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

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

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DISCLOSURES

- Consultation (2017)
  - PDI
  - ASP
- Honoraria (2017)
  - None
- Grants to UNC or UNC Hospitals (2017)
  - CDC, CMS

Can We Prevent All Infections Associated with Medical Devices in 5 Years?
www.disinfectionandsterilization.org

Our Responsibility to the Future

Prevent All Infectious Disease Transmission by Medical Devices in 5 years

Via Research/Technology/Automation/Competency

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 CRE/MDR outbreaks associated with ERCP procedures
- Discuss the alternatives that exist today that might improve the safety margin associated with duodenoscope 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)

Can We Prevent All Infections Associated with Medical Devices in 5 Years?

Can We Prevent All Infections Associated with Medical Devices and the Environment in 5 Years?

Futurist asked why he was so good at predicating the future…

I see the world the way it should be and I make it that way!

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
    - ~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, >100 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)

Endoscopes top ECRI's list of 10 health technology hazards

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.

RECENT ENDOSCOPY-RELATED OUTBREAKS OF MRDO WITHOUT REPROCESSING BREACHES

Rutala WA et al. Virulence. In press

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

Health Care Facilities Need to Immediately Review Medical Device Reprocessing Procedures

Train Staff, Audit Adherence to Steps, Provide Feedback on Adherence

This is an official

CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
September 11, 2015, 12:15 EDT (12:15 PM EDT)
CDCHAN-00382

Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

Summary

The Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) are alerting healthcare providers and facilities about the public health need to properly maintain, clean, and disinfect or sterilize reusable medical devices. Recent infection control lapses due to non-compliance with recommended reprocessing procedures highlight a critical gap in patient safety. Healthcare facilities (e.g., hospitals, ambulatory surgical centers, clinics, and doctors' offices) that utilize reusable medical devices are urged to immediately review current reprocessing practices at their facility to ensure they (1) are complying with all steps as directed by the device manufacturers, and (2) have in place appropriate policies and procedures that are consistent with current standards and guidelines.

Background

Recent media reports describe instances of patients being notified that they may be at increased risk for infection due to lapses in basic cleaning, disinfection, and sterilization of medical devices. These events involved failures to follow manufacturers' reprocessing instructions for critical[1] and semi-critical[2] items and highlight the need for healthcare facilities to review policies and procedures that protect patients.

Recommendations

Healthcare facilities should arrange for a healthcare professional with expertise in device reprocessing to immediately assess their reprocessing procedures. This assessment should ensure that reprocessing is done correctly, including allowing enough time for reprocessing personnel to follow all steps recommended by the device manufacturer. The following actions should be performed:

Training

Health Care Facilities Need to Immediately Review Medical Device Reprocessing Procedures

- Reprocessing lapses resulting in patient infections and exposures
- Healthcare facilities urged to immediately review current reprocessing practices to ensure comply with device manufacturer and guidelines
  - Training (upon hire and at least annually), demonstrate and document competency
  - Audit should assess all reprocessing steps including cleaning, disinfectants (conc, contact time), sterilizer (chemical, biological indicators). Feedback from audits to personnel regarding adherence.

GI ENDOSCOPES

- Widely used diagnostic and therapeutic procedure (~20 million GI procedures annually in the US; ~500,000 ERCPs/year)
- GI endoscope contamination during use (10^{7-10} in/10^{5} out)
- Semicritical items require high-level disinfection minimally
- Inappropriate cleaning and disinfection has lead to cross-transmission
- Although the incidence of post-procedure infection remains very low, endoscopes represent a significant risk of disease transmission. In fact, more outbreaks of infection associated with endoscopes than any reusable medical device in healthcare.

Transmission of Infection by Endoscopy

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

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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

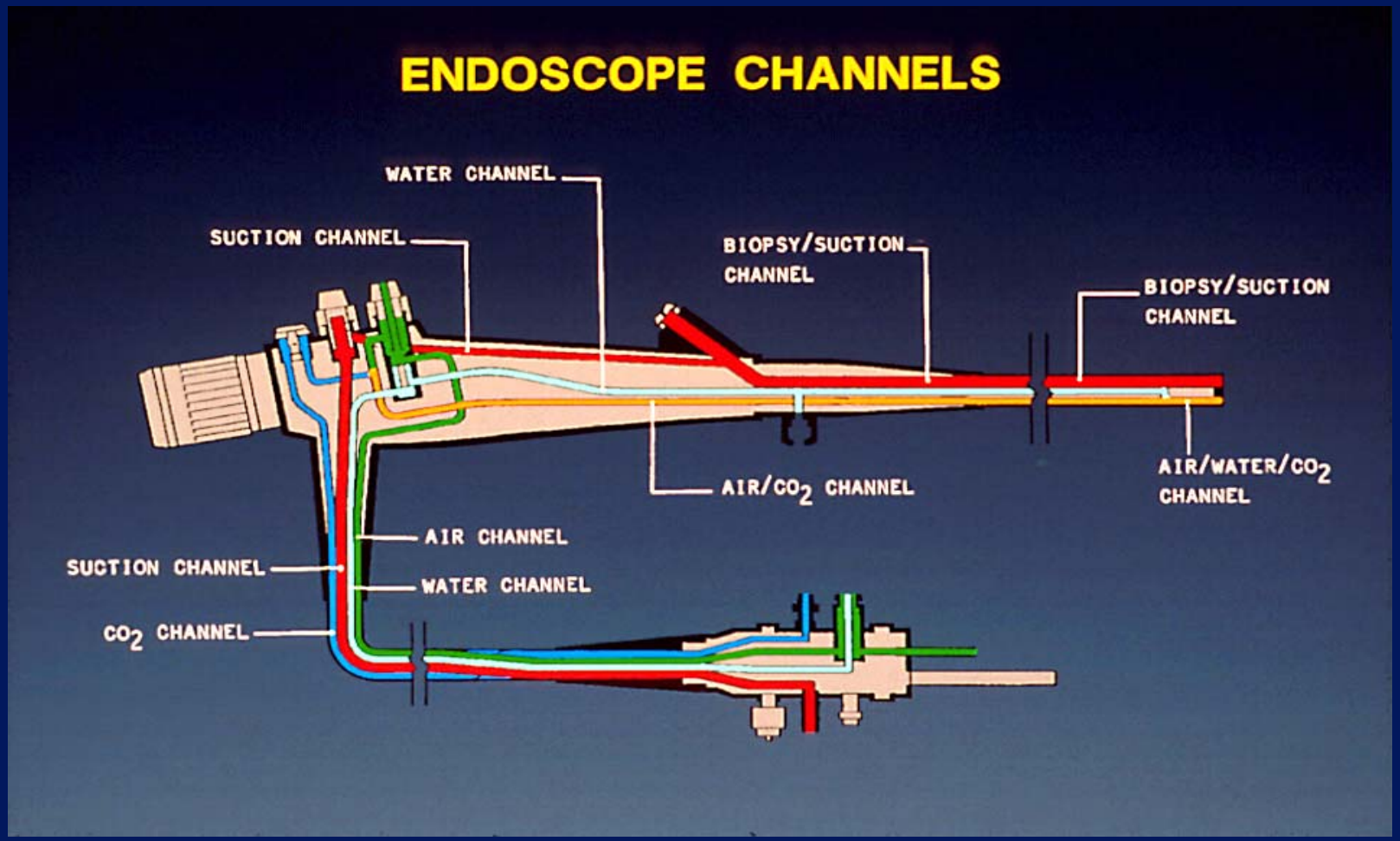
Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2007;28:146-155

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.

ENDOSCOPE REPROCESSING



CDC Guideline for Disinfection and Sterilization

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

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

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

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 for two reasons:
- 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

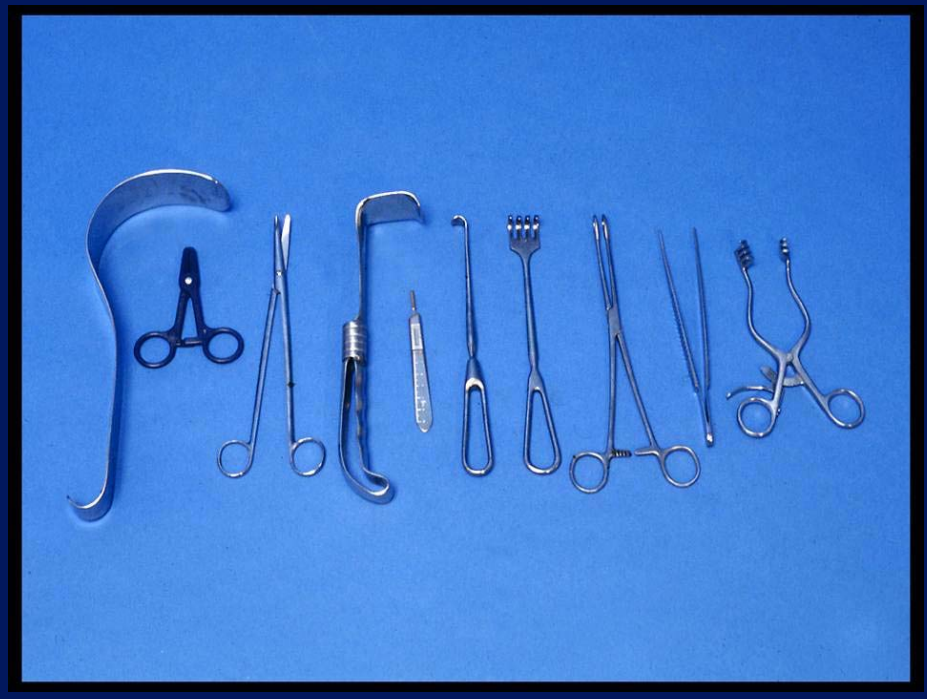
Bioburden on Surgical Devices
Non-Lumen Surgical Instruments Carry a Low Microbial Load

- Bioburden on instruments used in surgery (Nystrom, J Hosp Infect 1981)
  - 62% contaminated with $<10^1$
  - 82% contaminated with $<10^2$
  - 91% contaminated with $<10^3$
- Bioburden on surgical instruments (Rutala, Am J Infect Control 1997)
  - 72% contained $<10^1$
  - 86% contained $<10^2$
- Bioburden on surgical instruments (50) submitted to CP (Rutala, AJIC 2014)
  - 58% contained <10
  - 20% contained $\leq 10^2$
  - 16% contained $\leq 5x10^2$
  - 6% contained $<10^3$

