STATE HEALTH PLANNING AND DEVELOPMENT AGENCY
100 NORTH UNION STREET, SUITE 870
MONTGOMERY, ALABAMA 36104

NOTICE

DATE: February 23, 2022

TO: Applicant and Interested Parties

FROM: Emily T. Marsal
Executive Director

SUBJ: Proposed State Health Plan Amendment submitted by 2LR Healthcare Holdings LLC d/b/a Heart and Vascular Institute of Alabama PAm 2022-001

A Plan Amendment, designated PAm2022-001, has been accepted as complete on February 23, 2022. Persons other than the applicant have thirty (30) days from February 23, 2022, to electronically file statements in opposition to or in support of the application, as well as any other documentation they wish to be considered by the Statewide Health Coordinating Council (SHCC). Pursuant to SHPDA ALA. ADMIN. CODE r. 410-1-3-.09, all such statements and documentation must be filed at shpda.online@shpda.alabama.gov, together with a certification that the filing has been served on the applicant and/or any other persons that have filed notices of support for or opposition to the application.

This Plan Amendment can be viewed in its entirety at www.shpda.alabama.gov, under Announcements/SHP/Proposed Adjustments & Amendments /PAm2022-001 – 410-2-3-.03(1) 2LR Healthcare Holdings LLC d/b/a Heart and Vascular Institute of Alabama.

Interested parties may address the proposed Plan Amendment at the SHCC meeting, subject to such time limits and notice requirements as may be imposed by the SHCC Chairman. If the SHCC approves the Plan Amendment in whole or in part, the adjustment, along with the SHCC's favorable recommendation, will be sent to the Governor for consideration and approval/disapproval. A Plan Amendment shall be deemed disapproved by the Governor if not acted upon within fifteen (15) days.

SHPDA Rule 410-2-5-.04 – Plan Revision Procedures, may be viewed in its entirety on the Agency's website at www.shpda.alabama.gov, under Announcements/SHP/Approved Adjustments & Amendments/410-2-5-.04 Plan Revision Procedures (Effective 03/23/2018).

Detailed information regarding the applicable deadlines for the proposed Plan Amendment is listed on the following page.

STATE OF ALABAMA
STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

REVIEW SCHEDULE

TO: 1. Plan Amendment Applicant
2. All Providers of Similar Services in the Proposed County
3. All Providers of Similar Services in Adjacent Counties
4. Interested Persons

NOTICE: An application for Plan Amendment has been submitted for review under the provisions of Sections 22-21-260(13), Code of Alabama, 1975. A brief description of the Amendment and of the Review Schedule is set forth below:

Emily T. Marsal
Executive Director

February 23, 2022
Date

DESCRIPTION OF PROPOSED FACILITY AND/OR SERVICE		
1. Plan Amendment No.: PAm2022-001	2. TYPE FACILITY: ASC	3. COUNTY: Statewide
4. NAME OF APPLICANT: 2LR Healthcare Holdings LLC d/b/a Heart and Vascular Institute of Alabama		
5. BRIEF DESCRIPTION OF AMENDMENT (Change in bed capacity, service, equipment, units proposed, etc.): The applicant proposes an amendment to Rule 410-2-3-.03(1) of the *2020-2023 Alabama State Health Plan* to establish that licensed Ambulatory Surgery Centers (ASCs) may provide diagnostic and therapeutic cardiac catheterization services.		
REVIEW SCHEDULE		
6. REVIEW PERIOD BEGINS (DAY 1): February 23, 2022		
7. DEADLINE FOR PERSONS WISHING TO SUBMIT INFORMATION IN OPPOSITION TO OR SUPPORT OF THE PROPOSED AMENDMENT (DAY 30): March 25, 2022		
8. PROPOSED DATE OF PUBLIC HEARING: June 14, 2022		

BEFORE THE STATEWIDE HEALTH COORDINATING COUNCIL OF THE ALABAMA STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

Request for Amendment to the 2020-2023 Alabama State Health Plan

I. Identification of Applicant:

Applicant: 2LR Healthcare Holdings, LLC, d/b/a Heart and Vascular Institute of Alabama ("HVIA")
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II. Overview of Request for Amendment to the 2020-2023 State Health Plan

2LR Healthcare Holdings, LLC d/b/a Heart and Vascular Institute of Alabama ("HVIA") requests that the Statewide Health Coordinating Council ("SHCC") amend Section 410-2-3-.03(1) of the *2020-2023 Alabama State Health Plan* ("SHP") to clearly establish that licensed Ambulatory Surgery Centers ("ASCs") may provide diagnostic and therapeutic cardiac catheterization services.[1]

[1] Pursuant to Section 410-2-5-.04(2)(c), a Plan Amendment is the "alteration or adoption of rules, policies, methodologies, or any other plan revision that does not meet the plan adjustment or statistical update definition. An amendment is of 'general applicability' and subject to the AAPA's rulemaking requirements."

III. Background of the Request for Amendment

On September 25, 2020, HVIA filed a Certificate of Need ("CON") Application proposed to establish and operate a single-specialty ASC in Montgomery, Alabama, designed, equipped and staffed to perform endovascular and cardiac catheterization procedures, including percutaneous coronary interventions ("PCI").

The HVIA CON Application was opposed by local hospitals in the Montgomery County area, and a contested case hearing pursuant to the Alabama Administrative Procedure Act ("AAPA") was held, concluding on April 26, 2021. On July 28, 2021, the Administrative Law Judge ("ALJ") issued a Recommended Order, declining to recommend the HVIA proposal, stating that the performance of PCI in an ASC setting was not consistent with Section 410-2-3-.03(1) of the SHP, dealing with Fixed-Based Cardiac Catheterization Laboratories.

On September 15, 2021, the CON Review Board held a meeting where the ALJ's recommendations were reviewed, and all parties to the contested case hearing presented argument and testimony. At the conclusion of this meeting, the CON Review Board requested HVIA seek a modification of the SHP regarding the performance of PCI in an ASC setting[2]. Subsequently, the CON Application was carried over "until no earlier than the January [2022] regularly scheduled meeting."[3]

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[2] This issue was mentioned multiple times at the CON Review Board meeting. At one point, the Chairman asked HVIA "Would you be willing to consider the idea of tabling this until you attempt a modification to the SHCC plan that would then allow for an ASC to do procedures such as this in Alabama?" (Transcript, p. 99). Later, the Chairman again asked if HVIA was willing to table the CON Application and attempt an amendment to the State Health Plan. (Transcript, p. 107).

[3] Transcript, p. 108.

Following that decision, HVIA filed for a declaratory ruling pursuant to the AAPA, seeking a determination by SHCC that locating a cardiac catheterization laboratory in an ASC is consistent with the SHP, that the SHP does not prohibit PCI from being performed in a cardiac catheterization laboratory in an ASC setting, and that the relevant conditions imposed by the SHP on a hospital performing elective same-day discharge PCI procedures could be applied to the same procedures being performed in an ASC. However, at its meeting on December 14, 2021, the SHCC denied the request for declaratory ruling, "not on the merits but on the procedural issue that [the SHCC] does not have the authority to" grant the declaratory ruling requested.

Although the HVIA matter was placed on the agenda for the CON Review Board meeting scheduled for January 19, 2022, that meeting was cancelled.

IV. The Current Cardiac Services Section of the SHP

The Cardiac Services section of the State Health Plan is found at *Ala. Admin. Code* § 410-2-3-.03.[4] The specific portions relevant to the proposed SHP Amendment are found in § 410-2-3-.03(1), entitled "Fixed-Based Cardiac Catheterization Laboratories." In summary, the ALJ's recommendation claimed that the provisions found in Planning Policy 5 of this subsection prevent the award of a CON seeking to provide cardiac catherization services (particularly PCIs) in an ASC and require that such services be provided in a hospital.

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[4] Although the Cardiac Services Section contains two separate subsections ((1) Fixed-Based Cardiac Catheterization Laboratories and (2) Open Heart Surgery), the proposed Amendment to the SHP deals only with the first of these, so any discussion of the second is omitted here.

§ 410-2-3-.03(1)(a) provides a preliminary discussion of Fixed-Based Cardiac Catheterization Laboratories, including the statement that "Fixed-based cardiac catheterization services are the only acceptable method for providing cardiac catheterization services to the people in Alabama." At no point in the SHP is the term "fixed-based" defined. The discussion section also contains this specific language: "As newer cardiac diagnostic and treatment modalities are developed, it is highly likely that the role of cardiac catheterization will continue to evolve. Certain cardiac catheterization procedures are now offered in physicians' offices outside of the usual hospital environment."

§ 410-2-3-.03(1)(b) consists of six Planning Policies. Planning Policy 1 deals with equivalent calculations relating to the determination of need for additional cardiac catheterization services. Similarly, Planning Policy 2 relates to threshold statistical levels that govern determination of need for such additional services. Neither of these Planning Policies set forth any policy regarding the types of facilities in which cardiac catheterization services may be provided and are not relevant to the proposed SHP Amendment.

Planning Policy 3 deals with the expansion of existing cardiac catheterization services, Planning Policy 4 relates to the provision of pediatric cardiac catheterization services, and Planning Policy 6 relates to the number of catheterization procedures that are projected to be performed in the proposed facility. None of these three Planning Policies are relevant to the proposed SHP Amendment.

Planning Policy 5 provides, in part, that acute care hospitals providing diagnostic cardiac catheterization services may provide emergency interventional/therapeutic cardiac catheterization procedures and that an acute care hospital without on-site open-heart surgery capability may provide elective PCI if certain criteria are met. These requirements for such acute

care hospitals include certain provisions for physician coverage, participation in a recognized national data registry, procedures to obtain informed patient consent for all elective PCI procedures, and quarterly quality reviews, among others.

Planning Policy 5 ends with a directive to the CON Review Board that it "shall consider the most recent recommendations/guidelines for cardiac catheterizations adopted by the American College of Cardiology Foundation, the American Heart Association Task Force on Practice Guidelines, and the Society for Cardiovascular Angiography and Interventions as an informational resource in considering any CON application for elective PCI services."

V. **Argument**

As noted above, the Cardiac Services Section of the SHP acknowledges that cardiac catheterization services are continuing to evolve. When this is coupled with the Section's instruction that the CON Review Board shall consider the most recent recommendations from thought leading groups such as the American College of Cardiology ("ACC") and the Society for Cardiovascular Angiography and Intervention ("SCAI"), it becomes apparent that any examination of this subject should begin with the most recent position statements of those groups.

"In November 2019, the Centers for Medicare and Medicaid Services ("CMS") finalized a rule that added percutaneous transluminal coronary angioplasty and transcatheter placement of intracoronary stents to the list of procedures reimbursed in ambulatory surgery centers ("ASCs"), effective January 1, 2020. The previous year, the agency had also deemed diagnostic catheterization and angiography as reimbursable in ASCs. CMS changed these policies in light of evidence that supports the safety of same-day discharge following elective percutaneous

coronary intervention ("PCI") and of PCI performed without on-site cardiothoracic surgical support."[5]

After receipt of the notice of the 2019 proposed rule changes from CMS, both SCAI and ACC responded by filing comments. In a letter dated August 27, 2019, SCAI stated ". . . SCAI supports CMS's proposed addition of percutaneous coronary angioplasty and coronary stenting to the list of ASC Covered Surgical Procedures . . . We feel that elective, non-emergent percutaneous coronary angioplasty and coronary stenting procedures have relatively low complication rates and are not expected to pose a significant risk to . . . safety and do not typically require inpatient-level care following the procedure."[6]

Similarly, the ACC, in correspondence also date September 27, 2019, stated that the organization supports the proposed addition of the procedures to the list of ASC Covered Surgical Procedures, agreeing with the clinical assessment by CMS that these procedures can be safely performed in an ASC setting.[7]

Prior to the CMS decision in 2019, the agency had determined that coronary intervention procedures "can be safely performed in the ASC setting, for certain Medicare patients" and that "expert consensus, clinical guidelines and clinical studies establish that percutaneous coronary interventions can be safely performed in an ASC setting." 84 Fed Reg 61387.

The expert consensus, clinical guidelines, and clinical studies referred to by CMS are those issued by SCAI, the ACC, and the American Heart Association ("AHA"). These organizations set guidelines for cardiologists in this country, and, because of their importance

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5 Kevin Li, et als., "Elective Percutaneous Coronary Intervention in Ambulatory Surgery Centers," JACC Cardiovascular Interventions, Vol. 14, No. 3 (2021). A copy of this document is attached hereto as Exhibit A.

6 A copy of the SCAI letter to CMS is attached hereto as Exhibit B.

7 A copy of the ACC letter to CMS is attached hereto as Exhibit C.

and expertise, the SHP Cardiac Services Section already references the importance of their opinions in determining whether a CON Application for cardiac services in Alabama should be granted. *See* § 410-2-3-.03(1)(b)5.

These organizations have determined that PCIs are safely performed in an ASC setting on appropriately selected patients. In the 2014 article *SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup*,[8] recommendations were made in the areas of credentialing, agreements for emergency transfer, quality assessment and improvement, and others, to assist programs in providing PCI services safely without on-site cardiothoracic surgical backup.

Following the CMS addition of these procedures to the approved list for an ASC setting, SCAI issued the *SCAI Position Statement on the Performance of Percutaneous Coronary Intervention in Ambulatory Surgical Centers*.[9] This article was prepared by SCAI to provide guidance for the development of ASC-based PCI programs, while maintaining a high standard of care. SCAI wrote "[T]he high safety profile of [PCI] and success of same-day discharge programs have made it possible to perform elective PCI in non-hospital outpatient facilities. . . . Because of the excellent safety profile of elective PCI and the opportunity for lowering cost, [CMS] initiated reimbursement for PCI performed in [ASCs] on January 1, 2020. . . . In appropriately selected patients for outpatient PCI, clinical outcomes for same-day discharge or routine overnight observation are comparable without any difference in short-term or long-term adverse events."

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[8] Gregory J. Dehmer, et als., *SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup*, Journal of the American College of Cardiology (2014). A copy of this article is attached hereto as Exhibit D.

[9] Lyndon C. Box, et als., *SCAI Position Statement on the Performance of Percutaneous Coronary Intervention in Ambulatory Surgical Centers*, Catheter Cardiovasc Interv. (2020). A copy of this article is attached hereto as Exhibit E.

In the 2021 article *ACC Expert Consensus Decision Pathway on Same-Day Discharge After Percutaneous Coronary Intervention*, the authors wrote "PCI has evolved in safety and efficacy such that many patients can leave facilities the same day as the procedure, with retrospective data showing no increase in death or rehospitalization compared with patients who stay for overnight monitoring. In addition, [same-day discharge] is preferred by patients and can increase cost savings and bed capacity."[10]

In order to further educate the SHCC, attached to this amendment request is Exhibit G which is a White Paper prepared by representatives of HVIA and its Healthcare Consultants. This paper explains why ASCs are a safe and cost-effective setting for diagnostic and therapeutic cardiac catheterization procedures.

According to the proposed amendatory language, the current requirements for acute care hospitals providing elective PCIs without open heart backup capabilities will also apply to ASCs. Planning Policy 5 will vary slightly in its application to acute care hospitals and ASCs. Currently, acute care hospitals providing diagnostics and therapeutic cardiac catheterizations may provide emergency interventional/therapeutic cardiac catheterization services to any patient. However, because ASCs will be limited to treating only appropriately selected patients, ASCs will not be able to provide emergency interventional/therapeutic services to a patient who presents to the facility in an emergent state. ASCs will only provide such emergent services to patients of the facility who become emergent cases during their elective interventional or diagnostic cardiac catheterization procedure.

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[10] Sunil V. Rao, et als., *2021 ACC Expert Consensus Decision Pathway on Same-Day Discharge After Percutaneous Coronary Intervention, Journal of the American College of Cardiology* (2021). A copy of this article is attached hereto as Exhibit F.

The proposed amendatory language filed herewith merely establishes that the evolution and advances in the area of cardiac catheterization services have reached the point where it is clear that these procedures can be performed in an ASC setting subject to reasonable conditions to assure patient safety.

VI. Proposed Language

The proposed language of the requested State Health Plan Amendment is attached hereto as Exhibit H.

VII. Certification

I, David E. Belser, do certify the information contained in this application for amendment to the State Health Plan is true and correct to the best of my knowledge and belief.

David E. Belser
One of the attorneys for the Applicant

EXHIBIT A

JACC: CARDIOVASCULAR INTERVENTIONS
PUBLISHED BY ELSEVIER ON BEHALF OF THE
AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION

VOL. 14, NO. 3, 2021

Elective Percutaneous Coronary Intervention in Ambulatory Surgery Centers

Kevin Li, MD,[a] Neil M. Kalwani, MD, MPP,[b] Paul A. Heidenreich, MD,[b] William F. Fearon, MD[b]

ABSTRACT

OBJECTIVES The aim of this study was to explore characteristics and outcomes of patients undergoing elective percutaneous coronary intervention (PCI) in ambulatory surgery centers (ASCs).

BACKGROUND Little is known about patients who underwent ASC PCI before Medicare reimbursement was instituted in 2020.

METHODS Using commercial insurance claims from MarketScan, adults who underwent hospital outpatient department (HOPD) or ASC PCI for stable ischemic heart disease from 2007 to 2016 were studied. Propensity score analysis was used to measure the association between treatment setting and the primary composite outcome of 30-day myocardial infarction, bleeding complications, and hospital admission.

RESULTS The unmatched sample consisted of 95,492 HOPD and 849 ASC PCIs. Patients who underwent ASC PCI were more likely to be younger than 65 years, to live in the southern United States, and to have managed or consumer-driven health insurance. ASC PCI was also associated with decreased fractional flow reserve utilization (odds ratio [OR]: 0.31; 95% confidence interval [CI]: 0.20 to 0.48; $p < 0.001$). In unmatched, multivariate analysis, ASC PCI was associated with increased odds of the primary outcome (OR: 1.25; 95% CI: 1.01 to 1.56; $p = 0.039$) and bleeding complications (OR: 1.80; 95% CI: 1.11 to 2.90; $p = 0.016$). In propensity-matched analysis, ASC PCI was not associated with the primary outcome (OR: 1.23; 95% CI: 0.94 to 1.60; $p = 0.124$) but was significantly associated with increased bleeding complications (OR: 2.49; 95% CI: 1.25 to 4.95; $p = 0.009$).

CONCLUSIONS Commercially insured patients undergoing ASC PCI were less likely to undergo fractional flow reserve testing and had higher odds of bleeding complications than HOPD-treated patients. Further study is warranted as Medicare ASC PCI volume increases. (J Am Coll Cardiol Intv 2021;14:292–300) Published by Elsevier on behalf of the American College of Cardiology Foundation

In November 2019, the Centers for Medicare and Medicaid Services (CMS) finalized a rule that added percutaneous transluminal coronary angioplasty and transcatheter placement of intracoronary stents to the list of procedures reimbursed in ambulatory surgery centers (ASCs), effective January 1, 2020 (1). The previous year, the agency had also deemed diagnostic catheterization and angiography as reimbursable in ASCs (2). CMS changed these policies in light of evidence that supports the safety of same-day discharge following elective percutaneous coronary intervention (PCI) (3,4) and of PCI performed without on-site cardiothoracic surgical support (5,6). Same-day discharge has been associated with cost savings compared with overnight observation (7), and studies suggest that this practice has become more common within recent years (4,8,9) as a greater percentage of elective PCI cases are

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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performed under outpatient rather than inpatient admission status (10). However, little is known about commercially insured patients who underwent ASC PCI prior to this CMS rule change (11).

In this study, we used an administrative claims database of commercially insured patients to characterize a sample of adults who underwent outpatient elective PCI for stable ischemic heart disease in either a hospital outpatient department (HOPD) or ASC during the study period. We additionally used propensity score matching to assess the relationship between ASC treatment setting and adverse outcomes following PCI.

SEE PAGE 301

METHODS

DATA SOURCE. We conducted a retrospective, observational analysis of administrative claims data from the IBM MarketScan Commercial and Medicare Supplemental Databases. These claims reflect inpatient and outpatient services and outpatient pharmacy claims for persons in the United States covered by private and Medicare Supplement insurance. Procedures were identified using Current Procedural Terminology, Healthcare Common Procedure Coding System, and International Classification of Disease (ICD)-9th Revision and ICD-10th Revision procedure codes. Diagnoses were identified using ICD diagnosis codes. This study was deemed exempt from human studies review by the Institutional Review Board at Stanford University. Data were used as part of a prespecified data-use agreement and are not publicly accessible.

