Disinfection and Sterilization
Current Issues, New Research and New Technology

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DISCLOSURES

2018-2019

- Consultations
  - ASP (Advanced Sterilization Products), PDI
- Honoraria
  - PDI, ASP, 3M
- Scientific Advisory Board
  - Kinnos
- Grants
  - CDC, CMS

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  - Sterilization of critical items
    - Biological indicators, clarified Spaulding, sterilizer robustness
  - High-level disinfection for semi-critical items
    - Outbreaks with semicritical devices, endoscope reprocessing issues (duodenoscopes-lever position), channeled endoscopes, HPV risks/studies, ultrasound probes
  - Low-level disinfection of non-critical items
    - Noncritical surface disinfection bundle, “wet” time, floors, biofilms, continuously active disinfectant, colored disinfectant, sporicide for all discharges
  - 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)

Goal

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

Medical/Surgical Devices

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

- EH Spaulding believed that how an object will be disinfected depended on the object's intended use (developed 1968).
- CRITICAL-medical/surgical devices which enter normally sterile tissue or the vascular system or through which blood flows should be sterile.
- SEMICRITICAL-medical devices that touch mucous membranes or skin that is not intact require a disinfection process (high-level disinfection [HLD]) that kills all microorganisms but high numbers of bacterial spores.
- NONCRITICAL-medical devices that touch only intact skin require low-level disinfection.

Critical Medical/Surgical Devices

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

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

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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

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GI Endoscopes: Shift from Disinfection to Sterilization

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

EDITORIAL

Gastrointestinal Endoscopes
A Need to Shift From Disinfection to Sterilization?

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

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

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

Related article page 1447

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

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

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

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 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.
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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%
AER	27.2%
Manual	39.3%
Age of endoscope <2 years	18.9%
Age of endoscope >2 years	38.8%

Visual Inspection of GI Endoscopes and Bronchoscopes

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

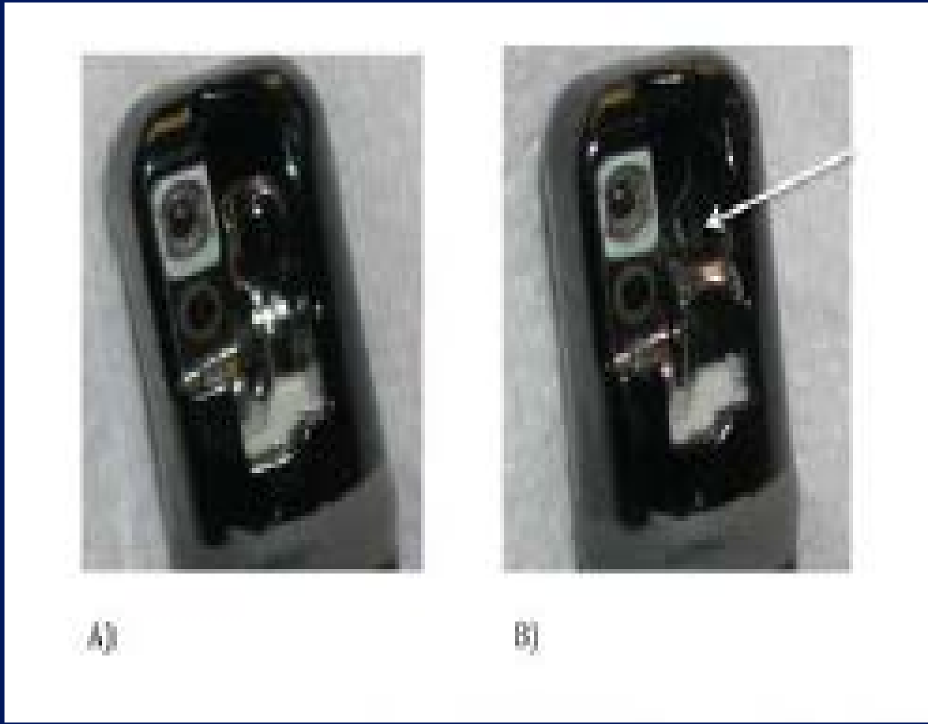
- All endoscopes (n=20) had visible irregularities (e.g., scratches)
- Researchers observed fluid (95%), discoloration, and debris in channels
- 60% scopes with microbial contamination

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



- Bacteria will survive if the elevator lever was improperly positioned (in horizontal position instead of 45^{o}) 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

Where are we?

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 (3 manufacturers)
- 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)

Potential Future Methods to Prevent Endoscope-Related Outbreaks

- Improved GI endoscope design (to reduce or eliminate reprocessing challenges-based on 50y of experience unlikely to resolve problem; closed channel duodenoscopes increased risk)
  - FDA recommends disposable end caps to reduce risk of infection associated with duodenoscopes. FDA cleared two duodenoscopes with disposable endcaps (Pentax and Fuji). August 2019

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DISINFECTION AND STERILIZATION

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Sterilization of “Critical Objects”

Steam sterilization

Hydrogen peroxide gas plasma

Ethylene oxide

Ozone and hydrogen peroxide

Vaporized hydrogen peroxide

Steam formaldehyde

STERILIZATION

Factors affecting the efficacy of sterilization

- Bioburden
- Cleaning
- Pathogen type
- Protein and salt
- Biofilm accumulation
- Lumen length and diameter
- Restricted flow

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Penicylinders Sterilized by Various Low-Temperature Sterilization Methods

Challenge:	12/88	100%ETO	HCFC-ETO	HPGP
10% Serum, 0.65% Salt (7 organisms, N=63)	97%	60.3%	95.2%	37%
No Serum or Salt, (3 organisms, N=27)	100%	100%	96%	100%

Alfa et al. Infect Cont Hosp Epidemiol 1996;17:92-100. The three organisms included: *E. faecalis*, *M. chelonei, B. subtilis* spores. The seven organisms included: *E. faecalis*, *P. aeruginosa, E.coli*, *M. chelonei, B. subtilis* spores, *B. stearothermophilus* spores, *B. circulans* spores

Comparative Evaluation of the Microbicidal Activities of Sterilization Technologies in the Presence of Salt and Serum

Study conditions not representative of practice or manufacturer's recommendations

Rutala et al. 2019

Organism	Steam	ETO	HPGP	VHP
Vegetative Cells-Pa, Ec, VRE, Sa, Mt	0% (0/140)	3% (6/220)	3% (5/180)	72% (129/180)
Spores-Ba, Gs, Cd	0% (0/80)	0% (0/90)	0% (0/90)	86% (77/90)
Overall Total	0% (0/220)	2% (6/310)	2% (5/270)	76% (206/270)

Comparative Evaluation of the Microbicidal Activity of Low-Temperature Sterilization Technologies to Steam Sterilization

Conclusions

- All LTST technologies have limitations
- LTST (ETO, HP gas plasma) demonstrate a significant number of failures in presence of serum or salt
- Salt and serum provide protection for spores and bacteria
- Steam sterilization is the most effective and had the largest margin of safety, followed by ETO and HPGP and lastly, VHP

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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, >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

High-Level Disinfection of "Semicritical Objects"

Exposure Time ≥ 8m-45m (US), 20ºC

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

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

Microbiological Disinfectant Hierarchy

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

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

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Infections/Outbreaks Associated with Semicritical Medical Devices

Rutala, Weber, AJIC 2019;47:A79-A89

Medical Device	No. Outbreaks/Infections	No. Outbreaks/Infections with Bloodborne Pathogens
Vaginal Probes	0	0
Ear-Nose-Throat Endoscopes	0	0
Urologic instruments (e.g. cystoscopes)	8	0
Hysteroscopes	0	0
Laryngoscopes	2	0
Transrectal ultrasound guided prostate	1	0
Applanation tonometers	2	0
TEE-Transesophageal echocardiogram	5	0
GI Endoscopes/Bronchoscopes	~130	3 (HBV-1 GI; HCV-2 GI; HIV-0)

Infections/Outbreaks Associated with Semicritical Medical Devices

Rutala, Weber. AJIC 2019;47:A79-A89

- HBV and HCV transmission during endoscopy and use of semicritical medical devices can occur, but it is rare
- Three 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

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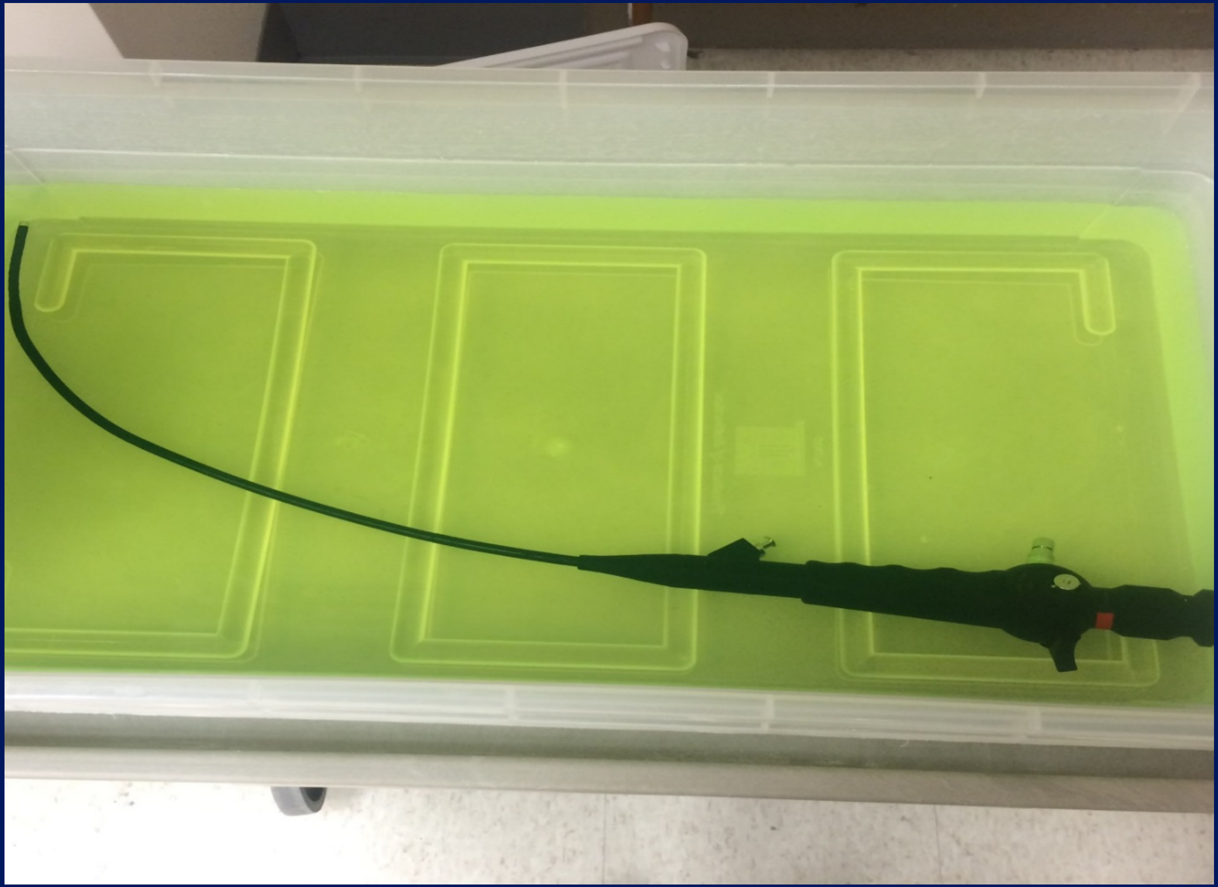
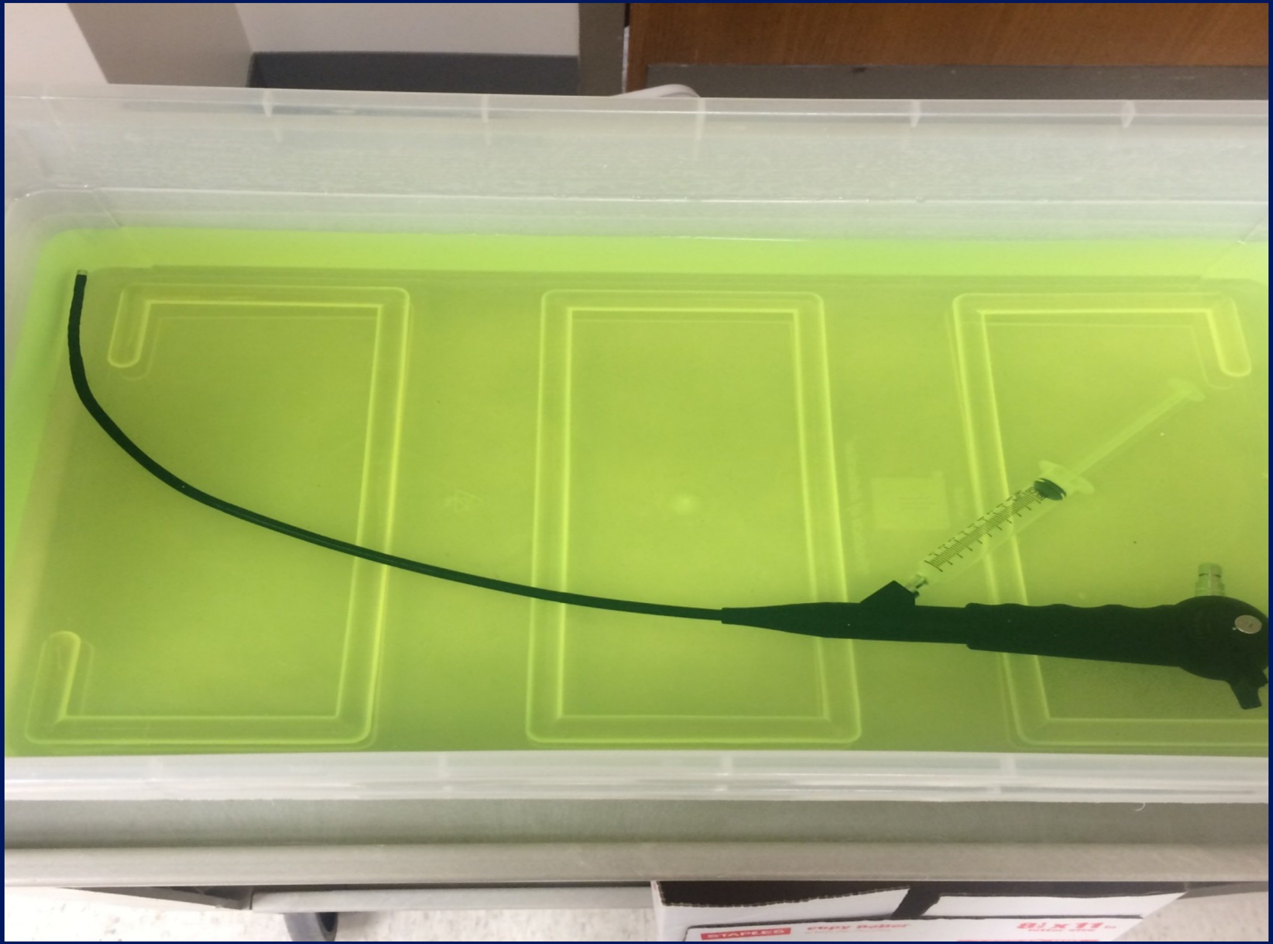
Reprocessing Channeled Endoscopes

