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November 22, 2022

Ms. Debra Savage, Chair
Illinois Health Facilities and Services Review Board
525 West Jefferson Street, 2nd Floor
Springfield, IL 62761

Re: Springfield Clinic – Springfield Ambulatory Surgery Center
Establishment of Cardiac Catherization, Project No. 22-027

Dear Chairwoman Savage:

As a physician at Springfield Clinic and in central Illinois, Springfield Clinic's application for a Certificate of Need to establish cardiac catherization services at our surgery center in Springfield will continue to help provide care along with new services expanding patient access for life-saving procedures in the greater Springfield and central Illinois area and in turn, allow patients to choose the location best suited for their time in need. As healthcare providers, we dedicate our lives and our practice to the health of our patients and the communities we serve. Currently Cath procedures are performed at 2 local hospitals (Springfield Memorial Hospital ("SMH") & HSHS St John's Hospital). This letter outlines the difficulties patients experience in obtaining timely cardiac catherization procedures.

Scheduling Challenges to Existing Hospital Based Model

Heart catheterization plays an important and integral part in the management of cardiology patients. With only 2 hospitals with capability of performing heart catheterization and coronary interventions in the Springfield area servicing surrounding areas with close to half million population, providing proper access for procedures to our patients often becomes challenging.

Prior to COVID-19 pandemic, scheduling elective cath procedures was already difficult because of availability of labs, number of cases, and complexity of procedures. More often than not, patients needed to endure longer wait time due to inpatient emergency and complex procedures which further delayed the start time of their procedures. COVID-19 pandemic made the matter even worse. With shortage in nursing staff, hospital resources, and radiology technicians, the number of cases can be completed each day has significant reduced. I have served as the chairman for the department of Cardiovascular Medicine at Springfield Memorial Hospital for the last 4 years. One of the biggest challenges was to have outpatient elective procedures completed on time. With inpatient procedures and emergent procedures for acute myocardial infarction, outpatient procedures often were delayed for prolonged duration. Sometimes, outpatient procedures had to be cancelled or rescheduled because of exceedingly long wait time.

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When elective cases were mixed with inpatient procedures, this tended to create unnecessary delays. Patients have been fasting for procedures and they had to endure such experience which in turn created unsatisfying patients. Furthermore, such delays often resulted in physicians and lab staff working beyond regular hours and creating tension amongst staff. Once passing regular work hours, the SMH lab began to operate with reduced numbers of crews which can further exacerbate the delay. Some staff could've been on call the night before and became fatigued after more exhausting cases. This could in turn created strains to the staff and potentially safety concerns to patients.

Naturally, local hospitals could be under the assumption that a Cath lab at Springfield Clinic ASC could take away some volume from the hospitals. This may be true in the beginning. However, in the long run, it is going to create a win-win situation for both hospitals and Springfield Clinic ASC. By moving some outpatient volume to ASC, it will create a better throughput strategy for the hospitals. Currently, with widespread staff shortage, this creates significant restrictions in available workforce on any given day. There was a long wait to be admitted from Emergency Room due to high inpatient census. In addition, it is even more difficult for patients who present to outlying medical facilities to be transferred to Springfield because of critical shortage in available inpatient beds. Sometimes, critical patients had to be turned away. By having elective cardiac procedures at the ASC cath lab, this will free up beds which could be accommodating patients with higher acuity at the hospitals.

CMS Changes to Outpatient Methodology

Same day discharge (SDD) in percutaneous coronary intervention (PCI) has made PCI in ASC possible. Observational studies and randomized controlled trials have supported SDD in appropriately selected patients with comparable outcome over standard overnight observation in the hospital. Therefore, CMS has initiated reimbursement for PCI performed in ASC since January 2020. Outpatient cardiac procedures provide improved efficiency of care, increased access to care, and reduced cost while maintaining similar short term and long-term outcome over in-hospital setting. The Society of Cardiovascular Angiography and Interventions (SCAI) has published position statement on PCI in ASC and updated the best practices in cath labs. To create a successful ASC Cath lab, SCAI has published several guidelines including proper equipment, operator experience, case screening/selection, discharge planning and follow up.

Project will follow Best Practices

Our cath labs will utilize state of the art fluoroscopy equipment, and follow criteria set forth by CMS and SCAI for best practice in the outpatient cath lab. Springfield Clinic ASC cath lab will follow such recommendations and adhere to best practice guidelines. In essence, the goal of Springfield Clinic ASC Cath lab is to create a safe and effective alternative for patients to receive care without sacrificing any safety regards. This strategy will aim to reduce the challenges when mixing inpatient and outpatient procedures in the hospital setting. In addition, we will continue to support

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local hospitals by bringing patients who are best suited to have procedures in the hospital setting. By doing so, we will utilize resources properly and ensure the safety of our patients.

We have a strong foundation of passionate providers and staff members in our community who will continue to collaborate to provide excellent safe care for our patients in both the hospitals and ASC setting. We kindly ask you to consider the safety of our community when considering approval of our project in ensuring the appropriate care is available to all who we aim to provide excellent care for every day.

Very truly yours,

Stephen Chen, DO, FACC, FSCAI
Interventional Cardiology
Springfield Clinic, LLP
Chair, Department of Cardiovascular Medicine
Springfield Memorial Hospital

cc: John Kniery, Administrator

Enclosures:
Article: SCAI expert consensus update on best practices in the cardiac catheterization laboratory (1)
Article: Length of Stay following percutaneous coronary intervention: An expert consensus document update from the society for cardiovascular angiography and interventions (2)
Article: SCAI position statement on the performance of percutaneous coronary intervention in ambulatory surgical centers (3)

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CLINICAL DECISION MAKING

WILEY

Length of stay following percutaneous coronary intervention: An expert consensus document update from the society for cardiovascular angiography and interventions

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Abstract

Since the publication of the 2009 SCAI Expert Consensus Document on Length of Stay Following percutaneous coronary intervention (PCI), advances in vascular access techniques, stent technology, and antiplatelet pharmacology have facilitated changes in discharge patterns following PCI. Additional clinical studies have demonstrated the safety of early and same day discharge in selected patients with uncomplicated PCI, while reimbursement policies have discouraged unnecessary hospitalization. This consensus update: (1) clarifies clinical and reimbursement definitions of discharge strategies, (2) reviews the technological advances and literature supporting reduced hospitalization duration and risk assessment, and (3) describes changes to the consensus recommendations on length of stay following PCI (Supporting Information Table S1). These recommendations are intended to support reasonable clinical decision making regarding postprocedure length of stay for a broad spectrum of patients undergoing PCI, rather than prescribing a specific period of observation for individual patients.

KEYWORDS

outpatient, percutaneous coronary intervention, quality improvement, same-day discharge

1 | BACKGROUND/INTRODUCTION

Percutaneous coronary intervention (PCI) is one of the most frequently performed medical procedures, yet there is considerable variability in the duration of hospitalization following such procedures. Traditionally, most patients undergoing elective uncomplicated PCI were admitted as inpatients and monitored overnight because of concerns about postprocedural complications. Discharging patients the same day following an uncomplicated procedure was uncommon, as the safety of this approach was not firmly established.

In 2007, the Centers for Medicare and Medicaid Services (CMS) and many payers changed their criteria for inpatient care such that PCI for indications other than acute coronary syndromes (ACS) was no longer eligible for inpatient facility reimbursement. Payment for elective PCI at the reduced outpatient rate increased financial pressures to eliminate short overnight admissions, eliciting concerns that patient safety and prudent medical practice were at risk. Accordingly, in 2009 the Society for Cardiovascular Angiography and Interventions (SCAI) published an Expert Consensus Document titled "Defining the Length of Stay (LOS) Following Percutaneous Coronary Intervention" [1]. The document specified that the standard of care was an overnight stay following uncomplicated elective PCI, and proposed that safeguarding patient welfare required LOS criteria be "dictated by a level of conservatism" in the absence of definitive studies.

Since the publication of the 2009 document, PCI practice has continued to evolve and rates of postprocedural complications have declined. In addition, studies have demonstrated the safety of same-day discharge (SDD) in patients undergoing PCI [2,3]. Many patients prefer to recover from a PCI procedure at home rather than spend a night in the hospital [4]. SDD has therefore become a reasonable, patient-centered approach for uncomplicated elective procedures. However, the use of SDD varies considerably around the world according to a recent survey [5]. For example, in the United Kingdom and Canada, 57% and 32% of cardiologists, respectively, utilized SDD as a routine practice, whereas in the US only 14% of respondents reported doing so. Among US respondents, 48% stated that they did not have standards for SDD after PCI at their respective institutions.

In response to these data and reflecting current practice, SCAI developed this update to the 2009 Consensus Statement to offer contemporary guidance on LOS following PCI. In contrast to the prior document, the current update addresses LOS across the spectrum of clinical presentations including ACS. Recommendations in this document replace those of the 2009 Consensus Statement and are patient-centered, evidence-based wherever possible, and focused on ensuring the best outcomes by establishing the critical milestones on the path to discharge.

2 | DEFINITIONS

Various and potentially overlapping terms from the medical literature, medical societies, and payers may cause confusion and require clarification (Table 1, Figure 1). For the purposes of this document, SDD specifically refers to a patient who presents for elective PCI, undergoes the procedure, and after a period of supervised recovery is sent home on the same calendar day. While this is frequently equated with an outpatient procedure, "outpatient" refers to a reimbursement classification and does not relate to a specific LOS. In the United States, inpatient and outpatient are the only two status determinations recognized by CMS for reimbursement purposes [6]. Other terms such as *extended recovery* and *outpatient in a bed* are not CMS terms; rather, they are terms developed by hospitals to classify patients for billing purposes or distinguish between certain outpatient areas. CMS policies make it clear that when patients with known diagnoses enter a hospital for a specific minor surgical procedure or other treatment that is expected to keep them in the hospital for $<$24 hr, they are considered outpatients for coverage purposes regardless of the hour they came to the hospital, whether they used an inpatient bed, or whether they remained in the hospital past midnight.

Thus, "outpatients" may remain in the hospital on *observation* status following PCI when appropriate. Observation after an elective PCI could be considered for a number of medical reasons such as prolonged or adverse effects from sedation, fluid or electrolyte imbalance, or ongoing pain, bleeding, ischemia, or dysrhythmia after the procedure. In addition, some patients may be considered higher risk for complications based on coronary anatomy, left ventricular dysfunction, procedural complexity, and comorbidities. Finally, there may be appropriate logistical reasons that require a patient to remain in the hospital overnight, such as procedures that end too late in the day for a safe discharge the same day, lack of transportation, or inadequate social support at home. Interpretation of these policies may vary by payer and region, and can potentially impact hospital reimbursement and patient copayments.

3 | PCI COMPLICATIONS AND RISK STRATIFICATION

The justification for a period of observation following uncomplicated PCI is to detect and manage potential complications that are not apparent during the procedure, especially bleeding, vascular access complications, stent thrombosis, and recurrent ischemia. Over the past 30 years, the incidence of complications following PCI has declined. The overall incidence of in-hospital complications in the most recent report of the NCDR CathPCI registry (2016 Q4–2017 Q3) comprising over 600,000 patients without ST-segment elevation myocardial infarction (STEMI) or coronary artery bypass surgery (CABG) was 4.8%. Specifically, stroke was 0.2%, bleeding within 72 hr was 1.4%, pericardial tamponade was 0.1%, heart failure was 0.9%, and acute kidney injury (AKI) requiring hemodialysis was 0.2%. PCI complications that resulted in emergency CABG occurred in 0.2% of patients. Overall in-hospital mortality was 0.93% (including patients undergoing CABG).

The specific timing of adverse events after elective PCI has been the focus of several cohort studies. In the STRIDE study, a cohort of 450 patients undergoing transradial PCI was evaluated for adverse events between 6 and 24 hr postprocedure. There were 24 postprocedural complications (5.3% of total), with most (20) occurring within 6 hr

TABLE 1 Definitions

Definition of cardiac catheterization/PCI status per NCDR		
Cardiac catheterization/ PCI status	Elective	The procedure can be performed on an outpatient basis or during a subsequent hospitalization without significant risk of infarction or death. For stable inpatients, the procedure is being performed during this hospitalization for convenience and ease of scheduling and NOT because the patient's clinical situation demands the procedure prior to discharge.
	Urgent	The procedure is being performed on an inpatient basis and prior to discharge because of significant concerns that there is risk of ischemia, infarction and/or death. Patients who are outpatients or in the emergency department at the time that the cardiac catheterization is requested would warrant an admission based on their clinical presentation.
	Emergency	The procedure is being performed as soon as possible because of substantial concerns that ongoing ischemia and/or infarction could lead to death. "As soon as possible" refers to a patient who is of sufficient acuity that you would cancel a scheduled case to perform this procedure immediately in the next available room during business hours, or you would activate the on-call team were this to occur during off-hours.
	Salvage	The procedure is a last resort. The patient is in cardiogenic shock at the start of the procedure. Within the last ten minutes prior to the start of the procedure the patient has also received chest compressions for a total of at least sixty seconds or has been on unanticipated extracorporeal circulatory support (e.g., extracorporeal membrane oxygenation, cardiopulmonary support)
Definitions of admission status per CMS criteria		
Admission status inpatient	Inpatient	• A patient who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. • Formally admitted as inpatient with the expectation that he or she will require hospital care that is expected to span at least two midnights. • The patient will occupy a bed even though it later develops that he or she can be discharged or transferred to another hospital and not actually use a hospital bed overnight.
Admission status outpatient	Outpatient (Same Day Discharge falls under this category)	• This status is for most outpatient procedures. • Routine observation is an inherit part of the procedure and the hospital cannot bill for it separately. • CMS does not define how long observation should be as long as it is less than 24 hr. • There is no additional reimbursement for overnight stay and/or nursing care.
	Observation	• Observation status cannot be defined preprocedure i.e. a patient cannot come as outpatient for a procedure and expect to be placed in observation. • A patient can remain in observation status for up to 48 hr if one of six CMS criteria for additional monitoring/care, beyond what is necessary for the procedure performed, are met. • The hospital may bill for additional nursing care and procedures to treat the patient

and none between 6 and 24 hr after PCI [7]. In the DISCHARGE study, over 2,000 transradial PCI patients were assessed for timing of post-procedural adverse events. Among the 1,174 higher-risk patients admitted overnight, all complications were identified either within 6 hr of procedure completion (3.4%) or after 24 hr (1.9%) [8]. Taken together these data corroborate the low incidence of postprocedural complications in elective PCI and support the notion that adverse events, when they do occur, are usually within the first 6 hr after PCI or after 24 hr and therefore not impacted by routine overnight observation.

The ability to predict PCI complications through risk stratification can inform decisions regarding LOS. Contemporary risk models and bedside scoring systems for mortality (Table 2), bleeding, and AKI have been developed and validated using the NCDR [9–11]. These models were derived from all patients undergoing PCI, including urgent and emergent PCI, rendering some variables less applicable to elective cases. Nevertheless, a number of risk factors emerge as recurrent variables and remain useful for risk stratification. Cardiogenic shock, renal function, and age are the strongest predictors of mortality. Although angiographic factors are generally less predictive of poor outcome, left main or proximal left anterior descending lesions are associated with increased mortality risk during elective PCI. Bleeding within 72 hr of PCI was most strongly predicted by female sex, baseline chronic kidney disease and hemoglobin levels, as well as clinical presentation (i.e., shock or salvage PCI). AKI and risk of dialysis was largely predicted by STEMI presentation, shock, and baseline chronic kidney disease.

The very low rates of in-hospital mortality and complications after elective PCI are reassuring for the development of SDD policies. The main challenge with risk scores is deciding how to incorporate them into LOS and discharge criteria. Acceptable thresholds for safety of

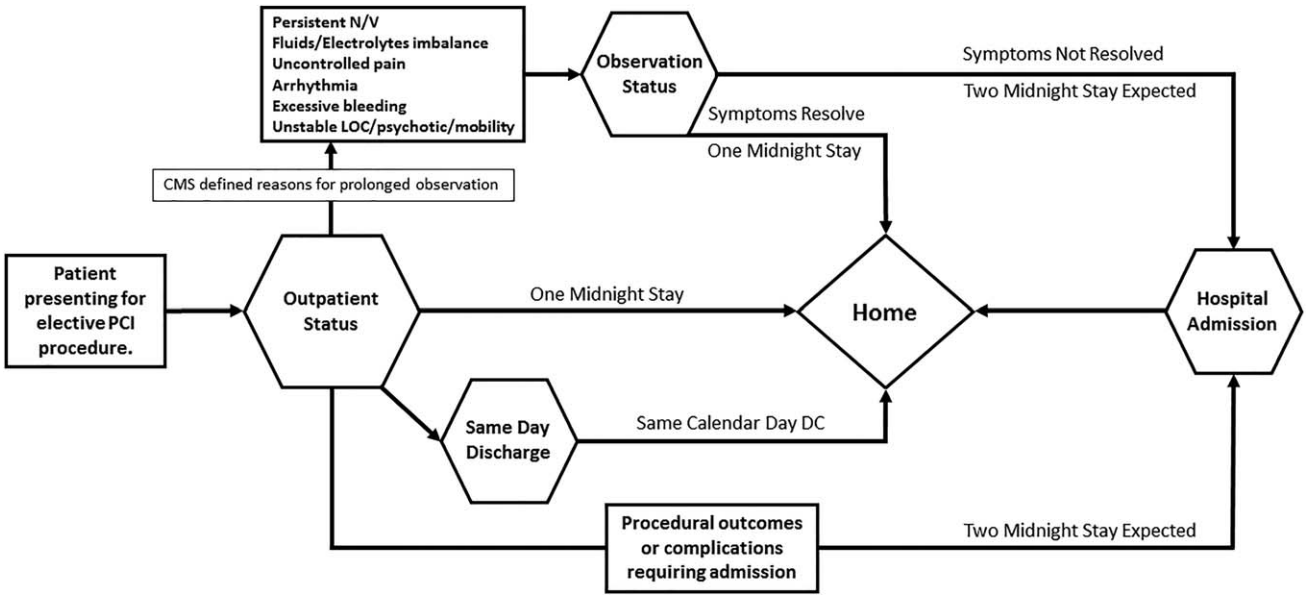

FIGURE 1 Flowchart of patient status following elective PCI

discharge based on risk of mortality, bleeding, and kidney injury have not been standardized. Moreover, risks of AKI are generally not evident until several days post-PCI, rendering decisions about SDD less of a contributing factor toward improving outcomes. On the other hand, the value of risk scores lies in early identification and implementation of strategies, such as bleeding avoidance strategies and preprocedure hydration, in patients who are at elevated risk of bleeding and AKI, respectively, which impacts postprocedural complications and LOS.

