American Society for Gastrointestinal Endoscopy Infection Control Summit: updates, challenges, and the future of infection control in GI endoscopy

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ERCP is a diagnostic and therapeutic procedure used to treat hepatic, biliary, and pancreatic pathology in nearly 700,000 patients annually in the United States.[1] In recent years, some infections after ERCP have been traced to duodenoscopes used during these procedures. Although infections can be attributed to improper disinfection practices, some cases occurred despite adequate reprocessing of the devices. As a result, there has been a plethora of research in this area; several guidelines are being updated to address these concerns, and the U.S. Food and Drug Administration (FDA) has issued several safety communications and convened multiple advisory panels to better understand the issue, inform providers and the public, and enumerate recommendations in an attempt to reduce the incidence of these infections. Subsequently, the American Society for Gastrointestinal Endoscopy (ASGE) assembled a diverse group of stakeholders including leading researchers in the field of infection control (gastroenterologists, microbiologists, and epidemiologists), regulatory agencies, and device manufacturers on December 2, 2019 in National Harbor, Maryland. The ASGE Infection Control Summit was organized into 4 sessions with the objectives of (1) providing state-of-the-art review of endoscope disinfection and reprocessing from a regulatory, practice, and training perspective and (2) exploring future avenues of technology and research for endoscope disinfection and reprocessing.

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SESSION 1: UPDATE 2016 TO THE PRESENT

The opening session provided a detailed overview of the first outbreaks of duodenoscope-related infections reported in the United States and outlined subsequent responses to and lessons learned from these outbreaks. The session then transitioned to reviewing data from FDA mandated after marketing surveillance studies of duodenoscopes and examining the risk to patients of developing an infection after undergoing an ERCP.

Actions taken since 2016

In 2015 several major outbreaks of infections linked to duodenoscopes were reported in the United States,[2-7] and, as a result, the ASGE convened its first duodenoscope infection control summit on March 30, 2015. Recommendations from this summit stressed identifying priority needs and best practices, communicating with device manufacturers and end users, and awarding grants to support research in the areas of detection, eradication, and prevalence of the organisms causing duodenoscope-related infections.

Several developments have occurred since these first reported outbreaks and the first ASGE infection control summit. First, in 2016 the U.S. Health, Education, Labor and Pensions Committee chaired by Senator Patty Murray published a report highlighting delays in reporting carbapenem-resistant Enterobacteriaceae infections, industry failures, and limitations of the FDA's ability to perform

data collection on devices and adverse events related to duodenoscopes.[8] Second, regulatory and accrediting agencies, such as the Centers for Medicare & Medicaid Services and the Joint Commission on Accreditation of Healthcare Organizations, initiated duodenoscope reprocessing audits in hospitals. Third, a number of national societies revised their reprocessing guidelines. In 2016 the multisociety guideline on reprocessing of flexible GI endoscopes was updated and focused on duodenoscope reprocessing.[9] Also, the Association for the Advancement of Medical Instrumentation is in the process of finalizing their reprocessing guideline. Fourth, the FDA has issued a number of safety communications and advisories that have questioned the effectiveness of duodenoscope reprocessing, in addition to raising other issues such as a lack of validation of culturing and sampling, the role of mechanical cleaning, and the need for increased communication with the public and end users around infection control and endoscope reprocessing.[10]

Review of major outbreaks and published culture studies

Since 2008, 7 outbreaks of multidrug-resistant organism infections have been reported in patients who had undergone ERCP in the United States.[3-7,11,12] Common themes observed among these outbreaks were as follows: (1) culprit organisms are often normal gut flora, (2) clinical infections are often distal from the site of infection (ie, urinary tract infection, pneumonia), (3) a long lag time exists before clinical symptoms develop, (4) the infection is silently carried among patients, (5) duodenoscopes are often culture negative, and (6) no failures in duodenoscope reprocessing were identified. Similar outbreaks have been reported across Europe and Asia.[13-20] Further investigations after these outbreaks have yielded contamination rates among duodenoscopes and echoendoscopes ranging from .7% to 60% with high-concern organism culture-positive rates on duodenoscopes ranging from .9% to 1.9%.[4,21-26] When data from these major outbreaks were used, an attack rate (ie, likelihood of developing an infection after exposure with a contaminated duodenoscope) was calculated to be 18.9%. This translates to an estimated risk of patients developing an infection from a high-concern organism after undergoing an ERCP with a contaminated duodenoscope to be 1 in 106 to 1 in 2632.[13]

