

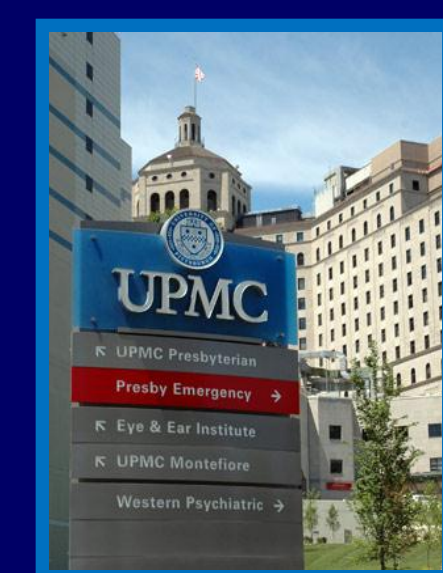


High Level Disinfection (HLD) Failure in Gastrointestinal Scopes with Elevator Channels – Is it Time to Switch to Ethylene Oxide (ETO) Sterilization?

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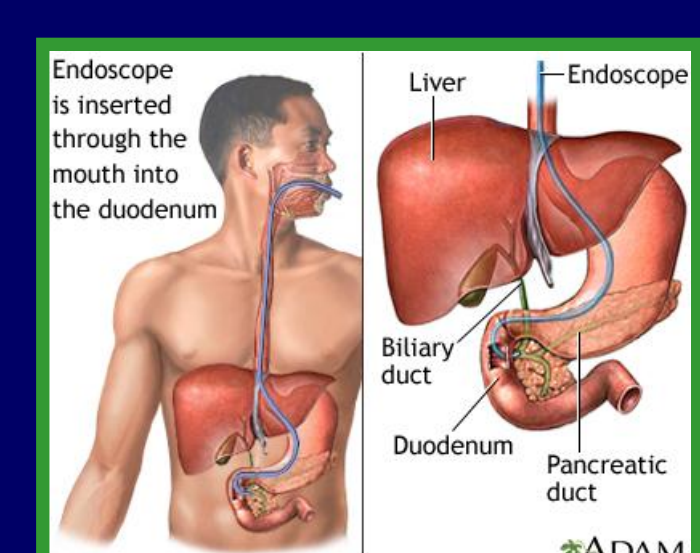
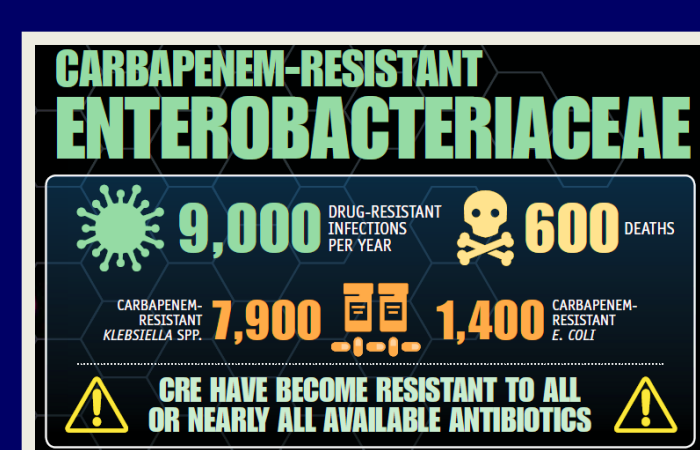
Setting



The University of Pittsburgh Medical Center (UPMC) Presbyterian is a 766-bed tertiary care facility affiliated with the University of Pittsburgh Schools of the Health Sciences

