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COVID-19 and Long-term Planning for Procedure-based Specialties During Extended Mitigation and Suppression Strategies

The coronavirus disease 2019 (COVID-19) pandemic has placed patients and their communities at tremendous risk from acute illness as well as economic uncertainty.[1] Given that varying degrees of mitigation and suppression may persist for 1–2 years, there is a critical need for pragmatic approaches for reopening procedural and surgical units, addressing backlogs, and establishing standards of care that balance patient risk and benefit while maintaining the procedural volumes needed for patient care during this time of ongoing disease control measures.

This commentary defines mitigation/suppression, describes its effects on procedure-related health care backlogs, and discusses strategies for risk stratification and patient care. These are supplemented by relevant examples from a large region of Kaiser Permanente, an integrated health care system that cares for approximately 1 of every 30 people in the United States.

Mitigation and Suppression

The successful management of epidemics from the World Health Organization[2] and the Imperial College COVID-19 Response Team[3] suggests several initial phases and recommended actions:

- emergence of infection (recommended action of early detection);
- localized transmission (recommended action of containment, using countermeasures such as isolation, contact tracing, and testing); and
- amplification and rapid spread (recommended action of control measures such as mitigation and suppression).

Mitigation permits a controlled outbreak; it slows viral spread to "flatten the curve" with the aim of maintaining levels of illness within existing health care system capacity, using measures such as quarantine of infected patients and their contacts and social distancing of those at increased risk of severe disease. Suppression, a more aggressive control approach, seeks to minimize cases, even to reverse epidemic growth, using additional measures such as social distancing of the entire population, with closures of schools and businesses (including elective medical visits).[4]

Health care systems have radically restructured their operations to brace for surges in acute COVID-19 hospital demand and in response to regional mitigation and suppression measures. These measures included deferrals of routine elective and semielective health care, including the majority of endoscopic and surgical interventions[5] for screening, diagnosis, and treatment. These actions may affect patients' health and, for many systems, modify revenues needed to sustain health care delivery during and after the pandemic.

At Kaiser Permanente in Northern California (KPNC), a Kaiser Permanente region serving 4.5 million members, early surges of COVID-19 inpatients at 2 medical centers led to regional mitigation/suppression measures and the rapid cancellation of elective procedures/surgeries throughout our 21-hospital system in March 2020, aligned with recommendations from the Centers for Disease Control and Prevention (CDC), gastrointestinal specialty societies, and the American College of Surgery.[6–8] The resulting number of deferred elective procedures across our system by May 2020 is substantial, because we typically have approximately 10,000 gastrointestinal procedures and 30,000 elective surgeries per month.

As communities begin relaxing COVID-19 mitigation and suppression measures, health care systems are preparing to reinstate elective procedures and surgeries. Addressing ongoing health care needs, ongoing mitigation/suppression, and procedure backlogs will require 3 primary components: (1) telehealth to continue social distancing and maintain mitigation, (2) risk stratification to maximize the benefits of procedures being scheduled and to minimize harm, (3) and methods for optimizing health care capacity and safety to provide relevant services to the most people possible.

Telehealth

Multispecialty collaborations and virtual care platforms will continue to be essential during ongoing mitigation/suppression for maintaining specialty and periprocedural care in almost all health care settings. Telehealth (video or telephone) visits accounted for approximately 18% of specialty care visits before March 1, 2020, in KPNC; in contrast, by the week of April 19, 2020, they accounted for approximately 76% of visits (albeit at a decline in total specialty visits from approximately 300,000 per month to approximately 150,000 per month). Between March 16, 2020, and April 17, 2020, at KPNC, gastroenterologists and surgeons received nearly 6000 and 30,000 outpatient referrals, respectively, and were able, using tele- and video-based consultations, to disposition >80% of referrals for procedures within 3 days of receipt, addressing urgent indications and deferring non–time-sensitive cases.

Although elective procedural volume decreased markedly over this period, urgent or emergent procedural and surgical caseloads (typically accounting for 30%–40% of our procedural/surgical volume) remained stable. This suggests that, even during high levels of mitigation/suppression, a combination of telehealth and highly selected office visits can allow the prompt evaluation and scheduling of critical procedures and surgeries

(including cancer-related care) despite decreased procedural volumes.