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

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

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

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Rutala, Weber, AJIC 2019;47:A79-A89

A publication has interpreted CDC and AIUM recommendations differently than most hospitals (AJIC 2018:46:913-920): ultrasound guided CVC insertion (critical-sterilize or HLD with sterile sheath and sterile gel); scan across unhealthy skin (semicritical-HLD and use with clean sheath and clean gel)

Transducer Disinfection for Insertion of Peripheral and Central Catheters

Association of Vascular Access Guideline. June 2018; AIUM 2017

- “All transducers/probes used for peripheral VAD insertion will undergo, at a minimum, low-level disinfection….” Clean (step 1) the probe prior to disinfection (step 2).
- “During assessment, consider using a single-use condom or commercially manufactured transducer sheath (excluded: transparent dressing, gloves) during all use where there is the possibility of contact with blood/body fluids or non-intact skin”
- “Perform ALL ultrasound guided vascular access device insertions (PIV, Midline, PICC, CVC, arterial line) with the use of a sterile sheath and single-use sterile gel”.
  - After the procedure, the used sheath should be inspected for tears and the transducer inspected for potential compromise
  - Once inspected, the probe should be cleaned and then disinfected.

Transducer Disinfection for Insertion of Peripheral and Central Catheters

Association of Vascular Access (AVA) Guideline. June 2018; AIUM 2017; Rutala, Weber, AJIC 2019;47:A79-A89

- All clinicians involved in ultrasound guidance should undergo comprehensive training on disinfection of the US transducers
- The AVA recommendations are similar to guidelines from the American Institute for Ultrasound in Medicine (AIUM): that is, internal probes-HLD; "interventional percutaneous procedure probes that are used for percutaneous needle or catheter placement…should be cleaned using LLD and be used in conjunction with a single-use sterile probe cover", if probe cover compromised HLD the probe.

Transducer Disinfection for Insertion of Peripheral and Central Catheters

Comments

- Blood contamination of probe is infrequent
- Sheath plus cleaning plus LLD should eliminate HBV, HCV, HIV
- Likelihood of transmission, even if probe still contaminated, very remote – would require contaminating virus gaining entry via contact with the actual injection site
- Transmission of HIV, HBV, HCV via a probe using on external body surface never demonstrated
- Only semicritical medical device to transmit HBV or HCV is GI endoscope (HIV not transmitted)
- If all devices that could contact non-intact skin or be blood contaminated require HLD prior to reuse that would include linen/mattresses (Burn Center), stethoscopes, BP cuffs, xray cassettes, etc

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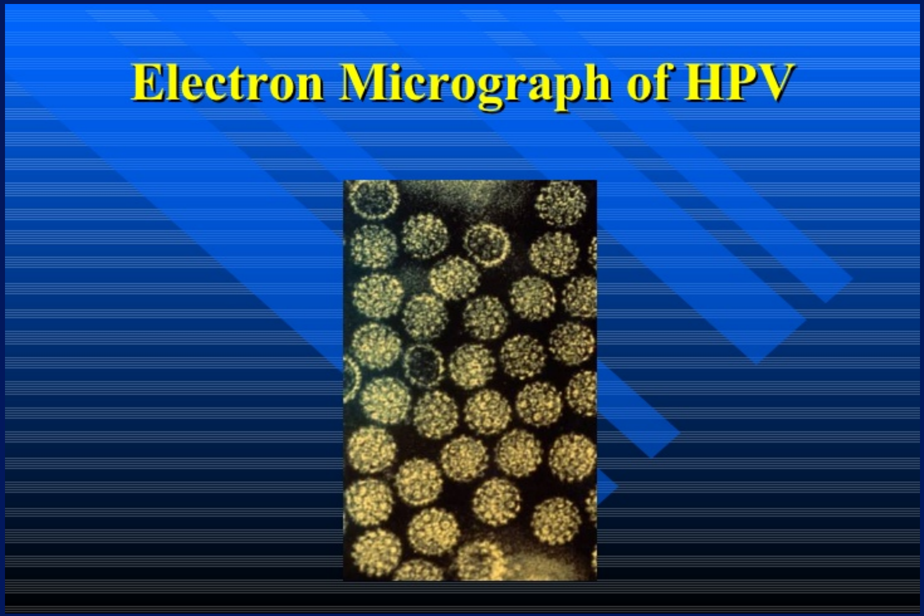
Human Papilloma Virus

- 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

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?



- 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)

Abstract by Ozbun et al Presented at the 32nd International Papillomavirus Conference in Australia 2018 (another HPV abstract at Eurogin 2018; 2.5-4 $\log_{10}$ reduction with OPA, hypochlorite, alcohols)

IPVC8-0887 POSTER SESSION BASIC RESEARCH - VIRUS LIFE CYCLE ASSESSING THE RISK OF HUMAN PAPILLOMAVIRUS TRANSMISSION AND HIHG-LEVEL DISINFECTION USING MOLECULAR VIROLOGY APPROACHES *M. Ozbun[1], N.A. Patterson[1], V. Bondu[1], E. LaBauve[1], R.T. Sterk[1], F.A. Schultz[2], A. Waxman[3], R. McKee[4], E.C. Bennett[4] [1]The University of New Mexico School of Medicine and Comprehensive Cancer Center, Molecular Genetics & Microbiology, Albuquerque, USA [2]The University of New Mexico School of Medicine and Comprehensive Cancer Center, Pathology, Albuquerque, USA [3]The University of New Mexico School of Medicine and Comprehensive Cancer Center, Obstetrics & Gynecology, Albuquerque, USA [4]The University of New Mexico School of Medicine and Comprehensive Cancer Center, Surgery, Albuquerque, USA* **Background and Aims**

Recent studies have suggested that HPVs are not susceptible to certain high-level disinfection protocols and that medical instruments may provide transmission of nosocomial HPVs infections. We aimed to determine the infectious load of HPVs from clinical lesions and to investigate HPV virions derived from model systems and clinical lesions in their abilities to be neutralized in classical disinfection protocols.

Methods

Infectious HPV virions were isolated from the 293T transfection system, organotypic epithelial tissue cultures, mouse xenografts. Clinical samples from respiratory papillomas and anogenital warts were obtained under IRB approval using emery paper to swab the apical tumors and were typed using the Seegene Anyplex™ HPV28 detection platform. A $TCID_{50}$assay was validated using RT-qPCR approaches to measure the end-point detection of viral E1^E4 mRNAs in infected HaCaT keratinocytes. Suspension-based disinfection protocols employed ortho-phthalaldehyde (OPA), hypochlorite and alcohols.

Results

Preliminary assessment of HPV infectious titers suggest that compared to common warts, clinical RRP and anogenital samples have low levels of virions present at apical surfaces. In contrast to other reports, we found HPVs from a variety of sources were susceptible to a 2.5 to 4 $\log_{10}$reduction in infectious titer when exposed as directed to the disinfectants.

Conclusions

We conclude that HPVs are susceptible to a variety of disinfection protocols. We plan to carefully assess the infectious titers of virions present HPV-induced lesions to better determine the risk of transmission from HPV-induced warts.

Disinfection and Sterilization
Current Issues, New Research and New Technologies

www.disinfectionandsterilization.org

- Current Issues, New Research and New Technologies
  - Sterilization of critical items
    - Biological indicators, clarified Spaulding, sterilizer robustness
  - High-level disinfection for semi-critical items
    - Outbreaks with semicritical devices, endoscope reprocessing issues (duodenoscopes-lever position), channeled endoscopes, HPV risks/studies, ultrasound probes
  - Low-level disinfection of non-critical items
    - Noncritical surface disinfection bundle, “wet” time, floors, biofilms, continuously active disinfectant, colored disinfectant, sporicide for all discharges
  - Emerging Pathogens
    - Inactivation data- *Candida auris*, CRE-carbapenem-resistant *Enterobacteriaceae*

Our Responsibility to the Future

Institute Practices that Prevent All Infectious Disease Transmission via Environment

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

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

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

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

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Disinfection of Noncritical Surfaces Bundle

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

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

Disinfection of Noncritical Surfaces Bundle

Rutala, Weber AJIC 2019;47:A96-A105

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

Effective Surface Decontamination

Product and Practice = Perfection

LOW-LEVEL DISINFECTION FOR NONCRITICAL EQUIPMENT AND SURFACES

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

Exposure time $\geq$ 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%
PA with HP, 4% HP, chlorine (*C. difficile*)	UD

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

Microbiological Disinfectant Hierarchy

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

Most Resistant

Spores (*C. difficile*)

Mycobacteria (*M. tuberculosis*)

Non-Enveloped Viruses (norovirus, HAV, polio) LLD

Fungi (Candida, *Trichophyton*)

Bacteria (MRSA, VRE, *Acinetobacter*)

Enveloped Viruses (HIV, HSV, Flu)

Most Susceptible

Disinfection of Noncritical Surfaces Bundle

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

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

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

No Touch

(supplements but do not replace surface cleaning/disinfection)

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

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

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

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

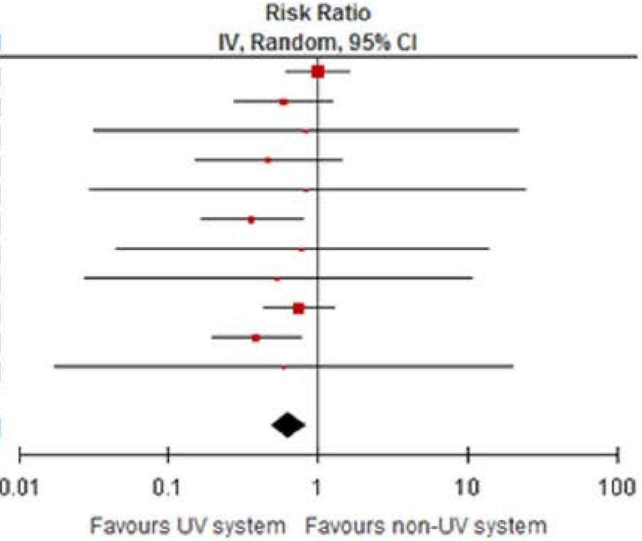
EFFICACY OF UVC AT TERMINAL DISINFECTION TO REDUCE HAIs
(A = *C. difficile*, B = VRE; UV effective in preventing VRE and *C. difficile*)

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

A

Study or Subgroup	log[Risk Ratio]	SE	Weight	Risk Ratio IV, Random, 95% CI
Anderson 2017	0	0.25	29.0%	1.00 [0.61, 1.63]
Bernard 2015	-0.53	0.38	12.6%	0.59 [0.28, 1.24]
Haas 2014	-0.19	1.67	0.7%	0.83 [0.03, 21.83]
Levin 2013	-0.76	0.57	5.6%	0.47 [0.15, 1.43]
McMullen 2016	-0.17	1.71	0.6%	0.84 [0.03, 24.08]
Miller 2015	-1.02	0.4	11.3%	0.36 [0.16, 0.79]
Nagajara 2015	-0.25	1.46	0.9%	0.78 [0.04, 13.62]
Napolitano 2015	-0.62	1.52	0.8%	0.54 [0.03, 10.58]
Pegues 2017	-0.29	0.28	23.2%	0.75 [0.43, 1.30]
Sampathkumar 2016	-0.94	0.35	14.8%	0.39 [0.20, 0.78]
Vianna 2016	-0.52	1.8	0.6%	0.59 [0.02, 20.25]
Total (95% CI)			**100.0%**	**0.64 [0.49, 0.84]**

