

# **Disinfection and Sterilization: What New?**

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

**Director, Statewide Program for Infection Control and Epidemiology  
and Research 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

2017-2018

- **Consultations**
  - ASP (Advanced Sterilization Products), PDI
- **Honoraria**
  - PDI, Kennall
- **Scientific Advisory Board**
  - KinnoS
- **Grants**
  - CDC, CMS

---

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

# Learning Objective

- Describe two new recommendations/practices/technologies associated with HLD and sterilization (new BIs, perfuse channel endoscopes)
- Identify at least one new change related to reprocessing critical or semicritical items (HPV, duodenoscope lever)
- Describe at least two technologies/research that will eliminate 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, clarified Spaulding
  - High-level disinfection for semi-critical items
    - ◆ Outbreaks with semicritical devices, endoscope reprocessing issues (duodenoscopes-lever position), channeled endoscopes, HPV risks/studies
  - Low-level disinfection of non-critical items
    - ◆ Noncritical surface disinfection bundle, “wet” time, “no touch” technology, new technology (monitoring cleaning, continuous room decontamination)
  - Emerging Pathogens
    - ◆ Inactivation data- *Candida auris*, CRE-carbapenem-resistant *Enterobacteriaceae*

# Disinfection and Sterilization: What's New

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

- Current Issues and New Technologies
  - Sterilization of critical items
    - ◆ Biological indicators, clarified Spaulding
  - High-level disinfection for semi-critical items
    - ◆ Outbreaks with semicritical devices, endoscope reprocessing issues (duodenoscopes-lever position), channeled endoscopes, HPV risks/studies
  - Low-level disinfection of non-critical items
    - ◆ Noncritical surface disinfection bundle, “wet” time, “no touch” technology, new technology (monitoring cleaning, continuous room decontamination)
  - Emerging Pathogens
    - ◆ Inactivation data- *Candida auris*, CRE-carbapenem-resistant *Enterobacteriaceae*

# Sources of Healthcare-Associated Pathogens

Weinstein RA. Am J Med 1991;91 (suppl 3B):179S

- Endogenous flora (SSI, UTI, CLABSI): 40-60%
- Exogenous: 20-40% (e.g., cross-infection via contaminated hands [staff, visitors])
- Other (environment): 20%
  - Medical devices
  - Contact with environmental surfaces (direct and indirect contact)

# 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**.



# Goal

**Prevent All Infectious Disease Transmission Associated  
with Medical/Surgical Devices in 5 years**

# Sterilization

## Enormous Margin of Safety!

100 quadrillion ( $10^{17}$ ) margin of safety

Sterilization kills 1 trillion spores, washer/disinfector removes or inactivates 10-100 million; ~100 microbes on surgical instruments

# 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”

---

Steam sterilization

Hydrogen peroxide gas plasma

Ethylene oxide

Ozone and hydrogen peroxide

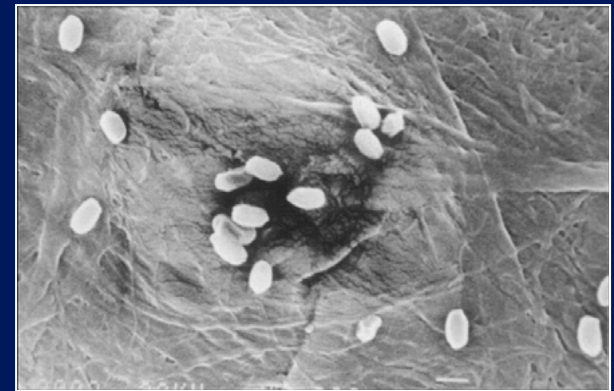
Vaporized hydrogen peroxide

# Disinfection and Sterilization: What's New Learning Outcomes

- 24m and 30m BI for HP sterilizers
- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes
- Perfuse channeled scopes
- Uncertain if OPA/glut kill HPV
- Develop a noncritical surface bundle including “no touch”
- Touchable surfaces should be wiped and monitor cleaning
- New continuous room decontamination technology
- CRE susceptible to germicides
- *C. auris* susceptible to most disinfectants but not antiseptics

# 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*

# 30m or 24m Biological Indicator for HP Sterilizers



# Disinfection and Sterilization: What's New Learning Outcomes

- 24m and 30m BI for HP sterilizers
- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes
- Perfuse channeled scopes
- Remain uncertain if OPA/glut kill HPV
- Develop a noncritical surface bundle including “no touch”
- Touchable surfaces should be wiped and monitor cleaning
- New continuous room decontamination technology
- CRE susceptible to germicides
- *C. auris* susceptible to most disinfectants but not antiseptics



# 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

# 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)

>130 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

# 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.

**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).

# 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).

# What's New with Shift from HLD to Sterilization

- GI physicians did not want to add the “secondary” to the definition...as they feel that it will make many GI scope procedures as critical devices, mandating terminal sterilization which basically means that they have to ETO sterilize most of their GI scopes. They argued that this will disrupt the business and significantly increase the cost of care, and therefore many people won't afford such procedures. Thus, increasing the bar from HLD to sterilization at this time without having practical fast and compatible sterilization technologies will create more harm than benefit to the patients.
- At present (March 2018), the new AAMI endoscope reprocessing (WG 84) guideline will not mandate sterilization, but will only recommend it if possible, until MDMs develop endoscopes that are sterilization compatible.

# Potential Future Methods to Prevent Endoscope-Related Outbreaks

Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643.

- Optimize current low temperature sterilization methods or new LTST proving SAL  $10^{-6}$  achieved (2 LTS technologies, FDA-cleared)
- Disposable sterile GI endoscopes/bronchoscopes (2 manufacturer's)
- Steam sterilization for GI endoscopes (1 bronchoscope manufacturer)
- Use of non-endoscope methods to diagnosis or treat disease (e.g., capsule endoscopy, stool or blood tests to detect GI cancer, stool DNA test)
- Improved GI endoscope design (to reduce or eliminate reprocessing challenges-based on 50y of experience unlikely to resolve problem; closed channel duodenoscopes increased risk)

# Disinfection and Sterilization: What's New

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

- Current Issues and New Technologies
  - Sterilization of critical items
    - ◆ Biological indicators, clarified Spaulding
  - High-level disinfection for semi-critical items
    - ◆ Outbreaks with semicritical devices, endoscope reprocessing issues (duodenoscopes-lever position, scope irregularities), channeled endoscopes, HPV risks/studies
  - Low-level disinfection of non-critical items
    - ◆ Noncritical surface disinfection bundle, “wet” time, “no touch” technology, new technology (monitoring cleaning, continuous room decontamination)
  - Emerging Pathogens
    - ◆ Inactivation data- *Candida auris*, CRE-carbapenem-resistant *Enterobacteriaceae*

# Disinfection and Sterilization: What's New Learning Outcomes

- 24m and 30m BI for HP sterilizers
- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes (reprocessing issues: lever 45°, non-compliance, irregularities like scratches, fluid)
- Perfuse channeled scopes
- Remain uncertain if OPA/glut kill HPV
- Develop a noncritical surface bundle including “no touch”
- Touchable surfaces should be wiped and monitor cleaning
- New continuous room decontamination technology
- CRE susceptible to germicides
- *C. auris* susceptible to most disinfectants but not antiseptics



# 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, **>130 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

# Infections/Outbreaks Associated with Semicritical Medical Devices

Rutala, Weber, AJIC, In preparation

Medical Device	No. Outbreaks/Infections	No. Outbreaks/Infections with Bloodborne Pathogens
Vaginal Probes	0	0
Ear-Nose-Throat Endoscopes	0	0
Cystoscopes	5	0
Hysteroscopes	0	0
Laryngoscopes	1	0
Ureteroscopes	1	0
Prostate Probes	3	0
TEE-Transesophageal echocardiogram	3	0
GI Endoscopes/Bronchoscopes	~130	4 (HBV-1 GI; HCV-3 GI; HIV-0)

# Infections/Outbreaks Associated with Semicritical Medical Devices

Rutala, Weber, AJIC, In preparation

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

# High-Level Disinfection of “Semicritical Objects”

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

<u>Germicide</u>	<u>Concentration</u>
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

# Microbiological Disinfectant Hierarchy

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

Most Resistant

Spores (*C. difficile*)

Mycobacteria (*M. tuberculosis*)

Non-Enveloped Viruses (norovirus, HAV, polio)

Fungi (*Candida*, *Trichophyton*)

Bacteria (MRSA, VRE, *Acinetobacter*)

Enveloped Viruses (HIV, HSV, Flu)

Most Susceptible

HLD



# 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**

# 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%
<b>AER</b>	27.2%
<b>Manual</b>	39.3%
<b>Age of endoscope &lt;2 years</b>	18.9%
<b>Age of endoscope &gt;2 years</b>	38.8%

# Visual Inspection of GI Endoscopes and Bronchoscopes

GI Endoscopes, 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**
- 60% scopes with **microbial contamination**

Bronchoscopes, Ofstead et al. Chest. 2018

- Visible irregularities were observed in 100% (e.g., retained fluid, scratches, damaged insertion tubes)
- Microbial contamination in 58%
- Reprocessing practices deficient at 2 of 3 sites



# Duodenoscope Lever Position

Alfa et al. AJIC 2018;46:73-75



A)



B)

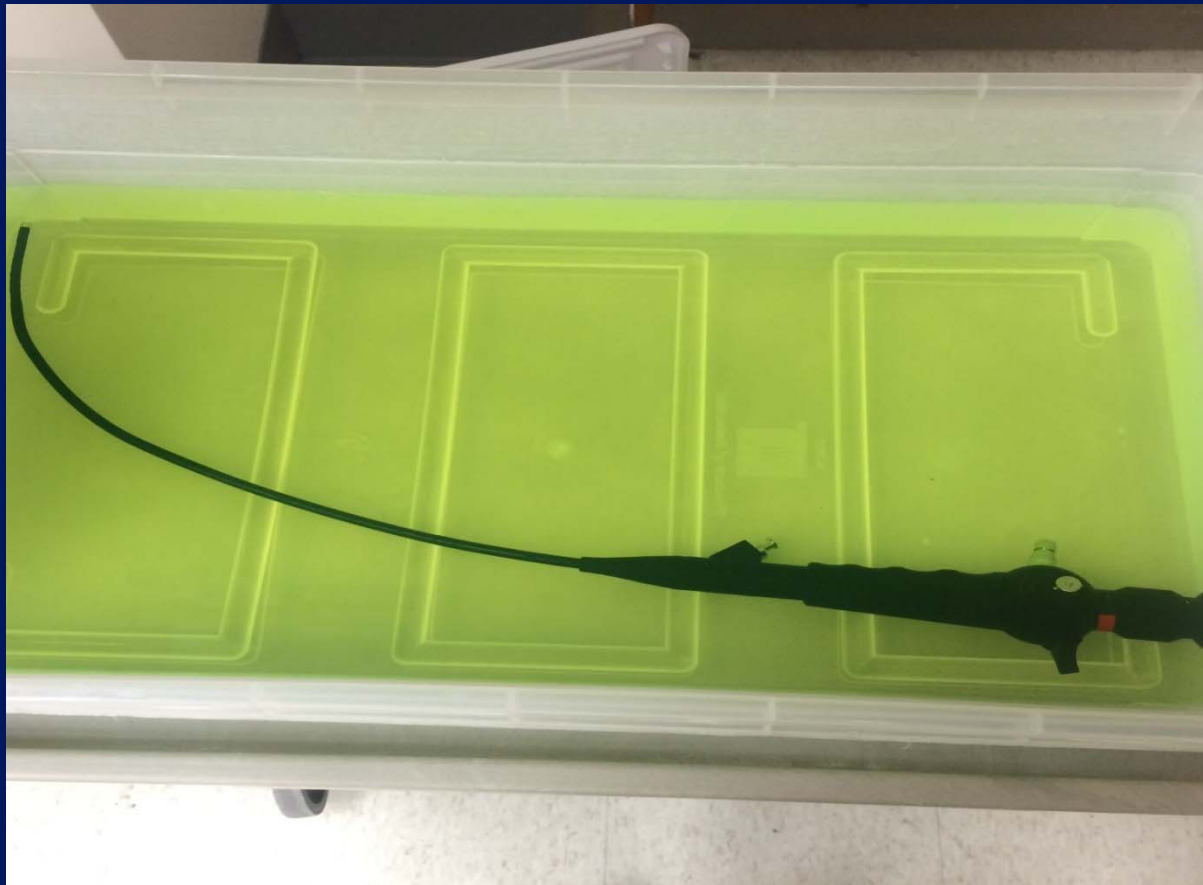
- Bacteria will survive if the elevator lever was improperly positioned (in horizontal position instead of 45°) in AER
- *E. faecalis* (7 log inoculum, 2-6 log recovered) and *E. coli* (0-3 log) survived disinfection of sealed and unsealed elevator wire channel duodenoscopes in 2 different AERs
- Ensure proper lever position when placed in AERs with PA