STUDY COHORT. We identified patients 18 years of age or older undergoing outpatient percutaneous transluminal coronary angioplasty with or without stenting between April 1, 2007, and December 1, 2016 (Supplemental Table 1). The first instance of PCI for each patient was designated as the index procedure. Patients with PCI billed in both inpatient and outpatient settings on the index date were excluded to ensure proper attribution of treatment setting (**Figure 1**). Patients were required to have at least 90 days of continuous insurance enrollment prior to and 30 days of continuous enrollment after the index date. Patients were excluded if demographic information or prescription drug use were not captured. To ensure that cases reflected stable ischemic heart disease, patients were excluded if they had diagnoses of myocardial infarction (MI) or acute coronary syndrome in the 90 days before the index date.

We also excluded patients who underwent same-day coronary artery bypass grafting (CABG) to exclude the possibility of planned hybrid revascularization, which was outside the scope of this study. We note that same-day CABG may also arise because of PCI complications, especially following PCI performed in the freestanding setting, in which planned hybrid procedures are unlikely. However, we were not able to determine from the data whether same-day CABG was planned or arose because of a PCI complication. After applying all other criteria, there was no statistically significant difference in same-day CABG between HOPD PCI and ASC PCI ($p = 0.376$, Fisher exact test), with incidence in both groups ≤0.1%.

EXPLANATORY VARIABLES. Our primary exposure of interest was the outpatient practice setting in which PCI was performed. Among PCI billed as outpatient procedures, we used CMS place-of-service codes 11 (office) and 24 (ASC) cross-referenced with CMS type-of-bill codes to distinguish those performed in freestanding ASCs from those performed in an HOPD on an ambulatory basis (11,12). Patients were characterized by age, sex, year of treatment, geography of residence, insurance plan type, comorbidities, procedural characteristics, and peri-procedural medication use. Geography was captured at the level of U.S. region, state, and metropolitan statistical area if applicable. Urban areas were defined as those associated with metropolitan statistical areas. Insurance plan groupings were defined by the nature of patient cost sharing and included comprehensive, managed (exclusive provider organization, health maintenance organization, preferred provider organization, point of service with or without capitation), and consumer-driven or high-deductible health plans. Comorbidities were assessed from the beginning of data collection (April 1, 2007) to the index date and included conditions previously found to be associated with PCI complications (13–15) such as heart failure, history of cardiogenic shock, diabetes, chronic obstructive pulmonary disease, chronic kidney disease, peripheral vascular disease, and malignancy (Supplemental Table 1). Other measured comorbidities included a history of MI or acute coronary syndrome diagnosed at least 90 days prior to the index date, previous CABG, and history of stroke, dyslipidemia, hypertension, obesity, and tobacco use. Procedural characteristics included multivessel PCI, stent implantation, use of glycoprotein IIb/IIIa inhibitors (GPIs), and performance of

ABBREVIATIONS AND ACRONYMS

ASC = ambulatory surgery center

CABG = coronary artery bypass grafting

CI = confidence interval

CMS = Centers for Medicare and Medicaid Services

FFR = fractional flow reserve

GPI = glycoprotein IIb/IIIa inhibitor

HOPD = hospital outpatient department

ICD = International Classification of Diseases

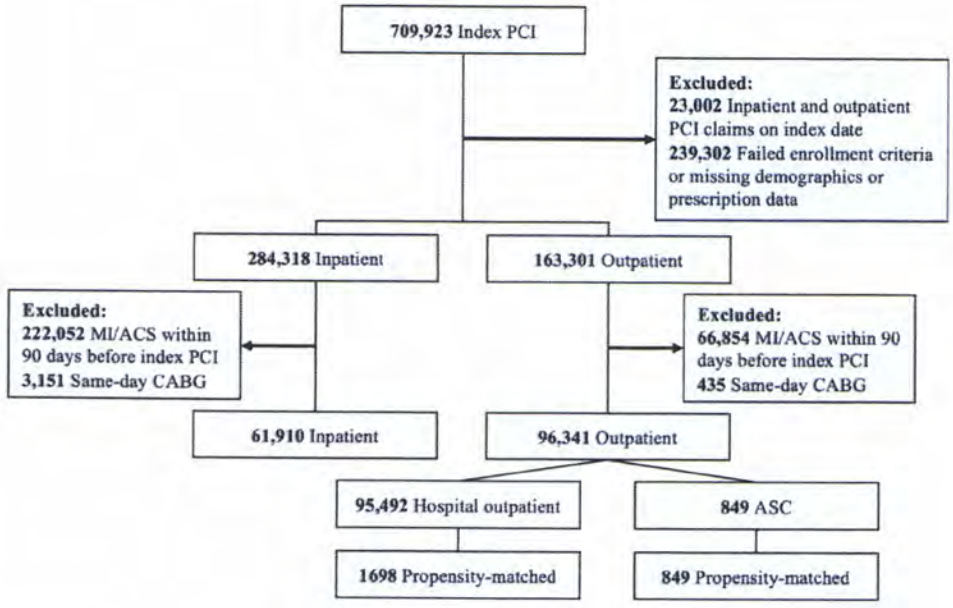
MI = myocardial infarction

OCT = optical coherence tomography

OR = odds ratio

PCI = percutaneous coronary intervention

FIGURE 1 Cohort Flow Diagram



A total of 96,341 patients undergoing outpatient percutaneous coronary intervention (PCI) for stable ischemic heart disease were included in the final study cohort, among whom 849 patients were treated in ambulatory surgery centers (ASCs). Patients may have been excluded on multiple exclusion criteria. ACS = acute coronary syndrome; CABG = coronary artery bypass grafting; MI = myocardial infarction.

fractional flow reserve (FFR), intravascular ultrasound, or optical coherence tomography (OCT). We also assessed whether patients filled outpatient prescriptions for nonsalicylate antiplatelet or anticoagulant medications within the 30 days before or after the index date.

OUTCOME VARIABLES. Our primary outcome was a composite of MI, bleeding or vascular complications (post-procedural hemorrhage, hematoma, or puncture; hemopericardium; cardiac tamponade; or hemoperitoneum including retroperitoneal hemorrhage), and hospital admission in the 30 days following and inclusive of the index date (Supplemental Table 1). Outcomes were also assessed individually. An event was identified if an outcome-related diagnosis was added in the follow-up period and was also not present in the 90 days prior to the index date. Mortality data were not available, and therefore death was not included as an outcome. Repeat PCI was also not included as an outcome, because of the inability to differentiate between planned staged and unplanned revascularization in the dataset. We note that codes corresponding to post-procedural hemorrhage, hematoma, or puncture were not specific to procedure type in ICD-9th Revision and were made specific to circulatory system structures and procedures only in ICD-10th Revision.

STATISTICAL ANALYSIS. Baseline characteristics were compared between the HOPD and ASC PCI groups, with differences in categorical and continuous variables assessed using chi-square and Student's *t*-tests, respectively. Associations of ASC treatment setting with demographic, comorbidity, and pre-procedural medication variables were assessed using multivariate logistic regression. Propensity score analysis was then used to compare outcomes after HOPD and ASC PCI (16). We matched patients who underwent ASC PCI with those treated in HOPDs using the nearest-neighbor method in order of descending propensity score. Propensity scores were calculated using age group, sex, year of treatment, geography (state and urban status) of residence, insurance plan type, comorbidities, and pre-procedural medication use. To match, a patient treated in an HOPD was required to have the logit of the propensity score be within 0.2 SDs of that of the index ASC patient (17). A 1-to-2 ASC-to-HOPD matching ratio was used to minimize sampling variability (18,19). Balance of variables between HOPD and ASC PCI groups before

and after propensity score matching was assessed using a standardized mean difference threshold of 0.1 (20).

Associations between outpatient treatment setting and outcomes were first estimated using multivariate logistic regression of unmatched cohorts, adjusting for age group, sex, treatment year, state of residence, urban status, insurance plan type, multivessel PCI, GPI use, peri-procedural medication use, and measured comorbidities. In propensity-matched analysis, effect size was estimated using multivariate logistic regression adjusting for multivessel PCI, GPI use, and post-procedural medication use, variables that were not used for matching. Effect size was represented as an odds ratio (OR) with a 95% confidence interval (CI). Statistical significance was assessed at $p < 0.05$. Analysis was conducted using R version 4.0.0 (R Foundation for Statistical Computing, Vienna, Austria) with propensity score analysis performed using the MatchIt (21) R package version 3.0.2.

RESULTS

COHORT CHARACTERISTICS. We identified 96,341 patients (**Figure 1**) undergoing outpatient elective PCI for stable ischemic heart disease. Among this cohort, 95,492 patients (99.1%) underwent HOPD PCI compared with 849 patients (0.9%) who underwent ASC PCI (**Table 1**). From 2007 to 2016, the HOPD share of total (inpatient and outpatient) elective PCI increased from 32.0% to 80.6% (Supplemental Figure 1), while the ASC share remained <1% throughout the study period. The majority of patients resided in urban areas and in the South and North Central regions of the United States. ASC utilization as a percentage of outpatient elective PCI varied among states and was highest in Alaska (3.7%), Texas (3.1%), Kentucky (2.8%), Indiana (2.1%), and Kansas (1.3%) (Supplemental Figure 2).

BASELINE CHARACTERISTICS ASSOCIATED WITH ASC PCI. Among the sample of outpatient elective PCI, patients treated in ASCs compared with HOPDs (**Table 2**) were more likely to be younger than 65 years of age (OR: 1.75; 95% CI: 1.46 to 2.10), to live in the southern U.S. (reference group), and to be covered by managed (OR: 2.25; 95% CI: 1.69 to 3.00) or consumer-driven or high-deductible (OR: 2.09; 95% CI: 1.41 to 3.10) health plans compared with comprehensive health plans. Patients undergoing ASC PCI were also more likely to have histories of dyslipidemia (OR: 1.20; 95% CI: 1.01 to 1.42) and less likely to have histories of stroke (OR: 0.44; 95% CI: 0.27 to 0.70). Sex, urban status, and other measured comorbidities were not associated with treatment in the ASC setting in multivariate regression.

TABLE 1 Cohort Characteristics

	HOPD* (n = 95,492)	ASC* (n = 849)	p Value
Demographics			
Age, yrs	64.0 ± 10.7	59.8 ± 9.7	<0.001
Female	26,523 (27.8)	223 (26.3)	0.348
Region			<0.001
Northeast	12,037 (12.6)	64 (7.5)	
North Central	28,152 (29.5)	178 (21.0)	
South	45,226 (47.4)	531 (62.5)	
West	10,077 (10.6)	76 (9.0)	
Urban	75,457 (79.0)	654 (77.0)	0.17
Plan type			<0.001
Comprehensive	19,377 (20.3)	58 (6.8)	
Managed	71,201 (74.6)	737 (86.8)	
CDHP/HDHP	4,914 (5.1)	54 (6.4)	
Comorbidities			
Prior myocardial infarction	2,965 (3.1)	25 (2.9)	0.866
Prior acute coronary syndrome	4,805 (5.0)	34 (4.0)	0.199
Heart failure	14,251 (14.9)	109 (12.8)	0.099
History of cardiogenic shock	182 (0.2)	–	1.00
Prior coronary artery bypass graft	2,666 (2.8)	24 (2.8)	1.00
Diabetes	39,405 (41.3)	324 (38.2)	0.073
Dyslipidemia	71,461 (74.8)	665 (78.3)	0.022
Hypertension	74,975 (78.5)	643 (75.7)	0.055
Chronic obstructive pulmonary disease	15,364 (16.1)	103 (12.1)	0.002
Chronic kidney disease	8,237 (8.6)	62 (7.3)	0.191
Prior stroke	5,646 (5.9)	18 (2.1)	<0.001
Peripheral vascular disease	13,147 (13.8)	103 (12.1)	0.184
Malignancy	14,012 (14.7)	83 (9.8)	<0.001
Obesity	11,622 (12.2)	99 (11.7)	0.689
Current tobacco use	11,210 (11.7)	104 (12.2)	0.684
Pre-procedural outpatient prescriptions			
Antiplatelet, nonsalicylate	16,073 (16.8)	138 (16.3)	0.688
Anticoagulation	3,612 (3.8)	17 (2.0)	0.009
Procedural			
Multivessel	11,240 (11.8)	99 (11.7)	0.964
Stent	90,524 (94.8)	784 (92.3)	0.002
Glycoprotein IIb/IIIa inhibitor use	6,964 (7.3)	34 (4.0)	<0.001
Intravascular imaging/physiology	17,494 (18.3)	106 (12.5)	<0.001
Intravascular imaging	11,219 (11.7)	87 (10.2)	0.194
Fractional flow reserve	7,241 (7.6)	21 (2.5)	<0.001

Values are mean ± SD or n (%). *Cell sizes <12 are hidden for reporting purposes.
ASC = ambulatory surgery center; CDHP = consumer-driven health plan; HDHP = high-deductible health plan; HOPD = hospital outpatient department.

In the 30 days before PCI, 16.8% and 16.3% of HOPD- and ASC-treated patients, respectively, filled prescriptions for nonsalicylate antiplatelet medications (**Table 1**). Pre-procedural outpatient anticoagulant prescriptions were filled by 3.8% and 2.0% of HOPD and ASC patients, respectively, a difference that was statistically significant ($p = 0.009$) in univariate analysis. However, neither pre-operative antiplatelet nor pre-operative anticoagulant use was significantly associated with the ASC setting in multivariate regression.

PROCEDURAL CHARACTERISTICS. The proportion of multivessel procedures was not significantly

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TABLE 2 Multivariable Analysis of Pre-Procedural Factors Associated With the Ambulatory Surgery Center Setting Among Outpatient Elective Percutaneous Coronary Intervention

	OR	95% CI	p Value
Demographics			
Age, yrs			
<65	1.75	(1.46–2.10)	<0.001
≥65	Reference		
Female	1.02	(0.87–1.19)	0.785
Region			
Northeast	0.51	(0.39–0.66)	<0.001
North Central	0.62	(0.52–0.74)	<0.001
South	Reference		
West	0.68	(0.54–0.87)	0.002
Urban	0.94	(0.8–1.10)	0.443
Plan type			
Comprehensive	Reference		
Managed	2.25	(1.69–3.00)	<0.001
CDHP/HDHP	2.09	(1.41–3.10)	<0.001
Comorbidities			
Prior myocardial infarction	1.11	(0.73–1.70)	0.617
Prior acute coronary syndrome	0.86	(0.60–1.25)	0.440
Heart failure	1.17	(0.94–1.45)	0.163
History of cardiogenic shock	1.32	(0.32–5.45)	0.702
Prior coronary artery bypass graft	1.06	(0.68–1.66)	0.790
Diabetes	0.91	(0.79–1.05)	0.215
Dyslipidemia	1.20	(1.01–1.42)	0.036
Hypertension	0.90	(0.76–1.07)	0.228
Chronic obstructive pulmonary disease	0.91	(0.73–1.13)	0.411
Chronic kidney disease	1.07	(0.82–1.41)	0.611
Prior stroke	0.44	(0.27–0.70)	<0.001
Peripheral vascular disease	1.15	(0.92–1.42)	0.220
Malignancy	0.83	(0.66–1.05)	0.127
Obesity	0.91	(0.73–1.13)	0.389
Current tobacco use	0.96	(0.77–1.18)	0.679
Pre-procedural outpatient prescriptions			
Antiplatelet, nonsalicylate	0.97	(0.80–1.16)	0.726
Anticoagulation	0.68	(0.42–1.10)	0.114

CI = confidence interval; OR = odds ratio; other abbreviations as in Table 1.

different between HOPD (11.8%) and ASC (11.7%) PCI in univariate analysis, while the proportion of PCI involving stent placement was higher in HOPDs (94.8%) compared with ASCs (92.3%; p = 0.002). GPI use was more common in HOPD PCI (7.3%) than in ASC PCI (4.0%; p < 0.001).

Notably, FFR and intravascular ultrasound or OCT were used more frequently in HOPD (18.3%) than in ASC (12.5%) PCI (p < 0.001). When adjusted for age group, sex, region, urban status, plan type, comorbidities, and pre-procedural medication use in multivariate logistic regression, the association between ASC setting and decreased use of either FFR or intravascular ultrasound or OCT was statistically significant (OR: 0.62; 95% CI: 0.51 to 0.76; p < 0.001). When modalities were considered individually, ASC setting was significantly associated with decreased FFR use (OR: 0.31; 95% CI: 0.20 to 0.48; p < 0.001) but not with intravascular ultrasound or OCT use (OR: 0.82; 95% CI: 0.66 to 1.03; p = 0.086).

ASC PCI OUTCOMES. In unmatched, multivariate analysis, ASC PCI was associated with increased odds of the primary composite outcome (OR: 1.25; 95% CI: 1.01 to 1.56; p = 0.039) and of bleeding complications (OR: 1.80; 95% CI: 1.11 to 2.90; p = 0.016) compared with HOPD PCI. The associations of ASC setting with MI (OR: 1.16; 95% CI: 0.69 to 1.95; p = 0.577) and with hospital admission (OR: 1.21; 95% CI: 0.95 to 1.53; p = 0.119) were not statistically significant.

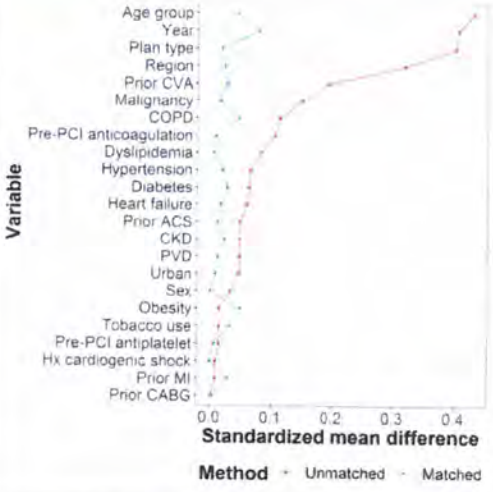
Propensity scores were used to match the 849 ASC-treated patients with 1,698 HOPD-treated patients. Both groups were well balanced, with a standardized mean difference <0.10 across all variables used in matching (Figure 2). Among the propensity-matched sample, the incidence of the primary composite outcome was 11.7% in ASC PCI and 9.8% in HOPD PCI (Central Illustration). The association between the ASC setting and the primary composite outcome was not statistically significant (OR: 1.23; 95% CI: 0.94 to 1.60; p = 0.124) after adjusting for multivessel PCI, GPI use, and post-procedural antiplatelet and anticoagulant use. Bleeding complications were more common in the ASC PCI group (2.1%) compared with the matched HOPD PCI group (0.9%), an association that was statistically significant (OR: 2.49; 95% CI: 1.25 to 4.95; p = 0.009) after adjustment. Hospital admission was the most common outcome in matched ASC (9.4%) and HOPD (8.2%) PCI groups. However, ASC PCI was not significantly associated with either hospital admission (OR: 1.18; 95% CI: 0.88 to 1.57; p = 0.274) or MI (OR: 1.15; 95% CI: 0.60 to 2.18; p = 0.674).

DISCUSSION

Although outpatient elective ASC PCI is now reimbursable under Medicare, there have been limited data on the outcomes of procedures previously performed in this setting. This is the first study to our knowledge to characterize patients treated in free-standing ASCs and their short-term outcomes.

In our sample of commercially insured patients, we did not observe a difference between propensity-matched ASC and HOPD PCI in the primary composite outcome of MI, bleeding complications, or hospital admission. However, we did find increased odds of post-procedural bleeding complications in the ASC-treated group when assessed as an individual outcome after controlling for covariables including GPI use, which was less common in ASC PCI. This may suggest increased risk associated with procedures performed in ASCs due to facility- or operator-level variation across factors such as vascular access site (22), use of vascular closure devices (23), and operator volume. In particular, the overall growth of radial

FIGURE 2 Balance of Hospital Outpatient and Ambulatory Surgery Center Cohorts Before and After Propensity Score Matching



Following matching, hospital outpatient and ambulatory surgery center cohorts were well balanced, with a standardized mean difference <0.10 (indicated by the **vertical line**) across all covariables used for matching. CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; CVA = cerebrovascular accident; Hx = history; PVD = peripheral vascular disease; other abbreviations as in Figure 1.

relative to femoral access during the study period may not have been fully realized in the ASC setting, a possible explanation for increased vascular complication rates in these facilities (24). The available data did not allow us to ascertain the severity of bleeding or definitively attribute complications to the index procedure, which limits our ability to judge the clinical significance of the observed difference. The absence of a statistically significant difference in hospital admissions between HOPD and ASC PCI may also suggest that complications arising in the ASC setting were not severe enough to warrant inpatient care. Nevertheless, our findings underscore the need for further study of post-procedural outcomes in the freestanding setting, especially as ASCs may not always be staffed to manage problems like early hematoma formation that could otherwise be observed overnight under outpatient status in a hospital.

