Surveillance of guideline practices for duodenoscope and linear echoendoscope reprocessing in a large healthcare system

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Background and Aims: To assess the adequacy of currently recommended duodenoscope and linear echoendoscope (DLE) automatic endoscope reprocessing (AER) and high-level disinfection (HLD), we collected daily post-reprocessing surveillance cultures of 106 DLEs in 21 Providence and Affiliate Hospitals.

Methods: Daily qualitative surveillance of dried, post-HLD DLEs was conducted for a minimum of 30 days at each facility. Positivity rates for any microbial growth and growth of high-concern pathogens were reported. Potential effects of DLE manufacturer, age, and AER processor on culture-positivity rate were assessed.

Results: Microbial growth was recovered from 201 of 4032 specimens (5%) or 189 of 2238 encounters (8.4%), including 23 specimens (.6%) or 21 encounters (.9%) for a high-concern pathogen. Wide variations in culture-positivity rate were observed across facilities. No striking difference in culture-positivity rate was seen among 8 DLE models, 3 DLE manufacturers, DLE age, manual or bedside cleanser, or automatic flushing system use. However, there was suggestive evidence that Custom Ultrasonics AER (Warminster, Pa, USA) had a lower culture-positivity rate than Medivators AER (Cantel Medical Corp., Little Falls, NJ, USA) for high-concern pathogen growth (0/1079 vs 21/2735 specimens or 0/547 vs 20/1582 encounters). Two endoscopes grew intestinal flora on several occasions despite multiple HLD. No multidrug-resistant organism was detected.

Conclusions: In this multicenter DLE surveillance study, microbial growth was recovered in 5.0% of specimens (8.4% of encounters), with most being environmental microbes. Enteric bacterial flora was recovered in .6% of specimens (.9% of encounters), despite compliance with 2014 U.S. guidelines and manufacturers' recommendations for cleaning and HLD process. The observed better performance of Custom Ultrasonics AER deserves further investigation. (Gastrointest Endosc 2016;84:392-9.)

Despite over 500,000 ERCP procedures using duodenoscopes having been performed annually in the United States[1] since 2011, when new guidelines on reprocessing GI endoscopes were published,[2] only 146 infection-associated medical device-adverse event reports involving duodenoscopes have been received by the U.S. Food

Abbreviations: AER, automatic endoscope reprocessing/reprocessor; CDC, Centers for Disease Control and Prevention; CI, confidence interval; DLE, duodenoscope and linear echoendoscope; FDA, U.S. Food and Drug Administration; HLD, high-level disinfection.

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and Drug Administration (FDA). An additional 152 reports involving automatic endoscope reprocessing (AER) systems have been filed for patient infection, patient exposures, or device contamination–related problems.[3] Before 2013, most ERCP-associated infections were attributed to breaches in end-user compliance with manufacturers' reprocessing instructions; since then, transmission of infections has been documented despite meticulous compliance with such instructions.[4-6]

GI endoscopes, including duodenoscopes and linear echoendoscopes (DLEs), are semicritical devices that present challenges for cleaning and high-level disinfection (HLD).[2,7] These challenges prompted the FDA to issue a safety communication listing supplemental duodenoscope reprocessing measures.[8] International guidelines recommend routine surveillance for bacterial contamination after reprocessing, using a variety of sampling methods at variable intervals.[9] Reports of ERCP-related carbapenem-resistant *Enterobacteriaceae* infections raised serious questions regarding the adequacy of existing guidelines for DLE reprocessing and HLD.[4,5] In response to these reports, Providence Health & Services and its affiliates, Swedish Health Services and Kadlec Medical, investigated the adequacy of current endoscope cleaning and reprocessing practices used in its facilities.

TABLE 1. Bacteria of high concern cultured from duodenoscopes and linear echoendoscopes

Bacteria of high concern	Number of specimens	Number of encounters
Single pathogen		
S aureus	1	1
E coli	5	5
Enterococcus spp	5	3
Pseudomonas aeruginosa	1	1
Klebsiella pneumoniae	1	1
Enterobacter gergoviae	1	1
Chryseobacterium	1	1
Leclercia adecarboxylata	1	1
Two pathogens		
Stenotrophomonas, Chryseobacterium	1	1
Enterococcus spp, gram-negative bacteria	1	1
Enterococcus spp, yeast	1	1
Three pathogens		
E coli, E gergoviae, Enterococcus spp	1	1
S aureus, CoNS, *Strep viridans*	2	2
Eikanella, apathogen *Neisseria, Strep viridans*	1	1
Sum	23	21

CoNS, Coagulase-negative staphylococci.

METHODS

Setting

This assessment was conducted within 21 facilities in which over 4500 ERCP procedures are performed each year, with individual facility volumes ranging from less than 1 ERCP procedure per week to an average of 10 per day. Twenty-three EUS and 61 ERCP endoscopes were in service during the study period, all from Olympus (Lake Success, NY, USA) except 3 Pentax (Montvale, NJ, USA) ERCP endoscopes (used in 1 facility) and 22 trial Fuji (Wayne, NJ, USA) endoscopes (15 ERCP and 7 EUS) at 5 facilities. Most Olympus ERCP endoscopes were models 160 (n = 38) and 180 (n = 15). Because no human subjects were involved in this surveillance study, no institutional review board approval was required by Providence Health & Services.

