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FDA

A Joint Commission/FDA Webinar on Reprocessing of Scopes

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Objectives

- Provide information on the FDA's past and ongoing activities to minimize patient exposure to infections that can result from improperly reprocessing of scopes.

- Review The Joint Commission's Infection Prevention and Control standards that are pertinent to challenges with duodenoscope (endoscope) reprocessing and associated outbreaks.

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Webinar Replay

There will be a link to a replay of today's webinar (along with the slide presentations) available on The Joint Commission website within the next few days.

An email that contains the replay and the slides will be sent to all registered participants. We hope that you find this information helpful and we encourage you to pass this on.

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Reprocessing Reusable Medical Devices: FDA's activities and you

Suzanne Schwartz, MD, MBA

Director Emergency Preparedness / Operations and Medical Countermeasures (EMCM)

Webinar Purpose

- To explain FDA's past and ongoing activities to minimize patient exposure to infections that can result from improperly reprocessed medical devices, like duodenoscopes.
- To understand what reprocessing challenges you face in the health care environment.

We want to take this opportunity to hear your questions and provide you with meaningful answers

Webinar Objectives

- Provide timeline of past and ongoing activities
- Clarify FDA's role in this investigation
- Explain the status of FDA's investigation on duodenoscopes and Automatic Endoscope Reprocessors (AERs)
- Understand your reprocessing challenges
  - Listen to your concerns about reprocessing reusable medical devices and implementing current recommendations
- Answer your questions

Background

- Reducing patient exposure to infections in the health care setting is a national priority.
- Shared responsibility among many stakeholders.
  - FDA's role
- For years, FDA has recognized and is actively attending to reprocessing issues with reusable medical devices.

2013: A Turning Point

- **Pre-2013:**
  - Breaches observed in end-user adherence to manufacturer's reprocessing instructions in the labeling.
- **Post-2013:**
  - Meticulous adherence to manufacturer's reprocessing instructions is not sufficient to mitigate transmission of bacterial infections.

2013: A Turning Point

- **September 2013:**
  - CDC alerts FDA to association of multi-drug resistant organisms and duodenoscopes
- **Fall 2013 – Winter 2014:**
  - FDA begins outbreak investigation
- **February 2015:**
  - FDA issues 1st Safety Communication

FDA Activities

- **March 2015:**
  - Final Reprocessing Guidance and webinar
  - FDA issues 2nd Safety Communication
- **April 2015:**
  - Continued collaborations with duodenoscope and AER firms to validate reprocessing instructions
- **May 2015:**
  - Advisory Committee Meeting

Ongoing FDA Activities and Collaborations

- Continuing collaborations with duodenoscope and AER firms to validate reprocessing instructions
- Evaluating information about infections from multiple sources
- Collaborating with other government agencies like CDC and EPA
  - Exploring utility of duodenoscope microbiological surveillance testing to reduce the risk of infections
- Talking with hospital representatives to understand their challenges

Common Themes at the May Advisory Committee Meeting

- Manual cleaning step is important and must be done accurately
  - Role of human factors testing in pre-market
  - Competencies and training
- Some panelists recommended a move toward sterilization
- Utility of surveillance testing
- Device design and maintenance

Next Steps

- FDA will continue to:
  - Assess strategies FDA can implement within our regulatory parameters
  - Investigate the association between reprocessed medical devices and cases of infection in U.S. health care facilities.
  - Work with industry as they validate their reprocessing instructions
  - Collaborate with international, federal and state partners
  - Share information and recommendations

Additional Resources

- Preventing Cross-Contamination in Endoscope Processing: FDA Safety Communication (2009)
- Public Workshop - Reprocessing of Reusable Medical Devices (June 2011)
- Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning: FDA Safety Communication (Feb 2015)

Additional Resources contd.

- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Final Guidance (March 2015)

- Olympus Validates New Reprocessing Instructions for Model TJF-Q180V Duodenoscopes: FDA Safety Communication (March 2015)

- Meeting Materials for the Gastroentrology and Devices Panel of the Medical Devices Advisory Meeting (May 2015)

Reporting problems to the FDA

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

- **Health Care Professionals:**
  - We encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program.
- **User Facilities:**
  - User facilities must comply with the applicable Medical Device Reporting (MDR) regulations.
  - Health care personnel employed by facilities that are subject to FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.
- **FDA encourages you to report:**
  - Transmission of an infection due to an inadequately cleaned duodenoscope.
  - Bacterial contamination after following the manufacturer's reprocessing instructions.

We want to hear from you!

- What are your reprocessing challenges?
- What are your concerns about reprocessing reusable medical devices?
- Are you experiencing challenges implementing current recommendations?

Further inquiries, please direct your questions to FDA's Division of Industry and Consumer Education
DICE@fda.hhs.gov

Relating Duodenoscopes and Associated Outbreaks to The Joint Commission Standards and National Patient Safety Goals

June 25, 2015

Lisa Waldowski MS, APRN, CIC
Infection Control Specialist
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Learning Objective

- Relate Infection Prevention and Control Standards, other Standards, and IC-related National Patient Safety Goals (NPSG's) to challenges with duodenoscope (endoscope) reprocessing and associated outbreaks

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IC.01.03.01
Identify risks for acquiring and transmitting infections

- EP 1 Population served
- EP 2 Based on care, treatment, services provided
- EP 3 Surveillance activities/Infection Control data

  Where are duodenoscopes located?

  Where are procedures being conducted?

  Include centralized/decentralized locations.

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IC.01.05.01
Have an Infection Prevention and Control Plan

- EP 1 Use of evidence-based guidelines or in the absence of such guidelines, expert consensus
- EP 5 A written process for investigating outbreaks
- EP 8 Method to report information to external organizations

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IC.02.01.01
Implements Infection Prevention and Control Plan

- Investigates outbreaks
- Reporting to local, state, and federal public health authorities in accordance with law and regulation

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IC.02.02.01

Reduce risk of infection with medical equipment, devices, and supplies

- EP 2 Performing intermediate, high-level disinfection and sterilization
- EP 4 Storing medical equipment, devices, and supplies

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IC.03.01.01
Evaluate the effectiveness of the Infection Prevention and Control Plan

- EP 1 Evaluate the plan annually and *whenever risks significantly change*

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NPSG.07.03.01

Implement evidence-based practices to prevent healthcare-associated infections due to multidrug-resistant organisms

- EP 1 Conduct periodic risk assessments
- Eps 2-3 Education – staff and patients
- EP 5 Surveillance may be targeted versus hospital-wide
- EP 8 Laboratory-based alert system – new patients
- EP 9 Alert system – readmitted or transferred patients

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Human Resources

- HR.01.02.01 Staff Qualifications
  - EP 1 job responsibilities
- HR.01.05.03 Ongoing education and training
- HR.01.06.01 Competent to perform responsibilities

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LD.04.01.05
Effectively manage programs, services, sites, or departments

- EP 1 Leaders of the service/department oversee operations
- EP 3 Define in writing who has responsibility of the service/department
- EP 4 Staff are held accountable for their responsibilities

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EC.02.04.03
Inspect, test, and maintain medical equipment

- EP 4 Conducts performance testing of and maintains all sterilizers. These activities are documented.

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EC.02.05.01
Inspect, test, and maintain utility systems

- EP 15 In areas designed to control airborne contaminants, the ventilations system provides appropriate pressure relationships, air-exchange rates, and filtration efficiencies.

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Resources

- American Society for Gastrointestinal Endoscopy (ASGE):
  - Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes (2011).

Resources

Society of Gastroenterology Nurses and Associates (SGNA):

- Guideline for Use of High Level Disinfectants & Sterilants for Reprocessing Flexible Gastrointestinal Endoscopes (2013).
- Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes (2012).

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Resources

ANSI/A AMI ST91: 2015. Flexible and semi-rigid endoscope processing in health care facilities.

ANSI/AAMI ST58: 2013. Chemical Sterilization and high-level disinfection in healthcare facilities.

Resources

http://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm439999.htm

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm

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Thank You!

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