Cleaning, Surface Disinfection and High-Level Disinfection in Healthcare Facilities

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

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

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

DISCLOSURES

2023

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

Cleaning, Disinfection and High-Level Disinfection in Healthcare Facilities

- Endoscopes-greatest risk of infection
  - Risk of infection associated with critical, semicritical and noncritical
  - High-level disinfection
  - Why we need to transition form HLD to sterilization
- Surface disinfection
  - Role of the environment in disease transmission
  - Why we need a bundle approach in surface disinfection
  - Discuss “no touch” room decontamination and continuous room decontamination
  - Emerging pathogens- *Candida auris*, CRE-carbapenem-resistant *Enterobacteriales*

Cleaning, Disinfection and High-Level Disinfection in Healthcare Facilities

- Endoscopes-greatest risk of infection
  - Risk of infection associated with critical, semicritical and noncritical
  - High-level disinfection
  - Why we need to transition form HLD to sterilization
- Surface disinfection
  - *Role of the environment in disease transmission*
  - Why we need a bundle approach in surface disinfection
  - Discuss “no touch” room decontamination and continuous room decontamination
  - Emerging pathogens- *Candida auris*, CRE-carbapenem-resistant *Enterobacteriales*

Medical/Surgical Devices

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

EH Spaulding believed that how an object will be disinfected depended on the object's intended use (developed 1968).

CRITICAL-medical/surgical devices which enter normally **sterile tissue** or the vascular system or through which blood flows should be **sterile**.

SEMICRITICAL-medical devices 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-medical devices that touch **only intact skin** require **low-level disinfection**.

Critical Medical/Surgical Devices

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

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

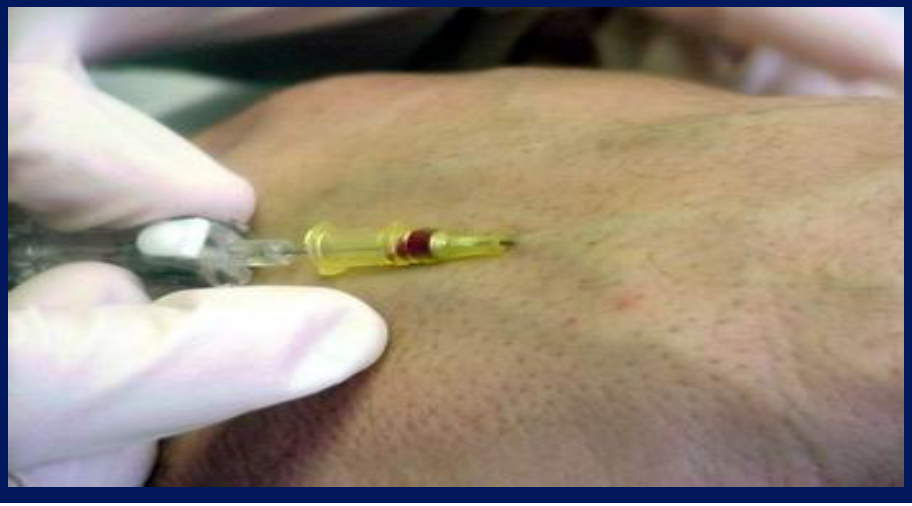
Semicritical Medical Devices

Rutala et al. Am J Infection Control (AJIC) 2019;47:A3-A9

- Semicritical
  - Transmission: direct contact
  - Control measure: high-level disinfection
  - Endoscopes top ECRI list of 10 technology hazards, >150 outbreaks (GI, bronchoscopes)
    - 0 margin of safety
      - Microbial load, 10^7-10^{10}
      - Complexity
      - Biofilm
  - Other semicritical devices, occasional outbreaks
    - ENT scopes, endocavitary probes (prostate, vaginal, TEE), laryngoscopes, cystoscopes
    - Reduced microbial load, less complex

Noncritical Environmental Surfaces and Medical Devices

Rutala et al. AJIC 2019;47:A3-A9; Rutala, Weber. Env Issues NI, Farber 1987



- Noncritical environmental surfaces and medical devices
- Transmission: secondary transmission by contaminating hands/gloves via contact with the environment and transfer to patient
- Control measures: hand hygiene and low-level disinfection
- Noncritical devices (stethoscopes, blood pressure cuffs, wound vacuum), rare outbreaks

Cleaning, Disinfection and High-Level Disinfection in Healthcare Facilities

- Endoscopes-greatest risk of infection
  - Risk of infection associated with critical, semicritical and noncritical
  - High-level disinfection
  - Why we need to transition form HLD to sterilization
- Surface disinfection
  - *Role of the environment in disease transmission*
  - Why we need a bundle approach in surface disinfection
  - Discuss “no touch” room decontamination and continuous room decontamination
  - Emerging pathogens- *Candida auris*, CRE-carbapenem-resistant *Enterobacteriales*

Evidence-Based Recommendation for Sterilization of Endoscopes

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

>150 plus endoscope-related outbreaks

GI endoscope contamination rates of 20-40% after HLD

Scope commonly have disruptive/irregular surfaces

>50,000 patient exposures involving HLD

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(>150 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 13

SES1 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,

High-Level Disinfection of "Semicritical Objects"

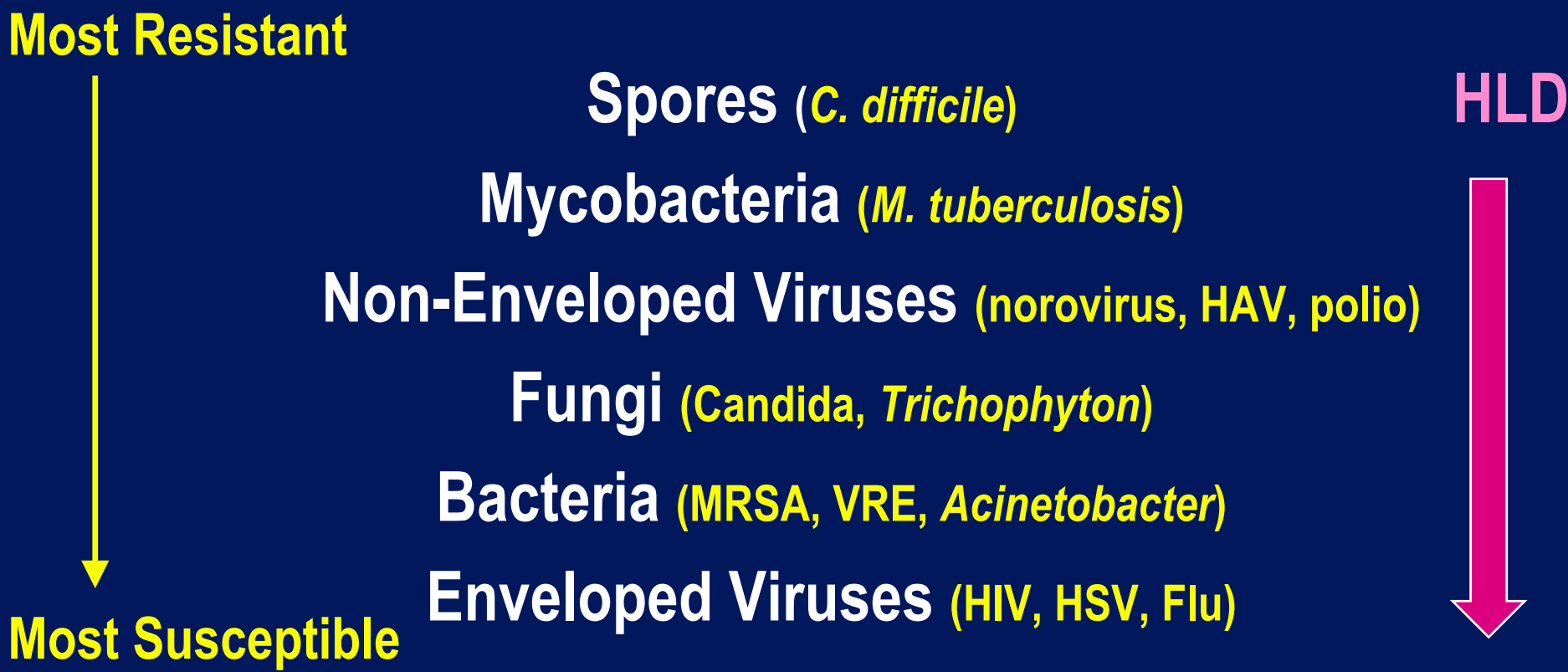
Exposure Time ≥ 8m-45m (US), 20°C

Germicide	Concentration
Glutaraldehyde	≥ 2.0%
Ortho-phthalaldehyde	0.55%
Hydrogen peroxide*	7.5%
Hydrogen peroxide and peracetic acid*	1.0%/0.08%
Hydrogen peroxide and peracetic acid*	7.5%/0.23%
Hypochlorite (free chlorine)*	650-675 ppm
Accelerated hydrogen peroxide	2.0%
Peracetic acid	0.2%
Glut and isopropanol	3.4%/26%
Glut and phenol/phenate**	1.21%/1.93%

*May cause cosmetic and functional damage; **efficacy not verified

Microbiological Disinfectant Hierarchy

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



What Should We Do Now?

GI Endoscopes: Shift from Disinfection to Sterilization

Rutala, Weber. JAMA 2014. 312:1405-1406

EDITORIAL

Editorials represent the opinions of the authors and *JAMA* and not those of the American Medical Association.

Gastrointestinal Endoscopes
A Need to Shift From Disinfection to Sterilization?

