



Transmission of CRE bacteria through Endoscopic Retrograde Cholangiopancreatography (ERCP)

Interim Guidance

NOTE: This document was distributed on 3/17/2015. It is subject to change and may be updated as new evidence or information arises. Please watch communications from ASGE and visit www.ASGE.org regularly.

Patient safety is a primary concern for ASGE. Transmission of multi-drug resistant bacteria, such as carbapenem-resistant enterobacteriaceae (CRE), through ERCP has been reported by multiple sites across the country. The ASGE contributed to the safety communication issued on February 19, 2015 by the FDA which stated that “the complex design of ERCP endoscopes (also called duodenoscopes) may impede effective reprocessing.” Further, that “meticulously cleaning duodenoscopes prior to high-level disinfection should reduce the risk of transmitting infection, but may not entirely eliminate it.”

Patients must continue to have access to this important and potentially life-saving procedure. ASGE physician members perform the vast majority of ERCPs across the country. Although simple answers to this complex problem are not readily available, we must take steps to ensure ongoing patient safety. The following guidance provides practical steps endoscopy unit directors can take at this time to help ensure continued patient safety.

ASGE’s Interim Guidance for all units that use duodenoscopes and other instruments with an elevator mechanism.

1. Review and adopt the guidance provided by the FDA on February 19, 2015.
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm>
2. Review the interim guidance provided by the CDC on March 12, 2015.
 - a. Interim Duodenoscope Surveillance Protocol:
<http://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html>
 - b. Interim Duodenoscope Sampling Method:
<http://www.cdc.gov/hai/settings/lab/lab-duodenoscope-sampling.html>
 - c. Interim Duodenoscope Culture Method:
<http://www.cdc.gov/hai/settings/lab/lab-duodenoscope-culture-method.html>

These CDC resources and related information can be found on this main page:
<http://www.cdc.gov/hai/outbreaks/index.html>

3. Reassess your reprocessing practices to ensure these practices are being done consistently and in accordance with manufacturer’s instructions for use.
 - a. Review your training programs and materials.
 - b. Reeducate your frontline staff about the issues specific to cleaning the elevator mechanism. Reeducation should include training sessions for all personnel involved in reprocessing. Units must ensure current reprocessing practices strictly adhere to

- manufacturers' guidance and should enlist the assistance of the manufacturer's representative, if necessary.
- c. Implement a comprehensive quality control program for reprocessing duodenoscopes and echoendoscopes that have an elevator mechanism. This should include observation by responsible education or supervisory staff, with documentation to ensure that all involved staff are performing the steps in reprocessing correctly, plus written procedures for monitoring training and adherence to the program.
 - d. Conduct and document performance and competency assessments for reprocessing now and at regular intervals. Competencies should be assessed at initiation of employee duties and at least annually and anytime a breach is identified or when a major technique or new endoscope or reprocessing equipment is introduced.
 - e. Include documentation of equipment tests, processes and quality monitors used during the reprocessing procedure.
4. All steps in reprocessing remain important and should be performed in accord with the guidance contained in the [Multisociety Guideline on Reprocessing Flexible Endoscopes](#).
 - a. Both the Multisociety Guideline and manufacturer's Instructions For Use (IFU's) provide specific guidance regarding the major elements of bedside prewashing and fluid aspiration until clear, manual washing and brushing with large volumes of water, high level disinfection, drying and appropriate storage.
 - b. For duodenoscopes and EUS endoscopes with elevators, concerted effort should be employed to meticulously clean the elevator mechanism and the recesses surrounding the elevator mechanism by hand, even when using an Automated Endoscope Reprocessor (AER). The elevator should be raised and lowered throughout the manual cleaning process to allow brushing on all sides.
 5. Units should document the specific endoscope used for each procedure to facilitate subsequent testing in the event that a patient is found to have a multi-drug resistant organism (MDRO), including CRE infections, following ERCP.
 6. Endoscopy unit directors should initiate conversations with your local institution's epidemiology or infectious disease staff, quality officers and hospital administration to better understand your local risk and to establish protocols for how you will deal with several clinical scenarios noted below, including suspected cases of post-ERCP MDRO/CRE infections.
 - a. Assess the prevalence of CRE in your institution and in your usual patient population. This may help guide your local practices relative to use of patient screening, episodic or universal endoscope culturing, or use of endoscope sterilization. Note at this time, the FDA and CDC have *not* recommended widespread screening for CRE in hospitalized patients.
 - b. Assess and consider developing your institution's ability to employ methods for avoidance or halting a problem with endoscope transmission beyond expert performance of cleaning and high-level disinfection (HLD). This evaluation should include consideration of local availability, staff resources and laboratory expertise. The methods can include:
 - i. Patient screening tools such as anal swab for culture or polymerase chain reaction (PCR) testing for CRE organisms. See CDC CRE Toolkit: http://www.cdc.gov/HAI/pdfs/labSettings/Klebsiella_or_Ecoli.pdf
 - ii. Double cycles of both washing *and* HLD after each use.

