Learning Objectives

• Identify the risk of infection from endoscopy and the potential impact of breaches in scope reprocessing
• Evaluate compliance with endoscope reprocessing and develop an action plan for improvement.
• Provide a comprehensive scope reprocessing educational program

Endoscopy in the News

May 2009: VA notified more than 11,000 patients that had colonoscopies performed of potential exposure to infectious body fluid

• Discovered MAJ-855 tubing used with the Olympus Flushing Pump had been fitted with a two-way valve instead of the one way valve designed to prevent contamination
Endoscopy in the News

January 1, 2010: Tulane Medical Center in New Orleans notified 360 patients that had GI endoscopy procedures of potential exposure to infectious diseases

• For 7 weeks the HLD was not at a sufficient temperature
• At least 1 patient and spouse filled a class action law suit

Endoscopy in the News

July 22, 2012: Forbes Regional Hospital negligent

• A jury decided in a class-action lawsuit that the Hospital was negligent in failing to properly clean colonoscopes used on more than 225 patients in 2004 and 2005.
• In 2004 the facility received two new colonoscopes and failed to read the enclosed instructions and following warnings that they required special cleaning of the auxiliary water channels.
• The Hospital was ordered to pay each patient $25,000 for a total $5,625,000 and legal fees.

This case demonstrates that a medical facility can be found legally responsible even if a reprocessing breach has not been linked to an infection.

Endoscopy in the News

April 30, 2013: Atlanta outpatient surgery center reports improper cleaning of colonoscopy equipment

• 456 patients were notified they may be at risk for Hepatitis and HIV
• The scopes were cleaned with enzymatic detergent with every use, but high-level disinfection did not occur.
Endoscopy in the News

January 19, 2015: UCLA Medical Center

- Outbreak of CRE from duodenoscopes between October-January even after disinfection guidelines were followed
- Seven patients were infected, and two died. 179 others were contacted to test for the bacteria

Financial Consequences

- Patient notification: $70-80/per patient
- Lab testing of possible infected patients: $700/patient
- Incident investigation: $25,000-$75,000
- Legal Defense: $220,000-$850,000
- Settlement/verdict: $250,000-$16 million
- Loss of volume and market share if reported in the media: $1-2 million
- Total estimated business cost per incident: $2-20 million
Health Risk from Endoscopy

• More than 55 million procedures were performed with GI endoscopic devices in 2009, nearly 50% of them colonoscopies
• Despite the large number and variety of GI endoscopic procedures performed, documented instances of infectious complications remain rare, with an estimated frequency of 1 in 1.8 million procedures*

*Risk of Transmission

The infection rate is underestimated because:
• Inadequate surveillance
• Breaches are not discovered or reported
• Asymptomatic infections
• Infections with long incubation periods
• Infections may not be recognized
• Patients don’t correlate the new disease with the recent procedure performed

Facts to Consider

• “There are more outbreaks from the use of endoscopes than any other medical device due to the complexity of the instrument and microbial contamination”

Dr. William Rutala
Health Risk from Endoscopy

Consider potential exposure to communicable diseases including:
- HIV
- Hepatitis B
- Hepatitis C

ECRI Institute

The ECRI Institute listed endoscope reprocessing on their list of the Top 10 Health Technology Hazards for the past 7 years:
- 2010: #1 Cross-contamination of endoscopes
- 2011: #3 Cross-contamination of endoscopes
- 2012: #4 Cross-contamination from flexible 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

ECRI Institute 2017

2017: Top 10 Health Technology Hazards
1. Infusion Errors Can Be Deadly If Simple Safety Steps Are Overlooked
2. Inadequate Cleaning of Complex Reusable Instruments Can Lead to Infections
3. Missed Ventilator Alarms Can Lead to Patient Harm
4. Undetected Opioid-Induced Respiratory Depression
5. Infection Risks with Heater-Cooler Devices Used in Cardiothoracic Surgery
6. Software Management Gaps Put Patients, and Patient Data, at Risk
7. Occupational Radiation Hazards in Hybrid ORs
8. Automated Dispensing Cabinet Setup and Use Errors May Cause Medication Mishaps
9. Surgical Stapler Misuse and Malfunctions
10. Device Failures Caused by Cleaning Products and Practices

Call to Action

All endoscopy facilities must ensure that:
• Scope reprocessing practices are based on manufacturers instructions for use
• Staff are trained and competent in all areas of scope reprocessing with ongoing education
• Audits are done frequently to ensure compliance

Contributing Factors

• Lack of education
• Improper training
• Non-compliance
• Complexity
• Complacency
• Lack of oversight
• Lack of ongoing process validation

Complex Procedures

• 200+ sub-tasks in endoscopy reprocessing a colonoscopy
• High memory demands
• Technical jargons
• Similar named items
• There is a very narrow margin of safety in endoscope reprocessing
• Any slight deviation can lead to the survival of microorganisms and risk of infection
• Human error
Is this you?