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

More than 10 million gastrointestinal endoscopic procedures are performed annually in the United States for diagnostic purposes, therapeutic interventions, or both.[1] Because gastrointestinal endoscopes contact mucosal surfaces, use of a contaminated endoscope may lead to patient-to-patient transmission of potential pathogens with a subsequent risk of infection.[1]

In this issue of *JAMA*, Epstein and colleagues[2] report findings from their investigation of a cluster of New Delhi metallo-β-lactamase (NDM)-producing *Escherichia coli* associated with gastrointestinal endoscopy that occurred from March 2013 to July 2013 in a single hospital in northeastern Illinois. During the 5-month period, 9 pa-

Related article page 1447

First, endoscopes are semicritical devices, which contact mucous membranes or nonintact skin, and require at least high-level disinfection.[3,4] High-level disinfection achieves complete elimination of all microorganisms, except for small numbers of bacterial spores. Because flexible gastrointestinal endoscopic instruments are heat labile, only high-level disinfection with chemical agents or low-temperature sterilization technologies are possible.[3] However, no low-temperature sterilization technology is US Food and Drug Administration (FDA)-cleared for gastrointestinal endoscopes such as duodenoscopes.

Second, more health care-associated outbreaks and clusters of infection have been linked to contaminated endoscopes than to any other medical device.[3,5] However, until now,

What Is the Public Health Benefit?
No ERCP-Related Infections

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

HLD (6 $\log_{10}$ reduction)

vs

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

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.

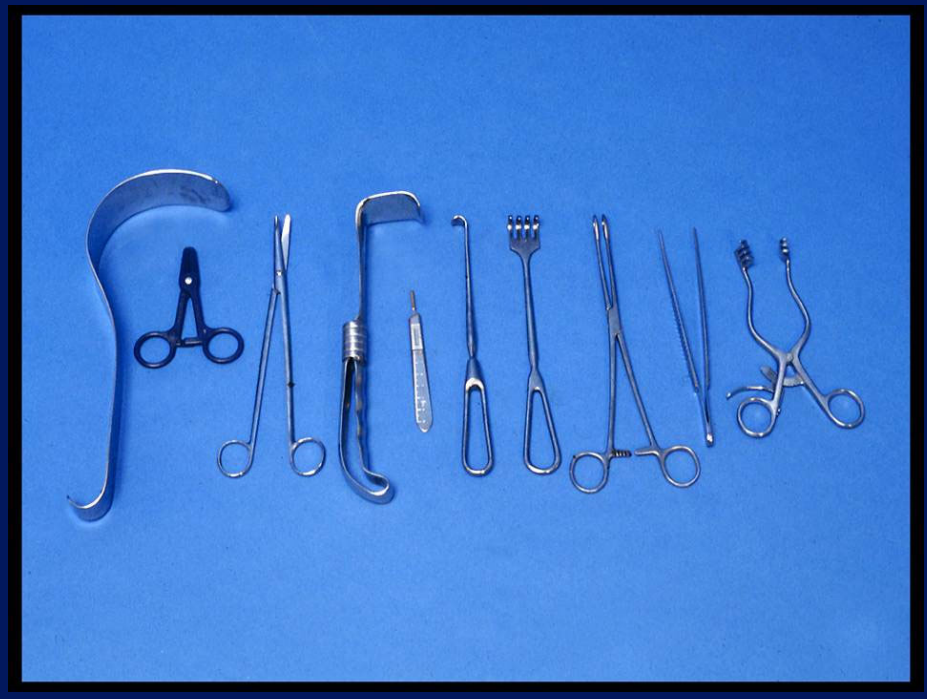
SEMICRITICAL - objects that touch mucous membranes or skin that is not intact require a disinfection process (high-level disinfection [HLD]) that kills all microorganisms but high numbers of bacterial spores.

NONCRITICAL -objects that touch only intact skin require low-level disinfection (or non-germicidal detergent).

ENDOSCOPE REPROCESSING: CHALLENGES

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

Surgical instruments-$<10^{2}$ bacteria



Reason for Endoscope-Related Outbreaks

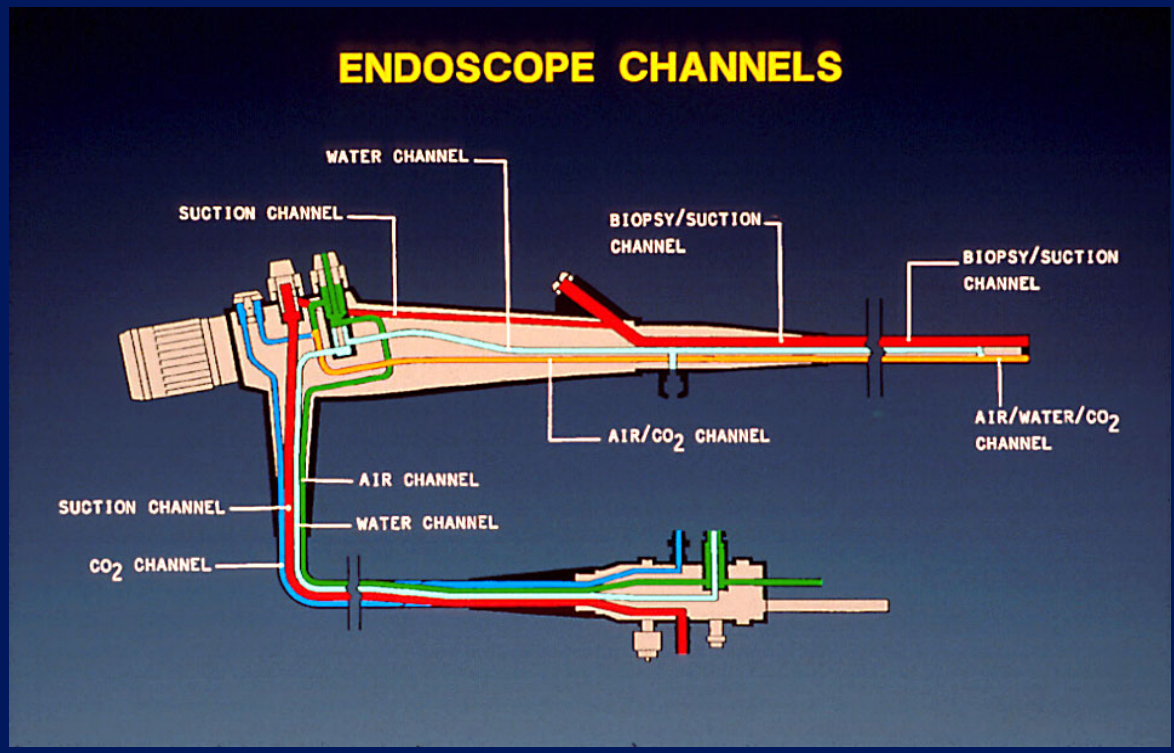
Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

- Margin of safety with endoscope reprocessing minimal or non-existent
- Microbial load
  - GI endoscopes contain 10^{7-10}
  - Cleaning results in 2-6 $\log_{10}$ reduction
  - High-level disinfection results in 4-6 $\log_{10}$ reduction
  - Results in a total 6-12 $\log_{10}$ reduction of microbes
  - Level of contamination after processing: $4\log_{10}$ (maximum contamination, minimal cleaning/HLD)
- Complexity of endoscope and endoscope reprocessing
- Biofilms-could contribute to failure of endoscope reprocessing

FEATURES OF ENDOSCOPES THAT PREDISPOSE TO DISINFECTION FAILURES

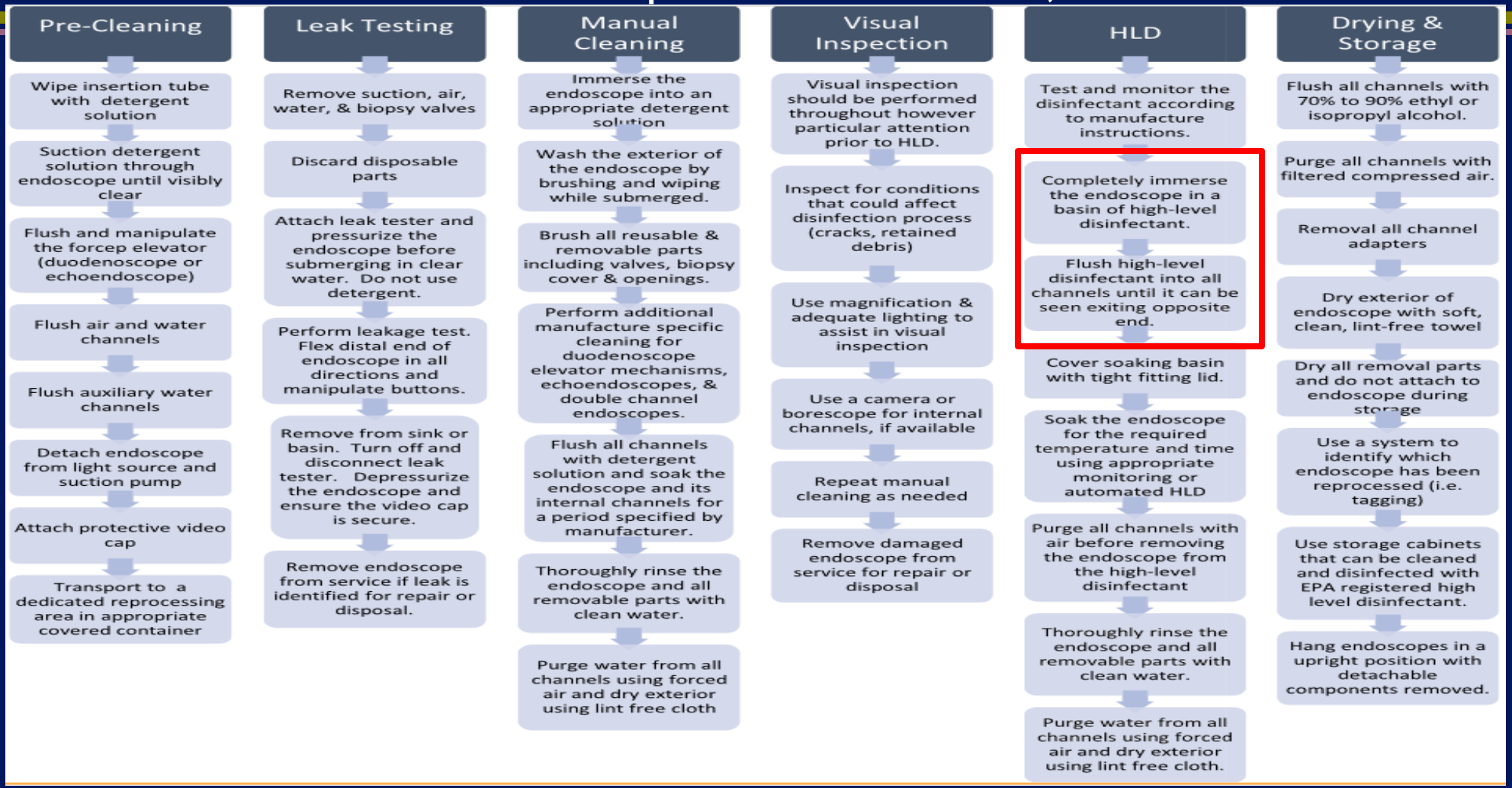
Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

