Endoscope Reprocessing: Current Issues and Future Perspectives

William A. Rutala, Ph.D., M.P.H., C.I.C.

Director, Statewide Program for Infection Control and Epidemiology (SPICE) and Professor of Medicine, University of North Carolina at Chapel Hill, NC, USA

Former Director, Hospital Epidemiology, Occupational Health and Safety, UNC Hospitals, Chapel Hill, NC (1979-2017)

DISCLOSURES

2020-2021

- **Consultations**
  - PDI
- **Honoraria**
  - ASP, PDI

Our Responsibility to the Future

Prevent All Infectious Disease Transmission by Medical Devices in 5 years

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**.

Sterilization
Enormous Margin of Safety!

100 quadrillion (10^{17}) margin of safety

Sterilization kills 1 trillion spores, washer/disinfector removes or inactivates 10-100 million; ~100 microbes on surgical instruments

Infections/Outbreaks Associated with Semicritical Medical Devices

Rutala, Weber, AJIC 2019;47:A79-A89

Medical Device	No. Outbreaks/Infections	No. Outbreaks/Infections with Bloodborne Pathogens
Vaginal Probes	0	0
Ear-Nose-Throat Endoscopes	0	0
Urologic instruments (e.g. cystoscopes)	8	0
Hysteroscopes	0	0
Laryngoscopes	2	0
Transrectal ultrasound guided prostate	1	0
Applanation tonometers	2	0
TEE-Transesophageal echocardiogram	5	0
GI Endoscopes/Bronchoscopes	~130	3 (HBV-1 GI; HCV-2 GI; HIV-0)

Why does HLD fail to provide patient safety?

Reason for Endoscope-Related Outbreaks

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

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

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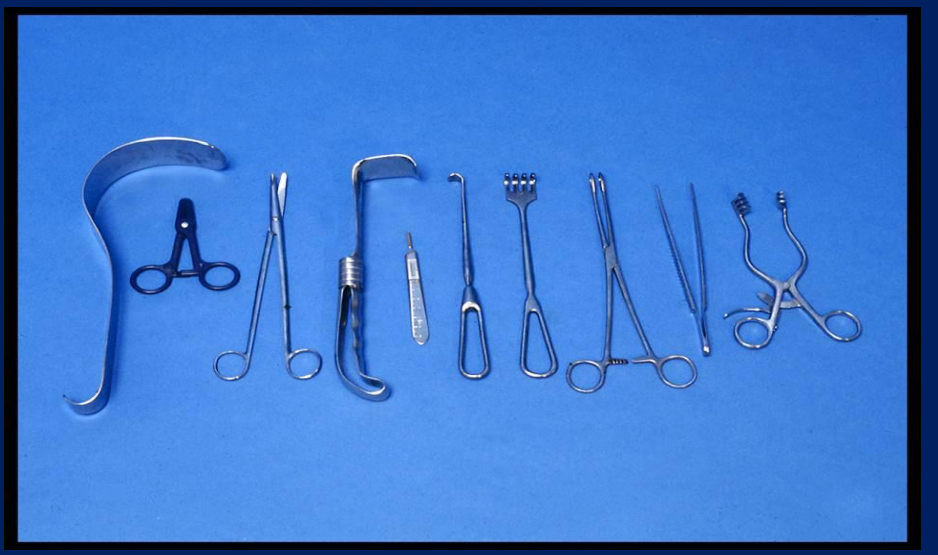
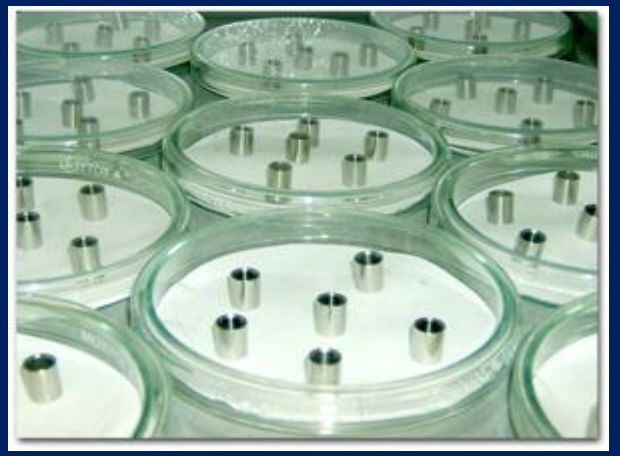
ENDOSCOPE REPROCESSING: CHALLENGES

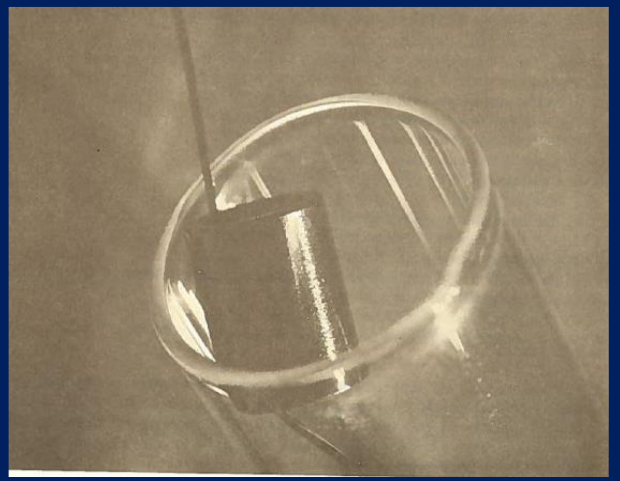
Complex [elevator channel]-10^{7-10} bacteria/endoscope

