



MEDIA Backgrounder

Transmission of Multi-Drug Resistant Organisms (MDRO) through Endoscopic Retrograde Cholangiopancreatography (ERCP)

Patient safety is a primary concern for the American Society for Gastrointestinal Endoscopy (ASGE). As recently reported, transmission of MDRO has occurred through an advanced procedure called ERCP. ASGE physician members -- gastrointestinal endoscopists -- perform the vast majority of ERCPs across the country. ERCP is an important and potentially life-saving procedure, and one that should not be seriously constrained, lest patients lose access to its benefits.

The following information provides background information and explains important concepts.

Can patients get these bacteria through colonoscopy or upper endoscopy?

No. This problem does not relate to common endoscopic procedures such as colonoscopy and upper endoscopy.

The recent cases of transmission of these difficult bacteria relate to a procedure called ERCP. Most people will never need an ERCP. ERCP is an advanced, highly technical endoscopic procedure. ERCP requires a special type of endoscope called a duodenoscope.

The FDA and experts have determined that the special design of the duodenoscope is the reason for transmission of these bacteria. The duodenoscope is not the same instrument as a colonoscope or upper endoscope, and is not used in routine endoscopic procedures such as colonoscopy and upper endoscopy.

What is ERCP?

ERCP stands for endoscopic retrograde cholangiopancreatography. It is an advanced, highly technical endoscopic procedure.

ERCP is performed using a special device called a duodenoscope. The duodenoscope is different from what is used in routine upper endoscopy or colonoscopy.

Most people will never have an ERCP. For patients who do need it, ERCP is a critical and often life-saving procedure. For these patients, the benefits of the procedure far outweigh the low risk of infection.

ERCP allows gastrointestinal endoscopists to diagnose and treat problems in the bile ducts and pancreatic ducts such as stones, narrowing (called strictures) and even complete blockages of a duct. The bile ducts and pancreatic ducts are the channels that carry fluids from the liver and the pancreas to the intestines.

The alternatives for treatment of problems in the bile duct include percutaneous transhepatic cholangiography, where the bile ducts are accessed by puncturing the liver from outside the skin or surgical options. ERCP is considered the least invasive and least dangerous option. ERCP remains a

relatively safe procedure that generally carries lower risks of complications than these other options, particularly for patients in need of ERCP who are often very sick.

Before an ERCP, the gastrointestinal endoscopist discusses the benefits and risks of the procedure with the patient and/or family members.

What are MDRO?

You may have seen these bacteria referred to as “MDRO,” or multi-drug resistant organisms; “CRE,” which stands for carbapenem-resistant Enterobacteriaceae (a type of MDRO); or even as “superbugs.”

Multi-drug resistant bacteria cannot be destroyed by common antibiotics. They have been called “superbugs” because of broad resistance to antibiotics but are not themselves more likely to cause infection than standard antibiotic-sensitive bacteria. Infections with MDRO are an important public health concern because treatment options are limited. These infections are a challenge for all areas of medicine, including gastrointestinal endoscopy.

People can carry these organisms in their intestinal tract without experiencing problems, but if they spread to the bloodstream and to other parts of the body, the bacteria can cause a difficult infection. For MDRO infections, fatality rates are estimated at 40-50%. The problem is that these infections are resistant to common antibiotics.

Unfortunately, many patients who need an ERCP are already in a weakened state or are critically ill. Therefore, in the rare case of transmission, these infections can be especially difficult for these patients.

How has CRE bacteria spread in these recent cases?

ERCP is a highly advanced procedure that requires a specialized device called a duodenoscope. The FDA and other experts have determined that the complex design of the duodenoscope, specifically the elevator and elevator cable, may present a challenge for high-level disinfection of the device. The FDA has advised that high-level disinfection reduces the risk, but may not completely eliminate it.

We do know that when manufacturers’ guidelines for cleaning duodenoscopes are followed, the risk of transmission is significantly reduced. Of course, all procedures carry infection risks.

Further investigation is needed to better understand this complex and concerning problem. State and federal agencies, medical professional groups, hospitals and other organizations are working together to address this issue. In recent months, the FDA has issued guidance and alerts related to optimal reprocessing (cleaning) of duodenoscopes, as well as some changes from the manufacturers of these instruments intended to make them easier to clean, or the reprocessing steps more effective.

As the leader in safety and quality in gastrointestinal endoscopy, ASGE recently developed a research agenda and related grant opportunities aimed at answering some of the important questions around this matter. We update our members on all important information and clinical guidance related to infection control, and we maintain a [web resource](#) for them on this topic.

How common is infection by MDRO through ERCP?

While the recent outbreaks are concerning and further investigation is imperative, infection by CRE bacteria or MDRO through ERCP is rare. It is important to keep in mind that most people will never need an ERCP.

For patients in need of an ERCP, it is a critical and often life-saving procedure. For these patients, the benefits of the procedure far outweigh the low risk of infection.

Approximately 500,000 to 600,000 ERCPs are performed each year in the US. At the time of an FDA statement on February 19, 2015, the agency reported that it had received 75 medical device reports, representing approximately 135 patients in the US with possible microbial transmission from duodenoscopes. Since this problem was identified, hospitals, agencies and other organizations, along with top experts in infection control, have devoted much time and many resources to addressing various aspects of this problem in an effort to make use of these devices as safe as possible. Helpful clues have emerged to guide our best efforts in infection control.

What is being done to improve patient safety?

In medicine, patient safety is of utmost concern. Many groups, such as the FDA, the CDC, manufacturers of the devices and other expert groups such as the American Society for Gastrointestinal Endoscopy, are working together to solve this important and complex problem.

What is ASGE, specifically, doing to resolve this important endoscopic issue?

Right now, ASGE is focusing on the following key components to address this complex problem:

- Awareness
- Communication
- Continuing education
- Research
- Response
- Reporting

First, as the lead society dedicated to safety and quality in gastrointestinal endoscopy, we have made gastroenterologists who perform ERCP aware of the potential for infection by MDRO through ERCP. We continue to update our physicians as new information becomes available.

We have advised our physicians to discuss this risk with their institution's infection control officers and anyone involved with reprocessing. We have urged increased vigilance around cleaning these highly specialized instruments and strict adherence to manufacturers' guidelines and infection control guidelines.

We have also encouraged hospitals and other facilities to conduct periodic assessments of their disinfection procedures and practices. Additionally, we have urged these facilities to ensure the competency of all staff involved in disinfecting these devices.

ASGE has updated its members on all communications from the FDA regarding duodenoscopes, and offers training courses to help endoscopy units ensure they are following best practices in reprocessing all endoscopes.

Although progress is being made in understanding the outbreaks that have occurred, simple answers are not readily available for this complex problem. In 2015, ASGE developed a research agenda around this subject and issued related research grants through a competitive process. Additionally, we convened a

Duodenoscope Infection Control Summit in Washington, DC, in 2015, with multiple stakeholders, including the FDA, CDC, manufacturers and others to support these efforts.

Finally, we have urged physicians to report any suspected infections immediately to the FDA and local CDC officials, as well as notifying device manufacturers. MDRO infections may appear days or months after a procedure, and related infections can involve sites remote from the biliary tree, including the urinary tract, blood stream, or wounds. It is imperative to identify, notify and monitor patients who may have been exposed to these difficult bacteria.