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



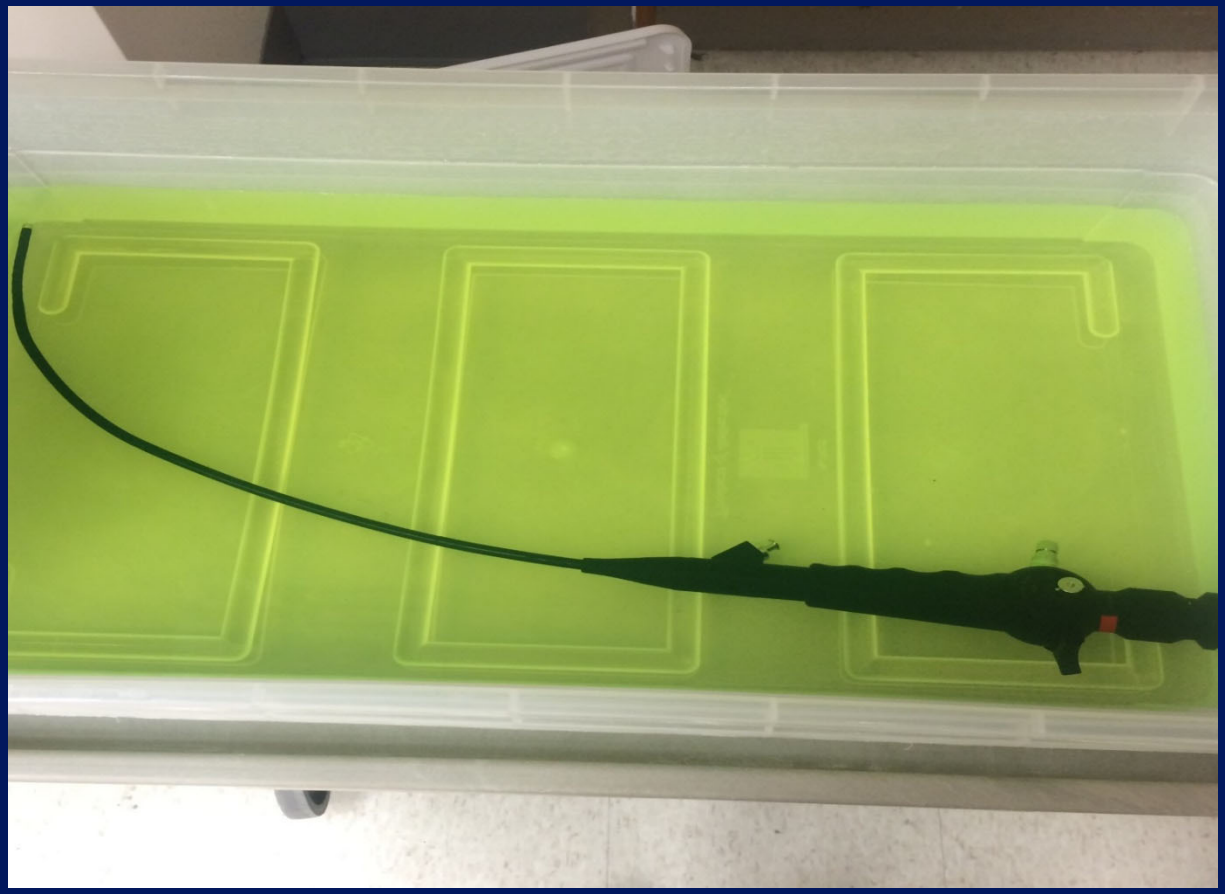
Complexity of Endoscope Reprocessing

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



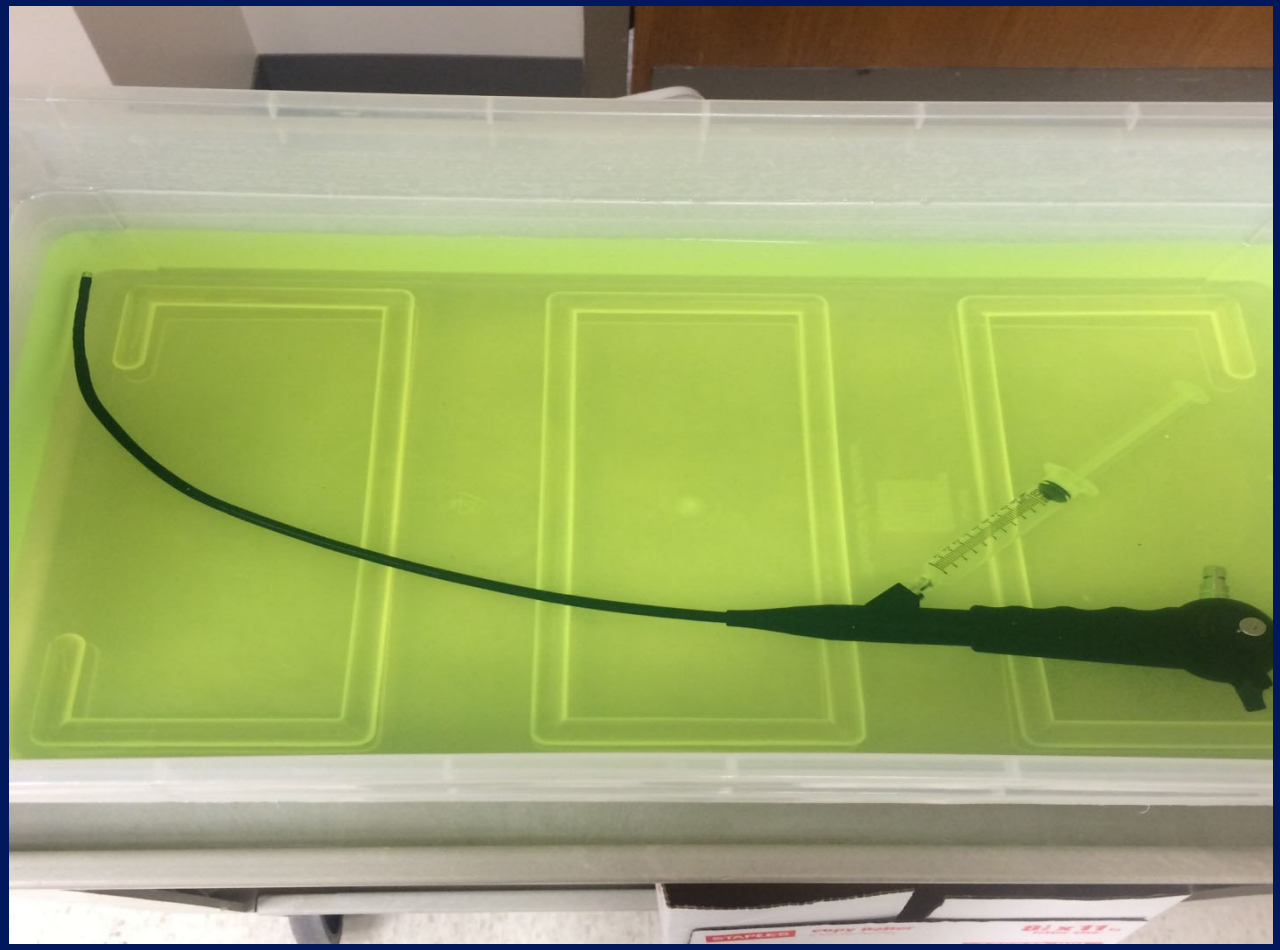
Reprocessing Channeled Endoscopes

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



Reprocessing Channeled Endoscopes Manually

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



Reprocessing Channeled Endoscopes

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

Exposure Method	CRE (*K. pneumoniae*) Inoculum before HLD (glutaraldehyde)	CRE (K. pneumoniae) Contamination after HLD
Passive HLD (immersed, not perfused)	$3.2x10^8$ $1.9x10^9$ $4.1x10^8$	$3.1x10^8$ $4.6x10^8$ $1.0x10^8$
Active HLD (perfused HLD into channel with syringe)	$3.0x10^8$ $9.2x10^8$ $8.4x10^8$	0 0 0

- Pathogens must have exposure to HLD for inactivation
- Immerse channeled flexible scope into HLD will not inactivate channel pathogens
- Completely immerse the endoscope in HLD and ensure all channels (e.g., hysteroscopes, cystoscopes) are perfused
- Air pressure in channel stronger than fluid pressure at fluid-air interface

Reason for Endoscope-Related Outbreaks

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

- Margin of safety with endoscope reprocessing minimal or non-existent
- Microbial load
  - GI endoscopes contain 10^{7-10}
  - Cleaning results in 2-6 $\log_{10}$ reduction
  - High-level disinfection results in 4-6 $\log_{10}$ reduction
  - Results in a total 6-12 $\log_{10}$ reduction of microbes
  - Level of contamination after processing: $4\log_{10}$ (maximum contamination, minimal cleaning/HLD)
- Complexity of endoscope and endoscope reprocessing
- Biofilms-could contribute to failure of endoscope reprocessing

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) and/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

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

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

Duodenoscopes with disposable endcap

Sterile, single-use duodenoscope for ERCP

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

Share | Tweet | Linkedin | Email | Print

Date Issued: April 5, 2022

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

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

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

Fully Disposable:

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

Disposable Components:

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

No Longer Marketed:

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

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

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

Where are we?

