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 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, ASP
- Scientific Advisory Board
  - Kinnos
- Grants
  - CDC, CMS

Learning Objective

- Describe two new recommendations/practices/ technologies/research associated with HLD, LLD 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
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
- Reprocessing laryngoscopes
- Endocavitary probes
- Uncertain if OPA/glut kill HPV
- Ultrasound probe reprocessing
- Develop a noncritical surface bundle including "no touch"
- Touchable surfaces should be wiped and monitor cleaning
- CRE susceptible to germicides
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www.disinfectionandsterilization.org

Disinfection and Sterilization: What's New

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- 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
  - Emerging Pathogens
    - Inactivation data- *Candida auris*, CRE-carbapenem-resistant *Enterobacteriaceae*

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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

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

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

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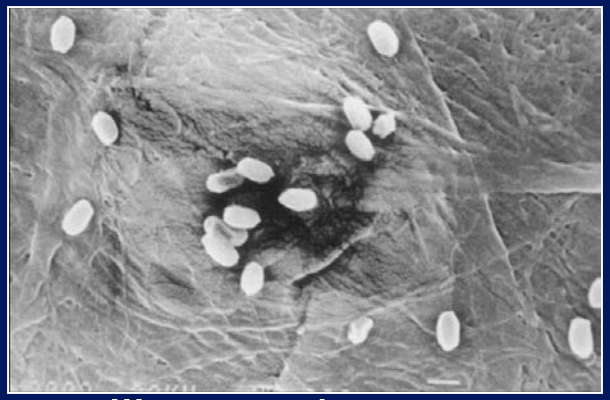
Biological Indicators

- 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

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

Gastrointestinal Endoscopes
A Need to Shift From Disinfection to Sterilization?

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

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

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

Related article page 1447

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

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

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

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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.

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Where are we?

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)

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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

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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

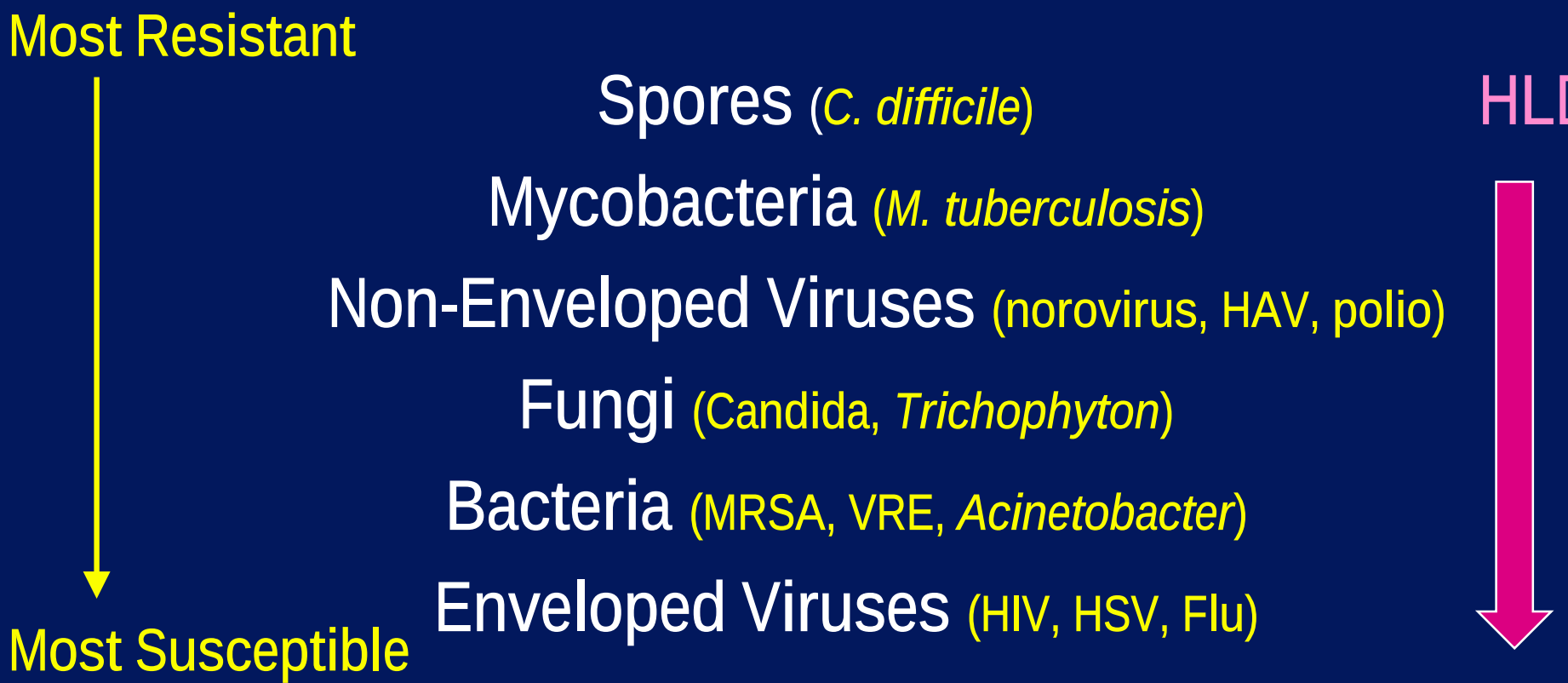
High-Level Disinfection of "Semicritical Objects"

Germicide	Exposure Time ≥ 8m-45m (US), 20°C 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



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

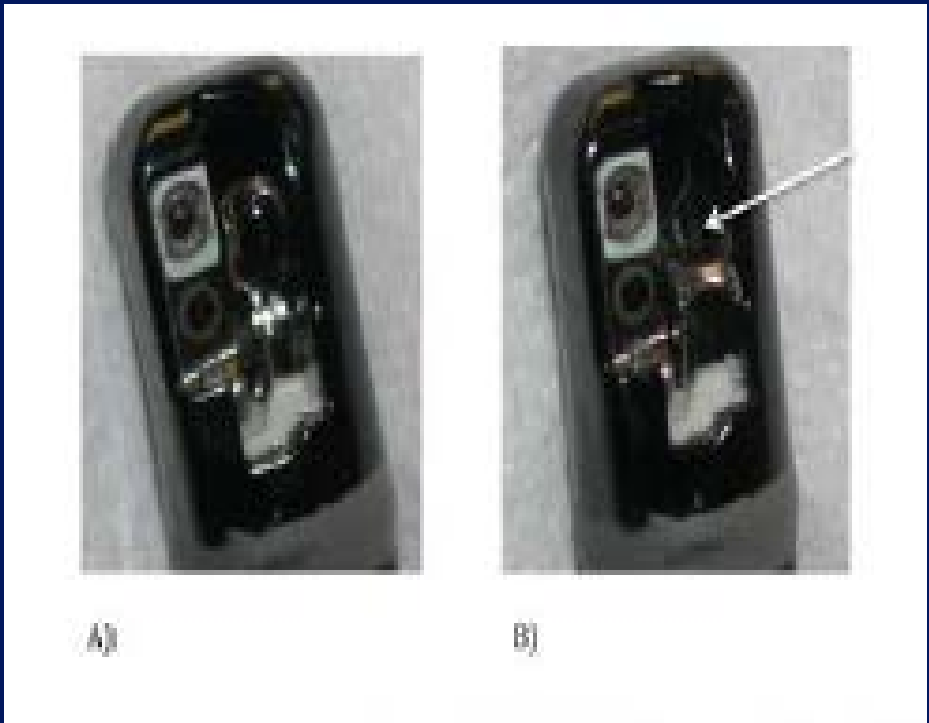
- All endoscopes (n=20) had visible irregularities (e.g., scratches)
- Researchers observed fluid (95%), discoloration, and debris in channels
- 60% scopes with microbial contamination

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 45^0) 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

