High-Level Disinfection, Sterilization and Disinfection

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

DISCLOSURES
2022

- **Consultations**
  - Professional Disposables International (PDI)
- **Honoraria**
  - PDI
- Other
  - Ideate Medical, Kinnos

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
- 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, if ever
    - ~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, occasional 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

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 2019;47:A3-A9

Heat resistant

- Steam sterilization

Heat sensitive

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

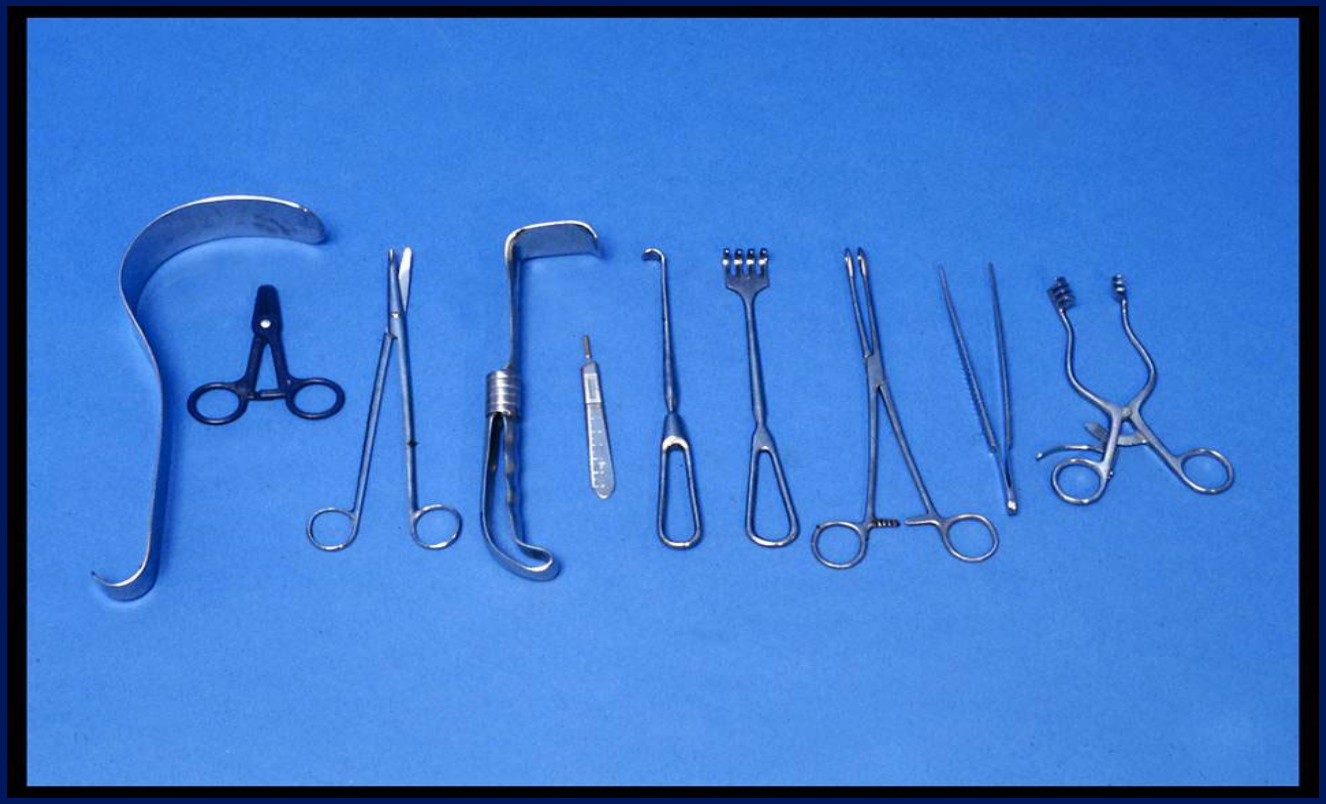

#7 GAS
#8 GAS
STERIS
STERIS

Pre-Cleaning

- Ideally, instruments should arrive in Central Processing free on visible contamination
- Wipe instruments clean and keep lumens flushed throughout surgery. Soiled instruments that will not be reused should be allowed to soak in a basin of sterile water for the remainder of the procedures
- Many hospitals spray instruments with an enzymatic solution
- Keep instruments moist (e.g., damp towel) as it prevents hardening

Microbial Load on Surgical Instruments

Surgical instruments-$<10^2$ bacteria



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.





Washer/Disinfector

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

- Five Chambers
  - Pre-wash: water/enzymatic is circulated over the load for 1 min
  - Wash: detergent wash solution (150°F) is sprayed over the load for 4 min
  - Ultrasonic cleaning: basket is lowered into ultrasonic cleaning tank with detergent for 4 min
  - Thermal and lubricant rinse: hot water (180°F) is sprayed over the load for 1 min; instrument milk lubricant is added to the water and is sprayed over the load
  - Drying: blower starts for 4 min and temperature in drying chamber 180F

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

Cleaning Indicators for Washers

- Monitor the automated washer and instrument cleaning chemistry functionality
- Complete soil removal of the dried test soil pattern is a “pass”
- Indicator includes proteins, lipids, and polysaccharides to mimic common challenging test soils



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

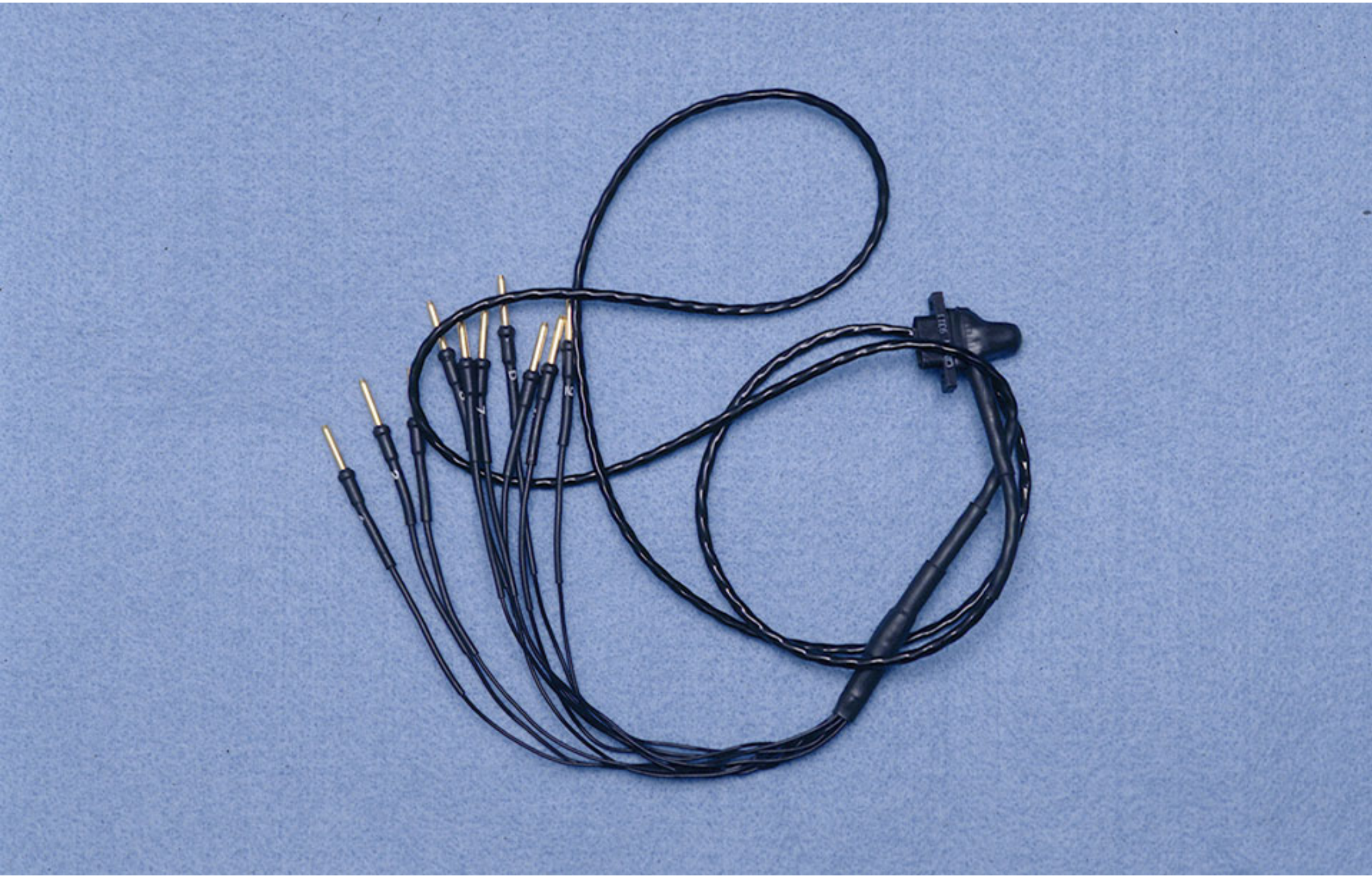
Item	Minimum exposure	Minimum drying time
Wrapped instruments	4 min	30 min
Textile packs	4 min	5 min

