Decreasing Human Error in Endoscope and Medical Device Reprocessing: It’s All About Validation, Competency and Process

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Successful completion: Participants must complete the entire program and submit required documentation.

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Objectives

Discuss most frequently identified human errors at each critical touch point in endoscope and medical device reprocessing

Explain methods for determining and developing measurement criteria for competency and validation of work processes in flexible endoscope and medical device reprocessing

Describe the validation process for medical devices
Guidelines
In the U.S., instrument reprocessing best practices are detailed in AAMI Standards, AORN Guidelines for Perioperative Practice, along with other documents, such as SGNA which focuses on flexible endoscopes.
BEST PRACTICES  Why are they so important?

Best practices should be adhered to in any profession, because they reflect the values of that profession. In healthcare, adherence to sterilization best practices ensures patient safety, as one of our greatest threats is healthcare associated infections (HAIs).

In the U.S., it is estimated that 1/25 patients contact at least one HAI during their hospital stay. That’s nearly 5,000 patients/day - with over 300 deaths/day!

Source: CDC.gov
Healthcare Associated Infections

- While the delivery of non-sterile instruments certainly is not a leading cause of surgical site infections, it has been documented by the CDC and the national media, as one of the causes.
- We must do everything possible to reduce HAIs, which means compliance with best practices not some of the time, not most of the time, but all of the time!
Top 10 Health Technology Hazards by the ECRI Institute included endoscopy reprocessing for the past 7 years:¹,²

- 2010: #1: Cross-contamination of endoscopes
- 2011: #3: Cross-contamination of endoscopes
- 2012: #4: Cross-contamination from flex. 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

Estimated Hospital Financial Consequence of Incident¹,²

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<tr>
<th>Estimated Hospital Financial Consequence of Incident¹,²</th>
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<td>Total estimated cost per incident: $2M-20M</td>
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Legal Fees: $0.5-$16M

PR Damage: $1-2M

Alerts & Testing: $775/patient

Consequences of Errors

FDA and CDC acknowledge³:
“Flexible endoscopes are fundamentally difficult to clean and disinfect or sterilize”

¹: “Excellence in Scope Reprocessing” session at 2016 SGNA Conference by Laura H. Schneider, RN, CGRN, CASC of AMSURG Corporation
²: “Is That Scope Really Clean?” session at 2016 SGNA Conference by Barbara Zuccala, MSN, RN, CGRN of The Valley Hospital
³: “Preventing Cross-Contamination in Endoscope Processing: FDA Safety Communication” FDA 2009
Patient Recalls Due to Lapses in Scope Reprocessing
Collected via Media Reports, Jan 2005-2012*

- American Journal of Infection Control, #41, 2013
- Article titled “Reported gastrointestinal endoscope reprocessing lapses: The tip of the iceberg”
- Results: Lapses occurred in various types of facilities and involved errors in all major steps of reprocessing.
- Each lapse continued for several months or years
- 33,150 patients recalled; over 200 facilities involved
- Patient implications: notification, testing, microbial transmission and increased morbidity and mortality
- Conclusion stated in article:
  - “Reprocessing lapses are an ongoing and widespread problem despite the existence of guidelines.
  - Lack of publication in peer-reviewed literature contributes to the perception that lapses are rare and inconsequential.”

*Only 1 lapse found in peer-reviewed journal article
Reprocessing Error Categories

Not sterilized, HLD → Documentation/Indicator strip missing or unchanged → Knowingly used unsterile/high level disinfected endoscope
Common errors in the reprocessing of Surgical instruments

**Reprocessing area** (Prep & Pack)
- Not inspecting 100% of instruments,
- Not using inspection lamps and/or lens,
- Cleaning instruments and/or rigid containers,
- Assembling hinged instruments in the closed position,
- Using improper materials (i.e. marking pens, sterilization tape and/or wrap inside trays, sterilization tape on rigid containers, peel pouches and/or count sheets inside trays).
- Improper location of lot control labels.
Inspection guides and magnification lens should be available and used.
Rigid sterilization containers must be cleaned in the Decontamination area with detergent, per the MFR’s validated cleaning IFU.
Never place indicator tape on the inside or outside of surgical trays or rigid containers.
Common errors in the reprocessing of Surgical instruments

- Improper loading of sterilizers and/or PCD,
- Incorrect sterilization mode and/or parameters,
- Not enough dry time for type of load,
- Wet packs,
- Not allowing sterilized packs to cool to room temperature,
- Placing sterilized items to cool near AC vent.
Common errors in the reprocessing of Surgical instruments

**Storage**

- Placing sterile items in a high traffic area,
- Improper ceiling tiles and/or storage shelves,
- Dust on storage shelves,
- Stacking wrapped items on top of each other,
- Putting clean items on top of sterile items,
- Exceeding temperature and/or humidity ranges.
Dust on storage shelves
KimGuard® and One-Step® Wraps
(Directions For Use)

Caution: Do not stack trays. Stacking trays can result in damage of the wrap caused by undue pressure from the weight.

