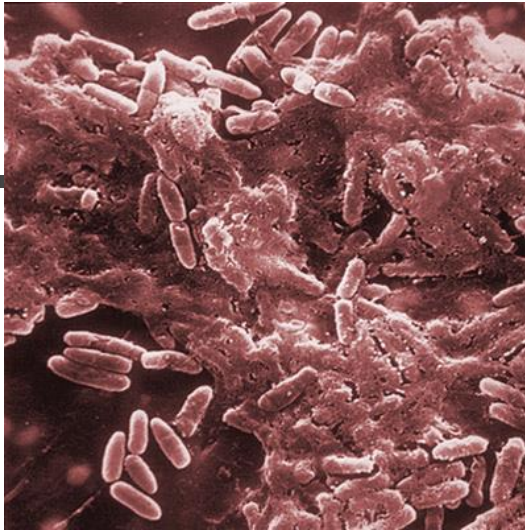


Dissecting Outbreaks of Multi-drug resistant organisms in GI Endoscopy



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St Boniface Research Centre

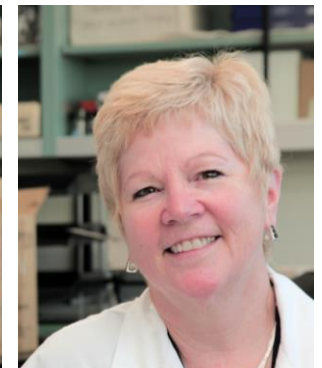
Winnipeg, Manitoba Canada



Pat DeGagne



Nancy Olson



Michelle Alfa

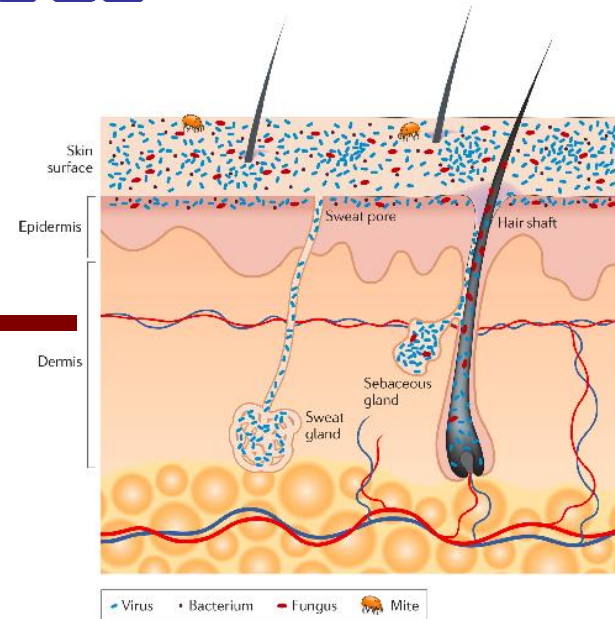
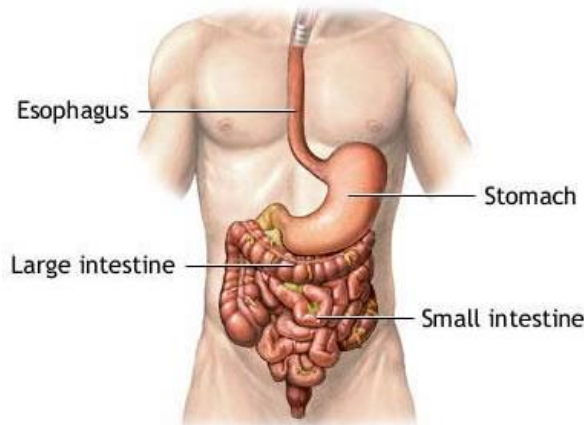
Objectives:



- **Infection transmission by GI endoscopes**
 - Recent data from Europe and USA
- **Dissection of “what went wrong?”:**
 - Contamination of flexible GI endoscopes
- **How to reduce risk of outbreaks:**
 - Flexible GI endoscopes