Surgical instruments-<10^{2} bacteria



High-Level Disinfectants Are Effective (no exposure to HLD, no inactivation)





- Registration test for high-level disinfectants against healthcare pathogens, HLD (OPA, PA, etc.) effective
  - Carriers are etc. inoculated with the test organism (*S. aureus, S. choleraesuis, P. aeruginosa*) and then dried. After drying, the carrier is transferred to a disinfectant tube and immersed in the disinfectant for the contact time (e.g., 12 minutes).
  - *Mycobacterium*, CRE, viruses (SARS-CoV-2), MDRO, *Candida* auris

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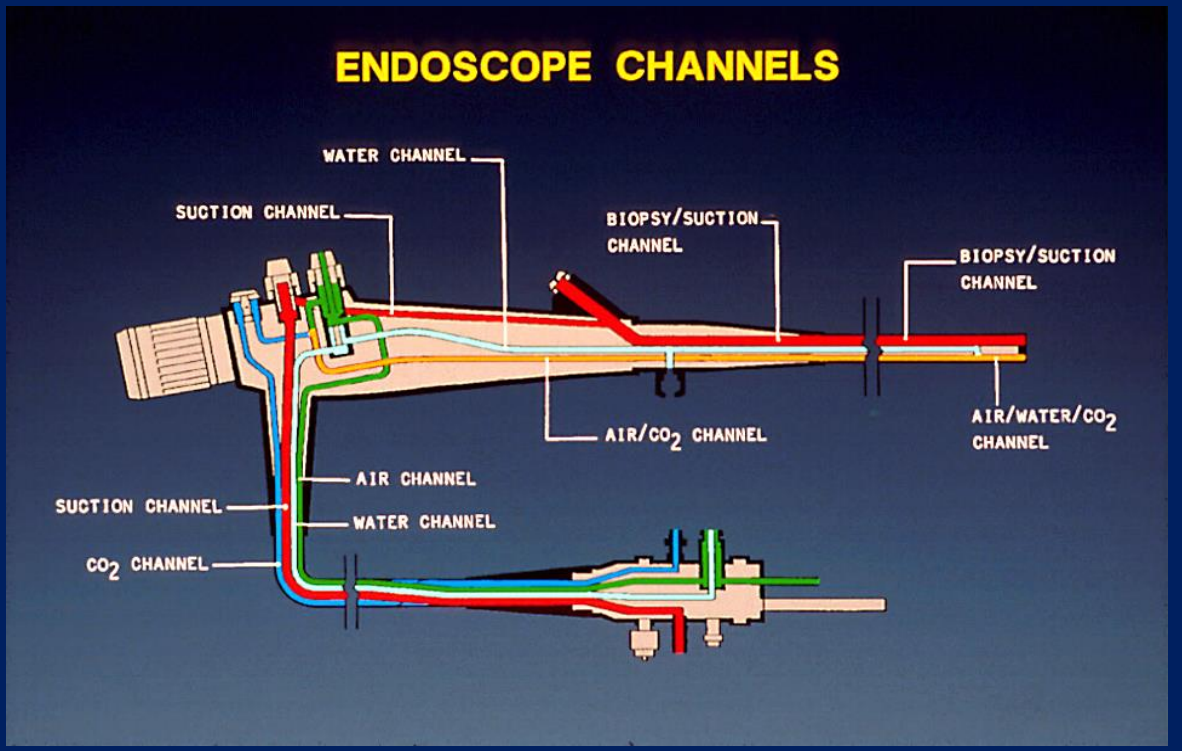
FEATURES OF ENDOSCOPES THAT PREDISPOSE TO DISINFECTION FAILURES