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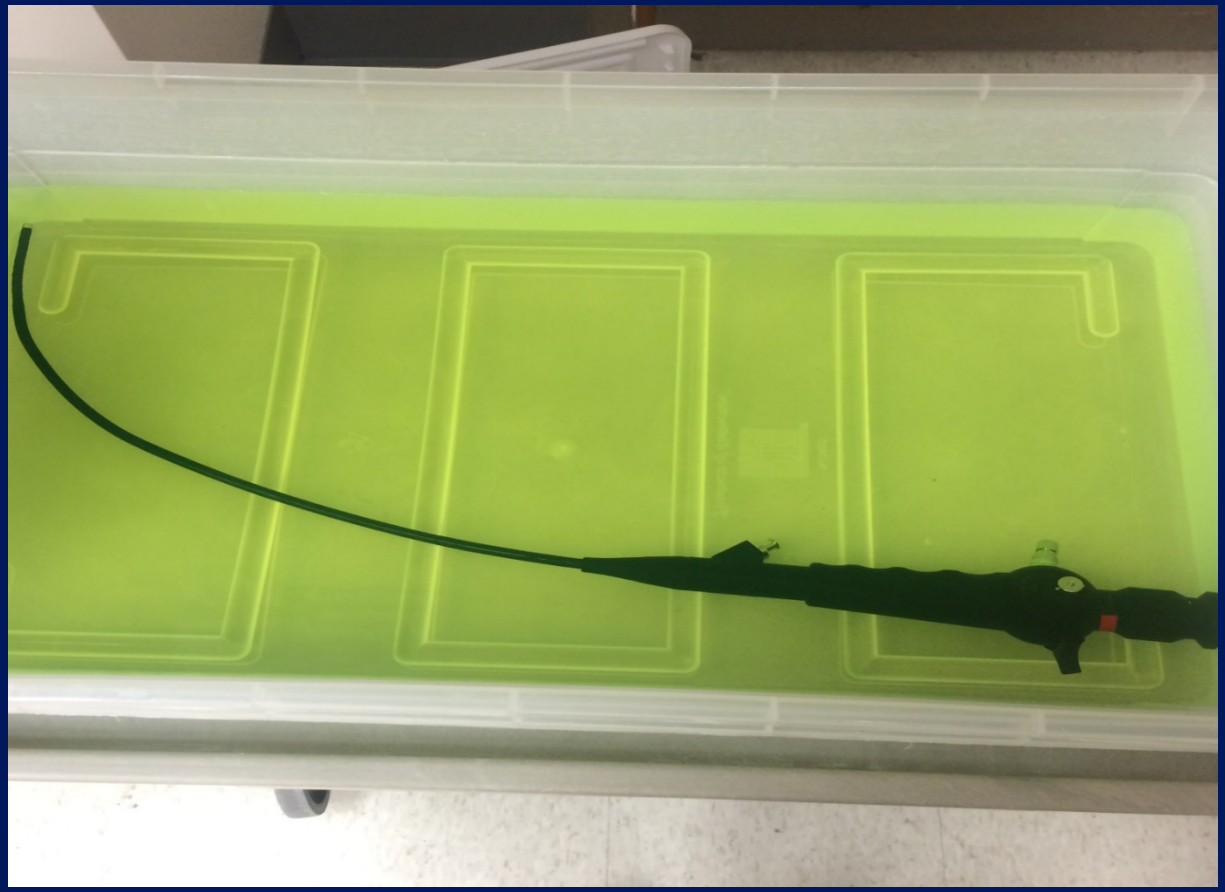
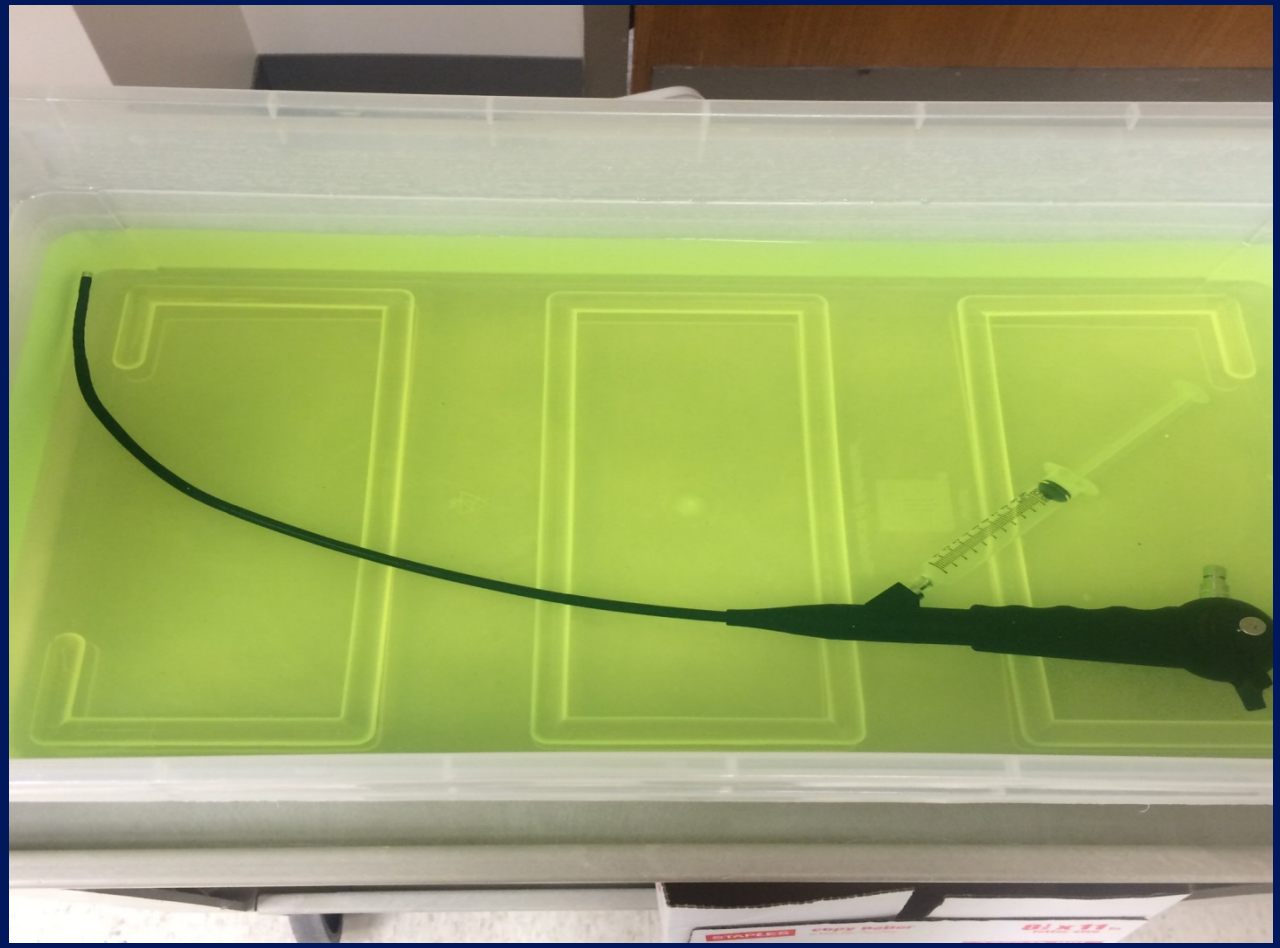
Reprocessing Channeled Endoscopes

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

Reprocessing Channeled Instruments

Cadnum et al, SHEA 2017 Poster

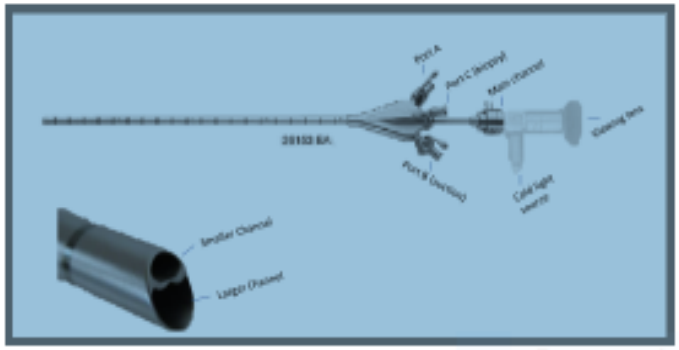


Figure 2. Hysteroscope Diagram

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
Valves disassembled: 12 min OPA soak (N=4)		
Main Channel (5mm)	5.0-7.0	0
Side Port A (≤ 1.5mm)	5.0-7.0	3.5
Side Port B (≤ 1.5mm)	5.0-7.0	3.8
Side Port C (≤ 1.5mm)	5.0-7.0	3.8
Without disassembly of valves: 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

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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


RUSCH
Mac. 2/s
RUSCH


RUSCH
RUSCH
Mac. 2

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).

