
Sterilization and Disinfection

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DISCLOSURES

2017-2018

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

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 **chemical agents** and mechanical processes used to disinfect medical equipment
- 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 2016;44:e47

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008



Rectangular Snip

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

William A. Rutala, Ph.D., M.P.H.^{1,2}, David J. Weber, M.D., M.P.H.^{1,2}, and the Healthcare

Infection Control Practices Advisory Committee (HICPAC)³

Medical/Surgical Devices

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

EH Spaulding believed that how an object will be disinfected depended on the object's intended use (developed 1968).

CRITICAL-medical/surgical devices which enter normally **sterile tissue** or the vascular system or through which blood flows should be **sterile**.

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

NONCRITICAL-medical devices that touch **only intact skin** require **low-level disinfection**.

Critical Medical/Surgical Devices

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



- Critical

- 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. AJIC 2016;44:e47



- Semicritical
 - Transmission: direct contact
 - Control measure: high-level disinfection
 - Endoscopes top ECRI list of 10 technology hazards, **>100 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 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**

Sterilization and Disinfection

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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 2016;44:e47

Steam sterilization

Hydrogen peroxide gas plasma

Ethylene oxide

Ozone and hydrogen peroxide

Vaporized hydrogen peroxide



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	2.6×10^7	Complete	0/8
Routine	VRE	2.6×10^7	Complete	0/8
Routine	<i>P aeruginosa</i>	2.1×10^7	Complete	0/8
Routine	<i>M terrae</i>	1.4×10^8	7.8	2/8
Routine	GS spores	5.3×10^6	4.8	11/14
No Enz/Det	VRE	2.5×10^7	Complete	0/10
No Enz/Det	GS spores	8.3×10^6	5.5	8/10

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

Steam Sterilization

Rutala, Weber AJIC 2016;44:e1-e6

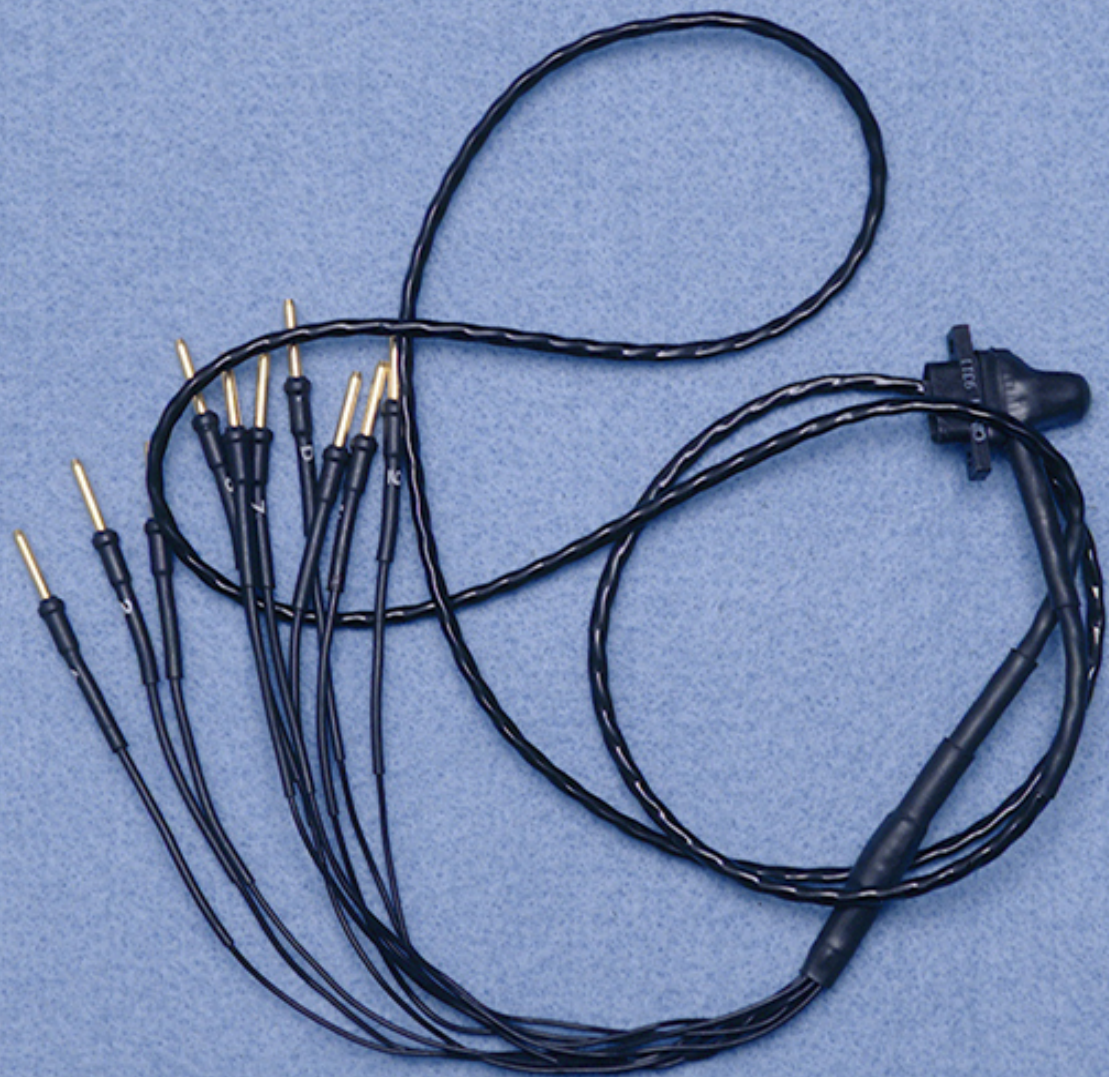
- Advantages
 - Non-toxic
 - Cycle easy to control and monitor
 - Inexpensive
 - Rapidly microbicidal
 - Least affected by organic/inorganic soils
 - Rapid cycle time
 - Penetrates medical packing, device lumens
- Disadvantages
 - Deleterious for heat labile instruments
 - Potential for burns

