Endoscope Reprocessing: The Need to Shift from HLD to Sterilization

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DISCLOSURES

2017-2018

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

Our Responsibility to the Future

Prevent All Infectious Disease Transmission by Medical Devices in 5 years

Duodenoscopes and Endoscope Reprocessing :
A Need to Shift from Disinfection to Sterilization

- Sources of healthcare-associated pathogens
- Evaluate the cause of endoscope-related outbreaks
- Review the outbreaks associated with ERCP and endoscopic procedures
- Discuss the alternatives that exist today that might improve the safety margin associated with duodenoscope/endoscope reprocessing
- Describe how to prevent future outbreaks associated with duodenoscopes and other endoscopes

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Semicritical Medical Devices

Rutala et al. AJIC 2016;44:e47





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

Infections/Outbreaks Associated with Semicritical Medical Devices

Rutala, Weber, AJIC, In preparation

Medical Device	No. Outbreaks/Infections	No. Outbreaks/Infections with Bloodborne Pathogens
Vaginal Probes	0	0
Ear-Nose-Throat Endoscopes	0	0
Cystoscopes	5	0
Hysteroscopes	0	0
Laryngoscopes	1	0
Ureteroscopes	1	0
Prostate Probes	3	0
TEE-Transesophageal echocardiogram	3	0
GI Endoscopes/Bronchoscopes	~130	4 (HBV-1 GI; HCV-3 GI; HIV-0)

What are the risks associated with GI endoscopes and bronchoscopes?

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/Colonoscopy	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.

Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fail Patients

Minority Staff Report, January 13, 2016, Patty Murray, Ranking Member

- In January 2015, after several outbreaks of serious infections, Senator Murray initiated an investigation to determine the extent of duodenoscope-linked infections
- Between 2012 and spring 2015, closed-channel duodenoscopes were linked to at least 25 different incidents of antibiotic-resistant infections that sickened at least 250 patients worldwide
- None of the manufacturers of the “closed-channel” duodenoscopes had sufficient data to show that duodenoscopes could be cleaned reliably between uses

RECENT ENDOSCOPY-RELATED OUTBREAKS OF MRDO WITHOUT REPROCESSING BREACHES

Rutala WA et al. Manuscript in preparation

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

Carbapenem-Resistant *Enterobacteriaceae* (CRE) and Multidrug Resistant Organisms (MDRO)

- *Klebsiella*, *Enterobacter* and *E. coli* are examples of *Enteriobacteriaceae*, a normal part of enteric microbes, that have become resistant to carbapenem
- Healthy people usually do not generally get CRE infections
- Infections with CRE and MDROs are very difficult to treat and can be deadly
- Likely that MDR pathogens are acting as a “marker” or ‘indicator” organism for ineffective reprocessing of duodenoscopes

