Gastrointestinal Endoscopes: A Need to Shift from Disinfection to Sterilization

William A. Rutala, Ph.D., M.P.H.
Director, Hospital Epidemiology, Occupational Health and Safety Program, UNC Health Care; Research Professor of Medicine, Director, Statewide Program for Infection Control and Epidemiology, University of North Carolina (UNC) at Chapel Hill, NC, USA

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

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July 23, 2015

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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“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”
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

GI ENDOSCOPEGES

- Widely used diagnostic and therapeutic procedure (~20 million GI procedures annually in the US)
- 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
- 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.
Transmission of Infection by Endoscopy

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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.

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>1,385</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 channels, test concentration, ineffective disinfectant, inappropriate disinfectant)
  - Failure to follow recommended disinfection practices (tapwater rinse)
  - Flaws and complexity in design of endoscopes or AERs

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

ENDOSCOPE CHANNELS

WATER CHANNEL
SUCTION CHANNEL
BIOPSY/SUCTION CHANNEL
AIR/WATER/CO2 CHANNEL

MULTISOCIETY GUIDELINE ON REPROCESSING GI ENDOSCOPES, 2011
Petersen et al, ICHG, 2011;32:527

The beneficial role of GI endoscopy in 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 are 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 verification guidelines on use of defective equipment. Despite the many published data regarding the safety of endoscope reprocessing, concerns over the potential spread of infection prevention practices. Over the years, a number of updates and revisions have been made to the guideline to reflect new evidence and changes in technology.
CDC Guideline for Disinfection and Sterilization


William A. Rutala, Ph.D., M.P.H.1,2, David J. Weber, M.D., M.P.H.1,2, and the Healthcare Infection Control Practices Advisory Committee (HICPAC)3

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-immersce 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

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

<table>
<thead>
<tr>
<th>TABLE 3. Documented Completion of Steps During Manual Cleaning With High-Level Disinfection Reprocessing</th>
</tr>
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<tbody>
<tr>
<td>Observed Activity</td>
</tr>
<tr>
<td>Leak test performed in clear water</td>
</tr>
<tr>
<td>Disassemble endoscope completely</td>
</tr>
<tr>
<td><strong>Brush all endoscope channels and components</strong></td>
</tr>
<tr>
<td>Immerse endoscope completely in detergent</td>
</tr>
<tr>
<td>Immerse components completely in detergent</td>
</tr>
<tr>
<td>Flush endoscope with detergent</td>
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Automated Endoscope Reprocessors

AERs automate and standardize endoscope reprocessing steps

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- Describe how to prevent future outbreaks associated with duodenoscopes and other GI endoscopes

Reason for Endoscope-Related Outbreaks


- Margin of safety with endoscope reprocessing is minimal or non-existent for two reasons:
  - 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
  - Complexity of endoscope
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ENDOSCOPE REPROCESSING

Bacterial Bioburden Associated with Endoscopes

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<th>Gastroscope, log_{10} CFU</th>
<th>Colonoscope, log_{10} CFU</th>
</tr>
</thead>
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<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>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></td>
<td>5.1</td>
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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 $<10^2$
  - 16% contained $<5 \times 10^2$
  - 6% contained $<10^3$
ENDOSCOPE REPROCESSING: CHALLENGES

Complex [elevator channel] - \(10^7-10^8\) bacteria

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)

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Reason for Endoscope-Related Outbreaks


- Margin of safety with endoscope reprocessing minimal or non-existent for two reasons:
  - Microbial load
    - GI endoscopes contain $10^7-10^9$
    - Cleaning results in a 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

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, $10^7-10^9$
- 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


- **Margin of safety with endoscope reprocessing minimal or non-existent for at least two reasons:**
  - **Microbial load**
    - GI endoscopes contain $10^7-10^9$ (reduction in 2-6 log$10$)
    - 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**

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

Is biofilm accumulation on endoscope tubing a contributor to the failure of cleaning and decontamination?26

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

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

Keywords: Biofilm; Endoscope; Disinfection; antimicrobial; Decontamination

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 microorganisms from disinfectant action and contribute to failure of decontamination prior to reuse. Tubing samples removed from 15 endoscopes that had been sent to an...
BIOFILMS

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

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.
Why CRE/MDR? Why now? Why ERCP?

