Flexible Endoscope Cleaning

This quote sums up the activity going on right now with flexible scopes

“If you want to truly understand something try to change it”

Kurt Lewis

Objectives

- To understand and make sure a scope is ready for your patient you need some background information to make sure that “the scope is clean enough to be used?”
  - We will review and help you understand
    - What your customer knows about your process
    - The anatomy of flexible scopes
    - The literature on the issues with flexible scope
    - The evidence based clinical relevant products on monitoring flexible scope
    - Possible quality improvement programs to help ensure your scope is patient ready.
- Remember our mantra
  - If it is not clean it might not be able to be high leveled disinfected or sterilized

What your customer knows about scopes

- Main source of news
  - Internet
  - Papers
  - TV
- Tipping Point for dirty scopes
- Articles released on the same day January 21, 2015
  - USA today Article
  - Seattle Times Article
  - Gastroenterology Societies Discuss Patient Safety in Gastrointestinal Endoscopy
- Plus ECRI list

Endoscope processing failures resulting in patient notifications

Consumer Pressure

<table>
<thead>
<tr>
<th>Location</th>
<th>Year</th>
<th>Reprocessing Failure</th>
<th>Patient notifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sacramento, CA</td>
<td>2002</td>
<td>Failure to clean auxiliary channel</td>
<td>150</td>
</tr>
<tr>
<td>Toronto, Canada</td>
<td>2003</td>
<td>Inadequate soak time</td>
<td>114</td>
</tr>
<tr>
<td>Seattle, WA</td>
<td>2004</td>
<td>Insufficient LCG soak time</td>
<td>139</td>
</tr>
<tr>
<td>Sacramento, CA</td>
<td>2004</td>
<td>AER malfunction</td>
<td>1231</td>
</tr>
<tr>
<td>Kingwood, MD</td>
<td>2004</td>
<td>Failure to test MEC of LCG</td>
<td>197</td>
</tr>
<tr>
<td>Redwood City, CA</td>
<td>2004</td>
<td>AER Malfunction</td>
<td>200</td>
</tr>
<tr>
<td>Charleston, WV</td>
<td>2004</td>
<td>Improper LCG use</td>
<td>1583</td>
</tr>
<tr>
<td>Hinsberg, PA</td>
<td>2005</td>
<td>Auxiliary channel</td>
<td>296</td>
</tr>
<tr>
<td>Westburg, NY</td>
<td>2005</td>
<td>Improper LCG soak time</td>
<td>144</td>
</tr>
<tr>
<td>San Diego, CA</td>
<td>2006</td>
<td>Failure to disinfect</td>
<td>229</td>
</tr>
<tr>
<td>Brazil, WA</td>
<td>2006</td>
<td>Improper adaptor</td>
<td>107</td>
</tr>
</tbody>
</table>

Suspected causes of outbreaks 1995-2005

The suspected causes of the 33 outbreaks published 1995-2005
The times they are a changing...

# 4 on the 2015 ECRI List of Hazards

ECRI - Last 4 years in the top 10

FDA in the News
Philadelphia Hospital had issues in 2014

- Just reported on 2/6/2015 – one year later
- A Philadelphia hospital was struck last year by an outbreak of drug-resistant bacteria associated with the use of a special kind of hard-to-clean endoscope, according to city data.
- Eight people examined with the scopes became infected with bacteria resistant to a class of last-resort antibiotics called carbapenems, and two died, the city Department of Public Health said.
- These “superbug” bacteria have an estimated mortality rate ranging from 25 percent to 50 percent in those infected. But both of the Philadelphia patients who died had serious underlying conditions, so their deaths were deemed “not clearly related” to the infection, department spokesman Jeff Moran said.
- Read more at http://www.philly.com/philly/health/20150206__Superbug__infects_eight_patients_at_Philly_hospital.html#vhj0c74mOVgGlMTF.99

US Senator Patty Murray letter to the FDA 2/3/2015

Gram Positive and Gram Negative Bacteria
2 Classes of Bacteria based on differences in the Cell Structure