ENDOSCOPE REPROCESSING: CHALLENGES

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

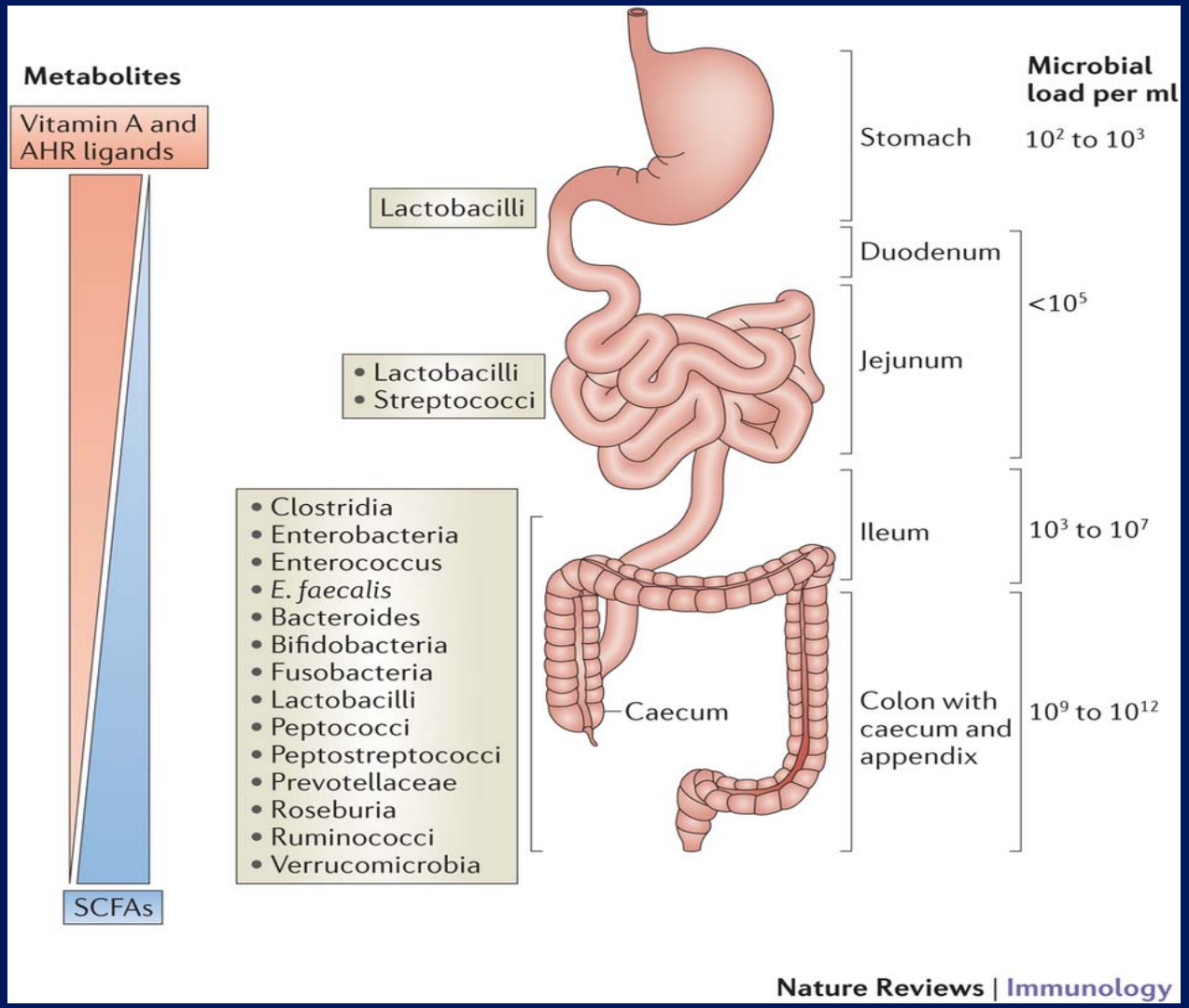
Surgical instruments-$<10^{2}$ bacteria



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)



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

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

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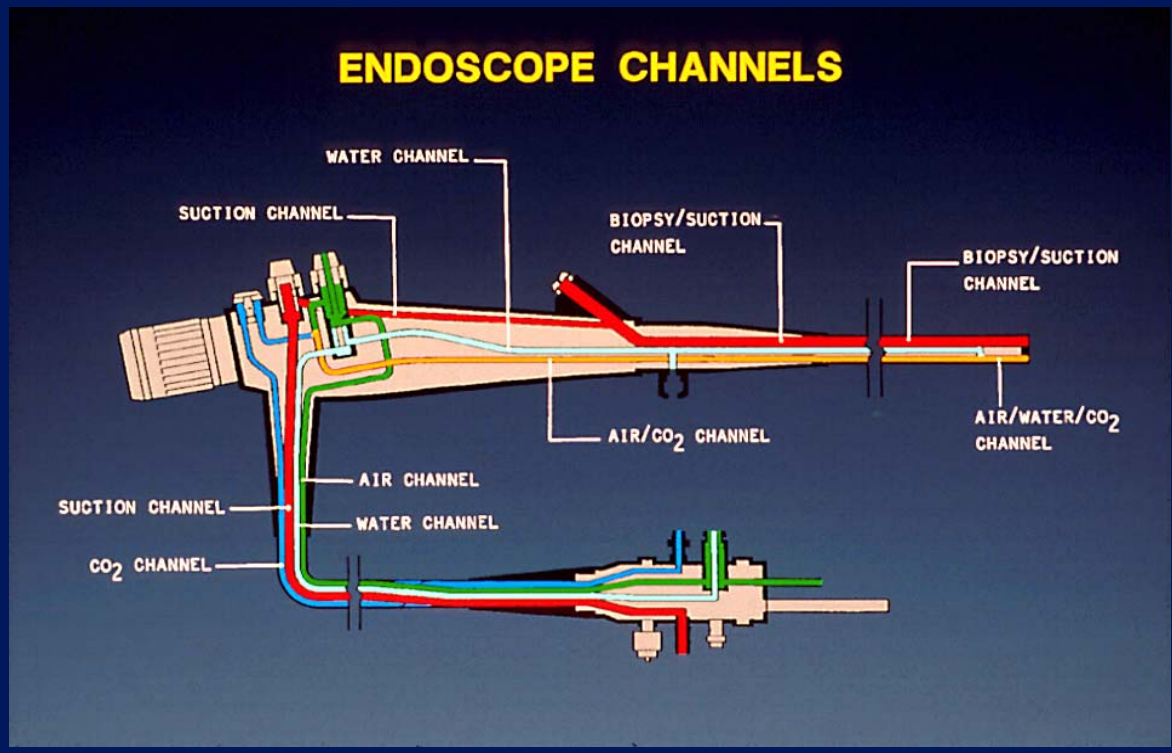
  - Results in a total 6-12 $\log_{10}$ reduction of microbes
  - Level of contamination after processing: $4\log_{10}$ (maximum contamination, minimal cleaning/HLD)
- Complexity of endoscope and endoscope reprocessing
- Biofilms-unclear if contribute to failure of endoscope reprocessing