Background

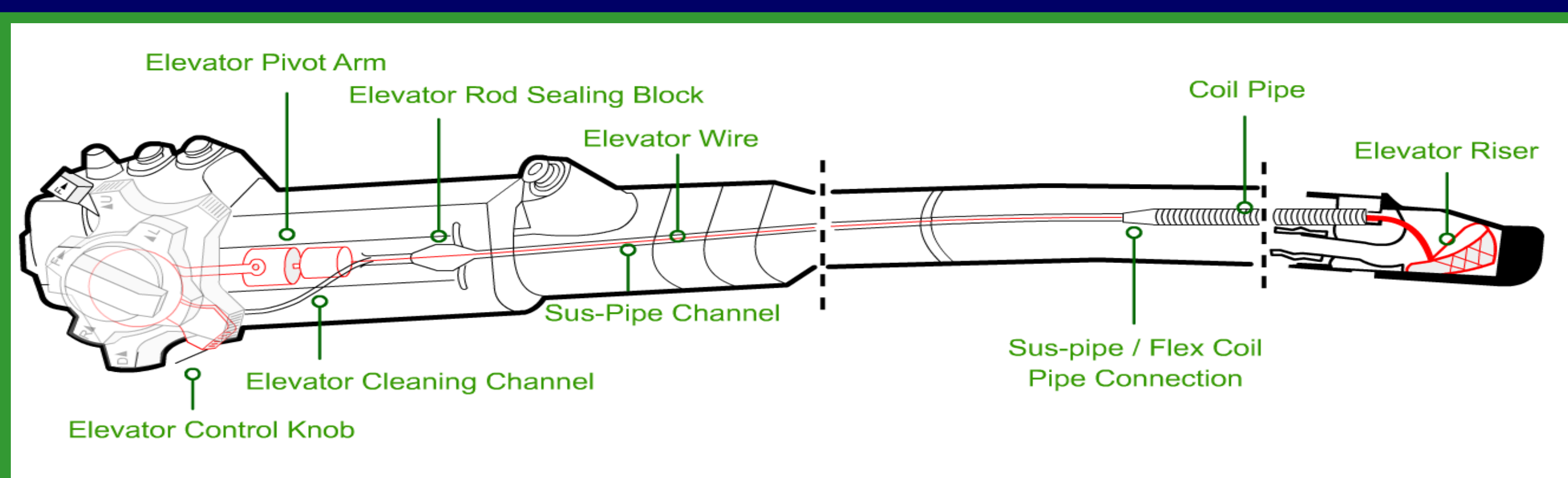
- Enterobacteriaceae are a family of bacteria that commonly cause infections in the community as well as in health-care settings
- Carbapenem-resistant Enterobacteriaceae (CRE) appear to have been uncommon in the United States before 1992
- Klebsiella pneumoniae* (KP) carbapenemase (C) is the most common carbapenemase
- Over the past decade, CRE have been recognized in health-care settings as a cause of serious infections with high mortality
 - Up to 50% in some studies
- CRE often carry genes that confer high levels of resistance to many other antimicrobials
 - “Pan-resistant”
 - Difficult-to-treat infections
- Flexible endoscopy procedures /ERCP’s are a routine part of patient diagnosis and treatment in healthcare
- Flexible scopes contain a number of internal systems that perform functions specific to the model
- ERCP scopes are equipped with a forcep raiser (elevator) at the distal end to deflect accessories passed through the biopsy channel. The elevator housing on the scope tip is recessed and collects bio burden during use
- Accessories may be passed through the endoscope into the ducts to remove stones, insert stents, or take tissue samples