We also observed geographic variation in the relative use of ASCs for outpatient elective PCI. This variation is likely multifactorial and may involve financial incentives as well as local practice patterns and provider supply (25). Physician ownership stakes in ASCs may encourage providers to preferentially perform elective cases in these facilities, a dynamic that has been associated with recent increases in office-based peripheral vascular intervention volume under Medicare (26,27). Patients may also be incentivized to undergo interventional procedures in ASCs through their health insurance plans. We found that patients undergoing ASC PCI were more likely to have managed or consumer-driven health plans than patients undergoing HOPD PCI. Compared with comprehensive policies, these plans may steer care toward lower cost settings through incentives such as reduced out-of-pocket payments. In the California Public Employees Retirement System, for example, ASC use increased after patients were required to pay the difference between a fixed employer contribution and the facility price, which tended to be higher in HOPDs than in ASCs (28).

With ASC PCI poised to grow under Medicare, the Society for Cardiovascular Angiography and Interventions has recommended that patients with unfavorable clinical features or high-risk lesions be treated in hospitals (29). The degree to which such patient selection practices were implemented in this sample is unclear. We found that ASC PCI patients were younger on average than HOPD PCI patients, which may reflect pre-procedural screening or limited ASC access among Medicare-age patients. Of the comorbidities we measured, however, only history of stroke was inversely associated with ASC treatment setting. We did not identify other baseline differences in measured comorbidities between HOPD and ASC PCI to suggest significant pre-procedural risk stratification in the latter.

Importantly, we also found that FFR was less likely to be performed in ASC PCI than in HOPD PCI after controlling for patient demographics, comorbidities, and pre-procedural medication use. This observation may be related to financial considerations or to lower prevalence of academic or teaching affiliations among ASCs (30). One might also expect decreased FFR use with more severe lesions for which the indication to treat is apparent with angiography alone. However, we believe it is unlikely that lesion severity was higher on average in ASC PCI than in HOPD PCI but acknowledge that the data do not allow us to make this determination. Nevertheless, neither intravascular imaging nor FFR are reimbursed under new CMS policies (29), even though FFR and intravascular ultrasound guidance of elective PCI for stable ischemic heart disease have been associated with improved long-term outcomes compared with conventional angiography alone (31,32). Long-term follow-up for adverse outcomes in this patient population is

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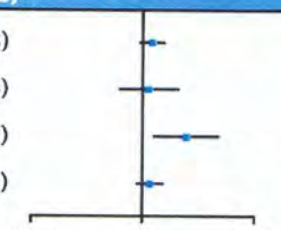
CENTRAL ILLUSTRATION Outcomes of Elective Percutaneous Coronary Intervention in Ambulatory Surgery Centers and Hospital Outpatient Settings

Outcome	Ambulatory Surgery Centers (%) (n = 849)	Hospital Outpatient Departments (%) (n = 1,698)	Odds Ratio (95% CI)	p Value
Any	99 (11.7)	167 (9.8)	1.23 (0.94–1.60)	0.124
Myocardial infarction	15 (1.8)	27 (1.6)	1.15 (0.60–2.18)	0.674
Bleeding complications	18 (2.1)	16 (0.9)	2.49 (1.25–4.95)	0.009
Hospital admission	80 (9.4)	139 (8.3)	1.18 (0.88–1.57)	0.274



Li, K. et al. J Am Coll Cardiol Intv. 2021;14(3):292-300.

Forest plot comparing outcomes in ambulatory surgery center (ASC) and hospital outpatient department (HOPD) percutaneous coronary intervention (PCI) following propensity score matching. The propensity-matched cohort consisted of 849 ASC and 1,698 HOPD PCIs. The difference in the primary composite outcome of 30-day myocardial infarction, bleeding and vascular complications, or hospital admission between groups was not statistically significant. The odds of bleeding and vascular complications alone were increased with ASC PCI. Data are graphed on a logarithmic scale.
CI = confidence interval.

therefore indicated given the relatively low observed use of these diagnostic tools in the ASC setting.

STUDY LIMITATIONS. First, the volume of elective ASC PCI was low compared with HOPD PCI. Additionally, the MarketScan databases include only patients with commercial or Medicare Supplement insurance plans. It is therefore possible that the population of patients who will undergo ASC PCI under new Medicare policies will differ from the patients in the present study, which could limit the generalizability of our results. External validity may also be limited by bias arising in database creation or from unmeasured confounders, for which propensity score analysis did not control.

Second, the accuracy with which administrative claims indicate exposures and outcomes may be limited by variation in coding practices between HOPDs and ASCs, specificity of diagnosis codes, or lack of data on clinical characteristics such as target vessel, extent of stenosis, vascular access site, and the severity of patient comorbidities and outcomes. Procedural history (e.g., PCI, CABG) prior to index PCI was also limited by the duration of data collection. We are reassured that the prevalence of measured comorbidities between HOPD and ASC PCI were similar in magnitude prior to matching and that our measured incidence of early MI, bleeding complications, and hospital admission is in line with what has been reported previously (3,33,34) in different populations. Such limitations could nevertheless bias results toward the null hypothesis and therefore reduce our ability to discern differences between ASC and HOPD groups.

Finally, the short follow-up associated with this analysis did not allow evaluation of differences in long-term outcomes that might result from higher bleeding rates and lower use of intravascular imaging and coronary physiology assessment.

Despite these limitations, we believe that this analysis provides an informative first look at the potential clinical implications of increased elective PCI volume in freestanding ASCs under Medicare, given the relative paucity of data in this area. Further work is needed to characterize procedures performed in this setting and validate findings from the present study as more robust data for this population become available.

CONCLUSIONS

In this study of commercially insured patients undergoing outpatient elective PCI, we found differences in age, geography, and insurance coverage between ASC and HOPD PCI. We additionally found decreased use of FFR in ASCs, a tool associated with improved long-term outcomes. After propensity score matching, we did not observe a difference between HOPD and ASC PCI in our primary composite outcome of MI, bleeding complications, and hospital admission. However, ASC PCI was associated with increased odds of bleeding complications when assessed as an individual outcome, supporting the need for risk stratification prior to treating patients in the free-standing setting. Future ASC-specific data collection will allow further study of this population.

FUNDING SUPPORT AND AUTHOR DISCLOSURES

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PERSPECTIVES

WHAT IS KNOWN? With PCI in ASCs now reimbursable under Medicare, further understanding of patients treated in this setting is warranted.

WHAT IS NEW? We found no difference between hospital outpatient and ASC PCI in a primary composite outcome of 30-day MI, bleeding complications, and hospital admission, though the risk for bleeding complications as an individual outcome was higher in ASC PCI. We also observed decreased use of FFR in ASC PCI. Pre-procedural risk stratification will likely be an important component of maintaining high quality of care in the free-standing setting.

WHAT IS NEXT? Prior studies suggest that PCI performed with same-day discharge and without on-site surgical support is safe, but there have been no studies of procedures performed in ASCs specifically.

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KEY WORDS health services research, ischemic heart disease, outcomes, PCI, percutaneous coronary intervention

APPENDIX For a supplemental table and figures, please see the online version of this paper.

EXHIBIT B

SCAI
Society for Cardiovascular Angiography & Interventions

August 27, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1717-P
PO Box 8013
Baltimore, MD 21244-1850

**Submitted electronically via
https://www.regulations.gov/comment?D=CMS-2019-0109-0002
and by email to Seema.Verma@cms.hhs.gov**

RE: **"Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; etc. [CMS-1717-P]"**

Dear Ms. Verma:

The Society for Cardiovascular Angiography and Interventions (SCAI) is a non-profit professional association with over 5,000 members representing the majority of practicing interventional cardiologists and cardiac catheterization teams in the United States, including those providing percutaneous coronary interventions (PCI). SCAI promotes excellence in invasive and interventional cardiovascular medicine through education, representation and the advancement of quality standards to enhance patient care.

SCAI, having reviewed the "Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; etc. [CMS-1717-P]" offers the following comments on issues of high interest to the interventional cardiology community:

Proposed Additions to the List of ASC Covered Surgical Procedures

First and foremost, SCAI is committed to quality, efficiency, patient experience and preference regarding treatment options, as well as site of service options. We are also committed to fiscal responsibility and identifying mechanisms that will bring cost-savings to the healthcare system.

Therefore, SCAI supports CMS's proposed addition of percutaneous coronary angioplasty and coronary stenting to the list of ASC Covered Surgical Procedures for CY2020.

We feel that elective, non-emergent percutaneous coronary angioplasty and coronary stenting procedures have relatively low complication rates and are not expected to pose a significant risk to Medicare beneficiary safety and do not typically require inpatient-level care following the procedure.

Regarding the list of other potential PCI procedures CMS is considering to add to the ASC Covered Surgical Procedure list, listed in Table 33 (titled, "POTENTIAL PROCEDURES ON WHICH WE REQUEST COMMENT FOR ADDITION TO THE CY 2020 ASC LIST OF COVERED SURGICAL PROCEDURES"), SCAI does not presently support the addition of these more complex PCI procedures to the ASC Covered Surgical Procedural list. These procedures may be associated with disproportionately higher rates of complications in Medicare populations and at this stage, they should only be performed with the extra support of the hospital setting. This may be revisited as experience with PCI in Medicare beneficiaries in the ASC setting grows.

It is imperative that patients undergoing PCI in the ASC setting receive the same quality of care afforded to cardiovascular patients receiving PCI in the hospital outpatient setting. We urge CMS to support the establishment of minimum facility standards that will assure quality of care in the ASC setting including a mandate for participation in a quality assurance and performance improvement process and to track outcomes for percutaneous coronary interventions (PCI) procedures performed in the ASC site of service. We urge CMS to identify a mechanism to directly cover the cost to ASCs to participate in a low-cost, quality registry. We believe this investment in the accrual of data will provide significant savings by aggregating data, enabling benchmarking, and providing a system which promotes process improvement.

SCAI has great concern that due to the current packaging of adjunct procedures known to enhance quality and known to reduce unnecessary PCI procedures, such as Fractional Flow Reserve Studies (FFR/iFR reported using CPT codes 93571, 93572) and Intravascular Ultrasound (IVUS reported using CPT codes 92978, 92979), physicians will be disincentivized to use these adjunctive technologies and will be unable to absorb the cost to perform them. Therefore, we strongly encourage CMS to unbundle these procedures. Greater use of these technologies has been shown to improve lesion selection for PCI and improve patient outcomes along with decreasing overall cost to the healthcare system.

SCAI would like to further engage CMS in exploring mechanisms to assure quality in the potentially efficient and cost-saving ASC site of service and will plan to reach out to CMS staff to request a face-to-face meeting after the Final OPP-ASC rule is released.

In conclusion, SCAI appreciates the opportunity to provide comment to CMS on issues of high interest to the interventional cardiology community contained in the "Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; etc. [CMS-1717-P]". If SCAI can be of any assistance as CMS continues to consider and review these issues, please do not hesitate to contact Mrs. Dawn R. Gray (Hopkins), Director of Reimbursement & Regulatory Affairs at (800) 253-4636, ext. 510 or dgray@scai.org.

Sincerely,

Ehtisham Mahmud, MD, FSCAI
SCAI President, 2019-2020

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EXHIBIT C

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September 27, 2019

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RE: CMS-1717-P; CY 2020 Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals

Dear Administrator Verma:

The American College of Cardiology (ACC) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule on the revisions to Medicare payment policies under the Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems for calendar year (CY) 2020, published in the August 9, 2019 Federal Register (Vol. 84, No. 154 FR, pages 39398-39644). The ACC envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned JACC Journals, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions. For more, visit acc.org.

The proposed rule includes both payment policy updates, modifications to individual Ambulatory Payment Classification (APC) rate setting and assignments, quality reporting programs, and other topics. In addition to other aspects, key areas on which the ACC focuses its comments include:

- Performance of percutaneous coronary intervention procedures in the Ambulatory Surgery Center (ASC) setting;
- Ongoing difficulties for some cardiovascular imaging modalities to find proper APC placement;
- Prior authorization for certain classes of services.

Proposed Additions to the List of ASC Covered Surgical Procedures

Percutaneous Coronary Interventions (PCI)

In CY 2019 rulemaking to revise the definition of "surgery" to include "surgery-like" procedures with CPT codes outside the CPT surgical range that are clinically similar to procedures in the CPT surgical range, do not pose a significant safety risk, are not expected to require an overnight stay, and are separately paid under the OPPS. For CY 2020 rulemaking, CMS conducted a review of codes not on the ASC Covered Procedures List (CPL) and is proposes to add three PCI procedures to the CPL. This proposal builds on CMS's decision to add a number of diagnostic coronary catheterization services to the CPL under the revised definition in CY 2019 rulemaking.

The ACC supports the proposed addition of three PCI procedures reported with six CPT codes to the ASC CPL for CY 2020. The College agrees with CMS's clinical assessment that these procedures can safely be performed in the ASC setting, though some amount of caution is necessary to ensure appropriate infrastructure and protocols are in place. Specific guidance for PCI performed without surgical backup exists and should serve as a framework for PCI in the ASC setting. The *SCAI/ACC/AHA Expert Consensus Document 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup* (attached) makes recommendations that will be helpful for sites. The document addresses credentialing, agreements for emergency transfer, and quality assessment and improvement.

Allowing these PCI procedures to be performed in an ASC is in line with CMS's goals to expand access to services and encourage the delivery of care in the lowest cost setting. However, merely identifying these services as covered services under the ASC setting does not necessarily mean that it will be economically feasible to do so. Cardiovascular interventions require the use of multiple devices. At around 60 percent of the OPPS payment rate, the ASC payment rate for these procedures may be insufficient to cover the costs of these procedures.

As CMS moves more surgical services to this setting, CMS should consider whether updates to the ASC payment methodology are needed in order to provide sufficient and sustainable payment. Recognizing the costs of device-intensive procedures in the ASC setting, the ACC encourages CMS to continue to evaluate policies and the appropriateness of payment amounts for services provided in the ASC as additional cardiovascular services are added to the ASC CPL. A specific consideration for these services should be the appropriate incorporation of related services recommended by literature and guidelines as commonly important for successful PCI.[1, 2, 3] Coronary intravascular ultrasound (IVUS) (92978-92979) and fractional flow reserve (FFR) (93571-93752) are both assigned status indicator "N" and are packaged into other services. With payment for ASC services made at a fraction of the OPPS payment rate, the ACC is concerned that packaging these services at the ASC payment rate could create

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[1] This study demonstrated that IVUS-guided DES implantation significantly improved clinical outcome in all-comers, particularly for patients who had an IVUS-defined optimal procedure compared to angiography guidance.
Zhang J, Gao X, Kan J, Ge Z, Han L, Lu S, Tian N, Lin S, Lu Q, Wu X, Li Q, Liu Z, Chen Y, Qian X, Juan Wang Chai D, Chen C, Li X, Gogas BD, Pan T, Shan S, Ye F, Chen SL, Intravascular Ultrasound-Guided Versus Angiography-Guided Implantation of Drug-Eluting Stent in All-Comers: The ULTIMATE trial, Journal of the American College of Cardiology (2018), doi: https://doi.org/10.1016/j.jacc.2018.09.013.

[2] Among patients requiring long coronary stent implantation, the use of IVUS-guided everolimus-eluting stent implantation, compared with angiography-guided stent implantation, resulted in a significantly lower rate of the composite of major adverse cardiac events at 1 year. These differences were primarily due to lower risk of target lesion revascularization.
Hong S, Kim B, MD; Shin, D, et al. Effect of Intravascular Ultrasound–Guided vs Angiography-Guided Everolimus-Eluting Stent Implantation The IVUS-XPL Randomized Clinical Trial. The Journal of the American Medical Association. 2015;314(20):2155-2163. doi:10.1001/jama.2015.15454. Published online November 10, 2015. Corrected on February 2, 2016.

[3] Among patients with complex coronary artery lesion, IVUS-guided PCI was associated with the lower long-term risk of cardiac death and adverse cardiac events compared with angiography-guided PCI. Use of IVUS should be actively considered for complex PCI.
Choi K, Song Y, Lee J, et al. Impact of Intravascular Ultrasound-Guided Percutaneous Coronary Intervention on Long-Term Clinical Outcomes in Patients Undergoing Complex Procedures. JACC: Cardiovascular Interventions. Volume 12, Issue 7, 8 April 2019, Pages 607-620.

an incentive for operators to forgo these enhancing technologies in some instances. One way to address this regarding PCI would be for CMS to unpackage these services, a solution the ACC recommends.[4, 5]

The College recommends that CMS consider how to measure and maintain the quality and safety of patient care provided in the ASC setting as more procedures are covered in this setting. At a minimum, CMS should continue to ensure that services for high risk patients are performed in the most appropriate setting as defined by clinical guidelines. Additionally, participation in a national data registry allows benchmarking, risk adjustment and facilitates outcomes analysis of local data and should be required.

Finally, while not proposing they be added to the ASC CPL, CMS also asks whether additional PCI services for atherectomy, of/through a bypass graft, and of a chronic total occlusion can be safely performed in an ASC setting. These services are more complex than those CMS proposes for addition to the CPL. The ACC believes it is appropriate for these services to remain in the facility setting at this time while additional experience in the ASC setting grows. Over time, after review of registry data and in discussion with subspecialty societies, the ACC can see the possibility of these procedures taking similar steps toward ASC, with certain protocols.

State Regulations

CMS asks how the Agency should think about the role of the CPL in the context of State regulations and other market forces as it makes decisions about which services to add to the CPL. The ACC appreciates that CMS is thinking about these additional factors that influence decision making. Members exploring this space have encountered various local aspects that require additional consideration, from certificate of need requirements to prohibitions in state law and/or regulation against provision of certain invasive procedures in the ambulatory setting. At this time the ACC believes it is appropriate for CMS to determine whether services fit criteria for inclusion on the CPL and then defer to state regulatory bodies to make local decisions. This is not unsimilar to the way CMS proposes to defer to state-level regulation of physician assistant scope of practice in the physician fee schedule.

Imaging APCs

Cardiac Magnetic Resonance Imaging and Cardiac Computed Tomography

The College remains concerned about payment stability for relatively low volume cardiac imaging services in the OPPS. Cardiac computed tomography (CT) (Code 75572-75574/APC 5571) and cardiac magnetic resonance (MR) imaging (Code 75561/APC 5572) have generally faced declining or unsteady payment levels in recent years. While the 2020 proposed rule maintains the same APC assignments for these services, payments are again slated to be reduced.

	CY 2020 Proposed	CY 2019	CY 2018	CY 2017
75572-75574	$179.91	$201.74	$252.72	$264.90
75561	$373.45	$385.88	$456.34	$426.34

[4] Functional revascularization for lesions with visually severe stenosis is clinically safe and associated with fewer stents use. This stu dy suggests that extending the use of FFR to more severe coronary lesions may be reasonable.
Zhang Y, Li J, Flammer A, et al. Long-term outcomes after fractional flow reserve reserve-guided percutaneous coronary intervention in patients with severe coronary stenosis. J Geriatr Cardiol 2019; 16: 329□337. doi:10.11909/j.issn.1671-5411.2019.04.001
[5] The authors conclude that on-site CT-FFR based on a ML algorithm can provide good diagnostic performance for detecting hemodynamically significant CAD, suggesting the high value of coronary CTA for selected patients in clinical practice.
Kurata A, Fukuyama N, Hirai K, et al. On-Site Computed Tomography-Derived Fractional Flow Reserve Using a Machine-Learning Algorithm - Clinical Effectiveness in a Retrospective Multicenter Cohort. Circ J.2019 Jun 25;83(7):1563-1571. doi: 10.1253/circj.CJ-19-0163. Epub 2019 Jun 8.

