
HLD and Sterilization

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DISCLOSURES

2023

- **Consultation, honoraria**
 - PDI (Professional Disposables International)
- **Consultation**
 - Kinnos, Ideate Medical

www.disinfectionandsterilization.org

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

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 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, **>150 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**

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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





Pre-Cleaning

- Surgical instruments are pre-cleaned in the OR. Ideally, instruments should arrive in Central Processing free on visible contamination
- To keep instruments wet from OR to CP, many hospitals spray instruments with an enzymatic solution
- 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
- Keep instruments moist (e.g., damp towel) as it prevents hardening



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	2.6×10^7	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

Cleaning Indicators for Washer-Disinfectors

- 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” was suboptimal: no BI, no effective decontamination, 3m at 132°C, unpackaged. Now only difference is dry time.
- “Flash” is an antiquated term and replaced by “immediate use steam sterilization”

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°C, 4min)
- The same critical reprocessing steps (such as cleaning, decontaminating, and transporting) must be followed
- Not a substitute for normal sterilization (urgent need)
- 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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Evaluation of Microbicidal Activities of Sterilization Technologies in Salt and Serum (simulate inadequate cleaning)

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							
<i>Pseudomonas aeruginosa</i>	8.1×10^8	2.0×10^6	3.5×10^4	0 (0/30)	0 (0/50)	0 (0/40)	13 (5/40)
<i>Escherichia coli</i>	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)
<i>Staphylococcus aureus</i>	4.8×10^8	2.3×10^6	2.5×10^6	0 (0/30)	0 (0/40)	0 (0/30)	93 (28/30)
<i>Mycobacterium terrae</i>	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)
<i>Bacillus atrophaeus</i> 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)
<i>Geobacillus stearothermophilus</i> 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)
<i>Clostridiodes difficile</i> 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.

^aTo 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. atrophaeus* and *G. stearothermophilus*; and 10% FCS and 0.52% salt *C. difficile* spores

^bRuns 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*).

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 # 0109505-22

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

U=inHg
P=psia

- TIME	T= F	P=psia
C 11:42:31A	104.5	0.0P
C 11:43:32A	213.6	8.6P
C 11:44:56A	179.5	10.1U
C 11:47:14A	263.1	26.0P
C 11:49:07A	200.1	11.3U
C 11:50:38A	264.0	26.0P
C 11:52:30A	204.9	11.4U
C 11:53:53A	264.3	26.1P
C 11:55:47A	206.6	11.9U
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	26.8U
Z 12:51:25P	115.0	2.0U

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

PRINTOUT CHECKED BY:

[Redacted Signature]

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

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

Table 2. Chemical Indicator Classifications

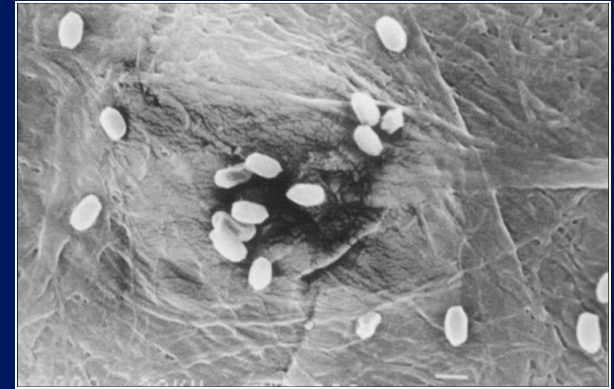
Class 1 Process indicators	Process indicators are attached to or printed on the outside of all packs to discern which packages have been processed from those that have not been processed in a sterilizer.
Class 2 Bowie-Dick test	The Bowie-Dick test is used to reveal the pass/fail rate in dynamic air removal 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.

Sterility Indicators Table

	Before Exposure (Do not use)	After Exposure (Sterile) (Ok if package is intact)
Steam Autoclave		
Tape		
Strip	STRATE-LINE™ sterilization mc FOR USE IN PRESSURE STEAM AUTOCLAVES. PLACE A STRATE-LINE STRIP ON EACH	Date _____ Contents _____ WRITE LINE ACROSS THE STRIP TURNING UNIFORMLY BLACK IT IS PROOF OF ATTACH
Peel Pack	SEALING CTIONS Reorder No. 8853026 *U.S. Pat. 4,276,882 Turns Brown / Black in Steam CM1206 	SEALING CTIONS Reorder No. 8853025 *U.S. Pat. 4,276,882 Turns Brown / Black in Steam CM1206 
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*
 - VHP- *G. stearothermophilus*

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

Rutala, Jones, Weber ICHE 1996. 17:423

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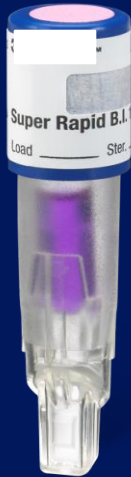
COMPARISON OF A RAPID READOUT BIOLOGICAL INDICATOR FOR STEAM STERILIZATION WITH FOUR CONVENTIONAL BIOLOGICAL INDICATORS AND FIVE CHEMICAL INDICATORS

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



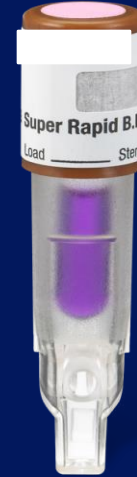
Super Rapid Readout Biological Indicators

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, SFPP-steam flush pressure pulse) steam sterilization cycles
- 24-minute result

Rapid (or Super Rapid) Readout Biological Indicator for Steam (20m-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
2 hours	1
30 minutes	2
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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Rutala et al. AJIC 2019;47:A3-A9



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High-Level Disinfection of “Semicritical Objects”

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

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

Microbiological Disinfectant Hierarchy

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

Most Resistant

Spores (*C. difficile*)

Mycobacteria (*M. tuberculosis*)

Non-Enveloped Viruses (norovirus, HAV, polio)

Fungi (*Candida*, *Trichophyton*)

Bacteria (MRSA, VRE, *Acinetobacter*)

Enveloped Viruses (HIV, HSV, Flu)

Most Susceptible

HLD



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^a

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 ^{51,54-57}	0
Applanation tonometers	2 ^{41,42}	0
GI endoscopes/bronchoscopes	~130 ^{7,8}	3 HBV ³⁴ ; HCV ^{35,36}

GI, gastrointestinal; HBV, hepatitis B virus; HCV, hepatitis C virus.

