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Natasha Facey
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Building 66, Room 1552
Silver Spring, MD 20993-0002

Re: Docket No. FDA-2015-N-0722; Gastroenterology and Urology Devices Panel meeting on reprocessing of duodenoscopes and other endoscopes.

To Members of the Gastroenterology and Urology Devices Panel:

The Association for Professionals in Infection Control and Epidemiology (APIC) appreciates the opportunity to provide comments to the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee. APIC is a nonprofit, multidisciplinary organization representing over 15,000 infection preventionists whose mission is to create a safer world through prevention of infection. Our members are charged with the prevention of healthcare-associated infections and are usually the first to identify outbreaks. In order to protect patients from harm, APIC welcomes the opportunity to work with both the Food and Drug Administration (FDA) and industry to ensure that devices used for necessary medical procedures are as safe as possible and do not cause increased risk to patients. What follows are our comments on the five questions posed by the Panel.

The effectiveness of cleaning, high level disinfection, and sterilization methods

The reprocessing of reusable patient care devices is a complex process with many steps. This is especially true in the case of duodenoscopes and endoscopic ultrasound scopes, which are highly complicated devices that are exceedingly difficult to clean effectively. In a prospective multisite study it was noted that all steps in manual high level disinfection are completed only 1.4% of the time.¹ The same study reflected that all steps in high level disinfection with an automated endoscope reprocessor (AER) are completed only 75.4% of the time.¹ For these reasons, to accept a manufacturer's high level disinfection process that assumes 100% compliance with the process does not reflect the reality in the field, and assumption that it will be followed puts patients at risk.

Endoscopes are classified as semi-critical items because they come into contact with an intact mucosal barrier that is naturally colonized with microorganisms and therefore not considered to be sterile. However this same exposure makes endoscopes far more likely to incur higher levels of contamination than items that are typically considered critical and require sterilization. The recurrent issue of outbreaks associated with endoscopes that are reprocessed using high level disinfection points to the need to reassess the threat level of these items. Gastrointestinal (GI) Physicians, Perioperative Services, Infection Prevention and Control, Risk Management, Organizational leadership and the appropriate manufacturer's



representatives should assume shared responsibility for performing a risk assessment and gap analysis to determine best practices for scope reprocessing.

The amount and type of premarket validation data and information needed to support labeling claims and technical instructions

APIC recommends improving endoscope design to allow for proper cleaning and disinfection/sterilization of the elevator area and all other scope components.

Collaboration with scope manufacturers is essential to determine the appropriate reprocessing guidelines. A robust process ensures that cleaning, high level disinfection and/or chemical sterilization for each type of scope utilized is congruent with the manufacturer recommendations/guidelines. Standardized processes should also be developed for transport, storage and tracking patient-specific use of each scope.

Our organization must work to improve the rates of compliance with the reprocessing steps. At the same time, manufacturers' guidelines for high level disinfection or sterilization must be successfully validated by third parties as eliminating all bacterial and viral challenges while reflecting actual practice rates around those processes.

Manufacturers' reprocessing instructions should state specific timetables for the reprocessing steps and avoid imprecise words such as "immediate". Instructions should also include data to show what process timeframes resulted in successfully reprocessed scopes.

The appropriate use of other risk mitigations, such as surveillance cultures

Current guidelines do not address the appropriate surveillance to assess effectiveness of endoscope reprocessing. Historically, scopes have only been cultured during outbreak situations. The Centers for Disease Control and Prevention (CDC) has stated that even the suggested current culturing technique has an unknown sensitivity and specificity.² Statements by individuals in one of the institutions experiencing a reported outbreak associated with scopes noted that despite overwhelming epidemiological data implicating the scopes, repeated culturing of those scopes failed to detect the organisms associated with the outbreak. Therefore, due to the unknown sensitivity of surveillance cultures, these can only be considered as part of an overall quality assurance program. Determination of culturing methods should establish the sensitivity and specificity of the method, recommend appropriate time intervals for culturing of scopes, standardized procedures for obtaining cultures, and recommended interventions based on results. It should be noted that quarantine of scopes while awaiting culture results could result in delay in patient care.

The FDA, in collaboration with the CDC and other experts, is urged to develop a validation approach that determines when the process has been successful at eliminating the risk of transmission. The approach should be used for both validating the submitted reprocessing instructions, and/or use by facilities utilizing and reprocessing the scopes.

Best practices and guidelines for reprocessing duodenoscopes and endoscopes at user facilities to minimize the transmission of infections

Each facility should implement standardized processes for educating reprocessing personnel that involves didactic education, demonstration and return demonstration and creation of a job aid. Direct



observations should occur utilizing a super user with initial training, then quarterly and at the time of an outbreak. An annual competency assessment should be completed. Users should adopt general best practices to meticulously pre-clean as well as clean all components of the scope (including the elevator mechanism and the recesses surrounding the elevator mechanism by hand), even when using an AER. Best practice includes the raising and lowering of the elevator throughout the manual cleaning process to allow brushing of both sides. APIC also supports certification for instrument processing personnel as a consideration to enhance quality.