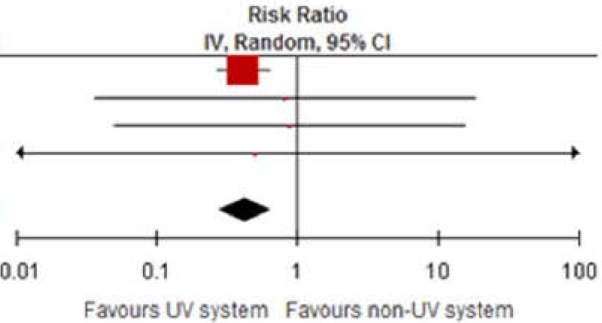
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 7.98$, df = 10 (P = 0.63); $I^2 = 0\%$
Test for overall effect: Z = 3.29 (P = 0.0010)



B

Study or Subgroup	log[Risk Ratio]	SE	Weight	Risk Ratio IV, Random, 95% CI
Anderson 2017	-0.89	0.22	95.5%	0.41 [0.27, 0.63]
Haas 2014	-0.2	1.58	1.9%	0.82 [0.04, 18.12]
Napolitano 2015	-0.13	1.46	2.2%	0.88 [0.05, 15.36]
Vianna 2016	-0.69	2.97	0.5%	0.50 [0.00, 169.20]
Total (95% CI)			**100.0%**	**0.42 [0.28, 0.65]**

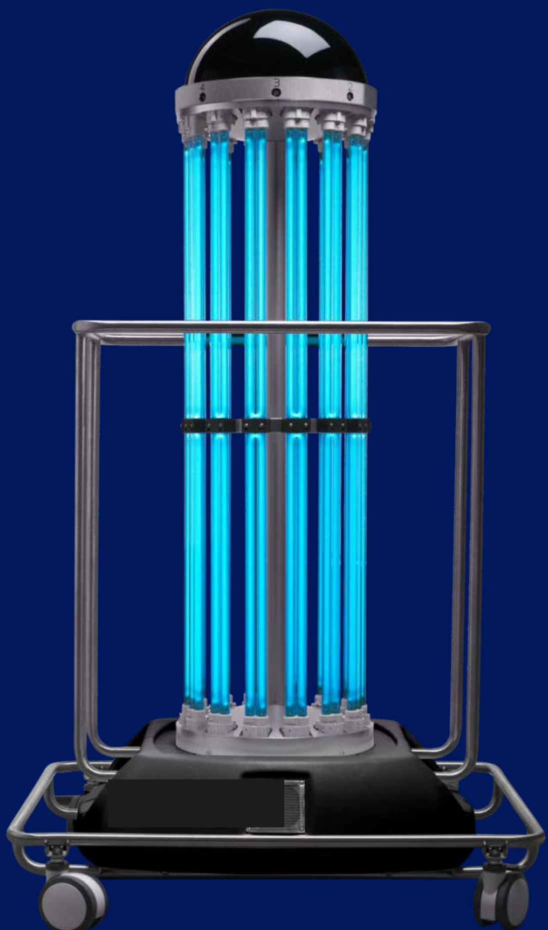
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.45$, df = 3 (P = 0.93); $I^2 = 0\%$
Test for overall effect: Z = 4.00 (P < 0.0001)

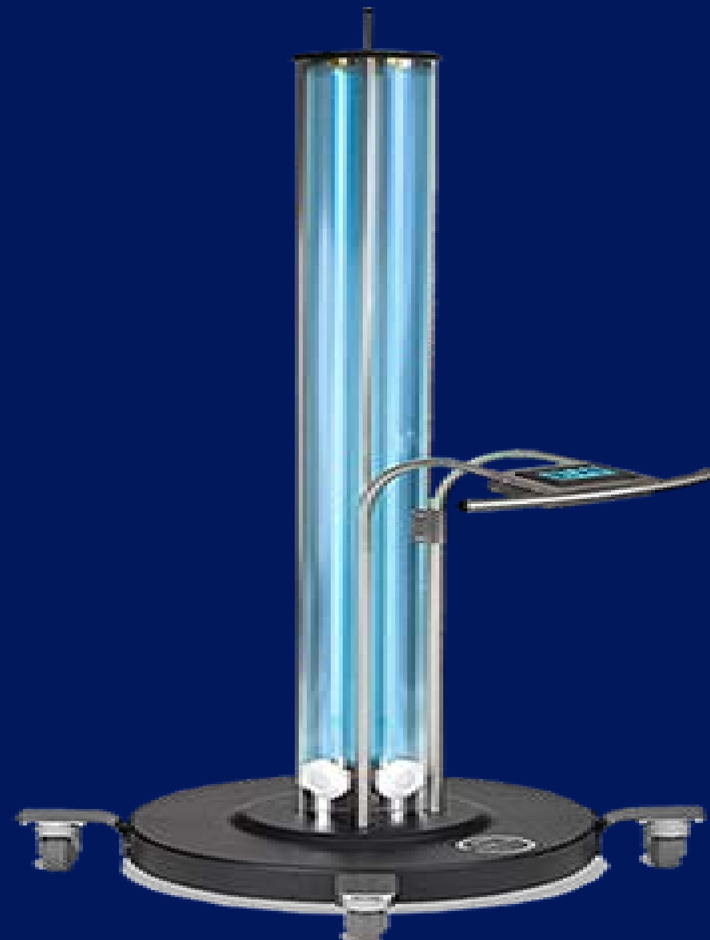


"NO TOUCH" APPROACHES TO ROOM DECONTAMINATION

(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.





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

Disinfection and Sterilization
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Disinfectant Kill Time

Rutala, Weber. AJIC. In 2019;47:A96-A105

- Each chemical disinfectant requires a specific length of time it must remain in contact with a microorganism to achieve complete inactivation.
- This is known as the “kill time” (or “contact time") and the registered kill times for each microorganism will be clearly listed
- There are only two papers in the peer-review literature that assessed EPA-registered disinfectants that are directly on point to the question will hospital disinfectants kill hospital pathogens in 1 minute

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

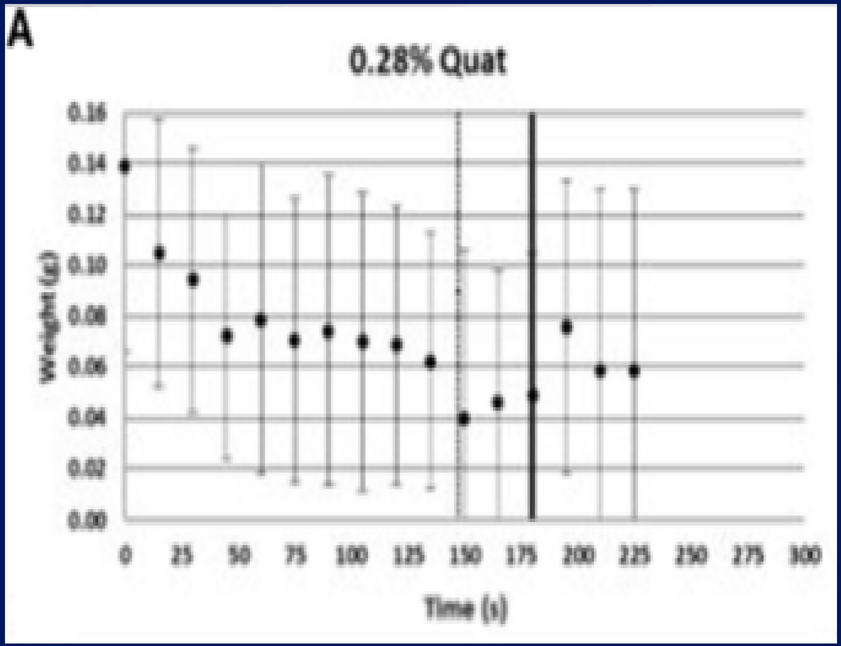
	Log$_{10}$ Reductions							
	VSE		VRE		MSSA		MRSA	
Product	**0.5 min**	**5 min**	**0.5 min**	**5 min**	**0.5 min**	**5 min**	**0.5 min**	**5 min**
Vesphene IIse	>4.3	>4.3	>4.8	>4.8	>5.1	>5.1	>4.6	>4.6
Clorox	>5.4	>5.4	>4.9	>4.9	>5.0	>5.0	>4.6	>4.6
Lysol Disinfectant	>4.3	>4.3	>4.8	>4.8	>5.1	>5.1	>4.6	>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.

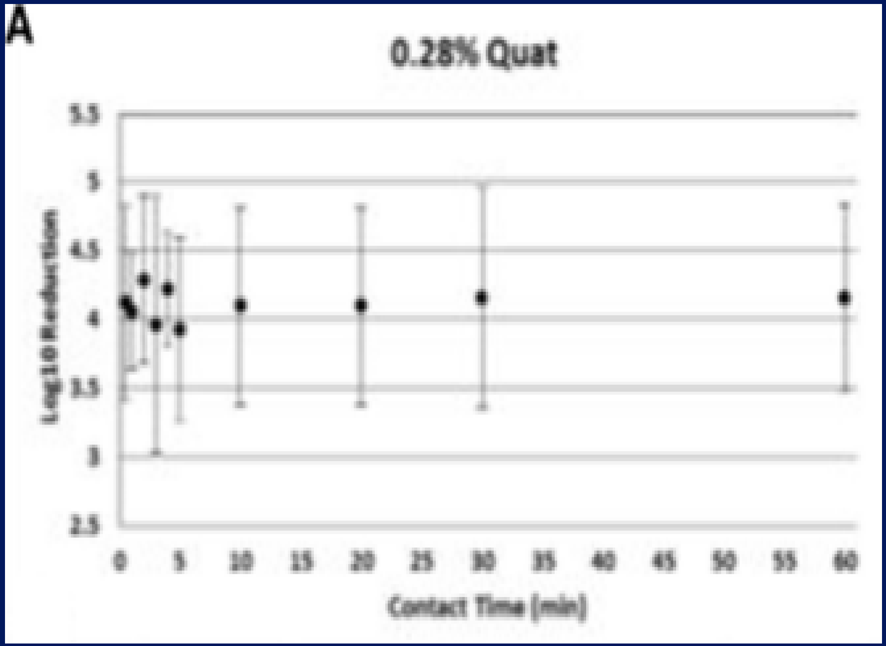
Bactericidal (*S. aureus*) Efficacy of EPA-Registered Towelettes

West, Teska, Oliver, AJIC, 2018

- Drying time curve based on surface wetness; bold-contact time (180s); dashed-dry (~145s)



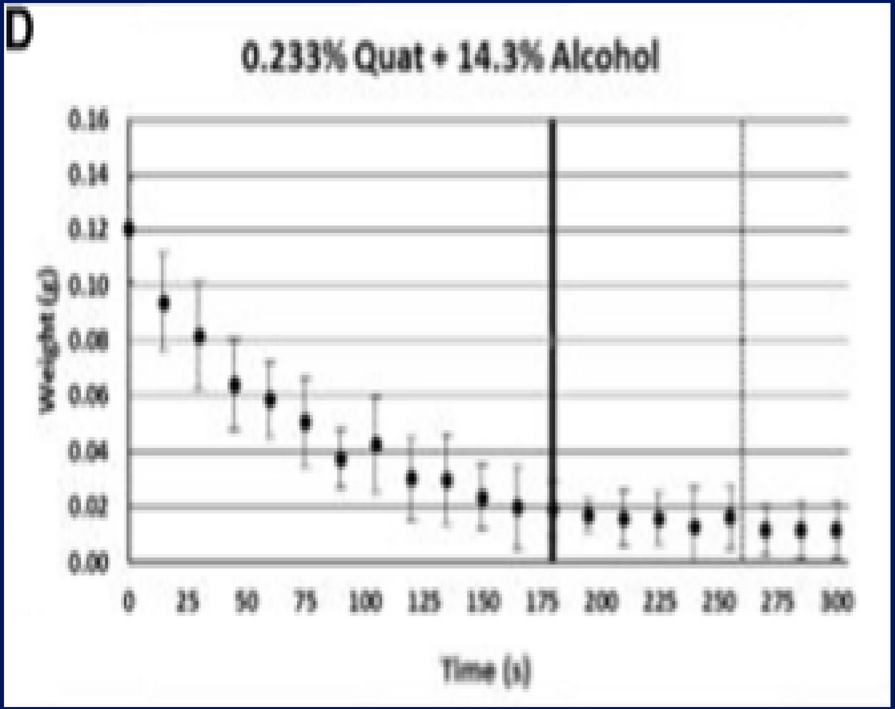
- Wet time is not crucial for complete disinfection (wet or dry ~4 $\log_{10}$ reduction); 30s for $\log_{10}$ reduction