# Disinfection and Sterilization: What's New Learning Outcomes

- 24m and 30m BI for HP sterilizers
- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes
- **Perfuse channeled scopes**
- Remain uncertain if OPA/glut kill HPV
- Develop a noncritical surface bundle including “no touch”
- Touchable surfaces should be wiped and monitor cleaning
- New continuous room decontamination technology
- CRE susceptible to germicides
- *C. auris* susceptible to most disinfectants but not antiseptics

# Reprocessing Channeled Endoscopes

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



# Reprocessing Channeled Endoscopes

Cystoscope-HLD perfused through lumen with syringe (luer locks onto port and syringe filled and emptied until no air exits the scope nor air in barrel of syringe-syringe and lumen filled with HLD)



# Reprocessing Channeled Endoscopes

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

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

# Reprocessing Channeled Instruments

Cadnum et al, SHEA 2017 Poster

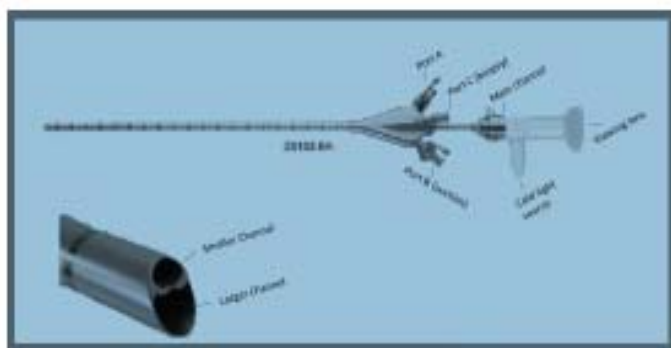


Figure 2. Hysteroscope Diagram

Table 1. Recovery of *E.coli* from hysteroscope lumens after OPA soak with passive filling

Conditions	Control Hysteroscope $\log_{10}$ CFU/mL	Test Hysteroscope $\log_{10}$ CFU/mL
<b>Valves disassembled:</b>		
12 min OPA soak ( N=4 )		
Main Channel ( 5mm )	5.0-7.0	0
Side Port A( $\leq$ 1.5mm )	5.0-7.0	3.5
Side Port B ( $\leq$ 1.5mm )	5.0-7.0	3.8
Side Port C ( $\leq$ 1.5mm )	5.0-7.0	3.8
<b>Without disassembly of valves:</b>		
4 hour OPA soak ( N=1 )		
All Lumens	5.0-7.0	4.2

- For the hysteroscope, a 12m soak in OPA eliminated  $>6 \log_{10}$  CFU of the test organisms from the larger central channel (~3.5mm)
- A 12 minute or 4 hour soak did not completely eliminate contamination from the 1.5mm channel
- Narrow channels limit full exposure to the disinfectant

# Disinfection and Sterilization: What's New Learning Outcomes

- 24m and 30m BI for HP sterilizers
- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes
- Perfuse channeled scopes
- HLD/sterilize laryngoscope
- Uncertain if OPA/glut kill HPV
- Develop a noncritical surface bundle including “no touch”
- Touchable surfaces should be wiped and monitor cleaning
- New continuous room decontamination technology
- CRE susceptible to germicides
- *C. auris* susceptible to most disinfectants but not antiseptics

# Disposable vs Reusable Laryngoscopes



- Many hospitals transitioning to disposable laryngoscopes
- Saves time
- Virtually eliminates risk of cross contamination
- Reduces likelihood on non-performing equipment
- Possibly cost-effective when considering reprocessing costs







# Reprocessing of Rigid Laryngoscopes

JHI 2008, 68:101; ICHE 2007, 28:504; AJIC 2007, 35: 536; AJIC 2013,41:S60

- Limited guidelines for reprocessing laryngoscope's blades and handles
- For years, many hospitals consider blade as semicritical (HLD) and handle as noncritical (LLD)
- Blades linked to HAIs; handles not directly linked to HAIs but contamination with microbes/blood/OPIM suggest its potential and blade and handle function together
- Ideally, clean then HLD/sterilize blades and handles (UNCH-blades and handles sterilized).



# Disinfection and Sterilization: What's New Learning Outcomes

- 24m and 30m BI for HP sterilizers
- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes
- Perfuse channeled scopes
- HLD/sterilize laryngoscope
- **Uncertain if OPA/glut kill HPV**
- Develop a noncritical surface bundle including “no touch”
- Touchable surfaces should be wiped and monitor cleaning
- New continuous room decontamination technology
- CRE susceptible to germicides
- *C. auris* susceptible to most disinfectants but not antiseptics

# Endocavitary Probes

Rutala, Weber, HIPAC. [www.cdc.gov](http://www.cdc.gov) 2008; Rutala, Weber. AJIC 2016.44:e53-e62

- Probes-Transesophageal echocardiography probes, vaginal/rectal probes used in sonographic scanning
- Probes with contact with mucous membranes are semicritical
- Guideline recommends that a new condom/probe cover should be used to cover the probe for each patient and since covers may fail (1-80%), HLD (semicritical probes) should be performed

# Endocavitary Probe Covers

Rutala, Weber. AJIC 2013. 41:S60-S66; Rutala, Weber. AJIC 2016.44:e53-e62

- Sterile transvaginal probe covers had a very high rate of perforations before use (0%, 25%, 65% perforations from three suppliers)
- A very high rate of perforations in used endovaginal probe covers was found after oocyte retrieval use (75% and 81% from two suppliers) but other investigators found a lower rate of perforations after use of condoms (0.9-2.0%)
- Condoms superior to probe covers for ultrasound probe (1.7% condom, 8.3% leakage for probe covers)

# Human Papilloma Virus

- **Human Papilloma Virus (HPV)**
  - HPV is transmitted through sexual and direct/indirect contact
  - Medical devices can become contaminated during use
  - If adequate disinfection of devices (e.g., endocavitary probes) does not occur, the next patient may be at risk for HPV infection
  - Based on two publications from the same researchers, currently FDA-cleared HLDs were not effective against HPV



# Human Papillomavirus Contamination of Gynecologic Equipment

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

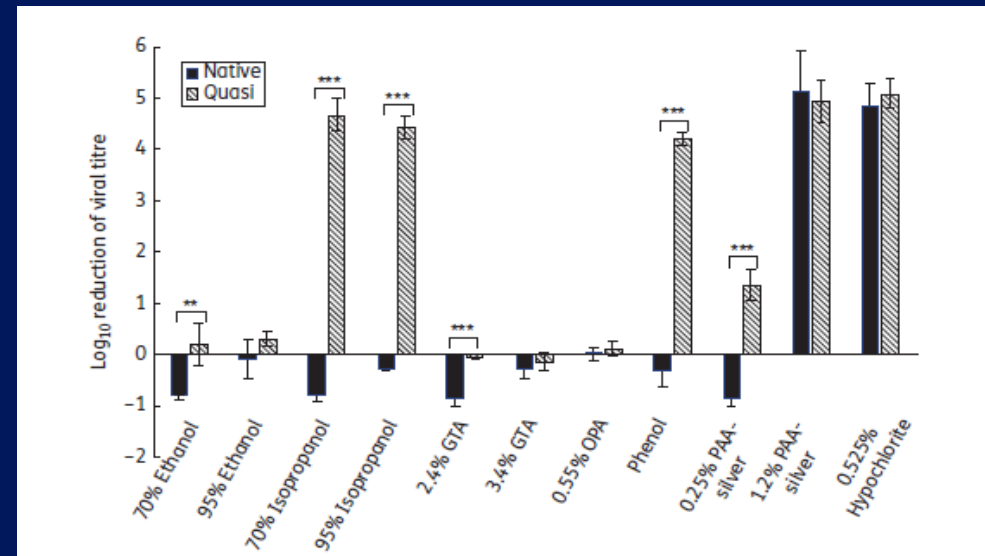
- Assess presence of HPV on equipment used in GYN practice
- Samples from fomites (glove box, lamp on GYN chair, gel tubes, colposcope, speculum) in 2 hospitals and 4 private practices
- Samples analyzed by real-time PCR
- 32 (18%) HPV-positive samples found
- Higher risk of HPV contamination in GYN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

# ENDOSCOPE REPROCESSING: CHALLENGES

## Susceptibility of Human Papillomavirus

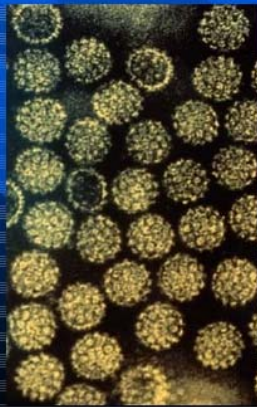
J Meyers et al. J Antimicrob Chemother, Epub Feb 2014

- Most common STD
- In one study, FDA-cleared HLD (OPA, glut), no effect on HPV
- Finding inconsistent with other small, non-enveloped viruses such as polio and parvovirus
- Further investigation needed: test methods unclear; glycine; organic matter; comparison virus
- Conversation with CDC: **validate and use HLD consistent with FDA-cleared instructions (no alterations)**



