Gastrointestinal Endoscopes:
A Need to Shift from Disinfection to Sterilization

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Hosted by Prof. Jean-Yves Maillard
University of Cardiff, UK

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- Review the CRE/MDR outbreaks associated with ERCP procedures
- Evaluate the cause of endoscope-related outbreaks
- Discuss the alternatives 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

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"Superbug" Outbreaks

- Cedars-Sinai Medical Center, UCLA Ronald Reagan Medical Center, University of Pittsburgh Medical Center, Virginia Mason Medical Center, tertiary care facility in NE Illinois, Wisconsin medical center
- ABC, CBS, NBC, CNN, New York Times, LA Times
- Lawmakers asked Congress why the FDA "didn't move more quickly and aggressively to ensure patient safety"

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Recent Outbreaks When Manufacturer's Instructions and Professional Guidelines Followed

- Epstein et al. JAMA 2014;312:1447-1455 (NE IL)
- Wendorf et al. ICHE 2015 (Seattle)
- At least four other CRE outbreaks related to ERCP
  - UCLA Ronald Reagan Medical Center
  - Cedar Sinai Medical Center
  - Univ of Pittsburgh Medical Center
  - Wisconsin medical facility

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GI ENDOSCOPES

- Widely used diagnostic and therapeutic procedure (~20 million GI procedures annually in the US)
- 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
- In the inanimate environment, although the incidence 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.

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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	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.

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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.

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Nosocomial Infections via GI Endoscopes

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

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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)**

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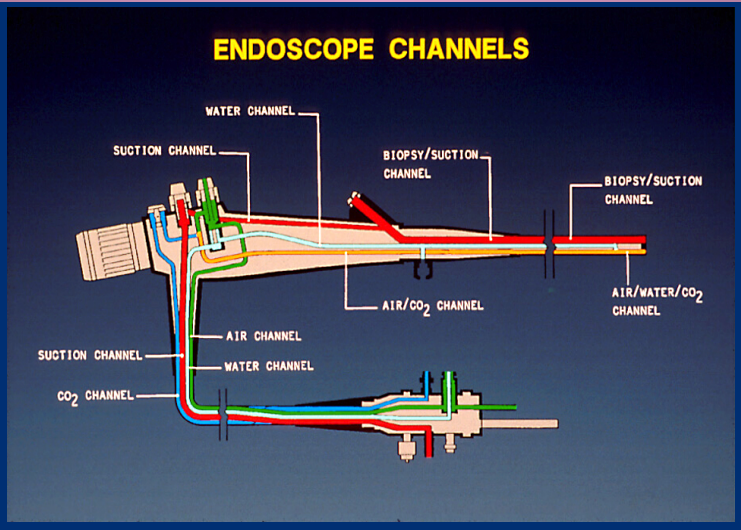
ENDOSCOPE REPROCESSING



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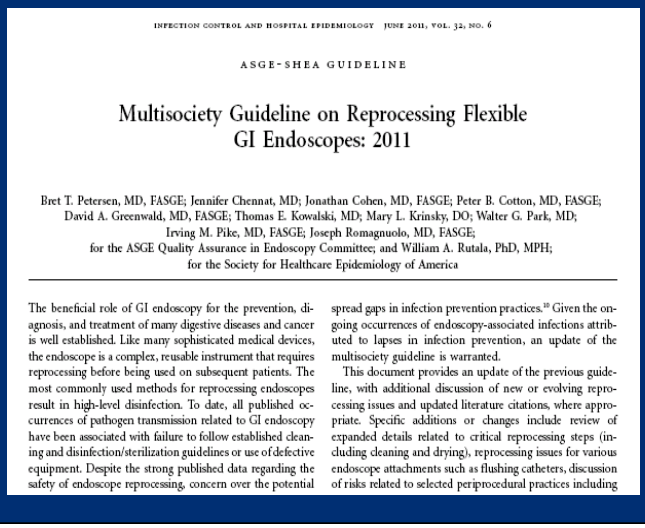
MULTISOCIETY GUIDELINE ON REPROCESSING GI ENDOSCOPES, 2011

