Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

COVID-19 polymerase chain reaction testing before endoscopy: an economic analysis

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Background and Aims: The novel coronavirus disease 2019 (COVID-19) pandemic has limited endoscopy utilization, causing significant health and economic losses. We aim to model the impact of polymerase chain reaction (PCR) testing into resuming endoscopy practice.

Methods: We performed a retrospective review of endoscopy utilization during the COVID-19 pandemic for a baseline reference. A computer model compared 3 approaches: strategy 1, endoscopy for urgent indications only; strategy 2, testing for semiurgent indications; and strategy 3, testing all patients. Analysis was made under current COVID-19 prevalence and projected prevalence of 5% and 10%. Primary outcomes were number of procedures performed and/or canceled. Secondary outcomes were direct costs, reimbursement, personal protective equipment used, and personnel infected. Disease prevalence, testing accuracy, and costs were obtained from the literature.

Results: During the COVID-19 pandemic, endoscopy volume was 12.7% of expected. Strategies 2 and 3 were safe and effective interventions to resume endoscopy in semiurgent and elective cases. Investing 22 U.S. dollars (USD) and 105 USD in testing per patient allowed the completion of 19.4% and 95.3% of baseline endoscopies, respectively. False-negative results were seen after testing 4700 patients (or 3 months of applying strategy 2 in our practice). Implementing PCR testing over 1 week in the United States would require 13 and 64 million USD, with a return of 165 and 767 million USD to providers, leaving 65 and 325 healthcare workers infected.

Conclusions: PCR testing is an effective strategy to restart endoscopic practice in the United States. PCR screening should be implemented during the second phase of the pandemic, once the healthcare system is able to test and isolate all suspected COVID-19 cases. (Gastrointest Endosc 2020;92:524-34.)

(footnotes appear on last page of article)

The first case of novel coronavirus disease 2019 (COVID-19) in the United States was confirmed on January 20, 2020.[1] The first case at our institution was confirmed on March 14, 2020. During the initial weeks of the COVID-19 pandemic, laboratory testing for the severe acute respiratory syndrome–coronavirus 2 (SARS-CoV-2) was provided by the Florida Department of Health only, and turnaround result time ranged between 4 and 10 days.

Parallel to the exponential number of patients requiring hospitalization for COVID-19, most hospitals, clinics, and endoscopy centers across the world started limiting endoscopy services to emergent and urgent procedures only. A recent survey showed no consensus among gastroenterologists regarding the best timing to perform semiurgent procedures for non–life-threatening conditions amid the COVID-19 pandemic.[2] Deferring semiurgent procedures may lead to delays in the diagnosis of critical conditions (eg, localized pancreatic cancer), closing a narrow window of opportunity for endoscopic treatment (eg, ablation of Barrett's esophagus with dysplasia and resection of advanced colon adenomas), and has already led to substantial economic losses.

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On March 24, 2020 our institution's laboratory started performing real-time polymerase chain reaction (PCR) testing for SARS-CoV-2, with results available within 3 to 4 hours. This was possible using a combination of commercially acquired and in-house developed reagents and working with providers early in the COVID-19 outbreak. The

following day all hospitalized patients were tested. Five days later a policy to test all patients within 48 hours before having an outpatient endoscopic or surgical procedure was implemented.

The primary objective of this study was to use a decision tree analysis to compare different approaches for COVID-19 testing in patients requiring semiurgent and elective endoscopy. We first modeled the impact of this policy at our institution and then extrapolated to all cases performed in the United States. The secondary objective was to identify clinical determining factors under which different strategies are more effective and safer to resume outpatient endoscopy workflow.

METHODS

A retrospective review of endoscopic procedures performed at our institution was conducted over a 1-week period (ie, March 4-10, 2019). This represents our baseline practice outside of the COVID-19 pandemic period. We recorded patient demographics, procedure type, and indication of all procedures scheduled during that time. Procedure indication was grouped into 3 categories: emergent/urgent (procedure that should be performed within 24 hours), semiurgent (procedures that should be performed between 24 hours and 7 weeks), and elective (procedures that could be performed within 8 or more weeks). The classification of procedures was adapted from a survey of gastroenterologists who had to cancel procedures during the COVID-19 pandemic (Supplementary Table 1, available online at www.giejournal.org).[2]

During the week of March 23 to 29, 2020, our institution started a policy to cancel all semiurgent and elective procedures. On March 24, PCR testing for SARS-CoV-2 became available in-house, and testing was performed systematically. We performed a second review of procedures performed between March 30, 2020 and April 5, 2020. During this week all patients were tested within 48 hours before their planned endoscopic procedure. This represents our baseline practice during the COVID-19 pandemic period (Table 1).

At our institution we used the assay Cobas SARS-CoV-2 test (Roche Molecular Systems, Inc, Basel, Switzerland), a TaqMan probe-based, real-time, reverse transcription-PCR assay designed for qualitative detection of SARS-CoV-2 RNA from human nasopharyngeal and oropharyngeal swabs.[3] This assay is considered an in vitro diagnostic test that received U.S. Food and Drug Administration emergency use authorization.[3,4] Performance reported by the manufacturer and by 2 research groups constituted our best scenario.[5,6] A third research group evaluated a similar PCR assay and comparatively investigated the diagnostic value and consistency of CT in patients with COVID-19.[7] The diagnostic accuracy reported in vivo by this group was lower and constituted our worse scenario (Table 2).

A decision tree model was created comparing 3 potential strategies using PCR COVID-19 testing to triage and perform endoscopic procedures at our hospital. The strategies compared in Figure 1 are as follows:

- Strategy 1: Patients requiring an emergent/urgent endoscopy (within 24 hours) are tested. Endoscopy is performed regardless of result. High-risk personal protective equipment (PPE) and decontamination after procedure is used for each emergent/urgent endoscopy.[8] All other procedures (semiurgent and elective) are postponed.
- Strategy 2: Patients requiring emergent/urgent and semiurgent procedures are tested within 48 hours before the planned endoscopic procedure. All emergent/urgent cases are completed regardless of PCR result using high-risk PPE. Semiurgent cases with a negative result proceed to endoscopy using low-risk PPE. Semiurgent cases with a positive result are postponed. All elective procedures are postponed.
- Strategy 3: PCR test is performed on all patients within 48 hours. All emergent/urgent cases are completed regardless of PCR result using high-risk PPE. Semiurgent and elective cases with a negative result proceed to endoscopy using low-risk PPE. Semiurgent and elective cases with a positive result are postponed.

Our economic model focused on short-term outcomes over 7 days. We did not measure the added benefit of identifying an asymptomatic patient with COVID-19 who presented for an elective procedure. We did not measure the impact of respiratory failure developed during endoscopy, the need to perform endotracheal intubation during endoscopy, or mortality associated with COVID-19. Our analysis did not include the risk of patients contracting COVID-19 from their visit to our endoscopy center.