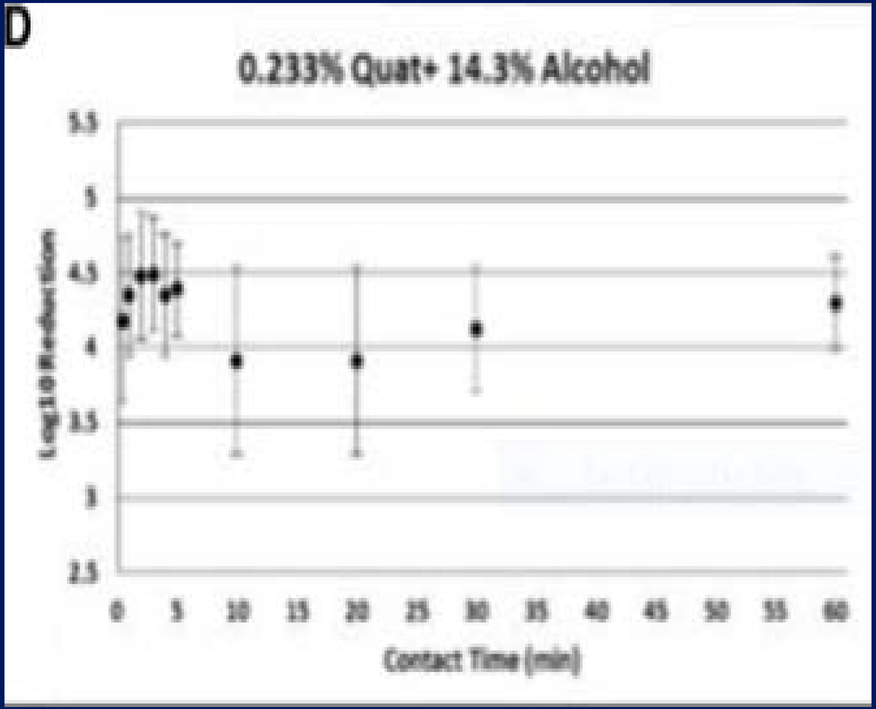


Bactericidal (*S. aureus*) Efficacy of EPA-Registered Towelettes

West, Teska, Oliver, AJIC, 2018

- Drying time curve based on surface wetness; bold-contact time (180s); dashed-dry (~260s)
- Wet time Is not crucial for complete disinfection (wet or dry ~4.5 $\log_{10}$ reduction); 30s for $\log_{10}$ reduction





Disinfectant Kill Time

Rutala, Weber AJIC 2019;47:A96-A105

- This refutes the proposition that visual wetness is a proxy for determining effective disinfection and challenges the need for citations and punitive actions by accrediting agencies when a disinfectant does not stay wet for its registered contact time (e.g., dries in 1 minute but registered contact time is 2 minutes).
- Clearly, wet times are important but there are no data that demonstrate that wet times beyond 1 minute improve microbial reduction and have an infection prevention benefit.

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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.

EVIDENCE THAT ALL TOUCHABLE ROOM SURFACES ARE EQUALLY CONTAMINATED

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

	Mean CFUs/RODAC (95% CI)	
Surface (no. of samples)	Precleaning	Postcleaning
High (n = 40)	71.9 (46.5–97.3)	9.6 (3.8–15.4)
Medium (n = 42)	44.2 (28.1–60.2)	9.3 (1.2–17.5)
Low (n = 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 E, 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[a]			
	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 (18.2%)	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.
[a] Number of contaminated samples/number of samples obtained.

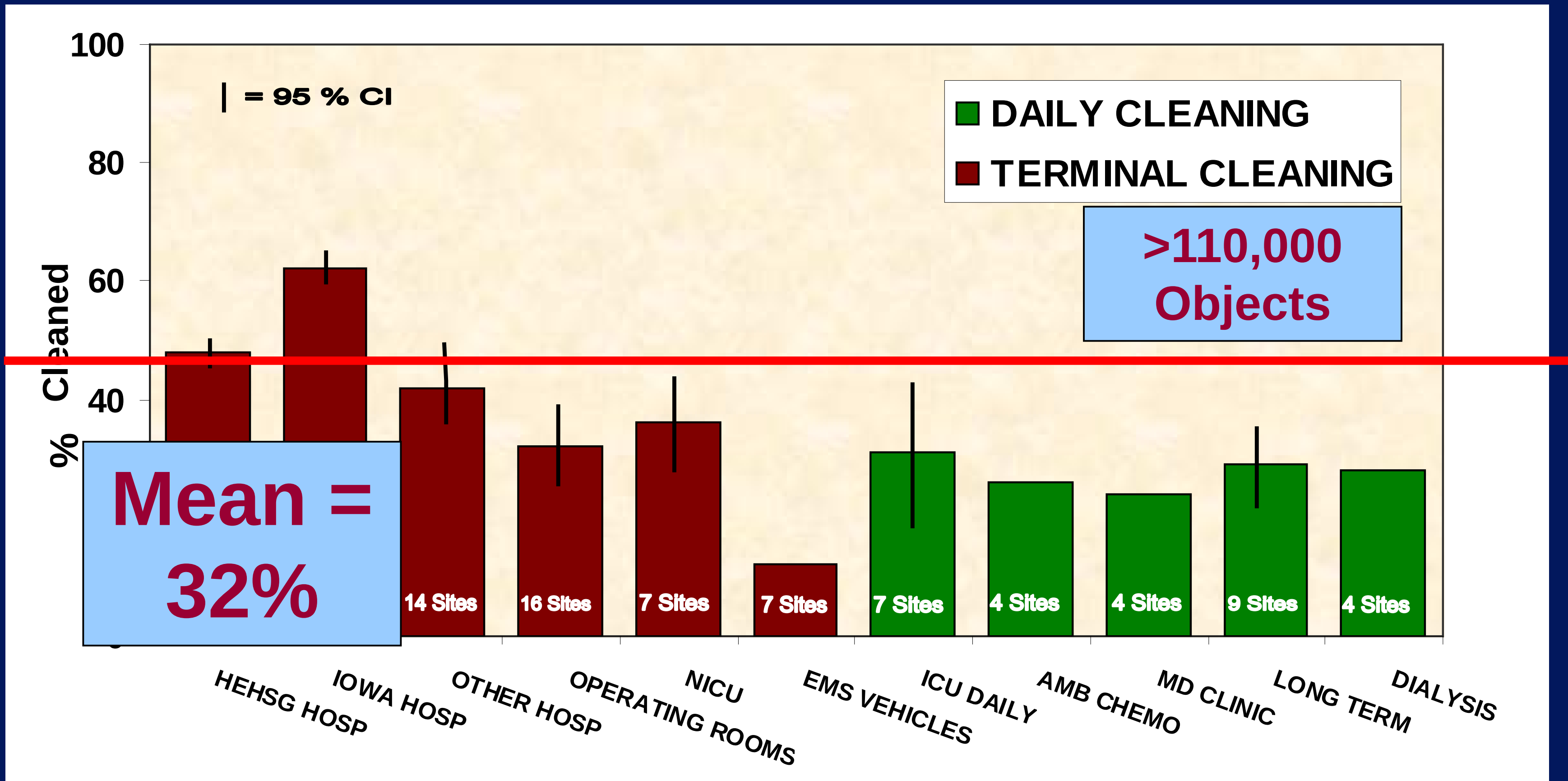
Willi I, Mayre A, Kreidl P, et al. JHI 2018;98:90-95

Effective Surface Decontamination

Product and Practice = Perfection

Thoroughness of Environmental Cleaning

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



MONITORING THE EFFECTIVENESS OF CLEANING

Cooper et al. AJIC 2007;35:338

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

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

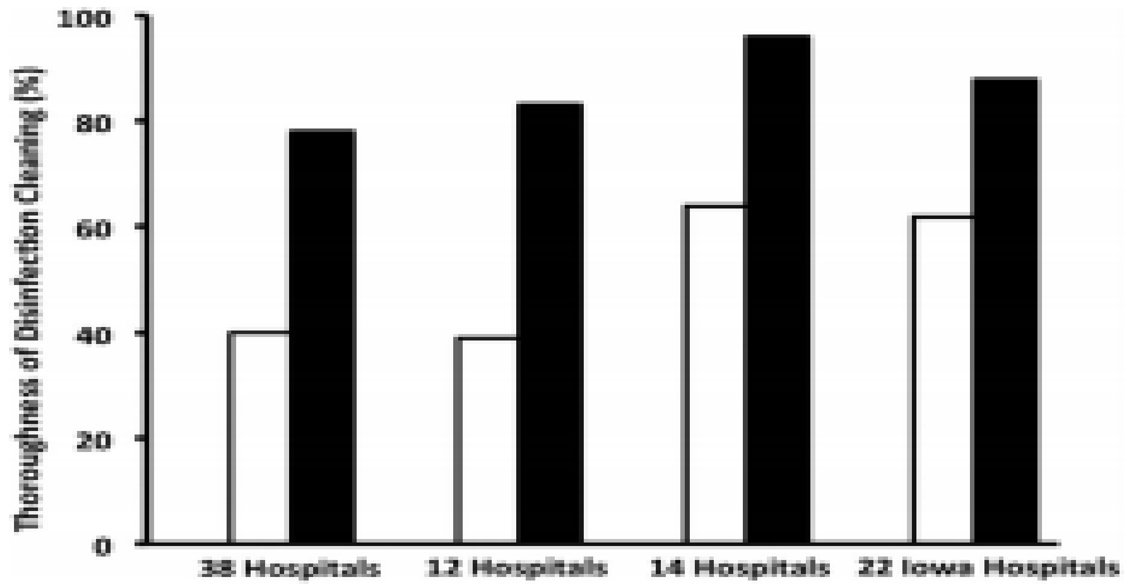
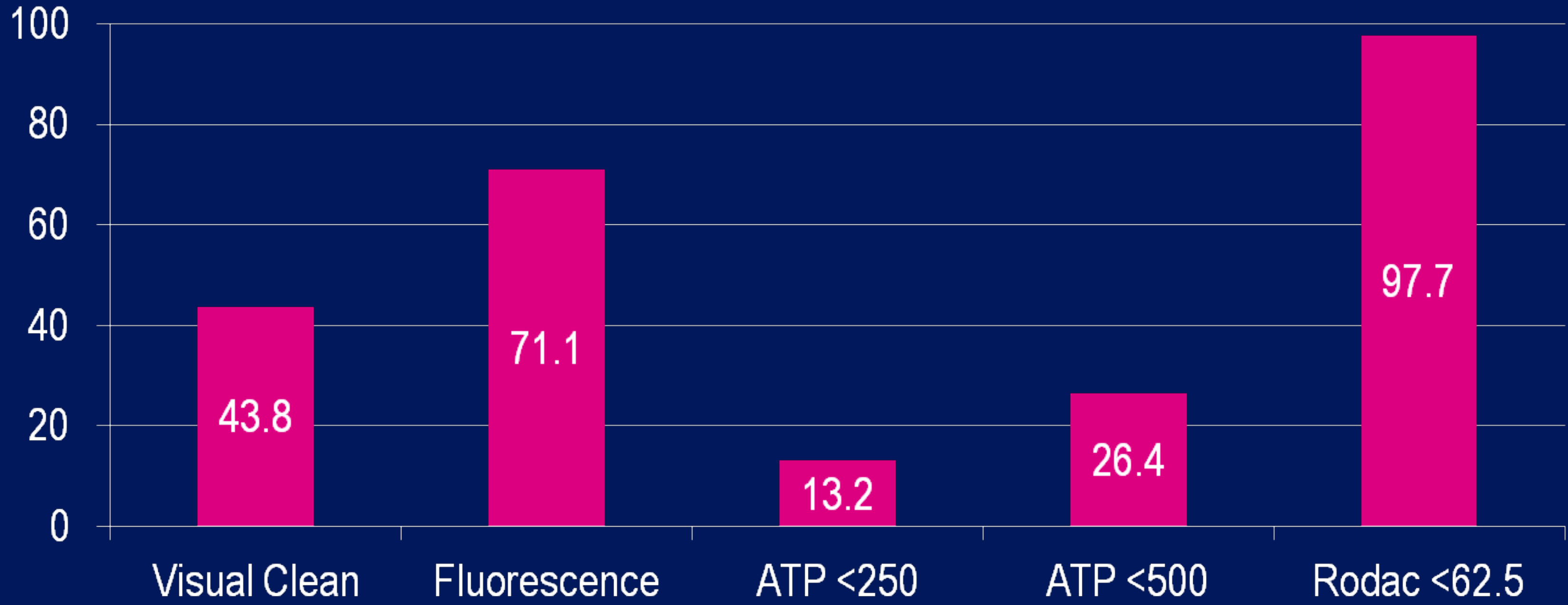


FIGURE 4. A comparison of the results of the 3 previously published multisite studies compared with results from the Iowa project. White bars represent the average baseline TDCs and black bars represent the average final TDCs for sites that completed each study.

