

Endoscope Disinfection: New Paradigm



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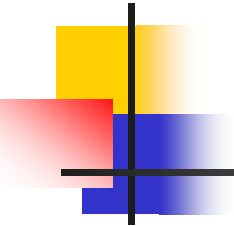
Nancy Olson



Michelle Alfa

Dr. Michelle Alfa

Financial Disclosures (over past 24 months)



	Speaker	Advisory	Research	Consultant
3M	√	√	√	√
Healthmark		√	√	√
STERIS			√	
Ruhof	√			
KARL STORZ			√	√
Olympus	√	√	√	√
Novaflux		√		√

CanMEDS Roles Covered

✓	Medical Expert (as <i>Medical Experts</i> , 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. <i>Medical Expert</i> is the central physician Role in the CanMEDS Framework and defines the physician's clinical scope of practice.)
	Communicator (as <i>Communicators</i> , physicians form relationships with patients and their families that facilitate the gathering and sharing of essential information for effective health care.)
✓	Collaborator (as <i>Collaborators</i> , physicians work effectively with other health care professionals to provide safe, high-quality, patient-centred care.)
✓	Leader (as <i>Leaders</i> , 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.)
✓	Health Advocate (as <i>Health Advocates</i> , 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.)
✓	Scholar (as <i>Scholars</i> , physicians demonstrate a lifelong commitment to excellence in practice through continuous learning and by teaching others, evaluating evidence, and contributing to scholarship.)
✓	Professional (as <i>Professionals</i> , 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.)

