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

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DISCLOSURES

- **Consultation (2017)**
  - PDI
  - ASP
- **Honoraria (2017)**
  - PDI
  - Kennall
- **Grants to UNC or UNC Hospitals (2017)**
  - CDC, CMS

Endoscope Reprocessing:
Are We Doing Enough to Protect Patients?

NO

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 GI endoscopes

Sources of Healthcare-Associated Pathogens

Weinstein RA. Am J Med 1991:91 (suppl 3B):179S

- Endogenous flora (SSI, UTI, CLABSI): 40-60%
- Exogenous: 20-40% (e.g., cross-infection via contaminated hands [staff, visitors])
- Other (environment): 20%
  - Medical devices
  - Contact with environmental surfaces (direct and indirect contact)

How Can We Prevent All Infections Associated with 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).

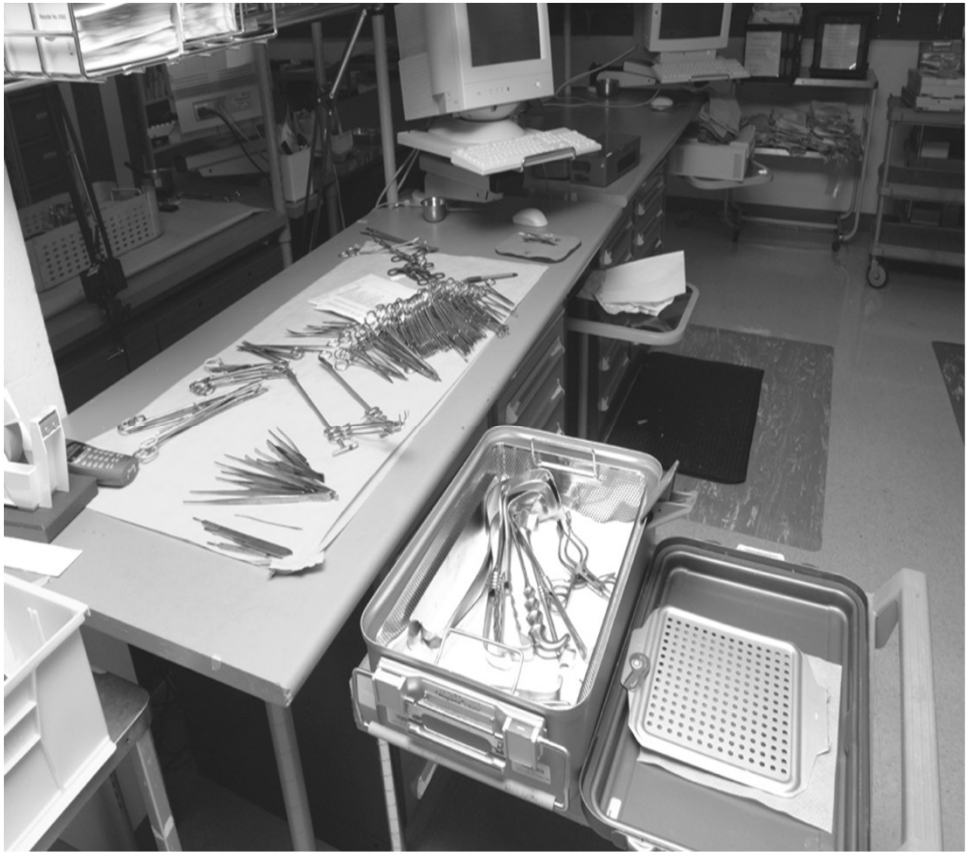
CRITICAL-medical/surgical devices which enter normally sterile tissue or the vascular system or through which blood flows should be sterile.

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.

Critical Medical/Surgical Devices

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



- Critical
  - Transmission: direct contact
  - Control measure: sterilization
  - Surgical instruments
    - Enormous margin of safety, rare outbreaks (2 in 60 years)
    - ~85% of surgical instruments <100 microbes
    - Washer/disinfector removes or inactivates 10-100 million
    - Sterilization kills 1 trillion spores

