Bacterial Infections Associated with Duodenoscopes: FDA's Actions to Better Understand the Problem and What Can be Done to Mitigate It

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Duodenoscopes are flexible, lighted tubes that are threaded through the mouth, throat, and stomach into the top of the small intestine (duodenum). Duodenoscopes are used in more than 500,000 procedures, called endoscopic retrograde cholangiopancreatography—or ERCP—in the United States each year. The procedure is the least invasive way of draining fluids from pancreatic and biliary ducts blocked by tumors, gallstones or other conditions. The duodenoscope is different than the endoscopes used for routine upper gastrointestinal endoscopy or colonoscopy. The duodenoscope is a more complex instrument than other endoscopes and can be more difficult to clean and disinfect.

In the fall of 2013, the Centers for Disease Control and Prevention (CDC) notified the FDA of a potential association of multidrug resistant bacterial infections and duodenoscopes. This raised a number of issues that needed to be investigated. Which duodenoscopes were involved? Was the problem unique to one model or to different models and manufacturers? Were the proper cleaning and disinfection protocols followed in the hospital where the infections occurred? Are the cleaning and disinfection protocols adequate? If not, what are the alternatives? Which device design features, if any, contributed to the outbreak? What could be done to prevent future outbreaks?

Even before FDA was notified of the infections by the CDC, FDA was working to strengthen cleaning and disinfection protocols of complex instruments like duodenoscopes to maximize patient benefit and reduce safety risks. We held a public meeting to discuss the scientific challenges, published a draft guidance in 2011 on cleaning and disinfecting or sterilizing medical

devices in health care settings and collaborated with standards developing organizations working to develop national and international standards. Since becoming aware of the 2013 infections and additional bacterial infections associated with duodenoscopes, we have further accelerated our work in this area. Specifically, we have gathered and reviewed information from facilities where the infections occurred, identified and studied the devices in question, collected and analyzed information from the manufacturers, analyzed medical device adverse event reports submitted to FDA, and reviewed the relevant published scientific literature.

We have been actively working with federal partners, manufacturers, hospitals, medical professional societies, and other stakeholders to better understand the issues that contribute to these infections and what can be done to mitigate them.

The FDA strives to provide the public with evidence-based information that patient and health care providers can use to make informed decisions. Once we developed a sufficient understanding of the issues to provide recommendations to help mitigate the risk, we issued a Safety Communication. The communication raised awareness that transmission of infections associated with duodenoscopes has occurred even when manufacturing reprocessing instructions were followed properly and that the complex design of duodenoscopes may impede effective cleaning. The Safety Communication included recommendations for patients, health care providers, and health care facilities about the steps they can take to minimize the risk of infections associated with these devices. Health care facilities should thoroughly clean and disinfect duodenoscopes between uses and have in place a comprehensive quality program for reprocessing. In addition, a duodenoscope that is suspected of being associated with a patient infection following ERCP should be taken out of service and meticulously cleaned and disinfected until it is verified to be free of pathogens.

The Safety Communication is only one step to address this problem. We continue our work in collaboration with federal partners, health care facilities and manufacturers to evaluate alternative cleaning protocols, test antibiotic-resistant organisms to assess their susceptibility to high-level disinfectants and explore additional strategies to reduce the risk of infections, such as the use of surveillance cultures of duodenoscopes.

So what should a patient do if they are advised to undergo a procedure with a duodenoscope? They should discuss with their health care provider the benefits and risks of the procedure and any alternatives for their condition. Fortunately, the vast majority of ERCPs are conducted without incident and often to the patient's great benefit. For most patients, the benefits of this potentially life-saving procedure far outweigh the risks of possible infection.

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