Risk Stratification to Maximize Benefit

The likely benefit of procedures varies markedly by indication and includes both disease morbidity (eg, amelioration of symptoms) and mortality (ie, likelihood of earlier intervention decreasing the likelihood of disease progression). Recent publications for gastrointestinal procedures provide important information regarding patient benefit for the most common indications for colonoscopy: screening, surveillance, and follow-up of fecal immunochemical test (FIT) results. Higher-risk patients include FIT-positive patients who are approaching 6 months from their test (after which there is a significantly increased risk of disease progression),[9–12] symptomatic patients (eg, those with dysphagia, weight loss, gastrointestinal bleeding, inflammatory bowel disease flare, etc), laboratory test abnormalities suggestive of acute disease (eg, acute or progressive iron deficiency anemia, abnormal imaging, obstructive jaundice, etc), and patients with large or incompletely resected polyps.[13]

Understanding disease risk around these factors can inform the prioritization of COVID-19 relative procedure backlogs during reopening and ongoing mitigation/suppression control measures, which may include repeated partial closures during local increases of disease incidence (Table 1). For example, a risk measurement process at KPNC to identify and schedule pending routine and high-risk (FIT positive, postcancer, high-risk adenoma follow-up) patients awaiting colonoscopy across all 21 facilities in KPNC in late 2019 and in early 2020 resulted in a 33% reduction in such patients within 10 weeks, from approximately 11,000 to 8000. However, after California's shelter in place orders were implemented, the number of patients awaiting colonoscopy initially plateaued and then rapidly rose to more than 12,000, exceeding the pre-COVID numbers. These risk measurement methods can now be used to prioritize patients for early scheduling of high-risk patients (Table 1).

Risk Stratification for Procedure-Related Harm

Procedure-related harm during a pandemic includes (1) patient infection risk, (2) medical staff infection risk, and (3) procedure-related complications. Although COVID-19 hospitalizations began subsiding in parts of California in late April, new cases continue to arise, lending considerable uncertainty to estimates of community transmission risk. Because patients presenting for procedures/surgery may also be at risk for COVID-19–related complications, KPNC is using regional data to identify patient characteristics associated with COVID-19 deterioration. Among 2168 KPNC patients with COVID-19–positive tests in our system at the time of analysis, we corroborated external reports that younger age and lower comorbid disease burden are associated with lower rates of hospitalization, critical care, mechanical ventilation, and death.[14] These data assist our clinicians in stratifying patients based on their risk of COVID-19 complications.

Given that endoscopic procedures are generally low risk, even among persons with high comorbidities, risk is primarily related to identification of a disorder amenable to surgery. For relevant indications (eg, evaluation of a colon mass seen on radiologic imaging), if such patients are unlikely to tolerate surgery, they are less likely to benefit from endoscopy. To assess surgical risk for all types of operations, we developed a risk score incorporating age, comorbid disease burden, and surgical venue for predicting postsurgical major morbidity or mortality using National Surgical Quality Improvement Program definitions. This model showed good discrimination for identifying patients at risk for postsurgical complications (c-statistic of 0.77 in training and test sets including 144,784 patients) and is now being automatically calculated in our surgical reopening electronic health record dashboards. Detailed online tools from the National Surgical Quality Improvement Program risk calculator are available to quantify patient surgical risk.[15] Applying such risk tools to our deferred surgical cases (all types of surgery), 39% of patients were at low COVID-19–related risk; for surgical risk, 76% were at low risk, 23% were at medium risk, and 1% were at high risk. These perioperative risk scores help contextualize discussions between surgeons and patients related to surgical timing during the reopening period.

Optimizing Health Care Capacity and Safety (During Reopening and Ongoing Mitigation/ Suppression)

With evolving decisions in many states to gradually ease mitigation and suppression restrictions, strategies are needed for optimizing procedure safety and throughput to complete new and deferred procedures. In California, for example, in response to a recent statewide declaration to resume elective procedures,[16] hospitals are preparing for surgical reopening. This requires a careful assessment of aggregate procedural/surgical capacity to ensure that local constraints can be addressed by conducting procedures at local or other hospitals with available capacity.

