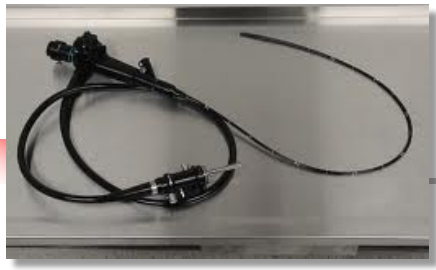
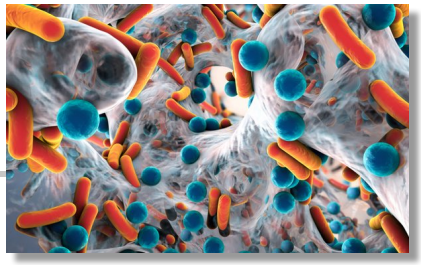
Endoscope Reprocessing: Paradigm Shift





Dr. Michelle J. Alfa, Ph.D., FCCM
Professor, Dept of Medical Microbiology, U of Manitoba, Winnipeg, Manitoba

Hosted by Barbara Catt
Public Health Ontario

www.webbertraining.com **October 10, 2019**

Dr. Michelle Alfa

Disclosures (over past 24 months)

	Speaker	Advisory	Research	Consultant
3M	√	√		√
Healthmark		√	√	√
STERIS			√	
Ruhof	√			
J&J	√	√		√
Olympus	√	√	√	√
Novaflux		√		√
Ambu	√			

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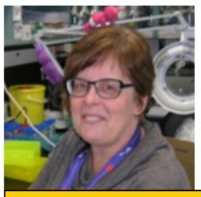
St Boniface Research Centre

Winnipeg, Manitoba Canada



Pat DeGagne Nancy Olson Michelle Alfa

Objectives:

- ***Endoscope Issues:***
  - Infection transmission risk
  - Contamination
- ***Manufacturer's Instructions: Effective?***
- ***FDA Recommendations: Effective?***
- ***Shift to Sterilization***
- ***Summary: what to do?***

All Clipart Pictures in this presentation are from Free Google Images

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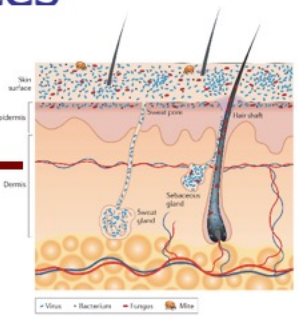
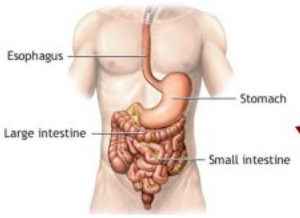
Patient Infections related to Medical Devices

Endogenous: Infections due to patient's own organisms





Exogenous: Infection due to contaminated medical device

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Current Published Data:

- Risk of Infection after endoscopy?
- Contamination of Patient-ready Endoscopes?

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Infection Rates 7 days after Colonoscopy and OGD procedures in Ambulatory Surgery Centres in 2014

Type of Procedure	Number evaluated	Infections/1000 procedures
Screening colonoscopy	462,068	**1.13**
Non-screening colonoscopy	914,140	**1.57**
Osophagogastroduodenoscopy	873,138	**3.04**
Bronchoscopy	30,116	**16.54**
Cystoscopy	68,432	**4.42**
Screening mammogram	647,212	**0.61**

Wang P et al Rates of infection after colonoscopy and osophagogastroduodenoscopy in ambulatory surgery centres in the USA. Gut 2018. (http://dx.doi.org/10.1136/ gutjnl-2017-315308).

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Types of Organisms causing infection

- Drug-resistant microorganisms
- *Escherichia coli*
- *Klebsiella pneumoni*ae
- *Clostridium difficile*
- *Pseudomonas spp.*
- *Staphylococcus spp.*
- *Streptococcus spp.*
- Gram-negative bacteria
- Anaerobes
- Human papillomavirus

Wang P et al Rates of infection after colonoscopy and osophagogastroduodenoscopy in ambulatory surgery centres in the USA. Gut 2018. (http://dx.doi.org/10.1136/ gutjnl-2017-315308).

