Health Devices Alerts
WEEKLY ACTION ITEMS AND NEWS FOR HEALTH DEVICES MEMBERS
ECRI Institute
The Discipline of Science. The Integrity of Independence.

February 20, 2015

[High Priority] - H0245 : Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes: Design May Impede Effective Cleaning

Medical Device Hazard Report

UMDNS Terms:

- Duodenoscopes [11359]

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

Geographic Regions: Worldwide

Suggested Distribution: Clinical/Biomedical Engineering, Infection Control, Nursing, OR/Surgery, Risk Management/Continuous Quality Improvement, Gastroenterology, Central Sterilization Reprocessing

Problem:
In a February 19, 2015, FDA Safety Communication , FDA states that the complicated design of ERCP endoscopes may impede effective reprocessing and multidrug-resistant bacterial infections have been associated with the use of reprocessed duodenoscopes, even when manufacturer reprocessing instructions are followed correctly. FDA also states that meticulously cleaning duodenoscopes before high-level disinfection should reduce the risk of transmitting infection, but may not entirely eliminate it. FDA has received 75 reports involving 135 patients of possible microbial transmission from January 2013 to December 2014 related to the use of duodenoscopes. Infectious agents may include multidrug-resistant agents, including carbapenem-resistant *Enterobacteriaceae* (CRE) such as *Klebsiella* spp. and *Escherichia coli.*

Action Needed:
Review the FDA MedWatch report and Safety Communication. FDA recommends the following:

- Adhere to the general endoscope reprocessing guidelines and practices established by the infection control community and endoscopy professionals, as listed in the FDA Safety Communication .
- Meticulously clean the elevator mechanism and the recesses surrounding the elevator mechanism by hand, even when using an automated endoscope reprocessor (AER). Raise and lower the elevator throughout the manual cleaning process to allow brushing of both sides.
- Implement a comprehensive quality control program for reprocessing duodenoscopes, including written procedures for monitoring training and program adherence and documentation of equipment tests, processes, and quality monitors used during the reprocessing procedure.
- Refer to the Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes: 2011 consensus document for evidence-based recommendations for endoscope reprocessing.
- Inform patients of the benefits and risks associated with ERCP procedures.
- Discuss with patients what they should expect following ERCP procedures, and inform them of the symptoms (e.g., fever or chills, chest pain, severe abdominal pain, trouble swallowing or breathing, nausea and vomiting, black or tarry stools) that should prompx additional follow up.
- Consider removing a duodenoscope from service until it has been verified free of pathogens if a patient develops a multidrug-resistant organism infection following ERCP and you suspect a link between the duodenoscope and the infection.
- Report patient infections suspected to be related to a reprocessed duodenoscope to the manufacturer and to FDA's MedWatch Adverse Event Reporting program by telephone at (800) 332-1088; by fax at (800) 332-0178; by mail (using postage-paid FDA Form 3500, available here) at Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787; or online at the MedWatch website .

FDA is working with the Centers for Disease Control and Prevention (CDC) and duodenoscope manufacturers to identify the causes and risk factors for transmission of infectious agents and to develop solutions to minimize patient exposure.

ECRI Institute Perspectives:

Hospitals should heed FDA's recommendations, but there is evidence that simply diligently following manufacturer and professional association instructions for cleaning and reprocessing duodenoscopes may be insufficient. Among the hospitals that have had outbreaks of CRE associated with the ERCP procedures, careful review of their reprocessing protocols found in some instances that the facilities were closely complying with the recommended procedures. This raises concerns that hospitals may still be at risk of a CRE outbreak even if reprocessing steps are meticulously followed.

To address this, ECRI Institute is investigating whether regular post-reprocessing sampling and culturing of duodenoscopes is warranted and practical. A significant concern is that it can reportedly take up to 48 hours for CRE cultures to grow out, meaning that hospitals would likely have to increase their duodenoscope inventory to accommodate the time scopes are quarantined waiting for culture results. Also, hospitals will need to carefully consider how they will respond if a scope cultures positive. These considerations, and possibly alternative solutions, will be presented with additional guidance in future ECRI Institute publications.

References:
United States:

- Food and Drug Administration. Design of endoscopic retrograde cholangiopancreatography (ERCP) duodenoscopes may impede effective cleaning: FDA safety communication [online]. 2015 Feb 19 [cited 2015 Feb 20]. Available from Internet: Click here .
- Food and Drug Administration. MedWatch. Endoscopic retrograde cholangiopancreatography (ERCP) duodenoscopes: FDA safety communication—design may impede effective cleaning [online]. 2015 Feb 19 [cited 2015 Feb 20]. Available from Internet: Click here .

ECRI Institute
The Discipline of Science. The Integrity of Independence.
©2015 ECRI Institute
5200 Butler Pike, Plymouth Meeting, PA 19462-1298, USA
May be reproduced by subscribing institution for internal distribution only.

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.

Source(s):

- 2015 Feb 20. MedWatch Download
- 2015 Feb 20. FDA Safety Communication Download

©2015 ECRI Institute
5200 Butler Pike, Plymouth Meeting, PA 19462-1298, USA
May be reproduced by subscribing institution for internal distribution only.