

On Monday, March 30, the American Society for Gastrointestinal Endoscopy (ASGE) 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 purpose of the Summit was to:

- Confirm the most current guidance from the FDA and industry for cleaning and disinfection of endoscopes
- Understand epidemiological impact of infection related to duodenoscopes from the CDC perspective
- Work with stakeholders to identify and describe scenarios of infection risk in order to develop facility and member proactive response mechanisms
- Outline interim guidance for members facing a variety of reprocessing scenarios
- Identify gaps in strategic approaches to infection risk surrounding ERCP

The full-day Summit brought together representatives from the US Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Department of Defense/US Army, the Veterans Administration (VA), professional societies in the field of gastrointestinal medicine, hospitals that experienced outbreaks and three manufacturers of duodenoscopes.

The following is a summary of activities that took place during the Summit, accompanied by recommendations related to scientific considerations, guideline development, educational programming and research.

Scientific Considerations

An invited group of experts in the medical, epidemiologic and regulatory aspects of the multi-drug resistant organism (MDRO) and the carbapenem-resistant Enterobacteriaceae (CRE) convened prior to the Summit to focus on establishing known facts and assumptions about MDRO/CRE and duodenoscope involvement in the transmission of infection. The discussion revealed a number of areas of agreement, and created a shared understanding and common ground upon which the rest of the day's discussion could be based.

Opening General Session

During the Opening General Session, a summary of the special session was presented of scientific considerations with input from attendees and ASGE leaders. After reviewing the items included in the shared understanding consensus, the following specific topics were presented for group discussion:

- Primary Concern/Target Organisms
- High-Level Disinfection
- Sterilization
- Environmental/Endoscope Cultures
- Endoscope Redesign

Outbreak Site Observations

Four sites where infection outbreaks occurred presented information on their experiences. Each site discussed how the outbreak was identified, how the site approached cleaning and disinfecting or sterilizing scopes. The sites discussed their current practices, screening protocols and measures taken to ensure the scopes affected by infection have been managed effectively. Staff training and assessment protocols have been instituted by each site and ongoing evaluation of scope tracking methodologies have been established.

FDA Summary

The FDA presented its initiatives to help practitioners deliver quality ERCP safely. Understanding the numerous challenges, the FDA urged sites to review its recommendations and provide feedback as more experience is gained. The FDA emphasized continued work with all device manufacturers to assess the risk of infection and to review their validation data for reprocessing. Further, FDA stated that any new 510(K) submission must include all the validation data collected in the submission and that validation studies should be done on a “worst case” contamination, as outlined in the Guidance document. FDA is committed to getting new scope designs to market as quickly as possible.

CDC Summary

The CDC discussed its initiatives to better understand the breadth of the CRE infection outbreak as well as future processes being considered to identify solutions. The CDC was asked to review its activities, including its most recent guidance, and provide an overview of next steps in addressing the issue.

Industry Updates

Industry representatives from the three major scope manufacturers provided a review of their activities to address duodenoscope transmission of infection and the steps being employed to eliminate the possibility of future conveyance. The presentations concentrated on units adhering to the guidance and instructions already provided. Companies stressed the importance of following manufacturer’s recommendations exactly, including both materials and methods.

Breakout Sessions

Following the Opening General Session, breakout sessions were conducted which addressed four major areas: Scientific Considerations, Guideline Development, Educational Programming and Research. Each of these discussions was designed to identify immediate, mid-term and long-term recommendations to best serve practitioners and patients.

Scientific Session Recommendations

Many questions still remain and many differences of opinion emerged on how to handle this multi-faceted topic. The group acknowledged that there is no single way to proceed and that action is predicated upon individual unit needs and abilities to incorporate steps. Short-term recommendations

focused on culture protocols, technician support, and current guidance. Intermediate- and long-term steps focused on additional steps in reprocessing, sterilization methods, and validation issues.

Guidelines Recommendations

The Guidelines discussion group determined that guidance, not instructional, documents are most valued by users. Stakeholders include providers/practitioners, institutions, government agencies and the public. Existing documents can be updated to reflect the current situation and incorporate appropriate supportive references. Short and intermediate recommendations will address gap analyses, intermediate and supplementary materials, and expansion of existing documents to reflect new issues that have surfaced with current outbreaks.

Educational Programming Recommendations

The Educational Programming group considered the development of educational programming *across entities* (GI endoscopists, GI nurses, technicians, FDA, CDC, DoD, VA, etc.) to address reprocessing gaps and management of equipment disinfection/sterilization. Content, format, credentialing and delivery mechanisms were addressed.

Research Recommendations

The Research Group discussed key research questions and criteria for moving the field forward with respect to duodenoscope infection control. Three specific areas were cited as priority: detection, eradication, and epidemiology of MDRO/CRE outbreaks.

Summary

We know that patient safety is our members' number one priority; we understand the urgency to deliver important information in a timely manner. In the coming weeks, ASGE will be taking the following steps:

- 1) Lead work with other stakeholders to continue to identify priority needs.
- 2) Partner with Federal agencies and others to identify best practices.
- 3) Communicate with device manufacturers to support sites with effective resource materials and training.
- 4) Award grants to support research in the areas of detection, eradication, and prevalence of the bacteria causing these infections.
- 5) Continue to develop tools and resources to assist members and their teams in incorporating useful practices into their units.