Each facility should develop and implement a comprehensive quality control program for reprocessing duodenoscopes and endoscopic ultrasound scopes. This program should include written procedures for monitoring training and program adherence. It should also include standard documentation of equipment tests, processes, and quality monitors used during the reprocessing procedure. Any duodenoscope suspected of being associated with a patient infection should be taken out of service. A process including validation of cleaning sterilization must be conducted before the scope is returned to service.

In summary, facilities must ensure strict adherence to all manufacturers' guidelines, endoscope reprocessing guidelines, and precautions established by the infection control community and endoscopy professionals.

Recommended approaches for ensuring patient safety during ERCP procedures, including a discussion of appropriate patient selection

Prior to undergoing the procedure, all candidate patients should have a detailed medical history that includes previous GI procedures and any detection of significant pathogens prior to this procedure. An understanding of the risks (including infection) and benefits of the procedure must be part of the patient's informed consent. Alternative approaches based on non-endoscopic methods to diagnose or treat disease (e.g. capsule endoscopy, blood tests to detect gastrointestinal cancer) should be considered and offered to the patient, if appropriate.

Providers must recognize that clinical risks of infection can be increased if the patient has a compromised immune status (e.g. transplant or chemotherapy patients), or a history of heart disease such as prosthetic heart valves, previous history of endocarditis, complex congenital heart disease, and surgically constructed systemic pulmonary shunts.

Antibiotic prophylaxis for the prevention of iatrogenic infections may be recommended for ERCP and associated pancreatobiliary procedures where there is duct obstruction, and tissue disruption or impaired immune status. This may also include patients who have undergone traumatic procedures with major tissue manipulation, or incomplete drainage of obstruction.

If the facility is utilizing surveillance culturing, the development of a tracking mechanism for identification of exposed patients and appropriate notification of patients that a potential exposure has occurred should be considered by facility leadership as suggested by Rutala's sterilization failure recall process modifying it to reflect all new risk data gathered since the documents publication.³

Future Considerations

We will continue to see outbreaks associated with endoscopes unless we implement new methods to prevent GI endoscope-related infections. One long-term solution to this infection prevention challenge would be to develop new endoscope reprocessing technologies that reliably result in sterilization of



duodenoscopes and other GI endoscopes via an FDA-cleared sterilization process that achieves a sterility assurance level of 10^{-6} .

Some sterilization technologies that should be evaluated include ozone plus hydrogen peroxide vapor, nitrogen dioxide, supercritical CO₂, peracetic acid vapor, gaseous chlorine dioxide, hydrogen peroxide gas plasma, and steam sterilization for heat-resistant endoscopes. Based on findings in numerous studies, sterilization methods dependent on needing direct contact in order to have an effective kill must be evaluated assuming bioburden still exists in the device lumens. Other potential future methods to prevent GI endoscope-related outbreaks include: disposable sterile GI endoscopes; improved GI endoscope design to reduce or eliminate challenges associated with current design; use of non-endoscopic methods to diagnose or treat disease (e.g., capsule endoscopy, blood tests to detect GI cancer, stool DNA test); and the utilization of technologies allowing complete visualization of all surface areas inside the endoscope likely to be contaminated. These new technologies could greatly improve the margin of safety and eliminate patient risk. The development of disposable endoscope technology has promise but diagnostic functionality and cost will be important considerations in their adoption by the medical community.

We urge the FDA to work toward sterilization of reusable endoscopes as the standard reprocessing approach. In addition, disposable scopes would also be a viable alternative. If, however, scopes were to be routinely sterilized, the manufacturer must provide users with information on the total number of complete reprocessing cycles a scope should be expected to tolerate during its usable lifespan.

APIC appreciates the opportunity to share our views with the Panel, and we look forward to working with manufacturers, government agencies, and provider organizations to ensure the safest possible procedures for patients.

Sincerely,

A handwritten signature in black ink that reads "Mary Lou Manning". The signature is fluid and cursive, with the first letters of each name being capitalized and prominent.

Mary Lou Manning, PhD, CRNP, CIC, FAAN, FNAP

¹ Ofstead, Wetzler, Snyder, Horton. Endoscope Reprocessing Methods. Gastro Nursing 2010; 33:204

² Available at <http://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol-FAQs.html>

³ Available at http://www.cleanhospitals.net/f/Rutala_WA_ICHE_2007_reprocessing_failure_GL.pdf