All facilities across 5 western states used minimum specifications consistent with American Society for Gastrointestinal Endoscopy guidelines[2] and manufacturers' reprocessing recommendations for leak testing, cleaning, disinfection, drying, and storage. Significant variation existed within the individual process steps, workflow, and facility design. At the end of an endoscopic procedure, each facility conducted a bedside clean with an enzymatic cleaner while still inside the endoscopy suite, followed by a thorough manual clean in a designated decontamination area, before placing each DLE in an AER for HLD. The manual cleaning consisted of wiping of all external surfaces, brushing of all internal channels and components, and flushing of the internal channels (manually in 3 facilities, and using an automatic flushing aid in 18 facilities). Across the system, 6 brands of bedside cleaner, 8 brands of manual cleaners, 4 AER systems, and 4 brands of high-level disinfectants were used, although each facility used only 1 cleaning method during the time of microbiologic surveillance in accordance with the manufacturers' instructions. All necessary quality control parameters were reviewed before each cycle.

Sampling

Collection. Between March and July 2015 daily cultures (Monday through Friday) from each DLE were collected for a minimum of 30 days at each facility. Culturing occurred each morning on stored DLEs that had previously undergone HLD and complete drying. Some facilities opted to not culture DLEs that had not been reprocessed since their last culturing encounter.

Sixteen of 21 facilities followed the protocol described in Appendix 1 (available online at www.giejournal.org). In brief, 1 sample was collected using a sterile swab for swabbing the auxiliary port (if available) and the elevator mechanism of the endoscope. A second specimen was collected using a sterilized, disposable channel cleaning brush for sampling the inside of the suction channels and working channel. Swab and brush tips were cut off and dropped into 2 separate vials containing 5 mL of tryptic soy broth. Three facilities collected cultures from