Percentage of Surfaces Clean by Different Measurement Methods

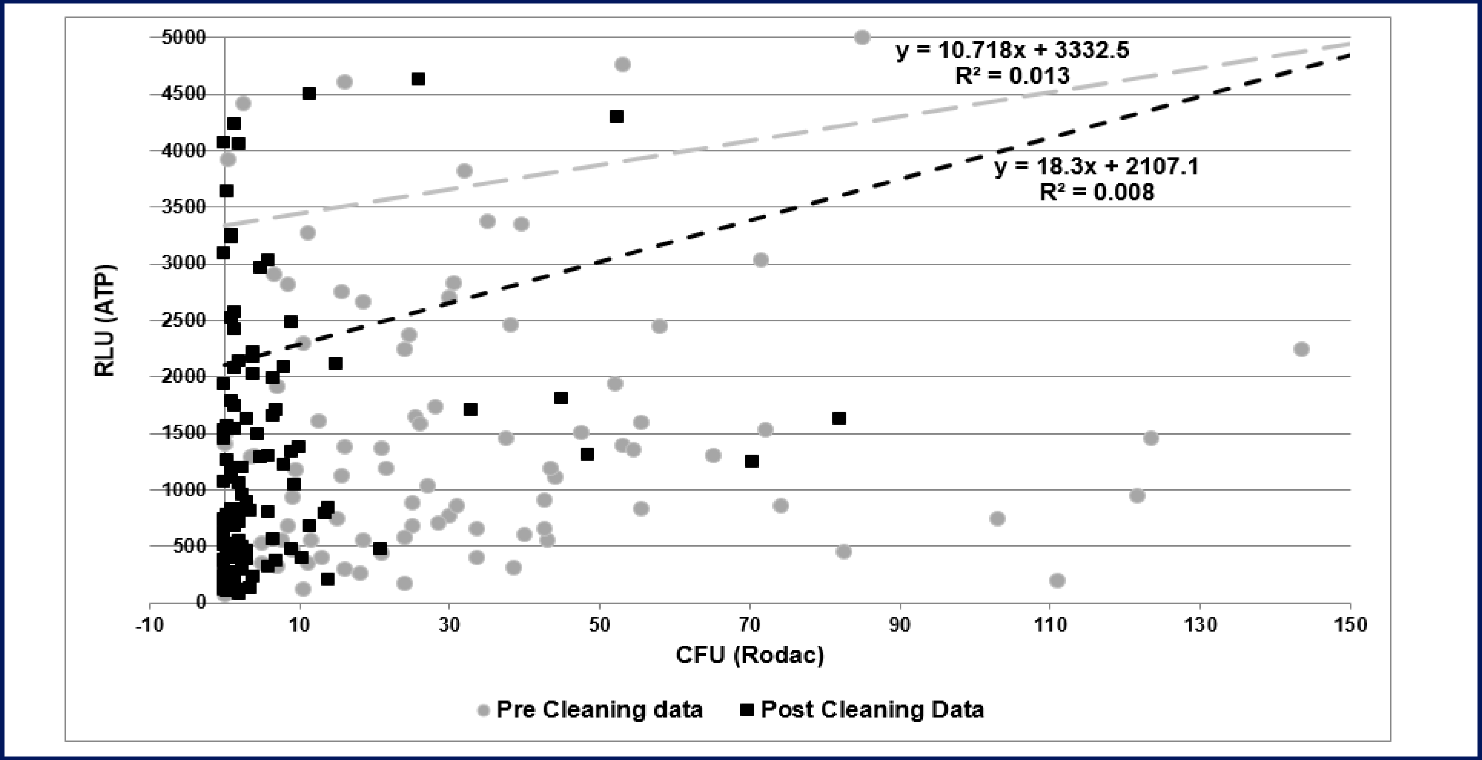
Rutala, Kanamori, Gergen, Sickbert-Bennett, Huslage, Weber. APIC 2017.

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 May Have Methods to Ensure Thoroughness Such as Colorized Disinfectant

Colorized disinfection – contact time compliance

- 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

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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

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.

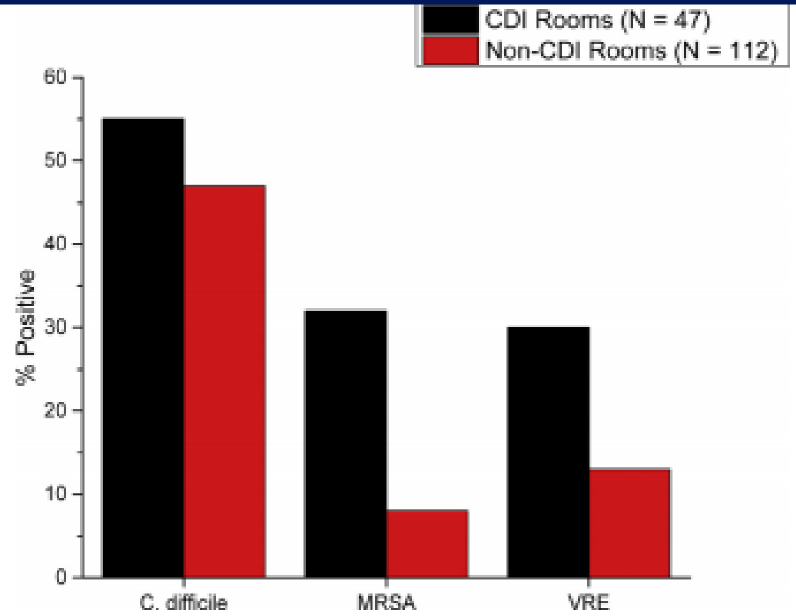

Fig 1. Recovery of *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus*, and vancomycin-resistant enterococci from floors in patient rooms from 5 hospitals in northeast Ohio.

- 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 chargers; 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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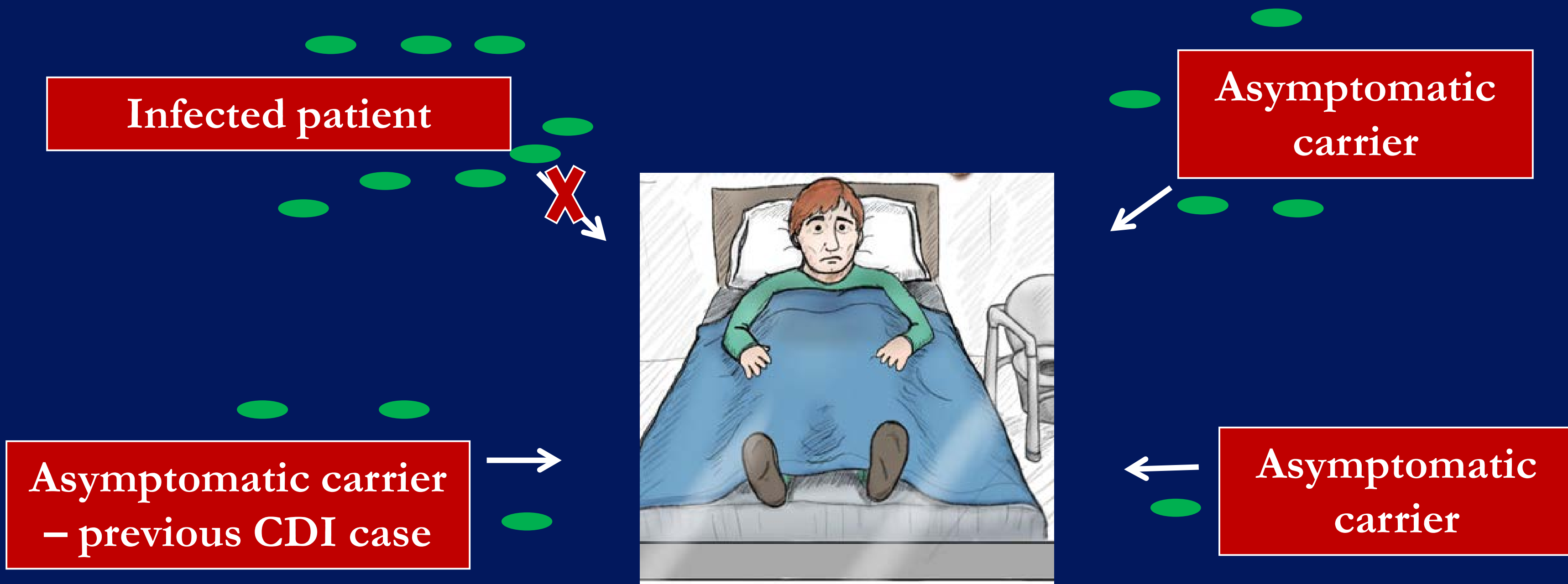
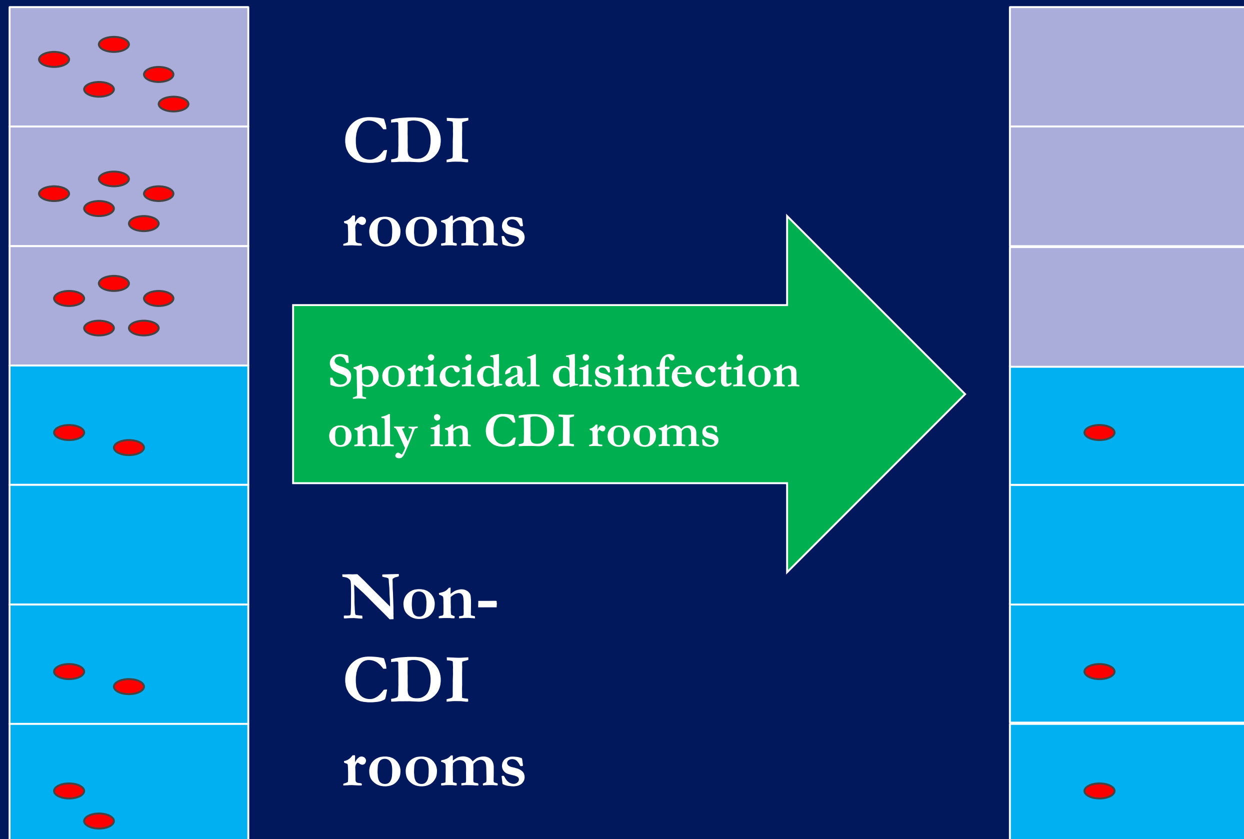
- CRE susceptible to germicides
- *C. auris* susceptible to most disinfectants but not antiseptics