Outcomes

The primary outcomes were the added cost of PCR testing per patient and the total number of procedures performed using each strategy. Secondary outcomes were the number of patients with COVID-19 who underwent endoscopy without high-risk PPE (for a false-negative result), healthcare staff infected, number of healthy patients who had their procedure postponed (for a false-positive result), and economic revenue for the endoscopy center. The analysis was completed under 3 disease scenarios (with prevalence at the time of writing, 5% and 10%).

We estimated that performing an endoscopic procedure on a false-positive case under urgent circumstances would translate into wasting high-risk PPE in 4 staff members (ie, physician, nurse, anesthetist, and technician). Cases with semiurgent and elective indications and a positive test result would be postponed. On the other end, a case

TABLE 1. Strategies compared over a 1-week period

	Source	Cases	Procedure type*	Indication
Baseline Procedures without COVID-19	Retrospective review 3/4/2019–3/10/2019	Tested .0% (0) PCR positive .0% (0) Performed 100.0% (361)	Colonoscopy 44.0% EGD 41.6% EUS 6.9% FlexSig 3.9% ERCP/others 3.6%	Urgent 7.5% Semiurgent 10.5% Elective 82.0%
Fist week with COVID-19 Day 1 (3/30/2020) Hospital: 10 inpatients, 1 death Duval County: 169 confirmed, 4 deaths[27] Day 7 (4/5/2020) Hospital: 6 inpatients, 4 recovered, 1 death Duval County: 401 confirmed, 9 deaths[27]	Retrospective review 3/30/2020–4/5/2020†	Tested 100.0% (49) PCR positive .0% (0) Performed 100.0% (49)	Colonoscopy 20.4% EGD 42.9% EUS 14.3% FlexSig 8.2% ERCP/others 14.3%	Urgent 30.6% Semiurgent 65.3% Elective 4.1%
Strategy 1 Test urgent cases. Scope without waiting for result. Postpone semiurgent and elective cases.	Modeling with current prevalence	Tested 8.0% PCR positive .4% (false positive .4%) Performed 8.0%	Colonoscopy 25.0% EGD 46.0% FlexSig 11.0% EUS .0% ERCP 18.0%	Urgent 100% Semiurgent .0% Elective .0%
Strategy 2 Test urgent and semiurgent cases. Scope urgent regardless of result. Scope semiurgent cases with negative result.	Modeling with current prevalence	Tested 20.0% PCR positive 1.0% (false positive 1.0%) Performed 19.4%	Colonoscopy 36.3% EGD 43.6% FlexSig 6.7% EUS 4.1% ERCP 9.3%	Urgent 41.2% Semiurgent 58.8% Elective .0%
Strategy 3 Test all patients. Scope urgent regardless of result. Scope semiurgent and elective with negative result.	Modeling with current prevalence	Tested 100.0% PCR positive 5.1% (false positive 5.0%) Performed 95.3%	Colonoscopy 42.0% EGD 42.4% FlexSig 4.5% EUS 6.3% ERCP 4.7%	Urgent 8.0% Semiurgent 12.0% Elective 80.0%

FlexSig, Flexible sigmoidoscopy.
*Combined cases were recorded as the 1 with highest reimbursement (eg, colonoscopy + EGD = colonoscopy, EUS + EGD = EUS).
†COVID-19 testing was implemented this week. First COVID-19 guidelines were circulated across our institution on February 28, 2020.

with a false-negative test result would undergo endoscopy with the use of low-risk PPE.[8] When current estimates that SARS-CoV-2 has an infective rate (R_0) of 1.5 to 3.5 in the community are used, performing such endoscopic procedures could infect a similar number of healthcare workers.[9]

Clinical probabilities and other inputs

We assumed that the probability of transmitting COVID-19 was independent of the endoscopic procedure requested. Clinical probabilities were obtained from different sources (Table 2). The presumed prevalence of COVID-19 was calculated from reports from Duval County, Florida on April 2, 2020. We used a reverse calculation using a corrected infection fatality rate (cIFR) of 1.3% (95% confidence interval [CI], .38-3.6) (Supplementary Material A and Supplementary Table 2, available online at www.giejournal.org).[10]

Primary analysis was performed using cost estimates from the Centers for Medicare & Medicaid Services data for hospital outpatient department payments in 2020.[11-13] Because Medicare payments vary geographically, depending on local operating costs, we varied our baseline costs by using a sensitivity analysis through the ranges shown in Table 2. Ranges were derived by adding 25% or subtracting 25% from the baseline estimate. Secondary analysis was performed using costs for ambulatory surgery centers in 2020 (Supplementary Table 3, available online at www.giejournal.org).

The cost of PPE was separated into low-risk and high-risk, which was calculated based on the recommendations of the Milan endoscopy group (Supplementary Table 4, available online at www.giejournal.org).[8] Compared with the Milan recommendations, the American Gastroenterological Association Institute advocates for high-risk PPE (ie, N95 masks and double gloves) for all upper and lower GI procedures.[14] We selected the former because American Gastroenterological Association recommendations were written assuming the absence of widespread rapid testing for COVID-19.

Only direct costs for a third-party payer perspective were considered, which were adjusted to the 2020 U.S. dollar (USD). We did not perform any adjustments for inflation or discounting. Additional details of cost calculations are provided in Supplementary Material B (available online at www.giejournal.org).

TABLE 2. Probabilities for health state transitions, costs and other inputs

Description	Estimate	Range*	Reference
Clinical probabilities			
Corrected infection fatality rate	.6%	.2-1.3%	10, 28
Percentage of emergency/urgency cases	8.0%	4.0-12.0%	Retrospective review
Percentage of semiurgent cases	12.0%	8.0-16.0%	
Percentage of elective cases	80.0%	72.0-88.0%	
Sensitivity and specificity in vitro†	95.0% 98.6%	92.5-97.5% 96.1-99.9%	5, 6
Sensitivity and specificity in vivo compared with CT‡	70.6% 97.8%	68.1-73.1% 95.7-99.9%	7
Sensitivity and specificity used in model	82.5% 95.0%	77.5-87.5% 90.0-99.9%	
Current prevalence in Duval County§	122 per 100,000	56-365 per 100,000	Supplementary Material A
True positive	.0010	.0001-.0019	5, 6
False positive	.0499	.0489-.0509	5, 6
True negative	.9488	.9088-.9888	5, 6
False negative	213×10^{-6}	$165\text{-}261 \times 10^{-6}$	5, 6
5% Infected population			
True positive	.0413	.0361-.0465	5, 6
False positive	.0475	.0417-.0533	5, 6
True negative	.9025	.8625-.9425	5, 6
False negative	.0088	.0078-.0098	5, 6
10% Infected population			
True positive	.0825	.0721-.0926	5, 6
False positive	.0450	.0394-.0506	5, 6
True negative	.8550	.8150-.8950	5, 6
False negative	.0175	.0153-.0197	5, 6

(*continued on the next page*)

Sensitivity analysis and statistical considerations

The robustness of the model was tested by performing probabilistic sensitivity analysis modifying important clinical probabilities and cost estimates. Clinical probabilities followed a beta distribution, and costs ranges followed a normal distribution.