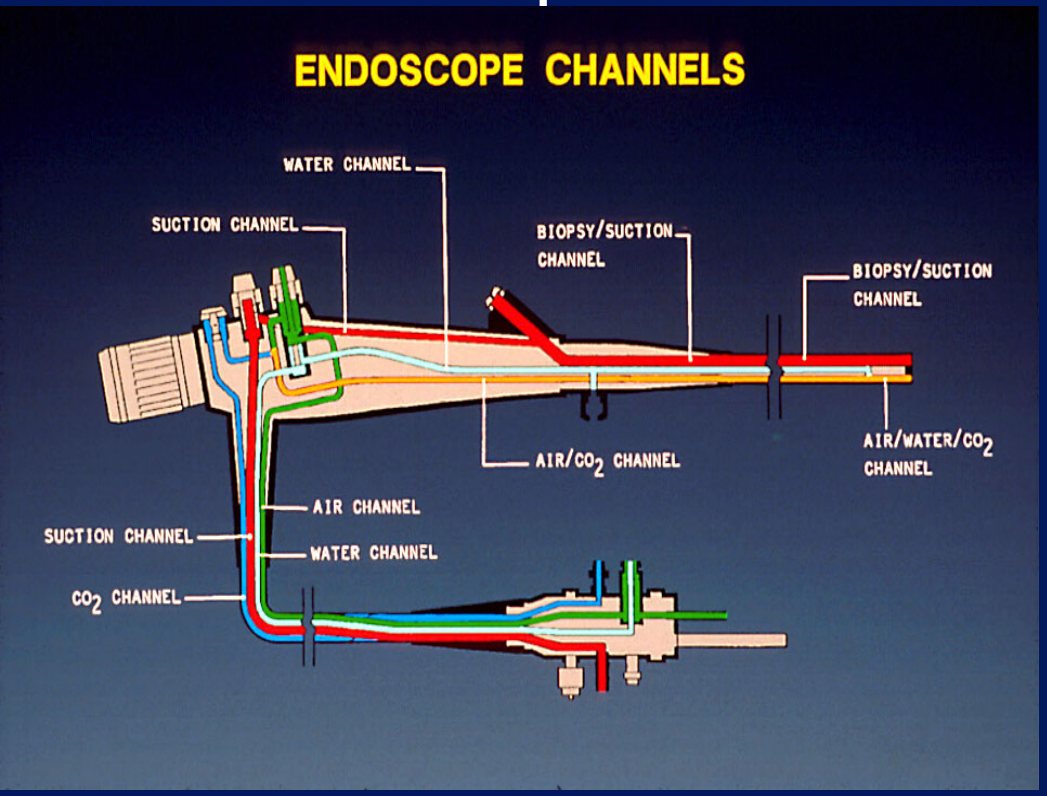
Future Approaches to Endoscope Reprocessing to Improve Patient Safety

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

Endoscope Reprocessing

Microbial Load/Complex Instruments



New Guidelines

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

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

Cleaning, Disinfection and High-Level Disinfection in Healthcare Facilities

- Endoscopes-greatest risk of infection
  - Risk of infection associated with critical, semicritical and noncritical
  - High-level disinfection
  - Why we need to transition form HLD to sterilization
- Surface disinfection
  - *Role of the environment in disease transmission*
  - Why we need a bundle approach in surface disinfection
  - Discuss “no touch” room decontamination and continuous room decontamination
  - Emerging pathogens- *Candida auris*, CRE-carbapenem-resistant *Enterobacteriales*

Our Responsibility to the Future

Institute Practices that Prevent All Infectious Disease Transmission via Environment

Environmental Contamination Leads to HAIs

Weber, Kanamori, Rutala. Curr Op Infect Dis .2016.29:424-431

Evidence environment contributes

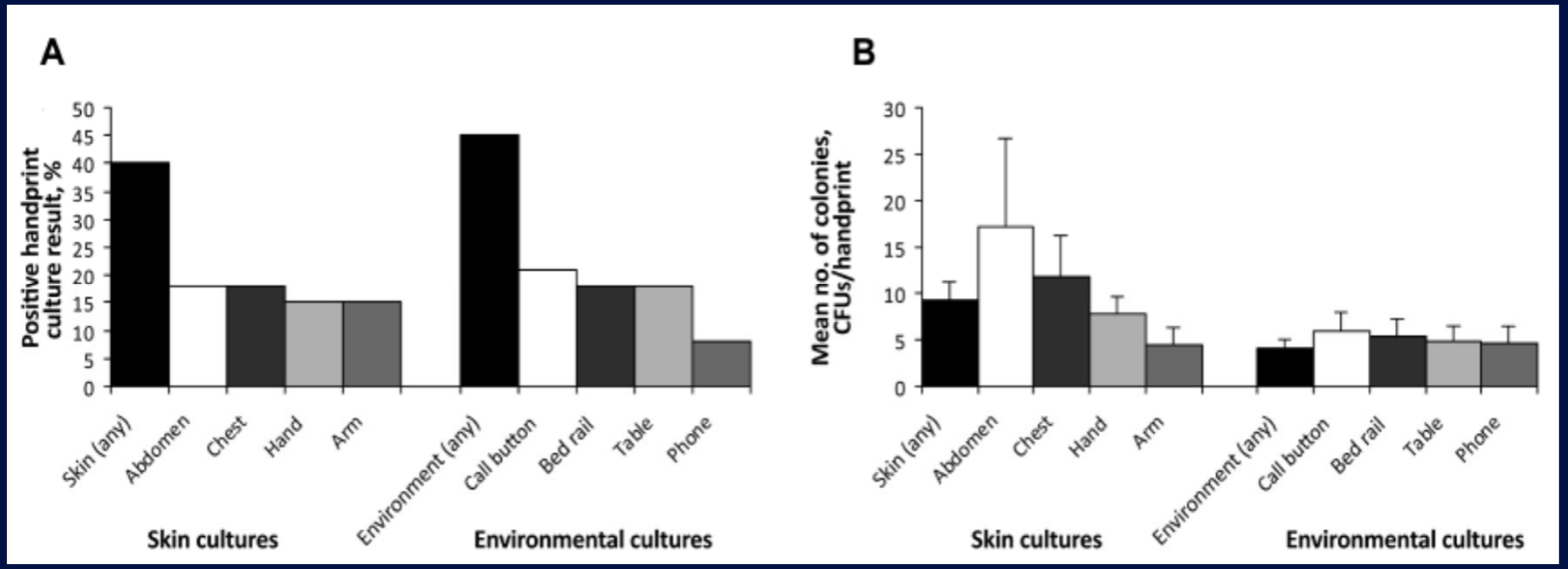
- Role-MRSA, VRE, *C. difficile*
- Surfaces are contaminated-~25%
- EIP survive days, weeks, months
- Contact with surfaces results in hand contamination
- Disinfection reduces contamination
- Disinfection (daily) reduces HAIs
- Rooms not adequately cleaned

Acquisition of EIP on Hands of Healthcare Providers after Contact with Contaminated Environmental Sites and Transfer to Other Patients

Acquisition of EIP on Hands of Patient after Contact with Contaminated Environmental Sites and Transfers EIP to Eyes/Nose/Mouth

FREQUENCY OF ACQUISITION OF MRSA ON GLOVED HANDS AFTER CONTACT WITH SKIN AND ENVIRONMENTAL SITES

No significant difference on contamination rates of gloved hands after contact with skin or environmental surfaces (40% vs 45%; p=0.59)



