WHY DO QC ON SCOPES??

The scopes are clean no problem
OBJECTIVES

- Describe the 2 advantages of a testing based quality assurance process
- Explain the 2 disadvantages of a testing based quality assurance process
- Identify all breeches in scope reprocessing
REVIEW OF THE ISSUES

- 100% of scopes are contaminated after use compared to much less than ½ in surgical instruments
- 1.4% of endoscopes manually cleaned have all steps performed (75.4% in AER have all steps performed in HLD)
- FDA states certain endoscopes reprocessed correctly may still be contaminated
- More HAI’s linked to endoscopes than any other medical device
- Endoscopes -Heat liable and can only tolerate HLD or low temperature sterilization
CRE OUTBREAKS ASSOCIATED WITH ERCP SCOPES

- Seattle 2012
- Chicago- March-July 2013
- Pittsburgh & Philadelphia-2014
- Los Angeles-February 2015
February 25, 2015

TO: General Acute Care Hospitals (GACHs)
Ambulatory Surgery Centers (ASCs)

SUBJECT: Endoscopic Retrograde Cholangiopancreatography (ERCP)
Duodenoscopes: Difficulty Cleaning and Association with Carbapenem-Resistant Enterobacteriaceae (CRE).

This All Facilities Letter (AFL) notifies GACHs and ASCs that perform endoscopic retrograde cholangiopancreatography (ERCP), and health care personnel responsible for these procedures and for the reprocessing of ERCP endoscopes (also called duodenoscopes), that the complex design of the duodenoscopes may impede effective reprocessing and has been associated with a number of outbreaks of infections of carbapenem-resistant Enterobacteriaceae (CRE).

On February 19, 2015, the U.S. Food and Drug Administration (FDA) issued a safety communication on this issue. The California Department of Public Health (CDPH) encourages all personnel involved with ERCP and reprocessing endoscopes to carefully review the alert at:

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

Send questions regarding this issue to CDPH’s Healthcare-Associated Infections Program at HIAProgram@cdph.ca.gov

Sincerely,

Original signed by Jean Iacino
Jean Iacino
Deputy Director
Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning: FDA Safety Communication

Date issued: February 10, 2015
Updated: February 25, 2015

Audience:
- Gastroenterologists
- Gastrointestinal surgeons
- Endoscopy nurses
- Staff working in endoscopy reprocessing units in health care facilities
- Infection control practitioners
- Patients considering endoscopic retrograde cholangiopancreatography (ERCP) procedures

Medical specialties: Gastroenterology, Infection Control

Device: All ERCP endoscopes (side-viewing duodenoscopes)

Purpose:
The FDA wants to raise awareness among health care professionals, including those working in reprocessing units in health care facilities, that the complex design of ERCP endoscopes (also called duodenoscopes) may impede effective reprocessing. Reprocessing is a detailed, multiphase process to clean and disinfect or sterilize reusable devices. Recent medical publications and adverse event reports associate multidrug-resistant bacterial infections in patients who have undergone ERCP with reprocessed duodenoscopes, even when manufacturer reprocessing instructions are followed correctly. Meticulously cleaning duodenoscopes prior to high-level disinfection should reduce the risk of transmitting infection, but may not entirely eliminate it.

Summary of Problem and Scope:
WHAT WE SHOULD BE ALL BE DOING

- Evaluating CRE, ESBL, and VRE bacteremias for a link to elevator scopes (EUS and ERCP)

- Evaluating your competency model for elevator scopes disinfection
  - Scope specific?
  - Volume done per year

- Familiarize yourself with the IFUs around disinfection of your elevator scopes

- Evaluating the disinfection practice or your elevator scopes

- Look for triggers for failure of elevator scope disinfection
  - Poor lighting or visualization
  - Wait time for pre-clean
  - Pressure for rapid turnaround

http://apic.informz.net/InformzDataService/OnlineVersion/Public?mailingInstanceId=4107001
Key points: Infections associated with duodenoscope procedures

Recent reports of carbapenem-resistant Enterobacteriaceae (CRE) infections related to endoscopic retrograde cholangiopancreatography (ERCP) duodenoscopes raised concerns among infection prevention experts, federal agencies, and the public. Most recently, Ronald Reagan UCLA Medical Center notified 179 patients who underwent ERCP that they may have been exposed to CRE from contaminated duodenoscopes. Ronald Reagan UCLA Medical Center reports that only patients who underwent ERCP procedures from October 3, 2014 to January 28, 2015 are at risk of CRE infection as a result of those procedures. UCLA Medical Center noted that it processed the scopes according to the standards stipulated by the manufacturer. As of February 23, a total of seven UCLA patients were infected and two have died.

The Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) are working together to explore optimal protocols for duodenoscope reprocessing. Read the APIC and Society for Healthcare Epidemiology of America (SHEA) statement to the media and access frequently asked questions for consumers.

APIC has developed key points on what infection preventionists (IPs) can do to ensure effective reprocessing of ERCP duodenoscopes to reduce the risk of infection:

- Start by conducting a risk assessment to understand the burden that CRE and other multidrug-resistant organisms (MDRO) pose to your facility. This will help you to put news about infection outbreaks linked to contaminated duodenoscopes into proper context and prioritize needed efforts. Incorporate the results of the risk assessment into your quality improvement program and infection control plan.
- Make sure your surveillance system is capable of finding post-ERCP bloodstream infections.
- Explore the potential burden of MDROs post-ERCP procedures. Take into consideration:
  - How many procedures are performed?
  - How many scopes do you have?
  - How many technicians do you have who are trained to reprocess duodenoscopes?
  - How many infections have been linked to ERCP procedures?
- Duodenoscopes are a greater challenge to clean than colonoscopes.
- Effective reprocessing requires meticulous cleaning to remove debris, followed by high-level disinfection or sterilization. It requires meticulous attention to detail and step-by-step precision.
- Human factors play a significant role due to the complexity of the devices. For example:
  - They are very labor intensive to clean and must be pretreated to avoid dried protein matter and biofilm buildup.
  - If technicians are not focused on every last detail, all of these could be a source of
EMERGING TECHNOLOGY

- Effective surveillance of flexible endoscope reprocessing ideally requires testing methods that allow for rapid assessment of compliance with current reprocessing standards.

