Endoscope Reprocessing:

Facing the new challenges

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Disclosures:

Director of Infection Prevention & Endoscopy

Excellentia Advisory Group

EXCELLENTIA

Endoscope Reprocessing: Facing the new challenges

Objectives:

The learner will be able to:

- List the steps in endoscope reprocessing
- Identify resources for guidance on endoscope reprocessing

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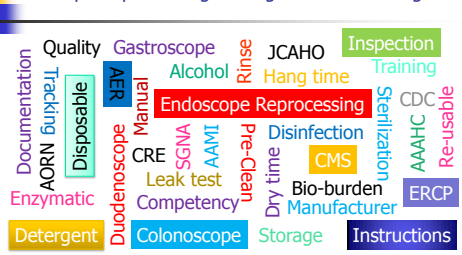

ANSI/AAMI ST91:2015

AORN Association of periOperative Registered Nurses

SGNA Society of Gastroenterology Nurses and Associates, Inc.

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INQUIRING MINDS:

Which guidelines does your facility follow?

A) AAMI
B) AORN
C) SGNA
D) Do not know

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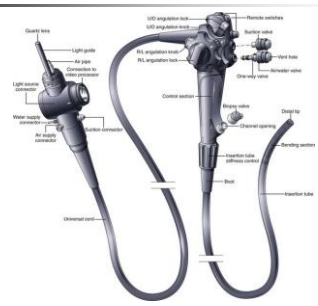

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Personnel factors that influence the quality of reprocessing include:

- Lack of knowledge or unfamiliarity with scope channels, accessories, and specific steps
- Inadequate number of staff to support volume, workflow, and throughput;
- Frequent disruptions or interruptions during reprocessing
- Inadequate training;
- Limited accountability;
- Time pressures/ demands for rapid endoscope turn-around.

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Reprocessing personnel should accomplish the following:

- Understand rationale/ importance of reprocessing
- Able to read, understand, and implement the manufacturer's instructions on proper cleaning and HLD of endoscopes and accessories
- Demonstrate competency for all steps of endoscope reprocessing, including proper use of AER systems and other equipment at least annually
- Undergo more frequent validation of competency for specialty endoscopes that are used infrequently;
- Complete reprocessing training with documented competency for new models of endoscopes, accessories, valves, and AER's as soon as they are introduced

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Reprocessing personnel should accomplish the following:

- Complete all reprocessing meticulously and efficiently, maintaining strict adherence to reprocessing steps
- Immediately report any breaches in reprocessing according to facility policies and protocols.
- Understand the safety hazards of endoscope reprocessing and take appropriate action to protect oneself and others.

NOTE: Temporary personnel should ***not*** be allowed to clean or disinfect instruments in either a manual or AER until competency has been established

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INQUIRING MINDS:

How many have a certified endoscope reprocessing tech?

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Management

Contribute to effectiveness and safety of reprocessing.

Responsibilities include:

- Allow adequate time for reprocessing
- Ensure adequate staff to support meticulous & timely reprocessing;
- Have facility protocols to readily identify endoscopes that have been properly reprocessed and are ready for use

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- Reprocessing protocol reviewed/ updated per policy;
- Consult with individuals responsible for IP&C when considering modifications protocol and when purchasing new equipment
- Conduct annual review of policies/ competencies to ensure compliance with current standards/ manufacturers' IFU's
- Maintain documentation of reprocessing activities (e.g. AER maintenance records; test results verifying HLD concentration, reuse life)
  - Essential for recognizing reprocessing error, identifying all scopes affected by error, naming individual patients who could be at risk

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- Following manufacturers' IFU's for maintenance/ repair of endoscopes and equipment used for reprocessing
- Ensure all staff involved in reprocessing are identified, well trained, and demonstrate initial & continued competency.
- Ensure decisions made consider the number and category of personnel that will be responsible for reprocessing;
- Have P&P detailing the facility's response to a reprocessing error
- Observe staff for adherence to P&P, possibly using an environmental tour checklist for endoscope reprocessing areas

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Reprocessing features that impede effectiveness

- Numerous steps that must be followed meticulously;
- Steps prone to human error (e.g., pre-clearing, manual cleaning)
- Lag time/ delay in reprocessing;
- Inadequate enzymatic concentration, temperature, or time;
- Inappropriate use of HLD (e.g. wrong concentration/ temperature, expired reuse life, inadequate exposure time)
- Inadequate concentration due to scope not dried adequately/ excess water diluted HLD;
- Inadequate cleaning prior to HLD;
- Inadequate drying before storage
- Lack of quality control measures to detect problems/ lapses in reprocessing.

Quality Control Measures

- Documentation
- Audits re: reprocessing activities
- Equipment performance/ maintenance
- HLD testing
- Manual cleaning validation documentation

Poll Question

INQUIRING MINDS:

Are you aware that the updated SGNA reprocessing standard includes a "safety stop"?