# What if HPV is Resistant to Aldehydes?

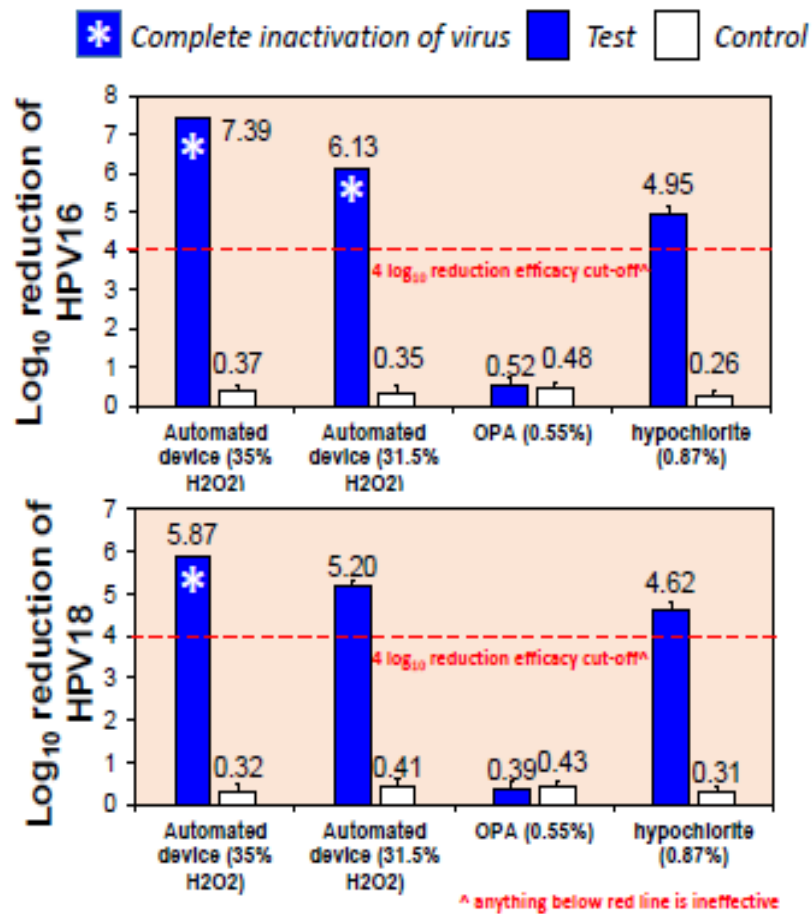
Electron Micrograph of HPV



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

# Efficacy of Hydrogen Peroxide 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 and hypochlorite >4 log<sub>10</sub> reduction, OPA achieved <1 log<sub>10</sub> reduction

# Effectiveness of HP Mist System in Inactivating Viruses

Becker et al. GMS Hyg Infect Control 2017;12

- A  $\geq 4$  log<sub>10</sub> reduction of virus was demonstrated with murine norovirus, adenovirus, and parvovirus

Test virus	Level in the device	Soil load	Residual virus	RF
AdV	top	clean	yes	4.61±0.35
	middle	clean	yes	4.63±0.37
	bottom	clean	yes	4.11±0.43
MNV	top	clean	yes	$\geq 4.75 \pm 0.54$
	middle	clean	yes	$\geq 4.98 \pm 0.77$
	bottom	clean	yes	$\geq 4.63 \pm 0.51$
MVM	top	clean	yes	4.04±0.56
	middle	clean	yes	4.57±0.64
	bottom	clean	yes	4.67±0.70

---

# **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

# 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%)



# Disinfection and Sterilization: What's New

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

- Current Issues and New Technologies
  - Sterilization of critical items
    - ◆ Biological indicators, clarified Spaulding
  - High-level disinfection for semi-critical items
    - ◆ Outbreaks with semicritical devices, endoscope reprocessing issues (duodenoscopes-lever position), channeled endoscopes, HPV risks/studies
  - Low-level disinfection of non-critical items
    - ◆ Noncritical surface disinfection bundle, “wet” time, “no touch” technology, new technology (monitoring cleaning, continuous room decontamination)
  - Emerging Pathogens
    - ◆ Inactivation data- *Candida auris*, CRE-carbapenem-resistant *Enterobacteriaceae*

# 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 Learning Outcomes

- 24m and 30m BI for HP sterilizers
- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes
- Perfuse channeled scopes
- HLD/sterilize laryngoscope
- Uncertain if OPA/glut kill HPV
- Develop a noncritical surface bundle including “no touch”
- Touchable surfaces should be wiped and monitor cleaning
- New continuous room decontamination technology
- CRE susceptible to germicides
- *C. auris* susceptible to most disinfectants but not antiseptics

# Disinfection of Noncritical Surfaces Bundle

NL Havill AJIC 2013;41:S26-30

- 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

# Disinfection of Noncritical Surfaces Bundle

- 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

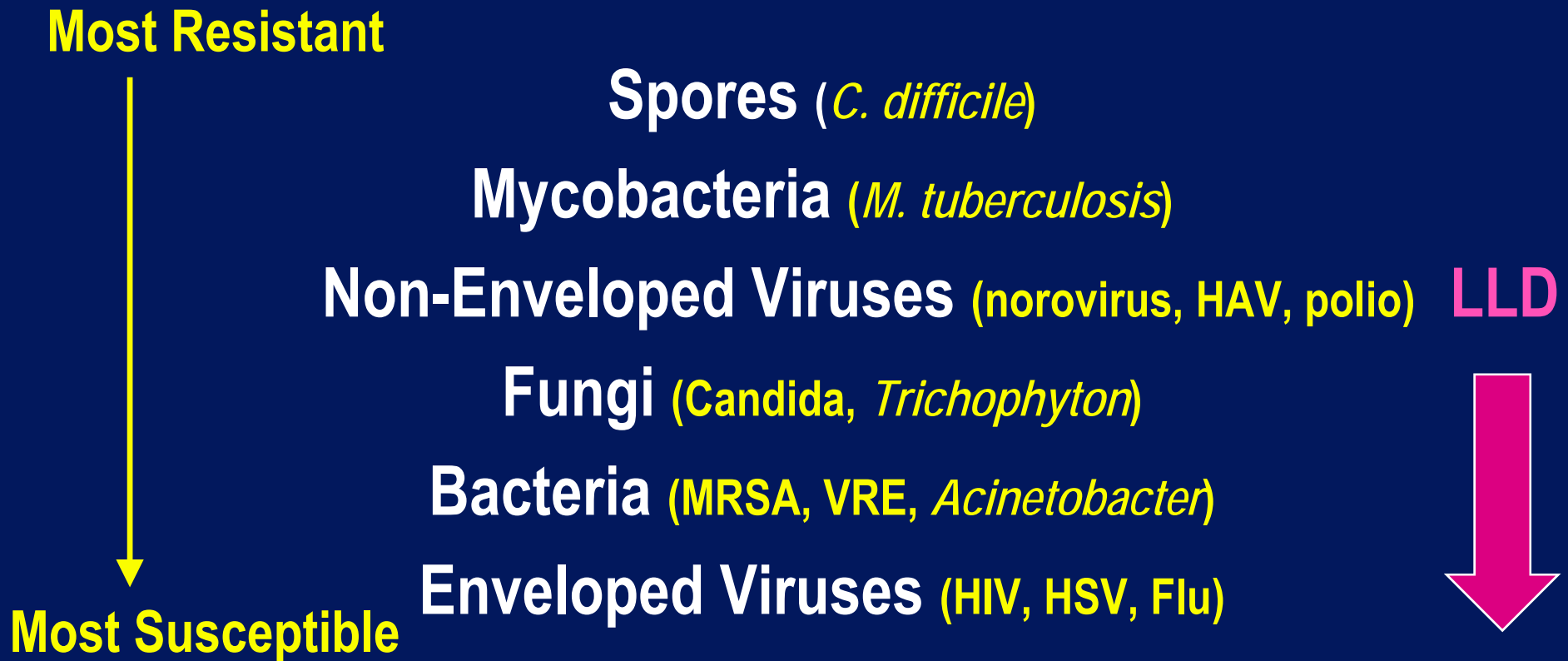
Exposure time  $\geq$  1 min

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)

# Microbiological Disinfectant Hierarchy

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





# EFFECTIVENESS OF DISINFECTANTS AGAINST MRSA AND VRE

Rutala WA, et al. *Infect Control Hosp Epidemiol* 2000;21:33-38

TABLE 2  
DISINFECTANT ACTIVITY AGAINST ANTIBIOTIC-SUSCEPTIBLE AND ANTIBIOTIC-RESISTANT BACTERIA

Product	Log <sub>10</sub> Reductions							
	VSE		VRE		MSSA		MRSA	
	0.5 min	5 min	0.5 min	5 min	0.5 min	5 min	0.5 min	5 min
Vesphene IIse	>4.3	>4.3	>4.8	>4.8	>5.1	>5.1	>4.6	>4.6
Clorox	>5.4	>5.4	>4.9	>4.9	>5.0	>5.0	>4.6	>4.6
Lysol Disinfectant	>4.3	>4.3	>4.8	>4.8	>5.1	>5.1	>4.6	>4.6
Lysol Antibacterial	>5.5	>5.5	>5.5	>5.5	>5.1	>5.1	>4.6	>4.6
Vinegar	0.1	5.3	1.0	3.7	+1.1	+0.9	+0.6	2.3

Abbreviations: MRSA, methicillin-resistant *Staphylococcus aureus*; MSSA, methicillin-susceptible *S aureus*; VRE, vancomycin-resistant *Enterococcus*; VSE, vancomycin-susceptible *Enterococcus*. Data represent mean of two trials (n=2). Values preceded by ">" represent the limit of detection of the assay. Assays were conducted at a temperature of 20°C and a relative humidity of 45%. Results were calculated as the log of Nd/No, where Nd is the titer of bacteria surviving after exposure and No is the titer of the control.

# Surface Disinfection: Treatment Time (Wipes/Sprays) versus Contact Time (Liquids)

Rutala, Weber. ICHE 2018;39

INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY MARCH 2018, VOL. 39, NO. 3

COMMENTARY

## Surface Disinfection: Treatment Time (Wipes and Sprays) Versus Contact Time (Liquids)

William A. Rutala, PhD, MPH;<sup>1</sup> David J. Weber, MD, MPH<sup>1,2</sup>

(See the article by Rutala W, Weber DJ, Selection of the ideal disinfectant. *Infect Control Hosp Epidemiol* 2014;35:855–865.)

In 2014, we published a paper on the “Selection of the Ideal Disinfectants.”<sup>1</sup> Disinfectant selection (ie, disinfectant product) is 1 of 2 essential components for effective disinfection. The other component, the practice, is the thorough application of the disinfectant such that the disinfectant contacts all contaminated surfaces. This practice should include proper training of hospital staff, especially environmental services and nursing staff, and adherence to the manufacturer’s label instructions. The combi-

The EPA position is this: “By law, all applicable label instructions on EPA-registered products must be followed. If the user selects exposure conditions that differ from those on the EPA-registered product label, the user assumes liability from any injuries resulting from off-label use and is potentially subject to enforcement action under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).”<sup>1,3</sup> According to this position, contact or kill times for the organisms listed on the label must be followed. Currently, EPA-registered disinfectants are available with contact times of 1–4 minutes against most

The term “wetness” is controversial. Based on EPA test, treatment time is the kill time and includes a wet time via wiping as well as the undisturbed time. Duration of wet time is not relevant.