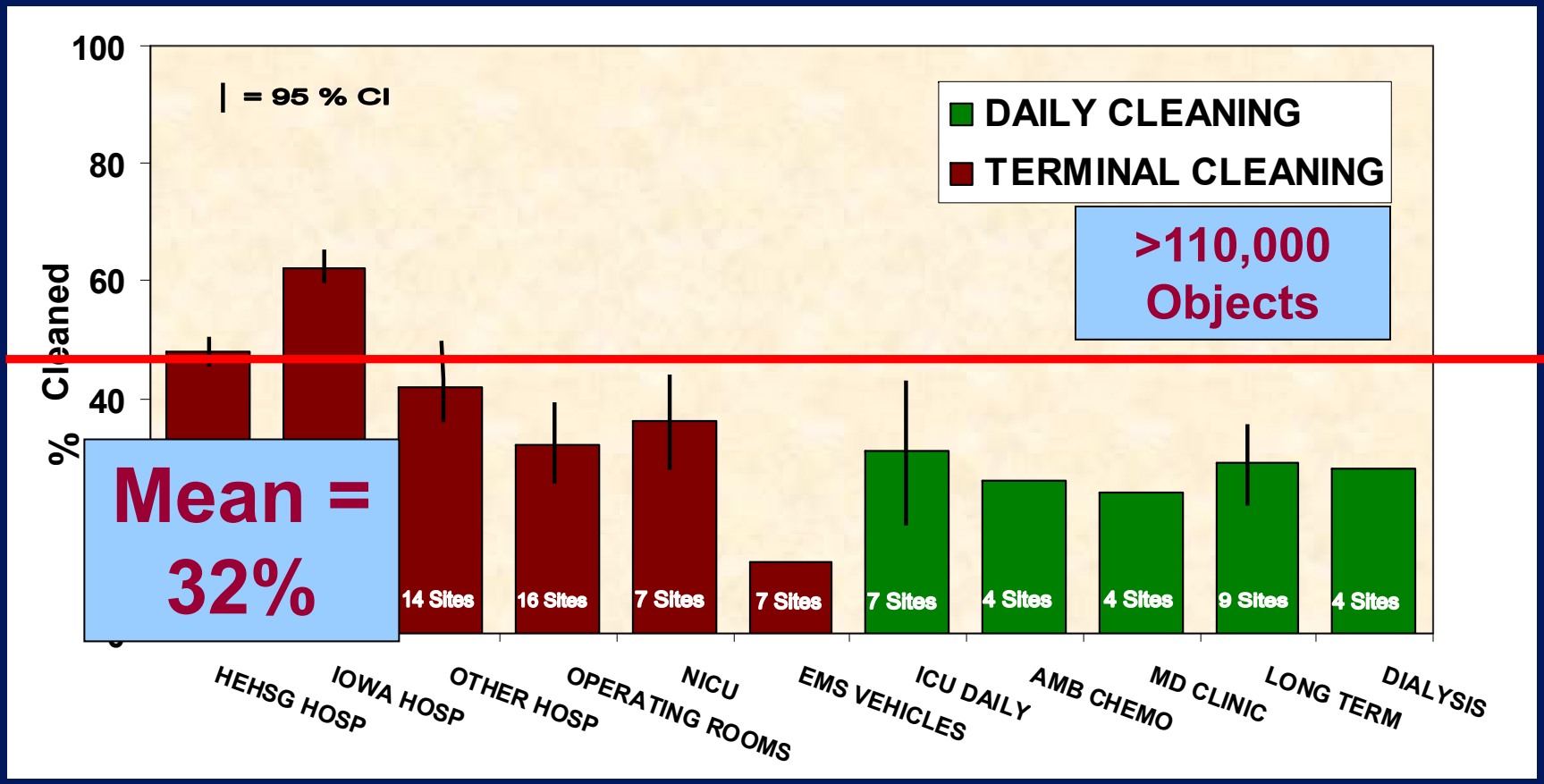
Stiefel U, et al. ICHE 2011;32:185-187

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

Thoroughness of Environmental Cleaning

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



Disinfection of Noncritical Surfaces Bundle

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

- 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

Disinfection of Noncritical Surfaces Bundle

Rutala, Weber AJIC 2019;47:A96-A105

- Develop policies and procedures
  - Standardize C/D patient rooms and pieces of equipment throughout the hospital
  - All touchable hand contact surfaces wiped with disinfection daily, when spills occur and when the surfaces are visibly soiled.
  - All noncritical medical devices should be disinfected daily and when soiled
  - Clean and disinfectant sink and toilet
  - Damp mop floor with disinfectant-detergent
  - If disinfectant prepared on-site, document correct concentration
  - Address treatment time/contact time for wipes and liquid disinfectants (e.g., treatment time for wipes is the kill time and includes a wet time via wiping as well as the undisturbed time).

Effective Surface Decontamination

Product and Practice = Perfection

LOW-LEVEL DISINFECTION FOR NONCRITICAL EQUIPMENT AND SURFACES

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

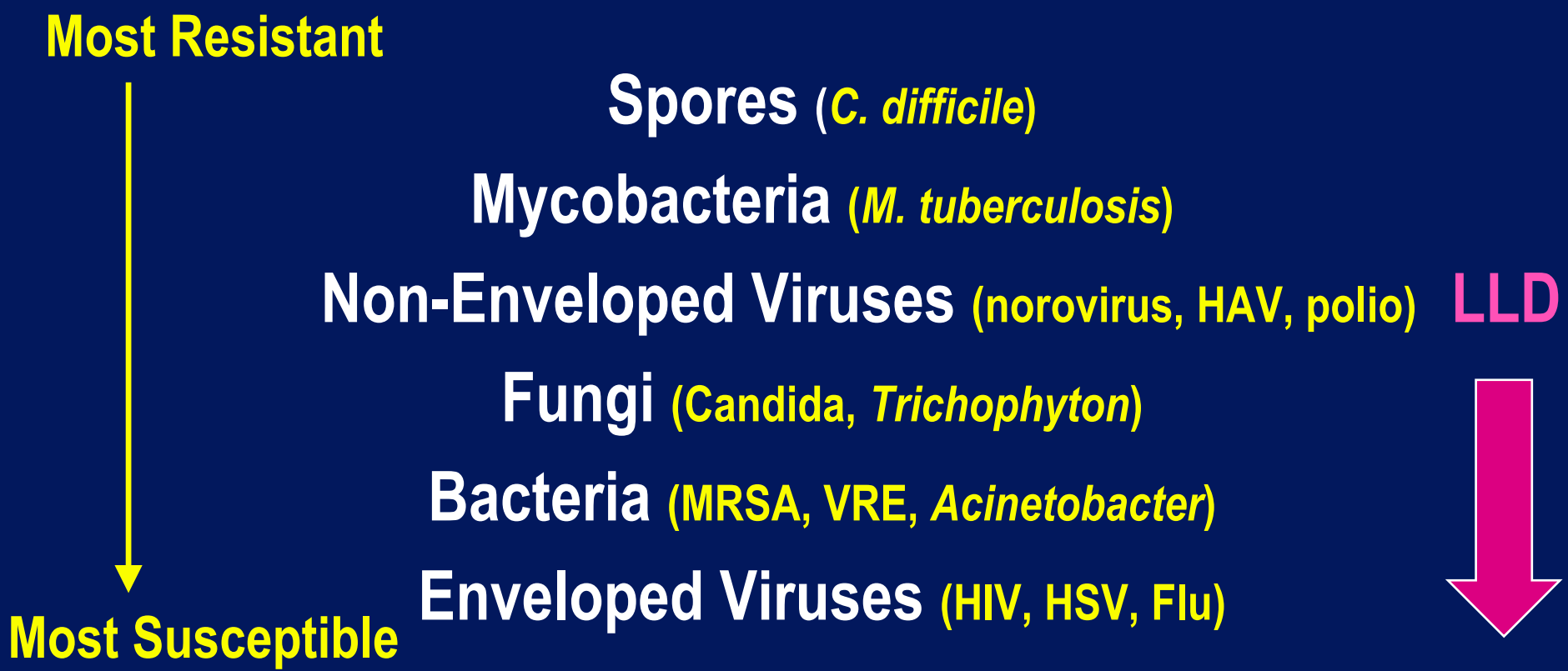
Exposure time ≥ 1 min

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

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

Microbiological Disinfectant Hierarchy

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



It appears that not only is disinfectant use important but how often is important

Daily disinfection vs clean when soiled

Daily Disinfection of High-Touch Surfaces

Kundrapu et al. ICHE 2012;33:1039

Daily disinfection of high-touch surfaces (vs cleaned when soiled) with sporicidal disinfectant (PA) in rooms of patients with CDI and MRSA **reduced acquisition of pathogens on hands after contact with surfaces and of hands caring for the patient**

