Virginia Mason™

Duodenoscope-Associated MDRO Transmission: Scope of the Current Problem

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Outline

- Context
- Review well described outbreaks
- Current State
- Next Steps

Perspectives on Endoscope Usage and HLD

Endoscopist

Most effective and efficient tool available, presumes that endoscopic transmission of infectious organisms is minimal to zero

Manager of endoscopy unit

Can the instrument be disinfected, can staff be trained, is the instrument affordable, is it available, is it durable?

Organizational

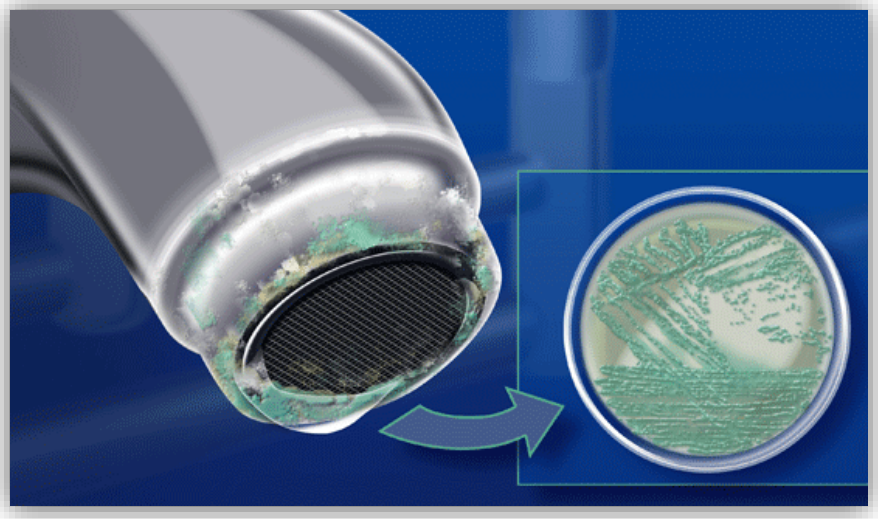
Is the process safe and effective for patients, measurable for quality, will the staff be safe providing it.

Patient

Presumes the procedure is effective and safe, but does not understand the difference between HLD and sterilization.

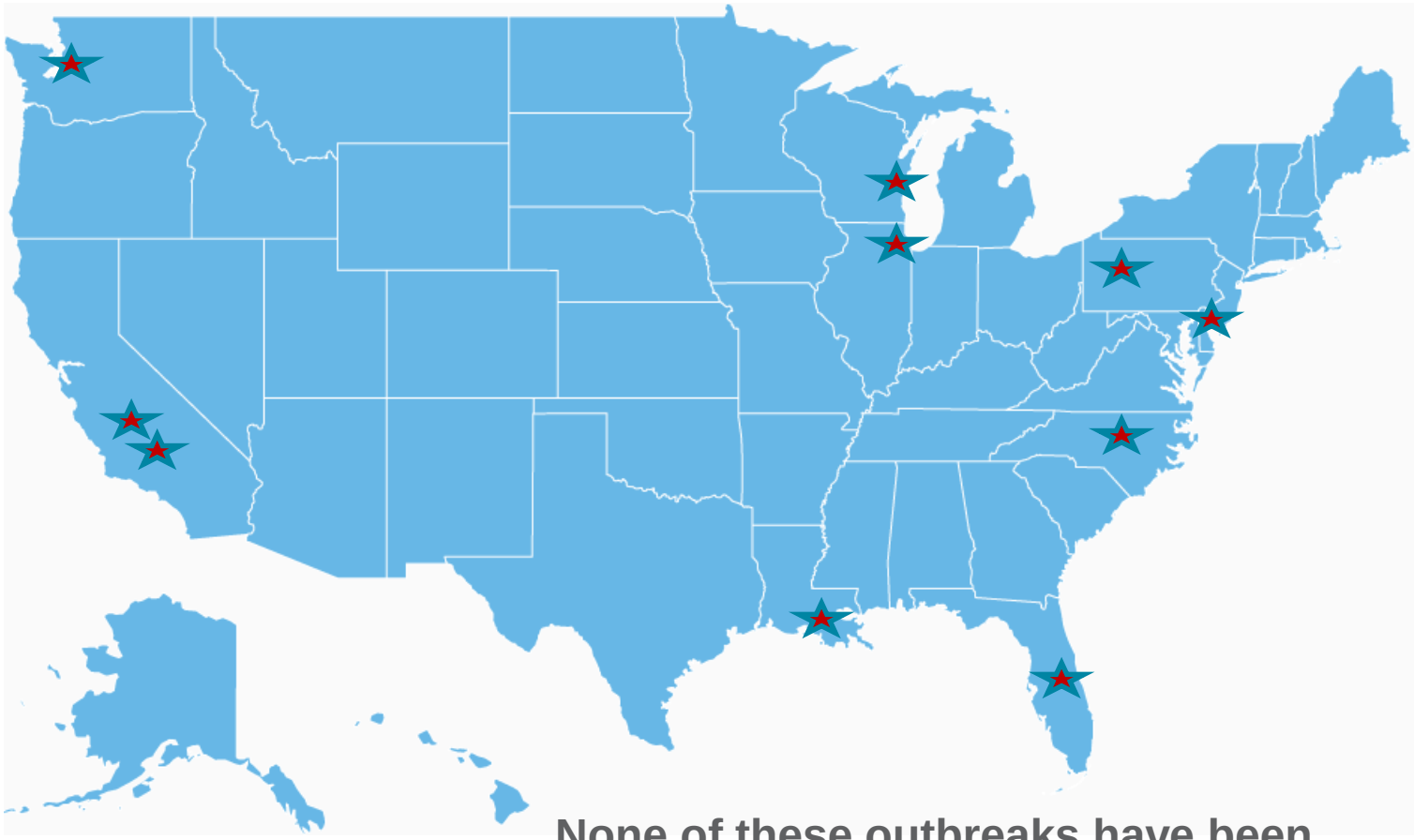
Endoscope-Associated Infection Transmission (in national and international publications)