Patient Infections related to Medical Devices

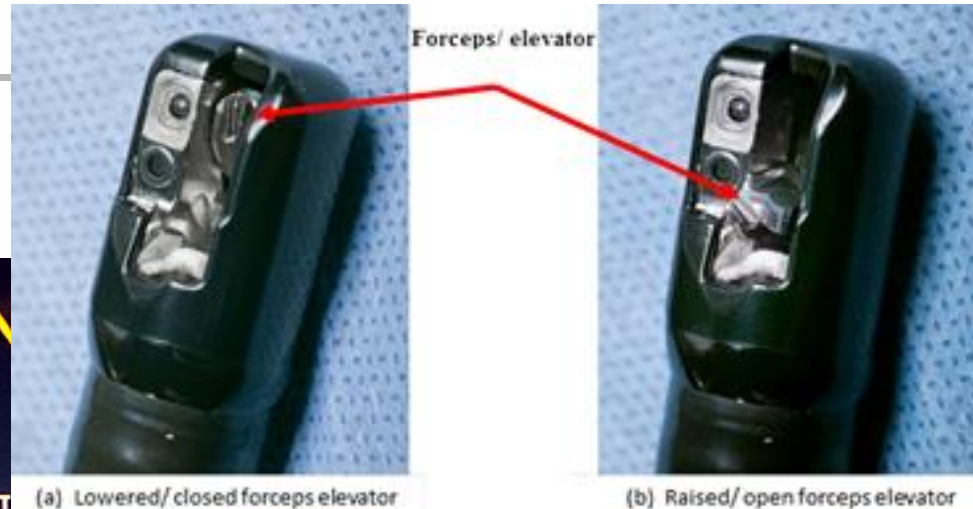
Endogenous: Infections due to patient's own organisms



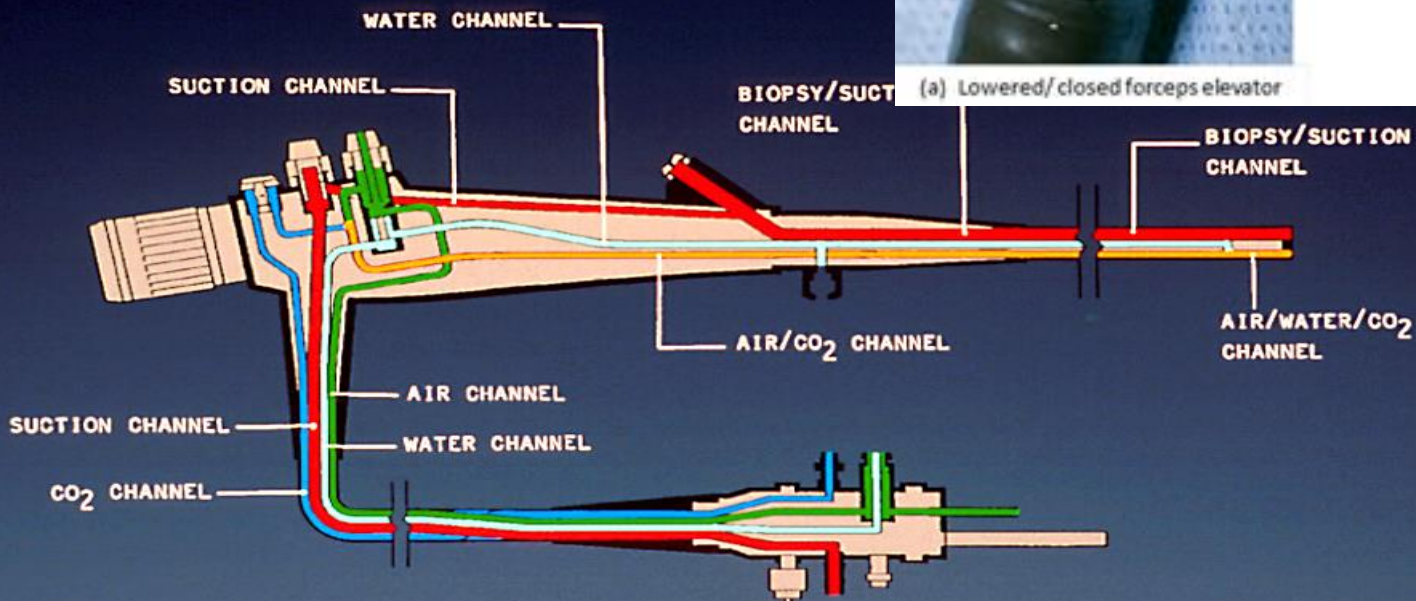
Exogenous: Infection due to contaminated medical device



Duodenoscope: Complex design



ENDOSCOPE CHANNEL



Are Endoscopes a Patient Safety Problem??