The College recognizes that other factors such as hospital cost reporting may contribute to inadequate payment amounts in the proposed rule calculations. Use of generic CT and MR cost center reporting systems will chronically underrepresent costs for these services because they fail to account for enhanced clinical staff time and additional medicines used to perform the service. That means that meaningful cost data will never show a geometric mean cost high enough to support APC reassignment based on costs alone. Additionally, since these services have relatively small utilization in comparison to the rest of an assigned APC, they would not meaningfully impact payment rates within an APC even with a higher geometric mean cost. The trend noted above has created a sustainability spiral where payment reductions mean the services are provided at a greater loss every year.

In the case of cardiac CT angiography, imaging acquisition time and resources are significantly different than other services in APC 5571. Before the scan begins, patients are evaluated by a highly-trained CT technologist and a nurse who administers IV medications. The patient is monitored for an extended period of time while these medications take effect. Electrocardiogram leads are attached for gating that allows images to be obtained at the exact moment in the cardiac cycle when the heart is not moving. When the scan is finally complete, the CT technologist executes imaging processing, which takes longer than other single-organ studies. It is only based on the inadequate cost data that these services are placed in APC 5571 with simpler CT, MR, and X-ray services. Additionally, with the growing number of structural heart procedures (TAVR, TMVR, LLA closures, etc.) that depend on CTA for procedural planning, CTA will only become more prevalent, especially in the outpatient setting. CTA is time intensive to both perform and to read, and therefore it should be reimbursed accordingly. **The ACC urges CMS to place cardiac CT codes with more resource intensive and clinically similar services in a higher payment APC, such as 5572 or 5573** while stakeholders work to identify better methods to account for costs.

Cardiac MR was previously included in a nuclear medicine APC, which was appropriate given the clinical and resource homogeneity of cardiovascular magnetic resonance and cardiac nuclear imaging services. However, since that time, CMR services have been shifted out of the nuclear imaging APCs and payment has dropped significantly in ways that could begin to diminish access to this service that provides important diagnostic information.

Different cost reporting methods used by hospitals may contribute to the artificially low relative payment weights and payment amounts for CT and MR discussed above. To address concerns about both these sets of services, the ACC requests that CMS continue to explore policies that ensure data accuracy and payment stability while minimizing the administrative burden on hospitals. This includes ongoing consideration of what cost allocation methods should be accepted by CMS for payment rate calculations, how to address the availability of sufficient and accurate data for low volume procedures, as well as monitoring and reconsidering the need for unique MR and CT CCRs in the future.

Fractional Flow Reserve Computed Tomography (FFRCT)

Fractional flow reserve can be measured using computed tomography to measure coronary artery disease and plan care for patients, possibly avoiding other downstream tests. FFRCT is currently calculated using proprietary data analysis executed at a central data processing facility to develop a three-dimensional image of patients' coronary arteries for measurement of fractional flow reserve. CMS assigned code 0503T for FFRCT to New Technology APC 1516 for services with costs between $1,401 and $1,500 based on pricing information provided by the technology developer.

For CY 2020 CMS proposes to assign 0503T to New Technology APC 1509 for services with costs between $701 and $800. This change stems from analysis of only 78 single-frequency claims and 844 total claims submitted for payment during 2018 that produced a geometric mean cost of $788.19. **The ACC recommends CMS not finalize this proposal, and instead consider changes in future rulemaking with at least one additional year of data.** While not the same program, new technology

payments and pass-through payments are typically made for 2-3 years while additional data is collected and considered. Given concerns highlighted about cost reporting in other areas of this comment letter, it would be unfortunate if this technology was stifled by a premature downward adjustment.

Prior Authorization

The ACC recognizes CMS' interest in managing rising health care spending by limiting unnecessary increases in service volume and shifting care to lower cost settings. While these are reasonable goals, the College urges CMS to ensure that proposals do not create additional barriers to patient access to care. CMS should not assume that an "increase" in the volume of covered OPD services automatically means correlates to an increase in "unnecessary" services. As CMS notes, there may be factors such as the severity of a patient's illness, patient demographics, or limited patient access to certain settings of care that may drive increased utilization in the outpatient setting. The clinician's documentation for services ordered should always be the source of determining the necessity of services for a specific patient.

During 2019 rulemaking the ACC recommended that **CMS should not consider blanket prior authorization as a method for controlling overutilization of services under the OPPS.** The ACC is concerned that enforcing prior authorization for services provided to the Medicare fee-for-service population will lead to increased inefficiency and may further contribute to delays in patient care. Furthermore, prior authorization continues to be a top administrative burden and frustration identified by both cardiologists and the medical community as a whole attempting to deliver high quality and effective care. Expanding prior authorization to outpatient services provided under Medicare without addressing current issues with the process would contradict CMS' Patients Over Paperwork initiative and goals to deliver quality patient care.

The ACC is disappointed CMS nevertheless proposes to implement a prior authorization process for provisional affirmation of coverage before a covered OPD service is furnished to a beneficiary and before the claim is submitted for processing. To allow additional time for providers to better understand the proposed process, the requirement would begin on/after July 1, 2020. **The ACC believes this proposal remains unnecessarily broad and should not be implemented.**

CMS identifies services for the prior authorization program as likely to be unnecessary because increased utilization exceeds what the Agency expects in light of the average rate-of-increase in the number of Medicare beneficiaries. For one of the classes of services for which CMS proposes to implement a prior authorization program, vein ablation, this logic ignores the enhanced clinical attention peripheral vascular disease has received in recent years. Patients with peripheral venous disease, including chronic venous insufficiency and varicose veins, can be treated with venous ablation when compression therapy fails. These patients can present with lower extremity pain that is worse with prolonged sitting or standing. Superficial venous ablation collapses these dilated vessels, which can improve the pain and discomfort that is associated with increased swelling.[6]

[6] Biemans AA1, Kockaert M, Akkersdijk GP, et al. Comparing endovenous laser ablation, foam sclerotherapy, and conventional surgery for great saphenous varicose veins. J Vasc Surg. 2013 Sep;58(3):727-34.e1. doi: 10.1016/j.jvs.2012.12.074. Epub 2013 Jun 13.

Vein Ablation Codes Proposed for Prior Authorization

CPT Code	Vein Ablation and Related Services
36473	Mechanochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36474	Mechanochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36475	Destruction of insufficient vein of arm or leg, accessed through the skin
36476	Radiofrequency destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36478	Laser destruction of incompetent vein of arm or leg using imaging guidance, accessed through the skin
36479	Laser destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36482	Chemical destruction of incompetent vein of arm or leg, accessed through the skin using imaging guidance
36483	Chemical destruction of incompetent vein of arm or leg, accessed through the skin using imaging guidance

Prior authorization should only be used if CMS can guarantee that it will not create additional burden for clinicians and patients.

The ACC, along with the American Medical Association and several specialty and state medical associations have developed principles that should apply to any prior authorization or utilization management program. These principles recommend that any program be based on clinical validity, support the continuity of patient care, be transparent and fair, provide timely access to care and administrative efficiency, and provide alternatives and exemptions to those clinicians with appropriate utilization rates.[7]

The Agency to should consider numerous issues with prior authorization that are currently experienced through Medicare Advantage (MA) and other health plans. Doctor visits are commonly delayed and/or extended while waiting for authorization decisions leading to multiple hour visits and rescheduled care. Clinicians have been forced to hire significant professional staff dedicated to managing requests and calls with prior authorization vendors, many of which result in the need for peer to peer (ordering physician to vendor-employed physician) discussion which pulls clinicians away from time with other patients.

While the ACC opposes the broad application of prior authorization, the College acknowledges that there may be a limited scope where prior authorization may be beneficial. For example, CMS should consider applying prior authorization to outliers or those whose ordering rates are not in compliance with clinical guidelines and standards of care. Subjecting a class of services to prior authorization, especially when a high rate of these services is eventually approved on a regular basis, creates unnecessary burden for clinicians, their patients, and even payers and prior authorization vendors. CMS seems to recognize as much when it proposes a scenario where it *may* exempt a provider from the proposed prior authorization process should a prior authorization provisional affirmation threshold of 90 percent be achieved during a semiannual assessment. **If CMS opts to finalize this program, it should improve**

[7] American Medical Association, American College of Cardiology, et al. *Prior Authorization and Utilization Management Reform Principles*. Available at: https://www.acc.org/~/media/Non-Clinical/Files-PDFs-Excel-MS-Word-etc/Latest%20in%20Cardiology/Advocacy%20and%20Policy/PA%20Reform%20Principles.pdf?la=en.

the proposed construct by saying it *will* exempt a provider under these circumstances. A preferable option would be to shift such a program as mentioned above—to one focused on outliers.

Proposed Requirements for Public Disclosure of All Hospital Standard Charges for All Items and Services

CMS proposes to make changes for hospitals and require they make public their standard charges (both gross and payer-specific negotiated charges) in two ways: (1) a comprehensive machine-readable file that makes public all standard charge information for all hospital items and services, and (2) a consumer friendly display of common "shoppable" services derived from the machine-readable file. This display of information refers to detailing a patient's expected out-of-pocket costs for nonurgent health care services that can be scheduled in advance. The Agency's proposal defines hospitals to include not only Medicare-enrolled institutions, but also non-Medicare enrolled institutions that are licensed as a hospital (or approved as meeting licensing requirements).

Proposed Standardized Data Elements

Under the proposed rule, CMS would require hospitals to make a list of items or services available for the public in a single digital file that is in a machine-readable format. The ACC appreciates CMS specifically defining machine-readable as not including PDF files, as these cannot be easily extracted without further processing or formatting. The ACC believes interoperability requires more than the ability of two or more health information systems or components to exchange clinical, cost and other information; it also requires that information be exchanged using common data standards to facilitate coordinated care and improved outcomes.

The ACC encourages CMS to build on additional efforts to provide patients with important health data through the development and implementation of an industry-wide open application program interface (API) standard. As recent interoperability successes following the development of common standards such as FHIR (Fast Healthcare Interoperability Resources specification) have shown, industry wide cooperation and development can lead to rapid deployment of technology that helps reduce installation costs and associated implementation burdens. Additionally, by encouraging the use of open APIs, CMS would continue to encourage the development of a health eco-system where trusted, third-party applications can provide value to patients through insights into health care costs and creation of cost and quality comparison tools. While open API standards in this space may not yet be mature, CMS should work with ONC, hospitals, standard-development organizations, and health IT vendors to evaluate and develop common standards that allow for industry-wide deployment in the future.

Proposed Requirements for Consumer-Friendly Display of the Payer-Specific Negotiated Charges for Selected Shoppable Services

CMS proposes that the hospital would display their payer-specific negotiated charges for the primary shoppable service side-by-side with payer-specific negotiated charges for all ancillary items and services the hospital customarily provides as part of or in conjunction with the primary service. Further, CMS defines shoppable services to include services which are typically those that are routinely provided in *non-urgent* situations that do not require immediate action or attention to the patient, thus allowing patients to price shop and schedule a service at a time that is convenient for them. CMS would select 70 services and the individual hospital would select the remaining 230 services to be included, a total of 300 required hospital-provided items and services. Under the proposal, hospitals may receive civil monetary penalties (CMPs) for noncompliance.

The ACC is concerned with the requirement that hospitals disclose their negotiated rates. The College understands and supports the attempted transparency to patients, but fears disclosing this information

could lead to suboptimal care and fuel anticompetitive behavior among commercial health insurers in an already concentrated market. Further, as seen with other proposed and final rules, if adopted, CMS may move to require this type of disclosure with other provider settings in the future. Finalizing this requirement would greatly undermine their ability to negotiate equitable payments for Medicare-enrolled and non-Medicare-enrolled hospitals.

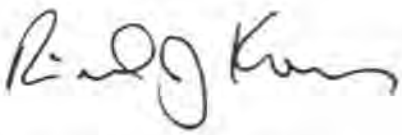
Patients seeking to minimize cost may seek services with less consideration for the quality of care. This could impact the underserved and low-income patients gravely, in some instances requiring repeat tests or services downstream. Patients may seek out imaging that proves suboptimal, for example, requiring greater coordination efforts amongst providers when determining a final course of treatment. A lack of interoperability would further delay ideal care of patients.

The ACC suggests CMS not finalize this portion of the proposed rule and instead develop a pilot program prior to full implementation. The ACC believes this proposed rule reaches outside of its statutory scope and could diminish not only the competitive market, but also the access and quality of care afforded to patients. Should CMS move forward with implementation, the ACC would recommend a phased approach with the requirement, expanding to a subset of hospitals and then identifying the potential challenges that this requirement would create.

Conclusion

CMS consideration of the comments in this letter is appreciated. The ACC looks forward to ongoing engagement with CMS to develop policies that support clinicians' ability to focus on delivering high-quality care to patients. The ACC acknowledges the tremendous thought and planning CMS is undertaking to improve the healthcare system. Should you or staff need additional information or have clarifying questions, please contact Claudia Vasquez, Associate Director of Medicare Payment & Quality Policy, at cvasquez@acc.org.

Sincerely,



Richard Kovacs, MD, FACC
President

Attachment

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EXPERT CONSENSUS DOCUMENT

SCAI/ACC/AHA Expert Consensus Document

2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

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Introduction

In 2007, the Society for Cardiovascular Angiography and Interventions (SCAI) published an Expert Consensus Document titled "The Current Status and Future Direction of Percutaneous Coronary Intervention without On-Site Surgical Backup" (1). This document summarized the available data on the performance of percutaneous coronary intervention (PCI) without on-site surgery in the United States (US), reviewed the existing literature, examined the recommendations for the performance of PCI in this setting from several professional organizations abroad and from experienced programs in the US, defined the best practices for facilities engaged in PCI without on-site surgery and made recommendations for the future role of PCI without on-site surgery.

Since publication of that document, new studies, meta-analyses, and randomized trials have been published comparing PCI with and without on-site surgery. In addition, the total number of PCIs performed annually has decreased, reports about the overuse of PCI have emerged, and appropriate use criteria for coronary revascularization have been published. A noteworthy change occurred in the 2011 PCI guideline in which elective PCI was upgraded to Class IIb and primary PCI was upgraded to Class IIa at facilities without on-site surgery (2). Several tables on the structure and operation of programs without on-site surgery from the 2007 SCAI Expert Consensus Document were used in the 2011 PCI guideline recommendations. Finally, new updates of the ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards and the ACCF/AHA/SCAI Clinical Competence in Coronary Artery Interventional Procedures have been published (3,4).

Although many of the concerns about the safety of PCI without on-site surgery have been resolved, there are new issues to consider as the delivery of PCI continues to evolve in the US. Accordingly, the SCAI, ACCF, and AHA have engaged in this effort to re-evaluate the current status of PCI without on-site surgery in the US. The specific goals of this effort were to:

1. Determine current trends in the prevalence of PCI without on-site surgery in the US;
2. Summarize new literature related to the performance of PCI without on-site surgery;
3. Review existing guidelines, expert consensus documents, competency statements and other documents related to PCI without on-site surgery and summarize all relevant information into a single resource document;

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Authors' relationships with industry are available in Appendix 1. Peer reviewers' relationships with industry are available in Appendix 2.

The American College of Cardiology requests that this document be cited as follows: Dehmer GJ, Blankenship JC, Cilingiroglu M, Dwyer JG, Feldman DN, Gardner TJ, Grines CL, Singh M. SCAI/ACC/AHA expert consensus document: 2014 update on percutaneous coronary intervention without on-site surgical backup. J Am Coll Cardiol 2014; 63:2624–41.

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4. Outline the current best practice methods and requirements for facilities engaged in performing PCI without on-site surgery; and
5. Evaluate the role of PCI without on-site surgery within the current US healthcare system.

Trends in the Performance of PCI

Although the use of PCI in the US had grown considerably since the early 1980s, data from the Nationwide Inpatient Sample cited by the Agency for Healthcare Research and Quality shows that the annual volume of PCI procedures peaked in 2006 and has since declined by over 30% (5). Numerous factors have contributed to this decline, including a reduction in restenosis by drug-eluting stents, a greater emphasis on medical therapy for the treatment of stable coronary artery disease, enhanced primary and secondary prevention efforts, a reduction in the incidence of ST-segment elevation myocardial infarction (STEMI), the increasing use of techniques such as fractional flow reserve to better evaluate lesion severity and the development and application of appropriate use criteria (5,6). As a result of these factors, many operators and hospitals now have low-volume practices. Using data from 2008, Maroney et al. estimated that 61% of interventional cardiologists performed 40 or fewer Medicare fee-for-service PCIs annually (7). Clinical data from 1298 facilities reporting to the National Cardiovascular Data Registry (NCDR) show that 49% of facilities performed ≤400 PCIs and 26% performed ≤200 PCIs annually (Fig. 1) (8). Approximately 33% of facilities had no on-site surgery, and among these, 65% (282 facilities) had an annual case volume of ≤200 PCI procedures.

Across the US, PCI without on-site surgery has increased since 2007. The writing committee assessed the current use of PCI without on-site surgery from a survey of ACC Governors for each state, data from industry sources and direct contact with physicians in various states (Fig. 2). Currently, 45 states allow both primary and elective PCI without on-site surgery, 4 states allow only primary PCI without on-site surgery, and 1 state prohibits PCI without on-site surgery. PCI without on-site surgery is regulated by the State Department of Health in 34 states but is unregulated in the remaining 16 states. Elective PCI without on-site surgery was allowed at selected facilities in 9 states but only as part of statewide demonstration projects or to allow participation in the Cardiovascular Patient Outcomes Research Team (CPORT) Nonprimary PCI (CPORT-E) trial (9). Since the conclusion of CPORT-E, the use of PCI without on-site surgery is being re-evaluated in several of these states. PCI without on-site surgery is currently performed in 19 of the 65 cardiac catheterization laboratories within the Veterans Health Administration (10).

Recent Literature on PCI Without On-Site Surgery

Since 2006, 11 original studies and 3 meta-analyses on the topic of PCI without on-site surgery have been identified by a computerized systematic literature search using Medline (PubMed and Ovid) and Cochrane Databases (9,11–23).

Primary PCI without on-site surgery. Seven studies and 2 meta-analyses of primary PCI showed no difference for in-hospital or 30-day mortality between sites with and without on-site surgery (Table 1). None of the individual studies examining the occurrence of emergency CABG surgery after primary PCI showed a difference between sites with and without on-site surgery. However, 1 meta-analysis showed that sites without on-site surgery had a lower occurrence of emergency CABG surgery after

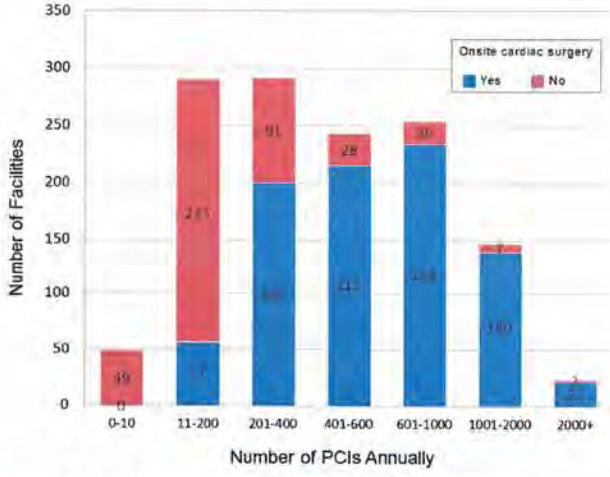

Figure 1. PCI Volume at Facilities With and Without Cardiac Surgery

Reproduced from Dehmer et al. (8) with permission.

Figure 2. Change in the Availability of PCI Without On-Site Surgery From 2007 to 2013

The numbers shown indicate the number of states where primary and nonprimary PCI without on-site surgery are allowed.