- 281 reports of GI endoscopy related infections mostly due to *Salmonella* and *Pseudomonas*: rate estimate of 1.8/1,000,000 procedures.
- HBV reported in 1983
- HCV reported in 1997
- HIV transmission has not been reported
- ERCP-specific infections:
  - *Psuedomonas*: 1980's
  - *Klebsiella*: Early 21st century



Most cases of infection transmission historically have been associated with breach in HLD protocol

Reported Duodenoscope-Related MDRO Outbreaks 2013-2015



None of these outbreaks have been associated with breach in HLD protocol

CRE associated with ERCP

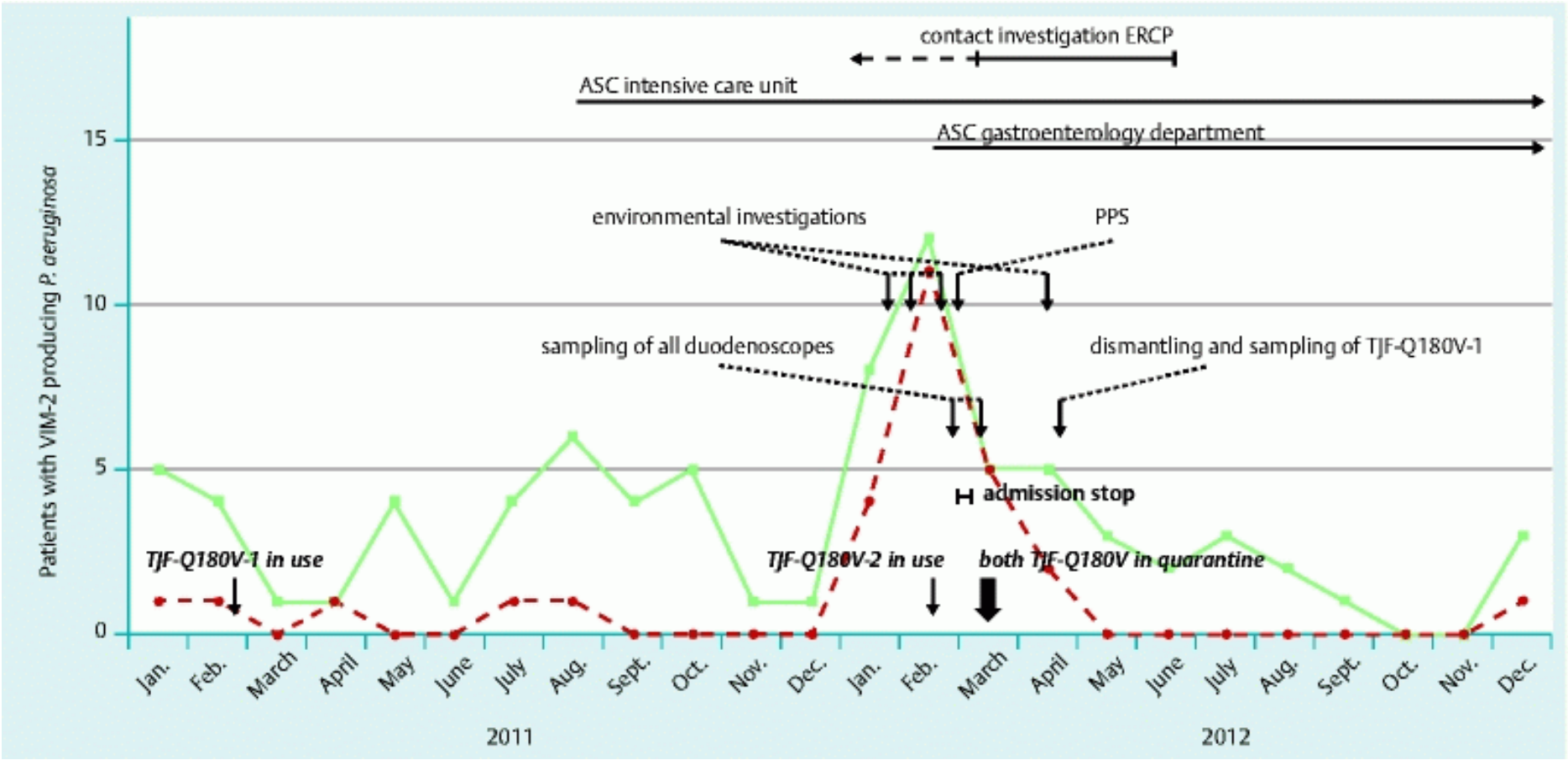
- New Delhi Metalo Beta-Lactamase producing CRE
- 39 cases at tertiary hospital in Chicago area January to December 2013
- 35 patients with duodenoscope exposure at 1 hospital
- No lapses in reprocessing could be found
- One scope had the NDM CRE with 92% homology to cultures in patients
- Hospital instituted new HLD with ETO and reported no new outbreaks

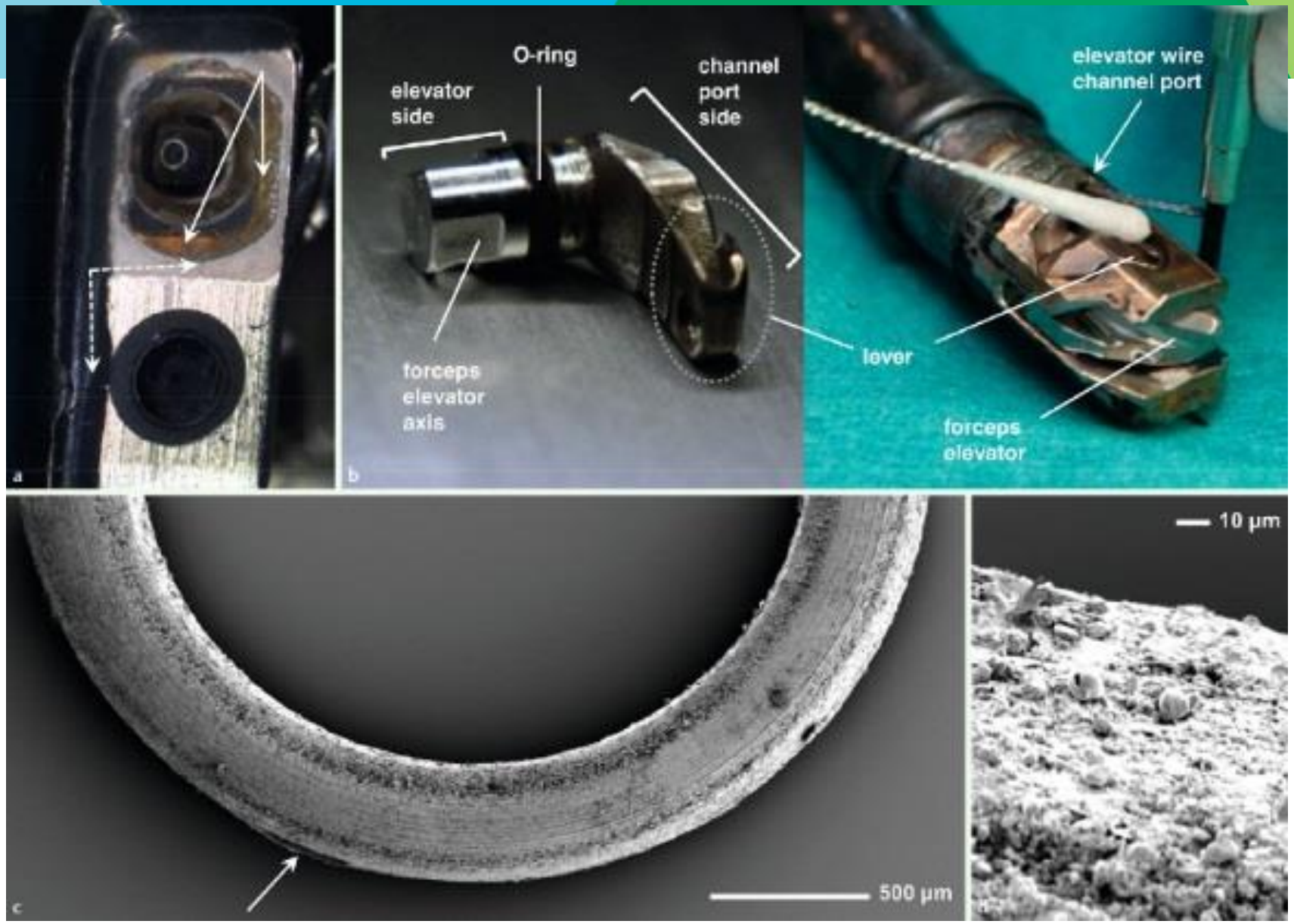
Published October 2014, JAMA, Epstein.

