Endoscope Disinfection: New Paradigm

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

Pat DeGagne       Nancy Olson     Michelle Alfa
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<th>Speaker</th>
<th>Advisory</th>
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### CanMEDS Roles Covered

<table>
<thead>
<tr>
<th>Role</th>
<th>Description</th>
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<tr>
<td><strong>Medical Expert</strong></td>
<td>Medical Experts, physicians integrate all of the CanMEDS Roles, applying medical knowledge, clinical skills, and professional values in their provision of high-quality and safe patient-centered care. <em>Medical Expert</em> is the central physician Role in the CanMEDS Framework and defines the physician’s clinical scope of practice.</td>
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<td><strong>Communicator</strong></td>
<td>Communicators, physicians form relationships with patients and their families that facilitate the gathering and sharing of essential information for effective health care.</td>
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<td><strong>Collaborator</strong></td>
<td>Collaborators, physicians work effectively with other health care professionals to provide safe, high-quality, patient-centred care.</td>
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<td><strong>Leader</strong></td>
<td>Leaders, physicians engage with others to contribute to a vision of a high-quality health care system and take responsibility for the delivery of excellent patient care through their activities as clinicians, administrators, scholars, or teachers.</td>
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<tr>
<td><strong>Health Advocate</strong></td>
<td>Health Advocates, physicians contribute their expertise and influence as they work with communities or patient populations to improve health. They work with those they serve to determine and understand needs, speak on behalf of others when required, and support the mobilization of resources to effect change.</td>
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<tr>
<td><strong>Scholar</strong></td>
<td>Scholars, physicians demonstrate a lifelong commitment to excellence in practice through continuous learning and by teaching others, evaluating evidence, and contributing to scholarship.</td>
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<tr>
<td><strong>Professional</strong></td>
<td>Professionals, physicians are committed to the health and well-being of individual patients and society through ethical practice, high personal standards of behaviour, accountability to the profession and society, physician-led regulation, and maintenance of personal health.</td>
</tr>
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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
Relationship of Gastroenterologists to Reprocessing Personnel

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
NE Illinois NDM-\textit{E. coli} Outbreak

Field Investigation (January-July 2013)
9 case patients

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

Duodenoscope A

39.7\% Transmission

Epstein L et al JAMA 2014;312:1447-55

Clinical Cases (September 2013)
2 case patients

- C9
- C10

Duodenoscope C

6.3\% Transmission

20.3\%
Duodenoscope-Related MDRO Outbreaks

- Highlands County (2008-09)
- Wisconsin (2013)
- Lutheran General (2013)
- U of Pitt (2012-13)
- VA Mason (2012-13)
- UCLA (2014-15)
- Cedars-Sinai (2015)

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
Cleaning Validation by Manufacturers: Now a Regulatory Requirement

Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
Guidance for Industry and Food and Drug Administration Staff

Document issued on: March 17, 2015
This document supersedes: “Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance” (available at http://www.fda.gov/...

The Center for Devices and Radiological Health (CDRH) is responsible for ensuring the safety, security, and performance of medical devices regulated by the Food and Drug Administration (FDA)

AS/NZS 4187:2014
Australian/New Zealand Standard™
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

ESGE/ESGENA guideline for process validation and routine testing for reprocessing endoscopes in washer-disinfector, according to the European Standard prEN ISO 15883 parts 1, 4 and 5

Authors
U. Bellenhoff, C. S. Neumann, H. Biering, R. Blum, V. Schmidt, J. F. Rey and the ESGE Guidelines Committee

Institutions
Institutions are listed at the end of the article.
Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

October 2016

Infection Control Advisories

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

- Verify the critical points in Endoscope reprocessing
- What are the problematic steps?
**All 12 steps completed:**

Manual cleaning & AER for HLD: 1.7%

<table>
<thead>
<tr>
<th>Observed Activity</th>
<th>Steps Completed (%) (n = 69)</th>
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<tbody>
<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>
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<tr>
<td>Wipe down external surfaces before hanging to dry</td>
<td>90</td>
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HLD Quality Assurance:

- Sterilization: use CI, BI to monitor cycles
- HLD: use CI to monitor MEC

Endoscopy Reprocessing Guideline; Health Canada 2010
Rapid Manual Cleaning Monitors

Endoscope Channel Sample

Organic residuals
- glucose
- Protein, Carb & Blood

ATP: microbes & human secretions
- Detects ATP

Dectes: 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!

**2004:** Air/Water channel of GI flexible endoscopes  Pajkos et al  J Hosp Infect 2004;58:224-9

**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>
<thead>
<tr>
<th>Endoscope type:</th>
<th>Number scopes tested</th>
<th>Target:</th>
<th>Alert:</th>
<th>ACTION:</th>
</tr>
</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>
</tr>
<tr>
<td>Duodenoscope</td>
<td>N = 118</td>
<td>60.2%</td>
<td>5.1%</td>
<td>34.7%</td>
</tr>
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</table>

**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)
  
  [I.Naryzhny et al  Gastrointestinal Endoscopy 2016; doi 10.1016/j.gie.2016.01.055]
WHAT TO DO...???
STAFF.....STAFF....STAFF.....!!

- **Initial training:**
  - clear written protocols
  - structured training process
  - verified initial competency

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