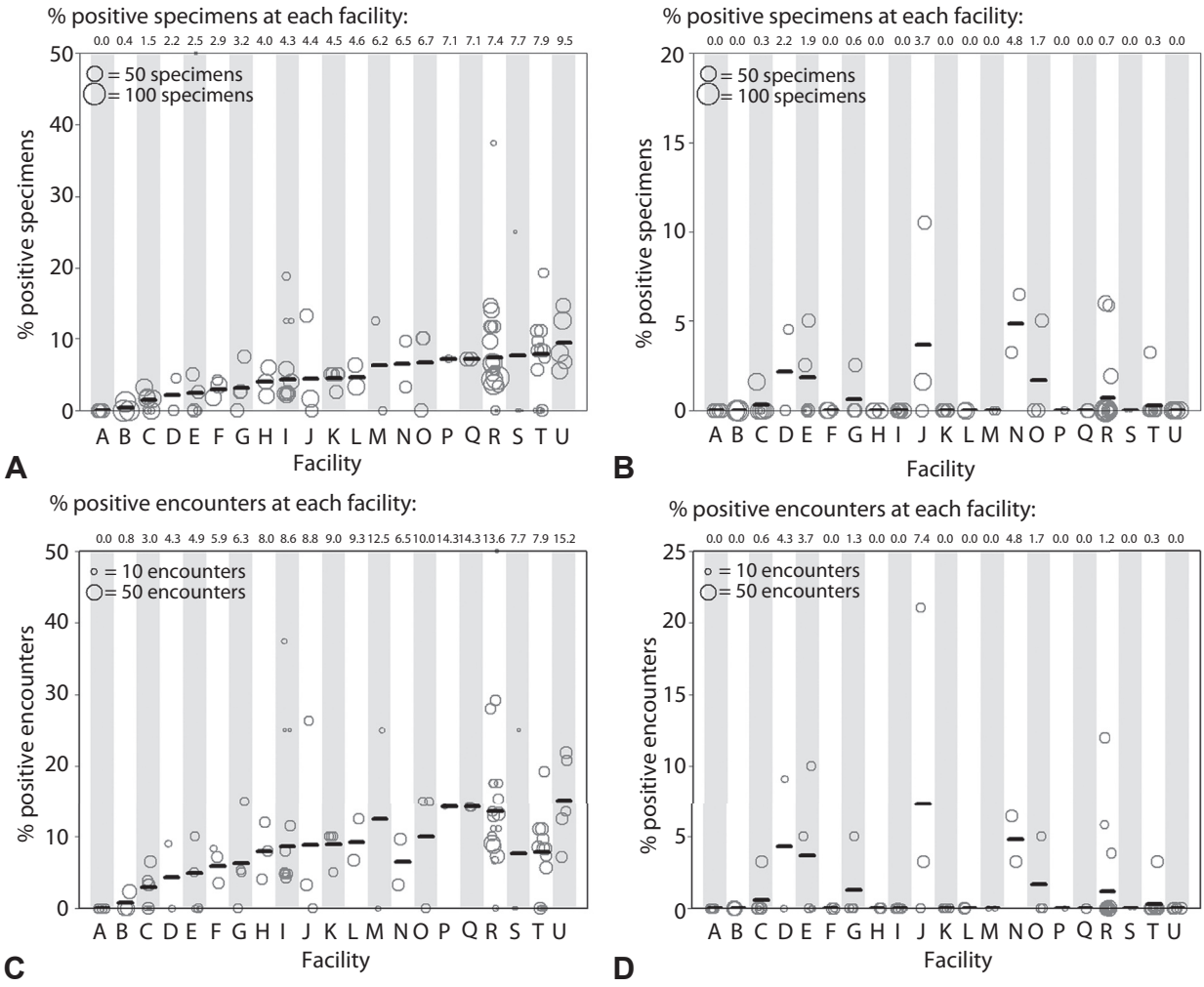

Figure 1. Facility variation in culturing results. Overall culture positivity for specimen-based (**A**) and encounter-based (**C**) results. High-concern culture positivity for specimen-based (**B**) and encounter-based (**D**) results. Each *circle* represents 1 endoscope, with the area proportional to the number of cultures collected. The *black bars* are the average rate for each facility.

the same sites but only using 1 or 2 swabs and no brush. Two facilities followed the flush method described by the Centers for Disease Control and Prevention (CDC)[10] and collected only a single sample from each endoscope. Four brands of brushes and 4 brands of swabs were used to collect culture specimens. Among the 4 culture collection methods used, no significant differences were detected (Supplementary Table 1, available online at www.giejournal.org).

Laboratory testing. Detailed instructions for processing the collected samples were provided to each facility's laboratory (Appendix 2, available online at www.giejournal.org). Broth cultures were incubated at 37°C in ambient air and read at 24 and 48 hours. Positive cultures were worked up to genus or species level using routine microbiology methods. High-concern pathogens included enteric gram-negative bacilli, *Pseudomonas aeruginosa*, *Acinetobacter baumannii*, *Staphylococcus aureus*, *Enterococcus* spp, and *Stenotrophomonas maltophilia*. Coagulase-negative staphylococci, *Bacillus* spp, coryneform gram-positive bacilli, and other gram-negative glucose-nonfermenters were considered environmental colonizers. In 1 laboratory the recently published CDC protocol[10] for quantitative cultures was followed. Variation existed in laboratory reporting format.

Reporting and follow-up. Culture results were documented in a shared electronic record. Endoscopy and infection prevention were alerted to the growth of any high-concern pathogens. If positive for microbial growth, the DLE was reprocessed, recultured, and quarantined before it was returned to use. The 2 endoscopes with multiple positive results were sent back to the manufacturer for additional investigation and repair.

Statistical analysis

Because either 1 or 2 specimens were collected at each culturing encounter, both specimen-based and encounter-based culture-positivity rates are reported.

Culture-positivity rates for any microbial growth and for high-concern pathogen growth were summarized with exact 95% confidence interval (CI) for binomial probability. Stratification of the culture-positivity rates by various categoric factors were used for assessing differences among each factor, relying on the 95% CIs. Because no significant differences in the culture-positivity rates were observed among the 4 culture collection methods (for details see Supplementary Table 1, available online at www.giejournal.org), they were not distinguished in subsequent analyses.

DLE manufacturer, AER system, and endoscope usage (endoscope age used as a proxy) were the factors of primary interest. Poisson regression, which accounts for the varying numbers of cultures collected for each endoscope, was used for evaluating the effect of endoscope age on culture-positivity rates. Because an older-age endoscope in a low-volume facility might have less usage than a newer endoscope in a high-volume facility, the regression evaluation was limited to the subgroup of endoscopes from the 3 high-volume facilities (possessing 10 or more endoscopes). The regression analysis was repeated for evaluating the collective effects of these 3 factors. Other potential factors available in the data were also investigated. Analyses were performed using R 3.1.0 statistical program (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Altogether, 4032 surveillance culture specimens were obtained from 2238 encounters for the 106 DLEs in clinical use. Of those, 201 specimens (5.0%; 95% CI, 4.3%-5.7%) or 189 encounters (8.4%; 95% CI, 7.3%-9.7%) showed microbial contamination after routine recommended bedside and manual cleaning, AER, and drying procedures. Pathogenic organisms as described above were found in .6% (n = 23) of specimens (95% CI, .4%-.9%) or .9% (n = 21) of encounters (95% CI, .6%-1.4%), none of which was a multidrug resistant organism (Table 1), cultured from 14 different endoscopes. Wide variations in the culture-positivity rates were noted among facilities (Fig. 1) and among cleaning and culturing processes (Table 2). One facility (4 endoscopes, 176 cultures) detected no organisms at all during the surveillance period. Pathogenic organisms occurred in 1 to 5 occasions from 9 of the 21 facilities.

Pathogenic organisms were recovered in endoscopes from all 3 manufacturers as well as from 5 of 8 endoscope models and 2 of 4 AER types. No trends were identified with cleaners or HLD solutions. Two endoscopes from different facilities had multiple repeat positive results. One duodenoscope grew *Escherichia coli* on 4 occasions/specimens, and 1 linear echoendoscope grew enteric flora on 3 occasions/specimens, including *E coli, Enterobacter gergoviae, Enterococcus faecalis*, and *Acinetobacter calcoaceticus-baumannii* complex (with multiple organisms isolated from 2 culture specimens). Both endoscopes were returned to the manufacturers for overhaul. The linear echoendoscope was noted to have significant deep grooves inside the working channel. Neither endoscope grew significant bacteria after service overhaul by the manufacturers. Of the 21 encounters positive for high-concern pathogens, 12 had a clearly defined culture source. Notably, the elevator was implicated in all 12 encounters. The working channel specimen was implicated in only 2 of 12 encounters.