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Evidence of GI Endoscope Contamination

Rauwers AW et al. Gut 2018 doi: 10.1136/gutjnl-2017-315082

Culture: Neutralizer & sample concentrated by filtration

Organism grown: GI flora	Number of Duodenoscopes	Quantity Range
Yeast	7	6 to 100 CFU
Klebsiella pneumoniae	4	100 to > 100 CFU
Enterobacter cloacae	3	100 to > 100 CFU
Escherichia coli	2	50 to 100 CFU
Klebsiella oxytoca	2	100 to > 100 CFU
Enterococcus faecium	1	1 CFU
Enterococcus faecalis	1	100 CFU
Pseudomonas aeruginosa	1	100 CFU
Staphylococcus aureus	1	> 100 CFU

- **Duodenoscopes: 15% of 155 tested were contaminated**
- **Current reprocessing & process control procedures not adequate**

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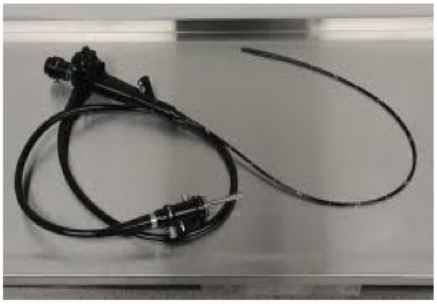
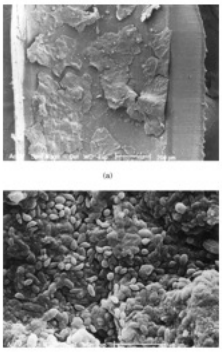
Can current duodenoscope Manufacturer's reprocessing instructions eliminate traditional biofilm?





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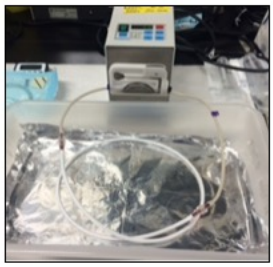
PTFE Biofilm Model (ISO 15883-2005 Annex F)

- Biofilm allowed to form overnight in PTFE channel
- Manufacturer's pump-assisted cleaning combined with liquid chemical sterilization (SS1E)
- Process repeated for 5 times (i.e. 5 consecutive days)
- Optimal culture method



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Five Repeated Rounds of Reprocessing

Test Condition	*E.faecalis* Log_{10} CFU/cm²	*P.aeruginosa* Log_{10} CFU/cm²	Protein ug/cm²
1. **Positive control** No cleaning No AER	7.72 (0.09)	9.10 (0.09)	172.31 (13.30)
2. **Enzymatic Det.** Bristle brush, AER: SS1E	**< LD**	**< LD**	4.60 (0.58)
3. **Enzymatic Det** Pull-through AER: SS1E	**< LD**	**< LD**	2.13 (2.07)
4. **Non Enzymatic** Bristle brush AER: SS1E	**2.24 (0.00)**	**2.24 (0.00)**	5.18 (1.50)
5. **Non Enzymatic** Pull-through AER: SS1E	**0.008 (0.08)**	**0.026 (0.44)**	4.31 (3.14)