Table 1. Studies on Primary PCI Without On-Site Surgery Published Since 2006

Author (Year)	Sites	On-Site Surgery	No. of Patients in Arm	Mortality		Emergency CABG		Comments
				Incidence %	OR (95% CI)	Incidence %	OR (95% CI)	
Carlsson (2007) (12)	Multicenter SCAAR registry	No	857	7.0	1.05 (0.79–1.40)	0.1		30-day mortality is reported; Incidence of emergency CABG is for all patients (primary and nonprimary PCI)
		Yes	4,595	6.7		0.2		
Peels (2007) (13)	Single center	No	336	2.1	2.17 (0.26–17.8)	0	0.10 (0.00–2.51)	
		Yes	103	0.97		1.0		
Pereira (2008) (14)	Multicenter Portuguese registry	No	1,214	5.0	0.79 (0.55–1.14)	1.8	1.52 (0.90–2.56)	Cardiogenic shock mortality was 53.4% with on-site surgery and 50.9% without (NS)
		Yes	1,470	4.0		2.7		
Kutcher (2009) (15)	Multicenter NCDR registry	No	1,934	5.1	0.97 (0.79–1.20)	0.7	0.60 (0.35–1.03)	In-hospital mortality reported. Only 42% of sites without on-site surgery performed ≥36 primary PCIs annually compared with 80% of sites with on-site surgery
		Yes	31,099	5.2		1.2		
Pride (2009) (16)	Multicenter NRMI database	No	1,795	3.3	0.86 (0.61–1.23)			Propensity matched patient cohort. In-hospital mortality reported and only for patients undergoing primary PCI. Incidence of emergency CABG not reported
		Yes	1,795	3.8				
Hannan (2009) (17)	Multicenter New York State database	No	1,729	2.3	1.22 (0.76–1.94)	0.06	0.17 (0.02–1.38)	Propensity matched patient cohort. In-hospital/30-day mortality reported
		Yes	1,729	1.9		0.35		
Singh (2009) (18)	3 sites	No	667	2.5	0.80 (0.42–1.54)	0.7	1.25 (0.33–4.68)	Propensity matched patient cohort of nonelective PCI defined as acute MI within 24 h or cardiogenic shock.
	Mayo Clinic experience	Yes	667	3.1		0.6		
Meta-analyses								
Zia (2011) (19)		No	8,703	6.1	0.93 (0.83–1.05)	3.0	0.87 (0.68–1.11)	9 studies included in the analysis
		Yes	97,386	7.6		3.4		
Singh (2011) (20)		No	16,489	4.6	0.96 (0.88–1.05)	0.22	0.53 (0.35–0.79)	11 studies included in the analysis
		Yes	107,585	7.2		1.03		

CABG, coronary artery bypass graft surgery; NCDR, National Cardiovascular Data Registry; NRMI, National Registry of Myocardial Infarction; OR, odds ratio; PCI, percutaneous coronary intervention; SCAAR, Swedish Coronary Angiography and Angioplasty Registry.

primary PCI (odds ratio, 0.53; 95% confidence interval 0.35–0.79) (20).

PCI without on-site surgery for conditions other than STEMI. Eight studies examined nonprimary PCI at sites with and without on-site surgery (Table 2). The majority of studies and meta-analyses showed no difference in mortality or a need for emergency CABG at sites without on-site surgery. One study at a high-volume facility performing only elective PCIs and staffed by high-volume interventionalists showed a lower mortality at the facility without on-site surgery (OR, 0.11; 95% CI 0.01–0.79) (21). However, the baseline clinical and angiographic characteristics of the study groups with and without on-site surgery were sufficiently different that a meaningful adjusted analysis could not be performed, and there is therefore the possibility of a case selection bias.

Two randomized trials of nonprimary PCI have now been published. The CPORT-E trial randomized over 18,000 patients in a 1:3 ratio to undergo PCI at hospitals with and without on-site cardiac surgery, respectively (9). High-risk patients were excluded, as was the use of atherectomy devices. The trial had 2 primary endpoints: 6-week mortality and 9-month incidence of major adverse cardiac events (composite of death, Q-wave myocardial infarction, or target-vessel revascularization). The 6-week mortality rate was 0.9% at hospitals without on-site surgery compared with 1.0% at those with on-site surgery ($p = 0.004$ for noninferiority). The 9-month rates of major adverse cardiac events were 11.2% and 12.1% at hospitals with and without on-site surgery, respectively ($p = 0.05$ for noninferiority). A similar, but smaller randomized study of nonemergency PCI was performed in Massachusetts hospitals (11). The rates of major adverse cardiac events were 9.5% in hospitals without on-site cardiac surgery and 9.4% in hospitals with on-site cardiac surgery at 30 days (relative risk, 1.00; 95% one-sided upper confidence limit, 1.22; $p < 0.001$ for noninferiority) and 17.3% and 17.8%,

Table 2. Studies on Nonprimary PCI Without On-Site Surgery Published Since 2006

Author (Year)	Sites	On-Site Surgery	No. of Patients in Arm	Mortality		Emergency CABG		Comments
				Incidence %	OR (95% CI)	Incidence %	OR (95% CI)	
Carlsson (2007) (12)	Multicenter SCAAR registry	No	7,981	0.81	1.23 (0.91–1.65)	0.1		30-day mortality is reported; Incidence of emergency CABG is for all patients (primary and nonprimary PCI)
		Yes	20,930	0.66		0.2		
Frutkin (2008) (21)	2 sites	No	1,090	0.09	0.11 (0.01–0.79)	0.2	6.10 (0.55–67.3)	Nonrandomized comparison of 2 sites. Stable and unstable angina plus NSTEMI included. In-hospital mortality shown
		Yes	3,317	0.8		0.03		
Pereira (2008) (14)	Multicenter Portuguese registry	No	4831	0.5	1.43 (0.85–2.41)	0.7	3.14 (2.13–4.63)	
		Yes	5584	0.7		2.1		
Kutcher (2009) (15)	Multicenter NCDR registry	No	6,802	0.8	0.99 (0.76–1.30)	0.2	0.69 (0.40–1.16)	72% of sites without on-site surgery performed <200 PCIs annually compared with 6% among sites with on-site surgery
		Yes	268,312	0.8		0.3		
Pride (2009) (22)	Multicenter NRMI registry	No	1,282	1.0	0.76 (0.37–1.58)			Only patients with NSTEMI included in study cohort
		Yes	1,282	1.3				
Singh (2009) (18)	3 sites Mayo clinic experience	No	1,842	0.2	0.57 (0.17–1.95)	0	1.00 (0.02–50.4)	Propensity matched patient cohort
		Yes	1,842	0.4		0.2		
Aversano (2012) (9)	Multicenter randomized trial	No	14,149	0.9		0.1		Mortality reported after 6 weeks and incidence of emergency CABG shown.
		Yes	4,718	1.0		0.2		
Jacobs (2013) (11)	Multicenter randomized trial	No	2,774	0.7	1.96 (0.58–6.64)	0.3	2.30 (0.3–18.6)	All-cause and cardiac mortality at 30 days were no different. PCI without on-site surgery was not inferior
		Yes	917	0.3		0.1		
Meta-analyses								
Zia (2011) (19)		No	28,552	1.6	1.03 (0.64–1.66)	1.0	1.38 (0.65–2.95)	6 studies included in the analysis
		Yes	881,261	2.1		0.9		
Singh M (2011) (20)		No	30,423	0.9	1.15 (0.93–1.41)	0.17	1.21 (0.52–2.85)	9 studies included in the analysis
		Yes	883,865	0.8		0.29		
Singh PP (2011) (23)		No	1,812	0.17	2.3 (0.60–12.97)	0.11	0.47 (0.07–3.19)	4 studies included in the analysis but only 2 with data on mortality and CABG; Risk ratios rather than OR are reported in this analysis
		Yes	4,039	0.72		0.02		

CABG, coronary artery bypass graft surgery; NCDR, National Cardiovascular Data Registry; NRMI, National Registry of Myocardial Infarction; OR, odds ratio; PCI, percutaneous coronary intervention; SCAAR, Swedish Coronary Angiography and Angioplasty Registry.

respectively, at 12 months (relative risk, 0.98; 95% one-sided upper confidence limit, 1.13; $p < 0.001$ for non-inferiority). The individual rates of death, myocardial infarction, repeat revascularization and stroke did not differ significantly between the groups at either time point.

Three meta-analyses conducted primarily with registry data have examined the use of nonprimary PCI at facilities with and without on-site surgery (19,20,23). Overall, the mortality rate and need for emergency CABG surgery did not differ between hospitals with and without on-site surgery. In 1 meta-analysis, after adjusting for publication bias, the mortality rate for nonprimary PCI was 25% higher at centers without on-site surgery compared with centers that had on-site surgery (OR, 1.25; 95% CI, 1.01–1.53; $p = 0.04$) (20). However, it is important to note that these meta-analyses preceded the publication of the 2 randomized trials (9,11). Therefore, based on these recent studies, there is no indication of increased mortality or a greater need for emergency CABG for either primary or nonprimary PCI at sites without on-site cardiac surgery.

Guidelines, Competency Documents, Policy Statements, and Other Programs

Since 2007, there have been several new documents published that provide guidance for the performance of PCI without on-site surgery. Each new document builds incrementally upon the recommendations from prior documents with slight modifications based on new information. The recommendations for PCI programs without on-site surgery are maturing and becoming uniform over time through the vetting of these recommendations by numerous separate writing committees and undergoing extensive external reviews during document development. Key recommendations for PCI without on-site surgery from those documents are briefly summarized below and have been combined to develop the unified recommendations in this document.

2009 Focused Guideline Update on the Management of Patients with STEMI and Guideline Update on PCI

The 2009 focused update of the ACC/AHA guidelines for the management of patients with STEMI and the ACC/AHA/SCAI guidelines on PCI has been superseded by newer separate guidelines for STEMI and PCI (2,24,25). However, a number of the recommendations from the 2009 document regarding triage and transfer of patients and the development of local STEMI systems have been incorporated into the current document.

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

Compared with prior guidelines, the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention stipulated new classification ratings for both primary and elective PCI at hospitals without on-site cardiac surgery (2). Primary PCI was assigned a Class IIa recommendation (*Level of Evidence: B*) stating that primary PCI is "reasonable," provided appropriate planning for program development has been accomplished. Previously, this was assigned a Class IIb recommendation. Elective PCI, previously assigned a Class III recommendation, was given a Class IIb recommendation (*Level of Evidence: B*) stating it "might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection". Elective PCI without on-site cardiac surgical backup was considered appropriate only when performed by experienced operators, with complication rates and outcomes equivalent or superior to national benchmarks. Importantly, the ACCF/AHA/SCAI PCI guidelines state, "desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery." The guideline assigns a Class III recommendation (*Level of Evidence: C*) to performing primary or elective PCI in hospitals without on-site cardiac surgery without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital and without appropriate hemodynamic support capability for transfers. The 2011 PCI guideline document adapted personnel, facility, operator and structural requirements for PCI without on-site surgery from the 2007 SCAI Expert Consensus document (1). New facility and operator volume requirements were not addressed in the 2011 PCI guidelines but deferred to the 2013 PCI Clinical Competency document (4). In 2011, ACCF/AHA also published a Guideline for Coronary Artery Bypass Surgery that did not discuss the performance of PCI without on-site surgery (26).

2012 ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update

Similar to the 2011 PCI guidelines, this document presented requirements for PCI at facilities without on-site cardiac surgery that were derived from the 2007 SCAI expert consensus document with some modifications (3). This document also presented criteria for excluding patients, based on risk and lesion characteristics, from PCI at facilities without on-site cardiac surgery. The document prescribed the quality assurance/quality improvement (QA/QI) program necessary for all cardiac catheterization laboratories with specific recommendations for structure, process, and outcome variables appropriate for monitoring. Moreover, it recommended that all major complications be reviewed by the QA/QI committee at least every 6 months and that any individual operator with complication rates above benchmarks for 2 consecutive 6-month intervals should have the issue directly addressed by the QA director with a written plan for remediation. The document also recommended that a random sample of cases from all operators should be reviewed at least annually.

2013 ACCF/AHA/SCAI Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures

In addition to defining numerous requirements for operator competency, new operator, and facility PCI volume requirements were established (4). Reflecting the overall decline in PCI volumes, this document recommended that laboratories performing both primary and elective PCI, with and without on-site cardiac surgery, should perform a minimum of 200 PCIs annually. Laboratories performing <200 cases annually must have stringent systems and process protocols in place with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger volume facilities. The existence of laboratories performing <200 PCIs annually that are not serving

isolated or underserved populations should be questioned, and any laboratory that cannot maintain satisfactory outcomes should be closed. This recommendation was based on an extensive review of studies that identified a signal suggesting worse outcomes in laboratories performing <200 PCIs annually. The writing committee recommended that operators perform a minimum of 50 PCIs annually (averaged over 2 years), including no less than 11 primary PCIs annually. Ideally, these procedures should be performed in institutions performing >200 total and >36 primary PCI procedures annually. However, it was emphasized that individual operator volume is but one of several factors that should be considered in assessing operator competence, which include lifetime experience, institutional volume, the operator's other cardiovascular interventions and quality assessment of the operator's ongoing performance. Operators who cannot maintain these case volume recommendations at their primary practice site should maintain privileges and continue to perform PCI procedures at a high-volume institution with on-site surgical backup to meet annual volume requirements. It was also recommended that operators should be board certified in interventional cardiology and maintain certification, with the exception of operators who have received equivalent training outside the US and are ineligible for board certification in the US.

2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction

This document did not specifically comment on PCI without on-site cardiac surgery but supported the 2011 ACCF/AHA/SCAI PCI guidelines recommendations (25). It recommended that primary PCI be performed in high-volume, well-equipped centers with experienced interventional cardiologists, and skilled support staff.

2010 European Society of Cardiology and European Association for Cardio-Thoracic Surgery Guidelines

In contrast to the 2011 ACC/AHA/SCAI PCI guidelines, the 2010 European Society of Cardiology and the European Association for Cardio-Thoracic Surgery guidelines on myocardial revascularization do not comment on PCI without on-site surgery or issues related to institutional or operator competency (27). However, the European guidelines continue to stress the importance of full disclosure regarding the lack of availability of on-site cardiac surgery and the inadvisability of performing PCI for high-risk patients/lesions at facilities that do not have on-site surgical backup.

The European guidelines for STEMI do not provide specific recommendations regarding PCI at centers without on-site surgery (28). Rather, emphasis is placed on the development of networks between hospitals with differing levels of technology, connected by an efficient emergency transport system. To maximize staff experience, the guidelines recommend that primary PCI centers perform procedures 24 h a day, 7 days a week for all STEMI patients.

Other models mentioned in the European guidelines, although not ideal, include weekly or daily rotation of primary PCI centers or multiple primary PCI centers in the same region. Hospitals that cannot offer a 24/7 service for primary PCI should be allowed to perform primary PCI in patients already admitted for another reason and who develop STEMI during their hospital stay. These hospitals should, however, be discouraged from initiating a service limited to daytime or within-hours primary PCI, because this generates confusion with Emergency Medical Services (EMS) operators and is unlikely to match the door-to-balloon time and quality of intervention of focused 24/7 primary PCI centers. In a survey of European countries, the mean population served by a single primary PCI center varied between 0.3 and 7.4 million inhabitants. In countries offering primary PCI services to the majority of their STEMI patients, this population varied between 0.3 and 1.1 million per center (29). In small service areas, experience can be suboptimal due to an insufficient number of STEMI patients, but the optimal size of a catchment area could not be clearly defined. For geographical areas where the expected transfer time to a primary PCI center makes it impossible to achieve satisfactory reperfusion times, thrombolysis with subsequent immediate transfer to a primary PCI center has been endorsed. Although there is a risk of intracranial bleeding, a potential role for this strategy in selected circumstances has been emphasized (30).

Other Guidelines and Recommendations

The 2007 SCAI Expert Consensus Document summarized the recommendations from the British Cardiac Society and British Cardiovascular Intervention Society, the Cardiac Society of Australia and New Zealand (CSANZ), the Spanish Society of Cardiology, the Brazilian Society of Hemodynamics and Interventional Cardiology (*Sociedade Brasileira de Hemodinamica e Cardiologia Intervencionista*) and from several other countries (31–39). Since 2007, only the guidelines from CSANZ have been updated, most recently in 2011 (32). CSANZ guidelines state that primary PCI without on-site surgery should be performed: (a) by operators and institutions meeting the overall requirements and standards of primary PCI centers; (b) by institutions with a proven plan for rapid transport to a cardiac surgical center; (c) in a timely fashion (<90 min); and (d) using rigorous case selection criteria. The CSANZ guidelines acknowledged that rural patients might have limited access to diagnostic angiography and PCI, and providing these services at institutions without on-site surgery by appropriately trained individuals facilitates equity of access, which should result in improved quality of care. However, the CSANZ guidelines also specifically state that rural and regional centers should not perform

elective, high-risk PCI procedures if they are located more than 1 hour travel time from cardiac surgery centers.

AHA Policy Statement on PCI Without Surgical Backup

In March 2012, the AHA issued a policy statement on PCI without surgical backup defining two major reasons for providing PCI without on-site surgery (40). First, PCI without on-site surgery is considered reasonable if the intent is to provide high quality timely primary PCI for patients with STEMI. The statement recommended that each community and facility in the community have an agreed-upon plan for how STEMI patients are to be treated. The plan should indicate hospitals that should receive STEMI patients from EMS units capable of obtaining diagnostic electrocardiograms, the management at the initial receiving hospital and written criteria and agreements for the expeditious transfer of patients from nonPCI-capable to PCI-capable facilities. Second, PCI without on-site surgery is a reasonable consideration for providing local care to patients and families who do not want to travel significant distances or who have certain preferred local physicians. This is an important consideration, but the policy statement emphasized that evolving evidence suggests that such centers should have mechanisms in place to ensure high quality care. In addition to emphasizing the current guideline classifications for PCI without on-site surgery, the AHA policy statement provided recommendations for states wishing to address the issue of PCI without on-site surgery through the regulation of legislation.

Mission Lifeline

The Mission Lifeline program developed in 2006 from a series of conferences sponsored by the AHA and has continued to mature (41–43). The goal of Mission Lifeline is to improve the quality of care and outcomes for patients with STEMI and to improve healthcare system readiness and response to STEMI. An important focus of Mission Lifeline is to increase the number of patients with timely access to primary PCI. Criteria for the structure and operation of a STEMI referral and STEMI-receiving hospitals are part of the Mission Lifeline initiative and apply to facilities without on-site surgery.

Door-to-Balloon Alliance

The Door-to-Balloon (D2B™) effort began in January 2006 when the ACC recognized the need to reduce D2B times for patients with STEMI. This led to the development of a national initiative to achieve D2B times ≤90 min for at least 75% of nontransfer primary PCI patients with STEMI in participating hospitals performing primary PCI. This alliance consists of a nationwide network of hospitals, physician champions and strategic partners committed to improving D2B times. Participation in the Alliance provides the necessary tools; information and support for helping hospitals achieve the D2B treatment goals and encourages the use of real-time performance feedback on D2B times to drive the quality improvement effort (44). The D2B program has been highly successful, having achieved its initial goals (45).

Access to Primary PCI in the United States

Data from the American Hospital Association and the 2000 US Census were used to estimate the proportion of the adult population (≥18 years of age) who lived within 60 min of a PCI hospital (46). An estimated 79.0% lived within a 1 hour drive of a PCI hospital, with a median driving time of 11.3 min. Even among those living closer to non-PCI hospitals, 74% would experience <30 min of additional delay with a direct referral to a PCI hospital. Approximately 5 years later, Concannon et al., using similar data sources and methodology, showed that despite a 44% relative increase in the number of facilities capable of performing PCI, the number of adults within a 1 hour drive of a PCI facility increased to only 79.9%, with the median driving time reduced by <1 min to 10.5 min (47). Access in rural areas remained far less than in urban areas, with driving times reduced for only 9% of the population compared with the earlier survey. These findings mirrored a smaller experience in Michigan where expansion of primary PCI to 12 hospitals without on-site surgery increased access for only 4.8% of the population (48). Finally, Horwitz et al. showed that hospitals are more likely to introduce new invasive cardiac services when neighboring hospitals already offer such services and confirmed that the increase in the number of hospitals offering invasive cardiac services has not led to a corresponding increase in geographic access (49). In total, these data support the argument that the addition of more PCI centers has not substantially improved access to PCI services for most patients.

Financial Considerations for Facilities Providing PCI Without On-site Surgery

Medicare payments to hospitals for invasive cardiac procedures have generally remained favorable, although physician reimbursement has decreased. Per-case revenue margins for PCI are typically higher than the overall hospital operating margins, and PCI improves the hospital case mix index. PCI programs bring prestige to an institution, and STEMI is one of the most prestigious diseases for treatment (50,51). The push to develop rapid STEMI care has led many to currently advocate for EMS bypassing non-PCI hospitals; there is even consideration being given to triaging patients based on D2B metrics. Exclusion from providing STEMI care might be a lesser financial concern than the loss of downstream revenue from additional testing in patients suspected of having an acute coronary syndrome. This includes not only testing performed to exclude CAD as the cause of chest pain but also testing to evaluate noncardiac causes of chest pain.