Table 3 shows the culture-positivity rates stratified by manufacturer or AER system. Olympus endoscopes accounted for 85% of all culturing encounters (84% of all specimens). No manufacturer stood out as better or worse based on the 95% CIs. Among the 4 AERs in use (Medivators accounting for 70% of the encounters or 68% of all specimens), culture-positivity rates were similar for any microbial growth, either encounter-based or specimen-based. Further stratification by both manufacturer and AER system again showed no difference in the overall culture-positivity rates either, with broad overlap of 95% CIs (Tables 4 and 5). However, the number of high-concern pathogens recovered was significantly lower for Custom Ultrasonics compared with Medivators AER (0/547 vs 20/1582 encounters or 0/1079 vs 21/2735 specimens; Table 3). The Custom Ultrasonics AER has since been removed from the market for unrelated reasons.[11] When stratified by manufacturer, a similar AER influence was observed among Olympus DLEs (0/912 Custom Ultrasonics vs 19/2394 Medivators specimens or 0/463 vs 19/1392 encounters; Tables 4 and 5). Because the 2 endoscopes with multiple positive encounters might skew the data, stratification of the high-concern positivity rates, by AER, was repeated with those 2 cases removed and the same observation remained (data not shown).

Because we were unable to determine the actual usage accrued by each individual DLE, we used individual DLE age from the time of purchase as a proxy for usage. Forty-three percent of DLEs were >72 months of age (median, 58 months; range, 1-192 months). Regression analysis revealed no age effect on the culture-positivity rates among the 3 high-volume facilities (all $P > .05$). Of note, the single duodenoscope that had both a high culture-positivity rate and persistent *E coli* growth had been used for 77 months, and the single linear echoendoscope that showed persistent growth (3 occasions during the study period and 2 additional positive results outside the study period) had been used for 54 months. No other potential contributing factors that were examined, including endoscope model type, contributed significantly to culture positivity (Supplementary Table 2, available online at www.giejournal.org).

Based on multivariable modeling for overall microbial growth, limited to DLEs from the 3 high-volume facilities, none of the factors of interest (DLE age, AER type, and manufacturer) was a significant independent determinant of culture positivity on routine surveillance (all $P > .1$).

TABLE 2. Cleaning and culturing processes among facilities

Facility no.	No. of endoscopes	Scope manufacturer	AER	HLD	Manual cleaner	Bedside cleaner
1	3	Olympus	Medivators	Rapicide	Endozime AW	Endochoice Compliance Kit
2	4	Olympus	Medivators	Rapicide	Intercept Detergent	First Step Kit
3	3	Pentax	Steris Reliance	Reliance DG	Endozime AW	Endozime SLR Kit
4	2	Olympus	Medivators	Metricide	Enzol	Endochoice Compliance Kit
5	1	Olympus	Steris System 1	Cidex OPA	Megazyme	Endozime AW
6	6	Olympus	Medivators	Rapicide	Endozime AW	First Step Kit
7	3	Olympus	Custom Ultrasonics	Cidex OPA	Ecolab Enzymatic	Endochoice Compliance Kit
8	2	Olympus	Custom Ultrasonics	Cidex OPA	Ecolab Enzymatic	Endochoice Compliance Kit
9	10	Olympus/Fuji	Custom Ultrasonics	Cidex OPA	Ecolab Enzymatic	Endochoice Compliance Kit
10	5	Olympus	Custom Ultrasonics	Metricide	Endozime AW	Endochoice Compliance Kit
11	15	Olympus/Fuji	Medivators	Cidex OPA	Endozime AW	Endochoice Compliance Kit
12	4	Olympus/Fuji	Custom Ultrasonics	Cidex OPA	Ecolab Enzymatic	Metrisponge
13	3	Olympus	Medivators	Rapicide	Tri-power Enzymatic	Tri-power Enzymatic
14	2	Olympus	Steris Reliance	Reliance DG	Endozime AW	Endozime SLR Kit
15	4	Olympus	Medivators	Rapicide	Intercept Detergent	First Step Kit
16	8	Olympus/Fuji	Medivators	Rapicide	Ecolab Enzymatic	Endochoice Compliance Kit
17	2	Olympus	Medivators	Rapicide	Cidex OPA	Endozime SLR Kit
18	2	Olympus	Medivators	Rapicide	Mediclean Enzymatic	First Step Kit
19	19	Olympus/Fuji	Medivators	Rapicide	Mediclean Enzymatic	First Step Kit
20	3	Olympus	Medivators	Rapicide	Mediclean Enzymatic	First Step Kit
21	5	Olympus	Custom Ultrasonics	Metricide	Ecolab Enzymatic	Endochoice Compliance Kit

AER, Automatic endoscope reprocessing/reprocessor; *DG*, Dry germicide; *HLD*, high-level disinfection; *KC*, Kimberly Clark; *OPA*, Ortho-Phthalaldehyde.

Very low event counts, and hence several no-event subcategories, rendered multivariable modeling unstable and unreliable for identifying contributing factors on the high-concern pathogen growth.