- Guidelines indicate the risk of infection transmission due to endoscopes is very rare (1 in 1.8 million endoscopies).



HOWEVER.....

- Outbreaks associated with medical devices have high transmission rates:
 - ***Flexible endoscopes: multi-antibiotic resistant bacteria***

Outbreak: France 2010

Carbonne A et al Control of multi-hospital outbreak of KPC-producing *K. pneumoniae* type 2 in France. Euro Surveill 2010;15(48)pli=19734



The strain of *K.pneumoniae* was multi-resistant

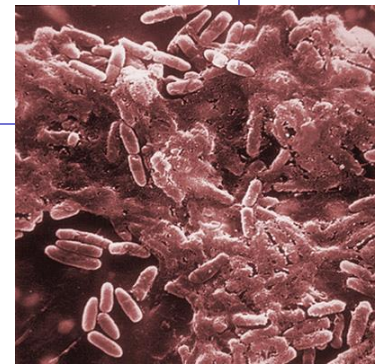
K.pneumoniae transmission by Duodenoscope

Case:	Date of duodenoscopy	Specimen	Infection/colonization	Outcome
2	Aug 29	Blood	Infection	Death (<i>unrelated to K.pneumoniae</i>)
3	Sept 14	Blood	Infection	Death (<i>unrelated to K.pneumoniae</i>)

Key Conclusions

- Endoscope cultures grew *K.pneumoniae*
- Not all transmissions resulted in infections (41% transmission rate)
- Cleaning and disinfection (Peracetic acid) done properly
- **Drying inadequate**
- *K.pneumoniae* survived multiple rounds of cleaning and HLD [? Biofilm]

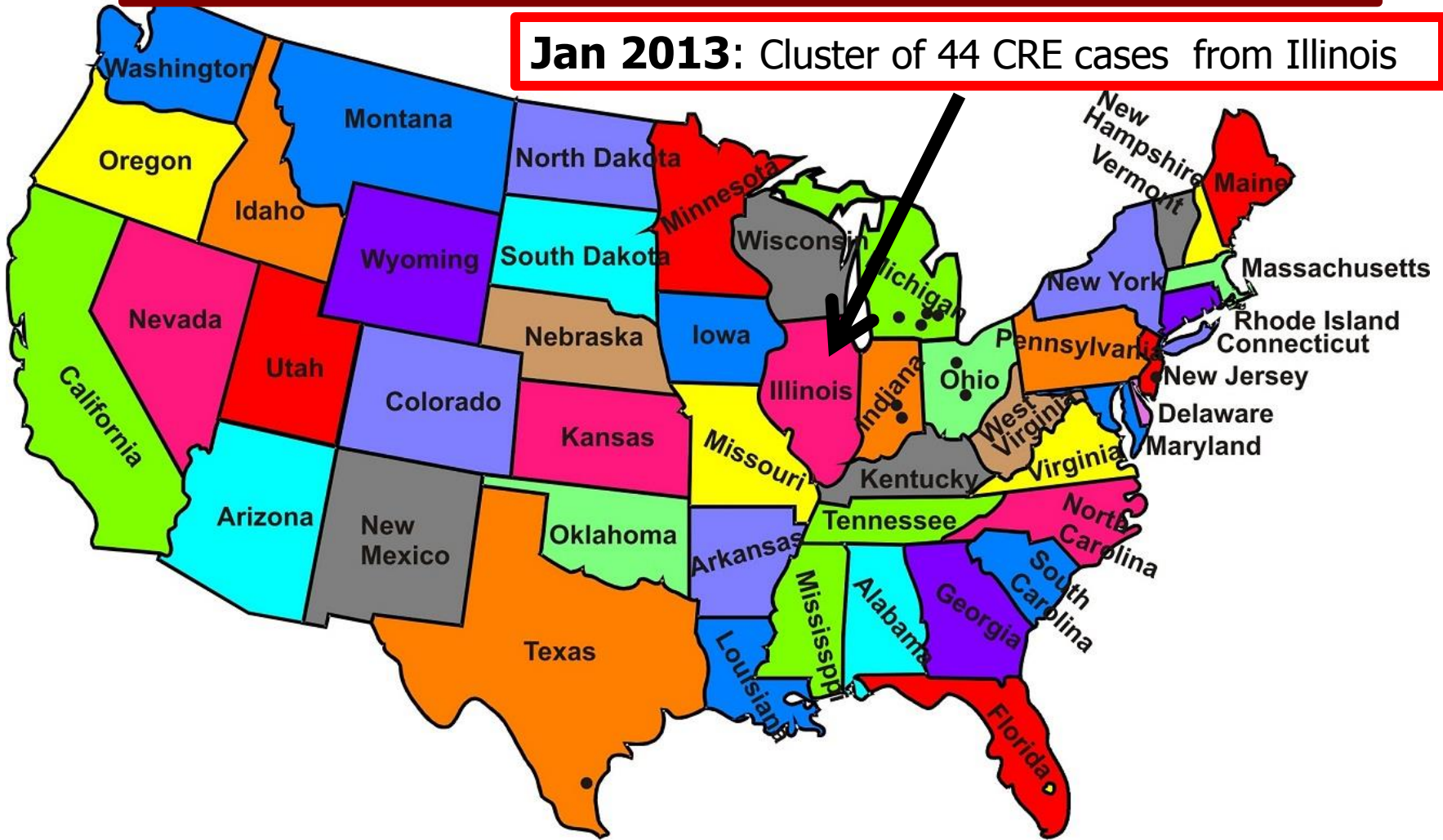
Carbonne A et al Control of multi-hospital outbreak of KPC-producing *K. pneumoniae* type 2 in France. Euro Surveill 2010;15(48)pli=19734