Reason for Endoscope-Related Outbreaks

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

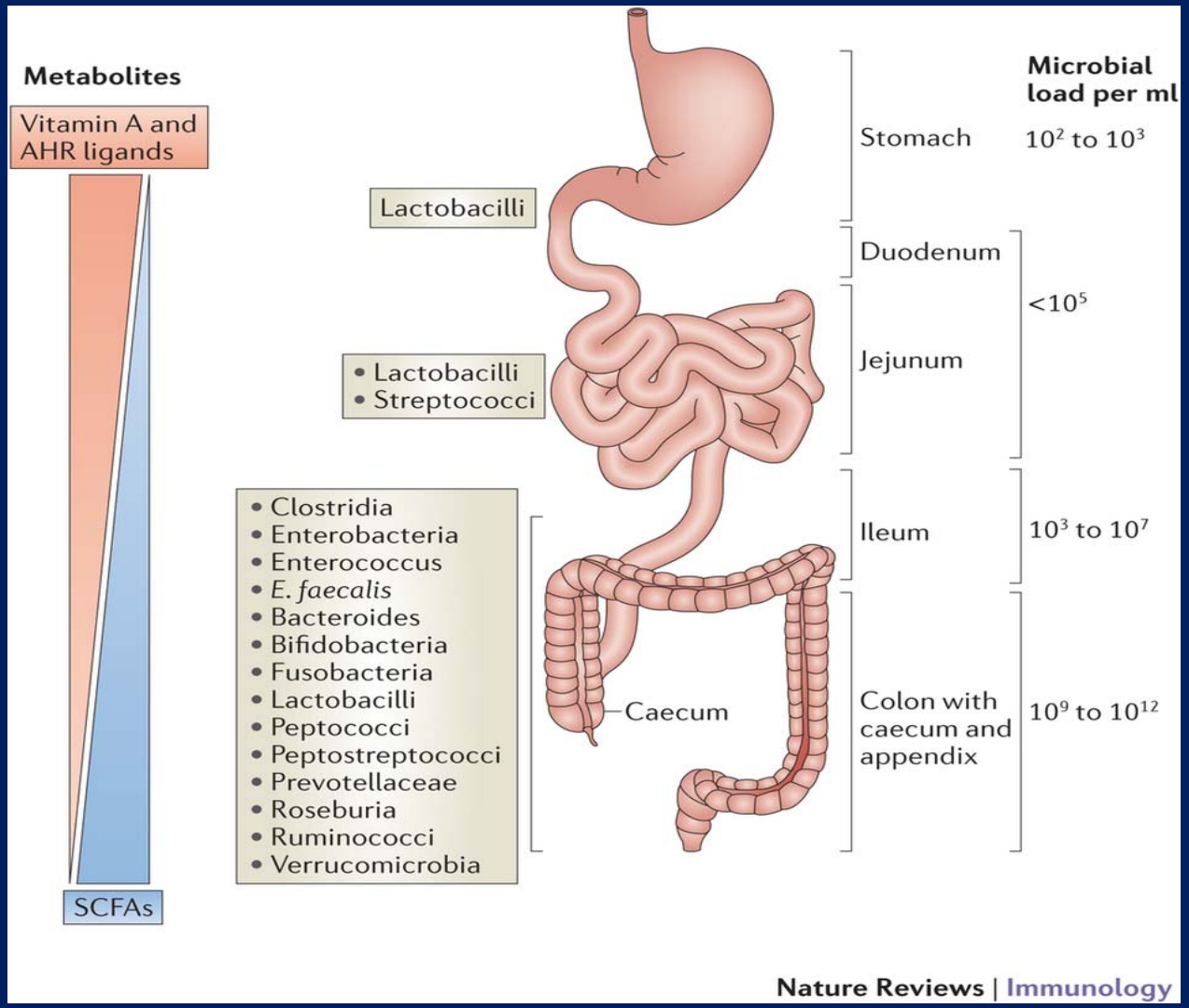
- Margin of safety with endoscope reprocessing minimal or non-existent
- Microbial load
  - GI endoscopes contain 10^{7-10}
  - Cleaning results in 2-6 $\log_{10}$ reduction
  - High-level disinfection results in 4-6 $\log_{10}$ reduction
  - Results in a total 6-12 $\log_{10}$ reduction of microbes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

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^{7-10}.