- We performed a second-order Monte Carlo simulation with 1000 computer iterations of our model.[15] By using tracker variables, the number of endoscopies performed was compared among the 3 strategies. Sensitivity analysis was done with Bayes revision.
- Threshold analysis was performed to determine clinical limits under which all cases are performed with adequate PPE (ie, no false-negative cases).
- Tornado diagrams were created to compare the weight of different variables (PCR testing performance, costs of anesthesia, and endoscopic procedures, etc) into the final estimates of our model.
- Using published reports, we estimated the number of needed colonoscopies, EGDs, flexible sigmoidoscopies, ERCPs, and EUSs in United States for 1 week in 2020, assuming COVID-19 had not developed.[16-18] We projected the effects of the 3 strategies in resuming endoscopic procedures toward that goal (Supplementary Table 5, available online at www.giejournal.org).

Patients presenting early in our model may have recovered from COVID-19 and could be considered for endoscopy a few days later. The World Health Organization recommends at least 14 days of quarantine and the U.S. Centers for Disease Control and Prevention at least 3 days after fever resolution.[19,20] For simplicity of the analysis, these patients were deemed poor endoscopy candidates throughout the rest of the study period. Given the relatively short period of time analyzed, we did not perform half-cycle corrections.

When estimates were unavailable or significant discrepancies were found in published literature, 3 authors (S.A.H., P.T.K., and M.B.W.) discussed and agreed on a final estimate. The decision tree was generated and analyzed using decision analysis software (TreeAge Pro, Williamstown, Mass, USA). Our study protocol was approved by the Mayo Clinic Institutional Review Board (protocol 20-003245).

TABLE 2. Continued

Description	Estimate	Range*	Reference
Costs (U.S. dollars)			
Basic PPE¶	4	2-6	8
High-risk PPE¶	20	10-30	8
PCR testing‖	100	75-125	
Room decontamination‖	5	3-7	
Anesthesia**	98	74-122	11
Colonoscopy (with biopsy/polypectomy)††	1004	754-1,254	11-13
EGD (diagnostic, no biopsy)‡‡	786	590-982	12, 13
Flexible sigmoidoscopy (diagnostic, no biopsy)§§	764	572-956	12, 13
EUS (diagnostic, no FNA)¶¶	1100	824-1370	12, 13
ERCP‖‖	2999	2249-3749	12, 13
Extras (average evaluation, pathology, labs, radiology, and management)	215	161-269	11, 12

PPE, Personal protective equipment; *PCR*, polymerase chain reaction; *HCPCS*, Healthcare Common Procedure Coding System.
*Clinical probabilities follow a beta distribution. Cost variations follow a normal distribution. Lower and upper values are 2 standard deviations from mean estimate.
†Authors' calculation. Real-time PCR using Cobas severe acute respiratory syndrome–coronavirus 2 test.[3] Reported sensitivity of 95% when there were at least 689.3 copies/mL.[6] In a small cohort of symptomatic admitted patients viral load at admission was ~150,000 copies/mL.[23] Emergency use authorization by U.S. Food and Drug Administration.
‡Authors' calculation. Real-time PCR using TaqMan One-Step from Shanghai Huirui Biotechnology Co, Ltd or Shanghai BioGerm Medical Biotechnology Co, Ltd. Authorization by China Food and Drug Administration.
§At the time of writing April 2, 2020. See Supplementary Material A for details.
¶There is significant variability in PPE definition. High-risk PPE included an N95 mask, covered with second surgical mask ($.14), shield, gown, shoe covers, and double set of gloves. Low-cost alternatives are designed on a regular basis.[29]
‖Authors' calculation.
**HCPCS Code 00810.
††HCPCS Code 45378.
‡‡HCPCS Code 43235.
§§HCPCS Code 45330.
¶¶HCPCS Code 43259.
‖‖HCPCS Code 43260.

RESULTS

During the COVID-19 pandemic, the weekly endoscopy volume at our institution decreased to 12.7% of baseline. The main difference was seen in elective procedures: Only 2 elective cases were performed during the week corresponding to the COVID-19 pandemic compared with 296 during that week in 2019.

Baseline analysis of the 3 different strategies for asymptomatic endoscopy candidates during the COVID-19 pandemic showed that PCR testing is a safe and effective intervention to resume endoscopy in semiurgent and elective cases. Our analysis showed that testing under strategy 3 allows completing more endoscopies than the other 2 strategies (Table 2). Implementing strategies 2 and 3 translates into expending 22 and 105 USD, respectively, in PCR testing per patient but allows an increase to 19.4% and 95.3% of baseline endoscopies. At the current disease prevalence (122 cases per 100,000 individuals), implementing all 3 strategies over 1 week is unlikely to diagnose a true-positive case (Table 3), and false negatives would also be exceedingly rare given the low population prevalence, even with moderate test sensitivity.

In our initial model all patients scheduled for a semiurgent or elective procedure who tested positive for COVID-19 would be rescheduled. This translated into 1, 4, and 18 cases canceled unnecessarily for false-positive results. If physicians deemed the procedure should still be completed, high-risk PPE equipment for 4, 16, and 72 workers would be wasted, or the equivalent of 204, 816, and 3672 USD per week, respectively (estimate includes unnecessary room decontamination) (Table 3).

Secondary analysis using reimbursement rates for ambulatory surgery centers did not change the cost of PCR implementation or test performance. Reimbursement for endoscopy decreased to 50% to 60% compared with hospital outpatient rates: 25,992 USD, 59,204 USD, and 280,858 USD per week for strategies 1, 2, and 3, respectively.

Sensitivity analysis

Our results were consistent over 1000 reiterations of the Monte Carlo simulation (Fig. 2). False-negative results were only seen after testing 4700 patients, or 3 months using strategy 2 in our practice (assuming disease prevalence remains stable). If disease prevalence increased to 5%, there was 1 false-negative result every week under strategy 2 and 1 false-negative result every 3 days under strategy 3. This translates into 1 to 10 infected healthcare workers over a 1-week period (Table 3).

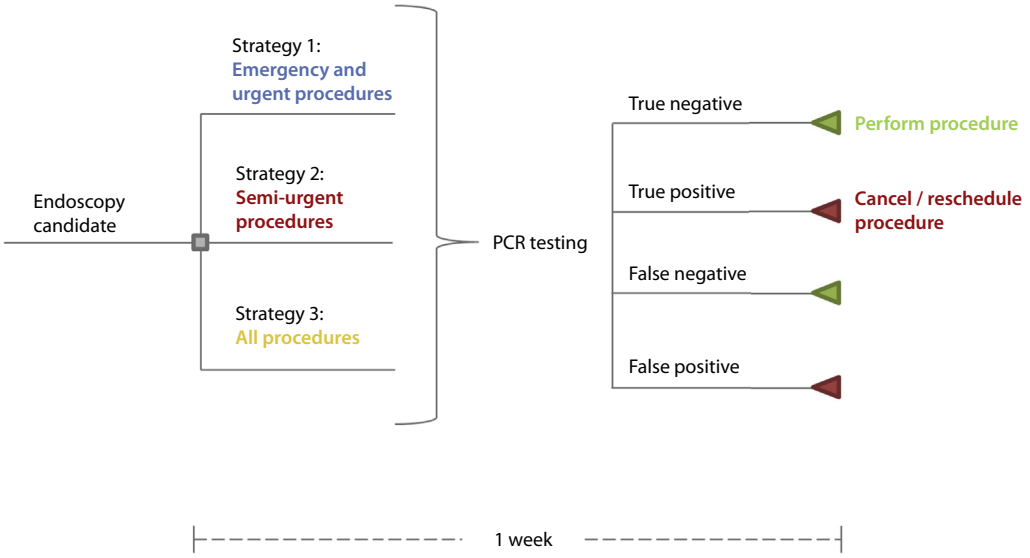

Figure 1. Decision tree for novel coronavirus disease 2019 PCR testing before endoscopy (not all stage transitions are shown. *PCR*, Polymerase chain reaction.

