High-Level Disinfection, Sterilization and Disinfection

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DISCLOSURES

2020-2021

- **Consultations**
  - Professional Disposables International (PDI)
- **Honoraria**
  - PDI

www.disinfectionandsterilization.org

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)

Sterilization and Disinfection

- Describe the Spaulding classification scheme for disinfection of patient care items
- Describe available methods for sterilization and types of indicators used to ensure the process was effective
- Understand the advantages and disadvantages of the various disinfectants and mechanical processes used to disinfect medical equipment and environmental surfaces
- Outline the controversies surrounding the reprocessing of endoscopes and disinfection of other complex medical instruments

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CDC Guideline for Disinfection and Sterilization

Rutala, Weber, HICPAC. November 2008. www.cdc.gov; Rutala et al. AJIC 2019;47:A3-A9

Medical/Surgical Devices

WA Rutala, DJ Weber, and HICPAC, www.cdc.gov; Rutala, Weber AJIC 2019;47:A3-A9

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/environmental surfaces 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 2019;47:A3-A9

- Critical
  - 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

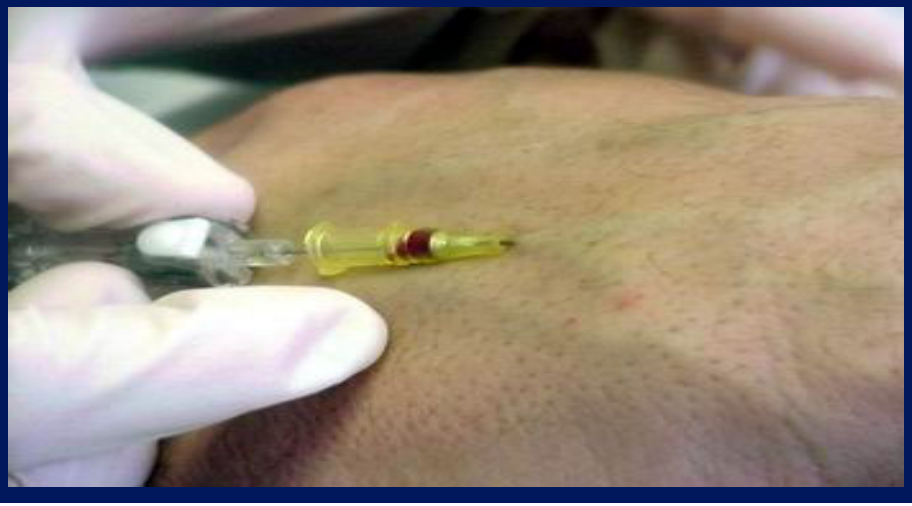
Semicritical Medical Devices

Rutala et al. Am J Infection Control (AJIC) 2019;47:A3-A9

- 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

Noncritical Environmental Surfaces and Medical Devices

Rutala et al. AJIC 2019;47:A3-A9; Rutala, Weber. Env Issues NI, Farber 1987



- Noncritical environmental surfaces and 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

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Critical Items
Sterilization

The complete elimination or destruction of all forms of microbial life and is accomplished in healthcare facilities by either physical or chemical processes

Sterilization of "Critical Objects"

Rutala, Weber, HICPAC. November 2008. www.cdc.gov; Rutala et al. AJIC 2019;47:A3-A9

Heat resistant

- Steam sterilization

Heat sensitive

- Ethylene oxide
- Hydrogen peroxide gas plasma
- Ozone and hydrogen peroxide
- Vaporized hydrogen peroxide

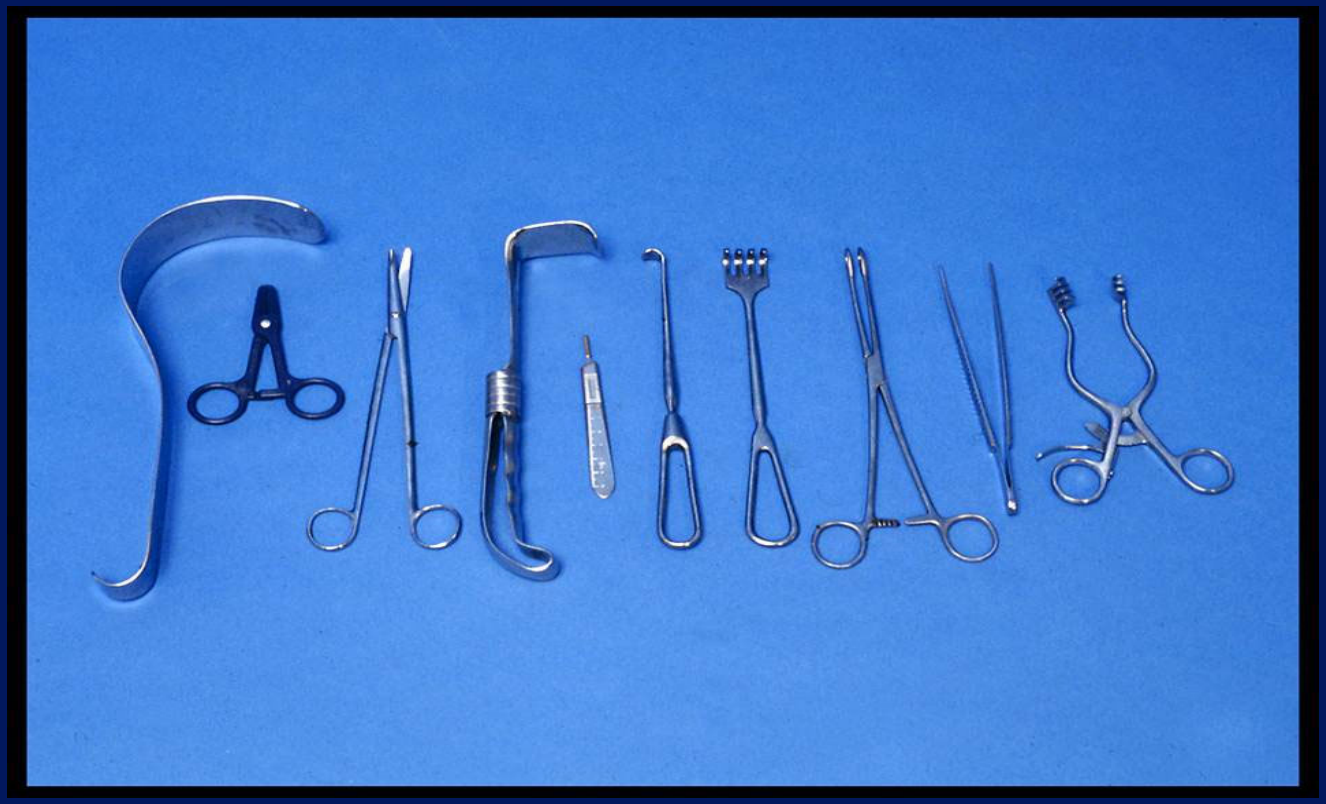

#7 GAS
#8 GAS
STERIS
STERIS

Cleaning

- Items must be cleaned using water with detergents or enzymatic cleaners before processing.
- Cleaning reduces the bioburden and removes foreign material (organic residue and inorganic salts) that interferes with the sterilization process.
- Cleaning and decontamination should be done as soon as possible after the items have been used as soiled materials become dried onto the instruments.