Alfa et al 2017 ICHE

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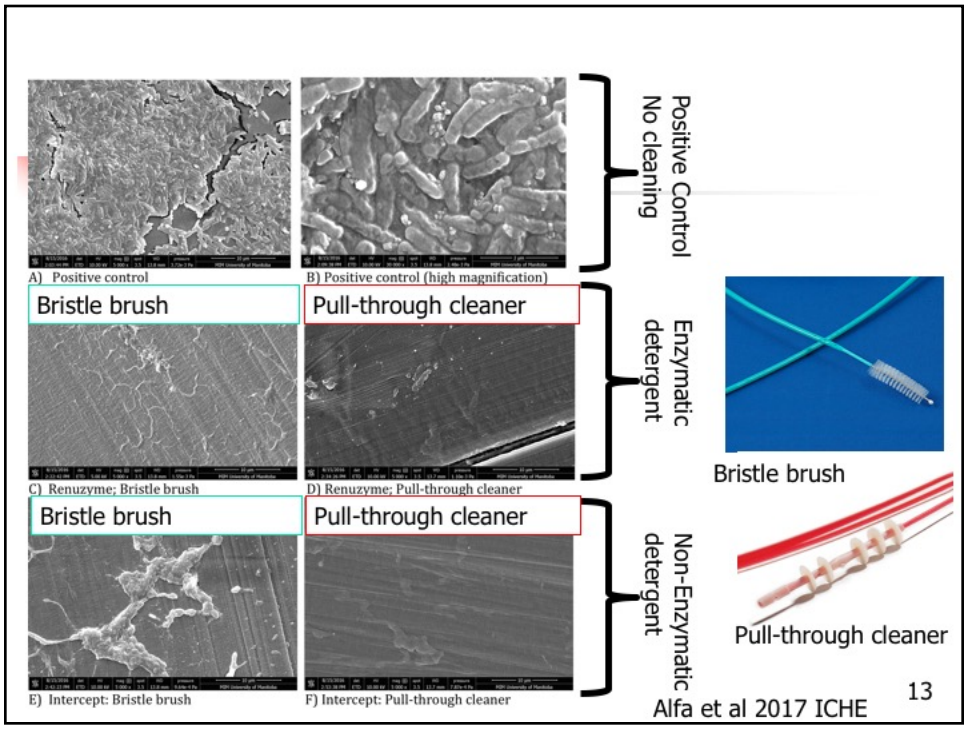
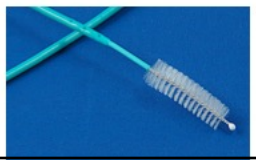


Biofilm Removal: PTFE channels

- **MIFU Cleaning:**
  Friction and detergent affect ability of biofilm bacteria to survive full reprocessing
- **Channel surface cleaning friction:**
  Bristle brush not as effective as pull-through cleaner.



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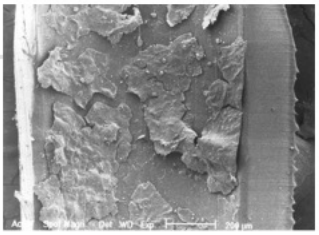
Flexible Endoscopes: Biofilm

- **Expectation:**
  Biofilm SHOULD NOT form inside **dry** endoscope channels
- **Reality:**
  Build-up biofilm does form!



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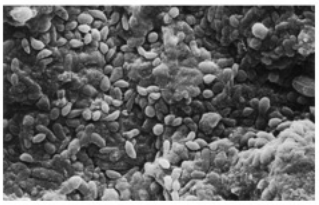

2004: Air/Water channel of GI flexible endoscopes Pajkos et al J Hosp Infect 2004;58:224-9

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

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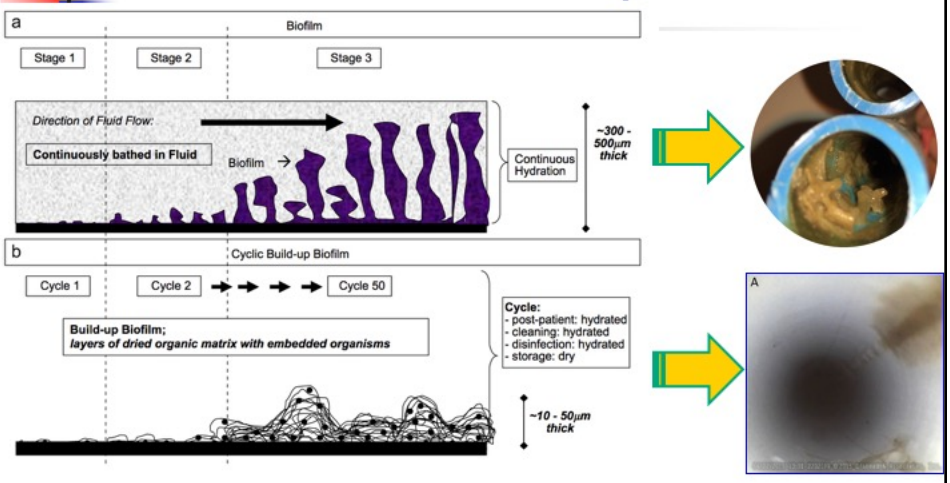
Comparison: Traditional to Buildup Biofilm



