3M Health Care Academy

Duodenoscopes: Are Current Reprocessing Guidelines Adequate?

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January 15, 2015

WELCOME!

TOPIC: DUODESCOPES: ARE CURRENT REPROCESSING GUIDELINES ADEQUATE?

FACILITATORS: CHRISTOPHE DE CAMPEAU, 3M
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SPEAKER: GRACE THORNHILL, PH.D.

HOUSEKEEPING
QUESTIONS
- Mute feature (*7 = unmute; *6 = mute)
- "Chat" feature

TECHNICAL DIFFICULTIES
POST SESSION FOLLOW-UP

FOR MORE INFORMATION: WWW.3M.COM/3MSTERILEU

2

HOW DO I GET A CE CERTIFICATE?

Next week, all of today's meeting participants will be sent an email containing instructions for obtaining a CE Certificate for today's meeting.

The email will be sent to the email address you provided when you logged-in to today's meeting. If there are others listening with you today who did not log-on, you may forward the CE certificate email to them.

3

DISCLOSURE STATEMENT

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Learning Objectives

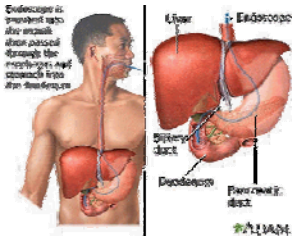
- Explain why duodenoscope reprocessing is currently under scrutiny.
- Summarize the clinical literature describing outbreaks following exposure to duodenoscopes.
- Discuss the reprocessing challenges that are unique to duodenoscopes.
- Outline available and proposed options for improving duodenoscope reprocessing.

Why focus on duodenoscopes?

In the past year there has been a significant increase in reports of outbreaks related to the use of Duodenoscopes for ERCP.

What is ERCP?

- Endoscopic retrograde cholangiopancreatography (ERCP) is a procedure that combines the use of endoscopy and fluoroscopy to diagnose and treat certain problems of the biliary or pancreatic ductal systems.
- You will often see the term "ERCP scope" used. ERCP is a *procedure* that uses a side-view duodenoscope (an upper GI flexible endoscope).



ERCP procedures are performed using a side-view duodenoscope

ERCP procedures linked to outbreaks of CRE

CRE = CARBAPENEM-RESISTANT ENTEROBACTERIACEAE

- Family of bacteria (over 128 species) that reside in the GI tract
- Highly drug resistant: *no treatment is available*
- Mortality rate is ~ 50%
- KPC – *Klebsiella pneumoniae*
- *NDM- E. coli*

- *3M archived 3-part webinar series on CRE, Dr. Jon Otter*

www.cdc.gov/drugresistance/threat-report-2013/

Largest Outbreak of CRE in US history

Original Investigation

New Delhi Metallo-β-Lactamase–Producing Carbapenem-Resistant *Escherichia coli* Associated With Exposure to Duodenoscopes

JAMA.2014;312(14):1447-1455

Lauren Epstein, MD, MSc; Jennifer C. Hunter, DrPH; M. Allison Arwady, MD; Victoria Tsai, MPH; Linda Stein, MPH; Marguerite Gribogiannis, MPA; Mabel Frias, MPH; Alice Y. Guh, MD; Alison S. Laufer, PhD; Stephanie Black, MD; Massimo Pacilli, MS; Heather Moulton-Meissner, PhD; J. Kamile Rasheed, PhD; Johannetsy J. Avillan, BS; Brandon Kitchel, MS; Brandi M. Limbago, PhD; Duncan MacCannell, PhD; David Lonsway, PhD; Judith Noble-Wang, PhD; Judith Conway, RN; Craig Conover, MD; Michael Vernon, DrPH; Alexander J. Kallen, MD

IMPORTANCE Carbapenem-resistant Enterobacteriaceae (CRE) producing the New Delhi metallo-β-lactamase (NDM) are rare in the United States, but have the potential to add to the increasing CRE burden. Previous NDM-producing CRE clusters have been attributed to person-to-person transmission in health care facilities.

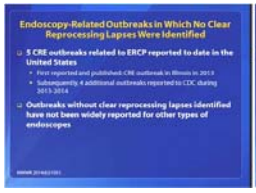
OBJECTIVE To identify a source for, and interrupt transmission of, NDM-producing CRE in a northeastern Illinois hospital.