<table>
<thead>
<tr>
<th>Gram Positive Examples</th>
<th>Gram Negative Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin flora</td>
<td>E. coli</td>
</tr>
<tr>
<td>Non pathogenic</td>
<td>Legionella</td>
</tr>
<tr>
<td>• S. epidermidis</td>
<td>Pseudomonas</td>
</tr>
<tr>
<td>• S. salivarius</td>
<td>Salmonella</td>
</tr>
<tr>
<td></td>
<td>Serratia</td>
</tr>
<tr>
<td></td>
<td>Helicobacter</td>
</tr>
</tbody>
</table>

Impact of Gram Negative Bacteria

- Frequently reported in endoscope acquired infections
- Replicate more easily in moisture
- Indicators for bacterial contamination in endoscopes
- Reduce the risk of false positives associated with the gram positive bacteria- normally occurring as skin flora.

The Problem with Gram Negative Bacteria

- Presence of double membrane surrounding bacterial cell.
- The outer membrane excludes certain drugs from penetrating the cell.
- Confers more Antibiotic-resistance than Gram positive bacteria.

CRE Bacteria

- Family of Gram negative bacteria
- Multidrug resistant
- Nearly immune to the ‘Carbapenem’ class of antibiotics, considered the last line of defense against Gram-negative infections
- Recent outbreaks of the deadly CRE bacteria in Chicago, Seattle and Pittsburg - linked to a Duodenoscopes/ ERCP endoscopes
Duodenoscopes and CRE

- The design of the ERCP endoscopes might pose a particular challenge for cleaning and disinfection.
- Endoscopic retrograde cholangiopancreatography (ERCP) is an effective technique for diagnosing and treating problems in the liver, gallbladder, and pancreas.
- To prevent risk of disease transmission during ERCP, the duodenoscope's complex internal surfaces, including its long and narrow elevator-wire channel — require special attention and thorough reprocessing.

How many of you process ECRP type scopes?

- Do you know how many manual steps there are in the cleaning Process?
  - 40
  - 50
  - 60
  - 70
- Prior to disinfection what must you do with the forceps elevator?
  - Keep in lock position
  - Place in the intermediate position

What's hiding inside the Endoscope Lumen?

- Is there any residual bioburden in the lumen that we cannot visualize?
- Do we need periodic surveillance to monitor this?
  - After cleaning
  - After disinfection
  - In storage
  - What do you think?

Public knowledge

Come from the TV, radio, newspaper, internet research and word of mouth from employees about their facility.
How would you answer this question?

- Do you have protocols that ensure that staff can readily identify whether an endoscope is contaminated or is ready for patient use?
- Are you conducting competency testing of personnel reprocessing endoscopes on a regular basis?
- Although vague present guidelines support these two statements.

Flexible endoscopes have topped the list of the biggest health hazards for many years. Why, decontamination of this particular equipment requires a very specific multistep process, and failure to adhere to any step could jeopardize patients.*

Flexible Endoscopes Anatomy

- Endoscopes are complex medical instruments having long and narrow working channels that are subjected to torque and angulation forces.
- These forces require special materials and engineering.
- Endoscopes have state of the art electronics, including fiber optics and imaging technology.

Flexible Endoscopes

- There are a variety of flexible endoscopes types with differing channel sizes and configurations.

A comment from a major repair facility staff member...“The biggest horror story we see is facilities not brushing the biopsy channels and pre-cleaning them before they send them in for repair,” he expounds. “There’s nothing more disgusting than to open up a case and find fecal matter because they didn’t brush out the biopsy or suction channels. That’s more common that we would like to see”
Air Water Channel
Cleaning Concerns

Any organic matter that remains after manual cleaning lowers the effectiveness of the disinfectant, but the complex nature of endoscopes makes them very difficult to thoroughly decontaminate. With imperfect cleaning, bacteria could survive the disinfection process and infect the next patient.