FDA postmarket surveillance studies

Since the inception of these outbreaks, the FDA has conducted 2 postmarket surveillance studies to better understand the factors surrounding infections developing from reprocessed duodenoscopes. One study examined human factors testing (ie, assessing how an individual uses a device in an environment that mimics actual use of reprocessing instructions), whereas a second study conducted microbiologic sampling and culturing of duodenoscopes. The human factors study concluded that endoscope user manuals could be improved for reprocessing staff; results showed that staff miss 1 or more reprocessing steps and that descriptions of reprocessing instructions are challenging and complicated to follow. In the microbiologic studies, .3% to 4.4% of duodenoscopes were contaminated with low- to moderate-concern organisms, whereas the contamination rate of duodenoscopes with high-concern organisms ranged from 4.1% to 6.1%. Initial data highlighted a number of potential contributing factors to contamination rates: the complex design of the distal end of the duodenoscope and endoscope working channels, prolonged storage of duodenoscopes in noncontrolled environments, human factors/errors in reprocessing, damaged areas on the exterior/interior of the duodenoscope, and waterborne pathogens from rinsing water used in reprocessing.[27]

SESSION 2: CURRENT STANDARD OF PRACTICE: CAN IT WORK? DOES IT WORK?

The second session shifted to the development of reprocessing instructions and the potential human factors that may impact their use and implementation. Along these lines, several healthcare institutions highlighted their challenges around training and maintaining competency of reprocessing staff and offered strategies for improving training and reducing reprocessing lapses and errors.

Instructions for use: where do they come from?

Instructions for use (IFU) for devices are formed through a multistep and collaborative process. This process begins with defining the intended use of the device, including the clinical need, part of the body, and type(s) of procedures in which the device will be used. This is followed by collaboration with intended users to understand how the device will be used in the clinical setting, what parts of the device may be contaminated during use, and what possible clinical "worst-case scenarios" may occur. A working draft of the reprocessing IFU is drafted, and human factor studies are conducted to better understand how the device will be used, identify areas of potential difficulty or confusion, and ensure the IFU is easy to understand and can be followed by reprocessing personnel.[28] In addition, a microbiologic validation protocol is developed, encompassing "worst-case scenarios" that may reflect use errors found by human factor testing (eg, skipped/missed steps, reprocessing delays) or suboptimal reprocessing (eg, hard water, diluted chemicals). As part of this process, inoculation points on the device are selected based on the likelihood of contamination, and microbiologic validation testing is conducted to ensure that the IFU can achieve effective reprocessing. For endoscopes, manual cleaning, high-level disinfection (HLD), and sterilization validation testing are conducted separately using different clinically relevant artificial test soils and microorganisms. Acceptable

criteria for reprocessing endpoints, such as protein, carbohydrate, hemoglobin, or X-log reduction, must be met accordingly.[29] The IFU, along with supportive data, is submitted to the FDA as part of the device 510(k). IFUs may change based on feedback from the FDA, customers, or adverse event reporting, and therefore reprocessing personnel should regularly review and verify the manufacturers' IFUs.[30]

Human factors

Human factors remain central to achieving safe, effective, and reliable endoscope reprocessing. However, human factors are also complex and may stem from issues related to (1) systems, staffing, training, and oversight; (2) environment, equipment, communication, and culture; (3) workflow and complexity; and/or (4) individual character, condition, and capability. When this framework was used, human factors studies conducted at reprocessing facilities identified opportunities for optimization. From a systems standpoint, deficiencies in training and competency testing of reprocessing personnel have been observed, which is further complicated by high staff turnover or absenteeism because of work-related injuries. Inadequacies in equipment include nonoriginal equipment manufacturer-validated cleaning brushes used as well as materially incompatible detergents and disinfectants used. Moreover, poor servicing and maintenance of devices and automated endoscope reprocessors (AER) exist. Workflow and complexity-related issues include environmental contamination because of inadequate endoscope sampling and storage practices. Finally, the reprocessing instruction manual format and content are incredibly complex and detailed, creating an environment where reprocessing steps may be skipped or incorrectly performed.

