DEPARTMENT OF HEALTH & HUMAN SERVICES
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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C-15-32 Hospitals/CAHs/ASCs

DATE: **April 3, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Alert Related to Outbreaks of Carbapenem-Resistant *Enterobacteriaceae* (CRE) during gastrointestinal endoscopy, particularly Endoscopic Retrograde Cholangiopancreatography (ERCP)

Memorandum Summary

- ***Situation:*** Recent newspaper articles, medical publications, and adverse event reports associate multidrug-resistant bacterial infections caused by CRE with patients who have undergone ERCP. Duodenoscopes used to perform ERCP are difficult to clean and disinfect, even when manufacturer reprocessing instructions are followed correctly, and have been implicated in these outbreaks. The U.S. Food and Drug Administration (FDA) has issued a Safety Communication warning, with related updates, that the design of duodenoscopes may impede effective cleaning.

- ***Expectations for Reprocessing Duodenoscopes:*** Hospitals, critical access hospitals (CAHs), and ambulatory surgical centers (ASCs) are expected to meticulously follow the manufacturer's instructions for reprocessing duodenoscopes, as well as adhere to the nationally recognized Multisociety consensus guidelines developed by multiple expert organizations and issued in 2011.

Background

Beginning in 2012, multiple outbreaks of a family of multidrug-resistant organisms (MDROs), called Carbapenem-Resistant *Enterobacteriaceae* (CRE), associated with duodenoscopes have caused significant mortality and morbidity.[1]

CREs are highly resistant to the carbapenem class of antibiotics, which are considered the "drugs of last resort" for life-threatening infections. CREs are known to cause significant mortality in patients who develop bloodstream infections. In certain outbreaks, investigators identified a common procedure, ERCP, as the likely source of infection transmission. More than 500,000 ERCP procedures using duodenoscopes are performed in the United States annually. Medical procedures performed using duodenoscopes are potentially life-saving; these procedures often prevent the need for more invasive procedures including surgery. During ERCP, a specialized

endoscope (duodenoscope) is threaded down the upper gastrointestinal (GI) tract to inject contrast dye into the biliary and pancreatic ducts, and to diagnose and treat blockages from tumors, gallstones, or other causes.

Duodenoscope Design Characteristics

Although the design of duodenoscopes improves the efficiency and effectiveness of ERCP, there are challenges associated with their cleaning and high-level disinfection (HLD). Some parts of the scopes may be extremely difficult to access, and effective cleaning of all areas of the duodenoscope can only be accomplished by meticulously following all the manufacturer's instructions. Further, even when following these instructions meticulously, elimination of the risk of transmission of MDROs may not be possible.

Recent FDA engineering assessments, and a growing body of literature, have identified design characteristics in duodenoscopes that complicate the reprocessing of these devices.[1] The main area of concern is cleaning of the elevator area. The moving parts of the elevator mechanism contain microscopic crevices that may not be reached with a brush. As a result, residual body fluids and organic debris may remain in these crevices after cleaning and disinfection. If this part of the duodenoscope harbors microbial contamination, subsequent patients may be exposed to serious infections.

The FDA's analysis indicates that the reported duodenoscope-associated infections have occurred in patients who have had procedures with all duodenoscopes currently in use (manufactured by Pentax, FUJIFILM, and Olympus). In 2013, the Centers for Disease Control and Prevention (CDC) conducted a CRE outbreak investigation related to duodenoscopes that occurred with no known breaches in infection control or cleaning protocols.[2,3] Prior to this, outbreaks of bacterial infection associated with endoscopes were often attributed to problems with reprocessing endoscopes.

Regulatory Requirements

Medicare-participating hospitals, CAHs, and ASCs are subject to Conditions of Participation (CoP) or Conditions for Coverage (CfC) regarding infection control practices in surgical settings, including but not limited to:

<u>Hospitals</u>:

42 CFR 482.42(a): "The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases."

<u>CAHs:</u>
42 CFR 485.635(a)(3)(vi): [The CAH's policies include] "A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel."

