Infection Control in Endoscopy: Using Guidelines to Achieve Excellence
Top 10 Health Technology Hazards by the ECRI Institute included endoscope reprocessing for the past 7 years: 1,2

- 2010: #1: Cross-contamination of endoscopes
- 2011: #3: Cross-contamination of endoscopes
- 2012: #4: Cross-contamination from flex. endoscopes
- 2013: #8: Inadequate reprocessing of endoscopes and surgical instruments
- 2014: #6: Inadequate reprocessing of endoscopic devices and surgical instruments
- 2015: #8: Inadequate reprocessing of endoscopes and surgical instruments
- 2016: #1: Inadequate cleaning of flexible endoscopes before disinfection can spread deadly pathogens

Estimated Hospital Financial Consequence of Incident 1,2

<table>
<thead>
<tr>
<th>Year</th>
<th>Incident</th>
<th>Legal Fees</th>
<th>PR Damage</th>
<th>Alerts &amp; Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>$0.5M-$16M</td>
<td>$1M-$2M</td>
<td>$775/patient</td>
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</tbody>
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Total estimated cost per incident: $2M-20M

FDA and CDC acknowledge3: “Flexible endoscopes are fundamentally difficult to clean and disinfect or sterilize”
Flexible Endoscope Reprocessing Concerns

- Mechanically complex devices
- Frequent technology or mechanical updates
- Increased technical difficulty of procedures
- Minimally invasive procedures are increasing
- Longer procedures means more difficulty during cleaning procedures
- Many models of scopes require many IFUs
- Skills acquisition for reprocessing takes time and ongoing education
- Ongoing oversite is critical to maintaining best reprocessing practices
Issues With Professional Guidelines

- No consensus
- Auditors may use more stringent ANSI/AAMI
- Specificity in the guidelines
- Understanding how to use guidelines
- Confusion of when to use manufacturers’ Instructions for Use (IFU) or follow guidelines
- What to do when guidelines don’t fit
<table>
<thead>
<tr>
<th>Departments Using Guidelines</th>
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<tr>
<td><strong>ANSI/AAMI</strong></td>
</tr>
<tr>
<td>Sterile Processing Department</td>
</tr>
<tr>
<td>Operating Room</td>
</tr>
<tr>
<td>Day Surgery</td>
</tr>
<tr>
<td>Infection Control Nurse</td>
</tr>
</tbody>
</table>
Reprocessing Steps

- **Point of Use Precleaning**
  - Immediately upon withdrawal
  - Water/air/detergent solution

- **Leak Test**
  - Dry – manual or automated
  - Wet – manual or automated

- **Manual Cleaning**
  - Brushing/flushing
  - Rinsing

- **Visualization**
  - Magnification 10X
  - Newest called out step
Reprocessing Steps

- **High Level Disinfection**
  - Manual
  - Automated

- **Rinsing**
  - Manual – Sterile water, Reverse Osmosis
  - Automated – Hepa Filtered

- **Forced air Alcohol Purge**
  - Low pressure instrument air – not syringe air
  - 70-90% isopropyl alcohol

- **Storage**
  - Vertical – hanging
  - Horizontal – drying/storage cabinet
Cycle of Reprocessing

Acquisition
1. Purchase
2. Loan
3. Repair

Disposition
1. Decontaminate and repair
2. Discard

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Where We Can Help

- Precleaning
  - Reducing initial bioburden
- Leak testing
  - Prevents fluid invasion and harboring microorganisms
- Manual cleaning
  - Organic soil removal prepares scope surfaces
- Drying
  - Just as important as cleaning
- Storage
  - Controlled environment
- Transport
  - Scope protected when contaminated and clean
- Traceability
  - Critical touch points
Point of Use

- Pre-Cleaning
  - Wiping down the scope
  - Immediate flushing of solution through the channels
  - Contained transport
Reprocessing Considerations

• One-way flow

• Transport

OSHA Regulatory Requirement
Storage
Traceability in Endoscope Reprocessing

- Storage
- Precleaning
- Leak Testing
- Manual Cleaning
- Rinsing
- Visual Inspection
- High Level Disinfection
- Drying Alcohol Flush
- Rinsing
### Critical Touch Points

- Procedure Room
- Leak Testing
- Manual / automated cleaning
- Manual / automated high level disinfection
- Drying, alcohol purge
- Storage

### Required Identifier Information

- Patient
- Scope
- Equipment
- Endoscopist
- Times
- Reprocessing personnel at all critical touch points
- Outcomes of all automated systems
- Outcomes of chemistry
Traceability the Hard Way
Traceability the New Way

Bar Coding
Data Matrix Tags

RFID – Radio Frequency Identification
• **FDA** – Mitigating Risk of Cross-Contamination from Valves and Accessories Use for Irrigation Through Flexible Gastrointestinal Endoscopes 11/29/2016

1. Highlight cross-contamination risk
2. Clarify terminology for these devices
3. Outline strategies to mitigate the risk of cross-contamination

Forward Water JJet / Auxiliary Water Connector

• Buttons and valves
  – Reusable buttons and valves should be cleaned and reprocessed with the scope to maintain a unique set for traceability *
  – Alternative solution – disposable buttons and valves †

* AORN, 2016; SGNA, 2015; AAMI, 2015
† SGNA 2015
Buttons and Valves

Air / Water Valves

Suction Valves
Auditing Agencies

The Joint Commission

DNV-GL

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Recommendations Frequently Given by Joint Commission

- No IFU present or followed
- Scopes touching other scopes or walls
- Scopes not protected during transport
- Complete traceability of the scope and accessories
- MRC test results missing
- Leak test results missing
- Education/competency for staff members
• Review multiple professional guidelines
• Review manufacturer’s Instructions For Use
• Convene a multidisciplinary team to review
  – Processes
  – Identify where you are with “best practice”
  – Identify where there are gaps
• Determine that Policies and Procedures are in alignment with guidelines and IFUs
• Identify and act on next steps to improve endoscope reprocessing
Summary

• Flexible endoscope reprocessing is a number 1 patient safety concern from the ERCI
• Auditing agencies are aware of this patient safety issue
• This issue requires multidisciplinary focus and execution to overcome the many challenges in getting it right the first time


Questions?