It was proposed that the responsibilities for addressing human factors should be divided among manufacturers and clinicians.[31] Manufacturers should consider all intended users (eg, clinicians, maintenance workers, reprocessing staff) when designing devices, provide IFUs that are effective for reprocessing devices and their accessories, and provide proper training. Healthcare facilities are responsible for providing adequate facilities and equipment that facilitate reprocessing, maintain readily accessible manufacturer IFUs, and ensure compliance with them and verify that any third-party accessories used are approved for their purpose. Several opportunities for collaboration and potential solutions were raised. Proposed solutions to human factors issues include a need for competency-driven reprocessing training and certification, raising awareness among stakeholders for continuing educational programs, shifting from in-service training to competency-driven clinical education, and having regulatory interventions that contain global quality programs, FDA inspection, and serious adverse event reporting.

Data on performance

Despite detailed manufacturer IFUs on endoscope reprocessing, human factors continue to play a central role in reprocessing lapses. In a series of reviews, up to 92% of patient-ready endoscopes had evidence of microbial contamination because of critical lapses such as failure to perform bedside precleaning, not performing manual brushing, and improper drying and storage after HLD.[32] Reasons for such disconcerting lapses are likely multifactorial and range from complexity of IFUs, a lack of demonstrable competency of endoscope reprocessing technicians, to hostile work environments. Furthermore, most surveyed front-line reprocessing technicians feel pressured to work faster, at the expense of not performing minimum effective concentration checks of HLD chemicals or even skipping reprocessing steps. These conditions have even resulted in alarming staff feedback where up to 40% of frontline technicians encounter bullying (from insults, abusive language, to even physical attacks) and feel pressured to send out deficient or damaged endoscopes.[22] It is likely that multifactorial causes of lapses will also require multifactorial solutions from easier-to-understand IFUs, promoting a culture of safety, to redesigning the process that enhances "error proofing" either through automation or through single-use devices.

Competency, testing, and oversight

To ensure that adequate reprocessing occurs for every endoscope, every patient, every time, it is crucial to address this process from a continuous quality improvement, or "kaizen," approach. To this end, the Cleveland Clinic model champions a 3-pronged approach. First, to promote competency, endoscope reprocessing training is designed to be model-specific, incorporating visual aids and using standard operating procedures and professional organization programs that support industry best practices. Second, from a testing perspective, their organizational strategy has evolved from a passive model (eg, annual in-service trainings) to an active model that uses video reprocessing guides and prompts test takers to demonstrate their competencies to the tester. Last, ongoing oversight is critical to maintaining competency in reprocessing. This can be achieved through ongoing mentorship of frontline technicians by supervisors, who themselves are familiar with the latest methods of endoscope reprocessing and have experience with commonly encountered reprocessing emergencies such as an AER failure.[33]

Training and certification

Further insight into improving reprocessing training was highlighted by the endoscopy team from MD Anderson Cancer Center in Houston, Texas. During the 2019 GI Endoscopy Nurse & Technician Training Course in Houston, Texas, over 80% of course attendees completed a voluntary survey on infection control in endoscopy. Even

in this self-selected cohort of highly motivated individuals, most obtained little to no formal education in endoscope reprocessing, and less than half received more than 1 month of mentorship before independently reprocessing endoscopes. Despite high levels of confidence in endoscope reprocessing, there was a markedly lower level of actual knowledge of infection control. To this end, educators at the MD Anderson Cancer Center have now developed a formal curriculum that comprehensively addresses both the "how" and "why" of endoscope reprocessing methods, with particular attention to enhancing learning among the target audience. For instance, a medical illustrator was charged with creating high-impact, easy-to-understand graphics for various concepts including proper handwashing and endoscope storage after reprocessing. To clarify key steps within the HLD process, educational video clips were incorporated into the curriculum. The post-test was similarly designed to be a holistic, case-based examination that is meant to be thought provoking and also to highlight problems that may occur in real life.[34]

SESSION 3: OPTIMIZING REPROCESSING

In this section core concepts were emphasized and reinforced to ensure the relatively narrow margin of patient safety is not further compromised by errors of omission or commission during reprocessing. Specifically, concerns around biofilm and endoscope reprocessing were discussed and ways in which biofilm could be minimized were outlined. Also, the importance of drying during reprocessing and the need for ongoing maintenance of endoscopes were emphasized as critical elements in preventing endoscopy related infections.

