Our Scope of Quality
Amanda Billings, MPH, CLS, CIC
Disclosures

- I have nothing to disclose
Objectives

- Discuss current infection prevention standards in endoscopy suite
- Discuss current endoscope reprocessing guidelines and standards
- List the decontamination and disinfection steps of a flexible endoscope from bedside to storage
- Discuss documentation practices, and tools to demonstrate quality assurance for endoscope reprocessing
Risk of transmitted infections related to contaminated endoscopes is very low
- 1 in 1.8 million procedures (Spach et al. 1993)

All reported cases of transmitted infections resulted from failure to adhere to established reprocessing guidelines or the use of defective equipment

Transmission of MDR organisms via contaminated duodenoscope
- Attack rate 6% to 42% at risk or exposed ERCP patients (Ofstead, C.L. 2013)
Pathogens

- Most commonly reported organism *P. aeruginosa*
  - Inadequate drying of channels with 70% alcohol and forced air
  - Colonization of AER or water supply to endoscope
  - Failure to disinfect elevator channel of duodenscope

- Other bacterial pathogens
  - *Salmonella* spp., *Heliobacter pylori*, *Enterobacter cloacae*, *Klebsiella* spp., *Clostridium difficile*, *Derratia marcescens*, *Mycobacterium fortuitum* and *Flavobacterium* spp.

- *Hepatitis C Virus*
  - Asymptomatic, long incubation period
    - Obstruct causation relationship between virus transmission and endoscopy
  - Improper reprocessing
  - Inadequate aseptic technique
  - Improper administration of intravenous medications

- *Hepatitis B Virus*
  - Transmission not well documented
  - Few cases implicate inadequate endoscope reprocessing
Transmission of Pathogens in Endoscopy

- February 2008 – Hepatitis C outbreak in Las Vegas
  - 50,000 patients, physicians and staff tested
  - Re-use of syringes and multi-dose vials of sedation drugs
  - Investigation found reprocessing lapses as well and re-use of single use items
- 2010 – Palomar Pomerado Health System
  - 3,400 patients who received care between Dec. 1, 2008 and March 22, 2010 notified
    that they could receive free testing for diseases after having endoscopies with potentially dirty equipment
  - "Although we were disinfecting all equipment, some of the steps as recommended by the manufacture were not always completed"
- October 2011 – Endoscopic Clinic in Ottawa, Ontario
  - 6,800 patients notified
  - Scheduled inspection the College of Physicians and Surgeons of Ontario
  - Improper reprocessing upper and lower GI endoscopes for almost a decade
    - Expired Chemicals
    - Cross contamination
Established in 1995 in response to the CDC’s 1994 strategy Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States

Network of 10 state health departments (CA, CO, CT, GA, MD, MN, NM, NY, OR, TN)

- Collaborators in local health departments, academic institutions, other federal agencies, and public health and clinical laboratories; infection preventionists; and healthcare providers

Between May 2010 and September 2011—Seven endoscope reprocessing breaches reported to Minnesota Department of Health by five healthcare facilities

- 6 Pseudomonas aeruginosa clinical isolates were identified following ERCP
- Breach reported by technicians, IPs or manufacturer representatives
- Incorrect use of endoscopic accessories, reprocessing of single use devices, and failure to follow FDA labeling and/or manufacturer’s reprocessing instructions
- Resulted in 3 FDA notifications; 4 patient notifications
April 2009– one patient tests positive for HIV and seven others for hepatitis C at VA facility in Miami, FL

- Rinsing water tubes and reservoirs used in endoscopies with H2O, but did not disinfect
2013– Chicago, IL “Hospital X”
- 28 patients were colonized and 10 were infected with CRE
- All 38 patients underwent endoscopic retrograde cholangiopancreatography (ERCP) performed between January and September, 2013
- The elevator channel of the side-viewing duodenoscope was sampled and found to be contaminated with both the outbreak strain of CRE and a second strain
- CDC– did not identify any obvious breaches in reprocessing protocol
- CMS– cited that the hospital “failed to reprocess ERCP endoscopes as recommended by the manufacturer”
  - Did not clean with manufacturer approved brush or detergent

Infection Control Assessment of Ambulatory Surgical Centers

- Seven states volunteered
  - Maryland, North Carolina, and Oklahoma selected
  - 68 ASC were assessed
- Incorporated infection control audit tool
- CMS state surveyor
- 28.4% (95% CI, 18.60%–40%; p=.05) failed to adhere to recommended practices regarding reprocessing of surgical equipment

Types of Lapses Identified in the Pilot Ambulatory Surgical Centers by State

- Equipment reprocessing
- Equip. not precleaned
- Chem or Bio indicators
- HLD chemical
- Documentation
- Storage
- Single-use devices

