Surgical Re-entry Strategy Following COVID-19 Pandemic A Tiered and Balanced Approach

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Abstract: Following the Presidential declaration of a national emergency, many health care organizations adhered to recommendations from the Centers for Medicare and Medicaid (CMS) as well as the American College of Surgeons (ACS) to postpone elective surgical cases. The transition to only emergent and essential urgent surgical cases raises the question, how and when will hospitals and surgery centers resume elective cases? As a large health care system providing multispecialty tertiary/quaternary care with across the Southeast United States, a collaborative approach to resuming elective surgery is critical. Numerous surgical societies have outlined a tiered approach to resuming elective surgery. The majority of these guidelines are suggestions which place the responsibility of making decisions about reentry strategy on individual health care systems and practitioners, taking into account the local case burden, projected case surge, and availability of resources and personnel. This paper reviews challenges and solutions related to the resumption of elective surgeries and returning to the pre-COVID-19 surgical volume within an integrated health care system that actively manages 18 facilities, 111 operating rooms, and an annual operative volume exceeding 123,000 cases. We define the impact of COVID-19 across our surgical departments and outline the staged re-entry approach that is being taken to resume surgery within the health care system.

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he coronavirus disease 2019 (COVID-19) pandemic represents an unprecedented challenge in the delivery of modern health care on a national and global level. On March 11, 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic. Shortly after, on March 13, President Trump declared it a national emergency. COVID-19 cases quickly rose from 1900 at the time of the announcement to > 1,000,000 cases as of April 29, 2020.² Following this announcement, states shut down nonessential businesses, issued stay at home orders, and recommended social distancing practices in an attempt to slow disease transmission and minimize the associated surge of patients to health care facilities. To preserve hospital resources and avoid placing patients at risk of unnecessary exposure, the Centers for Medicare and Medicaid (CMS) issued consensus statements recommending halting elective surgical cases.³⁻⁶ In response, the American College of Surgeons (ACS) and surgical subspecialty societies developed surgical case triage lists, recommending only emergent, urgent, and indicated acute cases.^{7–10} Health care systems adopted these recommendations and surgical case volume plummeted. 11 In areas that were more severely affected by COVID-19, demand for resources to respond to the pandemic grew, and operating room (OR) resources, personnel, and anesthesia staff were redeployed to provide appropriate care for this public health crisis. 12 With the rapid decrease in surgical workload, the obvious question of how and when to resume elective surgical procedures arose.

Since communities across the United States have been affected to varying levels by the COVID-19 pandemic, guidelines have remained vague regarding the timing of resuming elective surgical cases. ¹³ The White House released general guidelines for "Opening Up America Again" which delineate criteria for a phased response back to normal operations: a downward trend in influenza-like illness and documented COVID-19 cases over a 14-day period, hospital capacity and resources to treat all patients without crisis care, and a robust testing program. ¹⁴ In areas with minimal case surge due to rapid adoption of measures to slow disease transmission, resources remain adequate to consider resuming

elective surgical procedures. As a result, health care systems are developing to strategic plans for executing this resumption.

Resuming elective surgical cases in the face of a global pandemic is a complex issue with potentially conflicting interests. The needs of patients, surgeons, and health care systems to resume elective casework must to be balanced against public health interests and potential complications of an early resumption. Patient safety concerns are substantial as evidenced by the increased need for intensive care unit (ICU) admission and a mortality of 20.5% in patients who underwent elective surgery during the incubation period of COVID-19. As we return to elective surgery, how does a health care system determine an appropriate pace, patient, location, and resources for surgical re-entry?