Biofilm: avoidance, eradication, and the role of new technology

A culprit in the pathogenesis of endoscope infections is the presence of biofilm, which is a bacterial colony adhering to a surface and protected by exopolysaccharides. Biofilm can form in locations with nutrients and moisture, such as on the interior or exterior surfaces of an endoscope, and results in a great survival advantage for bacteria. A number of reprocessing steps help to prevent and reduce biofilm development. Importantly, the 2 most critical factors to reduce biofilm risk are implementing a high-quality reprocessing program and testing for compliance with manual brushing and endoscope drying after reprocessing.[35] For example, brushing of endoscope channels during manual cleaning is an effective method of biofilm elimination; however, this is not always possible, particularly in the air/water channel and auxiliary water channel, which have very narrow lumen diameters. Additional areas of where suboptimal manual cleaning may occur are the elevator mechanism and the recess behind the actuating elevator arm.[13,36] Equally important in preventing biofilm buildup is the drying of the endoscope. It is crucial to understand that the alcohol and air-drying steps incorporated into an AER cycle by itself are insufficient for endoscope drying.[37,38] In fact, some international endoscope reprocessing guidelines recommend abandoning alcohol for drying purposes because of its protein fixative properties and instead using automated drying cabinets.[39] Supporting this approach, Perumpail et al[40] recently demonstrated that automated drying cabinets significantly inhibited the growth of a test inoculum of *Pseudomonas aeruginosa* on various endoscope types compared with a standard storage cabinet in which internal channel moisture was still present after 24 hours. Thus, the risk of biofilm development on endoscopes can be significantly reduced by rigorously complying with and monitoring of all steps of manual cleaning and drying.

Drying: importance, timing, and options

Proper drying has taken a renewed importance in the context of endoscope-related infections. Although it is generally accepted that endoscope drying is important, there is widespread variation in practice. In a recent survey of over 200 U.S. endoscopy units, almost 10% performed no drying but instead opted for immediate reuse after reprocessing.[41] The benefit of dedicated, additional drying beyond the drying cycle in an AER was first described in the early 1990s. When using a short, terminal, 2-minute drying step in an AER, 21 of 42 duodenoscopes exhibited evidence of microbial contamination; on the other hand, none of the 19 duodenoscopes subjected to a longer 10 minutes of drying in the AER demonstrated detectable microorganisms.[42] The value of additional, automated drying was recently reaffirmed where a 10-minute drying time was identified as optimal. The ideal method of identifying residual moisture after drying (eg, cobalt chloride versus direct borescope visualization) remains to be determined. With the use of relatively inexpensive equipment, consistent, effective drying can reduce the likelihood of microbial recontamination of reprocessed endoscopes.[37]

The relationship between simethicone and endoscope drying was also explored. Simethicone is a defoaming agent that helps to reduce surface tension of bubbles and is frequently used during endoscopy to help aid in mucosa visualization. Yet, concerns about the use of simethicone during endoscopy have been raised. In a recent study of 36 endoscopes, medium (1%) and high (3%) concentrations of simethicone produced significantly higher amounts of retained fluid within the endoscope working channels after reprocessing compared with low (.5%) or no simethicone.[43] Of note, a repeat AER cycle did not reduce the number of fluid droplets visualized at any simethicone concentration used. Additionally, commercially available simethicone includes sugars, thickeners, and binding agents, all of which may

hinder reprocessing and could promote microbial growth. As a result, British[44] and Canadian[45] gastroenterological societies advise using the lowest possible concentration of simethicone, administered through a brushable channel. Accordingly, all 3 major endoscope manufacturers now recommend against the use of simethicone. Until improved or alternative defoaming solutions are developed to reduce the reliance on simethicone, it may be prudent to use the lowest possible concentration of simethicone administered through brushable channels.

Endoscope and AER maintenance

Preventative endoscope maintenance offers several advantages, including decreased equipment downtime and fewer major repairs, thereby increasing longevity of capital equipment. During a multidrug-resistant organism outbreak in Washington State, 75% of contaminated duodenoscopes were ultimately found to need critical repairs despite no apparent functional deficit.[4] The desire to identify endoscope-related problems before they result in patient harm is a paradigm shift. Three methods of ensuring endoscope maintenance have garnered moderate amounts of interest in recent years. First, all 3 major endoscope manufacturers now require annual inspection and maintenance of duodenoscopes. Second, a possible quality control method of interest has focused on direct visualization of the endoscope working channel using a slender small-caliber camera, known as a borescope. Although it is immediately useful in identifying residual moisture droplets, the clinical significance of borescopic findings is unclear.[4] Third, a culture and quarantine approach for duodenoscopes (ie, conducting microbiologic cultures on duodenoscopes and isolating those endoscopes that test positive) has been integrated into quality control programs. Using this approach has resulted in healthcare facilities reducing the rate of positive duodenoscope cultures and terminating infectious outbreaks.[46] All these methods are imperfect quality checks to assess the adequacy of HLD and highlight the need for more reliable and sensitive modalities that could identify contaminated endoscopes.