Microbial Load on Surgical Instruments

Surgical instruments-$<10^2$ bacteria



Washer/Disinfector

Removal/Inactivation of Inoculum (Exposed) on Instruments

Rutala WA, Gergen MF, Weber DJ. ICHE 2014;35:883-885

WD Conditions	Organism	Inoculum	Log Reduction	Positives
Routine	MRSA	$2.6x10^7$	Complete	0/8
Routine	VRE	$2.6x10^7$	Complete	0/8
Routine	*P aeruginosa*	$2.1x10^7$	Complete	0/8
Routine	*M terrae*	$1.4x10^8$	7.8	2/8
Routine	GS spores	$5.3x10^6$	4.8	11/14
No Enz/Det	VRE	$2.5x10^7$	Complete	0/10
No Enz/Det	GS spores	$8.3x10^6$	5.5	8/10

Washer/disinfectors are very effective in removing/inactivating microorganisms from instruments

Steam Sterilization

Rutala, Weber AJIC 2019;47:A3-A9

- Advantages
  - Non-toxic
  - Cycle easy to control and monitor
  - Inexpensive
  - Rapidly microbicidal
  - Least affected by organic/inorganic soils
  - Rapid cycle time
  - Penetrates medical packing, device lumens
- Disadvantages
  - Deleterious for heat labile instruments
  - Potential for burns

Minimum Steam Sterilization Times

Time at 132°C in Prevacuum Sterilizer

Rutala, Weber, HICPAC. November 2008. www.cdc.gov

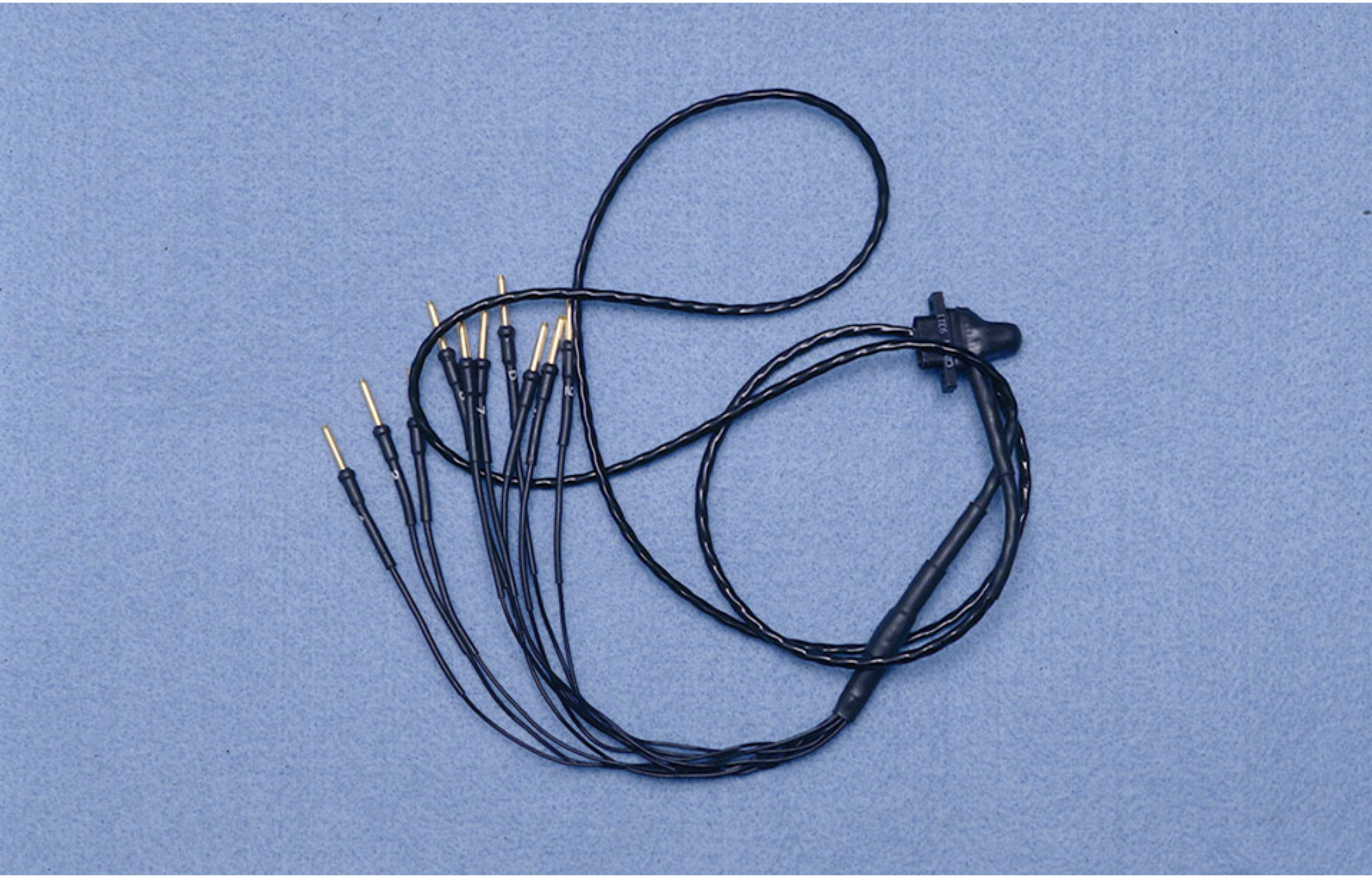
Item	Minimum exposure	Minimum drying time
Wrapped instruments	4 min	30 min
Textile packs	4 min	5 min

Immediate Use Steam Sterilization

- "Flash" originally defined as sterilization of an unwrapped object at 132°C for 3 min at 27-28 lbs pressure in gravity
- "Flash" used for items that must be used immediately and sterilized unpackaged (not sterile once removed from sterilizer)
- "Flash" is an antiquated term and replaced by "immediate use steam sterilization"
- The same critical reprocessing steps (such as cleaning, decontaminating, and transporting) must be followed