^aThese 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 activity

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	<i>Pa, H. pylori, Salmonella</i>	169	56	Cleaning/Disinfection (C/D)
Sigmoid/Colonoscopy	5	<i>Salmonella, HCV</i>	14	6	Cleaning/Disinfection
ERCP	23	<i>P. aeruginosa (Pa)</i>	152	89	C/D, water bottle, AER
Bronchoscopy	51	<i>Pa, Mtb, Mycobacteria</i>	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
<i>Klebsiella pneumoniae</i>	<i>mcr-1</i>	2	No	No	Yes-WGS	Shenoy et al, 2018 ²¹
<i>K pneumoniae</i>	<i>bla</i> _{oxa-232}	15 (8)	No	No	Yes-PCR	Kim et al, 2016 ¹⁹
<i>Escherichia coli</i> (AmpC)	<i>bla</i> _{CMY-2}	35	No	Yes (2)	Yes-PCR, PFGE	Wendorf et al, 2015 ¹⁶
<i>K pneumoniae</i>	<i>bla</i> _{oxa-48}	12	Yes	No	Yes-PCR, PFGE	Kola et al, 2015 ²³
<i>K pneumoniae</i>	<i>bla</i> _{KPC}	34?	No	Yes (3)	Yes-PCR, PFGE, MLST, WGS	Marsh et al, 2015 ²²
<i>E coli</i>	<i>bla</i> _{NDM}	39	Yes	Yes (1)	Yes-PCR, PFGE	Epstein et al, 2014 ¹⁷
<i>Pseudomonas aeruginosa</i>	<i>bla</i> _{VIM-2}	22	Yes	Yes (1)	Yes-PCR*, PFGE, repetitive-sequence-based PCR typing	Verfaillie et al, 2015 ²⁴
<i>E coli</i>	<i>bla</i> _{NDM-1}	3 (3)	No	No	Unknown	Smith et al, 2015 ²⁰
<i>K pneumoniae</i>	<i>bla</i> _{KPC-2} , <i>bla</i> _{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^{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^{10}
bacteria/endoscope



Surgical instruments- $<10^2$ bacteria



Reason for Endoscope-Related Outbreaks

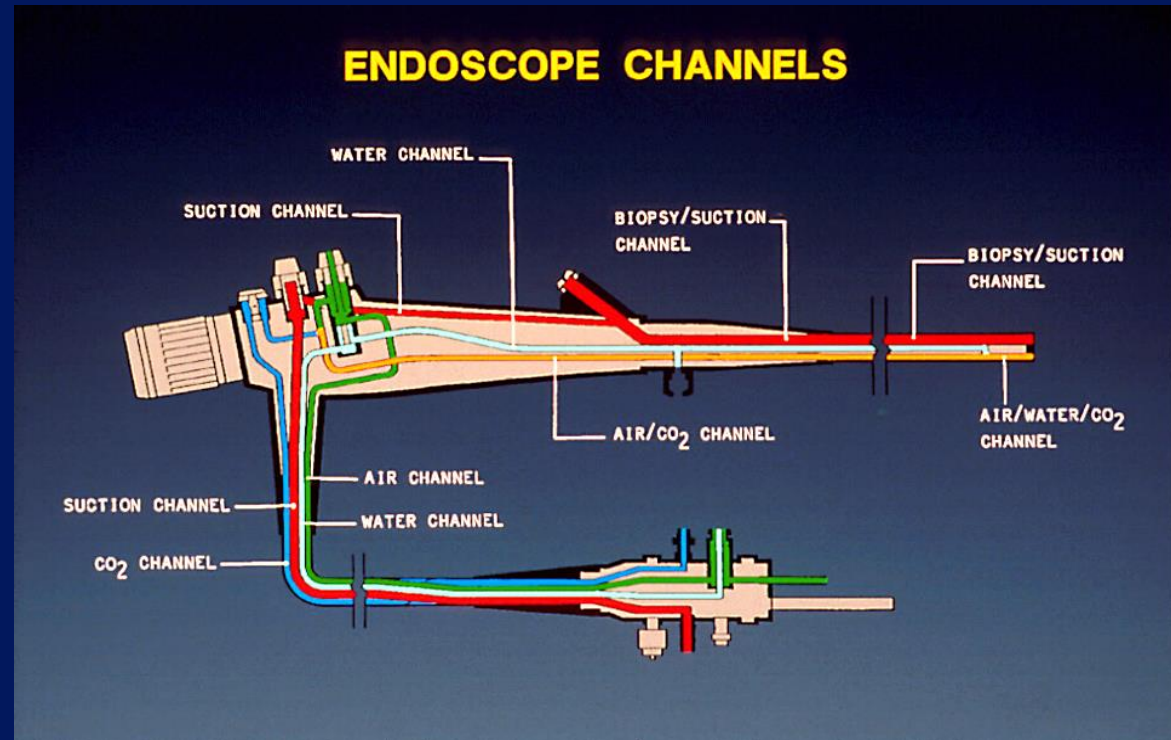
Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

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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^{7-10}
- Cleaning (2-6 $\log_{10}$ reduction) and HLD (4-6 $\log_{10}$ reduction) essential for patient safe instrument



