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Ramping up Delivery of Cardiac Surgery During the COVID-19 Pandemic: A Guidance Statement from The Society of Thoracic Surgeons COVID-19 Task Force

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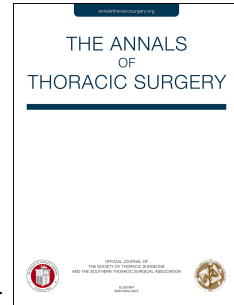


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Journal Pre-proof

Ramping up Delivery of Cardiac Surgery During the COVID-19 Pandemic: A Guidance Statement from The Society of Thoracic Surgeons COVID-19 Task Force

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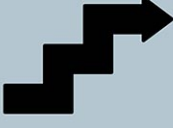
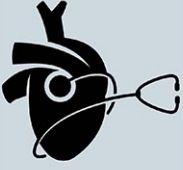
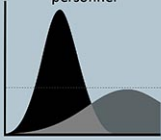
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CPR - Resuscitating Delivery of Cardiac Surgery During the COVID-19 Pandemic

<p>Collaborate to ramp up case volumes in a deliberate and graded manner</p> 	<p>Prioritize patients awaiting cardiac surgery</p> 	<p>Re-evaluate local conditions to minimize disease spread, ensure patient safety, and protect health care personnel</p> 
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Journal Pre-proof

**Ramping up Delivery of Cardiac Surgery During the COVID-19 Pandemic: A Guidance Statement
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The STS supports this document.

Abstract

The COVID-19 pandemic has had a profound global impact. Its rapid transmissibility has transformed healthcare delivery and forced countries to adopt strict measures to contain its spread. The vast majority of U.S. cardiac surgical programs have deferred all but truly emergent/urgent operative procedures in an effort to reduce the burden on the healthcare system and to mobilize resources to combat the pandemic surge. While the number of COVID-19 cases continues to increase worldwide, the incidence of new cases has begun to decline in many North American cities. This “flattening of the curve” has prompted interest in re-opening the economy, relaxing public health restrictions, and resuming non-urgent health care delivery.

The following document provides a template whereby adult cardiac surgical programs may begin to ramp up the care delivery in a deliberate and graded fashion as the COVID-19 pandemic burden begins to ease.

“Resuscitating” the timely delivery of care is guided by three principles (Figure 1):

1. **Collaborate** to permit increased case volumes, balancing the clinical needs of patients awaiting surgery against the local resources available within each healthcare system.
2. **Prioritize** patients awaiting elective surgery while proactively engaging all stakeholders, focusing on those with high-risk anatomy, changing/symptomatic clinical status, and, once these variables have been addressed, prioritizing by wait times.
3. **Re-evaluate** local conditions continuously, to assess for any increase in admissions due to a recrudescence of cases, to assure adequate resources to care for patients, and to monitor in-hospital infectious transmissions to both patients and health care workers.

Keywords: COVID-19, ramp up, infection control, healthcare worker safety, testing, quality improvement, patient safety

Word count: 3478

List of Abbreviations

AS - aortic stenosis

CABG - coronary artery bypass grafting

CAD - coronary artery disease

COVID-19 - coronavirus disease 2019

EF - ejection fraction

LAD - left anterior descending

LM - left main coronary artery

NAAT - Nucleic acid amplification testing

PPE - personal protective equipment

RT-PCR - real-time reverse transcription polymerase chain reaction

RVU - relative value units

TAVR – transcatheter aortic valve replacement

The Society of Thoracic Surgeons COVID-19 Task Force and the Workforce for Adult Cardiac and Vascular Surgery recently published guidance documents related to the practice of cardiac surgery during the acceleration phase of the COVID-19 pandemic.^{1,2} These documents were aimed at providing cardiac surgeons with guidance regarding patient triage, leadership, and infection risk reduction during the pandemic surge. In many locations, however, the incidence of new cases of COVID-19 are plateauing or declining after demonstrated flattening of the epidemiologic curve. Consideration must now be made how best to safely modify public health restrictions and resume non-urgent/emergent healthcare delivery, specifically elective cardiac surgery.