Zhong W, **Alfa M**, Howie R, Zelenitksy S.
Simulation of cyclic reprocessing buildup on reused medical devices. Comput Biol Med 2009 Jun; 39(6): 568-577.

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Drying Endoscope channels for Storage

1.Endoscope manufacturer's instructions:
- Endoscopes MUST be dried prior to storage.
- ALL channels: alcohol flush & forced air drying

2.Automated Endoscope Reprocessors (AER)
- many have alcohol flush and drying cycle
- they do NOT claim this dries sufficiently

3.Endoscopy clinic staff:
- Widespread believe that AER cycle adequately dries endoscopes for storage

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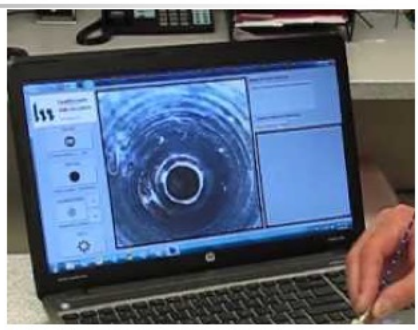
Borescope:
Inspect inner channel of endoscopes



Borescope use for endoscopes recommended by:
AAMI ST91 2015, AORN 2017, IAHCSSM 2017

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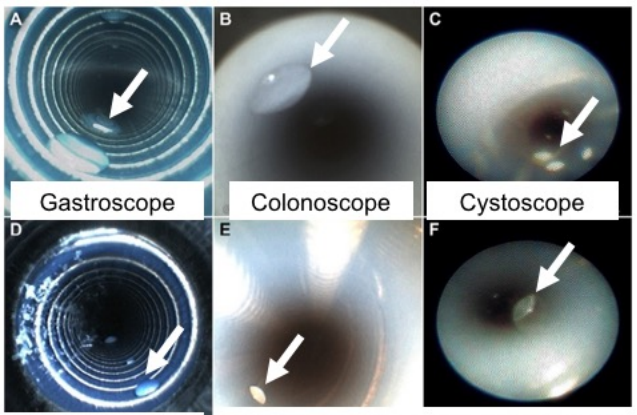
After AER; alcohol flush, 6 min air flush & overnight storage

Ambulatory Clinics: Visible Fluid in 95% Channels
[**Ofstead** et al AJIC 2017;45:e26-e33 doi.org/10.1016/j.ajic.2016.10.017]



Large healthcare systems: Visible fluid in 49% channels
[**Ofstead** et al AJIC 2018;45:e26-e33 doi.org/10.1016/j.ajic.2018.03.002]

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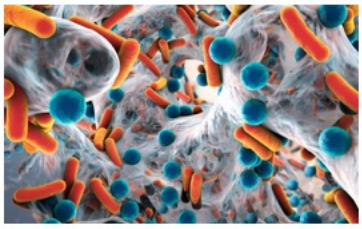
Storage of endoscopes with moisture in Channels

- Much more extensive than recognized
- Leads to Build-up biofilm (BBF)
- Bacterial survival in BBF increases risk of infection transmission.