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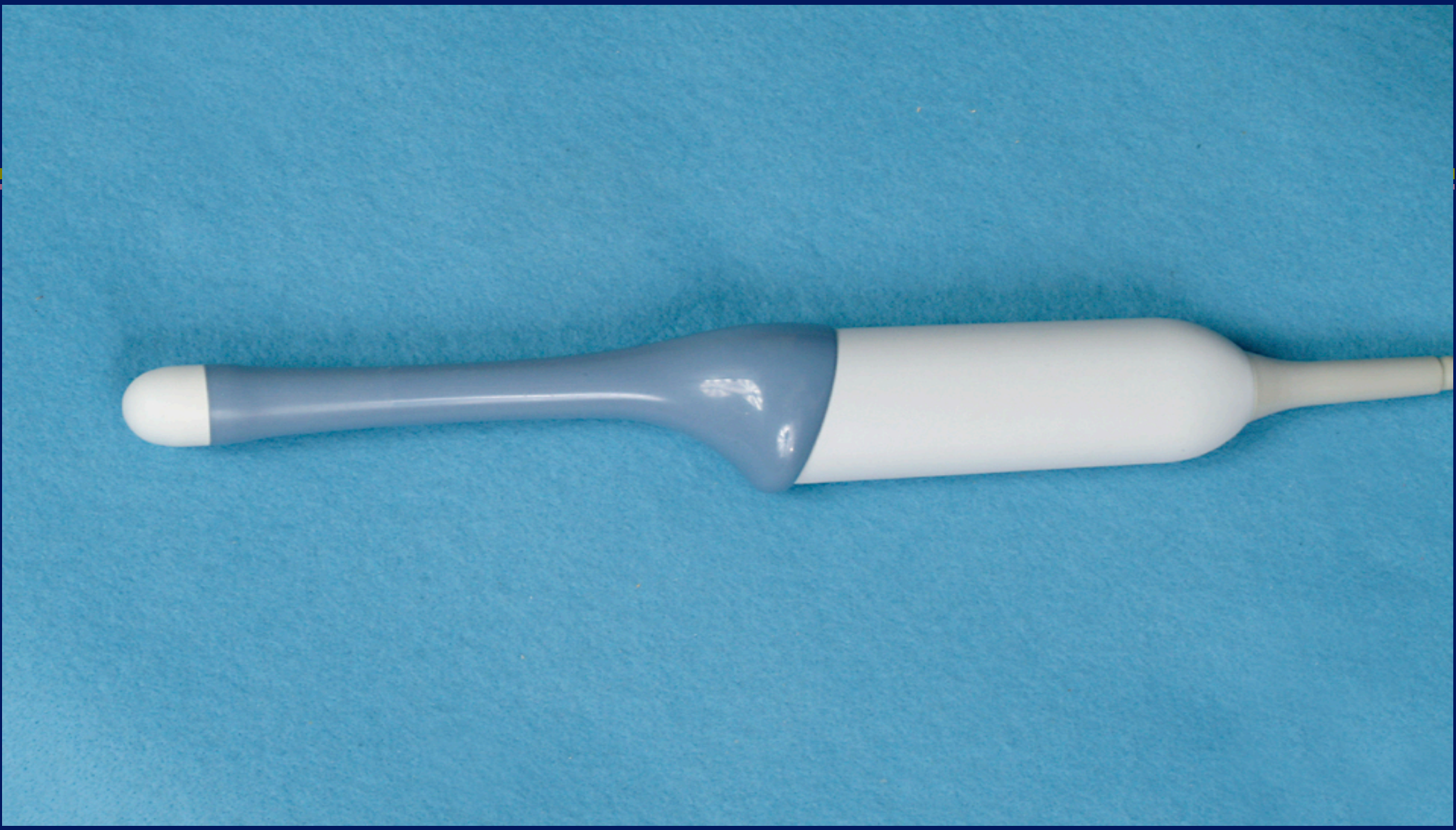

Endocavitary Probes

Rutala, Weber, HIPAC. 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 pf 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)

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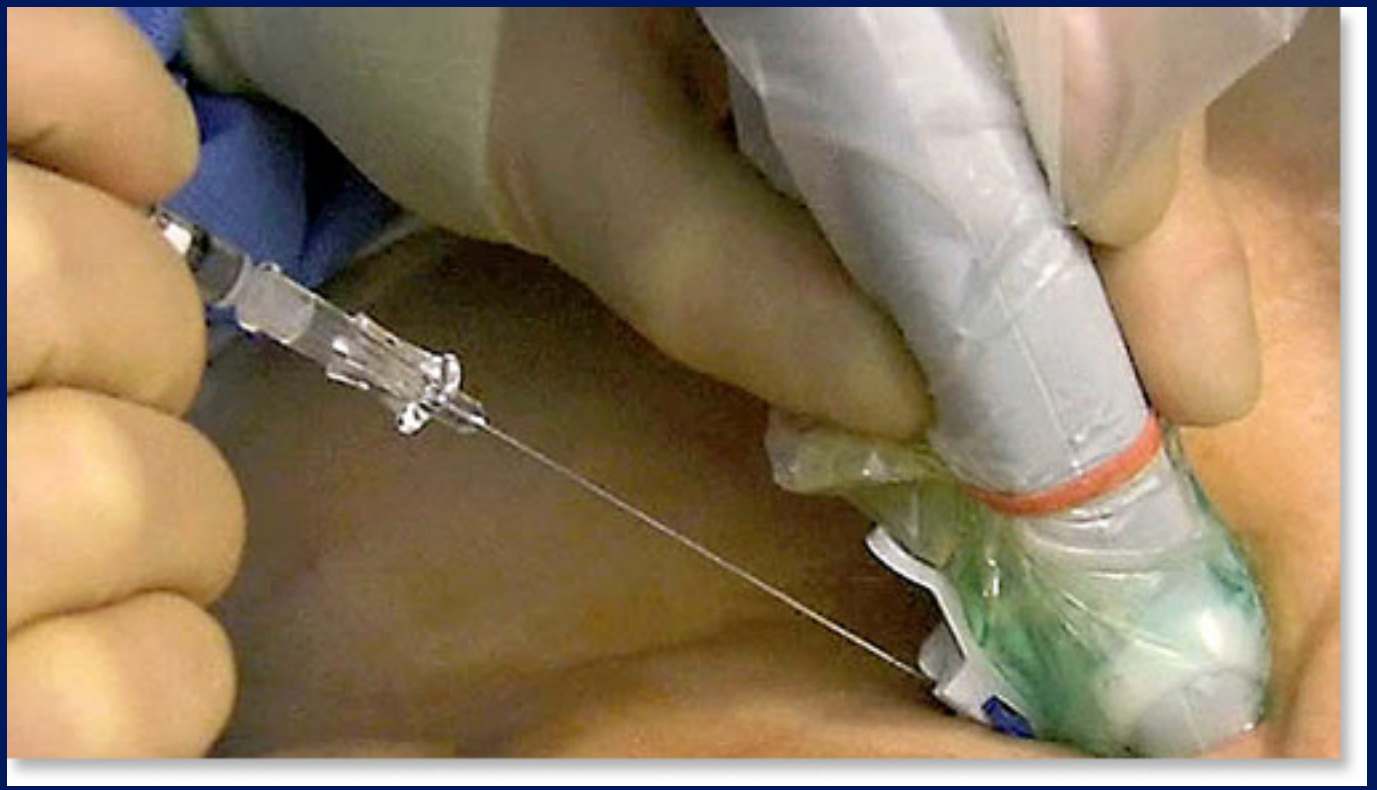
Do ultrasound transducers used for placing peripheral or central venous access devices require HLD/sterilization?



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

- 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.
- Some publications have interpreted CDC and AIUM recommendations differently (AJIC 2018:46:913-920): ultrasound guided CVC insertion (critical-sterilize or HLD with sterile sheath and sterile gel); scan across unhealthy skin (semicritical-HLD and use with clean sheath and clean gel)

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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- Reprocessing laryngoscopes
- Endocavitary probes
- Ultrasound probe reprocessing
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- CRE susceptible to germicides
- *C. auris* susceptible to most disinfectants but not antiseptics

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

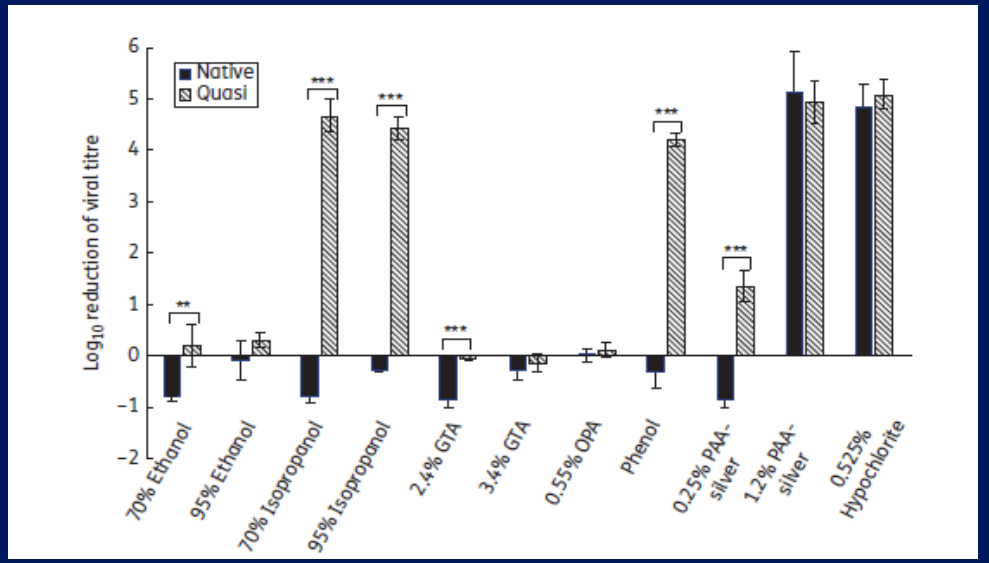
Human Papillomavirus Contamination of Gynecologic Equipment