During the early phases of the pandemic, significant efforts were made to prioritize and defer non-urgent cases to preserve mechanical ventilators and other critical care resources, personal protective equipment (PPE), blood products, hospital beds, and maintain sufficient healthcare personnel in preparation for the pandemic surge. In addition, the CDC recommended³ delaying elective inpatient and outpatient surgeries and procedures. This recommendation was intended to protect healthcare workers and uninfected, vulnerable patients (i.e. older with cardiovascular disease) by limiting their exposure to those with known COVID-19 and asymptomatic, undiagnosed carriers of the virus. However, there is growing concern about the increased risk of further delaying cardiac surgical procedures with established survival benefits. Programs need to start planning for the resumption of care for patients awaiting postponed elective surgery.

However, any decision to “ramp up” surgical case volume will require thoughtful and appropriate caution, with frequent re-evaluation as we navigate through the uncertainties of this global pandemic. There will be a need to make collaborative decisions with precise local and regional situational awareness of disease burden, carefully balancing the risks and benefits of increasing surgical case volume. Furthermore, we must maintain flexibility to readjust our escalation strategy in response to evolving conditions and rapidly changing diagnostic and therapeutic COVID-19 processes. There is the possibility of secondary surges as

populations re-emerge from lockdown, and the potential for increased COVID-19 infections in combination with other seasonal respiratory pathogens such as influenza virus.

Based on the expert opinions of cardiac surgical and critical care leaders, these guidance statements provide a template whereby cardiac surgical programs may consider safely increasing case volume in a deliberate and graded fashion as the COVID-19 local disease burden begins to ease.

1. Working with public health officials, local COVID-19 prevalence in the community must be under control. Communities should either have a low COVID-19 burden that can be physically isolated within the hospital or a consistent decrease in COVID-19 incidence creating the resource capacity to perform elective surgery.⁴ If COVID-19 incidence resurges locally, plans should be in place for re-entering the surge mitigation (i.e. surgical triage) phase.
2. Many patients are reluctant to enter hospitals for fear of exposure to COVID-19.⁵ Patients should feel comfortable that they can safely undergo cardiac surgical procedures without significant risk of exposure to COVID-19 within the hospital environment. This includes enhanced attention to equipment, meals, medication administration, PPE, and interactions with other patients, visitors, and hospital personnel. Hospitals should adjust policies, protocols and procedures to limit patient movement and exposure to potential COVID-19 fomites and personnel.⁶ All attempts should be made to avoid excessive imaging, bloodwork, procedures, and in-hospital transport to limit these exposures.⁷ Recommendations surrounding the need for repeat laboratory testing, imaging, and physical examinations should be reassessed. Video conferencing should be utilized for preoperative family meetings and postoperative visits, where available. In addition, hospitals' newly formed COVID-19 infection control processes and procedures should be discussed with patients at the time of surgical consent. This necessitates shared decision-making surrounding the risk of surgery during a pandemic, versus the risk of further deferring treatment of their

cardiovascular pathology. The surgical team should describe the special precautions being undertaken and disclose the uncertain risk of nosocomial COVID-19 infection. Patients should be advised of limited hospital visitor policies and the potential for unexpected case cancellations. Cardiac surgical patients should be limited to designated COVID-secure units (free from known COVID-19 patients), whenever possible.

New signage and messaging should be utilized to educate healthcare workers and patients. Offices, clinics, hospital public areas, and waiting rooms should practice physical distancing (e.g., six feet spacing of chairs). Hospital visitation rules need to be carefully considered so as to limit potential exposures. Finally, deliberate attempts should be made to preoperatively assess each patient's potential need for a post-acute care upon discharge, given the high incidence of known COVID-19 outbreaks in those facilities.⁸ Expectations for discharge should be reviewed preoperatively as longer hospital stays after heart surgery potentially place patients at additional risk. As such, patients should plan to be safely discharged to their homes as soon as possible following uncomplicated surgery.⁹