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



Notes from the Field

New Delhi Metallo- β -Lactamase–Producing *Escherichia coli* Associated with Endoscopic Retrograde Cholangiopancreatography — Illinois, 2013

Centers for Disease Control and Prevention (CDC). MMWR Morb Mortal Wkly Rep 2014; 62: 1051 [PMID: 24381080]

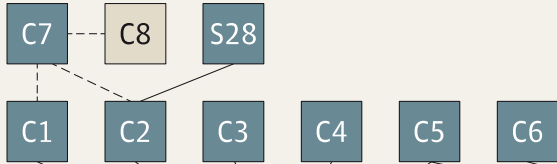


- First and largest U.S. outbreak with CRE (NDM-1 producing carbapenem-resistant *E. coli*) from a contaminated duodenoscope
- Occurred at Advocate Lutheran General Hospital (650-bed teaching hospital) in the suburbs of Chicago, IL; USA
- Incident patient with Alzheimer's disease, failure to thrive underwent ERCP 1/28/13, removal of stones, and stent placement followed by uncomplicated UTI 3/26/13

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



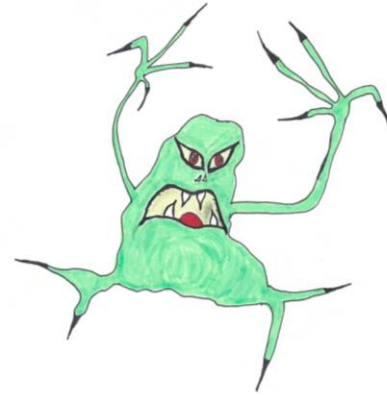
Duodenoscope C

20.3%

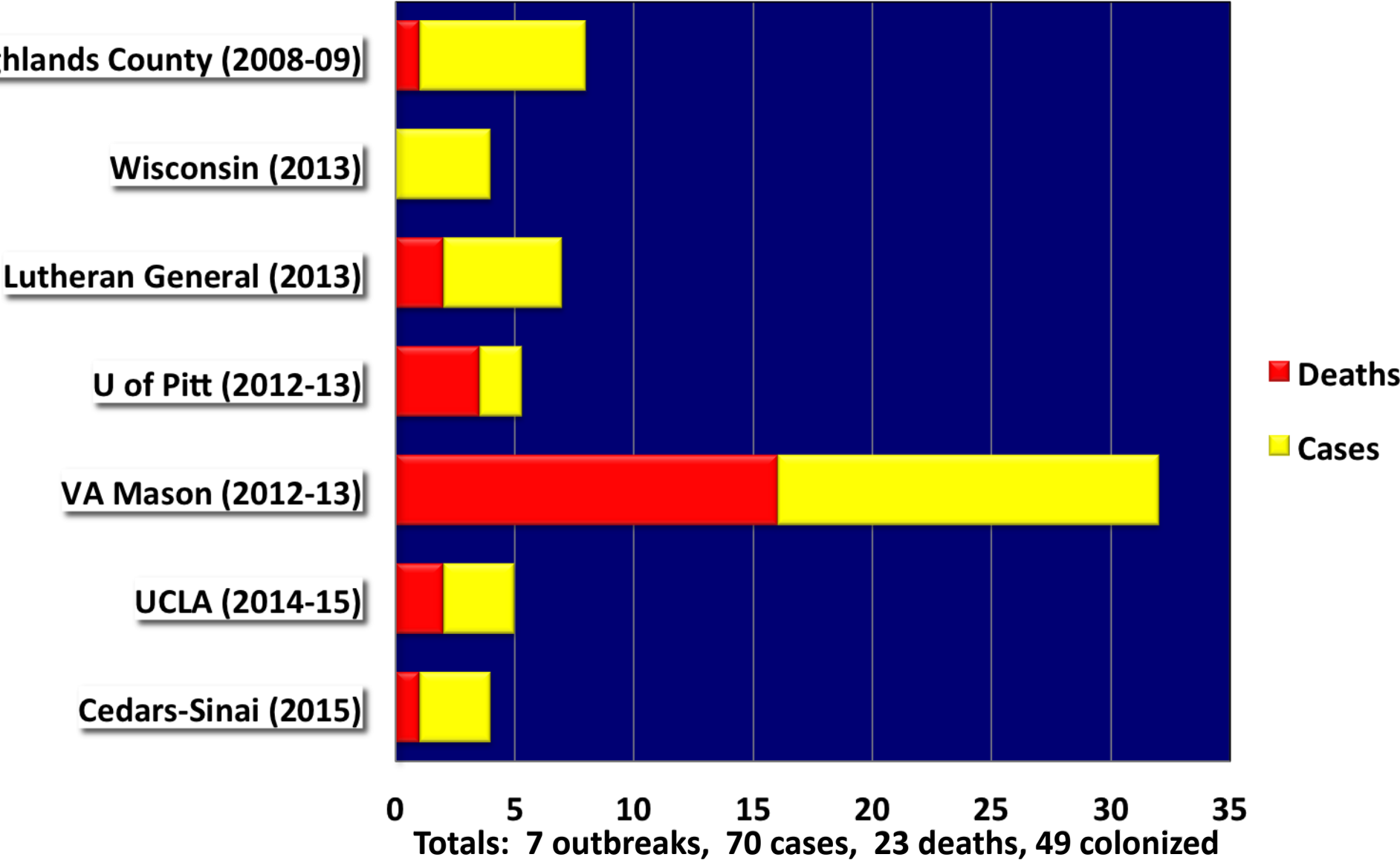
Outbreaks of NDM *E.coli*:

What does this mean to me???

