Lessons learned:

Questions and concerns regarding safety of endoscopes and validity of manufacturer guidance

Reports of carbapenem-resistant Enterobacteriaceae (CRE) infections related to endoscopic retrograde cholangiopancreatography (ERCP) duodenoscopes raised concerns among infection prevention experts, federal agencies, and the public. In February 2015, Ronald Reagan UCLA Medical Center notified 179 patients who underwent ERCP that they may have been exposed to CRE from contaminated duodenoscopes. Ronald Reagan UCLA Medical Center reported that only patients who underwent ERCP procedures from October 3, 2014, to January 28, 2015, were at risk of CRE infection as a result of these procedures. UCLA Medical Center noted that it processed the scopes according to the standards stipulated by the manufacturer. As of February 23, a total of seven UCLA patients were infected and two died.

Among infection preventionists, this incident has raised many questions about appropriate cleaning and disinfection of endoscopes, surveillance culturing process of endoscopes, and the validity of manufacturer guidance. Here, we present common questions that have arisen about these issues and answers from experts.

MEET THE EXPERTS

Centers for Disease Control and Prevention (CDC)
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James Davis represented APIC as part of the working group that helped develop the CDC's duodenoscope surveillance protocol.

Answers from experts

Q: How did the FDA approve the sale of endoscopes that are not properly validated to be reused without the risk of infection when manufacturer guidance is followed?

Frank Myers: Press reports have stated that some of the ERCP scopes linked to some of the outbreaks were not approved by the FDA in the configuration used. Manufacturers are allowed to make small changes to a design that does not significantly change the function or cleaning of the device. In this case, the company in 2010 felt the changes were not significant enough to warrant a new 510(k) approval. The FDA has since become aware of the changes and requested a new 510(k) application be submitted. Both the FDA and the manufacturer have supported using the scope in the interim despite not having 510(k) approval. Other scopes linked to outbreaks have been approved by the FDA. Because of this, the FDA has reached out to APIC and others to give input on new validation approaches for these scopes.

Citation: www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm437804.htm.

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Q: Does the cleaning and disinfection issue apply to just ERCP endoscopes or to other items with a similar elevator channel structure such as endoscopic ultrasound scopes (EUS)?

CDC: All endoscopes should undergo appropriate reprocessing in accordance with the manufacturers' instructions. Given the complex design of duodenoscopes, special attention should be paid to the cleaning and disinfection of the elevator mechanism located at the distal tip of the duodenoscope and to ensuring complete drying of all the channels and the elevator mechanism. Training and oversight of individuals performing endoscope cleaning and disinfection is an essential component of successful reprocessing. Clusters related to transmission of bacteria from EUS have not been reported to CDC; however, since these scopes have similar design features to duodenoscopes, similar challenges for transmission might also exist with these endoscopes. CDC's interim surveillance protocol (www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html) is primarily intended for duodenoscopes; however, the measures outlined in the protocol could also be applied to these devices.

Frank Myers: While the FDA and other organizations' guidance have focused on the ERCP scope, many institutions have begun to look at and speak about "elevator scopes" as being problematic. This grouping includes both ERCP and EUS. Since "elevator scopes" share a number of similar characteristics, it is being proactive to also look at processes and cleaning issues around these scopes. The American Gastroenterological Association (AGA) Center for GI Innovation and Technology convened a meeting, "Getting to Zero," in March with experts in gastroenterology, epidemiology, and infectious disease; the endoscope manufacturers Fuji and Pentax; and representatives from the U.S. Food and Drug Administration (FDA), CDC, and ECRI Institute to discuss how to prevent these infections and recommended "treating all elevator-channel endoscopes the same, including both FNA echoendoscopes (EUS) and duodenoscopes." There has been one outbreak linked to EUS, suggesting their design may not be different enough to prevent the issues seen with ERCP scopes.

Citation: www.prnewswire.com/news-releases/how-to-stop-duodenoscope-infections-300054158.html.

Q: If a facility is considering sending their ERCP endoscope(s) out for ethylene oxide (ETO) gas sterilization, what things do infection preventionists and administrators need to consider and plan for?