# Risk Assessment Worksheet

Justifies to TJC/CMS Off-Label Use for Surface Disinfection

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

## Risk-Assessment Worksheet

Issue: Off-label use for undisturbed time after environmental disinfection

Assessment Date: March 5, 2018

Scoring: Low = 1      Moderate = 3      High = 5

Team Members:

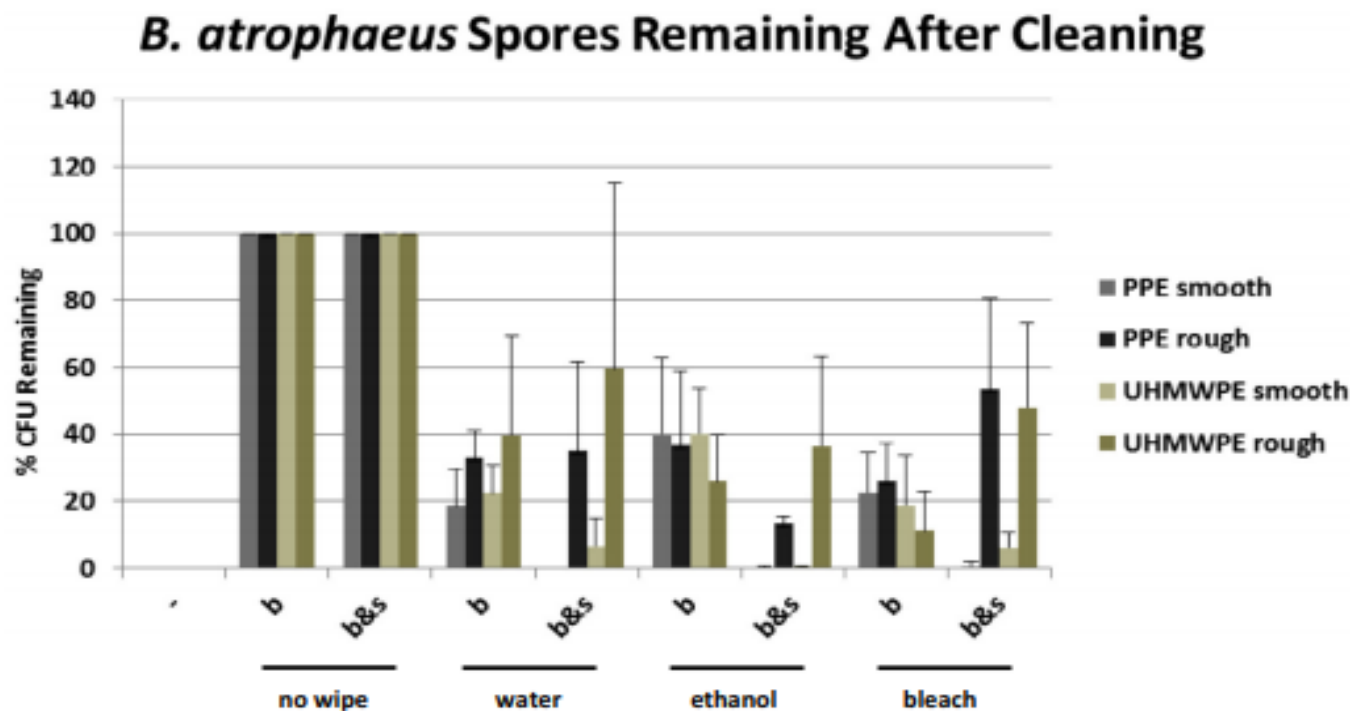
Meeting Actions: Team members evaluated the evidence and determined that off-label use of undisturbed time was sufficient to disinfect noncritical environmental surfaces and noncritical patient care equipment in a healthcare environment.

Suggested Questions	Benefit	Risk
What is the truth about disinfectant contact time?	Most manufacturers suggest the user maintain wetness for the duration of the contact time. The method used to assess efficacy of disinfectant wipes by the EPA is the Disinfectant Towelette Test. The procedure involves using one towelette to wipe ten carriers/slides. The area of the towelette used for wiping is folded and rotated so as to expose a new surface of the towelette for each carrier. To generate test cultures, carriers are inoculated using pathogens <i>Staphylococcus aureus</i> , <i>Pseudomonas aeruginosa</i> , and <i>Salmonella enteric</i> . The test procedure involves wiping the slide back and forth for a total of six passes across the inocula for ±5 seconds of	There is no risk to utilizing a treatment time instead of a wet time for the given contact time of a disinfectant. Score = 1

# Cleanability: Effects of Material, Surface Roughness and Presence of Blood and Bacteria on Devices

Gonzalez et al. AJIC 2017;45:194-6

Surface roughness can play a role in cleanability and bacteria and soil can adhere differently-significance?



**Fig 1.** Polypropylene (PPE) and ultra-high-molecular-weight polyethylene (UHMWPE) smooth and rough coupons were spotted with *Bacillus atrophaeus* spores alone or spores with blood test soil. Coupons were not cleaned or cleaned with gauze soaked in water, ethanol, or bleach. The data were normalized to the positive (no wipe) controls, which were set as 100%. b, bacteria; b&s, bacteria plus soil.

Rectangular Snip

**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)

# Disinfection of Noncritical Surfaces Bundle

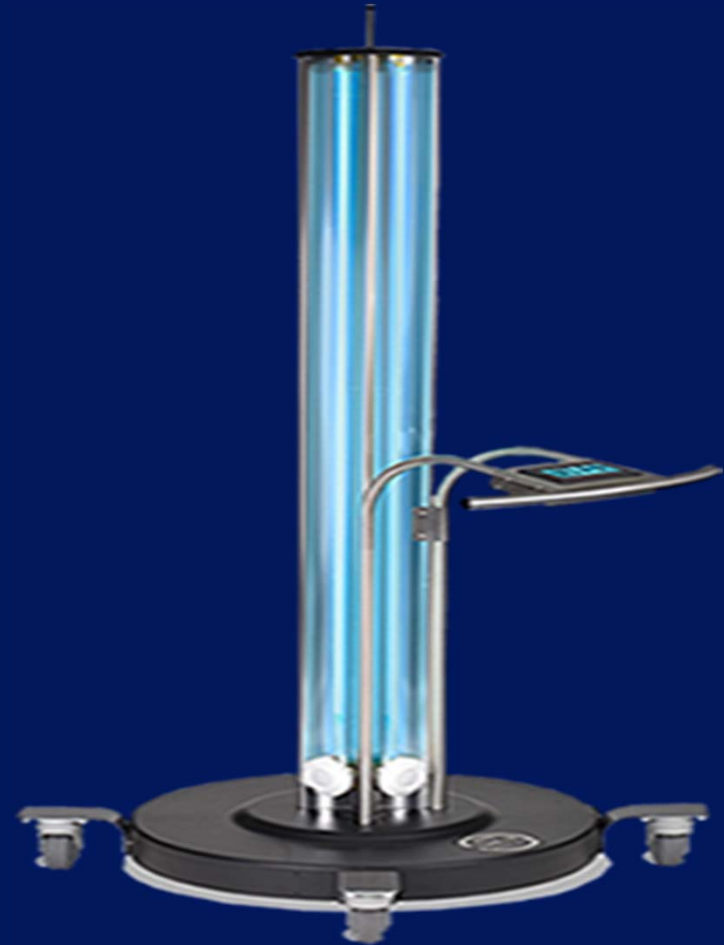
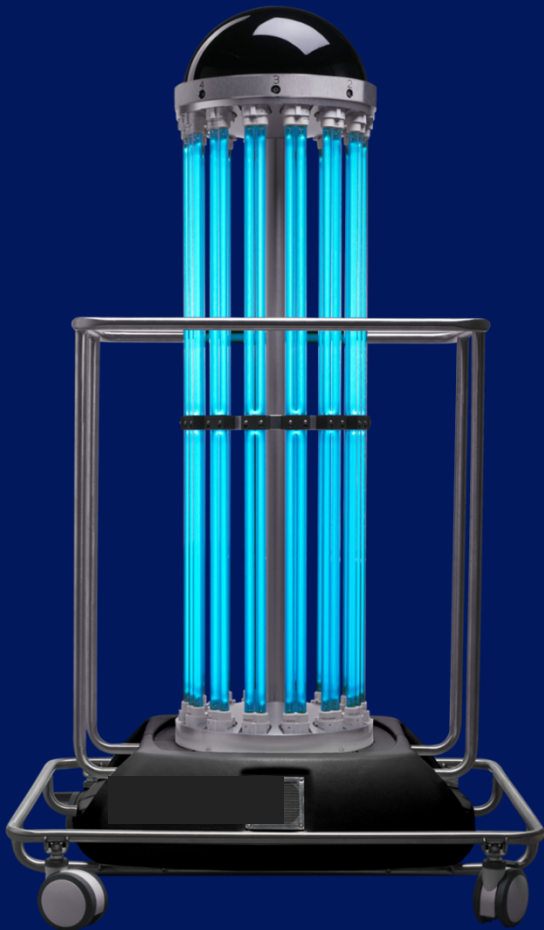
NL Havill AJIC 2013;41:S26-30

- 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

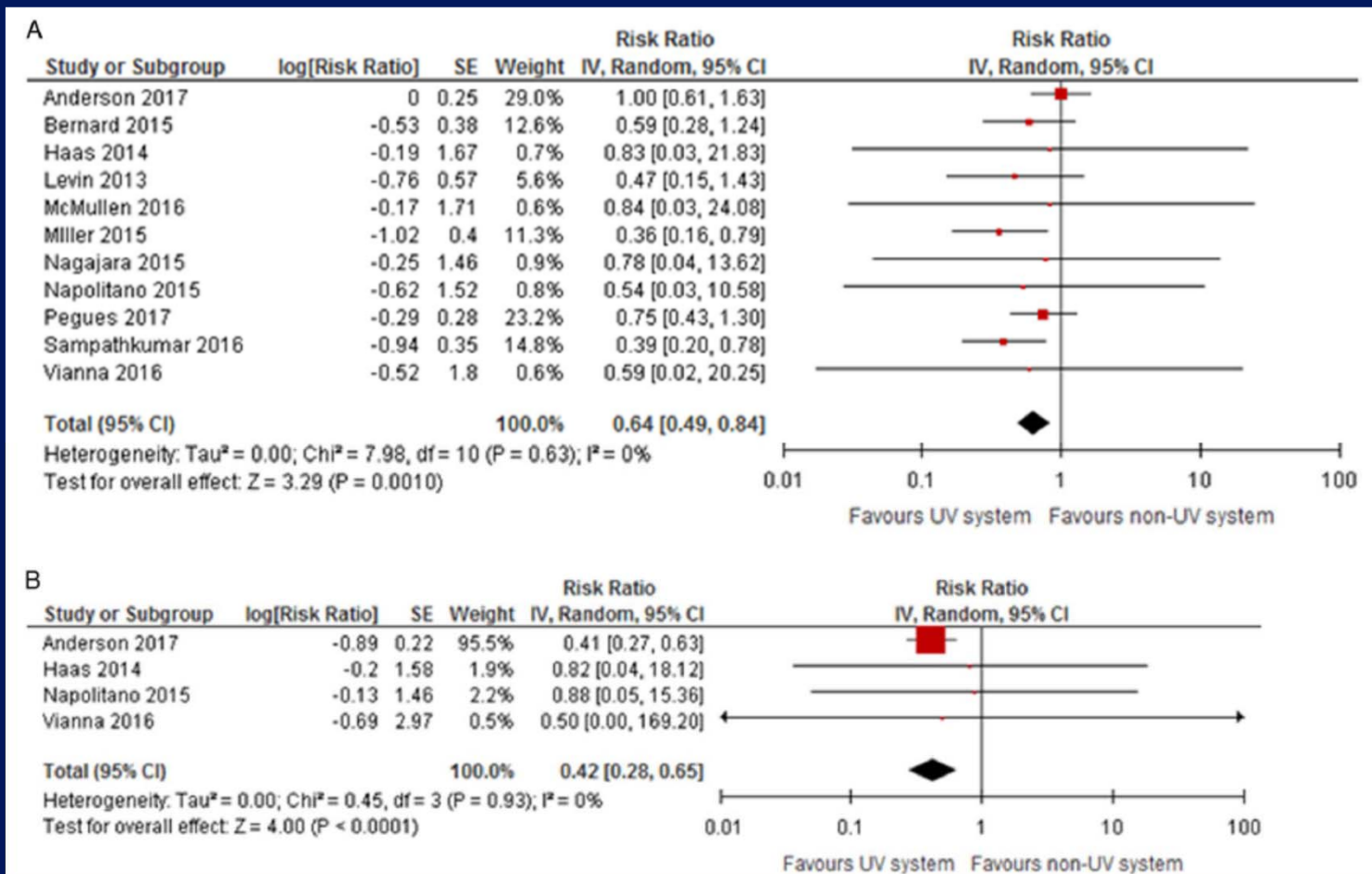
(UV/VHP~20 microbicidal studies, 12 HAI reduction studies; will not discuss technology with limited data)

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.



