

Update Regarding Duodenoscope Reprocessing and Infection Control

As previously shared with our members, late last year, the U.S. Food and Drug Administration (FDA) reported on preliminary data from manufacturer testing of duodenoscopes following reprocessing (cleaning). The report showed that, in about 5 percent of cases, samples tested positive for “high concern” bacteria after the scopes had been reprocessed as recommended. According to the FDA, these are bacteria that are more often associated with disease. The final results and more granular detail are expected later this year.

This is a serious and complex issue for our patients and our practices. Duodenoscopes are necessary for performing endoscopic retrograde cholangiopancreatography (ERCP). As is widely understood, this minimally invasive procedure is typically performed in patients with diseases of the liver, pancreas and gallbladder and obviates the need for more morbid surgical and radiologic procedures.

A recent *New York Times* article reviewing this issue largely understated the value of duodenoscopes and the procedure for which they are used. This is a potentially life-saving procedure for nearly 700,000 patients each year in the US. When a doctor recommends ERCP, it often is because the patient is seriously ill, and the benefits of the procedure far outweigh the risks. ERCPs also spare patients more invasive alternatives, including surgery. Withdrawal of these instruments from the marketplace is simply not feasible.

We do agree and support the that identification and development of safe and effective solutions that eliminate risk of infection transmission as a top priority. This cannot happen overnight: we cannot adopt new technologies, such as disposable duodenoscopes, without first understanding the new and unintentional risks we may be introducing to our patients such as an increased risk of procedural failure, perforation, or pancreatitis.

ASGE will host its second Infection Control Summit this December, bringing together experts from federal and state agencies, industry and national medical organizations to discuss the latest developments in this sphere and identify next steps.

The GI societies have been working closely with FDA and industry to identify and properly vet potential solutions. The FDA has already reviewed and cleared new reprocessing and sterilization technologies and revised designs for some duodenoscopes; all are intended to enhance ease of cleaning and reprocessing thereby improving safety from transmitted infection. Other redesigns and new technologies for endoscope reprocessing, as well as single-use instruments, are in the pipeline. All of these options, and others, will likely enter the marketplace in the coming months and years after FDA vetting and approval and with post-marketing studies to ensure the efficacy of the technology and patient safety.

Since it was discovered several years ago that cases of infection transmission associated with duodenoscopes had been experienced by hospitals in the U.S. and Europe, healthcare organizations across the board recognized the need to escalate infection control efforts and to swiftly identify and disseminate best practices. The FDA, the Centers for Disease Control

and Prevention, state and local health departments, scope manufacturers and medical societies have collaborated continuously to determine best practices for identifying and reporting sources of infection and effectively cleaning equipment.

Since this problem was identified, vigilance has been raised and infection rates have improved. As with all medical procedures, patients who require ERCP should discuss with their physician the risks and benefits of their treatment.

This article was developed in collaboration with the American Gastroenterological Association and the Society of Gastroenterology Nurses and Associates (SGNA).