- 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!*




Duodenoscope-Related MDRO Outbreaks



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

Reported MDRO Outbreaks with Duodenoscopes*

Institution* (occurrence)	Pathogens 	# Patients with clinical infections	# Patients exposed/ screened/ colonized	# Deaths	Duodenoscope (culture)
Highlands, FL (2008-2009)	CRKP	7	51/46/3	1	NR (+ NDM-1 E.coli)
UPMC, PA (2012-2013)	CRKP	7	NR/6	0	Olympus TJF-Q180V (Positive)
VA Mason (2012-2013)	Hyper-ampC E.coli	32	NR/0	16 (7 @ 31d)	Olympus160/180 (Positive)
LGH, IL (2012-2013)	NDM-1 E.coli	9	226/10	2	Pentax ED-3490TK (Positive)
MCW, WI (2013)	NDM-1 E.coli	4	NR/2	0	Olympus TJF-Q180V (Negative)
UCLA (2014-2015)	CRKP	7	179/1	3	Olympus TJF-Q180V (Negative)
Cedars Sinai (2015)	NDM-1 E.coli	4	71/1	1	Olympus TJF-Q160V? (Negative)
Totals		70	476/197/49	23	4 positive

HLD with Quarantine

Ethylene Oxide Sterilization

* Two additional outbreaks reported to FDA and limited data in news (Pentax ED-3670TK and Fujinon ED-530XT)