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

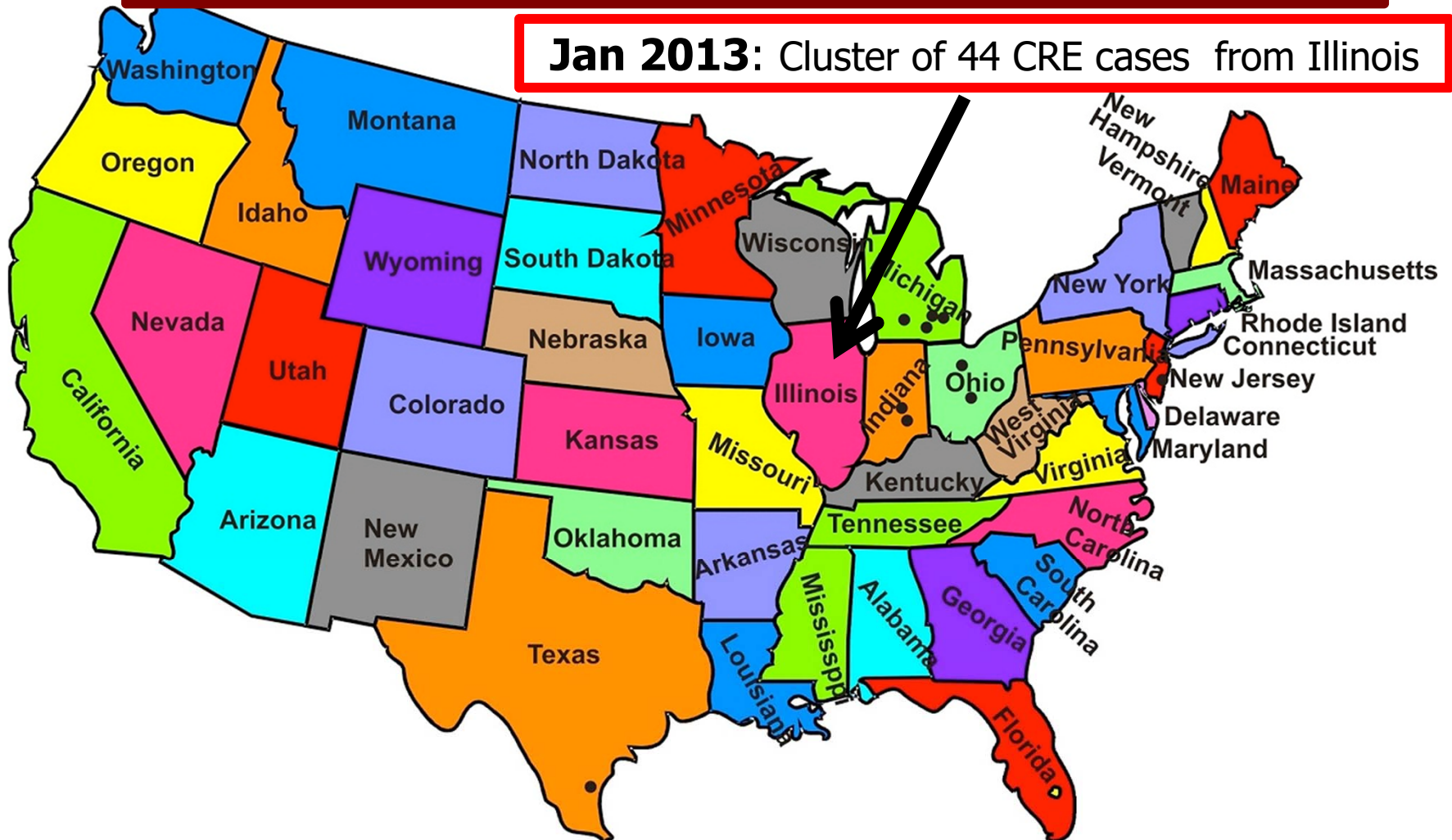


Gastroenterologists trust that the endoscope provided to them is safe to use (reasonable expectation).

USA:

- First isolate of Carbapenem Resistant Enterobacteriaceae (CRE) in 2009
- Only 29 isolates of CRE up until Dec 2012

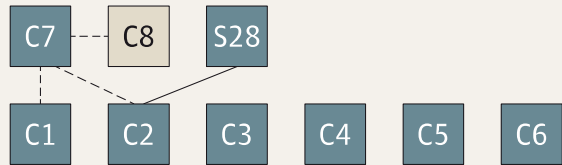
Jan 2013: Cluster of 44 CRE cases from Illinois