Carbenemase-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 Enteriobacteriaceae, 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
## 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

## 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.
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?

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 (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

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

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<th>Disadvantages</th>
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| 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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<td>• Based on recent ERCP outbreaks, infection risk related to device complexity and microbial load</td>
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<td>• Wide availability of HLD</td>
<td>• Some HLD (e.g., aldehydes) may cross-link proteins</td>
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<td>• A second HLD cycle may reduce or eliminate microbial contaminants remaining from first cycle</td>
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<td></td>
<td>• Microbiologic surveillance offered as supplement by CDC</td>
<td>• Sensitivity of microbiologic surveillance unknown</td>
</tr>
<tr>
<td></td>
<td>• Data demonstrate reduced infection risk</td>
<td>• 48-72 hours before culture results known</td>
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<td>• No cutoff to define effective disinfection</td>
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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 |
| 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?) |
### Summary of Advantages and Disadvantages of HLD and Sterilization Enhancements for Reprocessing Duodenoscopes


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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 |
| 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 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

Surveillance for Bacterial Contamination of Duodenoscopes after Reprocessing

- 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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Survey 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.

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 log10 CFUs/cm² or 10⁶ CFUs per endoscope
● Thus, an endoscope assessed as clean using ATP could still have a significant microbial load (e.g., 10⁶)
Gastrointestinal Endoscopes: A Need to Shift from Disinfection to Sterilization
Prof. William Butala, University of North Carolina
A Webber Training Teleclass

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

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.

Hosted by Prof. Jean-Yves Maillard, University of Cardiff, UK
www.webbertraining.com
What Is the Public Health Benefit?
No ERCP-Related Infections

Margin of Safety—currently nonexistent; sterilization will provide a safety margin (~6 log₁₀). To prevent infections, all duodenoscopes should be devoid of microbial contamination.

HLD (6 log₁₀ reduction)

vs

Sterilization (12 log₁₀ reduction=SAL 10⁻⁶)

FDA Panel, May 2015, Recommended Sterilization of Duodenoscopes
Potential future methods to prevent GI-endoscope-related infections?

- 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

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GI Endoscopes: Shift from Disinfection to Sterilization

More than 10 million gastrointestinal endoscopic procedures are performed annually in the United States for diagnostic purposes, therapeutic interventions, or both. Because gastrointestinal endoscopic contact mucosal surfaces, use of a contaminated endoscope may lead to patient-to-patient transmission of potential pathogens with a subsequent risk of infection.

In this issue of JAMA, Epstein and colleagues1 report findings from the 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 patients were infected with NDM-1 E. coli. The remaining infections were subsequently traced to the use of another NDM-1 E. coli–infected endoscope. The outbreak was stopped after these endoscopes were promptly removed from use and all personnel were trained on their proper reprocessing.

First, endoscopes are semicritical devices, which contact mucous membranes or nonintact skin, and require at least high-level disinfection. 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. 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. 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

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

Mandate for Sterilization

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 be heat sterilized between each patient use. A recent report indicates that a dentist, who performed dental procedures on a patient in 1987, later died from AIDS in 1991. The patient had been infected with HIV through dental procedures. The FDA recommends that all reusable dental handpieces and related instruments be heat sterilized between each patient use.

Sincerely,

[Signature]

[Department of Health & Human Services]

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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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THANK YOU!
www.disinfectionandsterilization.org

Coming Soon

August 13 ASSESSING THE IMPACT OF AN EDUCATIONAL INTERVENTION ON VENTILATOR-ASSOCIATED PNEUMONIA
Prof. Arti Kapil, All India Institute of Medical Sciences, New Delhi, India

September 3 (Free South Pacific Teleclass – Broadcast live from the 2015 IPCNC New Zealand Conference)
IS MANDATORY INFLUENZA VACCINATION FOR HEALTHCARE WORKERS THE BEST WAY TO PROTECT OUR PATIENTS?
Dr. Michael Gardam, University Health Network, Toronto
Sponsored by Johnson & Johnson (www.jnjnz.co.nz)

September 17 CAN ENERGY MANAGEMENT BENEFIT INFECTION PREVENTION?
Andrew Streifel, University of Minnesota

September 28 (Free British Teleclass ... Broadcast live from the 2015 IPS conference)
E.M. COTTRELL LECTURE
Carole Fry, Healthcare Infection Society

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