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Economic burden of enhanced practices of duodenoscopes reprocessing and surveillance: balancing risk and cost containment

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ABSTRACT

Background and study aims Recent outbreaks attributed to contaminated duodenoscopes have led to the development of enhanced surveillance and reprocessing techniques (enhanced-SRT) aimed at minimizing cross-contamination. Common enhanced-SRT include double high-level disinfection (HLD), ethylene oxide (EtO) gas sterilization, and culture-based monitoring of reprocessed scopes. Adoption of these methods adds to the operational costs and we aimed to assess its economic impact to an institution.

Methods We compared the estimated costs of three enhanced-SRT versus single-HLD using data from two institutions. We examined the cost of capital measured as scope inventory and frequency of scope use per unit time, the constituent reprocessing costs required on a per-cycle basis, and labor & staffing needs. The economic impact attributable to enhanced-SRT was defined as the difference between the total cost of enhanced-SRT and single HLD.

Results Compared to single HLD, adoption of double HLD increased the costs approximately by 47% ($80 vs $118). Similarly, culture and quarantine and EtO sterilization increased costs by 160% and 270%, respectively ($80 vs $208 and $296). Enhanced-SRT introduced significant scope downtime due to prolonged techniques, necessitating a 3.4-fold increase in the number of scopes needed to maintain procedural volume. The additional annual budget required to implement enhanced-SRT approached $406,000 per year in high-volume centers.

Conclusions While enhanced-SRT may reduce patient risk of exposure to contaminated duodenoscopes, it significantly increases the cost of performing ERCP. Future innovation should focus on approaches that can ensure patient safety while maintaining the ability to perform ERCP in a cost-effective manner.

Introduction

Duodenoscopes are utilized in more than 500,000 procedures in the United States annually [1]. Multiple reports of outbreaks involving multidrug resistant organisms via contaminated duodenoscopes have been published in the United States and worldwide [2–6]. Duodenoscopes, by their design, are intricate instruments with miniature moving parts and long working channels which are difficult to disinfect and can harbor micro-

organisms [1]. These outbreaks have led to adoption of enhanced surveillance and reprocessing techniques (enhanced-SRT) aimed at reducing and ultimately eliminating the transmission of pathogens by contaminated devices. In August 2015, the US Food and Drug Administration (FDA) issued a safety communication on supplemental measures to enhance duodenoscope reprocessing. In addition to strict adherence to manufacturer-recommended reprocessing instructions, FDA recommended adoption of one of four additional supplemental measures: Microbiological culturing, ethylene oxide (EtO) sterilization, use of a liquid chemical sterilant processing system or repeat high-level disinfection (HLD) [7].

Between January 2015 and June 2019, the Manufacturer and User Facility Device Experience (MAUDE) database of the FDA shows a total of 1115 medical device reports associated with duodenoscopes related to device contamination, exposure, and patient infection [8]. Despite manufacturer recommended reprocessing with HLD, the rate of contamination in reprocessed duodenoscopes have been reported to be around 13 % to 15 % [9–11]. While these include nonpathogenic organisms, studies and post-market surveillance by duodenoscope manufacturers have reported contamination with high-risk microorganisms to be around 2 % to 5 % [8, 9, 12, 13]. High-risk organisms (HRO) according to the Centers for Disease Control (CDC) are the non-contaminant, pathogenic microorganisms that are more often associated with disease such as gram-negative rods (*Escherichia coli*, *Klebsiella pneumoniae*, or other *Enterobacteriaceae*, *Pseudomonas*), gram-positive organisms (*Staphylococcus aureus*, Beta-hemolytic *Streptococcus*, *Enterococcus* species), and yeast [14]. These reports raise concern about effectiveness of the HLD process in providing pathogen-free scopes which are ready to be reused in a patient.

While the FDA has recommended additional reprocessing measures, device manufacturers also have introduced additional manual cleaning steps and FDA-approved brushes in an effort to enhance reprocessing [15]. In addition to enhanced manual cleaning, adoption of any enhanced-SRT could increase the operational costs for individual institutions, as the application of such techniques will have an economic impact in terms of additional training, cost and procurement of resources/materials, increased labor requirements, and extra capital costs required to purchase additional endoscopes. Finally, with the introduction of single-use duodenoscopes into clinical practice, health care facilities and systems engaged in the practice of ERCP will undoubtedly weigh the adoption of this new (and potentially expensive) technology with the efficacy and costs associated with enhanced reprocessing of reusable devices. We conducted this study to estimate the economic impacts of 3 commonly used enhanced-SRT compared to single HLD.

