The Challenges of Endoscope Cleaning

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Learning Objectives

• Review components of flexible and rigid endoscopes

• Discuss the challenges surrounding effective cleaning and reprocessing of endoscopes

• Describe the critical steps when reprocessing endoscopes
Centers for Disease Control

- "Endoscopes most commonly linked to health care-associated outbreaks and pseudo-outbreaks"
- Flexible endoscopes represent high-risk devices
  - High levels of bacterial contamination
  - Mouth - 200+ species
  - Large intestine - 1,000 species
- Complex designs
- Numerous reports of breaches in reprocessing

Infections

The Outbreak Bugs

The old news
- In United States, 11+ million GI Procedures each year.
- 500,000 ERCP (Duodenoscope) procedures
- Low risk of infection
- More health care acquired infections (HAIs) have been linked with the use of contaminated endoscopes than to any other medical device
But the New News..

Current risks are outdated and inaccurate (Ofstead et al, 2013; Dirlam-Langlay et al, 2013)
  • Most outbreaks not published
  • Most outbreaks not investigated
  • Difficult to link to contaminated endoscopes
  • Reviews of reprocessing practices show widespread lapses in essential steps
  • Risks are greater than just infections (e.g., toxicity with aldehydes)

Nosocomial Infections via GI Endoscopes
  • Infections traced to deficient practices
    – Inadequate cleaning (clean all channels)
    – Inappropriate/ineffective disinfection (time exposure, perfuse channels, test concentration, ineffective disinfectant, inappropriate disinfectant)
    – Failure to follow recommended disinfection practices (tapwater rinse)
    – Flaws and complexity in design of endoscopes or AERs

Features Predispose to Disinfection Failures
  • Heat labile
  • Long, narrow lumens
  • Right angle bends
  • Rough or pitted surfaces
  • Springs and valves
  • Damaged channels
  • Heavily contaminated with pathogens, $10^{7-10}$
  • Cleaning (4-6 log$_{10}$ reduction) and HLD (4-6 log$_{10}$ reduction) essential for patient safe instrument
Outbreaks

- Outbreaks associated with GI scopes have high transmission rates
- Recent infection outbreaks - transmission rate (~40%)
- Antibiotic resistant organisms: NDM-E.coli
- Adherence/non-adherence to cleaning and disinfection guidelines
- Improper use of reprocessing equipment
- Equipment problems
- Improper storage
- Inadequate drying
- Staff training/competency

CLEANR Study: Documented non-adherence with several essential steps (n = 69)

Multiple manual cleaning steps skipped 45% of the time

- Leak test with sudsy water: 22%
- Air purge after detergent flush: 16%
- Brush all channels and components: 57%
- Dry with forced air: 55%
- Alcohol flush: 14%
- Final wipe down: 10%

Manual cleaning n = 69; p = 0.001

Ofstead et al., Gastroenterology Nursing, 2010
Residual soil after reprocessing

- Poor bedside cleaning, heavy contamination
- 82% scopes tested positive for soil after manual cleaning (no visible soil)
  - Distal end, control handle, biopsy port, suction/bx channel
- Reduces efficacy of disinfectant/sterilant
- Remains contaminated
- Biofilm can develop
- Lead to infection
- Outbreaks of multi-resistant organism infections

Visrodia, Ofsted, Yeard, Tosh, Yellin, Wextler, Balon, Infection Control and Hospital Epidemiology August 2014, vol. 35, no. 8
Endoscope Characteristics

- Delicate, complex, expensive
- Require special care and handling
- Access internal structures/cavities
- Lens system for image
- Fiberoptic cable for light
- Internal lumens and channels
- Insufflation component
- Suction and irrigation systems
- Monitors connected through cable system to carry signals

Flexible Endoscope Anatomy

[Diagram showing the anatomy of a flexible endoscope with labeled parts such as Control Body, Bending Section, Insertion Tube, Light Guide Tube, Light Guide Connector, etc.]
Flexible Endoscope

- Distal tip
- Suction and Air/water channel inlets
- Biopsy port
- Directional Lever
- No fluid resistant cap

Simple Flexible Endoscopes

Flexible Endoscope Anatomy

- Mechanical system
  - Control body, insertion and light guide tubes, bending section
- Image
  - Fiberoptic cable, video electronics, connector, water resistant caps
- Channels
  - Suction/biopsy, air/water, irrigation, water-jet, elevator wire
- Accessories
  - Valves, suction, air/water, biopsy port
  - Biopsy forceps, snares, guide wires, irrigators, dilators
Distal tip of an ERCP endoscope

Rigid Endoscope Anatomy

Assembled View

Expanded View

Effectiveness of cleaning, disinfection, sterilization

- Contamination == 100,000,000,000 microbes
- Cleaning alone == 1,000,000 microbes (5 logs)
- Cleaning + HLD == 10 microbes (5 logs)
- Cleaning and sterilization == 0 microbes
Protein was never removed during reprocessing

Citation: Ofstead, et al. APIC Annual Conference; 2014; AJIC 2015 (in press).

Critical Steps in Reprocessing

New/Loan Devices
Patient Use (Non-Critical Devices)
Patient Use (Semi-and Non-Critical Devices)
Repair Disposal
Inspection
Disinfection/ Sterilization
Cleaning
Transport
Storage/ Distribution
Patient Use
Sterilization
Packaging
“Meticulous cleaning must precede any sterilization or high-level disinfection of these instruments. Failure to perform good cleaning can result in sterilization or disinfection failure, and outbreaks of infection can occur.”

(CDC)

Endoscope reprocessing steps

- Bedside cleaning
- Leak testing
- Thorough cleaning
- Rinsing
- High level disinfection/sterilization
- Rinsing
- Drying
- Storage

Note: This is an oversimplification! Reprocessing involves >100 steps.

Bedside Cleaning

- Keep devices free of soil and blood during use
  - Reduce microorganisms
  - Reduce potential for environmental contamination
- At completion of procedure
  - Wipe surfaces with gauze/non-lint sponges
  - Flush lumens
  - Water
  - Appropriate chemistry
  - Separate endoscope from accessories
- Prepare for transport
Containment and Transport

- Transport as soon as possible
- Closed/covered container
- Mark with biohazard label
- Regular scheduled pick-up
- Avoid high traffic areas

Leak Testing

Leak Testing Flexible Endoscopes

- Core element in reprocessing
- Can identify small leak prior to fluid invasion
- Risk of cross-contamination
- Perform prior to cleaning
- Pressurize prior to immersion in water
- Follow manufacturer's instructions
Cleaning
• Cleaning reduces number of microorganisms
• Thorough cleaning depends on:
  • Correct identification of specific endoscope model
  • Water quality
  • Compatible and effective cleaning chemistry
  • Time and temperature
  • Acceptable washing method
  • Proper rinsing and drying
  • Staff performance

Cleaning Methods
• Follow manufacturer instructions
• Manual
• Mechanical
  • Combination of both
• Mechanical friction
  • Physically remove debris
  • Wiping, brushing, spraying, flushing lumens
  • Should not damage endoscope
  • Safe for the worker performing the task

Cleaning Chemistry Decisions
• Select appropriate chemistry for soil removal
  • Materials compatibility
  • Neutral pH
  • Labeled for use on endoscopes
  • Effective in removing soils
  • Contains chelating and sequestering agents
  • Low foaming
  • Free rinsing
  • Biodegradable
First Step
Manual Cleaning

- Fresh solution
- Neutral pH cleaning chemistry
- Compatible with endoscopes
- Follow label instructions
- Dilute correctly
  - Mark water line on sink
- Correct water temperature
  - 100-140 F

Manual Cleaning

- Sink(s) of adequate size
- Clean as soon as possible (1 hour from use)
- Soak in cleaning solution to remove soil
- All surfaces including channels in contact with cleaning solution
- Follow label instructions

Manual Cleaning

- Physical action
  - Remove visible soil
  - Lint-free, disposable cloth
  - Appropriate cleaning accessories
  - Clean optical surfaces with gauze pad
  - Ports cleaned using a short brush, flushed with syringe
Manual Cleaning

- Determine size of endoscope channels
- Appropriate size brushes
- Replace when worn
- Metal bristle brushes used sparingly
- Brush under water
- Brush until clean
- Cleaned, disinfected

Manual Cleaning

- Access **all** channels
- Brush all ports
- Utilize channel irrigators
- Flush, brush, flush until clean

Mechanical Cleaning Options

- Flushes internal channels
- Consistent process
Manual Cleaning - ERCP

Mechanical Cleaning
Automated Endoscope Reprocessor
- Wash phase during cycle
- Augments manual cleaning for consistent outcome
- Cleaning chemistry labeled for endoscopes
- FDA cleared wash phase with minimal pre-cleaning
  - Pre-cleaning steps MUST be followed
- Follow endoscope manufacturer instructions
- Follow AER manufacturer instructions
- IFUs may be in conflict

Endoscope Accessories
- Reusable accessories, valves, tubing processed per manufacturer instructions
- Disassembled and cleaned
- Inspect for integrity
- AER manufacturer validates processing
Mechanical Cleaning for Rigid Endoscopes

- Utilized for fine cleaning
- Gross debris removed
- Effective cleaning chemistry
- Cavitation process
  - Sonic energy created bubbles
  - Unstable bubbles implode
  - Dislodges soil from surfaces
- Degas prior to use
- Change solution regularly
- No optical devices, mixed metals

Second Step -- Rinsing

- Clean, fresh water
- Thorough rinsing with warm water
- Endoscope thoroughly immersed in rinse water
- Flush all instrument channels several times
- Remove debris and cleaning chemistry

Adenosine Triphosphate (ATP) Validation

Alfa et al. Am J Infect Control 2013;41:245

- Validated as a monitoring tool for assessing cleaning because it detects organic residuals
- ATP is not a good indicator of microbial contamination and has not been validated as a method to assess the risk of patient-to-patient transmission
- ATP <200 RLU benchmark for clean, equates to <4 log_{10} CFUs/cm² or 10⁶ CFUs per endoscope
- Thus, an endoscope assessed as clean using ATP could still have a significant microbial load (e.g., 10⁶)
Cleaning Verification

- Retained soil causes patient infections!
- Manufacturers required to validate cleaning instructions
- Visual inspection combined with other verification methods
- Biochemical testing
- Cleaning efficacy of mechanical equipment
- Monitoring cleaning parameters (e.g., temperature)
- Repeat cleaning if soil present

Soil Detection

- Visual
- Below visual detection
  - Typically swab-type testing
  - Protein tests
    - Ninhydrin, OPA etc
  - ATP
    - Detects live cells
  - Others
    - Haemoglobin

Ineffective Soil Removal

- Ineffective cleaning chemistries can require extensive cleaning
- Residual soil can:
  - Foster biofilm formation
  - Trap cleaning chemistry
  - Cause damage to instrument surfaces
Incompatible Cleaning Chemistries

- Inappropriate chemicals
- Not labeled for use on endoscopes
- No sodium hypochlorite on endoscopes!
- Not neutral pH
- Use according to instructions
  - Time, temperature, dilution
  - Soaking times
  - Inadequate rinsing

Incompatible Cleaning Methods

- Biofilms -- microorganisms and debris left on a device surface that are allowed to grow!
- Delays in cleaning may lead to biofilm
- Unapproved reprocessing procedures
- Water quality/purity
- Water testing performed
- Quality control process to decrease risk

Ineffective Soil Removal

Effects on High Level Disinfection

High Level Disinfection
- M. Alfa and R. Howie (2009) demonstrated that gluteraldehyde solutions promoted the production of buildup biofilm within the lumens of endoscopes
- Oxidative solutions contributed less to buildup
- Enzymatic cleaning solutions can provide food source for formation of biofilms
Consequences of Inadequate Reprocessing

- High rates of colonization/infection transmission
- Biofilm
- Endoscopy related cross contamination

Resources and References

Updated FDA Guidance

- Published March, 2015
- Supersedes guidance issued in 1996
- Designed for INDUSTRY, not Healthcare Facilities
Increased Focus on Reprocessing Validations

- Quality of Reprocessing Instructions
- Attention to Human Factors
- Cleaning Validations

"IT IS IMPORTANT TO NOTE THAT CLEANING, DISINFECTION AND STERILIZATION ARE DISTINCTLY DIFFERENT PROCESSES"*  FDA

New statements and guidance for Endoscopy

- CDC interim protocol for microbial surveillance (duodenoscopes)
- FDA Safety notice for Olympus duodenoscopes
- AAMI Standard 91 for flexible endoscopes
- AORN Guideline for flexible endoscopes
- Joint Commission safety notice and actions to consider
Professional Organizations, Government Agencies

- Occupational Health and Safety Administration (OSHA)
- Centers for Disease Control and Prevention (CDC)
- Association for the Advancement of Medical Instrumentation (AAMI)
- American Institute of Ultrasound in Medicine (AIUM)
- American Urological Association (AUA/SUNA)
- Association of periOperative Registered Nurses (AORN)
- Society of Gastroenterology Nurses and Associates (SGNA)
- American Society of Gastroenterologists (ASGE)
- Multisociety guidelines

Quality Control and Competencies

- Quality control program to identify risks
- Target areas for improvement
- Initial training with clearly written protocols
- Structured training process
- Verified initial and ongoing competencies
- Training on all new scopes
- Mandated certification
- Develop clinical ladders
- Encourage additional formal education

Summary

- Endoscopes are complex, delicate devices
- All staff should be fully trained and knowledgeable regarding specific endoscope models
- Manufacturer instructions must be followed
- No critical steps can be missed
- Adequate time must be allowed for complete and appropriate reprocessing including cleaning steps
Action Plan

• Continuing education to staff on proper care, handling and maintenance of all endoscopes

• In-service training with new endoscope models, equipment and reprocessing methods

• Refer to scope manufacturer’s instructions for proper use and handling

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