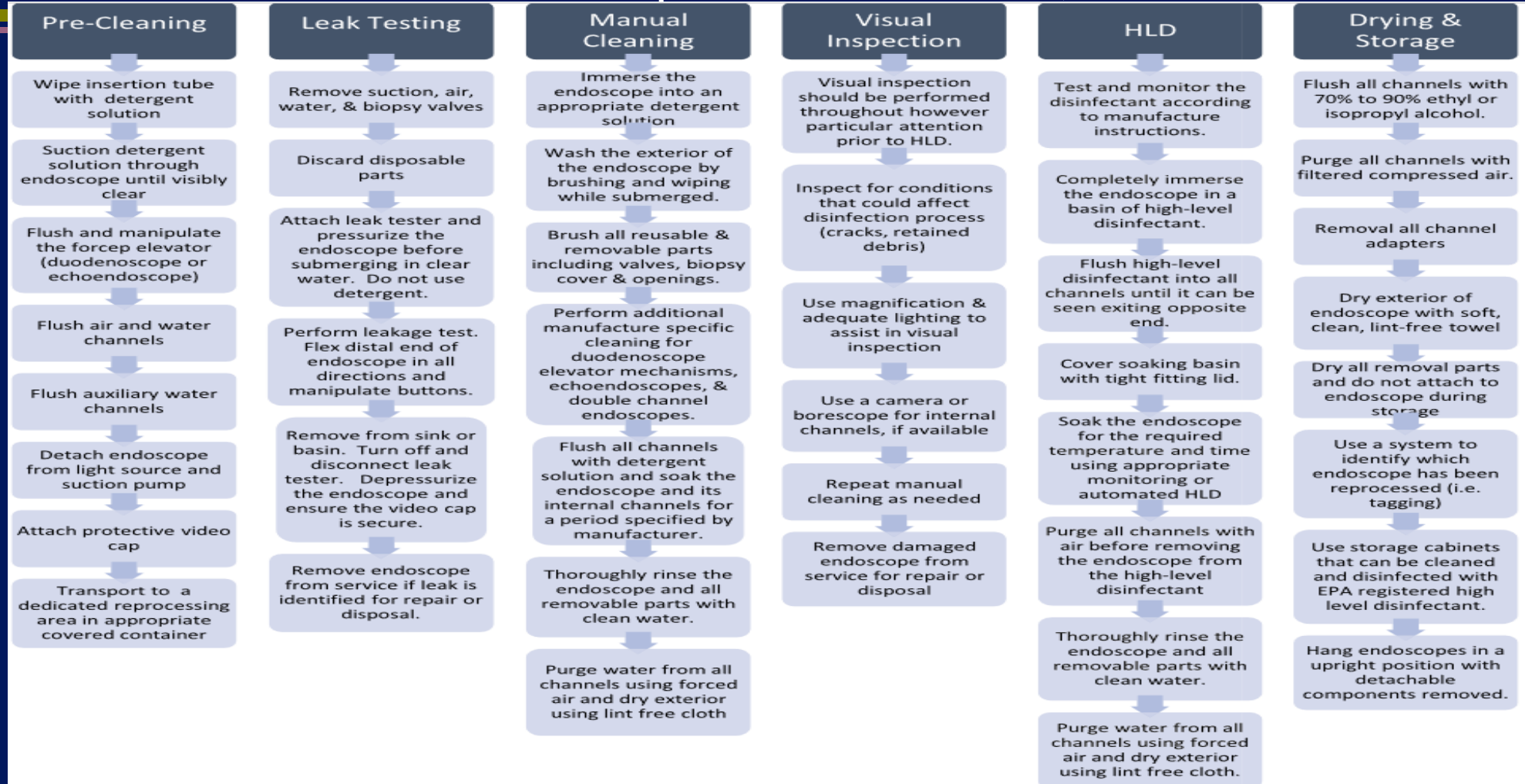
ENDOSCOPE REPROCESSING

CDC 2008: Multi-Society Guideline on Endoscope Reprocessing, 2021

- **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

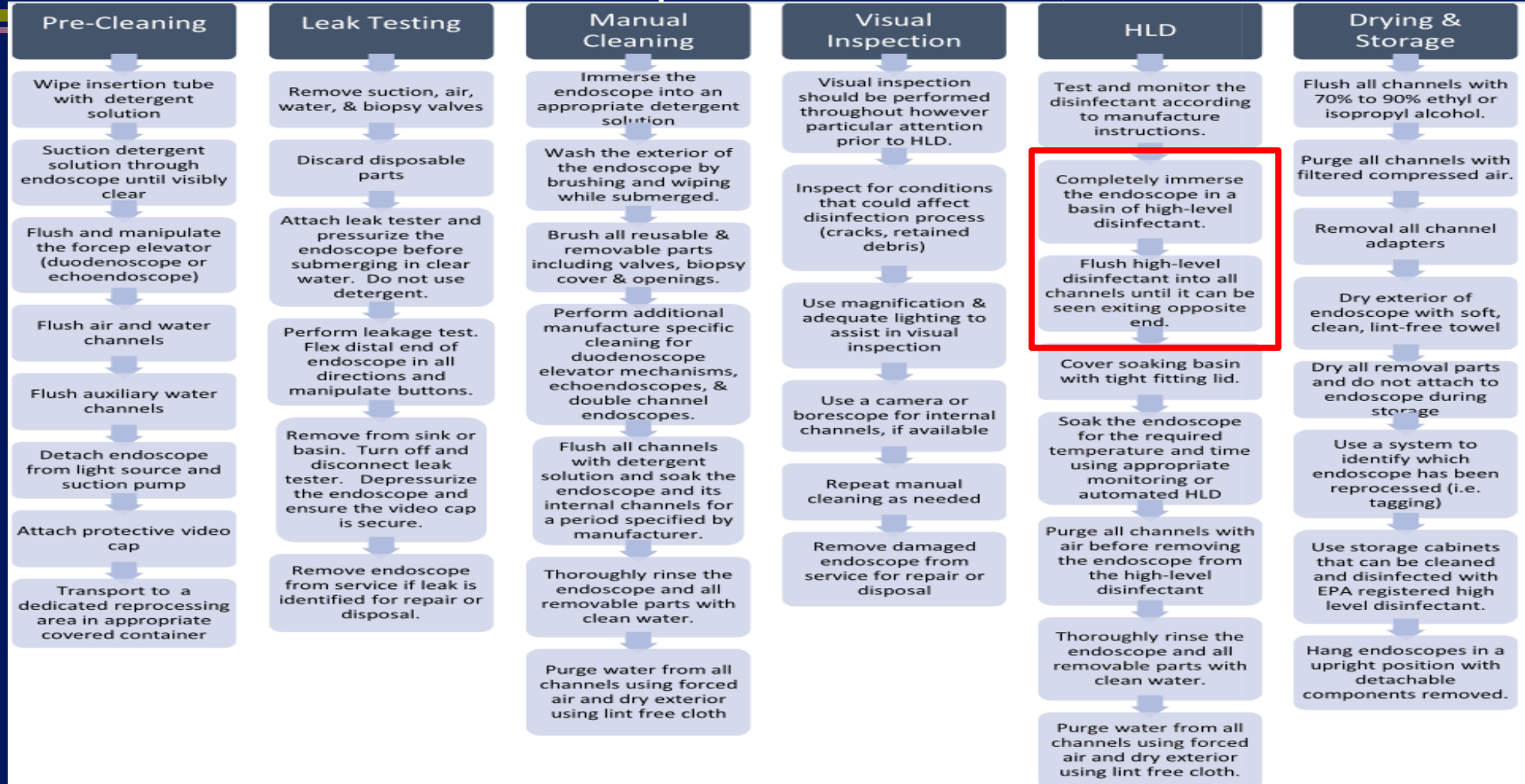
Complexity of Endoscope Reprocessing

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



Complexity of Endoscope Reprocessing

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



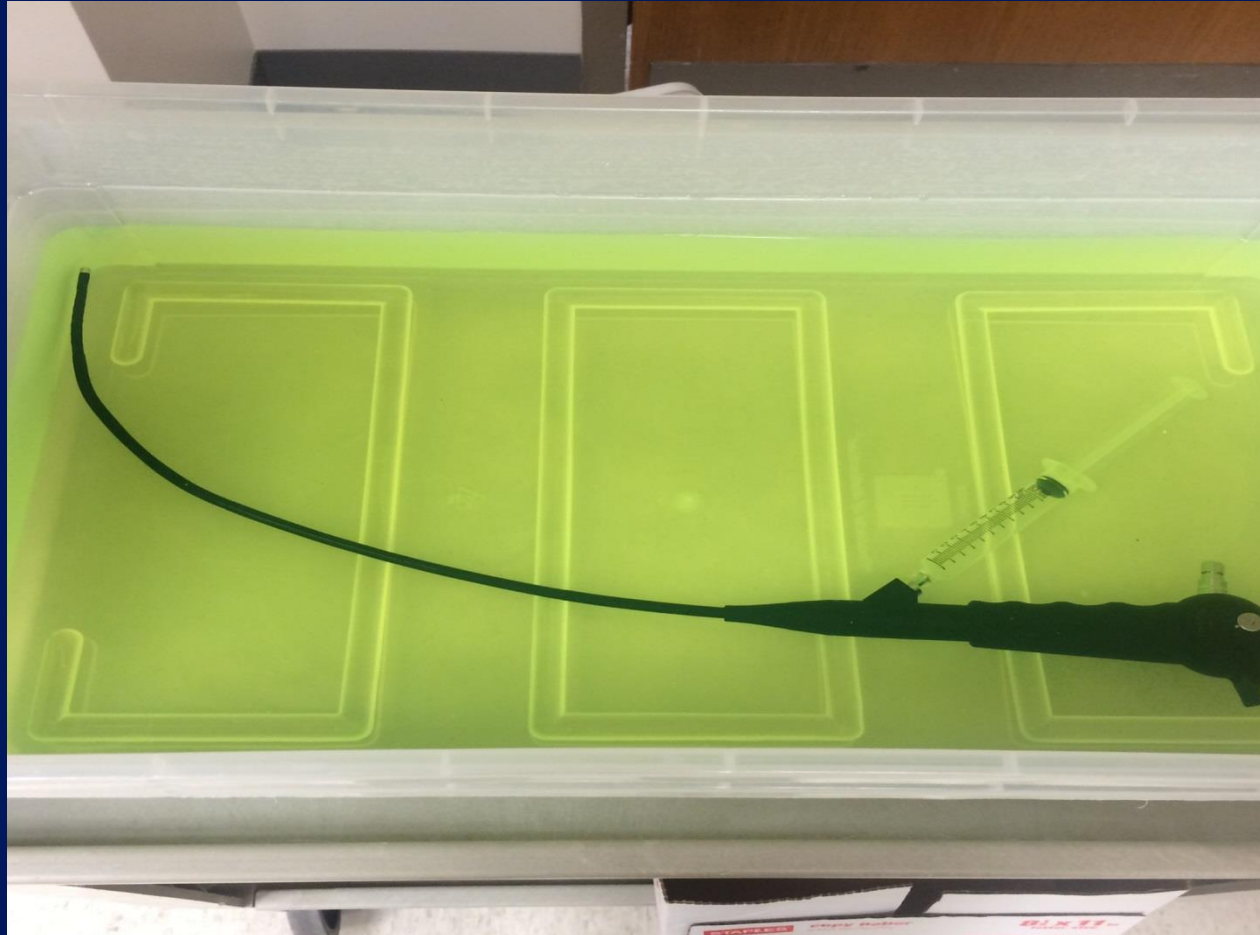
Reprocessing Channeled Endoscopes

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 (<i>K. pneumoniae</i>) Inoculum before HLD (glutaraldehyde)	CRE (<i>K. pneumoniae</i>) 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

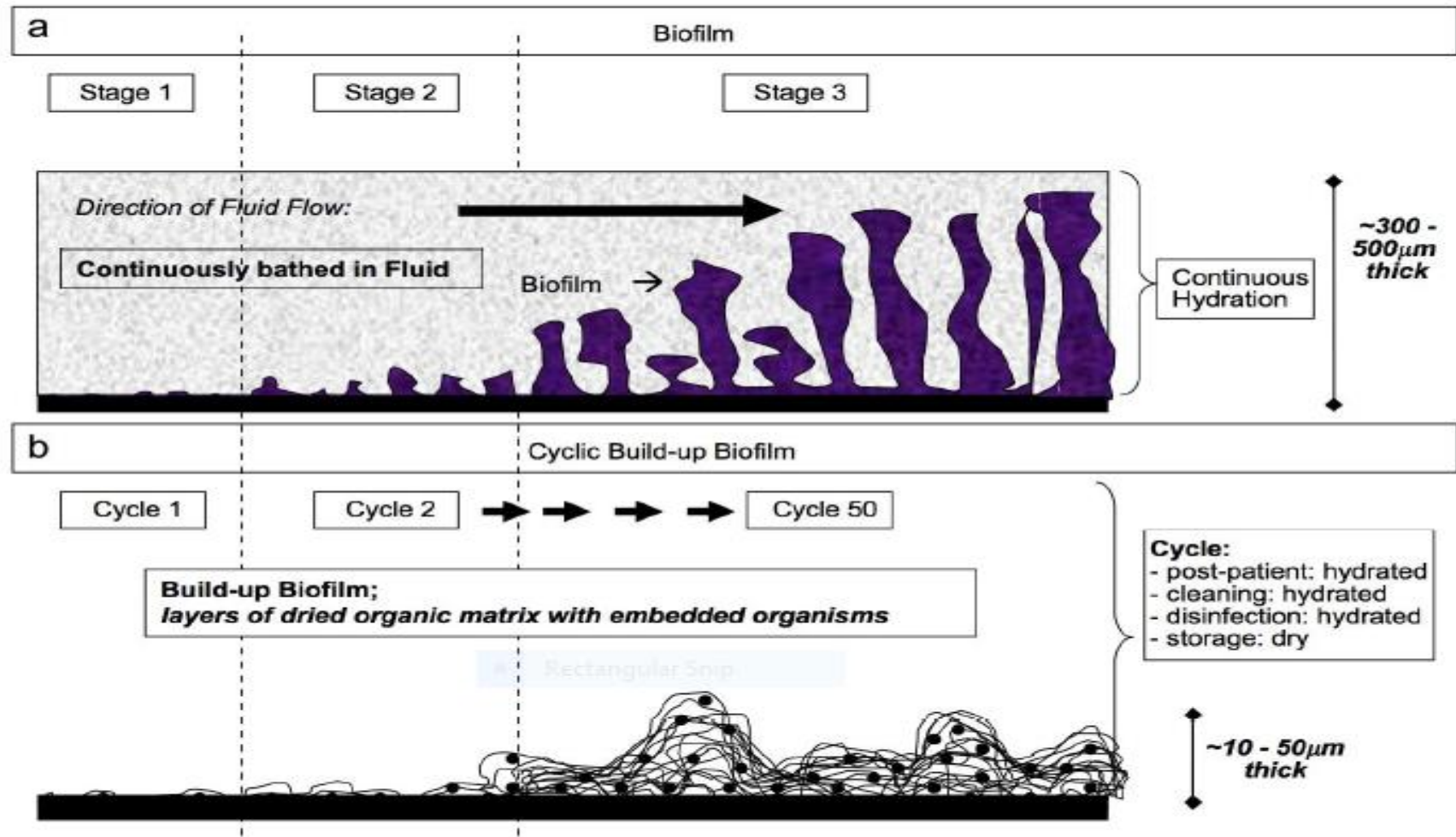
- Pathogens must have exposure to HLD for inactivation
- Immerse channeled flexible scope into HLD will not inactivate channel pathogens
- Completely immerse the endoscope in HLD and **ensure all channels (e.g., hysteroscopes, cystoscopes) are perfused**
- Air pressure in channel stronger than fluid pressure at fluid-air interface

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, Zelenitsky 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)

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 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

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)

>150 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 ($\sim 6 \log_{10}$). 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})

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).

Future Approaches to Endoscope Reprocessing to Improve Patient Safety

Rutala et al. AJIC 2019;47:A62; Chua et al. Techniq Innov Gastro Endo 2021;23:190

- Optimize current LTST (ETO, VHP, HP plus ozone) or new LTST proving SAL 10^{-6} achieved
- Disposable endoscopes (device innovations)
 - Partially-endcaps, decrease bacterial contamination after HLD
 - Fully-GI and bronchoscopes; cost, scope performance
