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# Disinfection and Sterilization: What New?

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# DISCLOSURES

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- Consultation
  - ASP (Advanced Sterilization Products), PDI
- Honoraria
  - PDI
- Grants
  - CDC, CMS

# Learning Objective

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- Describe two new recommendations/ practices/ technologies associated with HLD and sterilization (endoscope reprocessing, new BIs)
- Identify at least one new change related to reprocessing critical or semicritical items (HPV, duodenoscopes)
- Describe at least two technologies/research that will the environment as a source of pathogens (inactivation of CRE and *C. auris*, monitoring cleaning)

# Disinfection and Sterilization: What's New

[www.disinfectionandsterilization.org](http://www.disinfectionandsterilization.org)

- Current Issues and New Technologies
  - Sterilization of critical items
    - ◆ Biological indicators, modified Spaulding, extended claims
  - High-level disinfection for semi-critical items
    - ◆ Endoscope reprocessing issues (duodenoscopes), HPV risks/studies
  - Low-level disinfection of non-critical items
    - ◆ Over-dilution; monitoring cleaning, floors, “no touch” technology, continuous room decontamination
  - D/S and Emerging Pathogens
    - ◆ Inactivation data- *Candida auris*, CRE-carbapenem-resistant *Enterobacteriaceae*

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# Medical/Surgical Devices

WA Rutala, DJ Weber, and HICPAC, [www.cdc.gov](http://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

# Sterilization of “Critical Objects”

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Steam sterilization

Hydrogen peroxide gas plasma

Ethylene oxide

Ozone and hydrogen peroxide

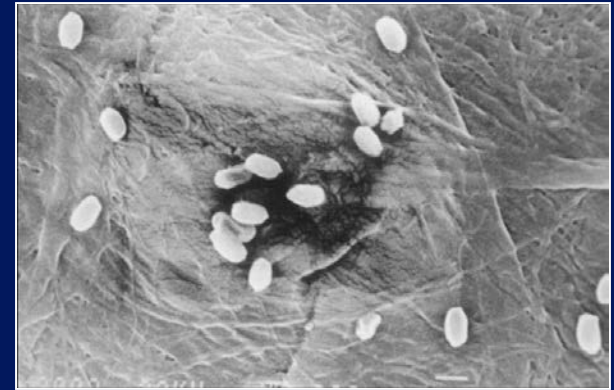
Vaporized hydrogen peroxide

Steam formaldehyde

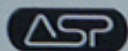


# Biological Indicators

- Select BIs that contain spores of *B. atrophaeus* or *Geobacillus sterothermophilus*
- Rationale: BIs are the only sterilization process monitoring device that **provides a direct measure of the lethality of the process**



*Bacillus atrophaeus*



STERRAD® 50

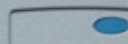


1. READ THE MANUAL  
BEFORE USING THIS UNIT



FOR  
EXPERIMENTAL NON-HUMAN  
USE ONLY

NOT AVAILABLE IN THE  
UNITED STATES



# ASP Submits 510(k) Application for 30m Sterrad Biological Indicator



# ASP Submits 510(k) Application for 30m Sterrad Biological Indicator



# ASP Submits 510(k) Application for 30m Sterrad Biological Indicator (BI)



- | Pending clearance, it will be the fastest HP BI on the market
- | BI are used to test and confirm sterilization cycle performance and provide sterility assurance.
- | Use with recently-cleared Sterrad100NX, NX with ALLClear Technology, as well as existing Sterrad NX, 100NX, and 100S Systems sterilizers

# SHEA Prion Guideline

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

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

SHEA GUIDELINE

## Guideline for Disinfection and Sterilization of Prion-Contaminated Medical Instruments

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

### EPIDEMIOLOGY OF THE CREUTZFELDT-JAKOB DISEASE PRION

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

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

### TRANSMISSION OF CJD VIA MEDICAL DEVICES

# Transmissible Spongiform Encephalopathies (TSEs) of Humans

- Kuru-now eradicated
- Gertsmann-Straussler-Scheinker (GSS)-1/40M
- Fatal Familial Insomnia (FFI)-<1/40M
- Creutzfeldt-Jakob Disease (CJD)-1/1M
- Variant CJD (vCJD), (221 cases, August 2011)  
Acquired from cattle with BSE. 1995: 172 UK, 25 France, 4 Ireland, 2 Italy, 3 USA, 2 Canada, 1 Saudi Arabia, 1 Japan, 3 Netherlands, 2 Portugal, 5 Spain, 1 Taiwan

# Epidemiology of CJD in the US

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

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



# Prion Diseases

- Etiology
  - Prions (proteinaceous infectious agent)
    - ◆ No agent-specific nucleic acid
    - ◆ Host protein (PrP<sup>c</sup>) converts to pathologic isoform (PrP<sup>sc</sup>); PrP gene resides on chromosome 20
    - ◆ The function of the normal prion protein is unknown
    - ◆ Mutation in this gene may trigger transformation
    - ◆ Accumulates in neural cells, disrupts function
    - ◆ Resistant to conventional D/S procedures

# Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants

Most Resistant

Prions

Spores (*C. difficile*)

Mycobacteria

Non-Enveloped Viruses (*norovirus, adeno*)

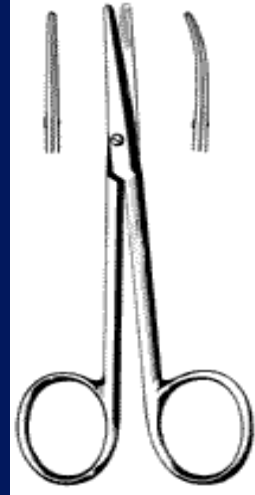
Fungi

Bacteria (*MRSA, VRE, Acinetobacter*)

Enveloped Viruses

Most Susceptible





**CJD : potential for secondary spread through contaminated surgical instruments (2 cases)**

# CJD: Disinfection and Sterilization

## Conclusions

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

- Critical/Semicritical-devices contaminated with high-risk tissue from high-risk patients requires special prion reprocessing
  - 134°C for 18m (prevacuum)
  - 132°C for 60m (gravity)
  - NaOH and steam sterilization (e.g., 1N NaOH 1h, then 121°C 1h)
- Discard instruments that are impossible to clean
- No low temperature sterilization technology currently recommended\*
- Noncritical-four disinfectants (e.g., chlorine, Environ LpH) effective (4 log decrease in LD<sub>50</sub> within 1h)

\*VHP and HP gas plasma (Sterrad NX) reduced prion infectivity but not cleared by FDA

# A New Practical Diagnostic Test for Creutzfeldt-Jakob Disease

Brown, Farrell. ICHE. 2015;36:849

- 14-3-3 protein in spinal fluid has proved to be an invaluable diagnostic aid for 2 decades but recognized as “marker protein” not causally related to CJD
- Two published independent studies of a newly modified prion protein amplification test named RT-QuIC (real-time quaking-induced conversion)
- Two studies yielded high sensitivity (85-96%) and specificity (99-100%)
- Tests results are available within 24 hours of specimen collection

# 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.<sup>1</sup> 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.<sup>1</sup>

In this issue of *JAMA*, Epstein and colleagues<sup>2</sup> report findings from their investigation of a cluster of New Delhi metallo- $\beta$ -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-

First, endoscopes are semicritical devices, which contact mucous membranes or nonintact skin, and require at least high-level disinfection.<sup>3,4</sup> 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.<sup>3</sup> 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.<sup>3,5</sup> However, until now,



Related article page 1447

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FDA Panel, May 2015, Recommended  
Sterilization of Duodenoscopes  
(requires FDA-cleared sterilization technology  
that achieves a SAL  $10^{-6}$  with duodenoscopes-  
not yet available)

# Disinfection and Sterilization

WA Rutala, DJ Weber, and HICPAC, [www.cdc.gov](http://www.cdc.gov)

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

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

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



# 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 modification**).

**CRITICAL** - objects which **directly or 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).

# How Will We Prevent Infections Associated with Medical Devices (HLD to Sterilization)?

- FDA Panel has accepted sterilization for duodenoscopes
- Sterilization manufacturer's are optimizing their LTST to sterilize GI endoscopes/bronchoscopes
- Sterile, single use GI endoscopes are developed
- Professional organizations (SHEA, APIC, AORN, SGNA, ASGE, IAHCSMM, AAMI) are starting to embrace conversion. Scheduled presentations on transition from HLD to sterilization with AAMI Sterilization/HLD Committees, APIC, SGNA, Canadian APIC, World Sterilization Congress
- Researchers/Opinion Leaders need to continue the science-based evaluations on why conversion is necessary

# Ozone and Hydrogen Peroxide

- Sterizone VP4, 510(k) FDA clearance, TSO<sub>3</sub> Canada
- Sterilizer has a 4.4ft<sup>3</sup> chamber
- Low temperature (41°C); uses VHP and ozone in multiple phases
- Can sterilize multi-channeled flexible endoscopes (max 4) having internal lumens  $\geq 1.45$  mm in inner diameter and  $\leq 3,500$  mm and  $\geq 1.2$  mm in inner diameter and  $\leq 1,955$  mm in overall length (commonly found in video colonoscopies and gastroscopes)
- Advantages/Disadvantages-limited information in peer-review literature

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# Semicritical Medical Devices

Rutala et al. AJIC 2016;44:e47



- Semicritical
  - Transmission: direct contact
  - Control measure: high-level disinfection
  - Endoscopes top ECRI list of 10 technology hazards, **>100 outbreaks** (GI, bronchoscopes)
    - 0 margin of safety
      - Microbial load,  $10^7$ - $10^{10}$
      - Complexity
      - Biofilm
  - Other semicritical devices, **rare outbreaks**
    - ENT scopes, endocavitary probes (prostate, vaginal, TEE), laryngoscopes, cystoscopes
    - Reduced microbial load, less complex

# High-Level Disinfection of “Semicritical Objects”

Exposure Time  $\geq$  8m-45m (US), 20°C

Germicide	Concentration
Glutaraldehyde	$\geq$ 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

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# Goal

Prevent All Infectious Disease Transmission Associated  
with Medical/Surgical Devices in 5 years (2021)

Endoscopes, HPV





# GI ENDOSCOPES

- Widely used diagnostic and therapeutic procedure (~20 million GI procedures annually in the US; ~500,000 ERCPs/year)
- GI endoscope contamination during use ( $10^{7-10}$  in/ $10^5$  out)
- Semicritical items require high-level disinfection minimally
- Inappropriate cleaning and disinfection has lead to cross-transmission
- Although the incidence of post-procedure infection remains very low, endoscopes represent a significant risk of disease transmission. In fact, more outbreaks of infection associated with endoscopes than any reusable medical device in healthcare.

# 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	<i>Pa, H. pylori, Salmonella</i>	169	56	Cleaning/Disinfection (C/D)
Sigmoid/Colonoscopy	5	<i>Salmonella, HCV</i>	14	6	Cleaning/Disinfection
ERCP	23	<i>P. aeruginosa (Pa)</i>	152	89	C/D, water bottle, AER
Bronchoscopy	51	<i>Pa, Mtb, Mycobacteria</i>	778	98	C/D, AER, water
Totals	98		1113	249	

Based on outbreak data, if eliminated deficiencies associated with cleaning, disinfection, AER , contaminated water and drying would eliminate about 85% of the outbreaks.

# Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fail Patients

Minority Staff Report, January 13, 2016, Patty Murray, Ranking Member

- In January 2015, after several outbreaks of serious infections, Senator Murray initiated an investigation to determine the extent of duodenoscope-linked infections
- Between 2012 and spring 2015, closed-channel duodenoscopes were linked to at least 25 different incidents of antibiotic-resistant infections that sickened at least 250 patients worldwide
- None of the manufacturers of the “closed-channel” duodenoscopes had sufficient data to show that duodenoscopes could be cleaned reliably between uses

# RECENT ENDOSCOPY-RELATED OUTBREAKS OF MRDO WITHOUT REPROCESSING BREACHES

Rutala WA et al. Manuscript in preparation

Outbreak Date and place	Manufacturer	No. Patients (infected)	MDRO	Positive Scope(s)	Molecular Link	Reference
<i>K. pneumoniae</i> UCLA Medical Center 2014-2015	Olympus 180 (per MDR)	15(8)	Yes <i>K. pneumoniae</i>	No	Yes-OPCR	Kim S, 2016
<i>E.coli (AmpC)</i> VM 2012-2014	<i>Olympus</i> <i>180, 160</i>	35	Yes <i>E.coli (AmpC)</i>	Yes (3)	Yes – PCR, PFGE	Wendorf KA, 2015
<i>K. pneumoniae</i> Berlin, Germany Dec 2012-2013	Olympus 180	12	Yes <i>K. pneumoniae</i>	No	Yes – PCR, PFGE	Kola A, 2015
<i>K. pneumoniae</i> UPMC 2011-2013	Olympus 180	34?	Yes <i>K. pneumoniae</i>	Yes (3)	Yes – PCR, PFGE, MLST, WGS	Marsh J, 2015
<i>E.coli</i> CDC, NE Illinois Jan-Dec 2013	Pentax	39	Yes <i>E.coli</i>	Yes (1)	Yes – PCR, PFGE	Epstein L, 2015
<i>P. aeruginosa</i> Eramus Jan-Apr 2012	Olympus 180	22	Yes <i>P. aeruginosa</i>	Yes (1)	Yes – PCR, PFGE, repetitive- sequence-based PCR typing	Verfaillie C, 2015
<i>E.coli</i> Wisconsin May-Nov 2013	Olympus 180 (per MDR)	3(3)	Yes <i>E.coli</i>	No	Unknown	Smith Z, 2015
<i>K. pneumoniae</i> France 2009	No Scope info	13	Yes <i>K. pneumoniae</i>	Yes (2)	Yes – PCR, PFGE, MLST	Carbonne A, 2010

# ENDOSCOPE REPROCESSING

CDC 2008: Multi-Society Guideline on Endoscope Reprocessing, 2017

- **PRECLEAN**-point-of-use (bedside) remove debris by wiping exterior and aspiration of detergent through air/water and biopsy channels; leak test
- **CLEAN**-mechanically cleaned with water and enzymatic cleaner
- **HLD/STERILIZE**-immerse scope and perfuse HLD/sterilant through all channels for exposure time (>2% glut at 20m at 20°C). If AER used, review model-specific reprocessing protocols from both the endoscope and AER manufacturer
- **RINSE**-scope and channels rinsed with sterile water, filtered water, or tap water. Flush channels with alcohol and dry
- **DRY**-use forced air to dry insertion tube and channels
- **STORE**-hang in vertical position to facilitate drying; stored in a manner to protect from contamination

# MULTISOCIETY GUIDELINE ON REPROCESSING GI ENDOSCOPES, 2017

Petersen et al. Gastro Endoscopy. In press

ARTICLE IN PRESS

GIE<sup>®</sup>

SPECIAL ARTICLE



## Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update

Prepared by: REPROCESSING GUIDELINE TASK FORCE

Bret T. Petersen, MD, FASGE, Chair, Jonathan Cohen, MD, FASGE, Ralph David Hambrick, III, RN, Navtej Buttar, MD, David A. Greenwald, MD, FASGE, Jonathan M. Buscaglia, MD, FASGE, James Collins, RN, Glenn Eisen, MD, MPH, FASGE

This article was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy (ASGE).

# 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**
- **Biofilms-unclear if contribute to failure of endoscope reprocessing**

## ENDOSCOPE REPROCESSING: CHALLENGES

### NDM-Producing *E. coli* Associated ERCP

MMWR 2014;62:1051; Epstein et al. JAMA 2014;312:1447-1455

NDM-producing *E.coli* recovered from elevator channel (elevator channel orients catheters, guide wires and accessories into the endoscope visual field; **crevices difficult to access with cleaning brush and may impede effective reprocessing**)

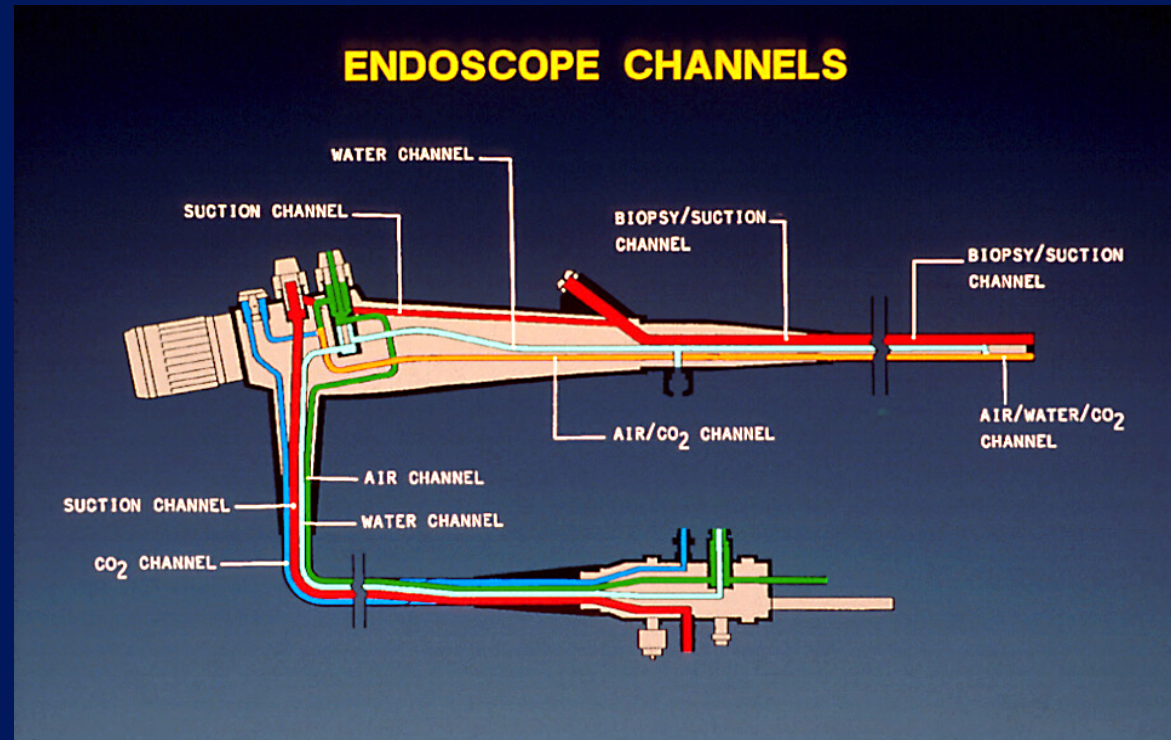




# FEATURES OF ENDOSCOPES THAT PREDISPOSE TO DISINFECTION FAILURES

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,  $10^{7-10}$
- | Cleaning (2-6  $\log_{10}$  reduction) and HLD (4-6  $\log_{10}$  reduction) essential for patient safe instrument



# High-Level Disinfection No Margin of Safety

0 margin of safety

Microbial contamination  $10^7$ - $10^{10}$ : compliant with reprocessing guidelines 10,000 microbes after reprocessing:  
maximum contamination, minimal cleaning ( $10^2$ )/HLD ( $10^4$ )

What does this off-road driver/vehicle have in common with endoscope? 10 billion particles, complex



# Microbial Surveillance of GI Endoscopes

Saliou et al. Endoscopy. 2016

Characteristics of Sample	Action Level (TCU>100/scope) or EIP
Gastroscope	26.6%
Colonoscope	33.7%
Duodenoscope	34.7%
Echo-endoscope	31.9%
AER	27.2%
Manual	39.3%
Age of endoscope <2 years	18.9%
Age of endoscope >2 years	38.8%

# Visual Inspections of Colonoscopes and Gastrosopes

Ofstead et al. Am J Infect Control. 2017. 45:e26-e33

- All endoscopes (n=20) had visible irregularities (e.g., scratches)
- Researchers observed fluid (95%), discoloration, and debris in channels
- Preventive maintenance?

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# What Should We Do Now?

Interim Response to ERCP Outbreaks

# How Can We Prevent ERCP-Related Infections?

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

- No single, simple and proven technology or prevention strategy that hospitals can use to guarantee patient safety
- Of course, must continue to emphasize the enforcement of evidenced-based practices, including equipment maintenance and routine audits with at least yearly competency testing of reprocessing staff
- Must do more or additional outbreaks will continue

# Current Enhanced Methods for Reprocessing Duodenoscopes

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

Hospitals performing ERCPs should do one of the following (priority ranked); **doing nothing is not an option:**

- 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



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# Long-Term Response To ERCP Outbreaks

# Some Potential Sterilization Technologies for Duodenoscopes

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

- Optimize existing low-temperature sterilization technology
  - Hydrogen peroxide gas plasma
  - Vaporized hydrogen peroxide
  - Ethylene oxide
  - Ozone plus hydrogen peroxide vapor
- Potential new low-temperature sterilization technology
  - Nitrogen dioxide
  - Supercritical CO<sub>2</sub>
  - Peracetic acid vapor
- Steam sterilization for heat-resistant GI endoscopes
- Redesign
- Sterile, single-use GI scopes

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

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

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

VS

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

# LTS Technology Is Being Optimized to Sterilize Endoscopes and Use a Sterile, Disposable GI Scopes

(disposable scope must have acceptable diagnostic and therapeutic capabilities)



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# True Cost of Reprocessing Endoscope

Ofstead et al. Communique. Jan/Feb 2017

\$114.07-\$280.71



# Human Papillomavirus Contamination of Gynecologic Equipment

Gallay et al. Sex Transm Infect. 2016. 92:19-23

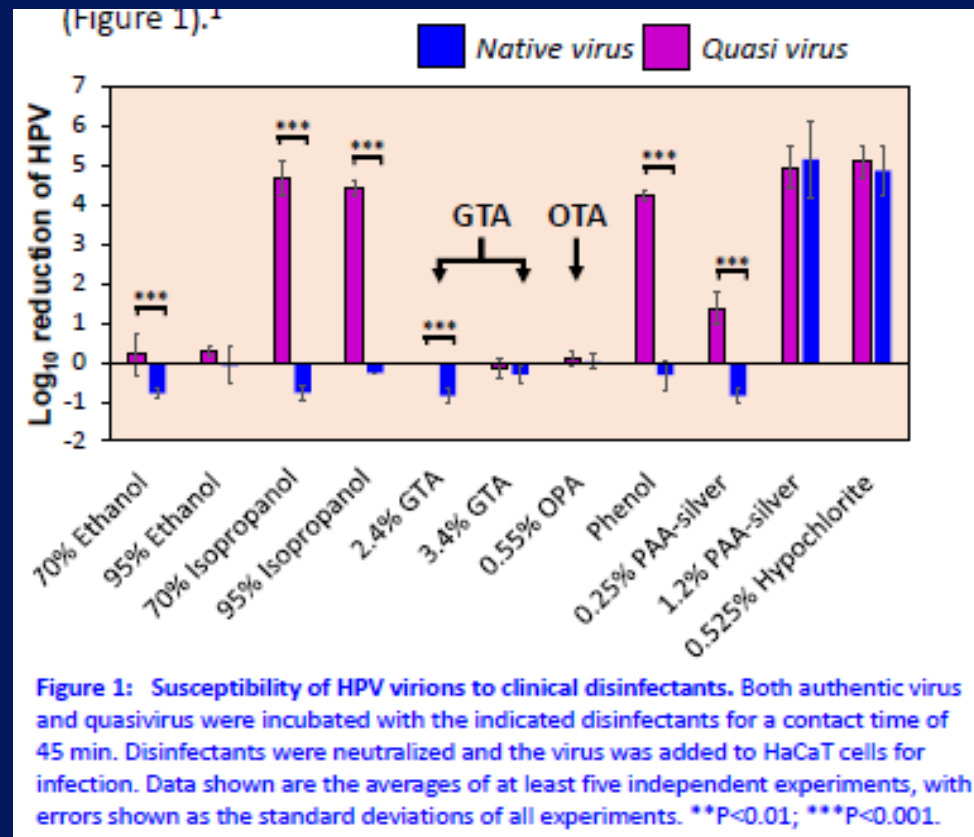
- Assess presence of HPV on equipment used in GYN practice
- Samples from fomites (glove box, lamp on GYN chair, gel tubes, colposcope, speculum) in 2 hospitals and 4 private practices
- Samples analyzed by real-time PCR
- 32 (18%) HPV-positive samples found
- Higher risk of HPV contamination in GYN private practices
- Colposcope had the highest risk of contamination
- Equipment and surfaces contaminated, need strategies to prevent contamination and transmission