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; now same time-temp (132^{o}C, 4min)
- 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



Sterilization of "Critical Objects"

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Heat resistant

- Steam sterilization

Heat sensitive

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

Evaluation of Microbicidal Activities of Sterilization Technologies in Salt and Serum

Rutala et al. Infect Control Hosp Epidemiol 2020 doi:10.1017/ice.2020.2

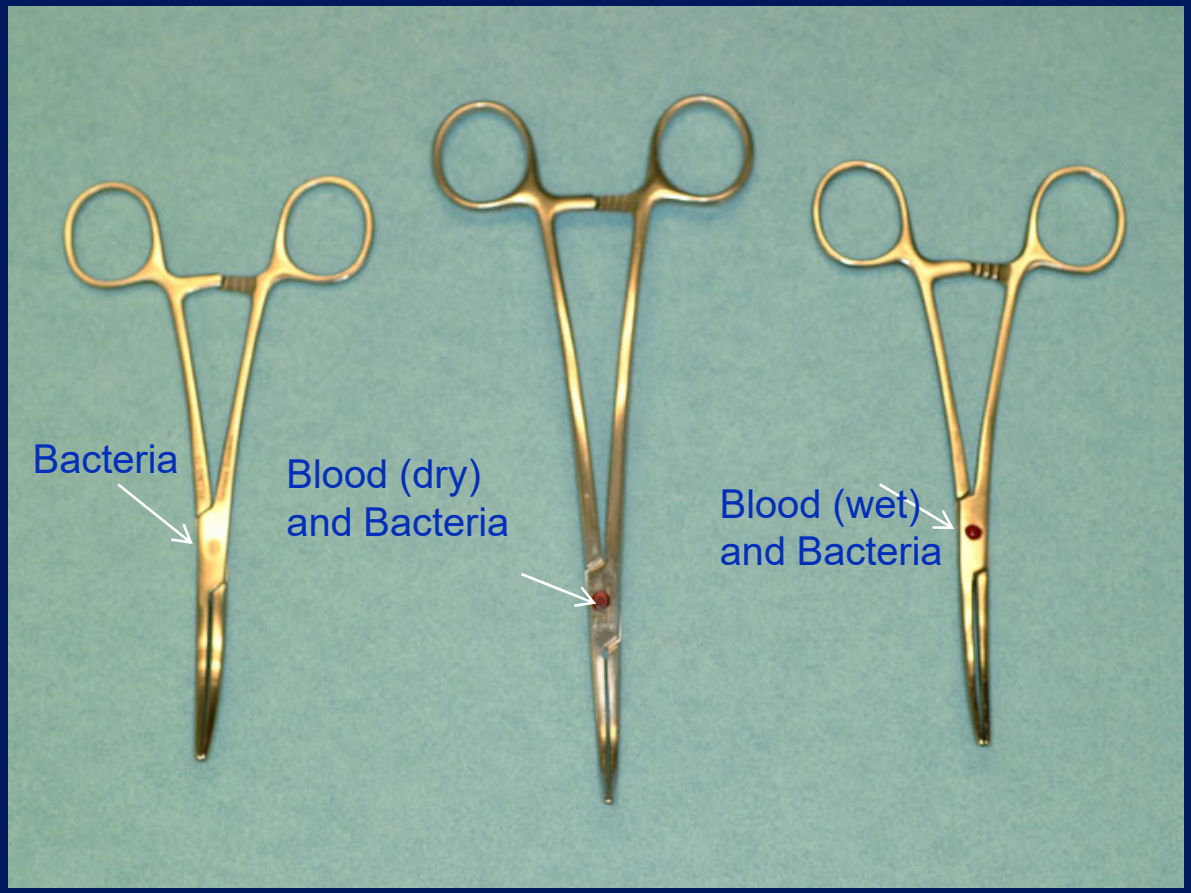
Organism	Mean Inoculating Suspension/mL	Mean Carrier Quantitation (Day of Run)	Mean Carrier Quantitation (24 h ETO)	% Failure (Carriers Positive/Carriers Tested)			
				Steam	ETO	HPGP	VHP
Vegetative cells							
Pseudomonas aeruginosa	8.1×10^8	2.0×10^6	3.5×10^4	0 (0/30)	0 (0/50)	0 (0/40)	13 (5/40)
Escherichia coli	1.1×10^9	3.4×10^6	5.1×10^5	0 (0/30)	4 (2/50)[b]	3 (1/40)[b]	75 (30/40)
Vanomycin-resistant enterococci	5.9×10^8	2.8×10^6	2.8×10^6	0 (0/30)	8 (4/50)[b]	10 (4/40)[b]	93 (37/40)
Staphylococcus aureus	4.8×10^8	2.3×10^6	2.5×10^6	0 (0/30)	0 (0/40)	0 (0/30)	93 (28/30)
Mycobacterium terrae	1.4×10^9	5.2×10^4	3.2×10^5	0 (0/20)	0 (0/30)	0 (0/30)	97 (29/30)
Vegetative cells, total				0 (0/140)	3 (6/220)	3 (5/180)	72 (129/180)
Bacillus atropheaus spores	1.5×10^7	1.2×10^5	1.3×10^5	0 (0/30)	0 (0/30)	0 (0/30)	83 (25/30)
Geobacillus stearothermophilus spores	5.4×10^6	5.1×10^4	6.0×10^4	0 (0/30)	0 (0/30)	0 (0/30)	73 (22/30)
Clostridiodes difficile spores	1.3×10^7	4.4×10^4	4.2×10^4	0 (0/20)	0 (0/30)	0 (0/30)	100 (30/30)
Spore total				0 (0/80)	0 (0/90)	0 (0/90)	86 (77/90)
Overall total				0 (0/220)	2 (6/310)	2 (5/270)	76 (206/270)

Note. ETO, ethylene oxide; HPGP, hydrogen peroxide gas plasma; FCS, fetal calf serum; ND, not done.