Personal protective equipment (PPE) availability is an overarching consideration for procedural/surgical reopening, given desires for the safety of the medical staff and the challenges of maintaining a stable supply chain in the COVID-19 era. Thus, it is important for facilities to use PPE forecasts that account for increasing use with surgical reopening, the number of surgical team members per case, and the type of PPE needed (airborne or standard surgical) to balance resources while accounting for the ongoing risk of the COVID-19 surge. KPNC, using this type of forecasting, has successfully modulated procedure volume, continuing PPE conservation and stewardship efforts using CDC guidelines for extended use and reuse to protect patients and providers.

Table 1. Prioritization Framework for Shared Decision Making

	Medical urgency (ongoing assessment of risk of disease progression based on debilitation, disability, pain, and other key clinical symptoms and factors)	
	Low	High
COVID-19 and procedure-related risk (risk scores developed based on predictive analytic tools based on 2168 COVID-19–positive patients and 170,814 surgical patients)		
Low	Consider nonprocedural care if available and discuss potential for long waiting time due to COVID-19–related deferred procedures	Priority to invite to proceed with procedures/surgery
High	Shared decision making to consider nonprocedure care. For patients ≥75 years of age for whom surgery is a consideration, use the American College of Surgeons geriatric surgery verification program)	Ongoing encouragement to optimize preprocedure health (based on risk factors known to improve outcomes) while awaiting procedure date
Medical urgency: gastroenterology Case Examples		
Schedule now	Schedule first after "schedule now" completed	Schedule after other categories addressed (likely >3 months)
• FIT positive (especially ≥3 months since positive test result) • Esophageal dysphagia (not globus) • IBD flare • Progressive or acute iron deficiency anemia (within 6 months) • GERD/abdominal pain/dyspepsia in older patients (≥60 years) with warning symptoms) • Unexplained weight loss with negative imaging findings • Rectal bleeding in the absence of prior imaging • GI workup before priority transplant/surgical referral • Melena • Imaging suggestive of cancer • Obstructive jaundice	• Chronic iron deficiency (eg, premenopausal female patient) • FIT positive (<3 months since positive test result) • GERD/abdominal pain/dyspepsia in younger patients (<60 years) with warning symptoms (tele-consult also) • Follow-up colonoscopy after high-risk polyp resection (eg, carcinoma in situ, high-grade dysplasia, possible incomplete resection) • Barrett's esophagus with high-risk features (nodules, high-grade dysplasia) or for ablation • Variceal banding for secondary prophylaxis • Follow-up gastric ulcers to exclude cancer	• GERD/abdominal pain/dyspepsia in younger patients (<60 years) without warning symptoms • Varices screening • Routine Barrett's esophagus surveillance • Bravo/pH probes • Routine screening colonoscopy • Colonoscopy for family history of colorectal cancer • Surveillance in low-risk patients o History of low-risk polyp (lacks features of column 2) o IBD surveillance

NOTE. Prioritization framework for shared decision making based on 3 primary axes: (1) medical urgency of surgical procedure based on potential for clinical deterioration, (2) COVID-19 and surgical risk based on quantitative tools, and (3) PPE availability. The availability of PPE is a key overarching consideration for effective and sustainable procedure/surgical reopening. Additional factors for consideration include anesthetic approach, home vs inpatient recovery, local COVID-19 case activity, public health agency guidance and regulations, and regional aggregate procedure-related care availability.
GERD, gastroesophageal reflux disease; GI, gastrointestinal; IBD, inflammatory bowel disease.

Increasing procedural capacity and safety will likely depend, in part, on preprocedural screening for infection. Throughput for gastrointestinal procedures was challenged by the gastrointestinal multisociety recommendations for airborne precautions for all patients, extending room dwell time for 45 minutes after each case to allow for adequate air exchanges.[17] Thus, expansion of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) preprocedure testing before bowel preparation can allow for more standard room turnaround times and use of standard PPE rather than airborne precautions for test-negative patients. Similarly, for surgical cases, as testing capacity increases, preoperative SARS-CoV-2 testing can clarify airborne PPE requirements for high-risk procedures (ie, endotracheal intubation, airway procedures) and ensure that those with an anticipated ICU stay are at low risk for COVID-19 complications during recovery.[18]