TABLE 3. Estimates of different strategies over a 1-week period (361 endoscopies per week)

	No. of patients tested (%)	Added costs per week* (U.S. dollars)	No. of endoscopies performed (%)	Endoscopy return per week† (U.S. dollars)	Δ Return – intervention (U.S. dollars)	True positive	False positive	False negative	Staff infected
Current prevalence (122 per 100,000 cases)									
Strategy 1	29 (8.0)	3610	29 (8.0)	44,764	41,604	0	1	0	0
Strategy 2	72 (20.0)	7942	70 (19.4)	97,831	89,889	0	4	0	0
Strategy 3	361 (100.0)	37,905	344 (95.3)	453,055	415,150	0	18	0	0
5% Prevalence									
Strategy 1	29 (8.0)	3610	29 (8.0)	44,764	41,604	1	1	0	0
Strategy 2	72 (20.0)	7942	68 (18.9)	96,026	88,084	3	3	1	1-2
Strategy 3	361 (100.0)	37,905	303 (83.9)	436,810	398,905	15	17	3	4-10
10% Prevalence									
Strategy 1	29 (8.0)	3610	29 (8.0)	44,764	41,604	2	1	1	1-2
Strategy 2	72 (20.0)	7942	66 (18.4)	93,860	85,918	6	3	1	2-4
Strategy 3	361 (100.0)	37,905	290 (80.3)	420,204	382,299	30	16	6	9-22

*Adding testing, personal protective equipment (low and high risk), and room decontamination (details in Supplementary Table 4).
†Adding Medicare payments for procedure, anesthesia, and extras (management, laboratories, electrocardiogram, imaging, pathology, etc) (details in Supplementary Material B).

Sensitivity analyses showed that the economic revenue for the hospital is greatly impacted by the cost of colonoscopies, EGDs, extras (eg, laboratories, pathology, and imaging), and ERCPs. The revenue for the hospital is much less impacted by test performance (ie, true-positive, true-negative, false-positive, and false-negative values) (Supplementary Fig. 1, available online at www.giejournal.org).

Implementing nationwide PCR testing using strategies 1, 2, and 3 would require investing 6, 13, and 64 million USD weekly under each strategy. This would yield a return of 75, 165, and 767 million USD to providers (Table 4). Assuming these patients undergo endoscopy with low-risk PPE and the R_0 rate is 1.5 to 3.5, that means 26, 65, and 325 healthcare workers would be infected for each strategy, respectively.

DISCUSSION

Testing patients for SARS-CoV-2 with PCR before endoscopy is an effective preventive strategy to resume endoscopy practice in different clinical scenarios. At the present rate of infection in low-prevalence populations, such as our center, this intervention seems safe over a 3-month period.

Despite the potential gains of PCR testing in all patients requiring endoscopy during the COVID-19 epidemic, we

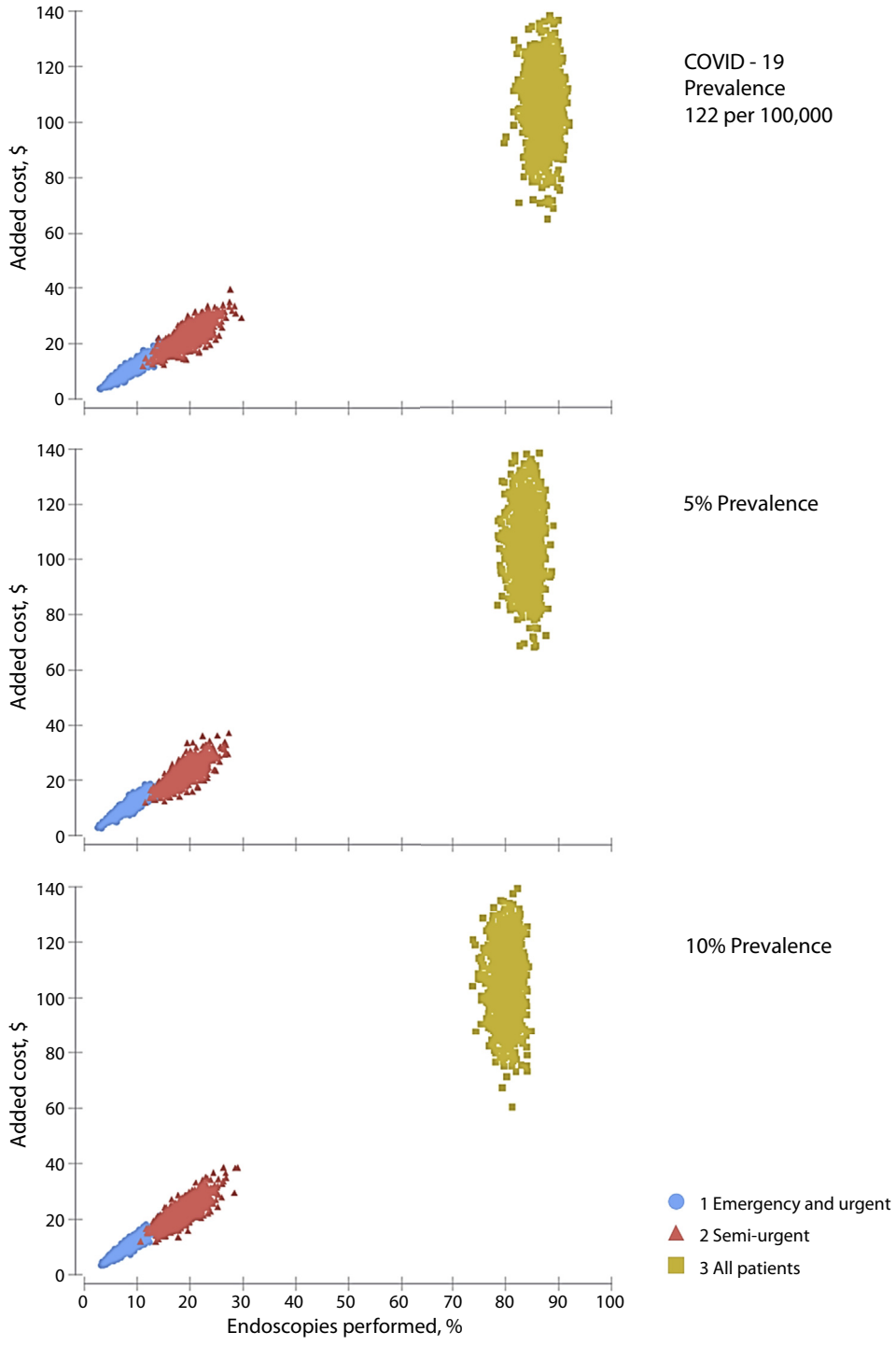

Figure 2. Percentage of endoscopy cases performed under each testing strategy. Monte Carlo simulation over 1000 iterations. *COVID-19*, Novel coronavirus disease 2019.