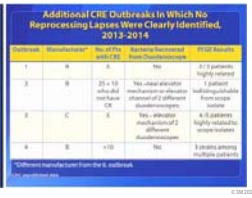
Editorial page 1405

CONCLUSIONS AND RELEVANCE In this investigation, exposure to duodenoscopes with bacterial contamination was associated with apparent transmission of NDM-producing *E coli* among patients at 1 hospital. Bacterial contamination of duodenoscopes appeared to persist despite the absence of recognized reprocessing lapses. Facilities should be aware of the potential for transmission of bacteria including antimicrobial-resistant organisms via this route and should conduct regular reviews of their duodenoscope reprocessing procedures to ensure optimal manual cleaning and disinfection.

Outbreaks of CRE due to contaminated duodenoscopes

ID Week Presentation: Thursday 10/9/2014 - Transmission of Drug Resistant Bacteria through Endoscopy - Current Issues, Challenges, and Opportunities - David Weber (UNC), Alice Guh (CDC)





FDA MAUDE Database Reports

- Manufacturer's And User Facility Device Experience
  - Passive surveillance system
  - monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. The MAUDE database houses reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

MAUDE reports: CRE transmission associated with ERCP

- 2014 – Five (5) reports filed
- 2013 – Two (2) reports filed
- 2012 – Two (2)reports filed

- *Most likely not a complete list. Reporting is voluntary.*

Muscarella, L. F. 2014. Risk of transmission of carbapenem-resistant Enterobacteriaceae and related "superbugs" during gastrointestinal endoscopy. World J Gastrointest Endosc October 16; 6(10): 457-474

13

Summary of Investigation Results

- Genetic fingerprinting found CRE bacteria cultured from duodenoscopes to be the same (or highly related) CRE bacteria that infected/colonized patients.
  - Not all investigations were able to perform genetic analysis
- Other GI microbes were also found on the scopes
- These bacteria were mostly found in the elevator mechanism, elevator guide wire (EGW) channel and suction/biopsy channels.
- Outbreaks were resolved by sterilizing endoscopes using ethylene oxide.

14

Summary of Investigation Results continued…

What were the problems?

In many cases (well documented) the problem was due to identified failures in the reprocessing procedures or equipment.

- more details later….

Of increasing concern is the finding of persistent contamination or outbreaks when no reprocessing failures could be identified (Illinois outbreak)

Are current protocols sufficient to produce a scope safe for patient use?

15

Overview of Flexible Endoscope Reprocessing

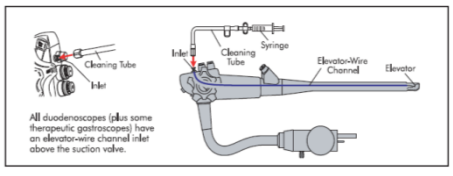
1. Pre-Cleaning: Occurs in procedure room. Wipe down and flush scope. Prepare for transport to reprocessing.
2. Leak testing: followed by complete disassembly of scope
3. Manual Cleaning: Flushing, brushing all parts and channels of the scope, purge with air
4. High-Level Disinfection: Automated in AER or can be performed manually
5. Drying: Air and Alcohol flush, Wipe down external surfaces
6. Storage: Vertical Hang

Why are flexible endoscopes difficult to reprocess?

- Complex design
- Multiple, long, narrow, channels that are difficult to clean
- Lack of consistent effective training
- Lack of time and resources for adequate reprocessing
- Visual inspection not adequate to monitor efficacy of reprocessing.
- > 120 step involved in reprocessing!!

Duodenoscopes have added complexity.

- Extra Elevator Guide wire channel and Elevator housing and mechanism on distal tip.



OLYMPUS

Reprocssing a Duodenoscope

- Follows same basic procedure as other scope types.
- Always follow manufacturer instructions for reprocessing
- EGW channel and Elevator mechanism need special attention due to small size and complexity.
- Know your scope!
  - Some staff members are not aware that the EGW channel exists and miss the reprocessing steps.
  - Open or Closed??
    - Older scopes have an open channel (exposed to patient soil) that needs special attention due to its small size. This channel is cleaned/HLD like other channels.
    - Newer scopes have a closed channel (not exposed to patient soil), cleaning/HLD is not performed.