- Yes
- No

SGNA Endoscope Reprocessing Steps

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

AAMI ST91

- A) Pre-clearing at point of use;
- B) Transporting;
- C) Leak testing;
- D) Cleaning;
- E) Rinsing;
- F) Inspecting or testing for cleanliness;
- G) Disinfection/High-level disinfection and monitoring of the process;
- H) Rinsing;
- I) Drying and alcohol flush;
- J) Storage

Endoscope Reprocessing: Facing the new challenges

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Pre-cleaning at point of use

To prevent buildup of bio-burden, development of bio-films, and drying of secretions

- Removes organic material (e.g., blood, body fluids, body soil)
- Decreases the bio-burden before bio-burden has an opportunity to dry and before complete decontamination
- At point of use; immediately after removal of the insertion tube from the patient and prior to disconnecting the endoscope from the power source.

Pre-cleaning at point of use

- Gather PPE
- Gather supplies:
  - ? enzymatic detergent vs. water
  - Lint free cloth
  - Adapters
  - Protective cap
  - Transport container

Leak Test

Detects damage to the interior or exterior of the endoscope

- Before immersion in solutions
  - Minimize damage to parts not designed for fluid exposure.
- Dry
- Wet
- AER

Leak Test

- Remove valves; discard disposables
- Pressurize before immersing in water
  - No detergent
  - Manipulate knobs to flex tip in all directions
  - Observe for bubbles
- Remove from water before depressurizing

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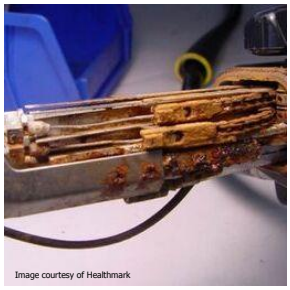

Image courtesy of Healthmark

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Manual cleaning

This is the most important step in removing the microbial burden from an endoscope

- Assemble supplies
- Mix fresh enzymatic detergent
- Wipe exterior of endoscope
- Brush all channels: air, water, suction
- Purge enzymatic, rinse with fresh water, purge with air

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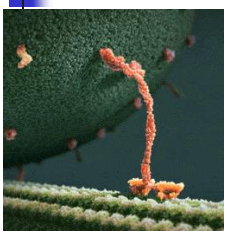

Just a few microorganisms can multiply to over a million colony-forming units in a few hours

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VISUAL INSPECTION

- Verify the endoscope is visibly clean
- Not a guarantee decontamination is complete, but considered a safety stop or "time out" to ensure the endoscope is visually clean before proceeding to the next step of HLD.
  - 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 (AAMI, 2015).
  - Repeat manual cleaning step(s) if not clean.

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Impossible to visualize internal channels

Literature suggests:

- Confirm the adequacy of manual cleaning, a rapid cleaning monitor (or rapid audit tool) for residual organic soil can be used prior to high-level disinfection (Visrodia et al., 2014).
- If the tool results are positive, this allows for the re-cleaning of the endoscope prior to disinfection.
- The frequency of the testing should be determined by the individual institutions (Alfa et al., 2013, 2014; AAMI, 2015; ASGE, 2014).

Spaulding Classification System

Device Classification	Examples	Spaulding process classification	EPA product classification
Critical (Enters sterile tissue or vascular system)	Implants, scalpels, needles, other surg. Instruments	Sterilization: sporicidal chemical; prolonged contact	Sterilant/ disinfectant
Semi critical (Touches mucous membranes)	Flexible endoscopes, laryngoscopes, ET tubes, vaginal specula	High Level Disinfection: sporicidal chemical; short contact	Sterilant/ disinfectant
Non critical (touches intact skin)	Stethoscopes, tabletops, blood pressure cuffs	Low level disinfection	EPA reg. hospital disinfectant

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High Level Disinfection (HLD)

- Destroys all viable microorganisms, but not necessarily all bacterial spores
- The effectiveness depends on:
  - Effective pre-cleaning, manual cleaning, and rinsing to decrease the organic load and microbial content
  - Drying after rinsing to avoid diluting the HLD; and
  - Proper preparation and use (in accordance with the manufacturer's directions).