Additional Outbreaks: Health, Education, Labor, and Pensions (HELP) Committee (Senate Report)

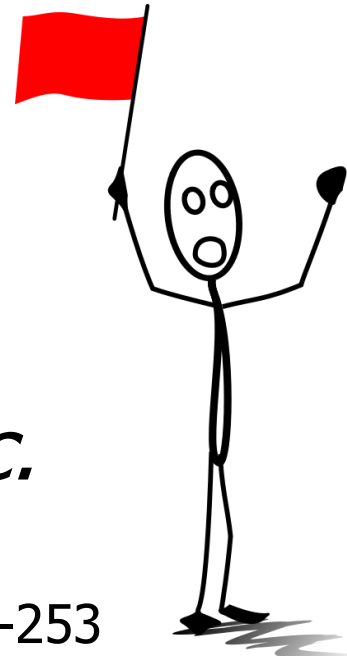
Hospital	Location	Clinical Infections (#)	Time of Infections	Duodenoscope Manufacturer
NY Presbyterian-Weill Cornell	New York City	15	December, 2012	Olympus
U. MA Medical	Worcester, MA	20	December, 2012	Olympus
Jefferson Univ. Hospital	Philadelphia, PA	8	January, 2013	Olympus
Hartford Hospital	Hartford, CT	12	January, 2014	Olympus
MGH	Boston, MA	7,5,3	2014 & 2015	Pentax
Boca Raton Regional Hospital	Boca Raton, FL	9	August, 2014	Olympus
Cedars Sinai	Torrance, CA	4	August, 2014	Olympus
Carolinas Medical	Charlotte, NC	18	2015	Olympus
Fox Chase	Philadelphia, PA	3	April, 2015	Fujifilm

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:

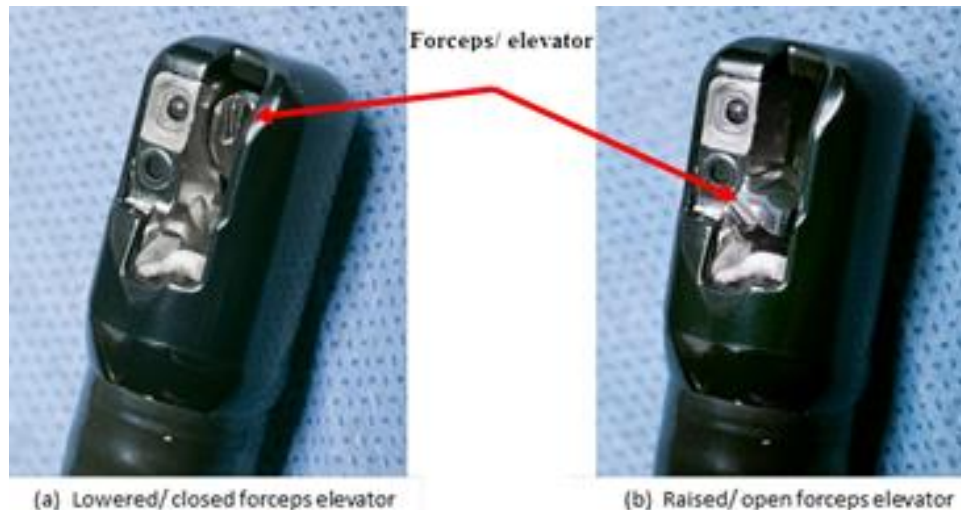
- Carbapenem Resistant Enterobacteriaceae (CRE): *Klebsiella pneumoniae*
- New Delhi Metallo-beta-lactamase (NDM) *Escherichia coli*
- Multi-drug resistant *Pseudomonas aeruginosa, E.coli etc.*



Olympus:

Revised Cleaning Protocol

- ***Newly validated cleaning of lever cavity***
 - tiny brushes fit under lever
 - flushing of the cavity with syringe



Supplemental Measures to Enhance Duodenoscope Reprocessing

FDA Safety Communication August 15, 2015

Outcome of FDA Expert Panel Meeting May 2015



- Microbiological Cleaning
 - quarantine scope until results available
- HLD & Ethylene Oxide Sterilization
- HLD & Liquid Chemical Sterilant
- Reprocessing System
- HLD & Repeat HLD

NO DATA to support ANY of these recommendations!