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

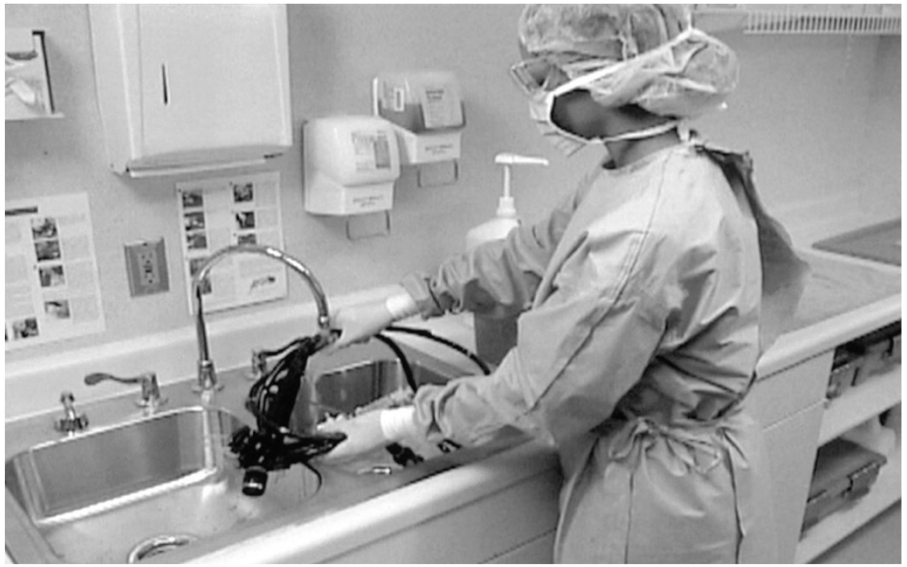
Noncritical Medical Devices

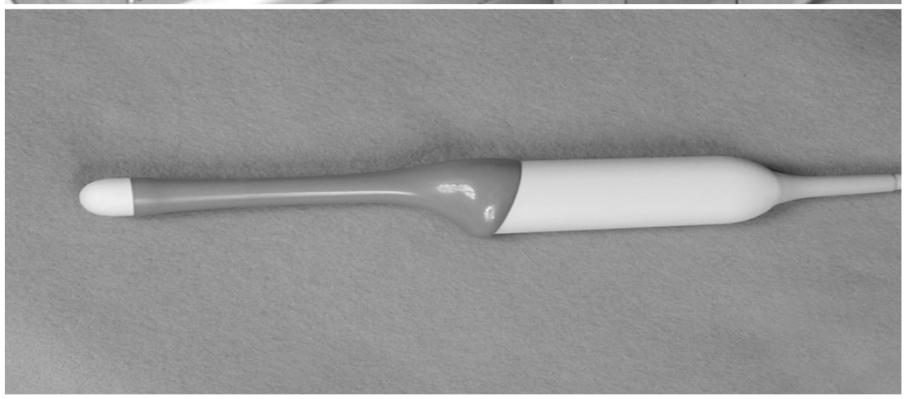
Rutala et al. AJIC 2016;44:e1; Rutala, Weber. Env Issues NI, Farber 1987

- Contact: intact skin (noncritical medical devices, surfaces)
- 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

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

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 are the risks associated with endoscopes?

Transmission of Infection by Endoscopy

Kovaleva et al. Clin Microbiol Rev 2013. 26:231-254

Scope	Outbreaks	Micro (primary)	Pts Contaminated	Pts Infected	Cause (primary)
Upper GI	19	Pa, *H. pylori*, *Salmonella*	169	56	Cleaning/Dis-infection (C/D)
Sigmoid/Colon oscopy	5	*Salmonella*, HCV	14	6	Cleaning/Dis-infection
ERCP	23	*P. aeruginosa* (Pa)	152	89	C/D, water bottle, AER
Bronchoscopy	51	Pa, Mtb, Mycobacteria	778	98	C/D, AER, water
Totals	98		1113	249	

Based on outbreak data, if eliminated deficiencies associated with cleaning, disinfection, AER, contaminated water and drying would eliminate about 85% of the outbreaks.

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

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

- *Klebsiella*, *Enterobacter* and *E. coli* are examples of *Enteriobacteriacea*e, 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

Endemic Transmission of Infections Associated with GI Endoscopes May Go Unrecognized

- Inadequate surveillance of outpatient procedures for healthcare-associated infections
- Long lag time between colonization and infection
- Low frequency of infection
- Pathogens “usual” enteric flora
- Risk of some procedures might be lower than others (colonoscopy versus ERCP where normally sterile areas are contaminated in the latter)

Reprocesssing Failures Have Led to Patient Notifications and Bloodborne Pathogens Testing

Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2007;28:146-155

TABLE 1. Reprocessing Failures of Semicritical or Critical Medical Instruments Resulting in Patient Notification

