Dissecting Outbreaks of Multi-resistant Bacteria in Gastrointestinal Endoscopy

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Objectives:

- Outbreaks: contaminated endoscopes
- What are “Bacteria of Concern”?
- Survival of HLD: Build-up biofilm
- Summary

All Clipart Pictures in this presentation are from Google Images
Gastroenterologists trust that the endoscope provided to them is safe to use (reasonable expectation).
USA:
- First isolate of Carbapenem Resistant Enterobacteriaceae (CRE) in 2009
- Only 29 isolates of CRE up until Dec 2012

Jan 2013: Cluster of 44 CRE cases from Illinois
Field Investigation (January-July 2013)
9 case patients

C7 → C8 → S28
C1 → C2 → C3 → C4 → C5 → C6

Duodenoscope A
39.7% Transmission

Duodenoscope B
6.3% Transmission

Duodenoscope C
20.3%

Clinical Cases (September 2013)
2 case patients

C9 → C10

Epstein L et al JAMA 2014;312:1447-55
DuodenoScope-Related MDRO Outbreaks

Totals: 7 outbreaks, 70 cases, 23 deaths, 49 colonized

Slide courtesy of Dr. David Lichtenstein, Boston University Medical Centre
Why are we detecting these outbreaks now?

**Invasive infection with bacteria having unusual antibiotic resistance:**
- Carbapenem Resistant Enterobacteriaceae (CRE): *Klebsiella pneumoniae*
- New Delhi Metallo-beta-lactamase (NDM) *Escherichia coli*
- Multi-drug resistant *Pseudomonas aeruginosa, E.coli etc.*

Kovaleva J et al, Clinical Microbiology Reviews 2013;26:231-253
Outbreaks of NDM *E. coli*:

What does this mean to me???

- Aggressive pathogen
- Limited treatment options
- High transmission rates with high infection & mortality rates

**GI Colonization is an issue:**
- *long lasting*
- “Last bug standing” in the gut under antibiotic pressure!
Culture: “Organisms of Concern”?

- **FDA committee (CDC protocol):**
  
  **Any amount of:**
  - Gram negatives (e.g. E.coli, Pseudomonas, etc)
  - Enterococci, S.aureus

  **High amount (> 100 cfu) of:**
  - Low/moderate concern organisms (e.g. Coagulase-Neg Staphyloccoci, Bacillus, Diphtheroids, Micrococcus, viridans Streptococci)

Interim Protocol for Healthcare Facilities Regarding Surveillance for Bacterial Contamination of Duodenoscopes after Reprocessing. CDC March 11, 2015
Reprocessing of reusable medical devices in health service organizations

HEALTH CANADA GUIDANCE DOCUMENT

Information to Be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices

Published by authority of the Minister of Health

Date Adopted 2011/06/01
Effective Date 2011/06/01

AS/NZS 4187:2014
Australian/New Zealand Standard™
Reprocessing of reusable medical devices in health service organizations

Cleaning Validation by Manufacturers: Now a Regulatory Requirement
Infection Control Advisories

Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

Recommendations to sites offering endoscopy:
- Training & ongoing competency assessment
- Audit of compliance with reprocessing protocol
- Infection Control Policies and Procedures

Annex A—Minimizing the Risk of Bacterial Transmission from Patient to Patient When Using Duodenoscopes

October 2016
Verification by Healthcare

- Verify the critical points in Endoscope reprocessing
- What are the problematic steps?
**Table 3. Documented Completion of Steps During Manual Cleaning With High-Level Disinfection Reprocessing**

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<th>Observed Activity</th>
<th>Steps Completed (%) (n = 69)</th>
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<tr>
<td>Leak test performed in clear water</td>
<td>77</td>
</tr>
<tr>
<td>Disassemble endoscope completely</td>
<td>100</td>
</tr>
<tr>
<td>Brush all endoscope channels and components</td>
<td>43</td>
</tr>
<tr>
<td>Immerse endoscope completely in detergent</td>
<td>99</td>
</tr>
<tr>
<td>Immerse components completely in detergent</td>
<td>99</td>
</tr>
<tr>
<td>Flush endoscope with detergent</td>
<td>99</td>
</tr>
<tr>
<td>Rinse endoscope with water</td>
<td>96</td>
</tr>
<tr>
<td>Purge endoscope with air</td>
<td>84</td>
</tr>
<tr>
<td>Load and complete automated cycle for high-level disinfection</td>
<td>100</td>
</tr>
<tr>
<td>Flush endoscope with alcohol</td>
<td>86</td>
</tr>
<tr>
<td>Use forced air to dry endoscope</td>
<td>45</td>
</tr>
<tr>
<td>Wipe down external surfaces before hanging to dry</td>
<td>90</td>
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**All 12 steps completed:**