# EFFICACY OF UVC AT TERMINAL DISINFECTION TO REDUCE HAIs (A = *C. difficile*, B = VRE; UV effective in preventing VRE and *C. difficile*)

Marra AR, et al. ICHE 2018;39:20-31





# 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 In press.

	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.

# RELATIONSHIP BETWEEN MICROBIAL BURDEN AND HAIs

Salgado CD, et al. ICHE 2013;34:479-86

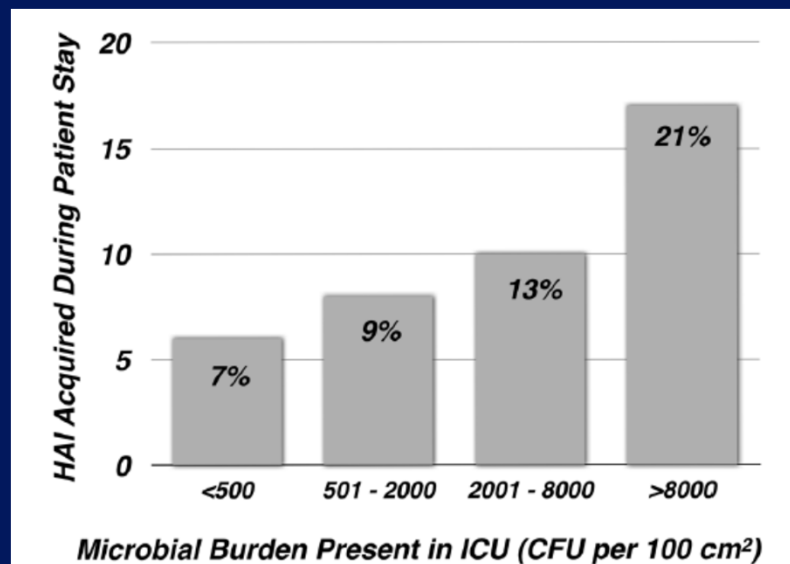


FIGURE 2. Quartile distribution of healthcare-acquired infections (HAIs) stratified by microbial burden measured in the intensive care unit (ICU) room during the patient's stay. There was a significant association between burden and HAI risk ( $P = .038$ ), with 89% of HAIs occurring among patients cared for in a room with a burden of more than 500 colony-forming units (CFUs)/100 cm<sup>2</sup>.

---

**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

# Disinfection and Sterilization: What's New Learning Outcomes

- 24m and 30m BI for HP sterilizers
- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes
- Perfuse channeled scopes
- HLD/sterilize laryngoscope
- Uncertain if OPA/glut kill HPV
- Develop a noncritical surface bundle including “no touch”
- **Touchable surfaces should be wiped and monitor cleaning**
- New continuous room decontamination technology
- CRE susceptible to germicides
- *C. auris* susceptible to most disinfectants but not antiseptics

---

---

# **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.**

# EVIDENCE THAT ALL TOUCHABLE ROOM SURFACES ARE EQUALLY CONTAMINATED

TABLE 1. Precleaning and Postcleaning Bacterial Load Measurements for High-, Medium-, and Low-Touch Surfaces

Surface (no. of samples)	Mean CFUs/RODAC (95% CI)	
	Precleaning	Postcleaning
High ( <i>n</i> = 40)	71.9 (46.5–97.3)	9.6 (3.8–15.4)
Medium ( <i>n</i> = 42)	44.2 (28.1–60.2)	9.3 (1.2–17.5)
Low ( <i>n</i> = 37)	56.7 (34.2–79.2)	5.7 (2.01–9.4)

NOTE. CFU, colony-forming unit; CI, confidence interval.

Huslage K, Rutala W, Gergen M, Sickbert-Bennett S, Weber D  
**ICHE 2013;34:211-2**

Number of culture sites and prevalence of contamination with nosocomial pathogens in intensive care units (N=523)

Ward	Culture sites <sup>a</sup>			
	HCWs' hands	Surfaces distant from patients	Surfaces close to patients	Prevalence of contamination
A	3/10 (30%)	0/22 (0%)	6/25 (24.0%)	9/57 (15.8%)
B	2/9 (22.2%)	4/19 (21.1%)	5/48 (10.4%)	11/76 (14.5%)
C	2/10 (20%)	2/26 (7.7%)	7/49 (14.3%)	11/85 (12.9%)
D	1/9 (11.1%)	2/24 (8.2%)	7/45 (15.6%)	10/78 (12.8%)
E	0/5 (0%)	4/22 (18.2%)	3/30 (10%)	7/57 (12.3%)
F	1/10 (10%)	0/11 (0%)	4/31 (12.9%)	5/52 (9.6%)
G	0/3 (0%)	2/14 (14.3%)	0/20 (0%)	2/37 (5.4%)
H	1/10 (10%)	0/16 (0%)	1/55 (1.8%)	2/81 (2.5%)
Total	10/66 (15.2%)	14/154 (9.1%)	33/303 (10.9%)	57/523 (10.9%)

HCW, healthcare worker.

<sup>a</sup> Number of contaminated samples/number of samples obtained.

Willi I, Mayre A, Kreidl P, et al.  
**JHI 2018;98:90-95**

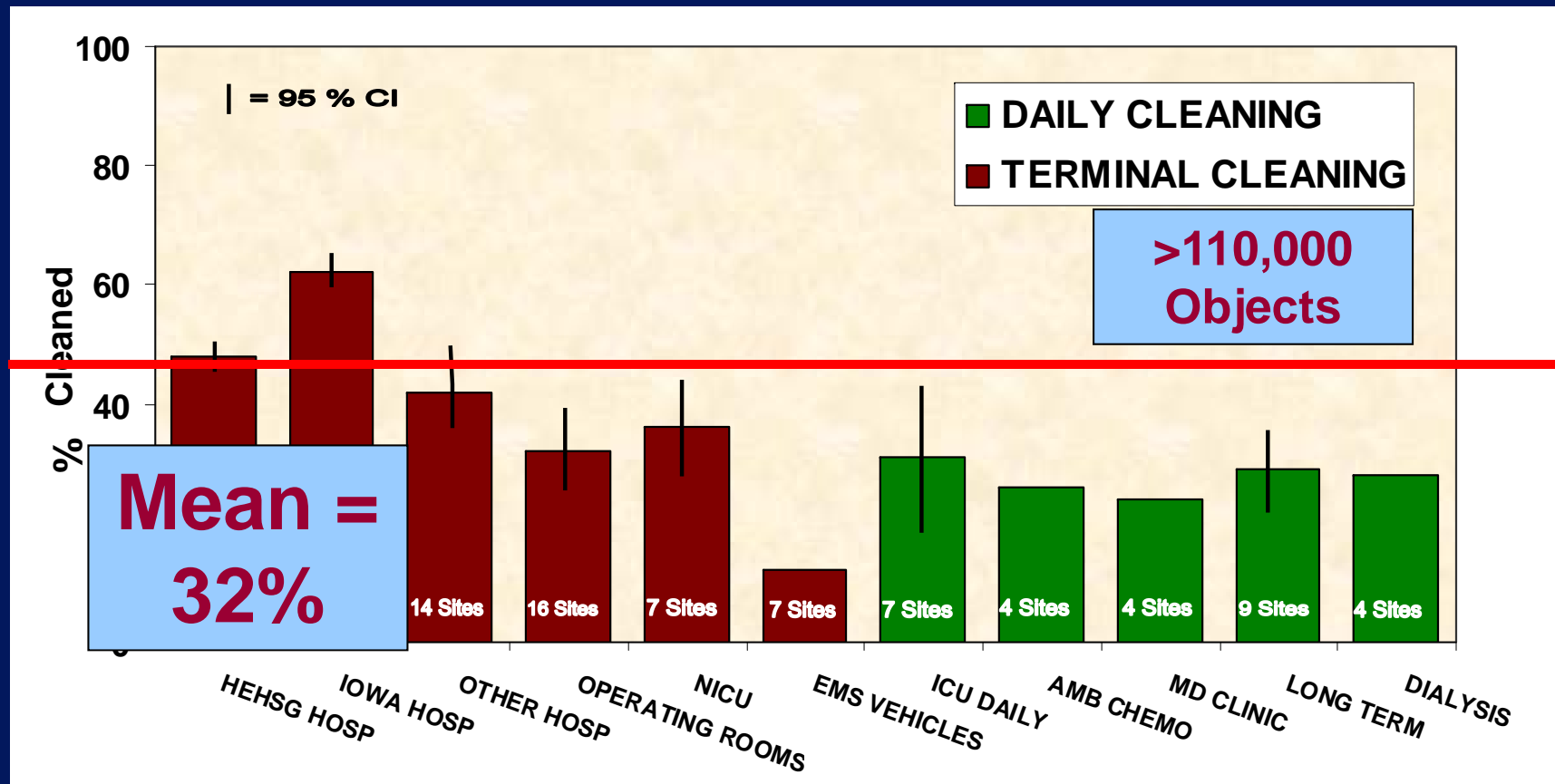
# Effective Surface Decontamination

Product and **Practice** = Perfection



# Thoroughness of Environmental Cleaning

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



# Thoroughness of Environmental Cleaning

Carling and Herwaldt. Infect Control Hosp Epidemiol 2017;38:960–965

Hospitals can improve their thoroughness of terminal room disinfection through fluorescent monitoring