Gain Confidence

• “I don’t know how to clean scopes, I’ll look foolish if I go in the scope room”
• “The techs that work in our scope reprocessing area have years of experience, I have nothing to offer them”
• “So far I haven’t heard of any problems with our scope room or reprocessing, so no news is good news and I want to keep it that way. Why rock the boat now by going in there?”

Challenges- Human Factors

• Staff turnover
• Complacency
• Compensation
• Bullying, intimidation
• Lack of appreciation/respect
• Conflicting information from manufacturer’s reps
Challenges - Education/Training

- Lack of standardized education
- Inadequate or improper training
- Lack of understanding
- Complexity of scope reprocessing procedures

Challenges - External Forces

- Pressure to reduce Turn-Around Times
- Pressure to control/reduce costs
- Increased procedure volume
- Decreased staffing

Challenges - Oversight and Management

- Inadequate oversight
- Lack of competencies for all processes
- Leadership's lack of knowledge
- Inadequate or absent tools for ongoing assessment and process validation

**Low Appreciation – High Expectations**
Resources

- Published guidelines and standards
- SGNA- Infection control
- SGNA-Reprocessing, HLD’s
- ASGE- Breach Protocols
- Vendor Representatives
- Professional Organizations
- Infection Control Specialist

Infection Control Guidelines

Q-0242
§416.51(b) Standard: Infection control program.
- The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.

Standards of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes, SGNA 1996, revised 2018
- Definitions
- Introduction
- Personnel
- Management
- Quality Assurance
- Reprocessing Environment
- Spill Containment Plan
- Reprocessing Accessories
- Endoscope Reprocessing Protocol
Guideline for Use of High Level Disinfectants & Sterilants for Reprocessing Flexible Gastrointestinal Endoscopes, SGNA 1998, revised 2017

Definition of Terms
A. Personal Protective Equipment
B. Ventilation Guidelines
C. Recommended Exposure Limits
D. Determining Minimum Effective Concentration (MEC)
E. Rinsing
F. Disposal
G. Spill Plan

II. Summary

References
Recommended Reading

Removed from the 2017 revision:

2. Soak time exception:

SGNA, in collaboration with the American Society for Gastrointestinal Endoscopy (ASGE), the American Gastroenterological Association (AGA), the American College of Gastroenterology (ACG), and the Association for Professionals in Infection Control and Epidemiology (APIC) adopted the Multisociety Guideline for Reprocessing Flexible Gastrointestinal Endoscopes.

This guideline, based on scientific data, supports the position that after meticulous manual cleaning, high-level disinfection is achievable with a 20-minute exposure at 20°C (room temperature) in a 2% glutaraldehyde solution which does not contain surfactant and which tests above its minimum effective concentration (Nelson et al. 2003, FDA 2009).

These conditions may not be extended to other glutaraldehyde solutions. This recommendation differs from the label claims on 2% glutaraldehyde stating a 45-minute exposure at 25°C for HLD because the current federal labeling regulation assumes no cleaning of the medical device prior to chemical exposure.

Standard of Infection Prevention in the Gastroenterology Setting, SGNA 2015

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SGNA supports the following positions:

A. Use sterile water in the water and irrigation bottles for all endoscopic procedures (ASGE, 2011; Beilenhoff et al., 2008).

B. Manually clean and high-level disinfect or sterilize the reusable water and irrigation bottles according to manufacturer’s recommendations, at least daily. (ASGE, 2011; Beilenhoff et al., 2008; Greenwald, 2011)
Thoroughly dry all water bottle surfaces before storage to reduce the potential for bacterial colonization (ASGE, 2011; Greenwald, 2011; SGNA, 2012).