3. Healthcare providers should be aware that their safety also remains a priority. Cardiac surgical programs should follow precautions and guidelines that have been put in place by their respective institutions, adhering to the recommendations of local, regional and national public health authorities to manage and contain COVID-19 transmission.¹⁰ The risk of nosocomial infection may be significantly reduced by vigilant attention to frequent hand hygiene, environmental cleaning, appropriate use of PPE, the creation of COVID-secure units, social distancing in the hospital, and self-isolation of COVID-19 positive healthcare workers. It is imperative that healthcare workers continue to follow institutional policies about reporting symptoms, undergoing testing, and implementing self-quarantine when appropriate. They must abstain from work if they become sick, no matter how mild their symptoms. Contingency planning for staffing

must be in place for healthcare workers who require self-isolation. This is particularly relevant for the small and highly specialized cardiac teams. In addition, support and treatment services should be available for providers who experience mental health concerns or physical and/or emotional exhaustion as a result of professional or personal experiences during the pandemic.^{11,12} Finally, it is likely that there will be evolution and institutional variation in COVID-19 nasopharyngeal and serologic screening for asymptomatic healthcare workers. Healthcare leaders must be aware of this dynamic process.

4. Hospitals should develop and implement comprehensive screening procedures to identify patients at increased risk for COVID-19 as cardiac surgical programs begin to ramp up. These include the following:
 - a. Standardized clinical screening telephone questionnaires within 48 hours prior to hospital admission, focusing on the clinical history of patients and their cohabitants (including viral-like symptoms, anosmia, and ageusia, all of which are frequently associated with COVID-19).
 - b. Unless recent outpatient testing suggests the patient is infection free, if possible, the initial admission should be to a single room within the hospital where rapid same-day preoperative additional screening and/or testing may be performed as needed.
 - c. Once admitted to the ward, each patient must be clinically screened for the signs and symptoms of viral illness with COVID-19 testing administered as needed.

5. Nucleic acid amplification testing (NAAT) for COVID-19 (e.g., by polymerase chain reaction (PCR)) should be strongly considered for patients in areas of high disease burden, those who have recently been exposed to infected individuals, and those who exhibit even mild symptoms. If there has been a recent exposure, a 2-week quarantine is recommended. Finally, when possible, all preoperative patients should be tested prior to admission. Unfortunately, there is no test

currently available that can reliably rule out COVID-19. Despite this, tests using nasopharyngeal (NP) swabs for COVID-19 NAAT, including rapid PCR tests, are being increasingly performed across the country, often with the ability to return results within minutes or hours. In light of this, we propose the following guidance regarding COVID-19 test interpretation in the ramp up phase based on the best available evidence at this time.

- a. Nasopharyngeal swab NAAT (or its equivalent) for COVID-19 should be considered prior to all elective surgery. The timing of sampling should be as close to surgery as possible (preferably within 24-48 hours), allowing sufficient time for results to return prior to surgery.
- b. When NAAT testing is positive, these results can be very helpful as delaying surgery should strongly be considered.
- c. When NAAT testing is negative, results must be interpreted with caution as false negative rates in asymptomatic patients can be as high as 30% - 50%.^{13,14} Clinical sensitivity can be reduced due to poor quality specimen collection¹⁵ or specimen collection early in the disease process (higher false negative rates have been noted in the asymptomatic or pre-clinical period).¹³ For patients in areas of high COVID-19 disease activity who require urgent or emergent surgery, if the NAAT testing and initial symptom screen are negative, consider repeat NAAT testing by NP swabs separated > 24 hours apart and consulting with local infection control practitioners.
- d. Elective surgical patients with negative NAAT testing in whom the clinical suspicion of COVID-19 infection remains high should self-quarantine for 2 week period of observation. Prior to surgery, patients should be rescreened for symptoms and exposures and retested in conjunction with local infectious disease consultation.
- e. If postoperatively patients develop a suspicious clinical syndrome concerning for COVID-19, additional investigative tools may include repeat nasopharyngeal specimen collection, endotracheal aspirates for NAAT testing, and/or CT scan imaging.¹⁶