ASCs:

42 CFR 416.51(a): "The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.... (b)…The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines…."

FDA Safety Communication and Multisociety Guidance

- ***FDA Recommendations for Facilities and Staff that Reprocess ERCP Duodenoscopes:***

  The FDA has issued recommendations including, but not limited to, the following: See: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm?

  Briefly summarized, this communication recommends:

  - Following all manufacturer instructions for cleaning and processing.
  - Adhering to general endoscope reprocessing guidelines and practices established by the infection control community and endoscopy professionals.
  - Adopting additional general best practices:
    - 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. The facility reprocessing program should include written procedures for monitoring training and adherence to the program. There should be documentation of equipment tests, processes, and quality monitors used during the reprocessing procedure.

  FDA's recommendation is that healthcare providers take a duodenoscope suspected of being associated with a patient infection following ERCP out of service and meticulously disinfect it until it is verified to be free of pathogens.

  FDA states that the benefits of using cleaning accessories not specified in the manufacturer's instructions, such as channel flushing aids, brushes, and cleaning agents, is not known.

- ***Multisociety Recommendations***

  In 2011, a consensus document of evidence-based recommendations for endoscope reprocessing was endorsed by the American Society for Gastrointestinal Endoscopy, Society for Healthcare Epidemiology, American College of Gastroenterology, American

Gastroenterological Association, American Society of Colon and Rectal Surgeons, Accreditation Association for Ambulatory Health Care, Association of periOperative Registered Nurses, Association of Professionals in Infection Control and Epidemiology, The Joint Commission, Society of American Gastrointestinal and Endoscopic Surgeons, Society of Gastroenterology Nurses and Associates.

Refer to the Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes The consensus recommendations of the Multisociety experts include, but are not limited to, the following:

- Precleaning should be performed at the point of use, before bioburden has the opportunity to dry and before complete decontamination. Point-of-use precleaning should remove visible debris by wiping the exterior of the endoscope with appropriate detergent solution and aspiration of a large volume of detergent solution through the air/water and biopsy channels.

- All health care personnel in the endoscopy suite should be trained in and adhere to standard infection prevention and control recommendations (e.g. standard precautions), including those to protect both patients and health care workers.

- The endoscope should be manually "leak tested" prior to cleaning in accordance with manufacturer's directions (unless otherwise instructed by the automated endoscope reprocessor manufacturer, if the AER is equipped with an automated leak tester).

- The endoscope should be visually examined, especially the distal sheath, for excessive wear and tear (e.g. cracks, tears) before reprocessing.

- Before manual or automated HLD, the scope should be meticulously cleaned including the entire endoscope valves, channels, connectors and all detachable parts. Endoscope components (e.g., air/water and suction valves) should be disconnected and disassembled as far as possible and the endoscope and components should be completely immersed in an appropriate detergent that is compatible with the endoscope, according to the manufacturer's instructions. All accessible channels should be flushed and brushed to remove all organic (e.g., blood, tissue) and other residues.

- The valves should be repeatedly actuated during cleaning to facilitate access to all surfaces. The external surfaces and components of the endoscope should be cleaned by using a soft cloth, sponge, or brushes.

- Brushes appropriate for the size of the endoscope channel, parts, connectors and orifices (e.g., bristles should contact all surfaces) should be used for cleaning. Cleaning items should be disposable or thoroughly cleaned and disinfected/sterilized between uses.

- Enzymatic detergents should be discarded after each use because these products are not microbicidal and will not retard microbial growth.

- Reusable endoscopic accessories (e.g., biopsy forceps, other cutting instruments) that break the mucosal barrier should be mechanically cleaned as described previously and then sterilized between each patient use (HLD is not appropriate).

- Ultrasonic cleaning of reusable endoscopic accessories and endoscope components may be used to remove soil and organic material from hard-to-clean areas.

- Endoscopes (and accessories) that come in contact with mucous membranes are classified as semicritical items and should receive at least HLD after each patient use.

- The HLD used should be cleared by the FDA for HLD. The HLD should make contact with all of the GI channels and endoscope's potentially contaminated surfaces. Nonimmersible GI endoscopes should not be used.