[a]To simulate inadequate cleaning, the inoculum for the vegetative bacteria contained 10% FCS and 0.65% salt but 10% FCS and 0.29% salt for the spores *B. atropheaus* and *G. stearothermophilus;* and 10% FCS and 0.52% salt *C. difficile* spores

[b]Runs with ETO and HPGP failure of vegetative bacteria had higher carrier quantitation (day of run) than the mean carrier quantitation for the other runs and that organism (ie, 4.07×10^6 vs 2.54×10^6 for VRE; 8.30×10^6 vs 2.40×10^6 for *E. coli*).

“Dirty” (non-cleaned) Instruments



Steam sterilization is the most effective sterilization technology with the largest margin of safety, followed by ETO and hydrogen peroxide gas plasma.

Table 1. Effectiveness of the Microbicidal Activity of Sterilization Technologies in the Presence of Blood on "Dirty" Instruments[a]

Test Organism	Method of Sterilization	Instruments "Dirty" (Uncleaned) With or Without Blood[b]	Instrument Quantitation (Mean)	No. of Positives/ No. of Runs (% Positive)
Geobacillus stearothermophilus (spores)	Steam Sterilization	Dirty	~ 1.56×10^5	0/10 (0)
		Dirty with blood (spores mixed with blood not sandwich[b])	~1.99×10^5	0/12 (0)
	ETO	Dirty	~1.53×10^5	0/10 (0)
		Dirty with blood	~2.35×10^5	0/11 (0)
	HPGP	Dirty	~1.58×10^5	5/10 (50)
		Dirty with blood	~2.35×10^5	9/15 (60)
Mycobacterium terrae	Steam Sterilization	Dirty	~4.25×10^6	0/10 (0)
P. aeruginosa	HPGP	Dirty	~1.81×106	3/15 (20)
Bacillus atrophaeus (spores)	ETO	Dirty	~ 2.30×10^7	6/10 (60)
		Dirty with blood	~4.08×10^7	9/10 (90)
MRSA	ETO	Dirty	~2.62×10^6	0/10 (0)
		Dirty with blood	~1.72×10^6	0/10 (0)
	HPGP	Dirty	~1.10×10^6	4/10 (40)
		Dirty with blood	~1.27×10^6	4/10 (40)
	Steam sterilization	Dirty	2.56×10^6	0/10 (0)
		Dirty with blood	5.20×10^5	0/10 (0)
VRE	ETO	Dirty	~2.27×10^6	0/10 (0)
		Dirty with blood	~3.59×10^6	0/10 (0)
	HPGP	Dirty	~2.63×10^6	3/10 (30)
		Dirty with blood	~2.34×10^6	9/10 (90)
	Steam sterilization	Dirty	1.90×10^6	0/10 (0)
		Dirty with blood	2.72×10^5	0/10 (0)

Note. ETO, ethylene
[a]Study conditions no
[b]Sandwich consists
experiment was don

76.6%

rmophilus

Effectiveness of the Microbicidal Activity of Steam Sterilization in the Presence of Blood on "Dirty" Instruments

Rutala et al. Infect Cont Hosp Epidemiol 2021 https://doi.org/10.1017/ice.2021.202

Test Organism	Method of Sterilization	Instruments "dirty" (non-cleaned) with or without blood[2]	Instrument Quantitation (Mean)	% Positive
Geobacillus stearothermophilus (spores)	Steam Sterilization	Dirty	~ 1.56×10^5	0/10 (0)
		Dirty with blood (spores mixed with blood not sandwich[2])	~ 1.99×10^5	0/12 (0)
Mycobacterium terrae	Steam Sterilization	Dirty	~ 4.25×10^6	0/10 (0)

[1]Study conditions not representative of practice or manufacturer's recommendations.

[2]Sandwich consists of "dirty" or non-cleaned instrument, then an inoculum of spores or vegetative bacteria, and lastly overlaid with blood after inoculum dry. One *G. stearothermophilus* experiment was done with the spores mixed with the inoculum and then placed on the dirty instrument.

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

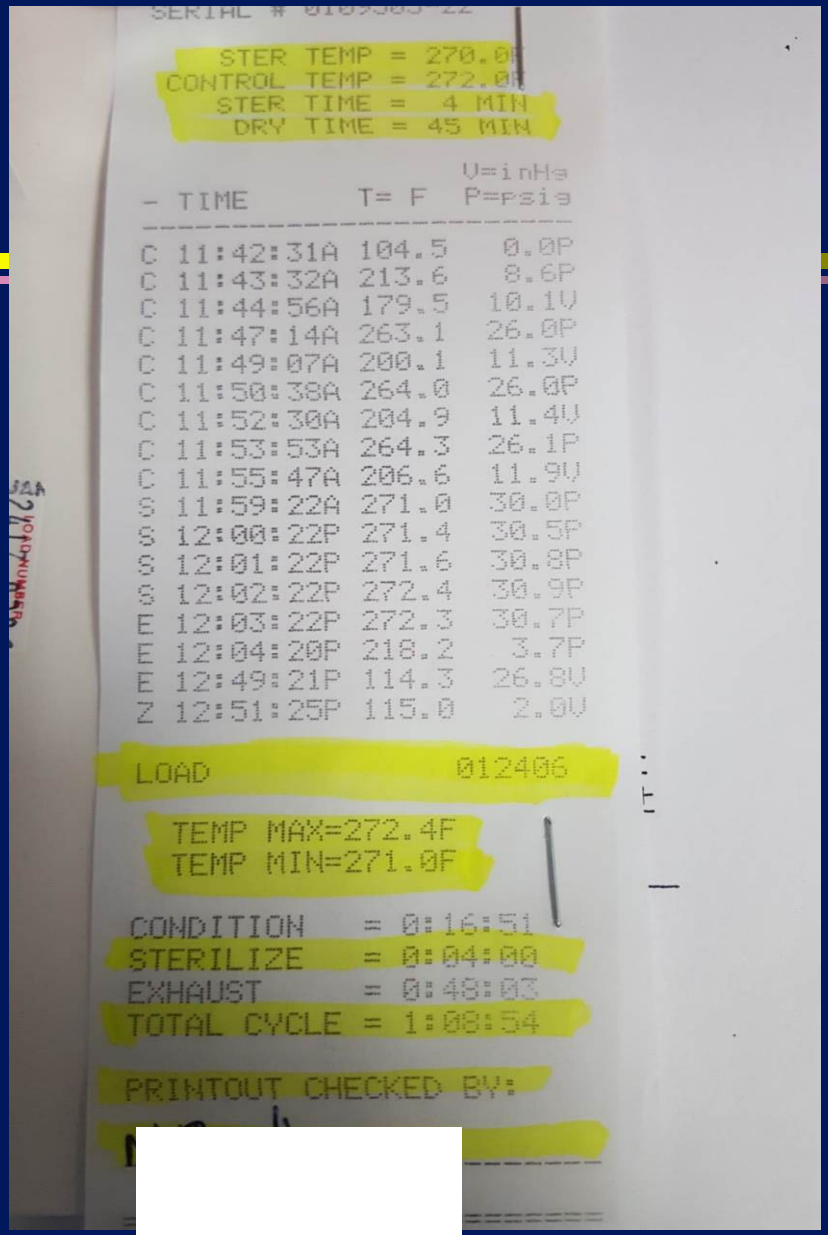
Sterilization monitored routinely by combination of physical, chemical, and biological parameters

- 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

Sterilizer Receipt



SERIAL # 0109383 22

STER TEMP = 270.0F
CONTROL TEMP = 272.0F
STER TIME = 4 MIN
DRY TIME = 45 MIN

-	TIME	T= F	V=inHg P=psig
C	11:42:31A	104.5	0.0P
C	11:43:32A	213.6	8.6P
C	11:44:56A	179.5	10.1V
C	11:47:14A	263.1	26.0P
C	11:49:07A	200.1	11.3V
C	11:50:38A	264.0	26.0P
C	11:52:30A	204.9	11.4V
C	11:53:53A	264.3	26.1P
C	11:55:47A	206.6	11.9V
S	11:59:22A	271.0	30.0P
S	12:00:22P	271.4	30.5P
S	12:01:22P	271.6	30.8P
S	12:02:22P	272.4	30.9P
E	12:03:22P	272.3	30.7P
E	12:04:20P	218.2	3.7P
E	12:49:21P	114.3	26.8V
Z	12:51:25P	115.0	2.0V