Methods

We compared the estimated costs of three commonly used enhanced-SRT [Double HLD, EtO gas sterilization and "culture and quarantine" (CQ)] to usual manufacturer recommended manual cleaning and single HLD. We used data from 2 institutions (Virginia Mason Medical Center, Seattle [VMMC] and University of California Los Angeles, CA [UCLA]) which have adopted enhanced-SRT. The CQ technique is used at VMMC, and EtO sterilization is used at UCLA.

The primary outcome was to calculate the economic impact attributable to enhanced-SRT, which was defined as difference in total costs between single HLD and 3 types of enhanced-SRT – the double HLD technique, the CQ technique used in VMMC, and the EtO technique used in UCLA. In addition to reprocessing costs, enhanced-SRT causes considerable scope downtime due to these prolonged disinfection techniques, which in turn decreases procedural efficiency (defined as procedures per scope per year). Our secondary outcome was to calculate the financial impact of altered scope efficiency due to enhanced-SRT. This was accounted for by calculating the costs resulting from the increase in the number of scopes required to maintain a constant annual procedural volume.

The steps involved in reprocessing of the duodenoscope using single HLD were defined as: a) Precleaning: This process is performed at the point of use, shortly after the procedure. This includes wiping of the external surface with an appropriate enzymatic detergent kit and aspiration of large volume of detergent solution through the channels. This prevents the bioburden from drying on the device. b) Leak testing: Leak testing is performed as per manufacturers' guidelines using a leak tester. This step assesses for minute damage to the interior channels or exterior of the duodenoscopes which could harbor microorganisms and cause cross contamination. c) Manual cleaning: This includes meticulously cleaning of the entire duodenoscope, channels, elevator mechanism, detachable parts using manufacturer and FDA-approved brushes and using appropriate enzymatic detergent and water. The leak testing and manual cleaning process takes approximately 20 to 25 minutes to complete. d) HLD: High-level disinfection can be performed manually, but most health care facilities use automated endoscope reprocessors (AER), and this step is performed based on manufacturer guidelines using liquid chemical sterilants or high-level disinfectants. Following this, the scopes are dried and stored as per manufacturer instructions for reuse [8, 16]. In double HLD, both the manual cleaning and HLD steps are repeated.

The CQ method of VMMC has been previously reported [9]. After manual cleaning and HLD using an AER (DSD Edge; Medivators Inc, Minneapolis, Minnesota, United States) is performed, duodenoscopes were cultured using a modified sampling protocol developed by the Centers for Disease Control (CDC) [14]. The protocol requires sampling of port openings, working channels, and the front and backside of the elevator mechanism. After the sampling, the HLD process using AER was repeated, and the devices were hung vertically in a storage cabinet (Starsys; Metro Industries Corp, USA) with passive airflow and quarantined until culture results were available. The samples were incubated at 37 °C and examined for growth at 24 and 48 hours. The scopes were released for patient use if the culture results were negative for pathogens after 48 hours. If potential bacterial pathogens were cultured, the duodenoscope reprocessing, CQ steps were repeated until negative.

EtO sterilization was used at UCLA. Scopes underwent manual cleaning and HLD using AER (Previously used Custom Ultrasonics, Inc., USA; however, currently using Steris system 1E, USA) after which they were transported to sterile processing and distribution (SPD) where the scopes were wrapped in Kimguard sterilization wrap and scanned out of SPM (surgical instrument reprocessing tracking software) and loaded and locked into an EtO tote. Scopes were couriered to a third-party company located in Torrance, California for EtO sterilization (Sterigenics, USA). After return of the scopes from the EtO sterilization the following day, they were checked in via rescanning, bagged, and transported to the endoscopy unit.

Costs involved in enhanced-SRT were calculated accounting for the costs of materials and labor and approximate time taken in each step of the process. Labor costs were categorized into 3 classes (low cost, mid cost, high cost) based on estimates of GI tech III salary/hour ($26/hr was deemed "low," $28.5 deemed "mid," and $31/hr was deemed "high") and SPD tech salary/hour ($19/hr was deemed "low," 20.83/hr was deemed "mid," and 22.65/hr was deemed "high"). Material costs used in each step of the process were calculated. ▶ **Table 1** describes the estimation of costs involved in each step for CQ technique at VMMC. ▶ **Table 2** describes the cost of using EtO sterilization at UCLA.

