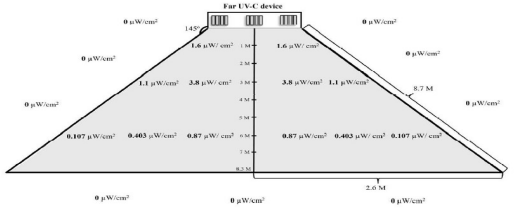

Figure 2. Illustration of a far ultraviolet-C (UV-C) device showing irradiance readings and the area where the device turned off and stayed off upon entry of a person into zone of detection which is the gray shaded area. The irradiance readings with the device on with no one in the zone of detection are shown; far UV-C light was not detected outside the shaded area while the device was on. Readings of 0 indicate no detection of far UV-C above baseline negligible levels measured with the device off. The device resumed far UV-C delivery 30 seconds after a person exited the zone of detection.

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Disinfection and Sterilization:
Current Issues, New Research and New Technology
Summary

- **Endoscope represent a nosocomial hazard. Urgent need to transition from HLD to sterilization. New technology (e.g., disposable endcaps, low temperature sterilization, disposable scopes/components) should reduce or eliminate infection risk.**
- **Implement evidence-based practices for surface disinfection (e.g., evidence-based policies; ensure use of safe and effective (against emerging pathogens such as *C. auris* and CRE) low-level disinfectants; enhanced disinfection of shared equipment**
- **Use "no touch" room decontamination technology for Contact Precaution patients**
- **Continue to assess new technologies: far UVC; electrostatic sprayers**

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THANK YOU!
www.disinfectionandsterilization.org

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