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

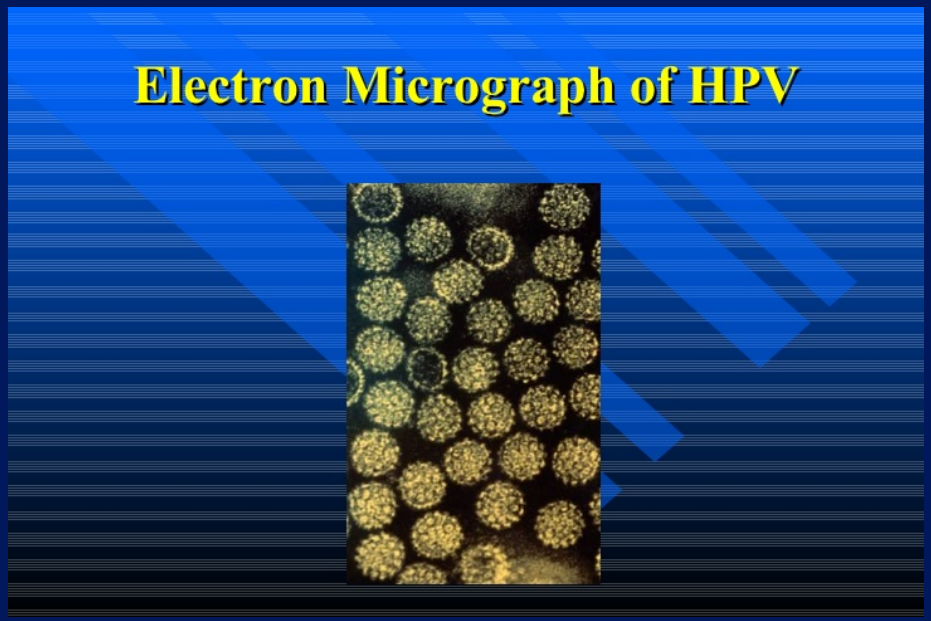
- Assess presence of HPV on equipment used in GYN practice
- Samples from fomites (glove box, lamp on GYN chair, gel tubes, colposcope, speculum) in 2 hospitals and 4 private practices
- Samples analyzed by real-time PCR
- 32 (18%) HPV-positive samples found
- Higher risk of HPV contamination in GYN 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)



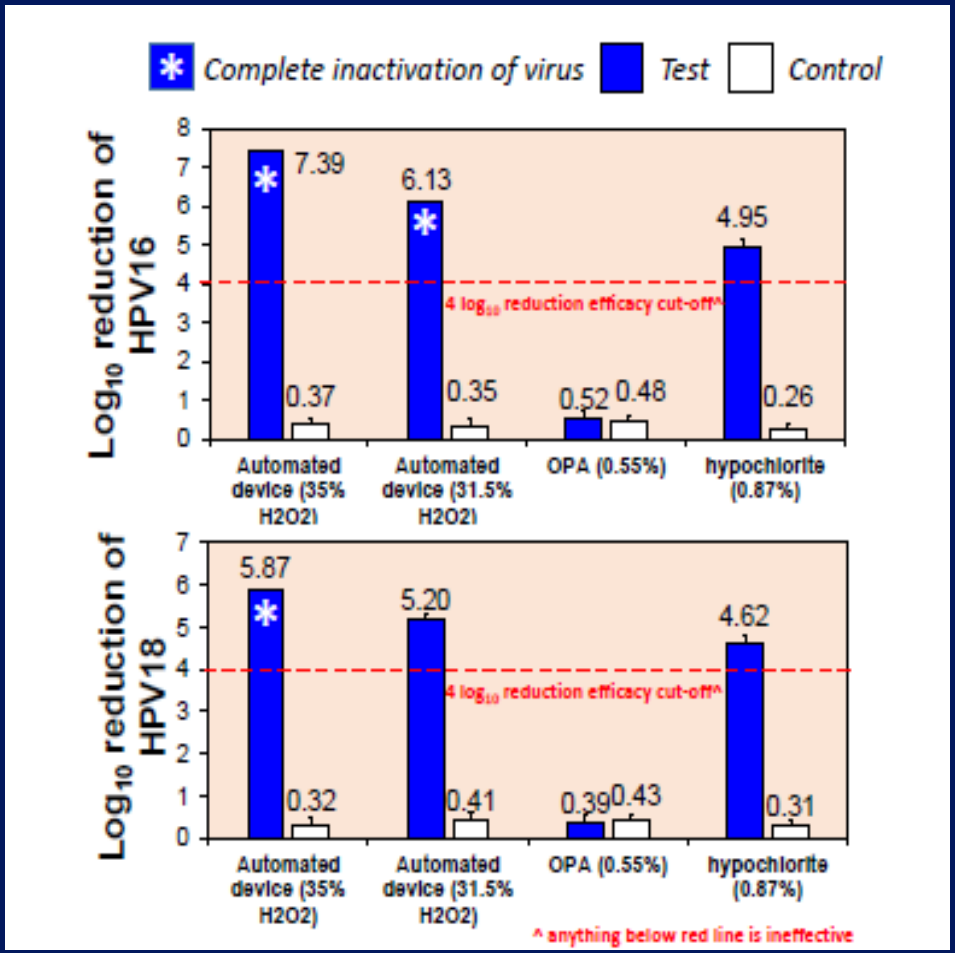
What if HPV is Resistant to Aldehydes?



- 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_{10} reduction, OPA achieved <1 log_{10} reduction

Disinfection and Sterilization: What's New

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
  - Emerging Pathogens
    - Inactivation data- *Candida auris*, CRE-carbapenem-resistant *Enterobacteriaceae*

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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%)
- 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)

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 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

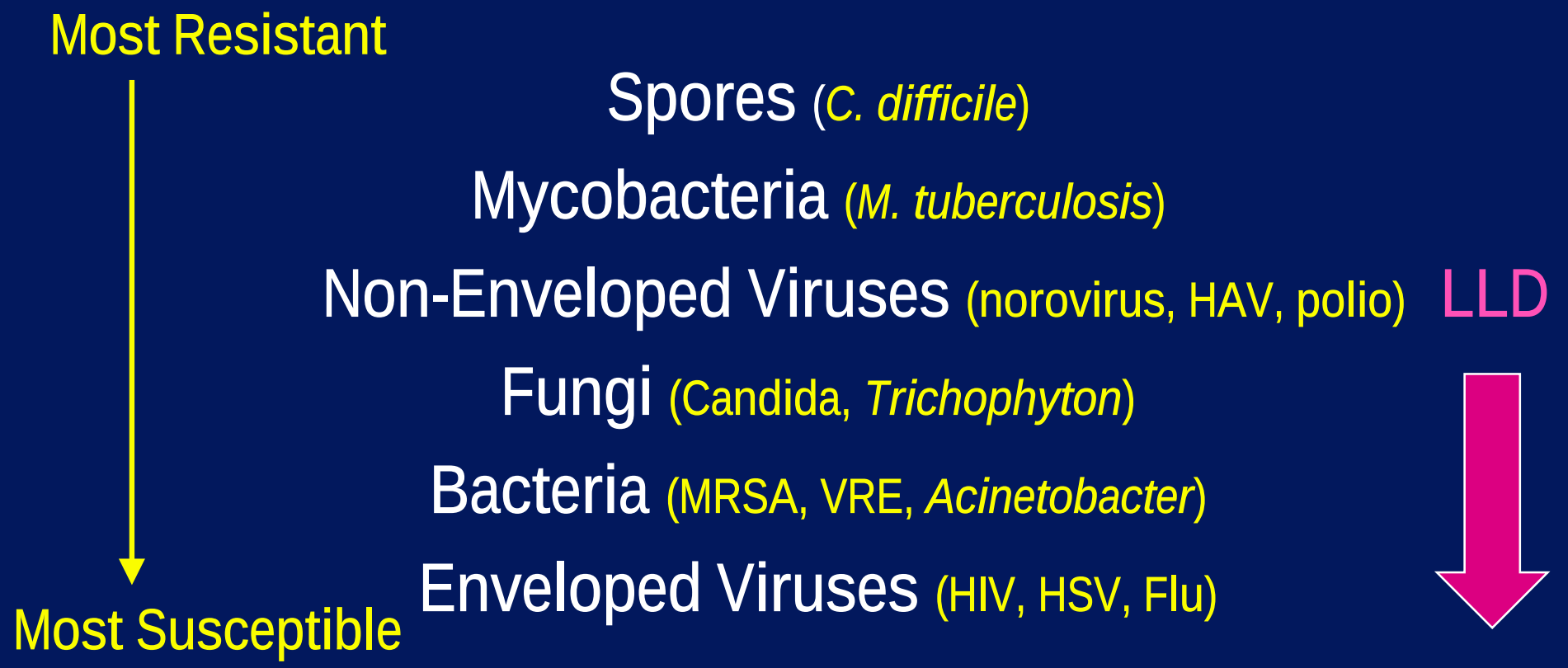
Exposure time ≥ 1 min

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 (*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



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.