# ENDOSCOPE/ENDOCAVITARY PROBES 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 no effect on HPV
- Finding inconsistent with other small, non-enveloped viruses such as polio, rhino, echo
- 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)





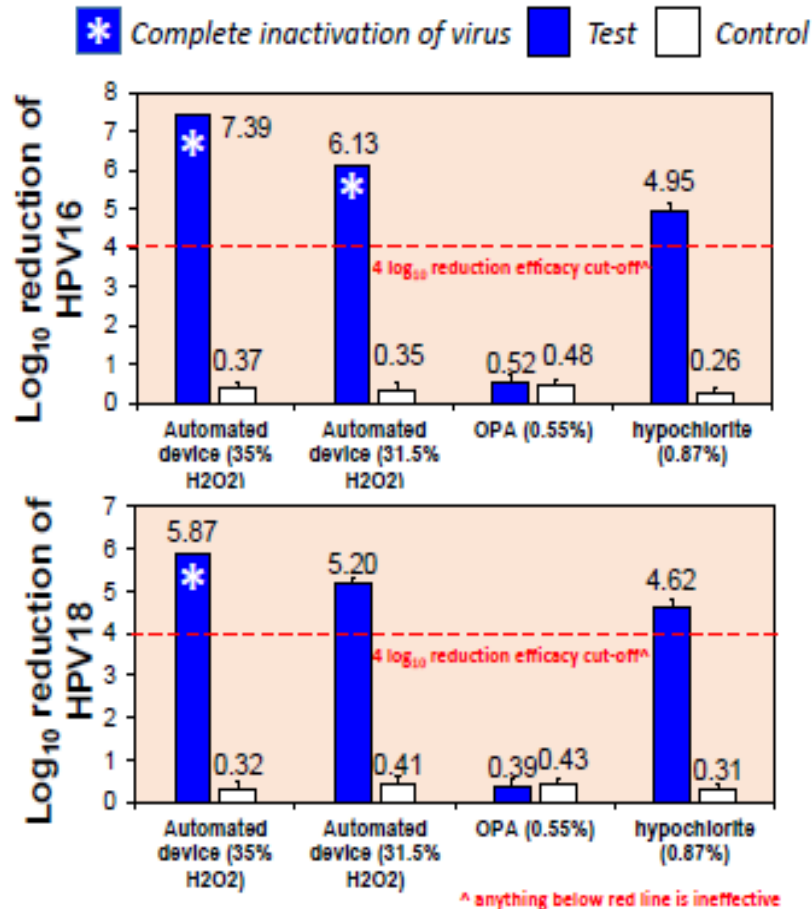
# Hydrogen Peroxide Mist

(uses HP mist to achieve HLD in 7m)



# Efficacy of HP Mist Against HPV

Meyers C et al. SHEA Poster, 2015



- HLD widely used to reprocess semicritical items including endocavitary probes
- Tested OPA, hypochlorite and HP mist
- HP mist system and hypochlorite >4 log<sub>10</sub> reduction, OPA achieved <1 log<sub>10</sub> reduction

# Effectiveness of HP Mist System in Inactivating Healthcare Pathogens on Probes

Rutala, Gergen, Sickbert-Bennett. ICHE 2016;37:613-614

TABLE 1. Proportion of Surface and Endocavitary Probes Positive After of an Organic Challenge\*

System Processing According to the Presence or Absence

	Probes with vancomycin-Resistant <i>Enterococcus</i> (VRE), No./Total	Probes with CR <i>Klebsiella pneumoniae</i> , No./Total	Probes with <i>Mycobacterium terrae</i> , No./Total (mean log <sub>10</sub> reduction and 95% CI)	Probes with <i>Clostridium difficile</i> spores, No./Total (mean log <sub>10</sub> reductions and 95% CI)
5% Fetal Calf Serum-FCS Present	0/7	0/6	4/9 (5.19 [4.61–5.76])	3/6 (5.12 [4.42–5.83])
Absent	0/6	0/6	1/6 (4.62 [4.07–5.17])	1/9 (6.23 [6.02–6.43])

- Automated, closed system that uses HP mist for HLD of ultrasound probes
- **>10<sup>6</sup> pathogens** inoculated onto probe at 2-3 sites
- **Inactivated bacteria and good but not complete kill of mycobacteria, spores**
- **Alternative to high-level disinfection by high-level disinfectants**

# Effectiveness of Germicides Against HPV

(Dr. Carey Allen Moody, UNC and Duke UMC)

- Germicides

- Aldehydes

- ◆ Glutaraldehyde
- ◆ Ortho-phthalaldehyde

- Others

- ◆ Phenolics
- ◆ Ethanol
- ◆ CHG-4%
- ◆ Quats

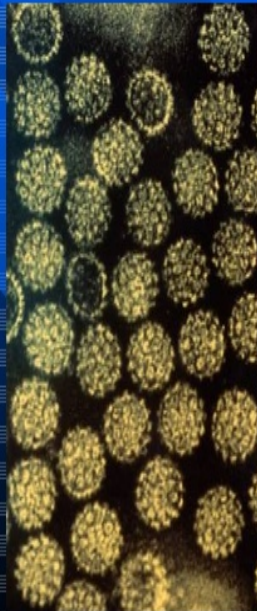
- Germicides

- Oxidizing agents

- ◆ 1.5% and 2.0% accelerated HP
- ◆ 0.525% sodium hypochlorite
- ◆ 1% HP/0.08% peracetic acid
- ◆ 0.2% peracetic acid, 55°C
- ◆ 1000-1300ppm peracetic acid

# What if HPV is Resistant to Aldehydes?

## Electron Micrograph of HPV



- If unlike all other non-enveloped viruses that are susceptible to aldehydes
- Upset the Spaulding classification scheme (HLD kill all viruses)
- If only oxidizing agents kill HPV (transition to PA or HP alone or combination)

# Noncritical Medical Devices

Rutala et al. AJIC 2016;44:e1; Rutala, Weber. Env Issues NI, Farber 1987



- Noncritical 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**

# Disinfection and Sterilization: What's New

- Current Issues and New Technologies
  - Sterilization of critical items
    - ◆ Biological indicators, modified Spaulding, extended claims
  - High-level disinfection for semi-critical items
    - ◆ Endoscope reprocessing issues (duodenoscopes), HPV risks/studies
  - Low-level disinfection of non-critical items
    - ◆ Over-dilution; monitoring cleaning, floors, “no touch” technology, continuous room decontamination
  - D/S and Emerging Pathogens
    - ◆ Inactivation data- *Candida auris*, CRE-carbapenem-resistant *Enterobacteriaceae*





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# Goal

Prevent All Infectious Disease Transmission Associated  
with Surface Environment in 5 years (2021)

# Environmental Contamination Leads to HAIs

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



- 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

# 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%)

# ACQUISITION OF MRSA ON HANDS AFTER CONTACT WITH ENVIRONMENTAL SITES



# ACQUISITION OF MRSA ON HANDS/GLOVES AFTER CONTACT WITH CONTAMINATED EQUIPMENT



# TRANSFER OF MRSA FROM PATIENT OR ENVIRONMENT TO IV DEVICE AND TRANSMISSION OF PATHOGEN



# ACQUISITION OF *C. difficile* ON PATIENT HANDS AFTER CONTACT WITH ENVIRONMENTAL SITES AND THEN INOCULATION OF MOUTH



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# Effective Surface Decontamination

Product and Practice = Perfection



# LOW-LEVEL DISINFECTION FOR NONCRITICAL EQUIPMENT AND SURFACES

Exposure time  $\geq$  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%
Peracetic acid with HP ( <i>C. difficile</i> )	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)

# Issues Related to Disinfection Protocols

Boyce et al. ICHE 2016;37:340-342

- Inappropriate over-dilution of disinfectant solutions by housekeepers or by malfunctioning automated dilutions systems may result in applying disinfectants using inappropriate solutions
  - Audit of 33 automated dispensing stations that mix concentrated disinfectant with water to yield **desired in-use QUAT conc of 800 ppm**
  - QUAT solutions dispensed were tested with test strips, **~50% of stations delivered solutions with 200-400ppm**
  - Several flaws in dispensing system

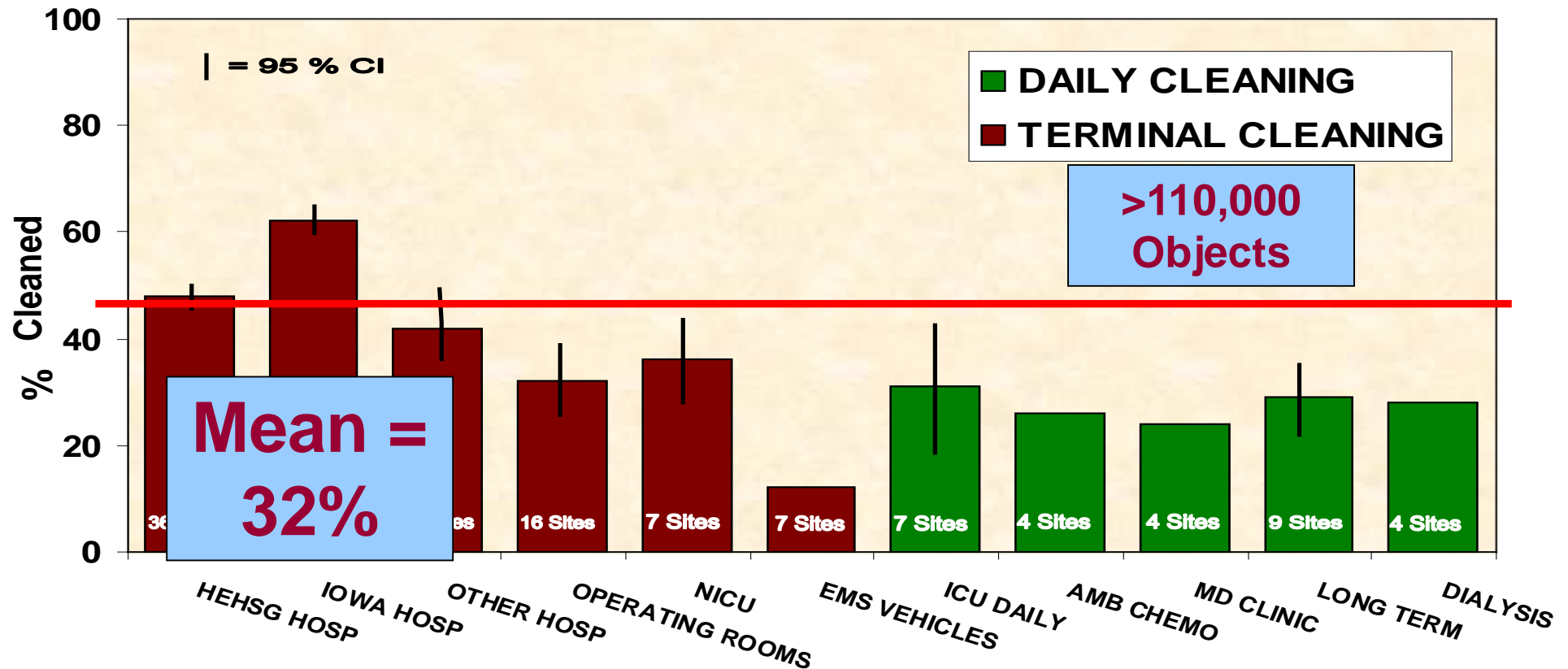
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# Effective Surface Decontamination