SESSION 4: PEERING INTO THE CRYSTAL BALL: CURRENTLY AVAILABLE AND FUTURE SOLUTIONS

In the final session, existing options as well those in the pipeline to enhance and improve endoscope reprocessing modalities were discussed. Similarly, the role of the FDA and regulatory bodies, as it relates to infection control within endoscopy units and the impact of reprocessing guidelines, was outlined.

Single-use options

Current reprocessing practices are hampered by endoscope complexity, regular personnel turnover, emergence of multidrug resistant organisms, evolving guidelines, and focus on auditing standards. All this complexity makes a single-use endoscope an attractive option. Ideally, a single-use device would not require relearning of the procedure; would be effective, durable, and safe to use; would provide similar results across a wide array of operator experience; and would be economically feasible and environmentally responsible.

A single-use duodenoscope was recently approved by the FDA, and recent data have shown promising results. In a bench study using a silicone model, 6 expert endoscopists rated the performance of a single-use duodenoscope versus duodenoscopes from 3 manufacturers in the performance of 4 common ERCP tasks: guidewire locking with an elevator, placement of a plastic stent, placement of a self-expanding metal stent, and sweeping of the bile duct with a basket. There were no statistically significant differences in time to completion of the tasks and similar ratings for overall performance on the 4 simulated tasks across the 4 duodenoscope models was noted. However, navigation and image quality were rated significantly lower for the single-use duodenoscope.[47] A second in vivo study was subsequently performed in which 7 experts enrolled consecutive patients for ERCP using a single-use duodenoscope. In this study, single-use duodenoscopes were rated highly. There were 177 total readings for 14 specific maneuvers (including cannulation, sphincterotomy, stone removal, stent placement, and balloon dilation), of which 160 (90.4%) were neutral for the single-use duodenoscope compared with the endoscopist's usual duodenoscope. In 2 cases (2%), the endoscopist switched to a reusable duodenoscope to complete the procedure.[48] Although this is an encouraging step toward single-use duodenoscopes, several questions remain, including its applicability across an array of operator experience, economic viability, recycling potential, and impact on the environment, patient selection, and patient reaction to its availability.

Sterilization: does it work?

Ninety percent of device-related infection outbreaks are attributed to GI and bronchoscopic endoscopes. This is likely because of the high microbial load that GI endoscopes incur during procedures ($10^{7\text{-}10}$ CFU/mL), complexity of endoscope design, and endoscope reprocessing and accumulation of biofilms.[49] The currently recommended standard for semicritical devices (eg, endoscopes) is HLD, which provides a narrow margin of safety that may not suffice in some settings. New cleaning chemicals and methods may enhance the efficacy of HLD and include antimicrobial detergents that reduce microbial load by an additional 4 to 6 $\log_{10}$, agents that have biofilm inhibiting/destruction properties, automated cleaning to reduce human factors, standardization of the reprocessing process, and cleaning verification to predict residual microbial contamination.

One such modality that may reduce infection outbreaks related to GI endoscopes is the sterilization of devices.

Sterilization achieves a 12-$\log_{10}$ reduction and provides an additional 6-$\log_{10}$ margin of safety compared with HLD. There are currently 5 legally marketed sterilizers for GI endoscopes: steam sterilization, hydrogen peroxide gas plasma, ethylene oxide, ozone, and vaporized hydrogen peroxide.[50] However, it is important to note that studies have shown that the sterilization failure rate of endoscopes also increases when serum and salt are added to the long narrow lumens of the endoscope channels,[50] underscoring the importance of cleaning. Steam sterilization appears to be the most robust in handling residual endoscope contamination and provides the greatest margin of safety, followed by ethylene oxide, hydrogen peroxide gas plasma, and vaporized hydrogen peroxide. Alternative strategies to reduce infection risk associated with endoscopes include optimizing existing low temperature sterilization methods or using newly available low temperature sterilization technology, disposable sterile GI endoscopes, steam sterilization for GI endoscopes, nonendoscopic methods to diagnose or treat disease (eg, capsule endoscope, stool or blood test to detect GI cancers, stool DNA test) or improving GI endoscope design such as the recent FDA recommendation to use disposable end caps.[50,51]