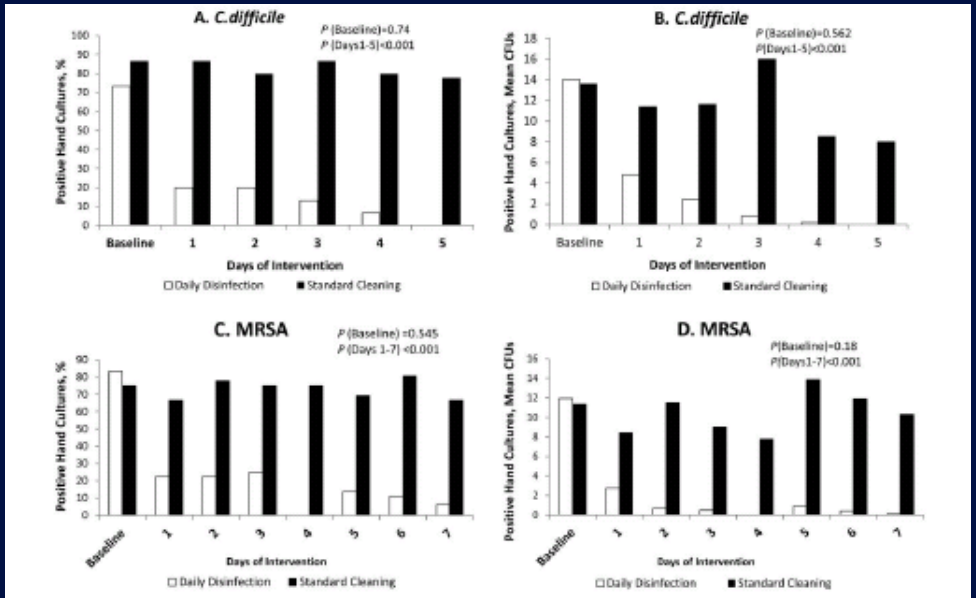


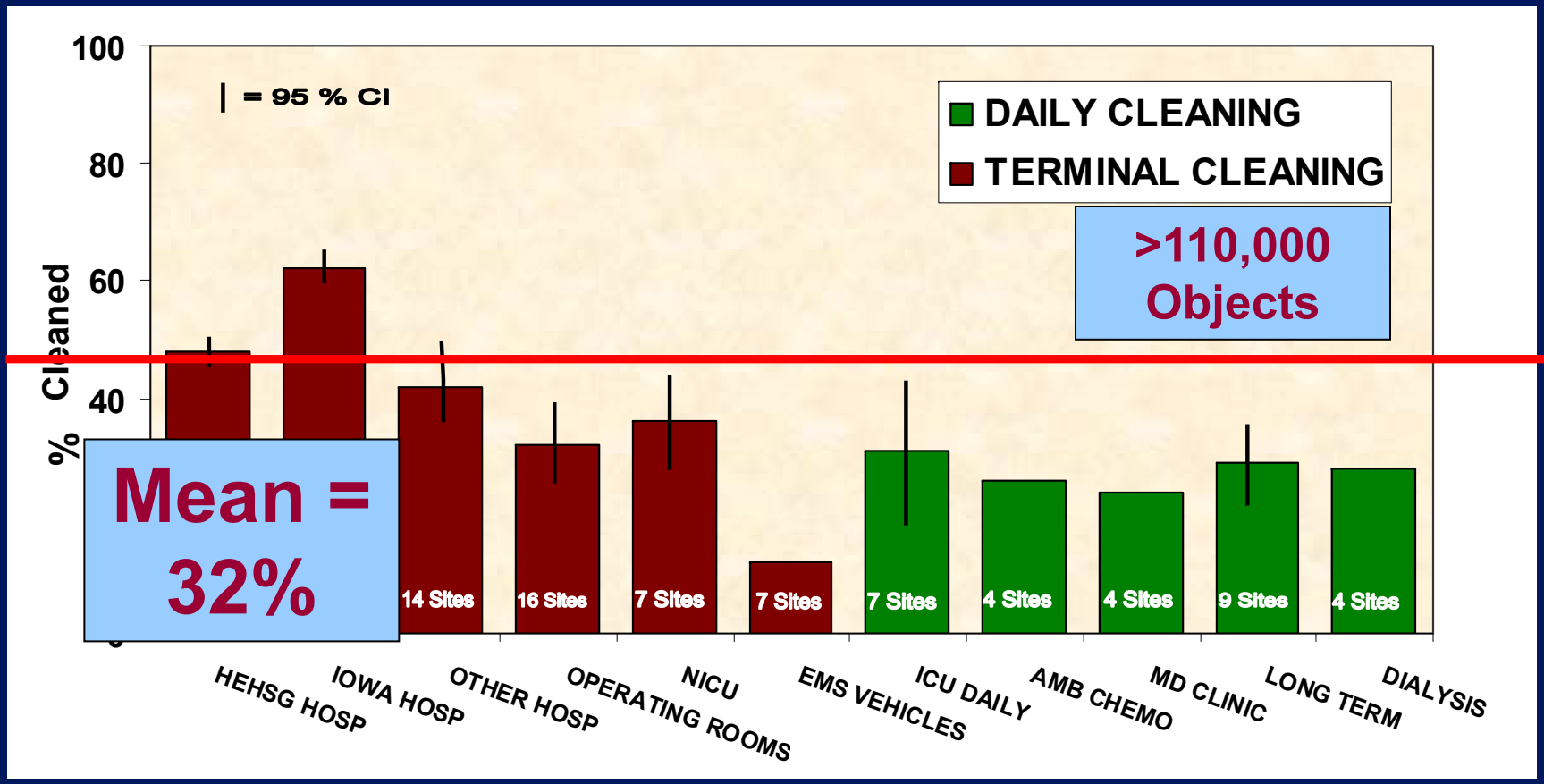
FIGURE 1. Effect of daily disinfection of high-touch environmental surfaces on acquisition of *Clostridium difficile* and methicillin-resistant *Staphylococcus aureus* (MRSA) on gloved hands of investigators after contact with the surfaces. *A*, Percentage of positive *C. difficile* cultures; *B*, mean number of *C. difficile* colony-forming units acquired; *C*, percentage of positive MRSA cultures; *D*, mean number of MRSA colony-forming units acquired.

Effective Surface Decontamination

Product and Practice = Perfection

Thoroughness of Environmental Cleaning

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



ALL “TOUCHABLE” (HAND CONTACT) SURFACES SHOULD BE WIPED WITH DISINFECTANT

“High touch” objects only recently defined (no significant differences in microbial contamination of different surfaces) and “high risk” objects not epidemiologically defined.

Microbiologic Assessment of High, Medium and Low Touch Surfaces

Huslage, Rutala, Gergen, Weber. ICHE 2013; 34:211

No correlation between touch frequency and microbial contamination

Surface	Before Cleaning Mean CFU/Rodac	After Cleaning Mean CFU/Rodac	Significance
High	71.9 (CI 46.5-97.3)	9.6	High=Low
Medium	44.2 (CI 28.1-60.2)	9.3	Medium=Low
Low	56.7 (CI 34.2-79.2)	5.7	

Disinfection of Noncritical Surfaces Bundle

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

- 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

MONITORING THE EFFECTIVENESS OF CLEANING

Cooper et al. AJIC 2007;35:338

- Visual assessment-not a reliable indicator of surface cleanliness
- ATP bioluminescence-measures organic debris (each unit has own reading scale, <250-500 RLU)
- Microbiological methods-<2.5CFUs/cm^2-pass; can be costly and pathogen specific
- Fluorescent marker-transparent, easily cleaned, environmentally stable marking solution that fluoresces when exposed to an ultraviolet light (applied by IP unbeknown to EVS, after EVS cleaning, markings are reassessed)

Fluorescent Marker

TARGET ENHANCED

Disinfection of Noncritical Surfaces Bundle

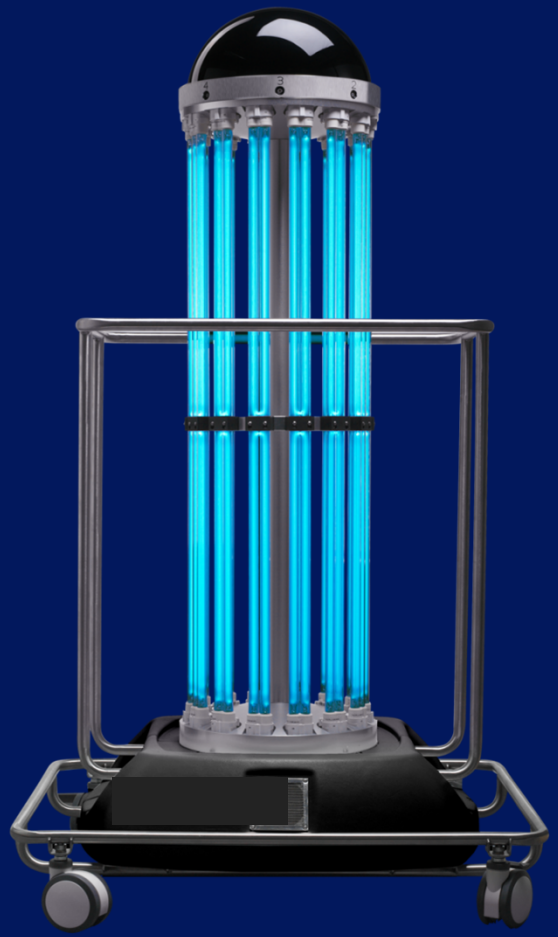
NL Havill AJIC 2013;41:S26-30; Rutala, Weber AJIC 2019;47:A96-A105

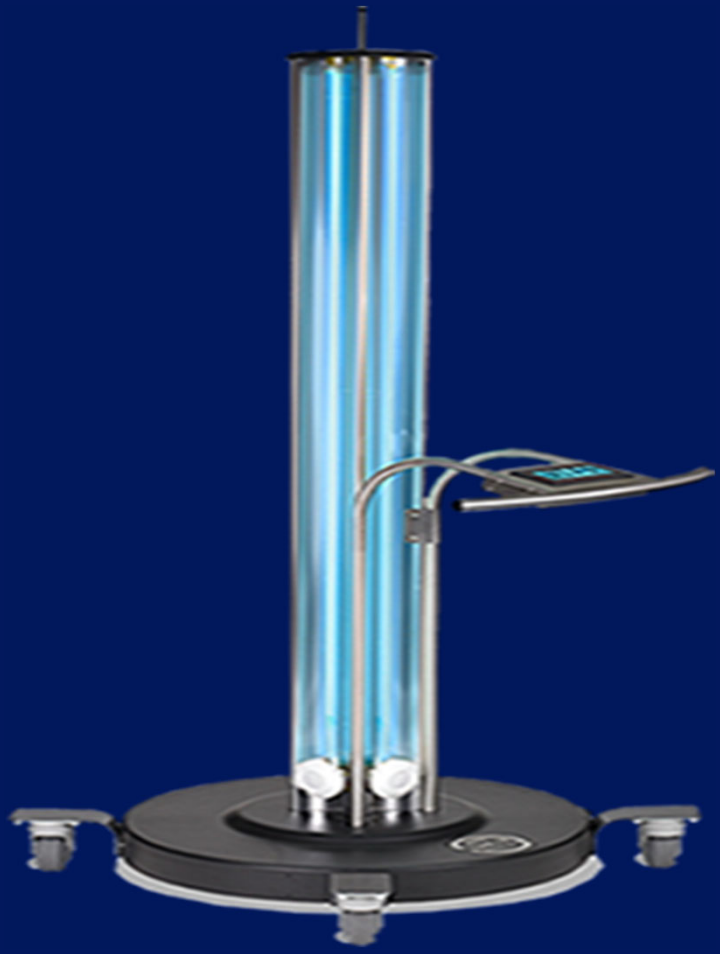
- Develop policies and procedures
- Select cleaning and disinfecting products
- Educate staff to environmental services and nursing
- Monitor compliance (thoroughness of cleaning, product use) and feedback
- Implement “no touch” room decontamination technology and monitor compliance

"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.





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

No Touch

(supplements but do not replace surface cleaning/disinfection)

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

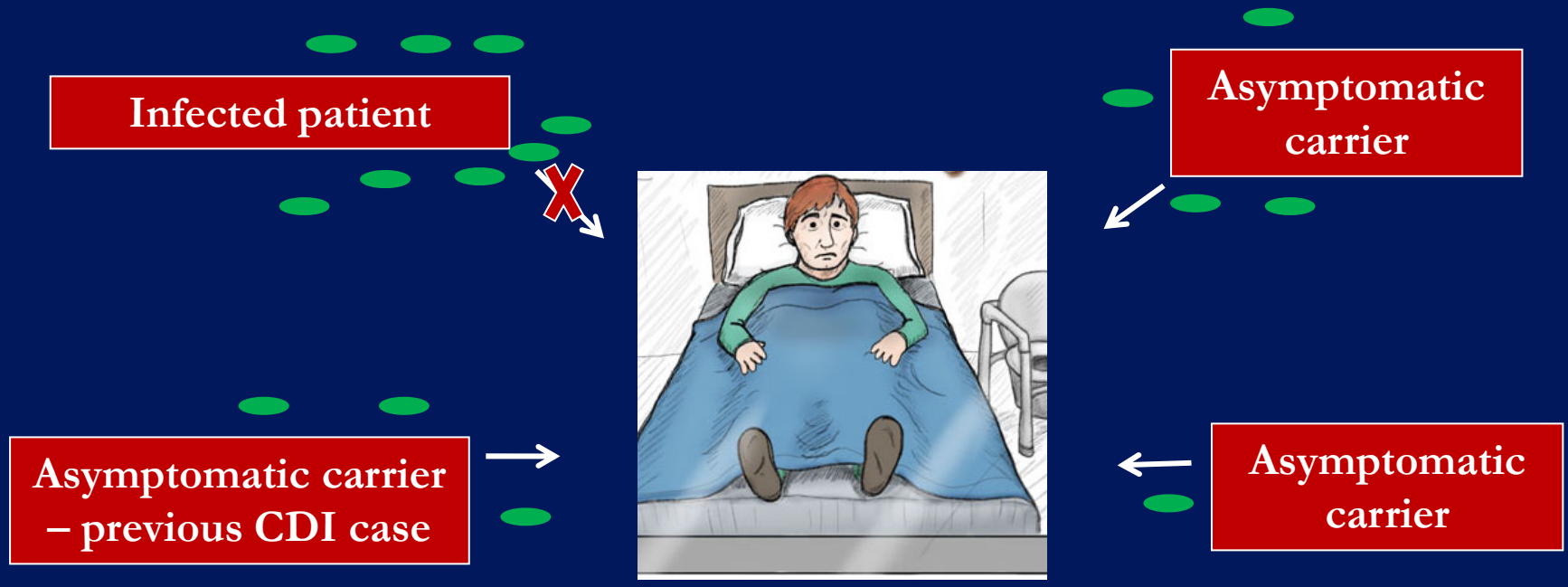
Anderson et al. Lancet 2017;289:805; Rutala et al. ICHE 2018