Product and Practice = Perfection

# Thoroughness of Environmental Cleaning

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



# 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<sup>2</sup>-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)

# DAZO Solution (AKA – Goo)

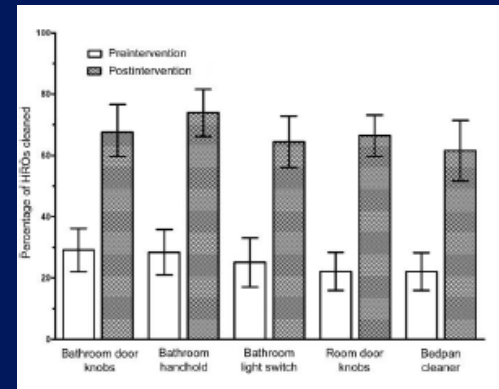
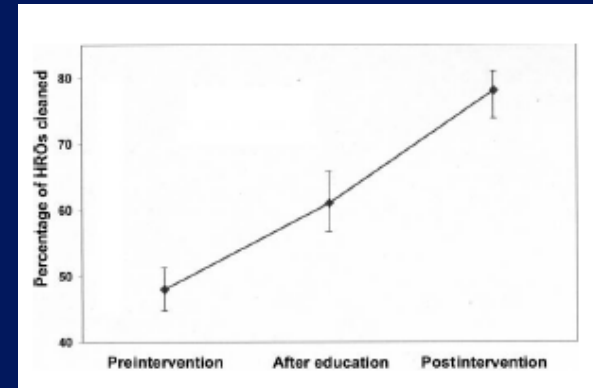


# TARGET ENHANCED



# TERMINAL ROOM CLEANING: DEMONSTRATION OF IMPROVED CLEANING

- Evaluated cleaning before and after an intervention to improve cleaning
  - 36 US acute care hospitals
  - Assessed cleaning using a fluorescent dye
  - Interventions
    - Increased education of environmental service workers
    - Feedback to environmental service workers
- †Regularly change “dotted” items to prevent targeting objects

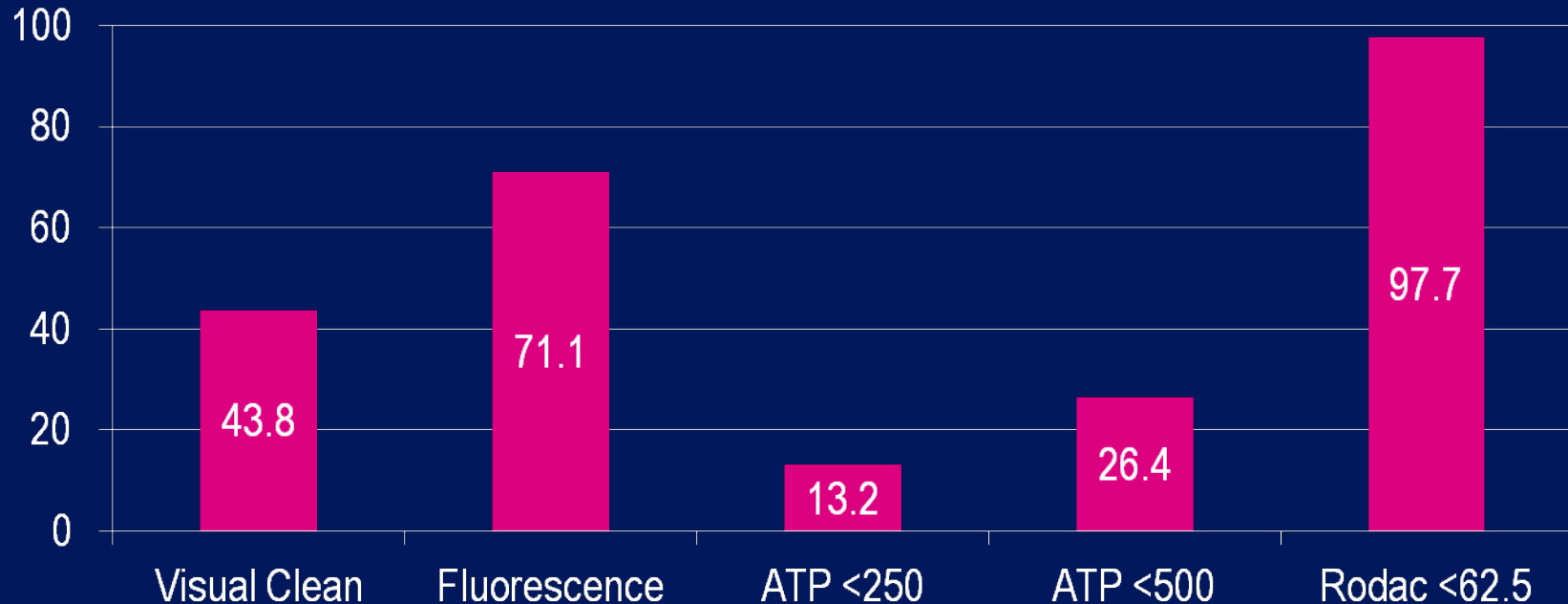




# Percentage of Surfaces Clean by Different Measurement Methods

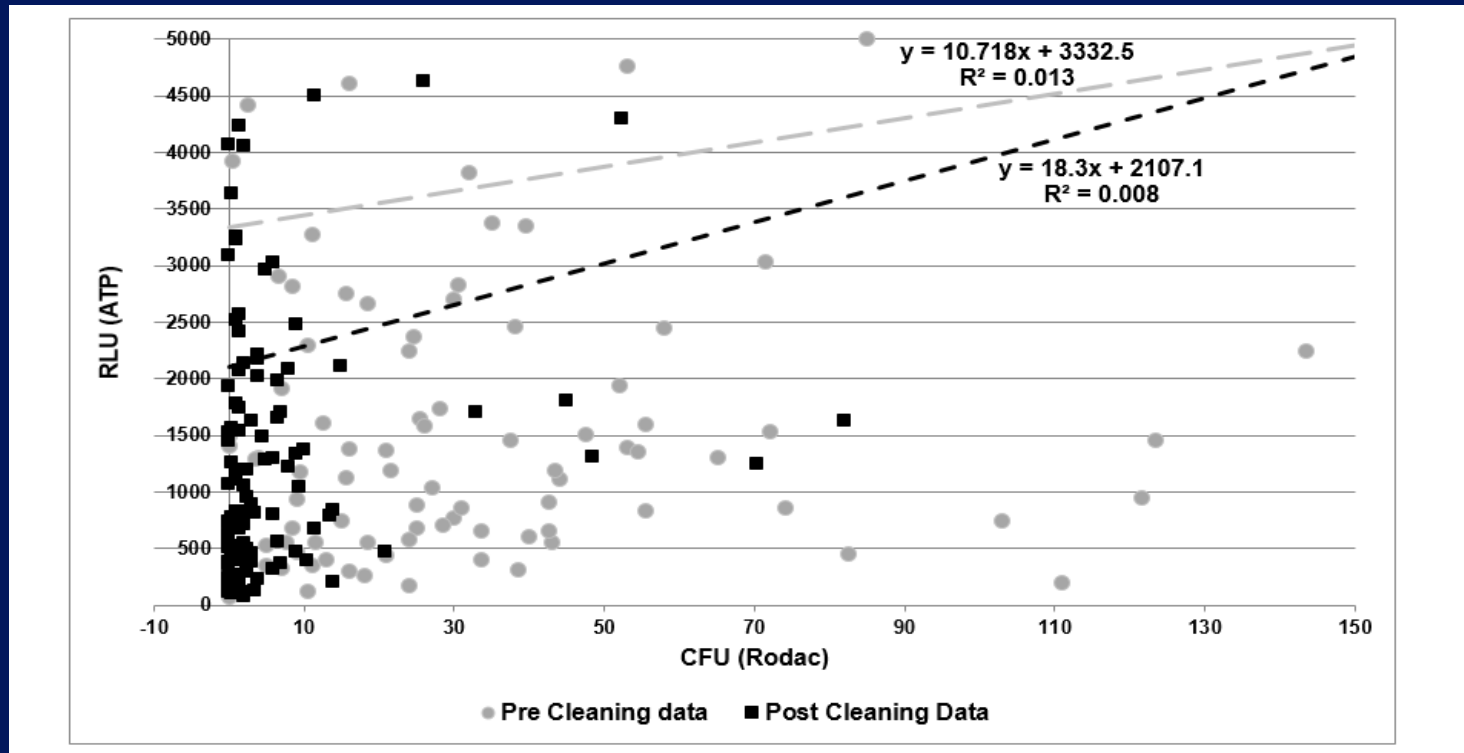
Rutala, Kanamori, Gergen, Sickbert-Bennett, Huslage, Weber. APIC 2017.

**Fluorescent marker is a useful tool in determining how thoroughly a surface is wiped and mimics the microbiological data better than ATP**



# Scatterplot of ATP Levels (less than 5000 RLU) and Standard Aerobic Counts (CFU/Rodac)

Rutala, Kanamori, Gergen, Sickbert-Bennett, Huslage, Weber. APIC 2017.



**There was no statistical correlation between ATP levels and standard aerobic plate counts.**

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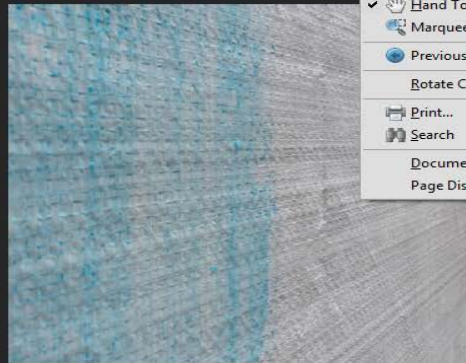
# Future Methods to Ensure Thoroughness

# Future May Have Methods to Ensure Thoroughness

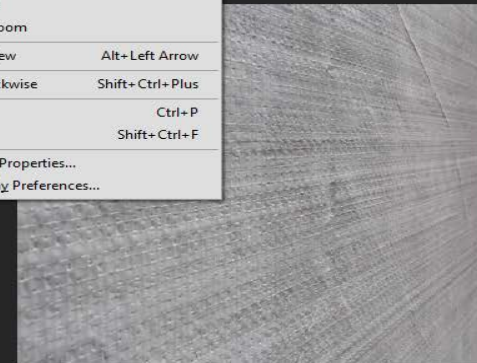
## Solution: Highlight®



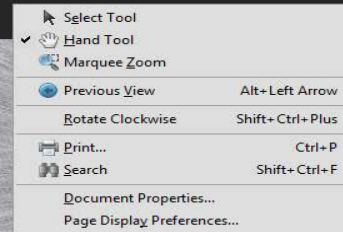
0 min



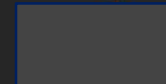
5 min



10 min



- Color-fading time can be matched to contact kill time for a disinfectant --> **enforces compliance**
- Prevents staining on permanent structures + reusable materials
- Provides **real-time feedback** when a surface is safe to touch



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# 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.

# Evaluation of Hospital Floors as a Potential Source of Pathogen Dissemination

Koganti et al. ICHE 2016. 37:1374; Deshpande et al. AJIC 2017. 45:336.

