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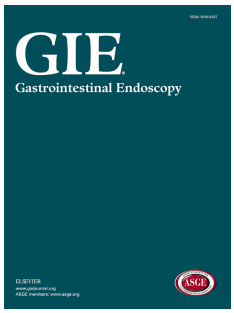

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Implementation of a systematic culturing program to monitor efficacy of endoscope reprocessing: outcomes and costs

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ABSTRACT

Background and Aims:
In 2015, the U.S. Food and Drug Administration and Centers for Disease Control and Prevention (CDC) issued guidance for duodenoscope culturing and reprocessing in response to outbreaks of carbapenem-resistant *Enterobacteriaceae* (CRE) duodenoscope-related infections. Based on this guidance, we implemented best practices for reprocessing and developed a systematic process for culturing endoscopes with elevator levers. The aim of this study is to report the outcomes and direct costs of this program.

Methods:
First, clinical microbiology data from 2011 to 2014 was retrospectively reviewed to assess for possible elevator lever equipped endoscope-related CRE infections. Second, a program to systematically culture elevator lever equipped endoscopes was implemented. Each week about 25% of the inventory of elevator lever equipped endoscopes is cultured based on the CDC guidelines. If any cultures return bacterial growth, the endoscope is quarantined pending repeat culturing. Costs of the program, including staff time and supplies, were then calculated.

Results:
From 2011 to 2014, none of 17 patients with documented CRE infection had undergone endoscopic retrograde cholangiopancreatography or endoscopic ultrasound in the 36 months prior. From June 2015 to September 2016, 285 cultures were performed. 3 (1.1%) had bacterial growth, 2 with skin contaminants and 1 with an oral contaminant. The associated endoscopes were quarantined and reprocessed, and repeat cultures were negative. The total estimated cost of our program for an inventory of 20 elevator lever-equipped endoscopes is $30,429.60 per year ($1,521.48 per endoscope).

Conclusions:
This 16-month evaluation of a systematic endoscope culturing program identified a low rate of positive cultures after elevator lever endoscope reprocessing. All positive cultures were with non-enteric microorganisms. The program was of modest cost and identified reprocessing procedures that may have led to a low rate of positive cultures.

Keywords:
elevator lever equipped endoscopes; carbapenem-resistant Enterobacteriaceae; healthcare-associated infections; costs

INTRODUCTION

Since 2008, multiple outbreaks of carbapenem-resistant *Enterobacteriaceae* (CRE) duodenoscope-related infections have been reported.[1-3] As a multidrug-resistant organism, CRE can cause serious infections with limited treatment options and a resultant high mortality.[4] Duodenoscopes possess an elevator mechanism that allows for advanced endoscopic maneuvers but pose a challenge for reprocessing and decontamination. Linear array echoendoscopes (LAEs) are also equipped with an elevator lever that facilitates diagnostic and therapeutic maneuvers and have also been shown to be at risk for persistent bacterial contamination.[5]

In 2015, the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) issued guidances for duodenoscope culturing and reprocessing in response to these outbreaks.[6-8] These guidances noted that routine culturing could be considered to assess adequacy of reprocessing; however, the frequency of culturing was not specified. Furthermore, the American Society for Gastrointestinal Endoscopy (ASGE) and the American Gastroenterological Association (AGA) provided recommendations, which included the periodic culturing of elevator lever-equipped endoscopes. [9, 10] Multiple different strategies to prevent duodenoscope-related transmission of infection have been proposed, including quarantine protocols, different culturing methods and frequencies, gas sterilization with ethylene oxide, and double reprocessing cycles.[9, 11-13] However, the effectiveness of these programs as well as their financial implications remain unclear.

A multidisciplinary process for systematic sampling and culturing of elevator lever equipped endoscopes was developed and implemented at our institution in June 2015. The

aims of this study are to assess if prior known CRE infections were potentially associated with procedures using elevator lever equipped endoscopes and to assess the effectiveness of this culturing program and the costs associated with its implementation.

