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Management Principles for the Cardiac Catheterization Laboratory During the Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) Pandemic

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KEYWORDS

• Cardiac catheterization laboratory • Coronavirus • Pandemic • COVID-19 vaccination status
• COVID-19 positive status • PPE • Infection control • Quality control

KEY POINTS

- The severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) is a highly contagious pathogen. The resulting illness, 2019 coronavirus disease (COVID-19), has significant morbidity and mortality and has a direct impact on cardiac catheterization laboratory (CCL) operations. The CCL needs formal preparedness protocols for safe, effective, and timely operations. There is a dire need for consensus evidence-based guidance and guidelines from international heart associations.
- CCL teams are frontline workers, similar to the emergency room and critical care teams. They directly care for patients with cardiovascular emergencies, including but not limited to ST-segment elevation MI (STEMI), in suspected or confirmed infected patients.
- Infection control Principles center on 3 levels of hierarchical controls: (a) protection of the health care worker with personal protective equipment (PPE), (b) administrative (staff training, restriction of nonessential personnel with an optimized staffing matrix), and (c) environmental/engineering controls (social distancing, isolation of personnel from the infectious hazard).
- All CCL staff in direct contact with potentially infectious patients should be provided with N95 respirators, whole face shields or protective eyewear, disposable caps, shoe covers, sterile gowns, and surgical gloves. Powered air-purifying respirators (PAPRs) are an acceptable alternative for staff who cannot wear N95 respirators.
- CCL readiness and sustainable continuation of operations should be the goal during global pandemics to provide emergency care for at-risk cardiac patients who are the most vulnerable to poor outcomes. Delays in nonemergent procedures may be necessary during major pandemic surges but cannot be deferred indefinitely.

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- Primary percutaneous coronary intervention (PCI) remains the primary mode of revascularization for patients with STEMI regardless of infection status. A lytic-based strategy is the second-line mode of revascularization at non-PCI capable hospitals or when primary PCI cannot be performed in a timely or safe manner.
- CCL personnel should be vaccinated against SARS-CoV-2. Patients with cardiovascular disease are at an increased risk of severe disease and death from COVID-19 and should be strongly encouraged to be vaccinated, with consideration for booster doses 6 months following their second doses of an mRNA vaccine.
- Like other respiratory viruses (ie, influenza), COVID-19 is strongly associated with an increased risk of acute coronary syndromes and myocardial infarction. All patients presenting for emergency cardiac care should be screened for COVID-19 symptoms and considered for screening by polymerase chain reaction (PCR) testing. Patients presenting for nonurgent, elective procedures should undergo symptom screening before their procedures. During times of high community transmission and in coordination with hospital leadership, PCR testing should be performed within 72 hours of nonurgent, elective procedures; in patients with positive tests, procedures should be delayed at least 10 days when practical and safe. Procedures that cannot be safely delayed should proceed with appropriate infection prevention precautions.

INTRODUCTION

Sterile techniques in the cardiac catheterization laboratory (CCL) have evolved in recent decades, from the days of arterial cutdowns in the 1970s to the current practices of micropuncture percutaneous vessel entry.[1] Percutaneous valve therapy implantation in the hybrid operating room (OR)/CCL has reinforced the importance of strict sterile techniques and infection control protocols. With more than 1 million cardiac catheterization procedures performed annually in the United States,[2] measures in infection control should be standardized to protect both patients and hospital workers.

Recently, the emergent care of patients infected with highly contagious pathogens such as the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has come to the fore. The resulting 2019 coronavirus disease (COVID-19) pandemic initially posed logistical challenges to limiting the spread of aerosolized pathogens until protocols and procedures were implemented to limit infectivity to staff and patients. Ongoing challenges remain as the world faces multiple pandemic waves and novel viral variants. Additionally, the increased risk of acute coronary syndromes and cardiogenic shock require acute management in the CCL due to multiple mechanisms from COVID-19[3] At present, the available evidence-based guidelines do not specifically address CCL preparedness and management of patients in the setting of infectious disease pandemic.[1,4,5] In this review, we seek to specify best practices in the CCL for the management of infected patients in the preprocedure, intraprocedure, and postprocedure environments harmonizing available evidence, recommendations from international heart associations, and consensus opinion.[6–10]