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

All enhanced disinfection technologies were significantly superior to Quat alone in reducing EIPs. Comparing the best strategy with the worst strategy (i.e., Quat vs Quat/UV) revealed that a reduction of 94% in EIP (60.8 vs 3.4) led to a 35% decrease in colonization/infection (2.3% vs 1.5%). Our data demonstrated that a decrease in room contamination was associated with a decrease in patient colonization/infection. First study which quantitatively described the entire pathway whereby improved disinfection decreases microbial contamination which in-turn reduced patient colonization/infection.

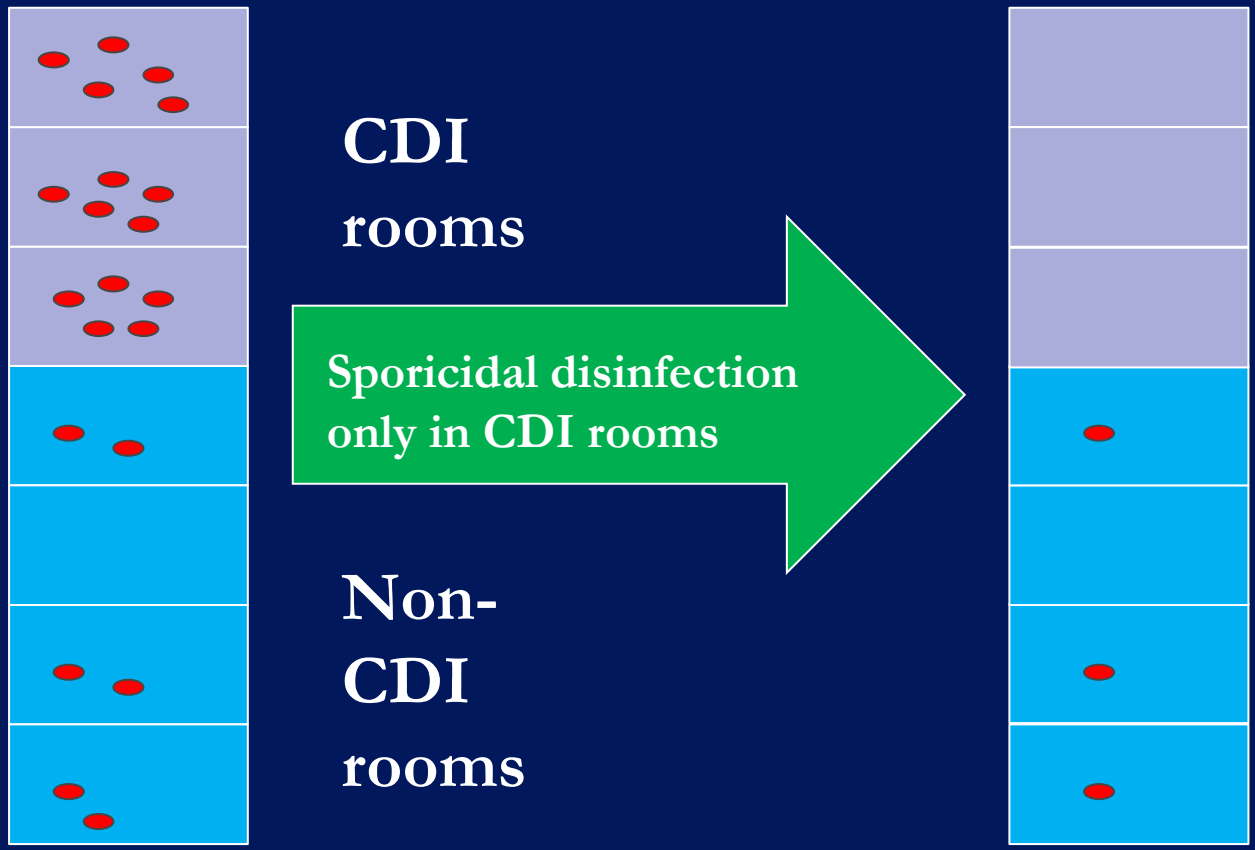
This technology ("no touch"-microbicidal and ideally, HAI reduction per peer-reviewed literature) should be used (capital equipment budget) for terminal room disinfection (e.g., after discharge of patients on Contact Precautions).

Asymptomatic carriers contribute to *C. difficile* transmission



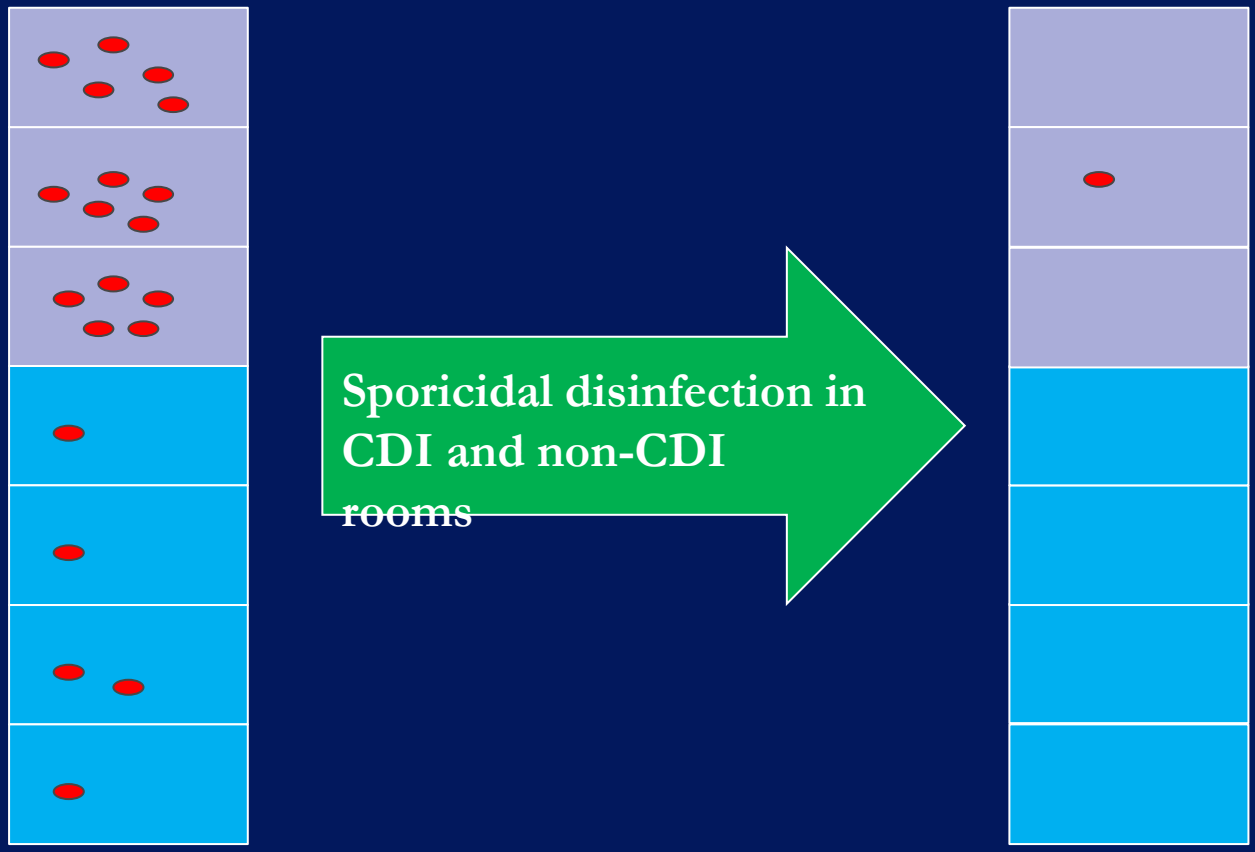
1. Curry SR. Clin Infect Dis 2013 (29% of hospital-associated CDI cases linked to carriers by MLVA); 2. Blixt T. Gastroenterol 2017;152:1031 (exposure to carriers increased CDI risk); 3. Longtin Y. JAMA Int Med 2016 (screening for and isolating carriers reduced CDI by 63%); 4. Samore MH. Am J Med 1996;100:32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