Location or institution, year	Instrument involved	No. of persons exposed
Sacramento, CA, 2002	Endoscope	750
Toronto, ON, 2003	Endoscope	146
Seattle, WA, 2004	Endoscope	600
Sacramento, CA, 2004	Endoscope	1,331
San Francisco, CA, 2004	Endoscope	2,000
Long Island, NY, 2004	Endoscope	177
Charleston, NC, 2004	Endoscope	1,383
Toronto, ON, 2003	Prostate biopsy probe	900
Pittsburgh, PA, 2005	Endoscope	200
Leesburg, VA 2005	Endoscope	144
San Diego, CA, 2006	Endoscope	300
Augusta, ME, 2006	Prostate biopsy needle	481
Dept Veterans Affairs, 2006	Prostate biopsy equipment	2,075
San Diego, CA, 2006	Surgical instrument	82

NOTE. Modified from a presentation by Douglas Nelson, MD, at the 33rd Annual Conference and International Meeting of the Association for Professionals in Infection Control and Epidemiology; Tampa, Florida, 2006.

Because more outbreaks associated with endoscopes than any other reusable medical device, endoscopes top ECRI's list of 10 health technology hazards

If we eliminate the risk of disease transmission associated with endoscopes, will eliminate risk associated with all medical and surgical devices

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,

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,

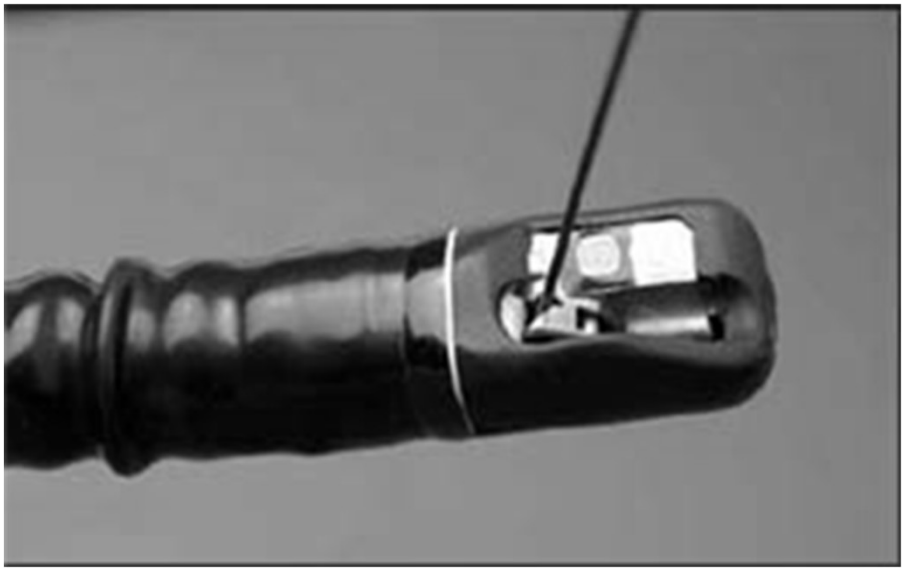
Reason for Endoscope-Related Outbreaks

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

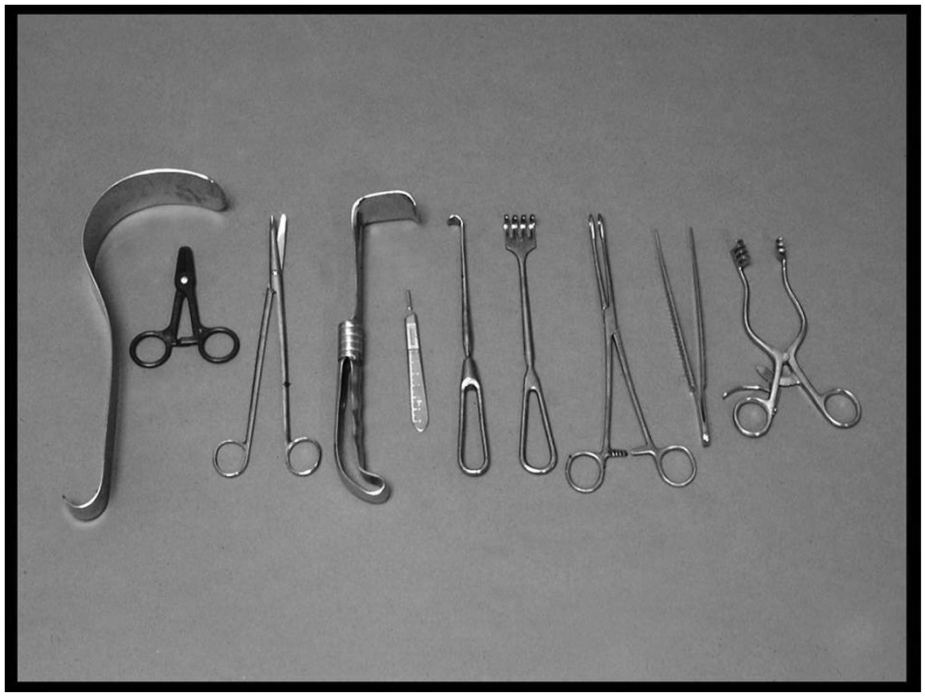
- Margin of safety with endoscope reprocessing minimal or non-existent
- Microbial load
  - GI endoscopes contain 10^{7-10}
  - Cleaning results in 2-6 $\log_{10}$ reduction
  - High-level disinfection results in 4-6 $\log_{10}$ reduction
  - Results in a total 6-12 $\log_{10}$ reduction of microbes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