EPIDEMIOLOGY

SARS-CoV-2 is the third highly pathogenic coronavirus to emerge since 2002, following SARS-CoV-2 and the Middle Eastern respiratory syndrome coronavirus (MERS-CoV). Despite genetic and structural similarities to the original SARS virus, SARS-CoV-2 has a lower case-fatality rate but is markedly more contagious, leading to its dramatic spread around the world and high numbers of total deaths, approaching 700,000 in the United States alone and more than 4.7 million deaths worldwide at the time of this writing.[11–13] Total case-fatality rates for COVID-19 are difficult to measure with accuracy given a large number of undiagnosed or minimally symptomatic cases but may be between 1% and 2%. Mortality among hospitalized patients in the US has generally decreased over time but ranges between 8% and 20%, with an increased risk of death noted during major surges when hospital resources are more taxed.[14,15]

The clinical syndromes produced by COVID-19 are well-known at this point. Most of the affected patients experience mild-to-moderate, self-limited respiratory infections.

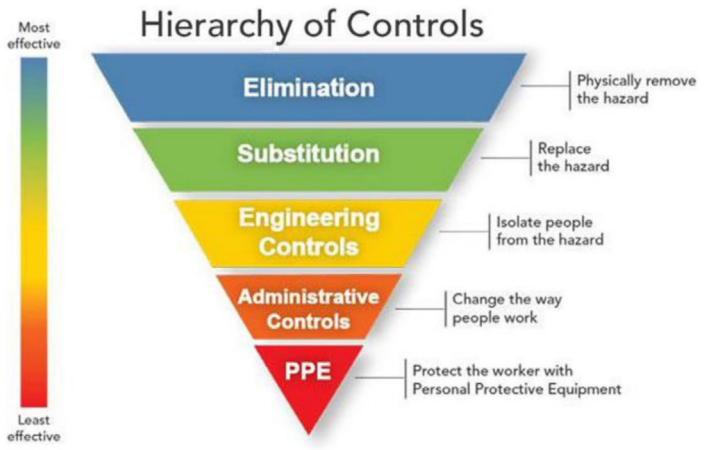


Fig. 1. Levels of infection control in the principles of CCL management.

Patients may be highly contagious and capable of transmitting the virus up to 2 days before symptom onset and for 10 to 21 days afterward, depending on immune status and disease severity.[16] Severe disease, defined as lower respiratory tract infection with oxygen saturation of less than 94% while breathing ambient air, is more common in older adults, those with obesity, or patients with impaired immunity. The most severely affected patients may progress to acute respiratory distress syndrome, shock, and multiorgan failure with an elevated hazard of death.[17] A number of therapies have been evaluated for the treatment of COVID-19, with current guidelines recommending supportive care and monoclonal antibodies for mild-to-moderate disease in high-risk individuals. Antiviral drugs (eg, remdesivir), antithrombotic therapy, glucocorticoids (principally dexamethasone), and immunomodulators such as tocilizumab and baricitinib all play a role in the pharmacologic management of severe disease, depending on illness severity and resource availability.[18]

In late 2020, following an extraordinary global research effort, effective vaccines against SARS-CoV-2 were made available. Multiple vaccine platforms have been studied. The current leading vaccines in the US and worldwide are based on either mRNA platforms, using viral mRNA segments that encode for the SARS-CoV-2 spike protein that are then taken up into the host cytosol, transcribed into their protein products, and then induce a host response and resulting protection; or viral vector platforms, most often a nonreplicating adenovirus that has been modified to encode for the same SARS-CoV-2 spike protein. Three vaccines are currently available in the US (mRNA-1273, Moderna; BNT162b2, BioNTech-Pfizer; JNJ-78436735, Janssen/Johnson & Johnson). The efficacy of these vaccines against any infection seems to wane over time, in no small part due to the emergence of the highly contagious Delta any Omicron variant, but they remain highly effective at preventing hospitalization and death.[19] In September 2021, the Food and Drug Administration authorized booster doses at 6 months after initial vaccination for high-risk persons, including those 65 years of age or greater, adults with significant medical comorbidities, and those at high risk of occupational exposure (including many health care workers). This was modified in October 2021 to state that boosters may be from any authorized vaccine, not necessarily the specific brand used in the initial vaccination.[20]