James Davis: Infection preventionists and administrators need to consider and plan for:

1. The tracking and management of scopes leaving and returning to the medical facility.
2. Performing due diligence related to cost and quality for companies that perform such work (consider the use of a due diligence checklist).
3. Knowing who is responsible if a scope is damaged during transport or reprocessing, how it will be replaced, and whether or not loaner equipment is available until a replacement is purchased will be important to know up front.
4. Reviewing the contract for assignment of liability related to lapses in reprocessing/sterilization by the contractor.
5. Knowing who provides the transport containers and how sterility is maintained during transport.
6. Conducting a FMEA [failure mode and effects analysis] prior to initiating the system change.
7. Simulating the process in-situ. (The best laid plans may need to change once the process is simulated where the work happens.)
8. Contacting the endoscope manufacturer regarding warranty issues related to off-IFU [instructions for use] reprocessing, and whether or not the manufacturer support will change if using ETO.

Q: ETO gas sterilization is known to degrade medical equipment after multiple exposures. Is any data available regarding how many times ERCP endoscopes may be treated with ETO before they degrade?

James Davis: The scope manufacturer will need to provide that answer based on validation and testing. One should also contact the manufacturer regarding warranty issues related to off-IFU reprocessing.

Frank Myers: I agree with James' comments. I would add that some institutions switching to ETO have reported significant losses in the number of scopes because of degradation. If your institution is considering ETO sterilization, it would seem prudent to query institutions that have or are using ETO sterilization on scope models that your institution will be sterilizing. Asking about their experiences with ETO sterilization, including attrition rate, will allow your institution to plan for all the issues around ETO sterilization.

Q: What turnaround time should facilities who move to ETO gas sterilization expect (e.g., transportation, sterilization, and aeration time)?

James Davis: Refer to the answer of question three. Simulation/FMEA of the process will be the only real way to answer the question given the variability of distance transported, facility processes, and contractor load and lead time.

Q: Should facilities that chose to perform surveillance cultures on endoscopes perform these cultures on all endoscopes or just ERCP endoscopes?

CDC: In the United States, bacterial transmission associated with endoscopes for which no obvious reprocessing breaches were identified have thus far been linked to only duodenoscopes. In light of this, CDC developed an interim protocol specifically for duodenoscopes that can serve as a guide for facilities considering cultures of duodenoscopes to assess the adequacy of their duodenoscope reprocessing. Although there is no requirement to perform duodenoscope cultures, some facilities have elected to perform regular surveillance cultures as part of their response to the issue. This is not a replacement for ongoing training and oversight to ensure that cleaning and disinfection steps are performed correctly; however, it does provide facilities considering duodenoscope cultures with a consistent starting point for a protocol that can be adapted for use. Some groups outside the United States have recommended routinely performing surveillance cultures of other types of endoscopes, in addition to duodenoscopes. However, the benefit of this approach is not known.

Q: Is it recommended that facilities test each endoscope or a random sample of endoscopes? If the latter, what is the recommended interval?

CDC: Facilities choosing to perform surveillance cultures of duodenoscopes should consider obtaining post-reprocessing cultures of each duodenoscope that is in service. However, the optimal frequency of surveillance cultures has not been determined and could range from after each duodenoscope use (after reprocessing) to interval sampling, e.g., monthly or after every 60 procedures for each duodenoscope. International guidelines have recommended intervals ranging from every four weeks to annually.

Q: Is the surveillance culturing process recommended by CDC validated such that it assures endoscopes that are surveillance cultured cannot transmit infection?

CDC: CDC's interim surveillance protocol represents one possible approach to culturing of duodenoscopes and has not yet been validated, i.e., the sensitivity, specificity and limits on quantitation or detection are not established for all organisms. As such, a negative culture result should not completely exclude the possibility of a contaminated duodenoscope. In the event of a suspected outbreak linked to duodenoscopes, negative surveillance cultures alone should not be used to exclude duodenoscopes as a source of cross-contamination.