NE Illinois NDM-*E.coli* Outbreak

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

Field Investigation (January-July 2013)
9 case patients



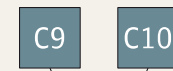
Duodenoscope A

39.7% Transmission

Duodenoscope B

6.3% Transmission

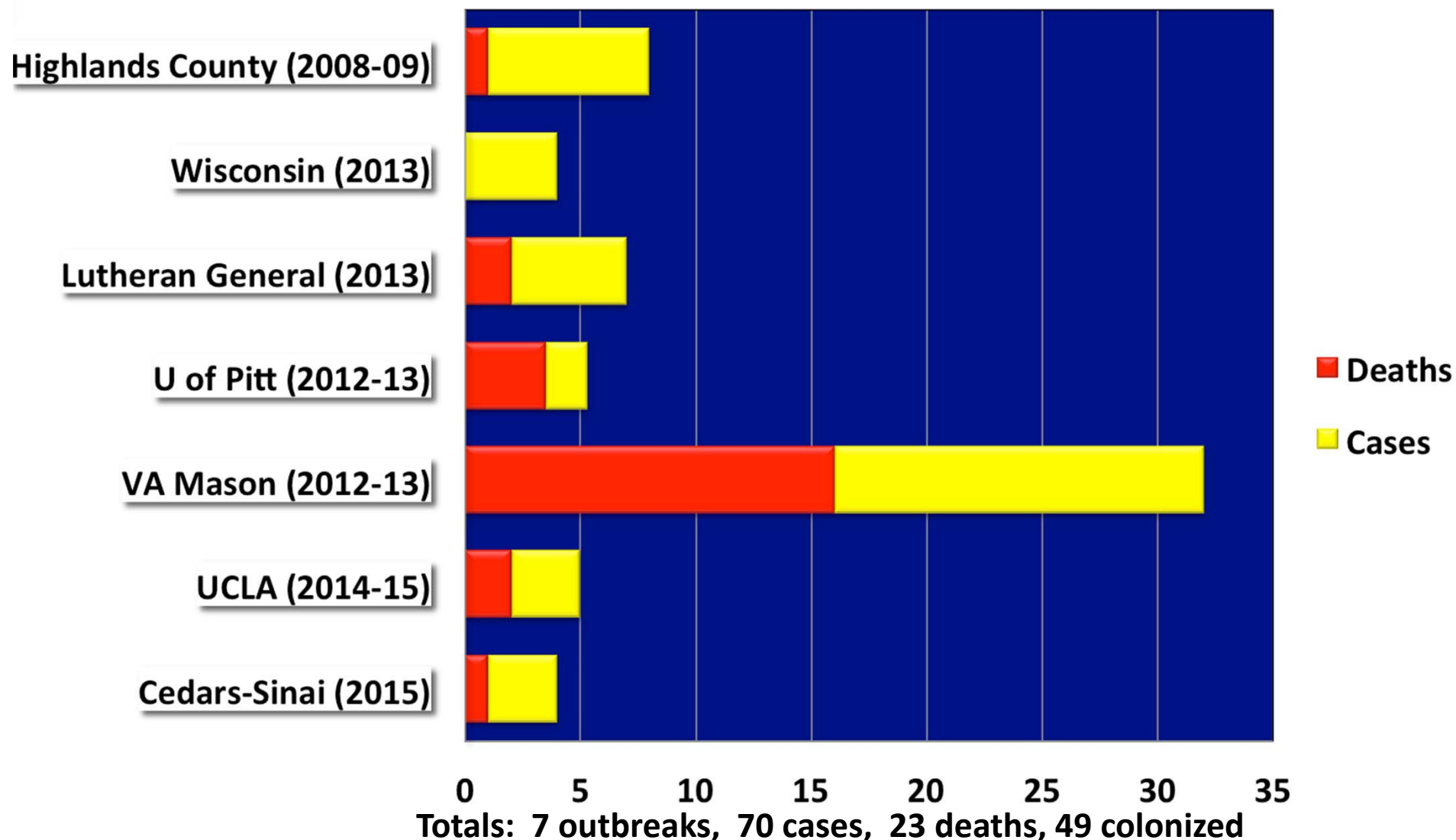
Clinical Cases (September 2013)
2 case patients



Duodenoscope C

20.3%

Duodenoscope-Related MDRO Outbreaks

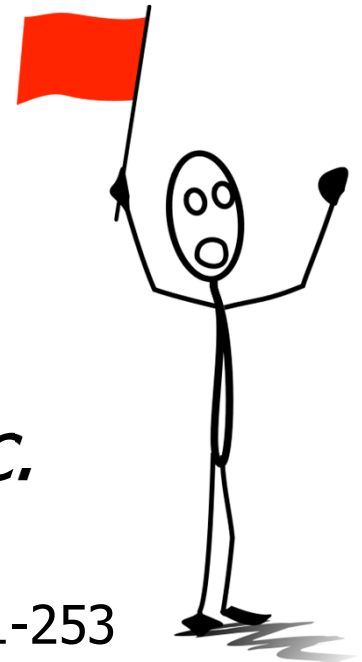


Slide courtesy of Dr. David Lichtenstein, Boston University Medical Centre

Why are we detecting these outbreaks now??