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Olympus Statement Simethicone use

[June 29, 2018]:

- **Simethicone:** not easily removed by current reprocessing methods
- **Do Not use:** water insoluble lubricants such as Simethicone
- **Can use:** water soluble lubricants such as K/Y jelly, lidocaine jelly for insertion tube
- **If simethicone used** – administer in bowel prep or through Biopsy port

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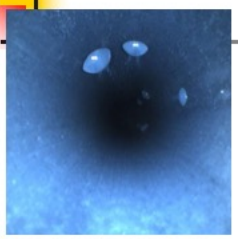
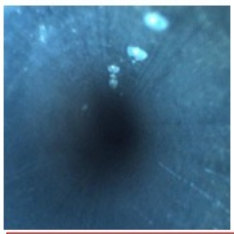
Simethicone retained despite reprocessing

Barak M. et al GIE 2018 10.1016/j.gie.2018.08.012





Simethicone tested at:
0.5%, 1%, 3% in water bottle as well as by biopsy port injection

Despite AER dry PLUS 10 min manual forced air dry:
Residual droplets & simethicone found in patient-used upper GI endoscopes even when used at lowest concentration 0.5%

Authors question clinical significance of simethicone residuals & suggested 2 x AER

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Winnipeg banned the use of Simethicone in endoscopes [Aug 20, 2018]

However… 10% more polyps identified with simethicone in water bottle versus without.

Kutyla et al Influence of Simethicone Added to the Rinse Water during Colonoscopies on Polyp Detection Rates: Results of an Unintended Cohort Study. Digestion 2018;98:217–221

ECRI report 2018 Aug 17, 2018:
Each site needs to decide whether to ban simethicone in endoscopes or not

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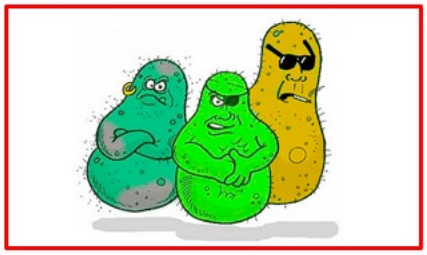
Take Home Message: DRY…..DRY……DRY….!!!

Ofstead 2017:
Humidicator strips correlate with borescope test for residual fluid

Dry channels:
NO bacterial replication



Moisture in channels:
Bacterial replication → BIOFILM

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Channel-purge Storage cabinets
- HEPA filtered or medical grade air flushed through all channels
- many manufacturers

Wassenburg Medical

ARC Healthcare Solutions

Commonly used in Europe but NOT commonly used in North America

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Small air-flushing pumps:
facilitate drying before storage

Air-Time Channel dryer

Tri-Core Systems Inc

Fujinon

Images from Manufacturer's website

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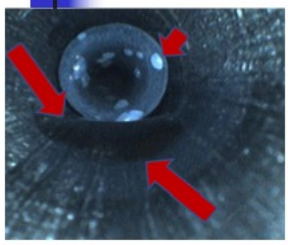
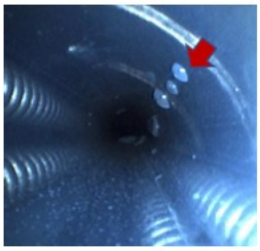
Automated vs Manual Drying:

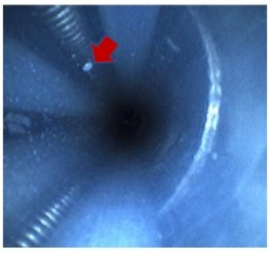
Barakat et al GIE 2018, doi: 10.1016/j.gie.2018.08.033



After AER alcohol flush and 1 min air dry



After AER alcohol flush and 1 min air dry and; ***10 min manual dry*** with forced air



After AER alcohol flush and 1 min air dry and; ***5 min DriScope drying***

Virtually no retained fluid after 10 min DriScope drying

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What more can happen.....?

- FDA supplemental recommendations
- Switch to sterilization of ALL endoscopes

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Current Situation:

- Supplementary Reprocessing Recommendations from FDA (2015)
  - Are these four recommendations effective?
- Transition to sterilization:
  - Limited options
- Widespread confusion!!