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;[1] David J. Weber, MD, MPH[1,2]

(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."[1] 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)."[1,3] 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 for wipes/sprays, 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

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 *Staphylococcus aureus, Pseudomonas aeruginosa, and Salmonella enteric.* 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

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

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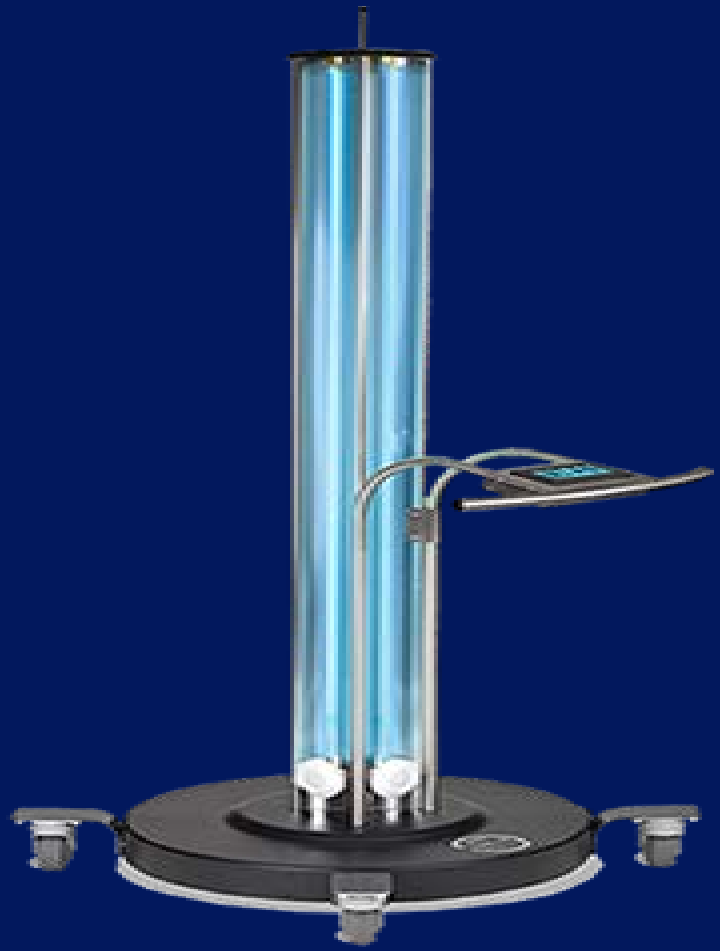
“NO TOUCH” APPROACHES TO ROOM DECONTAMINATION

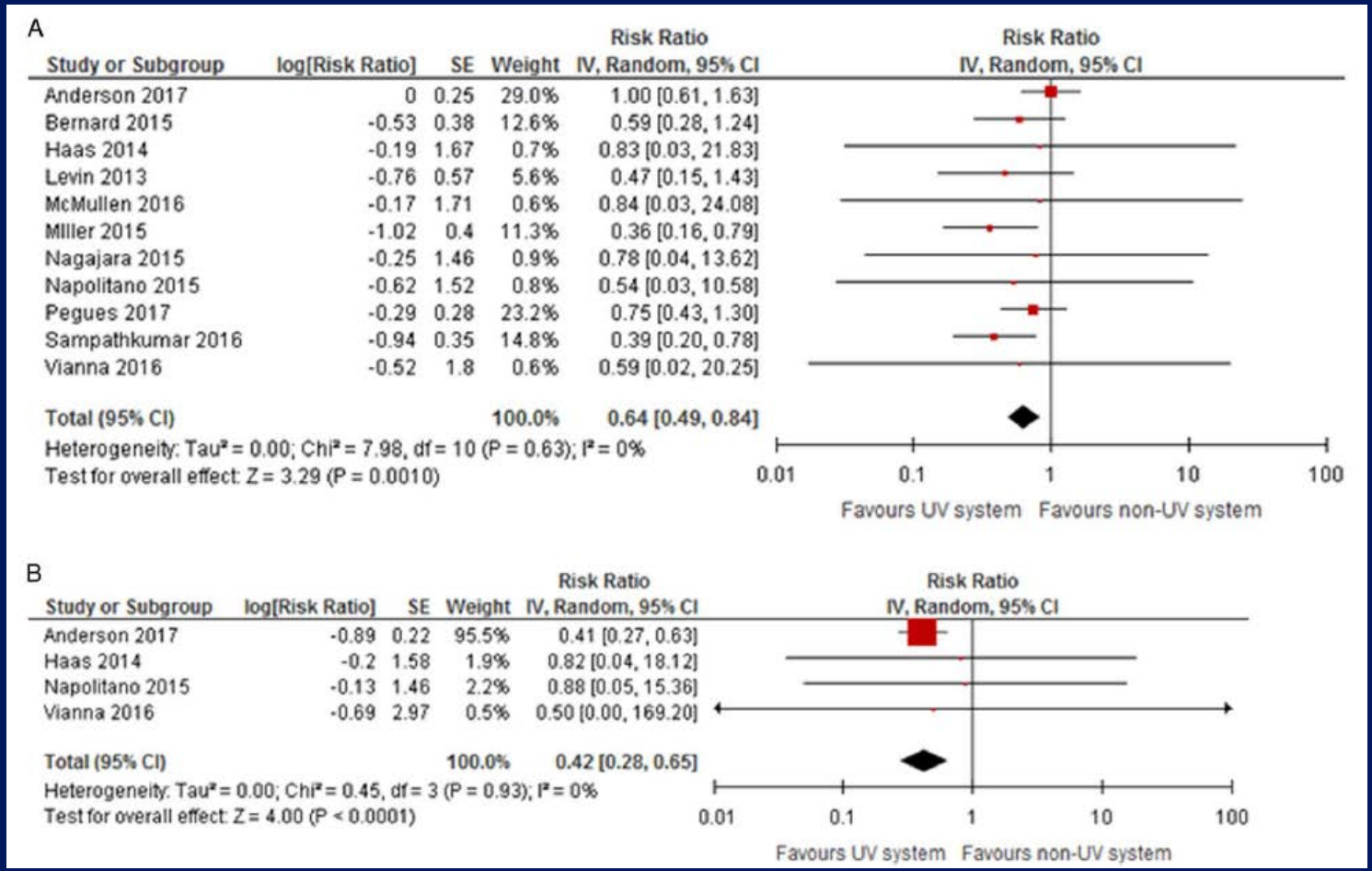
(UV/VHP~20 microbicidal studies, 12 HAI reduction studies; will not discuss technology with limited data)

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)[a]	60.8	3.4	11.7	6.3
Reduction (%)		94	81	90
Colonization/Infection (rate)[a]	2.3	1.5	1.9	2.2
Reduction (%)		35	17	4

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

This technology (“no touch”-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

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 (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 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[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