Petersen et al. ICHE. 2011;32:527



INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY JUNE 2011, VOL. 32, NO. 6

ASGE-SHEA GUIDELINE

Multisociety Guideline on Reprocessing Flexible GI Endoscopes: 2011

Bret T. Petersen, MD, FASGE; Jennifer Chennat, MD; Jonathan Cohen, MD, FASGE; Peter B. Cotton, MD, FASGE; David A. Greenwald, MD, FASGE; Thomas E. Kowalski, MD; Mary L. Krinsky, DO; Walter G. Park, MD; Irving M. Pike, MD, FASGE; Joseph Romagnuolo, MD, FASGE; for the ASGE Quality Assurance in Endoscopy Committee; and William A. Rutala, PhD, MPH; for the Society for Healthcare Epidemiology of America

The beneficial role of GI endoscopy for the prevention, diagnosis, and treatment of many digestive diseases and cancer is well established. Like many sophisticated medical devices, the endoscope is a complex, reusable instrument that requires reprocessing before being used on subsequent patients. The most commonly used methods for reprocessing endoscopes result in high-level disinfection. To date, all published occurrences of pathogen transmission related to GI endoscopy have been associated with failure to follow established cleaning and disinfection/sterilization guidelines or use of defective equipment. Despite the strong published data regarding the safety of endoscope reprocessing, concern over the potential spread gaps in infection prevention practices.[10] Given the ongoing occurrences of endoscopy-associated infections attributed to lapses in infection prevention, an update of the multisociety guideline is warranted.

This document provides an update of the previous guideline, with additional discussion of new or evolving reprocessing issues and updated literature citations, where appropriate. Specific additions or changes include review of expanded details related to critical reprocessing steps (including cleaning and drying), reprocessing issues for various endoscope attachments such as flushing catheters, discussion of risks related to selected periprocedural practices including

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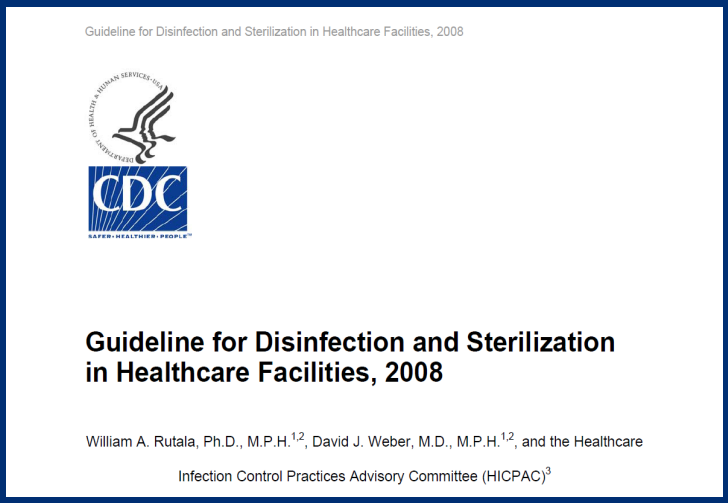
CDC Guideline for Disinfection and Sterilization

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



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ENDOSCOPE REPROCESSING

CDC 2008: Multi-Society Guideline on Endoscope Reprocessing, 2011

- PRECLEAN-point-of-use (bedside) remove debris by wiping exterior and aspiration of detergent through air/ water and biopsy channels; leak test
- CLEAN-mechanically cleaned with water and enzymatic cleaner
- HLD/STERILIZE-immerse scope and perfuse HLD/ sterilant through all channels for exposure time (>2% glut at 20m at 20°C). If AER used, review model-specific reprocessing protocols from both the endoscope and AER manufacturer
- RINSE-scope and channels rinsed with sterile water, filtered water, or tap water. Flush channels with alcohol and dry
- DRY-use forced air to dry insertion tube and channels
- STORE-hang in vertical position to facilitate drying; stored in a manner to protect from contamination