Reprocessing the Elevator Mechanism

- This is the site where CRE bacteria were found to survive.
- Needs special attention and time due to device complexity
- Hinged on one end and attached to a wire on the other
- Motion of wire moves the cantilevered riser up and down.
- Housing is recessed and can retain patient soil, form biofilm providing a source of pathogens

Reprocessing the Elevator Mechanism

- Always follow manufacturer instructions
- Pre-cleaning: Remove visible debris from elevator housing and mechanism. Do not allow anything to dry.
- Manual cleaning:
  - Use the correct brush, this is critical!!
  - Brush in front and behind the elevator thoroughly
  - It is critical that the elevator mechanism is moved up and down during cleaning so all surfaces are brushed
  - Any debris left behind will solidify

Reprocessing the EGW channel

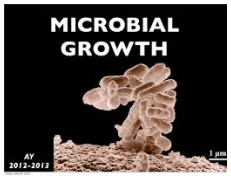
- Follow manufacturers instructions, these steps are a high-level overview only
- Because of the small lumen, this channel requires manual reprocessing for all steps. (SGNA)
- Pre-cleaning:
  - A special auxiliary cleaning adapter is attached to the EGW channel and the channel is flushed. Follow with air flush
  - Requires high pressure and extra time as the opening between the channel and suspipe is about the width of a human hair!!
- Manual cleaning: This channel is too small to be brushed, flushing using high pressure is critical
- High-level Disinfection
  - Make sure elevator is placed in 'halfway position"
  - There is a concern that even with the high pressure attachment, AER's might not supply enough pressure to get wire channel adequately cleaned. (CDC MMWR Morb Mortal Wkly Rep. 2014. 62 (51-52) 1051)

22

How can microbes survive HLD?

If you take a CRE bacteria and expose them to chemicals used for HLD – they die.

Somehow these bugs are surviving reprocessing.



23

How can microbes survive reprocessing?

- Inadequate cleaning
  - In order for HLD to work, the scope must be meticulously cleaned.
  - Use the correct brush
  - Take the correct amount of time
  - Monitor the effectiveness of cleaning
    - ATP bioluminescence, Protein, Hemoglobin, Carbohydrate tests available

24

Observed Activity	Steps Completed (%) (n = 69)
➢Leak test performed in clear water	77
➢Disassemble endoscope completely	100
➢**Brush all endoscope channels and components**	43
➢Immerse endoscope completely in detergent	99
➢Immerse components completely in detergent	99
➢Flush endoscope with detergent	99
➢Rinse endoscope with water	96
➢Purge endoscope with air	84
➢Load and complete automated cycle for high-level disinfection	100
➢Flush endoscope with alcohol	86
➢Use forced air to dry endoscope	45
➢Wipe down external surfaces before hanging to dry	90

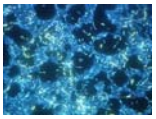
Guidelines were followed only 1.4% of the time (manual cleaning followed by automated high-level disinfection) vs 75.4% using ECR (automated cleaning and disinfection)

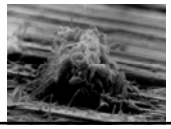
Multiple steps skipped 45% of the time.

Ofstead, Cori L., Wetzler, Harry, P., Alycea Snyder, Rebecca A. Horton Endoscope Reprocessing Methods: A Prospective Study on the Impact of Human Factors and Automation. 2010 Gasteroenterology Nursing. Vol 33, No. 4, pp. 304-311

How can microbes survive reprocessing?

- Inadequate manual cleaning and drying support the formation of biofilm
  - Biofilm is
    - Notoriously resistant to the action of disinfectants
    - Almost impossible to remove once established
    - Requires brushing, flushing to physically remove biofilm
    - Drying is critical – biofilm unlikely to form on a dry surface.





How can microbes survive reprocessing?

- Lack of proper contact time with detergents and disinfectants
  - Microbial kill requires sufficient contact time with surface. Mfr recommendations should be strictly followed. Anything less leaves living microbes behind….
  - Make sure disinfectant is properly made and is not expired
  - The Joint Commission Survey found:
    - Recommended soaking cycle – 20 minutes
    - Cycle reprogrammed to 5 minutes
    - Patients exposed? Transplant, HIV, Oncology, Cystic Fibrosis

Follow Manufacturers Instructions!!!!!

Manual Clean a Side-view Duodenoscope
How long does it take to clean?

Follow Manufacturer Instruction for Use – 25 min
Clinical Observation – 6.5 min

ALFA *ET AL.* 2006 AMERICAN JOURNAL OF INFECTION CONTROL 34(9), 561-570

The Joint Commission: Quick Safety Bulletin
Improperly Sterilized or High-Level Disinfected Equipment,May 2014

- At issue: Compliance with Standard IC.02.02.0 which requires facilities reduce the risk of infections associated with medical equipment, devices and supplies.
- Non-compliance rates for:
  - Hospitals: 46%
  - Critical Access Hospitals: 47%
  - Ambulatory Care: 38%
  - Office-based Surgery: 29%
- Immediate Threat to Life (ITL) – 13 found in 2013 surveys
  - 7 of 13 ITL related to improperly sterilized or HLD equipment
  - Problems usually long-standing and only found when out of control enough to cause an outbreak.