- Lack of both widely accepted bioburden/microbial benchmarks and widely validated means of assessing these have limited implementation of such strategies. Potential methods for surveillance include the following.
FOR ATP, ASSAY AND CULTURE

- Need sterile water for ATP and Assay
- For culture need sterile saline or media (if media must reprocess)
Different societies and professional organizations state different approaches

- FDA, CDC, APIC, SHEA, AORN are not recommending routine culturing of scopes unless in the midst of an outbreak.
  - ASGE is

- Culturing for bacterial load is impractical for many endoscopy centers that may not have easy access to microbiology laboratories.

- The slow turnaround time (minimum 24-72 hours) for results does not allow for rapid reuse of the tested endoscope.

- Viruses such as hepatitis B and C and HIV cannot be cultured by using standard methods.
CULTURING

- Europe randomly cultures scopes
  - They have the same incidence of exposures

- Risk Options
  - Do not release until results are finale
  - Culture then reprocess scope
  - Sensitivities?

- Organisms found
  - CNS  Do you care?
  - Mycobacteria
    - Likely secondary to water

- Can not culture entire device so false negatives

- “Legally” can not be done in a clinical lab
BIOBURDEN ASSAYS

Advantage:
- Can be done before HLD
- 95% pass rate at most clinics
- Training

Cons
- Cost
- Still may have viable organisms
- May not have viable organism
- Depends on staff hitting all the channels

Currently available methods allow rapid evaluation of residual bioburden and organic matter from the endoscope channels (eg, Scope-Check; Valisafe America, Tampa, Fla and EndoCheck and ChannelCheck; HealthMark Industries, Fraser, Mich).
Adenosine triphosphate (ATP) bioluminescence is present in microorganisms and human cells and therefore offers a means of testing for microbial and biological residue.
ATP

- Advantage:
  - Can be done before HLD
  - Training

- Cons
  - Cost
  - Still may have viable organisms
  - May not have viable organism
  - Depends on staff hitting all the channels
  - Cut offs are arbitrary
<table>
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<th>Assay</th>
<th>Manufacturer</th>
<th>Description</th>
<th>Testing</th>
<th>Cost, US$</th>
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<tr>
<td>Bioburden test kits</td>
<td><strong>Scope Check</strong> Valisafe America, Tampa, Fla</td>
<td>25 vials per box</td>
<td>Test for protein residue</td>
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<td><strong>EndoCheck</strong> HealthMark Industries, Fraser, Mich</td>
<td>12 test kits per box. Different boxes based on diameter and length of endoscope lumen</td>
<td>Separate kits for detection of protein and hemoglobin residue</td>
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<td><strong>ChannelCheck</strong> HealthMark Industries</td>
<td>2 boxes of 50 test strips, with control</td>
<td>Strips detect residual carbohydrate, protein, and hemoglobin</td>
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<td>ATP test kits</td>
<td><strong>Clean-Trace</strong> 3M (St. Paul, Minn)</td>
<td>ATP assay kit and luminometer</td>
<td>Surface and channel flush</td>
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<td><strong>GloMax 2020</strong> Promega (Madison, Wisc)</td>
<td>ATP assay kit and luminometer</td>
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<td><strong>PallChek</strong> Pall Corp (Port Washington, NY)</td>
<td>ATP assay kit and luminometer</td>
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<td><strong>Lumat</strong> Berthold Tech (Oak Ridge, Tenn)</td>
<td>Luminometer only</td>
<td>Works with most assays</td>
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<td>ATP assay kit only</td>
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*ATP, Adenosine triphosphate.*
Minimizing the potential for transmission of pathogens by using flexible endoscopes is an important issue for facilities at which endoscopy is performed. These technologies offer endoscopy units the ability to implement surveillance strategies, which may potentially improve the quality of endoscope reprocessing.
NEEDED RESEARCH

- Establishment and validation of standardized bioburden/microbial benchmarks and ATP bioluminescence thresholds after reprocessing of flexible endoscopes.
- Assessment of cost-effectiveness of implementing surveillance strategies for monitoring the quality of endoscope reprocessing.
- Large prospective studies to assess the relative clinical and cost-effectiveness of different available surveillance technologies as well as their impact on reducing the transmission of clinically significant infections.
- Potential for incorporating bioburden/microbial assessments into AERs.
OTHER KEY CONCERNS

- Endemic transmission of infections associated with gastrointestinal endoscopes may be unrecognized due to inadequate surveillance of outpatient procedures, long lag time between colonization and infection, and a low frequency of clinical infection.
- The margin of safety associated with HLD reprocessing endoscopes is minimal.
ADDITIONAL RECOMMENDATIONS/COMMENTS

- Development of sterile disposable gastrointestinal endoscopes or a shift to other sterile diagnostic modalities should be considered.
- Regardless of when these issues are resolved, endoscopy will remain an important diagnostic and therapeutic modality and should continue to be used while clinicians strictly adhere to current endoscope reprocessing guidelines.
Transmission of infection via endoscopes remains very rare.
Reported infections have usually been associated with a failure to follow established multi-society guidelines for reprocessing or defective equipment.
The manual components of reprocessing are prone to human error.
CLEAN SCOPES.....