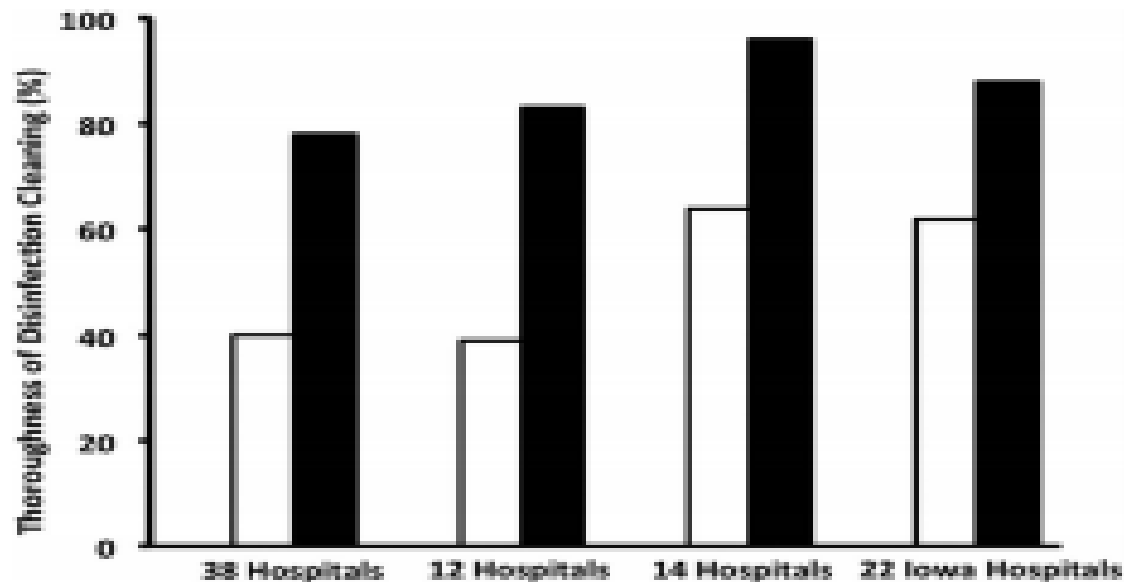


FIGURE 4. A comparison of the results of the 3 previously published multisite studies compared with results from the Iowa project. White bars represent the average baseline TDCs and black bars represent the average final TDCs for sites that completed each study.

# MONITORING THE EFFECTIVENESS OF CLEANING

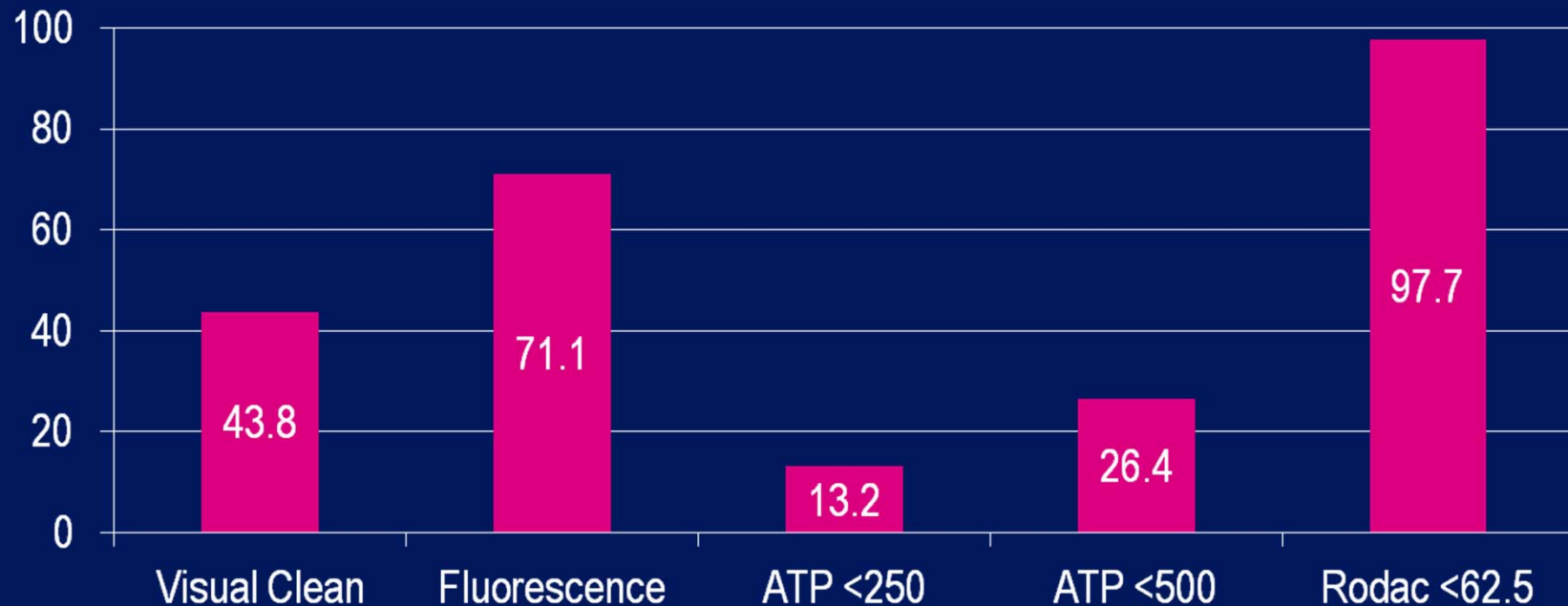
Cooper et al. AJIC 2007;35:338

- 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)

# Percentage of Surfaces Clean by Different Measurement Methods

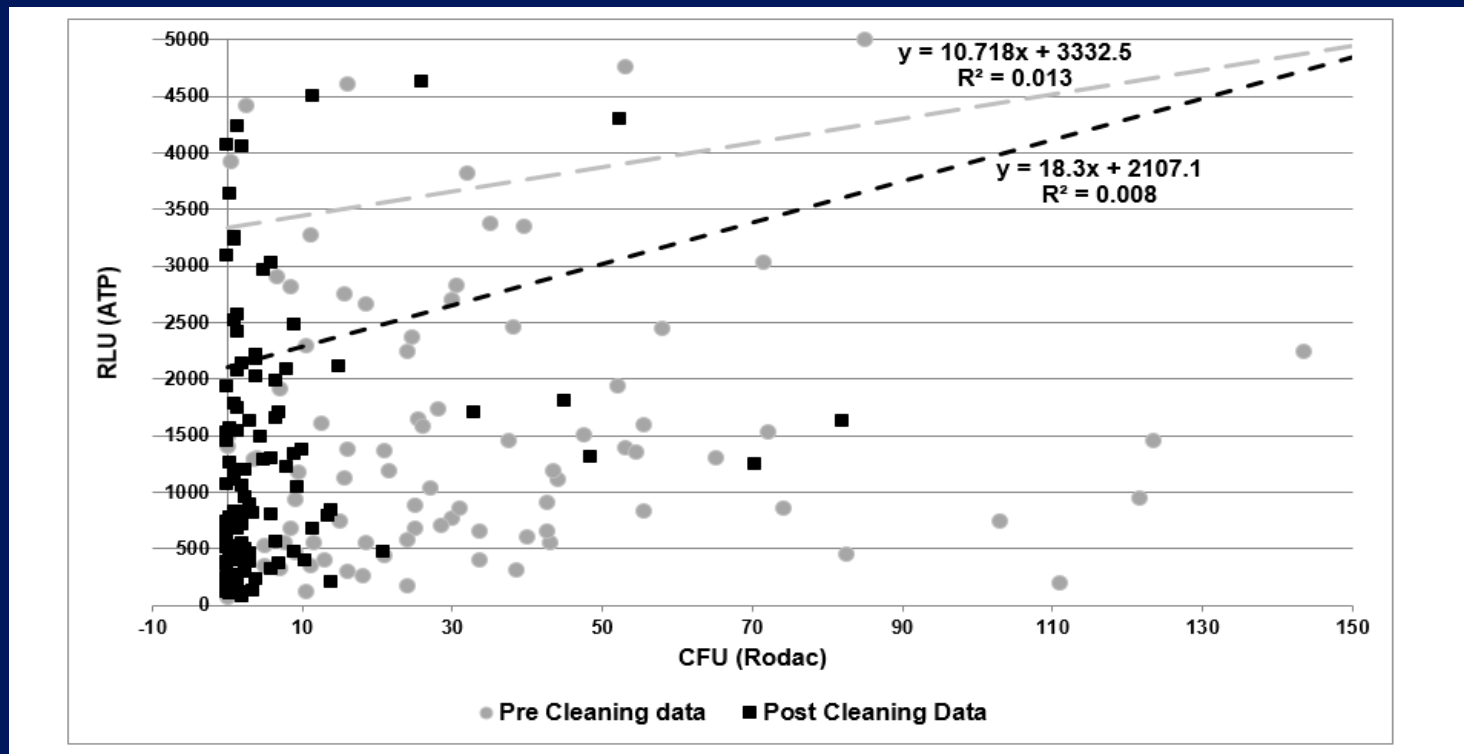
Rutala, Kanamori, Gergen, Sickbert-Bennett, Huslage, Weber. APIC 2017.

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 RLUs) 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.

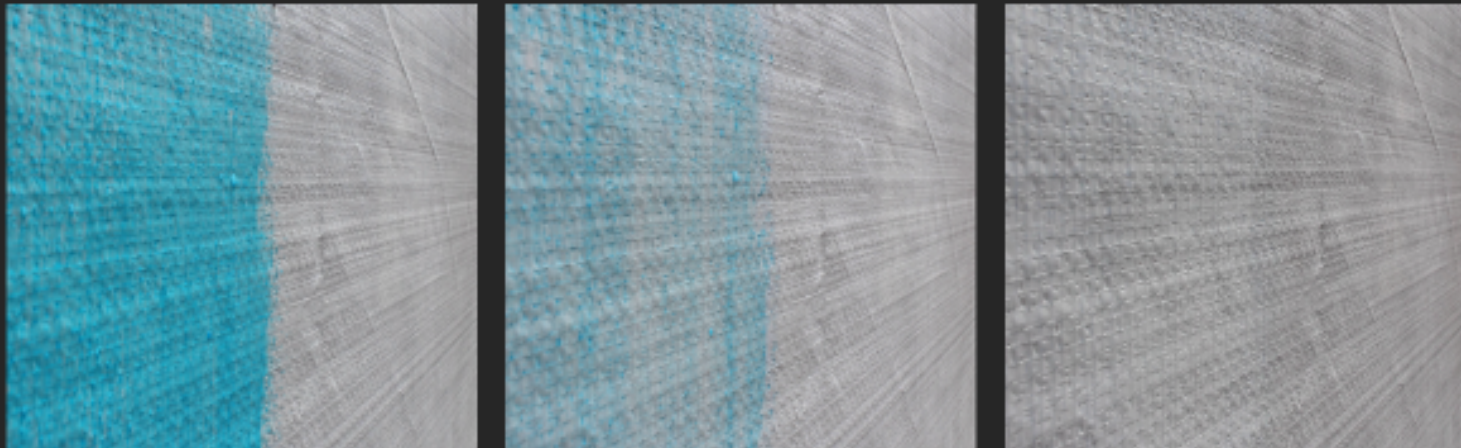
---

# **Future Methods to Ensure Thoroughness**

# Future May Have Methods to Ensure Thoroughness Such as Colorized Disinfectant

Kang et al. J Hosp Infect 2017

## Colorized disinfection – contact time compliance



0 min

2 min

4 min

- Color-fading time matched to disinfectant contact time --> enforces compliance
- Provides real-time feedback when disinfection is complete
- Trains staff on importance of contact time as they use the product

# Colorized disinfection – improved coverage

Regular disinfectant wipes



Colorized wipes



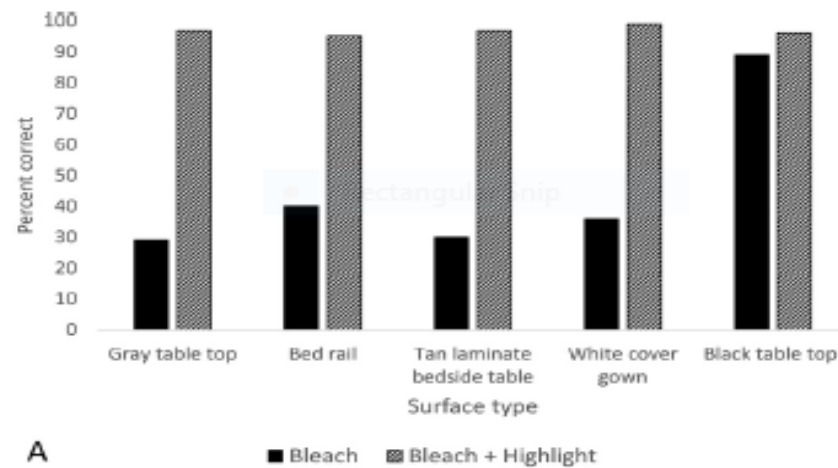
- Increased visibility when disinfecting surfaces, fewer missed spots
- Real-time quality control that allows staff to monitor thoroughness of cleaning



# Novel Chemical Additive That Colorizes Disinfectant to Improve Visualization of Surface Coverage

Mustapha et al . AJIC; 2018:48:191-121

By improving thoroughness will it reduce microbial contamination and reduce transmission?



