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”


Overview: Flexible Endoscopes

1. Endoscope: - Design flaw - Damage

2. Reprocessing Area: - Staff training - AER

3. Storage: - Valves - Dry channels

4. Bedside: - Reprocess prior to use

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?

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

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

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Endoscope Reprocessing – Problem Areas & Prevention Strategies
Presented by Dr. Michelle Alfa
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Endoscope Damage

Avoidance:
- Visual inspection
- Leak testing
- Service techs

Distal end: corrosion of epoxy
Biopsy port: corrosion

2. Reprocessing: Staff Training

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

Not cleaning all channels
- Elevator wire channel
- Auxiliary water channel
  (some flexible endoscopes)

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: Improper Manual Cleaning

PROBLEMS:
- Not cleaning some channels
e.g. elevator wire channel,
auxiliary water channel
  (some endoscopes)
- Not cleaning accessory devices
e.g. channel brushes, water bottle/tubing
- Suboptimal cleaning
e.g. not immersed, not enough brushing

AVOIDANCE:
- Review protocols; ensure staff are knowledgeable to assess competency
  (see check list provided)
- Infection Control audits to observe actual practices

Olympus GI scopes

2. Reprocessing: Tracking of Flexible Endoscope

PROBLEMS:
- No ability to trace which scope used on which patient
- No ability to trace which AER used for reprocessing which scope
- Damaged scope to be sent for repair used on patient

AVOIDANCE:
- Master record sheet for tracking scope use (patient name) and disinfection
- Record sheet for tracking scope reprocessing (see above)
- 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:

<table>
<thead>
<tr>
<th>PROBLEMS:</th>
<th>AVOIDANCE:</th>
</tr>
</thead>
<tbody>
<tr>
<td>i) Moisture in channels; overgrowth (Gram negatives)</td>
<td>i) Alcohol rinse/drying and store valves separate from scope.</td>
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<td>ii) Unknown break in filtration process of AER leading to water organisms in final rinse</td>
<td>ii) Surveillance cultures; controversial (Australian guidelines, Moses et al 2003)</td>
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<tr>
<td>iii) Stored for extended time between uses; fungal growth and/or bacterial overgrowth</td>
<td>iii) Colonoscopes; 7-days (if stored dry) maximum shelf-life (Riley et al 2002)</td>
</tr>
</tbody>
</table>

**NOTE:** New storage cabinets with continuous filtered air flow to all channels.

### 4. Prior to Patient Use:

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</tr>
</thead>
<tbody>
<tr>
<td>i) Viable organisms in scope channel after storage introduced to next patient (e.g. M.tuberculosis, H.pylori, P.aeruginosa etc.)</td>
<td>i) Reprocess all scopes prior to next patient-use</td>
</tr>
</tbody>
</table>

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

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](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!!
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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


References:

1. Disinfection of Reusable Medical Devices CSA International document Z314.8-00, March 2000

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