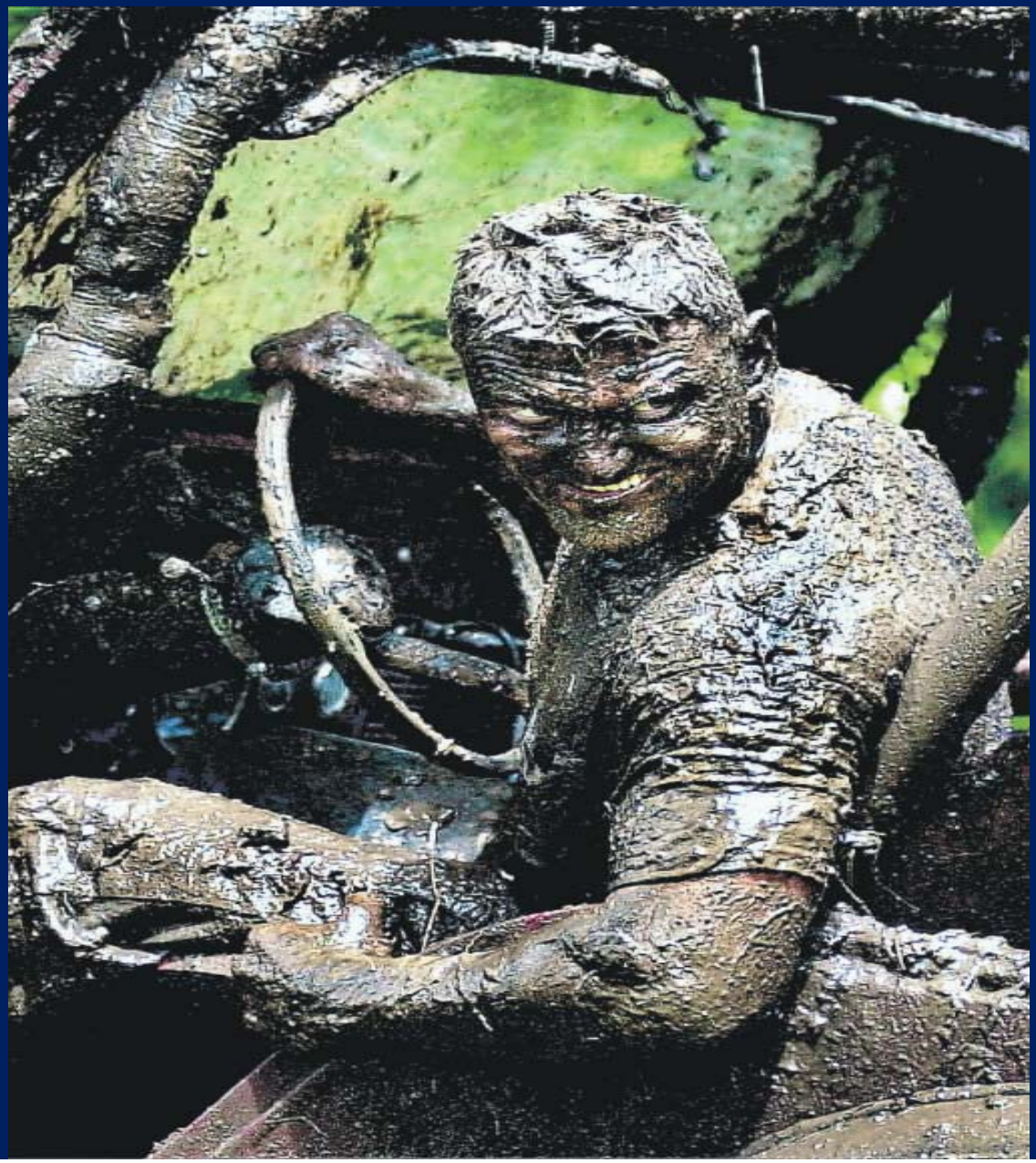
Mowat AM, Agace WW. Nat Rev Immunology 2014;14:667-685

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What does this off-road driver/vehicle have in common with endoscope? 10 billion particles, complex