PRINCIPLES FOR CARDIAC CATHETERIZATION LABORATORY MANAGEMENT DURING A GLOBAL PANDEMIC

Infection control in the CCL is dependent on careful screening of patients, the availability and proper use of personal protective equipment (PPE), social distancing, administrative and engineering controls (Fig. 1).[10]

HEALTH CARE WORKER PERSONAL PROTECTIVE EQUIPMENT

Protective measures should be taken when treating patients infected with or suspected of infection with pandemic agents. All CCL staff should be provided with PPE, to include N95 respirators, full-face shields, eyewear, disposable fluid impermeable gowns, disposable head caps, surgical gloves, and shoe covers. Proper training for

Box 1
Samples steps for donning and doffing personal protective equipment for Cardiac Catheterization Laboratory staff

Donning

1. Tall disposable shoe covers
2. COVID-19 designated lead apron
3. Leaded glasses or prescription glasses
4. First head cover (cover ears)
5. N95 mask
6. Second head cover (cover ears)
7. Surgical mask
8. Eye protection: Goggles or face shield
9. Hand hygiene: Surgical scrub
10. Nonsterile gown
11. Sterile gloves 1
12. Sterile gown
13. Sterile gloves 2

Doffing

1. Hand hygiene (HH1)
2. Remove surgical gown by breaking neck/back straps and dispose sterile gloves
3. HH2 with alcohol foam in room
4. Remove eye protection
5. Remove surgical mask
6. Remove second head cover in room
7. Remove personal protective equipment gown and gloves
8. HH3 with alcohol foam in room
9. Remove shoe covers at doorway in room and step out of room
10. HH4 with alcohol-based disinfectant (ie, Sterillium)
11. Remove N95 mask
12. Remove first head cover
13. HH5 with surgical scrub
14. Remove COVID-19 lead
15. Change to clean scrubs

donning and doffing PPE should be carried out with periodic refresher training for CCL staff as outlined in **Box 1** and referenced in guidelines, published by the CDC (**Fig. 2**) as well as by the Infectious Diseases Society of America (IDSA).[9,21,22]

In the setting of a pandemic that may last over several years, stockpiles of PPE should be made available for every wave. When CCL teams perform aerosol-generating procedures (AGP) in patients with suspected or confirmed infections, Powered air-purifying respirators (PAPR) should be worn. Per CDC guidance, AGPs in the CCL include[23]:

1. Open suction of airway secretions
2. Cardiopulmonary resuscitation
3. Endotracheal intubation and extubation
4. Noninvasive positive pressure ventilation (BIPAP, CPAP)
5. Manual ventilation
6. High-flow oxygen delivery

Fig. 2. Sequence for putting on personal protective equipment (PPE).

HEALTH CARE WORKER VACCINATION STATUS

All HCWs should be vaccinated against SARS-CoV-2 to protect themselves, colleagues, and patients. Many health systems in the United States and elsewhere in the world have policies mandating vaccination against COVID-19 for all HCWs. Such mandates have successfully led to vaccine rates in excess of 90% in affected staff.

