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Experts Convene to Explore the State of the Science and Set Priorities for Preventing Antibiotic-Resistant Infections Associated With Advanced Endoscopic Procedures

DOWNERS GROVE, III. – On Monday, March 30, the American Society for Gastrointestinal Endoscopy (ASGE), the lead society for safety and quality in gastrointestinal endoscopy, convened more than 60 experts and leaders in the fields of epidemiology, infection control, gastrointestinal endoscopy and medical device design and safety to exchange knowledge, explore best practices and to set priorities in key areas for preventing antibiotic-resistant infections associated with endoscopic retrograde cholangiopancreatography (ERCP).

The full-day *Duodenoscope Infection Control Summit* brought together representatives from the US Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), professional societies in the field of gastrointestinal medicine, hospitals that experienced outbreaks and three endoscope manufacturers.

ERCP is a highly technical and advanced endoscopic procedure performed using a specialized endoscope called a duodenoscope. ERCP allows gastrointestinal endoscopists to diagnose and treat problems in the bile ducts and pancreatic ducts, such as stones and strictures that can cause life-threatening blockages.

This procedure has been performed in the United States for more than 30 years, saving countless lives. However, outbreaks of antibiotic-resistant infections associated with ERCP in several prominent hospitals across the country have prompted experts to examine the procedure and the mechanism by which transmission is thought to occur.

In February, the FDA stated that the complex design of the duodenoscope, specifically the elevator mechanism, is believed to present challenges for high-level disinfection. Among the estimated 500,000 ERCP's performed in the United States annually, reports submitted to the FDA between January 2013 and December 2014 noted approximately 135 cases relating to possible microbial transmission from reprocessed duodenoscopes.

"Right now, all options for improving patient safety and eliminating this risk are on the table. ERCP is a critically important procedure for many of our most vulnerable patients. We wanted to bring together key stakeholders under the unified goals of examining this complex problem, exploring possible solutions and setting priorities as we advance this issue and work to ensure the safe delivery of ERCP to our patients," said ASGE President Colleen M. Schmitt, MD, MHS, FASGE.

Until definitive solutions become available, the FDA <u>recommends</u> that facilities strictly follow manufacturers' guidelines for duodenoscope reprocessing, which significantly reduces the already-low risk of infection by antibiotic-resistant bacteria.

While most people will never need an ERCP, for patients who do need it, the benefits of the procedure far outweigh the low risk of infection with these difficult bacteria. This is currently the least invasive treatment option and remains a relatively safe procedure.

According to Bret Petersen, MD, FASGE, Professor of Medicine, Gastroenterology and Hepatology at the Mayo Clinic in Rochester, Minn. and member of the ASGE Governing Board, "These instruments and this procedure have served us and our patients well for many years, but this is a new challenge with a new bug. Every gastrointestinal endoscopy unit performing ERCP needs a plan to address this, and leaders in the field intend to guide them by approaching this with best practices from every angle."

The *Summit* included presentations and breakout discussions focused on sharing expert perspectives, identifying questions and exploring next steps in several key areas such as research, reprocessing guidelines and education.

"Without question, there is more work to be done to solve this complex problem. What was unique about this Summit is that it brought together experts around many facets of the issue to critically examine the problem and discuss the hard topics. We must ensure the safe availability of ERCP to our patients," said Dr. Schmitt.

ASGE physician members perform the vast majority of ERCPs across the country. ASGE has demonstrated leadership on this critical issue by increasing awareness among members, urging vigilance around reprocessing and attention to guidelines, continually updating physician and nurse members about important FDA and CDC updates and by providing interim guidance to support endoscopy directors at their local hospitals. In addition, ASGE has defined a research agenda and is currently seeking research proposals to study this critically important issue. The endoscopy organization's *Duodenoscope Infection Control Summit* was convened as part of its effort to engage key stakeholders to solve this critically important issue and eliminate antibiotic-resistant infections associated with ERCP.

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About the American Society for Gastrointestinal Endoscopy

Since its founding in 1941, the American Society for Gastrointestinal Endoscopy (ASGE) has been dedicated to advancing patient care and digestive health by promoting excellence and innovation in gastrointestinal endoscopy. ASGE, with more than 13,000 members worldwide, promotes the highest standards for endoscopic training and practice, fosters endoscopic research, recognizes distinguished contributions to endoscopy, and is the foremost resource for endoscopic education. Visit www.asge.org for more information and to find a qualified doctor in your area.

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