■ Invasive infection with bacteria having unusual antibiotic resistance:

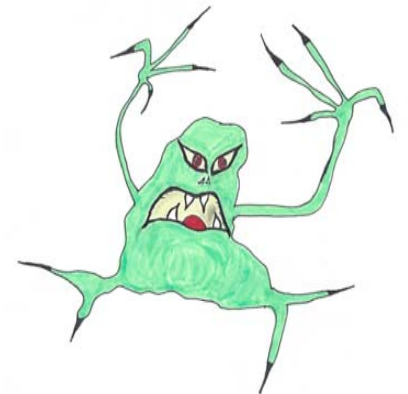
- Carbapenem Resistant Enterobacteriaceae (CRE): *Klebsiella pneumoniae*
- New Delhi Metallo-beta-lactamase (NDM) *Escherichia coli*
- Multi-drug resistant *Pseudomonas aeruginosa*, *E.coli* etc.



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!*

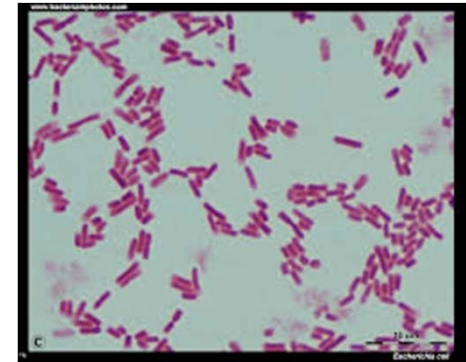


Culture: “Organisms of Concern”?

- **FDA committee (CDC protocol):**

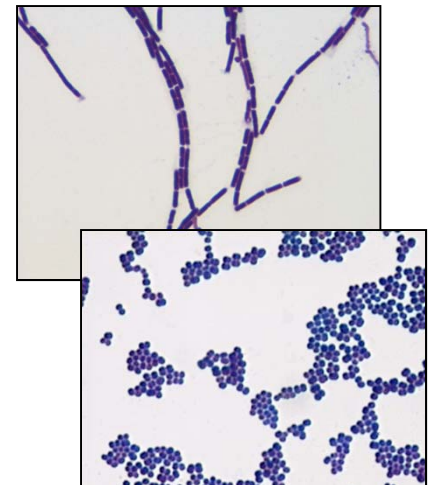
- Any amount of:**

- *Gram negatives (e.g. E.coli, Pseudomonas, etc)*
 - *Enterococci, S.aureus*



- High amount (> 100 cfu) of:**

- *Low/moderate concern organisms (e.g. Coagulase-Neg Staphylococci, 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/oc/guidance>

The document

For questions regarding
contact the Infection
devices regulated by
Office of Communication



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

Reprocessing of reusable
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-disinfectors, according to the
European Standard prEN ISO 15883 parts 1, 4 and 5



Authors

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Institutions

Institutions are listed at the end of article.

Infection Control Advisories

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



Centers for Disease
Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

This is an official CDC HEALTH ADVISORY
Distributed via the CDC Health Alert Network September 11, 2015, 12:15 EDT
(12:15 PM EDT) CDCHAN-00382

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PARTENAIRES POUR LA SANTÉ

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

October 2016

PIDAC

Provincial
Infectious Diseases
Advisory Committee

Infection Prevention and Control

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??



