Recent Outbreaks of CRE Transmission via Endoscopes: What Can We Do To Prevent Infections

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Recent Outbreaks of CRE Transmission via Endoscopes: What Can We Do To Prevent Infections

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DISCLOSURES

• Consultation
  ■ Clorox

• Honoraria (2014, 2015)
  ■ 3M, ASP

• Grants
  ■ CDC, CMS, Nanosonics
Recent Outbreaks of CRE Transmission via Endoscopes: What Can We Do To Prevent Infections

- Review the CRE/MDR outbreaks associated with ERCP procedures
- Evaluate the cause of endoscope-related outbreaks
- 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
## RECENT ENDOSCOPY-RELATED OUTBREAKS OF MRDO WITHOUT REPROCESSING BREACHES

<table>
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<tr>
<th>MDRO</th>
<th>Scope</th>
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<th>Molecular Link</th>
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<tbody>
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<td>Yes, under forceps elevator</td>
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<td><em>K. pneumoniae</em> (OXA)</td>
<td>Duodenoscope</td>
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<td>No</td>
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**Additional Outbreaks (not published; news media reports)**
- UCLA, 2015, CRE, 179 patients exposed (2 deaths), 2 colonized duodenoscopes
- CMC, 2015, CRE, 18 patients exposed (7 infected), duodenoscopes
- Cedars-Sinai, 2015, CRE, 67 patients exposed (4 infected), duodenoscopes
- Wisconsin, 2013, CRE, (5 infected), duodenoscopes
- University of Pittsburgh, 2012, CRE, 9 patients, duodenoscopes
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 sterile 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

Healthcare facilities should arrange for training sessions to review and demonstrate the critical steps of the reprocessing process.
Health Care Facilities Need to Immediately 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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<thead>
<tr>
<th>Scope</th>
<th>Outbreaks</th>
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<th>Pts Contaminated</th>
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</tr>
<tr>
<td>ERCP</td>
<td>23</td>
<td><em>P. aeruginosa</em> (Pa)</td>
<td>152</td>
<td>89</td>
<td>C/D, water bottle, AER</td>
</tr>
<tr>
<td>Bronchoscopy</td>
<td>51</td>
<td>Pa, Mtb, Mycobacteria</td>
<td>778</td>
<td>98</td>
<td>C/D, AER, water</td>
</tr>
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<td>Totals</td>
<td>98</td>
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</table>

Based on outbreak data, if eliminated deficiencies associated with cleaning, disinfection, AER, contaminated water and drying would eliminate about 85% of the outbreaks.
Reprocessing Failures Have Led to Patient Notifications and Bloodborne Pathogens Testing

Table 1: Reprocessing Failures of Semicritical or Critical Medical Instruments Resulting in Patient Notification

<table>
<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.
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
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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
- Likely CRE acting as a “marker” or “indicator” organisms for ineffective endoscope reprocessing
- Risk of some procedures might be lower than others (colonoscopy versus ERCP where normally sterile areas are contaminated in the latter)
ENDOSCOPE REPROCESSING
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. 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...

ENDOSCOPE REPROCESSING

- **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
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 multicenter, observational study was to evaluate reprocessing practices, employee perceptions, and occupational health issues. Data were collected utilizing interviews, surveys, and direct observation. Within reprocessing policies and procedures were in place at all five sites, and employees affirmed the importance of most recommended steps. Nevertheless, observed documented guideline adherence, with only 14.4% of endoscopes reprocessed using manual cleaning methods with automated high-level disinfection versus 75.6% 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 reprocers ($p = .001$). Enhanced training and accountability, combined with increased automation, may ensure guideline adherence and patient safety while improving employee satisfaction and health.
Perform all 12 steps with only 1.4% of endoscopes using manual versus 75.4% of those processed using AER

<table>
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<th>Observed Activity</th>
<th>Steps Completed (%)</th>
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<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>
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</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>
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Automated Endoscope Reprocessors

AERs automate and standardize endoscope reprocessing steps
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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.
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
ENDOSCOPE REPROCESSING: CHALLENGES

Complex [elevator channel]-10^7-10^10 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)
Reason for Endoscope-Related Outbreaks

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• Complexity of endoscope
FEATURES OF ENDOCOPES 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
Reason for Endoscope-Related Outbreaks