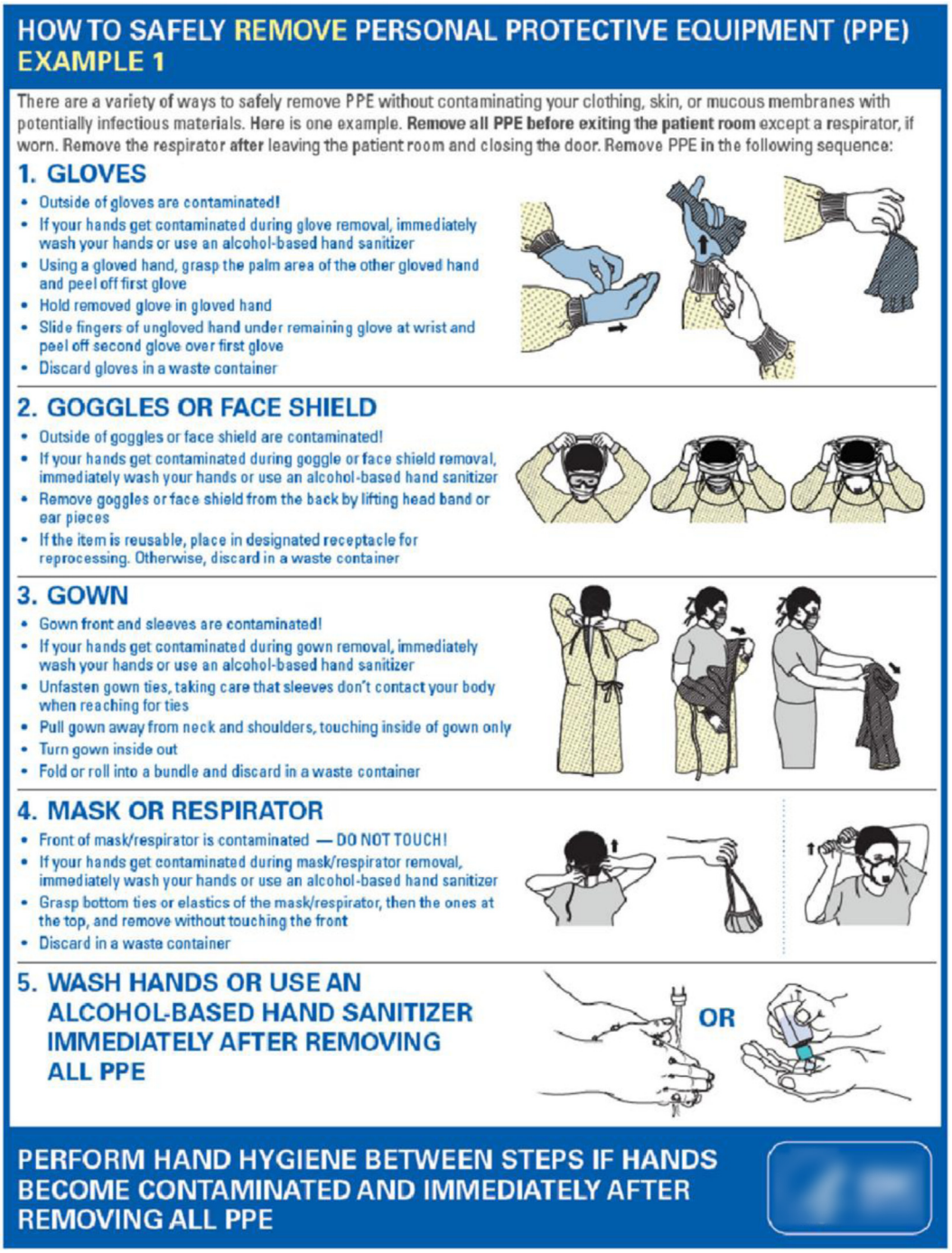
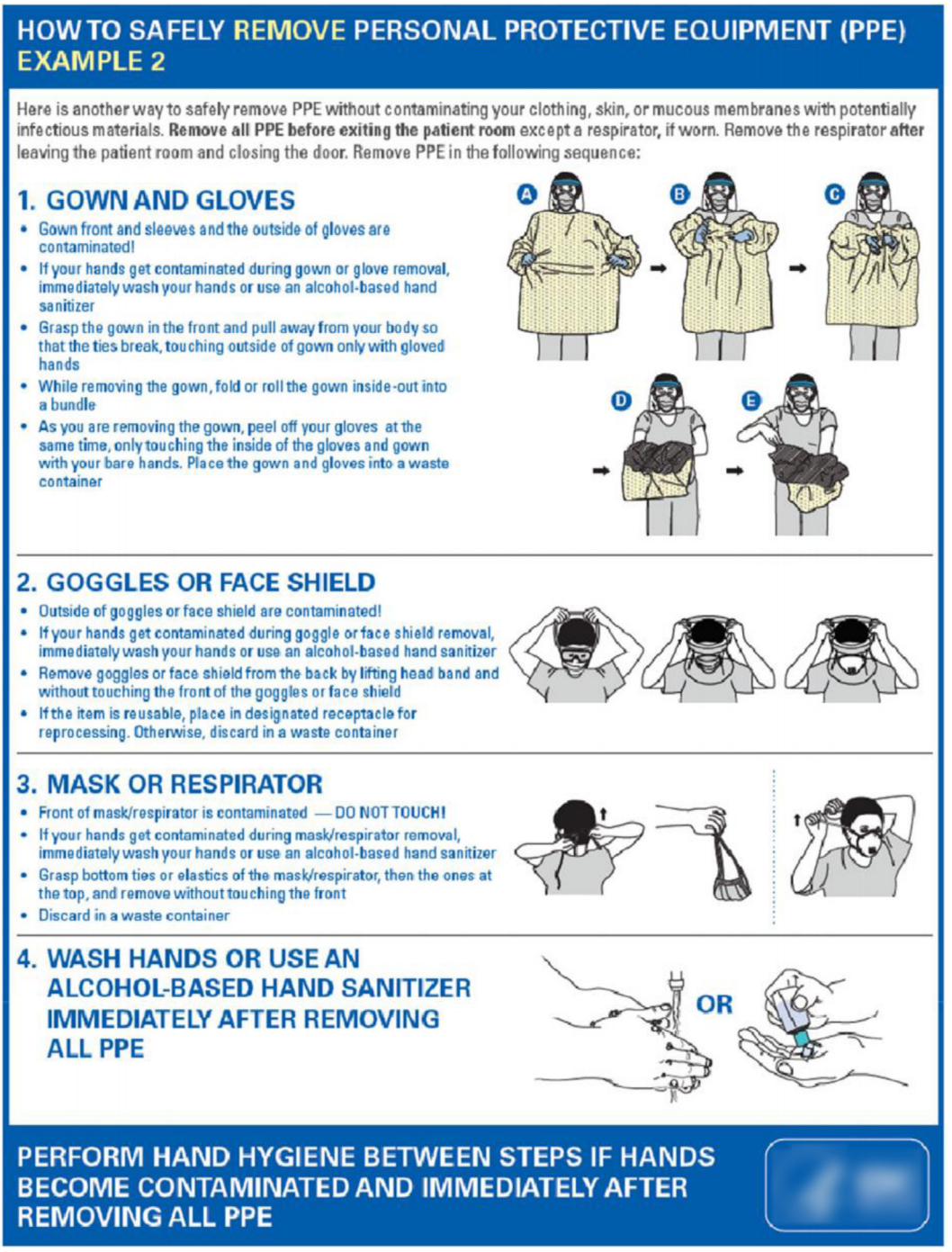