The Joint Commission: Quick Safety Bulletin
Improperly Sterilized or High-Level Disinfected Equipment, May 2014

- Found systemic issues
  - The mistaken belief that transmission of endoscope associated pathogens is rare.
  - Staff lack proper knowledge and training to reprocess endscopes
  - Lack of access to evidence-based guidelines
  - Lack of leadership support
  - Leadership turnover leads to de-prioritization of reprocessing issues
  - Lack of culture of safety, Lack of reporting of risks
- Staff are taking reprocessing shortcuts
- No dedicated staff to oversee proper sterilization/HLD

What are we doing wrong?

- Non-compliance with guidelines
- Failure to pre-clean
- Inadequate contact time with HLD
- Using expired disinfectants
- Dirty scopes allowed to dry
- Inadequate brushing of channels during manual cleaning, missing EGW channel
- Improper storage
- Incorrect programming of AER
- Insufficient training and competency program
- Unaware or failure to report staff/equipment failures

Reported gastrointestinal endoscope reprocessing lapses: The tip of the iceberg. Alexandra M. Dirlam-Langlay, etal. American Journal of Infection Control 2013 Dec;41(12):1188-94

Endoscope Reprocessing in 2014: Why is the Margin of Safety So Small? Edminston and Spencer. 2014 AORN J. 100 (6) 609.

31

What is being done to address this issue?

- Feb. 14, 2014. CDC organized a conference call to discuss the issue of CRE transmission via duodenoscopes.
- Who was there?
  - APIC – Association for Professionals in Infection Control and Epidemiology
  - SHEA – Society for Healthcare Epidemiologist of America
  - ASGE – American Society for GI Endoscopy
  - SGNA – Society of Gastroenterology Nurses and Associates
  - AAMI – Association for the Advancement of Medical Instrumention
  - FDA
  - CDC

32

Purpose of CDC Conference Call 2/14/2014

- Review findings from outbreaks
- Identify reprocessing challenges
  - Adherence to recommended procedures
  - Are procedures adequate?
- Discuss evidence gaps and improvement of reprocessing

33

Summary of CDC conference call

The extent of problem with duodenoscopes might be underestimated

Failure of duodenoscope reprocessing due to unrecognized lapses and/or intrinsic issues with these types of endoscopes.

- *In adequate cleaning or drying issues due to lack of appropriate training and/or regular review of practices*
- *Lack of standardized/required preventative maintenance schedules*
- *Design issues that may make cleaning difficult*
- *No standardized process to assess cleaning has been validated*

More information can be found here:
Outbreaks related to the use of duodenoscopes and future directions.
Healthcare Infection Control Practice Advisory Committee, Centers of Disease Control and Prevention.
http://www.cdph.ca.gov/programs/hai/Documents/HAI-AC-HICPAC-072014.pdf. Published July 17-18,2014.

34

Follow up to CDC conference call

- CDC is doing the following:
  - –Continued discussions with stakeholders and leading experts
  - – Piloted a protocol for culturing duodenoscopes
  - – Ongoing technical assistance to facilities and health departments
  - –Developing Interim Guidance for facilities that perform procedures with duodenoscopes.

35

CDC Draft Interim Guidance
Not disseminated, Not Official, No Policy

- Regularly review recommended duodenscope reprocessing procedures
- Perform microbiologic surveillance of reprocessed duodenoscopes
- Repeat processing of any duodenoscope with positive cultures and further evaluate if persistently positive
- Inform patients of risk of bacterial transmission associated with duodenoscope procedures.

More details:
Outbreaks related to the use of duodenoscopes and future directions.
Healthcare Infection Control Practice Advisory Committee, Centers of Disease Control and Prevention.
http://www.cdph.ca.gov/programs/hai/Documents/HAI-AC-HICPAC-072014.pdf. Published July 17-18,2014.

35

AAMI Standard 91:Comprehensive guide to flexible endoscope reprocessing in health care facilities

- Is now complete
- Publication for this year
- Has guidance on performance and monitoring of the manual cleaning step for endoscope reprocessing.

What do we do now??

- Make sure to keep manufacturers reprocessing instructions are up to date.
- Make sure your staff is trained and remains competent
- Use and follow evidence-based guidelines
- Ensure oversight of high-level disinfection processes
- Consider implementing a monitoring program to ensure efficacy of manual cleaning
- Review and update policies and procedures
- Informed consent for patients on risk of patient to patient bacterial transmission

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