A TIERED APPROACH

A tiered approach has been proposed by CMS, ACS and surgical subspecialty societies as health care institutions strive for an appropriate balance between minimizing the potential for increased COVID-19 transmission and ensuring patients receive safe, timely care for non-COVID-related surgical issues. 13,15 The tiered model focuses begins with outpatient cases in ambulatory surgery centers (ASCs), progressing to the hospital outpatient arena, and lastly the inpatient setting. Similarly, there is an emphasis on transitioning down in clinical tiers, from only emergent and urgent, to necessary time-independent elective cases. If possible, "non-COVID care" centers are the optimal sites at which to resume surgery. 16,17 These are locations that have appropriate screening practices in place, have been thoroughly cleaned and disinfected, and have minimal risk of exposure and transmission from other facilities. 16 The rate at which a facility is able to incrementally return to practice is largely limited by the hospital and local community needs responding to COVID-19. Before a large-scale resumption of elective surgery, physicians must ensure adequate resources:

- Staff—nursing and support staff in preoperative, perioperative, and postoperative environments.
- Hospital surgical and ICU beds.
- COVID-19 testing.
- Supplies [eg, personal protective equipment (PPE)—including surgical masks, N-95 respirators, facemasks, and shields].

Close communication with hospital administrators and public health officials is essential to make decisions that are in the best interest of both individual patients and the general public leading to the challenge, how does a health care system safely resume elective surgical cases in a manner that is balanced, appropriate, and aligns with the tiered approach detailed above?

THE CHALLENGE

The authors' institution is a large tertiary/quaternary health care organization in the Southeast United States comprised of over 40 hospitals and 900 care locations, including a level 1 trauma center and dedicated children's

hospital. Within the Charlotte metropolitan area, there are 10 hospitals that offer inpatient and hospital-based outpatient surgical procedures and 8 free-standing ASCs, totaling 111 ORs. Before COVID-19 restrictions, OR utilization across these facilities was between 65% and 76% with an average case volume of >10,000 cases per month in January and February. The health care organization reacted swiftly to the pandemic and on March 17, 2020 surgeons across all specialties were asked to cease elective surgical procedures to preserve resources and implement a public health decision that was in the best interest of patients and the community. As a result, the hospital system experienced dramatic decreases in normal patient volumes. Outpatient visits for adult medicine specialties decreased to 60.2% or pre-COVID volume, primary care decreased to 47.6% of pre-COVID volume and pediatric visits decreased to 36.6% of pre-COVID volume in the weeks immediately following cessation of elective surgical practice. In the same period of time, OR utilization across the same facilities dropped to 25%-30% resulting in a backlog of over 5800 cases as of April 27, 2020.

STRATEGICALLY PLANNING RE-ENTRY

Successful phasing of electively timed, appropriately indicated, essential surgery is a complex task that requires a strategic plan. Our institution identified several key requirements necessary for the development of a strategic plan to resume elective surgery: assessment of the perioperative environment, assessment of resources, evaluation of surgical case priority, balancing current and projected COVID-19 disease demands with increasing elective case volume, establishing a plan for facility specific redistribution of cases, and decisive leadership to navigate the complex circumstances.

Available Perioperative Environment

Following the deferment of elective cases, each facility was reduced to an OR complement that would be effective to manage emergent and urgent cases over a sustained period of time. The Surge and Re-entry Team made the decision to limit but not completely eliminate cases at some of the smaller facilities in the metropolitan area. This allowed for the successful redeployment of perioperative staff and space while consistently providing necessary surgical care at each facility. Limiting, but not eliminating OR activity, also helped avoid unnecessary transfers to other institutions, except for patients requiring high-level care. Facilities that typically provide more elective care experienced a more substantial decrease in case volume compared with the trauma center, but the majority of facilities were able to maintain ~20%-30% OR utilization (Fig. 1). The ability to maintain a foundational level of surgical care at each inpatient facility facilitated planning the re-entry process as it allowed scaling up or down based on need and distributed surgical burden across multiple locations. It also allowed for operational and tactical experience with the implementation of the components of the re-entry strategy (testing, PPE, protocols). Isolated, acute, ASC appropriate cases in healthier [American Society of Anesthesiology (ASA) class 1 and 2] patients were directed these facilities to reduce hospital utilization.