Immediate Use Steam Sterilization

- “Immediate Use” is defined as the shortest possible time between a sterilized item’s removal from sterilizer and aseptic transfer to sterile field
- A sterilized item intended for immediate use is not stored for future use.
- Sterilization process monitoring is essential
- Instruments inventories should be adequate to meet surgical volumes and permit the time to complete all critical elements of reprocessing



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Heat resistant

- Steam sterilization

Heat sensitive

- Ethylene oxide
- Hydrogen peroxide gas plasma
- Ozone and hydrogen peroxide
- Vaporized hydrogen peroxide

Conclusions

- All sterilization processes effective in killing spores
- Cleaning removes salts and proteins and must precede sterilization
- Failure to clean or ensure exposure of microorganisms to sterilant (e.g. connectors) could affect effectiveness of sterilization process

Sterilization Practices

Sterilization Monitoring

Rutala, Weber, CDC Guideline 2008. www.cdc.gov

Sterilization monitored routinely by combination of physical, chemical, and biological parameters

- Physical - cycle time, temperature, pressure
- Chemical - heat or chemical sensitive inks that change color when germicidal-related parameters present
- Biological - *Bacillus* spores that directly measure sterilization

Objectives of Monitoring the Sterilization Process

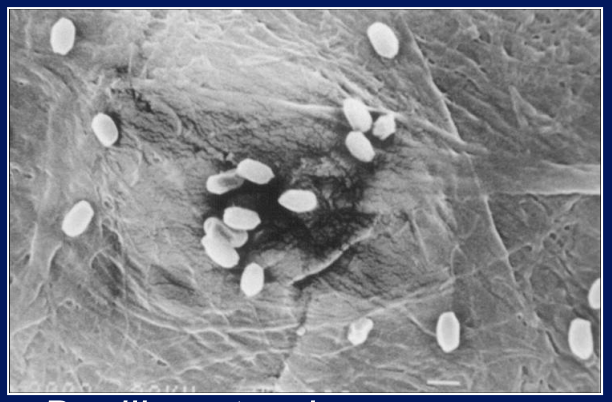
- Assures probability of absence of all living organisms on medical devices being processed
- Detect failures as soon as possible
- Removes medical device involved in failures before patient use

Sterilility Indicators Table

	Before Exposure (Do not use)	After Exposure (Sterile) (Ok if package is intact)
Steam Autoclave		
Tape		
Strip		
Peel Pack		
Ethylene Oxide (ETO. gas)		
Tape		

Biological Indicators

- **Select BIs that contain spores of *Bacillus atrophaeus***
  - Rationale: BIs are the only sterilization process monitoring device that provides a direct measure of the lethality of the process



Bacillus atrophaeus

Biological Monitors

Rutala, Weber, CDC Guideline 2008. www.cdc.gov

- Steam - *Geobacillus stearothermophilus*
- Dry heat - *B. atrophaeus (formerly B. subtilis)*
- ETO - *B. atrophaeus*
- New low temperature sterilization technologies
  - HP gas plasma - *G. stearothermophilus*
  - HP/Ozone -*G. stearothermophilus*

Rapid Readout BIs for Steam Now Require a 1-3h Readout Compared to 24-48h

Rutala, Jones, Weber ICHE 1996. 17:423

Vol. 17 No. 7 INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY 423

COMPARISON OF A RAPID READOUT BIOLOGICAL INDICATOR FOR STEAM STERILIZATION WITH FOUR CONVENTIONAL BIOLOGICAL INDICATORS AND FIVE CHEMICAL INDICATORS

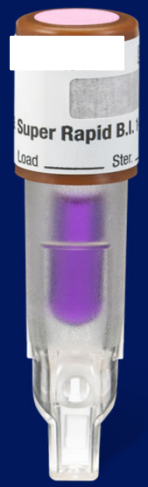
William A. Rutala, PhD, MPH; Suzanne M. Jones, MPH; David J. Weber, MD, MPH

Super Rapid Readout Biological Indicators

Commercially available

1491 BI (blue cap)

- Monitors 270°F and 275°F gravity –displacement steam sterilization cycles
- 30-minute result (from 1hour)



1492V BI (brown cap)

- Monitors 270°F and 275°F dynamic-air-removal (pre-vacuum) steam sterilization cycles
- 24 min (from 1 hour [3 hours])

Rapid Readout Biological Indicator for Steam (24-30m), ETO (4hr) and HP Sterilizers (variable)

Vaporized Hydrogen Peroxide (VHP) Biological Indicator Options (*all G. stearothermophilus*)

Refer to BI manufacturer's IFU for cycles the BI is cleared for

VHP read out time	Number of cleared biological indicators
24 hours	2
2 hours	1
30 minutes	1
24 minutes	1
20 minutes	1
15 minutes	1

Recommendations
Monitoring of Sterilizers
Rutala, Weber, CDC Guideline 2008. www.cdc.gov

- Monitor each load with physical and chemical (internal and external) indicators.
- Use biological indicators to monitor effectiveness of sterilizers at least weekly with spores intended for the type of sterilizer.
- Use biological indicators for every load containing implantable items

Recommendations
Monitoring of Sterilizers
Rutala, Weber, CDC Guideline 2008. www.cdc.gov

- Following a single positive biological indicator used with a method other than steam, treat as non-sterile all items that have been processed in that sterilizer, dating back to last negative biological indicator.
- Following a positive biological indicator with steam sterilization, objects, other than implantable objects, do not need to be recalled because of a single positive spore test unless the sterilizer or procedure is defective or inappropriate cycle settings. If additional spore tests remain positive, consider the items nonsterile and recall and reprocess the items from the suspect load.

Recommendations
Methods of Sterilization
Rutala, Weber, CDC Guideline 2008. www.cdc.gov

- Steam is preferred for critical items not damaged by heat
- Follow the operating parameters recommended by the manufacturer
- Use low temperature sterilization technologies for reprocessing critical items damaged by heat
- Use immediately critical items that have been sterilized by peracetic acid immersion process (no long term storage)

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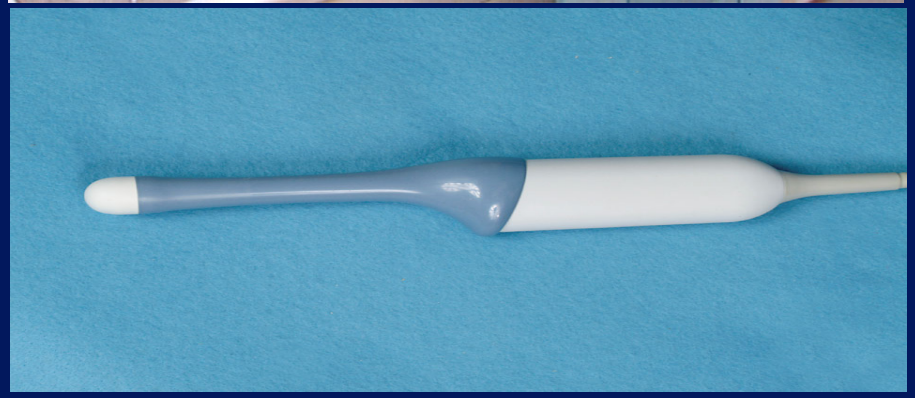
Semicritical Medical Devices

