



## Frequently Asked Questions

### Transmission of Multi-Drug Resistant Organisms (or bacteria) through Endoscopic Retrograde Cholangiopancreatography (ERCP)

You may have recently heard or read about the spread of bacteria through an advanced procedure called ERCP. The reports deal with specific bacteria sometimes referred to as “MDRO” or multi-drug resistant organisms, “CRE” - which stands for carbapenem-resistant Enterobacteriaceae, or even as “superbugs.” Rest assured that patient safety is our primary concern. This handout aims to answer some of the questions you may have about this important topic. Do not hesitate to ask your physician, if you have any further questions.

#### Can I get these bacteria through colonoscopy or upper endoscopy?

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

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

The FDA and experts have determined that the complex design of the duodenoscope is related to the transmission of these bacteria. Duodenoscopes are 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 that 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. If left untreated, these problems can lead to further complications.

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.

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

#### What are MDRO or CRE bacteria?

Multi-drug resistant organisms (MDRO) are bacteria that cannot be destroyed by common antibiotics. CRE bacteria are a type of MDRO. These organisms have been called “superbugs” because they are resistant to most antibiotics. Infections caused by MDRO are an important

public health concern because treatment options are limited. MDRO 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, they can cause a difficult-to-treat infection. In these infections, the risk of death is higher because they are resistant to common antibiotics. It is important to note that these bacteria are not more likely to cause an infection than other types bacteria, just that MDRO infections are harder to treat.

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

### **How did multi-drug resistant bacteria spread in these 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 or elevator channel, 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.

What we know is 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 being done to better understand this complex and concerning problem.

### **How common is infection by multi-drug resistant bacteria through ERCP?**

Even though this problem has been the focus of numerous media stories, infection by multi-drug resistant bacteria through ERCP is rare. It is important to keep in mind that most people will never need an ERCP, and for those who do need an ERCP, getting one of these infections is very unlikely.

For patients who do need an ERCP, it can be a critical and life-saving procedure. For these patients, the benefits of the procedure far outweigh the low risk of infection.

About 500,000 to 600,000 ERCPs are performed each year in the U.S. At the time of an FDA statement in February 2015, there had been 75 medical device reports, representing approximately 135 patients in the US with possible microbial transmission from duodenoscopes. Since that time, federal and state agencies, hospitals and other organizations have devoted much attention to understanding and addressing all aspects of this issue.

### **What is being done to improve patient safety?**

In medicine, patient safety is always our number one concern. As the leader in quality and safety in endoscopy, the American Society for Gastrointestinal Endoscopy (ASGE) is working alongside other groups, such as the FDA, the CDC, manufacturers of the devices and with other experts to solve this important and complex problem. In recent months, the FDA has issued guidance and alerts related to optimal cleaning of duodenoscopes as well as design changes intended to make these instruments easier to clean.

### **How are you keeping your patients safe?**

Patient safety is our number one concern. The American Society for Gastrointestinal Endoscopy (ASGE) is an organization that focuses on safety and quality in gastrointestinal endoscopy. Our member physicians receive regular updates on this important matter and the latest best practices and clinical guidelines in endoscopy. They have been advised of the importance of strictly following manufacturer's guidelines for reprocessing (cleaning) devices, as well as ASGE's reprocessing guidelines, including periodic assessment of their facility's technicians who reprocess endoscopes.

**Do not hesitate to ask your physician or nurse, if you have any further questions.**