Articles & Literature along with Clinically relevant & evidence based products

Applying the Principles to Product

Review of the Research

- Scientific Research
  - Residual soils in flexible endoscopes
  - Cleaning of flexible endoscopes
  - Organic & Microbial residuals
  - Organic & Bioburden markers to assess cleaning
  - Benchmarks for cleaning
- Clinical application of research to audit cleaning

Direct observation found guideline nonadherence with manual cleaning of GI endoscopes (69 total)

- 57% did not brush all channels & components
- 55% did not dry with forced air
- 22% leak tested with salty water
- 10% skipped final wipe down

99% of the time
**RUST Prototype Test:**
protein, blood, carbohydrate

- Prototype kits sent to 44 clinics from 23 Healthcare facilities; 1499 scopes tested
- Staff surveyed regarding test method
- Sample: S/B → distal using 10 ml sterile RO water [flush-brush-flush]

**What Organic Parameter to monitor?**
Guidelines: “Visibly Clean” is the standard; is it enough?

- Flexible endoscope biopsy channel: (Alfa et al 2002)
  - Protein; < 6.4 µg/cm²
  - Carbohydrate; < 1.8 µg/cm²
  - Hemoglobin; < 2.2 µg/cm²
  - Endotoxin; < 2.2 EU/cm²

**Olympus Study on The ChannelCheck**

**ChannelCheck™ Verification Test as a Tool to Assess Endoscope Cleanliness**
- ICT 1/2011 published
- The purpose of this study was to determine the real-world effectiveness of healthcare facilities' flexible endoscope cleaning procedures by utilizing the ChannelCheck™ residual soil test.
- A total of twelve health care facilities were recruited to participate in this study
- The ChannelCheck™ is an easy to use and effective tool for monitoring the endoscope cleaning process and demonstrating competency of facility reprocessing staff.

**HemoCheck Study**

**Flexible Endoscope Study**
  - Kovach & Humphries
    - Looked at 24 scopes
      - Pre and post cleaning
      - Used EndoCheck Hemoglobin
    - Three scopes remained positive for blood soil after the first cleaning and were again positive after a second cleaning
    - One scope needed a 4th cleaning
  - Testing helped them improve the process and let data help them make improvements
ATP Studies

- 100 of article
  - Peer reviewed and non peer reviewed
    - Monitoring the Effectiveness of Hospital Cleaning Practices by Use of an Adenosine Triphosphate Bioluminescence Assay; Infect Control Hosp Epidemiol 2009; 30:678-684
    - Monitoring the effectiveness of cleaning in four British hospitals; AJIC, June 2007
    - Establishing a clinically relevant bioburden benchmark: A quality indicator for adequate reprocessing and storage of flexible gastrointestinal endoscopes; American Journal of Infection Control 40 (2012) 233-6

Other articles

- 53% of Biopsy Ports valves after cleaning exhibited some form of debris or potential contamination Endosnare 11/6
- 57% of centers that process scopes were not in compliance with basic national standards
  - Infection Control and Hospital Epidemiology Volume 23; 2002
- The Question is are you sure your scopes are safe and clean????? What are you doing?

What does all of this data suggest?

- All of the studies support a need for a QA program
- Residual bio-burden is a concern on scopes after cleaning
- All the studies then raise at least these 3 question?
- What do we test for?
  - Organic residue or something else?
  - What can be done to improve the process of monitoring the cleaning process of flexible and all scopes in general?
  - If staff followed the IFU all the time we should not have any issues.
    - We know that is not happening

Keep the Scope Dry

- From a microbiology perspective, an absence of moisture means bacteria can’t replicate and biofilm can’t form. That’s a pivotal point. Flexible endoscopes are supposed to be stored dry. If staff follow proper reprocessing practices and store scopes properly, biofilm might not be an issue.
Storage of Flexible Scopes

- Improper Storage
  - Coiled scopes
  - Touching the base of the cabinet
  - Can cause Microbial growth
- Present testing methods for a scope in storage
  - Traditional culture plating
    - (2 days)
  - Enzyme detection for Bacteria
    - (10 minutes)
    - Specific to gram negative bacteria

Storage of reprocessed endoscopes

- Hung vertically with the distal tip hanging freely in a well-ventilated, clean area
- Scopes should not be touching each other
- All removable parts (e.g., valves and caps) should be detached from the endoscope.
- Detachable parts stored together with the scope, a small bag or similar device can be used to attach the parts to the scope.