A

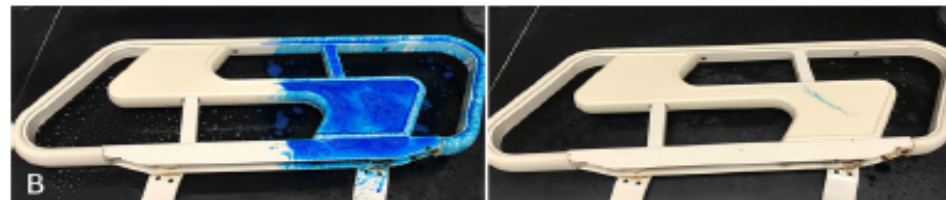
■ Bleach ■ Bleach + Highlight

At Application

5 Minutes After Application

Bleach Bleach + Highlight

Bleach Bleach + Highlight



B

Fig 1. (A) Percentage of sites correctly identified by personnel as having or not having bleach application when testing occurred within 30 seconds of application based on whether Highlight solution (Kinnos Inc, Brooklyn, NY) was added to colorize the bleach solution. (B) Image of a bed rail with application of bleach-plus-Highlight.

# Disinfection and Sterilization: What's New Learning Outcomes

- 24m and 30m BI for HP sterilizers
- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes
- Perfuse channeled scopes
- HLD/sterilize laryngoscope
- Uncertain if OPA/glut kill HPV
- Develop a noncritical surface bundle including “no touch”
- Touchable surfaces should be wiped and monitor cleaning
- **New continuous room decontamination technology**
- CRE susceptible to germicides
- *C. auris* susceptible to most disinfectants but not antiseptics



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

# Visible Light Disinfection in a Patient Room

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



White light  $\sim 0.12 \text{ mW/cm}^2$ - $0.16 \text{ mW/cm}^2$



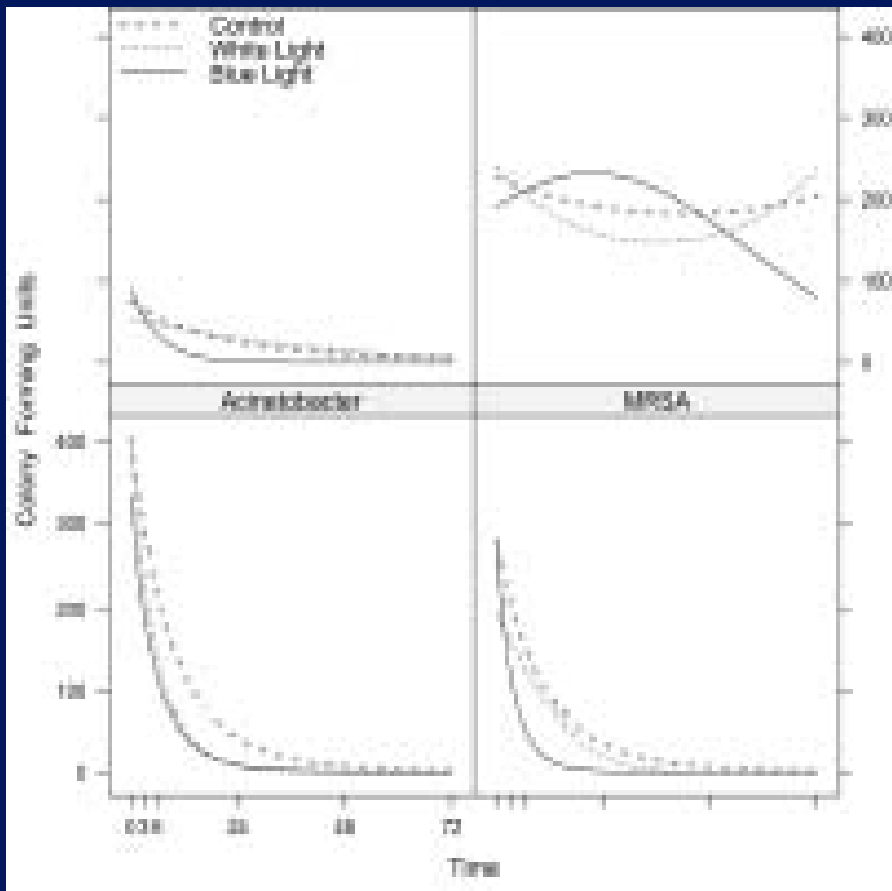
Blue light  $\sim 0.34$ - $0.44 \text{ mW/cm}^2$ ; increase kill, increase irradiance

# Antimicrobial Activity of a Continuous Visible Light Disinfection System

- **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

# 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

Time to specified percent reductions of epidemiologically-important pathogens with “blue” light and “white” light.

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



# Efficacy of UV-A Light System

Livingston, et al, SHEA Poster 2018

Figure 1. Reduction of organisms exposed to 3 W/m<sup>2</sup> of UV-A

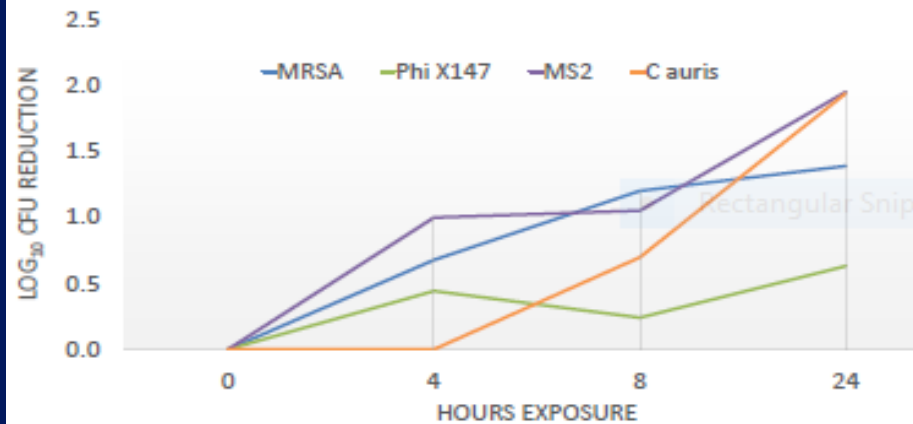
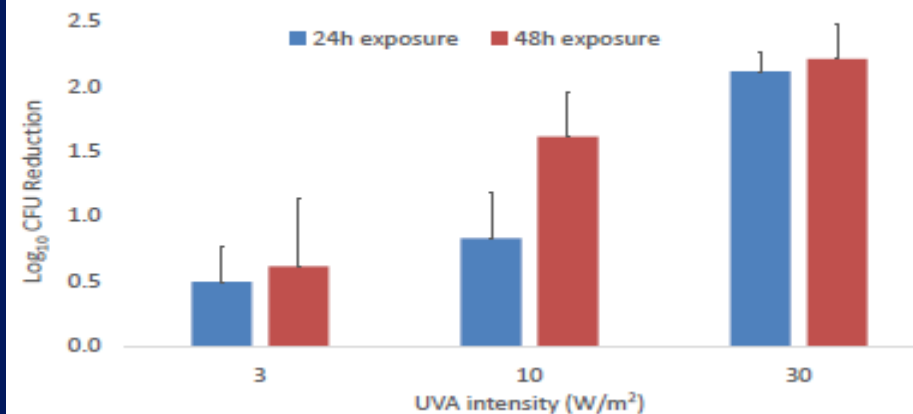


Figure 2. Reduction of *C. difficile* spores exposed to variable intensities of UV-A



- UV-A (315-400nm) proposed as a safe method to provide continuous disinfection of surfaces while patients and staff are in the room
- At 3W/m<sup>2</sup> of UV-A light was effective in reducing MRSA, *E. coli* and MS2 (1-2 log<sub>10</sub> reduction in 24h)
- At higher intensities (10, 30 W/m<sup>2</sup>), UV-A also effective against *C. difficile* spores

# SURFACE DISINFECTANTS: PERSISTENCE

Rutala WA et al. ICHE 2006;27:372-77

Surface disinfectant	Persistence
Phenolic	No
Quaternary ammonium compound	Yes (undisturbed)
Alcohol	No
Hypochlorite	No
Hydrogen peroxide	No
Silver	Yes

# Evaluation of A Persistent Surface Disinfectant Method

- Evaluation use the EPA “Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residuals on Hard, Non-Porous Surfaces”
- Surfaces-glass, formica and SS
- Organisms- *S. aureus*, CRE and *C. auris*

# Evaluation of A Persistent Surface Disinfectant Method



- Test method involves “wear” and re-inoculation of the test and control surfaces after
- Tester set to 5s for one pass
- Surface will undergo wear and re-inoculations over 24h
- Initial inoculation ( $10^5$ ), apply disinfectant (dry overnight); 6 re-inoculations ( $10^3$ , 30m dry), last inoculation ( $10^6$ )
- 24 passes (6 dry, 6 wet cycles )

# EFFICACY OF A PERSISTENT CHEMICAL DISINFECTANT

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

- Methods: Surfaces were inoculated, treated with the novel disinfectant, allowed to dry, and then abraded using a standardized abrasion machine under multiple alternating wet and dry wipe conditions (N=12) interspersed with 6 re-inoculations. After 24 hours, the surface was re-inoculated a final time and ability of the disinfectant to kill >99.9% of 9 test microbes within 5min was measured on test surfaces (glass).
- **Persistent disinfectants may reduce or eliminate the problem of recontamination. Preliminary studies with a new persistent disinfectant are promising (4- 5 log<sub>10</sub> reduction in 5m over 24h).** When the novel disinfectant was compared to three other commonly used disinfectants using the same methodology with *S. aureus*, the mean log<sub>10</sub> reductions were: 4.4 (novel disinfectant); 0.9 (quat-alcohol); 0.2 (improved hydrogen peroxide); and 0.1 (chlorine).