Guidelines: current and future

Several documents are available to inform endoscope reprocessing and are categorized into regulations, standards, and guidelines. Regulations are rules or directives developed and maintained by an authority and are mandatory. Standards provide requirements and specifications to ensure consistency and fit for purpose and are voluntary but can become mandatory. Guidelines, recommended practices, and technical information reports all provide technical guidance, information, or preferred practices regarding a given topic and are voluntary. It is incumbent on an organization (eg, hospital) to identify which documents should be followed. A number of organizations have outlined endoscope reprocessing guidelines, including the Association for the Advancement of Medical Instrumentation, multisociety guideline on reprocessing flexible GI endoscopes,[9,52] Society of Gastrointestinal Nurses and Associates,[53] and the Association of periOperative Registered Nurses.[54] These documents cover the entire reprocessing cycle from precleaning to reuse. Other foundational resources to guide best practices for endoscope reprocessing include Healthcare Infection Control Practices Advisory Committee,[55] FDA safety communications,[10] and manufacturers' IFUs.

The path to the future? The regulatory side

The FDA continues to play a central role in navigating providers, patients, and device manufacturers through endoscope reprocessing issues. The FDA regulatory purview specifically includes premarket review of endoscopes (ie, design, labeling, and testing), reporting of device-related adverse events, ensuring compliance with FDA regulations, conducting postmarket surveillance studies, and communicating on topics relevant to public health. Although topics related to training reprocessing personnel, development of new endoscope design, maintenance of endoscope and reprocessing equipment, assurance of reprocessing resources in healthcare facilities, and quality monitors for manual cleaning are important, they remain outside the mandates of the FDA. In line with these roles, a recent FDA advisory committee meeting held on November 6 and 7, 2019 focused on providing recommendations regarding duodenoscope reprocessing and new technologies. In particular, the FDA wanted to examine the level of concern with reprocessed duodenoscopes, standardization for durability testing, urgency toward moving toward new duodenoscope designs, premarket/postmarket data, and balancing HLD versus sterilization. The FDA panel's responses to questions pertaining to these issues are noted in Table 1. The FDA has also had discussions regarding labeling changes such as identification of necessary reprocessing resources, increased transparency regarding endoscope contamination rates and durability, and clearer instructions promoting user understanding and compliance with instructions.

NEXT STEPS AND FUTURE DIRECTIONS

Infection control has reached a seminal moment in the history of GI endoscopy. To ensure safe access to endoscopy for all patients, it is essential to begin incorporating best practices of high-performing industries, particularly using the concepts of *kaizen* (continuous quality improvement) and *poka yoke* (error proofing).[56] Both concepts have been quite effective across a number of business sectors at not only improving the quality but also enhancing the safety of their products. An example of *kaizen* in endoscope reprocessing is to train endoscope reprocessing staff using formal, evidence-based, and dynamic curriculums. These curriculums would seek input from all stakeholders and would have processes in place for auditing staff on their performance and providing real-time feedback. On the other hand, *poka yoke* in endoscope reprocessing might focus on the redesign of reprocessing devices to ensure that reprocessing staff avoid mistakes, in particular, having different shapes for various brushes to be used for different endoscope channels, such that an incorrectly sized brush could not be inadvertently placed into the wrong channel. Another example is to incorporate programmable features into devices (eg, AERs, washers, sterilizers) that would have lock-down mechanisms in place to prevent both users and manufacturers from deviating from the FDA-cleared IFU parameters for the device. Using the concepts of *kaizen* and *poka yoke* to improve patient safety requires a combination of short-, intermediate-, and long-term interventions with respect to endoscope reprocessing that are outlined below and in Table 2.