Ethylene oxide sterilization: is it the answer?

Pros:

- After ETO cycle; scope will be totally dry [extensive aeration]
- ETO case: sterile storage of scope

Cons:

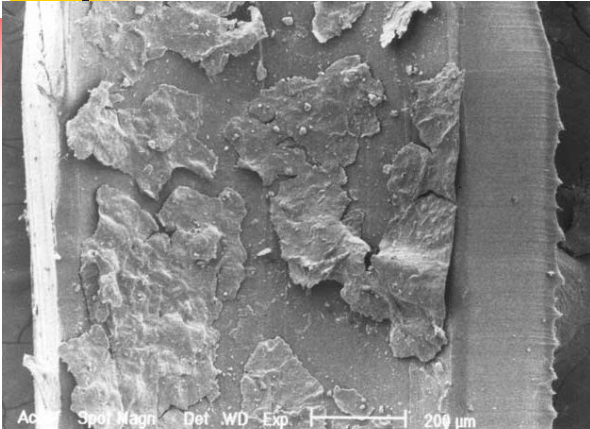
■ **Illinois site: 1/84 duodenoscopes grew CRE after sequential HLD & ETO**

[Naryzhny I et al Gastrointestinal Endoscopy 2016, DOI:10.1016/j.gie.2016.01.055]

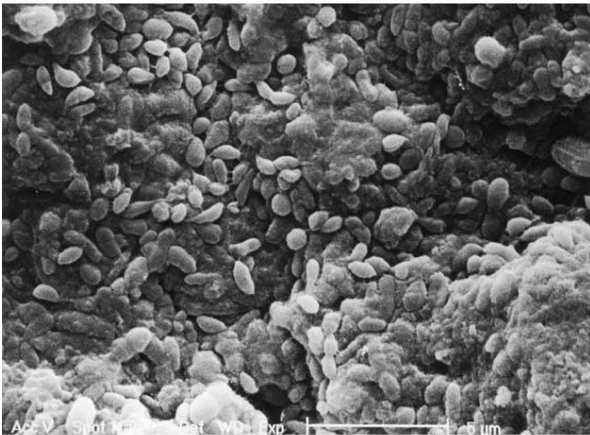
- If organic/salt material present – ETO fails [Alfa et al ICHE 1996;17:92-100].
- Long aeration times (18-24 hours): prolonged turn-around-time
- ETO being phased out due to environmental concerns



Flexible GI Endoscopes: Biofilm



(a)



- Dr. Karen Vickery – over 11 years ago cautioned about biofilm in patient-used flexible GI endoscopes
- Clinical study: SEM showed Biofilm in 54.6% (36/66) Biopsy channel and 76.9% (10/13) Air/water channels Ren-Pei W et al AJIC 2014; 42:1203-6