▶ **Table 1** Cost estimate for all steps involved in enhanced reprocessing with culture and quarantine technique.

	Description	Category	Time (min)	Low cost	Mid cost	High cost
1	Pre-cleaning w/enzymatic detergent					
	Gastroinestinal tech labor	Labor	5	$ 1.50	$ 1.75	$ 1.83
	Supply kit with enzymatic detergent	Materials	N/A	$ 5.21	$ 5.21	$ 5.21
2	Transported to reprocessing room					
	GI tech labor	Labor	5	$ 1.50	$ 1.75	$ 1.83
	Disposable scope tray liner	Materials	N/A		$ 1.63	$ 1.63
	Reusable CleanaScope tray	Materials	N/A			
3	Leak test					
	GI tech labor (see step 5)	Labor		$ –	$ –	$ –
	Olympus leak tester	Capital		($1300)		
4	Manual cleaning					
	Tech labor (see step 5)	Labor		$ –	$ –	$ –
	Enzymatic detergent	Materials	N/A	$ 0.96	$ 0.96	$ 0.96
	Disposable 60-cc tip syringe	Materials	N/A	$ 0.30	$ 0.30	$ 0.30
	Disposable scope brush	Materials	N/A	$ 1.60	$ 1.60	$ 1.60
	Disposable scope sponge	Materials	N/A	$ 0.20	$ 0.20	$ 0.20
	Disposable Olympus elevator brush	Materials	N/A	$ 10.98	$ 10.98	$ 10.98
5	Soaking caps applied & AER loading					
	Tech labor (includes leak test and manual clean)	Labor	25	$ 7.50	$ 8.75	$ 9.17
6	AER/Medivators Inc., DSD EDGE					
	Materials	Materials	N/A	$ 14.92	$ 14.92	$ 14.92
	Cost of AER capital/device	Capital	N/A	($ 45,000)		
7	Alcohol 70 % flush automated					
	Cost of alcohol	Materials	N/A	$ 0.33	$ 0.33	$ 0.33
8	Air flush automated		2	$ 0.60	$ 0.70	$ 0.73
9	Scope removed from AER exterior dried Cycle info logged		10	$ 3.00	$ 3.50	$ 3.67
	GI Tech labor	Labor	5	$ 1.50	$ 1.75	$ 1.83
10	Forced air dry					
	GI Tech labor	Labor	10	$ 3.00	$ 3.50	$ 3.67

▶ **Table 1** (Continuation)

	Description	Category	Time (min)	Low cost	Mid cost	High cost
11	Hung overnight					
	GI tech labor	Labor	15	$ 4.50	$ 5.25	$ 5.50
12	Culturing					
	GI tech labor	Labor	10	$ 3.00	$ 3.50	$ 3.67
	US endoscopy brush × 2 used for culture	Materials	N/A	$ 4.66	$ 4.66	$ 4.66
	Scope ID tags × 3	Materials	N/A	$ 0.16	$ 0.16	$ 0.16
13	Re HLD of scope					
	Materials	Materials	N/A	$ 14.92	$ 14.92	$ 14.92
	Test strips for rapicide	Materials	N/A	$ 2.02	$ 2.02	$ 2.02
14	Check off and release of scopes					
	GI tech labor	Labor	10	$ 3.00	$ 3.50	$ 3.67
	Scope tags	Materials	N/A	$ 0.03	$ 0.03	$ 0.03
15	PPE			$ 5.06	$ 11.42	$ 17.78
16	Culture and monitoring			$ 75.00	$ 100.00	$ 150.00
17	Stored until used			–	–	–
18	Total			$183.28	$208.28	$258.28

N/A, not applicable; AER, automated endoscope reprocessor; PPE, personal protective equipment; HLD, high-level disinfection.

Results

Both VMMC and UCLA are considered high-volume centers for ERCP and perform nearly 1200 and 850 procedures, respectively. Compared to the standard reprocessing techniques, we found that the cost for enhanced-SRT (approximated using standard reprocessing costs) were higher by 2.6-fold using the CQ approach and 3.7-fold with the EtO sterilization approach.