® Trademarks of Kimberly-Clark Corp.
Do not **FLASH (IUSS)** complex instruments!

Medical devices sterilized by immediate use steam sterilization (IUSS), formerly called flash sterilization, can increase the patient’s risk for acquiring a surgical site infection. As we have shown, complex instruments can take 4 to 5 hours to reprocess when following the MFR’s validated IFU.

Be sure to schedule your cases with enough time to fully comply (terminal sterilization) with reprocessing IFUs.
Tips on how to Eliminate Immediate-Use Steam Sterilization (IUSS)

- Update Policy & Procedures to reflect national standards.
- Clearly define “emergency situation” that justify IUSS.
- Educate all personnel as to risks associated with IUSS.
- Review sterilizer logs to identify what is being IUSS. Review each of these MFG’s IFUs to understand validated reprocessing steps. Use this info to justify need for terminal sterilization.
- Purchase additional instruments for back-back case schedules.
- Adjust steam sterilizers to terminal cycles with dry time.
- Hold all personnel AND loaner instrument vendors accountable to comply with Policy & Procedures.
Steps in Flexible Endoscope Reprocessing

- Precleaning
- Storage
- Leak Testing
- Manual Cleaning
- Rinsing
- Drying Alcohol Flush
- Rinsing
- Visual Inspection
- High Level Disinfection
- Drying
Endoscope Related Concerns

- Reprocessing Quality Assurance
  - Compliance to reprocessing guidelines not uniform
  - No consistency in determining if endoscope has been disinfected
  - Was the endoscope leak tested, manually cleaned and disinfected... Prove it.

- Efficiency
  - How do I make my department more efficient?
  - Pressure to increase endoscope turnaround is high
  - Efficiency leads to increased revenue opportunities

- Risk Aversion
  - HAI’s associated with contaminated endoscopes linked to breach of reprocessing steps
  - Improve and prove compliance with governing agencies requirements
Working During a Procedure

- Do not cross contaminate
- Do not reprocess in the room – only pre-cleaning
- Keep cabinet doors closed
- Personal protective equipment
  - Gown
  - Gloves
  - Face shield
  - Mask
  - Hair cover
Procedure Room Errors

- Precleaning not done
- Not wearing appropriate PPE
- Not having Manufacturer's IFUs
- Reprocessing delays and no way to document time between cleaning
- Failure to clean all channels during precleaning
- Transporting without using a closed container
- Buttons and valves not removed
- Not wiping down external surfaces between patients
- Not suctioning the appropriate amount of time
- Not following OSHA transport guideline
- Cloth or sponge reused
- Clean water or detergent not suctioned
Pre-cleaning at Bedside

- It’s just next door
- It won’t take long for them to do it
- No date or time precleaning was completed
Environmental Variables

- Type of cabinet
- Room temperature
- Humidity level
- Air exchanges
- Traffic control
- Limited access
Errors During Transport

- No biohazard label
- Not protecting the clean scope from storage to procedure room or department
Leak Testing

The AER leak tests

Speed leak testing

Speed leak testing

Most frequently skipped step*

*Ofstead, et al., 2013
Common Error Leak Testing

- Improper sequences of steps
- Leak tester unit incompatible
- Damaged water resistant cap
- Sink is too small to accommodate the endoscope size
- Incomplete immersion for the endoscope
- Using detergent solution versus water for leak testing
- Incomplete pressurization / depressurization of the scope
- Not angulating the knobs completely for assessment
- Not observing for the appropriate amount of time
- Not checking the leak tester to ensure that it is emitting air
- Knot knowing what the procedure is for reprocessing an endoscope with an identified leak
Automated Cleaning

- Make sure the AER is cleared by the FDA for scope cleaning
- Connectors have been validated for each scope
- Contact time is correct for the chemistry being used
- Temperature of the chemistry is correct
- Number of correct rinses is correct for the chemistry
- Channels requiring connections are connected
- Parameters for chemistries include detergent and the high level disinfectant used
Rinsing

- Types of water
  - Tap
  - Filtered
  - Sterile

- Filters
  - Dated changes recorded
  - Visual inspection
  - Print outs from AER

- Monitoring
  - Log – hand written
  - Computer – files
  - AER – print outs

- Temperature
Cleaning Errors

- Manual Cleaning
  - Water temperature not measured
  - Detergent concentration - ?
  - Detergent contact time - ?
  - We didn’t use that channel, we don’t need to clean it
- Scopes stacked on top of each other in decontamination
- Excessive manual pressure
- Failure to fully rinse and dry the scope before HLD
Cleaning Errors cont’d

- Not cleaned or deviation from protocol
- Reusable brushes used over and over without reprocessing
- Use of damaged or incompatible brushes
- Incomplete brushing / flushing / suctioning
- No leak test before cleaning
- Video cap not secured
Storage

- Cabinets
- Racks
- Well ventilated cabinet and room
- Vertical hanging
- Tip hanging free
- Protected access
- Stored scopes before reprocessing
Traditional Cabinets

Pass thru

hangers
Vertical Storage Cabinets
Pathogen in patient #1 enters scope via leak.