4 | PRACTICE EVOLUTION

Short-term post-PCI outcomes have improved significantly in the last decade mainly due to advances in arterial access, antithrombotic/antiplatelet therapy, and drug-eluting stent (DES) technology. Transradial PCI has played an important role in decreasing associated complications across a broad range of clinical presentations. In one meta-analysis of 24 studies, compared with femoral access, radial access was associated with a lower rate of mortality (odds ratio [OR] 0.71), major adverse cardiovascular events (MACE) (OR 0.84), major bleeding (OR 0.53), and vascular complications (OR 0.23) [12]. Transradial access has increased steadily in the United States from 1.2% in 2007 to as high as 37% in 2017 (2017 NCDR outcomes report).

The decline in post-PCI bleeding rates may be partly related to changes in procedural anticoagulation. Bivalirudin use is associated with a reduction in major bleeding rates (OR 0.52) compared with heparin plus routine administration of glycoprotein IIb/IIIa inhibitors (GPI) [13], with GPIs implicated as the major cause of increased bleeding. Data from the CathPCI Registry indicate that bivalirudin utilization increased and GPI use declined between 2009 and 2013, and since 2013 heparin monotherapy use increased and bivalirudin use has declined [14]. Newer $P2Y_{12}$ inhibitors (prasugrel and ticagrelor) provide faster, more potent, and more reliable $P2Y_{12}$ receptor inhibition compared with clopidogrel and are superior in preventing ischemic events in ACS [15]. The use of such agents may alleviate concerns of inadequate platelet inhibition and acute stent thrombosis following PCI.

DES have undergone several advancements in the last decade including improved deliverability and flexibility of the metallic stent scaffold, thinner and more biocompatible polymers, and newer antiproliferative drugs. These changes in second-generation DES have contributed to the low late lumen loss and thrombotic risk, resulting in lower rates of restenosis and stent thrombosis rates compared with bare metal stents and first generation DES [16].

5 | CLINICAL DATA ON SHORT LOS FOLLOWING PCI

5.1 | Clinical trials

There have been several prospective randomized trials comparing outcomes in patients undergoing SDD compared with overnight observation (Table 3). Most have focused on lower risk patients. In the EPOS study [17], 800 patients underwent randomization prior to PCI to either SDD or overnight observation. This study excluded ACS patients, but many patients underwent multivessel PCI. Some in the SDD group crossed over to the overnight group due to procedural complications or for issues that developed during the first few hours of observation. There were no differences between the groups for the composite primary endpoint of MACE, blood transfusion and access site complications within 24 hr. Notably, these patients all underwent PCI using transfemoral access and hemostasis was achieved using manual compression.

In the EASY trial, investigators randomized 1,005 ACS patients who underwent successful transradial PCI to abciximab bolus only plus SDD or abciximab bolus and infusion plus overnight stay. This trial recruited a higher-risk cohort of patients, with 18% having elevated troponin values at baseline. The study noted no difference in the

TABLE 2 CathPCI mortality risk scoring system [10]

	Scoring response categories					Total points	Risk of in-patient mortality, %
STEMI	No	Yes				0	0.0
	0	6				5	0.0
						10	0.1
Age	<60	60–70	70–80	≥80		15	0.1
	0	4	9	15		20	0.2
						25	0.3
BMI	<20	20–30	30–40	≥40		30	0.6
	5	1	0	3		35	0.9
						40	1.4
CVD	No	Yes				45	2.3
	0	2				50	3.7
						55	5.9
PAD	No	Yes				60	9.2
	0	3				65	14.2
						70	21.2
Chronic lung disease	No	Yes				75	30.4
	0	3				80	41.5
						85	53.6
Prior PCI	No	Yes				90	65.2
	3	0				95	75.3
						100	83.2
Diabetes mellitus	No	Noninsulin	Insulin			105	88.9
	0	2	3			110	92.9
						115	95.5
GFR	Renal failure	30–45	45–60	60–90	≥90	120	97.2
	16	11	7	3	0	125	98.2
						130	98.9
EF	<30	30–40	40–50	≥50		135	99.3
	9	4	2	0		139	99.5
Cardiogenic shock/PCI status	Sustained shock and salvage	Sustained shock alone or salvage alone	Transient shock but not salvage	Emergency PCI without shock/salvage	Urgent PCI without shock/salvage	Elective PCI without shock/salvage	
	54	43	37	22	11	0	
NYHA class within 2 weeks	NYHA class IV	NYHA class <IV	No HF				
	7	3	0				
Cardiac arrest within 24 hr	No	Yes					
	0	13					

BMI, body mass index; CVD, cerebrovascular disease; EF, ejection fraction; GFR, glomerular filtration rate; PAD, peripheral artery disease; NYHA, New York Heart Association.

TABLE 3 Randomized clinical trials of SDD following elective PCI

Study	Reference	Sample size	Access site	Findings	Time to discharge	Inclusion	Exclusion
Bertrand et al. (EASY)	Circulation. 2006;114:2636-2643	1005	TR	• No difference in 30 day clinical events • 88% of patients assigned to SDD were discharged home the same day	4–6 hr post PCI	• Successful TR-PCI with abciximab bolus	• STEMI within 72 hr • EF ≤30% • Vessel closure or hemodynamic collapse during PCI • Femoral artery sheath • External consideration precluding SDD • Allergy, intolerance to aspirin or thienopyridines • INR >2.0
Heyde et al. (EPOS)	Circulation. 2007;115:2299-2306	800	TF without VCD	• No difference in 24-hour safety endpoint between groups • 19% of patients assigned to SDD developed indication for extended observation during/after PCI	4 hr post PCI	• Elective planned PCI • Home factors allowed SDD	• **Preprocedure factors**: • Acute coronary syndrome • Ad hoc PCI • Catheter >6Fr • Oral anticoagulant therapy • Glycoprotein inhibitor use • Residence >60min from center • Difficult follow-up • **Procedural** • Occluded coronary artery or side branch • Suboptimal angiographic result • Residual dissection • Angiographic thrombus • No-reflow/slow-flow • Perforation • **Clinical** • Ischemic symptoms • ECG changes • Puncture site abnormalities • Congestive heart failure • Complicated hemostasis
Slagboom et al.	Cath and Cardiovasc Int. 2005;64:421-427	644	TF with MC and TR	• SDD PCI safe either TR or TF • Larger proportion of TR discharged due to fewer access site complications • 38% received only balloon angioplasty	4–6 hr after PCI	• Stable or unstable angina • 6Fr equipment • Normal Allen test	• **Suboptimal PTCA** • Dissection • Unstented Type C lesion • Unstented CTO • Intracoronary thrombus • Side branch occlusion/jeopardy • **General** • Transient vessel closure • Hemodynamic collapse • Prolonged chest pain, post-PCI • Persistent ECG changes • Multivessel PCI if >1 vessel remains unstented • Entry site complication

(Continues)

TABLE 3 (Continued)

Study	Reference	Sample size	Access site	Findings	Time to discharge	Inclusion	Exclusion
Kim et al. (ABCD-PCI)	Circ Cardiovasc Qual Outcomes. 2013;;6:186-192	298	TF + VCD	• After 7 days, no difference in coping ability, medication adherence, safety outcomes Significant (79% vs 49%) patient preference for SDD	3 hr post PCI	• Elective PCI • <65 years of age • Type A or B coronary lesions	• Recent ACS • >= 3 stents • Difficult femoral access • Use of anticoagulants other than unfractionated heparin or bivalirudin • Suboptimal angiographic outcome or clinical complication • PCI of bypass graft • Angiographic thrombus • INR >2, Platelets <100,000 or Hematocrit <25 • Occlusion of major side branch • EF ≤30% • Known allergy to PCI medications • Patient unable to ambulate 4 hr postprocedure • Vascular complication (dissection, hematoma, bleeding) • Pregnancy • Infection • Creatinine ≥1.5 mg/dL
Clavijo et al.	Cardiovasc Revasc Med. 2016 Apr-May;17(3):155-61.	100	TF with VCD	• No differences in clinical outcomes • Similar patient satisfaction scores • SDD associated with $1200 cost savings per patient	6 hr after PCI	• Stable angina, unstable angina, or NSTEMI with troponin-T < 1 ng/mL • Pretreatment with P2Y12 inhibitor • Anticoagulation with heparin or bivalirudin • Femoral access with VCD • Normal coronary flow • EF ≥30%. • Lives <60 min from the hospital	• **Clinical** • Age <30 or >80 years • STEMI • Non-STEMI with documented troponin-T > 1 ng/mL • Severe valvular heart disease • Cardiogenic shock or hemodynamic instability • Pregnancy • Bleeding diathesis • Creatinine >1.5 mg/dL not on hemodialysis • INR >1.5 • Unable to consent or follow-up • Inadequate social support • Life expectancy of <1 year • **Pharmacological** • Received a IIb/IIIa inhibitor or thrombolytics within 24 hr of the procedure

(Continues)

TABLE 3 (Continued)

Study	Reference	Sample size	Access site	Findings	Time to discharge	Inclusion	Exclusion
							• Received low molecular weight heparin within 12 hr of the procedure • Oral anticoagulation • **Angiographic and procedural** • Treatment of >2 lesions in >2 vessels • Major site branch occlusion • CTO, left main or vein graft PCI • Intracoronary thrombus • Dissection type C–F not stented • Target lesion is >55 mm in length or heavily calcified • **Access site-related** • Uncontrolled hypertension (>160 mm Hg systolic) • Recent prior TF-VCD • Hematoma, pseudoaneurysm, arteriovenous fistula, or graft present • Severe common femoral calcification • Small femoral arteries (<5 mm in diameter) • Femoral artery stenosis >50%
Carere et al.	Am Heart J 2000;139:52-8	100	TF	• 8F Prostar suture closure facilitated earlier discharge (7.1 vs.15.5 hr with C-Clamp) • 20% hematoma rate in both groups • Patients preferred closure	11 hr (from sheath removal)	Elective or urgent PCI where operator felt SDD was reasonable	• Peripheral arterial disease • Femoral hematoma, • Creatinine >150 mmol/L • Blood pressure >180/100
Knopf et al.	J Invasive Cardiol 1999;11:290-5.	90		• Similar procedural and clinical outcomes • Patient preference for SDD	N/A		
Falcone et al.	Proc (Bayl Univ Med Cent). 2011 Jul;24(3):192-4.	44	TF with VCD	• No significant differences for pain, tenderness, numbness, bruising • No difference in adverse events at 7 and 30 days	3 hr after PCI	• ≤75 years of age • Type A or B lesion • Femoral access siteamenable to vascularclosure device • >2 hr since PCI	• Life expectancy <12 months • Acute myocardial infarction

(Continues)

TABLE 3 (Continued)

Study	Reference	Sample size	Access site	Findings	Time to discharge	Inclusion	Exclusion
				• 6/7 events were related to femoral access site complications			• Anticoagulants besides heparin or bivalirudin used during procedure • PCI to nonnative vessel • Evidence of thrombus • Implantation of >3 stents • INR ≥2, platelets ≤100,000/μL, or hematocrit ≤25% • Occlusion of side branch during PCI • EF ≤30% • Residence >30 min from a hospital • Dissection, hematoma, or bleeding • Pregnancy • Infection • Creatinine ≥1.5 mg/dL

CTO, chronic total occlusion; ECG, electrocardiogram; EF, ejection fraction; INR, international normalized ratio; MC, manual compression; STEMI, ST-elevation myocardial infarction; TF, transfemoral; TR, transradial; VCD, vascular closure device.

primary composite endpoint of MACE, bleeding, rehospitalization, and access site complications at 30 days and 1 year [18].

The largest observational study of SDD from the CathPCI registry involved 107,018 patients aged 65 years or older undergoing elective PCI [2]. The primary outcome of 30-day death or rehospitalization was similar between patients discharged home the same day and those observed overnight.

Three systematic reviews and meta-analyses have been performed to assess differences between SDD and overnight observation from randomized trials alone [19,20] and randomized trials plus observational studies [3]. Each of these analyses demonstrated no difference in acute or medium-term mortality, myocardial infarction and MACE between groups (Figure 2). Rates of rehospitalization were also no different, according to one meta-analysis.

5.2 | Impact of access site on LOS

In the large observational CathPCI study noted above, nearly 96% of the patients underwent PCI via transfemoral access [2]. Femoral vascular closure devices were used in 65% of the patients undergoing SDD. While vascular closure devices are likely similar to manual compression with respect to vascular complications and bleeding, they do facilitate early postprocedure ambulation [21]. Other studies, like the EASY trial, included only patients who underwent transradial PCI. Radial approach is associated with significantly lower risks of vascular complications and bleeding compared with femoral approach and also leads to faster postprocedure recovery [12]. Ultimately, the choice of access site or method of hemostasis does not appear to directly influence the success of a discharge strategy. Moreover, the overall cost savings associated with radial access and SDD appear to be primarily related to SDD rather than to the use of radial access [22].

5.3 | Clinical data on LOS following primary PCI for STEMI

The studies summarized above included patients with non-ST-segment elevation ACS (NSTEACS). Primary PCI (PPCI) for STEMI, however, presents a higher risk clinical cohort due to the elevated risk for both acute ischemic and bleeding events. The United States has a very low median LOS (3 days) for these patients compared with other countries (esp. Germany, 8 days) [23], but there is significant variation in discharge practice within the United States [24].

A large observational study of 33,920 patients from the CathPCI registry provides insights into discharge patterns and associated outcomes after PPCI. LOS was divided into short (≤3 days), medium (4–5 days), and long (>5 days) groups. No significant differences were noted in 30-day mortality or MACE between the short and medium LOS groups. Long LOS was associated with higher mortality and MACE compared with the short LOS group, as was a very short LOS (<48 hr) [24]. Several clinical features were associated with either increased LOS (vascular complications, transfusion, preoperative balloon pump, shock, renal insufficiency) or decreased LOS (male sex, absence of diabetes).

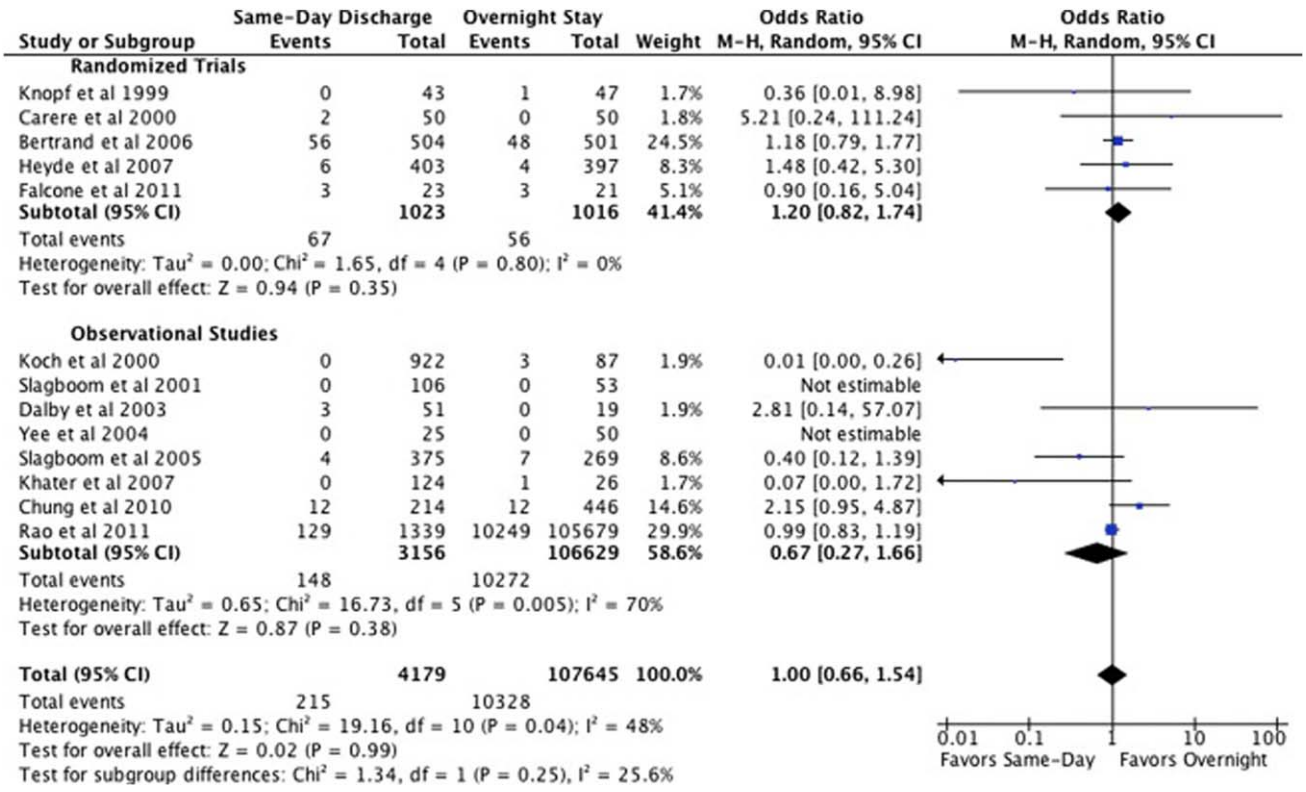

FIGURE 2 Total 30-day complications comparing SDD with overnight stay. From Abdelaal et al. [3] [Color figure can be viewed at wileyonlinelibrary.com]

Several observational and a few randomized studies have studied which patients might be candidates for early discharge after PPCI (Figure 3). In one study of 228 patients, patients with a low CADILLAC score, a validated STEMI risk assessment tool, had a lower rate of MACE beyond 3 days after PPCI compared to those with an intermediate or high score (0% vs 11.4%, $P = .0002$) [32]. In another study of 845 STEMI patients, the addition of N-terminal pro-brain natriuretic peptide (NT-pro-BNP) levels improved the prognostic value of the Zwolle risk score (ZRS) in predicting 30-day mortality. Based on a ZRS (<2) or NT-proBNP at 18–24 h (<2500 pg/mL), the study suggested that 75% of patients could be safely targeted for early discharge at 48 hr [33].

There are limited randomized trials comparing LOS in patients undergoing PPCI. In a Norwegian study, the ZRS was used to identify low-risk PPCI patients ($n = 215$) who were then randomized to early (≤ 3 days) or "routine" discharge [25]. Another trial used the ZRS to identify 54 low-risk patients and randomized them to routine care, or discharge within 72 hr with advanced practice nurse follow-up [26]. In both studies, there were no deaths and no difference in rehospitalization between groups, suggesting that low-risk STEMI patients can be safely discharged within 72 hr.

6 | REIMBURSEMENT AND LEGAL CONSIDERATIONS

6.1 | Reimbursement

Discharge planning after PCI is ultimately a medical decision and should be based on what is the best care for the patient. While reimbursement should not affect discharge decisions, the financial impact of LOS decisions merits a review of the relevant policy issues.

Any discussion of PCI reimbursement is limited by the variety of systems and policies present across different countries. Even in the United States, CMS reimbursement policies for PCI have changed over time and are likely to continue to change, creating confusion for patients, physicians, and hospitals. Hospital payments vary across different PCI procedures, but for any particular procedure, payments are higher for inpatients than outpatients (Supporting Information Table S2). Payments to physicians or facilities do not directly correlate with LOS. While CMS inpatient status is usually applied to patients staying two midnights or more, it may be also applied to patients staying only one night if the physician's judgment and documentation support inpatient classification (i.e., due to ACS). (Supporting Information Table S3) Elective PCI is reimbursed as an outpatient procedure, and there is no increase in reimbursement for patients who stay overnight or who are designated as observation status. Elective patients with a complication requiring more than one night in the hospital may be classified as inpatients with adequate documentation of the cause for admission.