TABLE 1. FDA questions and responses from the FDA advisory committee meeting on November 6-7, 2019 regarding duodenoscope reprocessing and new technologies

FDA questions	Responses from advisory panel
Considering the currently available multidrug-resistant organism data and postmarket surveillance data and challenges with implementation of new reprocessing methods and adoption of new technologies, does the panel recommend continued incremental improvements (eg, disposable end cap duodenoscopes, release of newly validated reprocessing instructions) to improve the safety of reprocessed duodenoscopes versus more substantial changes to duodenoscopes and reprocessing methods?	The consensus of the panel was that training of reprocessing personnel was of utmost importance. The panel recognized that such training falls outside of the FDA's purview; nonetheless, the FDA was encouraged to collaborate with manufacturers, accrediting organizations, and other stakeholders to promote correct reprocessing of duodenoscopes in healthcare settings. Some panel members commented that the magnitude of the problem did not raise concerns and that FDA mandates on strategies to reduce the risk of infection for duodenoscopes would not be helpful. The panel recommended that the FDA carefully consider next steps and make deliberate decisions.
Does the panel have comments on the FDA's proposal to standardize duodenoscope durability testing to include 250 cycles of simulated use, cleaning, high-level disinfection, and terminal sterilization?	The panel's consensus was that standardized durability testing was appropriate, because damage to duodenoscopes was not often recognized by healthcare personnel. The panel noted that the details of the durability testing should be further discussed and refined with industry.
The panel is asked to comment on the potential for new designs to reduce the observed contamination rate with reprocessed duodenoscopes and the urgency with which the transition to new duodenoscopes should be made.	The panel's consensus was that potentially new designs could reduce contamination, but there are insufficient data to demonstrate that reduction. The panel commented that additional modifications to the device design and reprocessing instructions, education, and practices could be made.
For technologies that are intended to reduce contamination rates for duodenoscopes, what is the appropriate balance between demonstrating the effectiveness of the technology before marketing versus the benefit of having the technology available for use?	The panel noted a need to demonstrate effectiveness of designs intended to reduce the risk of contamination before those devices are available for use; however, the challenges associated with generating such data before marketing were also noted.
Does high-level disinfection provide an adequate margin of safety? Considering the challenges and benefits of sterilization for routine duodenoscope reprocessing, is a transition toward sterilization warranted, and if so, how can the inherent challenges with sterilization be addressed?	The panel's consensus was that cleaning is the most important step in duodenoscope reprocessing. The panel noted that in properly cleaned duodenoscopes, high-level disinfection is appropriate. However, panel members acknowledged that reports indicate that duodenoscopes are not properly cleaned. The panel also discussed the challenges of implementing sterilization of duodenoscopes, such as potential decreased patient access to ERCPs and increased costs.

FDA, U.S. Food and Drug Administration.

In the short term, endoscopy units can focus on several critical elements to improve endoscope reprocessing steps:

- Build realistic endoscopy schedule templates (or purchase the necessary number of endoscopes) to account for the time it takes to fully reprocess an endoscope in accordance with manufacturers' IFUs (estimated to be 100 minutes). This will help to minimize a hostile work environment for endoscope reprocessing staff and ensure they are not pressured to perform faster at the expense of completing all reprocessing steps.
- Use existing or develop a reprocessing training curriculum that is evidence based and incorporates effective modalities for adult learning. Part of this curriculum should embed an auditing tool for reprocessing staff.
- Discontinue the administration of simethicone through the accessory water jet. If simethicone is required, then the lowest possible concentration (≤.5%) should be used and should be administered through the endoscope working channel.
- Transition to automated reprocessing equipment such as an AER or timed, automated drying equipment. When using automated drying equipment during reprocessing, a 10-minute, continuous cycle should be used.

In the intermediate term, a number of areas within reprocessing should be addressed:

- Assess the clinical significance of various borescopic findings and the role that borescopes play in reprocessing.
- Assess and define the role of technologies to perform real-time auditing of the manual cleaning step, such as testing for protein, blood, carbohydrates, or adenosine triphosphate.
- Develop defoaming alternatives to simethicone.
- Define the role of patient risk profiling (eg, carbapenem-resistant Enterobacteriaceae carriers) before endoscopy and how this might impact reprocessing protocols.
- Define the role of microbiologic assessment of duodenoscope reprocessing as a tool for outbreak investigation and surveillance purposes.
- Evaluate alcohol's contribution (or lack thereof) in the drying process.