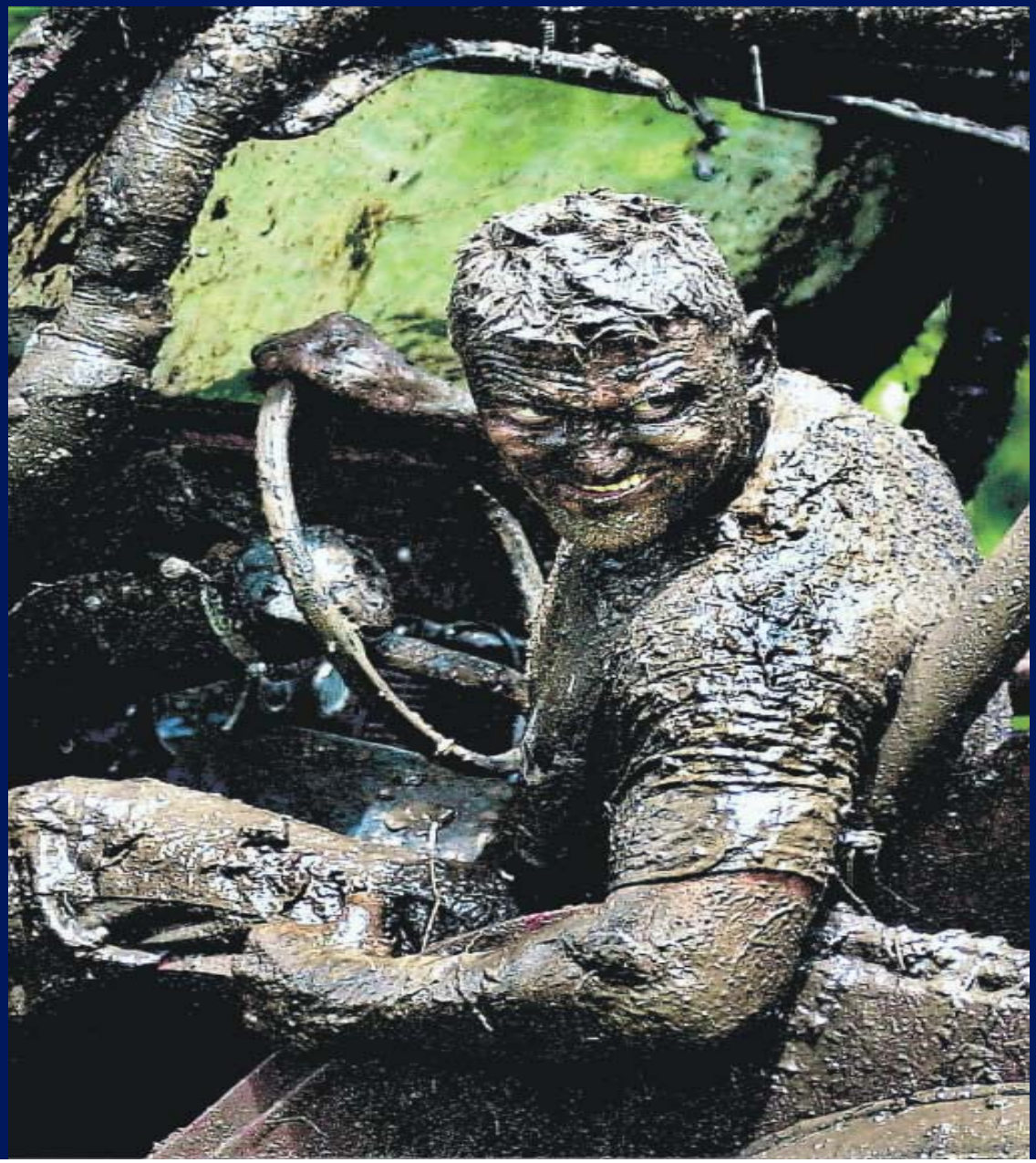
FEATURES OF ENDOSCOPES THAT PREDISPOSE TO DISINFECTION FAILURES

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



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



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

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

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

Education/Training/Competency

Judie Bringhurst

High Level Disinfection (HLD) Certificate Class

Class size is limited to 24 students

When: Tuesday, July 7, 2015
9am – noon

Where: On Campus
MacNider 18
Chapel Hill

At this class you will:

- Learn how to high-level disinfect semi-critical devices
- Understand your responsibilities related to HLD
- Learn the pitfalls of inadequate high-level disinfection
- Learn about OSHA regulations related to high level disinfectants
- *Earn 3 nursing contact hours!*

Faculty:
Judie Bringhurst, MSN, RN, CIC

Registration:
By email **ONLY** please. Email your **name**, your **clinic** name, and your **phone number** to Judie Bringhurst, Hospital Epidemiology: jbringhu@unch.unc.edu You will receive confirmation of your registration by return email.

Parking:
Staff without on-campus parking assignments may want to park in the visitor's parking deck on Manning Drive.

Managing Instrument (Semicritical and Critical) Reprocessing Competencies and Lists

- Healthcare facilities urged to immediately review current reprocessing practices to ensure comply with device manufacturer and guidelines
- Audit should assess all reprocessing steps including cleaning, disinfectants (concentration, contact time), sterilizer (chemical, biological indicators). Feedback from audits to personnel regarding adherence
- Managers should:
  - Keep list of HCP that reprocess semicritical or critical
  - List of instruments reprocessed in their unit/clinic
  - Ensure appropriate competencies in place upon hire and annually (also when new endoscopic models, new processing equipment/products)
  - Documentation using the valid competency form
  - Must be completed by another HCP who also has a valid competency
  - Must be stored in employees' records