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



GI ENDOSCOPE REPROCESSING: CHALLENGES

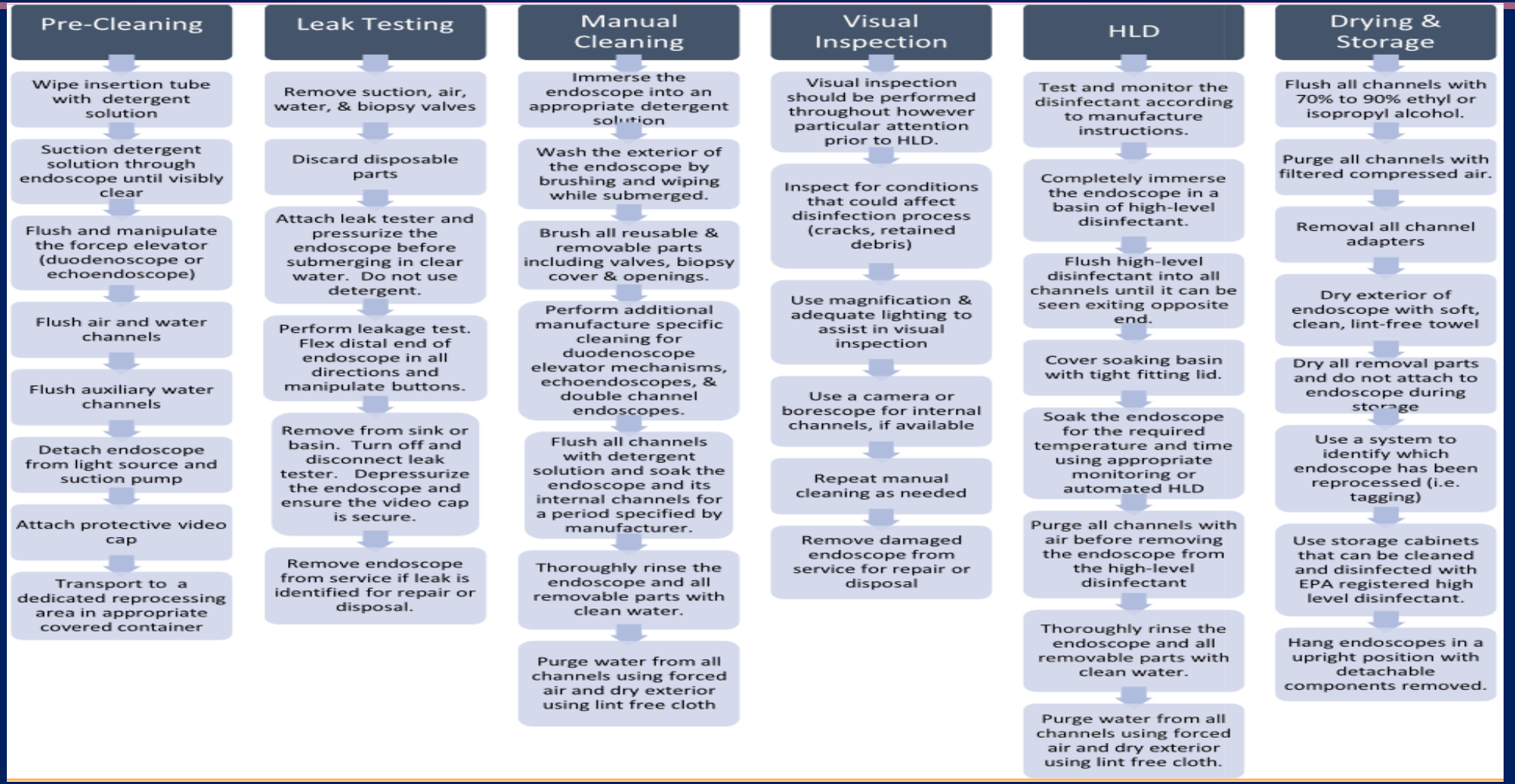
NDM-Producing *E. coli* Associated ERCP

MMWR 2014;62:1051; Epstein et al. JAMA 2014;312:1447-1455

NDM-producing E.coli recovered from elevator channel (elevator channel orients catheters, guide wires and accessories into the endoscope visual field; crevices difficult to access with cleaning brush and may impede effective reprocessing). Very high microbial load $10^{7\text{-}10}$.