Storage of reprocessed endoscopes

- Identification of Patient Ready Scope
- The tag or label is affixed to the endoscope after it has been reprocessed and before it is placed in the storage cabinet
- The tag should be labeled with the following information:
  a) Date of cleaning
  b) Name of person who performed the cleaning
  c) Date of high-level disinfection

Protecting the Distal tip

Green is Clean – Patient ready Scope

Identification of Patient Ready Scope

Quality Improvement and the Guidelines and Standards
Just some of our groups

What are these based on

- Clinically relevant & evidence based practices
- Peer reviewed literature
- Other articles
- Manufactures research and guidance
- Research and science
- Unfortunately some practices do not have the evidence to support the practice
- Dynamic process

AAMI

- “A problem analysis should be completed for any problem with any aspect of decontamination that can pose a risk to personnel or patients. The problem analysis should define and resolve the problem and the system should be monitored to ensure that the problem has been corrected. (AAMI ST 79)”

Quality Improvement Program Monitoring the process

Currently most just respond to problems after they occur….not the best way to prevent or reduce the concern of dirty scopes.

Suggestions for a quality improvement Program

Put in a proactive preventive maintenance program for all scopes.

Monitor the critical steps in the process.

What are they?

Monitoring steps in your process

- Look at your process
- Create an audit tool
  - Pre-cleaning
  - Leak Testing
  - Cleaning with enzymatic detergent solution
  - Rinsing
  - Monitor the cleaning process
    - Manual
    - Automatic
  - Disinfectant/Sterilant
  - Rinsing
  - Drying & Alcohol Flush
  - Storage
  - Transportation
Leak Testing

**Best Practices**
- Visualize bending section inflation before immersing
- Fully angulate distal tip in all directions
  - Document all results
- Follow OEM instructions for reprocessing a leaking endoscope
- Use same water-resistant cap throughout procedure

**LEAVE YOU WITH THESE FEW THOUGHTS**

Remember that endoscope leak testers give hospitals some of the most value in reducing repair costs.

Endoscope reprocessing:
Quality Improvement Program

- **Ensure Staff competency:**
  - Initial training verification,
  - Updated for new scopes
  - Yearly competency assessment needed
- **Ensure ongoing adequacy of reprocessing:**
  - Visible inspection inadequate for scope lumens
  - **Audit tool:**
    - Monitor scope lumens
    - Monitor AER cleaning adequacy (if used)
- Pick a product and base your policy on the information
Verifying Clean
Visual inspections and testing of the equipment
• Inspecting organic residues
• Testing for any cracks in the devices
• Checking integrity of fiber optic bundles
• Leak testing

Methods to measure organic and other residues found on scopes
• Protein
• Hemoglobin
• Carbohydrates
• Enzyme detection for Bacteria
• ATP
• Other test in the future

Closing
• It is in the patient’s best interest for a hospital to do the best it can each and every time. Testing scopes for cleanliness as part of a quality improvement program is part of that commitment to quality and to the patient.
• Which Headline would you like to see for your hospital....

Think of your medical facility
“Hospitals that eventually demonstrate a sustainable link between quality investments and better clinical outcomes will likely gain competitive advantage, thereby improving financial performance and possibly their bond ratings”

References:
8. www.mendicote.com
9. As noted on slides
Flexible Endoscope Reprocessing is Changing

- Why you need to do something now?
  - Consumer pressure for quality
  - Guidelines and Standards
  - Equipment failure
  - Staff training
  - Preventative maintenance program

- What are ways to implement?
  - Look at your process
  - User testing
  - Equipment testing

- Guidelines and standards support in general some type of quality improvement program for monitoring but are not specific at this time

- AAMI TIR 54 / ST 91
- AORN Document

It takes a lot of time to properly process any scope

When it comes to reprocessing medical devices, patients' lives are in your hands

- Your commitment and responsibility to providing safe, efficient and quality patient care should include testing scopes for cleanliness and proper reprocessing.
- Remember most medical facilities do not have in place adequate quality monitoring programs for flexible scopes... you will very soon.