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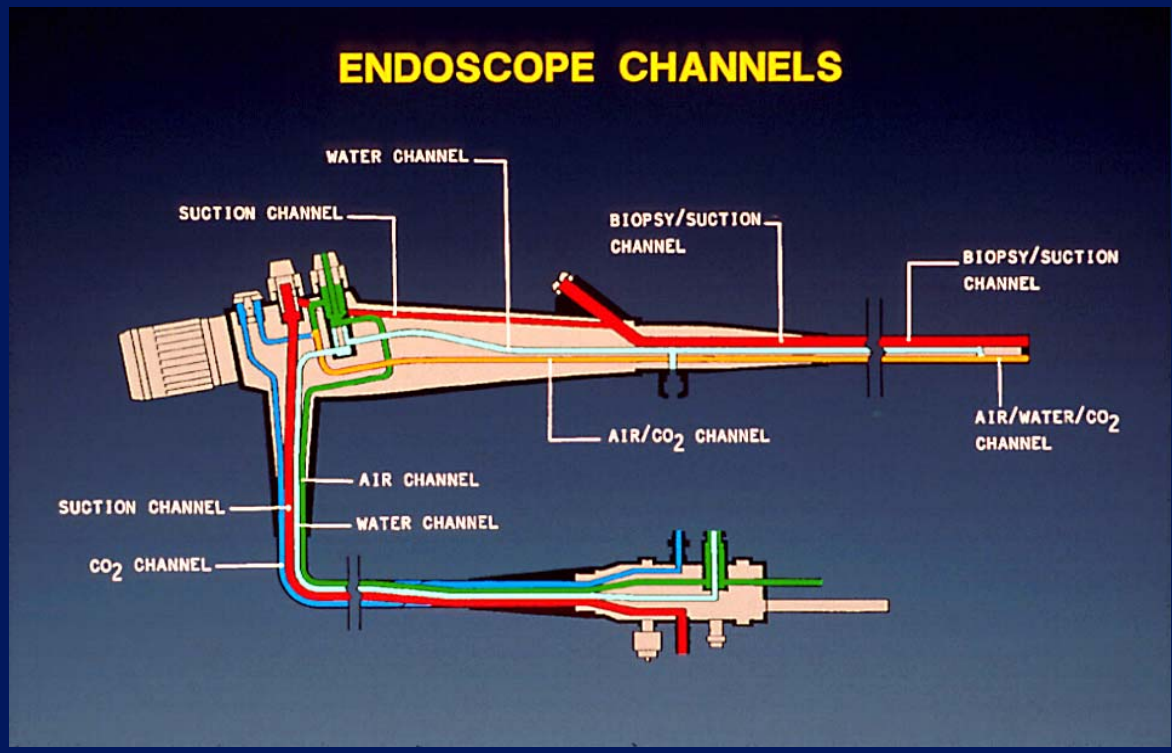

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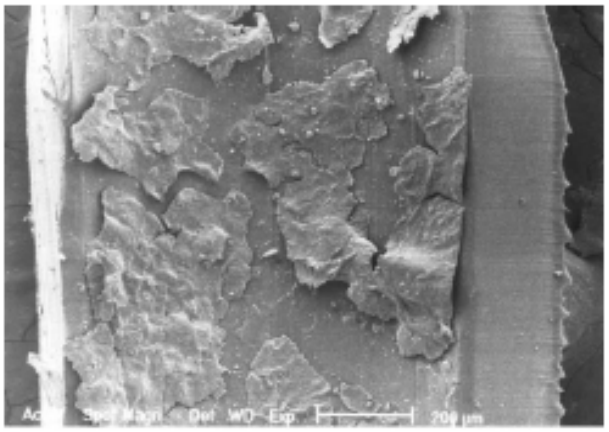
BIOFILMS

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



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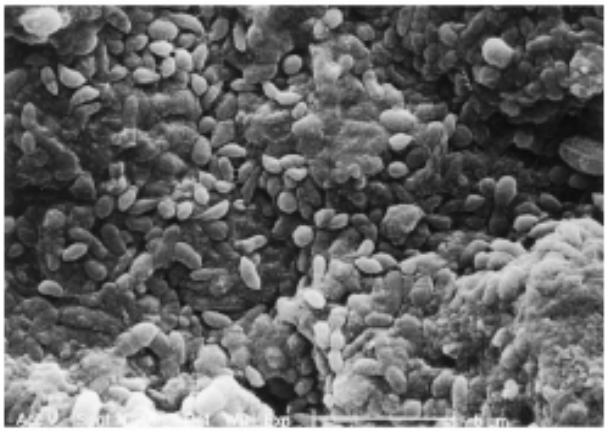

(b)

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What Should We Do Now?

Interim Response to ERCP Outbreaks

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Rutala WA et al. 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

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

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

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

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 only (not listed as an enhanced method for reprocessing endoscope)	• HLD inactivate MDR organisms including CREs • Current standard of care • Wide availability	• Based on recent ERCP outbreaks, infection risk related to device complexity and microbial load • No enhancement to reduce infection risk associated with ERCP scopes • Some HLD (e.g., aldehydes) may cross-link proteins

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, ATP only (not listed as an enhanced method for reprocessing endoscope)	• HLD inactivate MDR organisms including CREs • Real-time monitoring tool • Simple to conduct • Detects organic residue	• Based on recent ERCP outbreaks, infection risk related to device complexity and microbial load • No data demonstrating reduced infection risk • Does not detect microbial contamination • ATP not validated as risk factor for patient-to-patient transmission • Unknown cut-off level to assure safety

Adenosine Triphosphate (ATP) Validation

Alfa et al. Am J Infect Control 2013;41:245

- Validated as a monitoring tool for assessing cleaning because it detects organic residuals
- ATP is not a good indicator of microbial contamination and has not been validated as a method to assess the risk of patient-to-patient transmission
- ATP <200 RLU benchmark for clean, equates to <4 $\log_{10}$ CFUs/cm^2 or 10^6 CFUs per endoscope
- Thus, an endoscope assessed as clean using ATP could still have a significant microbial load (e.g., 10^6)

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
Double HLD, Microbiologic surveillance	• HLD inactivate MDR organisms including CREs • Wide availability of HLD • A second HLD cycle may reduce or eliminate microbial contaminants remaining from first cycle	• Based on recent ERCP outbreaks, infection risk related to device complexity and microbial load • Some HLD (e.g., aldehydes) may cross-link proteins

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 scope quarantine until negative culture	• HLD inactivate MDR organisms including CREs • Microbiologic surveillance offered as supplement by CDC • Data demonstrate reduced infection risk	• Based on recent ERCP outbreaks, infection risk related to device complexity and microbial load • Sensitivity of microbiologic surveillance unknown • 48-72 hours before culture results known • No cutoff to define effective disinfection

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
Liquid Chemical Sterilant Processing System using Peracetic Acid, rinsed with extensively treated potable water, Microbiologic surveillance	• HLD/chemical sterilant inactivate MDR organisms including CREs • Offered as liquid chemical sterilant processing option	• Based on recent ERCP outbreaks, infection risk related to device complexity and microbial load • Not considered sterile as not a terminal sterilization process and scope rinsed with extensively treated water • Unclear if peracetic acid will penetrate crevices in elevator channel and inactivate pathogens

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, Microbiologic surveillance	• HLD inactivate MDR organisms including CREs • Microbiologic surveillance offered as supplement by CDC	• Based on recent ERCP outbreaks, infection risk related to device complexity and microbial load • No data demonstrating reduced infection risk • Sensitivity of microbiologic surveillance unknown • 48-72 hours before culture results known • No consensus regarding sampling scheme, 100% or 10% of scopes per week/per month? • No cutoff to define effective disinfection (0 GNR?)