LOAD 012406

TEMP MAX=272.4F
TEMP MIN=271.0F

CONDITION = 0:16:51
STERILIZE = 0:04:00
EXHAUST = 0:48:03
TOTAL CYCLE = 1:08:54

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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
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- Biological - *Bacillus* spores that directly measure sterilization

Six Classes of Indicators Are Recognized by International Organization of Standards (ISO)

Table 2. Chemical Indicator Classifications

Class I Process indicators	Process indicators are attached to or printed on the outside of all packs to discern which packages have been processed from those that have not been processed in a sterilizer.
Class 2 Bowie-Dick test	The Bowie-Dick test is used to reveal the pass/fail rate in dynamic air removal steam sterilizers. This Class 2 chemical indicator should be used in an empty chamber daily, preferably before any loads are processed at the beginning of the day.
Class 3 Single parameter indicator	The single parameter chemical indicator is placed inside each package and provides data on time or temperature, revealing if one of these sterilization parameters has been met during a cycle.
Class 4 Multi-parameter indicators	Multiparameter indicators react to two or more sterilization parameters, such as time and temperature or time and pressure.
Class 5 Integrating indicators	React to all critical parameters of sterilization cycle over a range of temperatures; performance must equal that of the biological indicators.
Class 6 Emulating indicators	Cycle specific; react to all critical parameters for a specified sterilization level; used at the pack/tray level.

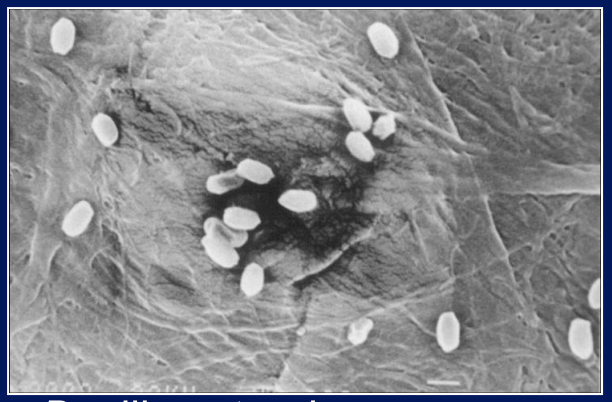
Dimensions of Dental Hygiene, March 2009

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



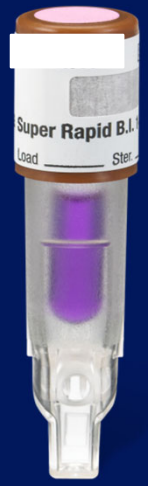
Super Rapid Readout Biological Indicators

Commercially available



1491 BI (blue cap)

- Monitors 270°F and 275°F gravity –displacement steam sterilization cycles
- 24-minute result



1492V BI (brown cap)

- Monitors 270°F and 275°F dynamic-air-removal (pre-vacuum) steam sterilization cycles
- 24-minute result

Rapid Readout Biological Indicator for Steam (24m), 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)

Sterilization and Disinfection

- Describe the Spaulding classification scheme for disinfection of patient care items
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- 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

Semicritical Medical Devices

Rutala et al. 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

High-Level Disinfection of "Semicritical Objects"

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

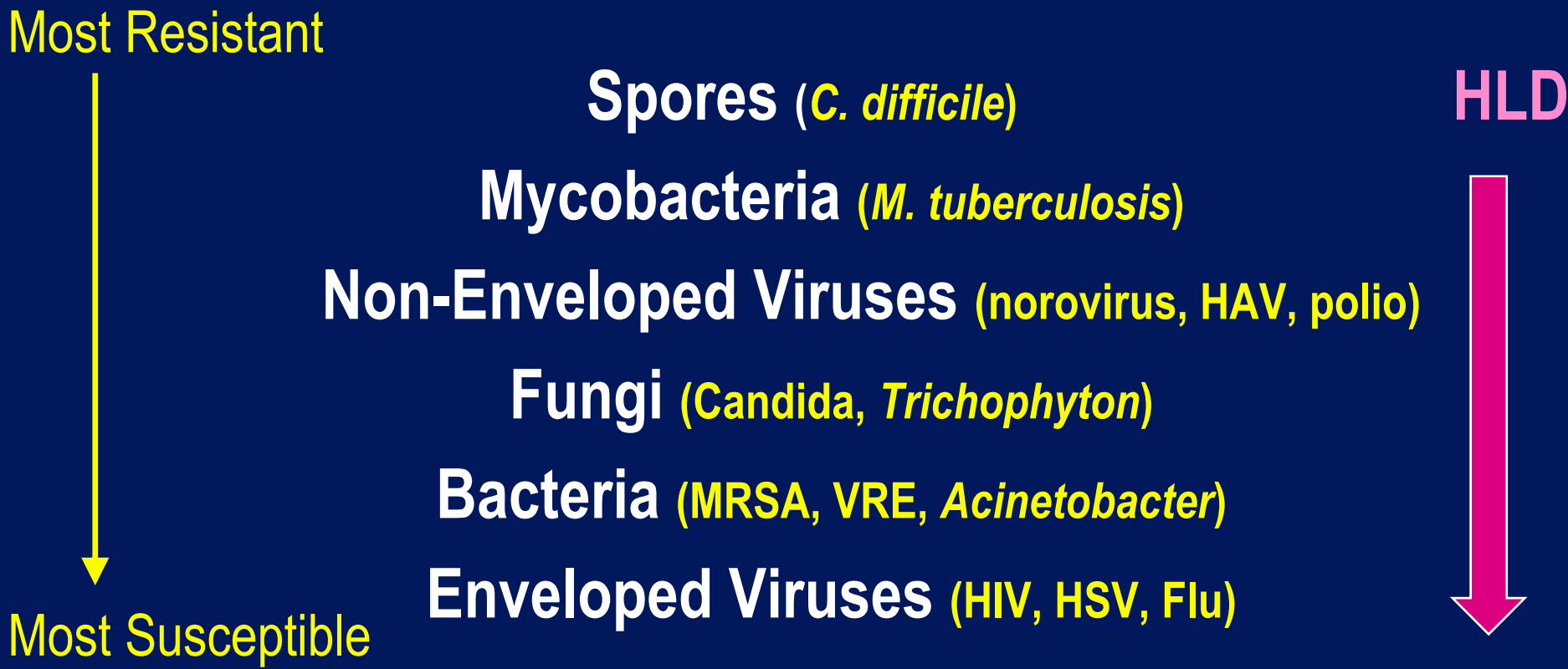
Exposure Time ≥ 8m-45m (US), 20°C

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



Infections/Outbreaks Associated with Semicritical Medical Devices

Rutala, Weber. Am J Infect Control. Rutala WA, Weber DJ. Am J Infect Control. 2019 Jun;47S:A79-A89.

