Flexible Endoscope Reprocessing and the Importance of Standards and Recommendations in Prevention of Infections

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• I am an employee of Healthmark Industries Fraser, Michigan USA.
• I am involved with the manufacture and distribution of medical products to healthcare facilities and healthcare professionals.
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Objectives

- Discuss the key provisions and competency recommendations from ANSI / AAMI ST 91, SGNA, AORN guidelines
- Identify best practices in reprocessing of flexible endoscopes
- Discuss how various methods of cleaning verification and surveillance testing can reduce Hospital Acquired Infections (HAI) and Surgical Site Infections (SSI) and help to determine if an endoscope is patient ready

The ECRI 2017 List

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

Processing / Reprocessing

Processing (or reprocessing) is a process carried out on a device to allow its subsequent safe use, which can include cleaning, disinfection, sterilization, and related procedures.
Risk of Endoscopy Related infection or Other Adverse Patient Reactions

- Spread on infections related to endoscopy:
  - **Exogenous** infections = Microorganisms spread from patient to patient by contaminated or malfunctioning scopes or equipment
  - Microorganisms may be transmitted from patients to endoscopy personnel and/or from endoscopy personnel to patients
  - **Endogenous** infections = Microorganisms spread from the GI tract through the bloodstream during an endoscopy procedure to susceptible organs, or may spread to adjacent tissues that are breached as a result of the endoscopic procedure

Risk of Endoscopy Related Infection or Other Adverse Patient Reactions

- Other risks related to endoscopy:
  - Chemical substances can remain on devices from various chemicals used during the procedure or processing that can cause toxic reactions in subsequent patients:
    - Chemical burns, colitis, anaphylaxis, death
  - Devices may be damaged or rendered difficult to use due to mishandling or inadequate processing.

What are the SGNA Guidelines?

SGNA Standards and Practice Guidelines:
2. Standards of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes (2016)
SGNA Reprocessing Steps

1. Precleaning;
2. Leak testing;
3. Manual cleaning;
4. Rinse after cleaning;
5. Visual inspection: (includes cleaning verification)
6. High-level disinfection (manual or automated);
7. Rinse after high level disinfection;
8. Drying (alcohol and forced air); and
9. Storage

What is ANSI/AAMI ST 91?

- Flexible and semi-rigid endoscope reprocessing in health care facilities
- Contains best practices for scope reprocessing in ANY setting
- Available for purchase at the www.aami.org

Objective – ST91

- Provide guidelines for processing of flexible endoscopes
  - Includes all stages of reprocessing HLD and sterilization of scopes and accessories
- Include flexible gastrointestinal (GI) endoscopes; bronchoscopes; ENT scopes; surgical flexible endoscopes (e.g., ureteroscopes); and semi-rigid operative scopes (e.g., choledochoscopes)
- Exclusions
  - Rigid endoscopes and probes (e.g., TEE probes)
Other Guidelines for Endoscopes

- FDA Safety Communications
- Manufacturer’s IFU for scope, AER and accessories.

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Best practices for processing flexible endoscopes

• Meticulous attention to all steps in processing endoscopes, their components and accessories is critical making them safe for subsequent patient use
• Steps are outlined in the document in detail and include the following categories
  o Precleaning, transportation, leak testing, cleaning, rinsing, inspection or testing for cleanliness, high-level disinfection & sterilization and monitoring of the process, rinsing, drying, alcohol flush, & storage

Best practices in Precleaning

• Prevents buildup of bioburden, development of biofilms, drying of patient secretions
• Occurs at point of use immediately after the procedure
• Don fresh PPE
• Prepare a cleaning solution (or water if validated) according to the solution manufacturer’s written IFU.
• Wipe insertion tube with a low or non-linting cloth/sponge soaked in the freshly prepared cleaning solution.
  o Note: cloth/sponge is single-use only

  Remember to follow the IFU for the endoscope and detergent!

