Value in Monitoring Manual Cleaning of Flexible Endoscopes

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Objectives:

- **Culture of channels to monitor flexible endoscopes**

- **Rapid Cleaning Monitors for flexible endoscopes**
  - ATP to detect organic and microbial residuals
  - Test strips to detect organic residuals

- **Flexible Endoscope cleaning**
  Why is a Quality Systems approach needed?

Pictures from Google Images

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What you can’t see...........
Can hurt you!

The outside looks clean, but
........ What lurks within??!
Flexible Endoscope Guidelines: What do they say?

- **Canada:**
  Decontamination of reusable medical devices. CSA guideline Z314.8-13
  **Recommends** consider rapid monitoring of manual cleaning of endoscopes especially if prolonged in transit.

- **USA:**
  Standards of Infection Control in Reprocessing of Flexible Gastrointestinal endoscopes SGNA 2011.
  **Recommends:** No cleaning monitoring recommendations.

- **Australia:** [Similar to European Guidelines]
  GENCA/GESA/AGEA Infection Control in Endoscopy (Australia) 2010.
  **Recommends:** bronchoscope & duodenoscope channels and AER tested for microbial growth monthly. All other scopes tested every 4 months.

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Microbe growth in Patient-Ready scopes: Due to Wet Channel

[(Alfa MJ & Sitter D 1991 J Hosp Infect.)](#)

- ~50% of scopes had growth

**Drying 10 mins:**
- [Manual or AER air purging]
- **No detectable microbes at 2, 24 or 48 Hrs**
  [N=19 scopes]

Scopes tested: 2 Hrs: N=12, 24 Hrs: N=15, 48 Hrs: N=15

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Manual Endoscope Reprocessing: What monitors are available?

1. **Culture of Channels post-HLD:**
   - scope used on other patients before results available at ~48Hrs

2. **Rapid Cleaning Monitors:**
   - failed scope gets reprocessed before going to HLD
   - **Organic residues** (protein, hemoglobin, etc)
   - **ATP residues** (human secretions & microbes)
Culture of Endoscope Channels

- **Post-HLD:** expect no viable microbes
- **Sample collection** may introduce contaminants
- **Process indicator:** not fast enough to prevent scope being used again
- **How to interpret results?**

**Australian approach:**
Colonscope culture positive

- **Skin microbes:** review collection protocol
- **GI Microbes:** > 10 cfu *S.aureus, viridans Streptococci, Enterococcus spp,* or Gram negatives (*E.coli, Pseudomonas sp*) requires action:
  - pull scope from use, test again
  - assess if patient notification is needed

GENCA, GESA, AGA Guideline: Infection Control in Endoscopy 2010

Culture of Endoscope Channels:

- **Gillespie et al 2008:**
  Over 5 years: 2374 scopes tested
  - 6 contamination events
  - 175 low level contamination events
  - No Mycobacteria in bronchoscopes
- **Recommended culture only at installation, annually and following scope/AER repair**

North American Endoscope Culture Data: Patient-ready scopes

1. **Miner et al 2007: N=5**
   Average of 200 cfu in patient-ready GI scopes.

2. **Chiu et al 2010: N=7**
   18% patient-ready GI scopes showed growth

3. **Alfa et al 2012: N=141**
   141 scopes over 7 months: 14% had growth:
   - 13 < 10 cfu/mL
   - 5 >10 but < 100 cfu/mL
   - 2 > 100 cfu/mL

Manual Cleaning Monitors

- Endoscope Channel Sample
- Organic residuals
- ATP: microbes & human secretions
- Carbohydrate, protein, hemoglobin

Tests assess how well the manual cleaning is being done by staff

Validated Sample Collection

1. **Sample Collection:**
   Flush 10 mLs of sterile deionized water from Biopsy port to distal end.

2. **Test sample:**
   organic residues, viable organisms or ATP
Cleaning Monitoring: Endoscope Channels

- **Organic Residuals**
  - Protein
  - Hemoglobin
  - Carbohydrate

  Commercially available rapid test kits from many different manufacturers

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**Trans-Canada Survey:**

**Patient-ready flexible endoscopes**

Cleaning monitoring of organic residuals in suction/biopsy channel: rapid test strip

<table>
<thead>
<tr>
<th>Instrument</th>
<th>No.</th>
<th>Pos. (%)</th>
<th>Carbohydrate</th>
<th>Protein</th>
<th>Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastroscope</td>
<td>543</td>
<td>50 (9.2%)</td>
<td>0</td>
<td>3</td>
<td>47</td>
</tr>
<tr>
<td>Colonoscope</td>
<td>463</td>
<td>32 (6.9%)</td>
<td>5</td>
<td>2</td>
<td>25</td>
</tr>
<tr>
<td>Bronchoscope</td>
<td>251</td>
<td>10 (4%)</td>
<td>0</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>ERCP scope</td>
<td>57</td>
<td>7 (12.3%)</td>
<td>0</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>[Elevator guide wire channel]</td>
<td>21</td>
<td>4 (18.1%)</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Sigmoidoscope</td>
<td>91</td>
<td>2 (2.2%)</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>