METHODS

Setting

Penn Medicine is comprised of, among other entities, 4 hospitals with 2,503 hospital beds, ranging from community to quaternary care. An average of 2,300 endoscopic procedures using elevator lever-equipped endoscopes are performed annually. Informed consent for procedures with elevator lever equipped endoscopes includes education regarding the possible risks of infection during the procedure. The risk of CRE infection is not directly addressed routinely.

Best Practices

Best practices for endoscopic reprocessing were implemented in March 2015 and included standard reprocessing procedures according to revised manufacturer's instructions for use recommendations. These recommendations include a goal to minimize the time between reprocessing steps to minimize the opportunity for biofilm development. We modified these recommendations to include 1 hour goals for the completion of the following steps: completion of manual cleaning after completion of bedside cleaning and initiation of automated endoscope reprocessing after completion of manual cleaning. Once an endoscopic procedure is completed, the technician performs an initial cleaning with wiping of the insertion tube, immersion in clean water with an air-water channel cleaning adapter, and suctioning of an enzymatic cleaner while in the endoscopy room. After

completion of this step, the endoscope is transported to the reprocessing area; the endoscope is then scanned, initiating a 1-hour countdown during which time the endoscope must have completed a manufacturer-recommended manual clean including brushing and flushing of internal channels, which includes brushing of the forceps elevator, elevator recess, and guidewire-locking groove in both the open and closed positions.[14] For elevator lever equipped endoscopes, 2 individuals complete the manual clean (one performing the cleaning and the other observing for quality control). Once the manual clean is completed, the endoscope is scanned to end the first countdown and to start a second one-hour countdown, during which time the endoscope must have begun automated endoscope reprocessing. The endoscopes are placed into an Olympus OER-Pro for high-level disinfection using either 6.8% peracetic acid (Acecide C) or 3.4% glutaraldehyde (Aldahol 1.8) following the manufacturer's instructions for use. After completion, the endoscopes are air dried using compressed medical air to dry all inner channels, the exterior is also dried using a lint-free cloth. The endoscopes are then stored in an air-ventilated cabinet to help remove any remaining moisture. The proportion of endoscopes meeting these 1-hour timeframes is automatically registered and reviewed on a weekly basis to assess adherence and opportunities for improvement with no direct interventions for individual endoscopes that did not meet the one-hour timeframes (Supplemental Figure 1). Data were used in aggregate to improve systems processes to increase compliance with the 1-hour timeframes.

Review of microbiology data

To determine if procedures using elevator lever equipped endoscopes were associated with transmission of CRE, a retrospective review of microbiology data for the period 2011 to 2014 was performed to identify any patients with CDC National Healthcare Safety Network reported CRE blood or abdominal infections who had undergone a procedure with an elevator lever-equipped endoscope in the prior 36 months.

Endoscope culturing process

A multidisciplinary group including physicians, nurses, and technicians from gastroenterology, infectious diseases, laboratory medicine, and perioperative services designed a program to prospectively identify elevator lever equipped endoscopes harboring infection in the absence of evidence of prior scope-related transmission events. Beginning in May 2015, once per week (preferentially on Fridays) approximately 25% of the inventory of elevator lever equipped endoscopes were cultured using a modification of the CDC interim guideline.[7] Each endoscope was cultured once monthly, and the schedule for culturing was based on convenience depending on scheduled volume. Endoscopes could be cultured even if not used during the prior week. The culturing process involved brushing of the elevator mechanism and channel and also flushing of the biopsy channel. Two nurses or operating room technicians, who have been trained to perform the culturing procedure, completed the process using aseptic technique (Supplemental Table 1). After culturing was complete, the endoscope was reprocessed and could return to use the next day with pending culture results; however, as endoscopes were preferentially cultured on Fridays, the endoscopes were essentially out of circulation for approximately 48 hours. Qualitative cultures were performed rather than quantitative cultures (either method was

acceptable per CDC/FDA Interim Culture Methods).[15] The advantage of qualitative cultures is that any positive culture is treated as potentially evidence of failure of reprocessing and/or sampling, rather than assigning arbitrary thresholds for clinical significance. All endoscopes with positive cultures are reprocessed, recaptured, and quarantined before return to circulation. This contrasts with the quantitative cultures whereby only cultures with >10 colony forming units of low concern organisms would be recaptured per CDC guidelines.[15] Culture reports were then automatically emailed on days 2 and 5 after collection to both perioperative services/instrument processing and infection control staff. If any cultures returned bacterial growth, the endoscope was quarantined and reprocessed; the endoscope was not placed into circulation until repeat cultures returned negative.

Cost analysis

Comprehensive costs of the culturing program were evaluated including costs of staff time, sampling supplies, culturing supplies, culturing, and reprocessing. Costs were analyzed per endoscope per year and also as a total cost per year for our health system's inventory of 20 elevator lever equipped endoscopes, including 8 linear array echoendoscopes (Olympus GF-UCT180) and 12 endoscopic retrograde cholangiopancreatography (ERCP) endoscopes (10 Olympus TJF-Q180V, 1 Olympus JF-140F, and 1 Olympus PJF-160).

The Institutional Review Board at the University of Pennsylvania approved the study.

RESULTS

Retrospective review of CRE infections

During the 4-year period from 2011 to 2014, review of clinical microbiology data identified 17 patients with CDC National Healthcare Safety Network reported CRE blood or abdominal infections. Of these 17 CRE infections, 10 were intraabdominal, 6 were from a surgical site, and 1 was blood borne. None of these 17 patients had undergone a procedure with an elevator lever equipped endoscope during the 36 months before their CRE infection.

Elevator lever equipped endoscope culturing

From June 2015 to September 2016, a total of 285 endoscopes were cultured including 110 cultures of LAEs and 175 cultures of ERCP endoscopes according to the systematic elevator lever equipped endoscope culturing protocol (Figure 1). Of these, 3 out of 285 (1.1%) cultures demonstrated bacterial growth: 2 with coagulase negative *Staphylococcus* species and 1 with *Rothia* species. These were considered skin and oral contaminants, respectively; however, these low-concern organisms can be associated with infection in uncommon cases. One LAE and one ERCP endoscope had a positive culture with coagulase negative *Staphylococcus* whereas a single ERCP endoscope had the positive culture with *Rothia*. These endoscopes were quarantined, reprocessed, and then had repeat culturing, which were negative for bacterial growth. The endoscopes were returned to active use, and all subsequent cultures did not demonstrate any bacterial growth. The three positive cultures occurred within the first 75 cultures and may reflect the early experience in adherence to culture technique.

Of note, there were 2 patients who had documented CRE colonization detected as a part of their standard clinical care who subsequently underwent ERCP. The endoscopes used for these 2 procedures were reprocessed routinely, cultured and quarantined pending the culture results. No evidence of bacterial growth was detected from either sample; the endoscopes were reprocessed a second time and returned to circulation.

Cost analysis

The cost of the program includes staff time, the cost of sampling and culturing, and the cost of additional reprocessing. Two staff members spend approximately 30 minutes sampling each endoscope. In addition to this staff time, which amounts to $49.00 per endoscope, the supply cost of sampling is $30.00 per endoscope (500 mL sterile saline solution, 120 mL sterile urine specimen cup, sterile 60 mL lure-loc syringe, 15G x 1.5" blunt tip fill needle, sterile disposable cytology brush, sterile gloves, bouffant hair coverings, sterile gowns, face masks/shields, dry skin prep tray, and sterile table drape). The laboratory cost for specimen processing is $15.00 per culture, including technologist time (an average of 10 minutes per culture) and materials (media, centrifuge tubes, and other disposables). The additional reprocessing after culturing costs $32.79 per endoscope, which includes $21.00 for 1 hour of staff time and $11.79 for material costs (elevator brush [$1.09], channel brush [$2.20], disposable cloth [$0.44], detergent [$3.75], disinfectant [$4.31]). The total cost of our program is estimated to be $1,521.48 per endoscope per year and $30,429.60 per year for an inventory of 20 elevator lever equipped endoscope (Table 1). Preferential sampling of endoscopes on Fridays allowed the weekend to determine culture results and eliminated the need to expand on-site inventory.

DISCUSSION

Several recent duodenoscope-associated CRE outbreaks have prompted re-evaluation of existing reprocessing and culturing practices.[1-3] Action plans have been developed by the FDA, CDC, AGA, and ASGE, and among the different points addressed by these plans, periodic culturing of elevator lever equipped endoscopes has been recommended; however, a specific protocol and frequency for such culturing has not been clearly defined.[6-10] A multidisciplinary team from gastroenterology, infectious diseases, laboratory medicine, and perioperative services developed a systematic elevator lever equipped endoscope culturing program that was implemented at our institution in May 2015.

Expeditious identification of contaminated endoscopes is of utmost importance as tracing the source of transmitted multi-drug resistant organisms can often be challenging and delayed. Additionally, the financial burden of an outbreak can be significant. Ross et al[11] described Virginia Mason Medical Center's experience with an outbreak that ultimately required aggressive reprocessing cycles, quarantine of duodenoscopes, and tripling of the inventory of duodenoscopes. This experience highlights that the costs associated with prevention or early detection of CRE transmission are small compared with the clinical and financial costs associated with an outbreak.

The cost-effectiveness of any elevator lever equipped endoscope culturing program must also be assessed. In a study by Almario et al,[12] the cost utility of different strategies to prevent endoscopic transmission of CRE was largely dependent upon institutional CRE prevalence. Given the current low pretest probability for CRE at most institutions, more

frequent culturing than is called for by the culturing program described in this study may be unnecessary and incur additional costs with only marginal additional benefit. Costs must also account for the removal of elevator lever equipped endoscopes from circulation due to the sampling procedure and need for repeat reprocessing. The rotating nature of this culturing program mitigates this operational cost because the maximum of elevator lever equipped endoscopes temporarily removed from circulation at any given time is 25%. Additionally, we preferentially performed endoscope sampling on Fridays to effectively "quarantine" the elevator lever equipped endoscopes over the weekend pending the preliminary culture results. Based on our very low rate of positive samples (1.1%) with no identification of high-risk organisms, routine quarantine of elevator lever equipped endoscopes pending culture results does not appear necessary at our facility. Ultimately, the cost-effectiveness and feasibility of a program will likely depend upon institutional CRE prevalence, elevator lever equipped endoscope inventory, and the availability of staff to allow for allocation of work-hours for systematic sampling and culturing.

Although these efforts may aid early detection of contaminated elevator lever equipped endoscopes and curb elevator lever equipped endoscope-related transmission of infection, the underlying issue at hand remains the design of elevator lever equipped endoscopes, specifically with the elevator channel posing a challenge for reprocessing. Re-evaluation of reprocessing methods, instructions, and training are necessary to ensure adequate manual cleaning and disinfection. Ross et al found that 1.9% of duodenoscope cultures remained positive even after strict adherence to reprocessing and high-level disinfection guidelines.[11] In a multicenter study, Brandabur et al[16] collected daily post-reprocessing surveillance cultures for elevator lever equipped endoscopes and had 5.0% of

cultures return bacterial growth. One area of interest includes decreasing the time between completion of procedure and initial reprocessing, which may prevent the development of an intractable biofilm that cannot be eradicated by standard reprocessing measures.[17] Ultimately, endoscope redesign to allow for enhanced access for cleaning may be the most impactful intervention to eliminate elevator lever equipped endoscope-related transmission of infection. Until such a redesign occurs, best practices, including decreasing time to completion of reprocessing to prevent biofilm formation, may decrease the rate of endoscope contamination as represented by positive endoscope cultures. In Brandabur et al's study, it is noted that all manufacturer's recommendations are followed with a resultant 5.0% rate of positive cultures. The lower rate of positive cultures seen in our study (1.1%) suggests that there remain opportunities to improve manual cleaning and reprocessing of endoscopes.

Patients and physicians should have the reasonable expectation that measures are being undertaken to effectively eliminate the risk of elevator lever equipped endoscope-related transmission of infection, which is a sentiment that is shared by many major medical societies.[18, 19] Ultimately, the goal of completely eliminating elevator lever equipped endoscope-related infections will likely involve a multi-pronged approach which will include the following: (1) education of staff at all levels regarding the importance of strict adherence to reprocessing protocols, (2) determination of an optimal surveillance culturing protocol, (3) monitoring of patients who have undergone a procedure with an elevator channel endoscope, (4) development and validation of advanced sterilization techniques, and (5) redesign of elevator channel endoscopes.

Our study has limitations that warrant examination. First, no outbreaks of elevator lever equipped endoscope-related CRE transmission have occurred at our institution; thus, the sensitivity of this systematic culturing program to identify CRE-contaminated elevator lever equipped endoscopes cannot be directly assessed. Second, there were only 3 positive elevator lever equipped endoscope cultures in our cohort, all of which were from non-enteric organisms that were likely contaminants. However, culture-negative endoscopes may still have clinically significant biological residue. Despite this potential gap, we believe periodic culturing provides the most effective widely available tool to detect system flaws that could increase the risk of transmission of infectious agents. Third, the cost analysis of the elevator lever equipped endoscope culturing program does not account for the purchasing of additional elevator lever equipped endoscopes, which may be required at some institutions. We had a sufficient supply of elevator lever equipped endoscope such that additional endoscopes did not need to be purchased to make up for those held for the culturing and reprocessing protocol. Institutions seeking to adopt this culturing program will need to assess if their inventory would allow for the periodic temporary removal of 25% of elevator lever equipped endoscopes from circulation.

In summary, this 16-month evaluation of a systematic elevator lever equipped endoscope sampling and culturing program identified a low rate of positive cultures after reprocessing. These positive cultures were associated with non-enteric microorganisms, which are believed to be contaminants. The program was determined to be of modest cost, identified reprocessing procedures that may have led to a low rate of positive cultures, and was successfully implemented at multiple sites within our health system. The favorable findings support our emphasis on processes to decrease the time between completion of

procedure and initial reprocessing and the thoroughness of mechanical cleaning, which may prevent the development of intractable biofilm that cannot be eradicated by standard reprocessing measures.

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FIGURES

Figure 1. Systematic endoscope culturing process. A. Each week, 25% of the inventory of elevator lever equipped endoscopes is selected to be sampled and cultured. B. Elevator lever equipped endoscopes are cultured based on CDC guidelines by two trained staff members using aseptic technique. C. On days 2 and 5, culture results are reported. D + E. If the culture for an elevator lever equipped endoscope returns with no growth, the elevator lever-equipped endoscope remains in circulation. F + G. If an elevator lever-equipped endoscope has a positive culture result, the implicated elevator lever-equipped endoscope is quarantined and repeat cultures are obtained.
CDC = Centers for Disease Control and Prevention

TABLES

Cost per endoscope culture	
Staff (30 minutes x 2 trained staff)	$49.00
Sampling/culturing supplies	$30.00
Culturing process	$15.00
Reprocessing costs per endoscope	
Staff	$21.00
Reprocessing supplies	$11.79
Total per culture/reprocessing cycle	$126.79
X 12 cultures per year	$1,521.48
X 20 elevator lever equipped endoscopes	$30,429.60

Table 1. Costs associated with culturing program

SUPPLEMENTAL

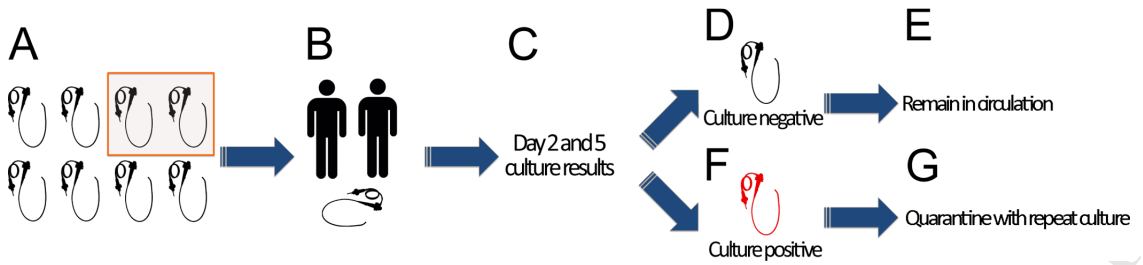
Supplemental Figure 1. Adherence to endoscope reprocessing best practices. The percentage of endoscopes completing two different steps of endoscope reprocessing within one hour for individual months from July 2015 to July 2016. The trend line with circular markers represents the percentage of endoscopes that successfully completed manual cleaning within one hour after completion of bedside cleaning. The trend line with square markers represents the percentage of endoscopes that successfully initiated AER within one hour after completion of manual cleaning.