Erasmus Hospital 2012

Verfaille, *Endoscopy;* March, 2015

Erasmus Hospital Outbreak 2012





Seattle Outbreak

- 2012: Virginia Mason participated in a voluntary statewide surveillance study and submitted samples containing MDRO to DOH
- 2013: Unique organism found: Hyper AmpC *E. coli* (HAC)
  - 32 patients identified who had complicated pancreatic and biliary disease
  - All had undergone ERCP or duodenoscopy

Wendorf, et al. Infection Control and Hospital Epidemiology, 2015

Descriptive Characteristics of Patient Cohort

	Alive (n=16)	Deceased (n=16)	Significance
Mean Age (years)	62 + 16	69 +12	*p*=NS
Male:Female	10:6	11:5	*p*=NS
Number of ERCP (mean +/- SD)	3.9 +3.0	3.8+3.9	*p*=NS
Underlying Disease			*p*=0.01 for the presence of an underlying malignancy in patients who died in less than 31 days.
Malignancy	5	8	
End-Stage Liver Disease	0	3	
Primary Sclerosing Cholangitis Without Cirrhosis	1	0	
Severe Acute Pancreatitis	2	1	
Other	8	4	

Table 1: Descriptive characteristics of the patient cohort

Case Study

- Environment, people, and standard endoscopes cleared by culture
- No breach in HLD protocol
  - Independent validation by CDC and manufacturer's representatives
- Duodenoscopes: HAC identical to patient strains cultured from elevator mechanism
  - Ultimately identified on 4/8 duodenoscopes in original inventory (over a period of several months)
  - All duodenoscopes were returned to manufacturer for inspection despite lack of functional defect

Duodenoscope Culture & Repairs

TABLE 2. Pathogenic Bacteria Isolated From Endoscopic Retrograde Cholangiopancreatography (ERCP)–Associated Scopes, Hospital A, Washington State