Table 3. Facility Requirements for PCI Programs Without On-Site Surgery

General Recommendations	Source
Requisite support equipment must be available and in good working order to respond to emergency situations.	PCI-GL PCI-CS ML
Should demonstrate appropriate planning for program development and should complete both a primary PCI development program and an elective PCI development program. Program developments to include routine care process and case selection review.	AHA D2B
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services such as intensive care, advanced imaging (CT, MR and other vascular imaging), respiratory care, blood bank and nephrology consultation with access to dialysis.	PCI-GL, PCI-CS ECD
The institution should have systems for credentialing and governing the PCI program. On-site data collection, quality assessment, quality improvement and error management are essential. Each institution must establish an ongoing mechanism for valid and continuous peer review of its quality and outcomes. A quality improvement program should routinely 1) review quality and outcomes of the entire program; 2) review results of individual operators; 3) include risk adjustment; 4) provide peer review of difficult or complicated cases; and 5) perform random case reviews. The review process should assess the appropriateness of the interventional procedures. Evaluation should include the clinical indications for the procedure, technical performance and the quality and interpretation of the coronary angiograms.	PCI-CS, AHA, PCI-GL ECD
Written agreements for emergency transfer of patients to a facility with cardiac surgery must exist. Transport protocols should be tested a minimum of 2 times per year involving both the referring and receiving facility. Develop agreements with a ground or air ambulance service capable of advanced life support and IABP transfer that guarantees a transport vehicle will be on-site to begin transport in ≤30 min *and arrival at the surgical hospital within 60 min of the decision to declare the need for emergency surgery*. Tertiary facility must agree to accept emergent and nonemergent transfers for additional medical care, cardiac surgery or intervention. *Tertiary centers should be able to establish cardiopulmonary bypass on emergency transfer patients within <120 min of an urgent referral.*	PCI-GL, AHA PCI-CS ECD *New*
Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability. The capability for real-time transfer of images and hemodynamic data (via T-1 transmission line) as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is highly recommended.	PCI-GL PCI-CS ML
Appropriate inventory of interventional equipment, including guide catheters, balloons and stents in multiple sizes; thrombectomy and distal protection devices; covered stents; temporary pacemakers; and pericardiocentesis trays. *Access to other diagnostic modalities such as intravascular ultrasound and fractional flow reserve is required.* Rotational or other atherectomy devices and the treatment of CTOs should not be performed in facilities without on-site surgery.	PCI-GL, PCI-CS *New*
Meticulous clinical and angiographic selection criteria for PCI (Table 5).	PCI-GL, AHA
Participation in a national data registry, such as the ACC NCDR in the United States is required. This allows benchmarking, risk adjustment and facilitates outcomes analysis of local data.	PCI-GL ECD AHA
A program should be in place to track and ensure treatments with ACC/AHA guideline-based Class I therapies, both acutely and at discharge.	PCI-CS, ML
Full service laboratories (both primary and elective PCI, with and without on-site cardiac surgery) performing <200 cases annually must have stringent systems and process protocols with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger volume facilities. Both physicians and staff should have the opportunity to work at a high volume center to enhance their skills. The continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations should be questioned and any laboratory that cannot maintain satisfactory outcomes should be closed.	PCI-CS
Geographic isolation exists if the emergency transport time to another facility is >30 min.	*New*
Satisfactory outcomes should be defined by each local facility as part of their quality review process and should be based on national or regional benchmarks. Programs that fail to meet their established criteria for satisfactory performance for 2 consecutive quarters must undertake efforts to improve engaging outside experts if necessary. Failure to improve quality metrics should also be grounds for program closure regardless of the location.	ML PCI-CS D2B
As part of the local continuous quality improvement program, there should be a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of improvement opportunities.	PCI-GL

Continued on the next page

This can be an additional financial motivator for developing PCI facilities (52). How the further bundling of payments and reimbursements on a global or capitated basis by accountable care organizations (ACO) will affect PCI programs is unclear at this time, but given the concerns about the cost of healthcare, increases in payments are unlikely (53,54). However, even in an ACO environment, hospitals might benefit from keeping cardiovascular procedures in-house where they have the ability to control costs rather than transferring patients to tertiary hospitals.

The Volume-Outcome Relationship for PCI and the Certificate of Need

There are 26 states with Certificate of Need (CON) regulations for the development of cardiac catheterization laboratories, but the effect of such regulations is uncertain. Ho et al. found that the removal of state cardiac CON regulations was associated with an increase in the number of hospitals performing CABG and PCI, but the statewide number of procedures was unchanged. The average procedure volume per hospital for both CABG and PCI therefore declined (55). Despite this, they found no

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Table 3. Continued

STEMI Treatment Recommendations	
Each community should develop a STEMI system of care that follows standards at least as strong as those developed for Mission Lifeline, including:	2009 PCI-GL
• Performance of primary PCI as the first-choice treatment for STEMI to ensure streamlined care paths and increased case volumes.	2011 PCI-GL
• A process for prehospital identification and activation.	ML
• Protocols for triage, diagnosis and cardiac catheterization laboratory activation should be established within the primary PCI hospital/STEMI-Receiving Center.	D2B
• A single activation phone call should alert the STEMI team. Criteria for EMS activation of the cardiac catheterization laboratory should be established in conjunction with EMS providers.	
• Transfer protocols for patients who arrive at STEMI referral centers who are in cardiogenic shock and/or are primary PCI candidates ineligible for fibrinolytic drugs.	
STEMI receiving centers should be available and on-call 24 hours/7 days a week (no diversion) to perform primary PCI. Primary PCI should not be performed at facilities unless it is provided on a 24/7 schedule.[a] The cardiac catheterization laboratory staff and interventional cardiologist should arrive within 30 min of a STEMI activation call. Facilities should have a plan for triage and treatment of simultaneous presentation of STEMI patients.	PCI-GL, AHA ML
STEMI receiving centers should perform a minimum of 36 primary PCI procedures annually, and these procedures should ideally be performed at facilities that perform a minimum of 200 total PCI procedures annually.	PCI-GL PCI-CS ML
Facilities performing only primary PCI should perform a minimum of 36 primary PCIs annually and work in collaboration with a high volume PCI facility to ensure good outcomes	PCI-GL PCI-CS
There should be a recognized STEMI-Receiving Center liaison/system coordinator to the system and a recognized physician champion.	ML
The STEMI-Receiving Centers should participate in the Mission Lifeline-approved data collection tool, ACTION Registry-Get with the Guidelines™.	ML D2B
They should also participate in the regional Mission Lifeline Stakeholder group (if available) to contribute to the development of a regional STEMI System of Care Plan	ML
Monthly multidisciplinary team meetings to evaluate outcomes and quality improvement data. Operational issues should be reviewed, problems identified, and solutions implemented. The following measurements should be evaluated on an ongoing basis: a. Door-to-first device time, nontransfer patients b. STEMI Referral Hospital ED door-to-balloon (first device used) time c. First medical contact to balloon inflation (first device used) time, nontransfer patients d. First medical contact to balloon inflation (first device used) time, transfer patients e. Proportion of eligible patients receiving reperfusion therapy f. Proportion of eligible patients administered guideline-based class I therapies g. Proportion of patients with field diagnosis of STEMI and activation of the Cardiac Catheterization Laboratory for intended primary PCI who i. do not undergo acute catheterization because of misdiagnosis ii. undergo acute catheterization and found to have no elevation in cardiac biomarkers and no revascularization in the first 24 h h. In-hospital mortality	ML

Italics font: New or modified recommendation in the document.

[a]Required for U.S. facilities but might not be possible for all facilities worldwide.

ACC, American College of Cardiology; AHA, American Heart Association policy statement; CT, computed tomography; CTO, chronic total occlusion; D2B, Door-to-Balloon Alliance; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; EMS, emergency medical systems; GL, Guidelines; IABP, intra-aortic balloon pump; IVUS, intravascular ultrasound; ML, Mission Lifeline; MR, magnetic resonance; New, New recommendation in this document; NCDR, National Cardiovascular Data Registry; PCI-CS, 2013 PCI Competency Statement; PCI-GL, 2011 ACCF/AHA/SCAI PCI guidelines; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; and STEMI, ST-segment elevation myocardial infarction.

evidence that CON regulations lowered procedural mortality rates for CABG or PCI. In other studies, CON regulation of cardiac catheterization was associated with care that was judged more appropriate, whereas the removal of CON regulation of cardiac surgery has been associated with an increase in low-volume cardiac surgical centers and increased mortality (56,57). Concerns have been raised that the proliferation of small centers performing complex procedures that have a small but definite risk of important complications might dilute the ability to provide efficient high quality service (52,58). Reduced mortality has been associated with an increased volume of primary PCI procedures in centers, higher volume operators, total volume of PCIs in centers, and the commitment of a center to provide PCI rather than fibrinolytic therapy (59–63). Lieu et al. reported that redundant or low-volume primary PCI programs were cost ineffective (64). Elective PCI at centers without on-site surgery was more expensive than PCI at centers with on-site surgery in one case-matched study (65). In addition, the high fixed costs of a cardiac surgery program in the face of decreasing surgical volumes is leading to the consolidation of numerous smaller surgery programs, depriving some PCI programs of surgical backup.

The issue of a PCI volume-outcome relationship was extensively reviewed in the 2013 PCI Competency document for centers with and without on-site surgery and for primary and elective PCI (4). The document concluded that in the current era, volume-outcome relationships are not as robust as in the past when balloon angioplasty was the only treatment modality. However, an institutional volume threshold of <200 PCIs annually appeared to be

consistently associated with worse outcomes. Primary PCI volume ≤ the guideline-recommended minimum of 36 annually was associated with worse in-hospital mortality in a recent series of over 86,000 patients in the NCDR (66). The cutoff points of <200 total PCIs annually and ≤36 primary PCIs annually has important implications because 26% of the PCI facilities submitting data to the NCDR performed ≤200 total PCIs annually and 38% performed ≤36 primary PCIs annually (8,66). Recent data suggested a modest volume-outcome relationship for variables other than mortality, but these data have limitations and are not consistent across all studies (4). Although there was an association between annual PCI volumes <200 and worse outcomes, there was no association between higher annual hospital volumes and improved outcomes at higher volume PCI centers. There was less evidence to support a threshold for individual operator volume for both elective and primary PCI.

Recommendations

We have provided recommendations for PCI without on-site surgery that are a composite of recommendations from the 2007 SCAI Expert Consensus Statement, the 2011 PCI guidelines, the 2012 Expert Consensus Document on Cardiac Catheterization Laboratory Standards, the 2013 PCI Competency statement and recommendations from the policy statement of the American Heart Association and requirements for the Mission Lifeline program and D2B Alliance (1–4,40,43,44). Redundant recommendations from these documents were consolidated, and the writing committee included several new recommendations consistent with evolving practice standards.

Facility Requirements for PCI Programs Without On-Site Surgery

Facility requirements are similar to those presented in past documents but now include a greater emphasis on the presence of quality review programs for facilities and operators, as described in the 2013 PCI competency document (4) (Table 3). Diagnostic modalities such as IVUS and especially fractional flow reserve previously considered desirable for facilities without on-site surgery have now increased in importance and are necessary for all PCI centers.

The 2013 PCI Competency Document identified a signal suggesting that an institutional volume threshold of <200 PCIs/year was associated with worse outcomes. Therefore, the 2013 Competency Document recommended that the continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations be questioned and that any laboratory that cannot maintain satisfactory outcomes should be closed. Past documents have not specified any criteria for geographic isolation. The writing committee suggests it be defined not by distance but by the time required for emergency transport of a STEMI patient to another facility. Hospitals justify the creation of new PCI centers without on-site surgery by stating that they improve access for geographically under-served populations and allow patients to be cared for in close geographic proximity to their own families and physicians. However, multiple low-volume and partial-service PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health system and have not been shown to improve access (46–49). If the transfer time is ≤30 min, it is reasonable

Table 4. Personnel Requirements for PCI Programs Without On-Site Surgery

Personnel Recommendations	Source
Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.	PCI GL PCI-CS
Coronary care unit nursing staff must be experienced and comfortable with invasive hemodynamic monitoring, operation of temporary pacemaker, management of IABP, *management of in-dwelling arterial/venous sheaths and identifying potential complications such as abrupt closure, recurrent ischemia and access site complications.*	PCI-GL PCI-CS *New*
Personnel should be capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.	PCI-GL
Operators should have ABIM board certification in interventional cardiology and maintain certification, with the exception of operators who have gone through equivalent training outside the United States and are ineligible for ABIM certification and recertification exams.	PCI CS
Interventional cardiologists should perform a minimum of 50 coronary interventional procedures per year (averaged over a 2-year period) to maintain competency.	PCI-CS
Primary PCI should be performed by experienced operators who perform a minimum of 50 elective PCI procedures per year and, ideally, at least 11 primary PCI procedures per year. Ideally, these procedures should be performed in institutions that perform more than 200 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.	PCI-CS ML
Facilities should develop internal review processes to assess operators performing <50 PCIs annually. Individual operator level volume is one of several factors that should be considered in assessing operator competence, which include lifetime experience, institutional volume, individual operator's other cardiovascular interventions and quality assessment of the operator's ongoing performance.	PCI-CS
It is unwise for a newly trained interventional cardiologist to start a new PCI program. Newly trained interventional cardiologists joining an established PCI program should be mentored by existing physicians until it is determined their skills, judgment and outcomes are acceptable.	*New*

Italics font: New or modified recommendation in the document.
ABIM, American Board of Internal Medicine; ML, Mission Lifeline; PCI-CS, 2013 PCI Competency Statement; PCI-GL, 2011 ACCF/AHA/SCAI PCI guidelines; IABP, intra-aortic balloon pump; New, new recommendation in this document; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.

to assume that transfer to the nearest PCI center will provide reperfusion as rapidly as if it were available at the first hospital. For transport times longer than 30 min, performing PCI on-site is likely to be quicker than a transfer. The development of PCI facilities within a 30-min emergency transfer time to an established facility is therefore strongly discouraged.

What constitutes a reasonable transport time for a patient requiring emergency surgery has not been consistently addressed in prior documents. Both CPORT-E and MASS-COMM studies provide guidance contained in their on-line supplementary materials (9,11). Both require a transport vehicle to be available to begin transport within 30 min and arrival at the surgical hospital within 60 min of the decision to declare the need for emergency surgery. MASS-COMM further recommends that surgical intervention begin within 120 min. Given the existing data on the distribution of PCI facilities in the US, the performance of elective PCI at facilities that cannot meet these transfer times is discouraged (46,47).

The 2013 PCI competency document also states that any laboratory that cannot maintain satisfactory outcomes should be closed; however, there is currently no national definition for "satisfactory outcomes". The writing committee recommends that these be defined by each PCI center, including those with on-site surgery, as part of their quality review process, using national benchmark

Table 5. Recommendations for Off-Site Surgical Backup and Case Selection

Recommendations—Cardiologist–Cardiac Surgeon Interactions	Source
Interventional cardiologists must establish a working relationship with cardiac surgeons at the receiving facility.	PCI-GL ECD
Cardiac surgeons should have privileges at the referring facility to allow review of treatment options as time allows.	PCI-GL ECD
Ideally, face-to-face meetings between cardiothoracic surgeons and cardiologists involved should occur on a regular basis *(Heart Team approach) especially for the discussion of management of patients undergoing nonprimary PCI who have left main, three-vessel CAD or two-vessel CAD with involvement of the LAD or comorbidities such as diabetes, depressed LV function or complex anatomy.*	PCI-GL ECD *New*
Cardiac surgeon and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours.	PCI-GL ECD
Surgeon and receiving facility ensure that patients will be accepted based on medical condition, capacity of surgeon to provide services at the time of request and availability of resources. If this cannot be ensured before the start of an elective procedure, the case should not be done at that time.	PCI-GL ECD
Interventional cardiologists must review with surgeons the immediate needs and status of any patient transferred for urgent surgery.	PCI-GL ECD
Interventional cardiologist should be familiar with and have immediate access to appropriate life support devices, such an intraaortic balloon pumps, and should be qualified for handling emergencies such as pericardial tamponade and embolization.	PCI-GL ECD
Hospital administrations from both facilities endorse the transfer agreement.	PCI-GL ECD
Transferring physicians obtain consent for surgery from patients or appropriate surrogates.	PCI-GL ECD
Initial informed consent for PCI discloses that the procedure is being performed without on-site surgical backup and acknowledges the possibility of risks related to transfer. The consent process should include the risk of urgent surgery and state that a written plan for transfer exists. *Consent for PCI should be obtained before the procedure and before any sedatives are given. Consent for PCI obtained while the patient is on the table is not informed consent and is unacceptable in non-emergency situations.*	PCI-GL ECD *New*
Recommendations—Case Selection and Management	
Avoid intervention in patients with: • >50% diameter stenosis of left main artery proximal to infarct-related lesion, especially if the area in jeopardy is relatively small and overall LV function is not severely impaired. • Long, calcified, or severely angulated target lesions at high risk for PCI failure with TIMI flow grade 3 present during initial diagnostic angiography. • Lesions in areas other than the infarct artery (unless they appeared to be flow limiting in patients with hemodynamic instability or ongoing symptoms). • Lesions with TIMI flow grade 3 in patients with left main or three-vessel disease where bypass surgery is likely a superior revascularization strategy compared with PCI. • Culprit lesions in more distal branches that jeopardize only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention. • *Chronic total occlusion.* *The management of patients with STEMI resuscitated from sudden cardiac death is complex, and decisions about the need for immediate PCI with or without therapeutic hypothermia or possible transfer to a tertiary facility for treatment should be individualized.*	PCI-GL ECD *New*
Emergency transfer for coronary bypass surgery patients with • High-grade left main or three-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with IABP support. • Failed or unstable PCI result and ongoing ischemia, with IABP support during transfer.	PCI-GL ECD

Italics font: New or modified recommendation in the document.
CTO, chronic total occlusion; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; PCI-GL, 2011 ACCF/AHA/SCAI PCI Guidelines; IABP, intraaortic balloon pump; LV, left ventricle; New, new recommendation in this document; PCI, percutaneous coronary intervention; TIMI, thrombolysis in myocardial infarction.

Table 6. Patient and Lesion Characteristics That Could Be Unsuitable for Nonemergency Procedures at Facilities Without On-Site Cardiac Surgery

High-risk patients	Source
• Decompensated congestive heart failure (Killip Class ≥3) without evidence for active ischemia.	PCI-GL
• Recent (<8 weeks) cerebrovascular accident.	AHA
• Advanced malignancy.	ECD
• Known clotting disorders.	
• LVEF ≤30%.	
• Chronic kidney disease (creatinine >2.0 mg/dL or creatinine clearance <60 mL/min).	
• Serious ongoing ventricular arrhythmias.	
• Patients with left main stenosis (>50% diameter) or three-vessel disease unprotected by prior bypass surgery (>70% stenoses in the proximal or mid segments of all major epicardial coronary arteries), treatment of any or all stenoses. Scoring systems, such as SYNTAX, may be useful in defining the extent of disease and type of revascularization procedure.	
• Patients with a single-target lesion that jeopardizes an extensive amount of myocardium.	
• Patients undergoing intervention on the last remaining conduit to the heart.	
High-risk lesions	
• Unprotected left main stenosis.	PCI-GL
• Diffuse disease (>20 mm in length).	
• Extremely angulated segment (>90%) or excessive proximal or in-lesion tortuosity.	ECD
• More than moderate calcification of a stenosis or proximal segment	*New*
• Inability to protect major side branches.	
• Degenerated older vein grafts with friable lesions.	
• Substantial thrombus in the vessel or at the lesion site.	
• Any other feature that could, in the operator's judgment, impede successful stent deployment.	
• Anticipated need for rotational or other atherectomy device, cutting balloon or laser.	
The characteristics listed above identify high-risk patient and lesion features but are not absolute contraindications to performing PCI at a facility without on-site surgery. For example, an elevated creatinine level increases the procedure risk for the patient, but this is not unique to facilities without on-site surgery and treatments to mitigate this complication can be used at all facilities. Ultimately, the operator should consider all factors and make a decision about the suitability of the patient for PCI at the facility.	*New*
Strategy for surgical backup based on lesion and patient risk	
• High-risk patients with high-risk lesions should not undergo nonemergency PCI at a facility without on-site surgery.	PCI-GL
• High-risk patients with nonhigh-risk lesions: Nonemergency patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room are immediately available is necessary.	
• Non-high-risk patients with high-risk lesions require no additional precautions.	
• Non-high-risk patients with nonhigh-risk lesions require no additional precautions. Best scenario for PCI without on-site surgery.	

