Objectsives

- Discuss additional steps to build quality into endoscope reprocessing such as proper labelling, transportation, & AER monitoring.
- Outline methods to perform cleaning verification of flexible endoscopes.
- Discuss methods for performing surveillance testing of flexible endoscopes after reprocessing.

Importance of Cleaning

- The removal of all soil and organic material. Cleaning must precede disinfection or sterilization.
- Residual organic soil refers to substances such as blood, carbohydrates, or proteins that are left on the scope after manual cleaning (Alfa, 2013).
- Soil that remains on the endoscope may interfere with the ability of the disinfection or sterilization process to effectively kill or inactivate microorganisms and may allow for biofilm development.

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
Manual Cleaning

- Composition of soil found on endoscopes includes proteins, fats, carbohydrates, and the various chemical salts that exist in blood and other body fluids.
- Manual cleaning of endoscopes is necessary prior to automated/manual high-level disinfection or sterilization. This is the most important step in removing the microbial burden from an endoscope.
- Retained debris contributes to biofilm development (Fang et al., 2010) and interferes with the HLD capability to effectively kill and/or inactivate microorganisms (Roberts, 2013).
- Manual cleaning and thorough brushing of channels are required even when AER manufacturers claim that manual cleaning is unnecessary (FDA, 2009).

SGNA – Visual inspection

- Minimum standard of care for endoscopes
- Inspect throughout reprocessing procedures
- Remove damaged endoscopes from use
- Incorporate use of cleaning verification tests to provide documentation and real-time feedback on the adequacy of reprocessing.
- Perform after manual cleaning prior to HLD
- Reclean if positive
- Facilities should consider the use of monitors to verify ongoing cleaning adequacy.

SGNA – Endoscope Inspection

**VISUAL INSPECTION**

- Visual inspection is recommended to make sure the endoscope is visibly clean.
- *Treat as a safety stop or “time out” to ensure the 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.

ST91 Visual inspection

- **AAMI ST91**: Visual inspections and testing of the equipment
  - Inspecting organic residues
  - Testing for any cracks in the devices
  - Checking integrity of fiber optic bundles
- Use lighted magnification and inspect throughout process
- Consider inspection with borescope
  - ST91 and AORN recommendations
AORN Scope Inspection

- 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.”

Endoscope Visualization

- AAMI
  - ST79
  - ST91
- AORN
- SGNA
- Others
- All support the practice of using some type of visual inspection to the unaided eye

Support for using enhanced visual inspection – Poster at AORN

http://www.ofsteadinsights.com/?p=2303
Examples of Debris and Damage Found in Endoscopes.

ST91 Cleaning Verification

- Residual organic soil and microbial contamination may be present on an accessible surface even though the device looks clean.
- The use of methods that are able to quantitatively or chemically detect organic residues that are not detectable using visual inspection should be considered and included in facility policies and procedures on device cleaning.
- What to measure, organic or indirect markers?
  - Protein, Carbohydrate, Hemoglobin, ATP

Frequency of Cleaning Verification

- 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

- Flush and swab methods
- Combination test strips
- Swab methods
- ATP Systems
- Detects ATP
  - Flush and swab methods
  - Many systems available

Carbohydrate, protein & hemoglobin
What about monitoring AERs

ST91 Testing cleaning efficacy

- QA Program should include ways to verify that the cleaning equipment used for processing of medical devices is working.
- Testing the equipment upon installation, during routine use (daily) and on all cycles used, after repairs, and when changing to a new type of cleaning solution allows the user to verify its continued effectiveness.
- The frequency of testing the efficacy of the manual cleaning step should occur on a regular basis, weekly or preferably daily.

AORN – monitoring AERs

- Mechanical processors should be tested for performance on installation; at regular, established intervals (eg, daily, weekly); after major repairs; and after changes in programmed parameters (eg, temperature, cycle time).
- Testing the function of mechanical processors confirms the equipment is operating correctly. Effective processing is dependent on correctly functioning equipment.
- Preventive maintenance should be performed by qualified individuals.

