HIGH PRIORITY HAZARD REPORT

ECRI Institute Recommends Culturing Duodenoscopes as a Key Step to Reducing CRE Infections

SUMMARY:

This Hazard Report updates and supersedes the information contained in Hazard Report Accession No. H0245 01, which was published on March 3, 2015. The updated information in the Problem and ECRI Institute Recommendations sections had been bolded.

This ECRI Institute Hazard Report addresses the serious risk of carbapenem-resistant Enterobacteriaceae (CRE) patient infections associated with the use of duodenoscopes. As this hazard has gained national attention, an ECRI Institute team of physicians, clinical specialists, infection control practitioners, biomedical engineers, and others have intensively researched and reviewed the best approaches to address this problem. Our current research efforts build on years of experience investigating endoscope-related infections.

We believe that this hazard requires immediate action and executive level attention. Our recommendations will likely require additional costs and changes in workflow and processes. Further, no single solution will work for all healthcare organizations and no solutions currently exist to completely eliminate this risk. However, through rigorous management, the infection risks can be minimized. The most effective course of action that healthcare facilities should take will depend on their existing processes, technology, procedure volumes, and financial resources. Also, we believe that despite the risk of infection, Endoscopic Retrograde Cholangiopancreatography (ERCP) endoscopy procedures are vital. Discontinuing ERCP procedures as a result of the infection risk would be more harmful to patients.

Please note that this series of recommendations is the most recent guidance available from ECRI Institute; we continue to investigate this problem. As new information becomes available, we will update our guidance and recommendations.

Publication Date:

May 13, 2015

Accession # H0245 02

UMDNS Terms:

- Duodenoscopes [11359]
- Duodenoscopes, Video [17654]
- Disinfectors, Liquid Germicide, Flexible Endoscope [11279]
- Sterilizing Units, Germicidal Gas, Ethylene Oxide [13740]

Product Identifier:

Various Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes [*Capital Equipment*]

Geographic Distribution:

Worldwide

PROBLEM:

- Over the past seven years, at least seven hospitals have reported outbreaks of carbapenem-resistant Enterobacteriaceae (CRE) bacterial infections associated with duodenoscopes used for Endoscopic Retrograde Cholangiopancreatography (ERCP) procedures. ERCP procedures are used to treat and diagnose a variety of conditions of the gall bladder and pancreas, including ductal obstructions, stones, and malignancy
  - Investigations of earlier infection outbreaks among these hospitals identified the cause as **poor reprocessing technique**.
  - Investigations of more recent outbreaks have determined that infections can still occur despite close adherence to recommended reprocessing procedures.

- We believe this is a generic hazard and that most, if not all, duodenoscope models in use as well as other endoscopes with elevator mechanisms (i.e., echoendoscopes) used to view and treat the same anatomy are susceptible.
- Because CRE bacteria have become resistant to most available antibiotics including carbapenem (considered a last resort, "big gun" antibiotic), infected patients can be very challenging to treat.
- The CDC estimates that CRE contributes to the cause of death in up to 44% of infected patients.[11]

ECRI INSTITUTE RECOMMENDATIONS:

Immediately begin to develop a plan to address this concern. While there might not have been a case of CRE infection resulting from a duodenoscope in your local area, the prevalence of CRE-infected or asymptomatic colonized patients appears to be increasing.

Confirm with your duodenoscope manufacturer that your scopes are compatible with the reprocessing method you are using or plan to use, such as liquid chemical germicide (LCG) in an automated endoscope reprocessor, or ethylene oxide (EtO).

Regardless of the reprocessing method you use (e.g., EtO or LCG), confirm and monitor for close adherence to manufacturer reprocessing instructions for duodenoscopes. This should include pre-cleaning at the point of care, thorough cleaning, and rinsing prior to disinfection or sterilization.[6,9]

Document the endoscope reprocessing policies and procedures, if that has not already be done. Periodically (e.g., monthly, semi-annually) perform routine observation of reprocessing steps and document whether reprocessing steps comply with policies and procedures.

Keep in mind that with any reprocessing method, if bioburden is not effectively removed from the scopes, you cannot be certain that even sterilization will be successful.