REPROCESSING

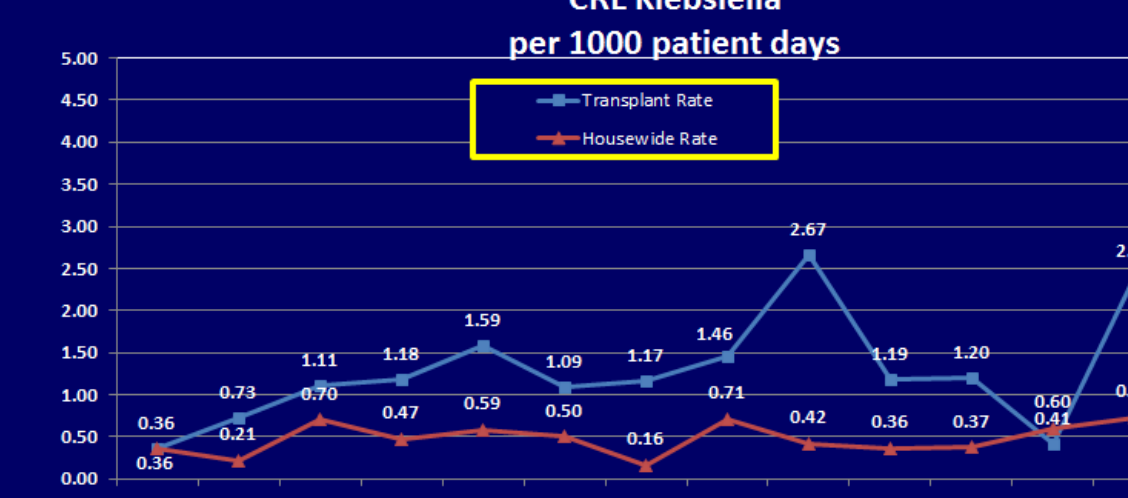
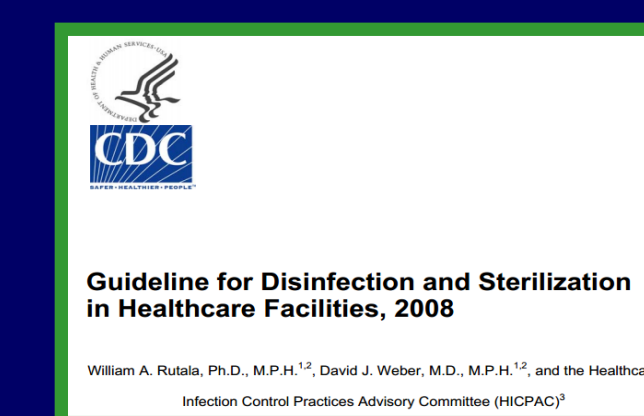
- The elevator channel components are the most challenging to reprocess

Elevator riser Wire channel assembly
 Control Knob Cleaning tube mount



Background

- Approximately 11 million gastrointestinal endoscopies are done annually and contaminated scopes have been linked to more Hospital-acquired infections (HAI’s) than any other type of medical device
- Post-ERCP bloodstream infections (BSI’s) and biliary tree infections are reported after 1-3% of procedures
- Outbreaks have been associated with insufficient cleaning/disinfection of channels, rinsing with tap water or by using defective scope washing machines
- Current CDC guidelines consider GI scopes as semi critical items and recommend proper cleaning (C) and FDA approved high level disinfection (HLD)
- In 2012 an increase in CRKP infections was noted
 - Many infections were in patients post – ERCP
- An investigation ensued to include:
 - All ERCP scopes were taken out of service
 - Notification to the scope manufacturer (Olympus)
 - Evaluation of C/HLD process
 - GI lab/scopes were inspected
 - Boroscopy – internal lumen without defect
 - Scope culturing
 - 5/31 (16%) scopes grew organisms consistent with GI flora
 - 1/5 (20%) grew both Carbapenem sensitive (CS) KP and CRKP
 - ECRI/Olympus performed observations
 - Molecular typing of CRKP isolates from post ERCP patients
 - The scope manufacturer, Olympus, suggested that the HLD failure was attributable to use of a competing manufacturers’ scope washer
 - Custom Ultrasonic (CU)/ortho-phthalaldehyde
 - Olympus suggested use of their product
 - OER/ Peracetic acid
 - Ultimately the CU AER was replaced with the Olympus AER
 - All ERCP/EUS scopes underwent HLD followed by Ethylene oxide gas sterilization (ETO)



