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

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Former Director, Hospital Epidemiology, Occupational Health and Safety Program, UNC Health Care, Chapel Hill
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


- 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 predicting the future...

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

• 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

<table>
<thead>
<tr>
<th>Scope</th>
<th>Outbreaks</th>
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<th>Pts Contaminated</th>
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<tr>
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<tr>
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<td><em>P. aeruginosa</em> (Pa)</td>
<td>152</td>
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<tr>
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<td>778</td>
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<td></td>
<td>1113</td>
<td>249</td>
<td></td>
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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

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<td>Duodenoscope</td>
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<td>Wendorf, 2015</td>
</tr>
<tr>
<td><em>K. pneumoniae</em> (OXA)</td>
<td>Duodenoscope</td>
<td>12</td>
<td>No</td>
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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

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 and semi-critical 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 (10^7-10^10 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


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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)
Reprocessing Failures Have Led to Patient Notifications and Bloodborne Pathogens Testing

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

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

ENDOSCOPE CHANNELS

- WATER CHANNEL
- SUCTION CHANNEL
- BIOPSY/SUCTION CHANNEL
- AIR/CO₂ CHANNEL
- AIR/WATER/CO₂ CHANNEL
- SUCTION CHANNEL
- WATER CHANNEL
- CO₂ CHANNEL
CDC Guideline for Disinfection and Sterilization


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, Navej 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-immersse 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
Reason for Endoscope-Related Outbreaks

• 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 $<10^2$
  - 16% contained $<5\times10^2$
  - 6% contained $<10^3$
ENDOSCOPE REPROCESSING: CHALLENGES

Complex [elevator channel] - $10^7$-$10^9$ bacteria/endoscope

Surgical instruments < $10^2$ bacteria
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

<table>
<thead>
<tr>
<th></th>
<th>Gastroscope, ( \log_{10} ) CFU</th>
<th>Colonoscope, ( \log_{10} ) CFU</th>
</tr>
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<tbody>
<tr>
<td>After procedure</td>
<td>6.7</td>
<td>8.5 Gastro Nursing 1998;22:63</td>
</tr>
<tr>
<td></td>
<td>6.8</td>
<td>8.5 Am J Inf Cont 1999;27:392</td>
</tr>
<tr>
<td></td>
<td>9.8 ( \sim10,000,000,000 ) or (10^{10})</td>
<td>10.8 Gastro Endosc 1997;48:137</td>
</tr>
<tr>
<td>After cleaning</td>
<td>2.0</td>
<td>2.3</td>
</tr>
<tr>
<td></td>
<td>4.8</td>
<td>4.3</td>
</tr>
<tr>
<td></td>
<td>5.1 ( \sim100,000 ) or (10^{5})</td>
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• Complexity of endoscope and endoscope reprocessing

• Biofilms-unclear if contribute to failure of endoscope reprocessing
FEATURES OF ENDOSCOPES THAT PREDISPOSE TO DISINFECTION FAILURES


- Heat labile
- Long, narrow lumens (3.5ft, 1-3mm)
- Right angle bends
- Rough or pitted surfaces
- Springs and valves
- Damaged channels may impede microbial exposure to HLD
- Heavily contaminated with pathogens, $10^7-10^{10}$
- 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
**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%
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

Endoscope Reprocessing Methods

A Prospective Study on the Impact of Human Factors and Automation

ABSTRACT

The main cause of endoscope-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 multi-site, 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, observatory 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 employees satisfaction and health.
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

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

AERs automate and standardize endoscope reprocessing steps
Reason for Endoscope-Related Outbreaks

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- Microbial load
  - GI endoscopes contain $10^7$-$10$
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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
Reason for Endoscope-Related Outbreaks

- 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
FEATURES OF ENDOCOPES THAT PREDISPOSE TO DISINFECTION FAILURES


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


• 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

• 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)
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
What Should We Do Now?

Interim Response to ERCP Outbreaks
## Recent Endoscopy-Related Outbreaks of MRDO Without Reprocessing Breaches

Rutala WA et al. In preparation

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


<table>
<thead>
<tr>
<th>Method</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
</table>
| 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


<table>
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<tr>
<th>Method</th>
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<th>Disadvantages</th>
</tr>
</thead>
</table>
| 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


<table>
<thead>
<tr>
<th>Method</th>
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<th>Disadvantages</th>
</tr>
</thead>
</table>
| 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)
<table>
<thead>
<tr>
<th>Method</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
</table>
| 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 |

<table>
<thead>
<tr>
<th>Method</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
</table>
| 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


<table>
<thead>
<tr>
<th>Method</th>
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<th>Disadvantages</th>
</tr>
</thead>
</table>
| 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


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• 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.
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 colleagues² 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-

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\textsubscript{10}). To prevent infections, all duodenoscopes should be devoid of microbial contamination.

HLD (6 log\textsubscript{10} reduction)

vs

Sterilization (12 log\textsubscript{10} reduction=SAL 10\textsuperscript{-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)
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).
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


• 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 CO₂
  ■ 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

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

<table>
<thead>
<tr>
<th>Exposure Method</th>
<th>CRE (K. pneumoniae) Inoculum before HLD (glutaraldehyde)</th>
<th>CRE (K. pneumoniae) Contamination after HLD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passive HLD (immersed, not perfused)</td>
<td>3.2x10^8 1.9x10^9 4.1x10^8</td>
<td>3.1x10^8 4.6x10^8 1.0x10^8</td>
</tr>
<tr>
<td>Active HLD (perfused HLD into channel with syringe)</td>
<td>3.0x10^8 9.2x10^8 8.4x10^8</td>
<td>0 0 0</td>
</tr>
</tbody>
</table>
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