Specifically, consider the following (Recommendation 1 applies to reprocessing with LCGs. The remaining recommendations apply to reprocessing with LCGs or EtO.):

1. If you are using an LCG for reprocessing, all duodenoscope channels should be flushed with alcohol and dried with filtered compressed air after disinfecting since this is a critical step in preventing growth of microbes.1,6,8,9 Drying can be best achieved by also using HEPA-filtered forced-air drying cabinets with channel connectors. The connectors will help ensure each channel is quickly and thoroughly dried.

2. To address the concern that duodenoscopes in current use might harbor CRE or other bacteria, do a baseline culture of all duodenoscopes. We recommend culturing for a broad range of bacteria including gram negative species. If positive cultures are identified, it is prudent to do additional selective media culturing to identify if the species present represent high or low concern bacteria. See the CDC Interim Duodenoscope Surveillance Protocol for more guidance details and how to respond if positive cultures are observed. If

Comments:

•This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our HDA Format Guide.

•This Hazard Report and other technology management, patient safety, and risk management guidance articles and recommendations are publicly available in ECRI Institute's new CRE and Duodenoscope Resource Center, located at www.ecri.org/cre

any high concern species are identified this indicates that the reprocessing protocol being used may be ineffective and therefore the protocol should be carefully reviewed and monitored to verify that it adheres to recommended instructions. The culturing should include the duodenoscope channels as well as the elevator mechanism at the distal end of the scope. Hospitals unfamiliar with endoscope culturing will need to quickly develop this skill and train appropriate staff. They also may need to obtain special supplies necessary for this activity. Guidance like that from the Gastroenterological Society of Australia and the CDC Interim Duodenoscope Sampling Method can be helpful to get started. Routine surveillance culturing of endoscopes is a common practice in Australia and several other countries.

3. Consider instituting regular **microbiologic** surveillance through duodenoscope culturing. Implementing this properly will not be trivial, but we believe it will provide the best means to monitor post-reprocessed duodenoscopes **for risk of CRE colonization**. This could be done in many ways, but until further culture recommendations are available we recommend one of the following approaches:

   —Culturing every duodenoscope after reprocessing is completed and waiting to release the cultured scopes until negative results are received. Culture incubation typically takes up to 48 hours. We believe this will provide the highest assurance of preventing CRE infections. While this approach can help ensure that no patient is treated with an instrument with positive cultures, it will likely require increasing duodenoscope inventories (perhaps two- or threefold). Because of the substantial cost required to increase inventories, this will not be practical for many hospitals. (Duodenoscopes cost approximately $40,000).

   —If current resources will not allow culturing of each scope after each reprocessing cycle, consider weekly culturing. Culturing at the end of the day on Fridays may be the least disruptive approach. This will allow cultured organisms to incubate over the weekend when procedure volumes are likely to be at their lowest. This will not provide the high degree of assurance that culturing after each reprocessing cycle provides. It also bears the risk of unknowingly using contaminated scopes between culturing intervals. However, weekly culturing will be less likely to require increases to duodenoscope inventories. It will also limit the risk of potentially exposing a large number of patients to contaminated scopes as compared to less frequent culturing.

   —**If culturing after each use or weekly is not possible, an alternate periodic culturing approach that can be considered, especially if initial baseline culturing reveals no contamination, is to culture duodenoscopes on a rotating basis. For example, culturing one quarter of your inventory each week will allow you to monitor your entire inventory monthly. This does not provide the same degree of assurance as weekly monitoring, but does provide an ongoing means to monitor reprocessing effectiveness. As with weekly culturing, it will also not likely require increasing duodenoscope inventories and can help limit the risk of potentially exposing a large number of patients to contaminated scopes.**

4. If a duodenoscope culture is positive, we recommend repeating reprocessing using your standard method and re-culturing the instrument. If this next reprocessing results in a positive culture, this can indicate that the reprocessing method is ineffective or that the duodenoscope is persistently colonized. A number of the publicized CRE outbreaks were associated with duodenoscopes that appeared to have been persistently colonized. If the repeat positive cultures are consistently associated with one or more specific scopes, while others do not culture positive, the scope may need to be refurbished (e.g., contaminated channel replaced) or possibly retired. Notify your infection control practitioners of all positive culture tests. Note that if you experience positive cultures with multiple duodenoscopes, this could signal the need to consider other sources of contamination (e.g., from reprocessing equipment).