- Maryland
- North Carolina
- Oklahoma
- All

- 3 out of 20 Gastrointestinal Scopes Contaminated
  - Conducted at five hospitals across the US
  - 3M’s Infection Prevention Division
  - 275 flexible endoscopes examined
    - After manual cleaning step
    - >200 relative light units of ATP considered a cleaning failure
  - Failure rates observed in the manual cleaning step–highest for duodenoscopes (30%), gastrosopes (24%), and colonoscopes (3%)

Comparison by Scope Type

- One-way ANOVA p-value < 0.0005. All pair wise p-values are less than 0.05.
- Manual cleaning of colonoscopes resulted in significantly lower RLU levels than gastroscopes and duodenoscopes.
183 endoscopes- after pre cleaning phase found 47.5% all steps were completed in accordance with guidelines.

Ofstead, CL et al.(2010). Factors that contribute to nonadherence with endoscope reprocessing guidelines: A prospective study overview of findings from the CLEANR study (clinical evaluation and assessment of endoscope reprocessing)
Lawsuits

- June 2012—Whistleblower lawsuit filed against owners of surgery centers affiliated with 1-800-GET THIN
  - Alleged Reprocessing failures exposed patients to hepatitis C virus
    - Reused single-use biopsy needles and forceps
    - Reused single use brushes for cleaning
- July 22, 2012: Forbes Regional Hospital, PA
  - Found negligent for failing to properly clean colonoscopes
  - Scopes used on more than 225 patients in 2004 and 2005
  - Did not follow manufacturer IFU
“Endoscopes are not Easy to Clean”
Society of Gastroenterology Nurses and Associates (SGNA)

- Standards of Infection Control in Reprocessing Flexible Gastrointestinal Endoscopes
- Guideline for the Use of High Level Disinfectants and Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes
- Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes
- Reuse of Single Use Critical Medical Devices – position statement
- Statement on Reprocessing of Water Bottles Used During Endoscopy
- Statement on Reprocessing of Endoscopic Accessories and Valves

SGNA
Society of Gastroenterology Nurses and Associates, Inc.
American Society For Gastrointestinal Endoscopy (ASGE)

- Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 2011
- Reprocessing failure guideline
Education

The Care and Handling of Rigid and Flexible Scopes
(An Online Continuing Education Activity)

GI Endoscope Reprocessing Steps

1. Pre-clean
2. Leak Test
3. Manual Clean
4. Rinse
5. High Level Disinfection
6. Rinse
7. Dry
8. Store
Pre-Cleaning

- Performed at point of use before bioburden has an opportunity to dry
- Follow manufacturer’s instructions
- Transport the soiled endoscope to reprocessing area in a manner that prevents exposure of staff, patients or the environment to the potentially infectious organisms
Leak Testing

- Detects damage to the interior or exterior of the endoscope
- Done before immersion of the endoscope in reprocessing solutions after each case
- Manual Leak Testing
  - Fresh, clear water
- Computerized Leak test
If a leak is detected, the endoscope must be repaired. Follow manufacturer’s instructions.
Necessary prior to automated or manual disinfection

Most important step in removing the microbial burden from the endoscope

Retained debris may inactivate or interfere with the capability of the high Level disinfectant
Medical-grade, low-foaming, neutral pH
- Clearly visualize scope
- Excessive foaming can inhibit good fluid contact with device surfaces

Freshly prepared detergent solution for each endoscope to prevent cross-contamination

Prepare according to manufacturers instructions
- Amount per gallon of H2O
- Submersion time
- Temperature
Follow endoscope manufactures instructions for cleaning
Use small, soft brushes to clean all removable parts, including under the suction valve, air/water valve, and biopsy port cover and openings
Use brush sizes compatible with each channel
After each passage, rinse the brush in detergent and reinsert into channel until brush is free of debris when removed
Discard disposable brushes
Reprocess reusable brushes between each case
Use manufacturer adaptors
Manual flush with syringe
Automated pumps eliminate manual flush
Disinfect sink with germicide after each use
Flexible endoscopes are complex devices, many consisting of long narrow lumens with multiple bifurcations as shown above.

All channels of a scope must be reprocessed whether utilized during the procedure or not.