UNC Hospitals
Interim Response to ERCP Outbreaks

- Ensure endoscopes are reprocessed in compliance with national guidelines (CDC, ASGE, etc)
- Evaluate CRE culture-positive patients for ERCP exposure
- In the short term, enhance reprocessing of ERCP scopes; reprocess duodenoscopes by double HLD
- Microbiologic surveillance, 5-10% of scopes monthly
- When new recommendations are available from ASGE, CDC, FDA, etc. comply

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)

Long-Term Response To ERCP Outbreaks

To protect the public health we (FDA, industry, professional organizations) must shift duodenoscope reprocessing from HLD to sterilization.

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})

FDA Panel, May 2015, Recommended Sterilization of Duodenoscopes

(requires FDA-cleared sterilization technology that achieves a SAL 10^{-6} with duodenoscopes- not yet available)

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.

NONCRITICAL -objects that touch only intact skin require low-level disinfection (or non-germicidal detergent).

Some Potential Sterilization Technologies for Duodenoscopes

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

- Optimize existing low-temperature sterilization technology
  - Hydrogen peroxide gas plasma
  - Vaporized hydrogen peroxide
  - Ethylene oxide
  - Ozone plus hydrogen peroxide vapor
- Potential new low-temperature sterilization technology
  - Nitrogen dioxide
  - Supercritical CO_2
  - Peracetic acid vapor
- Steam sterilization for heat-resistant GI endoscopes
- Redesign
- Sterile, single-use GI scopes

LTS Technology Is Being Optimized to Sterilize Endoscopes and Use a Sterile, Disposable GI Scopes

(disposable scope must have acceptable diagnostic and therapeutic capabilities)

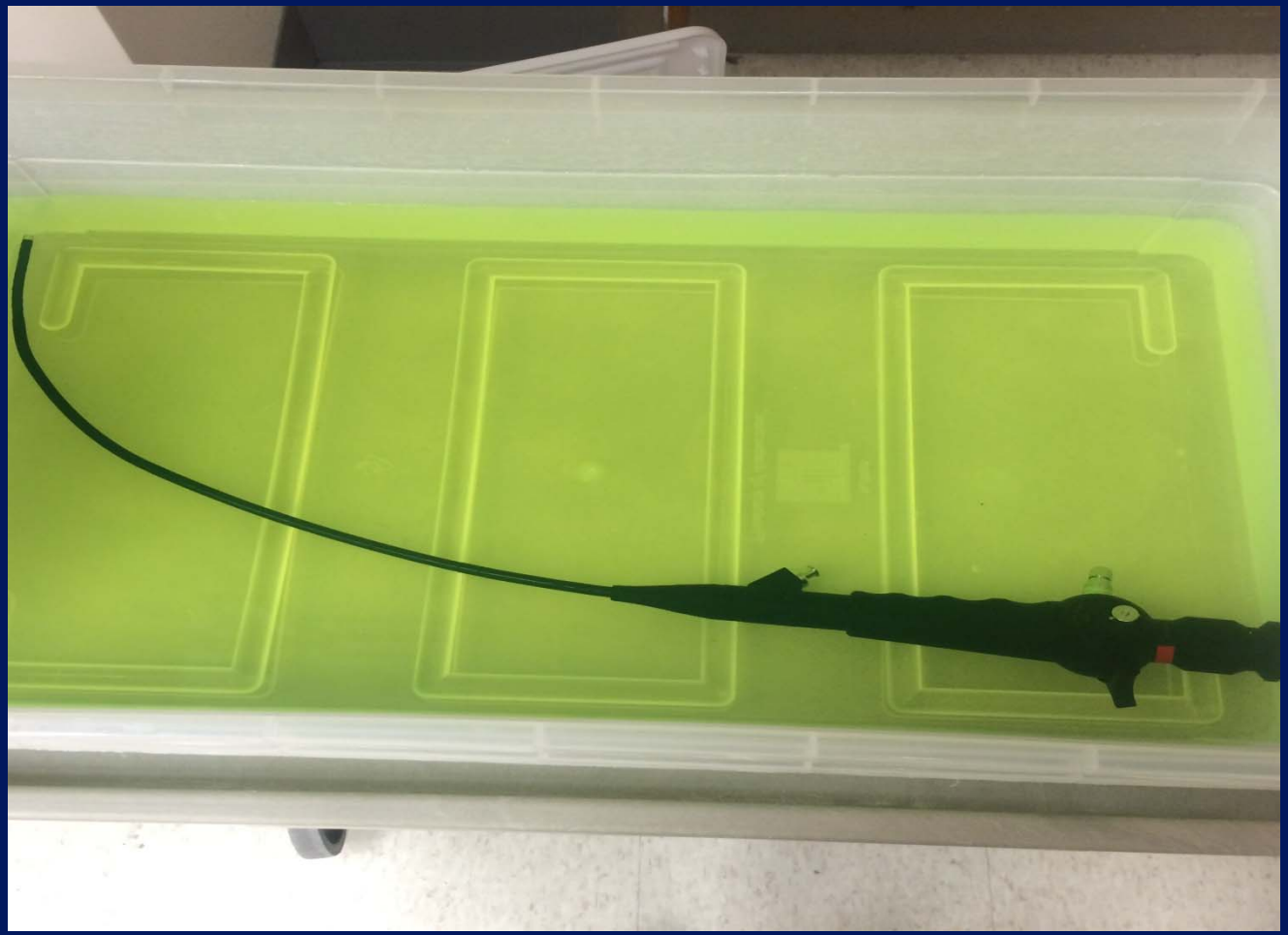
True Cost of Reprocessing Endoscope

Ofstead et al. Communique. Jan/Feb 2017

$114.07-$280.71

Reprocessing Channeled Endoscopes

Cystoscope- “completely immerse” in HLD (J Urology 2008.180:588) but air pressure in channel stronger than fluid pressure at fluid-air interface