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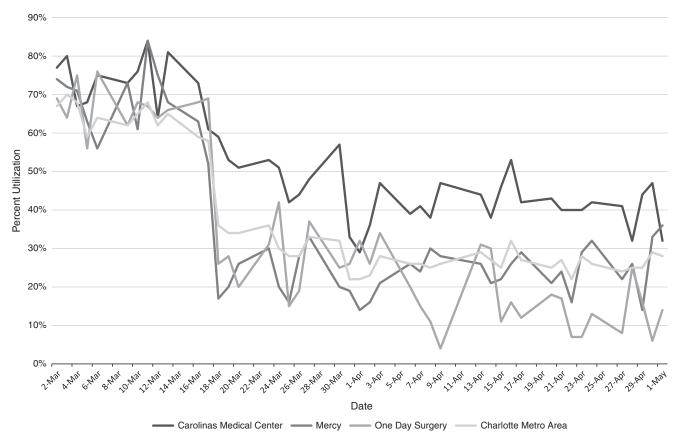


FIGURE 1. Operating room utilization percentage by date beginning March 2. The rapid decrease in utilization on March 17, corresponding with the cessation of elective cases. Carolinas Medical Center, the trauma center, maintained a higher utilization rate than 2 of the facilities that provide primarily elective care, Mercy Hospital, and One Day Surgery (outpatient procedures only).

Our system enacted measures to screen all patients and teammates and segregate COVID patient treatment areas to offer the safest access to patients undergoing procedures. Despite providing a CMS compliant "non-COVID care" environment, the health care system acknowledges that resuming surgical procedures places patients at a greater than baseline risk of contracting COVID-19 through exposure. Given this increased risk, our institution determined that an additional "enhanced" informed consent process be deployed. This consent serves to educate the patient that even with appropriate screening, testing, and precautions, the risk is still increased. Two methods for disseminating and documenting this information were developed including both a dictated segment to include in the preoperative note as well as written, signed consent (Fig. 2; see Fig., Supplemental Digital Content 1, http://links.lww.com/MLR/C162, Consent preoperative note). The additional consent process has been approved by our internal Office of General Counsel for reasonable use in our states of operation.

Resources Available During COVID-19

The availability of resources—including, but not limited to, OR space, beds, ICU space, ventilators, PPE, antigen testing, anesthesia staff—must be quantified so that needs for the re-entry of elective cases can be balanced against the

expected needs of the COVID patient load. While the majority of guidelines mention the importance of adequate assessment of these resources, no suggestion has been brought forth to steer decision making or coordinate these factors. ^{13,18}

Our Chief Surgical Officer (J.S.K.) identified 8 critical decision factors that served as the pillars for how to create a balanced surgical re-entry strategy (Tables 1, 2). The decision factors included patients, surgeons, anesthesia, staffing, ORs, equipment/technology, bed capacity, and infrastructure. These factors are each uniquely important but the interplay between them is also critical. Assessing increasing OR availability and the hours needed to make up cases requires examination of multiple areas (infrastructure, bed capacity, staffing). Taking these factors into account, a management template was developed under the leadership of the Surge and Re-entry Team. The template was designed and formatted to be flexible enough to allow the development of a plan for each surgical service line at each facility balancing the factors listed above.

Expansion of previously underutilized resources in terms of telehealth solutions also played an important role in the re-entry process. Where possible, surgical services shifted away from traditional in-person visits with increases in new patient consultations and initial postoperative visits being conducted in a virtual format when appropriate. The majority of these decisions were left to individual surgeons and their

Supplemental (Extra) Consent for Procedure or Operation (Covid-19, also known as Coronavirus)

By signing this form, you give your consent (agree to) to this procedure or operation (surgery) even though there is a risk of COVID-19 exposure. Please read carefully before signing.