Complexity of Endoscope Reprocessing

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



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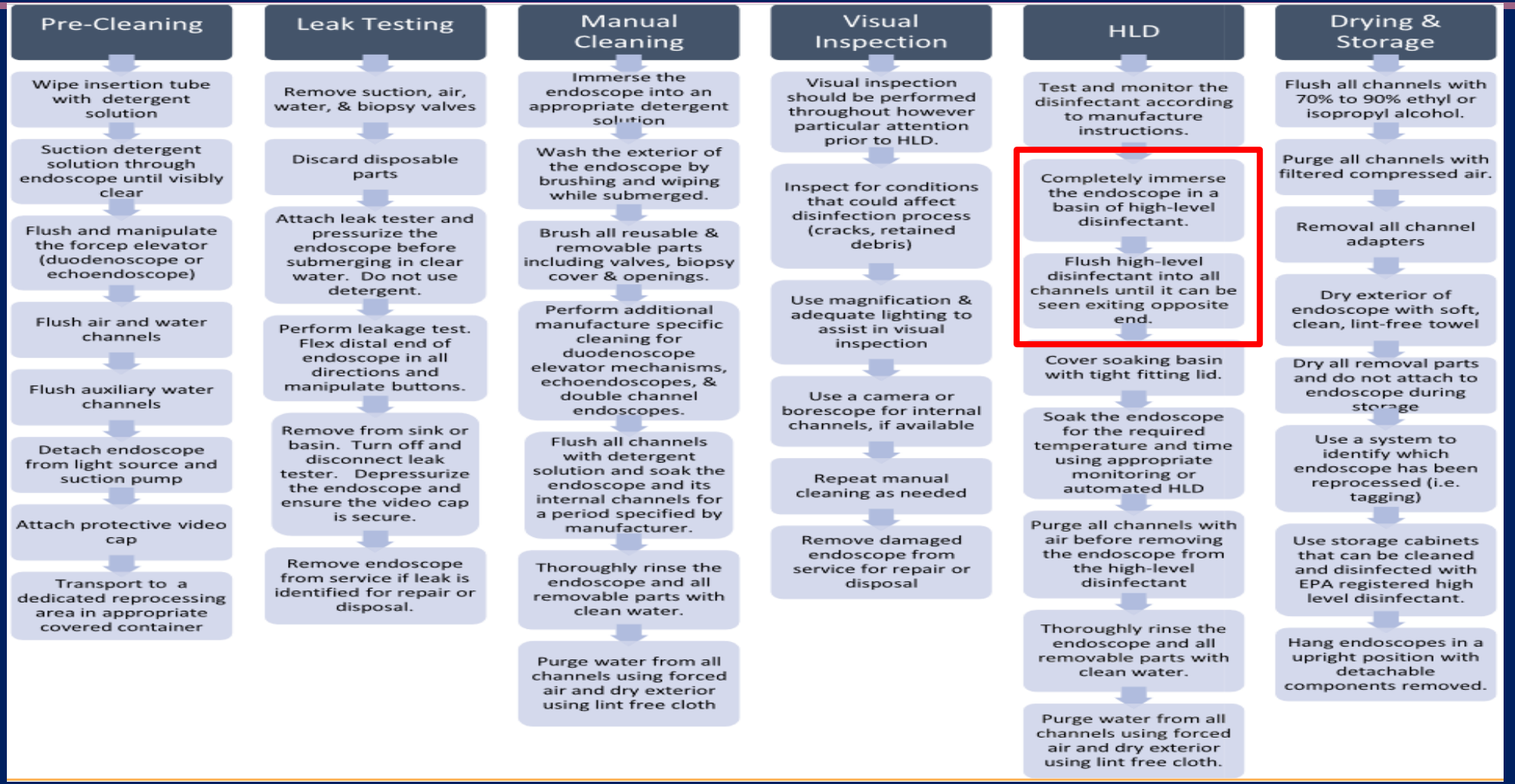
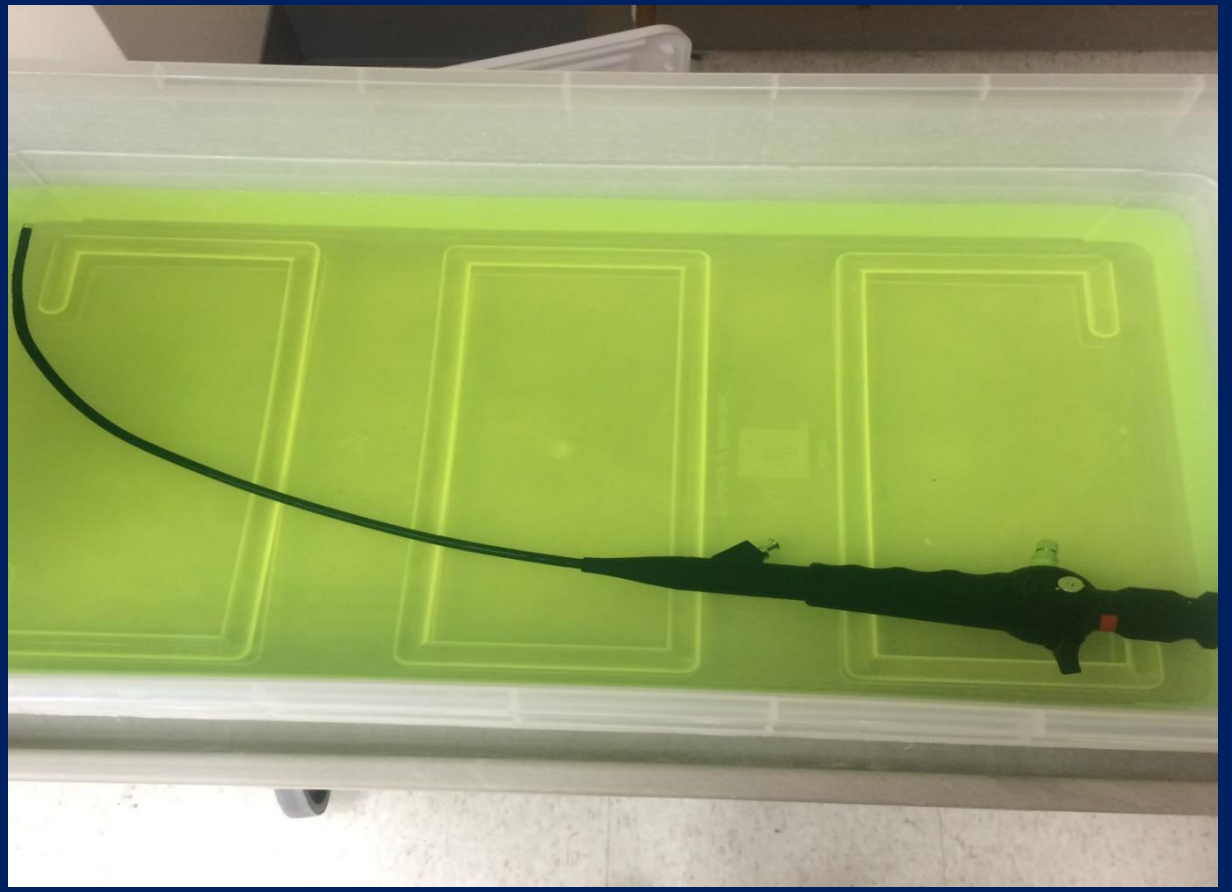