Scope (TJF)	Pathogen	PFGE cluster	Pathogen location	Culture date	Critical repair made	Critical damages
1. 160VF	*Acinetobacter*	—	Elevator channel	4/23/2014	Yes	C-Cover crack, I/T crack, frayed bending section, damaged K-Lever and forceps elevator
2. 160VF	AmpC *E. coli*	2	Elevator channel	11/22/2013	No	
	AmpC *E. coli*	Outlier	Biopsy channel	11/22/2013		
	AmpC *E. coli*	Outlier	Elevator channel	11/22/2013		
	Enterococcus	—	Elevator channel	5/2/2014		
3. Q180V	AmpC *E. coli*	1	Elevator channel	1/22/2014	Yes	C-cover insulation damage, D/E plastic cover damage, chip in LG lens, dim light breakage
	AmpC *E. coli*	Other	Elevator channel	2/3/2014		
4. Q180V	MDR *Pseudomonas aeruginosa*	—	Elevator channel	1/29/2014	Yes	Leak in biopsy port and C-Cover, C-cover insulation damaged, C-cover crack, I/T crack, forceps passage damage, buckle in insertion tube
	E. coli	—	Elevator channel	5/3/2014		
5. Q180V	AmpC *E. coli*	2	Elevator channel	11/22/2013	Yes	Leak in instrument channel, crack in LG lens, forceps passage damage, frayed bending section
6. Q180V	MSSA	—	Elevator channel	5/8/2014	New	
	Acinetobacter	—				
7. Q180V	MSSA	—	Elevator channel	1/30/2014	New	
8. Q180V	MSSA	—	Elevator channel	5/3/2014	New	
9. Q180V	MSSA	—	Elevator channel	4/24/2014	New	

NOTE. This table includes all ERCP-associated scopes with substantial bacterial contamination after reprocessing, including the 8 original ERCP scopes and the additional ERCP scopes purchased during the investigation. Each scope listed in the first column is a different scope. Scopes are used repeatedly and cultured after each use; therefore, 1 scope might have been contaminated multiple times. *E. coli*, *Escherichia coli*; MDR, multidrug-resistant; MSSA, methicillin-sensitive *Staphylococcus aureus;* PFGE, pulsed-field gel electrophoresis.

Wendorf, et al. Infection Control and Hospital Epidemiology, 2015

Deaths

- 7 patients died within 31 days of isolating HAC in culture
  - Metastatic malignancy with biliary obstruction (n=5)
  - Multisystem organ failure, prolonged ICU (n=1)
  - Walled-off necrosis of pancreas (n=1)
- 9 Deaths at a median of 180 days following isolation of HAC in culture
  - Malignancy (n=3)
  - Cirrhosis (n=3)
  - Other (n=3)

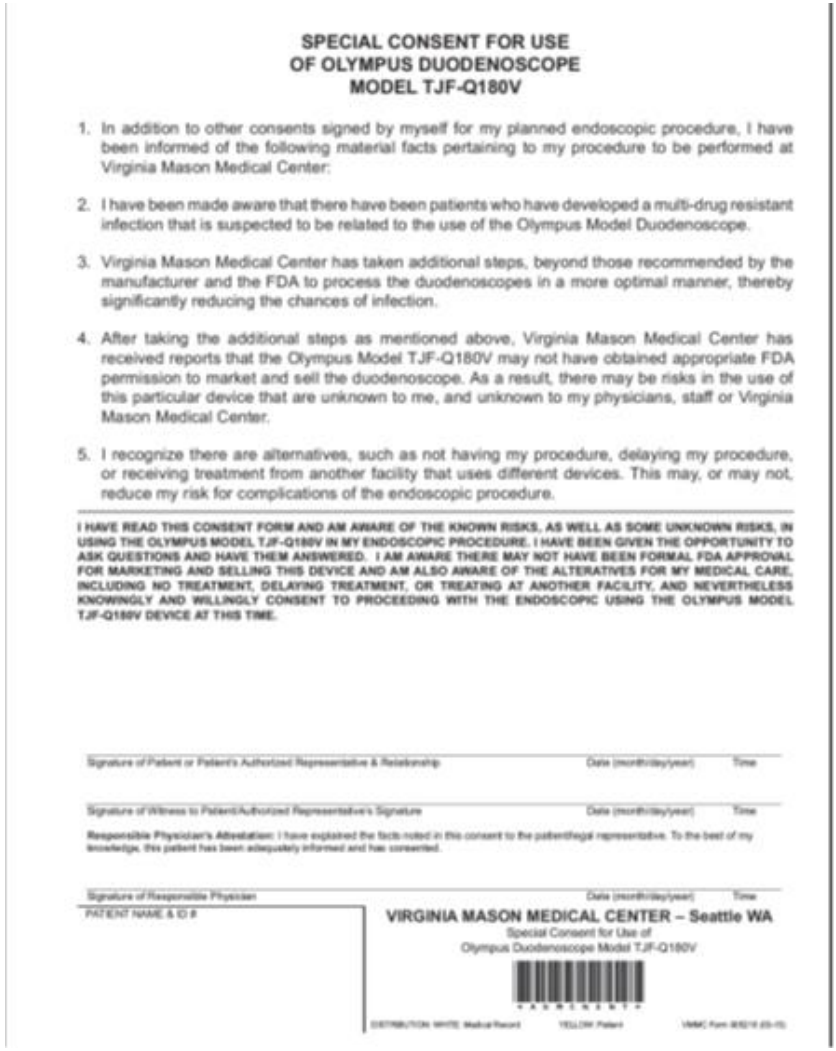
Measures Employed Subsequent to Outbreak