cannot overemphasize the importance of following adequate PPE use protocols. We recommend reviewing "Coronavirus (COVID-19) outbreak: what the endoscopy department should know"[8] as well as the gastroenterology societies recommendations periodically.[14]

The biggest determining factor in the safety and effectiveness of this intervention is by far disease prevalence. With our current prevalence (56-635 cases per 100,000 residents), an asymptomatic healthy individual has higher odds of having a false-positive result than a true-positive result. With the progression of the pandemic, this difference will likely narrow and invert. There are many uncertainties regarding the behavior of the COVID-19 pandemic if the incidence continues to increase. Clinical

TABLE 4. Procedures performed in the United States each week under different strategies

		Strategy 1			Strategy 2			Strategy 3		
Endoscopy needs in U.S. per week*		Added cost (U.S. dollars)	Return (U.S. dollars)	Infected staff (range)	Added cost (U.S. dollars)	Return (U.S. dollars)	Infected staff (range)	Added cost (U.S. dollars)	Return (U.S. dollars)	Infected staff (range)
Colonoscopy	373,997 (373,128 374,867)	3,739,972 (3,731,277 3,748,667)	46,375,655 (46,267,840 46,483,469)	16 (10-22)	8,227,939 (8,208,810 8,247,067)	101,353,245 (101,117,619 101,588,871)	40 (24-56)	39,269,707 (39,178,413 39,361,002)	469,366,504 (468,275,320 470,457,687)	199 (119-279)
EGD	213,054 (206,562 219,546)	2,130,542 (2,065,621 2,195,463)	26,418,722 (25,613,698 27,223,745)	9 (5-13)	4,687,193 (4,544,366 4,830,019)	57,737,690 (55,978,324 59,497,055)	23 (13-33)	22,370,692 (21,689,019 23,052,365)	267,383,029 (259,235,414 275,530,644)	113 (66-164)
Flexible sigmoidoscopy	10,678 (10,654 10,703)	106,784 (106,535 107,032)	1,324,117 (1,321,039 1,327,196)	0 (0-1)	234,924 (234,378 235,470)	2,893,837 (2,887,109 2,900,565)	1 (1-2)	1,121,228 (1,118,622 1,123,835)	13,401,348 (13,370,193 13,432,504)	6 (3-8)
EUS	7,386 (6,675 8,096)	73,856 (66,752 80,961)	915,817 (827,721 1,003,913)	0 (0-0)	162,484 (146,854 178,114)	2,001,503 (1,808,971 2,194,036)	1 (0-1)	775,490 (700,893 850,088)	9,268,954 (8,377,336 10,160,572)	4 (2-6)
ERCP	5,895 (5,769 6,022)	58,953 (57,688 60,219)	731,019 (715,326 746,713)	0 (0-0)	129,697 (126,913 132,481)	1,597,631 (1,563,334 1,631,929)	1 (0-1)	619,008 (605,720 632,297)	7,398,625 (7,239,794 7,557,455)	3 (2-4)
Total	611,011 (602,787 619,234)	6,110,107 (6,027,873 6,192,342)	75,765,330 (74,745,625 76,785,035)	26 (15-37)	13,442,236 (13,261,321 13,623,151)	165,583,906 (163,355,357 167,812,455)	65 (39-92)	64,156,126 (63,292,666 65,019,586)	766,818,459 (756,498,056 777,138,862)	325 (193-462)

*Calculations can be found in Supplementary Table 5.

judgment should prevail over any laboratory test in deciding the best timing for endoscopy. For example, a 5- or 10-year surveillance colonoscopy should still be postponed in a patient with underlying medical conditions despite having negative PCR results. Stool-based testing should be offered as an alternative to average-risk individuals seeking colorectal cancer screening.

Our 3 prevalence scenarios evaluate a sizeable spectrum of the COVID-19 pandemic. Even though some computer models suggest the prevalence of COVID-19 may reach an excess of 214 million Americans (65% of the total population), this represents cumulative prevalence counting patients that have been exposed and recovered.[21] Considering the clinical duration of COVID-19 is usually 2 to 3 weeks, our point estimates are well above maximum incidences reported in New York, Spain, and Italy at the time of writing (460, 187, and 171 per 100,000 residents, respectively). Without widespread testing in the population, the best estimates of disease prevalence are calculated retrospectively based on mortality rates. Such estimates lag days or weeks from actual prevalence. With current social distancing strategies, new cases will appear, although at a lesser rate, potentially matching recovery rates.

We speculate that the transmission rate in the endoscopy unit is similar to that in the community. Most calculations of R_0 originate from experience in China in a community setting.[9] The transmission rate within the endoscopy unit remains unknown, and the R_0 range used (1.5-3.5) is likely an overestimate. Case reports show that appropriate use of PPE (either with surgical masks or N95 masks), hand hygiene, and other standard procedures can reduce transmission rates up to zero (0/41 healthcare workers exposed in Singapore).[9,22] On the other hand, nonclinical personnel (eg, front desk, transportation) will be infected if they do not follow the same procedures.

The quality of any decision tree analysis depends on the quality of probabilities and input data to the computer model. A number of external factors affect diagnostic performance, including sampling operations, specimen source (oral, nasal swab), sampling timing (asymptomatic, symptomatic, recovery phase), and detection kit selected.[23]

We consider our estimates on PCR accuracy to be conservative and lower than that reported by the manufacturer in vitro. The test manufacturer reported a level of detection close to about 100 to 200 copies/mL of sample.[3] For reference, a cohort of 23 symptomatic patients in Hong Kong had a median viral load of ~150,000 copies/mL on the day of hospitalization.[24] Current estimates on PCR testing sensitivity and specificity of the SARS-CoV-2 assays are based on analytical validations. These measurements reflect performance against contrived samples (ie, spiked samples) and control material. There are no estimates of "clinical sensitivity" in patients with symptomatic COVID-19 and subclinical SARS-CoV-2 infection. The Wuhan study did not evaluate the cause for pulmonary infiltrates in those patients with negative PCR and positive CT findings (ie, infection with another virus or bacteria, inappropriate timing, testing misuse or malfunction).[7] For this reasons we allowed a broad CI for sensitivity and specificity. These estimates should be measured in a prospective fashion with patients at different ends of the clinical spectrum (both timing and disease severity). We are