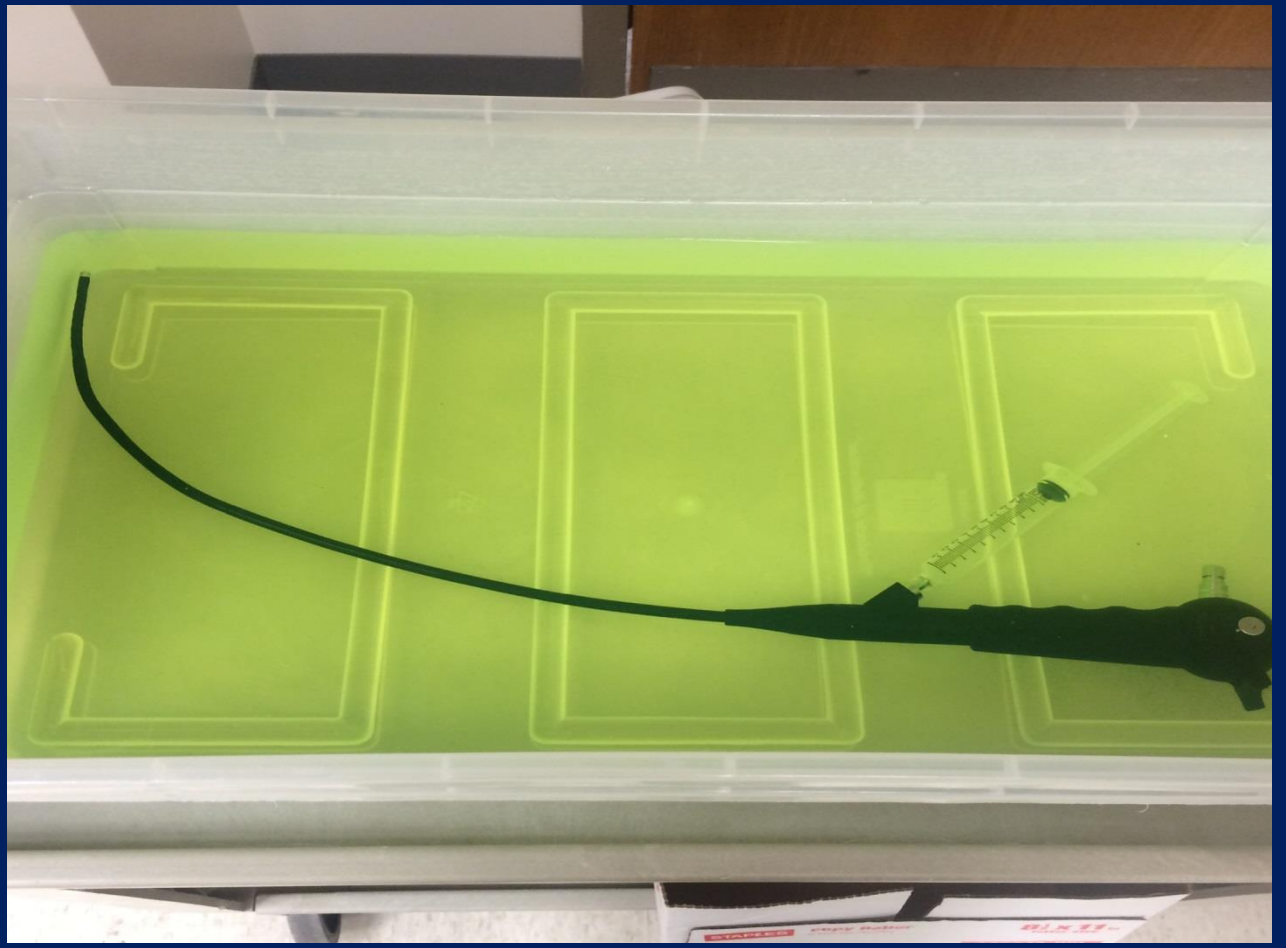
Reprocessing Channeled Endoscopes Manually