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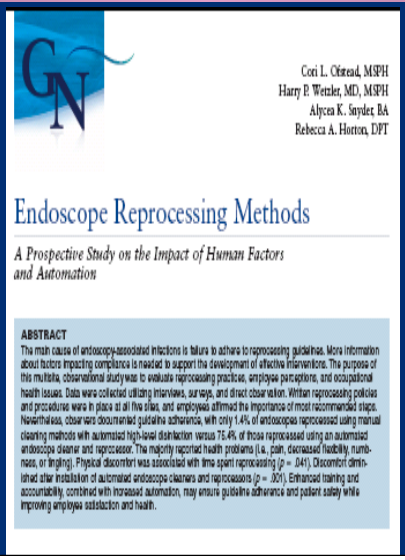
Endoscope Reprocessing Methods

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.

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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

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Automated Endoscope Reprocessors

AERs automate and standardize endoscope reprocessing steps

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

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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
- Complexity of endoscope

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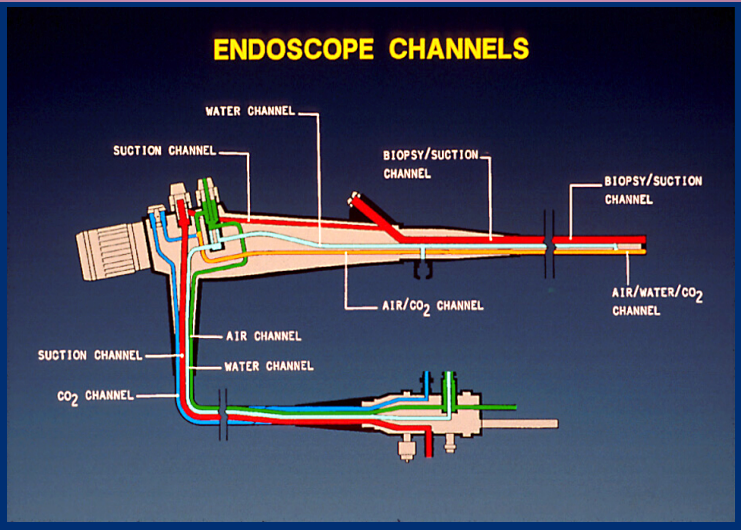
ENDOSCOPE REPROCESSING



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Bacterial Bioburden Associated with Endoscopes

	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 Gastro Endosc 1997;48:137
After cleaning	2.0	2.3
	4.8	4.3
		5.1