While payment does not vary by LOS, facility costs may increase with longer LOS. In a Canadian study of outpatient PCI, the average charge for SDD was C$1117 versus C$2258 for next day discharge [34]. Payment models may continue to evolve over time, but reimbursement under alternative payment models, episode payment models, or other bundled payment systems will likely continue to follow the same principles with fixed payments and facility costs increasing with longer LOS. Thus hospital margins, defined loosely as the difference

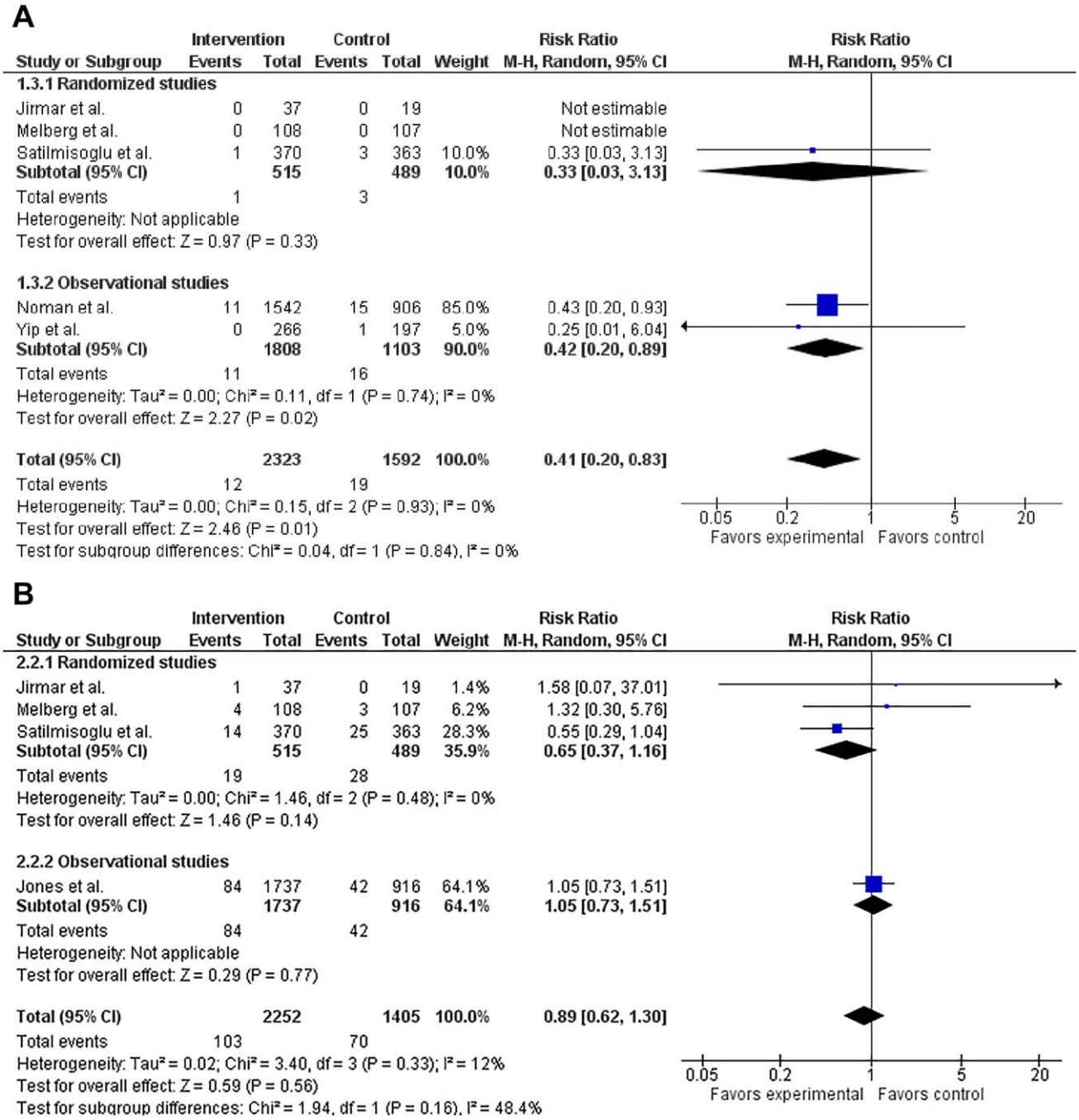

FIGURE 3 Forest Plots (random-effects model) of pooled risk ratios of (A) 30-day mortality and (B) 30-day hospital readmission from 6 studies of early discharge (intervention) following STEMI [References #25,26,27–31]. [Color figure can be viewed at wileyonlinelibrary.com]

between what the facility gets paid and what it "spends" to take care of patients, may be affected by earlier or later discharge.

6.2 | Legal issues

The primary medicolegal concern surrounding LOS after PCI is the occurrence of complications that may manifest after discharge. Most readmissions after PCI are not due to complications of the PCI procedure itself [35], but an adverse event that occurs after discharge may raise the question of whether a longer stay could have prevented or mitigated the complication. However, as described above, data supporting the safety of early appropriate discharge are robust and should overcome medicolegal concerns. Interventionalists should communicate to patients, families, and referring physicians that early discharge is safe and generally preferred by patients. Such communication is the foundation of the physician-patient relationship and reduces misunderstandings should adverse events occur. Each facility should have a policy regarding discharge after PCI describing the criteria for selecting patients and procedures suitable for SDD or early discharge. A thoughtful post-PCI discharge policy will not only facilitate the

TABLE 4 Consensus recommendations for discharge following PCI

	Expedited and same-day discharge requirements and milestones	Factors unfavorable for same-day discharge
Patient	Clinically stable	Chronic kidney disease requiring prolonged hydration
	At baseline functional and mental status	Decompensated CHF or fluid overload
	Baseline comorbidities (e.g., diabetes, CHF, COPD, PAD, ESRD) stable	Decompensated COPD
		Continuing angina
		Contrast reaction with ongoing symptoms
Procedure	Successful procedure, including: • Single or multivessel PCI, proximal LAD, or bifurcation PCI • Uncomplicated CTO attempt • Regardless of number, length of stents used	Angiographic complication (slow/no reflow, side branch closure, dissection, perforation) Inability to deliver stent/balloon angioplasty only Last remaining coronary artery PCI
	Adequate hemostasis	Bleeding complication
	Effective dual-antiplatelet therapy administered • Pretreatment not required	Vascular complication Large contrast volume
		Need for GP IIb/IIIa Infusion
		Periprocedural MI
		Left ventricular support device used
		Large-bore ($\geq$ 9 French) or brachial access
		Atherectomy
Program	Meets PCI program operational requirements for postprocedure care	Inadequate home support
	• Adequate caregiver support	No transportation home
	• Patient and caregiver education	Discomfort of patient, caregiver, or physician with same-day discharge
	• Provision of P2Y12 inhibitor and medication instruction	Inadequate access to emergency medical care following PCI
	• Contact information and follow-up appointment	

Abbreviations per Tables [1–3]; CHF, congestive heart failure; COPD, chronic obstructive lung disease; ESRD, end-stage renal disease.

discharge process, but also reduce medicolegal concerns if adherence to the policy is demonstrated.

7 | DETERMINING THE LENGTH OF STAY AFTER PCI

General principles of discharge readiness apply to all patients undergoing PCI regardless of whether the indication is elective, urgent, or emergent. These include, but are not limited to, clinical stability and arrangement of follow-up. While the 2009 consensus document made specific recommendations for LOS for different patient and procedure subgroups, the resulting exclusions to SDD have proven with time to be overly prescriptive and conservative, evident in the poor (<50%) agreement with the recommendations [5].

It is more prudent to identify the essential milestones that should be met before considering a patient ready for discharge, regardless of their presentation, with a focus on patient safety and good clinical judgment. One straightforward paradigm to assess readiness for discharge is to address the "three P's": Procedure, Patient, and Program, which serves as the framework for the updated consensus recommendations (Table 4).

7.1 | Procedure

The cornerstone of discharge readiness after a PCI procedure is a stable procedural outcome. In most cases this means a successful PCI defined traditionally as a residual stenosis <20% with Thrombolysis In Myocardial Infarction flow of 3 with no angiographic complications. In cases of unsuccessful PCI (e.g., unsuccessful wiring of a chronic total occlusion), the patient should be clinically stable (see below) prior to

TABLE 5 Sample nursing discharge checklist (adapted from the Ohio State University Medical Center)

Preprocedure
- ☐ Confirm transportation home
- ☐ Confirm someone will be home with patient the night of the PCI

Postprocedure
- ☐ Obtain postprocedure ECG if ordered
- ☐ Provider has checked access site and readiness for discharge
- ☐ Notify Cardiac Rehab if ordered
- ☐ Notify ACS educator if available
- ☐ Provide and document education on antiplatelet therapy
- ☐ Add applicable discharge instructions to After Visit Summary
  - ✓ Cardiac Cath, Care after Leg Site, Care after Wrist Site
  - ✓ Dual antiplatelet therapy
  - ✓ What to do if you have chest pain
  - ✓ Medicines for heart disease
- ☐ Patient has copy of stent card
- ☐ Follow up appointments are listed in After Visit Summary including:
  - ✓ Cardiac Rehab
  - ✓ Cardiology
  - ✓ Primary Care Physician
- ☐ For Same Day PCI: Aspirin, P2Y12 (Clopidogrel, Ticagrelor, Prasugrel), Statin, and Nitroglycerin are ordered as medically appropriate
- ☐ For STEMI: Aspirin, P2Y12 (Clopidogrel, Ticagrelor, Prasugrel), Statin, Nitroglycerin, Beta-Blocker, ACEI/ARB and Aldosterone Antagonist (if EF <40%) are ordered as medically appropriate
- ☐ Medications have been delivered from Pharmacy
- ☐ Work/School Excuse

Print and Review the After Visit Summary

discharge. Hemostasis of all vascular access sites should be achieved with no vascular complications or bleeding. Even with clinically stable results, certain high-risk angiographic or procedural situations like supported PCI, last remaining vessel, and use of atherectomy should still be considered for overnight observation. Any patient requiring prolonged postprocedure antithrombotic therapy (e.g., GPI infusion) should also be considered for overnight observation.

7.2 | Patient

The patient should be clinically stable, at their baseline mental status and vital signs, and have completed the appropriate recovery period for conscious sedation. In cases of procedures that are canceled or incomplete, the patient should be at their preprocedure level of symptoms. Baseline conditions such as diabetes, left ventricular dysfunction, and kidney disease should be stable and compensated. While such conditions may be risk factors for complications, overnight observation does not modify this risk, so well-controlled comorbidities need not preclude a safe discharge following a typical observation period.

7.3 | Program

Post-PCI discharge management should take place within the context of a program that encompasses: (1) safe monitoring in the immediate post-PCI period, (2) appropriate guideline directed medical therapy including dual antiplatelet therapy and counseling on treatment duration, (3) compliance with PCI performance measures including secondary prevention and education on risk factor modification, and (4) timely follow-up, including a phone call within 24–72 hr and a scheduled clinic appointment within 2–4 weeks. A responsible adult should be available to escort the patient home. Patients should be discharged to a location where there is a caregiver with instructions to monitor any potential late complications. For many patients, the PCI procedure may be the first indication that they have ischemic heart disease, and education and counseling are particularly important.

8 | ELECTIVE VERSUS NONELECTIVE PCI

8.1 | Elective PCI

As outlined elsewhere in this statement, patients undergoing elective PCI may either be discharged home (SDD) or observed overnight. Regardless of their length of stay, the paradigm and goals regarding the milestones above should be met before the patient is ready for discharge. Studies have shown that a 4- to 6-hour post-PCI observation period is typically sufficient to identify most potential complications. Thus, if the "three Ps" can be met on the same calendar day as the procedure, then the patient may be eligible for SDD. Checklists (Table 5) can be helpful in ensuring that all milestones are met for a safe discharge. A handout that includes a brief summary of the procedure, a summary of medications including duration of dual-antiplatelet therapy (DAPT), a contact number for questions and/or complications, and specific postprocedure follow-up appointments should also be provided to the patient and caregivers. It is essential to coordinate with pharmacy and provide medication education and DAPT to patients prior to discharge.

8.2 | PCI for acute coronary syndrome including primary PCI for STEMI

Although some patients with ACS were included in the observational studies of SDD, many patients are hospitalized for longer than one day

to confirm the diagnosis of NSTEACS, undergo invasive risk stratification, and ensure adequate recovery. If PCI is performed, discharge can proceed once a patient meets the milestones outlined previously, whether that occurs the day of or following the PCI procedure. Patients who present with or develop complications including (but not limited to) recurrent ischemia, heart failure, AKI, or ventricular dysrhythmias may require additional evaluation and longer LOS.

Patients undergoing primary PCI for STEMI represent a higher risk group depending on presenting clinical characteristics. As summarized above, several risk scores are available for use but randomized and observational studies generally support a 48-to 72-hour hospitalization in patients who undergo successful primary PCI and are clinically stable after the procedure. Again, the milestones of recovery, education, and follow-up should be met before the patient is ready for discharge.

9 | CONCLUSIONS

Advances in practices and technologies have made discharge following PCI demonstrably safe when milestones of clinical stability, procedural success, and process measures have been achieved. Ultimately, the duration of observation following PCI for an individual patient must be a professional medical decision based on individual procedural and patient factors. The schema proposed here is intended to support the reasonable judgment of physicians to allow expedited discharge following PCI, and should not be interpreted as prescribing a specific period of observation for individual patients.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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CORE CURRICULUM

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SCAI position statement on the performance of percutaneous coronary intervention in ambulatory surgical centers

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Abstract

The Centers for Medicare & Medicaid Services (CMS) began reimbursement for percutaneous coronary intervention (PCI) performed in ambulatory surgical centers (ASC) in January 2020. The ability to perform PCI in an ASC has been made possible due to the outcomes data from observational studies and randomized controlled trials supporting same day discharge (SDD) after PCI. In appropriately selected patients for outpatient PCI, clinical outcomes for SDD or routine overnight observation are comparable without any difference in short-term or long-term adverse events. Furthermore, a potential for lower cost of care without a compromise in clinical outcomes exists. These studies provide the framework and justification for performing PCI in an ASC. The Society for Cardiovascular Angiography and Interventions (SCAI) supported this coverage decision provided the quality and safety standards for PCI in an ASC were equivalent to the hospital setting. The current position paper is written to provide guidance for starting a PCI program in an ASC with an emphasis on maintaining quality standards. Regulatory requirements and appropriate standards for the facility, staff and physicians are delineated. The consensus document identified appropriate patients for consideration of PCI in an ASC. The key components of an ongoing quality assurance program are defined and the ethical issues relevant to PCI in an ASC are reviewed.

KEYWORDS

angioplasty, percutaneous coronary intervention, ambulatory surgery center

1 | INTRODUCTION

Interventional cardiology has undergone tremendous evolution since the initial percutaneous coronary intervention (PCI) was performed in 1977. In the early stages of procedural development, acute vessel closure occurred in almost 10% of patients, and therefore onsite cardiothoracic surgical support was required for provision of interventional coronary procedures. Over the ensuing years, advancements in

procedural technique, devices, and pharmacotherapy have led to a high proportion of procedural success with a low rate of major complications.[1,2]During this time, the complexity of patients and procedures has increased.[2,3]PCI without cardiothoracic surgical backup has transitioned from a Class III indication to a Class IIa indication[4,5] and is routinely performed in the outpatient hospital setting. Furthermore, the high safety profile of the procedure and success of same-day discharge (SDD) programs have made it possible to perform elective PCI in nonhospital outpatient facilities.[6] Performance of PCI in lower acuity settings reduces its cost.[6,7] Because of the excellent safety profile of elective PCI and the opportunity for lowering cost, the Centers for Medicare & Medicaid Services (CMS) initiated reimbursement for PCI performed in ambulatory surgical centers (ASC) on January 1, 2020.[8]

The Society for Cardiovascular Angiography and Interventions (SCAI) supported CMS' proposal to reimburse elective PCI in the ASC setting during the public comment period in 2019.[9] This support is contingent on the maintenance of high-quality standards as patients undergoing PCI in an ASC should receive the same quality of care as those receiving PCI as an outpatient in the hospital. This is a companion document to the SCAI Optimal PCI Therapy for Complex Coronary Artery Disease Consensus Statement differentiating appropriate patient care for PCI in the hospital and ASC setting.[3] It is intended to provide guidance for the development of an ASC-based PCI program, and for established programs seeking to maintain a high standard of care.

2 | METHODS

The need for a SCAI position paper on PCI performed in an ASC was identified by a working group of the SCAI Government Relations Committee. The writing group included members of the SCAI Government Relations Committee, the SCAI Quality Committee, the SCAI Executive Committee and SCAI members with significant prior experience with PCI in an ASC.

Before appointment, members of the writing group were asked to disclose financial relationships from the 12 months prior to their nomination. Author disclosures are included in Supporting Information Table S1. Consistent with the SCAI Publications Manual of Standard Operating Procedures, <50% of the writing group had any relevant conflict of interest.[10] Disclosures were periodically reviewed during document development and updated as needed. Writing group members with a current financial interest were recused from primary authorship of any relevant section of the document. The work of the writing committee was supported exclusively by SCAI, a nonprofit medical specialty society, without commercial support. Writing group members contributed to this effort on a volunteer basis and did not receive payment from SCAI.

The Writing Group found no substantive data regarding the safety and efficiency of performing PCI in the ASC setting. Therefore, this document primarily reflects expert consensus opinion. The writing group reviewed relevant clinical guidelines and consensus papers[4,11-17]as were available regarding performing PCI in an outpatient site of service and issues relevant to SDD after outpatient PCI.

The draft manuscript was peer reviewed in February 2020, and the document was revised to address pertinent comments. The writing group unanimously approved the final version of the document. The SCAI Publications Committee and Executive Committee endorsed the document as official society guidance in May 2020.

3 | PCI IN AN AMBULATORY SURGERY CENTER

The ability to perform PCI in an ASC has been made possible due to the outcomes data from observational studies and randomized controlled trials supporting SDD after PCI.[7,18-23] In appropriately selected patients for outpatient PCI, clinical outcomes for SDD or routine overnight observation were comparable without any difference in short-term or long-term adverse events. No safety signals were observed[7,18-23] and SDD was associated with a lower cost of care in both the Early Discharge After Transradial Stenting of Coronary Arteries (EASY) randomized clinical trial and observational registries.[7,22,24,25] These studies provide the framework and justification for performing PCI in an ASC.