Asymptomatic carriers contribute to *C. difficile* transmission



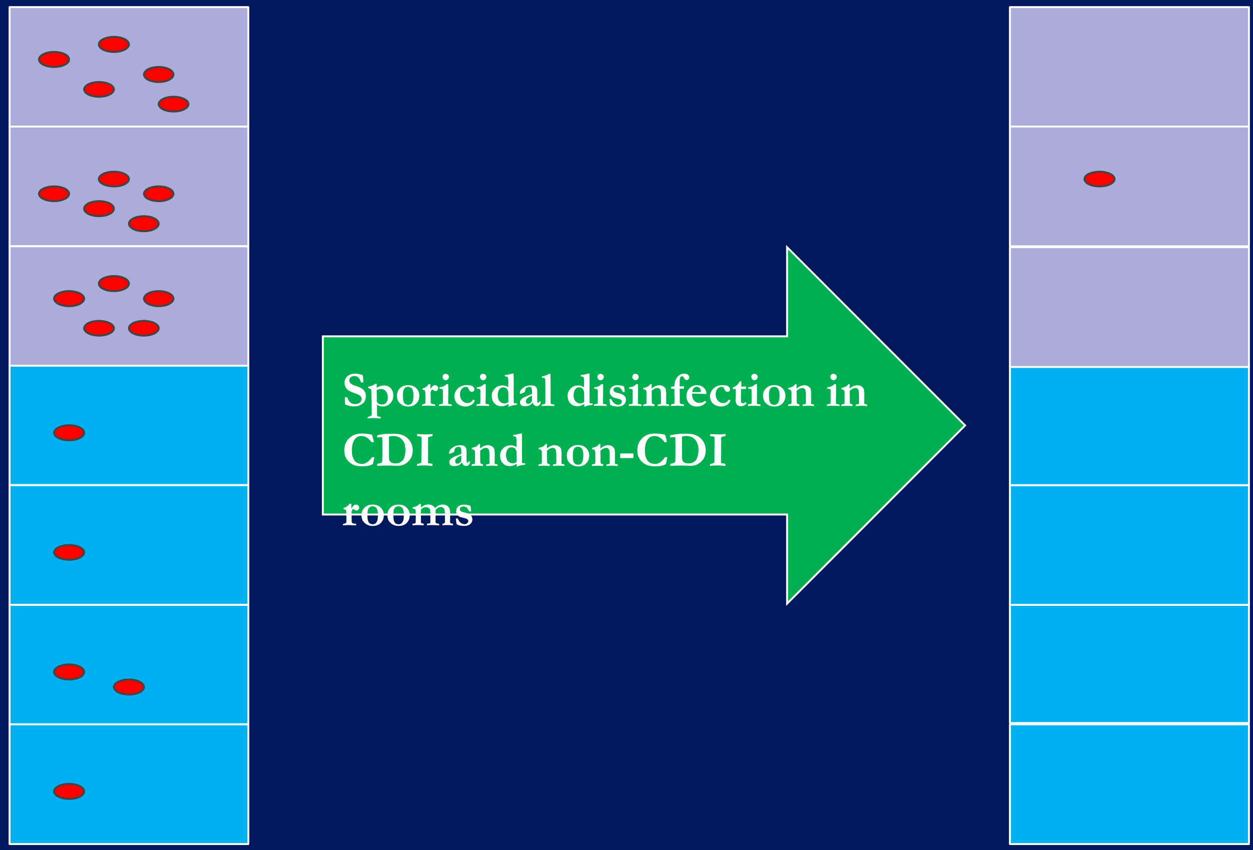
1. Curry SR. Clin Infect Dis 2013 (29% of hospital-associated CDI cases linked to carriers by MLVA); 2. Blixt T. Gastroenterol 2017;152:1031 (exposure to carriers increased CDI risk); 3. Longtin Y. JAMA Int Med 2016 (screening for and isolating carriers reduced CDI by 63%); 4. Samore MH. Am J Med 1996;100:32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

Interventions focused on CDI rooms



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

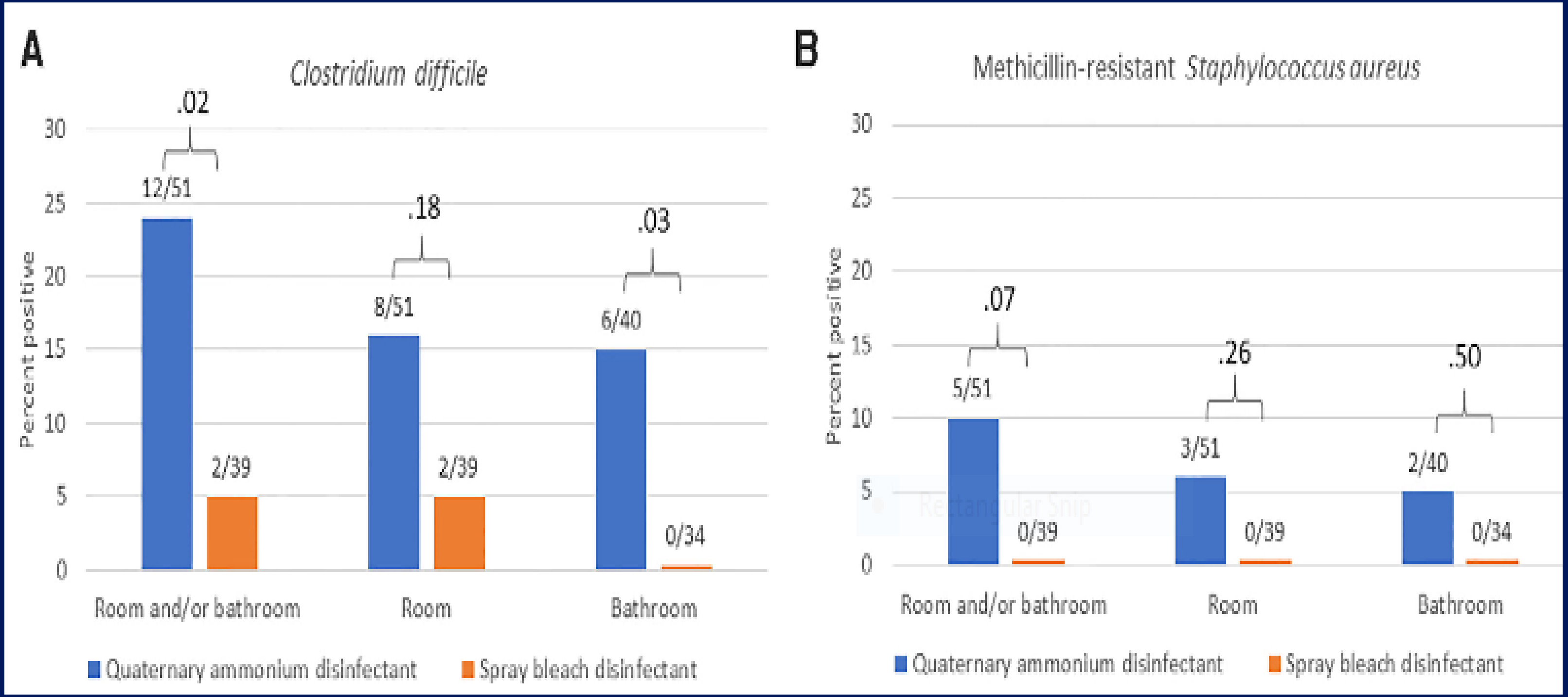
Interventions addressing CDI cases and asymptomatic carriers



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

Wong et al. AJIC, In press

The percentage of rooms contaminated with *C. difficile* was significantly reduced during the period with a sporicidal product was used 5% vs 24%. Results suggest sporicidal disinfectant in all postdischarge rooms could potentially be beneficial in reducing the risk *for C. difficile* transmission from contaminated surfaces



Disinfection and Sterilization
Current Issues, New Research and New Technologies

- 24m and 30m BI for HP sterilizers
- Shift from HLD to sterilization dependent on technology
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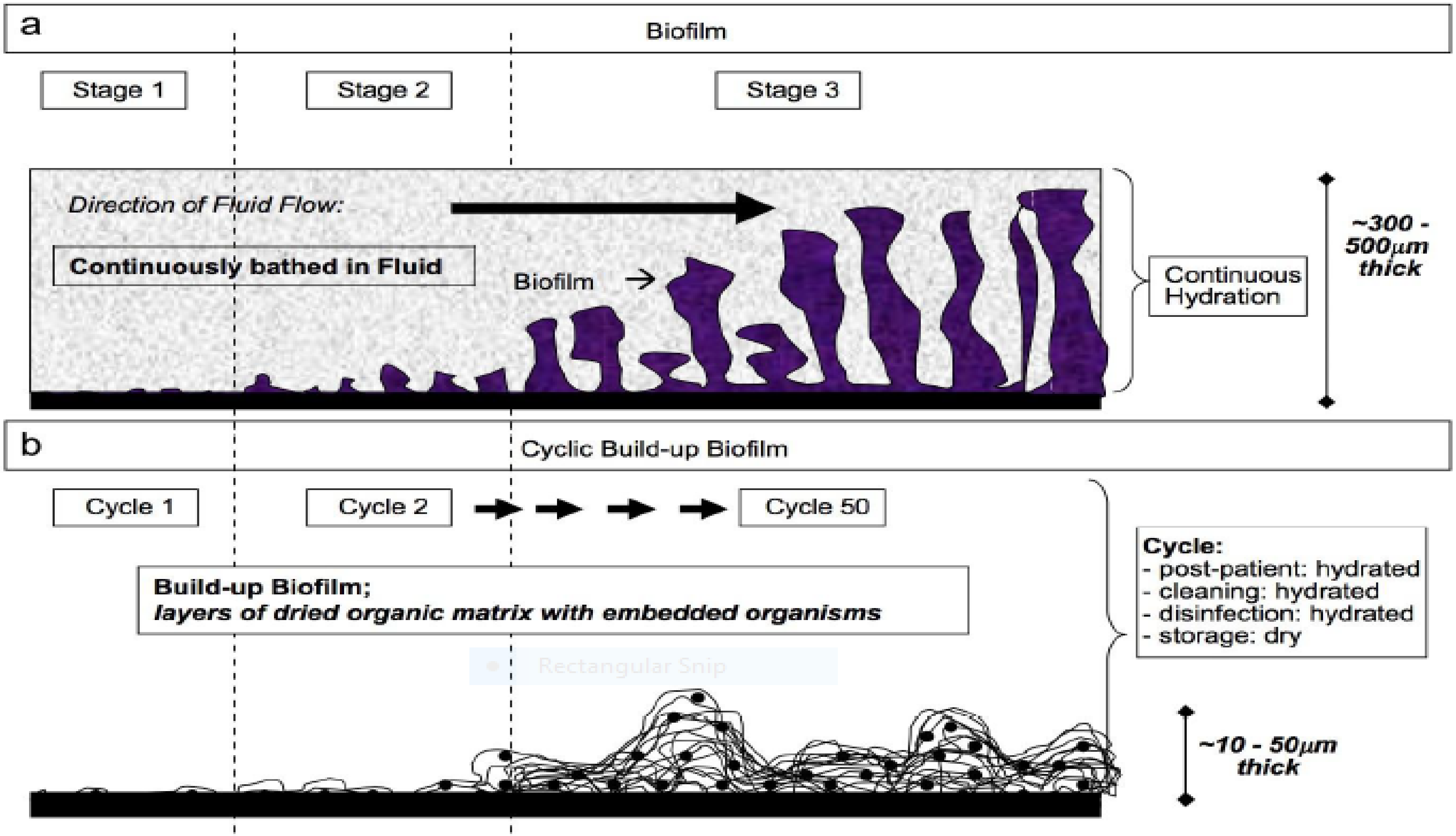
Biofilms on Instruments and Environmental Surfaces

Alfa, AJIC 2019;47:A39-A45

- Three types of biofilm
  - Traditional hydrated biofilm (water content 90%)
  - Build-up biofilm—occurs in endoscope channels
  - Dry surface biofilm-heterogenous accumulation of organisms and other material in a dry matrix (water content 61%)
    - Raises questions about the inactivation of microbes with a dry surface biofilm by currently used cleaning/disinfecting methods

Figure 1 Comparison of traditional to cyclic build-up biofilm



[Get permission from; Zhong W, **Alfa M**, Howie R, Zelenitksy S. Simulation of cyclic reprocessing buildup on reused medical devices. Comput Biol Med 2009 Jun; 39(6): 568-577.

Dry Biofilms on Healthcare Surfaces

Examples of “Dry” Biofilms Recovered from Surfaces

Ledwoch et al. J Hosp Infect 2018;100:e47-e56

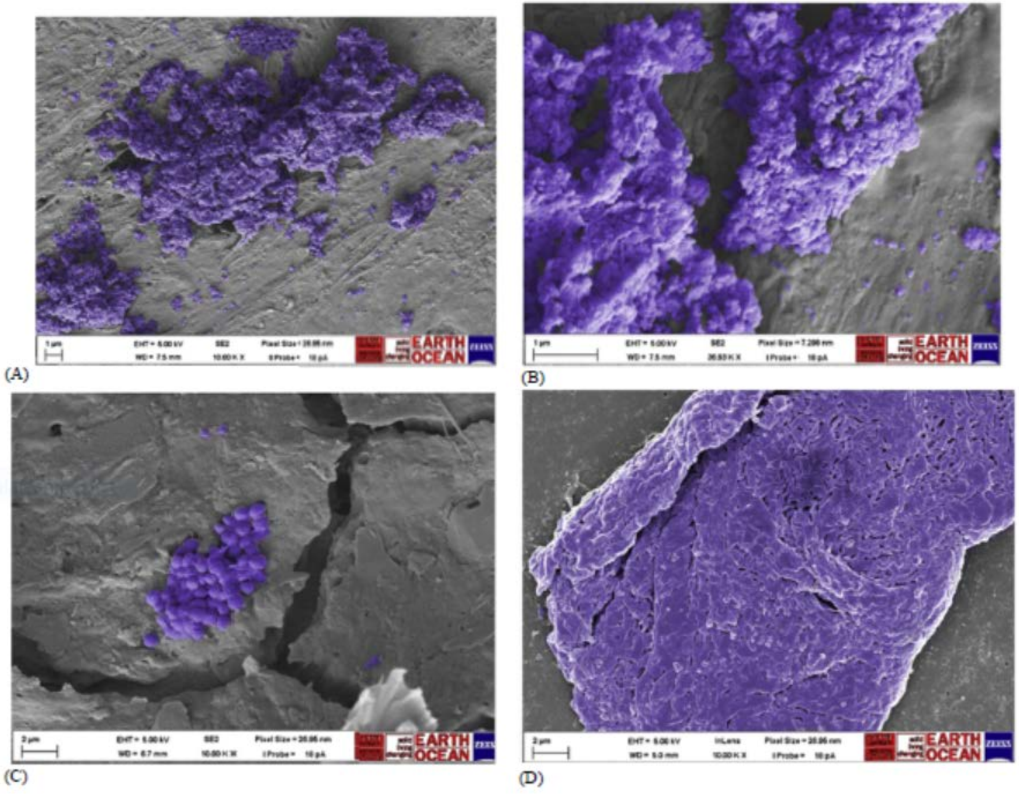


Figure 4. Examples of 'dry' biofilms recovered from surfaces; magnification ×10,000. (A, B) Patient folders, (C) patient chair, (D) keyboard key. Images of biofilms were coloured in purple to help visualization and contrast using GNU Image manipulation program (GIMP 2.8) software. Images were not otherwise altered.

