Infection Control and Safety In Endoscopy: Guidelines and Standards

CRE Infections in Endoscopy: What Happened and What Now?
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Infection control and safety in endoscopy
• > 20 million endoscopies performed annually in US
• 668,000 ERCPs annually in US
  • Vast majority with therapeutic intent
  • Proportion of ERCPs that are therapeutic has increased greatly since introduction of EUS and MRCP, and continues to rise

Table 5. Age-Adjusted ERCP Rate in Diagnostic Versus Therapeutic Cases From 1988–2002

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Diagnostic ERCP</th>
<th>Therapeutic ERCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>Female</td>
<td>Male</td>
</tr>
<tr>
<td>1999-00</td>
<td>35.66 (32.56–38.76)</td>
<td>43.18 (40.02–46.35)</td>
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<tr>
<td>1995-96</td>
<td>33.50 (30.70–36.42)</td>
<td>37.24 (34.59–39.89)</td>
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<tr>
<td>2000-02</td>
<td>29.06 (26.31–31.42)</td>
<td>29.26 (27.26–31.35)</td>
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Infection control and safety in endoscopy: we must be doing something right...

• Given millions of procedures performed annually, flexible gastrointestinal endoscopy and guidelines for reprocessing have produced a remarkable safety record in the infection control arena
  • Frequency of transmission of infection in GI endoscopy: 1 in 1.8 million – 1 in 6 million endoscopic procedures
  • Usually due to lapses in adherence to accepted protocols and manufacturer’s instructions

• But...recent issues arising in a small sector of endoscopy have provided a valuable wake-up call for us to reassess our cleaning and reprocessing algorithms and techniques, and to adhere to them


What’s changed recently, and why?

• Increased worldwide use of broad spectrum antibiotics has led to continued evolution of drug-resistant bacteria

• Hospital inpatient populations have evolved
  • Sicker
  • Older
  • Greater cumulative comorbidities
  • Increased need for more invasive and minimally-invasive procedures
  • Increased need for vigilance and greater reporting compliance in endoscopy-related, and other, infections
Endoscopic infection control and safety: how to think about it

- Hospital/institutional infection control and safety
- Endoscopy unit infection control and infection safety
  - Admission and recovery areas
  - Procedure rooms
  - Reprocessing facilities
  - Drying / storage / handling processes

The path taken by your endoscope

- Endoscope use in procedure
  - Procedure
  - Immediate POC cleaning/aspiration
  - Transport of endoscope to reprocessing area
- Reprocessing
  - Preparation for AER or ETO sterilizer
    - Manual cleaning, channel brushing, channel flushing
    - Leak testing
    - AER or ETO
- Post-processing / storage
  - Drying cabinet
- Handling
  - Each step is meticulously described by manufacturers’ instructions and guidelines from multiple agencies, societies, and organizations
Endoscope infection control lexicon

- **AER** Automated endoscope reprocessor
- **HLD** High-level disinfection
- **LCS** Liquid chemical sterilant
- **ETO** Ethylene oxide (also EtO, EO)
- **POC** Point of care
- **MDR** Multi-drug resistance
- **CRE** Carbapenem-resistant enterobacteraiceae

Infection control and safety in perspective: *part of the procedure*

- Maintenance of effective infection control is a crucial component of safety in endoscopy
- Infection control starts and ends in the procedure room
  - Observation of general infection control principles in preprocedure, procedure, and post-procedure areas
  - Safe injection practices
  - Meticulous endoscope reprocessing
- Proper reprocessing of endoscopic equipment is a crucially important part of every procedure
Infection control and safety: what the CDC says we should do

• Use personal protective equipment
  • Barrier protection
  • Mask, eye protection, or face shield
  • Gowns
• Proper injection practices
  • Proper use of vials, needles, syringes, tubing, connectors
  • Aseptic technique
• Endoscope reprocessing
  • Adherence to reprocessing guidelines for endoscopes, accessories, general medical equipment


How do reprocessing failures occur?