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FDA supplementary recommendations [August 4, 2015]

- Microbiological Culturing
- Ethylene Oxide Sterilization after High Level Disinfection
- Use of a Liquid Chemical Sterilant Processing System after High Level Disinfection
- High-Level Disinfection done twice

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Culture of Endoscopes:

Feb 2018: FDA/CDC/ASM Duodenoscope surveillance sampling and culturing: Reducing the risk of infection

- Friction during sample collection
- Neutralizer to protect damaged bacteria and stimulate them to grow
- Concentration of entire sample (e.g. filtration)

https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/UCM597949.pdf

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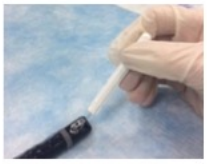
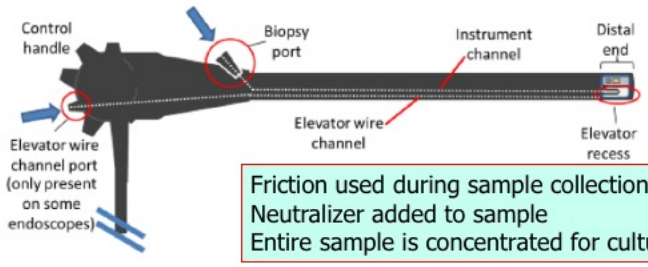
FDA/CDC/ASM Protocol

- **One combined sample collected from:**
  - Elevator recess (flush-brush-flush)
  - Instrument channel (flush-brush-flush)
  - Elevator wire channel (if unsealed)

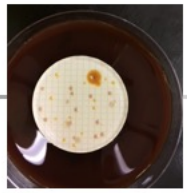




Friction used during sample collection
Neutralizer added to sample
Entire sample is concentrated for culture

Validated by Olympus, Pentax, Fujinon; 65% - 100% extraction efficacy

Implementation of Endoscope Culture



- **USA[1]:** 53.4% culture duodenoscopes
  Canada: Not yet widely implemented
- **FDA post-market clinical study: duodenoscope culture using FDA/CDC/ASM April 2018 method:**
  - ***Assumption***: right after HLD < 0.4% contamination
  - ***April 12, 2019 FDA report: Post HLD***
    - 3.6% contained > 100 CFU low concern organisms
    - 5.4% contained High concern organisms (E.coli, Pseudomonas etc)

[1]Thaker A et al Duodenoscope reprocessing practice patterns in USA endoscopy centers: a survey study. GIE 2018 https://doi.org/10.1016/j.gie.2018.04.2340)

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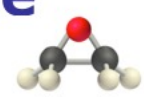
HLD followed by Ethylene Oxide Sterilization:

Turn around time > 24 Hrs



Ethylene oxide

Naryzhny et al GIE 2016: Outbreak site
Carbapenem Resistant *E.coli* still found in 1/84 duodenoscopes

Snyder et al Gastroenterology 2017:
Contamination: HLD alone = 16.1%, HLD plus EO = 22.5%
[No significant difference]

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EO Sterilization Approach:

Failure if organic/salts residuals remain

Test:	Residual bacteria Log_{10} CFU/lumen (SD) Exposed to 100% Ethylene oxide sterilization	
	Enterococcus faecalis	***Bacillus subtilis spores***
Positive control	6.76 (0.13)	6.13 (0.13)
Tissue culture media + 10% serum	2.67 (0.13)	3.60 (0.34)

Alfa et al *Comparison of liquid chemical sterilization with peracetic acid and ethylene oxide sterilization for long narrow lumens* (AJIC 1998;26:469-77)

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Implementation of EO

USA[1]: 12.0 % have adopted this approach

Canada: Not widely implemented

[1]Thaker A et al Duodenoscope reprocessing practice patterns in USA endoscopy centers: a survey study. GIE 2018 https://doi.org/10.1016/j.gie.2018.04.2340)

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HLD followed by Liquid Chemical Sterilization:

Turn around time ~ 60 mins

No published data

- drying before storage is a major concern as biofilm will form if channels are wet

Note: FDA no longer recommends this approach

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High Level Disinfection (HLD) done two times:

- ***Visrodia*** et al GIE 2017
  Persistent regrowth of same organism:
  K. pneumoniae, P.aeruginosa, S.maltophilia

- ***Bartels*** et al GIE 2018
  Presistent regrowth of same organism: *E.coli*
  No improvement using HLD x 2 versus HLD x 1