Dry Biofilms Containing Bacterial Pathogens on Multiple Healthcare Surfaces

Ledwoch et al. J Hosp Infect 2018;100:e47-e56

- Investigate the occurrence, prevalence and diversity of dry biofilms on hospital surfaces
- 61 terminally cleaned rooms were investigated for the dry biofilms using culture-based methods and SEM
- Multi-species dry biofilms were recovered from 95% of 61 samples
- Dry biofilms were predominately formed by gram-positive bacteria, although occasional *Acinetobacter spp* were identified
- Their role in transmission needs to be established

Dry Biofilms on Healthcare Surfaces

Difference in "Dry" Biofilm Composition Between Hospitals

Ledwoch et al. J Hosp Infect 2018;100:e47-e56

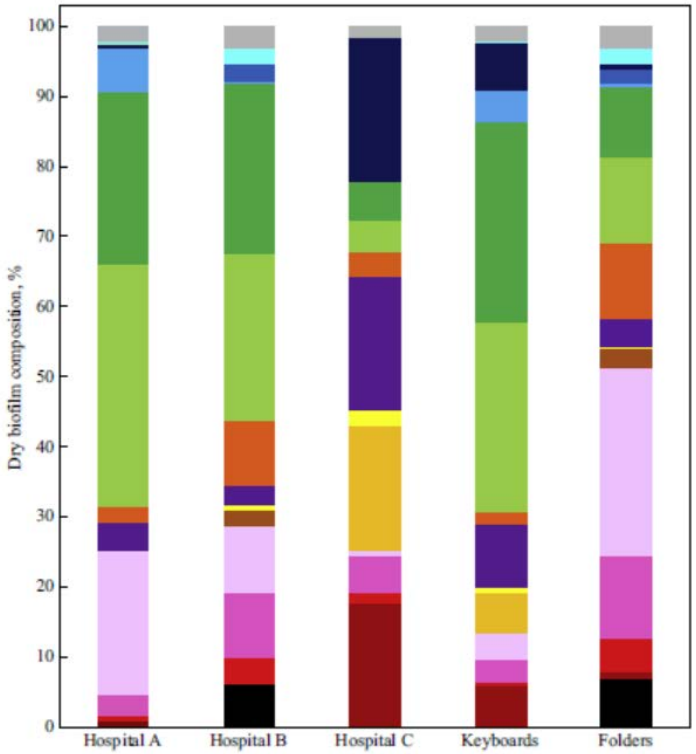


Figure 3. Difference in 'dry' biofilm composition between hospitals. ■, *Anoxybacillus flavithermus*; ■, *Bacillus amyloliquefaciens*; ■, *Bacillus anthracis*; ■, *Bacillus cereus*; ■, *Bacillus licheniformis*; ■, *Bacillus megaterium*; ■, *Bacillus pumilus*; ■, *Bacillus* sp.; ■, *Bacillus subtilis*; ■, *Bacillus thuringiensis*; ■, *Staphylococcus aureus*; ■, *Staphylococcus epidermidis*; ■, *Staphylococcus lugdenensis*; ■, *Staphylococcus pasteuri*; ■, *Staphylococcus saprophyticus*; ■, *Staphylococcus warneri*; ■, other.

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Relationship Between Microbial Burden and HAIs

Rutala WA et al. ICHE 2018;38:1118-1121; Salgado CD, et al. ICHE 2013;34:479-86

Table 2. Relationship between microbial reduction of epidemiologically-important pathogens (EIP) and colonization/infection in a patient subsequently admitted to a room of a patient colonized/infected with an EIP by decontamination method.

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

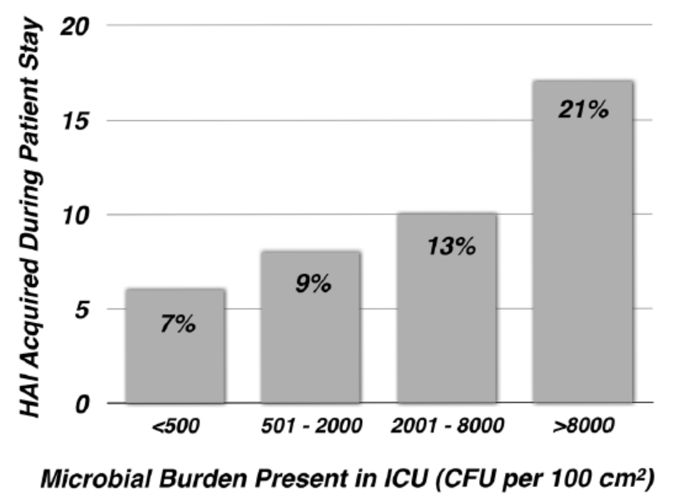


FIGURE 2. Quartile distribution of healthcare-acquired infections (HAIs) stratified by microbial burden measured in the intensive care unit (ICU) room during the patient's stay. There was a significant association between burden and HAI risk ($P = .038$), with 89% of HAIs occurring among patients cared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

To reduce microbial contamination

Continuous Room Decontamination Technology

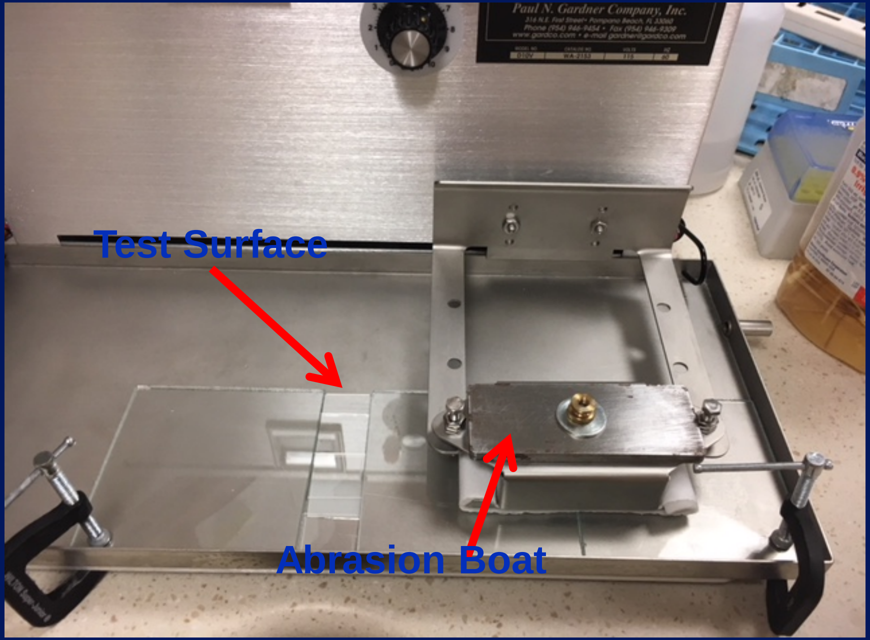
Continuous Room Decontamination Technologies for Disinfection of the Healthcare Environment

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

Evaluation of a Continuously Active Disinfectant

"EPA Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residuals on Hard, Non-Porous Surfaces"

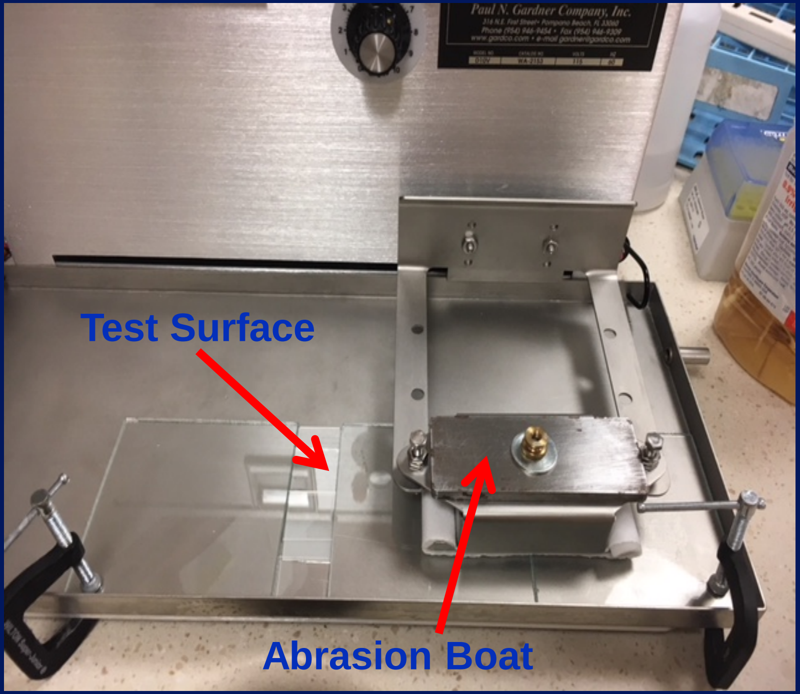
Abrasion Tester



Evaluation of a Continuously Active Disinfectant

"EPA Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residuals on Hard, Non-Porous Surfaces"

- Test surface inoculated (10^5), treated with test disinfectant, allowed to dry.
- Surface will undergo "wears" (abraded under alternating wet and dry conditions [24 passes, 12 cycles]) and 6 re-inoculations (10^3, 30min dry) over 24hr
- At the end of the study and at least 24 hours later, the ability of the test surface to kill microbes (99.9%) within 5 min is measured using the last inoculation (10^6)



Efficacy of a Continuously Active Surface Disinfectant

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

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

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

***Test surface glass unless otherwise specified**

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

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

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

Efficacy of a Continuously Active Disinfectant

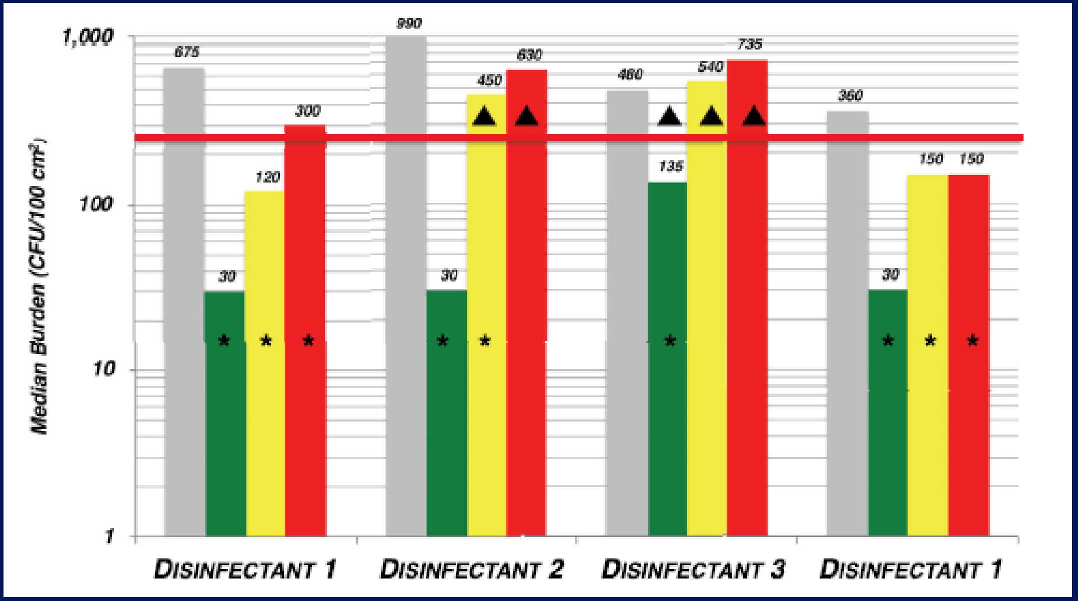
Summary

- Preliminary studies with a new continuously active disinfectant are promising (e.g., 4-5 log_{10} reduction in 5min over 24hr)
- Unclear why 99% reduction with *Klebsiella* and CR *Enterobacter* (another researcher [Donskey] found a 4 log_{10} reduction; most surfaces have <100 CFU/Rodac
- Continuously active disinfectants may reduce or eliminate the problem of recontamination.

Evaluation of Three Disinfectants for Ability to Limit Establishment of Bioburden After Disinfection

Schmidt et al. Am J Infect Control 2019;47:732-4

The CAD (disinfectant 1, red-24h sample) was able to significantly control bioburden on bed rails, a critical touch surface



Why do we need to consider continuous room decontamination technology?