- iii. Endoscope culturing for intermittent surveillance, case investigation or per procedure application, following the CDC interim guidance for interpretation and response to culture results (see <http://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html>).
 - iv. Low temperature sterilization using ethylene oxide (ETO). ETO might be employed on an ad hoc basis for endoscopes used in MDRO/CRE positive patients, or endoscopes thought to be contaminated for MDRO/CRE. Institutions may choose to develop an intermittent or regular per procedure schedule for ETO sterilization of these instruments. Note that ETO sterilization is not widely available and there are questions about instrument durability and expense using this method. Manufacturer's guidance should be carefully reviewed and followed before employing ETO sterilization on more than occasional ad hoc basis. If there are questions regarding implementation of ETO sterilization, contact the manufacturer's representatives.
 - c. Plan how the institution will respond in the situation of a positive culture for CRE.
 - d. Follow the FDA communication regarding patient notification guidance.
7. If you suspect that problems with reprocessing a duodenoscope have led to infection or to positive results of bacterial surveillance culturing of duodenoscopes then file voluntary reports with both the manufacturer and the FDA Medwatch Safety and Adverse Event Reporting Program (<http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>)

Potential Clinical Scenarios and Possible Options for Management

Scenario A: At this time, in the absence of known MDRO/CRE exposure or heightened risk

At this time, given the uncertainties raised by recent reports, even in the absence of known MDRO/CRE exposure or heightened risks for CRE, consider either:

- a. One time, post reprocessing surveillance culture of the entire inventory of elevator-equipped endoscopes in the unit.
 - If cultures are employed, endoscopes should be sequestered for a minimum of 48 hours until cultures confirm absence of contamination. Those found to be positive for contamination by pathogenic bacteria should undergo repeat manual cleaning, high-level disinfection, and sequestration, or ETO gas sterilization according to manufacturer's guidelines.
- b. Alternatively, proceed with one time ETO sterilization of the entire inventory of elevator-equipped endoscopes, with careful attention to manufacturer's guidelines.

Scenario B: For routine daily practice without known heightened CRE risk

Currently, in the absence of suspected exposure or known risks, no additional reprocessing practices beyond diligent standard washing and HLD of duodenoscopes are advised by the FDA.

Some centers however are employing double cycles of washing and reprocessing for all endoscopes with elevators. Other centers are employing culture and sequestration of these instruments until confirmed clear, or ETO sterilization after each procedure. These options should be reviewed with your hospital infection control staff and administration to determine which approach is most practical and efficacious at your institution.

Patients undergoing procedures using duodenoscopes should be informed during the consenting process that there is a risk of patient-to-patient bacterial transmission associated with the procedure, including uncommon transmission of a multidrug-resistant organism.

Scenario C: Known MDRO or CRE-positive patients

The FDA and ASGE have advised, when ERCP is performed in a patient with a known multi-drug resistant organism such as CRE, that the duodenoscope should be taken out of service until it has been verified to be free of pathogens before reuse. This would entail high-level disinfection followed by either endoscope culture and sequestration until confirmed culture-negative at 48 hours or ETO sterilization. This approach could also be implemented for other flexible endoscopes that have an elevator mechanism.

Scenario D: Infection (or carrier state) with MDRO or CRE identified in a patient with a history of ERCP in recent months

When a patient is newly identified with either a clinical infection or silent carriage of a MDRO/CRE organism, their history should be reviewed to identify potential exposure via endoscopy using an instrument with an elevator (ERCP or EUS) in the prior several months. This interval is poorly defined, but transmission at exposure many months earlier has been described. If exposure via these instruments is a possibility, the following steps should be undertaken:

- Identify the individual endoscope used in the case and culture it according to one of the standardized culture protocols (see CDC interim culture method: <http://www.cdc.gov/hai/settings/lab/lab-duodenoscope-culture-method.html>). Sequester the scope out of service for at least 48 hours until a culture for high-concern organisms is negative.
- If the endoscope tests positive for MDRO/CRE, then contact the hospital microbiology and infection control departments to assist with characterization of the cultured organisms to ascertain their equivalence.
- With your infection control department, identify all patients in whom the endoscope was used, both during an interval prior to the index patient's exposure and subsequent to their exposure up until the time it was taken out of use for culturing. Notification of these patients should be considered, in line with the CDC's guidance, for potential screening via anal swab PCR or culture and for tracking to identify potential illness.
- Treat the positive CRE contaminated scope with either ETO sterilization according to manufacture guidelines or repeat washing and HLD with sequestration until a repeat culture confirms absence of high-concern organisms after at least 48 hours.

What about testing endoscopes for ATP or other bioburdens during or immediately after reprocessing?

While widely practiced, for this particular issue we currently don't have sufficient data to rely upon routine use of surveillance testing of endoscopes for blood, ATP or other bioburdens. These approaches clearly warrant additional research.

Important Contacts and Resources

Manufacturers

Questions about proper manual cleaning and reprocessing steps and ETO sterilization for duodenoscopes should be addressed directly to the manufacturers:

Olympus Technical Assistance Center (TAC)
800/848-9024 option 1
www.olympusamerica.com

PENTAX Medical
800/431-5880 (Customer Service)
www.pentaxmedical.com

FUJIFILM USA
800/385-4633 (Technical Support)
800/872-3854 (Customer Service)
www.fujifilmusa.com

FDA

Direct concerns about a potential case of post-ERCP CRE infection to the FDA through the FDA MedWatch site: <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>.

CDC

<http://www.cdc.gov/hai/outbreaks/index.html>

ASGE

Any questions about the ASGE interim recommendations should be directed to 630-570-6788.