Position Statement on Water and Irrigation Bottles Used During Endoscopy, SGNA
2002, revised 2014

Position Statement Reprocessing Endoscopic Accessories and Valves, SGNA 2002, revised 2014

A. Endoscopic accessories and valves labeled as reusable must be reprocessed according to manufacturer’s instructions.
B. Endoscopic accessories and valves labeled as single-use must not be reprocessed or reused. (SGNA, 2013b)
C. Endoscopic accessories that are classified as critical medical devices require sterilization.
D. Valves must be removed, cleaned manually, and high-level disinfected or sterilized in accordance with the original equipment manufacturer’s instructions.
E. Automated endoscopic reproprocessors (AER) must be certified for the intended use of reprocessing accessories and valves in accordance with the original equipment manufacturer’s instructions.
F. Channel cleaning adaptors, reusable cleaning brushes, and other reprocessing accessories should be reprocessed according to manufacturer’s instruction after each use.
G. Endoscopic accessories and valves should be inspected for integrity and cleanliness before, during, and after use. Damaged items should be removed from service immediately and soiled items should be reprocessed. (ASGE, 2011)
H. A comprehensive quality control program should be implemented that includes visual inspections and equipment testing to identify conditions that may affect the cleaning or disinfection process. (FDA, 2009b)
I. Procedures for monitoring the useful life of accessory equipment and valves should be implemented which include inspection, scheduled maintenance, and removal of equipment from use based on the manufacturer’s guidelines. (FDA, 2009b)

ASGE Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update

• Developed by the ASGE Reprocessing Guideline Task Force- mostly physicians
• Recommendations are controversial, and historically do not follow standard recommended practices or manufacturers guidelines
• 2011: Perform routine testing of the liquid high-level disinfectant to ensure at least the minimum effective concentration of the active ingredient. Check the solution at the beginning of each day of use (or more frequently) and document the results. If the chemical indicator shows that the concentration is less than the minimal effective concentration, the solution should be discarded.
• 2016: Perform routine testing of the liquid HLD to ensure at least the minimum effective concentration of the active ingredient. Check the solution at the beginning of each day of use (or more frequently in accordance with manufacturer’s guidelines) and document the results. If the chemical indicator shows that the concentration is less than the minimal effective concentration, the solution should be discarded.
Common Reprocessing Issues

- Not following manufacturers instructions:
  - Using products that are not approved to clean scopes: bleach, hydrogen peroxide, surgical instrument detergent
  - MEC not checked with every HLD use and/or no timer used
  - HLD exp dates miscalculated, not documented on AER
  - Bedside cleaning not performed per manufacturer instructions
  - Enzymatic detergent not diluted properly or used full strength on sponge, water temperature too high
  - Reusable water bottles not disassembled and flushed correctly during high-level disinfectant and rinsing
  - Scopes put on counter after reprocessing and not hung to dry

Less Common Reprocessing Issues

- Centers borrowing specialty scopes
- Some centers have ERCP scopes at their centers
- Reusable forceps and rarely used devices
- Scope with lipids or hard to remove substances
- Different types of AER’s at one center
- Different brands of scopes at one center
- Not identifying scopes that need repair in the AER

Other Findings

- Inconsistent Practices
  - Each tech had their own way of cleaning scopes “this is the way I do it”
  - Failure to document all processes and patient / scope information
  - Lack of training or no documentation of training
  - Different practices for patients with history of HIV, hepatitis
  - No OSHA safety training, Spill Kit and Drills for Glutaraldehyde or high-level disinfectants, First Aid training, Eye Wash Station
  - Reusing or re-processing single-use devices
  - Door to scope room left open all day
  - Clutter/ disorganization of scope room
Misunderstood, confused, or just not followed?

- **Bedside Cleaning**
  - Amount of water/air to suction
  - Always flush auxiliary water channel, even if not used
  - Must use blue air/water cleaning adapter (credit card) Olympus
- **Manual Reprocessing** (Soak Pan)
  - Must meet minimum temperature of HLD- need to measure temperature
  - If below minimum temperature, must have a method to heat the HLD
  - Must follow the number of rinses specified by the HLD manufacturer
- **Automated Endoscope Reprocessor**
  - Verify scope number and cycle completion with AER printout and initial AER printout prior to removing scope from AER