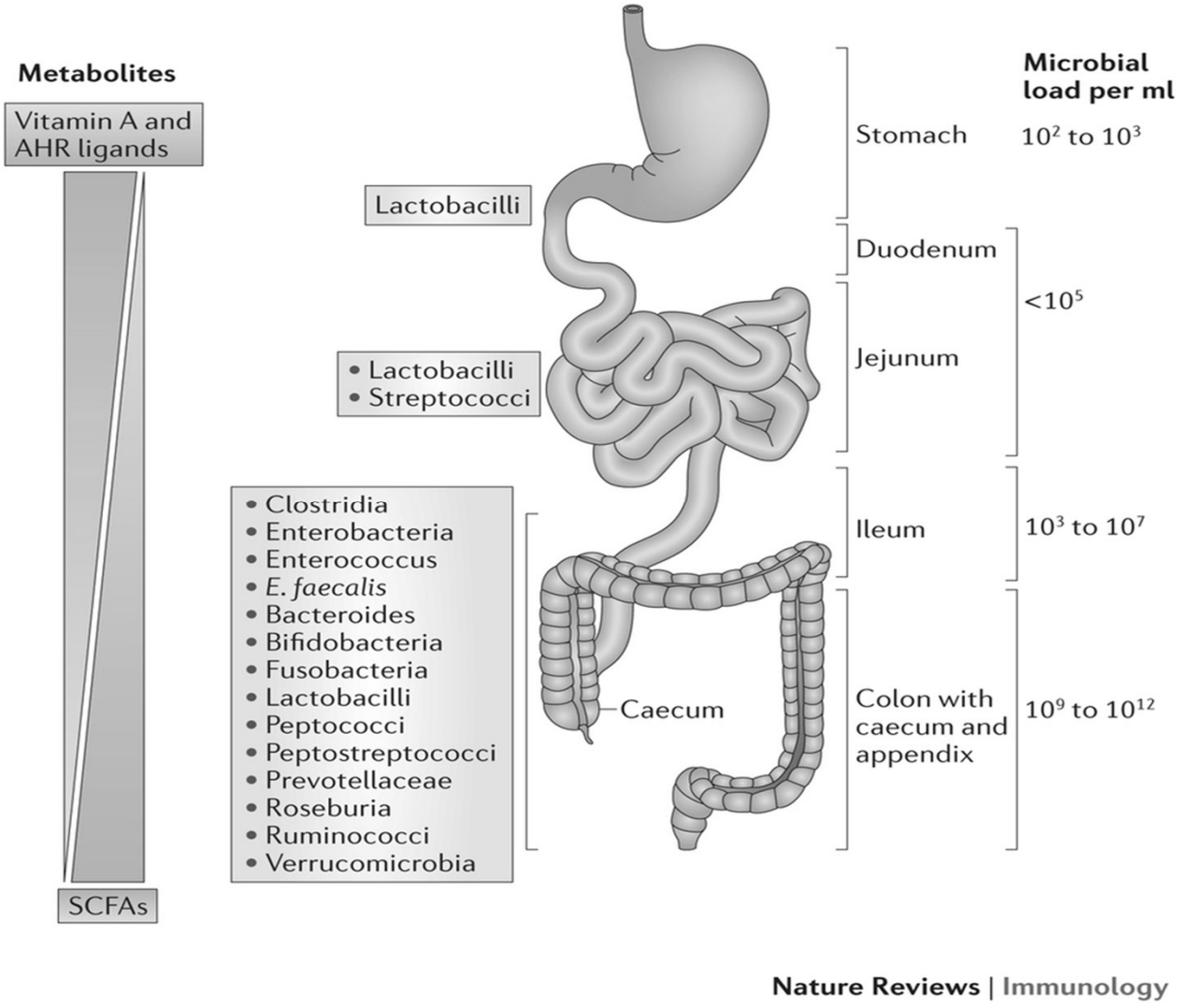
ENDOSCOPE REPROCESSING: CHALLENGES

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



Surgical instruments-$<10^{2}$ bacteria



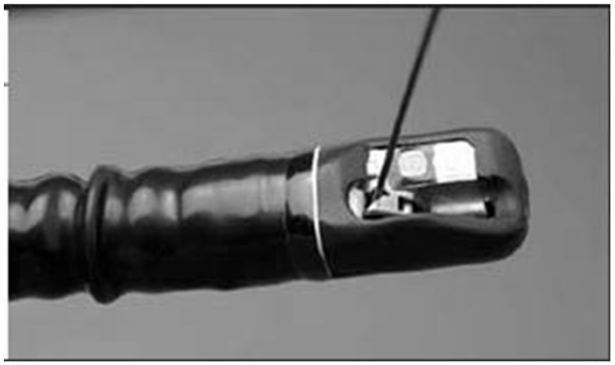


Mowat AM, Agace WW. Nat Rev Immunology 2014;14:667-685

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)



Bacterial Bioburden Associated with Endoscopes

Cleaning Results in 2-6 $\log_{10}$ Reduction

	Gastroscope, $\log_{10}$ CFU	Colonoscope, $\log_{10}$ CFU
After procedure	6.7	8.5 Gastro Nursing 1998;22:63
	6.8	8.5 Am J Inf Cont 1999;27:392
		9.8 ~10,000,000,000 or 10^{10}
		Gastro Endosc 1997;48:137
After cleaning	2.0	2.3
	4.8	4.3
		5.1 ~100,000 or 10^5