Fig. 2. (*continued*)

Despite early concerns regarding mass resignations, rates of staff dismissed due to vaccine noncompliance have been low, often less than 1% of HCWs.[24] Reasons for medical exemptions are rare and should be reviewed with the best available medical evidence, the risks of immunization weighed against the risk of morbidity and mortality to the staff member from



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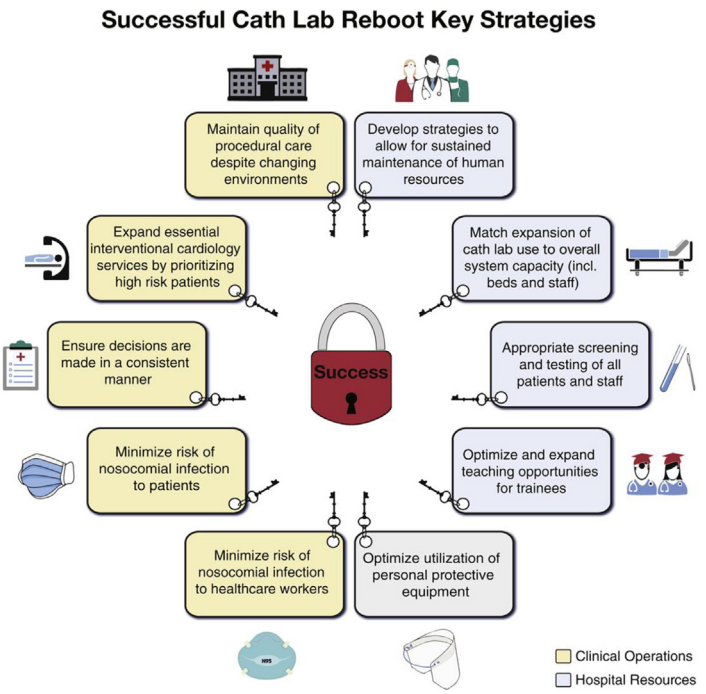

Fig. 3. Guiding principles for successful catheterization laboratory reboot.[30]

COVID-19, and the need to protect vulnerable patients from infection.

