

# Implementation and Outcomes of an Enhanced Duodenoscope Reprocessing and Culturing Program

## ABSTRACT

**Implementation and Outcomes of an Enhanced Duodenoscope Reprocessing and Culturing Program**  
**Background:** In February 2015, the FDA issued a safety alert regarding post-ERCP CRE transmission despite adherence to high level disinfection (HLD) of duodenoscopes.  
**Methods:** In response to the alert, our high volume center (approx. 2200 ERCPs/yr) evaluated current processes, reviewed literature, contacted peer institutions, developed and implemented an enhanced duodenoscope reprocessing and culturing protocol. All duodenoscopes were EtO sterilized and additional scopes were purchased to allow implementation of a culture-and-sequester program. The most frequently used scopes were selected for culturing. Phase 1: single reprocessing and scope culturing; brushings were obtained from both the elevator mechanism, sent as one sample, and the three working channels, sent together as a second sample. The brushes were placed in 10 ml of tryptic soy broth, vortexed and incubated. The samples were checked at 24 and 48 hours and if turbid, the broth was subcultured to solid media. Phase 2: double reprocessing (2 cycles of manual cleaning and HLD) and scope culturing with targeted sequestration and EtO sterilization after any known CRE case. Phase 3: double reprocessing and culturing the elevator only; growth was noted from the elevator mechanism but not the working channels.  
**Results:** From April 2015 through May 2016, each scope was cultured between 1 to 23 times. 989 cultures (28% of the total ERCP volume) were obtained from 62 individual duodenoscopes with varying rates of positivity.  
**Conclusion:** A resource-intensive intervention of double reprocessing, culture and sequestration reduced but did not completely eliminate pathogenic bacterial contamination of the duodenoscope elevator. This process sampled only 28% of the ERCP volume. Culture and sequestration of every duodenoscope in use is not sustainable with current resources and a new method for scope sterilization is needed.

## BACKGROUND

More than 500,000 ERCP procedures using duodenoscopes are performed annually in the United States. Duodenoscopes are flexible tubes with a light that are inserted through the mouth, stomach and small intestine (duodenum). This endoscope has a movable elevator mechanism at the tip that allows for navigation in treating problems with fluid drainage. This complex design makes it challenging to clean and disinfect. In February 2015, the FDA issued a safety alert regarding post-ERCP CRE transmission despite adherence to high level disinfection (HLD) of duodenoscopes.