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



New Trends in Sterilization of Patient Equipment

- Alternatives to ETO-CFC
ETO-CO₂, ETO-HCFC, 100% ETO
- New Low Temperature Sterilization Technology
Hydrogen Peroxide Gas Plasma
Ozone and hydrogen peroxide
Vaporized Hydrogen Peroxide

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 cannot be packaged, sterilized and stored before use
- “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

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

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













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

Sterility Indicators Table

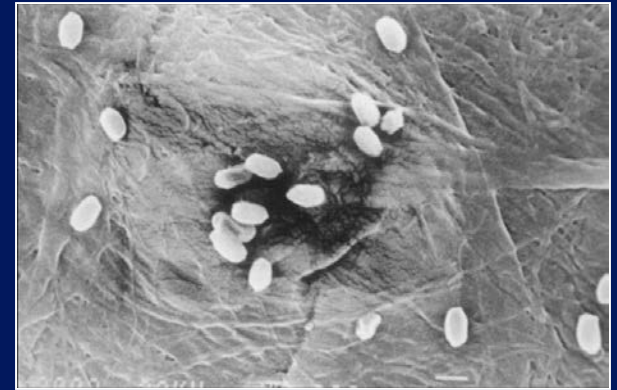
	Before Exposure (Do not use)	After Exposure (Sterile) (Ok if package is intact)
Steam Autoclave		
Tape		
Strip	<p>STRATE-LINE™ sterilization mc</p> <p><small>FOR USE IN PRESSURE STEAM AUTOCLAVES PLACE A STRATE-LINE STRIP IN EAC</small></p>	<p>Date _____ Contents _____</p> <p><small>WRITE LINE ACROSS THE STRIP TURNING UNIFORMLY BLACK IT IS PROOF OF ATTACK</small></p>
Peel Pack	<p>SEALING CTIONS CM1296</p> <p>Reorder No. 8853025 *U.S. Pat. 4,278,582 Turns Brown / Black in Steam</p> 	<p>SEALING CTIONS CM1296</p> <p>Reorder No. 8853025 *U.S. Pat. 4,278,582 Turns Brown / Black in Steam</p> 
Ethylene Oxide (ETO. gas)		
Tape		
Strip	<p>40003 Made in USA 4734</p> <p><small>Bar appears below when Gas processed.</small></p>	<p>Baxter</p> <p>Lower Gas Indicator Strip Cat.</p>
Peel Pack	<p>MEDI-PLUS® SELF SEAL™ POUCH 3 1/2" x 5 1/2" Turns Gold / Browns in Gas</p>  <p>READ INSTR.</p>	<p>MEDI-PLUS® SELF SEAL™ POUCH 3 1/2" x 5 1/2" Turns Gold / Browns in Gas</p>  <p>READ SEA INSTRUCT</p>
Sterrad		
Tape		
Strip	<p>STERAD® Chemical Indicator Strip REF 14100</p> <p><small>Use in STERAD® Sterilizer only. Bar changes from red to yellow (or lighter) as compared to bar when exposed to H₂O₂ during processing in the STERAD® Sterilizer.</small></p>	<p>STERAD® Chemical Indicator Strip REF 14100</p> <p><small>Use in STERAD® Sterilizer only. Bar changes from red to yellow (or lighter) as compared to bar when exposed to H₂O₂ during processing in the STERAD® Sterilizer.</small></p>
Steris		
Strip		