Disinfection and Sterilization: What's New
Learning Outcomes

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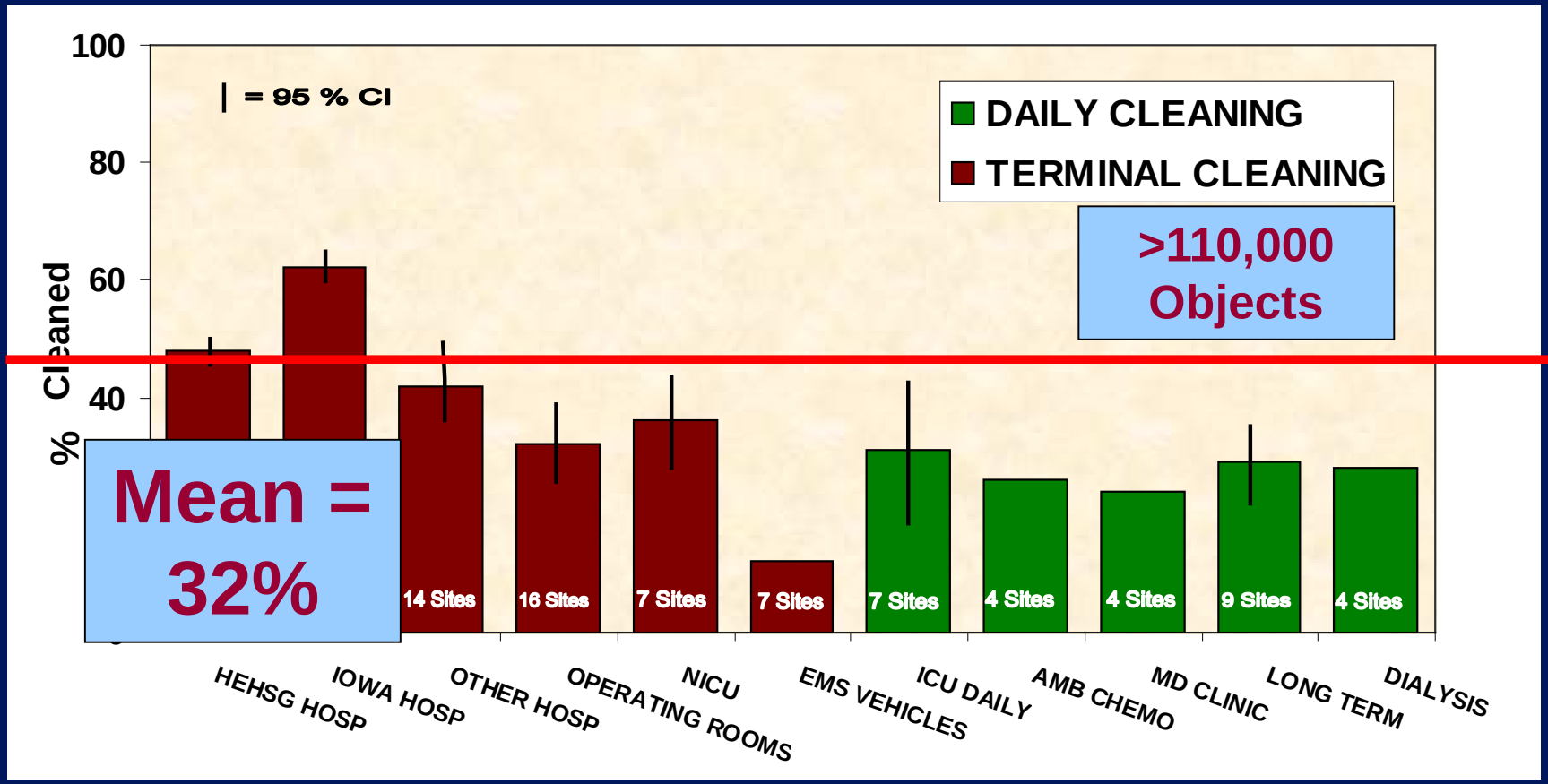
Effective Surface Decontamination

Product and Practice = Perfection

Thoroughness of Environmental Cleaning

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



MONITORING THE EFFECTIVENESS OF CLEANING

Cooper et al. AJIC 2007;35:338

- Visual assessment-not a reliable indicator of surface cleanliness
- ATP bioluminescence-measures organic debris (each unit has own reading scale, <250-500 RLU)
- Microbiological methods-<2.5CFUs/cm^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

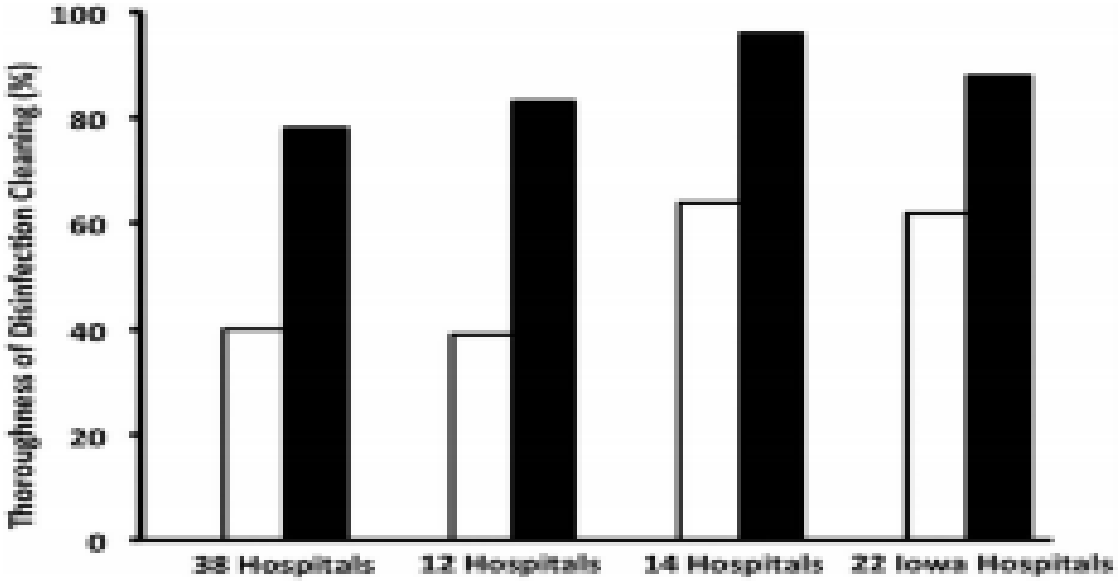
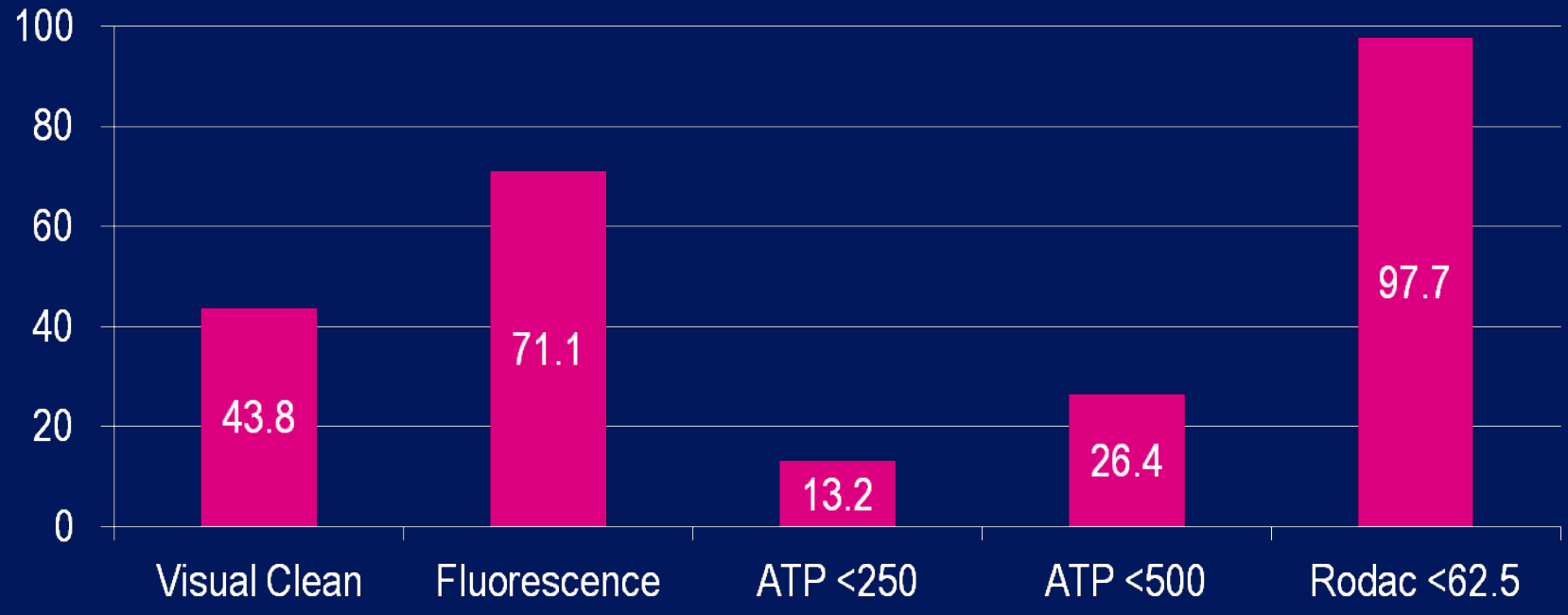


FIGURE 4. A comparison of the results of the 3 previously published multisite studies compared with results from the Iowa project. White bars represent the average baseline TDCs and black bars represent the average final TDCs for sites that completed each study.