Patient Name: _		
Doctor Who Will	Perform Procedure/Operation:	

My doctor has explained to me and I understand:

- the likely benefits (what I will gain) I could have by having this surgery
- major risks and problems I could have related to this surgery
- the extra risks there are by getting medical treatment due to the current COVID-19 pandemic.
- the hospital, its providers and staff are working hard to prevent and reduce the spread of COVID-19. This includes new steps and measures to help lower my chance of exposure to COVID-19.

I understand there are always steps taken to lower the risk of disease spread in the surgical setting. Extra steps will be taken to prevent the spread of COVID-19. A few of these steps include:

- o use of special masks
- o physical distancing when possible
- o extra cleaning and sterilization (removing germs) processes
- o carefully check all medical staff to lower the risk of infection.

My doctor explained to me:

- even with all of the extra steps taken to lower the risk of COVID-19, I could still be exposed to COVID-19.
- this disease is easily spread from close person-to-person contact.
- they can't guarantee that these steps will prevent the spread of disease.

I have asked my doctor questions about the extra risks from infection. I feel that my questions were answered. I have enough information to make an informed decision about whether to have the surgery even with the risk of COVID-19 infection. Based on the talks with my doctor and others, and the information I have received, I choose to have this surgery. I accept the risks and benefits related to this surgery.

Patient/Representative Signature:				
Name and relationship of Representative, if any:				
Date Signed:	Time Signed:			
Doctor's Signature:				
Date signed:	Time Signed:			

FIGURE 2. Supplemental consent for inclusion with preoperative note developed by the authors' institution for patients undergoing surgery during the COVID-19 pandemic.

comfort with shifting to virtual visits, though the details of telehealth implementation are outside of the scope of this paper.

Objective Evaluation of Surgical Case Priority

Clinical tiering is critical for prioritizing cases as elective surgery is resumed. The ACS has put forth guidelines for the stratification of patients and procedures based on the level of risk to the patient. For electively timed, less acute surgery, it is important to balance both need and benefit. In this context, "need" is defined as a patient who stands to have the

most significant long-term quality of life impairment from not undergoing elective surgery, and "benefit" as the patient who stands to have the most significant long-term quality of life improvement or survival benefit from undergoing surgery.¹⁸

To assist in determining case priority and appropriate location for an elective procedure, the ACS has provided 2 tools. The *Elective Surgery Acuity Scale (ESAS)*, developed by Sameer Siddiqui, ¹⁹ incorporates case acuity and patient health and recommends the appropriate location for the particular procedure. The *Medically Necessary, Time-Sensitive Procedures Score (MeNTS)*, developed by Prachand et al, ²⁰ is an additional tool

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TABLE 1. List of Critical Decision Factors With Challenges and Proposals