There is a complex interaction between test performance characteristics, background prevalence, and the potential for false negative (or positive) tests. This may influence confidence in using lower levels of PPE in test-negative persons, for conservation of this vital resource, particularly in regions with a very high prevalence of active infections. Performance characteristics depend, in part, on the test used (some rapid point-of-care tests may have lower sensitivity), adequacy of sample acquisition, and disease burden (a person with lower viral burden may be both less infectious and less likely to test positive). A disease prevalence of 3%, for example, would result in a negative predictive value of 99.7% for a test with 90% sensitivity (and 90% specificity) and 99.0% for a test with 70% sensitivity. After taking into account that patients with symptoms typical of infection can be treated as COVID positive, with regard to PPE precautions, the joint probability appears extremely low of (1) a person being infected (2) the person being asymptomatic (3) the person having a false negative test result, and (4) standard PPE use in this patient leading to the spread of disease within a health care setting. To minimize false negative testing, we recommend using higher-sensitivity tests (and updating test type as methods improve), having testing performed by trained personnel for adequate sampling, and adjusting evaluations as needed if community prevalence surges (thereby potentially increasing the proportion of total people tested who have a false negative test result).

Integrating Concepts

The current KPNC framework integrates all these factors for reopening procedural/surgical care (Table 1). Because care in the COVID-19 era engenders novel types of risks for patients and providers, this framework is designed to facilitate shared decision making between procedure-based physicians and patients for procedural timing. Using the described evaluations of benefit and risk,[19] before rescheduling, KPNC is currently having its procedure-based specialists, including gastroenterologists and surgeons, review each case, leverage expert internal guidance, and engage with their patients in shared decision making to assess whether a delay is in the patient's best interests.

We will initially focus on prioritizing procedures among patients with high medical urgency/likely benefit (based on internal expert opinion, gastrointestinal society guidelines, and the American College of Surgeons "Elective Case Triage Guidelines for Surgical Care"[20]) and low COVID-19 and procedural risk. Together, our clinicians have also worked across specialties to identify medically urgent non–cancer-related procedures needed for diagnosis or treatment for both gastrointestinal diseases (Table 1) and general surgical procedures across multiple specialties (er, bucket handle tears, bilateral ureteral stones, and aortic aneurysms of >6.5 cm).

For patients with low medical urgency and high COVID-19 or surgical risks, we will discuss the risks and benefits of nonsurgical care pathways. Older patients likely to proceed to surgery, who may be at higher risk of COVID-19 complications, will be encouraged to await vaccine availability or will participate in the American College of Surgeons geriatric surgery verification program based on risk and frailty. Special considerations will be given to those expected to need skilled nursing facility recovery given the emerging risks of COVID-19 now recognized in these facilities. Patients with high medical urgency and high procedural/surgical risk will continue to receive interventions to optimize their health—including for diabetes, hypertension, anemia, obesity, and smoking—while awaiting their surgical date.

Discussions with patients who have low medical urgency and low risk will focus on nonprocedural treatment options, given the potential for extended procedural/surgical waiting times. Disagreements between surgeons and their patients about the timing and risks of surgery will be assessed by a second opinion or through local multidisciplinary teams.

Alternative methods, for example, can be used for lower-risk patients needing screening and surveillance endoscopic examinations. Patients originally scheduled for screening colonoscopy can instead use a FIT testing approach while awaiting colonoscopy. This allows higher-risk patients to complete colonoscopies while providing average-risk patients with guideline-concordant care. Fecal testing can particularly be recommended to patients whose risk of complications from COVID-19 risk is high, such as those older than 60 years and those 50–59 years with at least 1 serious comorbidity. Concordant with recent gastrointestinal society guidelines, patients with a history of 1 or 2 small adenomas scheduled for follow-up 5 years after their initial examination can instead be recommended for testing at 7Ø10 years, given that their long-term risk appears comparable to that of people without any adenomas.[21]

Summary

COVID-19 has resulted in tremendous disruptions to routine health care and elective procedures, challenging our existing approaches for optimal periprocedural and procedural planning and care. In the setting of ongoing, albeit lower, rates of

COVID-19, reopening deferred procedures/surgeries requires a balanced and data-driven framework that prioritizes the timing of procedures based on medical urgency (patient likelihood of benefit), COVID-19 risk, procedural risk, and the availability of PPE and preoperative SARS-CoV-2 testing. This framework may help minimize the potential impact of deferred care and diminish additional waves of adverse outcomes among those affect by the COVID-19 pandemic until the threat of recurrent viral infection surges abates. The uncertainty of this pandemic calls for health care systems to prepare for sustained mitigation/suppression and the commitment of physicians and patients to discuss critical periprocedural and procedural decisions together.

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