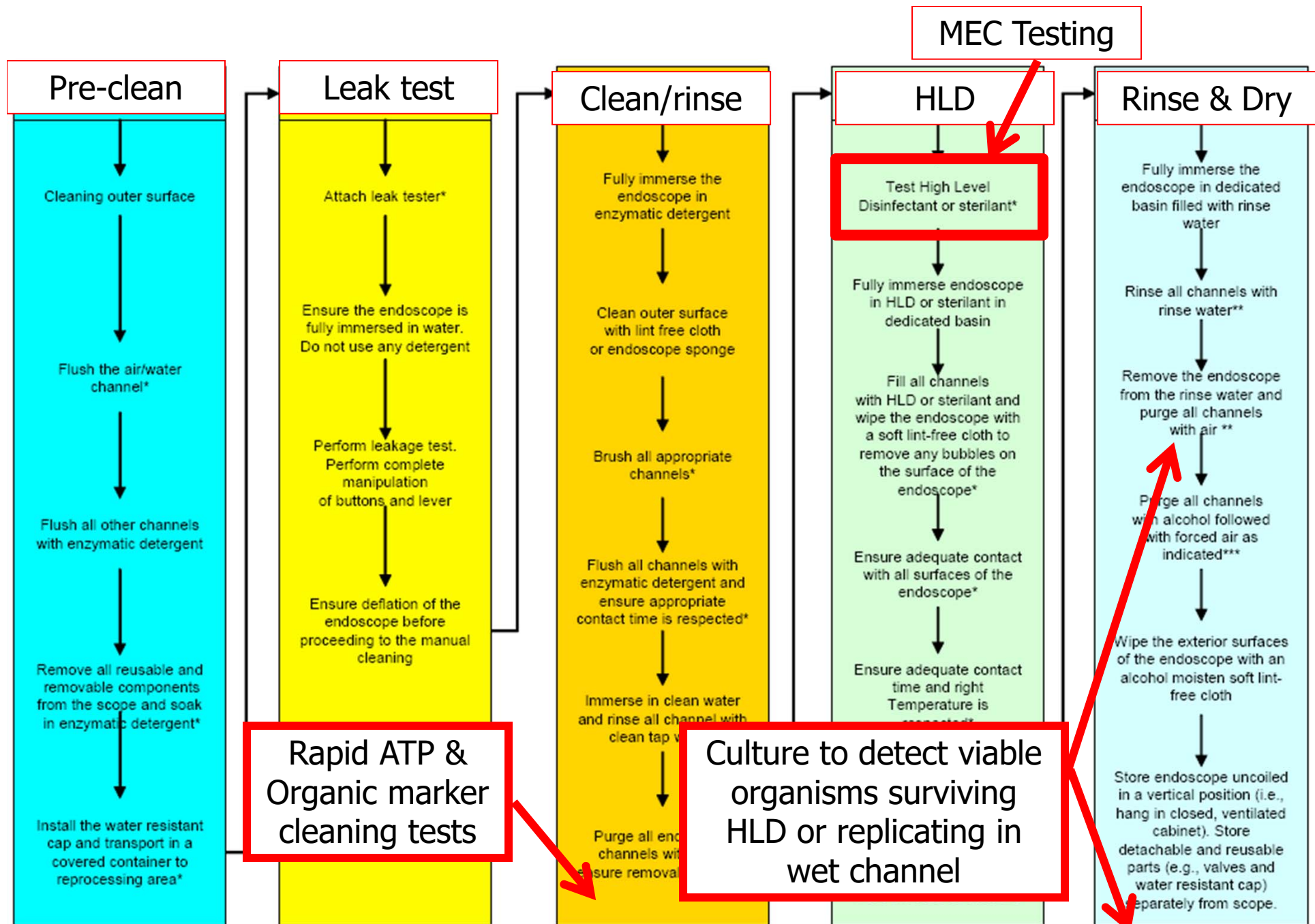
Ofstead C et al Gastroenterology
Nursing 2010 33:304-311

All 12 steps completed:

Manual cleaning & AER for HLD:
1.7%

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

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



Endoscope Reprocessing Guideline; Health Canada 2010

Rapid Manual Cleaning Monitors



**Endoscope
Channel Sample**

Organic residuals



Protein, Carb & Blood

glucose



protein

***Detects: Carbohydrate, protein,
hemoglobin (individually or together)***

ATP: microbes & human secretions

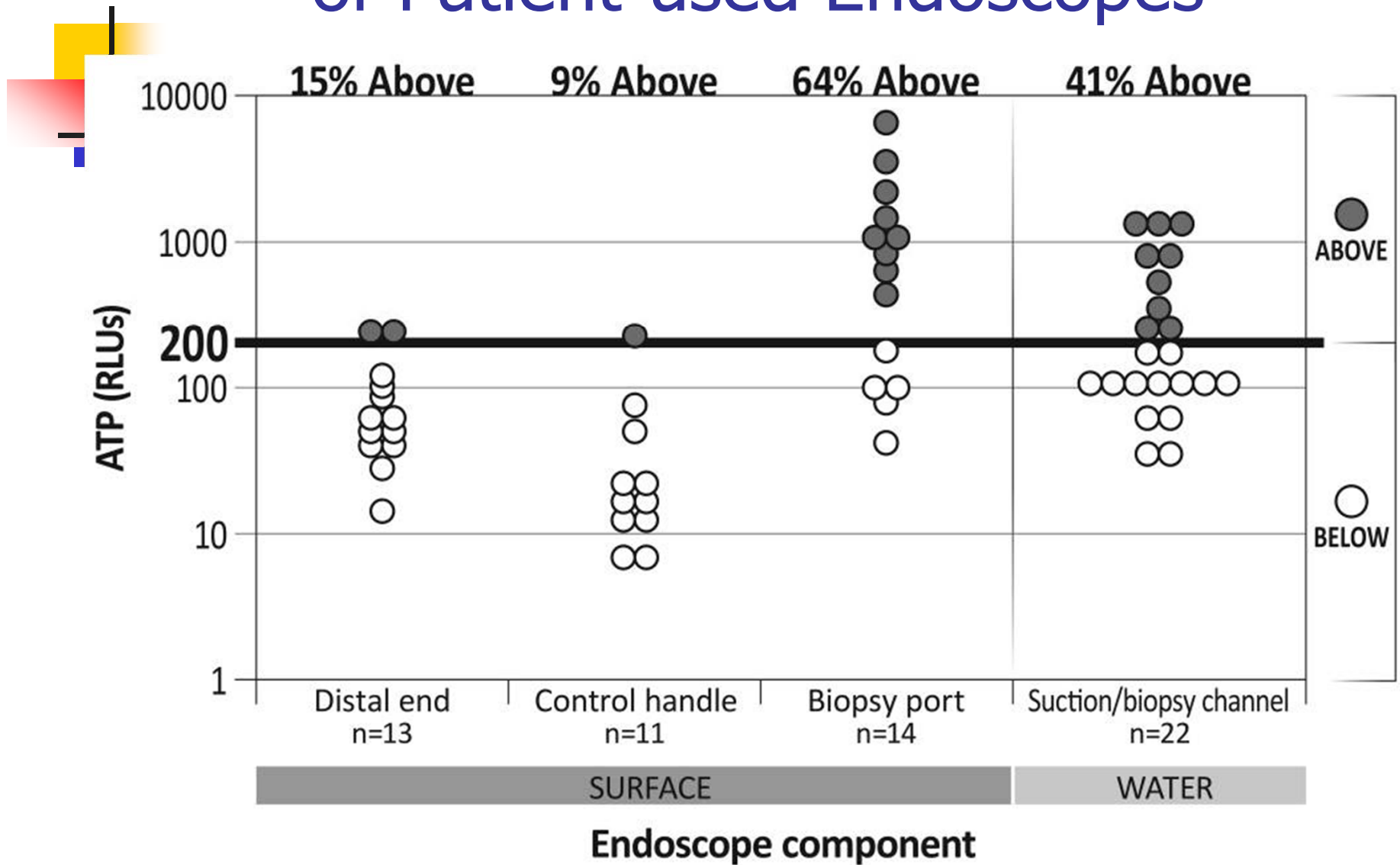


Detects ATP

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

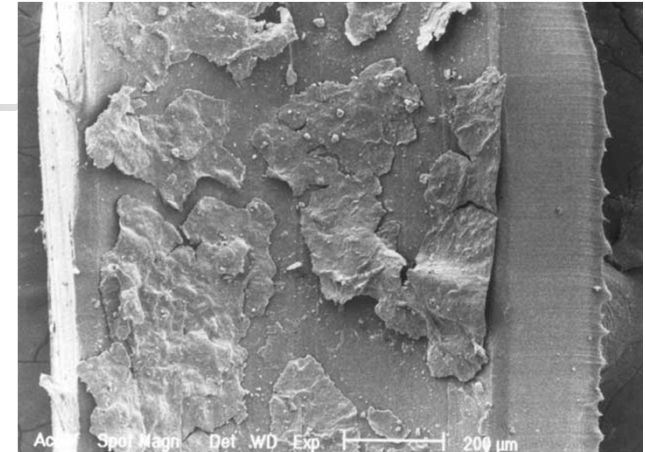
Flexible GI Endoscopes: Biofilm

- **Expectation:**

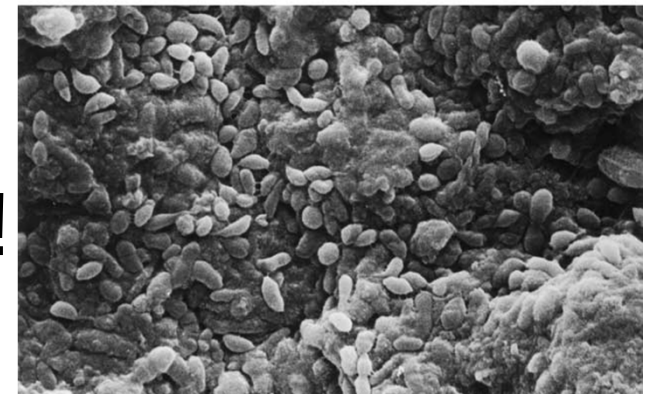
Biofilm SHOULD NOT form inside dry endoscope channels

- **Reality:**

Build-up biofilm does form!



(a)