- Effective disinfection of contaminated surfaces is essential to prevent transmission of epidemiologically-important pathogens
- Efforts to improve disinfection focuses on touched surfaces
- Although floors contaminated, limited attention because not frequently touched
- Floors are a potential source of transmission because often contacted by objects that are then touched by hands (e.g., shoes, socks)
- Non-slip socks contaminated with MRSA, VRE (Mahida, J Hosp Infect. 2016;94:273)

# Evaluation of Hospital Floors as a Potential Source of Pathogen Dissemination Using a Nonpathogenic Virus

Koganti et al. ICHE 2016. 37:1374



FIGURE 1. Illustration of high-touch surfaces sampled. Star, surfaces less than or equal to 3 feet from the center of the bed; square, surfaces more than 3 feet from the center of the bed; circle, personal items.

# Recovery of Nonpathogenic Viruses from Surfaces and Patients on Days 1, 2, and 3 After Inoculation of Floor Near Bed

Koganti et al. ICHE 2016. 37:1374

Variable	Day 1 (% Positive)	Day 2 (% Positive)	Day 3 (% Positive)
Patient Hands	40	63	43
Patient Footwear	100	100	86
High-touch surface <3ft	58	62	77
High-touch surface >3ft	40	68	34
Personal items	50	44	50
Adjacent room floor	NA	100	80
Adjacent room environment	NA	40	11
Nursing station	53	47	63
Portable equipment	33	23	100

Surfaces <3ft included bedrail, call button, telephone, tray table, etc; surfaces >3ft included side table, chair, IV pole, etc; personal-cell phones, books, clothing, wheelchairs; nurses station included computer keyboard, mouse, etc



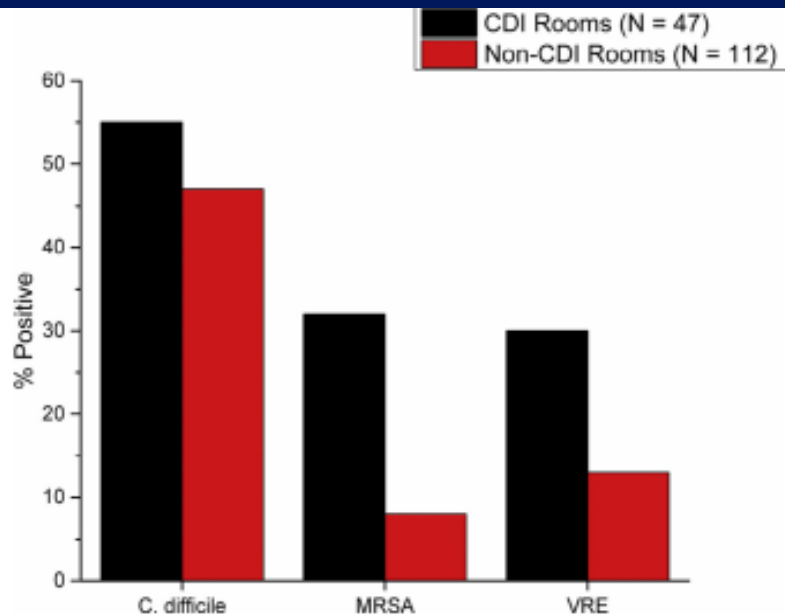
# Recovery of Nonpathogenic Viruses from Surfaces and Patients on Days 1, 2, and 3 After Inoculation of Floor Near Bed

Koganti et al. ICHE 2016. 37:1374

- Found that a nonpathogenic virus inoculated onto floors in hospital rooms disseminated rapidly to the footwear and hands of patients and to high-touch surfaces in the room
- The virus was also frequently found on high-touch surfaces in adjacent rooms and nursing stations
- Contamination in adjacent rooms in the nursing station suggest HCP contributed to dissemination after acquiring the virus during contact with surfaces or patients
- Studies needed to determine if floors are source of transmission

# Evaluation of Hospital Floors as a Potential Source of Pathogen Dissemination

Deshpande et al. AJIC 2017. 45:336.



**Fig 1.** Recovery of *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus*, and vancomycin-resistant enterococci from floors in patient rooms from 5 hospitals in northeast Ohio.

- 318 floors sites sampled in 159 rooms
- *C. difficile* most frequently isolated
- MRSA and VRE isolated more frequently from CDI rooms
- 41% (100) had objects (personal-clothing, phone charges; medical-BP cuff, call button) in contact with floor
- Of 31 objects on floor, 18% MRSA, 6% VRE, 3% Cd bare/glove cultures positive
- Demonstrates potential for indirect transfer of pathogens to hands from fomites on floor

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

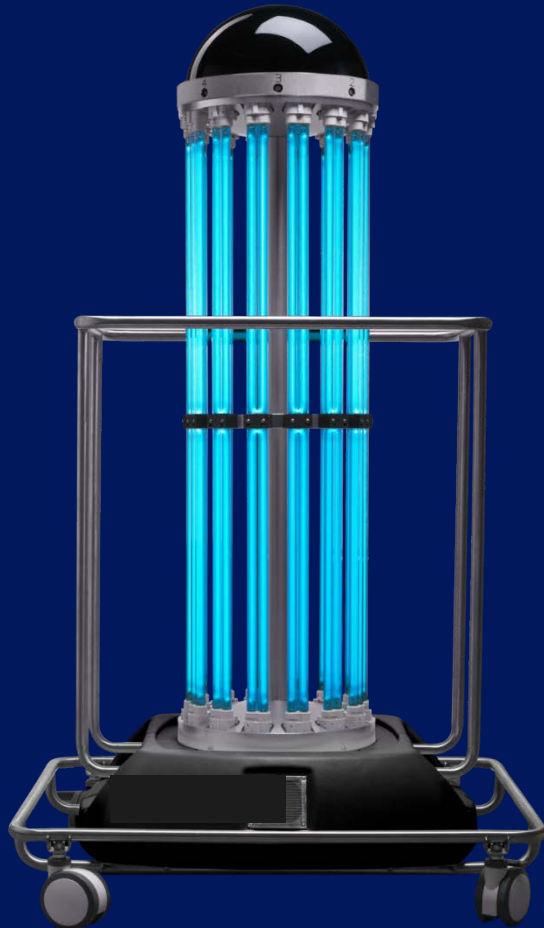
No Touch

(supplements but do not replace surface cleaning/disinfection)

# "NO TOUCH" APPROACHES TO ROOM DECONTAMINATION

(will not discuss technology with limited data)

Rutala, Weber. Infect Control Hosp Epidemiol. 2013;41:S36-S41



# EFFECTIVENESS OF UV DEVICES ON REDUCING MDROs ON CARRIERS

Author, year	UV system	MDROs	Time (min)	Energy ( $\mu\text{W}/\text{cm}^2$ )	Log <sub>10</sub> reduction direct (indirect)
Rutala, 2010 <sup>27</sup>	UV-C, Tru-D	MRSA, VRE, A	~15	12,000	4.31 (3.85), 3.90 (3.25), 4.21 (3.79)
Rutala, 2010 <sup>27</sup>	UV-C, Tru-D	Cd	~50	36,000	4.04 (2.43)
Boyce, 2011 <sup>28</sup>	UV-C, Tru-D	Cd	67.8 (1 stage)	22,000	1.7-2.9
Havill, 2012 <sup>29</sup>	UV-C, Tru-D	Cd	73 (mean)	22,000	2.2
Rutala, 2013 <sup>30</sup>	UV-C, Tru-D	MRSA	25	12,000	4.71 (4.27)
Rutala, 2013 <sup>30</sup>	UV-C, Tru-D	Cd	43	22,000	3.41 (2.01)
Mahida, 2013 <sup>31</sup>	UV-C, Tru-D	OR: MRSA, VRE	49	12,000	$\geq 4.0$ ( $\geq 4.0$ ), 3.5 (2.4)
Mahida, 2013 <sup>31</sup>	UV-C, Tru-D	Single patient room: VRE, A, As	23-93	12,000	$\geq 4.0$ ( $> 2.3$ ), $\geq 4.0$ (1.7), $\geq 4.0$ (2.0)
Rutala, 2014 <sup>32</sup>	UV-C, Optimum	MRSA	5	NS	4.10 (2.74)
Rutala, 2014 <sup>32</sup>	UV-C, Optimum	Cd	10	NS	3.35 (1.80)
Nerandzic, 2015 <sup>33</sup>	UV, PX, Xenon	Cd, MRSA, VRE	10 at 4 ft (2 cycles)	NS	0.55, 1.85, 0.6

A, *Acinetobacter* spp; As, *Aspergillus*; Cd, *Clostridium difficile*; MDRO, multidrug-resistant organism; MRSA, methicillin-resistant *Staphylococcus aureus*; NS, not stated; OR, operating room; PX, pulsed xenon; UV, ultraviolet light; VRE, vancomycin-resistant enterococci.

# EFFECTIVENESS OF UV DEVICES ON REDUCING MDROs IN CONTAMINATED PATIENT ROOMS

Author, year	UV system	MDROs	Time (min); energy ( $\mu\text{W}/\text{cm}^2$ )	Positive sites (before and after) (%)	Log <sub>10</sub> reduction
Rutala, 2010 <sup>27</sup>	UV-C, Tru-D	MRSA	~15; 12,000	20.2, 0.5	1.30
Nerandzic, 2010 <sup>34</sup>	UV-C, Tru-D	MRSA, VRE	20; 12,000	10.7, 0.8; 2.7, 0.38	0.68; 2.52
Nerandzic, 2010 <sup>34</sup>	UV-C, Tru-D	Cd	45; 22,000	3.4, 0.38	1.39;
Stibich, 2011 <sup>35</sup>	UV, PX, Xenex	VRE	12; NS	8.2, 0	1.36
Anderson, 2013 <sup>36</sup>	UV-C, Tru-D	All, VRE, A	25; 12,000	NS; 11, 1; 13, 3	1.35; 1.68; 1.71
Anderson, 2013 <sup>36</sup>	UV-C, Tru-D	Cd	45; 22,000	10, 5	1.16
Jinadatha, 2015 <sup>37</sup>	UV, PX, Xenex	MRSA	15 (3 cycles of 5 min), NS	70, 8	2.0
Nerandzic, 2015 <sup>33</sup>	UV, PX, Xenex	MRSA, VRE, Cd	10 (2 cycles of 5 min); NS	10, 2; 4, 0.9; 19, 8	0.90, 1.08, NS
Jinadatha, 2015 <sup>37</sup>	UV-PX, Xenex	MRSA	15 (3 cycles of 5 min); NS	NS, NS	0.63

A, *Acinetobacter* spp; All, all target organisms; Cd, *Clostridium difficile*; MDRO, multidrug-resistant organism; MRSA, methicillin-resistant *Staphylococcus aureus*; NS, not stated; PX, pulsed xenon; UV, ultraviolet light; VRE, vancomycin-resistant enterococci.

# Clinical Trials Using UV for Terminal Room Decontamination to Reduce HAIs

Weber, Rutala et al. Am J Infect Control. 2016;44:e77-e84.