Critical Decision Factor	Questions/Challenges	Action/Proposed Solution
Patients	Prioritize backlogged vs. new?	Prioritize healthy, outpatient
	Plan for preoperative testing/screening?	Screen and test all patients before surgery
	Comorbidities and risk?	Limit patients requiring ICU, transfusion, known need for SNF/
	Require ICU postoperative?	rehab postoperatively
	Blood requirements?	Surgeons proactive scheduling
	•	ESAS and MeNTS scores
Surgeons	Distribution of OR time with the amount of backlog?	Balance OR time by previous block time and case volume
	Quantity and quality by location?	Encourage appropriate case location (outpatient cases in
	Availability for evening and weekends if able to expand	outpatient/ASC settings)
	OR utilization?	Ascertain the availability of extending hours
	Plan for testing/screening?	Continue routine screening—test symptomatic
Anesthesia	MDs and CRNAs available?	Await end to redeployment
	Redeployment?	Increase anesthesia coverage proportional to ORs running and
	Coverage of increased case numbers?	increased hours
	Preoperative screening clinic?	Continue routine screening—test symptomatic
	Plan for testing/screening? (high risk)	
Staffing	Availability of RNs, scrub techs, OR assistants?	Strategic hiring new positions
	Effect of redeployment on staffing?	Await end to redeployment
	Flexibility to increase hours and staff appropriately?	Communication with the administration for increased OR
	Plan for testing/screening?	utilization
		Continue routine screening—test symptomatic
Operating rooms	Inpatient—strategic ramp up?	Active communication with administration regarding numbers
	ASC/HOPD—exposure to COVID?	Non-COVID care facilities
	COVID safe facilities?	
Equipment—capital/	Appropriate use of virtual technology?	Utilize virtual visit for preoperative screening
technology	Scheduling platform for patients/surgeons?	Increase access to online scheduling platform
	Adequate PPE for surgeons, anesthesia, staff?	Central evaluation of OR assets
		Confirm adequate supply of PPE
Bed capacity	Hospital bed utilization?	Ensure stable bed utilization
	ICU bed limit?	Limit elective cases with known or suspected need for ICU postoperatively
Infrastructure	Sterile processing capacity for OR flow?	Confirm ability to accommodate increased case numbers and
	Supply chain disruption for implants/supplies?	turnover
		Confirm maintained supply chain and adjust for disruptions

ASC indicates ambulatory surgery center; COVID, coronavirus disease; CRNA, certified registered nurse anesthetist; ESAS, Elective Surgery Acuity Scale; HOPD, hospital outpatient department; ICU, intensive care unit; MD, medical doctor; MeNTS, Medically Necessary, Time-Sensitive Procedures Score; OR, operating room; PPE, personal protective equipment; RN, registered nurse; SNF, skilled nursing facility.

TABLE 2. Tiering System Developed by the Authors' Institution to Resume Nonemergent Surgical Cases

Tier 1

ASA 1—no comorbidities

ASA 2—BMI <40, well-controlled HTN, DM, mild lung disease < 70 y old

Scheduled procedure length <120 min

Outpatient <24 h stay

Tier 2

ASA 1-no comorbidities

ASA 2-BMI <40, well-controlled HTN, DM, mild lung disease

< 70 y old

Scheduled procedure length <180 min

Inpatient, short LOS 1-2 d

Tier 3

ASA 3-1 or more moderate to severe diseases

ASA 1 or 2 and > 70 y old

Scheduled procedure > 180 min

Inpatient stay > 2 d

High-risk comorbidities, ASA 4 or higher

Inpatient stay > 4 d, assumed ICU admission postoperative

ASA indicates American Society of Anesthesiology Score; BMI, body mass index; DM, diabetes mellitus; HTN, hypertension; ICU, intensive care unit; LOS, length of stay.

that incorporates procedure factors (such as OR time), patient factors (such as age), and disease factors (such as patient outcomes after delays) to create a numeric score from 21 to 105 to risk stratify elective procedures. Both are useful tools that apply objectivity to case prioritization, but, given the relative paucity of literature on perioperative outcomes in the era of the COVID-19 pandemic, these tools have yet to be validated.

As an independent prioritization factor, postponed elective cases may take priority over new elective cases of the same acuity within the same specialty. To objectively address surgical case backlog and to accommodate new cases, governing bodies recommended compiling a list of all deferred cases and calculate the required resources and staff for each.7,13 Limiting individual block-time assignments, extending hours of elective operations, increasing elective OR time on the weekends, outfitting ORs with new equipment to expand the capacity for specific procedures, and grouping like cases together to increase efficiency are measures that have been proposed to accommodate the deferred cases. 13 Systemwide strategic planning is essential as the health care system must consider the risk of overextending perioperative services on elective cases with the ability to redirect resources in the event of a delayed, second surge.9

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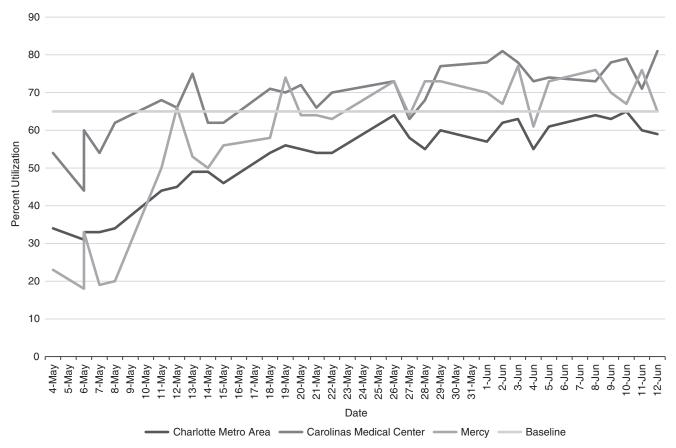


FIGURE 3. Operating room utilization rate beginning May 4, corresponding with the resumption of elective cases. Gradual return to baseline rates over the first 6 weeks of case resumption.

Ultimately, at the authors' institution, the goal for the safe resumption of medically necessary, elective cases and return to pre-COVID-19 surgical volume is to initially target the healthiest patients with the highest need and potential benefit from their procedure. A tiering system was developed in conjunction with surgical subspecialties for application across the health care system to assist surgeons and surgical teams with case prioritization (Table 2). Surgeons and surgical service line leaders were responsible for managing their own case backlog and prioritizing cases in a manner that adhered to the tiering requirements. Identification of healthy (ASA 1 and 2) patients with procedures <120 minutes, and anticipated length of stay <24 hours are being prioritized. Subsequent addition of case volume occurred as a gradual rollout achieving Tier 3 cases in the fifth week of elective case resumption. The gradual rollout allowed facilities to adjust to the screening, testing, and OR requirements of patients with increasing complexity and resource demands.

Balance and Redistribution of Cases

The decision to resume elective surgical cases and return to pre-COVID surgical volume represented a coordinated effort across multiple hospitals, ASCs, and surgical subspecialties. Delivering uncompromised patient care in the safest way possible while not placing the system at risk in the event of a second surge were the highest priorities. In terms of

redistributing cases, healthy patients with case-level acuity acceptable for ASCs were preferentially directed to these settings, reserving hospital outpatient and inpatient settings for patients that required a higher level of care.

Taking the above strategies and guidelines into account, the health care system made the decision to initiate outpatient cases in the ASC and hospital outpatient department settings a week before resuming elective inpatient cases. Outpatient surgeries were resumed on May 4 with the resumption of cases in the inpatient setting beginning May 11. The goal was for a gradual return to 100% or preutilization volume by 6 weeks after case resumption. Within one month, the majority of facilities in the area met this goal and the average utilization across the metropolitan area rose to within a few percentage points of pre-COVID levels (Fig. 3). A further increase to 120% of pre-COVID utilization was achieved by increasing elective OR availability on weekends and extending weekday hours until the backlog of the case was addressed. This occurred over the subsequent 6 weeks and beyond as community COVID-19 cases allowed. This gradual return allowed for a realtime assessment of workflow issues and challenges that arise as elective caseload returns to pre-COVID-19 levels.

SCREENING AND TESTING FOR COVID-19

An additional area of uncertainty across all treatment settings surrounds appropriate measures for screening and

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testing for COVID-19. Screening practices have been essential for limiting the spread and avoiding potential exposures. While the diagnosis of COVID-19 is largely clinical, confirmation cannot be made without laboratory testing and the true incidence of asymptomatic carriage remains a question. Testing recommendations from the Centers for Disease Control and Prevention (CDC) change frequently and as communities push past the surge of cases and testing becomes more available it is likely that the recommendations will continue to evolve.²¹ Questions surrounding testing for asymptomatic health care workers in the perioperative setting as well as preoperative patients remain largely unanswered.