Biological Indicators



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*
 - Ozone and HP - *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



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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 1 hour)



1492V BI (brown cap)

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

30m or 24m Biological Indicator for HP Sterilizers



Recommendations

Monitoring of Sterilizers

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

- Monitor each load with mechanical 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 2016;44:e47



- Semicritical
 - Transmission: direct contact
 - Control measure: high-level disinfection
 - Endoscopes top ECRI list of 10 technology hazards, **>100 outbreaks** (GI, bronchoscopes)
 - 0 margin of safety
 - Microbial load, 10^7 - 10^{10}
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Semicritical Items

- Endoscopes
- Respiratory therapy equipment
- Anesthesia equipment
- Endocavitary probes
- Tonometers
- Laryngoscopes

High-Level Disinfection of "Semicritical Objects"

Exposure Time \geq 8m-45m (US), 20°C

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

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

Comparison of Glutaraldehyde and OPA

Rutala, Weber. AJIC 2016;44:e1-e6

>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

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

Improved Hydrogen Peroxide

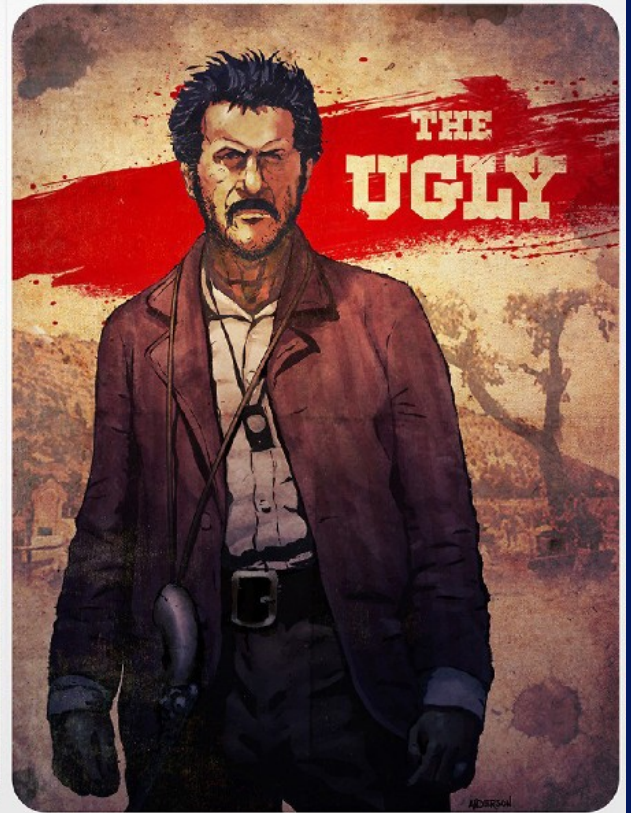
Rutala, Weber. AJIC 2016;44:e1-e6

- 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

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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	<i>Pa</i> , <i>H. pylori</i> , <i>Salmonella</i>	169	56	Cleaning/Disinfection (C/D)
Sigmoid/Colonoscopy	5	<i>Salmonella</i> , HCV	14	6	Cleaning/Disinfection
ERCP	23	<i>P. aeruginosa</i> (<i>Pa</i>)	152	89	C/D, water bottle, AER
Bronchoscopy	51	<i>Pa</i> , 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.