Rutala et al. AJIC 2019;47:A3-A9



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  - Control measure: high-level disinfection
  - Endoscopes top ECRI list of 10 technology hazards, >130 outbreaks (GI, bronchoscopes)
    - 0 margin of safety
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    - Reduced microbial load, less complex

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)

High-Level Disinfection of "Semicritical Objects"

Rutala, Weber AJIC 2019;47:A3-A9

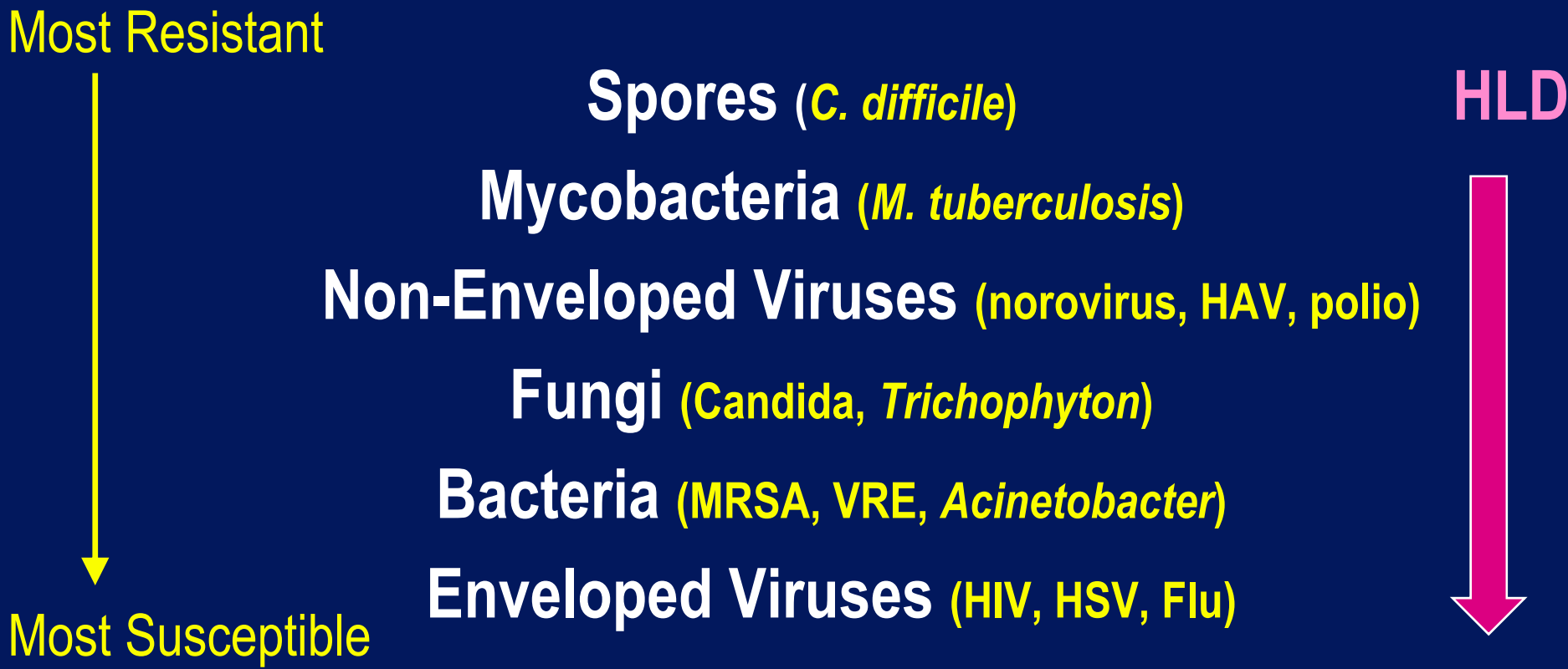
Exposure Time ≥ 8m-45m (US), 20°C

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



Comparison of Glutaraldehyde and OPA

Rutala, Weber. AJIC 2019;47:A3-A9

>2.0% Glutaraldehyde

- HLD: 45 min at 25°C
- Needs activator
- 14-day use life, 2-year shelf life
- ACGIH ceiling limit, 0.05ppm
- Strong odor
- MEC, 1.5%
- Cost - $10/gallon
- Disadv-slow mycobactericidal acttivity

0.55% Ortho-phthalaldehyde

- HLD: 12 min at 20°C
- No activator needed
- 14-day use life, 2-year shelf life
- No ACGIH or OSHA limit
- Weak odor
- MEC, 0.3%
- Cost - $30/gallon
- Disadv-Anaphylactic rxn w/ repeated exposure through cysto

Improved Hydrogen Peroxide

Rutala, Weber. AJIC 2019;47:A3-A9

- Advantages
  - No activation required
  - Enhanced removal of organisms
  - No disposal issues
  - No odor or irritation issues
  - No special venting requirements
  - Does not coagulate blood or fix tissues to surfaces
  - Use studies published
  - 8-min at 20°C HLD claim
- Disadvantages
  - Material compatibility concerns for brass, zinc, copper, and nickel/silver plating (cosmetic and functional damage)
  - Eye damage with contact

Peracetic Acid

Rutala, Weber. AJIC 2019;47:A3-A9

- Advantages
  - Enhanced removal of organisms
  - Single-use system eliminates need for concentration testing
  - Compatible with many materials and instruments
  - Does not coagulate blood or fix tissues to surfaces
  - Rapidly sporicidal
- Disadvantages
  - Used for immersible instruments only
  - More expensive than many HLD
  - Eye damage with contact
  - Potential material incompatibility (e.g., aluminum anodized coating becomes dull)

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Reprocessing Medical Devices:
The Good, The Bad and The Ugly

Transmission of Infection by Endoscopy

Kovaleva et al. Clin Microbiol Rev 2013. 26:231-254

Scope	Outbreaks	Micro (primary)	Pts Contaminated	Pts Infected	Cause (primary)
Upper GI	19	Pa, *H. pylori*, *Salmonella*	169	56	Cleaning/Dis-infection (C/D)
Sigmoid/Colon oscopy	5	*Salmonella*, HCV	14	6	Cleaning/Dis-infection
ERCP	23	*P. aeruginosa* (Pa)	152	89	C/D, water bottle, AER
Bronchoscopy	51	Pa, Mtb, Mycobacteria	778	98	C/D, AER, water
Totals	98		1113	249	