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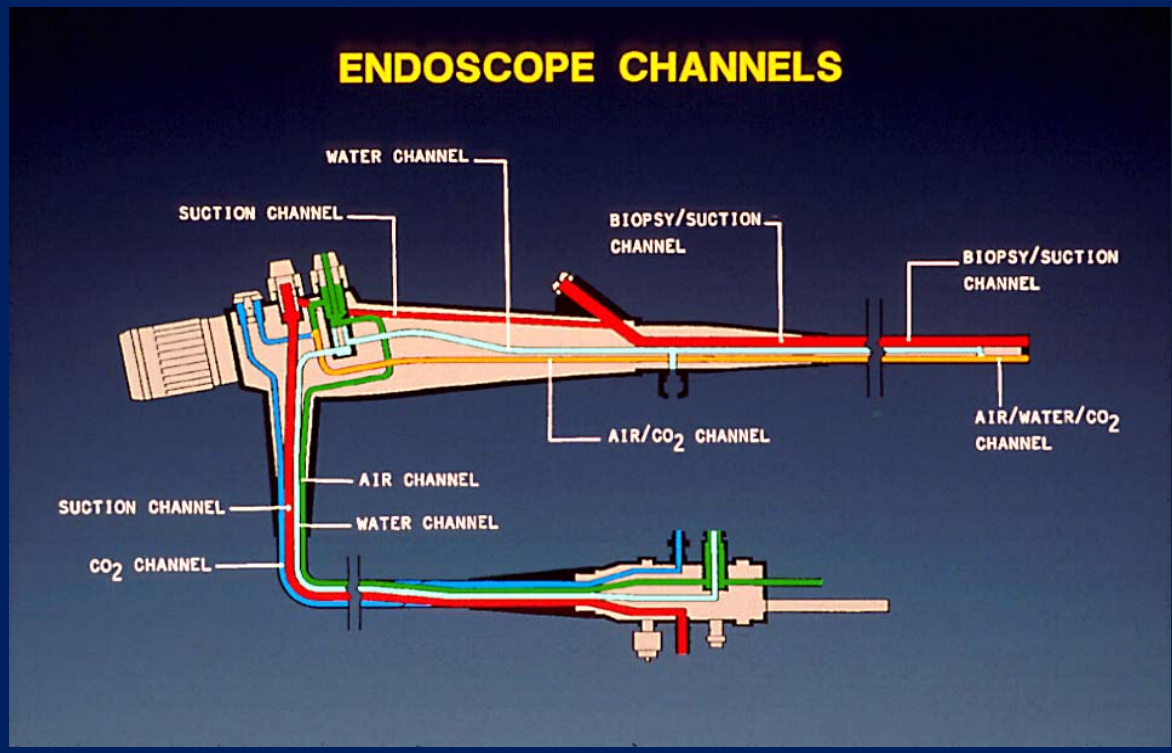
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FEATURES OF ENDOSCOPES THAT PREDISPOSE TO DISINFECTION FAILURES