The duodenoscope manufacturer recommend manual cleaning and single HLD which costs approximately $80 per procedure. The adoption of repeat disinfection (double HLD) increased the total costs to $118, which is 47 % higher than those associated with single HLD. Using the "mid" labor cost, reprocessing costs associated with the CQ technique were $208, which is 160 % higher than single HLD; similarly, the EtO sterilization technique cost $290, which is 270 % higher than single HLD (▶ **Table 3**). VMMC hired extra personnel for the scrupulous execution of the CQ technique, which cost the institution around $120,000/year [approximately $100 per procedure with a procedural volume of 1200/year]. Assuming comparable labor costs, if the procedure volume goes down, the labor cost per case goes up and vice versa (▶ **Table 3**).

In addition to directly impacting reprocessing costs, enhanced-SRT using CQ and EtO leads to considerable "scope downtime," which is the amount of time the scopes cannot be used due to these prolonged disinfection techniques. This, in turn, decreases procedural efficiency. Prior to introducing these enhanced-SRT, we estimated that the procedural efficiency in a high-volume center performing nearly 1200 procedures per year to be around 156 procedures/scope/year. With these enhanced-SRT, it dropped down by nearly 70 % to 46 procedures/scope/year. This means that an institution would need to increase the duodenoscope fleet size by 3.4-fold in order to maintain their annual procedural volume.

The total additional budget required for the CQ and EtO sterilization techniques, accounting for both increased reprocessing costs and scope downtime (necessitating additional scope purchase), approximates to $300,532–$406,384 annually in a high-volume center and $74,612–$92,254 annually in a medium volume center (200 procedures/year) (▶ **Table 4**). All estimates were made based on a new scope purchase cost of $40,000/scope with depreciation over 5 years. Service costs, training costs, capital costs of reprocessing equipment, and other costs of maintaining the instruments and intraprocedural degradation of efficiency that may be encountered due to adoption of enhanced SRT were not included, thus our estimates are probably conservative compared to real life.

Discussion

Having an efficient reprocessing technique that provides a clean, patient-ready duodenoscope is essential to prevent device-related patient cross contamination and outbreaks. Positive cultures for pathogens or contaminants after standard HLD process have been reported, and multiple recent studies have shown contamination or outbreaks even with no obvious breaches involving the HLD process [3, 6, 9]. This warranted improvement of the standard reprocessing techniques which led

▶ **Table 2** Cost estimate for all steps involved in enhanced reprocessing with ethylene oxide sterilization.

	Description	Category	Time (min)	Low cost	Mid cost	High cost
1	Pre-cleaning w/ enzymatic detergent					
	GI tech labor	Labor	5	$ 2.17	$ 2.38	$ 2.58
	Supply kit with enzymatic detergent	Materials	N/A	$ 6.41	$ 6.41	$ 6.41
2	Transported to reprocessing room					
	Reusable CleanaScope tray	Materials	N/A	$ –	$ –	$ –
3	Leak test					
	Gastointestinal tech labor (see step 5)	Labor		$ –	$ –	$ –
	Olympus leak tester	Capital	N/A	($1300)	$ –	$ –
4	Manual cleaning					
	Tech labor (see step 5)	Labor		$ –	$ –	$ –
	Enzymatic detergent	Materials	N/A	$ 0.66	$ 0.66	$ 0.66
	Disposable 60cc tip syringe	Materials	N/A	$ 0.30	$ 0.30	$ 0.30
	Disposable scope brush	Materials	N/A	$ 2.30	$ 2.30	$ 2.30
	Disposable green scope sponge	Materials	N/A	$ 0.60	$ 0.60	$ 0.60
	Disposable Olympus suction canister	Materials	N/A	$ 5.90	$ 5.90	$ 5.90
	Disposable Olympus elevator brush	Materials	N/A	$ 10.98	$ 10.98	$ 10.98
5	Soaking caps applied & AER loading					
	Tech labor (includes leak test and manual clean)	Labor	25	$ 10.83	$ 11.88	$ 12.92
6	AER*/Custom Ultrasonics Inc. cycle					
	Materials	Materials	N/A	$ 4.50	$ 4.50	$ 4.50
	Cost of AER capital/device	Capital	N/A	($ 45,000)	$ –	$ –
7	Alcohol 70 % flush automated					
	Cost of alcohol	Materials	–	$ 0.16	$ 0.16	$ 0.16
8	Air flush automated					
9	Scope removed from AER Exterior dried Cycle info logged					
	Gastrointestinal tech labor	Labor	5	$ 2.17	$ 2.38	$ 2.58
10	Forced air dry					
	Gastrointestinal tech labor	Labor	15	$ 6.50	$ 7.13	$ 7.75
	Cost of Dri-Scope Aid/scope	Capital	N/A	$ –	$ –	$ –
11	Hung overnight					
12	Forced air dry					
	GI tech labor	Labor	15	$ 6.50	$ 7.13	$ 7.75
13	Transported to SPD					
	GI tech labor	Labor	5	$ 2.17	$ 1.03	$ 2.58
14	Wrapped in Kimguard					
	SPD tech labor	Labor	10	$ 3.17	$ 3.17	$ 3.17
	Kimgard precut sterile indicators / scope	Materials	N/A	$ 2.62	$ 2.62	$ 2.62
15	Scope scanned out in SPM					
	SPD tech labor	Labor	2.5	$ 0.79	$ 0.87	$ 0.94