3.1 | Potential benefits

The value proposition for performing outpatient PCI in an ASC versus the hospital outpatient environment, while dependent on consistent procedural efficacy and safety, offers improved efficiency of care, increased access to care, better patient satisfaction, and reduced cost. Advances in clinical decision making, adjunctive pharmacotherapy, and procedural technology have continuously improved the safety profile of outpatient PCI. Data from the National Cardiovascular Data Registry (CathPCI) from 1,612 hospitals (n = 667,424) reveal that major complications after PCI are rare, and exceedingly so for elective PCI.[1] Cautious case selection based on patient and lesion characteristics can further reduce the risk of complication in the ASC setting.

A single randomized controlled trial from Canada and an observational registry in the United States show some cost savings with SDD after elective PCI, primarily by eliminating the cost of an overnight hospital stay.[7,22,25] The 2020 CMS-approved PCI reimbursement rates for the ASC setting are reduced by 30% as compared to the hospital outpatient setting. CMS anticipates $20 million saved in cost, and $5 million saved in copays, if just 5% of PCIs shift to ASCs.[26]

3.2 | Potential drawbacks of outpatient PCI in the ASC setting

While there are potential benefits of outpatient PCI in the ASC setting, it is important to consider the drawbacks. There are extensive published data on the safety of outpatient PCI in a hospital setting, but none available for outpatient PCI safety in an ASC setting. The shift in procedural volume from hospitals to ASCs will have financial

implications for hospitals that could potentially impact their ability to provide other necessary services. Although it is expected that PCI in an ASC would decrease overall expenditure, it is possible that the actual number of PCI procedures performed may increase. It is the goal of this document to provide guidance on reducing the possibility of any negative clinical or financial outcomes.

4 | REGULATORY CONSIDERATIONS

Outpatient PCI can be currently performed in four different types of outpatient environments as defined by the CMS Place of Service (POS) Code system: POS 11 Office (ie, Office Based Lab-OBL); POS 19 Off Campus-Outpatient Hospital; POS 21 On Campus-Outpatient Hospital; and POS 24 Ambulatory Surgical Center (ASC).[27] Prior to the new rule, Medicare only provided reimbursement for PCI in hospital-based settings. The rule enacted by CMS adds Medicare payment for PCI in the ASC setting but not in office-based labs (OBLs). An ASC must meet the criteria outlined by Medicare found in the Code for Federal Regulations (CFR) Title 42: Public Health, Part 416: ASCs.[28] The ASC must also meet any additional state level requirements, which are typically more stringent than those for OBLs.[29] The CMS rule has added coronary angioplasty and coronary stenting codes to the ASC Covered Procedure List establishing payment for six PCI Current Procedural Terminology (CPT) codes (Table 1).[8] Notably, PCI for coronary artery bypass grafts, chronic total occlusions (CTO), myocardial infarction or coronary atherectomy will not be reimbursed in an ASC site of service. It was the expressed written opinion by SCAI to CMS that these higher risk lesion subsets not be reimbursed in the ASC setting until more safety data are available regarding PCI in an ASC for lower-risk lesions.[8] However, SCAI strongly endorses reimbursement for physiologic and intravascular imaging studies, such as fractional flow reserve (FFR), intravascular ultrasound (IVUS) and Optical Coherence Tomography (OCT), respectively, in an ASC. The reimbursement, availability and utilization of these studies would likely lead to reduced inappropriate PCI and improved clinical outcomes.

Before an ASC can serve governmental payor beneficiaries, the entity must have an agreement with CMS to participate in Medicare as an ASC. Specific federal conditions for coverage can be found on the CMS website.[30] The first condition for coverage states that "The ASC must comply with State licensure requirements," and, therefore, to be eligible for CMS ASC Certification, the Catheterization Laboratory (Cath Lab) must first be licensed as an ASC in that individual state. Furthermore, regulation of the performance of PCI is under state jurisdiction and state licensing criteria that ASCs must meet prior to certification. Not all states allow the performance of PCI in the ASC setting. Some states require a certificate-of-need for a new Cath Lab, which is issued based on proof that the facility fulfills an unmet need in the community. Those considering starting an ASC-based PCI program should understand the legal requirements within their state.

Many ASCs choose to go through voluntary accreditation processes. Accreditation is sometimes referred to as a "third party survey" and is not mandatory for ASCs by federal regulations or to be contracted with CMS Medicare/Medicaid. However, accreditation may be mandatory in some states and with some payers. ASCs can seek accreditation from one of several accrediting bodies: The Accreditation Association for Ambulatory Health Care, Inc (AAAHC), The Joint Commission, or The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), and Healthcare Facilities Accreditation Program (HFAP).

Finally, the ASC's governing body must appoint an individual who has appropriate qualifications in accordance with State and Federal regulations to provide oversight of radiation issues.

TABLE 1 CPT codes approved for reimbursement by CMS

CY 2020 procedural code	CY 2020 procedural code long descriptor
CPT Code 92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch
CPT Code 92921	Percutaneous transluminal coronary angioplasty; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
CPT Code 92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
CPT Code 92929	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
HCPS Code C9600	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
HCPS Code C9601	Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)

Abbreviations: CPT, Current Procedural Terminology; HCPCS, Healthcare Procedure Coding System.

5 | STANDARDS

This writing group believes that a PCI Cath Lab in an ASC needs to meet the standards outlined in the 2012 ACC/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards.[11] The document describes facility design and standards for safe performance of PCI with assurance of staff safety. The document also addresses the requirement of adequate staffing to provide the required level of procedural and periprocedural care and operator competency standards.

5.1 | Facility and equipment standards

Cath Labs must be designed in accordance with industry standards. National organizations, such as the Facilities Guidelines Institute, may be used as a resource to evaluate Cath Lab design and construction.[6,31] Proper safety precautions including adequate radiation shielding for patients and personnel and personal radiation monitoring devices must be maintained.[32] There must be a distinct room within the ASC where patients recover immediately postprocedure. A "room" consists of an area with at least semipermanent walls from floor to ceiling separating it from other areas of the ASC. Adequate equipment for postprocedure monitoring such as telemetry, automated blood pressure cuffs, and pulse oximetry must be available.

The ASC must be equipped with the necessary supplies for PCI. Equipment must also be available to address potentially catastrophic complications, including:

- Pericardiocentesis tray.
- Echocardiography/ultrasound capable of assessing for pericardial effusions.
- Temporary transvenous pacemaker.
- Covered stents.
- Mechanical circulatory support (eg, intra-aortic balloon pump).
- Advanced Cardiac Life Support (ACLS) supplies, medications, and equipment including a defibrillator and a ventilator.
- On-site ASC provider with expertise in endotracheal intubation and airway management.

In addition to emergency equipment, the facility should be capable of performing physiologic lesion assessment. Either IVUS or OCT should also be available for anatomic lesion and stent assessment. Peripheral vascular ultrasound availability is important for safe access and the ability to measure point-of-care activated clotting time is essential.

5.2 | Procedural and periprocedural standards

The SCAI 2016 Best Practices in the Cardiac Catheterization Laboratory document should serve as a guide for clinical management.[14] All staff involved in direct patient care should be ACLS certified. The ASC must ensure that the nursing service is directed under the leadership of an RN. There must be sufficient nursing staff with the appropriate qualifications to address the nursing needs of all the patients. A mechanism to notify other health care personnel in the ASC of any patient emergency should be in place. Finally, the ASC must follow the American Society of Anesthesiology guidelines for sedation.[33]

5.3 | Transfer protocols

For medical emergencies requiring care beyond the capabilities of the ASC, an efficient procedure must be in place to facilitate immediate patient transfer from the ASC to an appropriate receiving hospital. A receiving facility should be located within 60 min travel time by ground or air transportation.[13] Ideally, a written transfer agreement would be in place between the ASC and the receiving facility even though this formality is not mandated by CMS.[34] The local receiving hospital must be either a Medicare-participating hospital, or a nonparticipating hospital meeting emergency services payment requirements per CMS guidelines. An "effective procedure" for immediate emergency transfers includes having an established written policy that addresses the circumstances warranting transfer, parties involved in the transfer decision on both the transferring and receiving end, accompanying documentation, emergency medical services (EMS) communication, and communication with the receiving facility at both a physician and nursing level. The ASC must also have an effective protocol with ambulance services and/or medical flight services to transfer patients requiring emergency services to a management capable hospital in an expedited fashion. An appropriate communication plan must be in place between the ASC and emergency transfer services. There must be evidence that the staff are aware of, and can implement the ASC's policy immediately upon development of, a medical emergency. The ASC must provide emergency care within its capabilities and initiate stabilizing treatment until the patient is transferred.

5.4 | Operator standards

The interventional cardiologist performing the PCI procedure must be licensed in the state in which the ASC is located and must practice within the scope of his/her license. Each physician performing procedures in the ASC must have been determined to be qualified and have been granted privileges under rules established by the governing body of the ASC. The ASC must have written policies and procedures that address the criteria for clinical staff privileges in the ASC and the process that the governing body uses when reviewing physician credentials, determining whether to grant privileges and defining the scope of privileges for each physician. Although all credentialing decisions are local, SCAI strongly endorses interventional fellowship training, board certification, and a minimum annual volume of at least 50 PCI procedures per operator.[16] SCAI also cautions against newly trained interventional cardiologists performing PCI in the ASC setting. The initial guideline for PCI without on-site surgical backup suggested >500 interventions as a primary operator.[35] It is recognized that this number may be difficult to reach in the current era, but it is the opinion of SCAI that PCI in an ASC be performed by experienced operators with an established record of acceptable outcomes. These concerns are of even greater importance in an ASC where additional providers may not be available to assist as the clinical need of the patient dictates.

The governing body is required to solicit the opinion of qualified medical personnel on the competence of the applicant for privileges. ASCs should consider seeking the recommendation of qualified outside physicians when they do not have the appropriate in-house expertise to evaluate the competency of the applicant for privileges. Medical staff privileges must be periodically reappraised by the ASC.

An explicit written policy should indicate how the medical staff is held accountable by the governing body. It is possible for an ASC to be owned and operated by one physician who is both the sole member of the governing body and also the sole member of the ASC's medical staff. In such cases, the physician owner must still implement a formal process for complying with all medical staff regulatory requirements.

6 | SCOPE OF PROCEDURES

Although many cardiovascular procedures can potentially be performed in an ASC, this position paper addresses adult PCI and diagnostic cardiac procedures only. Previously, procedures that may be unsuitable for PCI without on-site cardiac surgery have been described[11,13] and similar cautions apply to ASCs. As in the hospital setting, PCI may be performed "ad hoc" with a similar decision-making process.[12] However, there are additional concerns unique to the ASC setting that must be considered when proceeding to PCI.

6.1 | Appropriate patients and procedures

A concurrent SCAI document detailing state-of-the-art practice for complex CAD provides guidance regarding site performance locations for such patients.[3]PCI in patients with high-risk clinical features should be avoided in the ASC setting (Table 2). Lesions with complex features and those associated with higher complication rates should also be avoided in an ASC setting (Table 3). Elective procedures possibly requiring mechanical circulatory support should not be performed in ASCs, although the ability to emergently insert an intra-aortic balloon pump should be readily available.

TABLE 2 Unfavorable patient conditions warranting PCI deferment to the hospital setting

1	Decompensated CHF (NYHA class 3–4)
2	Recent TIA/stroke (<8 weeks)
3	Left ventricular ejection fraction <30%
4	Chronic kidney disease with an estimated glomerular filtration rate < 45 ml/min/1.73 m^2
5	Anemia (Hgb < 9 g/dl) or coagulopathy (eg, INR >1.5 or platelet count <100 K)
6	Acute coronary syndrome
7	Severe pulmonary hypertension or disease (advanced COPD or patients on supplemental oxygen)
8	Unprotected left main stenosis or three-vessel CAD
9	Any cardiac or noncardiac signs of clinical instability
10	Significant PAD limiting femoral and radial access
11	Severe aortic stenosis
12	Severe contrast allergy
13	Operator judgment on other condition(s)

Abbreviations: CAD, coronary artery disease; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; Hgb, hemoglobin; INR, international normalized ratio; PAD, peripheral artery disease; TIA, transient ischemic attack.

Diagnostic procedures (eg, left and right heart catheterization, coronary and graft angiography) are appropriate for ASCs. Invasive diagnostic testing that involves intravascular imaging (IVUS and/or OCT) or functional evaluation (FFR and/or resting indices) and coronary angioplasty and stenting are appropriate in an ASC. As discussed earlier, bypass graft PCI, coronary atherectomy, CTO PCI and PCI for acute coronary syndromes have higher complication rates and should be avoided in the ASC setting. These procedures are also not reimbursed by CMS when performed in an ASC. Until safety for lower risk PCI in an ASC can be demonstrated across the country in large populations, these and other more complex interventions should be restricted to a hospital environment.[3] The SCAI PCI risk calculator may be a useful tool for guiding decisions regarding the most appropriate setting for a specific patient. The calculator can be accessed at www.scaipciriskapp.org.

Only patients who are appropriate for SDD should be considered for intervention in an ASC. The 2018 SCAI Expert Consensus Document on Length of Stay Following PCI provides guidance on patient suitability for SDD.[17] However, not all patients that might be suitable for SDD in the hospital setting are appropriate for ASC-based PCI. The ASC setting does not provide the option of easily converting a patient to overnight observation. For example, a bifurcation intervention might be suitable for SDD but if there is side branch loss it would need to be converted to an overnight stay. The probability of such an event must be carefully considered in the ASC setting Another consideration is the lack of ancillary support in the ASC setting. Patients that might require additional resources postprocedure (eg, respiratory therapy, dialysis) would not be appropriate for the ASC setting. Patients must also have transportation home, adequate social support and reliable follow-up.

It is recommended that all ASC PCI facilities have a protocol in place that guides patient selection and procedural decision making. All operators should be educated on the protocol and monitored for adherence. Copies of the protocol should be kept on-site and readily accessible to all operators and staff. A suggested protocol is depicted in Figure 1 and Table 4. It is also encouraged that a "radial first" approach be utilized for ASC PCI. Radial access is ideal in the ASC setting to minimize bleeding, access site complications, reduce staff workload, and decrease the risk of an overnight observation for femoral access site concerns.[15]

TABLE 3 Complex or high-risk lesion characteristics warranting PCI deferment to the hospital setting

1	Bifurcation lesions with significant side branch involvement
2	Severe lesion calcification
3	Extremely angulated segment or excessive proximal tortuosity
4	Bypass graft lesions
5	Chronic total occlusions
6	Other vessel characteristics that the operator judges would impede stent deployment
7	Thrombus in target vessel or lesion
8	Unprotected left main lesions
9	Last remaining conduit
10	Possible need for upfront mechanical circulatory support

7 | ONGOING QUALITY

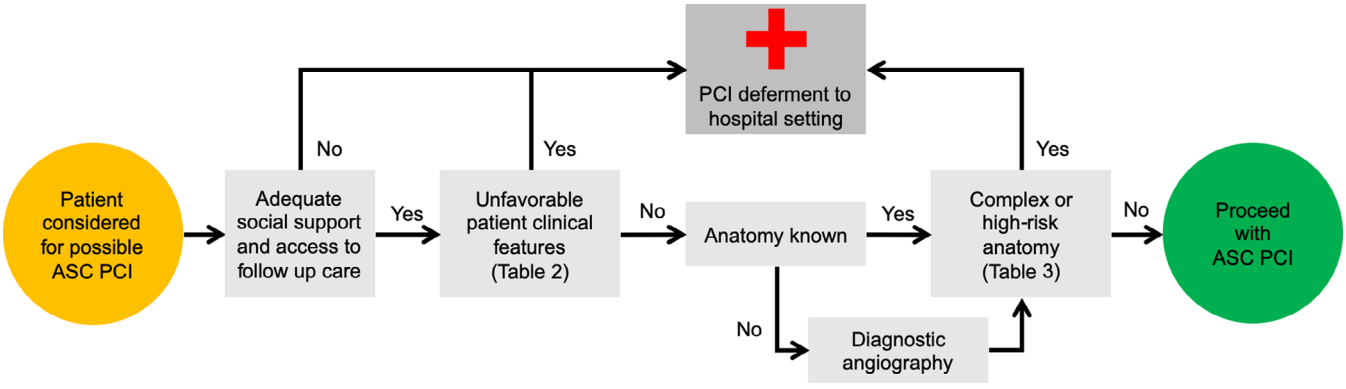
PCI in the ASC site of service should be performed with the same expectations for quality as in the hospital. A quality program must be in place to evaluate procedure appropriateness, technical performance, and assurance of quality of care. The SCAI/ACC/AHA Expert Consensus Document on PCI Without On-Site Surgical Backup contains recommendations applicable in the ASC setting.[13] In addition, key components of a recommended quality program have been recently outlined by SCAI but would need to be modified to account for the ASC environment.[14] Key topics to cover for ASCs are outlined in Table 5.

Participation in a PCI registry that is specifically designed or modified for the ASC setting will be necessary for ongoing quality assurance. This can be accomplished by the creation of a new outpatient PCI registry or through leveraging existing national cardiovascular registries, such as the NCDR CathPCI registry. Registry data should be used to monitor PCI operator and institutional volumes, outcomes, and procedural appropriateness.[36] This would allow benchmarking, establishment of performance standards and appropriate risk adjustment for evaluation of outcomes. There is no current registry specific to PCI in an ASC. The Outpatient Endovascular and Interventional Society (OEIS) has developed a national registry that is a Qualified Clinical Data Registry (QCDR) focused on outcomes within outpatient interventional suites (OIS) and ASCs.[37,38] While this QCDR only supports a peripheral vascular interventional module, the OEIS plans to offer a single cardiac module specifically focused on all cardiac interventions performed in the OIS and ASC. The NCDR CathPCI registry is well established but does not yet accept submission of data from ASCs and does not include metrics specific to the ASC site of service. The development of a registry suitable for assessing ASC PCI quality metrics is needed. It is imperative that such a registry be developed with consideration of the potential administrative burden that participation might have on an ASC and should only include essential quality assurance metrics. Data abstraction teams, as are typically found in the hospital setting, may not be financially sustainable in the ASC environment at the current reimbursement rates.

CMS is finalizing the Ambulatory Surgical Center Quality Reporting (ASCQR) Program to enhance the quality of care in the outpatient surgical setting. The ASCQR Program is a pay-for-reporting quality program for the ASC setting that requires an ASC to meet quality reporting requirements or else undergo a 2.0 percentage point reduction in its annually updated fee schedule. Relevant patient safety measures that are currently reported to CMS include all-cause hospital transfer/admission.[37] These measures for ASCs were developed because the transfer or admission of a surgical patient from an outpatient setting to an acute care setting could be an indication of a complication, serious medical error or other unplanned negative patient outcome. The ASCQR program should be improved with specific SCAI-recommended measures that would help better evaluate the safety of PCI in the ASC setting.