- Steam sterilization for GI and other endoscopes
- Use of non-endoscopic methods to diagnose or treat disease
- Stop HLD for affected Storz urological endoscopes, transition to sterilization

NEW STERILIZATION TECHNOLOGY



- Hydrogen Peroxide Gas Plasma sterilizer designed specifically for the terminal sterilization of flexible endoscopes
- Incorporates a proprietary vapor diffusion technology to direct Vaporized Hydrogen Peroxide (VHP) into the internal lumen channels of an endoscope
 - Utilizes a pressure differential in each internal endoscope channel to rapidly diffuse VHP to sterilize all endoscope channels
 - Achieves the required VHP efficacy concentration in all internal endoscope channels (up to 4 meters) in < 20 secs
 - Uses lower overall concentration of H_2O_2 with shorter exposure times, thereby eliminating potential damage to the endoscope
- Incorporates a proprietary sterilization container that interfaces with the sterilizer during the sterilization process and facilitates sterile storage (6 months) of the endoscope after processing
- Incorporates a proprietary pre-sterile single-use channel connector that is pressure activated. It seals during VHP transfer and then releases to allow sterilization of the mated connector interface
- Based on initial testing, we were able to sterilize an Olympus duodenoscope (TJF-Q160F) 125 times with no damage to the device

Future Approaches to Endoscope Reprocessing to Improve Patient Safety

Rutala et al. AJIC 2019;47:A62; Chua et al. Techniq Innov Gastro Endo 2021;23:190

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The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication



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Update as of April 4, 2022: The FDA provided [new information](#) supporting the transition to fully disposable duodenoscopes and those with disposable components as well as new information on completed postmarket surveillance studies (also known as 522 studies).

