Contaminated Duodenoscopes and CRE Transmission: DICON Response

Update 08/25/2015

On August 4th, 2015, the Food and Drug Administration (FDA) issued a Safety Communication describing supplemental measures that healthcare institutions could implement to reduce the potentially risk of infections related to duodenoscopes (Link). While there is currently no technological solution that will completely eradicate the risk of microbial contamination, these supplemental cleaning measures are logical and prudent applications of currently available technology that could increase endoscope safety. There are a total of six supplemental safety measures:

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<th>Strength of Recommendation</th>
<th>Availability of Technology</th>
<th>Minimal Inventory or Work Flow Impact</th>
<th>Evidence for Added Safety</th>
<th>Feasibility</th>
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<td>ETO after HLD</td>
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<td>HLD with micro surveillance</td>
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- ☢️ Yes
- ☢️ Uncertain
- ☢️ No
For most hospitals, repeat high-level disinfection (Double HLD) is likely the most feasible supplemental approach – it leverages existing technology, and has the least impact on clinical workflow and capital expenditure. Moreover, the repeat mechanical washing of the elevator channel of duodenoscopes would likely reduce any residual bioburden and improve margin of safety of these devices. We recommend that healthcare facilities performing ERCP evaluate whether they have the expertise, training and resources to implement one or more of these options.

Background

Multiple recent outbreaks of carbapenem-resistant *Enterobacteriaceae* (CRE) associated with contaminated duodenoscopes have received widespread media attention (1-3). Investigation of these outbreaks has not revealed breaches in infection control practices; in fact, cleaning and disinfection procedures followed duodenoscope manufacturer reprocessing guidelines (4,5). Despite these precautions, contaminated duodenoscopes at several hospitals across the US, most recently at UCLA Medical Center, have been associated with new CRE colonization in asymptomatic patients, as well as severe medical illness, including death, in patients with invasive CRE infection (6). In total, the FDA received reports of approximately 135 cases of possible microbial transmission from duodenoscopes that underwent standardized reprocessing during 2013 and 2014.

The transmission of potentially deadly, highly drug-resistant bacteria from an appropriately reprocessed endoscope to a patient undergoing a commonly performed gastrointestinal procedure is certainly unsettling and raises a number of important questions. For example: *Why does microbial transmission occur, particularly if hospital staff follow disinfection guidelines? What is the risk of transmission? What actions will reduce the risk of endoscope-related transmission of resistant bacteria at my hospital?* This newsletter addresses these questions, focusing on recommendations for community hospitals in the DICON network.

**Why does transmission of bacteria occur via reprocessed duodenoscopes?**

Contaminated endoscopes cause more healthcare-associated outbreaks than any other medical device (5). This fact emphasizes just how common endoscopic procedures have become: more than 10 million gastrointestinal endoscopic procedures are performed each year in the US. However, historic outbreaks from endoscopes, in contrast to the recent outbreaks described above, were associated with inadequate disinfection techniques and damaged endoscopes or automated endoscope reprocessors (AERs).
Recently reported CRE transmission from endoscopes occurred from duodenoscopes that are used for ERCP (endoscopic retrograde cholangiopancreatography), which is performed over 500,000 times in the US annually (7). ERCP is a procedure that allows drainage of biliary and pancreatic ducts that are blocked by gallstones, tumors, anatomic abnormalities, and other conditions. Duodenoscopes are flexible tubes that pass through the mouth, throat, and stomach to enter the duodenum (small intestine). Duodenoscopes are different from other endoscopes because they contain an “elevator channel” at the tip that allows changes in scope angle necessary to access the ductal system. One step of the duodenoscope cleaning process requires manual brushing of the elevator area; nevertheless, the manual brushing and automated reprocessing steps may not reach small or microscopic crevices in the elevator mechanism. As a result, the elevator channel is difficult to fully disinfect, and this problem may contribute to microbial transmission even if staff follow current reprocessing guidelines.