RECENT ENDOSCOPY-RELATED OUTBREAKS OF MRDO WITHOUT REPROCESSING BREACHES

Rutala WA et al. Submitted for publication

MDRO	Scope	No.	Recovered From Scope	Molecular Link	Reference
<i>P. aeruginosa</i> (VIM-2)	Duodenoscope	22	Yes, under forceps elevator	Yes	Verfaillie CJ, 2015
<i>E. coli</i> (AmpC)	Duodenoscope	35	Yes (2 scopes)	Yes	Wendorf, 2015
<i>K. pneumoniae</i> (OXA)	Duodenoscope	12	No	Yes	Kola A, 2015
<i>E. coli</i> (NDM-CRE)	Duodenoscope	39	Yes	Yes	Epstein L, 2015
<i>K. pneumoniae</i>	Duodenoscope	15	No	Yes	Kim S, 2016
<i>K. pneumoniae</i>	Duodenoscope	34	Yes	Yes	Marsh J, 2015
<i>E. coli</i>	Duodenoscope	3	No	Unknown	Smith Z, 2015
<i>K. pneumoniae</i>	Duodenoscope	13	Yes	Yes	Carbonne A, 2010

Reason for Endoscope-Related Outbreaks

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

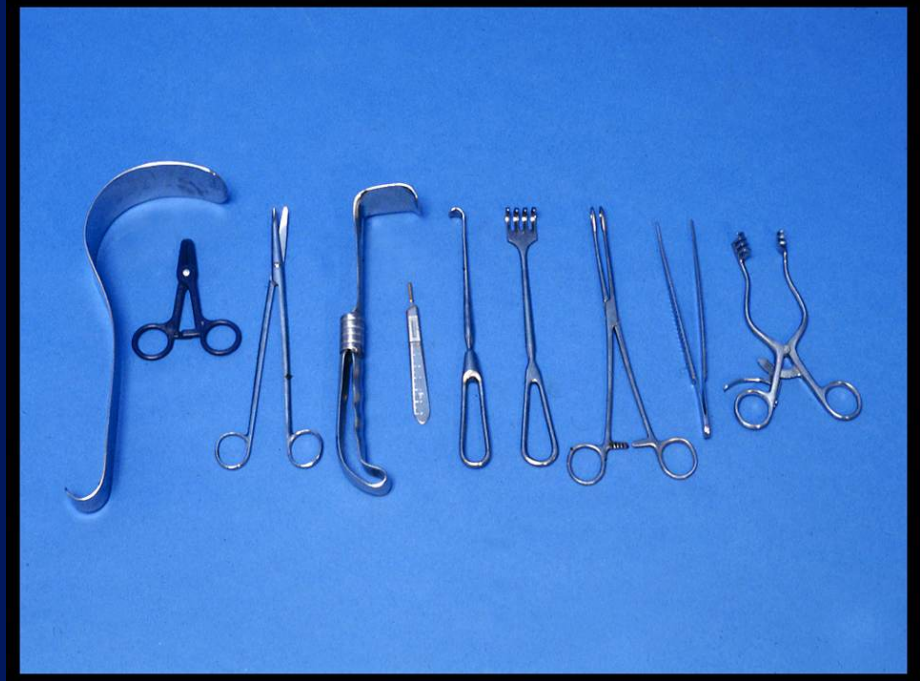
- Margin of safety with endoscope reprocessing minimal or non-existent
- **Microbial load**
 - ◆ GI endoscopes contain 10^{7-10}
 - ◆ Cleaning results in 2-6 \log_{10} reduction
 - ◆ High-level disinfection results in 4-6 \log_{10} reduction
 - ◆ Results in a total 6-12 \log_{10} reduction of microbes
 - ◆ Level of contamination after processing: 4 \log_{10} (maximum contamination, minimal cleaning/HLD)
- **Complexity of endoscope and endoscope reprocessing**
- **Biofilms-unclear if contribute to failure of endoscope reprocessing**