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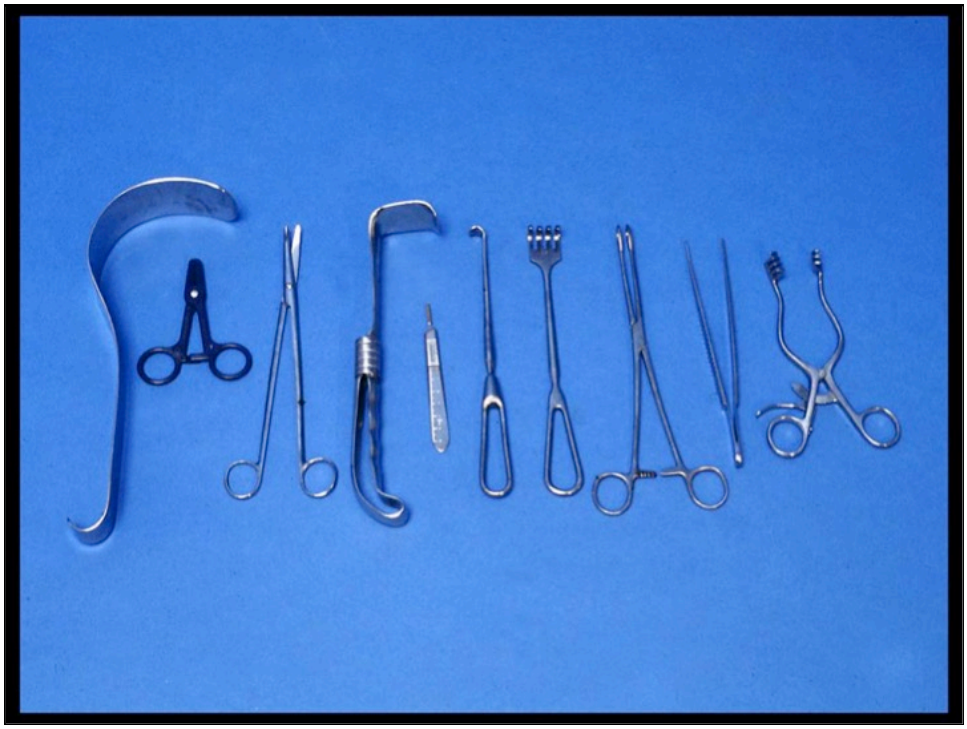

Bioburden on Surgical Devices

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 $<10^3$

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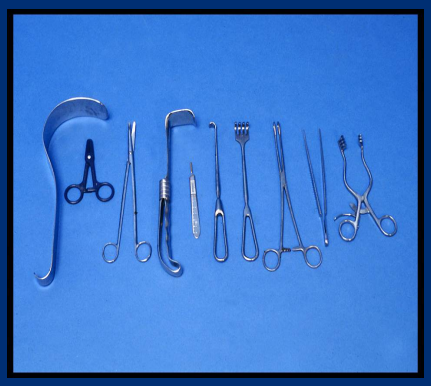
ENDOSCOPE REPROCESSING: CHALLENGES

Surgical instruments – $<10^2$ bacteria



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

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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)

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  - 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

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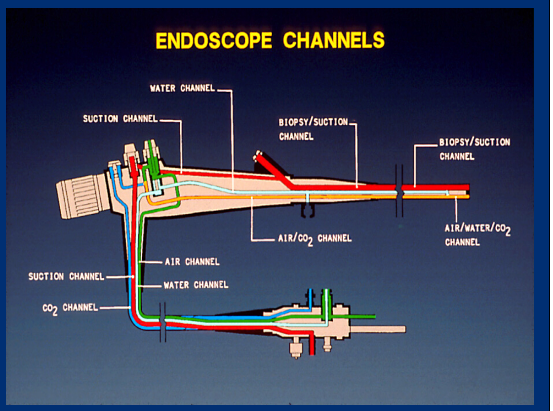
FEATURES OF ENDOSCOPES THAT PREDISPOSE TO DISINFECTION FAILURES

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



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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 at least 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
- Biofilms-unclear if contribute to failure of endoscope reprocessing

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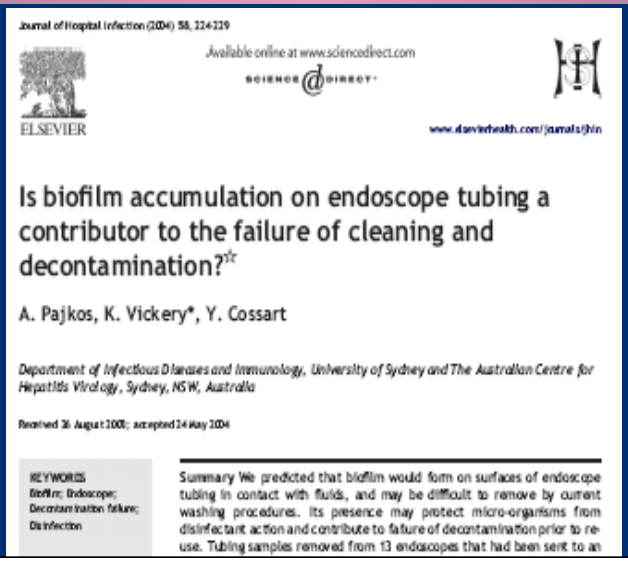
BIOFILMS

Pajkos, Vickery, Cossart. J Hosp Infect 2004;58:224



Journal of Hospital Infection (2004) 58, 224-229

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Is biofilm accumulation on endoscope tubing a contributor to the failure of cleaning and decontamination?☆

A. Pajkos, K. Vickery*, Y. Cossart

Department of Infectious Diseases and Immunology, University of Sydney and The Australian Centre for Hepatitis Virology, Sydney, NSW, Australia

Received 26 August 2003; accepted 24 May 2004

KEYWORDS
Biofilm; Endoscope; Decontamination failure; Disinfection

Summary We predicted that biofilm would form on surfaces of endoscope tubing in contact with fluids, and may be difficult to remove by current washing procedures. Its presence may protect micro-organisms from disinfectant action and contribute to failure of decontamination prior to re-use. Tubing samples removed from 13 endoscopes that had been sent to an

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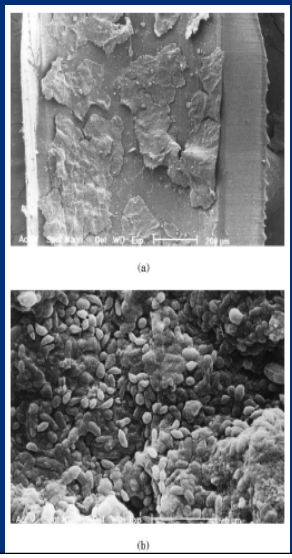
BIOFILMS

(Multi-Layered Bacteria Plus Exopolysaccharides That Cement Cell to Surface; Develop in Wet Environments)



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BIOFILMS

- Bacteria residing within biofilms are many times more resistant to chemical inactivation than bacteria in suspension
- Does formation of biofilms within endoscopic channels contribute to failure of decontamination process? Not known
- In addition to complexity and microbial load, a biofilm could contribute to failure of adequate HLD processes but if reprocessing performed promptly after use and endoscope dry the opportunity for biofilm formation is minimal

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Why CRE/MDR? Why now? Why ERCP?

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

- Microbes that are difficult to treat because they have a high level of resistant to antibiotics
- 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 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

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Recent Outbreaks When Manufacturer's Instructions and Professional Guidelines Followed

- Presence of an unusual pathogen that resulted in an investigation and recognition that duodenoscopes were the source of the outbreak
  - Epstein et al. JAMA 2014;312:1447-1455 (NE IL)
  - Wendorf et al. ICHE 2015 (Seattle)
  - At least four other CRE outbreaks related to ERCP (Endoscopic Retrograde Cholangiopancreatography)
    - UCLA Ronald Reagan Medical Center
    - Cedar Sinai Medical Center
    - Univ of Pittsburgh Medical Center
    - Wisconsin medical facility

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Why ERCP (Endoscopic Retrograde Cholangiopancreatography)?

- More than 500,000 ERCP procedures using duodenoscopes are performed in the US annually
- Procedure is the least invasive way of draining fluids from the pancreatic and biliary ducts blocked by cancerous tumors, gallstones or other conditions
- Complex design of duodenoscopes causes challenges for cleaning and HLD. Some parts of the scope are extremely difficult to assess and effective cleaning of all areas of the duodenoscope may not be possible.

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ERCP-Related Outbreaks

- No clear breaches in reprocessing the duodenoscopes were identified by hospital staff, CDC field team and/or manufacturer of the endoscope or AER
- Hospitals adhered to manufacturer's duodenoscope and AER service schedule
- No defects or improper functioning of the duodenoscope or AER identified by the manufacturer

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What Should We Do Now?