8 | ETHICAL CONSIDERATIONS

All ASC operations and clinical care must be conducted consistent with The American Medical Association Code of Medical Ethics.[39] The physician and the ASC have an ethical duty to place patient's interests first. This core value should guide the ASC's code of conduct. Ownership in an ASC presents a potential conflict of interest that requires active guidance, policy development and approaches to address this issue. ASC ownership may include a combination of physician investors and/or a regional/national business enterprise. In addition to the ownership of the ASC, physician-owned intermediaries (POI) have been developed to provide additional potential financial compensation via the sale of medical devices to the ASC. This provides a potential conflict as medical decision making could be impacted by implanting devices that result in a financial benefit to the



ASC=Ambulatory Surgical Center; PCI=percutaneous coronary intervention; Table 2. Unfavorable Patient Conditions Warranting PCI Deferment to the Hospital Setting; Table 3. Complex or High-Risk Lesion Characteristics Warranting PCI Deferment to the Hospital Setting

FIGURE 1 Patient pathway for ambulatory surgical center percutaneous coronary intervention (ASC PCI; Tables 2 and 3)

TABLE 4 Ambulatory surgical center PCI performance checklist

Prescheduling assessment:

- Confirmed transportation after procedure
- Adequate social support at home. Adequate caregiver at home the evening of discharge
- Patient resides or stays in close geographic proximity (≤ 30 min driving time) to a hospital capable of providing emergency care for complications that could occur after discharge
- No unfavorable patient clinical features or PCI indications (Table 2)
- No known complex/high-risk anatomical features (Table 3)
- Patient fully understands plans for ASC PCI and same day discharge

Morning of procedure assessment:

- Transportation, social support and postdischarge geographic location confirmed
- Patient signed informed consent and disclosures regarding relevant financial interests of the interventional physician
- Patient evaluated by physician and confirmed to be appropriate for ASC PCI

Post-PCI assessment:

- Favorable PCI features:
  - Successful PCI: <30% residual stenosis with final TIMI 3 flow
  - Transradial approach (preferred but not mandatory)
  - Successful access site hemostasis
- Unfavorable PCI features (consider patient transfer to hospital setting if present)
  - Loss of side branch >1 mm in diameter
  - Significant no-reflow during the procedure
  - NHLBI Type B-F dissection in the target vessel at the end of the procedure
  - Intracoronary thrombus that arose during the procedure
  - Transient vessel closure during the procedure likely to precipitate significant infarction
  - Vascular access complication
  - Any cardiac or noncardiac instability during PCI
  - At the discretion of the attending physician
  - Patient preference to stay overnight

Predischarge assessment:

- Absence of chest pain, access site hematoma and cardiac rhythm abnormalities
- Four hours of observation completed
- ECG prior to dismissal reviewed and without significant change
- Follow-up appointment scheduled within 1–2 weeks
- Patient is able to obtain DAPT and other prescriptions by the following morning
- Patient accompanied by an adult at the time of discharge and at home

Abbreviations: ASC, ambulatory surgical center; DAPT, dual antiplatelet therapy; ECG, electrocardiogram; NHLBI, National Heart Lung and Blood Institute; PCI, percutaneous coronary intervention; TIMI, thrombolysis in myocardial infarction.

physician and/or ASC. The three types of POI include the distributor POI, manufacturer POI and the group purchasing organization.

Important principles to consider in order to address this issue are as follows:

TABLE 5 Key features of a high-quality ASC PCI program

Preprocedural	Procedural	Postprocedural
Appropriate informed consent including risk of transfer for complications	Established criteria for high-risk coronary anatomy that require transfer for safe PCI performance	Appropriate documentation of required data elements for cath and PCI reporting
Appropriately trained staff and PCI operators	Appropriate training/ supplies for conscious sedation	Registry participation to evaluate procedural outcomes and appropriateness
Established quality insurance program for continuous peer review of quality and outcomes	Emergency preparedness protocols in place	Established criteria for clinical indications for transfer to acute care facility
Written transfer agreements with hospitals and surgeons	Mock transfer drills with EMS and "receiving" hospital	Evaluation of acute care required within 1 month after discharge
Established clinical criteria for determination of high-risk patients	Ability for real-time image review for CT surgical consultation	Appropriate clinical follow-up scheduled within 1–2 weeks of PCI

Abbreviations: EMS, Emergency Medical Services; PCI, percutaneous coronary intervention.

1. Remuneration should not be based on utilization and/or referrals. Neither the ASC, nor other investors, should provide loans to potential new physician investors.
2. Fee splitting is illegal. Payment by a physician to another physician/clinician for referrals should not occur.
3. A robust quality assurance and utilization review program should be implemented to monitor physician self-referral.
4. Referral to the ASC versus hospital should be determined by medical policy developed on evidence- or consensus-based principles.
5. Administrators/management should not pressure physician investors who select alternative sites for patients to receive care.
6. Policies should be developed that support the ability of physicians to care for patients more likely to experience disparities in care based on social demographics and/or insurance status.

Federal law, including Stark Law exceptions and Anti-Kickback Statute safe harbors, coupled with ethical principles, dictate that the physician must disclose both ownership and additional compensation factors to patients making informed choices. Ideally, disclosures would be performed before the patient arrives at the ASC for a procedure. Best practices would include:

1. Disclosure to the patient of ownership interest.
2. Disclosure to the patient of additional structure, which impacts physician compensation.

3. Disclosure, when requested by the patient, of a full list of investors.
4. Information regarding alternative choices including other ASCs and hospitals for patients.

9 | CONCLUSION

Interventional cardiology continues to be an innovative and rapidly evolving field that offers increasing safety for selected patients undergoing PCI. As performing PCI in an ambulatory environment can be performed safely and is now reimbursed, it is important to establish the optimal strategy and model to keep doing so. The decision to perform PCI in an ASC must be made in the context of the local healthcare environment, while initiation of an ASC PCI program requires transparent adherence to state and federal regulations and operational standards. Patients should receive the same quality of care regardless of the procedural site of service and ongoing quality assurance monitoring will be imperative for the long-term success of this endeavor. This SCAI writing group believes that it has laid a foundation of principles to promote safe performance of elective PCI in ambulatory surgery centers.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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CORE CURRICULUM

WILEY

SCAI expert consensus update on best practices in the cardiac catheterization laboratory

This statement was endorsed by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Rhythm Society (HRS) in April 2021

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Abstract

The current document commissioned by the Society for Cardiovascular Angiography and Interventions (SCAI) and endorsed by the American College of Cardiology, the American Heart Association, and Heart Rhythm Society represents a comprehensive update to the 2012 and 2016 consensus documents on patient-centered best practices in the cardiac catheterization laboratory. Comprising updates to staffing and credentialing, as well as evidence-based updates to the pre-, intra-, and post-procedural logistics, clinical standards and patient flow, the document also includes an expanded section on CCL governance, administration, and approach to quality

metrics. This update also acknowledges the collaboration with various specialties, including discussion of the heart team approach to management, and working with electrophysiology colleagues in particular. It is hoped that this document will be utilized by hospitals, health systems, as well as regulatory bodies involved in assuring and maintaining quality, safety, efficiency, and cost-effectiveness of patient throughput in this high volume area.

KEYWORDS
appropriate use, evidence-based medicine, econonics/cost-effectiveness, electrophysiology, health care outcomes, health care policy

1 | INTRODUCTION

This update to the Society for Cardiovascular Angiography & Interventions (SCAI) Expert Consensus Statement on Best Practices in the cardiac catheterization laboratory (CCL) builds upon previous statements in 2012 and 2016. Key tenets have remained, including patient-centric approach to the flow of patients through the laboratory, consistency with the requirements of regulatory and accreditation bodies, and contemporary standards incorporating new evidence. This clinical expert consensus statement pertains primarily to diagnostic and therapeutic coronary artery procedures, with somewhat less attention to structural or other procedures. Nonetheless, the general principles established here would apply to most structural and endovascular procedures, and a section on the collaboration with electrophysiology has also been included. Importantly, the purpose of this document is not to represent all acceptable practices, but to provide a consensus on "best practices" as goals for CCL. It is anticipated that regulatory bodies, accrediting organizations, hospitals and health systems, CCL directors and managers, as well as hospital administrators will reference this document for process improvement and standardization. Moreover, this document should serve as a guide for new CCLs, including both outpatient (ambulatory) and inpatient facilities.

2 | METHODOLOGY

This document has been developed according to SCAI Publications Committee policies for writing group composition, disclosure and management of relationships with industry (RWI), internal and external review, and organizational approval.[1]

The writing group has been organized to ensure diversity of perspectives and demographics, multi-stakeholder representation, and appropriate balance of RWI. Relevant author disclosures are included in Table S1. Before appointment, members of the writing group were asked to disclose all financial RWI from the 12 months prior to their nomination. A majority of the writing group disclosed no relevant financial relationships. Disclosures were periodically reviewed during document development and updated as needed. SCAI policy requires that writing group members with a current financial interest are recused from participating in discussions or voting on relevant recommendations. The work of the writing committee was supported exclusively by SCAI, a nonprofit medical specialty society, without commercial support. Writing group members contributed to this effort on a volunteer basis and did not receive payment from SCAI.

Literature searches were performed by group members designated to lead and contribute to each section and initial section drafts were authored by the respective section teams. Recommendations were discussed by the full writing group during a series of virtual meetings until all authors agreed on the text and qualifying remarks. All recommendations are supported by a short summary of the evidence or specific rationale.

The draft manuscript was peer reviewed in December 2020 and the document was revised to address pertinent comments. The writing group unanimously approved the final version of the document. The SCAI Publications Committee and Executive Committee endorsed the document as official society guidance in April 2021.

3 | INSTITUTIONAL AND OPERATOR QUALIFICATIONS AND COMPONENTS OF AN OPTIMAL CCL PROCEDURAL TEAM

3.1 | Provider/institutional competence and documentation

All physicians must maintain procedure-specific credentialing and privileging by their institution, typically requiring certification by the American Board of Internal Medicine (ABIM), American Osteopathic Association (AOA), or National Board of Physicians and Surgeons (NBPAS).[2] Each CCL should have a procedure for recertification of privileges. This is usually required every 2 years by accrediting bodies in health care. The most commonly used accrediting agency, The Joint Commission (TJC), also requires the completion of ongoing professional practice evaluations, typically performed twice yearly, for all physicians. TJC also mandates completion of a focused professional practice evaluation for newly hired operators, established operators requesting permission to perform a new procedure, and established operators performing a procedure in case of a perceived problem.[3] Case volume should be documented by CCL administration on a biannual basis. In addition, procedural outcomes including success rates and observed in-hospital complications, should be documented. Risk adjustment models are recommended to put these observed

outcomes in perspective.[4,5] Participation in national or regional quality improvement registries, such as the National Cardiovascular Data Registry (NCDR) Cath-percutaneous coronary intervention (PCI) registry, is necessary to meet quality standards.[6] In addition, physicians should participate in at least quarterly quality improvement, peer review, and/or morbidity and mortality (M&M) meetings with film review as appropriate to maintain privileges, as well as participate in post-procedural appropriateness evaluations. Other members of the team may be invited to participate in these meetings as appropriate. Technologists are strongly encouraged to obtain Registered Cardiovascular Invasive Specialist certification, and nursing staff ideally should have a minimum of 1 year of critical care experience. In addition, nursing, physician assistant (PA), and technologist staff must comply with continuing education requirements for their state(s) or certifying bodies, which may include ongoing certification for ACLS and/or BLS.

Clinical competence guidelines state that to maintain proficiency while keeping complications at a low level, a minimum volume of 200 PCIs/year be achieved by all institutions.[2] In addition, although the clinical competence guidelines acknowledge only a moderate correlation between operator PCI volume and mortality, for each operator a minimum PCI volume of 50/year is recommended, averaged over 2 years. That said, a recent report from the NCDR showed that around 40% of operators in the United States perform less than 50 PCIs/year.[7] The performance of primary percutaneous coronary intervention (PPCI, PCI in the setting of acute ST-elevation myocardial infarction [STEMI]) requires an additional cognitive and technical skill set for both operator and CCL team; therefore, it is recommended that operators perform 11 PPCI/year and that institutions should perform 36 PPCI/year.[2]

It is recognized that the breadth of procedures performed in the CCL continues to expand and includes peripheral vascular and structural heart procedures. In addition, some labs also perform transcatheter aortic valve replacement (TAVR), as well as electrophysiological procedures including diagnostic studies, therapeutic ablations, and device implantation. It follows that issues of involvement in appropriate registries, institutional and physician volume requirements, and quality assurance (QA) be tailored to include the entirety of procedures offered in any laboratory. In alignment with the current CMS National Coverage Determination (NCD) for reimbursement of TAVR, it is recommended that institutions perform ≥30 surgical aortic valve replacements (SAVRs)/year (or 60 over 2 years), ≥300 PCIs/year, and ≥50 TAVRs/year (or 100 over 2 years). In regards to transcatheter edge-to-edge repair procedures such as MitraClip, the 2019 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Mitral Valve Intervention recommends that an institution should perform ≥20 transcatheter mitral valve interventions/year (or ≥40 interventions every 2 years); ≥20 mitral valve surgeries per year (or ≥40 every 2 years); and perform ≥300 PCIs per year.[8] SCAI guidance on PFO and LAAO procedures have also been published.[9,10] As new procedures develop, similar types of standards will undoubtedly evolve.

For hospitals without on-site cardiac surgery, oversight to ensure the quality of procedures is paramount.[2,11] Less experienced operators should have additional oversight, such as backup support. The CPORT-E Trial serves as a model for facilities performing PCI without on-site cardiac surgery.[12] Consistent with its design, such facilities should participate in national registries, routinely utilize risk adjustment tools, have immediately available consultation with a tertiary care center, implement cross training of personnel, and have a well-developed system for emergent transfer if clinically indicated. In addition, CMS provides reimbursement for PCI procedures in freestanding ambulatory surgical centers (ASCs). These freestanding facilities have important differences in infrastructure and oversight that have implications for standards. The recent SCAI position statement on the performance of PCI in ASCs addresses the issues important to safe performance of procedures in this novel setting.[13] In brief, such laboratories should meet the same standards of design as those within acute care hospitals. Of importance, and similar to hospitals without on-site cardiac surgery, ASCs should have protocols in place for immediate consultation and transfer to tertiary care centers in case of untoward outcomes. In addition, the scope of procedures in ASCs should exclude patients who have unfavorable clinical characteristics and coronary anatomy.[14] For both hospitals without on-site cardiac surgery backup and ASCs, high-risk EP procedures such as complex VT ablation and lead extraction should be avoided.

3.2 | Optimal catheterization laboratory team

A multidisciplinary approach within the CCL is necessary. The primary operators must be adequately trained and credentialed. They are usually assisted by a physician trainee and/or physician extender (e.g., certified radiology or cardiovascular technologist, PA, or nurse). Typically, one to two non-physician CCL staff are tableside when there is no physician trainee, with an additional two CCL staff serving in "circulating" and "monitoring/recording" roles, with flexibility on the non-physician staffing ratio depending on the complexity of the case. For primary PCI, three non-physician staff are required. Tableside assistants must be trained in the setup of manifolds, automatic contrast injectors, the use and preparation of wires, catheters, balloons, and other devices, as well as in radiation safety and sterile technique. Appropriate staffing to ensure an adequate nurse-to-patient ratio should be ensured. A nurse administering moderate sedation during the procedure should not have other responsibilities that could compromise patient assessment. In cases where more than moderate sedation is used, an anesthesia provider should be present, and policies should be drafted for the administration of medications that are consistent with hospital credentialing and state guidelines.

3.3 | The heart team

The concept of the Heart Team stems largely from the design of large, randomized trials where specialists from different disciplines have been asked to render opinions regarding equipoise between two procedural approaches. The 2014 ACC/AHA/AATS/PCNA/SCAI/STS Focused Update of the Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease elevated the Heart

Team approach to a IC recommendation for patients with diabetes mellitus and complex coronary artery disease.[15] This approach is consistent with a number of clinical trials for coronary disease and is routinely utilized in TAVR. With regards to stable coronary artery disease, the team centers around cardiac surgeons and interventionalists, although other stakeholders including general cardiologists, imagers, anesthesiologists, and palliative care providers often play a role. It is recommended that hospitals have a formal process for Heart Team consultations on those patients with clinical or anatomical complexity.

3.4 | Maintenance of qualifications

ABIM or AOA certification in interventional cardiology is required for operators who completed fellowship training after 1993 and is strongly recommended for all operators. After the first certification, ongoing recertification by either ABIM or NBPAS is also strongly recommended. Utilization of national benchmarking and self-assessment tools such as the NCDR registries, hospital or CCL quality data, and patient satisfaction data is highly encouraged. Physician and CCL staff membership in professional societies such as SCAI and the American College of Cardiology (ACC) is highly encouraged. CCL staff should obtain, at a minimum, the continuing education units as required by the respective state. Physicians should also complete appropriate continuing medical education and/or maintenance of certification hours/points to satisfy hospital, state, and board regulations.

4 | PRE-PROCEDURE BEST PRACTICES

4.1 | Procedure indications and history and physical examination

Procedural indications should be well documented and reconciled with published appropriate use criteria (AUC). Key variables (e.g., anginal class and medication use) must be documented to confirm appropriateness.[16,17] An on-line application is available to assist in this process.[18] Supporting data, such as a pre-procedure electrocardiogram (ECG), prior cardiovascular procedures or surgeries, echocardiography, coronary computed tomography (CT) angiography, and/or stress testing results should be described.[16] For procedures with "rarely appropriate care" ratings, additional documentation should be included to explain why the procedure is appropriate for the particular patient.

All patients must have a history and physical examination (H&P) prior to the procedure, performed by either a physician or an advanced practice professional (APP) (e.g., PA or nurse practitioner). For emergency procedures, a targeted history and limited physical examination are reasonable, with more complete information added following the procedure. For outpatient procedures, a timed and dated H&P within 30 days or according to local hospital policy is acceptable, with a focused update by the attending physician or APP within 24 h prior to the procedure. This update should reflect any changes in history, physical examination findings, test results, or medications. For inpatients, an H&P should be performed within 24 h of admission or registration. This H&P should include the history of the present illness along with Canadian Cardiovascular Society angina and New York Heart Association heart failure classes as appropriate, documentation of relevant medications, including those received within the last 48 h, relevant comorbidities, and a focused review of systems, concentrating on the systems encountered during cardiac catheterization. Any history of contrast reaction or other allergies should be documented, including the specific reaction. Potential issues related to antiplatelet or anticoagulant therapy, such as a concomitant requirement for long-term oral anticoagulation, and barriers to long-term dual antiplatelet therapy (DAPT) adherence should be noted. The history should note any prior airway or moderate sedation issues.

The physical examination should be focused on the cardiopulmonary and vascular system and document peripheral pulses.[19,20] In addition, because the patient may undergo sedation, airway assessment should be performed as described below. Orthopedic, neurologic, or other conditions that might impact the performance of the procedure (e.g., an inability to remain supine) should be noted.

