Monitoring and Improving the Effectiveness of Cleaning Medical and Surgical Devices: *Ban the Biofilm!!*

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Disclosures:

Sponsored to give invited presentations at various National and International conferences by;
STERIS, 3M, J&J, Healthmark, APIC, CACMID, Virox, Medisafe, Ontario Hospital Association, CHICA, and multiple conference associations.

The University of Manitoba has licensed Dr. Alfa’s patent for Artificial Test Soil to Healthmark.

Opinion Leader Panel participation or Consulting Services for: 3M, J&J, STERIS, Serim, Olympus, bioMerieux, Serim, various Canadian Healthcare facilities.

Research projects for:
3M, STERIS, J&J, Novaflux, Virox, Serim, Olympus, Medisafe, Serim, Case Medical, Province of Manitoba, Public Health Agency of Canada
(NOTE: no funds from these research projects comes to Dr. Alfa – all funds handled by the St. Boniface Research Centre).
Objectives:

- **Manual vs Automated Cleaning:**
  - Roles for Manufacturers and Users

- **Infection transmission: recent publications**
  - Arthroscopic shavers
  - Flexible endoscopes

- **Monitoring cleaning**
  - What to monitor?
  - How to monitor?

- **Summary**

Pictures from Google Images
Medical Device Cleaning: Centre Stage

- **FDA:** Draft FDA guidance: manufacturers to validate cleaning instructions [www.fda.gov/reprocessingreusableddevices]

- **Reprocessing: 2011 Summit:** Priority issues from the AAMI/FDA Medical Device Reprocessing Summit [reprints: jbrenner@ammi.org]


- **NBC News:** Dr. Nancy Snyderman [2012]
Automated versus Manual?

- **Surgical Instruments:**
  - Manual allows specific observation of problem areas but automated is more reproducible/effective for some instruments (Alfa et al. 2006).

- **Flexible endoscopes**
  - *More Reproducible;* compliance with guidelines: 1.4% for manual vs 75.4% for automated (Ofstead C. et al. 2010)
  - *More cost effective;* Automated saved 2 hrs staff labour/day vs manual (Forte L, Shum C 2011)

- **Water quality:** affects all cleaning
  - mineral content > 50ppm → spotting on instruments
  - higher mineral content → chemical cleaners less effective
  - final rinse water needs monitoring (Uetera Y et al. 2012)
How clean is clean enough?

- Cleaning ensures removal of:
  - organic residuals (secretions, skin, bone, etc)
  - microorganisms
- Proper cleaning ensures disinfection/sterilization will be effective

MANUAL/ AUTOMATED:
Need Rapid Cleaning Monitors to verify if cleaning has been adequate.
Guidelines: What do they say?

- ANSI/AAMI ST79:2011*
  Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities. AAMI publishers

- AAMI TIR30:2011
  A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. AAMI publishers

- Decontamination of reusable medical devices. CSA guideline Z314.8-08

- Standards of Infection Control in Reprocessing of Flexible Gastrointestinal endoscopes SGNA 2011.

*Weekly (preferably daily) monitoring of automated washer cleaning is recommended

No specific recommendations for how to monitor manual cleaning
Are Medical Devices a Patient Safety Problem??

- Guidelines indicate the risk of infection transmission due to medical devices is very rare.

HOWEVER......

- Outbreaks associated with medical devices have high transmission rates:
  - Arthroscopic shaver Pseudomonas aeruginosa infection (2011):
  - Duodenoscope Klebsiella pneumonia infection (2010):
Arthroscopic Shavers:

**Case Patients:**
2 patients: ACL reconstruction
4 patients: Knee debridement [e.g. meniscectomy]

**Knee surgery:**
- *P. aeruginosa* infection in 7 patients over ~ 2 weeks
- Identical *P. aeruginosa* strains detected in water and suction canister [not detected in shavers]
- Shaver handpieces **autoclaved**

**Infections detected 4 - 19 days post knee surgery**

Tosh PG et al  Outbreak of *P. aeruginosa* surgical site infections after arthroscopic procedures: Texas, 2009  ICHE 2011;32:1179-86.
Retained tissue in
- cannula lumen
- Handpiece suction lumen

Key Conclusions:

- **Inadequate Cleaning:** Tissue remains in lumen of handpiece despite cleaning and sterilization
- **Source of *P. aeruginosa***: tap water used for cleaning
- **Autoclaving not adequate:** cross-transmission of same strain occurred
- **Transmission rate**: 1,045 cases/10,000 procedures (i.e. ~1 in every 10 get infected)
- **FDA issued a Safety Alert**: encouraged inspection of lumens with 3mm videoscope
Duodenoscope Transmission of *Klebsiella pneumoniae*

The strain of *K. pneumoniae* implicated was multi-resistant

Similar findings by:
- Carbonne A et al Endoscopy 2010 (France)
- Aumeran C. et al Euro Surveill 2010 (France)

Pictures from Google Images
### K. pneumoniae transmission by Duodenoscope

<table>
<thead>
<tr>
<th>Case:</th>
<th>Date of duodenoscopy</th>
<th>Specimen</th>
<th>Infection/colonization</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Aug 1</td>
<td>Rectal swab</td>
<td>Colonization</td>
<td>SOURCE CASE</td>
</tr>
<tr>
<td>9</td>
<td>Aug 18</td>
<td>Rectal swab</td>
<td>Colonization</td>
<td>Alive</td>
</tr>
<tr>
<td>2</td>
<td>Aug 29</td>
<td>Blood</td>
<td>Infection</td>
<td>Death (unrelated to K. pneumoniae)</td>
</tr>
<tr>
<td>8</td>
<td>Sept 1</td>
<td>Rectal swab</td>
<td>Colonization</td>
<td>Alive</td>
</tr>
<tr>
<td>11</td>
<td>Sept 3</td>
<td>Rectal swab</td>
<td>Colonization</td>
<td>Death (unrelated to K. pneumoniae)</td>
</tr>
<tr>
<td>3</td>
<td>Sept 14</td>
<td>Blood</td>
<td>Infection</td>
<td>Death (unrelated to K. pneumoniae)</td>
</tr>
<tr>
<td>10</td>
<td>Sept 15</td>
<td>Rectal swab</td>
<td>Colonization</td>
<td>Alive</td>
</tr>
<tr>
<td>13</td>
<td>Sept 28</td>
<td>Rectal swab</td>
<td>Colonization</td>
<td>Alive</td>
</tr>
</tbody>
</table>

Key Conclusions

- Endoscope cultures grew *K. pneumoniae*
- Not all transmissions resulted in infections (45% transmission rate from same scope)
- Cleaning and disinfection (Peracetic acid) done properly
- **Drying inadequate**
- *K. pneumoniae* survived multiple rounds of cleaning and HLD [? Biofilm]

What commercial rapid monitors are available to assess cleaning efficacy of automated washers?
Cleaning Monitors for Automated Washers

HealthMark USA, Medisafe UK, Steris/Browne UK, SteriTec, USA, Serim, USA

These represent some examples it is NOT an all-inclusive list

Medisafe Lumen check: Laparoscopic device lumen
Flexi check: Endoscope lumen

TOSI Lumcheck

Enzymatic Detergent test
Steritec Wash-Checks

Sono check
STF Load check

These monitors assess how effective the washer function is:
ISO TC 198 WG13 is working to standardize washer cleaning monitoring and develop testing methods that allow test soil comparison

Pictures from company websites or Google images
Frequency of Monitoring??

- **Quality Assurance Program:**
  - ANSI/AAMI ST79 recommends weekly (preferably daily) monitoring of mechanical washer cleaning efficacy

- **Site implementation:**
  - Establish site baseline: initial daily testing of all automated washers for a short period of time
  - Ongoing each washer tested minimally 1/week

- **Published data needed:**
  - Comparisons of various cleaning monitors
  - Impact of monitoring on improving detection of faulty washer cleaning function
Manual Cleaning: What monitors are available?