DISCUSSION

Recent high-profile multidrug resistant organism outbreaks associated with DLEs have presented endoscopists with an inconvenient truth: Despite strict compliance with published guidelines, bacteria may on occasion survive within our instruments.[12] We therefore collected surveillance microbiologic cultures after routine cleaning, automatic reprocessing, and drying in a non-outbreak setting. Our average rates of any bacterial growth (5.0% of specimens or 8.4% of culturing encounters) and growth of high-concern pathogens (.6% of specimens or .9% of encounters) were similar to other recent reports, including that from the Virginia Mason Medical Center.[13] Most organisms recovered were low-concern environmental microbes and were likely because of postcleaning contamination during the storage period. No multidrug-resistant organism was detected, and no patient transmission case, death, or significant patient morbidity related to DLE reprocessing was encountered during the study period.

All endoscope models from 3 manufacturers in clinical use during our month-long surveillance demonstrated microbial contamination at similar rates. Indeed, instruments from all 3 manufacturers and multiple models, including DLEs with similar elevator mechanisms, have been implicated in outbreaks.[3] No striking differences in bacterial recovery rates were noted among the various bedside or manual cleansers or HLD solutions. However, significantly greater high-concern pathogen recovery from nonultrasonic AERs suggests that further investigation should be undertaken to confirm our results. Our findings confirm the potential for transmission of bacteria between patients despite seemingly appropriate and optimal reprocessing techniques, as noted in the concluding remarks of panel members at the May 14 to 15, 2015 FDA advisory panel meeting.[3] The elevator mechanism was implicated in all our positive high-concern culturing encounters with clearly reported culture site. This lends evidence that the elevator, with its complex and difficult to clean design, might be the culprit underlying recent outbreaks.[14]

A small sample size could explain our finding of no significant differences among our culture collection methods. However, the variations we observed among these methods were much smaller than the variations among the 16 facilities using the same collection method, so we believed it was

TABLE 2. Continued

Automated flushing system	Culture method	Brush type	Swab type	Monthly EUS volume	Monthly ERCP volume
Yes	Providence Protocol	Olympus	Puritan	—	15
Yes	Providence Protocol	Olympus	FLOQ	12	36
No	Providence Protocol	Pentax	BBL	23	30
Yes	1 Flush	None	None	—	6
Yes	2 Swabs	None	FLOQ	4	2
Yes	2 Swabs	None	FLOQ	4	13
No	Providence Protocol	KC	Puritan	—	6
Yes	Providence Protocol	KC	BBL	—	3
Yes	Providence Protocol	KC	BBL	34	32
Yes	Providence Protocol	Olympus	BBL	27	23
Yes	1 Flush	None	None	97	106
Yes	1 Swab	None	FLOQ	7	11
Yes	Providence Protocol	KC	FLOQ	5	20
No	Providence Protocol	KC	BBL	—	2
Yes	Providence Protocol	US Endo	Medline	12	14
Yes	Providence Protocol	KC	BBL	37	24
No	Providence Protocol	KC	FLOQ	—	8
Yes	Providence Protocol	KC	FLOQ	—	5
Yes	Providence Protocol	KC	FLOQ	73	90
Yes	Providence Protocol	KC	FLOQ	9	10
Yes	Providence Protocol	KC	FLOQ	7	9

TABLE 3. Culture positivity stratified by endoscope manufacturer or AER system

	Specimen-based		Encounter-based	
	% Positive [n] (95% CI)		% Positive [n] (95% CI)	
Categories	**Any growth**	**High-concern organism**	**Any growth**	**High-concern organism**
Scope manufacturer				
Fuji 508 specimens/274 encounters (23 scopes)	5.9% [30] (4.0%-8.3%)	.4% [2] (.0%-1.4%)	9.5% [26] (6.3%-13.6%)	.4% [1] (.0%-2.0%)
Olympus 3404 specimens/1904 encounters (80 scopes)	4.8% [163] (4.1%-5.6%)	.6% [19] (.3%-.9%)	8.2% [157] (7.0%-9.6%)	1.0% [19] (.6%-1.6%)
Pentax 120 specimens/60 encounters (3 scopes)	6.7% [8] (2.9%-12.7%)	1.7% [2] (.2%-5.9%)	10.0% [6] (3.8%-20.5%)	1.7% [1] (.0%-8.9%)
AER system				
Custom Ultrasonics 1079 specimens/547 encounters (29 scopes)	5.6% [60] (4.2%-7.1%)	.0% [0] (.0%-.3%)	10.1% [55] (7.7%-12.9%)	.0% [0] (.0%-.7%)
Medivators 2735 specimens/1582 encounters (71 scopes)	4.6% [126] (3.9%-5.5%)	.8% [21] (.5%-1.2%)	7.6% [121] (6.4%-9.1%)	1.3% [20] (.8%-1.9%)
Steris Reliance 204 specimens/102 encounters (5 scopes)	6.9% [14] (3.8%-11.2%)	1.0% [2] (.1%-3.5%)	11.8% [12] (6.2%-19.6%)	1.0% [1] (.0%-5.3%)
Steris System 1 14 specimens/7 encounters (1 scope)	7.1% [1] (.2%-33.9%)	.0% [0] (.0%-23.2%)	14.3% [1] (.4%-57.9%)	.0% [0] (.0%-41.0%)

AER, Automatic endoscope reprocessing/reprocessor.