4.2 | Informed consent process

Informed consent (IC) is a legal, patient-oriented process. The patient must be competent and voluntarily provide consent; otherwise, a person with power of attorney may act as a surrogate. Any barriers to understanding should be evaluated and addressed, such as language, health literacy, and cultural issues.[21] A patient who has been sedated is not considered competent to provide IC. IC is necessary before every procedure and is consistent with the ethical principles of patient autonomy.[22] Each institution should have a written policy on IC that describes the process used to obtain consent, including timing, documentation, and surrogate decision-maker issues, as well as circumstances that would allow for exceptions to obtaining IC, such as emergency STEMI in a patient unable to provide consent.

Ideally, the IC process should include a shared decision-making discussion prior to arrival in the CCL and IC itself should be performed in a neutral environment. According to the 2012 ACC/SCAI Expert Consensus Document on Cardiac Catheterization Standards Update, "the written informed consent may be obtained by trained secondary operators or APPs, but the major concerns should be reiterated when the primary operator discusses the procedure with the patient."[23] The IC discussion should be in the patient's native language, using terms that allow a layperson to understand what the procedure entails; the risks, benefits, and alternatives to the procedure proposed, including the risks of alternative or no treatment; and potential outcomes and complications that may occur during and after the procedure.[24,25] For procedures occurring without onsite surgical backup, or without the ability to perform same sitting coronary intervention, alternatives should also be discussed with the patient during the consent process.

Potential treatments that may result from the findings of a diagnostic procedure (e.g., ad hoc PCI and its attendant risks) should be

reviewed, as well as issues surrounding DAPT and restenosis for coronary interventions. As a discussion of all possible risks may not be possible, the standard is that the risks that a reasonable person would want to know to make a decision regarding the procedure should be discussed, usually defined as the most serious risks (e.g., death, stroke, heart attack, transfusion, vascular injury), the most common risks (e.g., bleeding, defibrillation), and any elevated risks specific to the patient. The consent should also indicate a risk of complications that could result in treatment with emergency procedures or even transfer to another facility in unusual circumstances.

The consent may be obtained within 30 days of a procedure but must be reaffirmed on the day of the procedure and recorded in the medical record. It is important to review institutional policy on timing of the consent document, requirement for a witness, and requirements surrounding documentation of code status. If the patient has a do not resuscitate (DNR) code status, it is important to discuss temporary suspension with the patient or health care proxy and document the terms and duration of the temporary suspension. Ideally all aspects of the IC discussion should be documented, including details disclosed to the patient, questions asked and answered, and persons present during the IC discussion.

4.3 | Pre-procedure risk assessment and decision-making tools

SCAI has developed an online risk calculator (http://scaipciriskapp.org/porc) that uses pre-procedural patient information to estimate post-intervention risks for mortality, acute kidney injury, and transfusion. Ideally, risk calculators should be used to estimate pre-procedure risk prior to IC and specific risks should be discussed with the patient and be documented.[18,26,27] These tools can aid in the IC process by increasing patient knowledge, understanding, and engagement in the decision-making process.[25,28–30]

4.4 | Sedation, anesthesia, and analgesia evaluation

While some procedures require general anesthesia, including complex valve procedures and complex ablations, moderate sedation/analgesia is frequently sufficient to minimize patient discomfort and anxiety and is usually ordered by the performing physician. The need for moderate sedation can be individualized by the treating physician, and anxiolysis or pain control alone may suffice for coronary artery procedures. The American Society of Anesthesiologists (ASA) has defined a continuum of depth of anesthesia and has established guidelines in this area for the training and credentialing of physicians.[31] Physicians in the CCL should be credentialed by their hospital for providing moderate sedation/analgesia, typically referred to as "conscious sedation." Monitoring of the level of sedation, pulmonary ventilation, and oxygenation should be performed during the procedure and documented by the staff. ASA and Mallampati classification as part of the pre-sedation assessment is required in some hospitals, although there is no direct evidence to support this process in the CCL. For elective procedures, the 2017 guidelines from the ASA are typically followed, although there is growing consensus that they may be too stringent for the CCL. These guidelines recommend that clear liquids may be ingested up to 2 h prior to a procedure and light meals up to 6 h prior to a procedure (and 8 h for heavier meals).[32] However, a recent study compared safety and clinical outcomes of a non-fasting strategy as compared to the current standard fasting preparation, and found no difference in clinical outcomes.[33] Further investigation will be required to evaluate this finding as this practice is not yet supported by guidelines. It is important to note that nothing by mouth (NPO) instructions are typically waived for emergency procedures, recognizing some potential increased risk of aspiration.

4.5 | Patient preparation within 48 h and immediate pre-procedure checklist

4.5.1 | Medications

Patient medications should be reviewed with attention to those that could impact the conduct or outcome of the procedure.

Anti-platelet agents

When PCI is planned or anticipated, loading with aspirin 324 mg po (chewed) should be performed before the procedure if the patient is not already on daily aspirin. Loading before the procedure with a P2Y12 inhibitor is reasonable, although there is no evidence that pre-loading decreases ischemic complications compared to loading at the time of PCI or at its conclusion. Delaying P2Y12 loading until anatomy is known may prevent delays if that anatomy demonstrates a need for CABG.

Anticoagulants

When weighing the decision for interrupting anticoagulation therapy, the operator must balance the risk for access site bleeding with risks for ischemic or thrombotic events. This will include assessing the choice of access site, the projected risk of bleeding, the indication for the anti-coagulation, and the urgency and complexity of the procedure. When femoral access is planned, warfarin therapy is generally held until the international normalized ratio (INR) is <1.8, although there is little direct evidence to support this. For femoral access, direct oral anti-coagulants (DOACs) should be discontinued at least 24–48 h before the procedure based on operator perception of bleeding risk.[34] DOACs should be discontinued >48 h before the procedure if the GFR is reduced resulting in prolonged half-life. When radial access is planned, similar guidelines are followed, although evidence has shown that PCI with continuation of warfarin is generally safe when using radial access and PCI on warfarin is as safe as a bridging strategy while causing less minor bleeding.[35,36] Importantly, as radial access is feasible in the majority of cases, a routine strategy of continuing anti-coagulation may also be reasonable, recognizing that non-access site

bleeding may also occur. If radial access fails when anticoagulation has not been discontinued, the procedure may need to be delayed until anticoagulation is normalized. In emergency situations, Vitamin K or fresh frozen plasma may be considered for patients on warfarin and reversal agents can be used for patients taking DOACs.[37] There is a growing body of literature in electrophysiology suggesting maintenance of anticoagulation is safe for device placement, generator changes, and in AF ablations to minimize risk of stroke.[38]

Statins

High dose statins before PCI have a IIA recommendation in the 2011 ACCF/AHA/SCAI PCI guidelines to decrease the incidence of peri-procedural MI and therefore should be considered.[39–41]

Hypoglycemics

Long-acting insulin doses should be held starting the night before PCI. Short-acting insulin doses should be reduced by half on the morning of the procedure. Oral hypoglycemics should be held on the morning of the procedure and metformin should be held for 48 h after the procedure in those at risk of CKD or with contrast-induced nephropathy (CIN).[23,42] SGLT2 inhibitors and GLP-1 receptor antagonists may have beneficial effects during PCI and are unlikely to cause hypoglycemia, so they should not be held before PCI.[43,44]

Renin angiotensin blockers

Angiotensin converting enzyme inhibitors and angiotensin receptor blockers can be nephrotoxic and it has become common practice to hold them before catheterization.[45,46] Withholding these medications may cause hypertension during the procedure, and impact resting hemodynamics, and therefore the decision to hold or continue them should be individualized.

Diuretics

Diuretics are commonly held before PCI to prevent dehydration, which is a risk factor for acute kidney injury. However, in patients for whom determination of accurate steady-state hemodynamics and filling pressures are required, it may be reasonable to continue diuretics.

4.5.2 | Pre-procedural studies

Blood tests

Outpatients should have a complete blood count and metabolic profile within 30 days of the cath lab procedure. Ideally results would be available before the day of the procedure so that the procedure can be re-scheduled if unexpected abnormalities are identified. Patients with baseline renal insufficiency or on chronic warfarin (or liver dysfunction) should have glomerular filtration rate and prothrombin time (PT)/INR respectively checked on the day of the procedure. Routine PT/INR is not needed for healthy patients not taking warfarin. Serum or urine pregnancy testing (beta HCG) must be offered to women of child-bearing age and should be obtained prior to the procedure.[47]

Electrocardiograms

ECG should be obtained within 30 days prior to the procedure and should be repeated on the day of the procedure if there has been any recent change in clinical status.

Chest X-ray

Chest X-rays are not routinely needed before catheterization laboratory procedures but are appropriate if the pre-procedural evaluation suggests pulmonary congestion or new lung pathology.

Prior catheterization laboratory imaging

When available, angiograms from prior procedures should be reviewed along with prior catheterization or CT chest reports to identify problems with vascular access or coronary cannulation and how they were resolved. Records of coronary bypass graft surgeries should be reviewed, with careful attention to details of origin and distal anastomoses of grafts.

4.5.3 | Chronic kidney disease

Patients with baseline renal insufficiency (eGFR <60 ml/min/1.73 m^2) and/or elevated risk scores are at increased risk of developing CIN. The only strategies consistently shown to reduce the risk of CIN are hydration and minimizing the contrast dose.[39,48] Pre-procedure intravenous (IV) hydration with normal saline should be provided in patients at increased risk for CKD if not contraindicated. Administration of N-acetylcysteine does not offer a significant benefit and is no longer recommended.[39,48,49] In addition, the total contrast dose should be monitored, and risk scores can be helpful in identifying a suggested limit.[27,50] One tool uses the ratio of contrast volume to creatinine clearance (CrCl), with a ratio of contrast volume/CrCl >3.7 as predictive of renal injury.[50,51] In addition, particularly for those with compromised renal function, a strategy of recording the left ventricular end diastolic pressure and using it to guide fluid administration during the procedure should be considered.[52] Recent literature suggests that optimal use of intracoronary imaging may reduce contrast dose and is a developing strategy.[53]

4.5.4 | Allergies

Allergies to latex, contrast, heparin (and history of heparin-induced thrombocytopenia), aspirin, narcotics, anti-platelet agents, and other medications should be reviewed, and type of allergy documented. If an allergy is present, avoidance of the offending agent is the ideal strategy with use of alternatives, such as use of bivalirudin in heparin allergic patients. However, if contrast allergy or aspirin allergy is present, alternatives are limited, and appropriate precautions need to be taken.

Contrast allergies can be addressed with upfront use of steroids though there are no randomized trials, and a small risk remains despite pre-treatment. Each CCL should have a protocol for preventing contrast reactions including the use of oral

prednisone over at least 13 h prior to the procedure (50 mg prednisone at 13, 7, and 1 h prior to procedure) and a protocol for urgent/emergent IV steroid administration.[39,54,55] For emergent catheterization procedures of patients with a history of prior contrast reactions, a strategy of using an emergency medication preparation followed by immediate catheterization appears to be associated with a very low risk of break-through contrast reactions.[56] In addition to steroids, diphenhydramine and H2 blockers can be considered.[57,58] Shellfish allergy is not a predictor of contrast reactions and does not require pretreatment.

If an aspirin allergy is present, an aspirin desensitization protocol should be considered prior to stent placement when possible or after emergency placement with consideration of an IV antiplatelet agent in the interim.[59] Alternatively, non-aspirin monotherapy using oral P2Y12 inhibitors may be considered but large trials of this approach are lacking and this approach is not well studied.[60]

4.6 | Considerations for the choice of vascular access

It is recommended that all operators develop and maintain competency in both radial and femoral arterial vascular access, and that vascular ultrasound should be available for universal use. Several randomized controlled trials have demonstrated better vascular and bleeding outcomes with radial as compared to femoral access, particularly when performing PCI in the setting of ACS, and therefore many CCLs have adopted a radial-first approach when feasible. In addition, the specific choice of right- versus left-radial access should depend upon variables such as the age and height of the patient (higher incidence of right subclavian tortuosity in older and shorter patients), the presence of hemodialysis fistula grafts, the presence of internal mammary artery bypass grafting that would favor ipsilateral radial access, or any information about difficulty occurring during a prior procedure.[19] In patients in whom femoral access is being considered, careful assessment of prior history of peripheral arterial disease that may impact femoral access should be made, along with assessment of bleeding risk. Ultrasound guidance should be considered to decrease bleeding complications. A useful reference is the SCAI Vascular Access, Management, and Closure: Best Practices Manual.[61] Considerations for dual arterial access for chronic total occlusion procedures requiring dual coronary injections and large bore access for hemodynamic support also require careful planning of the route of access site(s) based on the size of catheter required.

5 | INTRA-PROCEDURE BEST PRACTICES

5.1 | Patient preparation in the procedure room

Upon arrival to the procedure room, the pre-procedure checklist (Table 1) should be reviewed by a member of the clinical team. If a checklist was not performed, a thorough review of the medical record, including documentation of NPO status and duration, access site concerns, allergies, results of blood tests, recent medications (such as heparin and other anticoagulants), advance directives, IC, and living wills must occur. All these items must be documented in the medical record prior to the procedure or as part of the checklist mentioned above. NCDR-related (or equivalent) preprocedural information should be entered into the electronic health record by the CCL staff member monitoring the case with confirmation by the attending physician as needed for accuracy. Noninvasive hemodynamic and oximetric monitoring of patient vital signs should be routine. Defibrillation pads should be placed on all STEMI patients and those at increased risk of cardiac arrest. CCL staff should ensure that at least one working IV is in place prior to the start of the procedure. The plan for the vascular access site should be discussed with the physician operator and the site(s) prepared accordingly.

5.2 | Sedation, anesthesia, and analgesia administration and documentation

All patients should have documentation of their suitability to receive moderate sedation according to five classes categorized by the ASA guidelines.[62] Moderate sedation should be considered for all patients with attention to patient preferences.[63] Delivery of oxygen via nasal cannula should be considered for all patients in whom moderate sedation is utilized. A nurse, or provider with equivalent credentials, should be continuously present during administration of sedation to monitor for side effects, hemodynamic or electrical instability, and changes in respiration and/or oxygenation. A combination of opioids, such as fentanyl 25–50 mcg, and benzodiazepines, such as midazolam 0.5–2 mg, is most frequently utilized, but dosage should be carefully considered based on age, body size, and comorbidities. Additional doses of sedation should be verified with the approval of the primary operator prior to administration. Reversal agents should be readily accessible. Naloxone 0.4 mg IV can be utilized and titrated to reverse narcotic analgesics, and re-bolus may be required, given its short duration of action. Flumazenil, a pure benzodiazepine antagonist, can be given at a dose of 0.2 mg IV every 1–2 min to a maximum of 1 mg. All drugs must be recorded in a procedure log or electronic record and signed by the attending physician, and such records should be easily accessible, particularly when the patient leaves the CCL.

5.3 | Infection control in the catheterization laboratory

Infectious complications resulting from cardiac catheterization are exceedingly rare; however, best practices for sterile technique are essential. Electric clippers should be used to prepare the femoral access site. A variety of antimicrobial agents are available, and chlorhexidine-based preparations with appropriate time-delayed use are most commonly used due to their demonstrated efficacy.[64] Patient

TABLE 1 Pre-procedure checklist for cardiac catheterization

Patient name: _____ MRN: _____ Procedure date:_____
Planned procedure:
Diagnostic cardiac catheterization
Diagnostic cardiac catheterization with possible PCI
Percutaneous coronary intervention
History and physical examination:
Elective outpatient procedures: H&P documented within 30 days? Yes No
Inpatient procedures: H&P documented within 24 h of admission? Yes No
History of prior PCI or CABG: Yes No
If yes, were reports obtained? Yes No
Allergies:
Contrast: Yes No
If yes, was the patient pre-treated? Yes No
Aspirin: Yes No
If yes, does the patient need desensitization? Yes No
Heparin (HIT) Yes No
If yes, consider alternative anti-thrombotic agents
Latex Yes No
If yes, remove all latex products from procedural use
Medications:
Is the patient taking aspirin chronically? Yes No
Is the patient taking clopidogrel or another P2Y12 inhibitor chronically? Yes No
Did patient take metformin within the past 24 h? Yes No
Did patient take sildenafil (or equivalent) within the past 24 h? Yes No
Did patient receive LMWH within the past 24 h? Yes No
If yes for LMWH, time and dose of last administration:
Informed consent:
Was informed consent obtained per institutional policy and updated on the day of procedure? Yes No
If the patient has DNR or DNI status, is it revoked for the procedure? Yes No
Sedation, anesthesia and analgesia:
Are ASA and Mallampati class documented? Yes No
Is there any contraindication to sedation present? Yes No
Bleeding risk assessment:
Is patient on chronic anticoagulation (e.g., warfarin, direct acting oral anticoagulants)? Yes No
Laboratories and studies:
CBC and basic electrolytes within 30 days (outpatient) or 24 h (inpatient)? Yes No
Was EKG performed within 24 h? Yes No
PT/INR performed within 24 h (for patients on warfarin or with liver disease)? Yes No
Does the patient require pre-procedure hydration? Yes No

Abbreviations: ASA, American Society of Anesthesiologists; CBC, complete blood count; HIT, heparin induced thrombocytopenia; LMWH, low molecular weight heparin.

drapes that adhere to skin around the access site without loosening during the procedure are important. Physicians may use chlorhexidine/ethyl alcohol FDA-approved surgical hand antiseptic solutions, which can be used for the first scrub of the day and all subsequent scrubs. However, a traditional surgical scrub with water and soap is an alternative. Although their efficacy remains unproven it is generally accepted that hats, masks, and gowns should be worn for every invasive procedure. For personnel who will rotate between cath and EP labs, attention must be paid to specific requirements for sterile implantation technique for cardiac implantable electronic devices. Antibiotic prophylaxis is not indicated for routine coronary procedures, but is often used before permanent implantations other than coronary stents and, at some institutions, before vascular closure device (VCD) placement in high-risk subsets, such as immunocompromised individuals or those with diabetes.[65]

5.4 | Radiation exposure and occupational hazards

All CCL procedures should be performed with the goal of keeping radiation doses as low as reasonably achievable and minimizing chronic orthopedic injuries.[65–67] All personnel in the room should wear radiation protection, including lead aprons and thyroid shields as well as radiation badges. For team members closest to the radiation source, leaded glasses should be used. Tableside radiation shields should be routinely employed. Staff should be frequently re-educated about radiation safety, including considerations for pregnant patients and staff, and radiation exposure should be carefully monitored. Table 2 summarizes best practices to lower radiation exposure to patients, operator, and CCL staff. A complete description of strategies to reduce radiation exposure to patients and operators is beyond the scope of this article.[67,68]

CCLs should record total radiation doses in Gray (Gy) in real time and inform the operator when thresholds indicative of potential radiation damage are reached.[65] Every CCL must develop and conform to a radiation safety policy based on published guidelines.[69,70]

5.5 | Angiographic contrast administration

Nonionic, low-osmolar contrast (e.g., iohexol, iopamidol, ioversol) should be utilized for most cases. While iso-osmolar contrast agents (e.g., iodixanol) could be considered for patients with chronic kidney disease, data suggest this approach may have no benefit.[71] Total contrast volume administered to the patient must be monitored in real time and limited to as low as clinically possible. In conjunction with a CIN risk score, contrast volume to eGFR ratio >3.7 can be used as an upper limit of acceptable contrast dose during a single procedure to help limit the risk of CIN.[50,51] CCL staff should inform physicians when these limits have been reached. The use of automated contrast injector systems can be considered over manual devices (i.e., manifold). Automated contrast injector systems have been associated with reduced contrast exposure, risk of acute kidney injury and radiation exposure to operators.[72–74]

TABLE 2 Summary of methods to decrease radiation dose and exposure to patient and CCL staff

1. Select low dose settings on fluoroscope, such as lower dose per frame, lower frame rate (4–7.5 fps for fluoroscopy, 7.5–15 fps for cine)
2. Use "Fluoro Save" instead of cine when possible
3. Use collimation to lower radiation dose and scatter to patient and staff
4. Avoid working in steep angles and change working angles to "spread the dose"
5. Raise table height to decrease patient dose, and minimize distance between patient and detector to decrease patient dose and scatter to operator
6. Use lower magnification (example 22 cm FOV instead of 19 cm)
7. Keep patient's extremities out of the beam path and away from the x-ray tube
8. Maintain furthest possible distance from x-ray tube by using long tubing, especially for radial cases, and "taking a step back". Ensure proper use of moveable lead shields and under-table drapes
9. Consider moveable lead screens to protect CCL staff
10. Consider use of real-time radiation monitoring, radiation protection drapes and robotic PCI to lower operator radiation exposure
11. Regular assessment and upgrading of equipment (hardware and/or software) to minimize radiation dose

Note: Adapted from Fiorilli et al.[68]
Abbreviations: FOV, field of view; fps, frames per second.