Transition to Innovative Duodenoscope Designs-Disposable Endcaps or Fully Disposable Duodenoscopes

Use Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication

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Date Issued: April 5, 2022

The U.S. Food and Drug Administration (FDA) is updating the [April 2020](#) Safety Communication to provide new information supporting the transition to fully disposable duodenoscopes and those with disposable components as well as new information on completed postmarket surveillance studies (also known as 522 studies).

Given the cleaning concerns and contamination data with fixed endcap duodenoscopes and the increasing availability of duodenoscope models that facilitate or eliminate the need for reprocessing, hospitals and endoscopy facilities should complete transition to innovative duodenoscope designs that include disposable components such as disposable endcaps, or to fully disposable duodenoscopes. The use of a removable component to facilitate cleaning leads to significantly less contamination; interim results from one

FDA Cleared at least 6 Duodenoscopes with Disposable Components or Fully Disposable

Fully Disposable:

- [Ambu Innovation GmbH, Duodenoscope model aScope Duodeno](#) (fully disposable duodenoscope cleared under K201098)
- [Boston Scientific Corporation, EXALT Model D Single-Use Duodenoscope](#) (fully disposable duodenoscope cleared under K193202)

Disposable Components:

- [Fujifilm Corporation, Duodenoscope model ED-580XT](#) (disposable endcap duodenoscope cleared under K181745)
- [Olympus Medical Systems, Evis Exera III Duodenovideoscope Olympus TJF-Q190V](#) (disposable endcap duodenoscope cleared under K193182)
- [Pentax Medical, Duodenoscope model ED34-i10T2](#) (disposable elevator duodenoscope cleared under K192245 and [K210710](#))
- [Pentax Medical, Duodenoscope model ED32-i10](#) (disposable elevator duodenoscope cleared under K202365)

No Longer Marketed:

- [Pentax Medical, Duodenoscope model ED34-i10T](#) (disposable endcap duodenoscope cleared under [K163614](#) and [K181522](#))

Transition to Innovative Duodenoscope Designs-Disposable Endcaps or Fully Disposable Duodenoscopes

Duodenoscopes with disposable endcap



Sterile, single-use duodenoscope for ERCP



Transition to Innovative Duodenoscope Designs-Disposable Endcaps or Fully Disposable Duodenoscopes: Why?

www.fda.gov

- Best solution to reducing the risk of disease transmission by duodenoscopes is through innovative device design that make reprocessing easier, more effective, or unnecessary.
- Postmarket surveillance studies on fixed endcap design indicate that as high as 6.6% (56/850) of samples tested positive with high concern organisms (e.g., *E. coli*, *Pa*). Interim results with removable components show 0.5% (2/417) tested positive with high concern organisms
- As a result, Pentax and Olympus are withdrawing their fixed endcap duodenoscopes from the market, and Fujifilm has completed withdrawal

Effect of Disposable Elevator Cap Duodenoscopes on Microbial Contamination

Forber et al. JAMA IM 2023;183:191-200

Microbial contamination detected in 11.2% of standard duodenoscopes and 3.8% of disposable elevator cap duodenoscopes without affecting technical performance and safety of ERCP

Table 2. Primary and Secondary Study Outcomes

Outcome	Disposable elevator cap duodenoscope			Standard duodenoscope			P value
	No. (%)	Scope ID	Occurrences/ cases performed	No. (%)	Scope ID	Occurrences/ cases performed	
Microbiology outcomes							
No.	208	NA	NA	214	NA	NA	NA
Persistent microbial contamination ^a							
Yes	8 (3.8)	NA	NA	24 (11.2)	NA	NA	.004
No	200 (96.2)	NA	NA	190 (88.8)	NA	NA	

WARNING LETTER

Olympus Medical Systems Corp.

MARCS-CMS 654013 — MARCH 15, 2023

- Issue: cap falling off the scope in the patient
- “Since November 2020, Olympus Medical has received approximately 160 complaints describing the ‘distal end cover’ code number MAJ-2315 has ‘dropped off’”
- Some patients suffered injuries, although no deaths were cited
- No similar problem identified yet for Pentax and Fujifilm

Sterilize Karl Storz Urological Endoscopes

www.fda.gov

UPDATE: Change in Reprocessing Methods with Certain Karl Storz Urological Endoscopes – Letter to Health Care Providers

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April 4, 2022

As the U.S. Food and Drug Administration (FDA) continues to evaluate the risk of patient infections and contamination issues associated with reprocessed urological endoscopes, the FDA is aware that the current reprocessing instructions for certain urological endoscopes manufactured by Karl Storz are inadequate and are being changed updated by Karl Storz. The affected urological endoscopes include cystoscopes, ureteroscopes, cystourethoscopes and ureterorenoscopes, used for viewing and accessing the urinary tract.

In April 2021, the FDA [communicated](#) about reported patient infections and possible contamination issues with reprocessed urological endoscopes. At the FDA's request, Karl Storz conducted reprocessing validation testing on a sample of flexible urological endoscopes and identified reprocessing failures following [high-level disinfection](#). Inadequate reprocessing of urological endoscopes may increase the risk of patient infection.

Sterilize Karl Storz Urological Endoscopes

www.fda.gov

- At FDA request, Karl Storz conducted reprocessing validation testing on a sample of flexible urological endoscopes and identified reprocessing failures following HLD.
- Do not use HLD methods or liquid chemical sterilization to reprocess affected urological endoscopes (HLD not achieved for affected products)
- Sterilize affected urological endoscopes after each use by using sterilization methods recommended in MIFU
- Do not use affected urological endoscopes if you do not have access to an appropriate sterilization method

Sterilize Karl Storz Urological Endoscopes

https://www.karlstorz.com/cps/rde/xbcr/karlstorz_assets/ASSETS/3680244.pdf



ENDOSCOPES FOR MEDICINE AND TECHNICAL SCIENCE
INSTRUMENTS FOR OTO-RHINO-LARYNGOLOGY

Rev 1: April 2022

FSN Ref: 22-0002

Date: April 1, 2022

Urgent Medical Device Recall Notice **Certain KARL STORZ Flexible Endoscopes for Urological Use**

For Attention of: Representatives for medical product safety, users, operators, importers, distributors

Commercial name(s):

See Appendix

Device Model/Catalogue/part numbers :

See Appendix

Affected serial numbers:

All serial numbers of devices listed

FSN Type:

New FSN, Ref.: 22-0002

Sterilize Karl Storz Urological Endoscopes

https://www.karlstorz.com/cps/rde/xbcr/karlstorz_assets/ASSETS/3680244.pdf



APPENDIX **Affected Endoscopes and Reprocessing Methods**

X = Method Not Acceptable and ✓ = Method Acceptable

Scope Base Part Number	Scope Kit Number	Product Description	Current IFU	Affected Reprocessing Methods	
				All High-Level Disinfection	Liquid Chemical Sterilization (STERIS System 1E)
11272C1	N/A	Flexible Cysto-Urethroscope Fiberscope	Z18449US-BD (08-2018)	X	X
11272C2	11272CK2	Flexible Cystoscope	Z18449US-BD (08-2018)	X	X
11272CU1	11272CUK1	Flexible Cystoscope	Z18449US-BD (08-2018)	X	X
11272V	N/A	Flexible CMOS Video Cysto Urethroscope	Z18446US-BE (01/2020)	X	X
11272VA	11272VAK	Flexible CMOS Video Cysto Urethroscope	Z18446US-BE (01/2020)	X	X
11272VH-TL	11272VHK-TL	HD-VIEW Flexible HD Cysto-Urethroscope	Z23875US-BC (10-2021)	X	X
11272VHU-TL	11272VHUK-TL	HD-VIEW Flexible HD Cysto-Urethroscope	Z23875US-BC (10-2021)	X	X
11272VN	11272VNK	Flexible Video Urethro Cystoscope	Z18442US-BD (08/2018)	X	X
11272VNU	11272VNUK	Flexible Video Urethro Cystoscope	Z18442US-BD (08/2018)	X	X
11272VU	11272VUK	Flexible CMOS Video Cysto Urethroscope	Z18446US-BE (01/2020)	X	X
11272VUA	11272VUAK	Flexible CMOS Video Cysto Urethroscope	Z18446US-BE (01/2020)	X	X
11272VUE	11272VUEK	Flexible Video Cysto-Urethroscope	96136031USCA V1.1 (04/2021)	X	X

Did supplemental measures work?

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

Supplemental Measures for Endoscope Reprocessing

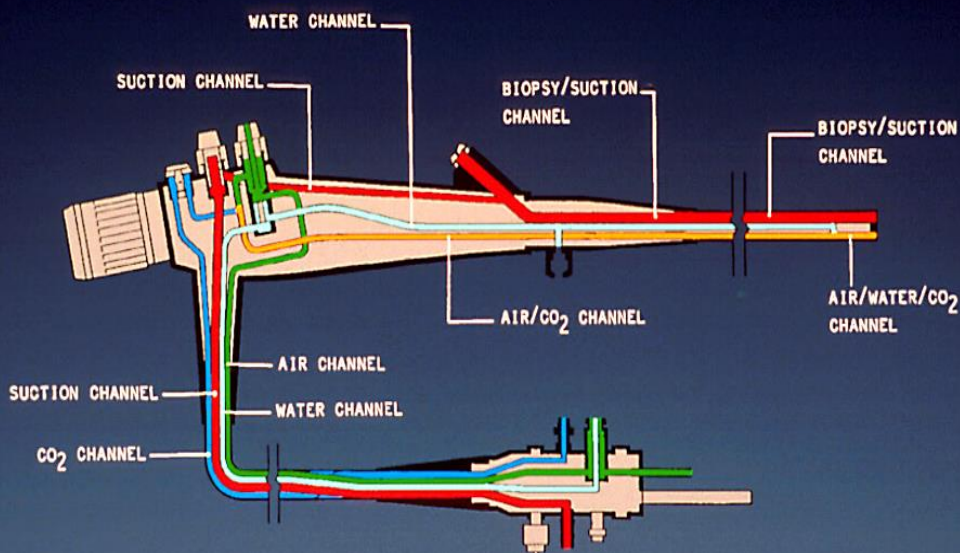
Day et al. Gastro Endosc 2021;93:11-35; Gromski et al. Gastro Endosc 2021;93:927; Synder et al. Gastroenterology 2017;153:1018; Bartles et al Gastro Endos 2018;88:306

- In a nonoutbreak setting, repeat HLD has no significant benefit compared with single HLD in reducing bacterial contamination rates for duodenoscopes (16.1% v 9.2%)
- 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

Endoscope Reprocessing

Microbial Load/Complex Instruments

ENDOSCOPE CHANNELS



New Guidelines

- Multi-society guideline-2021
- AAMI, ST91-2021
- SGNA-2021
- AORN-2016
- **Must educate/comply but confident will not prevent all infections and patient exposures due to microbial load and instrument complexity**

Efficacy of Microbiologic Surveillance in Detecting Bacterial Contamination in Processed Endoscopes

Day et al. Gastro Endosc 2021;93:11-35; Olafsdottir et al. AJIC 2018;46:697-705

- Microbiologic testing not advised per US standards
- Surveillance as a QA measure advised by some international organizations
- ATP proposed as alternative but not widely applied
- ATP testing does not correlate well with microbiological cultures after HLD of duodenoscopes and should not be recommended as a surrogate for terminal cultures
- ATP testing might have a role as a quality assurance test after the manual cleaning stage and for training endoscope reprocessing staff

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



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.

Human Papillomavirus

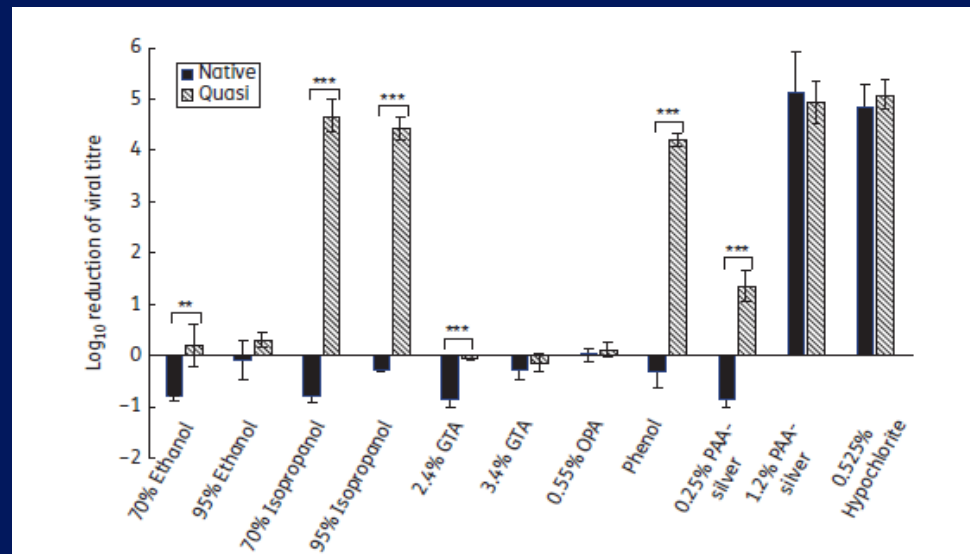
- Human Papillomavirus (HPV)
 - HPV is transmitted through sexual contact
 - Medical devices can become contaminated
 - If adequate disinfection of devices does not occur, the next patient may be at risk for HPV infection
 - **Based on one publication, there are currently no FDA-cleared HLDs that are effective against HPV**

ENDOSCOPE REPROCESSING: CHALLENGES

Susceptibility of Human Papillomavirus

J Meyers et al. J Antimicrob Chemother, Epub Feb 2014

- Most common STD
- In one study, FDA-cleared HLD (OPA, glut), no effect on HPV
- Finding inconsistent with other small, non-enveloped viruses such as polio and parvovirus
- Further investigation needed: test methods unclear; glycine; organic matter; comparison virus
- Conversation with CDC: **validate and use HLD consistent with FDA-cleared instructions (no alterations)**