Due to the complexity of the channel structure of flexible endoscopes only the Automated Endoscope Reprocessor manufacturers connectors can be used with their systems.
Suction Biopsy

- Runs from one end of the endoscope to the other
- There is a short length of tubing between the suction valve and Y pipe at the biopsy port—this is often missed when brushing gross debris
  - Less than 20 cm long
    - Cleaning requires inserting the brush at an acute angle into the suction valve unit
Air and Water System

- The air from the pump flows into the scope through air inlet pipe on light plug or water bottle.
- Flows to the body of scope and out of air/water valve.
  - To inflate organ, air/water valve is covered diverts air down the insertion tube to distal end.
    - Air infused into an organ may produce a luminal pressure high enough to force debris to back up several cm into the nozzle and air/water channels.
    - When air/water valve depressed air is split some is diverted to water bottle which forces water into another channel.
A look Inside the Common Olympus Flexible Endoscope

A. Flexible endoscopes are complex devices, many consisting of long narrow lumens with multiple bifurcations as shown above.
B. All channels of a scope must be reprocessed whether utilized during the procedure or not.
C. Due to the complexity of the channel structure of flexible endoscopes only the Automated Endoscope Reprocessor manufacturers connectors can be used with their systems.
ERCP

- Elevator Pivot Arm
- Elevator Rod Sealing Block
- Elevator Wire
- Sus-Pipe Channel
- Elevator Cleaning Channel
- Elevator Control Knob
- Coil Pipe
- Sus-pipe / Flex Coil Pipe Connection
- Elevator Riser
The ERCP Elevator Channel

- Hinged at one end and attached to a wire at the other end
- Cavity where riser moves back and forth
  - Cleaning can occur only by brushing through the instrument channel opening
  - Open/extend the riser as far as possible and brush the cavity thoroughly
  - The elevate the riser completely and clean behind the riser thoroughly
  - Some scopes have a removable distal cap

- Runs length of insertion tube and has 2 components
  - Distal end– plastic channel supported by coil pipe
  - Control body– metal sus–pipe
- Total length that must be flushe–125 cm long and the opening between the elevator wire and the sus–pipe is approximately 0.18 mm
Follow manufacturer’s guidelines

Ensure AER is compatible with elevator wire channel (appropriate hook up available)

Reprocessing the elevator wire can be time consuming if not automated
  ◦ Manual reprocessing the channel after each procedure
  ◦ Same steps should be followed as for any other channel
ERCP
ERCP

https://www.youtube.com/watch?v=Hrpgm-a8cl4&feature=player_detailpage
Thoroughly rinse endoscope and all removable parts with clean water to remove residual debris and detergent

Prevent dilution of the HLD used in subsequent steps

- Purge water from all channels using forced air
  - If using AER this step may be included with initiation of AER
- Dry exterior of the scope
HLD of Endoscopes

- Recognized as the standard for reprocessing of gastrointestinal endoscopes
- HLD destroys all viable microorganisms, but not necessarily all bacterial spores
- Should be prepared according to manufacturers instructions for use
- Follow manufacturer’s recommendations for reuse life, concentration and temperature
HLD Of Endoscopes

Automatic Endoscope Reprocessing

Manual Reprocessing
Rinse after AER or Manual HLD

Note: AER will have a rinse cycle following the disinfection cycle

- Thoroughly rinse all endoscope surfaces and removable parts, and flush all channels with clean water according to disinfectant manufacturer’s instructions.
- Prevent exposure and potential injury of skin and mucous membranes from chemical residue:
  - Chemical colitis occurs rarely
  - Glutaraldehyde directly injures crypt epithelium
  - Hydrogen peroxide compromises mucosal stroma, which can cause tissue necrosis
Drying is as important to the prevention of disease transmission and nosocomial infection as cleaning and high level disinfection.

- Purge all channels with air until dry
  - *Pseudomonas aeruginosa*

- Flush all channels, including accessory channels, with 70% isopropyl alcohol until the alcohol can be seen exiting the opposite end of the channel
  - Alcohol mixes with remaining water to encourage evaporation

- Purge all channels with air

- Dry exterior of the endoscope with a soft, lint-free towel
Storage

- Stored in a manner that will protect the endoscope from contamination
- Hang Scopes with all accessories removed
- Hang scopes vertically
- Storage area should be clean, well ventilated and dust free
The interval of storage after which endoscopes should be reprocessed before use has had limited investigation and warrants further data and research.

