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

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#### DISCLOSURES 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*)

# 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
- Endocavitary probes

- Uncertain if OPA/glut kill HPV
- CRE susceptible to germicides
- *C. auris* susceptible to most disinfectants but not antiseptics

# www.disinfectionandsterilization.org

# **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.

# 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 (duodenoscopeslever position), channeled endoscopes, HPV risks/studies
  - Low-level disinfection of non-critical items
    - Noncritical surface disinfection bundle
  - 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)

# 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.<sup>1</sup> Because gastrointestinal endoscopes contact mucosal surfaces, use of a contaminated endoscope may lead to patient-to-patient transmission of potential pathogens with a subsequent risk of infection.<sup>1</sup>

In this issue of JAMA, Epstein and colleagues<sup>2</sup> report findings from their investigation of a cluster of New Delhi metallo- $\beta$ -lactamase (NDM)-producing *Escherichia coli* associated with gastrointestinal endoscopy that occurred from March 2013 to

Related article page 1447

July 2013 in a single hospital in northeastern Illinois. During the 5-month period, 9 paFirst, endoscopes are semicritical devices, which contact mucous membranes or nonintact skin, and require at least highlevel disinfection.<sup>3,4</sup> High-level disinfection achieves complete elimination of all microorganisms, except for small numbers of bacterial spores. Because flexible gastrointestinal endoscopic instruments are heat labile, only high-level disinfection with chemical agents or low-temperature sterilization technologies are possible.<sup>3</sup> However, no low-temperature sterilization technology is US Food and Drug Administration (FDA)-cleared for gastrointestinal endoscopes.

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

# 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.

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

NONCRITICAL -objects that touch only intact skin require lowlevel 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 (bigb level disinfection).
- 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).

# Where are we?

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

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

# **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<sup>-6</sup> achieved (2 LTS technologies, FDA-cleared)
- Disposable sterile GI endoscopes/bronchoscopes (4 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<sup>7</sup>-10<sup>10</sup>
    - Complexity
    - Biofilm
- Other semicritical devices, rare outbreaks
  - ENT scopes, endocavitary probes (prostate, vaginal, TEE), laryngoscopes, cystoscopes
  - Reduced microbial load, less complex

# Infections/Outbreaks Associated with Semicritical Medical Devices

Rutala, Weber, AJIC, In preparation

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

# Infections/Outbreaks Associated with Semicritical Medical Devices

Rutala, Weber, AJIC, In preparation

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

# Infections/Outbreaks Associated with Semicritical Medical Devices

Rutala, Weber, AJIC, In preparation

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TEE-Transesophageal echocardiogram	3	0
GI Endoscopes/Bronchoscopes	~130	4 (HBV-1 GI; HCV-3 GI; HIV-0)

## High-Level Disinfection of "Semicritical Objects"

Exposure Time <u>&gt;</u> 8m-45m (US), 20°C		
Germicide	Concentration	
Glutaraldehyde	<u>&gt; 2.0%</u>	
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%	

<sup>\*</sup>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<sup>7-10</sup>
  - Cleaning results in 2-6 log<sub>10</sub> reduction
  - High-level disinfection results in 4-6 log<sub>10</sub> reduction
  - Results in a total 6-12 log<sub>10</sub> reduction of microbes
  - Level of contamination after processing: 4log<sub>10</sub> (maximum contamination, minimal cleaning/HLD)
- Complexity of endoscope and endoscope reprocessing
- Biofilms-may 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°) 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)



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

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

Rutala, Weber, HIPAC. <u>www.cdc.gov</u> 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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# 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 FDAcleared instructions (no alterations)



# What if HPV is Resistant to Aldehydes?



- If unlike all other nonenveloped viruses that are susceptible to aldehydes
- Upsets the Spaulding classification scheme (HLD kills all viruses)

 If only oxidizing agents kill HPV (transition to PA or HP alone or combination) or HP mist device (for probes)

# Efficacy of Hydrogen Peroxide Mist Against HPV

Meyers C et al. SHEA Poster, 2015



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

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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.

### • $\geq$ 3 log<sub>10</sub> 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



 $\it Candida\ auris$  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<sub>10</sub> (most <2 log<sub>10</sub>) 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<sup>2</sup>).

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## 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.
- 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