Options for Monitoring AER cleaning

- ST91 and AORN: Any mechanical cleaning process should be monitored: weekly, preferably daily
- Review recommendations from AER and endoscope manufacturer’s
- Some AER’s have automated monitoring
- Some have visual verification steps
- Others have nothing

Surveillance Options for Reprocessed Endoscopes
Microbial Surveillance

- Options include:
  - Traditional culturing
  - Gram negative test kits
- 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
- Not ATP or cleaning verification tests

CDC Culture Method

- Baseline levels of bacteria:
  - Fewer than 10 CFU of low concern microbes does not require intervention
  - 1 CFU or greater of high concern (pathogenic) bacteria warrants further remedial actions
  - Frequency: Every 30 days or 60 cycles
- Not all hospital labs can do this type of testing
- Mail back service for endoscope samples are now available

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

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
Quality Infection Prevention Measures for your Facility

Implementation of quality practices to reduce infection risks

Drying

- 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
    - If not, then HEPA filtered cabinets
- Instrument air: A medical gas that falls under the general requirements for medical gases as defined by the NFPA 99: Health Care Facilities Code, 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).

Drying and Alcohol Flush

- Drying is achieve 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

Is this Bone dry?
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
  o (small bag or similar device)
- Wear clean gloves

SGNA Storage

- Store in an area that is clean, well-ventilated and dust-free in order to keep the endoscopes dry and free of microbial contamination.
- An endoscope that is not dry must be reprocessed before use.
- Endoscopes should also hang freely so that they are not damaged by physical impact.
- Endoscopes should be stored in accordance with the endoscope and storage cabinet manufacturers’ IFU.
- Use storage cabinet, hang vertically when using a normal storage cabinet.
- Store valves together with the scope

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 multi-disciplinary 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.

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.
Simethicone usage

- Recent research:
  - Ofstead and associates. 2016 AJIC.
    - Demonstrates that simethicone residue remains inside gastrointestinal endoscopes despite reprocessing.
  - Ofstead and associates. 2017 AJIC.
    - Again, showed fluid in scopes.
  - 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.
  - SGNA Q&A:
    - Can simethicone be used in irrigation bottles? Follow endoscope manufacturer's instructions for use

- Represents an off-label use of the simethicone drops.

Patient Recalls or Notifications

- Written policies should be in place for a recall event (HLD 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: Audits should be conducted in all areas of the facility where reprocessing occurs.
  - Healthcare facilities should provide feedback from audits to personnel regarding their adherence to cleaning, disinfection, and sterilization procedures.
  - http://emergency.cdc.gov/han/han00382.asp
- SGNA: Audits should monitor all reprocessing steps and provide feedback to personnel regarding their adherence to cleaning and disinfection procedures

Available Audit Tools

CMS.gov encourages HOPD and ASC to use worksheet as part of self assessment tools to help promote quality and patient safety.

http://emergency.cdc.gov/han/han00382.asp

Accessed 1/21/2017
Quality Systems for IP

- Conduct a comprehensive gap analysis or risk assessment and report back to your facility.
- Your Infection Prevention Champion will partner with the nurse manager and appropriate infection prevention stakeholders to evaluate current practices and areas for improvement, guided with ST91, SGNA resources along the way.
- For facilities with limited personnel where formation of a multidisciplinary team is not possible, consider seeking external expertise to obtain multidisciplinary input.
  - HICPAC, 2016.
    - https://www.cdc.gov/hicpac/pubs/flexible-endoscope-reprocessing.html#a3

Next Steps – A Call to Action!

- Agree on guideline to follow
- Gather all IFUs
- Supplement with interim FDA guidance for reprocessing side-viewing duodenoscopes.
- Have the latest version of guidelines available.
- Perform a gap analysis to figure out what steps you are missing and what quality parameters you can add in.
- Create an action plan to fill in the gaps
  - Hold people accountable
  - Audit and provide feedback

References

- And as noted on slides...

Summary

- With heightened public concern and documented cases of improper reprocessing endoscopes, it is imperative that we must reducing 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.
- Build quality in up front to prevent issues in the future!
  - ST90 coming soon... Quality systems for reprocessing
We can do better than this

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