▶ **Table 2** (Continuation)

	Description	Category	Time (min)	Low cost	Mid cost	High cost
16	Loaded/locked in EtO tote					
	SPD tech labor	Labor	2.5	$ 0.79	$ 0.87	$ 0.94
	EtO cost/tote	Materials		$ 1.78	$ 2.68	$ 5.35
17	Transport to Sterigenics					
	Courier pick-up	Service		$ 6.50	$ 10.40	$ 26.00
18	Sterigenics EtO					
	EtO cost/scope	Service		$ 183.33	$ 183.33	$ 183.33
19	Transport to UCLA					
	Courier pick-up	Service		$ 6.50	$ 10.40	$ 26.00
20	Tote/scopes scanned into SPM Bagged for transport to endo unit/SPD					
	SPD tech labor	Labor	6	$ 1.90	$ 1.90	$ 1.90
	Cost/bag	Materials		$ 2.75	$ 2.75	$ 2.75
21	Transport back to unit					
	Gastrointestinal tech labor	Labor	5	$ 2.17	$ 2.38	$ 2.58
22	PPE			$ 5.06	$ 11.42	$ 17.78
23	Stored until use			$ –	$ –	$ –
24	Total			$ 279.51	$ 296.49	$ 341.35

N/A, not applicable; AER, automated endoscope reprocessor; SPD, sterile processing department; SPM is a surgical instrument reprocessing tracking software; EtO, ethylene oxide; UCLA, University of California, Los Angeles; PPE, personal protective equipment.
* UCLA previously used Custom Ultrasonics, Inc AER, but later transitioned to Steris system 1E with corresponding AER material costs of $8.25 per scope instead of $4.50.

▶ **Table 3** Cost comparison between single HLD and other enhanced surveillance and reprocessing techniques.

	Single HLD	Double HLD	Ethylene oxide (EtO) gas sterilization	Scope culturing-monitoring
Reprocessing costs				
Staff labor	$ 30.88	$ 42.75	$ 41.08	$ 33.95
Materials	$ 49.59	$ 74.83	$ 51.28	$ 64.53
EtO gas sterilization (3rd-party)	–	–	$ 204.13	–
Culturing/monitoring	–	–	–	$ 109.82
Labor	–	–	–	$ 100[1]
Materials	–	–	–	$ 9.82
Total reprocessing[2]	$ 80.47	$ 117.58	$ 296.49	$ 208.28

HLD, high-level disinfection; EtO, ethylene oxide.
[1] Dependent on scope volume, per-procedure costs based on 1,200 procedures per year; lower-volume would have higher costs in the amount of approximately $120,000/V, in which V is volume per year.
[2] Costs estimated using mid labor costs.

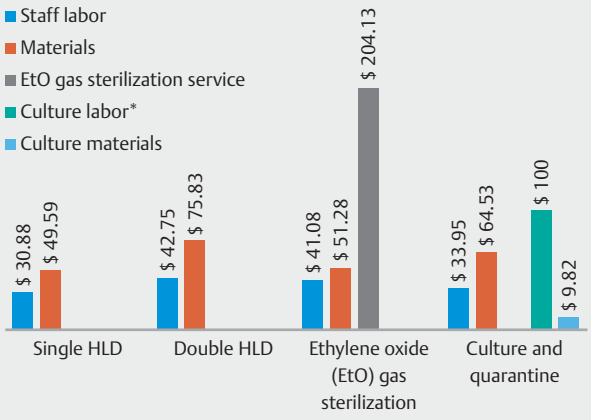
▶ **Table 4** Procedural efficiency and total budget estimation for high- and medium- volume institutions for culture & quarantine and ethylene oxide sterilization techniques.