Best practices in precleaning

• Ensure that controls are in the free/unlocked position.
• Suction solution through the suction channel as per manufacturer’s written IFU.
• Flush the air/water channels with solution using the cleaning adapter per manufacturer’s IFU.
• Flush all other channels (e.g., auxiliary water or elevator channels) with solution, if present.
• Suction the solution through the endoscope until clear.
• Detach the endoscope from the light source and suction pump.
• If applicable, attach the fluid-resistant cap.
• Visually inspect the endoscope for damage.
Contaminated Transport

- From procedure room to reprocessing area
- Closed, labeled transport containers
- Place a single endoscope in a container by naturally coiling it in large loops.
- Separate endoscopy accessories.
- Governed by OSHA regulation!
  - Leak proof sides and bottom
  - Puncture resistant
  - Labelled appropriately as biohazard

Best practices for Leak Testing

- Occurs in processing area prior to immersion in cleaning solution.
- Serves to detect damage that would allow for fluid-invasion
- Wear PPE
- Ensure fluid-resistant cap is on prior to submersion
- Use a basin of water or surface large enough to ensure that the endoscope is not coiled too tightly to mask holes.
- Allow for sufficient time to observe the endoscope for leaks, manipulate knobs and buttons

Best practices for Leak Testing

- Outlines 4 general methods for performing leak test:
  - Manual (dry) leak testing
  - Mechanical (wet) leak testing
  - Mechanical (dry) leak testing
  - Mechanical AER leak testing
- Refer to manufacturer’s IFU for detailed steps
- For failures, refer to manufacturer’s IFU for modified processing steps being sure to maintain positive pressure throughout
Best practices for manual cleaning

• Soil remaining on the endoscope may interfere with the ability of the disinfection or sterilization process to effectively kill or inactivate microorganisms
• If process is not initiated immediately, follow written IFU for delayed reprocessing from manufacturer
• General process is outlined including
  o Don fresh PPE, use fresh detergent solution, monitor the temperature of the cleaning solution

Best practices for manual cleaning

• Cleaning steps:
  o Clean with a single-use lint-free cloth/sponge
  o Submerge scope to prevent splashing contaminated fluids
  o Use a cleaning brush with specifications per manufacturer’s IFU
  o Brush all channels, cylinders, openings and forceps elevators per IFU
  o Suction

Best practices for manual cleaning

• Cleaning steps (continued):
  o Use recommended cleaning adapters
  o Flush all channels, rinse all channels, air purge all channels
  o Repeat until there is no visible debris
  o Soak, scrub, brush & rinse all reusable/removable parts
  o Automated flushing pumps may be used during manual cleaning
Rinsing after cleaning

- Thoroughly rinse with copious volumes of potable water
  - AAMI TR34
- Follow IFU of endoscope & cleaning solution to determine the amount of water needed for rinsing, psi/pressure, and number of rinses
- Use recommended cleaning adapters
- Rinse all external and internal surfaces
- Perform an air purge of all channels
- Dry exterior with a lint-free cloth/sponge
- Keep detachable valves together with the same endoscope as a unique set

Automated flushing systems

- If a flushing pump is used, follow manufacturer’s written IFU
- Ensure compatibility of endoscope with model of flushing system
- Use fresh solution with each endoscope
- Clean and disinfect tubing and equipment according to manufacturer’s IFU
- Perform any other QA testing as recommended (e.g. daily volume verification)

Best Practices for Endoscope Inspection and Cleaning Verification

- Inspection of endoscopes should include:
  - Both a visual inspection, enhanced inspection
  - Cleaning verification processes
- Cleaning verification is performed following cleaning to verify the effectiveness of a cleaning process PRIOR TO DISINFECTION
- Use of methods to detect organic residue should be considered
Verifying Clean through Inspection

- Use lighted magnification and inspect throughout process
- Consider inspection with borescope
  - ST91 and AORN recommendations
- SGNA – Treat as a “Time out”
- Methods to measure organic & other residues found on scopes
  - Protein
  - Hemoglobin
  - Carbohydrates
  - ATP

SGNA – Visual inspection

- Endoscopes and reusable accessories should be visually inspected during all stages of handling, including before, during, and after use, as well as after cleaning and before HLD.
- Damaged endoscopes and accessories should be removed from use for repair or disposal, as this may affect their function and interfere with adequate reprocessing (Peterson et al., 2011; FDA, 2009).

SGNA – Endoscope Inspection

- Recommended to make sure endoscope is visibly clean.
- Treat as a safety stop or “time out” to ensure endoscope is visually clean before proceeding to the next step of HLD.
- Visually inspect for conditions that could affect the disinfection process (e.g., cracks, corrosion, discoloration, retained debris).
- Use magnification and adequate lighting to help assist in visual inspection.
- Repeat manual cleaning step(s) if not clean.
SGNA “Visibly Clean”

- Minimum standard for cleaning assessment of scopes.
- May involve use of a magnifying glass to inspect for gross soil.
- Visual inspection alone is insufficient to determine cleaning adequacy in narrow and internal channels of a scope and cannot detect microorganisms or bioburden (Alfa, 2014).
- Rapid cleaning verification tests are available. These monitors can provide documentation on cleaning efficacy but do not reflect microbial activity.
- Real-time testing of endoscope should be done immediately after manual cleaning so that any improperly cleaned devices are re-cleaned prior to HLD.
- Facilities should consider the use of monitors to verify ongoing cleaning adequacy.

Optical & Enhanced Inspection

AOE Recommendations:

- Visually inspect with lighted magnification for cleanliness, integrity, and function before use, during the procedure, after the procedure, after cleaning, and before disinfection or sterilization.
- Inspection helps to identify residual organic material and defective items and remove from service soiled/defective items that might put patients at risk for infection or injury.
- An endoscope that appears clean may harbor debris that cannot be seen without magnification. Lighted magnification may increase the ability to identify residual soil or damage.
- Internal channels of endoscopes may be inspected using a borescope. Borescopes penetrate the lumen and allow for improved visual inspection.

APIC Duodenoscope Inspection


“Because duodenoscopes are more complex than other endoscope instruments, it requires meticulous attention to detail and step-by-step precision to render them safe for re-use.

After observing the cleaning and disinfecting processes and asking questions so that each step of the process is understood, the IP or HE may visit the department regularly to observe scope cleaning practices and reinforce the importance of the work being done.

The IP or HE will evaluate human factors, including ensuring that the cleaning area is set up with a bright light and magnification so all sections of the scope being cleaned can be well visualized.”
Cleaning verification recommendations

- Current recommendations support testing of the manual cleaning process at pre-established regular intervals:
  - AAMI ST91: Regular intervals, i.e., weekly or preferably daily
  - AORN: Regular intervals such as with each reprocessing cycle or daily
  - SGNA: Confirm the adequacy of manual cleaning by using a rapid cleaning monitor. If the tool results are positive, this allows for the re-cleaning of the endoscope prior to disinfection. Frequency determined by facility.

Manual Cleaning Verification Monitors

- Combination test strips
- ATP Systems
- Channel Sample
- Flush methods
- Swab methods
- Carbohydrate, protein & hemoglobin
- Protein swabs
- Hemoglobin swabs
- Detects ATP Flush and swab methods
- Many systems available

Best practices for High-Level Disinfection

- Standard of care for reprocessing semi-critical instruments
  - Those devices which contact mucous membranes
  - Sterilization preferred or HLD with an FDA-cleared HLD prior to next use
- HLD defined as a germicide that inactivates all microbial pathogens, except large numbers of bacteria endospores when use in accordance with labeling
- HLD can be performed manually or with an automated endoscope reprocessor (AER)
High-level Disinfection

- Fully saturate an HLD
- All channels with HLD
- Disc in two and at temperature specified by HLD manufacturer
- After wash, purge, drainage of HLD
- Remove if manufacturer's instructions and air purge
- Follow air with 70% isopropyl alcohol reader

Best practices for High-Level Disinfection

- Reusable HLDs must be monitored to ensure that it is above the Minimum recommended concentration (MRC)
  - Test prior to each use per IFU
  - Solution is used repeatedly until it fails test strip or meets its maximum use life, whichever comes first
  - Do not “top off” HLD unless instructed by HLD manufacturer
    - Can not be used to extend the use life of HLD

Best practices for High-Level Disinfection

- Single-use HLD’s:
  - Used with specific AER’s
  - Can be concentrated or ready to use
    - Examples concentrated OPA and peracetic acid
  - MRC is tested through either test strip of chemical monitoring by the AER
- HLD’s need to contact ALL surfaces
  - Internal channels and external surfaces
  - Complete immersion
  - Monitor exposure times precisely
  - Remove air bubbles from surfaces of endoscope
Remember to Rinse!

- Rinsing is often overlooked and underestimated
  - Removal of chemicals and residual soil such as protein (e.g., enzymes used during cleaning)
  - Devices should not present a toxic risk to patients
  - Water quality/purity can impact this
  - Number of rinses and rinsing method using fresh water with each rinse

Use of Automated Endoscope Reprocessors (AER)

- Machines designed to clean and/or disinfect endoscope and components using an LCS/HLD solution
- Use of AER’s may be more efficient and leads to less user exposure and helps to ensure repeatable results
- Section has detail on types of AER available and features of their cycles
- If AER cycle is interrupted, it should be repeated

What About Automated Cleaning in an AER?

- Some have FDA cleared cleaning claims.
- SGNA Redundant process:
  - “Manual cleaning and brushing are still necessary when a washer-disinfector is used in order to assure the overall efficacy of HLD. The redundancy achieved by adding an automated washing step following manual cleaning can undoubtedly provide an extra level of safety. Users are cautioned about dispensing with manual cleaning endoscope reprocessing and brushing steps before the capabilities of the new machines are confirmed in independent studies and in clinical practice.”
  - Manual cleaning and thorough brushing of channels are required even when AER manufacturers claim that manual cleaning is unnecessary (FDA, 2009).
Drying and Alcohol Flush

- Drying is achieved by flowing air through the endoscope channels.
- Facilitate drying with alcohol flush (70-80% ethyl or isopropyl alcohol).
- Follow with instrument quality forced air to ensure residual alcohol is removed.
- Refer to endoscope IFU for psi recommendations.
- Dry all removable parts (valves) and do not reattach.
- Keep valves with the endoscope to ensure traceability.

Drying Best Practices

- Moisture remaining on the surface or in the endoscope lumens may dilute the high-level disinfectant or interfere with the sterilization process, potentially reducing its effectiveness.
- Instrument quality compressed air:
  - Latest research shows it takes 10 minutes of drying.
  - AORN: Drying cabinets are preferred. Use less HEPA filtered cabinets.
- Exterior surfaces should be dried with a soft, lint-free cloth & channels purged with instrument air.
- Instrument air: A medical gas that falls under the general requirements for medical gases as defined by the NFPA 99: Health Care Facilities Code. It is not respired, is compliant with the ANSI/ISA S-7.0.01: Quality Standard for Instrument Air, and is filtered to 0.01 micron, free of liquids and hydrocarbon vapors, and dry to a dew point of -40° F (-40° C).

Proper Storage of Reprocessed Endoscopes

- Endoscope should be hung vertically with the distal tip hanging freely in a well-ventilated, clean area following endoscope manufacturer’s IFU for storage.
- Angulation locks in the free position.
- Sufficient space between endoscopes.
- All removable parts should be detached, but kept together with the endoscope.
  - (small bag or similar device)
- Not touching?
- AORN: Wear clean gloves when handling processed scopes and when transporting them to and from the storage cabinet.
- SGNA: An endoscope that is not dry must be reprocessed before use.
Current recommendations for length of storage “hang time”

- **AAMI ST91**: Due to lack of consensus it is recommended to perform a risk assessment to establish maximum length of storage.
- **AORN**: Perform a risk assessment with a multidisciplinary team to establish a policy for maximum storage time that processed flexible endoscopes are considered safe to use without reprocessing.
- **SGNA**: 7 days based on a systematic review, if scopes are effectively reprocessed and stored in a way that keeps them completely dry and free from environmental and human contamination.