- HBV and HCV transmission during endoscopy and use of semicritical medical devices can occur, but it is rare (3)
- 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.
- Several other semicritical medical devices are associated with infections related to inadequate reprocessing

Table 2
Infections and outbreaks associated with semicritical medical devices*

Instruments	# Outbreaks/ Infections	# Outbreaks/ Infections with bloodborne pathogens
Vaginal probes	0**	0
Nasal endoscopes	0	0
Hysteroscopes	0	0
Laryngoscopes	2[43-45]	0
Urologic instrumentation (eg, cystoscopes, ureteroscopes)	8[46-53]	0
Transrectal-ultrasound guided prostate probes	1[40]	0
Transesophageal echocardiogram	5[31,54-57]	0
Applanation tonometers	2[41,42]	
GI endoscopes/bronchoscopes	~130[7,8]	3 HBV[34]; HCV[35,36]

GI, gastrointestinal; *HBV*, hepatitis B virus; *HCV*, hepatitis C virus.
*These infections/outbreaks were found in the peer-review literature through PubMed and Google.
**Does not include outbreaks associated with contaminated ultrasound gel used with vaginal probes or transmission via health care personnel.

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)

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

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

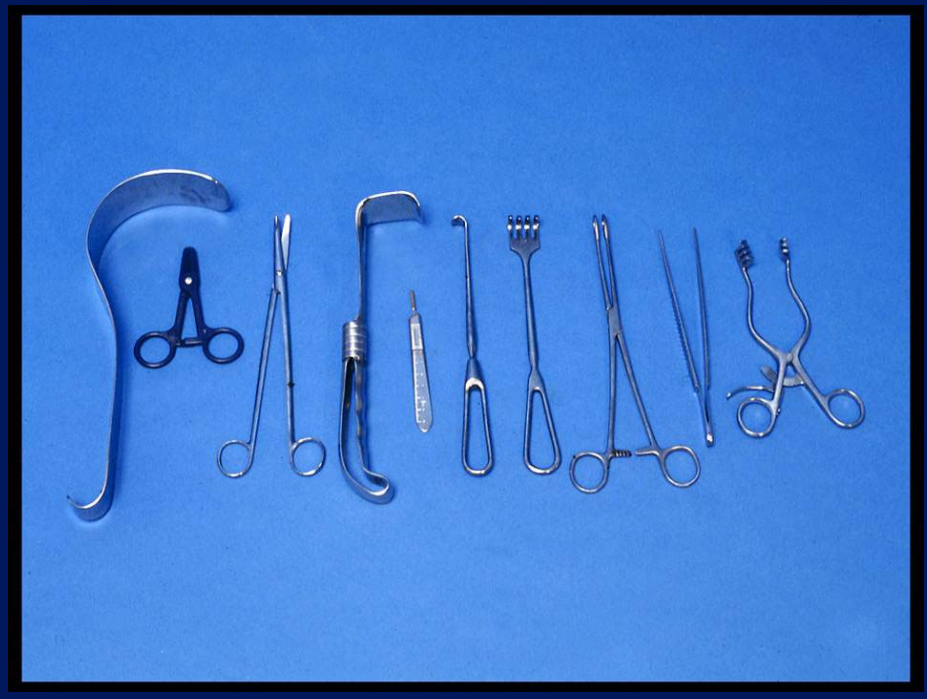
- Margin of safety with endoscope reprocessing minimal or non-existent
- Microbial load
  - GI endoscopes contain 7-10 $\log_{10}$ (10^{7-10})
  - Cleaning results in 2-6 $\log_{10}$ reduction
  - High-level disinfection results in 4-6 $\log_{10}$ reduction
  - Results in a total 6-12 $\log_{10}$ reduction 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



Reason for Endoscope-Related Outbreaks

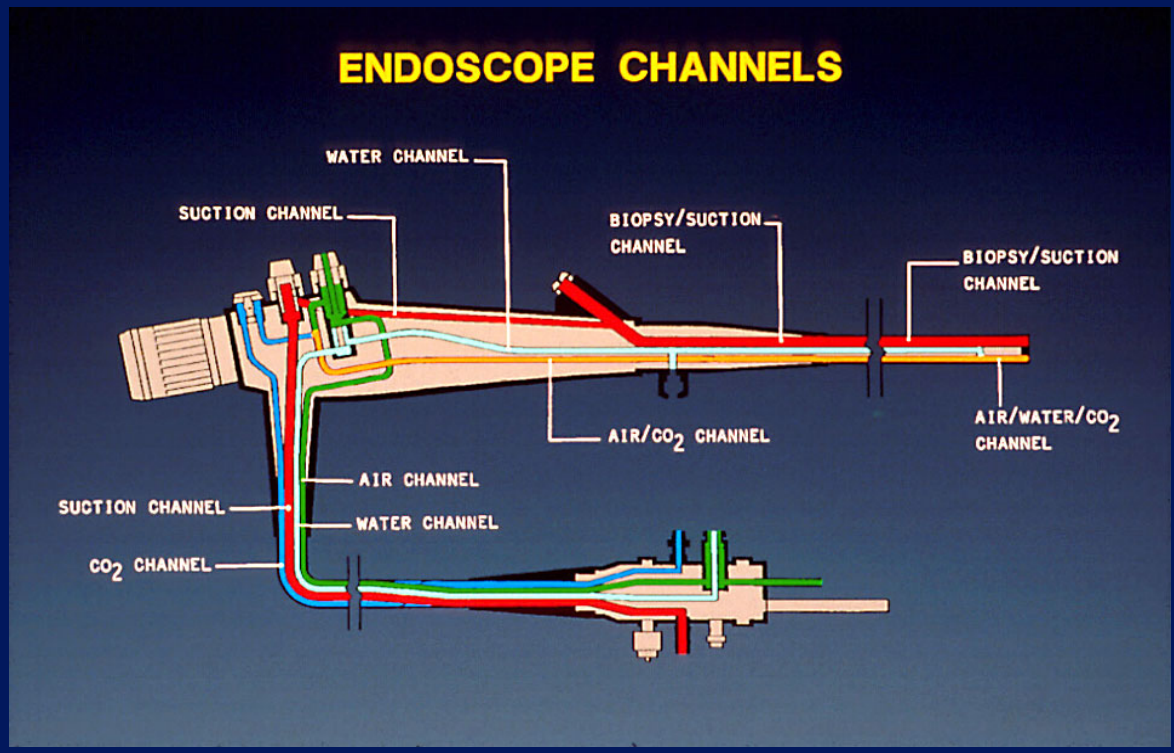
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FEATURES OF ENDOSCOPES THAT PREDISPOSE TO DISINFECTION FAILURES