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

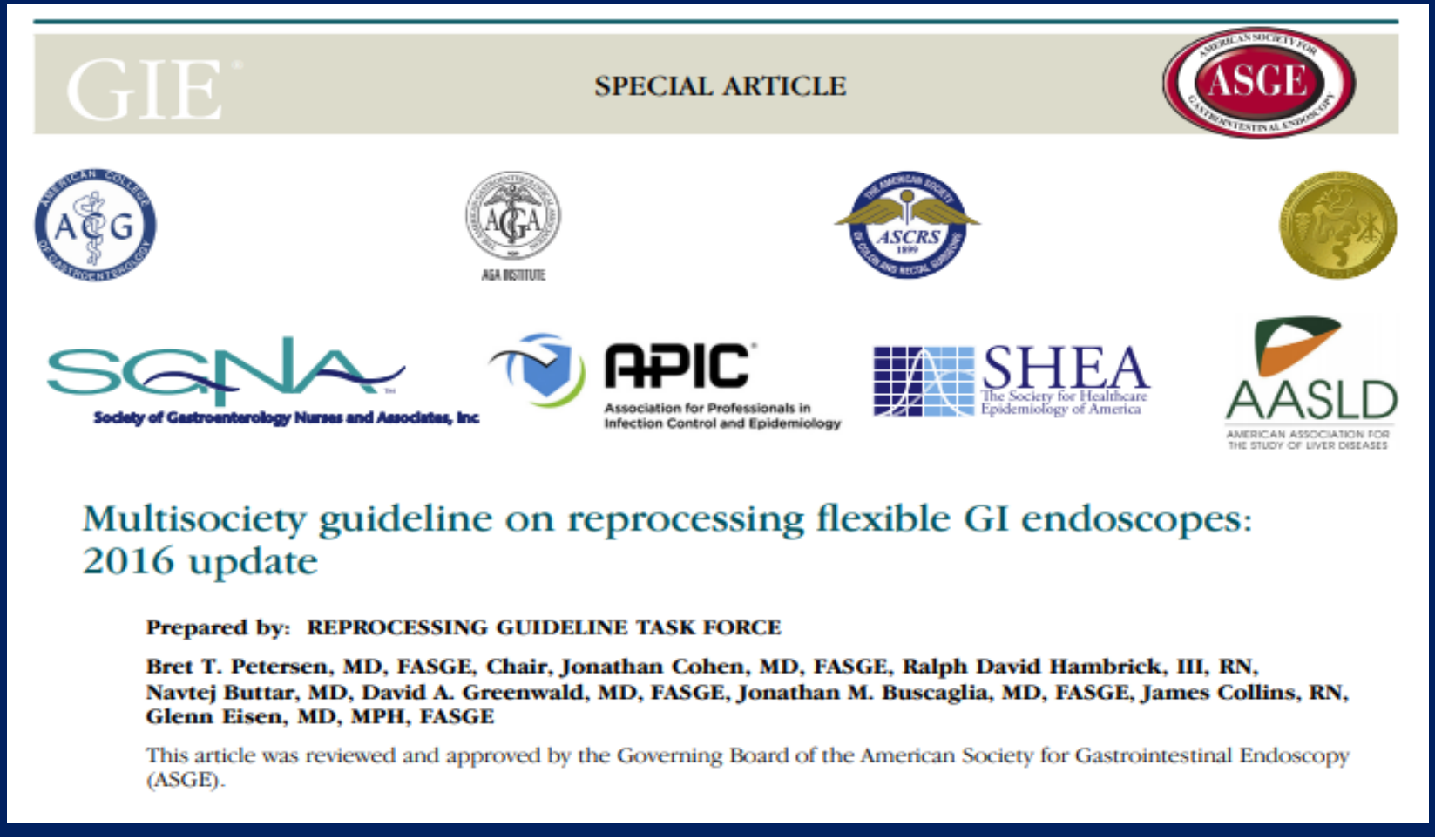
- Heat labile
- Long, narrow lumens (3.5ft, 1-3mm)
- Right angle bends
- Rough or pitted surfaces
- Springs and valves
- Damaged channels may impede microbial exposure to HLD
- Heavily contaminated with pathogens, $10^{7\text{-}10}$
- Cleaning (2-6 $\log_{10}$ reduction) and HLD (4-6 $\log_{10}$ reduction)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





MULTISOCIETY GUIDELINE ON REPROCESSING GI ENDOSCOPES, 2017

Petersen et al. Gastro Endoscopy. 2017 Feb;85(2):282-294



GIE

SPECIAL ARTICLE

Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update

Prepared by: REPROCESSING GUIDELINE TASK FORCE

Bret T. Petersen, MD, FASGE, Chair, Jonathan Cohen, MD, FASGE, Ralph David Hambrick, III, RN, Navtej Buttar, MD, David A. Greenwald, MD, FASGE, Jonathan M. Buscaglia, MD, FASGE, James Collins, RN, Glenn Eisen, MD, MPH, FASGE

This article was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy (ASGE).