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- Most HLD/sterilants are reused
- Must be tested to assure remain above minimum effective concentration (MEC)
- Test HLD before each load/use

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- Never use beyond the date specified on activation
- Change when the solution fails to meet MEC or exceeds the HLD manufacturer's recommended reuse life, whichever comes first
- Use a product-specific test strip
- Establish program for monitoring occupational exposure to regulated chemicals (e.g., formaldehyde, EtO), which adheres to state and federal regulations

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MANUAL HIGH LEVEL DISINFECTION

- Purge with air and externally dried prior to immersion to minimize diluting the HLD.
- Completely immerse
  - Basin: accommodate endoscope without undue coiling (AAMI, 2015); tight-fitting lid to contain the chemical vapors (AAMI, 2010; Peterson et al., 2011).
  - Flush disinfectant thru all channels until seen exiting. no air pockets remain

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Note:

1) Complete microbial destruction cannot occur unless all surfaces are in complete contact with the chemical
2) Since internal contact cannot be visually confirmed because of scope design, purging until a steady flow of solution observed is necessary

- Soak in the HLD/sterilant for the time/temperature required to achieve HLD. Use a timer to verify soaking time.
- Do not exceed the manufacturer's recommended time for soaking (e.g. leaving a scope to soak overnight).
- Purge completely with air before removing from the HLD/sterilant. Purging channels preserves concentration & volume of chemical, and prevents exposure from dripping and spilling.

RINSE AFTER HIGH LEVEL DISINFECTION

- Thoroughly rinse all surfaces and removable parts, and flush all channels and its removable parts with clean water according to disinfectant and endoscope manufacturer's recommendations.

Note:

- Rinsing prevents exposure/ potential injury of skin/mucous membranes from chemical residue.
- Fresh, clean water used for each rinse

Automated Endoscope reprocessor (AER):

- Manual cleaning of the endoscope must occur
- Verify AER has been validated to reprocess specific endoscope/ accessories
- Prepare AER according to the manufacturer's guidelines.
- Place the endoscope in AER, attach all channel adapters according to the manufacturer's IFU.
  - The elevator channel of a duodenoscope has a very small lumen.
  - most AER cannot generate pressure required to force fluid through the lumen, a 2 ml-5 ml syringe must be used to manually reprocess (all steps) the elevator channel unless the AER is validated to perfuse this channel.

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- Check endoscope manufacturer for model specific information such as the elevator position on duodenoscopes during HLD.
- Place valves and removable parts into the soaking basin of AER.
  - Unless AER has a dedicated space for accessories, reprocess these items separately.
- Check chemical MEC

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NOTE:

If cycles/phases are interrupted, HLD cannot be ensured and the full cycle must be repeated.

- If final alcohol rinse cycle is not included in the AER cycle, should be done manually, followed by purging all channels with air until dry
- The duodenoscope elevator and elevator channel must be manually flushed/ dried per the manufacturer's instructions.
- Do not allow the endoscope that has completed reprocessing to sit in the AER for long periods (such as overnight).

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DRYING

- Drying is a critical element in reprocessing.
- Moisture allows microorganisms to survive and multiply;
  - All channels/ surface must be thoroughly dried before storage.
  - Outbreaks of *Pseudomonas aeruginosa, Acinetobacter spp.*, carbapenemase producing *K pneumoniae* have been traced to inadequately dried equipment
  - A few microorganisms may survive HLD.
    - Multiply to over a million colony-forming units in just a few hours if any moisture remains in the endoscope channels or on its surface
- Moisture promotes biofilm development

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- Alcohol will displace water and evaporates more easily than water.
- Alcohol mixes with remaining water and encourages evaporation of the residual water as air flows through the channel.
- Store the alcohol in a closed container between uses.
- Alcohol evaporates rapidly when exposed to air, and the remaining solution may be too diluted to effectively promote drying of endoscope channels.

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- Flush with 70% to 90% isopropyl alcohol until seen exiting opposite end
- Dry/ purge with pressurized, filtered, air
  - Avoid excessively high air pressure. Can damage internal channels
- Remove channel adapters
- Dry scope exterior
- Rinse/ dry removable parts. Do not re-attach

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STORAGE

Two types of storage cabinets exist:

- Conventional cabinets
- Drying cabinets.
  - Drying cabinets are designed to control air quality, humidity, and access
  - Bacteria-free air under pressure to keep surfaces dry.
    - (HEPA) filters provide microbial-free air that is blown through the endoscope channels to ensure remain dry.

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Storage

Key considerations

- Area clean, well-ventilated/ dust-free to keep endoscopes dry/free of microbial contamination.
  - An endoscope that is not dry must be reprocessed before use.
- Use cabinets that can be disinfected.
- hang endoscopes in a vertical position (with caps, valves, and detachable components removed) to prevent moisture accumulation/microbial growth.
- Make sure hang freely so not damaged by contact

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Storage

- Drying cabinets
  - Follow the cabinet manufacturer's instructions.
  - Drying does not rely on gravity, can be stored horizontally or vertically depending on the design of the cabinet.
- Reusable buttons/ valves reprocessed and stored together with the endoscope as a unique set for tracking purposes
- 7-day storage interval for reprocessed endoscopes-but only if they were reprocessed and stored according to professional guidelines and manufacturer instructions.

References:

- Mitigating the Risk of Cross-Contamination from Valves and Accessories Used for Irrigation through Flexible Gastrointestinal Endoscopes; FDA draft guidance, http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM430550.pdf, accessed 1/18/2016
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Questions

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