Testing with reverse transcription polymerase chain reaction (RT-PCR) has been well described and limitations related to high false-negative rates and poor swab collection are documented.^{22–26} Serologic tests are being developed, however, these also have known limitations (potential cross-reactivity with other virus strains, time delay for the immune system to make antibodies, questionable duration of immunity) and are currently not recommended for testing for acute infection in isolation. Further review of testing methods is beyond the scope of this paper.

Given there is not likely to be the highly sensitive and specific mass testing ability for several months, as elective surgical cases are resumed, decisions must be made regarding appropriate testing for patients with current methods. RT-PCR testing provides the highest ability to detect subclinical or acute infection through active identification of the virus. While there is a clinically relevant false-negative rate, this is currently the most reliable way to screen patients preoperatively. Despite lower sensitivity, the negative predictive value of a negative RT-PCR in an asymptomatic individual without risk factors for COVID-19 exposure 2 weeks before surgery remains significantly higher.

In conjunction with serial screening for the presence of COVID-19 symptoms and potential exposure, the health care system has implemented a plan to test all elective surgical patients undergoing aerosolizing procedures preoperatively using RT-PCR. Patients are required to present for testing within 96 hours of surgery. Following the administration of the test, patients are asked to self-isolate as best as possible until their procedure. If all aspects of preoperative screening and testing are negative, the patient is contacted to proceed with surgery as planned. Should a patient screen or test positive, surgery is be postponed. The patient is then be referred through appropriate channels for follow-up in the virtual hospital that has been established to manage and oversee all COVID-19-positive patients tested within the health care system. In addition, if the patient presents to the preoperative area and fails a screening, despite a negative test 48 hours prior, surgery will likewise be postponed. As of June 1, 4683 patients had undergone testing for preprocedural purposes alone. Sixty-nine of these asymptomatic patients tested positive, for a rate of 1.5%.

There is no plan for testing of asymptomatic health care workers outside of unprotected exposure at this time. Utilization of current screening questions to assess symptoms and temperature monitoring before entry to hospitals and surgery centers will be continued. health care workers that are symptomatic, or

otherwise fail screening, will be sent home and undergo RT-PCR testing. As testing reliability and availability improves, however, this recommendation may evolve. In addition, the health care system has continued its plan for utilization for of the most effective PPE for health care workers for their protection and to maintain a safe "non-COVID care" environment.

DISCUSSION

The emerging COVID-19 pandemic presented challenges for health care facilities and surgical practices to rapidly reduce their surgical volumes with innumerable unexpected and unplanned cancellations of all but emergent and urgent surgery. For those who experienced the most abrupt shutdowns, the COVID-19 pandemic also fundamentally disrupted perioperative operations, staff, and resources, including an impact on urgent and emergent surgery. The challenge facing those who are preparing a surgical re-entry plan is the reestablishment of fundamental perioperative operations, with the critical mass of staff and resources being objectively determined to move forward with this plan. The logistics can be complex, particularly at larger institutions and for organizations navigating the needs of multiple service lines, in multiple locations. The process and template described herein, in combination with a decisive leadership team, were extremely useful to develop both strategy and implementation tactics to facilitate surgical re-entry at the authors' institution. The same process is designed to serve equally well in the case of any COVID-19 rebound or resurgence.

CONCLUSIONS

The development of a surgical re-entry strategy is complex and challenging, with many factors to consider before resuming elective surgical cases. First and foremost is making the decision to return based upon the availability of local resources, medical personnel, adequate testing supplies, and PPE to ensure safe patient care. As we return to elective surgery, it is important that we do so at an appropriate pace, on the appropriate patient, in the appropriate location, and with appropriate resources. We must also be prepared to reverse direction in an expedient manner should community or hospital incidence of COVID-19 cases increase sharply. These decisions should not be made in a vacuum, but rather in conjunction with local and regional government and health care institutions in a balanced and collaborative fashion so as not to jeopardize the health of the community as a whole.

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