TABLE 5. Coronavirus response phases and roadmap to reopening endoscopy services

Phase	Status	Population strategy	Endoscopy interventions
1: Slow the spread, ie, "flattening the curve"	Community transmission progresses rapidly in each state. Increasing infections and deaths.	Social distancing for all (closing schools, restaurants, malls, gyms, etc). Quarantines, gatherings, and travel bans. Transition to work from home. Public to wear masks. Scale up health infrastructure to safely manage the outbreak and take care of the sick.	Transfer endoscopy staff to first response line. Endoscopy rooms and ventilators used for COVID-19 patients. Treat all cases as potential positive. Restrict endoscopy to emergent and urgent indications. PPE and room decontamination based on risk stratification.[8]
2: Reopening state by state	Able to test and isolate all COVID-19 suspected cases. Reduction in new cases for 14 days. Sufficient critical care capacity.	Resume schools and business Social distancing for high-risk populations (adults >60 years old, underlying health conditions). Comprehensive surveillance systems.	PCR testing (strategy 2 or 3) according to local resources and disease prevalence. Rooms and teams conditioned to scope COVID-19 patients. Telemedicine and online appointments. PPE and room decontamination based on risk stratification.[8]
3: Establish immune protection and lift physical distancing	Safe and effective tools to mitigate or cure COVID-19: vaccines or medical treatments become available.	Therapeutics to rescue patients with severe disease. Provide prophylaxis (vaccination) to those exposed. Lift all distancing measures.	Resume all endoscopy cases and normal workflow. Resume face to face appointments.
4: Prepare for next pandemic	Successful control of the pandemic.	Investment in research and development initiatives. Expansion of public health and healthcare infrastructure and workforce.	Epidemic vigilance. Select rapid response teams in case demand is needed. Design protocols for future pandemics.

COVID-19, Novel coronavirus disease 2019; *PCR*, polymerase chain reaction; *PPE*, personal protective equipment.
Adapted from the American Enterprise Institute.[26]

conducting a prospective analysis of cases tested in our institution for that purpose.

Of all potential outcomes of the test, false-negative results are the most relevant for isolation and personal protection. Exposing a healthcare worker to SARS-CoV-2 because of PCR testing limitations has significant ethical implications. The most common reported cause for a false negative is low viral load.[5,6] It is conceivable that a false-negative patient has a lower viral load and likely is less contagious (lower R_0 factor). These strategies should be avoided at institutions or geographic areas where the prevalence of active cases approaches 5%.

We assumed that the hospital or endoscopy center would be responsible for the costs of the SARS-CoV-2 PCR test. In the United States, Medicare services and most insurance programs reimburse the cost of COVID-19 testing (paying between 36 and 51 USD per test). These reimbursement programs will favor more comprehensive testing strategies.

On the other end of the spectrum, false-positive results can lead to potential waste of valuable PPE and other resources used in disinfection and isolation. Postponing a semiurgent or elective case for a false-positive test result would be preferred. Alternatively, performing a second PCR or antibody testing (IgG serum) are potential options.

Strengths and limitations

The most critical estimates were PCR test performance and procedure classification. We were cautious to allow a broad range of sensitivity and specificity for PCR test performance including worst case scenarios. Additionally, we performed a systematic retrospective review of cases performed in March 2019 and 2020. Our analysis accounts for clinical uncertainties and valid statistical measures with a second-order Monte Carlo simulation.

One limitation was the inability to include the effect of respiratory symptoms and patients with active disease into our model. We presumed that symptomatic patients may proceed straight to a general provider and miss their scheduled endoscopy. Both patient and providers may contract COVID-19 from other healthcare workers in the endoscopy lab. We did not account for periodic screening of healthcare workers, and this population represents 10% to 20% of all positive cases.[25]

Our study did not evaluate emerging tests for serologic exposure (IgM/IgG) and the potential that these patients may be immunized to future infections. As data emerge on the accuracy of these tests, a strategy combining rapid viral PCR and serology should be studied.

Despite the sensitivity analysis and Monte Carlo simulation, our model represents a simplification of a complex and dynamic process. We agree that the definition of

endoscopy candidate is a broad umbrella term that covers diverse conditions.

The benefits of COVID-19 testing have significant geographic variability. Our hospital serves a population that extends beyond Duval County. Several healthcare systems exist in our geographic area, at least 4 of which offer testing for SARS-CoV-2. The costs of a testing program encompasses more than direct costs of testing. Testing and phone calls disrupt workflow in fast-paced ambulatory endoscopy centers. Economic models from the societal perspective are still needed. These include the cost of infections transmitted to patients coming to the endoscopy center, days missed from work by infected healthcare workers and caregivers, and cost of healthcare worker deaths (3-5 per week across the United States on strategy 3 assuming a cIFR of 1.3%).[10]

Implications and future directions

The American Enterprise Institute has proposed a road map to reopen regular services as COVID-19 transmission is brought under control.[26] They describe a transition through 4 different phases (Table 5). We consider this intervention to be ideally implemented in phase 2: once each center is able to safely diagnose, treat, and isolate COVID-19 cases and their contacts. The value of PCR testing grows as the prevalence of COVID-19 increases, with an inversion of the false positive-to-true positive ratio (with the caveats of false negatives discussed above).

Upscaling this intervention across the country will increase healthcare workers' exposure to SARS-CoV-2. By our estimates, this means that 325 or more healthcare workers across the country will potentially become infected in the endoscopy unit on a weekly basis. Although constituting a fundamental aspect of the strategy, testing alone is not sufficient enough to reopen practice. Testing should be integrated into an institution-wide plan that coordinates the notification of results before returning to the procedure, ensures isolation, and promotes follow-up monitoring. Additional strategies that can be implemented from the endoscopy unit are suggested in Table 5.

Finally, our findings are applicable to ambulatory surgery centers and other facilities like dialysis or infusion centers. Further computer models should estimate the infection risk in such institutions and potential gains of PCR testing with different patient populations (eg, chronically immunosuppressed). Our model was designed for healthcare institutions in high-income countries but is likely prohibitive in countries with limited testing and other resources. In such instances, symptomatic patients, patients with exposure to confirmed cases, and healthcare workers remain the priority in testing.

Conclusion

This economic analysis shows that PCR testing is an effective strategy to restart endoscopic practice in the United States. Our findings support strategy 3, which involves testing all patients, performing urgent endoscopy irrespective of testing result, and endoscopy in the remaining SARS-CoV-2–negative cases, but the extent of testing will rely on local resources and disease prevalence. The implementation of PCR screening is ideal for the second phase of the COVID-19 pandemic, once the health system is able to test and isolate all suspected COVID-19 cases and critical care capacity is secured. Further research is needed to measure PCR performance in vivo over different clinical scenarios while, in parallel, we continue to develop effective medical treatments.

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Abbreviations: cIFR, corrected infection fatality rate; COVID-19, novel coronavirus disease 2019; PPE, personal protective equipment; PCR, polymerase chain reaction; SARS-CoV-2, severe acute respiratory syndrome–coronavirus 2; USD, U.S. dollars.

