Medical Device Reprocessing: Can we “Ban the Biofilm”?! 

Dr. Michelle J. Alfa, Ph.D., FCCM
Professor, University of Manitoba,
Principal Investigator, St Boniface Research Centre
Winnipeg, Canada

St Boniface Research Centre
Winnipeg, Manitoba Canada

Disclosures:

Sponsored to give invited presentations at various National and International conferences by: STERIS, 3M, &J, Healthmark, Ruhof, 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, STERIS, Serim, Olympus, bioMerieux, Serim, Borden Ladner Gervais LLP, various Canadian Healthcare facilities.

Research projects for: 3M, STERIS, &J, Novaflux, Ruhof, 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:

• What is biofilm:
• Infection transmission: biofilm related
  - Arthroscopic shavers
  - Flexible endoscopes
• Ban The Biofilm:
  - Medical devices
• Summary

Pictures from Google Images
What is biofilm??

- Biofilm: Constantly hydrated surface:
  - indwelling line
- Build-up Biofilm: Cyclical hydration and non-
  sterile dry storage
  - flexible endoscopes*
- Build-up of tissue/bone: steam inadequate
  - medical instruments

Water Quality

*Impact on all medical device cleaning*
- mineral content > 50ppm → spotting on instruments
- higher mineral content → chemical cleaners less effective
- final rinse water needs monitoring (Uetera Y et al 2012)

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)
  - GI Endoscope transmitted infections (2010-2014)

Patient Infections related to Medical Devices

**Endogenous:** Infections due to patient’s own organisms

**Exogenous:** Infection due to contaminated medical device
Arthroscopic Shavers:

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

Case Patients:
- 2 patients: ACL reconstruction
- 4 patients: Knee debridement

Infections detected 4 – 19 days post knee surgery

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

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.

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.
What commercial rapid monitors are available to assess cleaning efficacy of automated washers?

- **Flexi check**: Endoscope lumen
- **Medisafe Lumen check**: Laparoscopic device lumen
- **TOSI Lumcheck**: Endoscope lumen
- **Steritec Wash Checks**: Enzymatic Detergent test

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

ISO TC 198 WG13 is working to standardize washer cleaning monitoring and develop testing methods that allow test soil comparison.

### Frequency of Monitoring??

- **Quality Assurance Program**: ANSI/AAMI ST79 & CSA Z318-3 recommend 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

### Infection Transmission from contaminated flexible endoscopes

- **France**: Aumeran 2010, & Carbonne 2010  - ESBL and Carbapenem resistant strains of *K. pneumoniae* (duodenoscopes)
- **USA**: Alrabaa 2013  - Carbapenem resistant *K. pneumoniae* (ERCP scopes)
- **USA**: MMWR 2014  - New Delhi Metallo-β-Lactamase (NDM) producing *E. coli* (ERCP scopes)
**NDM E.coli strain: What does this mean to me??**

**North-eastern Illinois Outbreak:**
- **Colonization:** 50 of 90 other patients who had ERCPs at this site were screened and 46% were colonized with same NDM E.coli strain.
- **ERCP elevator channel** grew NDM-E.coli & CRE-K.pneumoniae
- **No apparent breaks** in flexible endoscope reprocessing protocol??

**NDM E.coli strain:**

**North-eastern Illinois Outbreak:**

- **First USA isolate reported**
- **27 USA cases since 2009**

- **Jan-Sept: 69 cases (44 from N.E. Illinois)**

2009 2012 2013

**NDM-E.coli:** resistant to carbapenems

- Multi-antibiotic resistant
- Infections: blood, urine, biliary tract
- Treatment options limited (Alrabaa 2013):
  - Colistin
  - Tigecycline + aminoglycoside
- High transmission rates and high infection/mortality rates
- ?Biofilm development?

**Key Conclusion from Outbreaks**

- **Cleaning of elevator was inadequate:** debris remained under elevator piece
EGW Design Change

**Un-sealed EGW:**
Fluid flow for cleaning of EGW channel

**Sealed EGW:**
No cleaning of EGW channel

---

How do you know if an endoscope is contaminated?

- Channels are too narrow and long to visually inspect
- What monitoring could be done?

---

Guidelines: What do they say?

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

- **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 2010.
  *Recommends*: endoscope channels and AER final rinse water tested for microbial growth monthly

---

Manual Cleaning Monitors

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

- **Endoscope Channel Sample**
  - **Organic residuals**
  - **ATP: microbes & human secretions**

Dectes: Carbohydrate, protein, hemoglobin (individually or together)

---

CANADIAN ASSOCIATION OF MEDICAL DEVICE REPROCESSING

October 16 – 18, 2014
Winnipeg, MB
Simulated-Use: Validation of Endoscope Channel Cleaning

<table>
<thead>
<tr>
<th>Suction Channel:</th>
<th>3M ATP TEST</th>
<th>Ruhof ATP TEST*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cutoff for adequate clean:</td>
<td>&lt; 200 RLUs</td>
<td>&lt; 100 RLUs</td>
</tr>
<tr>
<td>Background ATP level:</td>
<td>≤ 20 RLUs</td>
<td>≤ 14 RLUs</td>
</tr>
<tr>
<td>Scale for Luminometer:</td>
<td>0 to &gt; 50,000 RLUs</td>
<td>0 to 9999 RLUs</td>
</tr>
<tr>
<td>Microbial residuals when clean:</td>
<td>&lt; 2.5 Log_{10}/cm²</td>
<td>&lt; 2.0 Log_{10}/cm²</td>
</tr>
<tr>
<td>Protein residuals when clean:</td>
<td>&lt; 0.10 ug/cm²</td>
<td>&lt; 0.23 ug/cm²</td>
</tr>
</tbody>
</table>

*Data not yet published

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: 100% clean: None > 200 RLUs
- Air/Water channel: 100% clean: None > 200 RLUs

Duodenoscopes Post manual cleaning (N = 20):
- Suction/Biopsy channel: 100% clean: None > 200 RLUs
- Air/Water channel: 100% clean: None > 200 RLUs
- Elevator GW channel: 75% clean: 25% > 200 RLUs


Endoscope Reprocessing RISKS:
- Biofilm not killed
- Final Rinse water
- Wet storage
- Biofilm Formation


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

TABLE 3, Documented Completion of Steps During Manual Cleaning With High-Level Disinfection Reprocessing

<table>
<thead>
<tr>
<th>Disinfect Activity</th>
<th>Steps Completed (%)</th>
<th>Prior %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Task performed in clear water</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Steamtable endoscope completely</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suction, endoscope channels and components</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inclined endoscope components and components</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rinse endoscope with water</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Steam endoscope with water</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purge endoscope with air</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Load and complete automated cycle for high-level disinfection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flush endoscope with water</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use force at its dry endoscope</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wipe down external surfaces before handing to dry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Rapid Cleaning Monitors will help prevent errors up to this stage
What can be done to reduce the risk of outbreaks of AROs from flexible endoscopes?

1. Ensure manual cleaning of flexible endoscopes is done properly [i.e. Monitoring manual cleaning]
2. Ensure channels are thoroughly dried prior to storage

Take Home Messages:

- **Biofilm in Medical Instruments**: buildup biofilm/retained tissue most common
- **Infection transmission: recent issues**: High rate of infection transmission can occur if medical instruments not properly cleaned → related to biofilm
  - Flexible endoscopes: NDM- *E.coli* transmission
- **Ban the Biofilm**: Automated washers; verify cleaning cycle
  - Flexible endoscopes: verify manual cleaning
  - STORE SCOPES DRY!

Prevent Infections.....

Don’t Accept Inadequate Medical Device Cleaning!!