• Procedural errors in cleaning and disinfecting
  • Retained organisms in and on the endoscope
• Inappropriate solutions or insufficient exposure time to solutions
• Improper operation of AER
• Contaminated water bottles and irrigant solutions
• Inadequate drying and improper handling/storage of endoscopes post-reprocessing

What is CRE?

- Carbapenems
  - β-lactam antibiotics
  - Bactericidal, binding to penicillin-binding protein to inhibit cell-wall synthesis
  - High affinity to PBPs; highly stable against β-lactamases
  - Broader spectrum of activity than penicillins and cephalosporins; mainly gram negative with some and variable gram positive coverage
  - Examples: imipenem, meropenem, ertapenem, doripenem, [panipenem, biapenem]
- Increasing rates of resistance to carbapenems
  - CRE are MDR bacteria resistant to carbapenems
  - Produce β-lactamases that hydrolyze carbapenems
  - Other mutations exploit other mechanisms and vulnerabilities to confer carbapenem resistance

What happened that brought CRE into the endoscopic spotlight?
2013 Chicago CRE outbreak

- Largest in US
- 10 patients infected; 28 colonized
- Investigated by CDC; reported in MMWR Jan 2014
- Stated that while scopes implicated in transmission (duodenoscopes) were particularly challenging to reprocess
- “If performed in strict accordance with the endoscope manufacturer’s labeling, supplemented as needed with professional organizations’ published guidelines, current practices for reprocessing GI endoscopes, which include high-level disinfection, are reportedly adequate for the prevention of transmission of CRE and their related superbugs”

Exactly what are these guidelines?

2013 Chicago CRE outbreak

- CDC did not identify any reprocessing protocol breaches during its investigation of the Chicago hospital’s outbreak
- However, independent (CMS) inspection of this hospital’s infection control practices found them not to be consistent with the recommendations of the manufacturer
  - Did not use the recommended type of brush or detergent
  - Outbreak involved use of 3 different endoscopes of the same model
  - At least 2 of the 10 infected patients died
- CDC further reported that duodenoscope’s complex design might pose a particular challenge to cleaning and disinfection
What are the current major guidelines?

**US Government**
- FDA
  - Safety communication February 19, 2015
  - Update March 4, 2015
  - References
    - Multisociety Guidelines 2011
    - SGNA Guidelines
- FDA Executive Summary from May 14-15, 2015 meeting of Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee
  - References CDC Interim Protocol above, and March 2015 Reprocessing Guidance

**Societal; Foreign**
- ASGE
  - 2011 Multisociety Reprocessing Guideline
  - 2008 Infection Control Guideline
- SGNA
  - 1996; revised 2012
  - 2013 HLD and sterilants
- AORN endorsement of 2011 ASGE-led Multisociety Guideline
- GESA (Australian) 2010
- ESGE / ESGENA (European) 2007
- Public Health Agency of Canada 2010

FDA Safety Communication
February 19, 2015

• FDA wishes to “raise awareness” amongst healthcare professionals
  • FDA had received 75 medical device reports encompassing 135 US patients related to possible microbial transmission from reprocessed duodenoscopes
  • Complex design of duodenoscopes may impede effective reprocessing
    • One step of manual cleaning instructions is to brush the elevator area
    • Moving parts of the elevator contain microscopic crevices that may not be reached with a brush
    • Residual body fluids and organic debris remain in crevices after cleaning and HLD
    • If this material contains microbial contamination, subsequent patients may be exposed to serious infection
  • MDR bacterial infections have been associated with properly reprocessed duodenoscopes following manufacturers’ instructions
  • Meticulous cleaning prior to HLD should reduce infection transmission risk, but may not entirely eliminate it


FDA Safety Communication
February 19, 2015

• Recommendations for facilities and staff that reprocess duodenoscopes
  • Follow all manufacturer instructions for cleaning and processing strictly and closely
    • FDA recommends adherence to reprocessing guidelines and practices established by infection control community and endoscopy professionals, specifically referencing:
      • 2011 ASGE / Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes
      • 2012 SGNA Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes
      • 2011 FDA Draft Document: Reprocessing of Reusable Medical Devices
      • 2009 FDA Safety Communication: Preventing Cross-Contamination in Endoscope Processing
    • FDA notes benefit of using cleaning devices not specified in the manufacturer’s instructions is not known (brushes, channel flushing aids and cleaning agents)
  • Report problems with reprocessing the device to the manufacturer and to the FDA
FDA Safety Communication
February 19, 2015