Manufacturer Instructions

Keep Scope Room Supplies Organized
High-Level Disinfection Forms

Standardize all the Processes in the Scope Room

• The scope room is always set up the same way
• All scope room staff perform scope reprocessing the same way
• Encourage routine peer audits
• Documentation is consistently completed the same way
  • Avoids confusion and missed steps
• Assist each other with AER maintenance, filter changes
• Track scope repairs and AER repairs
• Label cabinets and shelves for easier supply stocking
• Set up a par level for supplies and a regular ordering system

The Reprocessing Room

• Looked at the functionality and working conditions for personnel who work all day in the scope room
• Fall hazards from wet floors, dripping scopes
• Counter tops, floors, sinks and walls that cannot handle the water and chemical exposure
• Poor lighting
• Poor sink height, techs having to bend over to clean scopes
• No flushing devices, having to manually flush each scope with large volumes of enzymatic, water and air causing hand injuries
• No eye wash station within 10 seconds, no hand hygiene sink
• No doors
### AER Maintenance

- Preventative Maintenance Agreement by manufacturer in place
- Repair Log in place, repairs tracked and trended
- Verify that AER settings are returned to appropriate settings after repairs are completed
- Filters changed regularly and documented
- Water line sanitation and internal water filter changes are completed per manufacturer recommendations
- Several employees are trained in AER maintenance - not just one employee

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### It can happen at your facility

1. Tech A manually cleans scope – places in the AER, but does not initiate the cycle; Tech B comes into reprocessing room and retrieves scope for a procedure, assuming scope has been processed and does not verify with reprocessor printout
2. Failure to check minimum effective concentration (MEC) with each scope reprocessed.

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### It can happen at your facility

3. DSO minimum Rapicide temperature setting incorrect and temperature goes below minimum requirement
4. HLD not changed when expired
5. Lapses and errors in scope reprocessing documentation
6. All personnel not following the same processes, ‘This is the way I do it’
7. Steps shortened or skipped because of staff being rushed and pressured by physicians.
Risk Identification/Exposure Assessment

- Breach confirmed – now what?
- Complete and thorough analysis of all reprocessing-related activities
- Process immediately corrected
  - Education
    - Comprehension and Performance validated
    - Expectations clearly communicated
  - Performance, Documentation and Communication
  - Monitor for compliance / QAPI reporting
  - Regular and frequent audits to assess overall process

Breach-Communication

- Infection Control Professionals
- Risk Management
- Local and state health departments
- Affected healthcare providers
- Licensing or other regulatory agencies, if appropriate
- Equipment Manufacturer, Biomed
- Malpractice Carrier

Breach-Communication

- Complete thorough investigation through root cause analysis
- Determine who will conduct testing, obtain consent, consider counseling
- Notify patients at risk in a timely manner of the breach and risk of infection
- Determine if follow-up testing is needed
- Address media and legal issues
Ongoing Education In Progress

- Education for all new equipment
- For each new scope: the manual should be reviewed for any differences in reprocessing
- New Policies and Procedures related to scope reprocessing
- Release of the Scope Reprocessing Toolkit
  - Manufacturer Instructions
  - Product Bulletins
  - Training Videos
  - Competencies
  - Policies and forms

Center Leader Monthly Scope Audits

- Confirm MEC is checked prior to each use of high-level disinfectant
- Review the MEC QC documentation and verify the frequency of bottles opened and the number of procedures performed at the center to ensure MEC checked with each use
- Confirm that disposable/single-use items are not used more than once (cleaning brushes, enzymatic solutions, valve brushes)
- Confirm that all HLD's are used at the recommended temperature and soak time with each use
- Confirm that the AER print out is verified with initials prior to each scope removed from the AER

Observational Surveillance - Ongoing

- Are practices consistent between the techs?
- Are gloves always being used to handle scopes?
- Is PPE being worn properly?
- When was badge testing last completed?
- If there was a spill, would they know what to do?
- Are staff aware of first aid measures and where SDS documentation is?
Frequent meetings with the Scope Room Staff

- Share best practices, techs are proud to show improvement
- Give time for discussion, encourage questions
- Provide training on infection control, PPE, Scope Repairs
- Recognize top performers – champion
- Assist with training for new employees
- Review Manufacturer Instructions for updates and revisions
- Review Nationally Recommended Guidelines- CMS Infection Control Worksheet
- Trial new products and get feedback from staff
- Complete Competencies or have Skills Days

Questions, Comments, Discussion?

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