Air/Water channel of GI flexible endoscope Pajkos et al JHI 2004;58:224-9

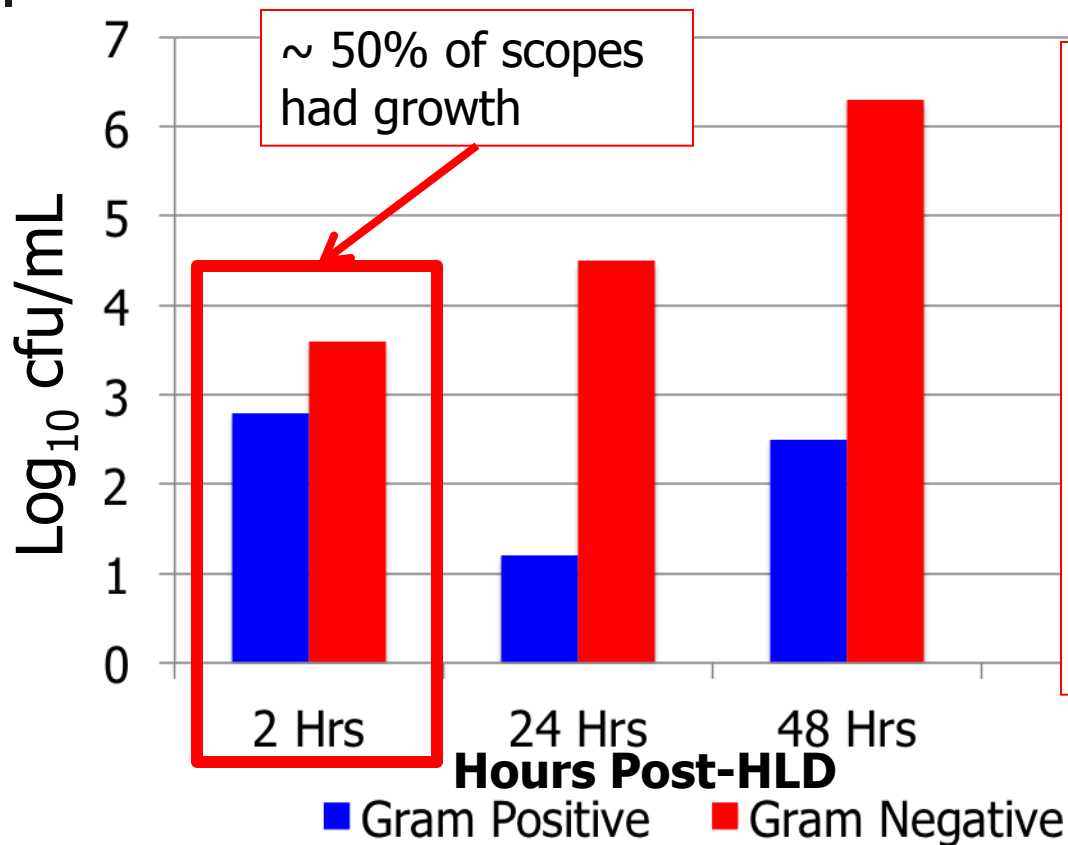
HUMAN FACTORS STUDY: Manual Cleaning

Observed reprocessing of 69 scopes at 4 different facilities

OBSERVED ACTIVITY [12 steps] [Only those < 90% shown]	% COMPLETION
Leak test performed in clear water	77%
Brush all endoscope channels & components	43%
Purge endoscope with air (after cleaning prior to HLD)	84%
Flush endoscope with alcohol	86%
Use forced air to dry endoscope	45%

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

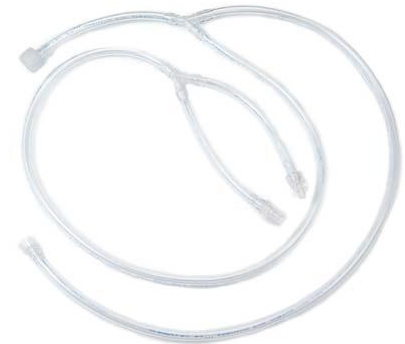
[N=19 scopes]

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

Drying Endoscope channels

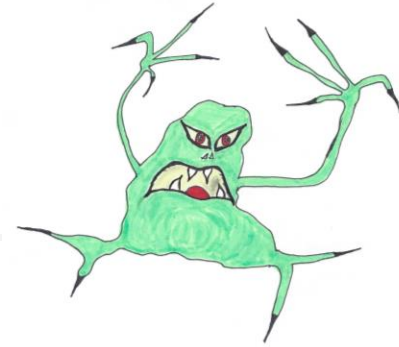


Channel-purge Storage cabinet
- air flushed through channels
- many manufacturers



Dri-scope Aid
- air flushed through channels

How can users prevent build-up Biofilm?



- **Cleaning:**

Manual cleaning: ensure it is done thoroughly EVERY TIME (Rapid cleaning monitors)

- **HLD:** ensure MEC testing done (where applicable)

- **AER Final Rinse:** ensure 0.2um filters intact

- **Dry Storage:** EVERY TIME

- use channel-purge storage cabinets OR:

- use air-pump to dry channels before storage OR:

- *ensure alcohol/forced air drying* adequately done

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

Take Home Messages:



- **Recent Infection outbreaks:**
 - High rate of transmission (~40%)
 - Antibiotic resistant organisms: NDM-*E.coli*
- **Cleaning, HLD and Storage:**
 - improper; cleaning, HLD or wet storage leads to → build-up biofilm
 - perform each step correctly EVERY TIME!
- **Ban build-up Biofilm:**
 - verify manual cleaning
 - STORE SCOPES DRY!



Remember.....if you don't look

- you won't know what risk is at your door step!!