- The HLD solution concentration should be routinely monitored (at least daily or more often if needed) to ensure the minimum effective concentration of the active ingredient and documented in a log.

- In the reprocessing of the endoscope, HLD immersion time and temperature should be verified per the manufacturer's IFU and recorded.

- After HLD, rinse the endoscope and flush the channels with sterile, filtered or tap water to remove the disinfectant solution. Discard the rinse water after each use/cycle. Flush all channels with 70 percent to 90 percent ethyl or isopropyl alcohol, and dry by using forced air. The final drying steps greatly reduce the risk of remaining pathogens, as well as the possibility of recontamination of the endoscope by waterborne microorganisms.
    - Note that flushing of the endoscope internal channels and drying by forced air includes the elevator mechanism.

- If an AER is used, there should be documentation that the endoscope and endoscope components can be effectively reprocessed with the AER (for example, the elevator wire channel of duodenoscopes is not effectively disinfected by most AERs and this step should be performed manually). Users should obtain and review model-specific reprocessing protocols from both the endoscope and the AER manufacturers and check for compatibility.

- If an AER is used, the endoscope and endoscope components should be placed in the reprocessor and all channel connectors attached according to the AER and endoscope manufacturers' instructions to ensure exposure of all internal surfaces to the HLD solution.

- If an AER is used for HLD, there should be documentation it has been serviced and maintained as required; and that the internal services and components are being routinely self-disinfected as instructed by the AER manufacturer.

- The endoscope should be stored by hanging it vertically in a clean, dry, and well ventilated area or cabinet, or in a horizontal ventilated cabinet, with forced air.
    - The insertion tube should hang freely.
- Healthcare personnel should be routinely trained and their competency in reprocessing endoscopes, including duodenoscopes tested.

Expectations for Health Care Facilities and Surveyors

Hospitals, CAHs, and ASCs are expected to strictly and meticulously follow the manufacturer's instructions for cleaning and reprocessing endoscopes, and to adhere to a current nationally recognized practice guideline such as the standards of practice reflected in consensus recommendations found in the Multisociety Guidance document. Although we recognize FDA states that using brushes and cleaning accessories not specified in manufacturer's instructions is of unknown benefit, CMS expects surveyors to assess facilities' compliance with the manufacturer's instructions for use. Failure to adhere to these instructions and practice guidelines poses a significant risk of serious harm to patients

Surveyors, when surveying hospitals, CAHs or ASCs, must ask during the entrance conference whether duodenoscopes are used. If the answer is yes, then surveyors must request a copy of the manufacturer's instructions for use (IFU) for the duodenoscope(s) as well as any AERs the facility uses in reprocessing duodenoscopes. Further, surveyors must observe endoscopes being reprocessed and should ask the responsible staff to demonstrate and explain how they are adhering to manufacturers' instructions and the Multisociety Guidance recommendations. Any identified noncompliance must be cited accordingly, and the increased risk to patient safety resulting from improper reprocessing should be taken into consideration when determining the appropriate level of citation.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

Training: This information should be shared with all survey and certification staff, their managers, and the State/regional office (RO) training coordinator within 30 days of this memorandum.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

References:

1. Lawrence F. Muscarella, Risk of transmission of carbapenem-resistant Enterobacteriaceae and related 'superbugs' during gastrointestinal endoscopy.World J Gastrointest Endosc 2014; 6(10):457-474.

2. Centers for Disease Control and Prevention. Notes from the field: New Delhi metallo-β-lactamase–producing *Escherichia coli* associated with endoscopic retrograde cholangiopancreatography—Illinois, 2013. *MMWR Morb Mortal Wkly Rep*. 2014; 62(51-52):1051.

3. Lauren Epstein, MD, MSc; Jennifer C. Hunter, DrPH, et al, New Delhi Metallo-β-Lactamase–Producing Carbapenem-Resistant *Escherichia coli* Associated With Exposure to Duodenoscopies. *JAMA*. 2014; 312(14):1447-1455.