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



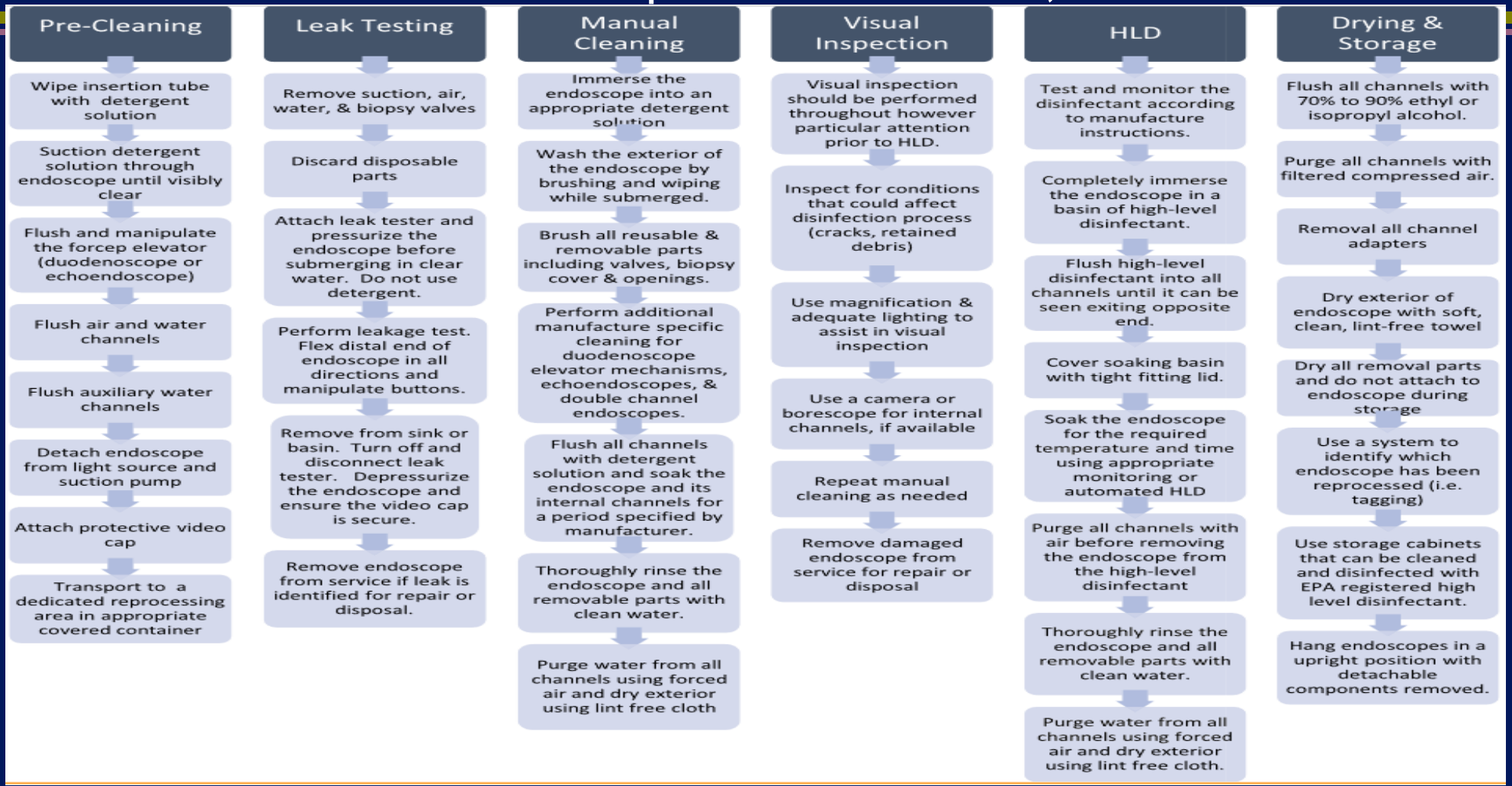
ENDOSCOPE REPROCESSING

CDC 2008: Multi-Society Guideline on Endoscope Reprocessing, 2017

- **PRECLEAN**-point-of-use (bedside) remove debris by wiping exterior and aspiration of detergent through air/water and biopsy channels; leak test
- **CLEAN-mechanically cleaned with water and enzymatic cleaner**
- **HLD/STERILIZE-immerse scope and perfuse HLD/sterilant through all channels for exposure time (>2% glut at 20m at 20°C).** If AER used, review model-specific reprocessing protocols from both the endoscope and AER manufacturer
- **RINSE-scope and channels rinsed with sterile water, filtered water, or tap water.** Flush channels with alcohol and dry
- **DRY-use forced air to dry insertion tube and channels**
- **STORE**-hang in vertical position to facilitate drying; stored in a manner to protect from contamination