Author, Year	Design	Pathogens	Reduction in HAIs
Levin, 2013	Before-After, Pulsed Xenon	CDI	Yes
Hass, 2014	Before-After, Pulsed Xenon	CDI, MRSA, VRE, MDRO-GNR	Yes
Miller, 2015	Before-After, Pulsed Xenon	CDI	Yes
Nagaraja, 2015	Before-After, Pulsed Xenon	CDI	Yes (p=0.06)
Pegues, 2015	Before-After, Optimum	CDI	Yes
Anderson, 2017	Randomized-controlled trial, Tru-D	MRSA, VRE, CDI	Yes

Enhanced terminal room disinfection and acquisition and infection caused by multidrug-resistant organisms and *Clostridium difficile* (the Benefits of Enhanced Terminal Room Disinfection study): a cluster-randomised, multicentre, crossover study

Deverick J Anderson, Luke F Chen, David J Weber, Rebekah W Moehring, Sarah S Lewis, Patricia F Triplett, Michael Blocker, Paul Becherer, J Conrad Schwab, Lauren P Knelson, Yuliya Lokhnygina, William A Rutala, Hajime Kanamori, Maria F Gergen, Daniel J Sexton; for the CDC Prevention Epicenters Program

Anderson DJ, et al. Lancet (epub ahead of print)

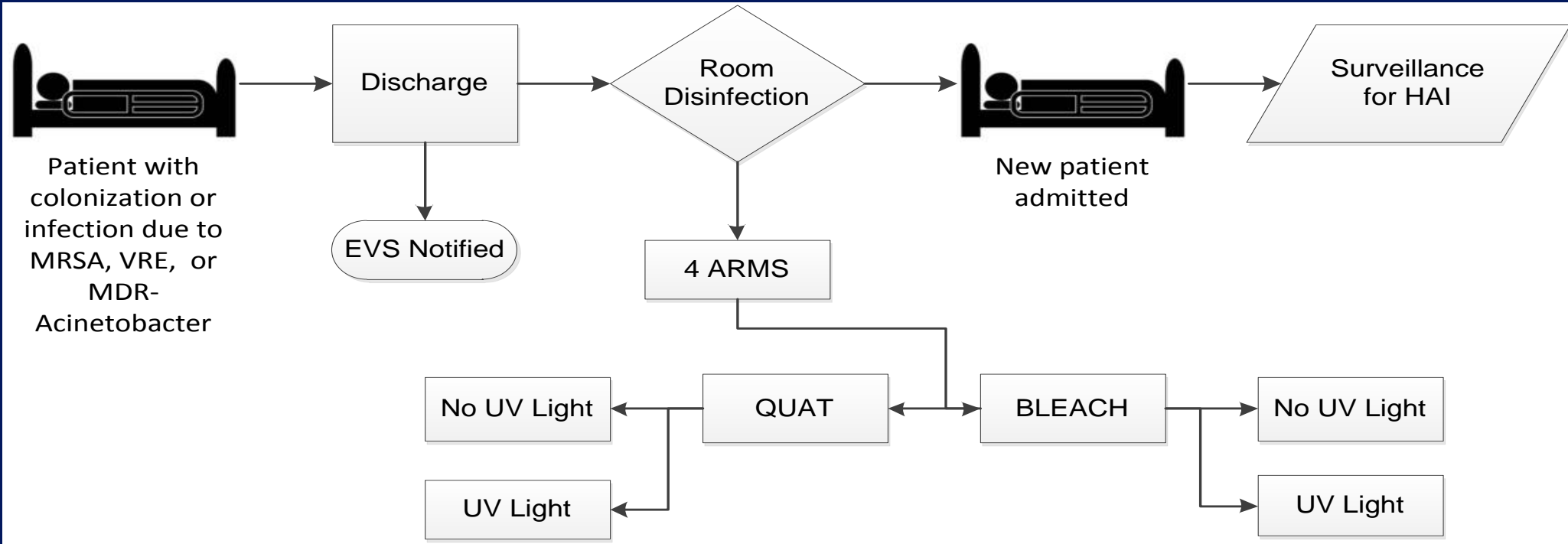


# 2x2 Factorial Design

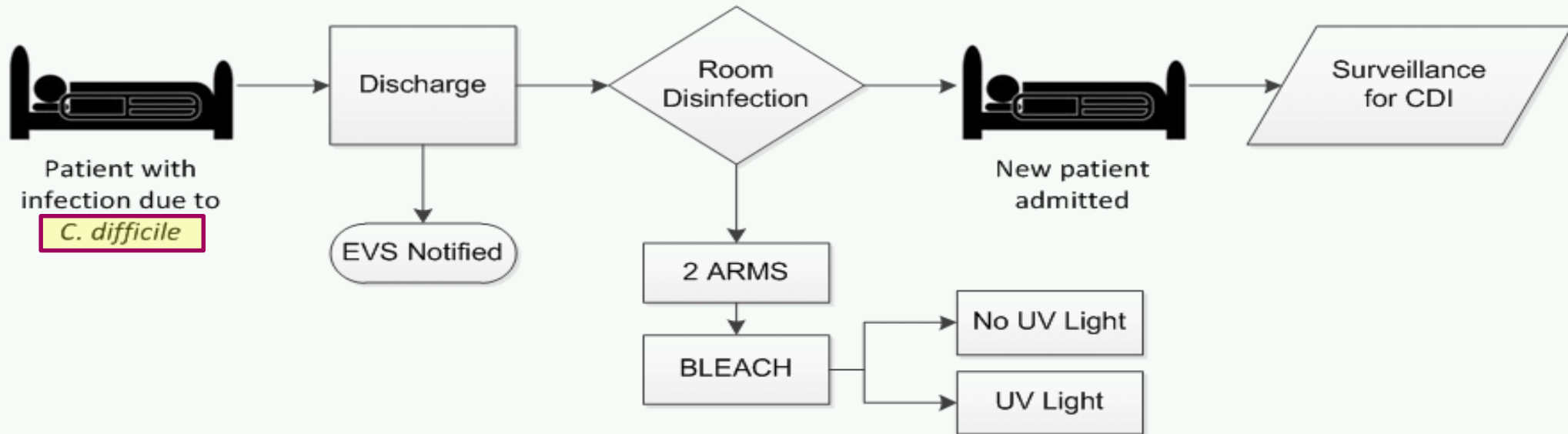
	No UV Light	UV Light
Quat*	A	B
Bleach	C	D

**\*NOTE: Bleach always used in rooms of patients with suspected or confirmed *C. difficile***

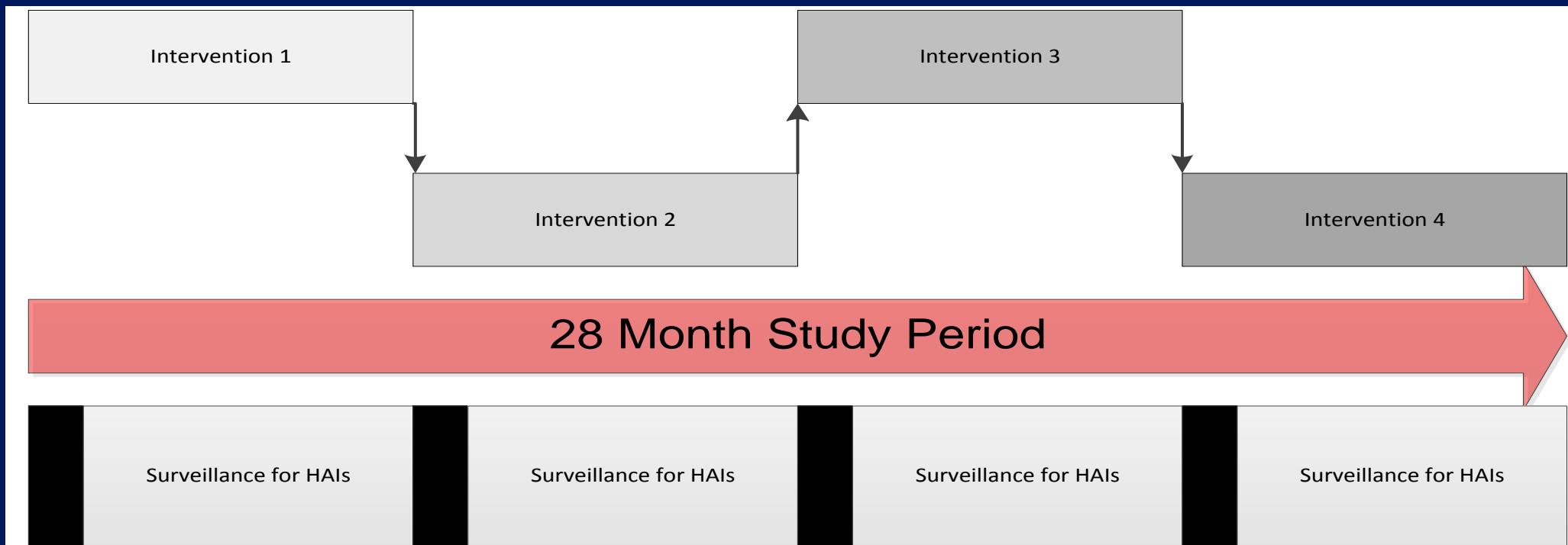
# DUKE/UNC BETR-D STUDY: MRSA, VRE, MDR-Acinetobacter



# DUKE/UNC BETR-D STUDY: CDI



# DUKE/UNC BETR-D STUDY: DESIGN



# BETR RESULTS: INTENTION-TO-TREAT ANALYSIS

**Conclusion: Enhanced terminal room disinfection strategies decreased the clinical incidence of target MDROs by 10-30%**

	Reference	UV group	Bleach group	Bleach + UV group
Exposed patients	4916	5178	5438	5863
Incidence cases (%)	115 (2.3%)	76 (1.5%)	101 (1.9%)	131 (2.2%)
Exposure days	22,426	22,289	24,261	28,757
Rate (per 10,000 exposure-days)	51.3	33.9	41.6	45.6
Risk reduction	Reference	17.4	9.7	5.7
RR (p value)	Reference	0.70 (0.036)	0.85 (0.116)	0.91 (0.303)

Anderson DJ et al. Lancet (epub ahead of print)

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

Rutala, Kanamori, Gergen et al. 2017

	Standard Method		Enhanced method	
	Quat	Quat/UV	Bleach	Bleach/UV
EIP (mean CFU per room) <sup>a</sup>	60.8	3.4	11.7	6.3
Reduction (%)		94	81	90
Colonization/Infection (rate) <sup>a</sup>	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.**

# UV ROOM DECONTAMINATION: ADVANTAGES AND DISADVANTAGES

Rutala WA, Weber DJ. Am J Infect Control 2013;41:S36

## ● Advantages

- Reliable biocidal activity against a wide range of pathogens
- Surfaces and equipment decontaminated
- Room decontamination is rapid (5-25 min) for vegetative bacteria (*C. difficile* spores 10-50m)
- HVAC system does not need to be disabled and room does not need to be sealed
- UV is residual free and does not give rise to health and safety concerns
- No consumable products so operating costs are low (key cost = acquisition)
- Studies show use of UV reduces HAIs

## ● Disadvantages

- Can only be done for terminal disinfection (i.e., not daily cleaning)
- All patients and staff must be removed from room
- Substantial capital equipment costs
- Does not remove dust and stains which are important to patients/visitors
- Sensitive use parameters (e.g., UV dose delivered)

# HP Systems for Decontamination of the Hospital Environment

Falagas et al. J Hosp Infect. 2011;78:171

Author, Year	HP System	Pathogen	Before HPV	After HPV	% Reduction
French, 2004	VHP	MRSA	61/85-72%	1/85-1%	98
Bates, 2005	VHP	<i>Serratia</i>	2/42-5%	0/24-0%	100
Jeanes, 2005	VHP	MRSA	10/28-36%	0/50-0%	100
Hardy, 2007	VHP	MRSA	7/29-24%	0/29-0%	100
Dryden, 2007	VHP	MRSA	8/29-28%	1/29-3%	88
Otter, 2007	VHP	MRSA	18/30-60%	1/30-3%	95
Boyce, 2008	VHP	<i>C. difficile</i>	11/43-26%	0/37-0%	100
Bartels, 2008	HP dry mist	MRSA	4/14-29%	0/14-0%	100
Shapey, 2008	HP dry mist	<i>C. difficile</i>	48/203-24%; 7	7/203-3%; 0.4	88
Barbut, 2009	HP dry mist	<i>C. difficile</i>	34/180-19%	4/180-2%	88
Otter, 2010	VHP	GNR	10/21-48%	0/63-0%	100



# Clinical Trials Using HP for Terminal Room Disinfection to Reduce HAIs

Weber, Rutala et al. Am J Infect Control. 2016;44:e53-e62

Author, Year	Design	Pathogen	Reduction in HAIs
Boyce, 2008	Before-After	CDI	Yes
Cooper, 2011	Before-After	CDI	Decrease cases (incidence not stated)
Passaretti, 2013	Prospective cohort	MRSA, VRE, CDI	Yes, in all MDROs
Manian, 2013	Before-After	CDI	Yes
Mitchell, 2014	Before-After	MRSA	Yes
Horn, 2015	Before-After	CDI, VRE, ESBL GNR	Yes

# HP ROOM DECONTAMINATION: ADVANTAGES AND DISADVANTAGES

Rutala WA, Weber DJ. Am J Infect Control 2013;41:S36

- Advantages

- Reliable biocidal activity against a wide range of pathogens
- Surfaces and equipment decontaminated
- Demonstrated to reduce HAIs
- Residual free and does not give rise to health and safety concerns (aeration units convert HPV into oxygen and water)
- Useful for disinfecting complex equipment and furniture
- Does not require direct or indirect line of sight

- Disadvantages

- Can only be done for terminal disinfection (i.e., not daily cleaning)
- All patients and staff must be removed from room
- Decontamination takes approximately 1.5-5 hours
- HVAC system must be disabled and the room sealed with tape
- Substantial capital equipment costs
- Does not remove dust and stains which are important to patients/visitors
- Sensitive use parameters (e.g., HP concentration)

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

# Selection of a UV or HP Device

Weber, Rutala et al. Am J Infect Control. 2016;44:e77-e84.