James Davis: The CDC has provided an interim protocol to help guide facilities. Validation of a culture method is possible; however, to say that the validation of the culture method will eliminate the risk of infection from a fomite is improbable. One must consider false results/negatives and an individual laboratorian's performance of the task. Each facility that will be performing screening will need to design a system that validates their own lab processes and performance.

Frank Myers: No, the CDC has stated explicitly that the sensitivity of this culturing method is not known, meaning false negatives are a distinct possibility. Unpublished reports have stated that some scopes implicated epidemiologically in outbreaks have cultured negative using this method.

Citation: www.cdc.gov/hai/settings/lab/lab-duodenoscope-sampling.html

Q: Who should perform the processing, culture, and identification of resultant bacteria from the samples collected?

CDC: Samples should be processed by personnel with microbiological understanding of culturing principles and identification of common environmental and clinical bacteria. Facilities should use discretion in determining personnel best qualified and trained for these activities. A multi-disciplinary team should be brought together to decide the best approach for the individual facility. The facility can consider using an external laboratory for the laboratory protocol (e.g., academic environmental microbiology laboratory associated with the hospital or private contract laboratory, etc.) if necessary.

James Davis: Culturing methodology should not deviate from the standards currently used by a facility/industry. If a facility does not conduct environmental or fomite-based cultures, consider consultation with an environmental hygienist or an experienced contractor. As for who should culture, if facility-based, the laboratorians (culturing is what they do). If non-facility, confirm the contract stipulates the competency and training the culturing staff receives.

Q: Do facilities need to quarantine the endoscopes until results are known? If not, what should the recall process be for endoscopes that culture positive but have already been used on a patient?

CDC: Facilities could consider holding duodenoscopes out of use while surveillance culture results are pending, especially if surveillance cultures are performed after each use. For facilities that choose to not quarantine duodenoscopes, and a high-concern organism (as defined in CDC's Interim Duodenoscope Surveillance Protocol) is detected through surveillance cultures, the duodenoscope should be taken out of use until remedial actions are taken and cultures no longer detect presence of the organism. The decision to notify exposed patients should be made in consultation with appropriate facility staff, including infection prevention staff and hospital epidemiologists, and public health authorities. Patient notification should generally target all patients who underwent a procedure with the contaminated duodenoscope since the time of the last known negative duodenoscope culture. Facilities should routinely document the specific endoscope used for each patient to facilitate the identification of exposed patients in the event of a patient notification.

Q: Significant caution must be observed when performing surveillance cultures to prevent contamination. What type of room or location should be used for duodenoscope sampling?

CDC: Duodenoscopes should be sampled on a clean surface away from traffic, obvious airflow (e.g., vents), and potential contamination with water. A sectioned-off area of a reprocessing room or a separate room can be designated for duodenoscope sampling.

Q: Is there any work being done with the manufacturers to change the design of ERCP endoscopes so that they can be adequately cleaned and disinfected?

James Davis: I am unaware of any design revisions being proposed. However, a company may want to investigate such an option. A scope design that would perform the same ERCP as the traditional elevator channel type scope and has been designed with reprocessing ease in mind, would likely provide that company with a sales edge over the competition.

Q: What future standards regarding endoscope cleaning do you expect we will see?

James Davis: Healthcare is a hands-on business, always relying on humans who need to perform tasks in order for the system to function. ERCP scopes combined with the CRE organism have shown a potential weakness in high level disinfection/cleaning methods. However, where there is weakness there are opportunities for improvement.