Italics font: New or modified recommendation in the document.
CTO, chronic total occlusion; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; PCI-GL, 2011 ACCF/AHA/SCAI PCI Guidelines; LVEF, left ventricular ejection fraction; New, new recommendation; PCI, percutaneous coronary intervention; SYNTAX, Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery.

data. Programs failing to meet established criteria for satisfactory performance for two consecutive quarters must undertake efforts to improve their performance, engaging outside experts if necessary. Failure to improve quality metrics should lead to program closure regardless of the location. To ensure proper assessment and monitoring, laboratories are required to submit data to a national data registry, have regular meetings to discuss key performance metrics and develop plans for the correction of any deficiencies. Especially with facility PCI volumes decreasing, it becomes increasingly difficult to determine whether there are significant differences in the data reports from year to year. For example, to detect (with statistical certainty) a doubling of in-hospital mortality from 1% to 2% at a hospital with an annual case volume of 200 PCIs, nearly 4 years of continuous data collection would be required. This does not negate the importance of data submission to a national registry that can help identify trends, but it emphasizes why these same data must be carefully evaluated and adjudicated at the local facility. The importance of unbiased local or external peer review cannot be overemphasized (67,68). Implementation of the SCAI Quality Toolkit and certification by Accreditation for Cardiovascular Excellence (ACE) are recommended as resources for improving quality (69,70).

Personnel Requirements for PCI Programs Without On-Site Surgery

Recognizing the potential for isolation and the advantage of clinical experience, the 2007 SCAI Expert Consensus Document included a recommendation that operators at PCI programs without on-site surgery perform at least 100 total and 18 primary PCIs annually, a recommendation that might not be achievable in the current environment. The 2013 PCI Competency Document moves away from strict volume requirements to focus more on achieving quality metrics for facilities and individual operators. As noted earlier, the 2013 Competency document recommended that operators perform a minimum of 50 PCIs annually (averaged over 2 years), including no less than 11 primary PCIs annually. Ideally, these procedures should be performed in institutions performing >200

total and >36 primary PCI procedures annually (Table 4). Again acknowledging the importance of experience, the 2007 SCAI Expert Consensus Document suggested that initial operators at a new program without on-site surgery should have a lifetime experience of >500 PCIs as primary operator after completing a fellowship. In the current environment of decreasing PCI volumes and in view of the recommendations of the 2013 PCI competence document, this number would be difficult to achieve. Nevertheless, it is unwise for a newly trained interventional cardiologist to start a new PCI program. Newly trained interventional cardiologists joining an established PCI program should be mentored by more experienced physicians until it is determined that the skills, judgment and outcomes of these new cardiologists are acceptable.

Requirements for Off-Site Surgical Backup

Recommendations for the interactions between cardiologists and cardiac surgeons are listed in Table 5. A limitation of programs performing PCI without on-site surgery is the lack of on-site access to a cardiac surgeon for consultation about revascularization options. This makes the concept of a Heart Team consultation more difficult to achieve and could necessitate performing only diagnostic catheterization until a case review with a cardiac surgeon can be performed. The application of telemedicine consultations with a heart surgeon could facilitate these interactions. In reality, many of the nonemergency patients who merit discussion by a Heart Team are not optimal candidates for PCI at facilities without on-site cardiac surgery. It is important to emphasize that the role of the cardiac surgeon is not confined to the treatment of PCI complications but includes the participation in decisions about revascularization options. Recommendations for case selection at facilities without on-site surgery are shown in Table 5, and criteria for identifying high-risk lesions and patients are contained in Table 6. There are statistical models for identifying PCI patients at higher risk for mortality or emergency CABG that could be helpful for identifying patients who should not undergo PCI at facilities without on-site surgery (18,71). However, these models have not been tested or applied on a large scale to determine the advisability of performing a PCI at facilities without on-site surgery.

The Delivery of PCI Services in the Future

As a result of the additional randomized studies on PCI without on-site surgery and the recent change in guideline recommendations, the performance of PCI without on-site surgery in the US has gained greater acceptance, and questions about its safety in the presence of a proven, well defined, and protocol driven approach have diminished. PCI programs should be evaluated based on their ability to: (a) sustain adequate quality metrics, (b) provide access to elective and emergency PCI procedures that would otherwise be unavailable in their service area, and (c) maintain the operator and institutional volumes recommended in the 2013 PCI Competency Document. For the future, the focus must now shift to developing a rational plan for the distribution of PCI services. Small PCI programs with large fixed costs are inefficient and unnecessary if they do not improve access in areas of need. However, it is unlikely that issues of system-wide efficiency will be addressed without central planning on the state or federal level. This writing group reaffirms the statement from the 2011 ACCF/AHA/SCAI PCI Guidelines that "desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery" and suggests that new programs offering PCI without on-site surgery are inappropriate unless they clearly serve geographically isolated populations. The writing group recognizes the need for ongoing study and surveillance of all PCI programs through participation in national databases encourages public reporting of their results and acknowledges that further declines in PCI volumes might necessitate the closure of PCI programs in the future.

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Key Words: ACC Clinical Expert Consensus Document ■ angioplasty ■ consensus ■ coronary artery bypass surgery.

Appendix 1. Author Relationships With Industry and Other Entities (Relevant)—SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
James C. Blankenship	Geisinger Medical Center—Director, Cardiac Catheterization Laboratory	None	None	None	• Abiomed* • AstraZeneca* • Boston Scientific* • Kai Pharmaceutical* • Novartis* • Schering Plough • The Medicines Company* • Volcano*	• SCAI—Vice President*	None
Mehmet Cilingiroglu	Arkansas Heart Hospital	None	None	None	None	None	None
Greg J. Dehmer (Chair)	Texas A&M College of Medicine, Scott & White Clinic Cardiology Division—Professor of Medicine; Director of Cardiology	None	None	None	None	None	None
James G. Dwyer	Heart and Vascular Center of Northern Arizona	None	None	None	None	None	None
Dmitriy N. Feldman	New York Presbyterian Hospital/Cornell	• Gilead • Maquet	• Abbott Vascular • Bristol-Myers Squibb* • Daiichi-Sankyo • Eli Lilly • Pfizer • The Medicines Company*	None	None	None	None
Timothy J. Gardner	Christiana Care Health System—Medical Director	None	None	None	None	None	None
Cindy L. Grines	Harper University Hospital—Vice President	• Abbott Vascular • Bristol-Myers Squibb • Lilly USA • Merck • The Medicines Company • Volcano*	None	None	None	• *Journal of Interventional Cardiology*†	None
Mandeep Singh	Mayo Clinic	None	None	None	None	None	None

This table represents all healthcare relationships of committee members with industry and other entities that were reported by authors, including those not deemed to be relevant to this document, at the time this document was under development. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$10,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Please refer to http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx for definitions of disclosure categories or additional information about the ACCF Disclosure Policy for Writing Committees.

*No financial benefit.

†Significant relationship.

ACC indicates American College of Cardiology; AMA, American Medical Association; FDA, U.S. Food and Drug Administration; NHLBI, National Heart, Lung, and Blood Institute; SCAI, Society for Cardiovascular Angiography and Interventions.

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Appendix 2. Peer Reviewer Relationships With Industry and Other Entities (Relevant)—SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

Peer Reviewer	Representation	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Eric R. Bates	Content Reviewer—AHA and Content Reviewer—ACCF/AHA/SCAI PCI Guideline	University of Michigan Hospitals and Health Centers—Professor of Medicine	• AstraZeneca • BMS • Daiichi-Sankyo • Eli Lilly • Merck/ Schering-Plough • Sanofi-aventis	None	None	None	None	None
Ashequl M. Islam	Official Reviewer—SCAI	Baystate Medical Center—Program Director, Interventional Cardiology Fellowship	• Edwards Lifesciences	• Daiichi-Sankyo • Eli Lilly	None	None	None	None
Hani Jneid	Official Reviewer—ACCF Task Force on Clinical Expert Consensus Documents	Baylor College of Medicine - MEDVAMC—Associate Professor of Medicine	None	None	None	None	None	None
Steven P. Marso	Official Reviewer—SCAI	Saint Luke's Mid America Heart Institute; University of Missouri-Kansas City—Professor of Medicine	None	None	None	None	• Amylin* • St. Jude Medical* • Terumo Medical* • The Medicines Company* • Volcano Corporation*	None
Laura Mauri	Official Reviewer—AHA	Harvard Medical School—Associate Professor of Medicine; Brigham & Women's Hospital	• Medtronic • St. Jude Medical	None	None	• Abbott Vascular* • Boston Scientific* • Bristol-Myers Squibb* • Cordis Corporation* • Daiichi-Sankyo* • Eli Lilly* • Medtronic* • Sanofi-aventis*	None	None
Srinivas Murali	Official Reviewer—ACC Board of Governors	Allegheny General Hospital—Director, Division of Cardiovascular Medicine	• Advisory Board • Actelion • Gilead Pharma	• Actelion	None	• Gilead Pharma • St. Jude Medical	None	None
Barry Uretsky	Official Reviewer—SCAI	University of Arkansas for Medical Sciences—Clinical Professor of Medicine	None	None	None	• St. Jude Medical*	None	None
Howard Walpole	Official Reviewer—ACCF Board of Trustees	Okyanos Heart Institute—Chief Medical Officer	None	None	None	None	None	None
Thomas M. Bashore	Content Reviewer—ACCF/AHA/SCAI Clinical Competence Statement on CIP	Duke University Medical Center—Professor of Medicine; Clinical Chief, Division of Cardiology	None	None	None	None	None	None

Continued on the next page

Appendix 2. Continued

Peer Reviewer	Representation	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
James A. Burke	Content Reviewer—ACCF Interventional Section Leadership Council	Lehigh Valley Heart Specialists—Associate Chief of Cardiology	None	None	None	None	None	None
John G. Byrne	Content Reviewer—ACCF Interventional Section Leadership Council	Brigham & Women's Hospital—Chief, Division of Cardiac Surgery; Harvard Medical School—Professor	None	None	None	None	None	None
Joaquin E. Cigarroa	Content Reviewer—ACCF Interventional Section Leadership Council and ACCF/AHA CABG Guideline	Oregon Health & Science University—Associate Professor of Medicine	None	None	None	None	• Catheterization and Cardiovascular Intervention† • Portland Metro Area AHA†	None
Frederick E. Grover	Content Reviewer—ACCF Surgeons Section Leadership Council	University of Colorado—Professor and Chair, Department of Surgery	• Somahlution†	None	None	None	None	None
Maureen B. Julien	Content Reviewer—ACCF Interventional Section Leadership Council	Hospital of the University of Pennsylvania—Nurse Practitioner	None	None	None	None	None	None
Glenn N. Levine	Content Reviewer—ACCF/AHA/SCAI PCI Guideline and ACCF/AHA/SCAI Clinical Competence Statement on CIP	Baylor College of Medicine—Professor of Medicine	None	None	None	None	None	None
Pasala S. Ravichandran	Content Reviewer—ACCF Surgeons Section Leadership Council	Oregon Health & Science University—Associate Professor	None	None	None	None	None	None
Sidney C. Smith, Jr.	Content Reviewer—ACCF Individual	Center for Cardiovascular Science and Medicine—Professor of Medicine; Director	None	None	None	None	None	None

This table represents the relationships of reviewers with industry and other entities that were disclosed at the time of peer review and determined to be relevant. It does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$10,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review.

According to the ACCF/AHA, a person has a *relevant* relationship IF: a) The *relationship or interest* relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the *document*; or b) The *company/entity* (with whom the relationship exists) makes a drug, drug class, or device addressed in the *document*, or makes a competing drug or device addressed in the *document*; or c) The *person or a member of the person's household*, has a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the *document*.

*Significant relationship.

†No financial benefit.

ACCF indicates American College of Cardiology; AHA, American Heart Association; CABG, Coronary Artery Bypass Graft Surgery; CIP, Coronary Interventional Procedures; PCI, Percutaneous Coronary Intervention; SCAI, Society of Cardiovascular Angiography & Interventions.

EXHIBIT D

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EXPERT CONSENSUS DOCUMENT

SCAI/ACC/AHA Expert Consensus Document

2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

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Introduction

In 2007, the Society for Cardiovascular Angiography and Interventions (SCAI) published an Expert Consensus Document titled "The Current Status and Future Direction of Percutaneous Coronary Intervention without On-Site Surgical Backup" (1). This document summarized the available data on the performance of percutaneous coronary intervention (PCI) without on-site surgery in the United States (US), reviewed the existing literature, examined the recommendations for the performance of PCI in this setting from several professional organizations abroad and from experienced programs in the US, defined the best practices for facilities engaged in PCI without on-site surgery and made recommendations for the future role of PCI without on-site surgery.

Since publication of that document, new studies, meta-analyses, and randomized trials have been published comparing PCI with and without on-site surgery. In addition, the total number of PCIs performed annually has decreased, reports about the overuse of PCI have emerged, and appropriate use criteria for coronary revascularization have been published. A noteworthy change occurred in the 2011 PCI guideline in which elective PCI was upgraded to Class IIb and primary PCI was upgraded to Class IIa at facilities without on-site surgery (2). Several tables on the structure and operation of programs without on-site surgery from the 2007 SCAI Expert Consensus Document were used in the 2011 PCI guideline recommendations. Finally, new updates of the ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards and the ACCF/AHA/SCAI Clinical Competence in Coronary Artery Interventional Procedures have been published (3,4).

Although many of the concerns about the safety of PCI without on-site surgery have been resolved, there are new issues to consider as the delivery of PCI continues to evolve in the US. Accordingly, the SCAI, ACCF, and AHA have engaged in this effort to re-evaluate the current status of PCI without on-site surgery in the US. The specific goals of this effort were to:

1. Determine current trends in the prevalence of PCI without on-site surgery in the US;
2. Summarize new literature related to the performance of PCI without on-site surgery;
3. Review existing guidelines, expert consensus documents, competency statements and other documents related to PCI without on-site surgery and summarize all relevant information into a single resource document;

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Authors' relationships with industry are available in Appendix 1. Peer reviewers' relationships with industry are available in Appendix 2.

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4. Outline the current best practice methods and requirements for facilities engaged in performing PCI without on-site surgery; and
5. Evaluate the role of PCI without on-site surgery within the current US healthcare system.

Trends in the Performance of PCI

Although the use of PCI in the US had grown considerably since the early 1980s, data from the Nationwide Inpatient Sample cited by the Agency for Healthcare Research and Quality shows that the annual volume of PCI procedures peaked in 2006 and has since declined by over 30% (5). Numerous factors have contributed to this decline, including a reduction in restenosis by drug-eluting stents, a greater emphasis on medical therapy for the treatment of stable coronary artery disease, enhanced primary and secondary prevention efforts, a reduction in the incidence of ST-segment elevation myocardial infarction (STEMI), the increasing use of techniques such as fractional flow reserve to better evaluate lesion severity and the development and application of appropriate use criteria (5,6). As a result of these factors, many operators and hospitals now have low-volume practices. Using data from 2008, Maroney et al. estimated that 61% of interventional cardiologists performed 40 or fewer Medicare fee-for-service PCIs annually (7). Clinical data from 1298 facilities reporting to the National Cardiovascular Data Registry (NCDR) show that 49% of facilities performed ≤400 PCIs and 26% performed ≤200 PCIs annually (Fig. 1) (8). Approximately 33% of facilities had no on-site surgery, and among these, 65% (282 facilities) had an annual case volume of ≤200 PCI procedures.

Across the US, PCI without on-site surgery has increased since 2007. The writing committee assessed the current use of PCI without on-site surgery from a survey of ACC Governors for each state, data from industry sources and direct contact with physicians in various states (Fig. 2). Currently, 45 states allow both primary and elective PCI without on-site surgery, 4 states allow only primary PCI without on-site surgery, and 1 state prohibits PCI without on-site surgery. PCI without on-site surgery is regulated by the State Department of Health in 34 states but is unregulated in the remaining 16 states. Elective PCI without on-site surgery was allowed at selected facilities in 9 states but only as part of statewide demonstration projects or to allow participation in the Cardiovascular Patient Outcomes Research Team (CPORT) Nonprimary PCI (CPORT-E) trial (9). Since the conclusion of CPORT-E, the use of PCI without on-site surgery is being re-evaluated in several of these states. PCI without on-site surgery is currently performed in 19 of the 65 cardiac catheterization laboratories within the Veterans Health Administration (10).

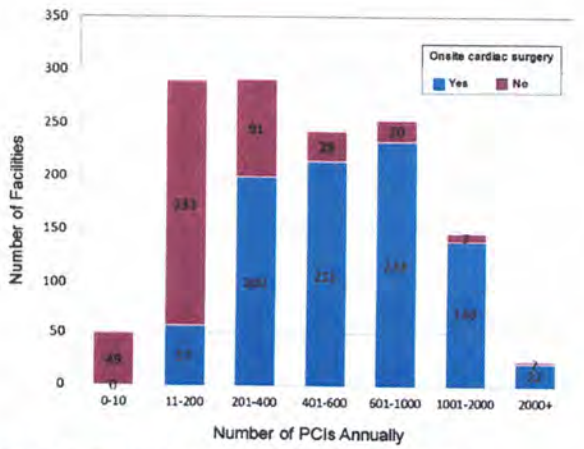

Figure 1. PCI Volume at Facilities With and Without Cardiac Surgery

Reproduced from Dehmer et al. (8) with permission.

Recent Literature on PCI Without On-Site Surgery

Since 2006, 11 original studies and 3 meta-analyses on the topic of PCI without on-site surgery have been identified by a computerized systematic literature search using Medline (PubMed and Ovid) and Cochrane Databases (9,11–23).

Primary PCI without on-site surgery. Seven studies and 2 meta-analyses of primary PCI showed no difference for in-hospital or 30-day mortality between sites with and without on-site surgery (Table 1). None of the individual studies examining the occurrence of emergency CABG surgery after primary PCI showed a difference between sites with and without on-site surgery. However, 1 meta-analysis showed that sites without on-site surgery had a lower occurrence of emergency CABG surgery after

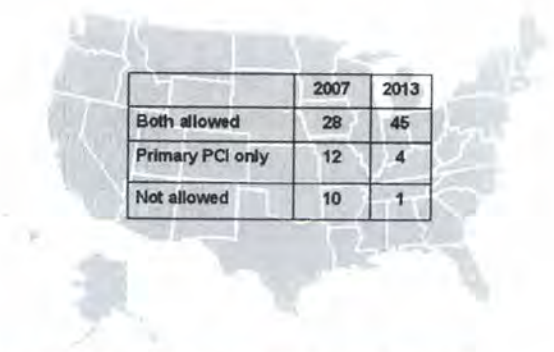

Figure 2. Change in the Availability of PCI Without On-Site Surgery From 2007 to 2013

The numbers shown indicate the number of states where primary and nonprimary PCI without on-site surgery are allowed.