TABLE 4. Culture positivity stratified by both AER system and endoscope manufacturer, specimen-based

Endoscope manufacturer	AER system	No. of specimens (no. of endoscopes)	% Positive [n] (95% CI)	
			Any growth	High-concern organism
Olympus	Custom Ultrasonics	912 (24)	6.1% [56] (4.7%-7.9%)	.0% [0] (.0%-.4%)
	Medivators	2394 (53)	4.2% [100] (3.4%-5.1%)	.8% [19] (.5%-1.2%)
	Steris Reliance	84 (2)	7.1% [6] (2.7%-14.9%)	.0% [0] (.0%-4.3%)
	Steris System 1	14 (1)	7.1% [1] (.2%-33.9%)	.0% [0] (.0%-23.2%)
Fuji	Custom Ultrasonics	167 (5)	2.4% [4] (.7%-6.0%)	.0% [0] (.0%-2.2%)
	Medivators	341 (18)	7.6% [26] (5.0%-11.0%)	.6% [2] (.1%-2.1%)
Pentax	Steris Reliance	120 (3)	6.7% [8] (2.9%-12.7%)	1.7% [2] (.2%-5.9%)

AER, Automatic endoscope reprocessing/reprocessor.

TABLE 5. Culture positivity stratified by both AER system and endoscope manufacturer, encounter-based

Endoscope manufacturer	AER system	No. of encounters (no. of endoscopes)	% Positive [n] (95% CI)	
			Any growth	High-concern organism
Olympus	Custom Ultrasonics	463 (24)	11.0% [51] (8.3%-14.2%)	.0% [0] (.0%-.8%)
	Medivators	1392 (53)	7.1% [99] (5.8%-8.6%)	1.4% [19] (.8%-2.1%)
	Steris Reliance	42 (2)	14.3% [6] (5.4%-28.5%)	.0% [0] (.0%-8.4%)
	Steris System 1	7 (1)	14.3% [1] (.4%-57.9%)	.0% [0] (.0%-41.0%)
Fuji	Custom Ultrasonics	84 (5)	4.8% [4] (1.3%-11.7%)	.0% [0] (.0%-4.3%)
	Medivators	190 (18)	11.6% [22] (7.4%-17.0%)	.5% [1] (.0%-2.9%)
Pentax	Steris Reliance	60 (3)	10.0% [6] (3.8%-20.5%)	1.7% [1] (.0%-8.9%)

AER, Automatic endoscope reprocessing/reprocessor.

reasonable to not distinguish the culture collection methods in analyzing our data. To our knowledge, no direct comparative culture methodologic studies have been published involving DLEs, whose elevator mechanisms are particularly difficult to clean.[14,15] The CDC acknowledges that their advised method for obtaining endoscope cultures, designed for outbreak investigations, has not been validated for ensuring sterility in routine settings.[10] Moreover, the American Society for Microbiology has advised against the routine performance of endoscope cultures by clinical diagnostic laboratories.[16] Our use of disparate culture collection methods reflects "real-life" data; we are planning a randomized study using a standardized culture collection method to further investigate enhanced processing methods of DLEs going forward. It remains unclear how often surveillance should be done. The low prevalence of enteric pathogens makes it difficult to imagine that the use of current routine surveillance methods would be sufficient to avert an outbreak if done any less frequently than daily with quarantining of endoscopes until results are known. The real-time, nonculture monitoring methods show promise but are not yet validated for this purpose.[7]

Persistent bacterial growth noted on some endoscopes in our study replicates the findings of other recent investigations[17] and suggests the presence of a biofilm that renders microorganisms more resistant to repeated single cycles of HLD and/or small defects in instruments not otherwise compromising their functionality.[18] Indeed, the use of

repeated washing and HLD at Virginia Mason Medical Center eradicated most persistent infections[13] and has been advocated as an enhanced safety measure.[7] It is unknown what impact routine repeated HLD will have on the effective clinical use lifespan of these delicate instruments.

Interestingly, endoscope age had no impact on our bacterial growth rates. DLE age is an inexact proxy for endoscope usage over its lifetime. Although we attempted to indirectly assess the number of times a DLE was used over its lifetime by performing subset analyses of high-volume facilities and by determining the frequencies of cultures obtained from older versus newer endoscopes, future studies should seek to directly measure the lifetime number of individual endoscope uses. Tracking of each use of every endoscope is now implemented in our system.

The large variability observed across the 21 facilities included in this study highlights the importance of multicenter studies in examining the multistep, operator-dependent, complex cleaning and reprocessing of DLEs. Operator-dependent variability could also have contributed to the observed variability. Coordinated efforts may play an increasingly important role in assisting agencies such as the CDC or FDA to quickly gather sufficient, generalizable data with which to provide timely evidence-based advice. We are planning a prospective evaluation with standardized culture methods to determine whether an already available, enhanced reprocessing method such as double HLD will enhance the margin of safety for our patients.