Percentage of Surfaces Clean by Different Measurement Methods

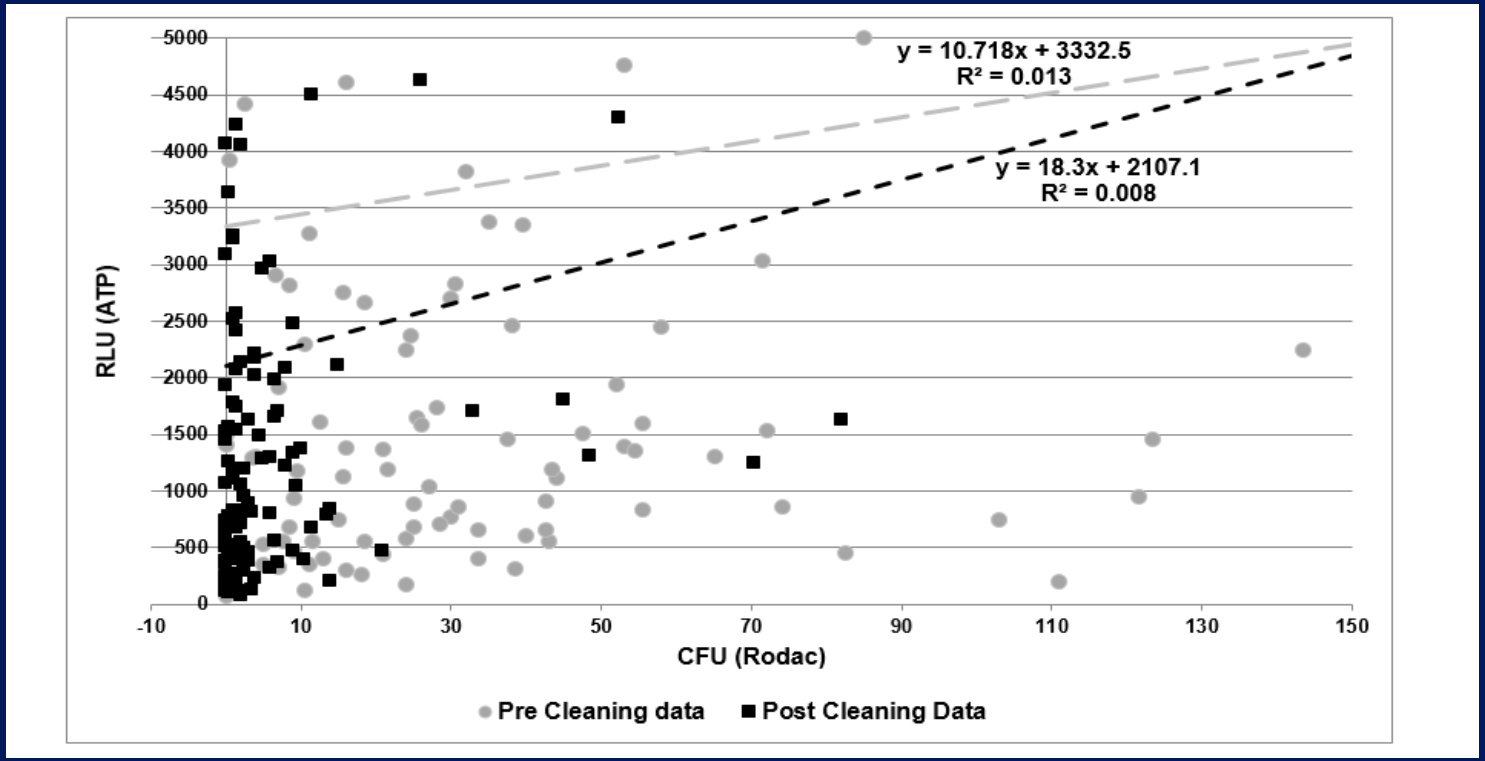
Rutala, Kanamori, Gergen, Sickbert-Bennett, Huslage, Weber. APIC 2017.

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.

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

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

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

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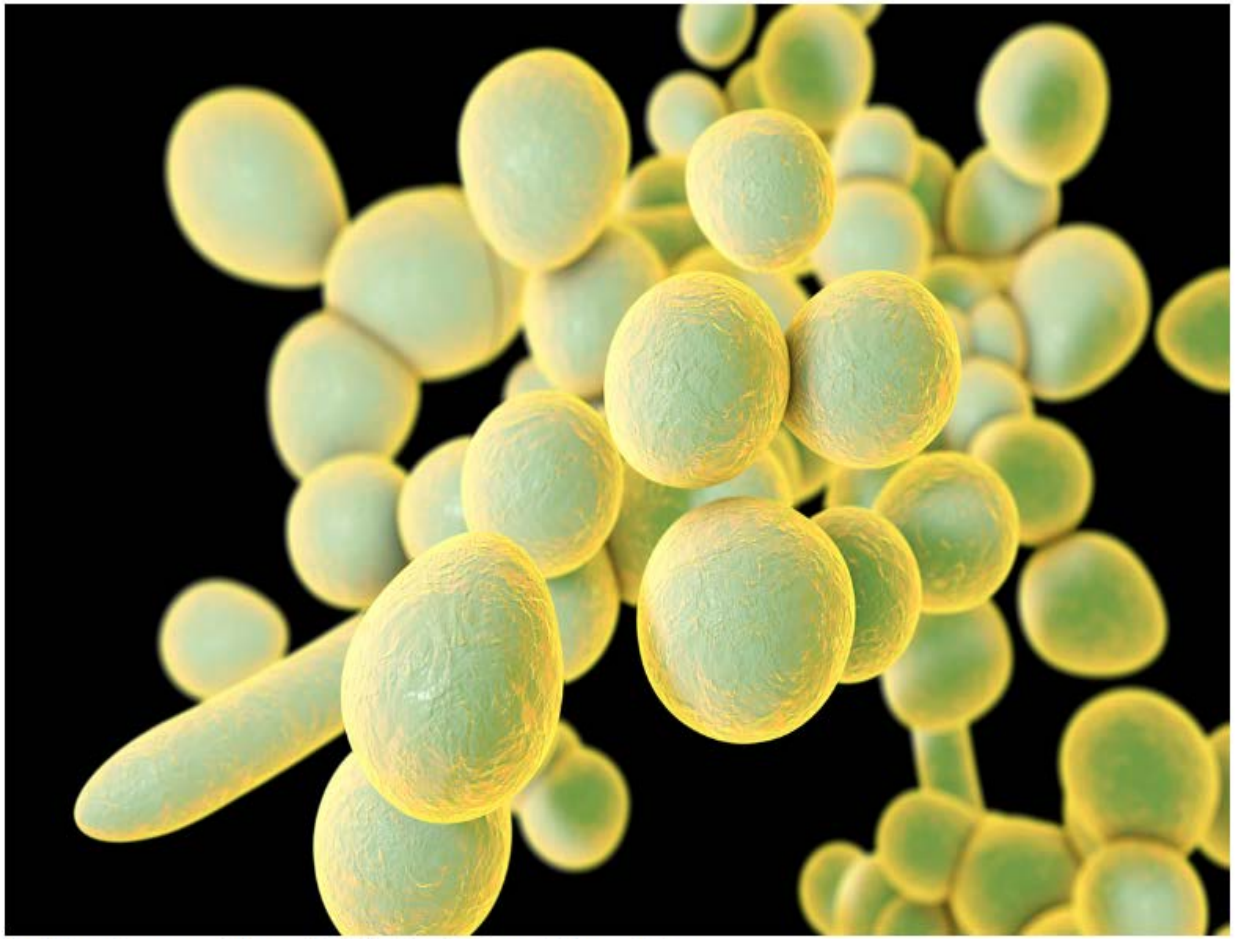
Deadly, drug-resistant Candida yeast infection spreads in the US



Candida auris causes multidrug-resistant infections that can result in organ failure