Human Papillomavirus

- Two recently published studies identified methodological artifacts (did not use refined virus) and question the validity of the original results.
 - Ozbun et al. EBioMedicine 2021;63:103165. Showed OPA treatment inactivated refined HPV 31 raft virus, xenograft-derived HPV 11, recombinant quasivirus HPV 11, HPV 16 and HPV 31
 - Egawa et al. EBioMedicine 2021; 63:103177. Showed that refined raft-derived HPV18 and HPV pseudovirus and mouse papilloma virus were inactivated
- Based of findings by Ozbun and Egawa, we believe that aldehydes are effective against HPV

HLD Inactivate Papillomavirus

Egawa et al. EBioMedicine 2021;63

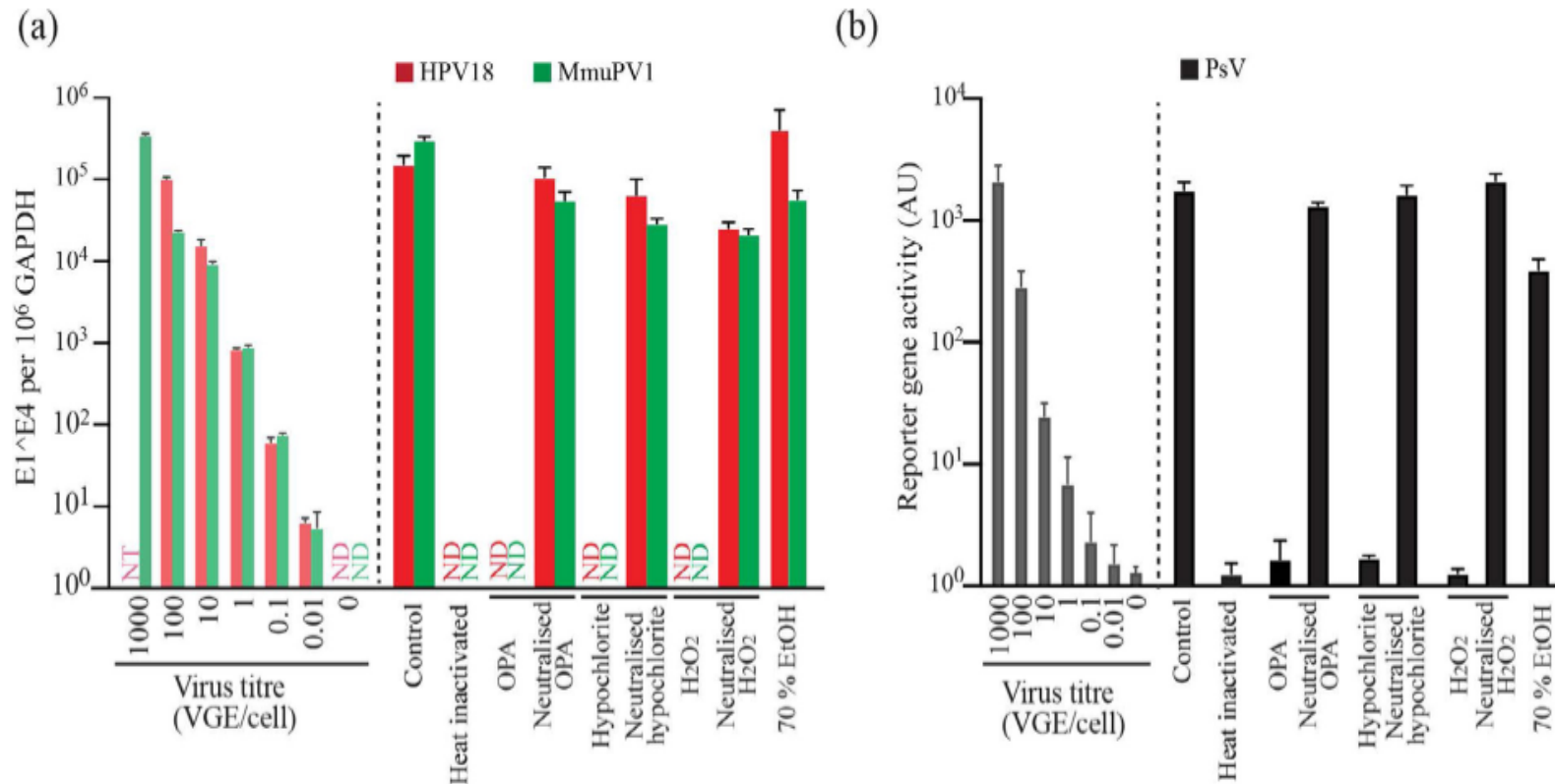


Fig. 5. Evaluation of disinfectant efficacy using in vitro infection assay

(a, b) Measurement of viral infectivity (E1^E4 viral gene transcripts or reporter gene activity shown as Mean and SD) of HPV18, MmuPV1 and PsV in HaCaT cells following incubation with viruses treated with disinfectants or their neutralised equivalent (except 70% ethanol). AU, arbitrary unit; ND, not detected. Data were obtained with biological triplicates and shown as Mean and SD.

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°C)

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

1. Confirm disinfection or sterilization reprocessing failure
2. Impound any improperly disinfected/sterilized items
3. Do not use the questionable disinfection/sterilization unit (e.g., sterilizer, automated endoscope reprocessor) until proper functioning can be assured
4. Inform key stakeholders
5. Conduct a complete and thorough evaluation of the cause of the disinfection/sterilization failure
6. Prepare a line listing of potentially exposed patients
7. Assess whether disinfection/sterilization failure increases patient risk for infection
8. Inform expanded list of stakeholders of the reprocessing issue
9. Develop a hypothesis for the disinfection/sterilization failure and initiate corrective action
10. Develop a method to assess potential adverse patient events
11. Consider notification of state and federal authorities
12. Consider patient notification
13. Develop long-term follow-up plan
14. Perform after-action report