- f. Clearly, as improved testing methods become available, they should be utilized, all the while recognizing that elective surgery is just that, and a 2-week quarantine with retesting may be the safest approach for any patient, regardless of pretest probabilities.
6. Non-urgent patients waiting for prolonged periods prior to surgery are at risk for clinical deterioration or adverse events. Cardiac surgery programs should proactively reassess each patient on their waitlist while pursuing a graded increase in elective case volume. Aspects of this management may include, but are not limited to, the following:
 - a. All waitlist patients should be contacted via telephone or videoconference for reassessment at least every 2 to 4 weeks to assess their clinical status and should be instructed to call if their symptoms were to worsen.
 - b. Hospitals should have a clear plan in place to formally escalate the care of patients with deteriorating symptoms or unstable clinical characteristics, particularly in the face of high-risk anatomy.
 - c. Peer review among the interdisciplinary heart team is highly encouraged for complex patients.
 - d. Continued re-evaluation of local pandemic conditions should occur regularly as part of the cardiac surgical ramp up strategy. Programs should be prepared to immediately stop ramping up or to even de-escalate cardiac surgical volumes should there be a resurgence in the number of local COVID-19 cases, admissions, and deaths.
 7. A phased approach is recommended to resuming elective surgery based upon each hospital's re-expansion capacity (Figure 1). We have defined an increase in hospital capacity as the percentage of resources previously allocated to the COVID-19 pandemic that have now been reallocated to the management of non COVID-19 patients. Phase 1 reflects up to a 25% increase in capacity, Phase 2 a 25%-50% increase, and Phase 3 a 50%-100% increase, or a return to

normal institutional activity. Depending on which phase of re-expansion your institution is currently in, your cardiac surgical program should have a defined approach as to which elective cases will be given priority during the ramp up. The number of elective cases by which each program may ramp up depends upon the urgent case demands at the institution and the overall institutional capacity in the context of COVID-19 prevalence and the impact on the healthcare workforce.

8. Hospitals should create and operationalize sustainable plans to ensure that they continue to care for patients with COVID-19 infections while concurrently addressing all the other healthcare needs of their non-infected local populations. Increased surgical volume will consume PPE and other resources which should be modelled to ensure capacity. Policies regarding the use of PPE during surgery for patients deemed to be non-COVID should be established. Those institutions with a high incidence of persistent COVID-19 disease burden will likely need to designate separate COVID-care and COVID-secure units for the foreseeable future. We must continue to assume that we will have hospitalized symptomatic COVID-19 patients until we have a vaccine or sufficient herd immunity.
9. Efforts to escalate cardiac surgical volumes require regular communication between members of the cardiac surgical team, intensive care units, hospital administration, and public health officials. Ideally, a regional dashboard that provides real-time trending of resource utilization (e.g. hospital admissions, ICU admissions, ventilator use, PPE availability) should be created to facilitate communication and well-informed forecasting to allow for thoughtful decision making.
10. Real-time quality assurance teams should be focused on monitoring COVID-19 transmission within cardiac surgery units, postoperative complications in the pandemic time period related or unrelated to COVID, deficiencies in hospital workflow, or other related quality issues. Potential sources of concern may include non-cardiac specific personnel staffing our cases and/or the

cardiac intensive care unit, expedited workup or inadequate preoperative testing, “pandemic” level care that does not meet standard of care.

Summary

The COVID-19 pandemic has introduced unique challenges for cardiac surgical programs. Elective cases have been cancelled and urgent cases delayed in order to reallocate resources for patients with COVID-19. Waitlists have grown, and those being asked to postpone their surgery have been forced to experience necessary but prolonged delays. Patients who were once deemed surgical candidates have increasingly been referred for medical management or alternative percutaneous therapies, with potential adverse long-term impacts.

The effect of the COVID-19 pandemic on individual hospitals varies widely. It is important for institutions to continuously reassess their capabilities and potential limitations, while simultaneously surveying for potential subsequent waves of COVID-19. As new data emerges, these statements may change over time given the fluidity and scope of the current pandemic. Geographic differences in epidemiology and practice patterns across the country must be acknowledged and do not substitute for individualized expertise when operationalizing a deliberate and graded increase in cardiac surgical volume as the incidence of COVID-19 begins to ease.