	Procedures/yr.	Procedural efficiency pre-enhanced-SRT {procedures/scope/year}	Procedural efficiency post-enhanced-SRT {procedures/scope/year}	Additional scopes req'd (addn'l annual budget)	Enhanced-SRT additional budget impact per-procedure[1] (annually)	Total additional budget required d.t. enhanced-SRT (annually)
High volume	1,200	156	46	18.4 scopes ($147,160/yr)[3]	$127.81–$216.02 ($153,372/yr–$259,224/yr)	$300,532–$406,384
Medium volume	200	78	23 estimated[2]	6.1 scopes ($49,050/yr)[3]	$127.81–$216.02 ($25,562/yr–$43,20/yr)	$74,612–$92,254

Enhanced-SRT, enhanced surveillance and reprocessing technique.
[1] Reported as a difference from single-HLD costs ($80.47, ▶ **Table 3**) to use culture & quarantine and ethylene oxide sterilization techniques.
[2] Estimation based on ratio measured among high volume.
[3] Based on $40,000 per scope estimated list price and depreciated 5 years, service costs not considered and may thus be a conservative costing.

to the recommendation of enhanced-SRT. These techniques come with added costs, increased scope downtime and requirement of additional resources, all of which have economic impacts on an institution, which we assessed in our study.

To our knowledge, this is the first study to evaluate a detailed real-world cost analysis and economic impact of three distinct enhanced-SRT techniques: Double HLD, CQ, and EtO sterilization, at two separate high-volume centers. A study by Ma et al estimated the cost associated with a single institution's culturing program to be $126.79 [17]. In that study, only 25 % of 20 scopes in inventory were cultured once every week and monitored. By comparison, our study estimated the cost of CQ to be $208 per endoscope. This can largely be attributed to labor and materials associated with an additional AER HLD cycle performed after culturing. In addition, as opposed to a periodic sampling method, CQ was applied to every endoscope after every use in a procedure and subsequent reprocessing. A recent abstract by Barakat et al has estimate the cost of CQ to be $386 and EtO sterilization as $643 [18]. Our estimates are lower than this and may reflect variability of technique, labor, and materials costs. Labor costs can have significant variability across different locations. ▶ **Fig. 1** compares costs associated with labor versus other material/service costs based on various reprocessing techniques used.



*Culture labor cost is dependent on scope volume; Per-procedure costs here are based on 1,200 procedures per year; lower-volume would have higher costs in the amount of approximately $120,000/V, in which V is volume per year.

▶ **Fig. 1** Graph illustrating the labor costs and other material/service costs in various reprocessing techniques.

The choice of an enhanced-SRT depends on facilities' availability of resources. For instance, the availability of EtO sterilization is limited, and only 20 % of US hospitals have the ability to perform EtO on site [19]. In the current study, UCLA used a third-party company for EtO sterilization. Scopes were couriered to and from the processing units which adds further costs and increases inter-procedural time, necessitating purchase/lease of additional scopes. There is also the potential for scope damage resulting from such frequent transfers. Furthermore, the process of EtO sterilization requires a minimum 15 to 16 hours, excluding the HLD times and courier times [20]. Finally, there are concerns regarding potential toxicity to personnel with EtO use as well as adverse environmental impacts [21]. These latter concerns have led to increasing restrictions on the use of EtO, which likely will further limit availability and increase cost. On the other hand, the CQ method is a resource and is labor intensive, time consuming, and an expensive process. Not all the hospital labs can process the culture from scopes, which are considered "non patient/environmental" samples and may have to be sent out. There is always risk of environmental contamination during sampling process which can render false positive results or even contaminate the scope during the sampling process, hence, reprocessing of scopes again after sampling becomes important. Moreover, a negative culture may not necessarily guarantee a non-contaminated scope. Furthermore, the ideal frequency of culture and surveillance of scopes has not been defined by the FDA. This process of diligent CQ after each procedure identified two scopes at VMMC which

were frequently and serially positive, and they were taken out of clinical use, rendering two capital-intensive resources clinically useless.