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 Manually

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

Reason for Endoscope-Related Outbreaks

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

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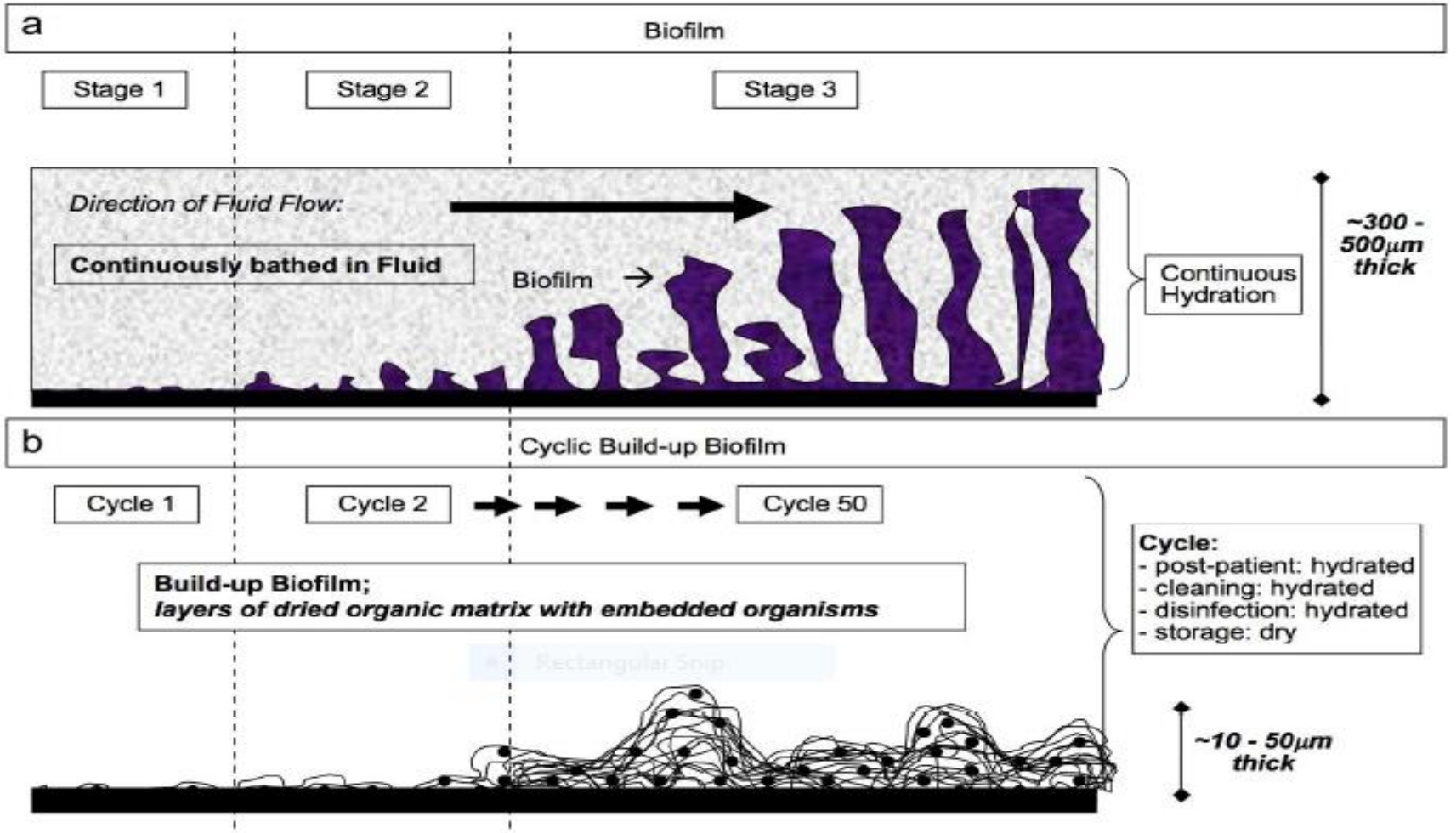
Biofilms on Instruments and Environmental Surfaces

Alfa, AJIC 2019;47:A39

- Three types of biofilm
  - Traditional hydrated biofilm (water content 90%)
  - Build-up biofilm—could occur in endoscope channels; layers of dried organic matrix and embedded organisms
  - 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

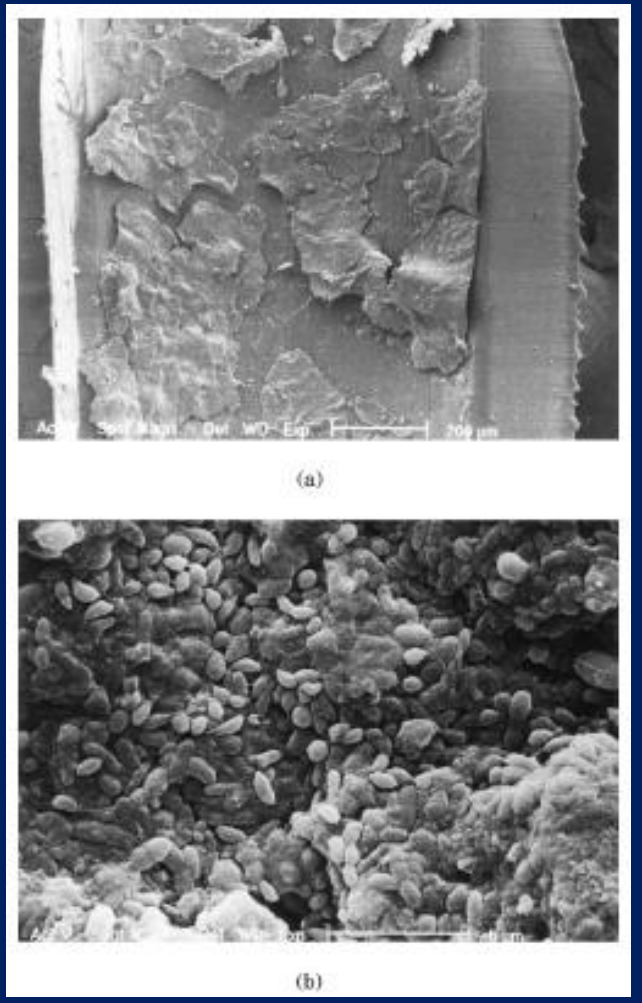


[Get permission from; Zhong W, **Alfa M**, Howie R, Zelenitksy S. Simulation of cyclic reprocessing buildup on reused medical devices. Comput Biol Med 2009 Jun; 39(6): 568-577.

Build-Up Biofilm

(no evidence of biofilm development when MIFU/guidelines followed; organisms in organic matrix)

Pajkos et al. J Hosp Infect 2004;58:224



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)

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

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})

What Should We Do Now?

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 to Reduce Infection Risk

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Randomized Trial of Single versus Double HLD of Duodenoscopes

Bartles et al Gastro Endos 2018;88:306

Double HLD demonstrated no benefit over single HLD; no significant differences observed

TABLE 2. Summary of culture positivity rates in the 2 study arms

	Double HLD	Single HLD	*P* value*
	All cultures		
Specimen-based			
No. of specimens	3052	2798	
Any growth	127 (4.2)	108 (3.9)	.60 (.64)
Growth of high-concern pathogens	3 (.1)	5 (.2)	.49 (.43)
Encounter-based			
No. of encounters	1526	1399	
Any growth	122 (8.0)	102 (7.3)	.52 (.54)
Growth of high-concern pathogens	3 (.2)	5 (.4)	.49 (.43)

Randomized Trial of Single versus Double HLD of Duodenoscopes

Bartles et al Gastro Endos 2018;88:306

All 8 high-concern pathogen cultures were recovered from elevator mechanism samples

TABLE 1. Details of 8 cultures positive for high-concern pathogens, cultured from 5 different duodenoscopes and linear echoendoscopes

Facility	Culture date	Duodenoscope and linear echoendoscope identification	High-level disinfection method	High-concern pathogen(s) detected
A	2/26/2016	1	Single	*Enterococcus* spp
A	4/8/2016	2	Double	*Enterococcus* spp
A	4/29/2016	2	Single	*Enterobacter cloacae*
A	5/6/2016	3	Double	*Aeromonas* spp
A	8/8/2016	4	Double	*Escherichia coli* (ESBL+), *Enterococcus* spp
B	7/15/2016	5	Single	*E coli* (ESBL−) and *Enterococcus faecalis*
B	7/29/2016	5	Single	*E coli* (ESBL+) and *Enterococcus faecalis*
B	8/1/2016	5	Single	*Enterococcus faecium*

ESBL+, extended spectrum β-lactamase; +, positive; −, negative.

Comparison of High-Level Disinfection and Sterilization Procedures

Synder et al. Gastroenterology 2017;153:1018

Table 1. Frequency of the Primary Outcome (≥1 Multidrug-resistant Organism), or Secondary Outcomes of any Growth > 0 CFU and Growth of ≥10 CFU on any Duodenoscope Culture

		Growth, Elevator Mechanism or Working Channel (%)		
Trial Arm	(N)	≥1 MDRO	>0 CFU[a]	≥10 CFU[b]
sHLD	174	0	28 (16.1)	4 (2.3)
dHLD	169	0	27 (16.0)	7 (4.1)
HLD/ETO	173	0	39 (22.5)	9 (4.2)
Total	516	0	94 (18.3)	20 (3.9)

[a] $P = .21$.
[b] $P = .36$ by Fisher's exact test.

- Found no significant differences between groups (sHLP, dHLD and HLD/ETO)
- Enhanced disinfection methods did not provide additional protection against contamination
- However
  - Sterilizer used not FDA cleared with SAL10^{-6} for duodenoscopes
  - AER was not indicated for reprocessing duodenoscopes
  - Storage in non-ventilated cabinet per AORN, AAMI/ANSI ST91; SGNA

Multisociety Guideline on Reprocessing Flexible GI Endoscopes

Day et al. Gastro Endosc 2021;93:11-35

Communication from the ASGE Quality Assurance In Endoscopy Committee

MULTISOCIETY TASK FORCE ARTICLE

ASGE American Society for Gastrointestinal Endoscopy

AASLD American Association for the Study of Liver Diseases

ACG American College of Gastroenterology

aga American Gastroenterological Association

AORN Safe Surgery Together

APIC Association for Professionals in Infection Control and Epidemiology

ASCA Ambulatory Surgery Center Association

ASCRS American Society of Colon & Rectal Surgeons

SGNA Society of Gastroenterology Nurses and Associates, Inc.