Kateryna Kon/Science Photo Library

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, 2017 ID Week Poster

- ≥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%

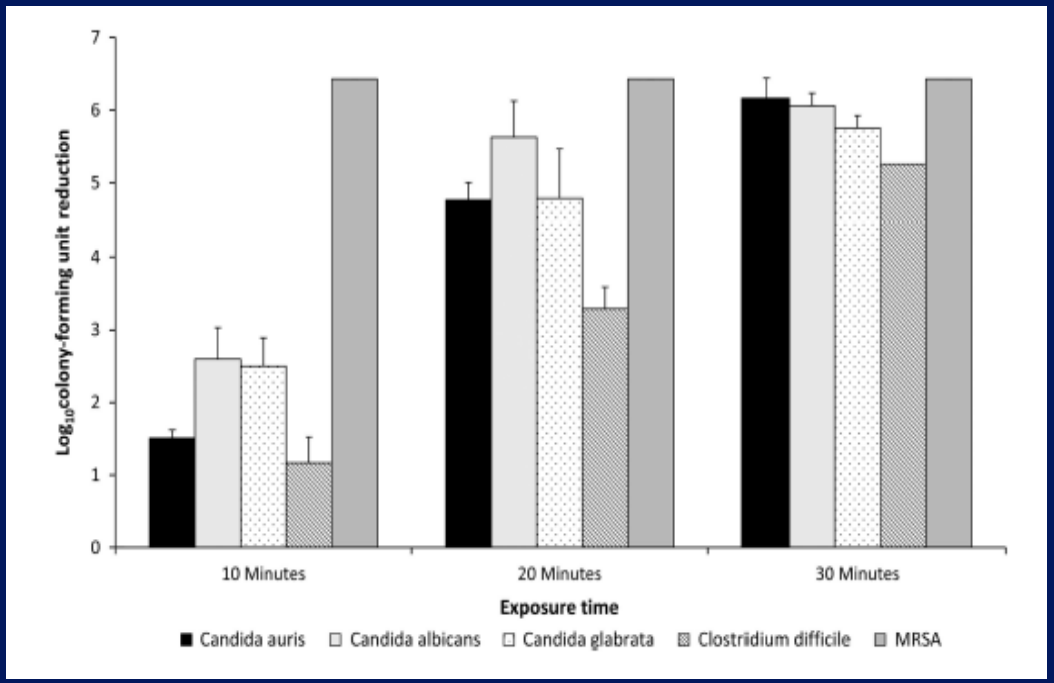
Efficacy of Disinfectants and Antiseptics against *Candida auris*

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

- ≤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

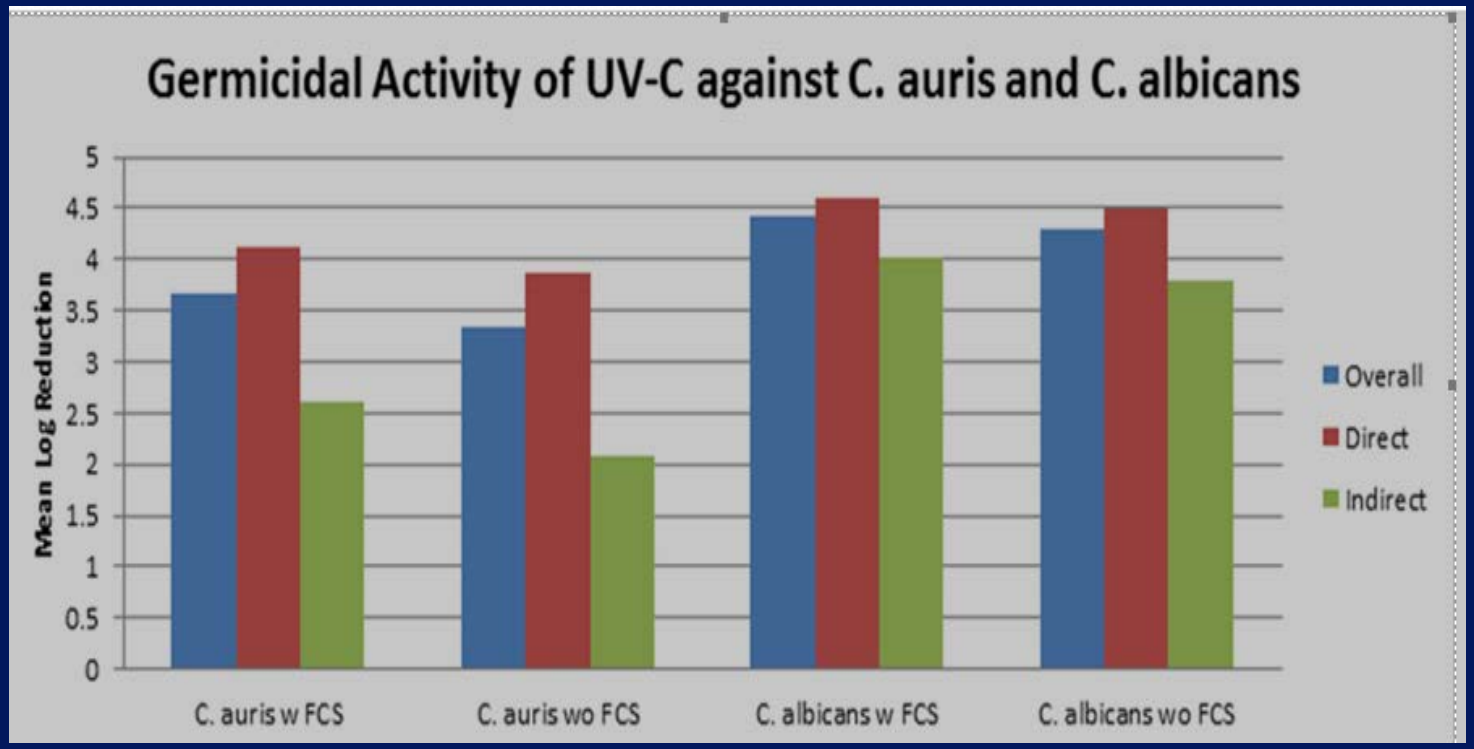


Inoculum spread to cover 20mm diameter steel disk, disk placed 5 feet from UV device

- 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*)

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, 12,000µWs/cm^2).

Disinfection and Sterilization: What's New

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
  - 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
- Reprocessing laryngoscopes
- Endocavitary probes
- Uncertain if OPA/glut kill HPV
- Ultrasound probe reprocessing
- Develop a noncritical surface bundle including "no touch"
- Touchable surfaces should be wiped and monitor cleaning
- 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

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

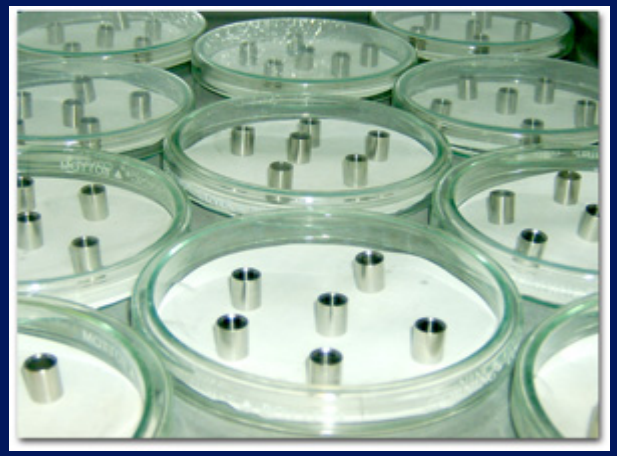
Dilutable liquid disinfectant-contact time is “wet” time

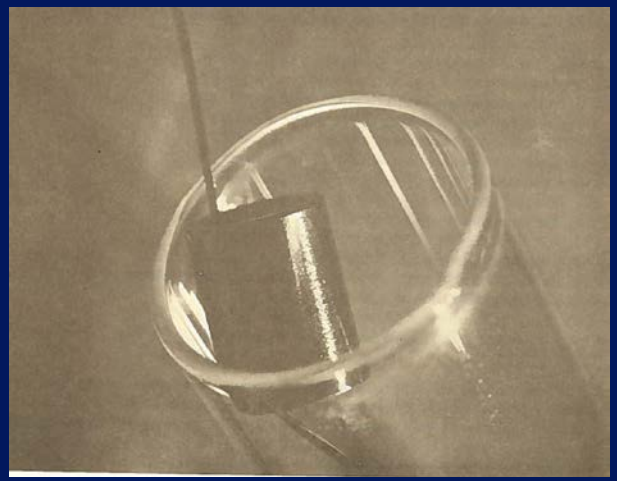
Wipes/Sprays-treatment time is undisturbed time (“wet” time is not relevant)

Surface Disinfection:

Treatment Time (Wipes/Sprays) versus Contact Time (Liquids)

Rutala, Weber. ICHE 2018;39:329-331





- Registration test for liquid disinfectants is the AOAC Use-Dilution Method (UDM).
- SS cylinders are inoculated with the test organism (*S. aureus, S. choleraesuis, P. aeruginosa*) and then dried. After drying, the cylinder is transferred to a disinfectant tube and immersed in the disinfectant for the contact time (e.g., 5 minutes).
- Thus, for liquid disinfectants tested by the UDM, the contact time should be the “wet” time (not undisturbed time).

Surface Disinfection:

Treatment Time (Wipes/Sprays) versus Contact Time (Liquids)

Rutala, Weber. ICHE 2018;39:329-331. Photos James Clayton.

- Registration test for wipe is EPA Disinfectant Towelette Test
- Treatment time is equal to combination of physical removal and inactivation caused by the disinfectant regardless of the surface appearance (i.e. wet or dry)
- Thus, if disinfectant wipe has a registration time of 1 minute, then the surface should be allowed to remain undisturbed for the registration time of 1 minute (i.e. wet time is not relevant)