Manual cleaning & AER for HLD: 1.7%
Endoscope Reprocessing Guideline; Health Canada 2010
Rapid Manual Cleaning Monitors

Endoscope Channel Sample

Organic residuals

ATP: microbes & human secretions

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

This is not an exhaustive list: many different manufacturers

Pictures from company websites
ATP Residuals Post Manual Cleaning of Patient-used Endoscopes

Visrodia KH et al ICHE 2014;35:997-984
Flexible GI Endoscopes: Biofilm

- **Expectation:**
  Biofilm SHOULD NOT form inside dry endoscope channels

- **Reality:**
  Build-up biofilm does form!


2014: SEM showed biofilm in 54.6% of 66 Biopsy channels and 76.9% of 13 Air/water channels Ren-Pei W AJIC 2014; 42:1203-6
Microbe growth in Patient-Ready scopes: Due to Wet Channel

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

~ 50% of scopes had growth

Drying 10 mins:

No detectable microbes at 2, 24 or 48 Hrs

[N=19 scopes]

Stop Dirty Endoscopes at the Cleaning stage!!

- Once disinfected or sterilized residues are fixed → hard to extract and analyze.
- Inadequate cleaning results in residuals (biofilm) that protect bacteria from disinfection/sterilization.
How can Bacteria survive HLD?

Any bacteria (whether multi-antibiotic resistant or sensitive) can survive HLD when in BIOFILM

What Clinical data on Biofilm in Endoscopes are available?
What level of residual “Organisms of concern” remain post-HLD in clinical studies??

P.Saliou et al Endoscopy 2016;48:704-710

<table>
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<tr>
<th>Endoscope type</th>
<th>Number scopes tested</th>
<th>Target: &lt; 25 CFU No Organisms of concern</th>
<th>Alert: 25-100 CFU No Organisms of concern</th>
<th>ACTION: &gt; 100 CFU or: Any Organism of concern</th>
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</thead>
<tbody>
<tr>
<td>Gastroscope</td>
<td>N = 270</td>
<td>68.3%</td>
<td>5.2%</td>
<td>26.6%</td>
</tr>
<tr>
<td>Colonoscope</td>
<td>N = 190</td>
<td>61.1%</td>
<td>5.3%</td>
<td>33.7%</td>
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<tr>
<td>Duodenoscope</td>
<td>N = 118</td>
<td>60.2%</td>
<td>5.1%</td>
<td>34.7%</td>
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**Culture:** Neutralizer & total sample from ALL channels concentrated by filtration

**Scope Age:** older the scope the higher the risk of contamination

**Channel purge storage cabinet:** Significantly lower contamination rates
Drying Endoscope channels

*Ofstead* et al AJIC 2017;45:e26-e33  doi.org/10.1016/j.ajic.2016.10.017

95% of PATIENT-READY Gastoscopes and Colonscopes:
- visible fluid in suction channel after AER alcohol flush with 1 min air drying and vertical storage.

Channel-purge Storage cabinet
- air flushed through channels
- many manufacturers

Dri-scope Aid
- air flushed through channels
Is Ethylene Oxide the Answer?

- Some outbreak sites in USA do HLD followed by Ethylene oxide.
- Culture only for CRE: found 1.2% Carbapenem resistant *K. pneumoniae* (CRE) after HLD followed by Ethylene oxide (1/84 duodenoscopes cultured).

WHAT TO DO...???
**Initial training:**
- clear written protocols
- structured training process
- verified initial competency

**Ongoing Competency:**
- yearly competency assessment
- training on all new scopes acquired
DRY.....DRY......DRY.....!!!

- Alcohol rinse and **adequate** forced air drying is critical prior to storage
- Channel-purge storage cabinets preferred

**Dry channels:**
NO bacterial replication

**Moisture in channels:**
allows bacterial replication → BIOFILM
ENDOSCOPE REPROCESSING: NEW PARADIGM:

- What is the situation in your facility??
- PIDAC 2016: Audit endoscope reprocessing
- Do you have a “game plan” for CRE endoscope outbreak?

Audit
Remember.....if you don’t look ...... you won’t know what risk is at your door step!!