SHEA The Society for Healthcare Epidemiology of America

Multisociety guideline on reprocessing flexible GI endoscopes and accessories

Check for updates

Lukejohn W. Day, MD,[1] V. Raman Muthusamy, MD, MAS,[2] James Collins, BS, RN, CNOR,[3] Vladimir M. Kushnir, MD,[4] Mandeep S. Sawhney, MD, MS,[5] Nirav C. Thosani, MD,[6] Sachin Wani, MD[7]

Multisociety Guideline on Reprocessing Flexible GI Endoscopes

Day et al. Gastro Endosc 2021;93:11-35

- In a nonoutbreak setting, repeat HLD has no additional benefit compared with single HLD in reducing bacterial contamination rates for duodenoscopes

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

Double HLD versus Liquid Chemical Sterilization for Reprocessing Duodenoscopes

Gromski et al. Gastro Endosc 2021;93:927

No significant difference of positive cultures when comparing double HLD (8) with duodenoscopes undergoing liquid chemical sterilant (9). Most isolates low-concern organisms.

TABLE 2. Organisms detected in positive cultures from all duodenoscope reprocessing surveillance cultures

Organism	Double high-level disinfection (8 positive cultures)*	Liquid chemical sterilization (9 positive cultures)†
Coagulase-negative *Staphylococcus* spp.	5	5
Micrococcus spp.		2
Bacillus spp.	2	3
Streptococcus viridans		1
***Enterococcus* spp.**		1
Klebsiella pneumoniae	1	
Enterobacter cloacae	1	

Organisms in bold type are considered high-concern organisms.

*One culture in the double high-level disinfection group had more than 1 organism grow in a positive culture.

†Three cultures in the liquid chemical sterilization group had more than 1 organism grow in a positive culture.

ETO Sterilization for Endoscope Reprocessing

Day et al. Gastro Endosc 2021;93:11-35

- In nonoutbreak setting, limited data suggest that ETO sterilization does not reduce bacterial contamination rates in duodenoscopes compared with single HLD
- 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 including cost, only 20% hospital use ETO (availability), possible damage to scopes, exposure of staff to ETO, exposure/turnaround time

Prevent All Infectious Disease Transmission by Medical Devices in 5 years

Disinfection and Sterilization

Rutala, Weber. AJIC 2016;44:e1-e6; Rutala, Weber ICHE 2015;36:643; Rutala et al. AJIC 2019:47:A62

EH Spaulding believed that how an object will be disinfected depended on the object's intended use (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/Novel 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

- Antimicrobial detergents-reduce microbial contamination
- Automated Endoscope Reprocessing-HLD should be provided in an approved AER (manual-1.4% compliance vs 75.4% using AER)
- Endoscope sterilization-materials compatibility, throughput
- Disposable endoscopes (device innovations)
  - Partially-does it decrease bacterial contamination after HLD
  - Fully-GI and bronchoscopes; cost, scope performance
- Use of non-endoscopic methods to diagnose or treat disease
- Assessment tool that is predictive of microbial contamination or infection risks

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

Robert A. Weinstein, MD

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Terminal Sterilization of Duodenoscopes using HP-Ozone Sterilizer

Molly-Sinard et al. Am J Infect Control 2019;47:243

- Simulated-use and clinical in-use studies demonstrated the efficacy of a HP-ozone sterilizer for terminal sterilization of duodenoscopes
- FDA-cleared for multi-channel flexible endoscopes of up to 3.5 meters

Terminal Sterilization of Duodenoscopes using HP Gas Plasma Sterilizer

Omidbakhsh et al. J Hosp Infection 2021;110:133-138

- Endoscope (colonoscopes, duodenoscopes) sterilization cycle was developed
- Testing demonstrated the vaporized HP can sterilize flexible GI scopes with a SAL 10^{-6}
- Not FDA cleared; materials compatibility issues may require changes (e.g., lubricant)

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Characteristics of Disposable Duodenoscopes

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

Table 2. Characteristics of disposable duodenoscopes.

	EvisExera III TJF-Q190V (Olympus)	ED34-i10T (Pentax)	ED34-i10T2 (Pentax)	ED-580XT (Fujifilm)	EXALT Model D (Boston Scientific)	aScopeDuodeno (Ambu)
Disposable component	Endcap	Endcap	Endcap	Endcap	Entire endoscope	Entire endoscope
Field of view (degrees)	100	100	100	100	108	130
Depth of view (mm)	5-60	4-60	4-60	4-60	5-60	Not available
Working length (mm)	1240	1250	1250	1250	1240	1240
Instrument channel (mm)	4.2	4.2	4.2	4.2	4.2	4.2
Insertion tube diameter (mm)	11.3	11.6	11.6	11.3	11.3	11.3
Distal end diameter (mm)	13.5	13	13	13.1	15.1	13.7
Distal end with endcap (mm)	13.5	13.8	13.4	14.9	15.1	13.7

Future/Novel 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

- Antimicrobial detergents
- Automated Endoscope Reprocessing-HLD should be provided in an approved AER (manual-1.4% compliance vs 75.4% using AER)
- Endoscope sterilization-materials compatibility, throughput
- Disposable endoscopes (device innovations)
  - Partially-does it decrease bacterial contamination after HLD
  - Fully-GI and bronchoscopes; cost, scope performance
- Use of non-endoscopic methods to diagnose or treat disease
- Assessment tool that is predictive of microbial contamination or infection risks

Implementing these advances will allow us to prevent endoscope-related infections

Thank you!

www.disinfectionandsterilization.org