Reprocessing Channeled Endoscopes

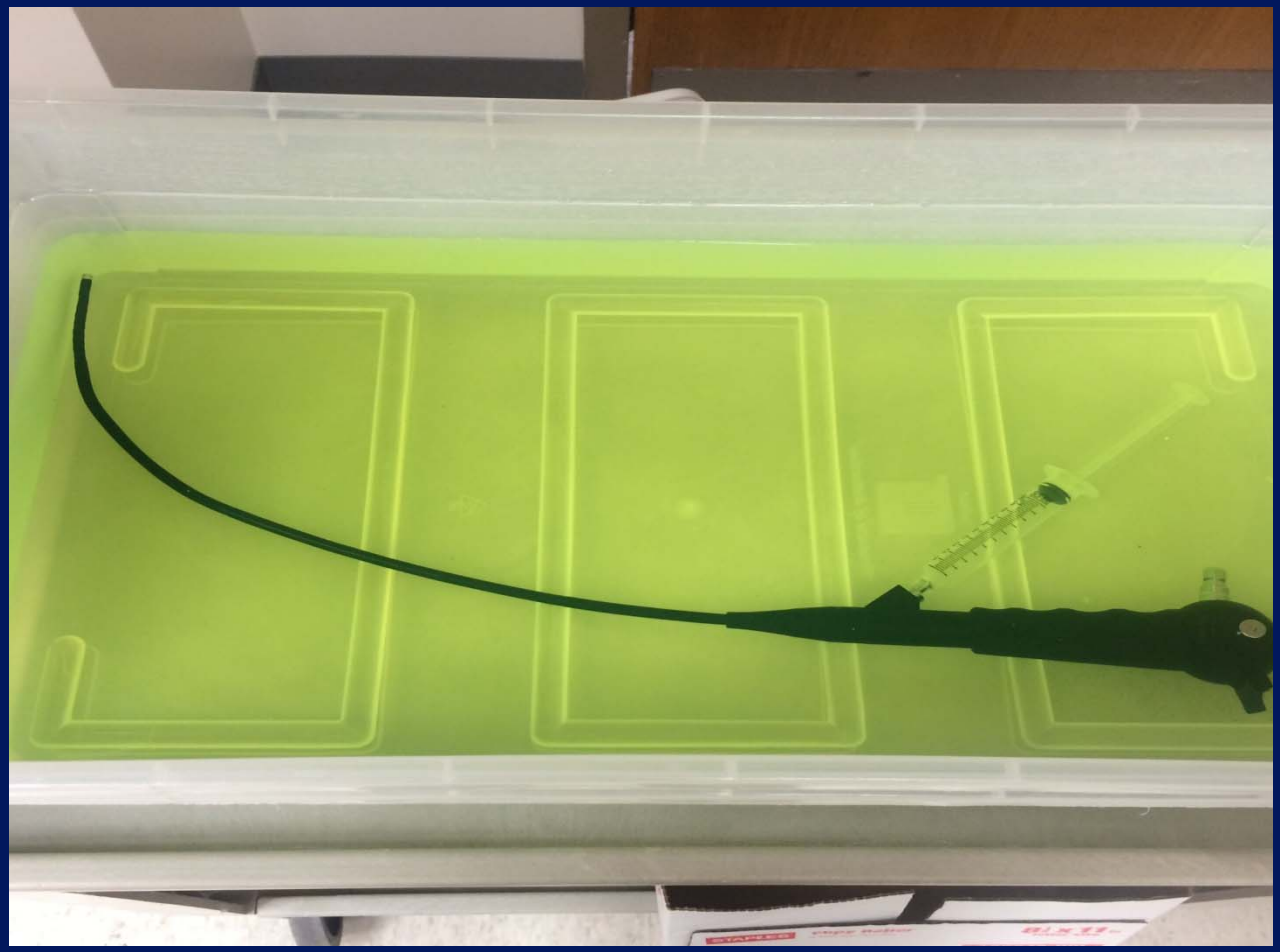
Rutala, Gergen, Bringhurst, Weber. ICHE. 2016;37:228-231

Exposure Method	CRE (*K. pneumoniae*) Inoculum before HLD (glutaraldehyde)	CRE (K. pneumoniae) Contamination after HLD
Passive HLD (immersed, not perfused)	$3.2x10^8$ $1.9x10^9$ $4.1x10^8$	$3.1x10^8$ $4.6x10^8$ $1.0x10^8$
Active HLD (perfused HLD into channel with syringe)	$3.0x10^8$ $9.2x10^8$ $8.4x10^8$	0 0 0

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

Reprocessing Channeled Endoscopes

Cystoscope-HLD perfused through lumen with syringe (luer locks onto port and syringe filled and emptied until no air exits the scope nor air in barrel of syringe-syringe and lumen filled with HLD)



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 CRE/MDR outbreaks associated with ERCP procedures
- Discuss the alternatives that exist today that might improve the safety margin associated with duodenoscope reprocessing
- Describe how to prevent future outbreaks associated with duodenoscopes and other GI endoscopes

How Will We Prevent Infections Associated with Medical Devices (HLD to Sterilization)?