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

Duodenoscope-Related Outbreaks of CRE and Other MDROs Without Reprocessing Breaches

Rutala et al. AJIC 2019;47:A62-A66

MDRO	Resistance gene	No. of patients (infected)	Propagated outbreak	Positive scope(s)	Molecular link	Reference
Klebsiella pneumoniae	*mcr-1*	2	No	No	Yes-WGS	Shenoy et al, 2018[21]
K pneumoniae	$bla_{oxa-232}$	15 (8)	No	No	Yes-PCR	Kim et al, 2016[19]
Escherichia coli (AmpC)	bla_{CMY-2}	35	No	Yes (2)	Yes-PCR, PFGE	Wendorf et al, 2015[16]
K pneumoniae	bla_{oxa-48}	12	Yes	No	Yes-PCR, PFGE	Kola et al, 2015[23]
K pneumoniae	bla_{KPC}	34?	No	Yes (3)	Yes-PCR, PFGE, MLST, WGS	Marsh et al, 2015[22]
E coli	bla_{NDM}	39	Yes	Yes (1)	Yes-PCR, PFGE	Epstein et al, 2014[17]
Pseudomonas aeruginosa	bla_{VIM-2}	22	Yes	Yes (1)	Yes-PCR*, PFGE, repetitive-sequence-based PCR typing	Verfaillie et al, 2015[24]
E coli	bla_{NDM-1}	3 (3)	No	No	Unknown	Smith et al, 2015[20]
K pneumoniae	bla_{KPC-2}, bla_{SHV-12}	13	Yes	Yes (2)	Yes-PCR, PFGE, MLST	Carbonne et al, 2010[18]

CRE, carbapenem-resistant *Enterobacteriaceae*; *MDRO*, multidrug-resistant organism; *MLST*, multilocus sequence typing; *PCR*, polymerase chain reaction; *PFGE*, pulsed-field gel electrophoresis; *WGS*, whole-genome sequencing.

*PCR for resistance gene.

Reason for Endoscope-Related Outbreaks

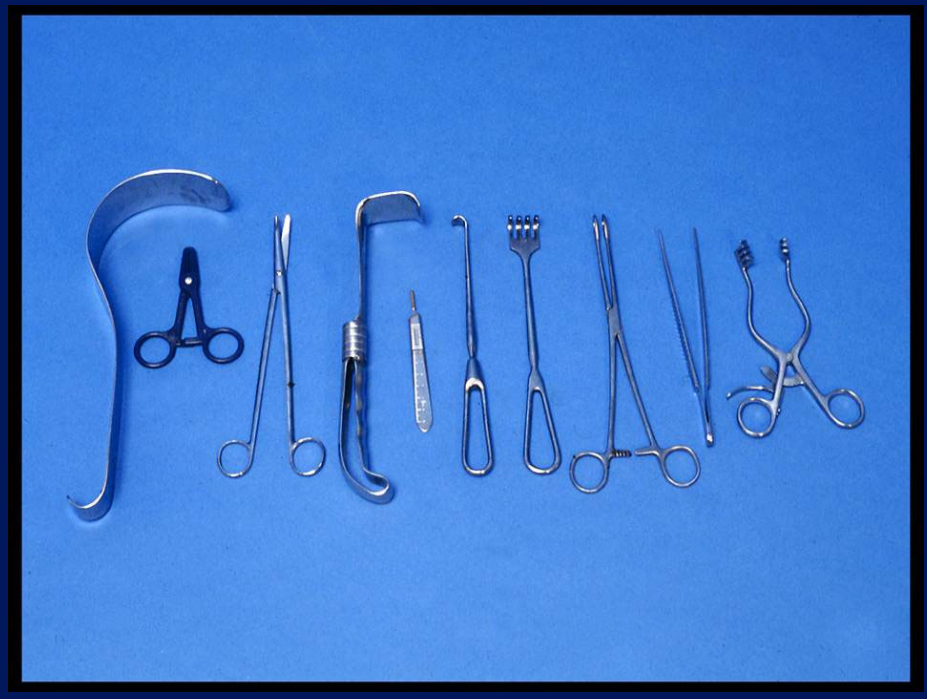
Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

- Margin of safety with endoscope reprocessing minimal or non-existent
- Microbial load
  - GI endoscopes contain 7-10 $\log_{10}$ (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-may contribute to failure of endoscope reprocessing