- Instituted after identification of duodenoscopes as likely source of transmission, aiming for 0% chance of transmission
- Culture and Quarantine
  - Duodenscopes are cultured (following CDC protocol issued on 3/11/15) for pathogenic organisms after HLD (AER is repeated after culture)
  - Held for 48 hours until cultures return negative for pathogenic bacteria
  - Scopes which culture positive undergo repeat HLD, culture, and quarantine
  - Increased duodenoscope inventory from 8 to 28
    - Cost of equipment alone: $750,000
  - Increased staff in microbiology lab by 1.0 FTE
    - 1 Year culture costs: $73,000

Ross, et al., GIE 2015

Measures Employed Subsequent to Outbreak

- Patient surveillance
  - Bile & perianal cultures
- Special informed consent
- Skill task alignment
- Routine duodenoscope maintenance
- Ergonomic changes to the reprocessing room
- Local, national and international resource for GI community
- Outbreak considered fully contained
  - No further infections identified in over 2,000 ERCPs since implementation



SPECIAL CONSENT FOR USE OF OLYMPUS DUODENOSCOPE MODEL TJF-Q180V

1. In addition to other consents signed by myself for my planned endoscopic procedure, I have been informed of the following material facts pertaining to my procedure to be performed at Virginia Mason Medical Center:
2. I have been made aware that there have been patients who have developed a multi-drug resistant infection that is suspected to be related to the use of the Olympus Model Duodenoscope.
3. Virginia Mason Medical Center has taken additional steps, beyond those recommended by the manufacturer and the FDA to process the duodenoscopes in a more optimal manner, thereby significantly reducing the chances of infection.
4. After taking the additional steps as mentioned above, Virginia Mason Medical Center has received reports that the Olympus Model TJF-Q180V may not have obtained appropriate FDA permission to market and sell the duodenoscope. As a result, there may be risks in the use of this particular device that are unknown to me, and unknown to my physicians, staff or Virginia Mason Medical Center.
5. I recognize there are alternatives, such as not having my procedure, delaying my procedure, or receiving treatment from another facility that uses different devices. This may, or may not, reduce my risk for complications of the endoscopic procedure.

I HAVE READ THIS CONSENT FORM AND AM AWARE OF THE KNOWN RISKS, AS WELL AS SOME UNKNOWN RISKS, IN USING THE OLYMPUS MODEL TJF-Q180V IN MY ENDOSCOPIC PROCEDURE. I HAVE BEEN GIVEN THE OPPORTUNITY TO ASK QUESTIONS AND HAVE THEM ANSWERED. I AM AWARE THERE MAY NOT HAVE BEEN FORMAL FDA APPROVAL FOR MARKETING AND SELLING THIS DEVICE AND AM ALSO AWARE OF THE ALTERATIVES FOR MY MEDICAL CARE, INCLUDING NO TREATMENT, DELAYING TREATMENT, OR TREATING AT ANOTHER FACILITY, AND NEVERTHELESS KNOWINGLY AND WILLINGLY CONSENT TO PROCEEDING WITH THE ENDOSCOPIC USING THE OLYMPUS MODEL TJF-Q180V DEVICE AT THIS TIME.

Signature of Patient or Patient's Authorized Representative & Relationship — Date (month/day/year) — Time

Signature of Witness to Patient/Authorized Representative's Signature — Date (month/day/year) — Time

Responsible Physician's Attestation: I have explained the facts noted in this consent to the patient/legal representative. To the best of my knowledge, this patient has been adequately informed and has consented.