- FDA Panel has accepted sterilization for duodenoscopes
- Sterilization manufacturer's are optimizing their LTST to sterilize GI endoscopes/bronchoscopes
- Sterile, single use GI endoscopes are developed
- Professional organizations (SHEA, APIC, AORN, SGNA, ASGE, IAHCSMM, AAMI) are starting to embrace conversion. Scheduled presentations on transition from HLD to sterilization with AAMI Sterilization/HLD Committees, APIC, SGNA, Canadian APIC, World Sterilization Congress
- Researchers/Opinion Leaders need to continue the science-based evaluations on why conversion is necessary

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

- Comply with endoscope reprocessing guidelines
- Implement enhanced method for reprocessing duodenoscopes. Doing nothing is not an option.
- Only when we implement new technologies (e.g., single-use sterile scopes; sterilization of GI scopes with technology that achieves an SAL 10^{-6}) will we eliminate the risk of infection

Can We Prevent All Infections Associated with Medical Devices in 5 Years?
www.disinfectionandsterilization.org

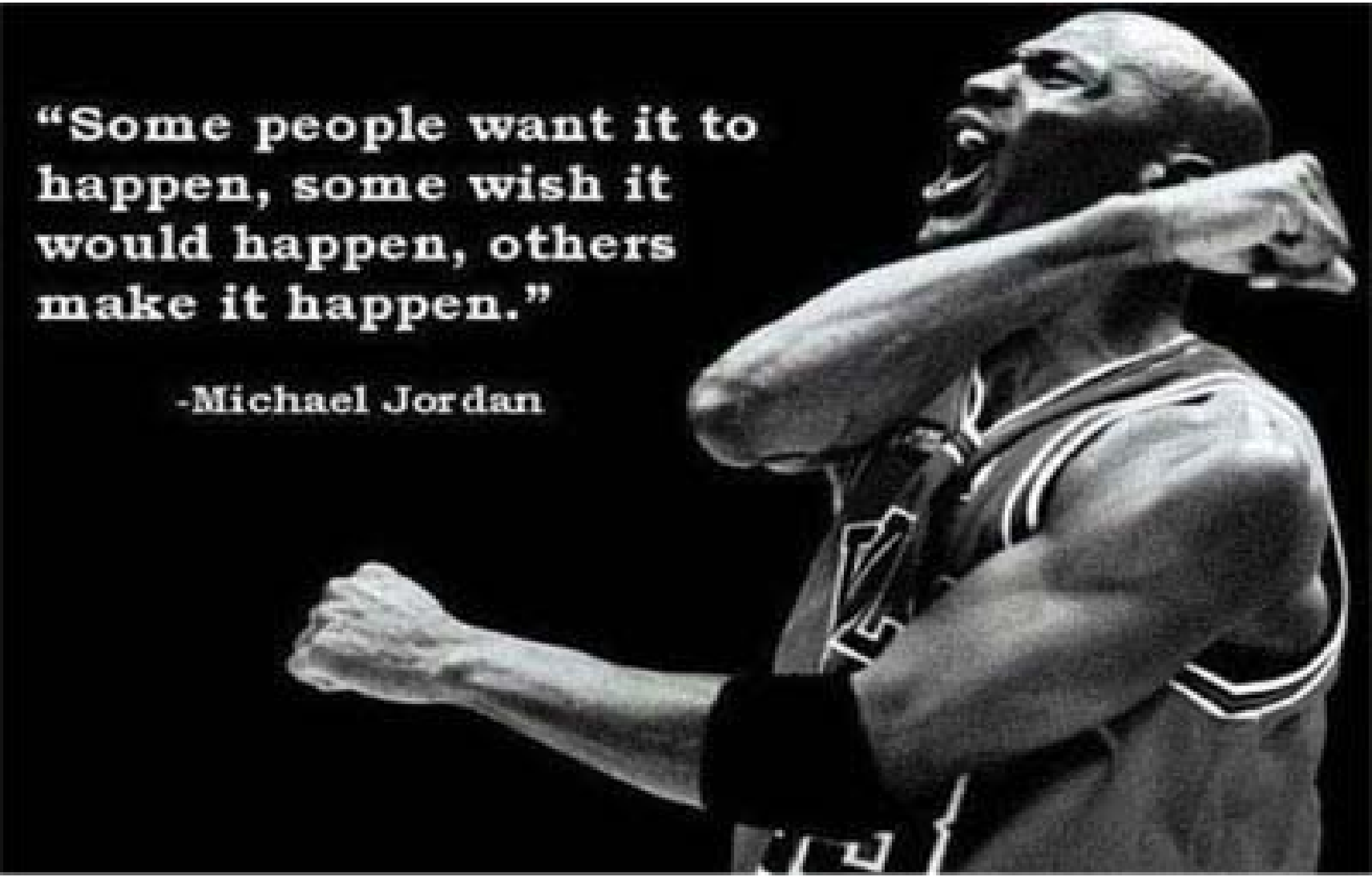
Our Responsibility to the Future

Prevent All Infectious Disease Transmission by Medical Devices in 5 years

Via Research/Technology/Automation/Competency

No Infections Associated with Instruments

Set our goal, made a plan, we have a purpose, it is our passion that will make it happen!


"Some people want it to happen, some wish it would happen, others make it happen."
-Michael Jordan

THANK YOU!

www.disinfectionandsterilization.org

Surveillance for Bacterial Contamination of Duodenoscopes after Reprocessing

www.cdc.gov

- No requirement to perform regular surveillance cultures as part of their response to the issue
- Method intended to culture bacteria from reprocessed duodenoscopes (after drying) specifically from the distal end and instrument channel
- Samples should be collected by personnel familiar with the instrument
- ASM recommends that routine duodenoscope cultures not be performed in a clinical diagnostic laboratory

MICROBIOLOGICAL CULTURES

- CDC recommendations (accessed 11 may 2015)
  - Limited information to guide the use of surveillance cultures to assess reprocessing outside of recognized outbreak settings
  - Culturing should supplement and not replace or modify manufacturer's reprocessing recommendations ("negative cultures do NOT exclude possibility of contamination")
  - Cultures should be obtained after duodenoscope reprocessed and should include at least the instrument channel and the distal end of the duodenoscope (elevator channel)
- Olympus revised disinfection (26 March 2015)
  - No mention of culturing scopes
- ASM, Laboratory Practices Committee (9 April 2015)
  - "At this time, it seems that clinical microbiology laboratories should not perform routine cultures of reprocessed duodenoscopes due to lack of data on the utility of such culturing."

Nosocomial Infections via GI Endoscopes

- Infections traced to deficient practices
  - Inadequate cleaning (clean all channels)
  - Inappropriate/ineffective disinfection (time exposure, perfuse all channels, test concentration, ineffective disinfectant, inappropriate disinfectant)
  - Failure to follow recommended disinfection practices (tapwater rinse)
  - Flaws and complexity in design of endoscopes or AERs