- Since different UV and hydrogen peroxide systems vary substantially, infection preventionists should review the peer-reviewed literature and choose only devices with demonstrated bactericidal capability as assessed by carrier tests and/or the ability to disinfect actual patient rooms
- Ideally, one would select a device that has demonstrated bactericidal capability and the ability to reduce HAIs

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

# Continuous Room Decontamination

Rutala, Gergen, Kanamori, Sickbert-Bennett, Weber, 2015-2018

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- Visible light disinfection system-effective
- Dilute hydrogen peroxide system-not effective (potential)
- Self-disinfecting surface coating-some data
- Others-copper-some data

# Continuous Room Decontamination Technology

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

# Continuous Room Decontamination Technology

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





# Antimicrobial Activity of a Continuous Visible Light Disinfection System

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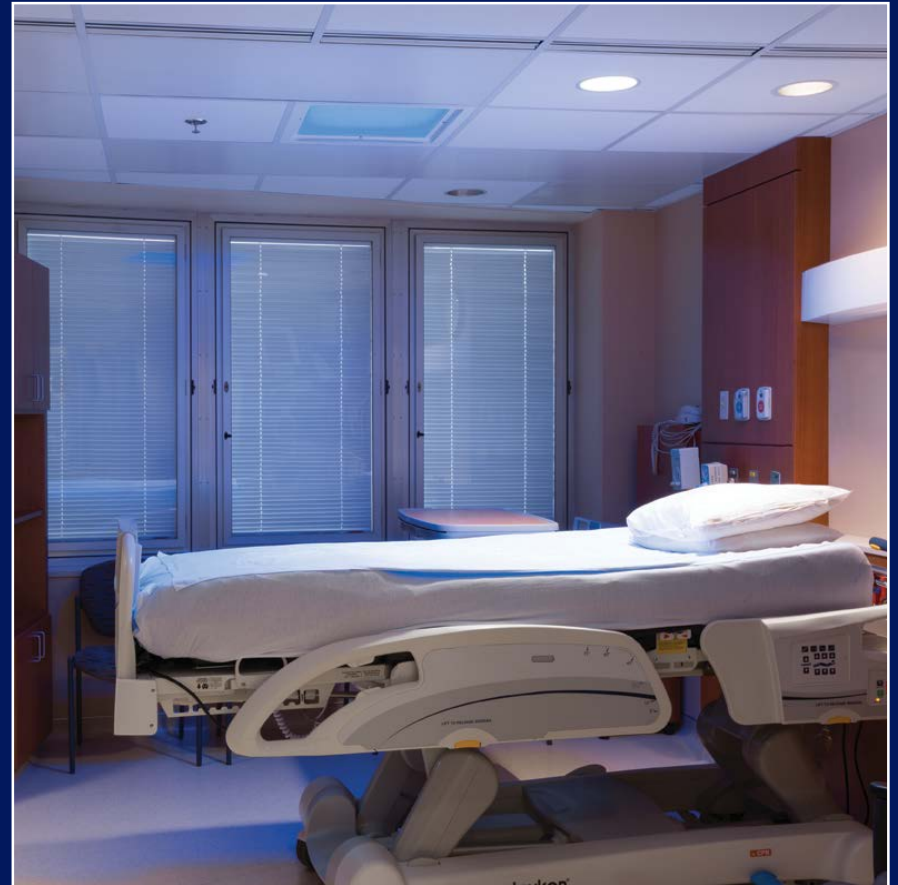
- Visible Light Disinfection uses the blue-violet range of visible light in the 400-450nm region generated through light-emitting diodes (LEDs)
- Initiates a photoreaction with endogenous porphyrin found in microorganisms which yield production of reactive oxygen species inside microorganisms, leading to microbial death
- Overhead illumination systems can be replaced with Visible Light Disinfection counterparts

# Visible Light Disinfection in a Patient Room

(automatic switching between modes performed by wall-mounted controls)



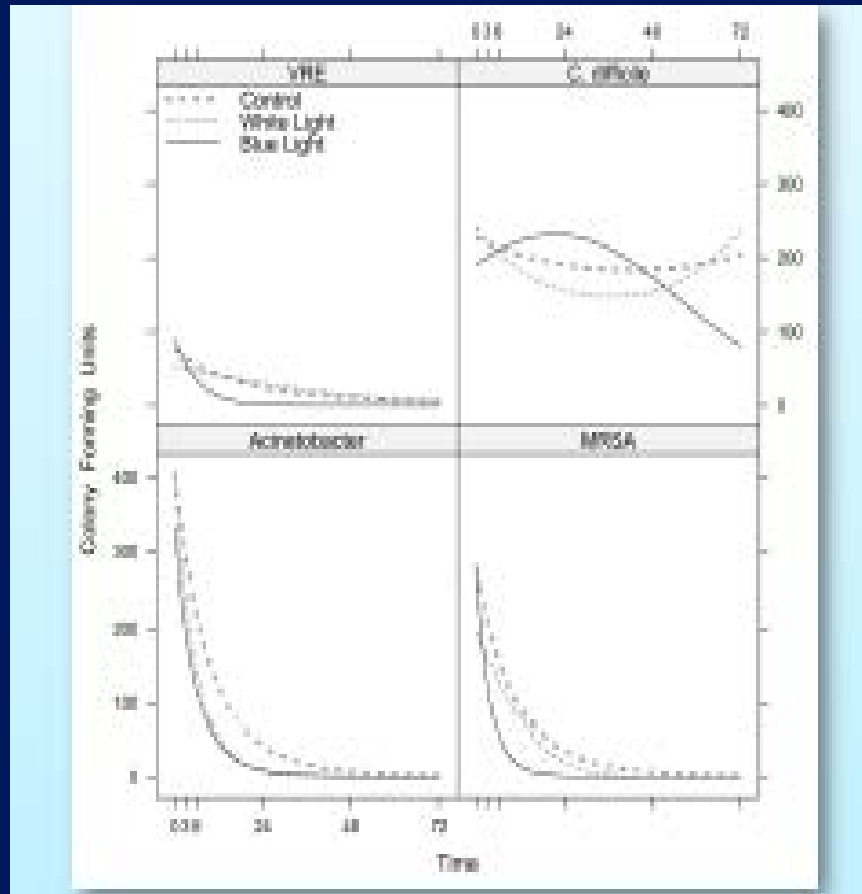
**White light**



**Blue light-increase irradiance, increase**

# Inactivation of Health Pathogens by Continuous Visible Light Disinfection

Rutala et al. APIC 2017



- The treatment (i.e. both “blue” and “white” light) had significantly different rates over time for all four organisms
- Both light treatments were associated with more rapid decreases in observed bacterial counts over time with all four organism
- Overall, the model demonstrated improved inactivation of pathogens with the “blue” and “white” light

# Time to Specified Percent Reduction of Epidemiologically-Important Pathogens with “Blue” and “White” Light

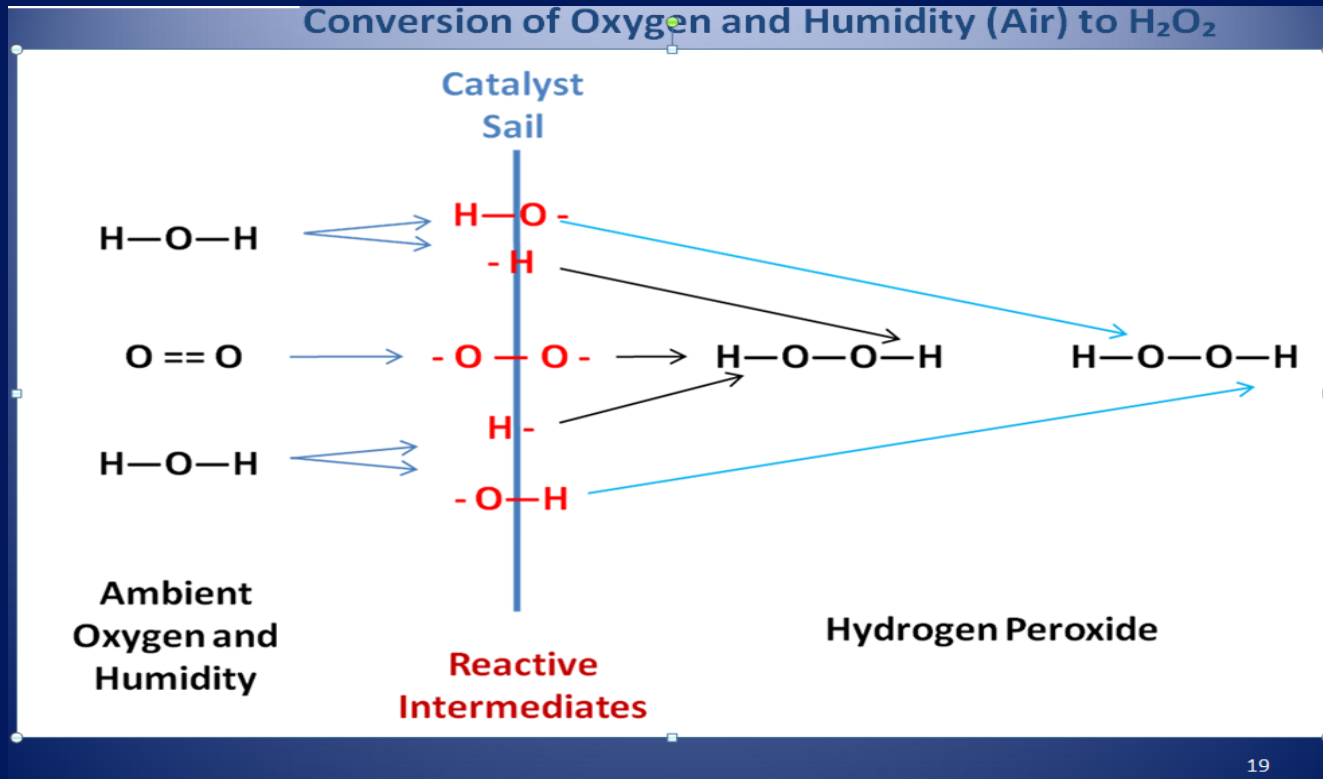
Rutala et al. APIC 2017

Pathogen	Treatment (light)	Time (least number of hours) to achieve sustained microbial reduction of listed percentage			
		25%	50%	75%	90%
MRSA	White	5	10	17	24
	Blue	2	3	6	10
VRE	White	13	29	51	NA
	Blue	2	5	9	15
MDR- <i>Acinetobacter</i>	White	2	5	9	14
	Blue	2	4	9	15
<i>C. difficile</i>	White	NA	NA	NA	NA
	Blue	56	68	NA	NA

The earliest hour after which the model predicts a sustained reduction of CFUs by the stated percentage for epidemiologically-important pathogens with the “white” light and the “blue” light. “NA” indicates that a sustained reduction of the given was level was not achieved. Note that the largest reduction listed is 90% because the model cannot predict a 100% reduction except after infinite hours have passed.