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SUPPLEMENTARY TABLE 1. Classification of procedure urgency

Timing	Indications
Emergent, <8 h Urgent, 8-24 h	EGD: upper GI bleeding Food bolus impaction Colon/FlexSig: lower GI bleeding hemodynamically unstable Acute intestinal obstruction ERCP: cholangitis, acute biliary leak. EUS: none DBE: none
Semiurgent, 24 h to 7 wk	EGD: gastric cancer diagnosis Acute-onset dysphagia Colon/FlexSig: lower GI bleeding hemodynamically stable Partial intestinal obstruction New-onset bloody diarrhea with negative cultures Ulcerative colitis flare Crohn's disease flare ERCP: choledocholithiasis w/o cholangitis Biliary pancreatitis w/o cholangitis EUS: concerns for pancreatic cancer or cholangiocarcinoma (mass seen) DBE: small-bowel bleeding
Elective, ≥8 wk (56 days) Also semiurgent indication in setting of epidemic*	EGD: ampullary adenoma Isolated weight loss GERD/heartburn Dyspepsia/noncardiac chest pain Established dysphagia Barrett's (regardless of dysplasia) Esophageal varices evaluation or follow-up banding Iron-deficiency anemia Endoscopic submucosal dissection for early gastric cancer PEG tube placement Colon/FlexSig: possible FIT or fecal FIT-DNA test Chronic diarrhea Colorectal cancer screening Colon EMR Ulcerative colitis with dysplasia ERCP: biliary stent replacement Pancreatic stent removal EUS: concerns for submucosal mass (GIST, leyomioma, lipoma) Double duct sign without a discrete mass Concerns for neuroendocrine tumor Celiac plexus block Pancreatic cyst evaluation DBE: small-bowel tumor

Colon, Colonoscopy; *FlexSig*, flexible sigmoidoscopy; *DBE*, double-balloon enteroscopy; *FIT*, fecal immunochemical test; GIST, GI stromal tumor.
*Adapted from Bilal M, Simons M, Rahman AU, et al. What constitutes urgent endoscopy? A social media snapshot of gastroenterologists' views during the COVID-19 pandemic. Endoscopy 2020.[2]

SUPPLEMENTARY MATERIAL A: CALCULATIONS FOR NOVEL CORONAVIRUS DISEASE 2019 PREVALENCE IN DUVAL COUNTY (FLORIDA, USA) AS OF APRIL 2, 2020 AFTERNOON

Crude prevalence

Cumulative 263 residents reported with confirmed novel coronavirus disease 2019 (COVID-19).[1] Duval population estimated to be 957,755 in July 2019.[2] Crude prevalence of 22 COVID-19 infected patients per 100,000 Duval County residents.

Prevalence based on fatality rate

Seven COVID-19 deaths confirmed in duval County.[2] Corrected infection fatality rate (cIFR) in Diamond Princess ship was 1.3% (95% confidence interval [CI], .38%-3.6%) and cIFR in China was .6% (95% CI, .2%-1.3%). Both adjusted for delay from confirmation to death.[3,4]

Reverse calculation using reported deaths yields 538 infected patients (95% CI, 194-1842) using Diamond Princess ship cIFR (an homogeneous older population) and 1167 infected patients (95% CI, 538-3500) using China cIFR (less homogeneous, larger sample). Prevalence calculated with cIFR estimated to be 56 (95% CI, 20-192) infected patients per 100,000 residents and 122 (95% CI, 56-365), respectively.

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SUPPLEMENTARY TABLE 2. Estimated prevalence of novel coronavirus disease 2019 infected patients per 100,000 residents, Duval County, Florida, USA, April 2, 2020

Confirmed severe acute respiratory syndrome–coronavirus 2 positive	Corrected infection fatality rate Diamond Princess ship	Corrected infection fatality rate China
Prevalence per 100,000 residents		
28	56 (20-192)	122 (56-365)
Number needed to test		
3534	1779 (520-4926)	821 (274-1779)

Values in parentheses are 95% confidence intervals.

SUPPLEMENTARY MATERIAL B: ADDITIONAL COST CALCULATIONS

Emergency cases

All candidates were tested. All received endoscopy without waiting for results and managed as potential novel coronavirus disease 2019 (COVID-19) positive.

Input cost = cost of polymerase chain reaction (PCR) test + cost of personal protective equipment (PPE) high risk + cost of decontamination after each case. Output reimbursement = Medicare payment for procedure + payment for anesthesia + payment for extras (management, laboratories, electrocardiogram, pathology, imaging, emergency department care for patients who had adverse events).

Semiurgent and elective cases

Testing was based on strategy (1, 2 or 3) selected. Management depended on result of the test. For COVID-19 positive (true positive and false positive), procedure was postponed; hence, input cost = cost of PCR test and output reimbursement = 0. For COVID-19 negative (true negative and false negative), procedure was completed; hence, input cost = cost of PCR test + cost of PPE low risk.

Output reimbursement = Medicare payment for procedure + payment for anesthesia + payment for extras (management, laboratories, electrocardiogram, pathology, imaging, emergency department care for patients who had adverse events).

If done with COVID-19 cases, the room was cleaned only at the end of the day. Cost of decontamination once a day was considered zero.

SUPPLEMENTARY TABLE 3. Hospital outpatient department and ambulatory surgery center reimbursement for procedures included in our model

	Hospital outpatient department costs	Ambulatory surgery center Costs
Basic PPE	4	4
High-risk PPE	20	20
Polymerase chain reaction testing	100	100
Room decontamination	5	5
Anesthesia	98	98
Colonoscopy (with biopsy/polypectomy)*	1004	507
EGD (diagnostic, no biopsy)†	786	397
Flexible sigmoidoscopy (diagnostic, no biopsy)‡	764	386
EUS (diagnostic, no FNA)§	1100	663
ERCP¶	2999	1306
Extras (average evaluation, pathology, labs, radiology, and management)	215	215

Reimbursement for ambulatory surgery centers is approximately 50%-60% of hospital outpatient departments. All costs are adjusted to U.S. 2020 dollars. Cost variations follow a normal distribution. Lower and upper values are 2 standard deviations from the mean estimate.

PPE, Personal protective equipment; *HCPCS*, Healthcare Common Procedure Coding System.

*HCPCS Code 45378

†HCPCS Code 43235

‡HCPCS Code 45330

§HCPCS Code 43259

¶HCPCS Code 43260

SUPPLEMENTARY TABLE 4. Recommended personal protective equipment during endoscopy

Low risk*	Intermediate risk†	High risk‡
Endoscopy personnel		
Surgical mask	Upper GI endoscopy → consider as high risk	N95 mask
Hairnet		Hairnet
Goggles	Lower GI endoscopy → consider as low risk	Goggles and/or face shield
Single-use gown		Long-sleeved water resistant gown
Gloves		Two pairs of gloves
Patient		
Surgical mask		Surgical mask
		Gloves
Decontamination endoscopy rooms		
Standard disinfection at the end of procedure day		At the end of each procedure

*Low risk defined as no symptoms, no contact with severe acute respiratory syndrome–coronavirus 2–positive person, nonstay in high-risk area during the previous 14 days.
†Intermediate risk defined as the presence of symptoms with no history of contact with positive person and nonstay in high-risk area during previous 14 days OR no symptoms but contact with positive person or stay in high-risk area during the previous 14 days.
‡High risk defined as at least 1 symptom and 1 of the following: contact with positive person or stay in high-risk area during the previous 14 days.