Our study has several strengths. It is a multicenter study and includes two centers with high ERCP volumes that identified and successfully managed outbreaks of duodenoscope-transmitted CRE infections. It analyzes the cost and economic impact of commonly used enhanced-SRT techniques. Cost analyses were done using three different labor cost estimates (low, mid, and high labor costs). Our study not only analyzed the cost of these enhanced-SRT but also studied the impacts of scope downtime with these prolonged techniques and their implications on the size of the fleet of duodenoscopes needed to maintain a constant procedure volume. Study limitations include that our estimates do not include training costs, capital costs of reprocessing equipment like AERs and leak testers. Service, maintenance and repair costs of scopes and reprocessing equipment were also not included in our study, and thus our findings likely represent conservative estimate of total burden. Also, the cost and impact of newer generation duodenoscopes with disposable endcaps and their implications on reprocessing costs were not analyzed in our study.

Many potential causes for outbreaks due to duodenoscope cross contamination have been reported. These can be broadly classified as—factors related to the instrument and factors related to the disinfection process. Instrument-related issues include the complex design of the duodenoscopes which make them difficult to be disinfected [8]. Similar to other endoscopes, they are not designed to endure the high temperatures needed for steam/autoclave sterilization. Furthermore, damage/breaches to the device channels may impair future disinfection, and bioburden caused by inadequate disinfection may lead to biofilm formation, rendering the contaminated scopes resistant to future standard disinfection techniques [22, 23]. The factors related to disinfection process include non-adherence to strict HLD practices [4]. There have been reports of flawed AER devices [24]. HLD process has a very low margin for safety, which is unforgiving for even minor errors and has led some to suggest the possibility that the HLD process itself is inadequate for proper disinfection of these devices [25, 26]. A combination of the above factors is likely to blame for most outbreaks of duodenoscope-associated infections. For these reasons, enhancing the quality of duodenoscope reprocessing will likely require solutions at various levels. With the stringent use of CQ technique, we were able to bring down the duodenoscope contamination rate with HRO to 0.697 % [27]. Up to 5 % contamination rates with HRO after a standard single HLD reprocessing has been reported in post market surveillance studies by duodenoscope manufacturers [8, 12, 13]. A study by Naryzhny et al. reported a contamination rate of 1.2 % with HRO after EtO sterilization [20]. There were no further outbreaks reported in either of the centers involved in the current study after implementation of these enhanced-SRT. However, randomized studies comparing single HLD versus double HLD or HLD followed by EtO did not support significant benefit from these enhanced techniques [28, 29].

In the performance of any medical procedure, patient safety is paramount, and as it pertains to duodenoscopes, it is imperative to practice techniques and strategies that would mitigate the risk of patient cross contamination. Enhanced-SRT adds considerably to the per procedure costs of ERCP and, in an era of continuous downward pressure on reimbursement, can have significant negative financial consequences to healthcare facilities. This has several potential significant implications. First, access to ERCP may be limited to those centers that can afford to implement enhanced-SRT. In the era of healthcare consolidation, this may lead to the centralization of procedures within larger population centers, thus limiting access to procedures that are critical for the care of patients with pancreaticobiliary disorders. Second, despite the added cost of enhanced-SRT, these methods are not 100 % reliable in preventing endoscope cross contamination, and it remains unclear as to the actual clinical benefit associated with the significant financial investment. Finally, and perhaps most importantly, these recent outbreaks have led to significant innovation. The FDA has called for a transition to duodenoscopes with innovative designs to improve reprocessing and enhance safety [30]. Currently, six duodenoscopes, four with disposable components and two of them fully disposable, have recently been cleared by the FDA. Hopefully, these new designs and other potential innovations will make duodenoscope reprocessing reliably effective in producing clean and contaminant-free scopes or, in the case of single use devices, ultimately even eliminate the need for reprocessing entirely.

Conclusions

In summary, revelation that life-saving modern medical instruments with miniature-scale components can act as vectors for transmission of infection between patients has led to a re-evaluation of current endoscope technologies and the techniques used for cleaning and disinfection. The significant costs associated with implementing enhanced-SRT may impact patient access to ERCP in institutions unable to shoulder such a burden. The purpose of this study is to allow the broader endoscopy community to estimate the costs among the choices and to understand the pros and cons of navigating through each of these enhanced-SRT approaches to choose the most practical choice for their site. Future innovation should focus on approaches that can ensure patient safety while maintaining patient access to ERCP by allowing it to be performed in a cost-effective manner.

Competing interests

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