- ***Snyder*** et al Gastroenterology 2017
  Contamination the same using HLD x 2 versus HLD x 1

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Implementation of HLD x 2

USA[1]: 63.1% have adopted this approach

Canada: not widely implemented

NOTE: Adequate drying after HLD X 2 is still needed

[1] Thaker A et al Duodenoscope reprocessing practice patterns in USA endoscopy centers: a survey study. GIE 2018 https://doi.org/10.1016/j.gie.2018.04.2340)

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New Low Temperature Sterilization: Sterizone VP4

Turn-around-time ~ 1 Hr

- *H_2O_2 + Ozone*
- *Mixed loads*

FDA cleared for many endoscope lumen dimensions (duodenoscopes?). Limited published data

Vanessa Molloy-Simard et al *Elevating the standard of endoscope processing: Terminal sterilization of duodenoscopes using a hydrogen peroxide–ozone sterilizer. AJIC 2019;47:243-250*]

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Shift to Sterilization of Flexible Endoscopes

- **AAMI ST91 committee meeting Oct 2017**
  - accepted that this recommendation will be in the 2019 revision of AAMI ST91 Endoscope Reprocessing guideline

  [***This guideline has not yet been released***]
- **Transition period once AAMI ST91 released**
- **Many USA & Canadian sites already sterilize bronchoscopes, cystoscopes, ureteroscopes**

ANSI/AAMI ST91:2015 Flexible and semi-rigid endoscope processing in health care facilities

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Shift to Sterilization of Flexible Endoscopes

- **FDA Ethylene Oxide (ETO) Advisory Panel meeting Nov 2019**
  - Illinois EPA ordered closure of commercial High-capacity ETO sterilization company
  - Low temperature sterilization of duodenoscopes

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Key Take Home Messages:

- Endoscope contamination: 9% to 15%
- MIFU issues:
  - HLD & Sterilization failure if Biofilm & BBF present
  - Simethicone – not reliably removed by current MIFU
- Wet Storage is widespread → biofilm
- FDA Supplementary recommendations
  - double reprocessing; no more effective than single reprocessing
- Shift to sterilization: limited options

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WHAT TO DO…???

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ENDOSCOPE REPROCESSING: *NEW PARADIGM*

- ***What is the situation in your facility??***
- **Specific Audit with Data:**
  - **Test:** efficacy of manual cleaning
  - **Test:** Dry Storage
  - **Test:** Culture of endoscopes

Audit

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Endoscope Reprocessing: Paradigm Shift!

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Endoscope Reprocessing: Paradigm Shift
Dr. Michelle Alfa, University of Manitoba
A Webber Training Teleclass

www.webbertraining.com/schedulep1.php	
October 16, 2019	*(South Pacific Teleclass)* SELF-REPORTED BEHAVIORS AND PERCEPTIONS OF AUSTRALIAN PARAMEDICS IN RELATION TO HAND HYGIENE AND GLOVING PRACTICES IN PARAMEDIC-LED HEALTHCARE Speaker: **Prof. Nigel Barr**, University of the Sunshine Coast, Australia
October 24, 2019	INFECTION CONTROL ISSUES IN HEALTHCARE CONSTRUCTION, PART 2 – NEW BUILDS Speaker: **Andrew Streifel**, University of Minnesota
November 7, 2019	HEALTHCARE-ASSOCIATED PNEUMONIA THAT IS NOT VENTILATOR-ASSOCIATED: BIG PROBLEM, BUT GUIDELINE-FREE ZONE Speaker: **Martin Kiernan**, University of West London
November 12, 2019	*(FREE European Teleclass)* THE ROLE OF CLEANERS IN INFECTION PREVENTION - NEGLECTED FRONT LINE WORKERS IN HEALTHCARE FACILITIES Speaker: **Prof. Wendy Graham**, London School of Hygiene & Tropical Medicine, and **Claire Kilpatrick**, The Soapbox Collaborative ***Sponsored by the World Surgical Infection Society*** WSIS

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