Leak harbors pathogen from disinfection.

Pathogen dislodged in subsequent procedures and moves into other patients.

Exposure or Transmission
Visualization

- Not inspecting for integrity or damage and cleanliness
- Not looking at the scope
- Not checking to make sure it works correctly
- Not using magnification X10
Automated High Level Disinfection

- Outdated chemistry – use life or shelf life
- Inaccurate number of rinses
- Chemistry temperature
- Non validated instruments
- Failure to fully immerse the scope and accessories
Human Errors in High Level Disinfection

- Inappropriate testing and documentation of MEC results
- Not drying endoscopes prior to immersion in disinfectant
- Inappropriate use of adapters as per OEM
- Incomplete immersion of all scope surfaces
- Not adhering to the recommended time of the HLD
- Inadequate traceability and documentation of scopes and accessories
- Not monitoring the temperature of the HLD
- Use of HLD after expiration date
Storage

- Easy identification of a ready to use scope
- Scopes touching walls, floor or other scopes
Documentation

- Print outs lost
- Documentation not signed by staff member
- Log books get wet and ink becomes unreadable
Documentation

- Patient unique identifier
- Scope unique identifier
- Leak test results
- Person doing precleaning and reprocessing
- Chemistry MRC results
- Preventative maintenance care
Validation of Process

- Pre-Cleaning
- Biological Testing
- MRC Outcomes
- Leak Testing
- Cycle Parameter Checks HLD
Validation
Validation
Education and Competency
Definitions

- **In-service** – the instructions for how to use a new piece of equipment, reprocess it and trouble shoot it; this is usually done by the medical device manufacturer’s representative

- **Competency** – Skills acquisition through experience and use of medical devices or equipment, is not expected until some experience has been gained through repeated use

- **Evaluation** – Satisfactory completion of a series of tasks in a recommended order so that the medical device is used and reprocessed correctly, this is completed by a representative from the staff that has been designated as a content expert and has received additional training from the manufacturer and other outside sources
Required Education

- Orientation and training program
- Setup
- Disassembly
- Reprocessing of scopes
- Ongoing education on infection control and patient safety
- In-services on new technology or equipment
- Procedures for waste management

Complete Circle of Protection

- Standard precautions
- Personal Protective Equipment
- OSHA Bloodborne Pathogens
- Instructions for reprocessing scopes and accessories
- Mechanism of disease transmission
- Maintenance of a safe work environment
- Safe handling of high level disinfectants and sterilants
Basic knowledge of all the equipment they will be evaluating

Specific additional documented training for trouble shooting

A specific criteria skills list that must be passed by the staff

SGNA’s Train the Trainer Program

SGNA’s Infection Prevention Champions Program

CBSPD certification

SGNA’s Technician and Advanced Technician Certification
Sterile processing personnel play a critical role in your infection prevention efforts and therefore must receive training and continuing education.

Failing to follow reprocessing "best practices" can result in infections, which causes harm to patients and increased costs to the health care facility.
Supervisors should:

- be certified,
- be experienced,
- participate in CE programs and courses,
- provide in-service training,
- participate in Infection Prevention and Safety committees (member or resource).
Technicians should be certified, be competent in Standard Precautions, be knowledgeable in worker safety, and be knowledgeable in all aspects of sterilization and the operation of their facility’s sterilizers.
Certification

IAHCSMM
International Association of Healthcare Central Service Materiel Management
www.iahcsmm.org

Mission Statement
Provide the members of the Association and healthcare facilities with organized educational opportunities, professional development, a forum for information exchange, member services in response to member identified needs and priorities; and to represent Central Service Materiel Management in the professional community.
Mission Statement

To promote and encourage high standards of ethical and professional practice through a recognized, credible credentialing program that encourages the competency of personnel performing sterile processing and distribution activities.
Measuring Competency

- Competency checklist from the medical device manufacturer
- Review quiz
- Return demonstration
- Able to articulate the steps to be taken
- Can discuss the “why” the steps are being done
- Some competencies should be done more than annually for complex devices
Summary