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SUPPLEMENTARY TABLE 1. Culture positivity stratified by culture collection methods

	Specimen-based		Encounter-based	
	% Positive [n] (95% CI)		% Positive [n] (95% CI)	
Culture collection method	**Any growth**	**High-concern organism**	**Any growth**	**High-concern organism**
1 Flush 429 specimens/429 encounters (17 scopes)	7.7% [33] (5.4%-10.6%)	.9% [4] (.3%-2.4%)	7.7% [33] (5.4%-10.6%)	.9% [4] (.3%-2.4%)
1 Swab 13 specimens/13 encounters (4 scopes)	7.7% [1] (.2%-36.0%)	.0% [0] (.0%-24.7%)	7.7% [1] (.2%-36.0%)	.0% [0] (.0%-24.7%)
2 Swabs 176 specimens/88 encounters (7 scopes)	2.8% [5] (.9%-6.5%)	1.7% [3] (.4%-4.9%)	5.7% [5] (1.9%-12.8%)	3.4% [3] (.7%-9.6%)
Providence Protocol 3414 specimens/1708 encounters (78 scopes)	4.7% [162] (4.1%-5.5%)	.5% [16] (.3%-.8%)	8.8% [150] (7.5%-10.2%)	.8% [14] (.4%-1.4%)

SUPPLEMENTARY TABLE 2. Culture positivity stratified by other potential factors

	Specimen-based		Encounter-based	
	% Positive [n] (95% CI)		% Positive [n] (95% CI)	
Categories	**Any growth**	**High-concern organism**	**Any growth**	**High-concern organism**
Endocope type				
ERCP 2932 specimens/1619 encounters (76 scopes)	4.9% [145] (4.2%-5.8%)	.5% [16] (.3%-.9%)	8.5% [137] (7.2%-9.9%)	.9% [14] (.5%-1.4%)
LEUS 1100 specimens/619 encounters (30 scopes)	5.1% [56] (3.9%-6.6%)	.6% [7] (.3%-1.3%)	8.4% [52] (6.3%-10.9%)	1.1% [7] (.5%-2.3%)
Scope model among Olympus ERCP scopes				
130 40 specimens/20 encounters (1 scope)	5.0% [2] (.6%-16.9%)	.0% [0] (.0%-8.8%)	10.0% [2] (1.2%-31.7%)	.0% [0] (.0%-16.8%)
140 164 specimens/82 encounters (3 scopes)	2.4% [4] (.7%-6.1%)	.0% [0] (.0%-2.2%)	4.9% [4] (1.3%-12.0%)	.0% [0] (.0%-4.4%)
160 1418 specimens/796 encounters (38 scopes)	4.7% [66] (3.6%-5.9%)	.8% [11] (.4%-1.4%)	8.0% [64] (6.2%-10.2%)	1.4% [11] (.7%-2.5%)
180 810 specimens/459 encounters (15 scopes)	5.1% [41] (3.7%-6.8%)	.1% [1] (.0%-.7%)	8.7% [40] (6.3%-11.7%)	.2% [1] (.0%-1.2%)
HLD solution				
Cidex OPA 986 specimens/683 encounters (35 scopes)	5.6% [55] (4.2%-7.2%)	.1% [1] (.0%-.6%)	8.1% [55] (6.1%-10.4%)	.1% [1] (.0%-.8%)
Metricide 536 specimens/300 encounters (12 scopes)	7.3% [39] (5.2%-9.8%)	.6% [3] (.1%-1.6%)	11.3% [34] (8.0%-15.5%)	1.0% [3] (.2%-2.9%)
Rapicide 2306 specimens/1153 encounters (54 scopes)	4.0% [93] (3.3%-4.9%)	.7% [17] (.4%-1.2%)	7.6% [88] (3.2%-9.3%)	1.4% [16] (.8%-2.2%)
Reliance DG 204 specimens/102 encounters (5 scopes)	6.9% [14] (3.8%-11.2%)	1.0% [2] (.1%-3.5%)	11.8% [12] (6.2%-19.6%)	1.0% [1] (.0%-5.3%)
Bedside cleaner				
Endochoice Compliance 1981 specimens/1206 encounters (53 scopes)	5.2% [103] (4.3%-6.3%)	.3% [5] (.1%-.6%)	8.1% [98] (6.6%-9.8%)	.4% [5] (.1%-1.0%)
Endozime AW 14 specimens/7 encounters (1 scope)	7.1% [1] (.2%-33.9%)	.0% [0] (.0%-23.2%)	14.3% [1] (.4%-57.9%)	.0% [0] (.0%-41.0%)
Endozime SLR 236 specimens/118 encounters (7 scopes)	6.8% [16] (3.9%-10.8%)	.8% [2] (.1%-3.0%)	11.9% [14] (6.6%-9.1%)	.8% [1] (.0%-4.6%)
First Step 1652 specimens/826 encounters (38 scopes)	4.5% [74] (3.5%-5.6%)	.7% [11] (.3%-1.2%)	8.4% [69] (6.6%-10.5%)	1.2% [10] (.6%-2.2%)
Metrisponge 13 specimens/13 encounters (4 scopes)	7.7% [1] (.2%-36.0%)	.0% [0] (.0%-24.7%)	7.7% [1] (.2%-36.0%)	.0% [0] (.0%-24.7%)
Tripower Enzymatic 136 specimens/68 encounters (3 scopes)	4.4% [6] (1.6%-9.4%)	3.7% [5] (1.2%-8.4%)	8.8% [6] (3.3%-18.2%)	7.4% [5] (2.4%-16.3%)
Manual cleaner				
Cidex OPA 32 specimens/16 encounters (2 scopes)	6.3% [2] (.8%-20.8%)	.0% [0] (.0%-10.9%)	12.5% [2] (1.6%-38.3%)	.0% [0] (.0%-20.6%)
Ecolab Enzymatic 1215 specimens/615 encounters (32 scopes)	4.6% [56] (3.5%-5.9%)	.1% [1] (.0%-.5%)	8.3% [51] (6.2%-10.8%)	.2% [1] (.0%-.9%)
Endozime AW 1083 specimens/725 encounters (34 scopes)	4.7% [62] (4.4%-7.3%)	.6% [6] (.2%-1.2%)	8.3% [60] (6.4%-10.5%)	.7% [5] (.2%-1.6%)
Enzol 62 specimens/62 encounters (2 scopes)	6.5% [4] (1.8%-15.7%)	4.8% [3] (1.0%-13.5%)	6.5% [4] (1.8%-15.7%)	4.8% [3] (1.0%-13.5%)
Intercept Detergent 334 specimens/167 encounters (8 scopes)	1.5% [5] (.5%-3.5%)	.3% [1] (.0%-1.7%)	3.0% [5] (1.0%-6.8%)	.6% [1] (.0%-3.3%)