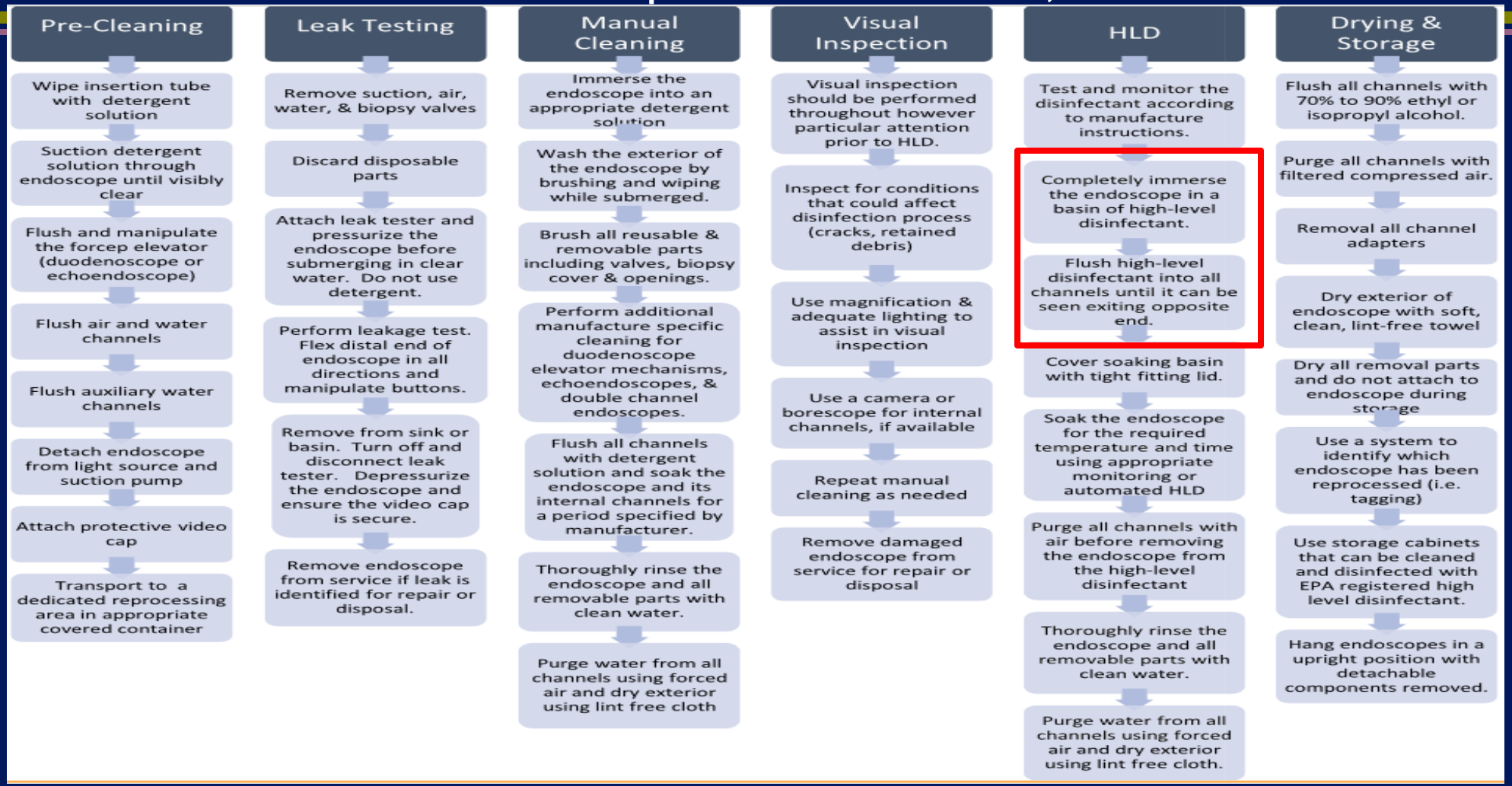
Complexity of Endoscope Reprocessing

Chua et al. Techniq Innov Gastro Endo 2021;23:190



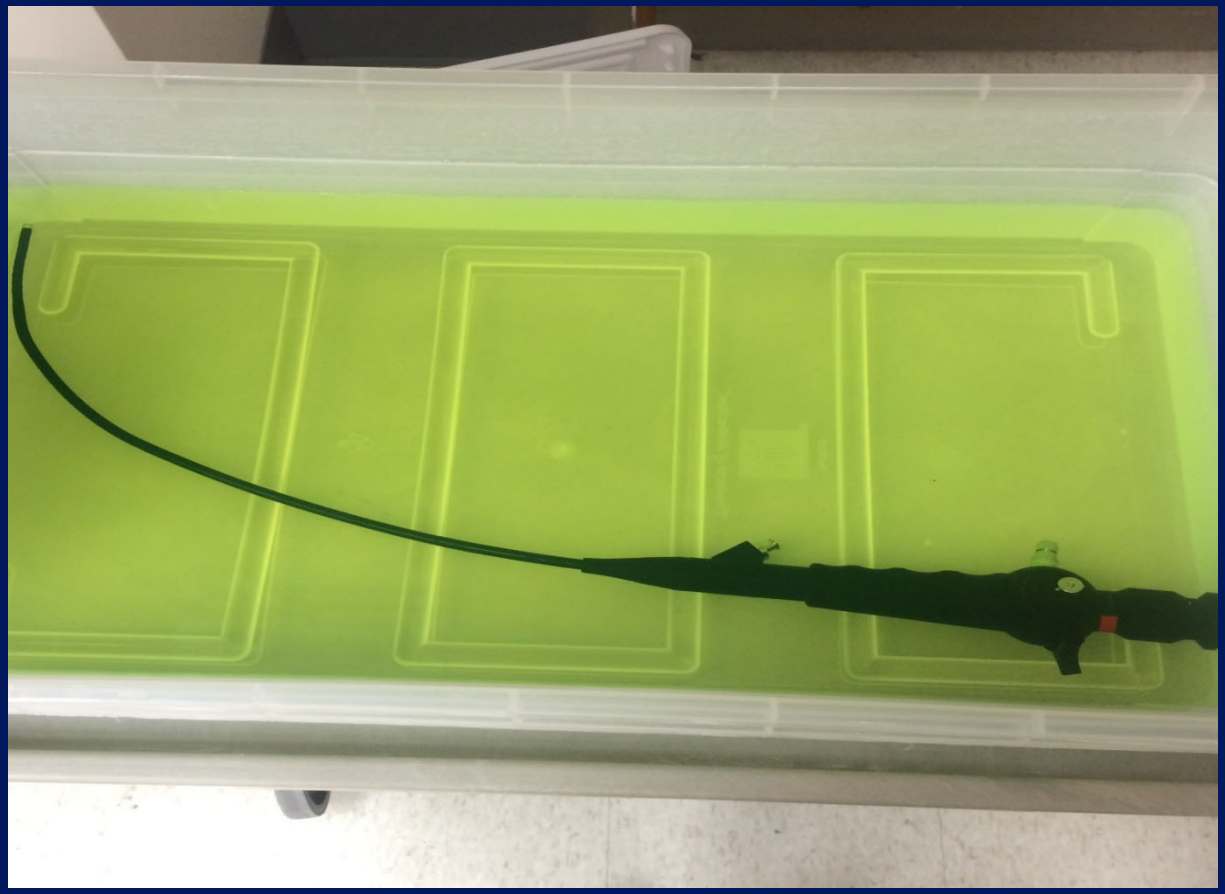
Complexity of Endoscope Reprocessing

Chua et al. Techniq Innov Gastro Endo 2021;23:190



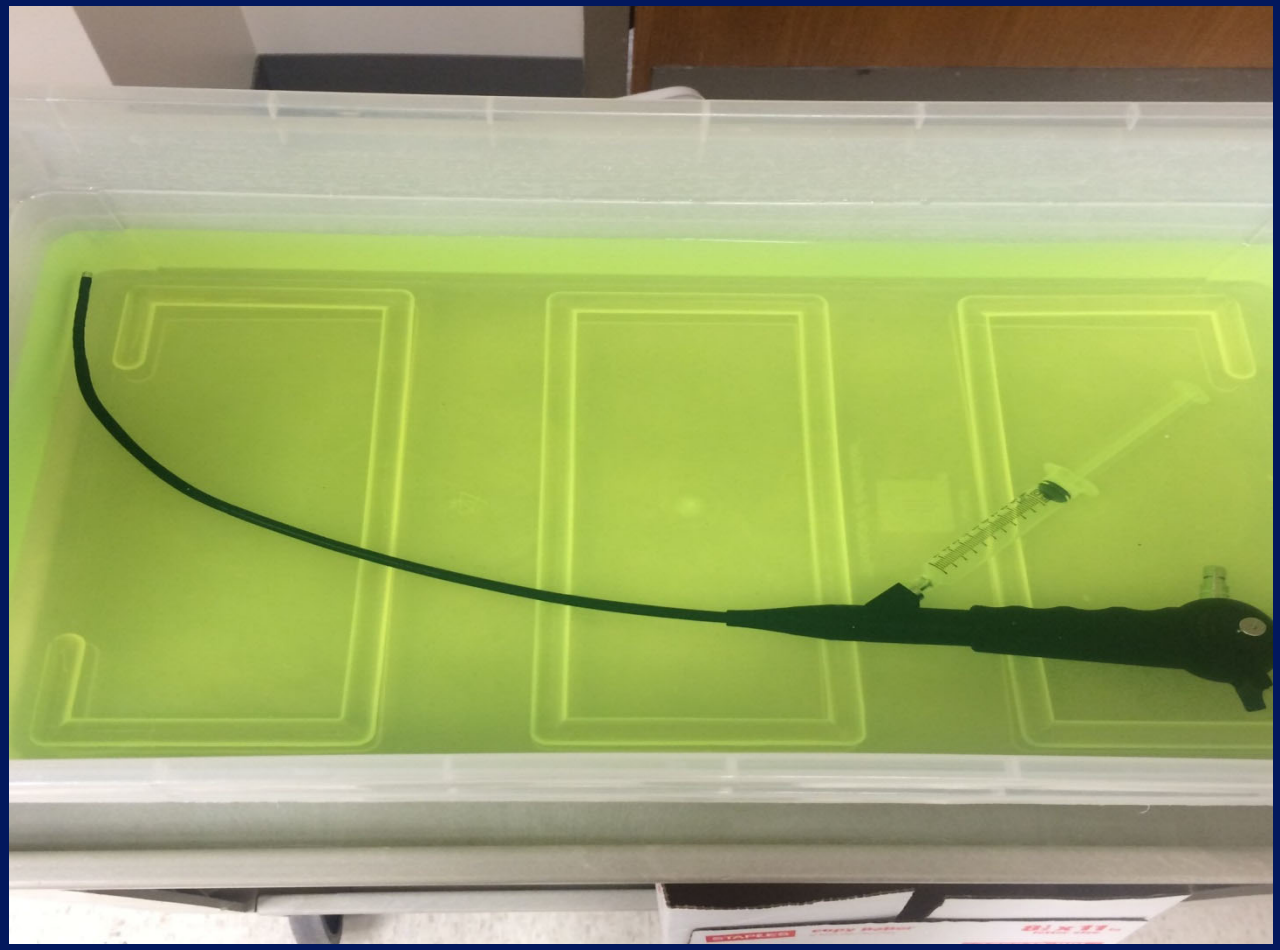
Reprocessing Channeled Endoscopes

Cystoscope- “completely immerse” in HLD (J Urology 2008.180:588)



Reprocessing Channeled Endoscopes Manually

Cystoscope-HLD perfused through lumen with syringe (luer locks onto port and 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

Endoscope Reprocessing Methods

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



Cori L. Ofstead, MSPH
Harry P. Wetzler, MD, MSPH
Alycea K. Snyder, BA
Rebecca A. Horton, DPT

Endoscope Reprocessing Methods

A Prospective Study on the Impact of Human Factors and Automation

ABSTRACT

The main cause of endoscopy-associated infections is failure to adhere to reprocessing guidelines. More information about factors impacting compliance is needed to support the development of effective interventions. The purpose of this multisite, observational study was to evaluate reprocessing practices, employee perceptions, and occupational health issues. Data were collected utilizing interviews, surveys, and direct observation. Written reprocessing policies and procedures were in place at all five sites, and employees affirmed the importance of most recommended steps. Nevertheless, observers documented guideline adherence, with only 1.4% of endoscopes reprocessed using manual cleaning methods with automated high-level disinfection versus 75.4% of those reprocessed using an automated endoscope cleaner and reprocessor. The majority reported health problems (i.e., pain, decreased flexibility, numbness, or tingling). Physical discomfort was associated with time spent reprocessing ($p = .041$). Discomfort diminished after installation of automated endoscope cleaners and reprocessors ($p = .001$). Enhanced training and accountability, combined with increased automation, may ensure guideline adherence and patient safety while improving employee satisfaction and health.

