Medical Device Reprocessing: How to “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.

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Objectives:

- **What is biofilm:**
  - traditional biofilm
  - build-up biofilm

- **Infection transmission: biofilm related**
  - Arthroscopic shavers
  - Flexible endoscopes

- **Ban The Biofilm:**
  - Endoscopes
  - Medical devices

**Summary**

Pictures from Google Images
What is biofilm??

- **Constantly hydrated surface:**
  - indwelling line

- **Cyclical hydration and dry storage:**
  - flexible endoscopes*
  - medical instruments
Stage 1

Stage 2

Stage 3

Direction of Fluid Flow:

Biofilm

Biofilm

Continuous Hydration

~300 - 500 µm thick

Cyclic Build-up Biofilm

Cycle 1

Cycle 2

Cycle 50

Build-up Biofilm;

layers of dried organic matrix with embedded organisms

Cycle:

- post-patient: hydrated
- cleaning: hydrated
- disinfection: hydrated
- storage: dry

10 - 50 µm thick
Biofilm on MBEC pins: \textit{Enterococcus faecalis}

Alfa MJ, Howie R. 
\textit{Modeling microbial survival in buildup biofilm for complex medical devices.} 
BMC Infect Dis. 2009 May 8; 9:56.
Biofilm on MBEC pins: *Pseudomonas aeruginosa*

How can medical devices form biofilm?

**Surgical Instruments:**
- Not stored wet, build-up biofilm
- Poor design: difficult/impossible to clean
- ?Sterile crud?

**Flexible endoscopes**
- repeated rounds of hydration (secretions/bioburden),
  clean, HLD, then dry storage (not always stored dry)
- Ofstead et al 2011: commonly omitted → drying

**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)
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. menisectomy]

**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

Tosh PG et al  Outbreak of *P.aeruginosa* surgical site infections after arthroscopic procedures: Texas, 2009  ICHE 2011;32:1179-86.
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>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Aug 1</td>
<td>Rectal swab</td>
<td>Colonization</td>
<td>SOURCE CASE</td>
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<td>Aug 18</td>
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<td>Alive</td>
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<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>
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<tr>
<td>11</td>
<td>Sept 3</td>
<td>Rectal swab</td>
<td>Colonization</td>
<td>Death (unrelated to K.pneumoniae)</td>
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<td>3</td>
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<td>Blood</td>
<td>Infection</td>
<td>Death (unrelated to K.pneumoniae)</td>
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<td>Rectal swab</td>
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<td>13</td>
<td>Sept 28</td>
<td>Rectal swab</td>
<td>Colonization</td>
<td>Alive</td>
</tr>
</tbody>
</table>

Key Conclusions

- Endoscopy 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]

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.
Endoscope Channel cleaning: New device designs

Pull-through "squeegie": single-pass, disposable [ConMed Canada]

Traditional channel brush; single or multiple brushes [Multiple suppliers]

% removal (weight of test soil)

- Used 5mm lumen from endoscope
- Single-pass in channel
- 3 passes in channel

Charlton T Aust Infect Control 2007;12:81-90
What commercial rapid monitors are available to assess cleaning efficacy of automated washers?

Pictures from Google Images
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

Flexi check: Endoscope lumen

TOSI Lumcheck

Enzymatic Detergent test

Steritec Wash-Checks

Medisafe Lumen check: Laparoscopic device lumen

TOSI

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
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)

Pictures from Google Images
Endoscope Lumens: Rapid Manual Cleaning Monitors

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

Channel Sample

Healthmark, Serim, 3M, etc

3M, Ruhoff, etc

Carbohydrate, protein, hemoglobin [combined or individually]

Detects ATP

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

Pictures from company websites
Take Home Messages:

- **Biofilm in Medical devices:**
  - buildup biofilm most common
  - flexible endoscopes: wet storage

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

- **Ban the Biofilm:**
  - Automated washers; verify cleaning cycle
  - Flexible endoscopes; improve channel cleaning, verify manual cleaning, STORE DRY
Medical Device Reprocessing

Pictures from Google Images