ENDOSCOPE REPROCESSING: CHALLENGES

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



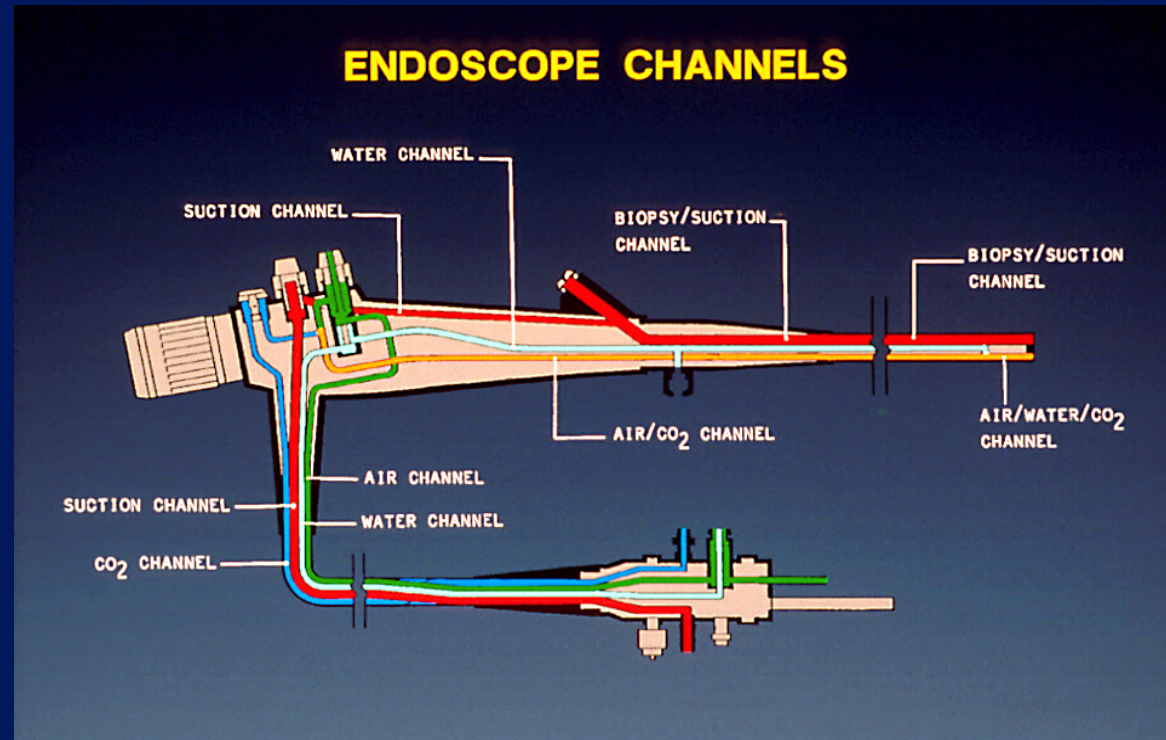
Surgical instruments- $<10^2$ bacteria



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^{7-10}
- 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

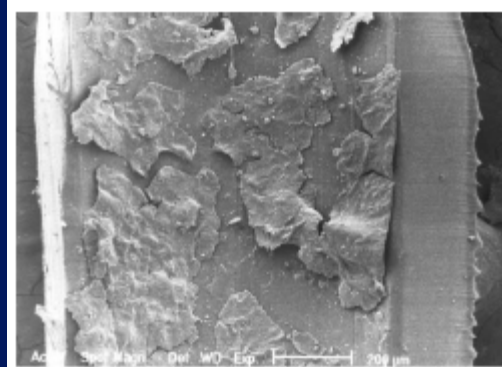
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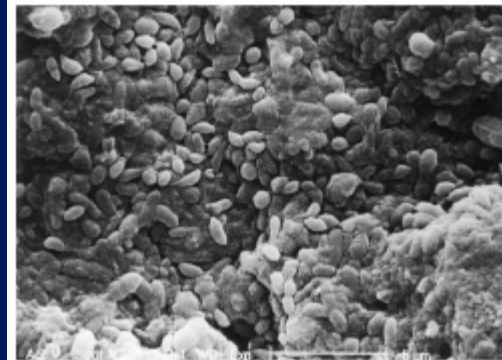
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- **Complexity of endoscope**
- **Biofilms-unclear if contribute to failure of endoscope reprocessing**

BIOFILMS

(Multi-layered bacteria plus exopolysaccharides that cement cell to surface; **develop in wet environments; if reprocessing performed promptly after use and endoscope dry the opportunity for biofilm formation is minimal**; Pajkos et al. J Hosp Infect 2004;58:224



(a)



(b)

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%

To protect the public health we (FDA, industry, professional organizations) must shift duodenoscope reprocessing from HLD to sterilization.

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 colleagues² 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-

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,



Related article page 1447

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

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

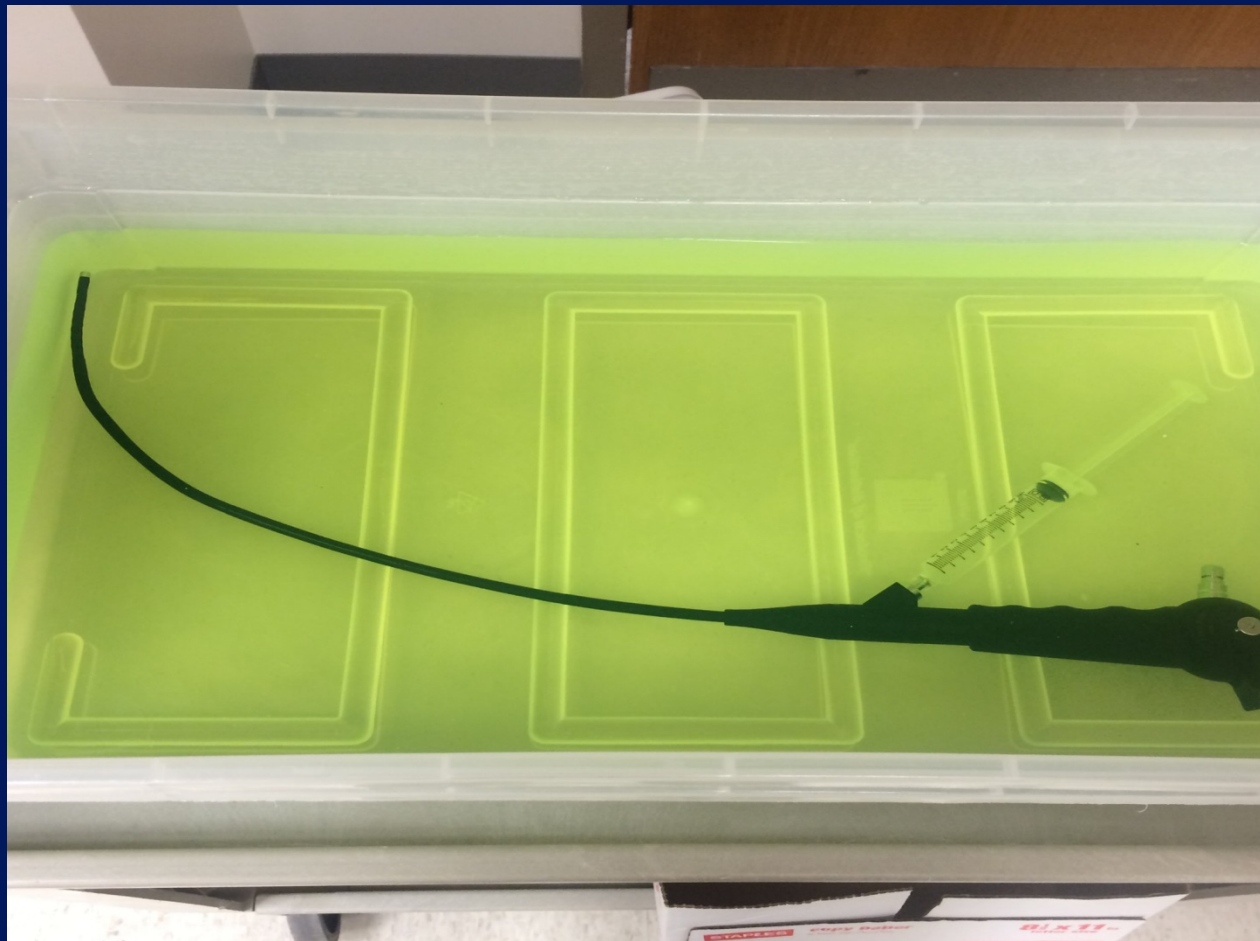
HLD ($6 \log_{10}$ reduction)

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

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

- 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 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**

LOW-LEVEL DISINFECTION FOR NONCRITICAL EQUIPMENT AND SURFACES

Rutala, Weber, HICPAC. November 2008. www.cdc.gov; Rutala et al. AJIC 2016;44:e47

Exposure time \geq 1 min

Germicide	Use Concentration
Ethyl or isopropyl alcohol	70-90%
Chlorine	100ppm (1:500 dilution)
Phenolic	UD
Iodophor	UD
Quaternary ammonium (QUAT)	UD
QUAT with alcohol	RTU
Improved hydrogen peroxide (HP)	0.5%, 1.4%
Peracetic acid with HP (<i>C. difficile</i>)	UD

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

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 chemical agents and mechanical processes used to disinfect medical equipment
- Outline the controversies surrounding the reprocessing of endoscopes and disinfection of other complex medical instruments

Sterilization and Disinfection Summary

D/S guidelines must be followed to prevent exposure to pathogens that may lead to infection

THANK YOU!

www.disinfectionandsterilization.org