The current standard of care for reprocessing of gastrointestinal endoscopes includes cleaning followed by high-level disinfection. High-level disinfection is traditionally defined as “complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores (8).” However, inherent limitations in high-level disinfection of gastrointestinal endoscopes increase the risk of microbial transmission. The combination of prescribed cleaning and high-level disinfection steps creates at best a very small safety margin in reduction of microbes (9). As opposed to disinfection, the process of steam sterilization used for reprocessing surgical equipment creates an exponentially larger safety margin of microbe reduction. Unfortunately, flexible gastrointestinal endoscopes are heat labile and cannot tolerate standard sterilization techniques.

**What is the risk of microbial transmission?**

The risk of microbial transmission via gastrointestinal endoscopic procedures is difficult to quantify because surveillance of outpatient procedures is often absent or inadequate. Asymptomatic and transient colonization is probably much more common than clinical infection. However, while the recently scrutinized outbreaks and clusters are concerning, the overall number of bad patient outcomes, especially considering how frequently physicians perform gastrointestinal endoscopy, remains low. Furthermore, ERCP is often a critical diagnostic or therapeutic maneuver that precludes many of the significant risks of much more invasive surgical alternatives. When the procedure is indicated, the benefit of ERCP outweighs the current risk, and even improved reprocessing protocols will not eliminate all risk.

**What will reduce the risk of microbial transmission at my hospital?**

In response to the recent CRE outbreaks, many hospitals have added new steps to cleaning and disinfection procedures for duodenoscopes intended to decrease risk of bacterial transmission. For example, some centers are performing additional disinfection of the elevator channel with channel flushing aids and other cleaning agents not recommended by current guidelines. Other hospitals are culturing duodenoscopes after ERCP and are not using reprocessed endoscopes until these cultures return negative. Finally, some infection control practitioners have suggested screening patients for CRE
and other resistant bacteria before and after endoscopic procedures. We do not currently recommend these new steps which have unproven benefit and could actually contribute to contamination or otherwise introduce patient harm. **DICON does, however, recommend that your hospital do the following:**

- Review your current duodenoscope (and other gastrointestinal endoscope) reprocessing protocol, and ensure that this protocol detailing cleaning and high-level disinfection steps is compliant with duodenoscope manufacturer reprocessing guidelines. Formal documentation confirming that staff follow an appropriate reprocessing protocol is essential.

- Reprocessing guidelines include meticulous cleaning of the elevator channel by hand, in addition to any use of an automated endoscope reprocessor. Raise and lower the elevator during manual cleaning to promote brushing of both sides. Recent FDA guidance strongly emphasized this component of reprocessing (7).

- Implement a thorough quality control program for duodenoscope reprocessing. Internal auditors should periodically monitor training practices, adherence to the reprocessing protocol, and documentation of appropriate reprocessing of duodenoscopes and testing of related equipment.

- In the short term, it would be reasonable (although not required) to follow your high-level disinfection protocol with ethylene oxide (EtO) gas sterilization. One of the CRE outbreak hospitals used ethylene oxide sterilization to help terminate the outbreak (4). The use of EtO, however, comes with several logistical hurdles and will not be feasible for many hospitals that no longer have ethylene oxide. Furthermore, the FDA has not approved this agent for sterilization of gastrointestinal endoscopes, and the sterilization and aeration process takes 12-15 hours (5).

- Discuss risks and benefits of ERCP with patients, including the possibility of procedure-related infection.

- If a duodenoscope is suspected as a cause of patient colonization or infection, take the duodenoscope out of service, and ensure it is no longer contaminated before using again.

- Report any suspected duodenoscope-related patient infections to DICON.

- Review the recently released FDA safety communication discussing ERCP duodenoscopes, available here (7), for additional details and references.

**Conclusion**

Multiple hospitals across the country have recently reported outbreaks of CRE related to contaminated duodenoscopes. The complicated design of existing duodenoscopes and substantial limitations in sterilization options create risk for such outbreaks, and adherence to best practices of cleaning and high-level disinfection cannot entirely eliminate this risk. We anticipate that long-term solutions will include changes in duodenoscope design or reprocessing technology that lead to FDA-approved methods of duodenoscope sterilization. However, until these improvements occur, concern over these outbreaks provides an important short-term opportunity to review current duodenoscope reprocessing protocols at your hospital and develop comprehensive quality control programs to minimize known risks.
References