Test Pathogen	Mean Log <sub>10</sub> Reduction, 95% CI n=4
<i>S.aureus</i> *	4.4 (3.9, 5.0)
<i>S.aureus</i> (formica)	4.1 (3.8, 4.4)
<i>S.aureus</i> (stainless steel)	5.5 (5.2, 5.9)
VRE	≥4.5
<i>E.coli</i>	4.8 (4.6, 5.0)
<i>Enterobacter sp.</i>	4.1 (3.5, 4.6)
<i>Candida auris</i>	≥5.0
<i>K pneumoniae</i>	1.5 (1.4, 1.6)
CRE <i>E.coli</i>	3.0 (2.6, 3.4)
CRE <i>Enterobacter</i>	2.0 (1.6, 2.4)
CRE <i>K pneumoniae</i>	2.1 (1.8, 2.4)

# Disinfection and Sterilization: What's New

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

- Current Issues and New Technologies
  - Sterilization of critical items
    - ◆ Biological indicators, clarified Spaulding
  - High-level disinfection for semi-critical items
    - ◆ Outbreaks with semicritical devices, endoscope reprocessing issues (duodenoscopes-lever position), channeled endoscopes, HPV risks/studies
  - Low-level disinfection of non-critical items
    - ◆ Noncritical surface disinfection bundle, “wet” time, “no touch” technology, new technology (monitoring cleaning, continuous room decontamination)
  - Emerging Pathogens
    - ◆ Inactivation data- *Candida auris*, CRE-carbapenem-resistant *Enterobacteriaceae*

# Disinfection and Sterilization: What's New Learning Outcomes

- 24m and 30m BI for HP sterilizers
- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes
- Perfuse channeled scopes
- HLD/sterilize laryngoscope
- Uncertain if OPA/glut kill HPV
- Develop a noncritical surface bundle including “no touch”
- Touchable surfaces should be wiped and monitor cleaning
- New continuous room decontamination technology
- **CRE susceptible to germicides**
- *C. auris* susceptible to most disinfectants but not antiseptics

# 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. In press

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



# Disinfection and Sterilization: What's New Learning Outcomes

- 24m and 30m BI for HP sterilizers
- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes
- Perfuse channeled scopes
- HLD/sterilize laryngoscope
- Uncertain if OPA/glut kill HPV
- Develop a noncritical surface bundle including “no touch”
- Touchable surfaces should be wiped and monitor cleaning
- New continuous room decontamination technology
- CRE susceptible to germicides
- *C. auris* susceptible to most disinfectants but not antiseptics

# 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 ID Week Poster

- $\geq 3 \log_{10}$  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%

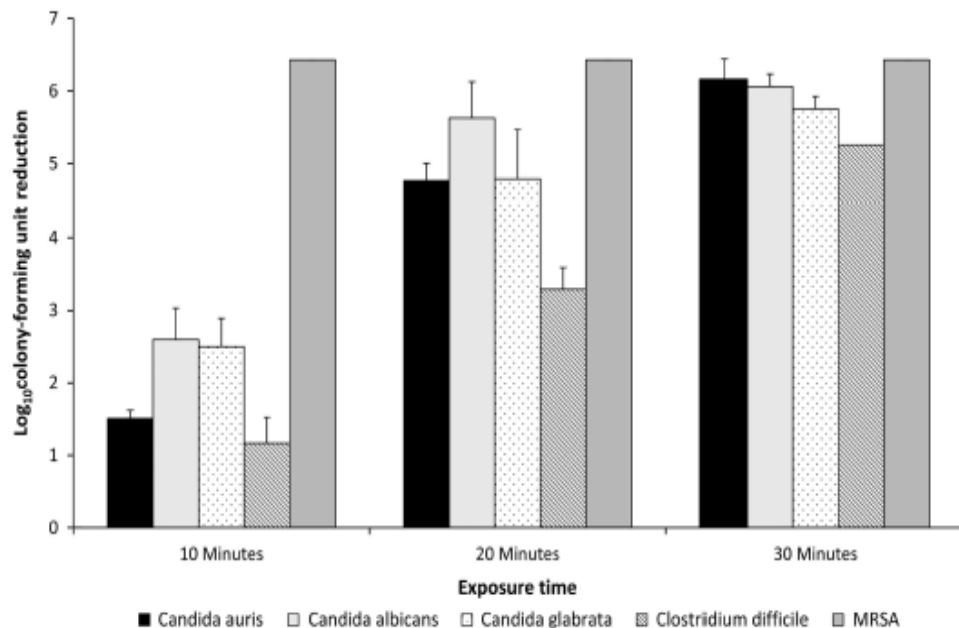
# Efficacy of Disinfectants and Antiseptics against *Candida auris*

Rutala, Kanamori, Gergen, Sickbert-Bennett, Weber, 2017 ID Week Poster

- $\leq 3 \log_{10}$  (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

# Effect of UV-C on Reduction *C. auris* and Other Pathogens

Cadnum et al. ICHE 2017

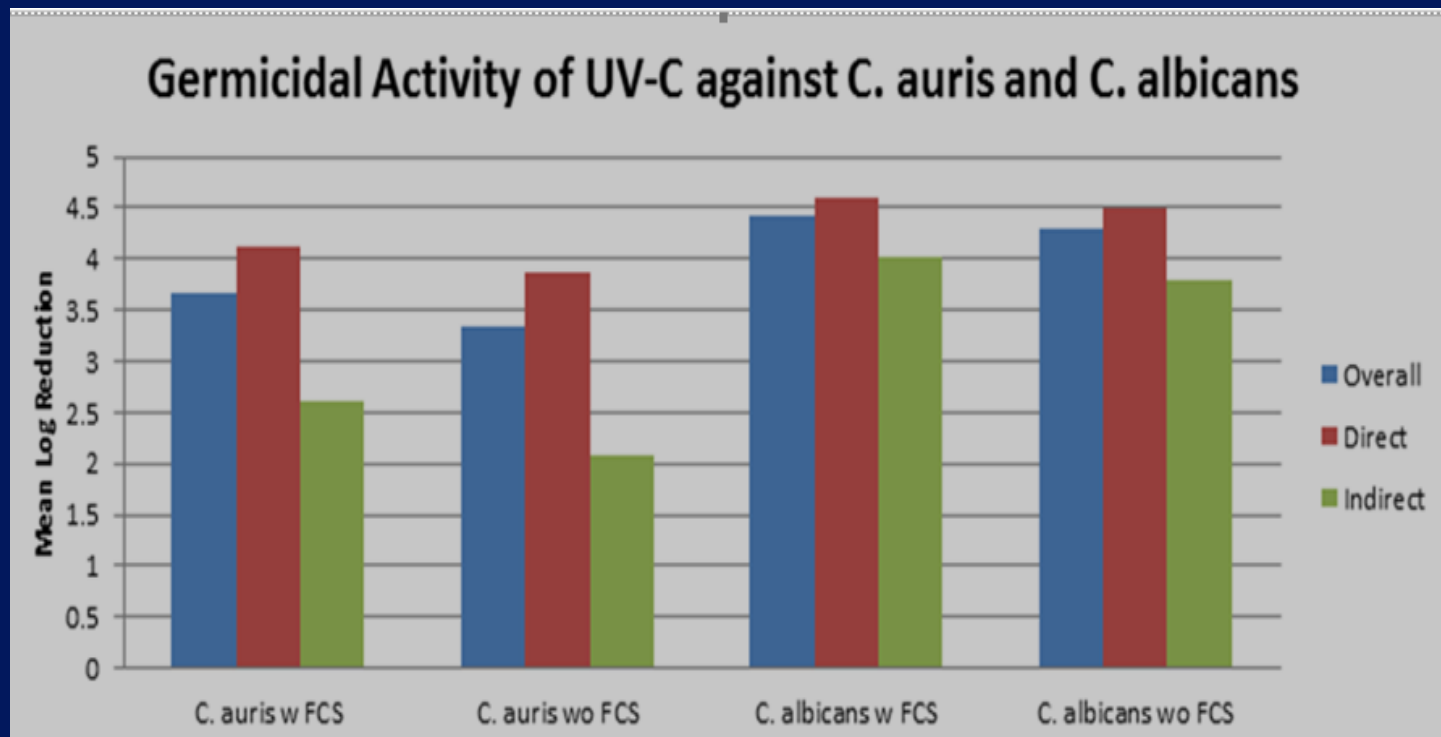


- Multidrug-resistant *Candida auris* and two other *Candida* species were significantly less susceptible to killing by UV-C than MRSA
- UV-C could be useful as an adjunct to standard cleaning/disinfection
- These results suggest longer cycle times may be beneficial (per *C. difficile*)

Inoculum spread to cover 20mm diameter steel disk, disk placed 5 feet from UV device

# 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

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

- Current Issues and New Technologies
  - Sterilization of critical items
    - ◆ Biological indicators, clarified Spaulding
  - High-level disinfection for semi-critical items
    - ◆ Outbreaks with semicritical devices, endoscope reprocessing issues (duodenoscopes-lever position), channeled endoscopes, HPV risks/studies
  - Low-level disinfection of non-critical items
    - ◆ Noncritical surface disinfection bundle, “wet” time, “no touch” technology, new technology (monitoring cleaning, continuous room decontamination)
  - Emerging Pathogens
    - ◆ Inactivation data- *Candida auris*, CRE-carbapenem-resistant *Enterobacteriaceae*

# Disinfection and Sterilization: What's New Learning Outcomes

- 24m and 30m BI for HP sterilizers
- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes (reprocessing issues: lever 45°, non-compliance, irregularities like scratches, fluid)
- Perfuse channeled scopes
- Uncertain if OPA/glut kill HPV
- Develop a noncritical surface bundle including “no touch”
- Touchable surfaces should be wiped and monitor cleaning
- New continuous room decontamination technology
- CRE susceptible to germicides
- *C. auris* susceptible to most disinfectants but not antiseptics



# Disinfection and Sterilization: What's New

- New D/S technologies (“no touch”, BIs, persistent disinfectant) 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 narrow margin of safety and manufacturers should be encouraged to develop practical sterilization technology.
- 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)





---

# Effective Surface Decontamination

**Product** and Practice = Perfection

# 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**

# Disinfection of Noncritical Surfaces Bundle

- Develop policies and procedures
  - Environmental cleaning and disinfection is an integral part of preventing transmission of pathogens
  - In addition to identifying products and procedures, **ensure standardization of cleaning throughout the hospital**
    - ◆ Some units utilize ES to clean pieces of equipment (e.g., vital sign machines, IV pumps); some units use patient equipment, and some units utilize nursing staff.
    - ◆ Multidisciplinary group to create a standardized plan for cleaning patient rooms and pieces of patient equipment throughout the hospital

# Health Care Facilities Need to Immediately Medical Device Reprocessing Procedures

- Reprocessing lapses resulting in patient infections and exposures
- Healthcare facilities urged to immediately review current reprocessing practices to ensure comply with device manufacturer and guidelines
  - Training (upon hire and at least annually), demonstrate and document competency
  - Audit should assess all reprocessing steps including cleaning, disinfectants (conc, contact time), sterilizer (chemical, biological indicators). Feedback from audits to personnel regarding adherence.