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





Microbial Surveillance of GI Endoscopes

Saliou et al. Endoscopy. 2016

Characteristics of Sample	Action Level (TCU>100/scope) or EIP
Gastroscope	26.6%
Colonoscope	33.7%
Duodenoscope	34.7%
Echo-endoscope	31.9%
AER	27.2%
Manual	39.3%
Age of endoscope <2 years	18.9%
Age of endoscope >2 years	38.8%

Visual Inspection of GI Endoscopes and Bronchoscopes

GI Endoscopes, Ofstead et al. Am J Infect Control. 2017. 45:e26-e33

- All endoscopes (n=20) had visible irregularities (e.g., scratches)
- Researchers observed fluid (95%), discoloration, and debris in channels
- 60% scopes with microbial contamination

Bronchoscopes, Ofstead et al. Chest. 2018

- Visible irregularities were observed in 100% (e.g., retained fluid, scratches, damaged insertion tubes)
- Microbial contamination in 58%
- Reprocessing practices deficient at 2 of 3 sites

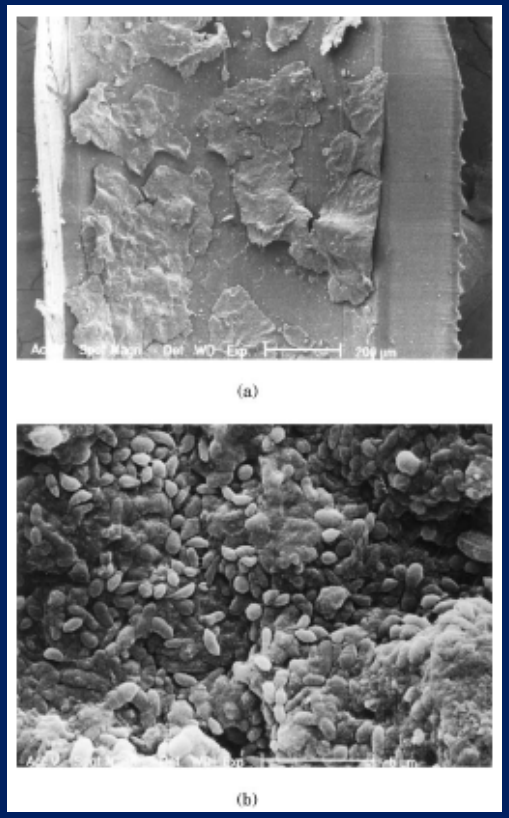
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BIOFILMS

(Multi-layered bacteria plus exopolysaccharides that cement cell to surface; develop in wet environments; if reprocessing performed promptly after use and endoscope dry the opportunity for biofilm formation is minimal; Paikos 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)

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 is a real-world setting

What Should We Do Now?

Interim Response to ERCP Outbreaks

How Can We Prevent ERCP-Related Infections?

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

- No single, simple and proven technology or prevention strategy that hospitals can use to guarantee patient safety
- Of course, must continue to emphasize the enforcement of evidenced-based practices, including equipment maintenance and routine audits with at least yearly competency testing of reprocessing staff
- Must do more or additional outbreaks will continue

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^{o}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

Education/Training/Competency/Compliance



Judie Bringhurst

GI Endoscopes: Shift from Disinfection to Sterilization

Rutala, Weber. JAMA 2014. 312:1405-1406; Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643.

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})

FDA Panel, May 2015, Recommended Sterilization of Duodenoscopes (requires FDA-cleared sterilization technology that achieves a SAL 10^{-6}, technology not yet available)

Not the FDA's First Shift from HLD to Sterilization

FDA has mandated a shift from HLD to sterilization in 1992 with dental handpieces

HIV Transmission in Dental Settings



- First case of dentist-to-patient transmission; removed molars in 1987, AIDS in 1990, died in 1991
- Even though no documented cases of disease transmission, FDA recommends that reusable dental handpieces and related instruments be heat sterilized between each patient use. September 1992.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Dental Handpiece Sterilization

September 28, 1992

Dear Doctor:

This is to notify you that the Food and Drug Administration (FDA) recommends that reusable dental handpieces and related instruments (such as air/water syringes and ultrasonic scalers) be heat sterilized between each patient use. Handpieces that cannot be heat sterilized should be retrofitted to attain heat tolerance. Handpieces that cannot be retrofitted and thus not heat sterilized should not be used. Chemical disinfection is not recommended.