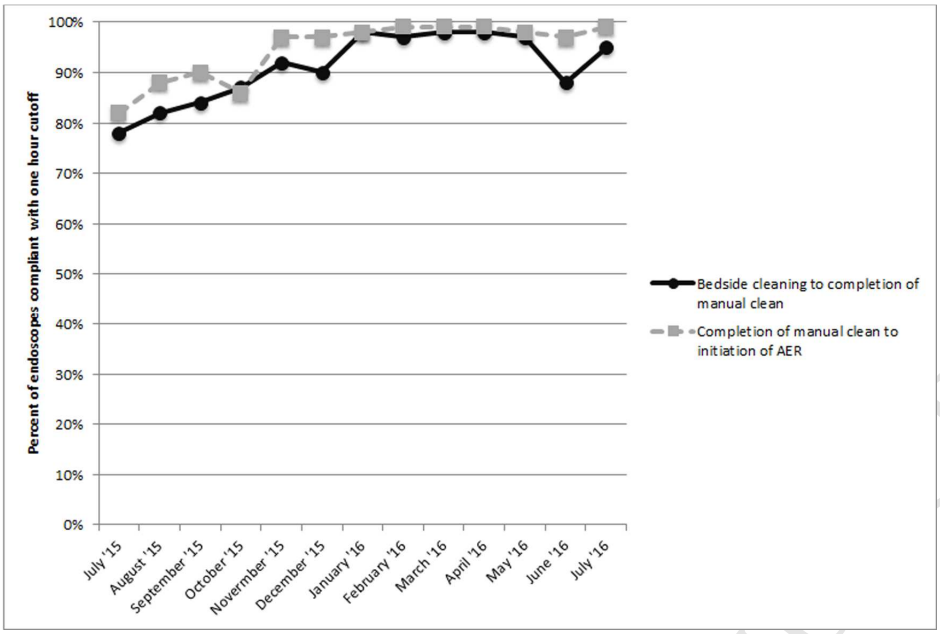
AER = automated endoscope reprocessing

MATERIALS AND REAGENTS	
Sterile solution for irrigation (500mL bottle)	
Sterile urine specimen cup (120mL)	
Sterile 60cc lure-loc syringe	
15G x 1.5" blunt tip fill needle	
Sterile disposable cytology brush	
Sterile wire cutters	
High-level disinfected red suction button, blue air-water button, and black biopsy cap	
Additional materials: sterile alcohol pads, bouffant hair coverings, sterile gloves, sterile gowns, face masks/shields, dry skin prep tray, sterile table drape, specimen labels	
DEFINITIONS	
Lowered/Closed position	Notes the position of the elevator forceps being parallel or within the elevator channel relative to the distal end of the duodenoscope
Raised/Open position	Notes the position of the elevator forceps being perpendicular to the distal end of the duodenoscope
PREPARATION OF MATERIALS	
1	Disinfect the surface of the back table with a PDI SaniWipe with 3 minutes of contact time
2	Perform hand hygiene with alcohol hand rub or antimicrobial soap and water
3	Don sterile gowns, face masks/shields, hair covers, and sterile gloves
4	Drape back table with a sterile table drape
5	Prepare the sampling materials by laying out the sterile sampling containers as well as other needed sterile items: 60cc syringe, wire cutter, sterile disposable cytology brush, dry skin prep tray, red suction button, blue air-water button, 5cc sterile syringe for use with linear array echoendoscopes. Pour 200-300mL of 500mL sterile saline solution for irrigation into dry skin prep tray reservoir.
6	Prepare duodenoscope - Place red suction button on the suction port - Place blue air-water button on air-water port

	- Place black biopsy cap on biopsy channel - Close water-resistant cap on end of duodenoscope - Remove "Clean" tag from duodenoscope
BRUSH ELEVATOR FORCEPS AND CHANNEL	
7	Open sterile alcohol pad for use
8	Sanitize outer surface of duodenoscope tip with sterile alcohol pad. Do not wipe elevator forceps and lens face at distal end that will be sampled with cytology brush; allow alcohol to air dry before sampling
9	Place duodenoscope on sterile draped back table
10	Using the controller, set the elevator forceps in the raised/open position
11	Using the cytology brush, firmly sample under the elevators forceps in the raised/open position and scrub the face of the lens
12	Using the controller, set the elevator forceps in the lowered/closed position and orient the distal end relative to the person sampling for optimal sampling
13	Dip the cytology brush into the sterile saline solution
14	Using the pre-moistened cytology brush, with twisting motion of the brush, sample the inside of the elevator forceps and channel in the lowered/closed position
15	Pass the cytology brush into the distal end of the elevator channel and advance until slight resistance is encountered (~120cm)
16	Remove the cytology brush from the channel and position the brush above the mouth of the specimen container
17	Using wire cutters, cut the wire above the bristles and just below the plastic sheath. The brush should fall into the specimen container. Place lid on specimen container.
FLUSH BIOPSY CHANNEL	
18	Fill 60cc syringe with 50mL of sterile irrigation saline solution. Place 15G x 1.5" blunt fill tip needle on tip of 60cc syringe
19	Insert the blunt tip fill needle with saline solution-filled syringe into the black biopsy port cap
20	Coordinate how to hold the duodenoscope at the optimal angle to flush the biopsy channel and to collect the sample in the specimen container
21	Flush the biopsy channel with 50mL of sterile saline solution to collect sample in the sterile specimen container that contains the brush head. Flush the biopsy channel two times each with 20-30mL of air from the 60mL syringe to ensure that all the fluid is flushed from the biopsy channel.
22	If applicable, attach auxiliary channel adapter to the elevator wire channel inlet
23	Using a 5cc syringe with 5mL of sterile saline solution, flush saline solution into the same specimen jar as above. Repeat flush a second time with an additional 5mL of sterile saline solution into the same specimen jar.
24	Flush using a 5cc syringe with 5mL of air into the same specimen jar. Repeat flush a second time with an additional 5mL of air.
25	Tighten the lid to the specimen jar, label the specimen (i.e. endoscope type [ERCP versus linear array echoendoscope], serial number), and place container in a specimen bag. Place clinical microbiology requisition in specimen bag.

Supplemental Table 1. Duodenoscope sampling method.





Acronyms and Abbreviations Used

AGA = American Gastroenterological Association
ASGE = American Society for Gastrointestinal Endoscopy
CDC = Centers for Disease Control and Prevention
CRE = carbapenem-resistant *Enterobacteriaceae*
ERCP = endoscopic retrograde cholangiopancreatography
FDA = Food and Drug Administration
LAE = linear array echoendoscopes