COMMENTS

- All endoscopes and reusable accessories should be disinfected according to standard guidelines.
- Endoscopies of intermediate-/high-risk patients should preferably be performed in a negative pressure room. Delay the next procedure with 30 minutes to allow airborne particles to vanish. If no negative pressure room is available, the room should be kept empty for at least 1 hour.
- Discourage reuse.

Adapted from Repici A, Maselli R, Colombo M, et al. Coronavirus (COVID-19) outbreak: what the department of endoscopy should know. Gastrointest Endosc. Epub 2020 Mar 14.

SUPPLEMENTARY TABLE 5. Calculations for endoscopic procedures performed in the United States per month in 2020

	2013 Medicare cases*	Percent of cases	2017 Estimated U.S. cases†	Distribution adapted from Medicare beneficiaries	2020 Projected annual cases (average of lower and higher estimate)	Lower estimate using annual population growth (see below)	Upper estimate using annual procedure growth (see below)	One week 2020 projected cases (annual/ 52.1)	Lower estimate	Upper estimate
Colonoscopy	10,964,034	61.90	19,000,000	.6190040	19,501,337	19,456,000	19,546,673	373,997	373,128	374,867
EGD	6,069,647	34.27	10,518,327	.3426782	11,109,285	10,770,767	11,447,804	213,054	206,562	219,546
Flexible sigmoidoscopy	313,045	1.77	542,488	.0176738	556,802	555,508	558,096	10,678	10,654	10,703
EUS	196,144	1.11	339,906	.0110738	385,108	348,063	422,154	7,386	6,675	8,096
ERCP	169,510	.96	293,750	.0095701	307,400	300,800	313,999	5,895	5,769	6,022
Total	17,712,380	100.00	30,694,471	1.0000000	31,859,932	31,431,138	32,288,726	611,011	602,787	619,234

Volume increase based on U.S. annual population growth	Volume increase based on Medicare annual procedure reports‡				
Estimated increase 2017-2020		2009	2010	Difference	Estimate increase 2017-2020
1.024	Colonoscopy/flexible sigmoidoscopy	3,330,829	3,336,136	.0015908	1.004772
	EGD	2,833,863	2,895,999	.0214558	1.064367
	ERCP	284,391	288,715	.0149767	1.04493
	EUS	59,604	64,274	.0726577	1.217973

*Peery AF, Crockett SD, Murphy CC, et al. Burden and cost of gastrointestinal, liver, and pancreatic diseases in the United States: update 2018. Gastroenterology 2019;156:254-72.
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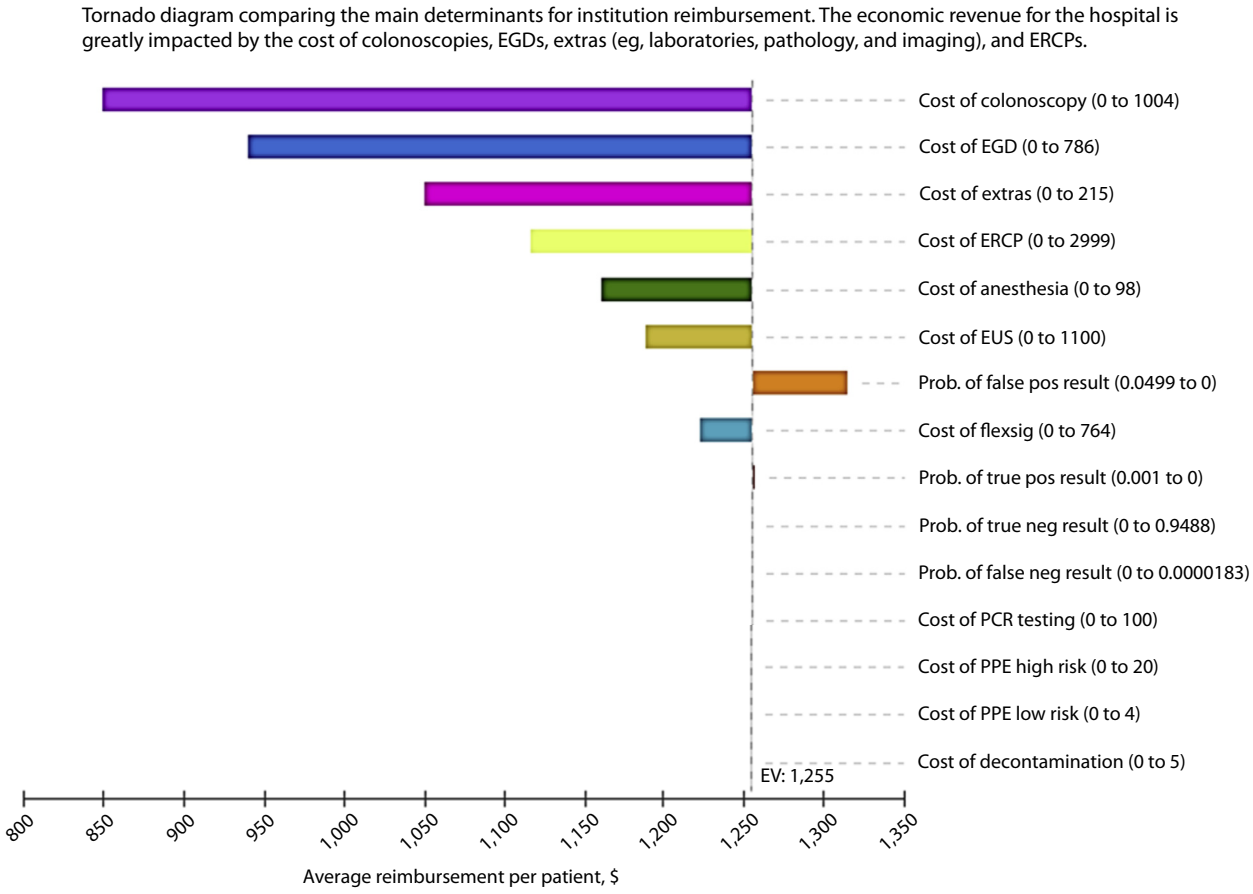
‡Peery AF, Dellon ES, Lund J, et al. Burden of gastrointestinal disease in the United States: 2012 update. Gastroenterology 2012;143:1179-87.



Supplementary Figure 1. The revenue for the hospital is much less impacted by the test performance (ie, true-positive, true-negative, false-positive, and false-negative values). *flexsig*, Flexible sigmoidoscopy; *PCR*, polymerase chain reaction; *PPE*, personal protective equipment.