# Dilute Hydrogen Peroxide Technology

UV activates the catalyst which creates H ion and hydroxyl radical and free electron, hydroxyl radicals removed from catalyst and combine to form HP; also H<sub>2</sub> and O<sub>2</sub> and electron make HP





ELSEVIER

Contents lists available at [ScienceDirect](#)

# American Journal of Infection Control

journal homepage: [www.ajicjournal.org](http://www.ajicjournal.org)



## Major article

# Long-term efficacy of a self-disinfecting coating in an intensive care unit



Akrum H. Tamimi PhD, Sheri Carlino BS, Charles P. Gerba PhD \*

*Department of Soil, Water, and Environmental Science, University of Arizona, Tucson, AZ*

### Key Words:

Disinfection

Bacteria

Self-disinfecting surface

Efficacy

**Background:** Cleaning and disinfecting fomites can effectively remove/kill pathogens on surfaces, but studies have shown that more than one-half the time, surfaces are not adequately cleaned or are recontaminated within minutes. This study evaluated a product designed to create a long-lasting surface coating that provides continuous disinfecting action.

**Methods:** This study was performed in an intensive care unit (ICU) in a major hospital. Various sites within the ICU were cultured before treatment and then at 1, 2, 4, 8, and 15 weeks after application of an antimicrobial coating. Samples were cultured for total bacteria, as well as *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant enterococcus, and carbapenemase-resistant Enterobacteriaceae.

**Results:** The average bacterial count on all treated surfaces was reduced by >99% (2 logs) for at least 8 weeks after treatment. Overall, average levels of bacteria never returned to those observed before treatment even after 15 weeks. Antibiotic-resistant bacteria were found on 25% of the sites tested before treatment, but were isolated at only 1 site during the 15 weeks after treatment.

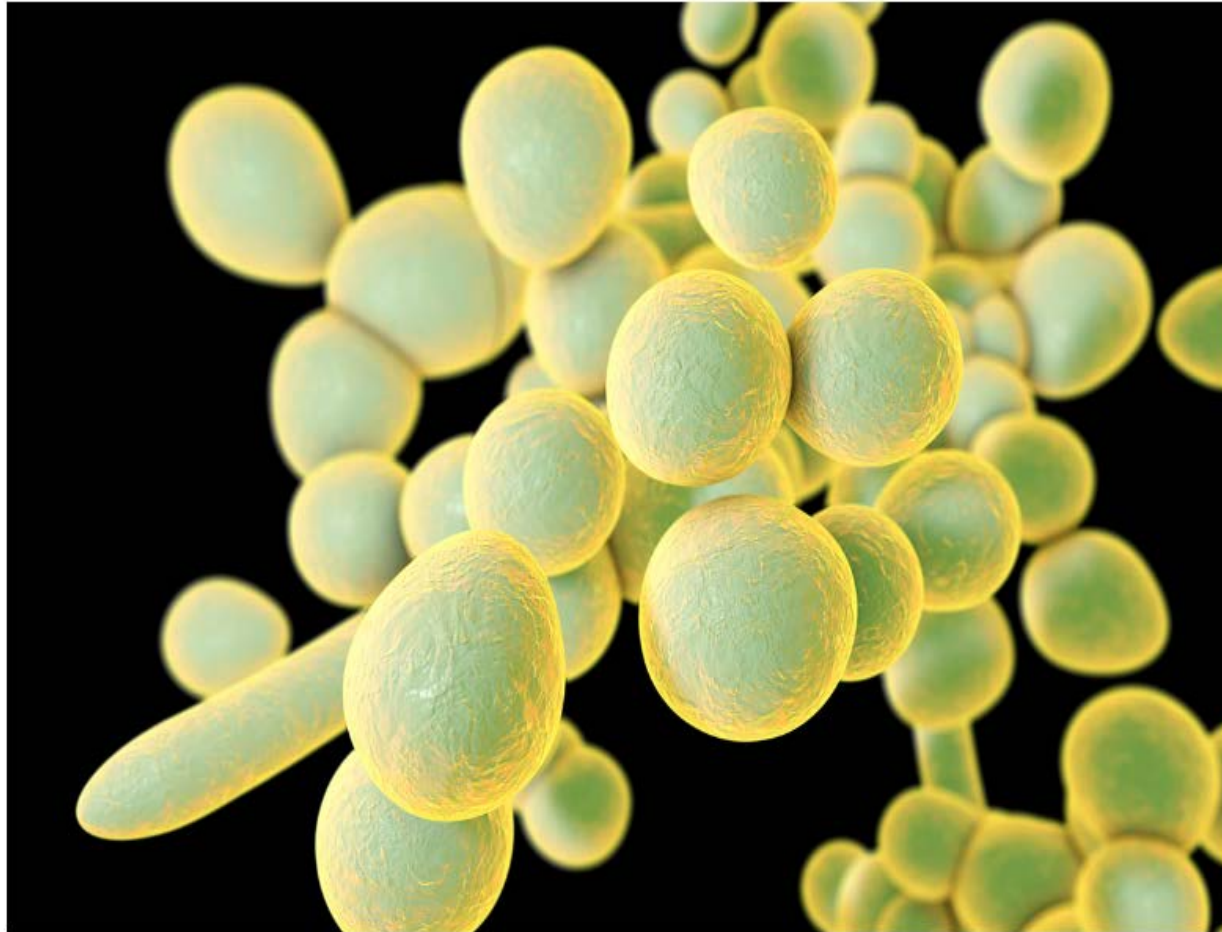
**Conclusions:** The product assessed in this study was found to have persisted over 15 weeks in reducing the total number of bacteria and antibiotic resistant bacteria on surfaces within an ICU.

# Disinfection and Sterilization: What's New

- Current Issues and New Technologies
  - Sterilization of critical items
    - ◆ Biological indicators, modified Spaulding, extended claims
  - High-level disinfection for semi-critical items
    - ◆ Endoscope reprocessing issues (duodenoscopes), HPV risks/studies
  - Low-level disinfection of non-critical items
    - ◆ Over-dilution; monitoring cleaning, floors, “no touch” technology, continuous room decontamination
  - D/S and Emerging Pathogens
    - ◆ Inactivation data- *Candida auris*, CRE-carbapenem-resistant *Enterobacteriaceae*



# 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



# Efficacy of Disinfectants and Antiseptics against *Candida auris*

Rutala, Kanamori, Gergen, Sickbert-Bennett, Weber, 2017

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

# Efficacy of Disinfectants and Antiseptics against *Candida auris*

Rutala, Kanamori, Gergen, Sickbert-Bennett, Weber, 2017

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

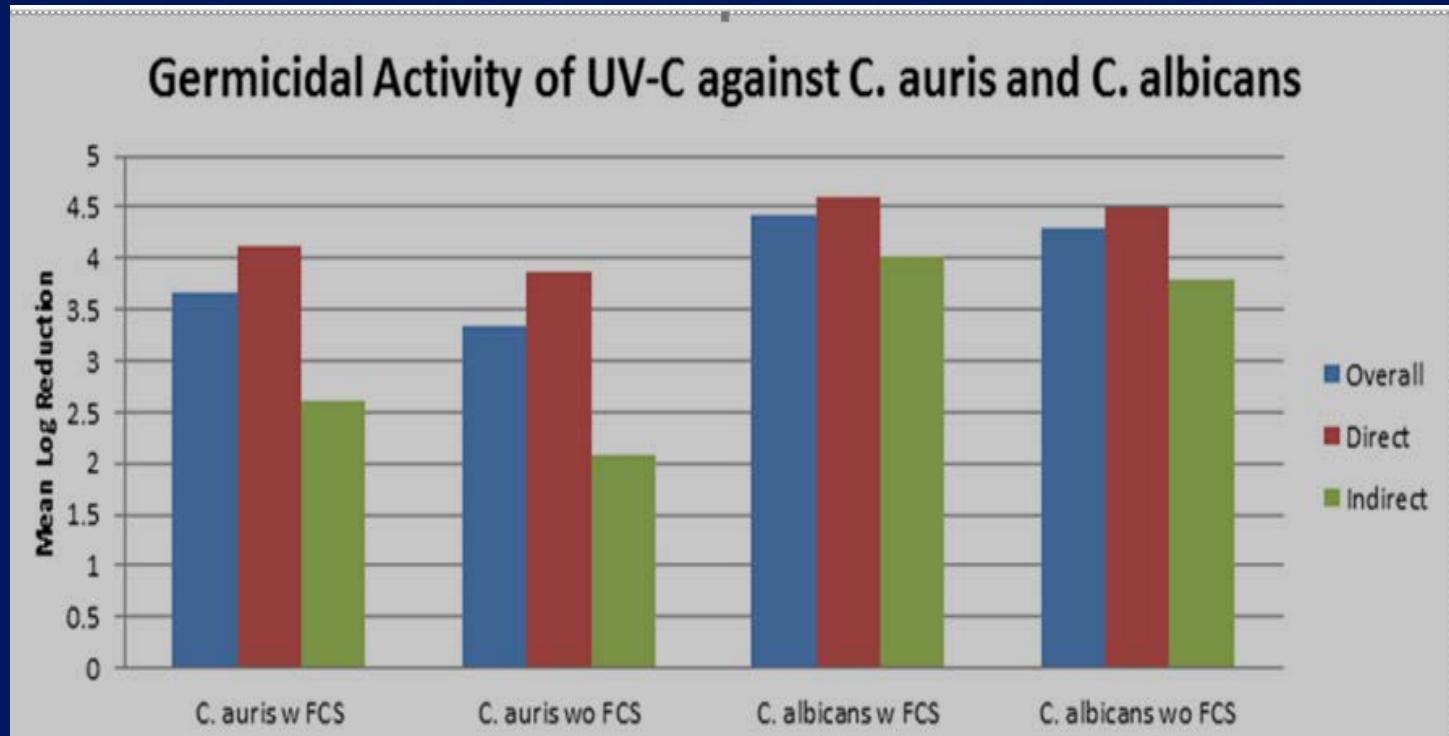
# Efficacy of Disinfectants and Antiseptics against Carbapenem-Resistant *Enterobacteriaceae*

Rutala, Kanamori, Gergen, Sickbert-Bennett, Weber, 2017

- $\geq 3 \log_{10}$  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*)

# Germicidal Activity of UV-C Against *C. auris* and *C. albicans*

UNC Hospitals, 2017



Very good inactivation of *Candida auris* by UV. Used Tru-D bacteria cycle (17-19 minute cycle, 12,000 $\mu$ Ws/cm<sup>2</sup>).

# Disinfection and Sterilization: What's New

- Current Issues and New Technologies
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# Disinfection and Sterilization: What's New

- New D/S technologies (“no touch”, BIs) and practices (e.g., monitoring cleaning, duodenoscopes) 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 narrow margin of safety and manufacturers should be encouraged to develop practical sterilization technology. Enhanced methods used for duodenoscopes.
- 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). However, some pathogens need additional information (e.g., HPV).



# THANK YOU!

[www.disinfectionandsterilization.org](http://www.disinfectionandsterilization.org)