(*continued on the next page*)

SUPPLEMENTARY TABLE 2. Continued

Categories	Specimen-based % Positive [n] (95% CI)		Encounter-based % Positive [n] (95% CI)	
	Any growth	High-concern organism	Any growth	High-concern organism
Mediclean Enzymatic 1156 specimens/578 encounters (24 scopes)	5.6% [65] (4.4%-7.1%)	.6% [7] (.2%-1.2%)	10.4% [60] (8.0%-13.2%)	1.0% [6] (.4%-2.2%)
Megazyme 14 specimens/7 encounters (1 scope)	7.1% [1] (.2%-33.9%)	.0% [0] (.0%-23.2%)	14.3% [1] (.4%-57.9%)	.0% [0] (.0%-41.0%)
Tripower Enzymatic 136 specimens/68 encounters (3 scopes)	4.4% [6] (1.6%-9.4%)	3.7% [5] (1.2%-8.4%)	8.8% [6] (3.3%-18.2%)	7.4% [5] (2.4%-16.3%)
Automatic flushing equipment				
No 372 specimens/186 encounters (10 scopes)	5.4% [20] (3.3%-8.2%)	.5% [2] (.1%-1.9%)	9.7% [18] (5.8%-14.9%)	.5% [1] (.0%-3.0%)
Yes 3660 specimens/2052 encounters (96 scopes)	4.9% [181] (4.3%-5.7%)	.6% [21] (.4%-.9%)	8.3% [171] (7.2%-9.6%)	1.0% [20] (.5%-1.5%)
Maintenance company*				
Manufacturer 1762 specimens/1082 encounters (40 scopes)	5.4% [96] (4.4%-6.6%)	.6% [11] (.3%-1.1%)	8.6% [93] (7.0%-10.4%)	.9% [10] (.4%-1.7%)
Third party 1561 specimens/781 encounters (38 scopes)	4.0% [63] (3.1%-5.1%)	.3% [5] (.1%-.7%)	7.6% [59] (5.8%-9.6%)	.6% [5] (.2%-1.5%)
Both 136 specimens/68 encounters (3 scopes)	4.4% [6] (1.6%-9.4%)	3.7% [5] (1.2%-8.4%)	8.8% [6] (3.3%-18.2%)	7.4% [5] (2.4%-16.3%)
Maintenance frequency*				
Annually 919 specimens/655 encounters (24 scopes)	7.4% [68] (5.8%-9.3%)	1.0% [9] (.4%-1.9%)	9.8% [64] (7.6%-12.3%)	1.4% [9] (.6%-2.6%)
Biannually 1264 specimens/632 encounters (25 scopes)	4.1% [52] (3.1%-5.4%)	.6% [8] (.3%-1.2%)	8.1% [51] (6.1%-10.5%)	1.3% [8] (.5%-2.5%)
Repairs only 1276 specimens/644 encounters (32 scopes)	3.5% [45] (2.6%-4.7%)	.3% [4] (.1%-.8%)	6.7% [43] (4.9%-8.9%)	.5% [3] (.1%-1.4%)

Culture positivity was seemingly not affected by endoscope model type, HLD solution, use of automatic flushing system (used in all but 3 facilities), or maintenance frequency. For high-concern pathogens, there were some differences in the culture-positivity rate for some bedside cleansers, manual cleansers, and maintenance company. However, most differences disappeared when the 2 scopes with multiple positive encounters were excluded (data not shown). The manual cleansing agent Enzol still showed higher positivity rate than Ecolab Enzymatic (3/62 vs 1/1215 specimens or 3/62 vs 1/615 encounters). Because Enzol was used in only 1 facility equipped with 2 DLEs and both the total number of positive events and sample size were small, this difference was not convincing.

HLD, high-level disinfection; *DLE*, linear echoendoscope.

*Trial endoscopes were excluded because they were not applicable.