Objective

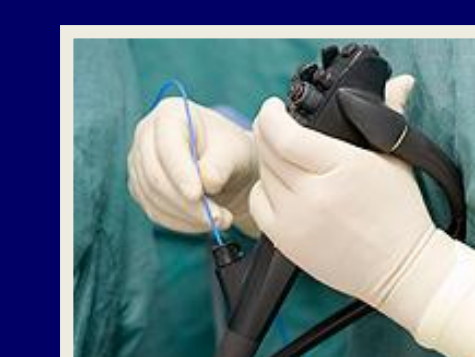
- The objective of this study was to determine if the use of the Olympus endoscopic reprocessor (OER)/peracetic acid would eliminate scope bacterial contamination

Methods

- Scope reprocessing with 2 OER scope washers, provided by the scope manufacturer began in 9/2013
- A maximum of 30 scopes were to undergo culture post- use and HLD but prior to ETO
 - The study would terminate if a positive culture was identified
 - This would demonstrate failure of the recommended OER scope washer
- Targeted scopes included patients who had undergone an ERCP and had a history of KP colonization/infection

Microbiology Methods

- Sterile gloves were donned for scope sampling
- Biopsy Channel/Elevator Sampling
 - Sterile Trypticase soy broth (TSB) was injected into the biopsy channel in the ante retrograde direction
 - The fluid was collected into a sterile specimen cup which was held at the distal end of the scope
 - During this manipulation, the elevator was moved up and down
 - The broth was aspirated back up the biopsy channel into a Luken's trap with vacuum
- Water Reservoir Sampling
 - Sterile TSB was placed into the water reservoir
 - Sterile TSB was injected into the water channel
 - The broth was collected in a sterile specimen cup held at the distal end of the scope.
- Samples were incubated at 37⁰ C
- Samples with growth were inoculated onto appropriate agar media
- Isolated organisms were identified and had antimicrobial susceptibility performed using the Siemens Micro scan Walkaway instrument
- KPC production was verified using a BLAKpc PCR



Results

- Over a period of 2 months, 6 scopes were cultured
- Bacteria were recovered from 5/6 (83.3%) scopes post OER
- The 6th scope was from a patient post-ERCP with known h/o ESBL KP
 - Last ESBL KP culture 12/25/13
 - ERCP - 1/7/2014
- Post-HLD- culture grew *Klebsiella pneumoniae* (ESBL), *E.coli* and *E. Faecium* (VRE).

Date	Scope Number	Biopsy Port/Elevator	Water Channel	Patient Culture		
				Date	Specimen	Result
11/18/13	1	Viridans strep	Micrococcus	07/06/13	Blood	CR KP
11/25/13	2	Coag Neg Staph	Viridans strep & Coag Neg Staph	09/01/13	Wound	CR KP
11/25/13	3	Viridans strep & Coag Neg Staph	Viridans strep	10/04/11	BAL	KP
11/27/13	4	Micrococcus	No Growth	09/08/08	Urine	KP
11/27/13	5	Viridans strep & Micrococcus	Viridans strep	06/30/13	Urine	KP
01/07/14	6	KP(ESBL) E. coli E. Faecium (VRE)	No Growth	12/25/13	Urine	KP (ESBL)

Conclusions

- HLD was not effective in eradicating bacteria from Olympus ERCP and EUS scope biopsy channels with elevators using either CU (OPA) or OER (peracetic acid) scope washers
- All scopes with elevators (ERCP/EUS) have been reprocessed using ETO gas sterilization at UPMC-PUH since 10/2013
- Changing ERCP/EUS scope reprocessing was associated with significant changes
 - New ETO sterilizers were purchased to meet demand
 - ETO turnaround time is ~18 hours
 - Scope volume was doubled
- UPMC Health System
 - It was time to change to ETO gas sterilization for scopes with elevators
 - All scopes with elevators (ERCP/EUS) are now reprocessed using ETO
 - Routine scope culturing should occur at a regular frequency to ensure proper reprocessing.
- No additional healthcare-associated infections have been noted since ERCP/EUS scope reprocessing included ETO