Device SubCategory:

Clinical/Biomedical Engineering, Central Sterilization Reprocessing, Infection Control, Staff Education, Risk Management/Continuous Quality Improvement, Nursing, Gastroenterology, OR/Surgery

CRE and Duodenoscope Resource Center

This Hazard Report and other technology management, patient safety, and risk management guidance articles and recommendations are publicly available in ECRI Institute's new CRE and Duodenoscope Resource Center, located at www.ecri.org/cre.

REFERENCES

1. AAMI. TIR55:2014, Human factors engineering for processing medical devices. 2014.

2. Alfa MJ, Sitter DL. In-hospital evaluation of contamination of duodenoscopes: a quantitative assessment of the effect of drying. J Hosp Infect.1991 Oct;19(2):89-98.

3. Alrabaa SF, Nguyen P, Sanderson R, et al. Early identification and control of carbapenemase-producing Klebsiella pneumonia, originating from contaminated endoscopic equipment. Am J Infect Control. 2013 Jun;41(6):562-4.

4. American Society for Gastrointestinal Endoscopy. Multisociety guideline on reprocessing flexible gastrointestinal endoscopes. Gastroint Endoscopy. 2011;73(6):1075-1084.

5. ANSI/AAMI. ST58: Chemical sterilization and high level disinfection in health care facilities. 2013.

6. ANSI/AAMI. ST91: Flexible and semi-rigid endoscope processing in health care facilities (forthcoming in spring 2015).

7. APIC and SHEA issue statement on infections associated with duodenoscope procedures. Infect Control Today. http://www.infectioncontroltoday.com/news/2015/02/apic-and-shea-issue-statement-on-infections-associated-with-duodenoscope-procedures.aspx

8. CDC Healthcare Infection Control Practices Advisory Committee (HICPAC) - Guideline for disinfection and sterilization in healthcare facilities. 2008.

9. ECRI Institute. Clear channels–Ensuring effective endoscope reprocessing. Health Devices. 2010 Oct;39(10);350-9.

10. Epstein L, et al. New Delhi metallo-beta-lactamase-producing-Carbapenem-resistant Escherichia coli associated with exposure to duodenoscopes. JAMA. 2014, 312(14): 1447-1455.

11. Falagas ME, Tansarli GS, Karageorgopoulos DE, et al. Deaths attributable to carbapenem-resistant Enterobacteriaceae infections. Emerg Infect Dis. 2014 Jul;20(7);1170-5.

12. Fraser TG, et al. Multidrug-resistant Pseudomonas Aeruginosa cholangitis after endoscopic retrograde cholangiopancreatoagraphy: Failure of routine endoscope cultures to prevent an outbreak. Infect Control Hosp Epidemiol. 2004 Oct;25(10):856-9.

13. Gastmeier P, Vonberg RP. Klebsiella spp. In endoscopy-associated infections: we may only be seeing the tip of the iceberg. Infection. 2014, 42:15-21.

14. Gastroenterological Society of Australia. Infection control in endoscopy [clinical update]. 3rd ed. Victoria, Australia. 2010.

15. Guh A. Outbreaks related to the use of duodenoscopes and future directions. Presentation at: Healthcare Infection Control Practices Advisory Committee meeting; Atlanta: 2014 Jul 17.

16. Japanese Gastroenterological Endoscopy Technicians Society – Safety Management Committee Edition. Guidelines for cleaning and disinfecting endoscopes. 2nd Edition March 2004.

17. Kovaleva J, et al. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. Clin Microbiol Rev. 2013 Apr;26(2):231-254.

18. Kovaleva J, Neessen NE, Peters FT, et al. Is bacteriologic surveillance in endoscope reprocessing stringent enough? Endoscopy. 2009 Oct;41(10):913-6.

19. Muscarella LF, Risk of transmission of Carbapenem-resistant Enterobacteriaceae and related "superbugs" during gastrointestinal endoscopy. World J Gastrointest Endosc. 2014 Oct;6(10): 457-474.

20. Pyrek KW. Best practices for high-level disinfection and sterilization of endoscopes. Infect Control Today. 2012 March.

21. Rutala WA, Weber DJ. Gastrointestinal endoscopes; a need to shift from disinfection to sterilization? JAMA. 2014 Oct 8;312(14):1405-6.

22. Smith SL, et al. Transmission of carbapenem-resistant Enterobacteriaceae during ECRP: time to revisit the current reprocessing guidelines. Gastroint Endoscopy. 2014.