ENDOSCOPE REPROCESSING: CHALLENGES

Complex [elevator channel]-10^{7-10} bacteria/endoscope

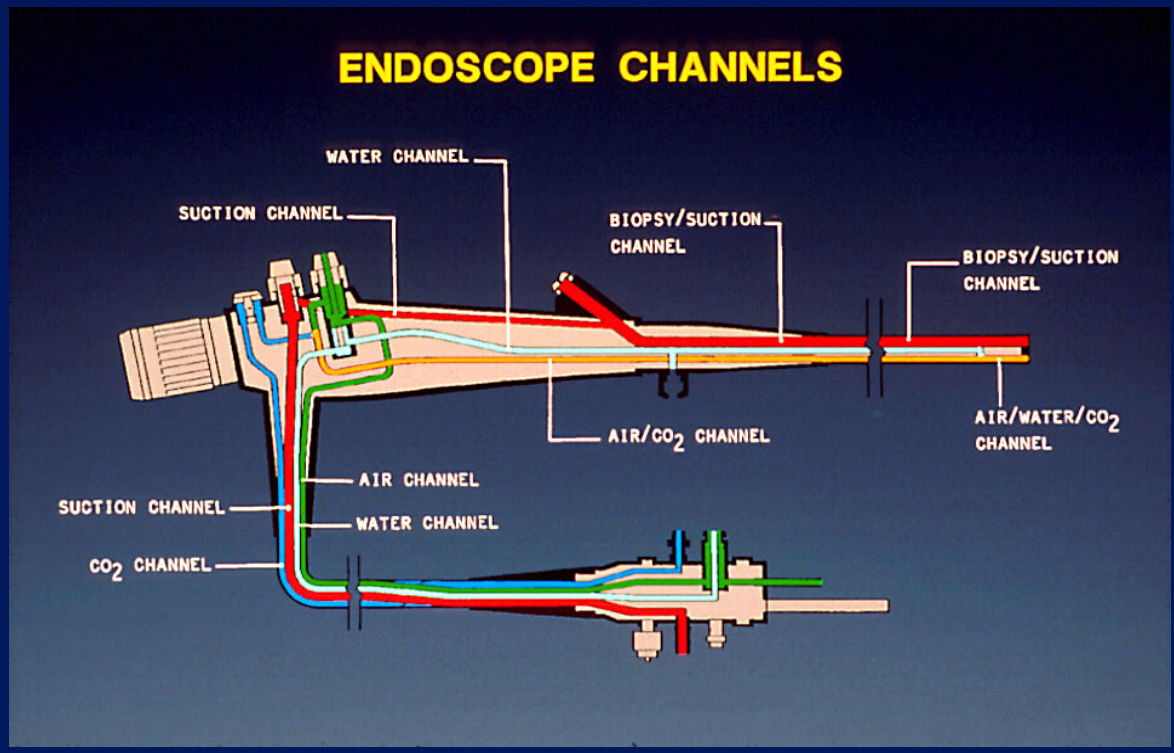
Surgical instruments-$<10^{2}$ bacteria



FEATURES OF ENDOSCOPES THAT PREDISPOSE TO DISINFECTION FAILURES

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

- Heat labile
- Long, narrow lumens (3.5ft, 1-3mm)
- Right angle bends
- Rough or pitted surfaces
- Springs and valves
- Damaged channels may impede microbial exposure to HLD
- Heavily contaminated with pathogens, $10^{7\text{-}10}$
- Cleaning (2-6 $\log_{10}$ reduction) and HLD (4-6 $\log_{10}$ reduction) essential for patient safe instrument



Endoscope Reprocessing Methods

Ofstead , Wetzler, Snyder, Horton, Gastro Nursing 2010; 33:204

Performed all 12 steps with only 1.4% of endoscopes using manual versus 75.4% of those processed using AER

TABLE 3. Documented Completion of Steps During Manual Cleaning With High-Level Disinfection Reprocessing

Observed Activity	Steps Completed (%) (n = 69)
Leak test performed in clear water	77
Disassemble endoscope completely	100
Brush all endoscope channels and components	43
Immerse endoscope completely in detergent	99
Immerse components completely in detergent	99
Flush endoscope with detergent	99
Rinse endoscope with water	96
Purge endoscope with air	84
Load and complete automated cycle for high-level disinfection	100
Flush endoscope with alcohol	86
Use forced air to dry endoscope	45
Wipe down external surfaces before hanging to dry	90

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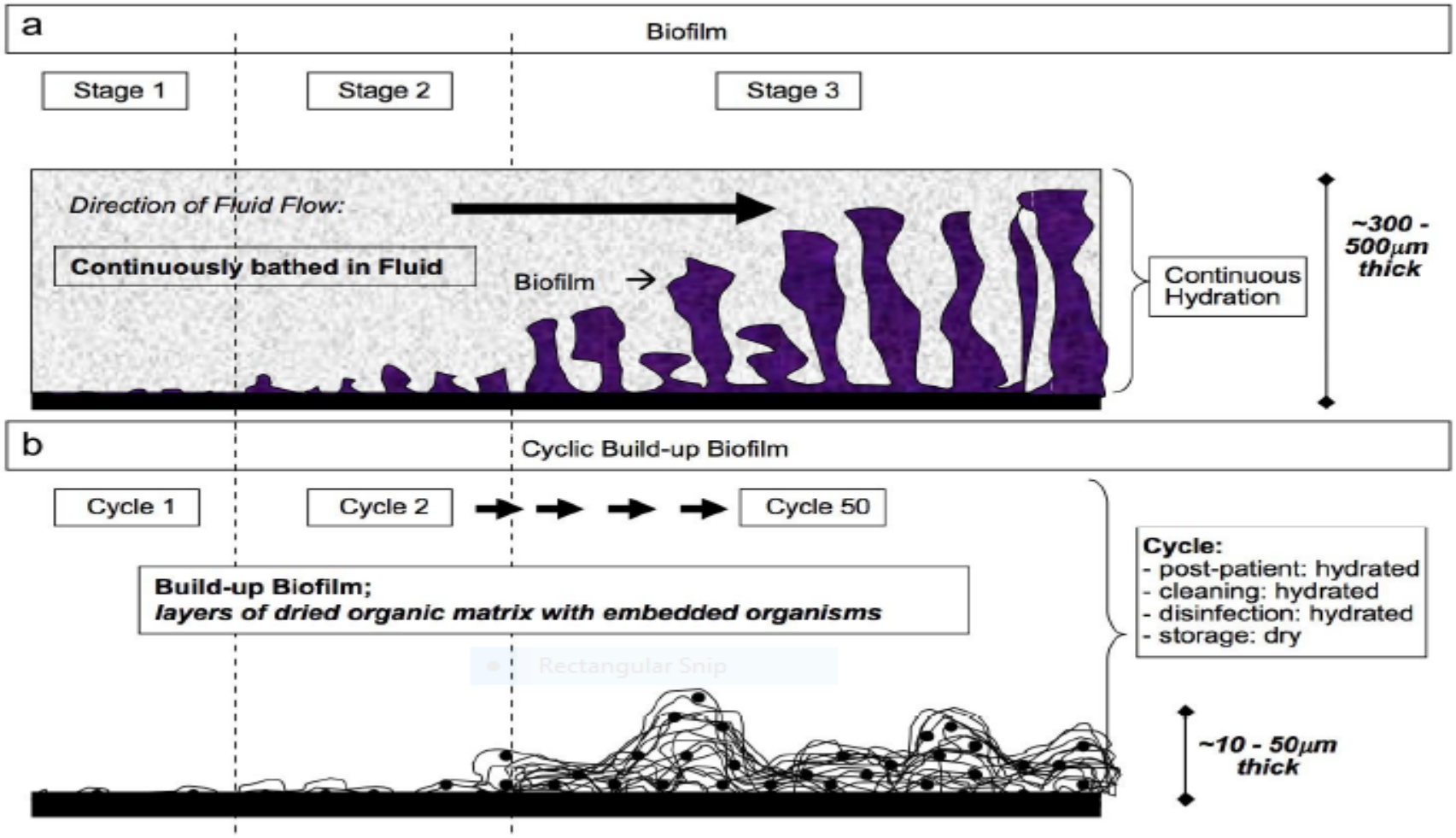
- Biofilms-may contribute to failure of endoscope reprocessing

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—may contribute to failure of endoscope reprocessing
  - 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.

If the margin of safety is so small that perfection is required, then the design is too complex and the process is too unforgiving to be practical in a real-world setting

What Should We Do Now?

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,

Disinfection and Sterilization

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

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

CRITICAL - objects which directly or indirectly/secondarily (i.e., via a mucous membrane such as duodenoscope, cystoscope, bronchoscope) enter normally sterile tissue or the vascular system or through which blood flows should be sterile.