- AORN Advises 5 days
- APIC advises 7 days
- Mulisociety Guideline (2012) states reuse within 10–14 days of HLD appears safe
- Per Guideline may be advisable, particularly for instruments:
  - used infrequently because of low volumes or specialty applications
  - used in patients at high-risk of infection such as those whose immune systems are suppressed by medications or disease
  - Used in procedures with anticipated entry to otherwise sterile regions such as the biliary tree, pancreas and peritoneal space
Maintain a log for each procedure to assist in an outbreak investigation

Log must indicate the following

- Patient’s name
- Medical record number (if available)
- Procedure
- Serial number or other identifier of the endoscope and AER
Perform routine testing of the liquid high-level disinfectant to ensure at least the minimum effective concentration of the active ingredient

Check the solution prior to each use and document the results
- Document on HLD log
- If the chemical indicator shows that the concentration is less than the minimal effective concentration, the solution should be discarded

Perform MEC monitor strip QC each time new bottle of monitoring strips are opened
- Document on QC log
Disinfection Logs

- Monitor and Document
  - HLD temp
  - Soak time
  - Expiration date
  - Date of reprocessing

- AER print outs
  - Includes:
    - temp
    - soak time
    - MEC result
    - Date

Manual Disinfection  Automated Disinfection
## MEC Monitor strip QC Log

### Verify Chemical Monitoring Strip Quality Test Log

- **Department**: HVMC □, MVMC □
- **Quality Control test to be performed each time a new bottle of monitoring strips are opened**

**(+)** PASS: Monitoring strip is completely black  **(-)** FAIL: Monitoring strip is yellow or yellow with black speckles

<table>
<thead>
<tr>
<th>Test Date</th>
<th>Test Strip Lot #</th>
<th>Date Test Strips Expire</th>
<th>Negative Control Test (+/-)</th>
<th>Positive Control Test (+/-)</th>
<th>Initials</th>
<th>Comments</th>
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### Revital-Ox High Level Disinfection Log

- **Department**: [HVMC, MVMC]
- Perform Verifly Chemical Monitoring Strip Prior to each use
- (+) PASS-Monitoring strip is completely black
- (-) FAIL-Monitoring strip is Yellow or yellow with black speckles
- 8 Minute Soak Time

<table>
<thead>
<tr>
<th>Date</th>
<th>Revital-Ox 21-day expiration date</th>
<th>Monitoring strip Lot #:</th>
<th>Monitoring strip Test Result (+,-)</th>
<th>Revital-Ox Temp (60-75°F or 20-24°C)</th>
<th>Scope (H)</th>
<th>Soak Start Time</th>
<th>Soak End Time</th>
<th>TESTED BY (Initials)</th>
<th>SOLUTION CHANGED &amp; INITIALS</th>
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Monitoring Scope–Cleaning Process (Quality Assurance Program)

- Understand your baseline
  - Observe practice
  - Interview
  - What Equipment/chemicals are they using

- Monitoring Options
  - Visual Inspection
  - Microbial Surveillance
  - New monitoring tools
    - Channel Check
    - ATP monitoring
Visual Inspection

- Common form for monitoring manual cleaning
- Ineffective
- Cannot detect microorganisms or bioburden left in endoscope channels
Microbial Surveillance

- Not practical as real time verification of reprocessing verification
- “The Multi-Society Guidelines for Reprocessing Flexible Gastrointestinal Endoscopes” does not recommend routine environmental monitoring of endoscopes
- High rate of false positives, and investigative resources
- Appropriate for outbreak investigation
AMMI TIR 12 recommends testing and validation of cleaning process
Provide instantaneous results for residual bioburden and organic matter
Test for protein/hemoglobin/carbohydrate residues
Test for residual adenosine triphosphate (ATP)
Healthmark Industries Channel Check™

- 3 in 1 test strips
- Detect low levels of protein, carbohydrate and hemoglobin residues
- Use after manual cleaning before HLD
- Flush sterile saline through channel, dip test strip, read after 90 seconds
Ruhoft ATP Complete®

- Detects presence of ATP
- Uses a special sponge passed through channel
- Sponge immersed in reagent
- Within 15 sec light is emitted in direct proportion to the amount of ATP present
**Monitoring Limitations**

<table>
<thead>
<tr>
<th>Residue</th>
<th>ATP</th>
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<tbody>
<tr>
<td>Test strips are meant to be used as a residual check and do not check for bacteria</td>
<td>ATP not produced in certain microbes, i.e. viruses</td>
</tr>
<tr>
<td>Only test scope channels</td>
<td>Unable to detect gram-negative bacteria as efficiently do to incomplete cell lysis</td>
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<tr>
<td>Check only for cleaning efficacy not disinfection</td>
<td>Cannot differentiate ATP from different sources</td>
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<td>Detection does not always translate to viable microbes</td>
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<td>No universal ATP RLU standard</td>
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Conclusion

- All manufacturer’s instructions for use for endoscopes, AER, high level disinfectants, and enzymatic detergents need to be read, understood and followed at all times
- Follow the recognized Guidelines and Standards
- Ensure documentation is accurate
- Monitor cleaning process