The Centers For Disease Control (CDC) fact sheet entitled "HIV Transmission in Dental Settings," issued May 15, 1992, states "CDC and the American Dental Association have always recommended that dental handpieces be autoclaved between each patient, but in the 1980's not all handpieces could physically withstand heat sterilization. Since 1989 CDC has recommended that those dental handpieces that cannot be autoclaved only be used until the practitioner can replace them with a handpiece that can be autoclaved. Components of all dental handpieces currently made in the U.S. are either heat-stable or can be replaced with components that are heat-stable."

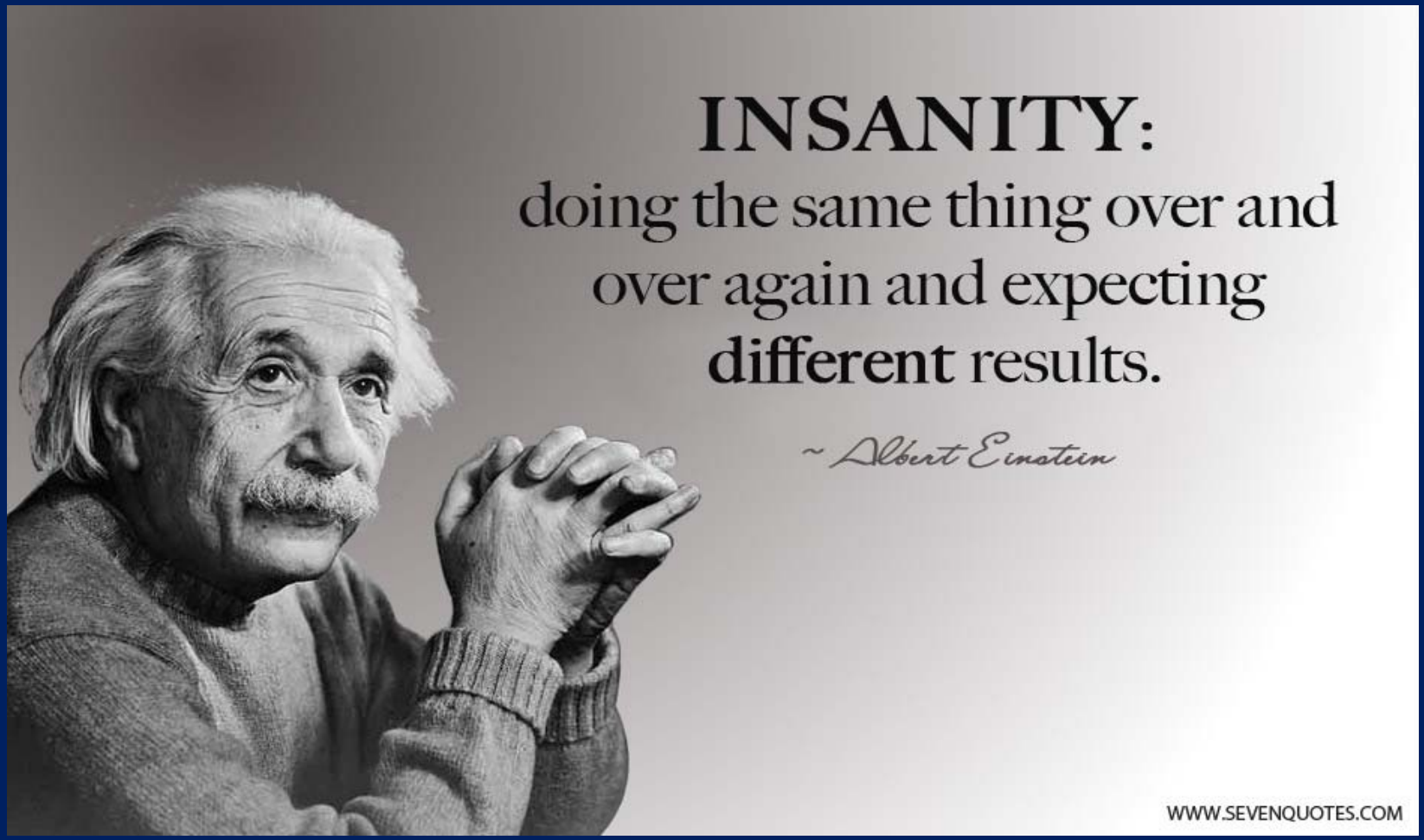
The American Dental Association document entitled "Infection Control Recommendations for the Dental Office and the Dental Laboratory" published in a supplement to the August 1992 issue of *The Journal of the American Dental Association* states, "Although no documented cases of disease transmission have been associated with contaminated dental handpieces or prophy angles, sterilization between patients with acceptable methods which assure internal as well as external sterility is recommended for these instruments." For the complete text of this document, refer to the supplement to the August 1992 issue of *The Journal of the American Dental Association*.