Reason for Endoscope-Related Outbreaks

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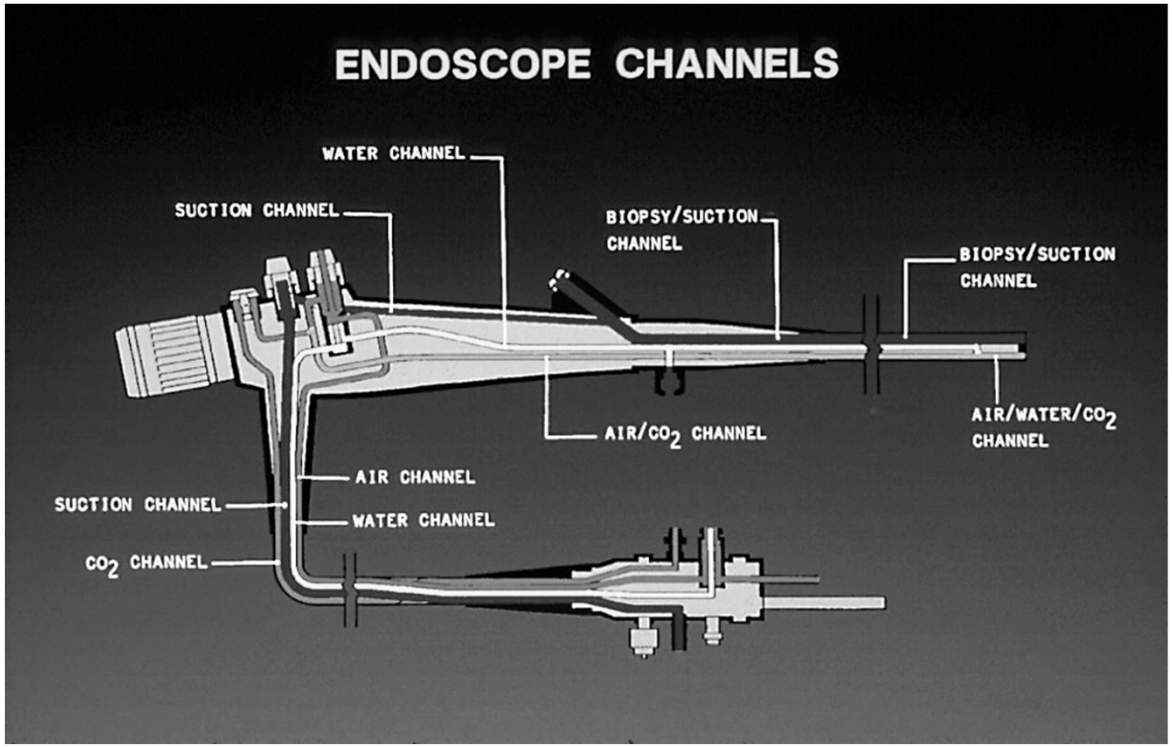
What does this off-road driver/vehicle have in common with GI endoscope? 10 Billion particles, complexity

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



CDC Guideline for Disinfection and Sterilization

Rutala, Weber, HICPAC. November 2008. www.cdc.gov

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

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]

MULTISOCIETY GUIDELINE ON REPROCESSING GI ENDOSCOPES, 2017

Petersen et al. Gastro Endoscopy. In press

ARTICLE IN PRESS

GIE®

SPECIAL ARTICLE

Society of Gastroenterology Nurses and Associates, Inc.

Association for Professionals in Infection Control and Epidemiology

The Society for Healthcare Epidemiology of America

AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

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

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**

Endoscope Reprocessing Methods

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

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

Endoscope Reprocessing Methods

A Prospective Study on the Impact of Human Factors and Automation

ABSTRACT

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

Endoscope Reprocessing Methods

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

Performed all 12 steps with only 1.4% of endoscopes using manual versus 75.4% of those processed using AER

TABLE 3. Documented Completion of Steps During Manual Cleaning With High-Level Disinfection Reprocessing

Observed Activity	Steps Completed (%) (n = 69)
Leak test performed in clear water	77
Disassemble endoscope completely	100
Brush all endoscope channels and components	43
Immerse endoscope completely in detergent	99
Immerse components completely in detergent	99
Flush endoscope with detergent	99
Rinse endoscope with water	96
Purge endoscope with air	84
Load and complete automated cycle for high-level disinfection	100
Flush endoscope with alcohol	86
Use forced air to dry endoscope	45
Wipe down external surfaces before hanging to dry	90

Automated Endoscope Reprocessors

AERs automate and standardize endoscope reprocessing steps

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)

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 Inspections of Colonoscopes and Gastroscopes

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

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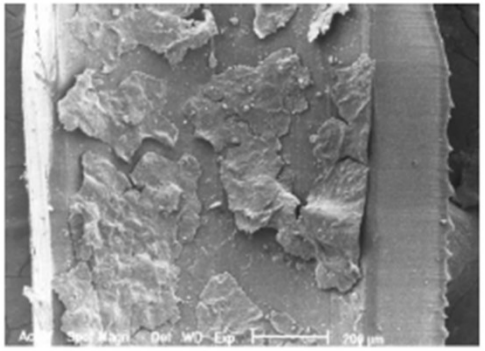
- Complexity of endoscope and endoscope reprocessing
- Biofilms-unclear if contribute to failure of endoscope reprocessing

BIOFILMS

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



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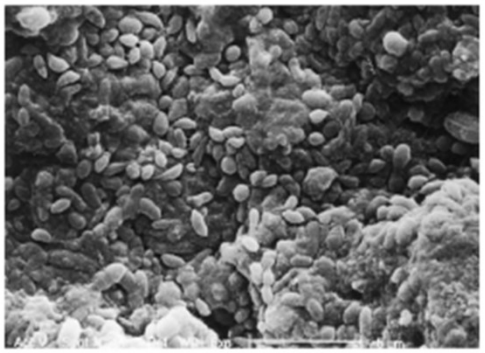

(b)

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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

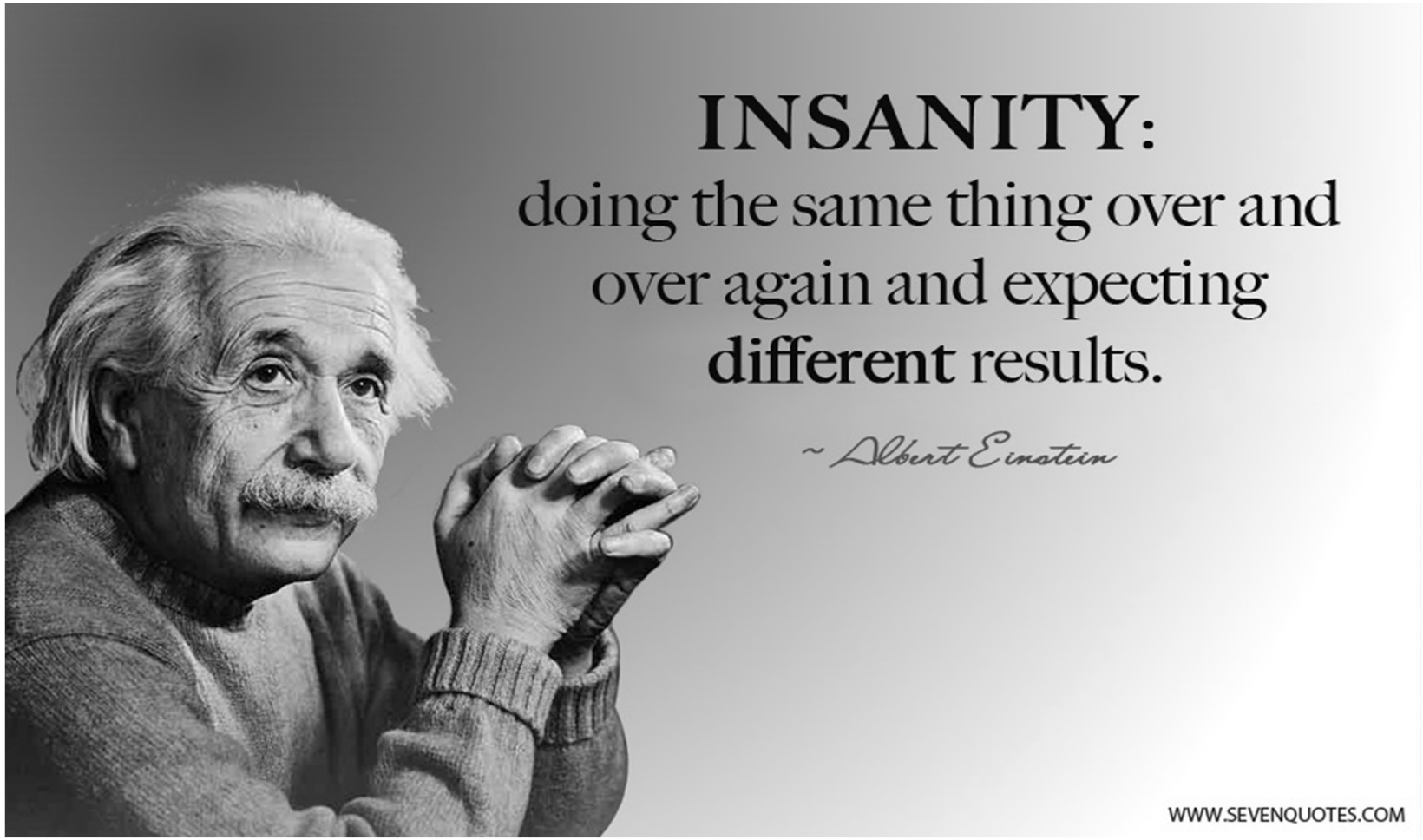
Education/Training/Competency/Compliance

Judie Bringhurst

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



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No Margin of Safety

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

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

Endoscope Reproccesing:
A Need to Shift from Disinfection to Sterilization

- When Spaulding scheme designed 50 years ago, semicritical items rarely, if ever, penetrated sterile tissue and we did not appreciate the infection risk associated with endoscope reprocessing. Early endoscopes used primarily for diagnostic purposes.
- New enhancements to include visualization when combined with radiography results in high-quality visualization of sterile body sites for treatment (e.g., endoscopic ultrasound with fine needle aspiration for embolization or thermal or alcohol injection ablation of tumors) or non-radiographic peroral endoscopic myotomy.
- Even when duodenoscope are used for stones or tumors and the area is no longer sterile, the infection risk is unacceptable as demonstrate by >125 published outbreaks and a significant portion of scopes are contaminated after processing.
- In some cases, endoscopies now replace invasive surgery. Unfortunately, these highly complex devices (e.g., long, narrow lumens, right angle bends, rough or pitted surfaces, springs and valves) exceed the ability of high-level disinfection to eliminate all pathogens (including multidrug-resistant pathogens such as CRE which will have higher mortality).

Current Enhanced Methods for Reprocessing Duodenoscopes

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

Hospitals performing ERCPs should do one of the following (priority ranked); doing nothing is not an option:

- **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**

Comparison of High-Level Disinfection and Sterilization Procedures

Synder et al. Gastroenterology 2017

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
- 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

Summary of Advantages and Disadvantages of HLD and Sterilization Enhancements for Reprocessing Duodenoscopes

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

Method	Advantages	Disadvantages
HLD with ETO, Microbiologic surveillance	• **Major endoscope manufacturer offers ETO as sterilization option** • **Ideally, should be used after standard high-level disinfection** • **Some data demonstrate reduced infection risk with HLD followed by ETO** • Single-dose cartridge and negative-pressure chamber minimizes the potential for gas leak and ETO exposure • Simple to operate and monitor • Compatible with most medical materials	• **Requires aeration time to remove ETO residue** • **Only 20% of US hospitals have ETO on-site** • **Lengthy cycle/aeration time** • **No microbicidal efficacy data proving SAL 10^{-6} achieved** • **Studies question microbicidal activity in presence of organic matter/salt** • **ETO is toxic, a carcinogen, flammable** • May damage endoscope

Long-Term Response To ERCP/Endoscope Outbreaks

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 Endoscopy-Related Infections

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

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)

Endoscope Reprocessing:
A Need to Shift from Disinfection to Sterilization

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

- Where are we today-significant risk of being exposed to healthcare pathogens and an infection risk; peer-reviewed literature demonstrates risk and offers recommendations
- Where do we want to be in the future- eliminate all infections associated with medical /surgical devices
- How do we get there-modify Spaulding
- Roadmap for implementation
- Challenges associated with changeover to sterilization
- Timelines

Disinfection and Sterilization

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 - objects which 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).

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 (modified).

CRITICAL - objects which directly or 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.

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Endoscope Reproccesing:
A Need to Shift from Disinfection to Sterilization

Rutala, Weber. 2017. Manuscript in preparation.

- **CRITICAL - objects which directly or 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.**
  - **Duodenoscopes**
  - **Bronchoscopes**
  - **Cystoscopes**
  - **Other GI scopes such as colonoscopies and gastroscopes**
    - **Many patients need a biopsy, which by definition enters sterile tissue**
    - **Many patients will have disruptive or non-intact mucous membranes (e.g., gastric ulcers, other erosions)**

Endoscope Reproccesing:

A Need to Shift from Disinfection to Sterilization

High-Level Disinfection of "Semicritical Objects"

Rutala, Weber, HICPAC. www.cdc.gov

Exposure Time ≥ 8m-45m (US), 20°C

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

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

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 (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)

Endoscope Reproccesing:
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- Where are we today-significant risk of being exposed to healthcare pathogens and an infection risk; peer-reviewed literature demonstrates risk and offers recommendations
- Where do we want to be in the future-eliminate all infections associated with medical /surgical devices
- How do we get there-modify Spaulding
- Roadmap for implementation-peer-reviewed literature recommending transition; FDA Panel; evolution of LTST (FDA-cleared) and single-use endoscopes ($170-225 and reprocessing cost $114-281)
- Timelines-urgent but not more than 5 years (new technology acceptable in terms of sterilization performance, scope performance (disposable), cost, throughput, materials compatibility
- Challenges associated with changeover to sterilization

Endoscope Reproccesing:
A Need to Shift from Disinfection to Sterilization

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

- Challenges-urgent but not more than 5 years (new technology acceptable in cost, compatibility, and turnaround time)
  - AAMI should modify the Spaulding classification scheme for critical items from “direct contact with sterile tissue” to “direct or secondary contact with sterile tissue”
  - AAMI should incorporate this new modification into the HLD and sterilization guidelines now
  - AAMI should incorporate verbiage that this transition should happen as soon as new sterilization technology (or single use endoscopes) acceptable in terms of sterilization performance, scope performance (disposable), cost, throughput, materials compatibility
  - TJC should ensure implementation of this AAMI recommendation as soon as new sterilization technology are available and acceptable (based on literature and hospital usage)

Endoscope Reproccesing:
A Need to Shift from Disinfection to Sterilization

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- Challenges-urgent but not more than 5 years (new technology acceptable in cost, compatibility, and turnaround time)
  - Endoscope manufacturer's must make their endoscopes compatible with LTST (e.g., adhesives, lubricants). FDA must ensure endoscope manufacturer's facilitate compatibility with LTST.
  - FDA must clear in a timely manner LTST or single-use, endoscopes when data demonstrate they achieve an SAL 10^{-6}
  - To protect the public health and prevent endoscope-related infections/outbreaks, FDA should mandate a shift from HLD to sterilization as they did in in 1992 with dental handpieces
  - Manufacturers that submit critical devices to FDA for clearance that secondarily enter normally sterile tissue need to offer a FDA-cleared sterilization method.

Endoscope Reproccesing:
A Need to Shift from Disinfection to Sterilization

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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 GI endoscopes

Duodenoscope and Endoscope Reprocessing?

A Need to Shift from Disinfection to Sterilization

Summary

- Endoscopes represent a significant nosocomial hazard for healthcare-associated infetcions. Narrow or nonexistent margin of safety associated with high-level disinfection of semicritical items due to microbial load, complexity and biofilms.
- To protect the public health and prevent endoscopy-related (e.g., ERCP) outbreaks, there is an urgent need to shift from HLD to sterilization.
- AAMI should modify the Spaulding classification to require sterilization of endoscopes that directly or secondarily 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 must enforce this transition when technology is acceptable
- Professional organizations (APIC, SHEA, ASGE, SGNA, AORN, IAHCSMM, others) must facilitate this change (e.g., guidelines, research, 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