Narrow lumened instruments (e.g. flexible endoscopes)

Surgical instruments: (e.g. fragile, lock box, retractable parts etc)
Rapid Audit Tools: Manual Cleaning

1. **Organic residuals**: [Protein, Hemoglobin most common]
   - Alfa et al 2010: Medical Device washers (Protein)
   - Witfield 2011: flexible endoscopes; ChannelCheck (Hemoglobin, Protein, Carbohydrate)

2. **ATP**: [Medical Device; new application]
   - Obee et al 2005: flexible endoscopes < 500 RLU
   - Alfa et al 2012: flexible endoscopes < 200 RLU

**AAMI TIR 12:2010 and AAMI TIR 30:2003**
Benchmarks: protein: < 6.4 μg/cm², hemoglobin< 2.2 μg/cm²
Endoscope Lumens: Rapid Manual Cleaning Monitors

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

Channel Sample

Channel Chek: Healthmark

Carbohydrate, protein, hemoglobin

Detects ATP

3M

Alfa et al 2012 AJIC; two studies: ATP validation for endoscope channels
Alfa et al 2012 AJIC: Organic residual test validation for endoscope channels

Pictures from company websites
## Trans-Canada Survey: patient-ready flexible endoscopes

Rapid Cleaning test for Carbohydrate, Protein, Blood

<table>
<thead>
<tr>
<th>Endoscope</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</td>
<td>0</td>
<td>3</td>
<td>47</td>
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<tr>
<td>Colonoscope</td>
<td>463</td>
<td>32</td>
<td>5</td>
<td>2</td>
<td>25</td>
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<tr>
<td>Bronchoscope</td>
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<td>10</td>
<td>0</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>ERCP scope</td>
<td>57</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>[Elevator wire]</td>
<td>21</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Sigmoidoscope</td>
<td>91</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>
Clinical Study: ATP to monitor manual cleaning of endoscopes

Validated cut-off for adequate cleaning = < 200 RLUs

**Colonoscopes** Post manual cleaning (N = 20):
- L1: 0% > 200 RLUs
- L2: 0% > 200 RLUs
- L3: 0% > 200 RLUs

**Duodenoscopes** Post manual cleaning (N = 20):
- L1: 0% > 200 RLUs
- L2: 0% > 200 RLUs
- L4: 20% > 200 RLUs (all < 700 RLUs)
Manufacturer Validation of Manual Cleaning Monitors:

- **Which channels to monitor?**
- **How should channel sample be collected:**
  - Realistic in busy clinic
  - Liquid: volume, type of liquid
  - Sponge or brush sample method?
- **Benchmark for adequate clean:**
  - relate to “clean” benchmarks to be achieved
What stage should be monitored and how?

**ENDOSCOPE CLEANING AND DISINFECTION PROCESS:**

**PROCEDURE ROOM**

1. **CLEANING**
   - IPRECLEAN
   - LEAK TEST → PASS
   - REMOVE ALL DETACHABLE PARTS
   - CLEAN
   - RINSE

   Some AERs: cleaning cycle replaces manual clean

   Manual cleaning: ATP or Organic

2. **DISINFECTION**
   - SET ASIDE FOR REPAIR
   - CHOOSE DISINFECTION METHOD
   - AUTOMATED DISINFECTANT
   - MANUALLY DISINFECT

   HLD: Organic or Viable count

3. **DRYING**
   - PURGE ALL CHANNELS WITH AIR UNTIL DRY
   - ALCOHOL RINSE

4. **STORAGE**
   - HANG TO STORE
   - IMMEDIATE REUSE
   - REPLACE ALL DETACHABLE PARTS
   - REUSE

**REPROCESSING AREA**

Storage: Viable count
Stop Dirty Instruments 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 on instruments.

Azizi J, Basile RJ  The need to verify the cleaning process.  Horizons, Spring 2012 page 48-54.
Natural Orifice 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.il3.1655
Cleaning Monitors: Quality Program

- **Ensure Staff competency for Manual cleaning:**
  - initial training verification,
  - updated for new scopes/instruments
  - yearly competency assessment

- **Ensure ongoing adequacy of automated washers & manual cleaning:**
  - monitor flexible endoscope lumens
  - monitor cleaning of mechanical washers
Take Home Messages:

- **Manual vs Automated Cleaning:**
  - Automated methods more reproducible but still need to be monitored

- **Infection transmission: recent issues**
  - High rate of infection transmission can occur if medical instruments not properly cleaned

- **Monitoring cleaning:**
  - Automated washers; verify cleaning cycle
  - Flexible endoscopes; verify manual cleaning
Medical Instrument Cleaning

Your are NOT ALONE:

Teamwork is the key!
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