ENVIRONMENTAL/ENGINEERING CONTROLS

Hospital facilities departments and leadership should devise an overarching plan to limit aerosol transmission in procedural areas. Facilities should test the positive pressure ventilation systems of the CCL and verify OR conditions to ensure proper functioning air-handling units with adequate air exchange rate, room differential pressure, relative humidity, and air temperature. If possible, hospitals should isolate a single CCL or operating room for patients presumed or confirmed to be infected with COVID-19. Furthermore, modification of ventilation systems should be considered to eliminate the virus from the operating room environment in an expeditious manner. If available, negative pressure ventilation rooms can be designated as the "COVID-19 operating room," thereby providing the ideal protection to health care personnel in adjoining operating rooms or corridors. In some instances, departments have been able to convert existing CCLs into negative pressure rooms temporarily.[25] Most importantly, doors of the CCL should remain closed at all times during the procedure. Opening doors could result in loss of positive room pressure and cause viral burden in the air to be dispersed out of the CCL and cross-contaminate adjoining areas, corridors, or even the adjacent operating room.[26,27]

To preserve optimal clean airflow into the CCL or operating room, an OR should have an air exchange rate of greater than or equal to 20 times the room volume in an hour.[28] An air exchange rate lower than that will increase the viral burden in the environment due to stagnant airflow. There are standard calculations for air exchange depending on the pressurization of the operating room. In a positive pressure OR, the following calculation can be made[29]:

Air exchange per hour = Total supply air (m^3/min) x 60 divided by Room volume (m^3)

Once adequate air exchanges are confirmed, positive pressurization of the rooms should be confirmed compared with adjoining areas thereby creating the proper barrier between the OR doors to prevent dispersion of airborne viral particles.

ADMINISTRATIVE CONTROLS

Only CCL personnel and health care workers involved in the procedure for presumed or confirmed patients with COVID-19 should be permitted inside the CCL. As always, the CCL

Table 1
Classification of interventional procedures according to their indication during the Coronavirus disease 2019 pandemic

Category[a]	Coronary Angiography/PCI	Structural Intervention	Peripheral Anglography/PVI

I	• Class III/IV angina despite medical therapy
	• Recent hospitalization for angina/NSTEMI
	• High-risk stress
	  ○ Drop in BP with exercise (>10 mm Hg)
	  ○ Angina at low effort
	  ○ Sustained VT
	  ○ ST-segment elevation
	  ○ Drop in LVEF
	  ○ TID on imaging
	  ○ Large Ischemic burden
		• TAVR: severe AS or bioprosthetic failure with
		  ○ Class IV symptoms
		  ○ Recurrent or refractory heart failure requiring hospitalization
		  ○ Decline in LVEF
		  ○ Syncope
		• Percutaneous mitral valve repair/replacement
		  ○ Refractory to medical therapy while inpatient
		• Acute post-MI VSD
			• Critical limb ischemia with rest pain/nonhealing ulcer
			• Endovascular repair of symptomatic AAA or enlarging TAA
			• Nonfunctioning dialysis fistula
			• Acute iliofemoral DVT with concern for phlegmasia
			• Acute pulmonary embolism with corpulmonale

II	• Class II angina despite maximal medical therapy
	• Abnormal stress test result without high-risk feature
	• Pre-TAVR or cardiothoracic procedure
	• Pretransplantation evaluation (cardiac or other)
	• Pulmonary hypertension evaluation
		• Progressive or escalating symptoms (Class III/IV) or recent hospitalization for heart failure (<30 d>)
		  ○ TAVR
		  ○ Percutaneous mitral valve repair/replacement
		  ○ Percutaneous pulmonary valve repair/replacement
		  ○ Percutaneous tricuspid valve repair/replacement
		• Severe AS with mean gradient >60 mm Hg or peak velocity >5 m/s
		• Severe MR with recent decline in LVEF
			• Progressive or escalating claudication (limb or abdominal)
			• Endovascular repair of enlarging AAA or IAA
			• Symptomatic carotid stenosis
			• IVC filter placement for acute DVT