5.6 | Universal protocol and "time out" procedure

All team members should understand the intended procedure and the sequence of that procedure. This should be confirmed during a dedicated "time out" protocol, performed before vascular access or moderate sedation is initiated, when all members of the team are present. Patient identification should be confirmed with unanimous agreement on the procedure to be performed. Since the goal is to access the heart and its associated vasculature, "wrong site" procedures are generally not a concern (access to the coronary arteries can be gained via radial, ulnar, brachial, and femoral arteries) and therefore site marking is not indicated for cardiac procedures.[75,76] Table 3 provides a sample "time out" checklist. If team members rotate out, then it is their responsibility to brief their replacement, who must introduce themselves to the team and announce their role.

Universal infection precaution protocols should be followed by the staff. All solutions on the table must be labeled in real-time (not prelabeled), including syringes specifically used for lidocaine and other agents (e.g., iodinated contrast). Preprinted labels of common medications should be incorporated into drape kits, and sheets of blank labels and felt-tip markers must also be available as part of the sterile field. For ad-hoc coronary interventions, a "Pre-PCI time out" should be considered, during which there is consideration of: (1) appropriate use classification; (2) radiation exposure and contrast dose; (3) appropriateness or need for intravascular imaging or physiologic assessment; (4) issues regarding dual-antiplatelet therapy; (5) adequate pretreatment with aspirin and P2Y12- receptor inhibitors; and (6) baseline hemodynamics. A pre-PCI time out assumes more importance if another operator is performing the PCI. For structural heart interventions, procedural-specific considerations should be incorporated into the time out. For example, the time out for TAVR procedures should include valve type, size, implantation angle, and surgical bailout strategy. The implanting physician must ensure proper valve orientation prior to device insertion. Finally, appropriate documentation of the physician's verbal orders needs to be carried out by the recording technologist or nurse and these orders confirmed by the performing physician at the close of the case with a signature.

5.7 | Intraprocedural anticoagulation monitoring

For patients who receive heparin for PCI, an activated clotting time (ACT) should be checked to document adequate anticoagulation. While it is recognized that ACT measurement may lack precision, and there are differences between the two main ACT measurement

TABLE 3 The Joint Commission Standards for the pre-procedural checklist and "time-out"[a]

Requirements for the pre-procedure "time-out"

1. The organization determines the exact items to be reviewed in the time-out
2. The time-out procedure is standardized
3. The patient should be involved in the time-out when possible
4. Performed immediately before starting the invasive procedure with all of the immediate members of the procedure team present
5. All relevant members of the procedure team actively communicate during the time-out
6. Team members agree on correct patient identity, procedure to be done, and anticipated access site
7. When the same patient has two or more procedures: If the person performing the procedure changes, another time-out needs to be performed before starting each procedure
8. Document the completion of the time-out. The organization determines the amount and type of additional documentation
9. The procedure is not started until all questions or concerns are resolved

Items typically reviewed during the time-out

1. Patient's identity (name and medical record number or date of birth)
2. Procedure to be performed (e.g., left heart catheterization, coronary angiography, right heart catheterization)
3. Planned primary and backup access site (e.g., right femoral artery)
4. Confirm that the equipment needed, including for potential complications, is available
5. Patient's allergies, pre-medication if appropriate, and recommended maximal contrast dose (e.g., heparin-induced thrombocytopenia, contrast allergy, aspirin, P2Y12 inhibitors)
6. Special laboratory or medical conditions (e.g., elevated INR, chronic kidney disease)
7. Appropriate documentation is completed and available (e.g., history and physical updated within the past 24 h), informed consent form signed

[a]Considerable additional requirements may be imposed by individual institutions. For example, some institutions require a separate conscious sedation informed consent, require all members of the team to introduce themselves during the time-out, or require calculation of a "fire score" to assess the likelihood of a fire arising during the procedure.

devices currently in use (Hemochron and Hemotech), data have suggested decreased thrombotic complications with higher ACT values albeit at some increased risk of bleeding.[77,78] It is reasonable to target ACT >200 s in the presence of IV anti-platelet therapy, >250 s in the presence of adequate oral anti-platelet therapy, and potentially >300 s in the absence of both.[77] This should be repeated as appropriate to be sure that the ACT is maintained at or above goal for patients on heparin. A single initial acceptable ACT is used for patients receiving bivalirudin to ensure adequate drug delivery. Results and timing of such testing should be recorded in the procedure log.

5.8 | Procedural data recording

All elements of the procedure should be recorded into an electronic record that documents the procedure and events that took place. The record should contain the patient's vital signs during the procedure, the access site, the time and dosage of medication administration, the ACT values during the procedure, what catheters were used and when, hemodynamic measurements, the target lesion or valve for PCI or structural intervention and equipment that was used, the names of the CCL staff, and whether a closure device was used at the end of the procedure. This record should be immediately available to the staff in the next level of care.

NCDR-specific information (or equivalent) is critical for maintenance of quality standards in the CCL. Accordingly, methods to facilitate the transfer of information collected in the CCL during procedures should be established among physicians and CCL staff. Prior to closure of the case, the physician should be responsible for reviewing all the pre- and intra-procedural data entered for NCDR purposes to ensure accuracy and completeness.

5.9 | Collaboration between interventional cardiology and cardiac electrophysiology

Collaboration between interventional cardiology and cardiac electrophysiology is increasingly commonplace, especially for procedures with complementary skillsets (left atrial appendage occlusion), or when a post-procedure pacemaker is likely (high-risk TAVR). An invasive or interventional cardiologist may be requested in the cardiac electrophysiology laboratory to assist with emergencies, provide angiography, or as a true partnership in select procedures.[79] Interventional cardiologists may be called to assist by performing coronary angiography to help define the coronary artery anatomy during a catheter ablation procedure, or to assist or provide emergent pericardiocentesis. Epicardial catheter ablations as well as ablations performed at the aortic root may require application of radiofrequency energy close to the epicardial coronary arteries and it is important that the electrophysiologist avoid energy delivery within close proximity of these vessels. Two potential issues arise in these situations: consent and having proper coronary angiographic equipment in the electrophysiology laboratory. Institutions are encouraged to anticipate this possible need prior to the procedure so that appropriate consent is obtained in advance from the patient as well as having equipment for the interventional cardiologist readily available.

6 | POST-PROCEDURE BEST PRACTICES

6.1 | Direct communication of procedure results

For outpatients, the operator should discuss findings, interventions performed, complications and post-procedure management plans directly with the patient and family. After routine inpatient procedures the operator may discuss these findings or delegate these discussions to the managing physician, but when a complication has occurred it is best for the operator to discuss this directly with the patient and family, making sure that opportunities for additional communication are clearly defined. Discussions with patients should be delayed until cognitive impairment due to sedation has resolved.

Although an invasive cardiologist performs the procedure, noninvasive cardiologists, internists/hospitalists, and nursing personnel can subsequently assume patient care. When the procedural operator is not the managing inpatient physician, it is good practice for the operator to discuss results of the procedure and recommendations for care directly with the managing physician.

6.2 | Procedure report

A procedure report should be generated immediately post-procedure and included in the patient's chart prior to transferring to the next level of care. If a procedure report cannot be placed in the medical record immediately after the procedure, then a brief progress note should be entered with sufficient information for immediate post-procedure care, including the name of the operator, indication and type of procedure, access site and hemostasis method, findings, estimated blood loss, specimens removed if appropriate, complications, post-procedure diagnosis, and initial recommendations. In this instance, a formal procedure report should be completed within 24 h of the procedure and include essential elements mandated by TJC for operative procedures, as well as comprehensive documentation of indications for PCI to satisfy AUC metrics.[80,81] Since terminology is critical for a quality procedure report, we recommend that key data elements and definitions from the 2013 ACCF/AHA Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients with Acute Coronary Syndromes and Coronary Artery Disease be adopted.[82,83] For a comprehensive procedure report consistent with CathPCI, we recommend including the additional information outlined in Table 4. The writing committee concurs with the ACC/AHA/SCAI 2014 Health Policy Statement on Structured Reporting for the CCL, which states that a structured report is the optimal format for generating procedure reports.[84]

6.3 | Access site management and closure devices

Hemostasis for radial access site is usually obtained with wristband compression devices. Sheaths are removed immediately after the procedure, regardless of anticoagulation status. The patent hemostasis technique should be used for radial access sites.[19,61,85–87] Employing evidence-based techniques and establishing standardized institutional hemostasis protocols for radial access sites improves efficiency and patient safety. After recovering from sedation, ambulation is not restricted with radial access, but patients should avoid carrying objects or excess activity of the arm for 2–4 h after sheath removal. Further information is available in a separate expert consensus statement on transradial best practices from SCAI.[19]

Manual compression and VCDs may be used for hemostasis after femoral access unless contraindicated. Selection of technique or device should be guided by clinical characteristics and femoral angiography. Unless contraindicated, femoral angiography should be performed after obtaining access to guide management of vascular access site after procedure and is mandatory prior to VCD placement.[20,88] While VCDs are noninferior to manual compression with respect to access site complications, infection rates may be higher. Shorter time to hemostasis, earlier ambulation and reduced resource utilization are among the potential advantages.[20,61,89]

Large bore access or mechanical circulatory support (MCS) require special post procedure considerations with access site management. In cases where MCS is left in place after the procedure, access site assessment should include confirmation of distal limb perfusion with plans for limb perfusion techniques when needed. Proper MCS positioning should be confirmed at the conclusion of the case and the device secured. Post procedure care should be protocolized and include instruction on limb immobilization and patient activity. Large bore vascular access closure can include various techniques including assisted manual compression, suture based or dedicated large bore closure devices and a proximal balloon occlusion technique. Further information and details on large bore vascular access

TABLE 4 Select elements of the procedure report

Element	Notes
Patient demographics	• Age, gender, risk factors, medications
Primary operator and CCL team members	• Primary and assisting physician, fellows, nurses, technologists, anesthesiologists
Procedures performed	• Right/left heart catheterization, PCI, pressure wire, IVUS, OCT, peripheral angiography
Indications	• Clinical presentation, symptoms, exam findings, prior studies
Access site	• Specify vessel accessed and if ultrasound used, specify if access was obtained using direct visualization, description of vessel patency, image archiving
Equipment	• Sheaths, catheters, balloons and other interventional equipment, wires
Drugs and doses	• Cardiac medications, sedation and amount of fluid administered
Contrast data	• Type and amount used
Radiation exposure	• Dose
Complications	• Clear description of complications, otherwise report "none"
Hemodynamics	• Computer generated measurements must be verified by the operator. Reports may include initial and end aortic pressure, left ventricular systolic and end-diastolic pressure, valve gradients and areas, right sided chamber pressures, pulmonary artery pulsatility index, cardiac output, cardiac power output, mixed venous saturation, arterial oxygen saturation, shunt data
Left ventriculogram	• Ejection fraction, wall motion abnormalities, valvular abnormalities
Coronary angiography	• Detailed anatomy, lesions, variants, size of vessels, collaterals; include graphic if available
Interventional procedures	• Procedure description including equipment, results and complications. TIMI flow pre- and post-PCI; include graphic if available
IVUS, OCT	• Indication, artery segment evaluated, vessel diameter measurement and methodology used, plaque morphology, stent expansion, stent apposition, presence of dissection, changes in management
FFR, iFR, RFR	• Indication, documentation of vasodilator used and route, location of lesion evaluated, results, pullback findings, assessment for drift, interpretation
Method of hemostasis	• If VCD, comment on whether or not device successful. If hemostasis band used, comment on type of band and use of adjunctive therapy that is, hemostatic disc, gauze, and so forth
Summary of findings, diagnosis and follow up	• Management plan, admission or observation status, follow up
Communication	• Report that results and complications were discussed with the patient and/or family, receiving team, consultants and referring provider.

Abbreviations: FFR, fractional flow reserve; iFR, instantaneous wave-free ratio; IVUS, intravascular ultrasound; OCT, optical coherence tomography; RFR, resting full-cycle ratio; VCD, vascular closure device.

management and closure can be found in the SCAI Vascular Access Management, and Closure: Best Practices eBook.[61]

6.4 | Appropriate monitoring and length of stay

Patients should be monitored on telemetry in a unit specializing in the care of patients receiving cardiac procedures. Vital signs should be monitored every 15 min for the first 2 h post procedure by personnel trained in recovery from moderate/conscious sedation and access site management. Telemetry is continued throughout the hospital stay, unless specified otherwise by the attending physician. Following PCI, electrocardiography should be performed immediately after the procedure. Length of stay for diagnostic catheterization ranges from 2 to 6 h, depending on the access site used and the nursing assessment of patient ambulation and wellbeing. The length of stay for PCI is dependent on access site complications, patient comorbidities, the need for further procedures or therapy, absence of ischemic symptoms, and absence of new ECG changes or testing.[90,91] Selected patients after elective PCI should be considered for same-day discharge after appropriate monitoring (usually 4–6 h) and the assessment of discharge readiness following the framework outlined in the SCAI and ACC consensus documents on length of stay and same day discharge following PCI.[91–93] Select EP procedures may also be considered for same day discharge.[94–97]

6.5 | Discharge instructions and patient information

At the time of discharge, a summary of the procedure should be provided to the patient and caregivers. If a patient received a stent, a card with the device information should be provided. Routine instructions regarding secondary prevention should be provided (e.g., DAPT, A1c < 7, systolic blood pressure control to <130 mmHg, high intensity statin therapy, threshold for additional lipid lowering therapy, etc.). Limitations on physical activity and driving, which may vary by access site, along with instructions for the follow-up appointment and further tests should be discussed and included with discharge instructions. Patients at increased risk for CIN should have serum creatinine checked within 3–5 days. All patients, especially those having same-day discharge post-PCI, should be given a contact number for questions and/or complications and ideally contacted by a CCL team member within 24–72 h of the procedure to ensure that no complications have occurred, medication adherence is reinforced, and to answer questions.

In cases with radiation exposure greater than 5 Gy, patients should be educated regarding potential skin changes (e.g., erythema) and arrangements for follow up should be made to detect any late radiation damage. For >10 Gy exposure, a qualified medical physicist should promptly calculate peak skin dose with skin examined at 2–4 weeks. TJC considers exposures over 15 Gy a sentinel event for which hospital risk management and regulatory agencies should be contacted within 24 h.[98] Suspected tissue injury should be referred to a specialist and a biopsy performed if required.

6.6 | Medication reconciliation

Medication reconciliation and review of appropriate guideline directed medical therapy is necessary before discharge to update all medications, including those deleted or added during the procedure, and must be clearly documented on the discharge instructions and discussed immediately with the referring physician. Bedside delivery of new medications may be helpful. The expected duration of DAPT should be based on current guidelines and documented as part of the medication reconciliation. This should also be discussed with the patient and the importance of adherence stressed. Particular attention should be given to patients requiring "triple therapy" (antiplatelets/anticoagulants), and duration of each medication should be explicitly stated. Due to increased bleeding risk, triple therapy should be maintained for the least amount of time possible (e.g., 1 week to 1 month).[99] There is growing experience with using a single antiplatelet agent along with oral anticoagulation to minimize bleeding risk and this should be considered.[100] Patients previously on a direct oral anticoagulant can restart the same or next day. Patients previously on warfarin should restart their standard regimen immediately and arrange for follow-up PT/INR within 1 week of discharge. LMWH as a bridge to therapeutic warfarin is not routinely recommended due to the potential for bleeding, except in patients at high risk of thrombosis including those with mechanical prosthetic valves, or recent deep venous thrombosis or pulmonary embolism.[101] Metformin should be held for 48 h in those at risk of CKD or with CIN.[102] Proton-pump inhibitors should be considered for patients with prior history of gastrointestinal bleeding or at increased risk of bleeding who are discharged on DAPT, and should be routinely prescribed for all patients on triple therapy.[39]

6.7 | Appropriate follow-up evaluation

The patient should have a follow-up visit with a provider (physician or APP) who is competent in the management of post-procedure care within 2–4 weeks of discharge. For patients with baseline renal insufficiency, anemia, or procedural complications, follow-up should be earlier, with indicated studies performed prior to or during the visit. It is good practice to assess the access site for symptoms and potential complications. The patient's medical therapy should be assessed for effectiveness, side effects, compliance, and conformity with guidelines. Additional outpatient care should address lifestyle modifications and smoking cessation and reinforce the plan for long-term follow-up based on procedural results.[39] All patients following PCI should be referred to cardiac rehabilitation.[39]

7 | CATHETERIZATION LABORATORY GOVERNANCE

7.1 | Role of CCL medical director and administrative/nursing director or manager

Management of the CCL presents unique challenges due to the volume and complexity of patients treated, the diversity of procedure types, and the multidisciplinary (e.g., anesthesia, surgery) coordination required. In addition, use of advanced and continuously evolving technologies and resultant magnitude of resources required, including complexities of staffing ratios and diversity of necessary skills and expertise must be considered. Ideally, all CCLs should have a physician medical director and an administrative/nursing director or manager working in a dyad partnership and in collaboration with relevant stakeholders, personnel, and hospital administration. Hospital administration is critical to providing requisite resources for the CCL to perform its duties safely and efficiently and within all regulations and policies. These include not only staffing and capital needs but also the personnel required for collection, maintenance, submission, and retrieval of accurate quality data for both internal and external purposes.