1. **Human factors/ergonomics:** As is the case with most instruments used by proceduralists, the instrument is designed around the procedure. The reprocessing of said equipment will vary in level of difficulty as the complexity of the instrument increases. The ERCP scope has been designed to do a very specific job within the human body; it has been designed to not only perform the procedure, but aide the proceduralist in completing the tasks related to the procedure. One may ask if the ERCP scope design has prioritized reprocessing at the same level as procedural performance. Industry may want to look at future design and address all of the needs of all of the users who come in contact with the device. If industry does not answer the call, in my opinion, there should be standards set forth that ensure human factors and ergonomics are addressed for each stage of the device's use.
2. **Certification/licensure of reprocessing/sterilization staff:** Medical devices that are reprocessed range in complexity from a simple pair of hemostats to the ERCP-type duodenoscopes being discussed. Each device type is processed in a certain way by a certain method. Due to the complexity and exactness of the tasks reprocessing staff must perform, several states have proposed bills that would make certification or licensure a requirement. Currently, I am unaware of a federal proposal for certifying or licensure; however, the combination of ERCP and CRE has proven to be a warning of what is possible. I would expect to see more state—and perhaps federal—legislation introduced that would require formal validation of competency that sets standards for reprocessing staff. PS

AJIC American Journal of Infection Control

READ MORE ABOUT ENDOSCOPES IN THE *AMERICAN JOURNAL OF INFECTION CONTROL*

Aldehyde-resistant mycobacteria bacteria associated with the use of endoscope reprocessing systems, Fisher, Christopher W. et al., *American Journal of Infection Control*, Volume 40, Issue 9, 880-882.

Establishing a clinically relevant bioburden benchmark: A quality indicator for adequate reprocessing and storage of flexible gastrointestinal endoscopes, Alfa, Michelle J. et al., *American Journal of Infection Control*, Volume 40, Issue 3, 233-236.

An Outbreak of Carbapenem-resistant *Klebsiella pneumoniae* Infections Associated with Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures at a Hospital, Sanderson, Roger et al., *American Journal of Infection Control*, Volume 38, Issue 5, e141.

Validation of adenosine triphosphate to audit manual cleaning of flexible endoscope channels, Alfa, Michelle J. et al., *American Journal of Infection Control*, Volume 41, Issue 3, 245-248.

Early identification and control of carbapenemase-producing *Klebsiella pneumoniae*, originating from contaminated endoscopic equipment, Alrabaa, Sally F. et al., *American Journal of Infection Control*, Volume 41, Issue 6, 562-564.

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Additional CRE and scope resources

VISIT APIC'S CRE webpage (www.apic.org/Resources/Topic-specific-infection-prevention/CRE) for resources and guidance from CDC and others on preventing infections associated with duodenoscopes. Here is a small sampling of what you'll find on this page:

GOVERNMENT RESOURCES

Centers for Disease Control and Prevention resources

- Interim Duodenoscope Surveillance Protocol
- Interim Duodenoscope Sampling Method
- Interim Duodenoscope Culture Method
- Stop Infections from Lethal CRE Germs Now (Vital Signs report)
- Guidance for control of Carbapenem-resistant Enterobacteriaceae (CRE)
- Tracking CRE
- Management of multidrug-resistant organisms in healthcare settings
- Laboratory protocol for detection of carbapenem-resistant or carbapenemase-producing *Klebsiella* spp. and *E. coli* from rectal swabs

U.S. Food and Drug Administration resources

- FDA releases final guidance on reprocessing of reusable medical devices, issued 3/12/2015
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued 3/12/2015
- Safety communication, issued 2/19/2015
- Olympus validates new reprocessing instructions for model TJF-Q180V duodenoscopes, issued 3/26/15

Agency for Healthcare Research and Quality resources

- Carbapenem-resistant Enterobacteriaceae (CRE) control and prevention toolkit

OTHER RESOURCES

- ECRI Institute recommends culturing duodenoscopes as a key step to reducing CRE infections—ECRI Institute, March 3, 2015
- How to stop duodenoscope infections—American Gastroenterological Association, March 23, 2015
- Superbug reveals challenges with high level disinfection—The Joint Commission Quick Safety advisory, March 2015

APIC CRE REPORTING MAP

- Summary of state CRE reporting requirements—APIC Government Affairs resource

APIC COMMUNICATIONS RESOURCES

- Key talking points for infection preventionists to ensure effective reprocessing of ERCP duodenoscopes to reduce the risk of infection
- The APIC and Society for Healthcare Epidemiology of America (SHEA) press release
- ERCP procedures and duodenoscopes frequently asked questions for consumers