III	• CTO case
	• CardioMEMS implantation
		• Stable symptoms (Class II) or asymptomatic with an indication for intervention
		  ○ TAVR
		  ○ Mitral valve repair/replacement
		  ○ Pulmonary valve replacement
		• ASD/PFO closure
		• LAA occlusion
		• PDA closure
		• Chronic VSD closure
		• Alcohol septal ablation
			• All stable symptomatic PAD
			• Chronic venous disease
			• IVC filter removal

Abbreviations: AAA, abdominal aortic aneurysm; AS, aortic stenosis; ASD, atrial septal defect; BP, blood pressure; CTO, chronic total occlusion; DVT, deep vein thrombosis; IVC, inferior vena cava; LAA, left ductus appendage; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NSTEMI, non-ST segment elevation infarction; PCI, percutaneous coronary intervention; PDA, patent ductus arteriosus; PFO, patent foramen ovale; PVI, peripheral vascular intervention; TAA, thoracic aortic aneurysm; TABR, transcatheter aortic valve replacement; TID, transient ischemic dilatation; VSD, ventricular septal defect; VT, ventricular tachycardia.

[a] Category I (urgent procedure): patient at high risk for CV complications while waiting; Category II (semiurgent procedure): at moderate CV risk; category III (elective): at low CV risk.

door should remain closed at all times during the procedure. All necessary equipment should be stored within the CCL to avoid the opening of the CCL doors to procure supplies. All nonessential personnel such as vendors or visitors should be prohibited from entering the CCL during procedures for presumed or confirmed patients with COVID-19.

Table 2
Phased-in model for restarting interventional elective procedures during the COVID-19 pandemic

Phases	Cases	Dependencies	Tactics
Phase 1: urgent/ emergent procedures and those not affecting surge resources 25% usual capacity	1. Category I patients 2. Patients who have been waiting >4 wk	1. Nursing staff to open procedure room to accept elective outpatients 2. "Clean" waiting area 3. "Clean" area of overnight stay 4. Equipment removed to support other areas 5. Recover TAVR and high-risk patients in the procedure room 6. Availability of cardiac anesthesia and cardiac surgery 7. ICU bed availability	1. Return of 25% of catheterization laboratory nurse FTEs 2. Physicians review patient list to identify priority patients 3. No visitors 4. Greeter to escort through a separate entrance 5. Direct to room/social distancing 6. Open holding area or dedicated overnight stay area. 7. Anesthesia machines, procedure tables, and equipment carts reclaimed 8. Testing all outpatients prior to arrival 9. COVID-19 procedure room for patients 10. Careful patient selection to reduce the likelihood of needing ICU bed 11. Cluster procedure types
Phase II: semiurgent procedures, possibility affecting surge resources 50% usual capacity	1. Category I and II patients 2. Patients who have been waiting >3 wk	As above 1. Holding area space reopened for pre/ postprocedural care 2. Staffing and room availability 3. Throughput	As above 1. Universal COVID-19 testing for patients 2. Continue to isolate high-risk population to reduce exposure 3. Adequate staffing for cases (nursing and technologist) 4. Adequate staffing to provide pre/ postprocedural care 5. Return of 1 FTE for environmental services and patient transport
Phase III: routine procedures 75% usual capacity	1. Category I, II, and III patients 2. Patients who have been waiting >2 wk	As above 1. Staffing and room availability 2. Throughput	As above 1. Return of 80% FTEs to procedural area including transport, environmental services, and catheterization laboratory and holding area nursing

(*continued on next page*)

Table 2
(*continued*)

Phases	Cases	Dependencies	Tactics
Phase 4: 110% of FY20 budgeted procedural cases	1.Category I, II, and III patients	As above 1. Staffing and room availability 2. Throughput	As above 1. Running 1 procedure room on saturday 2. Reestabilish all blocks for ORs and anesthesia support 3. Return of all clinical/ nonclinical staff members to procedural and pre/ postprocedural care areas 4. Seek additional blocks as needed

Abbreviations: COVID-19, Coronavirus disease 2019, FTE, full-time equivalent; FY20, fiscal year 2020; ICU, intensive care unit; OR, operating room; TAVR, transcatheter aortic valve replacement.