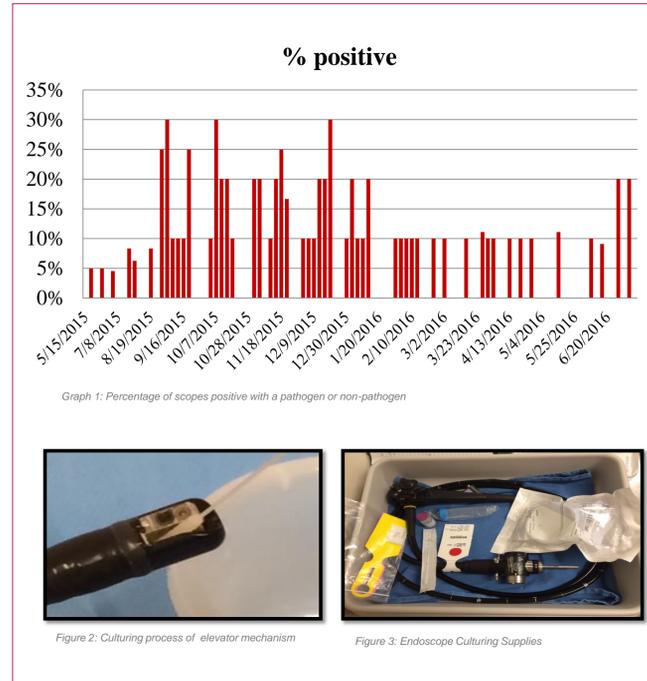


## MATERIALS & METHODS

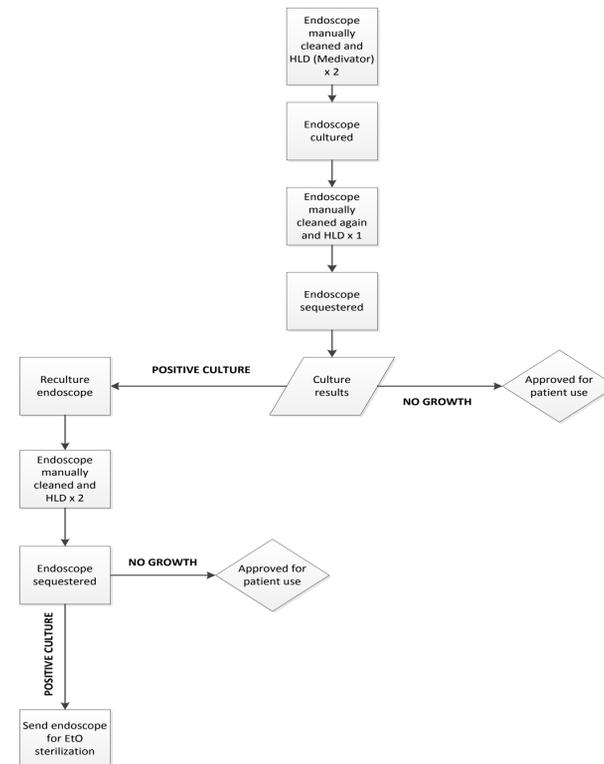
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**Phase 1:** single reprocessing and scope culturing; brushings were obtained from both the elevator mechanism, sent as one sample, and the three working channels sent together as a second sample. The brushes were placed in 10 ml of tryptic soy broth, vortexed and incubated. The samples were checked at 24 and 48 hours and if turbid, the broth was subcultured to solid media.  
**Phase 2:** double reprocessing (2 cycles of manual cleaning and HLD) and scope culturing with targeted sequestration and EtO sterilization after any known CRE case.  
**Phase 3:** double reprocessing and culturing the elevator only; growth was consistently noted from the elevator mechanism but not the working channels.

## RESULTS



## CULTURE ALGORITHM



## RESULTS TABLE

Study Rates Combined (5/15/15-7/11/16)								
scope type	# of each scope type	total Cx per scope	total positive Cx (path & non-path)	positive Cx rate per scope type	positive Cx rate overall	total positive pathogen Cx	positive pathogen Cx rate overall	positive pathogen rate per scope type
180	8	123	9	7.3%	0.9%	0	0.0%	0.0%
160	40	671	56	8.3%	5.9%	4	0.4%	0.6%
140	7	117	6	5.1%	0.6%	2	0.2%	1.7%
130	3	46	2	4.3%	0.2%	0	0.0%	0.0%
totals	58	957	73		7.6%	6	0.6%	

Chart 1: Culture results by scope type

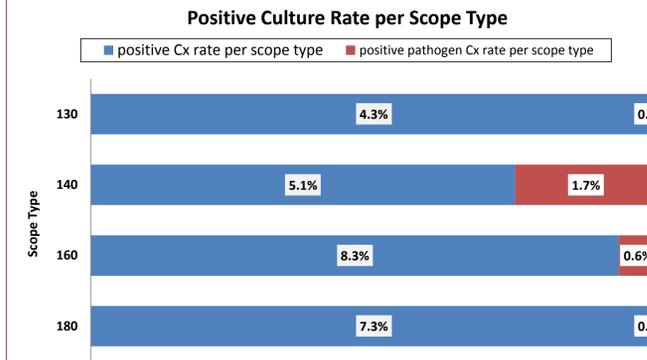


Chart 2: Positive culture rates per scope type

## CULTURE RESULTS

### Microorganisms Cultured

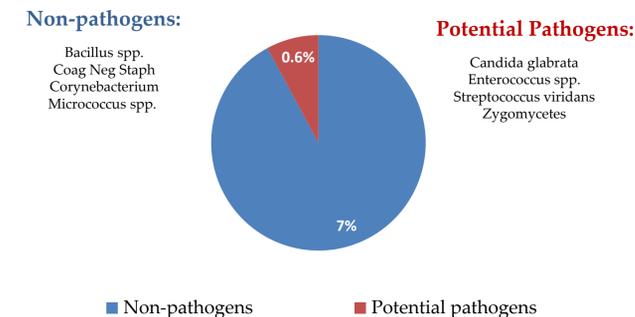


Chart 3: Types of microorganisms cultured

## SUMMARY

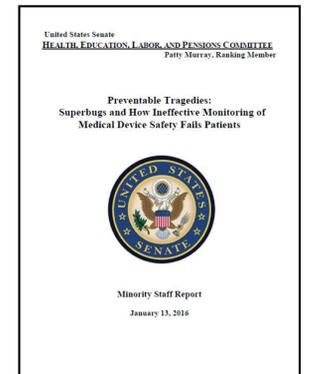
A resource-intensive intervention of double reprocessing, culture and sequestration reduced but did not completely eliminate pathogenic bacterial contamination of the duodenoscope elevator. This process sampled approximately 28% of the ERCP volume.

Barriers to achieving 100% elimination of microbial contamination included:

- EtO hazards to both scopes and personnel
  - Limited availability
  - Long cycle time
- Endoscopy suite
  - Labor intensive culture process (two people per scope)
- Microbiology laboratory
  - Limited capacity to accept additional cultures
  - Lack of standardized and accepted methods for clinical microbiology laboratory to perform device cultures
  - High cost of outsourcing to an outside laboratory

## CONCLUSIONS

Culture and sequestration of every duodenoscope in use is not sustainable with current resources. Improved technology—changes in either duodenoscope design or sterilization methodology—will be needed to assure duodenoscopes that are free of microbial contamination.



## REFERENCES

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