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

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

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

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

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

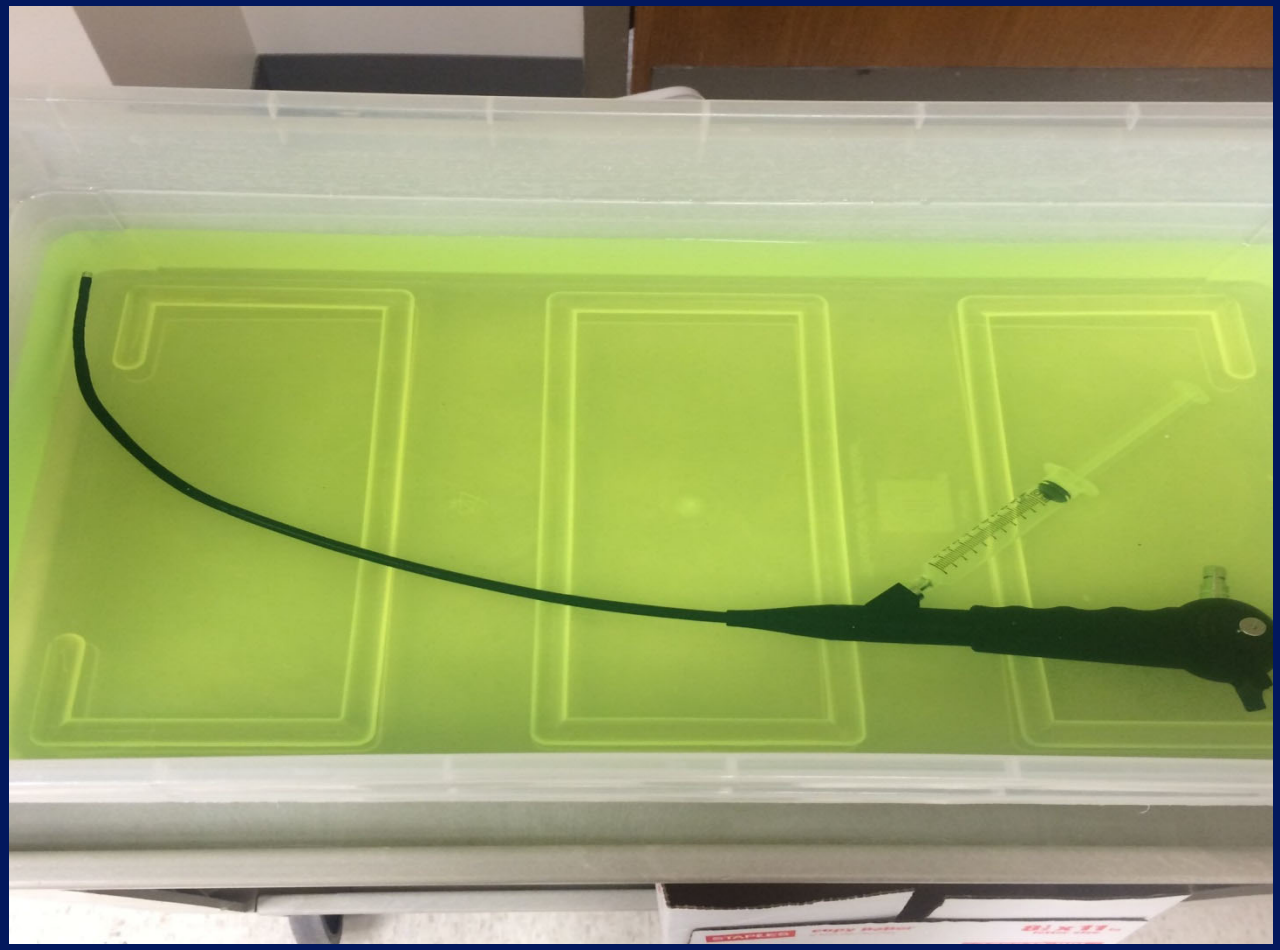
HLD (6 $\log_{10}$ reduction)

vs

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

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

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY FEBRUARY 2007, VOL. 28, NO. 2

ORIGINAL ARTICLE

How to Assess Risk of Disease Transmission to Patients When There Is a Failure to Follow Recommended Disinfection and Sterilization Guidelines

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

BACKGROUND. Disinfection and sterilization are critical components of infection control. Unfortunately, breaches of disinfection and sterilization guidelines are not uncommon.

OBJECTIVE. To describe a method for evaluating a potential breach of guidelines for high-level disinfection and sterilization of medical devices.

METHODS. The appropriate scientific literature was reviewed to determine the frequency of failures of compliance. A risk assessment model was constructed.

RESULTS. A 14-step protocol was constructed to aid infection control professionals in the evaluation of potential disinfection and sterilization failures. In addition, a model is presented for aiding in determining how patients should be notified of the potential adverse event. Sample statements and letters are provided for communicating with the public and individual patients.

CONCLUSION. Use of a protocol can guide an institution in managing potential disinfection and sterilization failures.

Infect Control Hosp Epidemiol 2007; 28:146-155

In the United States in 1996, there were approximately 46,500,000 surgical procedures and a much larger number of

infection failure on record involved the distribution of an inactive lot of glutaraldehyde disinfectant solution that had

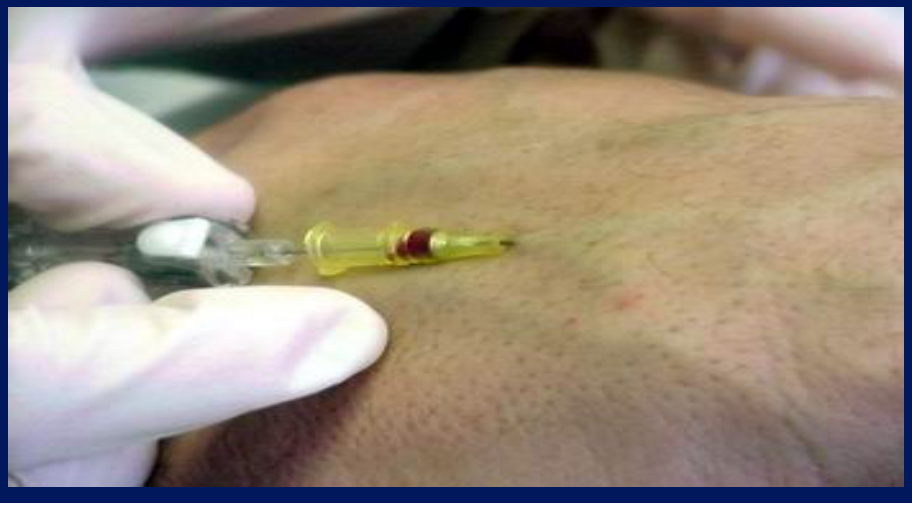
Failure to Follow Disinfection and Sterilization Principles