An important aspect of CCL governance is keeping senior leadership and administration abreast of the CCL as it pertains to business development, innovation, cost containment strategies, and stakeholder satisfaction, including patients, physicians, and staff, in addition to managing the logistics of the day-to-day operation of the CCL. Ongoing communication is required to align vision and set both attainable and aspirational goals for the CCL, as well as advocate for necessary resources.

The medical director should be a licensed, board-certified invasive or interventional cardiologist with a minimum of 5 years' experience.[23] Likewise, the administrative/nursing director or manager should have a minimum of 5 years' CCL and/or critical care cardiology experience, and administrative expertise to participate in institutional and CCL decision making. The medical director role requires dedicated administrative time, with larger labs requiring more resources, and potentially including a team of other medical, clinical, and administrative/nursing leaders with assigned expertise and responsibilities. In general, for the medical director, a total of one half-day per week is a minimum requirement for administrative time dedicated to the CCL, with larger and busier labs requiring a full day. Medical director administrative time should be compensated by the institution at a level commensurate with the physician's roles, responsibilities, dedicated time, and capabilities and consistent with fair market value. In addition to the primary focus on the CCL, the dyad should meet regularly with stakeholders who interface with the catheterization laboratory to identify their unique needs including but not limited to interventional radiology, heart failure and transplantation, anesthesia, electrophysiology, cardiothoracic and vascular surgery, the emergency department, intensive care unit, operating room, and other relevant areas and teams.

The medical and administrative leadership dyad is responsible for setting an example, assigning respective roles, responsibilities, expectations, and culture for all other medical, clinical, and administrative personnel. Along with other stakeholders, the medical and administrative/nursing leaders are also responsible for developing policies, establishing criteria for granting and renewing privileges, reviewing physician performance, and overseeing clinical and administrative personnel. Additionally, the medical and administrative/nursing leaders should partner with all relevant stakeholders on quality improvement, operational excellence, fiscal performance, patient throughput, personnel recruitment and retention, onboarding, provision of debrief and feedback after adverse events, delegation of authority, and facilitating education and mentorship to all personnel (Table 5). In many cases this takes the form of regularly scheduled meetings that are both informational and feedback-generating from all relevant stakeholders. During these meetings, all aspects of CCL management should be discussed, including but not limited to quality reporting, supplies and equipment, physical plant, staffing, efficiency, policies and procedures, and new research, procedures, and developments.

7.2 | Management of industry relationships

Industry often provides, supports, and/or facilitates meaningful functions, including FDA, CMS or other entity-required proctoring, training and education (particularly for new and/or seldom-utilized technologies, and those where a NCD is applicable), and sharing of best CCL practices. Maintenance of equipment such as imaging or cardiovascular information systems is also often performed by industry, as is real-time clinical support for device use (structural heart procedures, electrophysiologic device implantation). To achieve these objectives, it can be beneficial to have industry interaction with CCL medical and administrative/nursing leadership. Beyond that, there may be value in industry interaction and presence with broader CCL personnel to facilitate the above objectives or more effectively provide clinical care. In addition, in order to ensure sound decision-making for the contracting, use and comparisons between high-value healthcare products, the CCL (especially the medical and administrative/nursing leadership) should collaborate closely to understand supply chain pricing, clinical and operational value of and differences between products.

However, industry influence at the point of care may raise a number of ethical issues and it has been shown that even small gifts may influence physician behavior.[103,104] Industry representatives in the CCL have been shown to influence use of products, and this effect may be variable among physicians.[105] Accordingly, many institutions set strict limits on the presence of industry.[106,107] To the extent possible, professional societies, such as SCAI, may be better suited to provide some of the above functions (e.g., trans-radial education; cath lab bootcamp administrative education), when feasible. Organizations representing industry have established codes of ethics to define appropriate interactions between industry and physicians.[108–110]

TABLE 5 Responsibilities of CCL medical director and the administrative/nursing director or manager

Administrative
- Co-lead CCL administrative meetings including representatives of pre- and post-procedure areas
- Resolve personnel problems in collaboration with CCL nurse manager
- Attend CCL staff meetings and serve as liaison between CCL personnel and physicians
- Lead administrative meetings of CCL physicians
- Resolve CCL issues among CCL physicians
- Coordinate CCL physician call schedule
- Co-lead (with CCL nurse manager) CCL Quality Committee meetings, including reporting data on NCDR outcomes, M&M conferences, adverse event reports, root cause analyses, Department of Health inspections and TJC or other accreditation body surveys
- Assist CCL nurse manager to prepare for Department of Health and TJC or other accreditation body surveys
- With CCL nurse manager and administration, assist in cost effectiveness and efficiency strategies

Quality improvement
- Oversee QI data collection and reporting processes for NCDR PCI Registry, review quarterly reports from NCDR and communicate with CCL physicians, perform annual review of individual physician data
- Quality review of non-registry procedures (e.g., atrial septal defect closures)
- Arrange for random case reviews and monitor results of reviews
- Ensure review of adverse events either by M&M conference or CCL Quality Committee
- Coordinate/oversee CCL M&M conference, report minutes to appropriate hospital committees
- Co-chair (with CCL manager) CCL Quality Committee responsible for all other aspects of CCL quality, including door to balloon initiatives
- Set criteria for privileging for CCL procedures
- Review physician performance as necessary for bi-annual re-credentialing for procedures

Academic responsibilities
- Oversee (with program director) fellows' CCL rotation, provide evaluations
- Oversee research in the CCL
- Oversee acquisition and launch of new technologies, medications and programs

Abbreviations: CCL, cardiac cath lab; M&M, morbidity and mortality; QI, quality improvement; TJC, The Joint Commission.

General principles regarding industry representatives or clinical specialists in the CCL include the following:

1. Their role in individual CCLs should be consistent with policies set by the hospital, under the oversight of medical and administrative/nursing leadership, in conjunction with other relevant stakeholders.
2. They should not handle equipment in the CCL, except for compliant, defined educational purposes (clinical support), device preparation, and/or maintenance. This is particularly the case for structural procedures but may be relevant to other technologies or techniques.
3. They should always provide information and advice that is in the best interests of the patient, regardless of other considerations.
4. Their presence in the CCL is reasonable when it is helpful to the physician in providing patient care. Hospital policies should not prohibit these interactions. In fact, the complete absence of industry in these settings may be detrimental to patient care and scientific advancement.
5. Their presence in the CCL without specific purpose, (e.g., to "observe"), is of uncertain appropriateness and is discouraged, as is their presence solely for the purpose to enhance sales relative to competitor products.

7.3 | Incorporation of guidelines, new data, and new procedures

The CCL is a dynamic environment shaped by everchanging technologies, guidelines, and clinical data. As such, the entire CCL team, led by the medical and administrative/nursing leaders, should review and regularly update CCL policies and processes to reflect new high-quality evidence-based information and evolving standards of care, and provide appropriate education and training to medical, clinical and administrative personnel. Protocols for new technology or techniques should define the roles of all relevant personnel. When appropriate, related process and/or outcome metrics should be reviewed for continuous quality improvement. A nurse educator is particularly suited to keeping nursing and clinical staff updated and competent in procedures and techniques that are vital yet seldom used, as well as new technologies approved for use. Industry, as noted above, may also serve in this role if abiding by the above principles and supervised by members of the clinical staff.

7.4 | Cost and revenue considerations

Providing the highest value healthcare is a major element of healthcare reform and the medical and administrative/nursing directors should be highly engaged in advancing this objective.[111] Components of high-value care include appropriateness, efficiency and throughput, reducing complications, and the judicious use of resources. Cost reduction efforts may target CCL operating costs and/or costs of care outside the CCL.[111–113] Specific recommendations include the following:

1. CCL physicians should collaborate with the medical and administrative/nursing directors to understand and reduce in-lab expenses through consolidation of products, negotiating lower prices, assisting in volume-related discounts and supply-chain management, reduction of turnover times, and minimizing unused open products, procedural time, and overtime pay.
2. When two products differ in cost but not clinical performance, it is reasonable for physicians to preferentially use the most cost-effective, higher value option. Cost reduction efforts should not compromise patient care, but physicians should be aware of the cost consequences of their decisions. Tracking and discussing physician-

specific cost data (e.g., cost per case) in order to better understand physician-specific variability may be useful, but should be adjusted for relevant factors such as case complexity and should be anonymized outside of directors and hospital administration.

3. The medical and administrative/nursing directors, along with other medical, clinical and administrative stakeholders should have a leadership role and/or participate on hospital technology assessment committees to coordinate access to and acquisition of equipment.[114]
4. Leadership should remain up to date on relevant knowledge and evolving strategies to reduce out-of-lab costs and evaluate and/or employ them when appropriate.[115] Additionally, novel technology and clinical advancements should be routinely reviewed to determine whether incorporation confers a financial advantage, balancing device and procedural costs with turnaround times, procedural times, hospital reimbursement, as well as indirect benefits such as competitive market share advantage and so-called "halo effects" of innovative technology and techniques.[111]

7.5 | QA and performance improvement: Registry participation, M&M conference and public reporting

Every CCL must have a continuous QA program, which includes appropriate quality registries and, at least quarterly, scheduled conferences comprising QA, case review, and/or M&M conferences. Quality registries may be regional or national and should allow for institution-level and anonymous, operator-specific benchmarking of process and outcome metrics against other operators and institutions. The medical and administrative/nursing directors should have or delegate a leadership role in ensuring these processes. Procedure-based registries are available for cardiac catheterization and PCI, peripheral arterial catheter-based interventions, and transcatheter valve replacement/repair procedures (e.g., ACC NCDR, http://cvquality.acc.org/NCDR-Home/Registries.aspx). Outpatient registries (e.g., ACC NCDR PINNACLE) may provide additional pre- and post-procedure data and allow for linkage of follow up with procedural data. Institutions should provide dedicated, trained personnel and/or processes to perform data abstraction, data entry, registry query, and report generation/distribution. Registries should be utilized to monitor operator and institutional volumes and outcomes as well as procedural appropriateness. It is important that when comparing outcomes (e.g., bleeding, CIN, mortality) across operators/institutions that these rates be risk adjusted.[116–118]

All major CCL and in-hospital complications should be reviewed at an M&M conference, held at least quarterly.[119] Cases requiring review may be identified using procedural registries such as those cited above, assuming that data are entered in timely fashion. CCL M&M should be distinct from Clinical Cardiology M&M, as the former may emphasize technical aspects of the procedure. Presentation of more serious events (e.g., death) should take precedence over less serious (e.g., vascular complications) events, and review should occur as soon as feasible after an adverse event has occurred, especially when a preventable cause is suspected. A formal phase of care (pre-procedure, intra-procedure, post-procedure) analysis is recommended, in which various aspects of care at each stage are critically analyzed and where consensus is reached over preventability of the complication.[120]

The aim of review conference is process of care and outcome improvement; thus, it is critical that the environment remain non-punitive. Ideally, physicians, physician trainees, APPs, nursing, technical staff, and hospital quality representatives should be required to attend. A statement of confidentiality should appear on any material distributed in print or electronically. Applicable state and federal laws should also be cited, and unauthorized disclosure or duplication should be prohibited.

Each CCL should have a quality process or a committee that includes the medical and administrative/nursing directors and representatives of other stakeholders. This committee is responsible for reviewing complications not discussed in M&M conferences and other metrics of CCL quality, such as completion of time-outs, moderate sedation reporting, monitoring accuracy of data reported to registries including those used for public reporting, QA checks of equipment, door to balloon times, and others as required by the hospital, state department of health, and TJC or other accreditation bodies.[121] Procedures for initial credentialing and ongoing practice assessment have been established by TJC, including use of focused professional practice evaluations and ongoing professional practice evaluations, and are well described in the literature.[3]

Public reporting of PCI outcomes may be mandatory or voluntary depending on institutional location. Public reporting emerged as a method to prompt institutions and providers to improve care delivery and to empower patients to make more informed decisions on healthcare. While controversy exists on the benefits of public reporting without clear data supporting an improvement in clinical outcomes, and an unintended consequence of physician risk aversion, public reporting is now commonplace and anticipated for most CCLs. Performance measures used for public reporting are developed by cardiovascular societies through specific methodology and endorsed by the National Quality Forum. For PCI, these include PCI risk-adjusted mortality, composite therapy with aspirin, P2Y12 inhibitor, and statin at discharge following PCI in eligible patients, and hospital 30-day risk-standardized readmission rate following PCI. There is recognition that risk adjustment is imperfect and methods to address this have been proposed, and in some cases implemented. These include the ability to exclude the highest risk patients, report at the institutional not operator level, extend time interval of accumulated data, present disease related (i.e., acute MI) rather than procedure related mortality, and include variables such as "compassionate use" within models. Public reporting should be supported while physicians and societies remain committed to assuring that relevant data is available to the public and that improvements in outcomes are ultimately realized.[122,123]

7.6 | Preparedness for high risk, low frequency events: Protocols and simulation drills

Though serious complications are rare, they can have devastating consequences if not addressed in a methodical and timely manner. In

TABLE 6 Examples of high risk, low frequency complications for protocol implementation and simulation drills

Emergency complication topics	Elements to include: (1) Location of diagnostic tools for rapid assessment (2) Activation numbers of key participants (3) Location and inventory of therapeutic tools
Vascular complications	Anticoagulation and antiplatelet reversal protocols Paging protocol for immediate assistance from surgery or an endovascular specialist Protocol for manual compression, blood availability, and immediate invasive angiography to allow balloon tamponade or stenting of bleeding vessel where available (e.g., covered stent) Protocol for obtaining emergency imaging such as non-contrast computed tomography for suspected retroperitoneal bleed or computed tomography angiography to identify bleeding site, as examples Protocol for severe forearm hematoma management
Acute stroke	Protocol for calling stroke alert and activating stroke team (including a neurologist, neurological interventionalist, and access to emergent neuroimaging), including rapid brain imaging protocol Protocol for emergent transfer to institutions for higher level care when appropriate
Emergency pacing	Protocol for emergency transcutaneous and transvenous pacing
Ventricular fibrillation/ Cardiac arrest	Protocol for emergency defibrillation Protocol for obtaining immediate anesthesia care and intubation in CCL Protocol for initiation of standard or mechanical cardiopulmonary resuscitation (e.g., LUCAS device) Protocol for running a code including location of crash cart and roles of key players
Coronary perforation	Protocol for immediate locations of echocardiography machine, supply of covered stents and/or coils and pericardiocentesis kit Protocol for placement of covered stent or coils (including second access site, larger guide catheter, and so forth.) Protocol for obtaining emergency echocardiography Protocol for emergency pericardiocentesis
Contrast reaction	Protocol for emergent treatment of contrast allergy Protocol for emergency treatment of anaphylactic/anaphylactoid reaction including IV fluids, IV steroids, and epinephrine (1 ml 1:10,000 epinephrine IV over 1 min for life-threatening reactions) Protocol for obtaining immediate anesthesia care and intubation in the CCL
Tamponade	Protocol for emergency pericardiocentesis
Sudden cardiogenic shock or cardiac arrest	Protocol for alerting cardiac surgery as needed for emergency CABG or ECMO (i.e., SHOCK TEAM alert, if available) Protocol for obtaining immediate anesthesia care and intubation in the CCL Protocol for emergency IABP, Impella or peripheral ECMO
Emergency transfers	Protocol for transferring patient to the OR for emergency surgical procedure Protocol for transferring patient to another hospital for emergency procedure Protocol for converting procedure to an emergency open procedure in a hybrid cardiac cath lab

addition to emphasizing prevention strategies, it is important to maintain preparedness strategies. Select complications for which specific protocols should be developed are listed in Table 6. Protocols should include how to activate the key participants and the location and inventory of diagnostic and therapeutic tools.

Simulation drills with all team members together should be performed at routine intervals in the CCL to practice response to these high risk, low frequency events, and may be coordinated by the medical and administrative/nursing directors as well as a nurse educator. These simulation drills should include rapid assessment of a complication, activation of emergency protocols as well as mobilization of therapeutic interventions. Simulation centers or simulation-based programs can be engaged to initiate or maintain skills and have been shown to improve team communication and clinical competency outside of the patient care setting. In the case of an actual complication in the CCL, tools such as same-day or next-day debriefing, root-cause analysis, and M&M case reviews should be implemented to optimize protocol to improve CCL readiness and patient outcomes.

Emergency preparedness protocols may also be required for unexpected circumstances which affect the safety of cath lab personnel and patients or dramatically alter procedural volume. Examples include natural disasters and infectious outbreaks, such as the recent response to the COVID-19 pandemic.[124–128]

7.7 | Patient experience optimization

Patient experience and satisfaction may impact clinical outcomes. All hospitals participate in a patient survey process that measures patients' perceptions of their hospital care, known as Hospital Consumer Assessment of Healthcare Providers and Systems, (HCAHPS, http://www.hcahpsonline.org). HCAHPS is designed and regulated by CMS, endorsed by the National Quality Forum, and results are

TABLE 7 Key techniques for enhancing patient satisfaction in the CCL

Pre-procedure
• Prompt, easy scheduling and pre-admission testing requirements for outpatients
• Minimize or eliminate NPO period before procedure (some institutions allow clear liquids until 2 h before procedure as per ASA guidelines, or no longer require NPO)[62]
• Pre-procedure patient education tools to aid informed consent
• All outpatient suite and CCL personnel introduce themselves by name
• Update patients when delays are anticipated
• Emphasize comfort and privacy, including of family members
• Respect confidentiality
Intra-procedure
• Careful attention to adequate sedation and pain control during the procedure
• Time out with introduction of all team members to the patients
Post-procedure
• Full explanation of results of procedure to patients and, when appropriate, family
• Prompt food and drink when tolerated after procedure
• Discuss follow-up plans, provide instructions for emergency help after discharge, and provide appointment before discharge
• Provide prescriptions and, if available, important medications prior to discharge
• Follow-up call to answer questions and identify post-procedure problems

publicly available on the website hospitalcompare.hhs.gov. However, these surveys do not directly measure patient satisfaction with CCL services. CCL physicians interested in assessing the CCL patient experience would need to develop and administer a unique survey for this purpose. In this regard, some CCLs assign nurses to contact patients after their procedure to query about complications, follow-up appointments, medication adherence and overall satisfaction with the CCL services, and this process is encouraged and should be adequately resourced.

CCL team members as well as those involved in scheduling and post-procedure care all have the ability to impact the overall patient experience and, thus, overall outcome. Some techniques for enhancing patient satisfaction are listed in Table 7.[129]

8 | CONCLUSIONS

From the patient, physician, physician extender, and hospital or facility perspective, these "best practices" help assure the consistent delivery of high-quality care in the CCL. These measures are critical to patient safety, laboratory efficiency, patient and referring physician satisfaction, as well as CCL governance and economics. Health care systems should provide resources through adequate staffing, equipment, and information technology, inclusive of physician extenders where appropriate, to assure the performance of these practices and their ongoing review.

CONFLICT OF INTEREST

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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