Interventions focused on CDI rooms



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

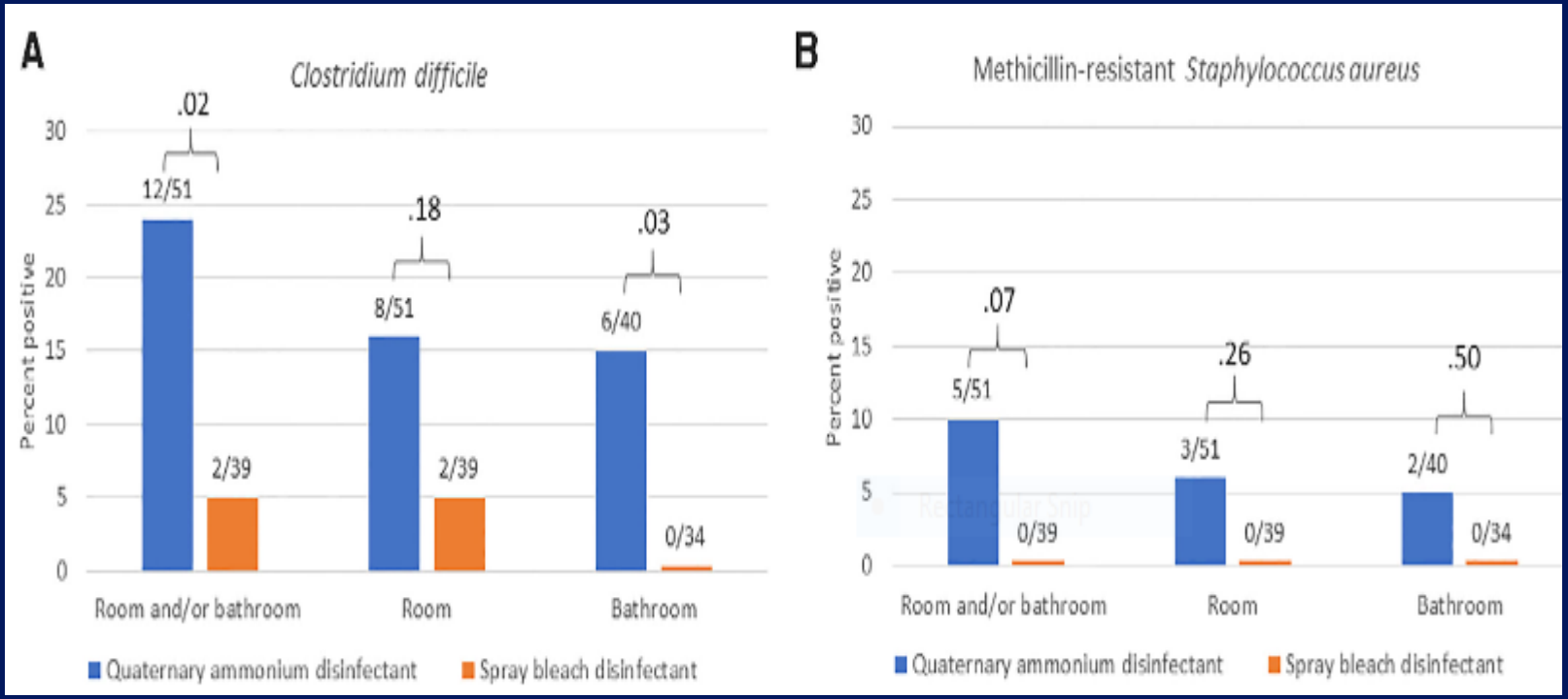
Interventions addressing CDI cases and asymptomatic carriers



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

Wong et al. AJIC, In press

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



To reduce microbial contamination

Continuous Room Decontamination Technology

Continuous Room Decontamination Technologies for Disinfection of the Healthcare Environment

- Visible light disinfection through LEDs
- Low concentration hydrogen peroxide
- Self-disinfecting surfaces
- **Continuously active disinfectant (CAD) or persistent disinfectant that provides continuous disinfection action**
  - Allows continued disinfection (may eliminate the problem of recontamination)
  - Patients, staff and visitors can remain in the room

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

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

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 a Continuously Active Surface Disinfectant

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

4-5 log_{10} reduction in 5min over 24hr for most pathogens; ~99% reduction with *Klebsiella* and CR *Enterobacter*.

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)
CR *E.coli*	3.0 (2.6, 3.4)
CR *Enterobacter*	2.0 (1.6, 2.4)
CR *K pneumoniae*	2.1 (1.8, 2.4)

***Test surface glass unless otherwise specified**

AMERICAN SOCIETY FOR MICROBIOLOGY | Antimicrobial Agents and Chemotherapy®

EXPERIMENTAL THERAPEUTICS

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

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

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

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

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

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

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

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

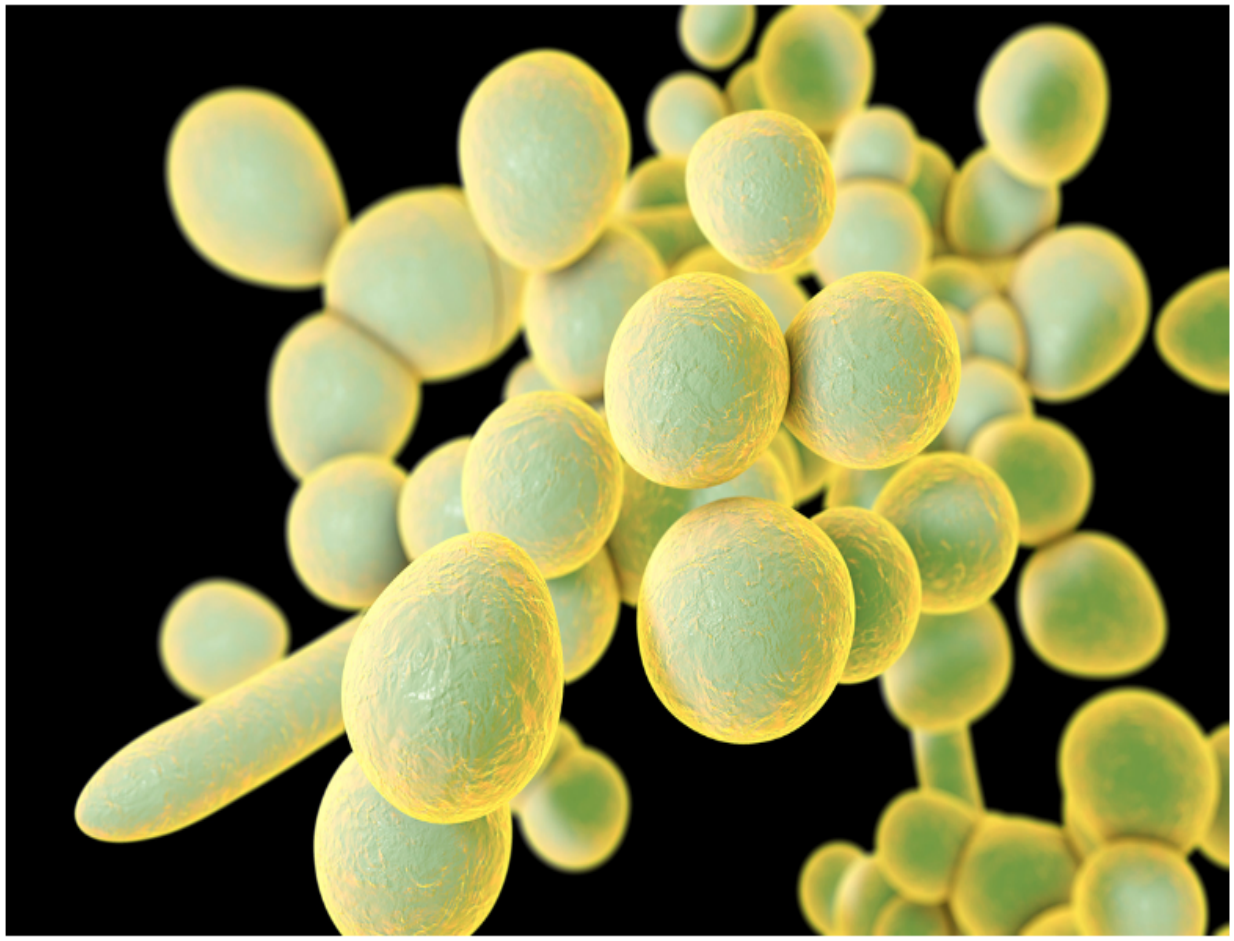
- ≥3 $\log_{10}$ reduction (CRE, 1m, 5% FCS, QCT)
  - **0.20% peracetic acid**
  - **2.4% glutaraldehyde**
  - **0.5% Quat, 55% isopropyl alcohol**
  - **58% ethanol, 0.1% QUAT**
  - **28.7% isopropyl alcohol, 27.3% ethyl alcohol, 0.61% QAC**
  - **0.07% o-phenylphenol, 0.06% p-tertiary amylphenol**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

Candida auris

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

- *Candida auris* is a globally emerging pathogen that is often resistant to multiple antifungal agents
- In several reports, *C. auris* has been recovered from the hospital environment
- CDC has recommended daily and post-discharge disinfection of surfaces in rooms of patients with *C. auris* infection.
- Many hospital disinfectants are registered for use specifically against *C. auris* (Quats only not effective)

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

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

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

Cleaning, Disinfection and High-Level Disinfection in Healthcare Facilities

- Endoscopes-greatest risk of infection
  - Risk of infection associated with critica, semicritical and noncritical
  - High-level disinfection
  - Why we need to transition form HLD to sterilization
- Surface disinfection
  - *Role of the environment in disease transmission*
  - Why we need a bundle approach in surface disinfection
  - Discuss “no touch” room decontamination and continuous room decontamination
  - Emerging pathogens- *Candida auris*, CRE-carbapenem-resistant *Enterobacteriales*

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

- New D/S technologies (sterilization of endoscopes) and practices (e.g., monitoring cleaning) could reduce risk of infection associated with devices and surfaces.
- Endoscope represent a nosocomial hazard. Urgent need to understand the gaps in endoscope reprocessing. Reprocessing guidelines must be followed to prevent exposure to pathogens that may lead to infection. Endoscopes have no margin of safety and transition to sterilization should be encouraged.
- The contaminated surface environment in hospital rooms is important in the transmission of healthcare-associated pathogens (MRSA, VRE, *C. difficile*, *Acinetobacter*). Thoroughness of cleaning should be monitored (e.g., fluorescence).
- In general, emerging pathogens are susceptible to currently available disinfectants and technologies (UV).

THANK YOU!

www.disinfectionandsterilization.org