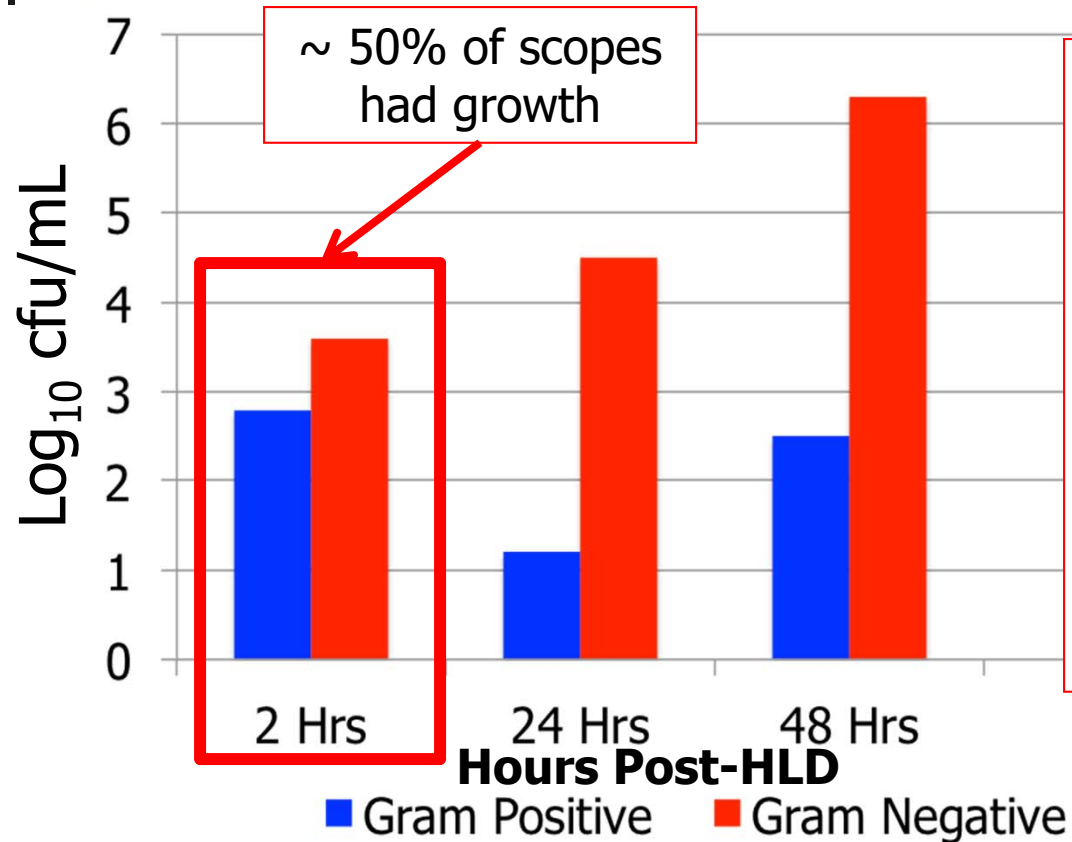


2004: Air/Water channel of GI flexible endoscopes Pajkos et al J Hosp Infect 2004;58:224-9

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

[Alfa MJ & Sitter D 1991 J Hosp Infect.]



Drying 10 mins:

No detectable microbes at 2, 24 or 48 Hrs

[N=19 scopes]

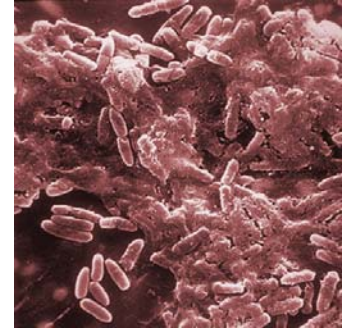
Scopes tested: 2 Hrs: N=12, 24 Hrs: N=15, 48 Hrs: N=15

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

Endoscope type:	Number scopes tested	Target: < 25 CFU No Organisms of concern	Alert: 25-100 CFU No Organisms of concern	ACTION: ≥ 100 CFU or: Any Organism of concern
Gastroscope	N = 270	68.3%	5.2%	26.6%
Colonoscope	N = 190	61.1%	5.3%	33.7%
Duodenoscope	N = 118	60.2%	5.1%	34.7%

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 Colonoscopes:

- visible fluid in suction channel after AER alcohol flush with 1 min air drying and vertical storage.



Channel-purge Storage cabinet

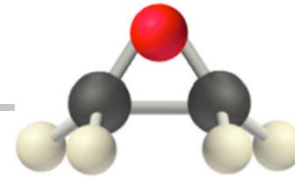
- air flushed through channels
- many manufacturers



Dri-scope Aid

- air flushed through channels

Is Ethylene Oxide the Answer?



Ethylene oxide

- 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

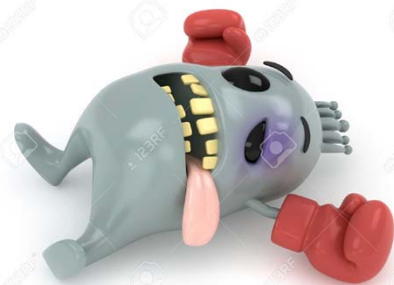


- ***Ongoing Competency:***

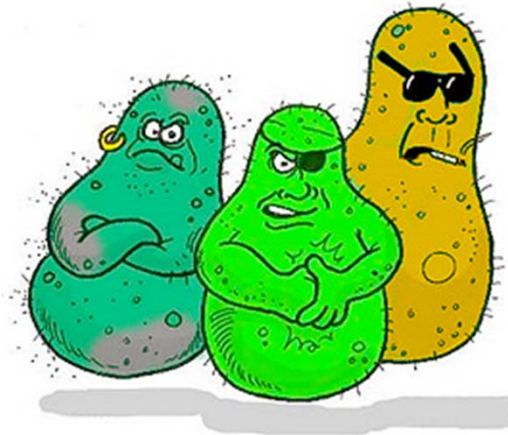
- yearly competency assessment
- training on all new scopes acquired

DRY.....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!!