Clearly, economic factors remain highly relevant in U.S. healthcare. Some surgeons are compensated on a model that correlates with production of relative value units (RVU). Non-military hospitals are also heavily reimbursed based upon procedural volume. The financial impact to medical centers has also been well described and are substantial with hospitals under major financial crises.¹⁷ Nevertheless, it is imperative that cardiac surgeons advocate in the best interest of their patients and function as good citizens for their institutions by supporting the principles stated in the STS Adult Cardiac Triage Guidance Document: ¹ 1) protect our patients 2) protect the healthcare team and 3) protect society.

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Figure Legend

Figure 1: Phased implementation approach to cardiac surgery ramp-up based on the increase in hospital capacity (AS: aortic stenosis; ASD: atrial septal defect; CABG: coronary artery bypass grafting; CAD: coronary artery disease; CHF: congestive heart failure; ECMO: extracorporeal membrane oxygenation; ELSO: Extracorporeal Life Support Organization; EF: ejection fraction; ICU: intensive care unit; LM: left main artery; LAD: left anterior descending artery; LOS: length of stay; MR: mitral regurgitation; PFO: patent foramen ovale; TAVR: trans-catheter aortic valve replacement; VAD: ventricular assist device). Reprinted with permission from Hassan A, Arora RC, Adams C, et al. Cardiac Surgery in Canada During the COVID-19 Pandemic: A Guidance Statement from the Canadian Society of Cardiac Surgeons. Can J Cardiol 2020.

RAMP UP PHASE 1



< 25%
Increase in capacity

- 1 Focus on in-patient urgent/emergent services with gradual introduction of appropriately prioritized out-of-hospital patients
 - 2 Careful consideration of patients who may require prolonged ICU and hospital length of stay
 - a. Avoid frail, older adult patients (Clinical Frailty Score > 4, Edmonton Frailty Score >6 or equivalent)
 - b. Avoid other vulnerable patients including those with renal insufficiency, depressed EF, advanced CHF
 - c. Avoid complex procedures, including re-operative surgery, that not only carry risk of prolonged ICU/ hospital length of stay but also may require excessive blood product transfusion
 - 3 Prioritize isolated CABG, isolated valve procedures and less complex procedures to maximize patient flow
 - a. Emphasis on patients with aortic stenosis (AS) and coronary artery disease (CAD) with prognostic benefit (e.g. critical aortic stenosis, left main disease, proximal LAD stenosis)
- Perform TAVR procedures in patients who are most symptomatic

RAMP UP PHASE 2



25%-50%
Increase in capacity

- 1 Maintain in-patient urgent/emergent services while broadening inclusion of appropriately prioritized out-of-hospital patients
- 2 Consider expanding essential procedures to include all types of interventions based on the ICU capacity at your institution
- 3 Continue to prioritize those patients with greatest survival benefit
 - a. Severe symptomatic valvular heart disease
 - b. CABG in patients left main (LM), proximal left anterior descending (LAD) or 3-vessel disease / depressed EF
 - c. Aortic aneurysm disease with high-risk features (>6.0 cm, rapid growth) and/or symptoms
 - d. Cardiac tumors with high-risk features for obstruction or embolism

RAMP UP PHASE 3



50%-100%
Increase in capacity

- 1 Maintain in-patient urgent/emergent services
- 2 Return to normal outpatient services while continuing to prioritize those at greatest risk on the wait list
- 3 Consider ongoing deferral of truly elective interventions
 - a. Asymptomatic severe MR
 - b. ASD and/or PFO surgery
 - c. Asymptomatic aneurysm with demonstrated stable size

ALL PHASES

- 1 Contact patients on the waitlist for surgery to prioritize their symptoms
- 2 Adopt a mechanism by which waitlisted patients who are having increased symptoms or who are not doing well can contact the program to receive additional screening
- 3 Utilize guidance regarding ventricular assist device (VAD), cardiac transplantation and mechanical circulatory support, including extracorporeal membrane oxygenation (ECMO) provided by the Extracorporeal Life Support Organization (ELSO)