Rutala, Weber. ICHE 2007;28:146-155; Weber, Rutala, AJIC 2013;41:S67-71

- What do you do?
  - Follow the 14 steps at website disinfectionandsterilization.org (confirm failure, embargo improperly D/S items, investigate the cause, etc)
  - The steps provide a general outline, but each event is unique and you must be flexible and adaptable
  - Communication among key stakeholders is very important
  - Ethical to notify patients if there is a risk-should be upfront and factual
  - Train staff and access processes/practices to minimize recurrence
  - These are stressful events (patients and staff) but the goal is to assess failure and protect patients rather than assessing blame

Noncritical Environmental Surfaces and Medical Devices

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



- Noncritical environmental surfaces and 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

Weber, Kanamori, Rutala. Curr Op Infect Dis 2016:29:424-431

- Results in the newly admitted patient having an increased risk of acquiring that pathogen by 39-353%
- For example, increased risk for *C. difficile* is 235% (11.0% vs 4.6%)

Acquisition of 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

ALL “TOUCHABLE” (HAND CONTACT) SURFACES SHOULD BE WIPED DAILY WITH DISINFECTANT

“High touch” objects only recently defined (no significant differences in microbial contamination of different surfaces) and “high risk” objects not epidemiologically defined.

Effective Surface Decontamination

Product and Practice = Perfection

LOW-LEVEL DISINFECTION FOR NONCRITICAL EQUIPMENT AND SURFACES

Rutala, Weber, HICPAC. November 2008. www.cdc.gov; Rutala et al. AJIC 2019;47:A3-A9

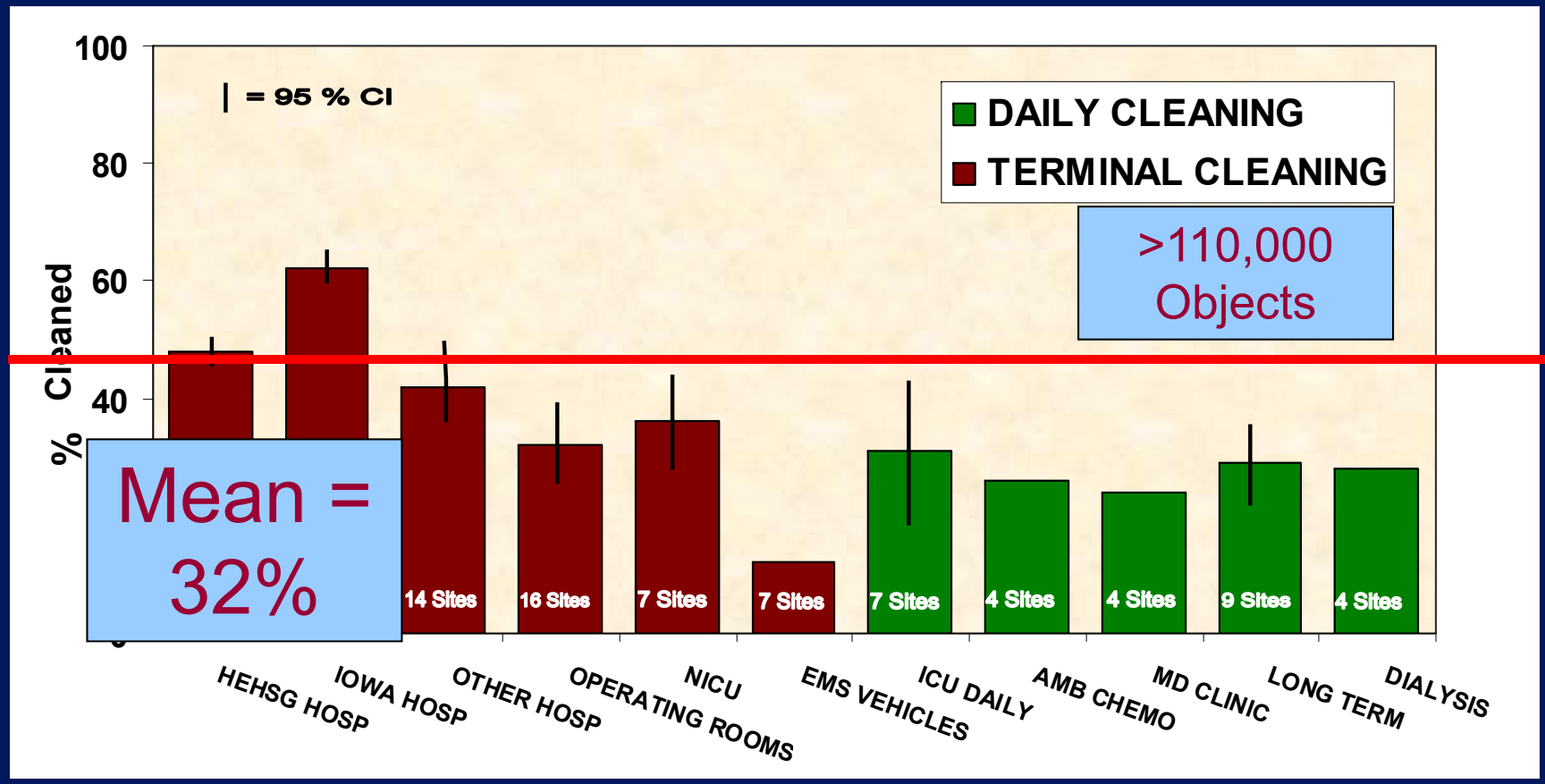
Exposure time ≥ 1 min

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%
PA/HP or chlorine (*C. difficile* spores)	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)

Thoroughness of Environmental Cleaning

Carling P. AJIC 2013;41:S20-S25



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)

Sterilization and Disinfection

- Describe the Spaulding classification scheme for disinfection of patient care items
- Describe available methods for sterilization and types of indicators used to ensure the process was effective
- Understand the advantages and disadvantages of the various disinfectants and mechanical processes used to disinfect medical equipment and environmental surfaces
- Outline the controversies surrounding the reprocessing of endoscopes and disinfection of other complex medical instruments

High-Level Disinfection, Sterilization and Disinfection
Summary

- Disinfection and sterilization technologies and practices (e.g., monitoring cleaning) must be followed to prevent exposure to pathogens that may lead to infection.
- 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.

THANK YOU!

www.disinfectionandsterilization.org