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• Microbial load
  ◆ GI endoscopes contain $10^7$-$10^{10}$
  ◆ 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: 4log$_{10}$ (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)
What Should We Do Now?
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


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<th>Method</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>HLD with ETO, Microbiologic surveillance</td>
<td>• Major endoscope manufacturer offers ETO as sterilization option</td>
<td>• Requires aeration time to remove ETO residue</td>
</tr>
<tr>
<td></td>
<td>• Ideally, should be used after standard high-level disinfection</td>
<td>• Only 20% of US hospitals have ETO on-site</td>
</tr>
<tr>
<td></td>
<td>• Some data demonstrate reduced infection risk with HLD followed by ETO</td>
<td>• Lengthy cycle/aeration time</td>
</tr>
<tr>
<td></td>
<td>• Single-dose cartridge and negative-pressure chamber minimizes the</td>
<td>• No microbicidal efficacy data proving SAL 10^-6 achieved</td>
</tr>
<tr>
<td></td>
<td>potential for gas leak and ETO exposure</td>
<td>• Studies question microbicidal activity in presence of organic</td>
</tr>
<tr>
<td></td>
<td>• Simple to operate and monitor</td>
<td>matter/salt</td>
</tr>
<tr>
<td></td>
<td>• Compatible with most medical materials</td>
<td>• ETO is toxic, a carcinogen, flammable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• May damage endoscope</td>
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<td>Double HLD, Microbiologic surveillance</td>
<td>• HLD inactivate MDR organisms including CREs</td>
<td>• Based on recent ERCP outbreaks, infection risk related to device complexity and microbial load</td>
</tr>
<tr>
<td></td>
<td>• Wide availability of HLD</td>
<td>• Some HLD (e.g., aldehydes) may cross-link proteins</td>
</tr>
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<td>• A second HLD cycle may reduce or eliminate microbial contaminants remaining from first cycle</td>
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| 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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| 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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<td>• No consensus regarding sampling scheme, 100% or 10% of scopes per week/per month?</td>
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| 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>
<th>Advantages</th>
<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 |
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
To protect the public health we (FDA, industry, professional organizations) must shift duodenooscope reprocessing from HLD to sterilization.
GI Endoscopes: Shift from Disinfection 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. 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.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 (~$6\ \text{log}_{10}$). 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 technology that achieves a SAL $10^{-6}$ with duodenoscopes)
Potential future methods to prevent GI-endoscopy-related infections?
Potential Future Methods to Prevent GI-Endoscope Related Outbreaks

- 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)
Some Potential Sterilization Technologies for Duodenoscopes


- 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 CO₂
  - Peracetic acid vapor

- Steam sterilization for heat-resistant endoscopes
Other endoscope reprocessing issues
FDA Recommends HCF Transition from Custom Ultrasonics AER to Alternate AER

November 13, 2016

- Ordered Custom Ultrasonics to recall all of its AERs due to violations of federal law
- Users transition away from their use ASAP
- Applies to all Custom Ultrasonics AERs
- Custom Ultrasonics has not demonstrated that its AERs clean and disinfect endoscopes
Reprocessing Channeled Endoscopes
Cystoscope- “completely immerse” in HLD (J Urology 2008.180:588)
Reprocessing Channeled Endoscopes
Cystoscope-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)
Reprocessing Channeled Endoscopes

<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>

- 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 are perfused
- Air pressure in channel stronger than fluid pressure at fluid-air interface
Recent Outbreaks of CRE Transmission via Endoscopes: What Can We Do To Prevent Infections

- Review the CRE/MDR outbreaks associated with ERCP procedures
- Evaluate the cause of endoscope-related outbreaks
- 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
Recent Outbreaks of CRE Transmission via Endoscopes: What Can We Do To Prevent Infections

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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
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., $10^6$)
Upcoming Webinars, Safe Tables and Workshops

Webinar:
Luer Connectors: Plan Now For a Safe Transition, April 20, 2016

Safe Tables:
Patient Violence and Aggression  Lisa Terry, CHPA CPP, Director of Hospital Police and Transportation at UNC Hospitals
  • April 19, 2016 - Morganton, NC
  • April 26, 2016 - Greenville, NC

Workshops:
“it’s A Game Changer - Overcoming Action Planning Challenges”, May 10, 2016
“Second Victim Train-the-Trainer Workshop”, September 14, 2016