To reduce microbial contamination

(associated with suboptimal CD practices and recontamination)

Evaluation of Three Disinfectants for Ability to Limit Establishment of Bioburden After Disinfection

Schmidt et al. Am J Infect Control 2019;47:732

- The use of a continuously active disinfectant (CAD) offers the infection prevention community a new opportunity to limit the re-establishment of bacteria on touch surfaces in the hospital environment
- Several studies (Salgado et al., Anderson et al, Rutala et al) were able to demonstrate that when the microbial bioburden of a patient room was kept low, the risk of acquisition of HAIs was reduced

Relationship Between Microbial Burden and HAIs

Rutala WA et al. ICHE 2018;38:1118-1121; Salgado CD, et al. ICHE 2013;34:479-86

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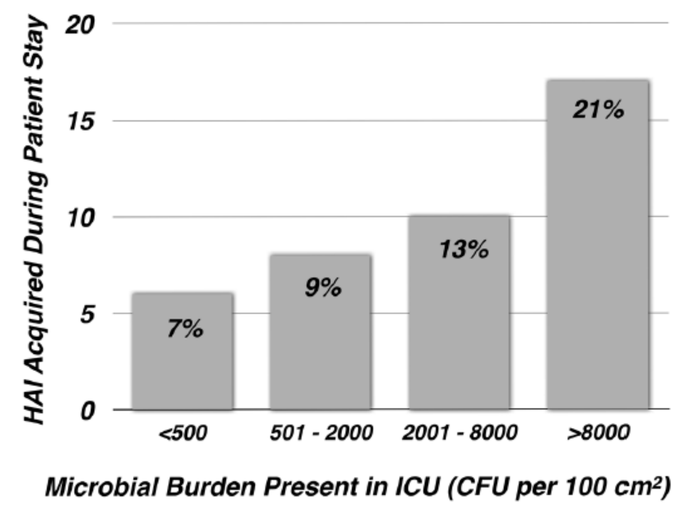

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Environmental Disinfection in Health Care Facilities

Recommendations

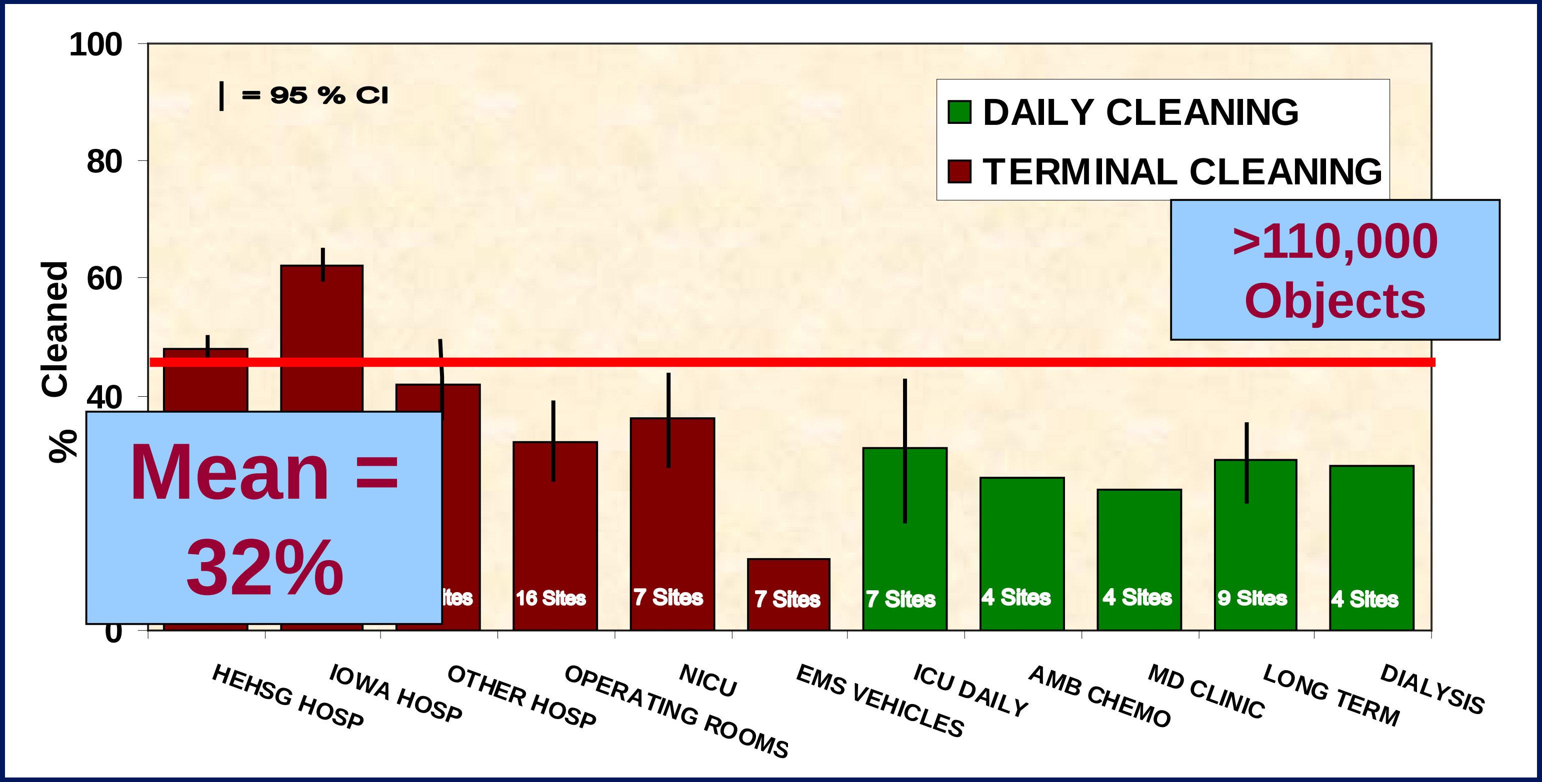
- Decontaminate **surfaces in patient room** that are touched by health care workers and patients (**daily, terminal**)
- **Decontaminate portable equipment** that is shared among patients such as medication carts, wheelchairs, portable x-ray machines, etc. **after each patient use**

Environmental Disinfection in Health Care Facilities

- Environmental disinfection is suboptimal
  - Patient rooms are contaminated due to suboptimal cleaning/disinfection and recontamination
  - Portable equipment not decontaminated per policy
  - Outbreaks and environmental-mediated infections occur

Thoroughness of Environmental Cleaning

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

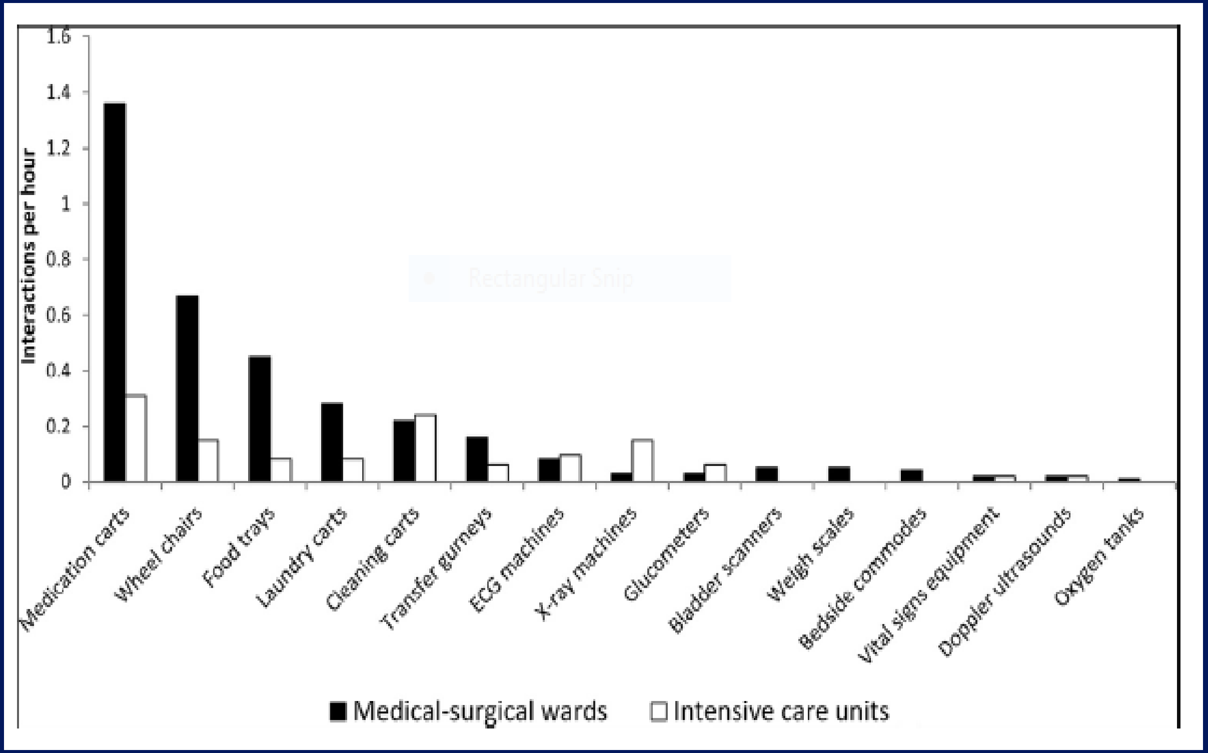


Portable Equipment
(decontaminate after each patient use)

Interactions Between Patients and Shared Portable Equipment

Suwantarat N, et al. AJIC 2017;45:1276

Of 360 interactions between portable equipment and patients, 42% involved equipment or fomites that made direct contact with the patient or surfaces in the room



Frequency of Recovery of Healthcare Pathogens from Portable Equipment

Suwantarat N, et al. AJIC 2017;45:1276

Of 80 items cultured, 12 (15%) were contaminated with ≥ 1 healthcare pathogen

Frequency of recovery of health care–associated pathogens from portable equipment and fomites on medical-surgical wards and in intensive care units

Portable equipment and fomites	MRSA	VRE	*Clostridium difficile*
Medication carts	2/31 (7)	1/31 (3)	1/31 (3)
Wheelchairs	1/12 (8)	0/12 (0)	0/12 (0)
ECG machines	1/8 (13)	1/8 (13)	0/8 (0)
Food trays	0/7 (0)	0/7 (0)	0/7 (0)
Laundry carts	3/5 (60)	2/5 (40)	1/5 (20)
Bladder scanners	0/3 (0)	2/3 (67)	0/3(0)
Portable x-ray machines	1/3 (33)	0/3 (0)	0/3 (0)
Weight scales	0/3 (0)	0/3 (0)	0/3 (0)
Doppler ultrasound machines	0/2 (0)	0/2 (0)	0/2 (0)
Glucometers	0/2 (0)	0/2 (0)	0/2 (0)
Transfer gurneys	0/2 (0)	0/2 (0)	0/2 (0)
Vital sign machines	0/2 (0)	0/2 (0)	0/2 (0)
Total	8/80 (10)	6/80 (8)	2/80 (3)

NOTE. Values are the no. of positive samples/no. sampled (%).
ECG, electrocardiogram; *MRSA*, methicillin-resistant *Staphylococcus aureus*; *VRE*, vancomycin-resistant enterococci.

Environmental Disinfection in Healthcare Facilities

- Continuously active disinfectants reduces bioburden
- Whether a CAD translates in a reduction of HAIs remains to be determined
- Continuously active disinfectants should not alter the frequency of cleaning and disinfection as one of the purposes of routine cleaning and disinfection is to remove dirt and debris in addition to the reduction of microbial contamination

Disinfection and Sterilization
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- Current Issues, New Research and New Technologies
  - Sterilization of critical items
    - Biological indicators, clarified Spaulding, sterilizer robustness
  - High-level disinfection for semi-critical items
    - Outbreaks with semicritical devices, endoscope reprocessing issues (duodenoscopes-lever position), channeled endoscopes, HPV risks/studies, ultrasound probes
  - Low-level disinfection of non-critical items
    - Noncritical surface disinfection bundle, "wet" time, floors, biofilms, continuously active disinfectant, colored disinfectant, sporicide for all discharges
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    - Inactivation data- *Candida auris*, CRE-carbapenem-resistant *Enterobacteriaceae*

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EXPERIMENTAL THERAPEUTICS

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

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

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

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

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

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

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

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

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

Candida auris

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

- *Candida auris* is a globally emerging pathogen that is often resistant to multiple antifungal agents
- In several reports, *C. auris* has been recovered from the hospital environment
- CDC has recommended daily and post-discharge disinfection of surfaces in rooms of patients with *C. auris* infection.
- No hospital disinfectants are registered for use specifically against *C. auris*, and its susceptibility to germicides in not known

Efficacy of Disinfectants and Antiseptics against *Candida auris*

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

- ≥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 amylphenol
  - 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, ICHE 2018

- ≤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

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

- New D/S technologies (BIs, continuously active disinfectant) and practices (e.g., monitoring cleaning, sporicide for CDI) could reduce risk of infection associated with devices and surfaces.
- Steam sterilization most effective sterilization technology.
- Endoscope represent a nosocomial hazard. 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