Sincerely yours,

Methods to Prevent GI-Endoscope Related Outbreaks

- For nearly 40 years have had the opportunity to be part of the infection prevention team and conduct research on disinfection/sterilization at UNC Hospitals and UNC School of Medicine
- During that time every 2-3 years there have been newsworthy endoscopy-related outbreaks which resulted in meeting with various professional organization, industry and/or government to discuss the outbreak(s)
- Each time we would focus on strict adherence to cleaning and endoscope reprocessing guidelines and/or a design tweak but the outbreaks continue

Endoscope Reproccesing:
A Need to Shift from Disinfection to Sterilization



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

Potential Future Methods to Prevent Endoscope-Related Outbreaks

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

- Optimize current low temperature sterilization methods or new LTST proving SAL 10^{-6} achieved (2 LTS technologies, FDA-cleared)
- Disposable sterile GI endoscopes/bronchoscopes (2 manufacturer's)
- Steam sterilization for GI endoscopes (1 bronchoscope manufacturer)
- Use of non-endoscope methods to diagnosis or treat disease (e.g., capsule endoscopy, stool or blood tests to detect GI cancer, stool DNA test)
- Improved GI endoscope design (to reduce or eliminate reprocessing challenges-based on 50y of experience unlikely to resolve problem; closed channel duodenoscopes increased risk)

At present (March 2018), the new AAMI endoscope reprocessing (WG 84) guideline will not mandate sterilization, but will only recommend it if possible, until MDMs develop endoscopes that are sterilization compatible.

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Endoscope Reprocessing: What Can We Do To Prevent Infections?

Summary

- Endoscopes represent a significant nosocomial hazard for healthcare-associated infections. Narrow or nonexistent margin of safety associated with high-level disinfection of semicritical items due to microbial load, complexity in design and formation of biofilms.
- To protect the public health and prevent endoscopy-related (e.g., ERCP, bronchoscopes) outbreaks, there is an urgent need to shift from HLD to sterilization.
- Professional organizations should clarify the Spaulding classification to require sterilization of endoscopes that directly or indirectly enter normally sterile tissue.
- Industry must develop sterilization technology (or single use) and make endoscopes compatible
- FDA must support this change through mandates and regulatory guidance
- TJC/CMS must enforce this transition when technology is acceptable
- Professional organizations (APIC, SHEA, ASGE, SGNA, AORN, IAHCSMM, AUA, ATS) must facilitate this change (e.g., guidelines, research, user education, presentations at meetings)
- Only after transition from HLD to sterilization for endoscopes that contact sterile tissue will we prevent all healthcare-associated infections associated with these medical devices.

THANK YOU!

www.disinfectionandsterilization.org