TABLE 2. Proposed next steps and future directions developed at the 2019 American Society for Gastrointestinal Endoscopy Infection Control Summit stratified into short-, intermediate-, and long-term interventions

Short-term
• Build realistic endoscopy schedule templates to account for the true time it takes to reprocess an endoscope. • Use existing or develop a reprocessing training curriculum that is evidence based and incorporates effective modalities for adult learning. • Discontinue the administration of simethicone through the accessory water jet. If simethicone is required, then use the lowest possible concentration (≤.5%) and administer it through the endoscope working channel. • Transition to automated reprocessing equipment.
Intermediate-term
• Assess the clinical significance of various borescopic findings and the role that borescopes play in reprocessing. • Assess and define the role of technologies to perform real-time auditing of the manual cleaning step. • Develop defoaming alternatives to simethicone. • Define the role of patient risk profiling (eg, carbapenem-resistant Enterobacteriaceae carriers) before endoscopy and how this might impact reprocessing protocols. • Define the role of microbiologic assessment of duodenoscope reprocessing as a tool for outbreak investigation and for surveillance purposes. • Evaluate alcohol's contribution (or lack thereof) in the drying process.
Long-term
• Complete a redesign of the endoscope to ensure easier and more effective reprocessing. • Establish practical, validated, and outcomes-based methods for documenting the absence of residual bacterial contamination in duodenoscopes. • Define the role of sterilizable or single-use options in the proper clinical setting. • Assess the feasibility, cost, and impact of low-temperature sterilization on endoscope optics/function. • Measure applicability, cost, environmental impact, patient selection, and patient experience with single-use endoscopes.

Finally, long-term interventions should be directed toward endoscope design and effective modalities to improve reprocessing:

- Complete redesign of the endoscope to ensure easier and more effective reprocessing. In particular, attention to smooth, brushable crevices, or perhaps even a complete transition to "drive by wire" systems, in which the elevator riser is actuated by electrical signals rather than a physical cable; such a design change would eliminate a channel of entry for microorganisms.
- Establish practical, validated, and outcomes-based methods for documenting the absence of residual bacterial contamination in duodenoscopes.
- Determine the role of sterilizable or single-use options in the proper clinical setting.
- Assess the feasibility, cost, and impact of low temperature sterilization on endoscope optics/function.
- Measure the applicability, cost, environmental impact, patient selection, and patient experience with single-use endoscopes.

CONCLUSIONS

ERCP is a complex, challenging therapeutic modality that aids in the diagnosis and treatment of many hepatic, biliary, and pancreatic diseases. Equally complex is the design and reprocessing of the duodenoscope used in these procedures. The ASGE Infection Control Summit sought to assemble key stakeholders and leaders from around the United States to outline the current state of infection control as it relates to the reprocessing of duodenoscopes, assess current reprocessing practices, critically evaluate the literature, and discuss the future of endoscope reprocessing. Since the first outbreaks attributed to duodenoscopes were reported in 2013, a great deal has been learned regarding attack rates and modalities to help reduce culture positivity in duodenoscopes. A wealth of research has been performed on disinfection techniques, adequacy of reprocessing, drying, and storage of endoscopes with the goal of improving reprocessing. Critical to reducing duodenoscope-related infections is ensuring that individuals are adequately trained and assessed in terms of competency and maintenance of reprocessing skills. Human factors continue to play a central role in reprocessing lapses, and future efforts should be directed at addressing these issues. Presently, efforts are focused on reducing biofilm risk through implementing high-quality reprocessing programs, testing for compliance, optimizing and standardizing drying modalities, avoiding components during endoscopy that could promote biofilm development, and preventative maintenance for endoscopes and AER equipment. Future work will explore disposable devices or endoscope redesign; new disinfection methods, such as the role of sterilization; and updating guidelines to assist end users with the reprocessing process. A collaborative approach among gastroenterologists, microbiologists, epidemiologists, healthcare practices, regulatory agencies, and device manufacturers is essential to the success of all current and future work in this area.

DISCLOSURE

The following authors disclosed financial relationships: L. Day: Expert witness for Boehringer Ingelheim, Partner worked for, owned stock in Pfizer; B. Petersen: Consultant on reprocessing issues for Olympus America, Consultant on reprocessing issues for Pentax, Inc, Consultant and investigator on single use duodenoscope for Boston Scientific, Consultant on single use devices for Ambu, Inc, Consultant on ERCP device, GI Medical, Stock ownership in Exact Sciences and Johnson and Johnson. All other authors disclosed no financial relationships.

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Abbreviations: AER, automated endoscope reprocessor; ASGE, American Society for Gastrointestinal Endoscopy; FDA, U.S. Food and Drug Administration; HLD, high-level disinfection; IFU, instructions for use.

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