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How Can We Prevent ERCP-Related Infections?

- 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

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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 (UNC Hospitals)
- 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

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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 • 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

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

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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

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

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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

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

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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**

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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?)**

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

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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

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

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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

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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 ERCP scopes by HLD followed for ETO sterilization
- Microbiologic surveillance, 5-10% of scopes monthly
- When new recommendations are available from ASGE, CDC, FDA, etc. comply

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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

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Surveillance for Bacterial Contamination of Duodenoscopes after Reprocessing
Questions

- What cutoff should be used to define proper disinfection (0 CFUs?)
- Should there be a separate cutoff based on relatively nonvirulent pathogens?
- If a hospital cultures 2 duodenoscopes of 4 and 1 is positive, do they reprocess all 4 duodenoscopes as 50% positive?
- If a hospital does periodic microbiologic culturing and 20% of sampled endoscopes are positive, what actions should be undertaken (e.g., patient notification with an offer of BBP testing, stool exam for CRE)?
- Trigger based on level of contamination or frequency of contamination?
- Answer: Until evidence-based guidelines, hospitals should base their decisions on best available information (e.g., clinical risk) and what is feasible.

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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)

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Gastrointestinal Endoscopes:
A Need to Shift from Disinfection to Sterilization

- Review the CRE/MDR outbreaks associated with ERCP procedures
- Evaluate the cause of endoscope-related outbreaks
- Discuss the alternatives 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

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To protect the public health we (FDA, industry, professional organizations) must shift endoscope reprocessing from HLD to sterilization. FDA should mandate that duodenoscopes (preferably all GI scopes) used in healthcare facilities be sterile.

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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})

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FDA Panel, May 2015, Recommended Sterilization of Duodenoscopes

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Potential future methods to prevent GI-endoscope-related infections?

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Potential Future Methods to Prevent GI-Endoscope Related Outbreaks

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

- Steam sterilization of GI endoscopes
- New low temperature sterilization methods proving SAL 10^{-6} achieved
- Disposable sterile GI endoscopes
- Improved GI endoscope design (to reduce or eliminate challenges listed earlier)
- Use of non-endoscope methods to diagnosis or treat disease (e.g., capsule endoscopy, blood tests to detect GI cancer, stool DNA test)

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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
- Potential new low-temperature sterilization technology
  - Ozone plus hydrogen peroxide vapor
  - Nitrogen dioxide
  - Supercritical CO_2
  - Peracetic acid vapor
- Steam sterilization for heat-resistant endoscopes

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GI Endoscopes: Shift from Disinfection to Sterilization

Rutala, Weber. JAMA 2014. 312:1405-1406

EDITORIAL

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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, in collaboration with industry and infection prevention clinicians, must develop future success from past failures and pursue new prevention strategies with urgency and laser-like focus

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FDA must mandate dramatic change as it did in 1992

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HIV Transmission in Dental Settings

- First case of dentist to patient transmission; removed molars in 1987, AIDS in 1990, died in 1991
- FDA recommends that reusable dental handpieces and related instruments be heat sterilized between each patient use. September 1992

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Mandate for Sterilization

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,

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Conclusions

- Endoscopes represent a nosocomial hazard. Narrow margin of safety associated with high-level disinfection of semicritical items. Endoscope reprocessing guidelines must be strictly followed.
- AERs can enhance efficiency and reliability of HLD of endoscopes
- For hospitals performing ERCPs, implement 1 or 5 enhanced methods for reprocessing duodenoscopes. For infection prevention and medical-legal reasons, doing nothing is not an option.
- Only when we implement new technologies (LTST proving SAL 10^{-6} achieved, steam-sterilization of GI endoscopes, disposable sterile GI endoscopes, non-endoscopic methods) will we eliminate the risk of infection.

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Gastrointestinal Endoscopes: A Need to Shift from Disinfection to Sterilization
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