Best practices for Sterilization

- Sterilization processes for flexible and semi-rigid scopes is discussed in detail
- Recommended for devices entering sterile body cavities
- Section outlines special considerations for terminal sterilization with primary source of info being endoscope’s IFU
- More modalities compatible with surgical flexible endoscopes
- Sterilization is dependent on adequate cleaning, rinsing and device preparation

Quality Systems for IP

- “Healthcare facilities should have a reliable, high-quality system for endoscope reprocessing which minimizes infection risks. To achieve this goal, all reprocessing programs must have an infrastructure that supports training and competencies, quality measurement, and management.”

Labelling for identification

- AORN: Scopes should be clearly identified with a distinct visual cue as processed and ready for use.
- ST91: Develop protocols to ensure that users can readily identify an endoscope that has been processed and is ready for patient use.
- SGNA: Have a system in place to identify scopes that are clean and ready to use.

Product Recalls

- ST91: Written policies should be in place for a recall event (HLDS or sterilization failure)
  - Policies developed in cooperation with infection prevention and risk management
  - Establishing recall procedures helps to ensure patient safety, compliance with user facility reporting requirements to the FDA & allows for adequate follow-up actions
- SGNA: Health care facilities must have policies and procedures detailing the response to any suspected or identified breaches in reprocessing. The procedure should indicate how the potentially affected patients should be identified, notified, and followed.

Audit Recommendations

- CDC: Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices:  
  http://emergency.cdc.gov/han/han00382.asp
- Healthcare facilities should regularly audit adherence to all steps in reprocessing procedures.
  - Performing prompt precleaning after use
  - Using disinfectants in accordance with manufacturers’ IFUs (e.g., dilution, contact time, storage, shelf-life)
  - Monitoring sterilizer performance (e.g., use of CIs and BIs, read-outs of sterilizer cycle parameters, appropriate record keeping)
  - Monitoring AER performance (e.g., print out of flow rate, time, and temperature, use of chemical indicators for monitoring high-level disinfectant concentration)
- SGNA: Audits should monitor all reprocessing steps and provide feedback to personnel regarding their adherence to cleaning and disinfection procedures.
Microbial Surveillance

- Options include:
  - Traditional culturing
  - Gram negative test kits
- Not ATP or cleaning verification tests
- AAMI: No recommendation is made in the current version because of the timing of release.
  - Studies have identified the nature of microbial contamination likely to be found in improperly reprocessed endoscopes and have demonstrated the value of surveillance testing.
- AORN: Base decision on a risk assessment.
- SGNA: Surveillance cultures can be used as a method for assessing reprocessing quality and aid in identifying particular endoscope defects that hamper effective reprocessing.

Guidance on culturing

- CDC Interim Guidance on culturing duodenoscopes updated 4/3/15
  - Sites to be cultured?
    - Instrument channel (suction/biopsy channel)
    - Distal end (elevator mechanism, elevator recess)
    - Elevator channel (on older, unsealed)
    - Frequency: Every 30 days or 60 cycles
- Mail back service for endoscope samples are now available


Monitoring for Gram-negative organisms in reprocessed scopes

- Enzymes specific to Gram-negative bacteria hydrolyze the substrate in the reagent vial
  - This generates fluorescence, which is read by the fluorometer, which then gives a reading.
- ST91: Types of verification testing may include enzyme based tests
  - Such as the gram negative test kit
Simethicone usage

- Recent research: Ofstead and associates, 2016
  - Demonstrates that simethicone residue remains inside gastrointestinal endoscopes despite reprocessing.

- News articles:
  - Fuji and Pentax state not to use
  - ASGE: Findings from Ofstead are preliminary, clinical significance is unclear. ASGE does not have any evidence to make recommendations to change current clinical practice.

We can do better than this

References

- And as noted on slides...
Summary

• With heightened public concern and documented cases of improper reprocessing endoscopes, it is imperative that we must reduce the risk of exposure to improperly reprocessed medical devices.
• This is a shared responsibility among the healthcare facilities responsible for cleaning, disinfecting or sterilizing the devices.
• ST91 is the national standards in endoscope reprocessing and highlights best practices and quality control measures for each step along the way. Available at www.aami.org
• SGNA guidelines available at www.sgna.org
• AORN guidelines available for purchase at www.aorn.org