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

Automated Endoscope Reprocessors

AERs automate and standardize endoscope reprocessing steps





“Given the choice of improving technology or improving human behavior, technology is the better choice”

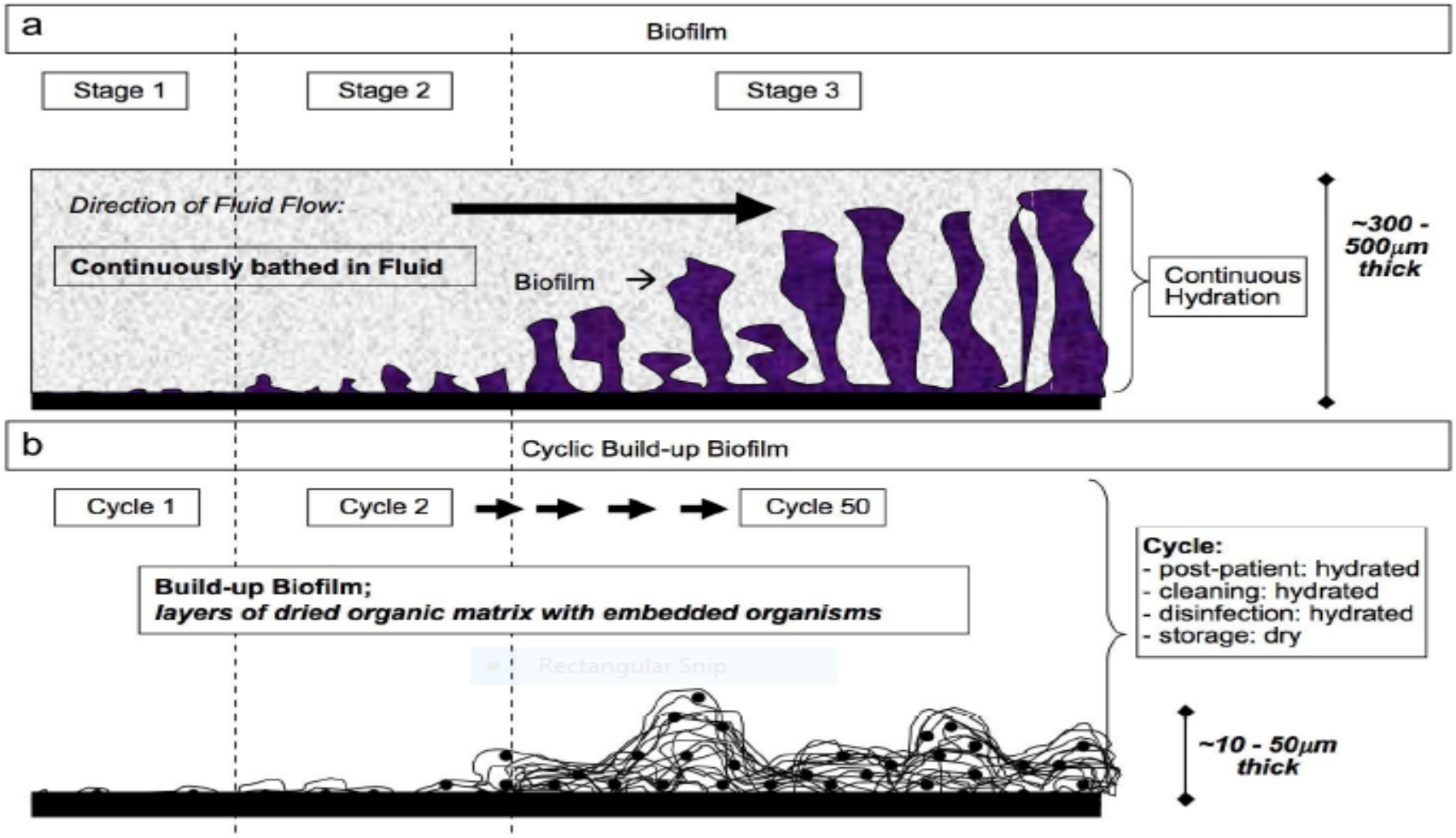
Robert A. Weinstein, MD

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.

High-Level Disinfection
No Margin of Safety

0 margin of safety

Microbial contamination 10^7-10^{10}: compliant with reprocessing guidelines 10,000 microbes after reprocessing:

maximum contamination, minimal cleaning (10^2)/HLD (10^4)

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,

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})

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

Supplemental Measures to Reduce Infection Risk

Rutala WA, Weber DJ. ICHE 2015;36:643-648; Rutala et al. AJIC 2019:47:A62

Hospitals performing ERCPs should do one of the following; FDA adopted these recommendations

- **Ethylene oxide sterilization** after high level disinfection with periodic microbiologic surveillance
- **Double high-level disinfection** with periodic microbiologic surveillance
- High-level disinfection with scope quarantine until negative culture
- **Liquid chemical sterilant** processing system using peracetic acid (rinsed with extensively treated potable water) with periodic microbiologic surveillance
- High-level disinfection with periodic microbiologic surveillance

Did supplemental measures work?

Supplemental Measures for Endoscope Reprocessing

Day et al. Gastro Endosc 2021;93:11-35; Gromski et al. Gastro Endosc 2021;93:927; Synder et al. Gastroenterology 2017;153:1018; Bartles et al Gastro Endos 2018;88:306

- In a nonoutbreak setting, repeat HLD has no additional benefit compared with single HLD in reducing bacterial contamination rates for duodenoscopes
- In nonoutbreak setting, limited data suggest that ETO sterilization does not reduce bacterial contamination rates in duodenoscopes compared with single HLD
- No significant difference of positive cultures when comparing double HLD (8) with duodenoscopes undergoing liquid chemical sterilant (9).
- The use of ETO sterilization on duodenoscopes during infectious outbreaks has been associated with terminating these outbreaks and such a modality should be considered in selected settings and patient populations
- However, many barriers to widespread use of ETO including cost, only 20% hospital use ETO (availability), possible damage to scopes, exposure of staff to ETO, exposure/turnaround time

GI Endoscopes: Shift from Disinfection to Sterilization

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

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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 https://www.aium.org/officialstatements/57

- "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 https://www.aium.org/officialstatements/57

- 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.

Semicritical/Critical Reprocessing Failures

- Examples of failures
  - Use Quat/Alcohol wipe rather than HLD (ENT, vaginal probes)
  - Failure to monitor concentration of HLD
  - Staff did not flush and brush all channels
  - Channels not perfused with HLD (cystoscopes)
  - Time and/or temperature on AER was wrong
  - Steam cycle at 0 minutes rather than 4 minutes (132^{o}C)

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 www.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

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.

THANK YOU!

www.disinfectionandsterilization.org