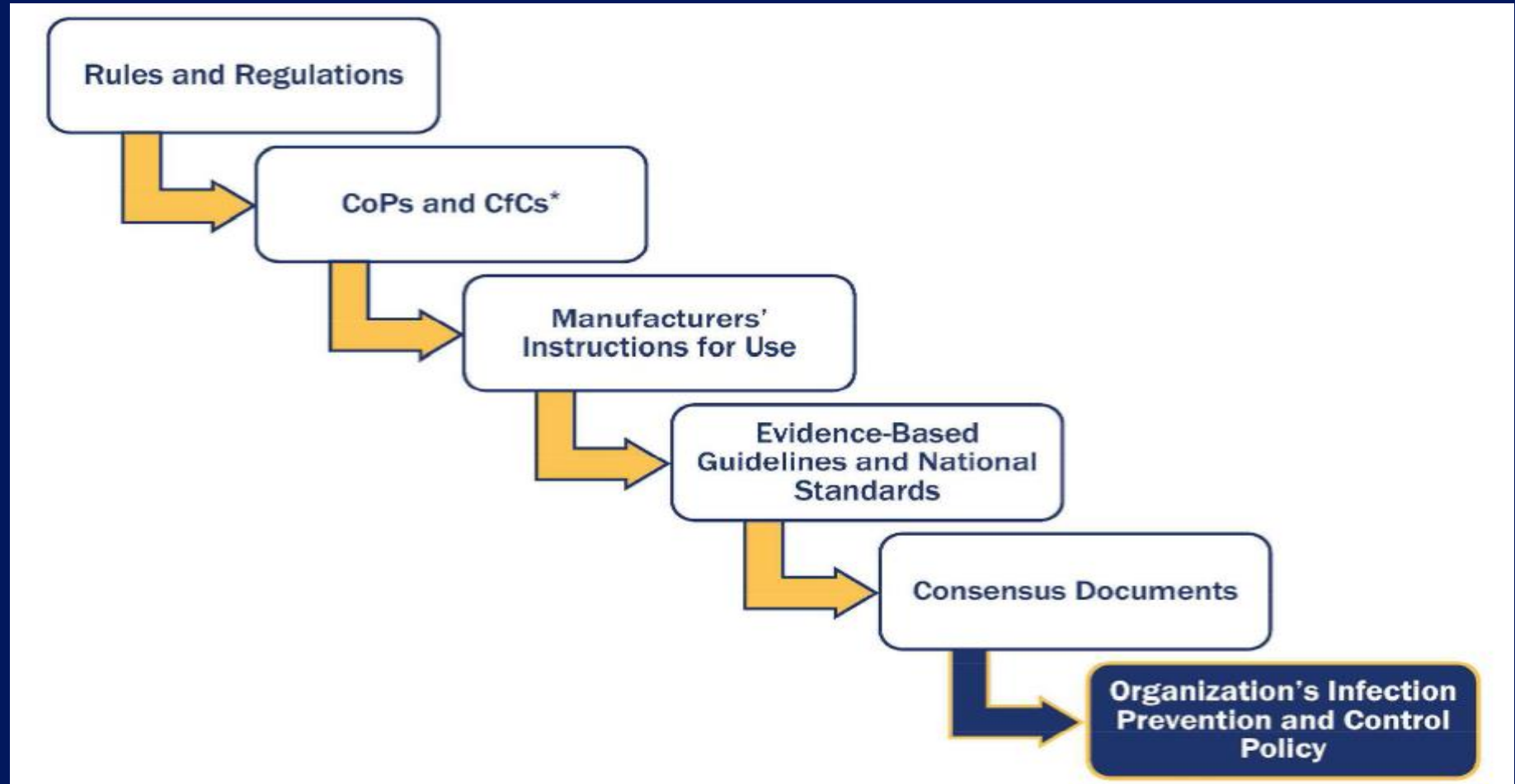
FIGURE 1. Protocol for exposure investigation after a failure of disinfection and sterilization procedures

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

Hierarchy of Various References that Organization Needs to Include in Policies

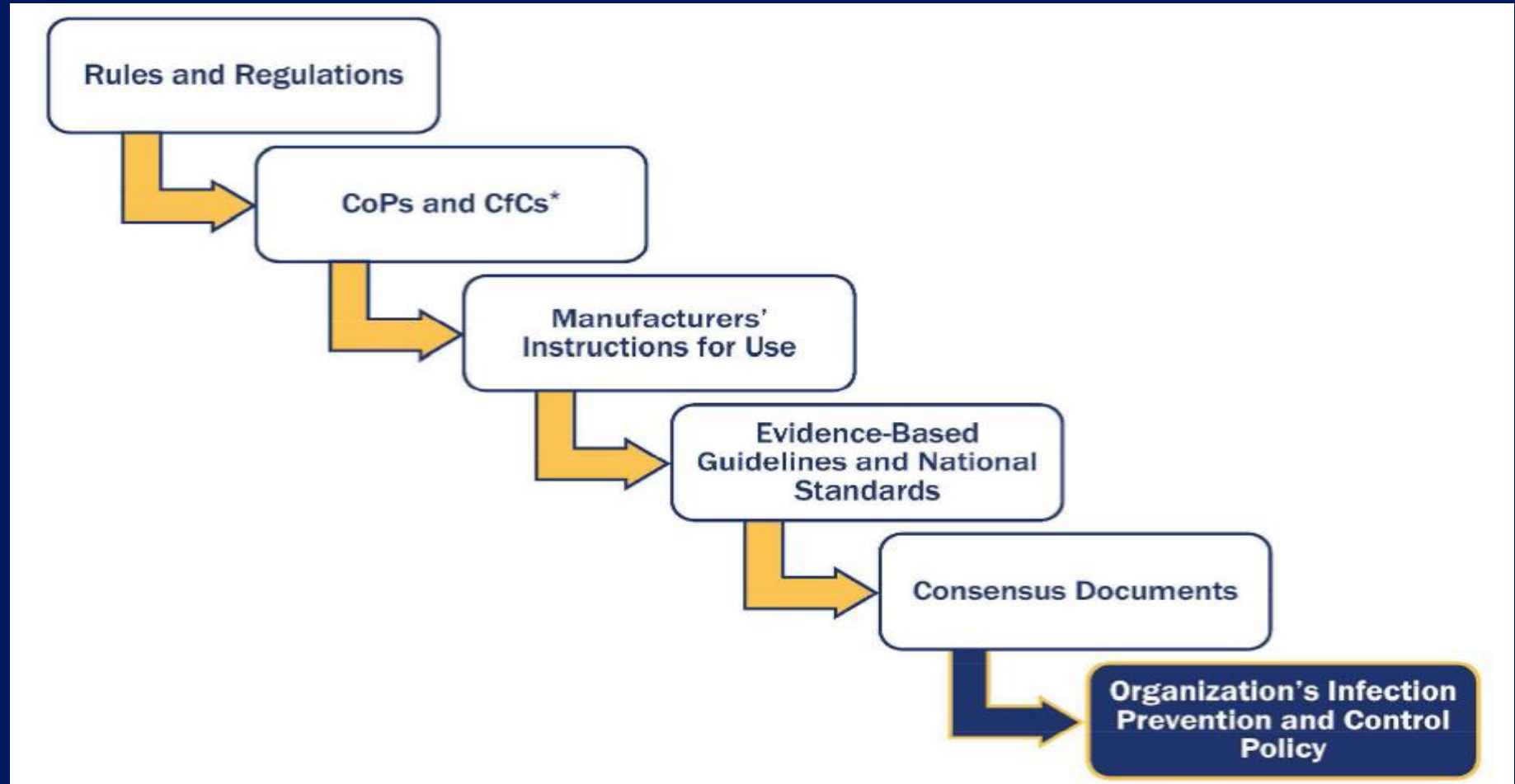


Clarifying Infection Control Policy Requirements-The Joint Commission

<https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/infection-prevention-and-hai/ic-hierarchical-approach-to-scoring-standards-april-2019-perspectives.pdf>

- JC standards and elements of performance written to allow each HCF determine methods and best practices
- TJC finding many HCF build policies on evidence-based guidelines alone
- TJC recommends HCF apply a hierarchical method to address the IC requirements
- The following graphic illustrates the hierarchy of various references organizations should use as they draft and/or revise their IC-related policies

Hierarchy of Various References that Organization Needs to Include in Policies



Clarifying IC Policy Requirements

(must comply with first three groups in illustration to comply with JC)

- Rules and regulations (e.g., BBP)
- CoPs and CfCs-CMS conditions of participation or conditions of coverage.
- Manufacturers Instructions for Use-deviation may result on biological, chemical or functional incompatibility
- Evidence-based guidelines (EBG) and National Standards. Organizations may choose to follow a variety of EBG
- Consensus Documents.

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 and must transition to other modalities (e.g., sterilization, disposable scopes/components). Until then, reprocessing guidelines must be followed to prevent exposure to pathogens that may lead to infection.

THANK YOU!
www.disinfectionandsterilization.org