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**Cleaning Monitoring: Endoscope Channels**

- **ATP**
  - Relative light units [RLUs]

  - **Bacteria:** requires ~ 1000 bacteria to give 1 RLU
    - Not sensitive enough to replace culture to detect bacteria
  - **Human secretions** have high ATP levels

  Commercially available rapid test kits from many different manufacturers
RECOMMENDATIONS FOR ATP MONITORING:
Gastrointestinal Endoscopes

Post cleaning: Monitor endoscope channels to assure adequacy of cleaning

Post HLD: Monitor endoscope distal tip
(high ATP post-HLD may be due to organic residuals – so more data needed)

Clinical Study: ATP to monitor manual cleaning of endoscope channels

Validated cut-off for adequate cleaning of: ≤ 200 RLUs

Colonoscopes Post manual cleaning (N = 20):
- Suction/Biopsy channel: 0% > 200 RLUs
- Air/Water channel: 0% > 200 RLUs
- Auxiliary water channel: 0% > 200 RLUs

Duodenoscopes Post manual cleaning (N = 20):
- Suction/Biopsy channel: 0% > 200 RLUs
- Air/Water channel: 0% > 200 RLUs
- Elevator GW channel: 25% > 200 RLUs
(all < 700 RLUs)

Stop Dirty Endoscopes at the Cleaning stage!!

- Once disinfected or sterilized residues are fixed → hard to extract and analyze

- Need to do routine monitoring of cleaning to prevent build up of fixed material in endoscope channels.

Azizi J, Basile RJ  The need to verify the cleaning process. Horizons, Spring 2012 page 48-54.

The Future .......... is going to be even more complex!!

Natural Oriface translumenal Endoscopic Surgery (NOTES)

Access to peritoneal or thoracic space through incision in; stomach, vagina, rectum, oesophagus

Santos BF, Hungness ES  World J Gastroenterol 2011 DOI: http://dx.doi.org/10.3748/v17.31.1655

Rapid Cleaning Monitors will help prevent errors up to this stage


All 12 steps completed: Manual cleaning & AER for HLD: 1.7% Automated cleaning and HLD: 75.4%

<table>
<thead>
<tr>
<th>Observed Activity</th>
<th>Steps completed (%) (in 90)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean and perform initial stages</td>
<td>77</td>
</tr>
<tr>
<td>Disassemble endoscope</td>
<td>100</td>
</tr>
<tr>
<td>Clean all components</td>
<td>99</td>
</tr>
<tr>
<td>Remove all instruments</td>
<td>99</td>
</tr>
<tr>
<td>Disassemble accessories</td>
<td>99</td>
</tr>
<tr>
<td>Flush endoscope with detergent</td>
<td>99</td>
</tr>
<tr>
<td>Rinse endoscope with water</td>
<td>99</td>
</tr>
<tr>
<td>Purge endoscope with air</td>
<td>99</td>
</tr>
<tr>
<td>Clean and assemble endoscope</td>
<td>99</td>
</tr>
<tr>
<td>Flush endoscope with alcohol</td>
<td>99</td>
</tr>
<tr>
<td>Use vacuum air to dry</td>
<td>99</td>
</tr>
<tr>
<td>Wipe down external surfaces</td>
<td>99</td>
</tr>
</tbody>
</table>

TABLE 3: Documented Completion of Steps During Manual Cleaning With High-Level Disinfection Reprocessing
Cleaning Monitors: Quality System Program

- Ensure Staff competency for Manual cleaning:
  - initial training verification,
  - updated for new scopes/instruments
  - yearly competency assessment
- Ensure ongoing adequacy of manual cleaning:
  - monitor flexible endoscope lumens

Paradigm Shift: Medical Device Cleaning....

Quality System Process:
1. Validated Manufacturer's cleaning instructions
2. Staff training & appropriate cleaning equipment
3. Cleaning monitoring
4. HLD and Sterilization monitoring

Summary:
- Culture of channels to monitor flexible endoscopes
  - Needed to investigate outbreaks
  - Results take too long for routine monitoring; contaminated scope could still used on next patient
- Rapid Cleaning Monitors for flexible endoscopes
  - ATP to detect organic and microbial residuals
  - Test strips to detect organic residuals
- Quality System for Flexible Endoscope cleaning:
  - Ensures unclean scope is reprocessed before used on next patient

Pictures from Google Images
Flexible Endoscope Reprocessing

Pictures from Google Images

References

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- AAMI TIR23:2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices