Endoscope Reprocessing – Problem Areas & Prevention Strategies

Presented by Dr. Michelle Alfa
A Webber Training Teleclass

FLEXIBLE ENDOSCOPE REPROCESSING: "Problems that have occurred and how to prevent them"

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Flexible Endoscopes: Semi-critical Device Liquid Chemical Methods for Reprocessing most Commonly used

- "These studies emphasize that currently recommended reprocessing protocols have a lower than desirable margin of safety, and that failure is likely if cleaning steps are not followed in meticulous detail"

Cowan AE *The clinical risks of infection associated with endoscopy.* Can J. Gastroenterol 2001;15:321-331.

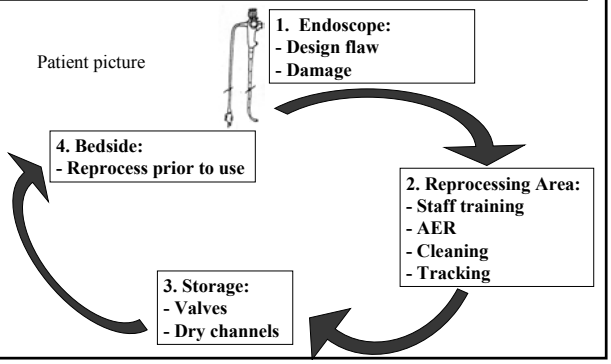
Infections Reported: Repeated usage

- TB: Up to 17 days survival (multiple reprocessing, multiple patients)
- Hepatitis C: three successive patients within a few days (reprocessed between patients)

Survival within channels of reprocessed flexible endoscopes:

?Role of Biofilm build-up?

Overview: Flexible Endoscopes



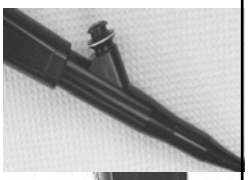
1. Flexible Endoscope: Defects

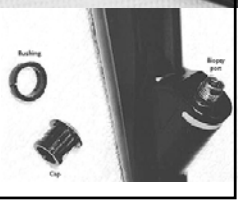
- Design Flaw
  - Bronchoscope; Olympus
- Damage
- Different Design
  - bronchoscope; frequent flushing of liquid through suction channel into lung → highest risk of transmitting infection from patient to patient
  - colonoscope; most physical abuse due to insertion path; most frequently needing repair
  - duodenoscope; side-viewing →invasive surgical procedures, hardest to clean

Olympus Recall of Bronchoscopes

- Nov 30, 2001; Olympus America→ recall on bronchoscopes; biopsy channel port – loose
  Feb 27, 2002; Olympus America → second recall notification
- Dec 2001; Johns Hopkins University; high rate of Pseudomonas infections associated with defective bronchoscopes (BAL). 3/7 bronchoscopes contaminated with Pseudomonas, 100 of ~ 410 patients tested positive for exposure to Pseudomonas.

www.fda.gov/cdrh/recalls/recall-032002.html





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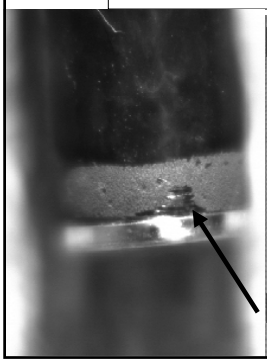
Endoscope Damage

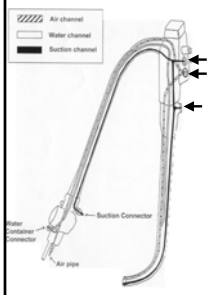


Biopsy port: corrosion

Avoidance:
- visual inspection
- leak testing
- service techs

Distal end: corrosion of epoxy

2. Reprocessing: Staff Training



Not cleaning all channels
- elevator wire channel
- auxillary water channel
(some flexible endoscopes)

Avoidance:
- Document training; knowledge of type of scope being reprocessed
- Review protocols with Infection Control
- Competency reviews (AORN 2003)
(observe process; check list)

2. Reprocessing: Automated Endoscope Reprocessor (AER)

Examples of AERs:

STERIS SYSTEM 1*: PA

MEDIVATOR: Glut or OPA

CUSTOM ULTRASONICS: Glut or OPA

ENDO-3*: Glut

J & J AER: Glut or OPA

Cycle parameters:
- Leak testing
- Wash; enzymatic detergent
- Reused or Single-use agent
- Filtered rinse water
- Alcohol rinse
- Dry

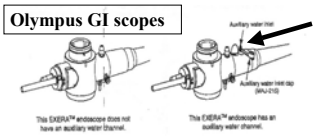
2. Reprocessing: Automated Endoscope Reprocessor (AER)

PROBLEMS:	AVOIDANCE:
i) Wrong connections; scope to AER → suboptimal or no flow in channels	i) Review protocols: ensure staff are knowledgeable → assess competency
ii) Wrong agent delivered; - swapped connection - incorrect agent HLD, Alcohol, Detergent	ii) Ensure tubing/bottles have unique connectors Double signature when new bottle/batch attached.
iii) Suboptimal MEC - test MEC each day used - Single-use HLD/sterilant	iii) Record of MEC testing Record of CI testing Ensure process cannot be "altered"

2. Reprocessing: Improper Manual Cleaning

PROBLEMS:	AVOIDANCE:
i) Not cleaning some channels e.g. elevator wire channel, auxillary water channel (some endoscopes)	i) Review protocols: ensure staff are knowledgeable → assess competency (see check list provided)
ii) Not cleaning accessory devices e.g. channel brushes, water bottle/tubing	ii) Infection Control audits to observe actual practices
iii) Suboptimal cleaning e.g. not immersed, not enough brushing	

Olympus GI scopes



2. Reprocessing: Tracking of Flexible Endoscope

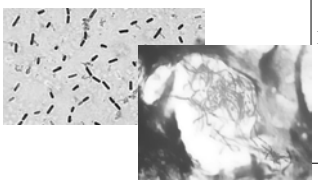
PROBLEMS:	AVOIDANCE:
i) No ability to trace which scope used on which patient	i) Master record sheet for tracking scope use (patient name) and disinfection
ii) No ability to trace which AER used for reprocessing which scope	ii) Record sheet for tracking scope reprocessing (see above)
iii) Damaged scope to be sent for repair used on patient	iii) Develop protocol to prevent after-hours access to scopes by untrained personnel. Also ensure labeling to warn that scope is NOT disinfected and is NOT to be used on patients

3. Storage:

PROBLEMS:	AVOIDANCE:
i) Moisture in channels; overgrowth (Gram negatives)	i) Alcohol rinse/drying and store valves separate from scope.
ii) Unknown break in filtration process of AER leading to water organisms in final rinse	ii) Surveillance cultures; controversial (Australian guidelines, Moses et al 2003)
iii) Stored for extended time between uses; fungal growth and/or bacterial overgrowth	iii) Colonoscopes; 7-days (if stored dry) maximum shelf-life (Riley et al 2002)
	NOTE: New storage cabinets with continuous filtered air flow to all channels

4. Prior to Patient Use:

PROBLEMS:	AVOIDANCE:
i) Viable organisms in scope channel after storage introduced to next patient (e.g. *M.tuberculosis, H.pylori, P.aeruginosa* etc.)	i) Reprocess all scopes prior to next patient-use Recommended by AORN (2003) and Australian guidelines for bronchoscopes and ERCP scopes (2000)
	NOTE: not routinely done in North America even for point of use AERs such as STERIS SYSTEM 1. Riley's data suggests this is not needed for colonoscopes if stored dry



Overview: Flexible Endoscopes

Patient picture

1. Endoscope:
   - Design flaw
   - Damage

2. Reprocessing Area:
   - Staff training
   - AER
   - Cleaning
   - Tracking

3. Storage:
   - Valves
   - Dry channels

4. Bedside:
   - Reprocess prior to use

FDA/CDC Advisory Bulletin

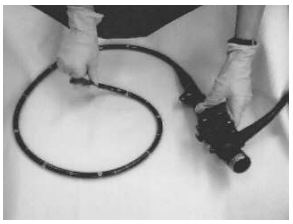
- **Advise institutions offering endoscopic procedures to:**
  - **ensure compatibility of endoscope with AER**
  - **need to dry before storage regardless of AER used**
  - **comprehensive training of staff to ensure competency**
  - **implement comprehensive QA program**

Ref: http://www.fda.gov/cdrh/safety/endoreprocess.html

CONCLUSIONS:

1. **Flexible Endoscopes: margin of safety is narrow.**
2. **Compliance of Actual reprocessing with Guidelines**
   - Staff Training
3. **Cleaning Verification tests for users are needed**

Reprocessing of Flexible Endoscopes



If you don't look…you won't know!!

Critical Steps in Reprocessing Flexible Endoscopes

1) Pre-Clean (bedside flush with enzymatic)
2) Leak test
3) Manual clean (immersed in enzymatic, brush)
4) Rinse to remove detergent & soil
5) Disinfect (HLD or sterilize)
6) Rinse (after HLD or peracetic acid)
7) Dry: alcohol and forced air
8) Storage; dry

HLD/Sterilization for Flexible endoscopes

- Ethylene Oxide (100% or HCFC)*
- Peracetic Acid (0.2%) *
- Glutaraldehyde (≥ 2%)
- Hydrogen peroxide (7.5%)
- Peracetic acid + Hydrogen peroxide (0.8%/1%)
- Orthophthalaldehyde (0.55%)

Alternatives: Autoclavable, Sheathed, and Disposable-channel scopes

Rutala & Weber, Infect. Control & Hosp. Epid. 1999 20:69-76

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