Signature of Responsible Physician — Date (month/day/year) — Time

PATIENT NAME & ID #

VIRGINIA MASON MEDICAL CENTER – Seattle WA

Special Consent for Use of Olympus Duodenoscope Model TJF-Q180V

DISTRIBUTION: WHITE: Medical Record — YELLOW: Patient — VMMC Form 8/02/10 (03-15)

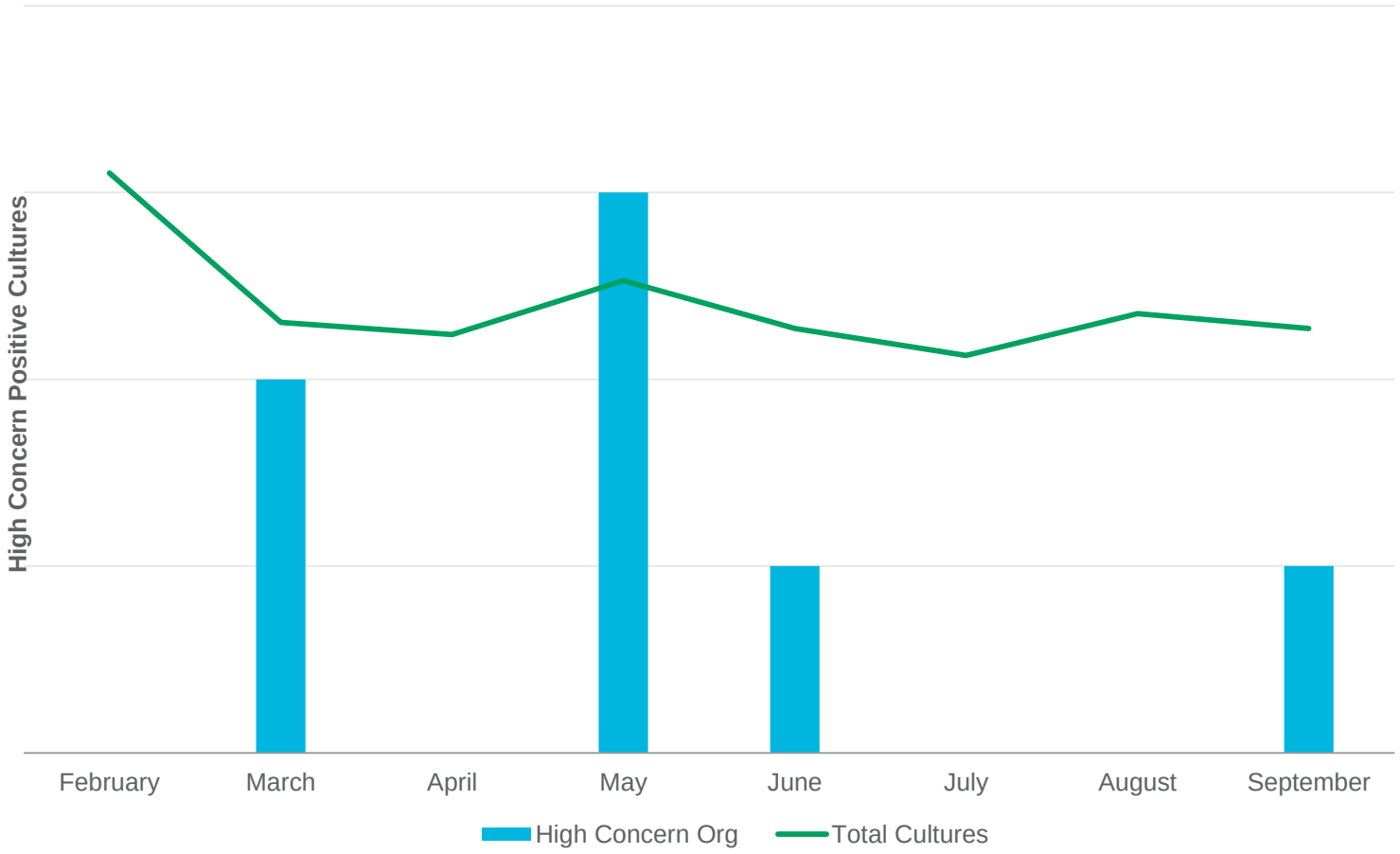
HLD Defect Rate Defined: 2014

Bacterial Growth on Reprocessed Duodenoscope	Number
Acinetobacter	2
Enterococcus	9
E. Coli	4 (2 HAC)
Enterobacter	1
Pseudomonas aeuroginosa	2
Non-fermenting gram negative rods	3
Staphylococcus aureus (Methicillin-sensitive)	7
Staphylococcus aureus (Methicillin-resistant)	1