REOPENING CARDIAC CATHETERIZATION LABORATORY SAFELY FOR ELECTIVE CASE SCHEDULING

With gradual recovery from the peak of the COVID-19 pandemic, CCL have safely resumed elective cardiovascular procedures with continued guiding Principles to limit the risk of exposure of CCL health care workers to patients with active COVID-19 infection. Central to these principles is the testing of all patients with a single swab 24 to 48 hours before their elective procedure. In the event this preliminary test is positive, the patient is instructed to self-isolate and reschedule their elective procedure in 10 to 14 days with the confirmation of a negative test. Successful strategies for CCL recovery are outlined in Fig. 3, Tables 1–3[30] with proper case selection.[31,32]

SUMMARY

The severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) is a highly contagious pathogen leading to its dramatic spread around the world and high numbers of total deaths, approaching 700,000 in the United States and more than 4.7 million deaths worldwide. CCL teams are frontline workers and should be provided with N95 respirators, whole face shields or protective eyewear, disposable caps, shoe covers, sterile gowns, and surgical gloves. The CCL needs formal preparedness protocols in the form of consensus evidence-based guidance and guidelines from international heart associations. All CCL personnel should be vaccinated against SARS-CoV-2 along with timely booster vaccinations. Patients with cardiovascular disease are at an increased risk of severe disease and death from COVID-19 and should be strongly encouraged to be vaccinated, with consideration for booster doses 6 months following their second doses of an mRNA vaccine. Like other respiratory viruses (ie, influenza), COVID-19 is strongly associated with an increased risk of acute coronary syndromes and myocardial infarction. All patients presenting for emergency cardiac care should be screened for COVID-19 symptoms and considered for screening by polymerase chain reaction (PCR) testing. During times of high community transmission and in coordination with hospital leadership, PCR testing should be performed within 72 hours of nonurgent, elective procedures; in patients with positive tests, procedures should be delayed at least 10 days when practical and safe. Procedures that cannot be safely delayed should proceed with appropriate infection prevention precautions.

Further research characterizing the effectiveness of implemented measures during the COVID-19 pandemic so that caregivers and medical institutions can understand the logistics of implementing policies. Iterative improvements to minimize the transmission of pathogens, particularly aerosolized microorganisms, should be disseminated and routinely reviewed as part of the contingency policies of CCL for future pandemics.

Table 3
Specific considerations for structural heart procedures during the COVID-19 pandemic

Procedure	Procedural Considerations	Operational Considerations
TAVR	• MAC or conscious sedation (avoid general anesthesia) • Early permanent pacemaker implantation for advanced heart blocks seen Post-TAVR • Same-day discharge in low-risk patients with home cardiac monitoring	• Dedicated COVID-19-negative pathway (pre and postprocedure) • Only essential team present in the room (8) • Same-day or next-day discharge • Discharge home (not to a rehabilitation center or nursing home) • Crash ICU bed available • Telehealth for pre and postprocedural visits
MitraClip	• No preprocedural TEE (diagnostic imaging obtained during the case)	
ASD/PFO closure	• No preprocedural TEE (imaging obtained during the case) • ICE for procedural guidance (avoid TEE)	
LAAO	• No preprocedural TEE • ICE for procedural guidance (avoid TEE)	

Abbreviations: ICE, intracardiac echocardiography; LAAO, left atrial appendage occlusion; MAC, monitored anesthesia; PTEE, transesophageal echocardiography; other abbreviations as in Tables 1 and 2.

CLINICS CARE POINTS

- All CCL staff should be provided with PPE, to include N95 respirators, full-face shields, eyewear, disposable fluid impermeable gowns, disposable head caps, surgical gloves, and shoe covers
- Proper training for donning and doffing PPE should be carried out with periodic refresher training for CCL staff
- Primary percutaneous coronary intervention (PCI) remains the primary mode of revascularization for patients with STEMI regardless of infection status
- All HCWs should be vaccinated against SARS-CoV-2 to protect themselves, colleagues, and patients
- Only CCL personnel and health care workers involved in the procedure for presumed or confirmed patients with COVID-19 should be permitted inside the CCL
- To limit the risk of exposure of CCL health care workers to patients with active COVID-19 infection, testing of all patients with a single swab 24 to 48 hours before their elective procedure is recommended.

DISCLOSURE

The authors have nothing to disclose.

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