• Recommendations for facilities and staff that reprocess duodenoscopes
  • Recommended these best practices
    • Clean elevator mechanism and recesses surrounding elevator mechanism meticulously by hand, even when using an AER. Raise and lower elevator throughout manual cleaning process to allow brushing of both sides
    • Implement a comprehensive quality control program for reprocessing duodenoscopes
      • Program should include written procedures for monitoring training and adherence to the program, and documentation of equipment tests, processes, and quality monitors used during the reprocessing procedure
    • Refer to the 2011 ASGE / Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes consensus document for evidence-based recommendations for endoscope reprocessing

FDA Safety Communication
February 19, 2015

• Recommendations for health care providers
  • Inform patients of benefits and risks associated with ERCP
  • Discuss with patients what they should expect following ERCP and what symptoms should prompt additional follow-up
  • Thoroughly disinfect duodenoscopes between uses, and have in place a comprehensive quality program for reprocessing
  • If a duodenoscope is suspected of being associated with a patient infection following ERCP, take it out of service and meticulously disinfect it until verified to be free of pathogens
  • Submit a report to manufacturer and to FDA if you suspect that problems with reprocessing a duodenoscope have led to patient infections
FDA Executive Summary May 2015: Emphasis on proper process; less on outcome measures without adequate evidence basis

- 2013: CDC conducted investigation of CRE outbreak in Illinois related to reprocessing of duodenoscopes with no clear breaches in protocol
- Some user facilities that had a CRE outbreak began conducting routine culturing of duodenoscopes to ensure proper reprocessing
- Since routine culturing of reprocessed duodenoscopes was not currently recommended in the US guidelines, the topic of culturing was discussed at the CDC Healthcare Infection Control Practices Advisory Committee (HICPAC) public meeting in July 2014
- Although it was recognized that routine surveillance culturing of duodenoscopes is performed in other countries such as Australia and parts of Europe, HICPAC did not recommend routine surveillance culturing in the U.S., instead recommending further research to clarify culturing methodology and interpretation of results
- CDC responded to HICPAC by further refining surveillance culturing protocols for duodenoscopes with FDA and other stakeholder input and on March 11, 2015, released an interim protocol for duodenoscope surveillance culturing
- CDC has stated there is limited information to guide use of surveillance cultures to assess endoscope reprocessing outside of recognized outbreak settings, and that surveillance of cultures is not replacement for appropriate training and oversight of endoscope reprocessing practices

From FDA Executive Summary, May 14-15, 2015 meeting of Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee:

“The FDA believes health care facilities that use duodenoscopes, especially those that have experienced infections associated with these devices, should assess whether they have the expertise, training, and resources to implement the CDC’s recommended surveillance protocol as part of their institutional infection control program.”
There is currently very limited information to guide the use of surveillance cultures to assess endoscope reprocessing outside of recognized outbreak settings.

Surveillance cultures are not a replacement for appropriate training and oversight of endoscope reprocessing practices.

Before initiating surveillance cultures, facilities considering their use should involve key facility staff, including the clinical laboratory director, clinical staff, infection prevention staff, hospital epidemiologists, and risk management staff to develop a plan for implementation, and response (e.g., patient notification) to surveillance culture results.

This document is intended to supplement and not replace or modify manufacturer recommended reprocessing procedures. This is an interim protocol and measures outlined below may change as new information becomes available.


 CDC Interim Surveillance Protocol

Testing duodenoscope after 60 ERCP procedures or once a month

- Test duodenoscope and consider holding the instrument until culture thresholds available.
- Culture method options:
  - (A) Pre-enrichment by enrichment or (B) Quantitative

Positive

Low-concern organisms
- Examples: Corynebacterium species, Bacillus spp., and other gram-positive rods
  - Culture Method: Enrichment
    1. Reprocess and culture again
    2. Do not return to circulation until cultures are negative or are below acceptable levels of low-concern organisms

Positive

High-concern organisms
- Examples: Staphylococcus aureus, Enterococcus spp., Streptococcus spp., Pseudomonas aeruginosa, Acinetobacter spp., and other antibiotic-resistant bacteria
  - Culture Method: Quantitative
    1. Reprocess and culture again
    2. Do not return to circulation until cultures are negative or are below acceptable levels of low-concern organisms
    3. Consider notification of patients exposed to duodenoscope since last negative cultures

If cultures are repeatedly positive (2 times or more) for either any high-concern organism or ≥10 CFU/duplicate duodenoscope, re-examine and re-evaluate their culture technique and send the duodenoscope to the manufacturer for evaluation.

CDC Interim Surveillance Protocol


March 2015 FDA Reprocessing Guidance

Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

Guidance for Industry and Food and Drug Administration Staff

Document issued on: March 17, 2015


The draft of this document was issued on May 2, 2011.
Key differences between 1996 and 2015 FDA reprocessing guidance

1. SCOPE – 1996 Guidance focused on reprocessing instructions/labeling; current guidance has added focus on validation of the instructions, including methodology and impact of design on ability to adequately reprocess a reusable medical device.

2. METHODS – Current guidance focuses on reprocessing validation. 1996 guidance provided an outline of reprocessing validation steps in an appendix; current guidance provides comprehensive discussion of validation in three sections of the guidance including specific recommendations and detailed examples.

3. METHODS – Current guidance introduces human factors, and provides recommendations regarding human factors in developing reprocessing instructions.

4. METHODS – Current guidance discusses "extended cycles," sterilization cycles that deviate from those found on FDA-cleared sterilizers (e.g., longer exposure times and higher temperatures). To complement FDA's recommendations, current guidance includes an Appendix outlining "Examples of Sterilization Cycles used in Health Care Settings" to provide better clarity regarding compatibility of reprocessing instructions with existing FDA-cleared reprocessing equipment.

5. METHODS – Current guidance provides more detailed recommendations regarding use of cleaning and lubricating agents, visual inspection, and drying which were not addressed in 1996 guidance. More detailed information regarding disassembly/reassembly instructions is also provided.

6. DOCUMENTATION – Current guidance more clearly describes expectations for 510(k) review of reprocessing validation information or reprocessing instructions. Current guidance also clearly states that validation of the reprocessing instructions should be completed prior to submission of a 510(k). The 1996 guidance outlined situations in which the reprocessing instructions may not be validated prior to 510(k) submission.

From FDA Executive Summary, May 14-15, 2015 meeting of Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee:

External guidelines and resources referenced by FDA


Conclusion

- Guidelines on safety and infection control in endoscopy are likely to be in substantial flux for the foreseeable future
  - Agencies and investigators awaiting more specific information and clarity regarding causality
  - Further time is required for comparative study between various HLD and sterilization processes before robust evidence-based recommendations can be made
  - Manufacturers will need to respond in kind to study endoscope design with specific aims toward mitigating infection risks posed by elevator and elevator cable design, and other design elements that may be implicated as further study nets additional specific information
In the meantime, endoscopy units, particularly those in hospitals, will need to 1) adopt and adhere meticulously to, and 2) reassess their reprocessing practices to assure adherence to

- All components of the FDA warning which was developed with input of ASGE
- Manufacturer’s specific instructions for endoscope use, POC cleaning, reprocessing, and post-reprocessing handling and storage

- Implement a quality control program for reprocessing duodenoscopes according to FDA recommendations
  - Re-educate leadership and key staff
  - Review the training program and have documented procedures for monitoring training
  - Documentation of strict adherence to the quality control program
  - Perform and document competency assessments at regular intervals

- Stay tuned closely for expected, impending, and likely iterative changes to the various interim recommendations made in guidelines, CDC, and FDA communications