29/1524=1.9%

Ross, et al. GI Endoscopy 2015

High-Concern Organism Positivity Rate February 2015– September 2015



HLD Defect Rate: 7/1200= **0.6%**

Perianal Screening Results

Results of testing for MDR-GNR recovered from perianal swab specimens obtained over a 12-month period

No. of Swabs	No. (%) Positive
855	Negative for MDR-GNR (93.7%)
52	AmpC *E. coli* (5.7%)
2	Carbapenemase-negative carbapenem-resistant *E. coli* (0.2%)
2	Carbapenem-resistant *E. cloacae* (0.2%)

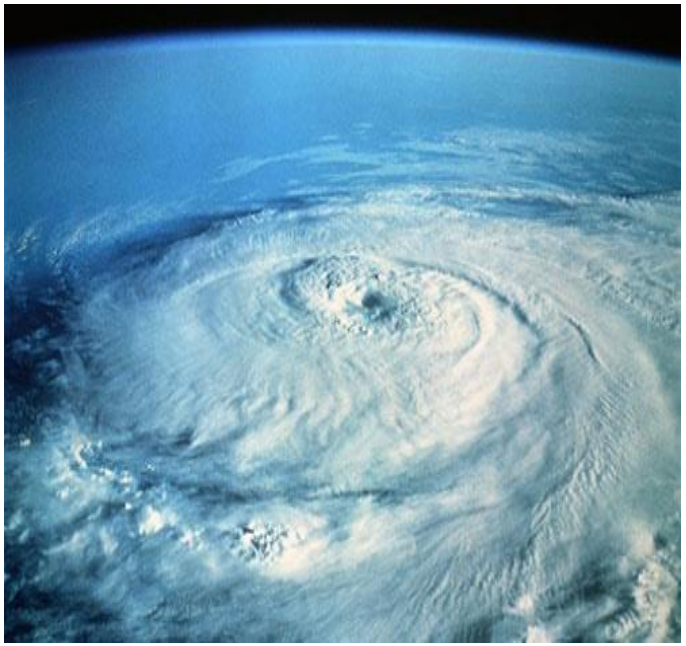
Manufacturers' Recommended HLD Protocols for Duodenoscopes are Inadequate

- FDA: Extremely difficult to clean instrument
- Existing manufacturer's recommended HLD protocols have never been validated in clinical practice
  - Revised HLD protocol for duodenoscopes from all 3 manufacturers now approved by FDA
  - Post-market surveillance mandated by FDA for clinical validation
- Existing manufacturer's guidelines for HLD lack redundancy, ability to identify defects and mistake proofing
  - Leave no margin for error
  - Significant differences exist between a controlled laboratory and clinical practice

Ross, et al., GIE 2015

A Perfect Storm?

- Difficult to clean endoscope
- Increasing antimicrobial resistance
- Bacteria now leave a "fingerprint"
- ERCP is a necessary procedure
    - Poor alternatives
- Long term solution is design change
  – This may take years to achieve
  – ? What can be done in the interim



FDA Supplemental Measures

- Gas sterilization with ETO
- Microbiologic culture
- Repeat HLD
- Low temperature sterilization

    - All of these measures have their inherent imperfections

Chicago Outbreak Surveillance

- 589 ERCPs performed in 18 month period
- Standard HLD followed by ETO
- Monthly cultures of all duodenoscopes (n=84) for CRE
- 1/84 scopes cultured positive for CRE after ETO (1.1%)
- No new infections

Naryzhny, et al. GI Endoscopy, In Press

Conclusions-I

- The scope and impact of this problem are significant
  - True number of patients impacted and real risk difficult to quantify
- 500,000 ERCP's performed in the USA annually
  - 0.7% defect rate is 3,500 patients potentially at risk
- The current problem represents a regulatory failure
- Trust has been violated
  - The patient must remain the focal point

Conclusions-II

- Ultimate solution may be design change to the duodenoscope
  - This will require time
- Short-term changes should be employed
  - Enhanced cleaning methods
  - Redundancy
  - Quality controls/Visual cues
  - Measurement of time required to adequately perform HLD
  - Exhaustive informed consent
  - Appropriateness of indications
  - Continued vigilance and surveillance for duodenoscope-related infections

Conclusions-III

- ERCP is an important, minimally-invasive, potentially life-saving procedure for patients
  - The available alternatives are more invasive and involve higher risk
- Goal of any changes should be to enhance the safety of ERCP relative to infection control