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Table 1. Studies on Primary PCI Without On-Site Surgery Published Since 2006

Author (Year)	Sites	On-Site Surgery	No. of Patients in Arm	Mortality		Emergency CABG		Comments
				Incidence %	OR (95% CI)	Incidence %	OR (95% CI)	
Carlsson (2007) (12)	Multicenter SCAAR registry	No	857	7.0	1.05 (0.79–1.40)	0.1		30-day mortality is reported; Incidence of emergency CABG is for all patients (primary and nonprimary PCI)
		Yes	4,595	6.7		0.2		
Peels (2007) (13)	Single center	No	336	2.1	2.17 (0.26–17.8)	0	0.10 (0.00–2.51)	
		Yes	103	0.97		1.0		
Pereira (2008) (14)	Multicenter Portuguese registry	No	1,214	5.0	0.79 (0.55–1.14)	1.8	1.52 (0.90–2.56)	Cardiogenic shock mortality was 53.4% with on-site surgery and 50.9% without (NS)
		Yes	1,470	4.0		2.7		
Kutcher (2009) (15)	Multicenter NCDR registry	No	1,934	5.1	0.97 (0.79–1.20)	0.7	0.60 (0.35–1.03)	In-hospital mortality reported. Only 42% of sites without on-site surgery performed ≥36 primary PCIs annually compared with 80% of sites with on-site surgery
		Yes	31,099	5.2		1.2		
Pride (2009) (16)	Multicenter NRMI database	No	1,795	3.3	0.86 (0.61–1.23)			Propensity matched patient cohort. In-hospital mortality reported and only for patients undergoing primary PCI. Incidence of emergency CABG not reported
		Yes	1,795	3.8				
Hannan (2009) (17)	Multicenter New York State database	No	1,729	2.3	1.22 (0.76–1.94)	0.06	0.17 (0.02–1.38)	Propensity matched patient cohort. In-hospital/30-day mortality reported
		Yes	1,729	1.9		0.35		
Singh (2009) (18)	3 sites	No	667	2.5	0.80 (0.42–1.54)	0.7	1.25 (0.33–4.68)	Propensity matched patient cohort of nonelective PCI defined as acute MI within 24 h or cardiogenic shock.
	Mayo Clinic experience	Yes	667	3.1		0.6		
Meta-analyses								
Zia (2011) (19)		No	8,703	6.1	0.93 (0.83–1.05)	3.0	0.87 (0.68–1.11)	9 studies included in the analysis
		Yes	97,386	7.6		3.4		
Singh (2011) (20)		No	16,489	4.6	0.96 (0.88–1.05)	0.22	0.53 (0.35–0.79)	11 studies included in the analysis
		Yes	107,585	7.2		1.03		

CABG, coronary artery bypass graft surgery; NCDR, National Cardiovascular Data Registry; NRMI, National Registry of Myocardial Infarction; OR, odds ratio; PCI, percutaneous coronary intervention; SCAAR, Swedish Coronary Angiography and Angioplasty Registry.

primary PCI (odds ratio, 0.53; 95% confidence interval 0.35–0.79) (20).

PCI without on-site surgery for conditions other than STEMI. Eight studies examined nonprimary PCI at sites with and without on-site surgery (Table 2). The majority of studies and meta-analyses showed no difference in mortality or a need for emergency CABG at sites without on-site surgery. One study at a high-volume facility performing only elective PCIs and staffed by high-volume interventionalists showed a lower mortality at the facility without on-site surgery (OR, 0.11; 95% CI 0.01–0.79) (21). However, the baseline clinical and angiographic characteristics of the study groups with and without on-site surgery were sufficiently different that a meaningful adjusted analysis could not be performed, and there is therefore the possibility of a case selection bias.

Two randomized trials of nonprimary PCI have now been published. The CPORT-E trial randomized over 18,000 patients in a 1:3 ratio to undergo PCI at hospitals with and without on-site cardiac surgery, respectively (9). High-risk patients were excluded, as was the use of atherectomy devices. The trial had 2 primary endpoints: 6-week mortality and 9-month incidence of major adverse cardiac events (composite of death, Q-wave myocardial infarction, or target-vessel revascularization). The 6-week mortality rate was 0.9% at hospitals without on-site surgery compared with 1.0% at those with on-site surgery ($p = 0.004$ for noninferiority). The 9-month rates of major adverse cardiac events were 11.2% and 12.1% at hospitals with and without on-site surgery, respectively ($p = 0.05$ for noninferiority). A similar, but smaller randomized study of nonemergency PCI was performed in Massachusetts hospitals (11). The rates of major adverse cardiac events were 9.5% in hospitals without on-site cardiac surgery and 9.4% in hospitals with on-site cardiac surgery at 30 days (relative risk, 1.00; 95% one-sided upper confidence limit, 1.22; $p < 0.001$ for noninferiority) and 17.3% and 17.8%,

Table 2. Studies on Nonprimary PCI Without On-Site Surgery Published Since 2006

Author (Year)	Sites	On-Site Surgery	No. of Patients in Arm	Mortality		Emergency CABG		Comments
				Incidence %	OR (95% CI)	Incidence %	OR (95% CI)	
Carlsson (2007) (12)	Multicenter SCAAR registry	No	7,981	0.81	1.23 (0.91–1.65)	0.1		30-day mortality is reported; Incidence of emergency CABG is for all patients (primary and nonprimary PCI)
		Yes	20,930	0.66		0.2		
Frutkin (2008) (21)	2 sites	No	1,090	0.09	0.11 (0.01–0.79)	0.2	6.10 (0.55–67.3)	Nonrandomized comparison of 2 sites. Stable and unstable angina plus NSTEMI included. In-hospital mortality shown
		Yes	3,317	0.8		0.03		
Pereira (2008) (14)	Multicenter Portuguese registry	No	4831	0.5	1.43 (0.85–2.41)	0.7	3.14 (2.13–4.63)	
		Yes	5584	0.7		2.1		
Kutcher (2009) (15)	Multicenter NCDR registry	No	6,802	0.8	0.99 (0.76–1.30)	0.2	0.69 (0.40–1.16)	72% of sites without on-site surgery performed <200 PCIs annually compared with 6% among sites with on-site surgery
		Yes	268,312	0.8		0.3		
Pride (2009) (22)	Multicenter NRMI registry	No	1,282	1.0	0.76 (0.37–1.58)			Only patients with NSTEMI included in study cohort
		Yes	1,282	1.3				
Singh (2009) (18)	3 sites Mayo clinic experience	No	1,842	0.2	0.57 (0.17–1.95)	0	1.00 (0.02–50.4)	Propensity matched patient cohort
		Yes	1,842	0.4		0.2		
Aversano (2012) (9)	Multicenter randomized trial	No	14,149	0.9		0.1		Mortality reported after 6 weeks and incidence of emergency CABG shown.
		Yes	4,718	1.0		0.2		
Jacobs (2013) (11)	Multicenter randomized trial	No	2,774	0.7	1.96 (0.58–6.64)	0.3	2.30 (0.3–18.6)	All-cause and cardiac mortality at 30 days were no different. PCI without on-site surgery was not inferior
		Yes	917	0.3		0.1		
Meta-analyses								
Zia (2011) (19)		No	28,552	1.6	1.03 (0.64–1.66)	1.0	1.38 (0.65–2.95)	6 studies included in the analysis
		Yes	881,261	2.1		0.9		
Singh M (2011) (20)		No	30,423	0.9	1.15 (0.93–1.41)	0.17	1.21 (0.52–2.85)	9 studies included in the analysis
		Yes	883,865	0.8		0.29		
Singh PP (2011) (23)		No	1,812	0.17	2.3 (0.60–12.97)	0.11	0.47 (0.07–3.19)	4 studies included in the analysis but only 2 with data on mortality and CABG; Risk ratios rather than OR are reported in this analysis
		Yes	4,039	0.72		0.02		

CABG, coronary artery bypass graft surgery; NCDR, National Cardiovascular Data Registry; NRMI, National Registry of Myocardial Infarction; OR, odds ratio; PCI, percutaneous coronary intervention; SCAAR, Swedish Coronary Angiography and Angioplasty Registry.

respectively, at 12 months (relative risk, 0.98; 95% one-sided upper confidence limit, 1.13; $p < 0.001$ for non-inferiority). The individual rates of death, myocardial infarction, repeat revascularization and stroke did not differ significantly between the groups at either time point.

Three meta-analyses conducted primarily with registry data have examined the use of nonprimary PCI at facilities with and without on-site surgery (19,20,23). Overall, the mortality rate and need for emergency CABG surgery did not differ between hospitals with and without on-site surgery. In 1 meta-analysis, after adjusting for publication bias, the mortality rate for nonprimary PCI was 25% higher at centers without on-site surgery compared with centers that had on-site surgery (OR, 1.25; 95% CI, 1.01–1.53; $p = 0.04$) (20). However, it is important to note that these meta-analyses preceded the publication of the 2 randomized trials (9,11). Therefore, based on these recent studies, there is no indication of increased mortality or a greater need for emergency CABG for either primary or nonprimary PCI at sites without on-site cardiac surgery.

Guidelines, Competency Documents, Policy Statements, and Other Programs

Since 2007, there have been several new documents published that provide guidance for the performance of PCI without on-site surgery. Each new document builds incrementally upon the recommendations from prior documents with slight modifications based on new information. The recommendations for PCI programs without on-site surgery are maturing and becoming uniform over time through the vetting of these recommendations by numerous separate writing committees and undergoing extensive external reviews during document development. Key recommendations for PCI without on-site surgery from those documents are briefly summarized below and have been combined to develop the unified recommendations in this document.

2009 Focused Guideline Update on the Management of Patients with STEMI and Guideline Update on PCI

The 2009 focused update of the ACC/AHA guidelines for the management of patients with STEMI and the ACC/AHA/SCAI guidelines on PCI has been superseded by newer separate guidelines for STEMI and PCI (2,24,25). However, a number of the recommendations from the 2009 document regarding triage and transfer of patients and the development of local STEMI systems have been incorporated into the current document.

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

Compared with prior guidelines, the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention stipulated new classification ratings for both primary and elective PCI at hospitals without on-site cardiac surgery (2). Primary PCI was assigned a Class IIa recommendation (*Level of Evidence: B*) stating that primary PCI is "reasonable," provided appropriate planning for program development has been accomplished. Previously, this was assigned a Class IIb recommendation. Elective PCI, previously assigned a Class III recommendation, was given a Class IIb recommendation (*Level of Evidence: B*) stating it "might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection". Elective PCI without on-site cardiac surgical backup was considered appropriate only when performed by experienced operators, with complication rates and outcomes equivalent or superior to national benchmarks. Importantly, the ACCF/AHA/SCAI PCI guidelines state, "desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery." The guideline assigns a Class III recommendation (*Level of Evidence: C*) to performing primary or elective PCI in hospitals without on-site cardiac surgery without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital and without appropriate hemodynamic support capability for transfers. The 2011 PCI guideline document adapted personnel, facility, operator and structural requirements for PCI without on-site surgery from the 2007 SCAI Expert Consensus document (1). New facility and operator volume requirements were not addressed in the 2011 PCI guidelines but deferred to the 2013 PCI Clinical Competency document (4). In 2011, ACCF/AHA also published a Guideline for Coronary Artery Bypass Surgery that did not discuss the performance of PCI without on-site surgery (26).

2012 ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update

Similar to the 2011 PCI guidelines, this document presented requirements for PCI at facilities without on-site cardiac surgery that were derived from the 2007 SCAI expert consensus document with some modifications (3). This document also presented criteria for excluding patients, based on risk and lesion characteristics, from PCI at facilities without on-site cardiac surgery. The document prescribed the quality assurance/quality improvement (QA/QI) program necessary for all cardiac catheterization laboratories with specific recommendations for structure, process, and outcome variables appropriate for monitoring. Moreover, it recommended that all major complications be reviewed by the QA/QI committee at least every 6 months and that any individual operator with complication rates above benchmarks for 2 consecutive 6-month intervals should have the issue directly addressed by the QA director with a written plan for remediation. The document also recommended that a random sample of cases from all operators should be reviewed at least annually.

2013 ACCF/AHA/SCAI Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures

In addition to defining numerous requirements for operator competency, new operator, and facility PCI volume requirements were established (4). Reflecting the overall decline in PCI volumes, this document recommended that laboratories performing both primary and elective PCI, with and without on-site cardiac surgery, should perform a minimum of 200 PCIs annually. Laboratories performing <200 cases annually must have stringent systems and process protocols in place with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger volume facilities. The existence of laboratories performing <200 PCIs annually that are not serving

isolated or underserved populations should be questioned, and any laboratory that cannot maintain satisfactory outcomes should be closed. This recommendation was based on an extensive review of studies that identified a signal suggesting worse outcomes in laboratories performing <200 PCIs annually. The writing committee recommended that operators perform a minimum of 50 PCIs annually (averaged over 2 years), including no less than 11 primary PCIs annually. Ideally, these procedures should be performed in institutions performing >200 total and >36 primary PCI procedures annually. However, it was emphasized that individual operator volume is but one of several factors that should be considered in assessing operator competence, which include lifetime experience, institutional volume, the operator's other cardiovascular interventions and quality assessment of the operator's ongoing performance. Operators who cannot maintain these case volume recommendations at their primary practice site should maintain privileges and continue to perform PCI procedures at a high-volume institution with on-site surgical backup to meet annual volume requirements. It was also recommended that operators should be board certified in interventional cardiology and maintain certification, with the exception of operators who have received equivalent training outside the US and are ineligible for board certification in the US.

2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction

This document did not specifically comment on PCI without on-site cardiac surgery but supported the 2011 ACCF/AHA/SCAI PCI guidelines recommendations (25). It recommended that primary PCI be performed in high-volume, well-equipped centers with experienced interventional cardiologists, and skilled support staff.

2010 European Society of Cardiology and European Association for Cardio-Thoracic Surgery Guidelines

In contrast to the 2011 ACC/AHA/SCAI PCI guidelines, the 2010 European Society of Cardiology and the European Association for Cardio-Thoracic Surgery guidelines on myocardial revascularization do not comment on PCI without on-site surgery or issues related to institutional or operator competency (27). However, the European guidelines continue to stress the importance of full disclosure regarding the lack of availability of on-site cardiac surgery and the inadvisability of performing PCI for high-risk patients/lesions at facilities that do not have on-site surgical backup.

The European guidelines for STEMI do not provide specific recommendations regarding PCI at centers without on-site surgery (28). Rather, emphasis is placed on the development of networks between hospitals with differing levels of technology, connected by an efficient emergency transport system. To maximize staff experience, the guidelines recommend that primary PCI centers perform procedures 24 h a day, 7 days a week for all STEMI patients.

Other models mentioned in the European guidelines, although not ideal, include weekly or daily rotation of primary PCI centers or multiple primary PCI centers in the same region. Hospitals that cannot offer a 24/7 service for primary PCI should be allowed to perform primary PCI in patients already admitted for another reason and who develop STEMI during their hospital stay. These hospitals should, however, be discouraged from initiating a service limited to daytime or within-hours primary PCI, because this generates confusion with Emergency Medical Services (EMS) operators and is unlikely to match the door-to-balloon time and quality of intervention of focused 24/7 primary PCI centers. In a survey of European countries, the mean population served by a single primary PCI center varied between 0.3 and 7.4 million inhabitants. In countries offering primary PCI services to the majority of their STEMI patients, this population varied between 0.3 and 1.1 million per center (29). In small service areas, experience can be suboptimal due to an insufficient number of STEMI patients, but the optimal size of a catchment area could not be clearly defined. For geographical areas where the expected transfer time to a primary PCI center makes it impossible to achieve satisfactory reperfusion times, thrombolysis with subsequent immediate transfer to a primary PCI center has been endorsed. Although there is a risk of intracranial bleeding, a potential role for this strategy in selected circumstances has been emphasized (30).

Other Guidelines and Recommendations

The 2007 SCAI Expert Consensus Document summarized the recommendations from the British Cardiac Society and British Cardiovascular Intervention Society, the Cardiac Society of Australia and New Zealand (CSANZ), the Spanish Society of Cardiology, the Brazilian Society of Hemodynamics and Interventional Cardiology (*Sociedade Brasileira de Hemodinamica e Cardiologia Intervencionista*) and from several other countries (31–39). Since 2007, only the guidelines from CSANZ have been updated, most recently in 2011 (32). CSANZ guidelines state that primary PCI without on-site surgery should be performed: (a) by operators and institutions meeting the overall requirements and standards of primary PCI centers; (b) by institutions with a proven plan for rapid transport to a cardiac surgical center; (c) in a timely fashion (<90 min); and (d) using rigorous case selection criteria. The CSANZ guidelines acknowledged that rural patients might have limited access to diagnostic angiography and PCI, and providing these services at institutions without on-site surgery by appropriately trained individuals facilitates equity of access, which should result in improved quality of care. However, the CSANZ guidelines also specifically state that rural and regional centers should not perform

elective, high-risk PCI procedures if they are located more than 1 hour travel time from cardiac surgery centers.

AHA Policy Statement on PCI Without Surgical Backup

In March 2012, the AHA issued a policy statement on PCI without surgical backup defining two major reasons for providing PCI without on-site surgery (40). First, PCI without on-site surgery is considered reasonable if the intent is to provide high quality timely primary PCI for patients with STEMI. The statement recommended that each community and facility in the community have an agreed-upon plan for how STEMI patients are to be treated. The plan should indicate hospitals that should receive STEMI patients from EMS units capable of obtaining diagnostic electrocardiograms, the management at the initial receiving hospital and written criteria and agreements for the expeditious transfer of patients from nonPCI-capable to PCI-capable facilities. Second, PCI without on-site surgery is a reasonable consideration for providing local care to patients and families who do not want to travel significant distances or who have certain preferred local physicians. This is an important consideration, but the policy statement emphasized that evolving evidence suggests that such centers should have mechanisms in place to ensure high quality care. In addition to emphasizing the current guideline classifications for PCI without on-site surgery, the AHA policy statement provided recommendations for states wishing to address the issue of PCI without on-site surgery through the regulation of legislation.

Mission Lifeline

The Mission Lifeline program developed in 2006 from a series of conferences sponsored by the AHA and has continued to mature (41–43). The goal of Mission Lifeline is to improve the quality of care and outcomes for patients with STEMI and to improve healthcare system readiness and response to STEMI. An important focus of Mission Lifeline is to increase the number of patients with timely access to primary PCI. Criteria for the structure and operation of a STEMI referral and STEMI-receiving hospitals are part of the Mission Lifeline initiative and apply to facilities without on-site surgery.

Door-to-Balloon Alliance

The Door-to-Balloon (D2B™) effort began in January 2006 when the ACC recognized the need to reduce D2B times for patients with STEMI. This led to the development of a national initiative to achieve D2B times $\leq$90 min for at least 75% of nontransfer primary PCI patients with STEMI in participating hospitals performing primary PCI. This alliance consists of a nationwide network of hospitals, physician champions and strategic partners committed to improving D2B times. Participation in the Alliance provides the necessary tools; information and support for helping hospitals achieve the D2B treatment goals and encourages the use of real-time performance feedback on D2B times to drive the quality improvement effort (44). The D2B program has been highly successful, having achieved its initial goals (45).

Access to Primary PCI in the United States

Data from the American Hospital Association and the 2000 US Census were used to estimate the proportion of the adult population ($\geq$18 years of age) who lived within 60 min of a PCI hospital (46). An estimated 79.0% lived within a 1 hour drive of a PCI hospital, with a median driving time of 11.3 min. Even among those living closer to non-PCI hospitals, 74% would experience <30 min of additional delay with a direct referral to a PCI hospital. Approximately 5 years later, Concannon et al., using similar data sources and methodology, showed that despite a 44% relative increase in the number of facilities capable of performing PCI, the number of adults within a 1 hour drive of a PCI facility increased to only 79.9%, with the median driving time reduced by <1 min to 10.5 min (47). Access in rural areas remained far less than in urban areas, with driving times reduced for only 9% of the population compared with the earlier survey. These findings mirrored a smaller experience in Michigan where expansion of primary PCI to 12 hospitals without on-site surgery increased access for only 4.8% of the population (48). Finally, Horwitz et al. showed that hospitals are more likely to introduce new invasive cardiac services when neighboring hospitals already offer such services and confirmed that the increase in the number of hospitals offering invasive cardiac services has not led to a corresponding increase in geographic access (49). In total, these data support the argument that the addition of more PCI centers has not substantially improved access to PCI services for most patients.

Financial Considerations for Facilities Providing PCI Without On-site Surgery

Medicare payments to hospitals for invasive cardiac procedures have generally remained favorable, although physician reimbursement has decreased. Per-case revenue margins for PCI are typically higher than the overall hospital operating margins, and PCI improves the hospital case mix index. PCI programs bring prestige to an institution, and STEMI is one of the most prestigious diseases for treatment (50,51). The push to develop rapid STEMI care has led many to currently advocate for EMS bypassing non-PCI hospitals; there is even consideration being given to triaging patients based on D2B metrics. Exclusion from providing STEMI care might be a lesser financial concern than the loss of downstream revenue from additional testing in patients suspected of having an acute coronary syndrome. This includes not only testing performed to exclude CAD as the cause of chest pain but also testing to evaluate noncardiac causes of chest pain.

Table 3. Facility Requirements for PCI Programs Without On-Site Surgery

General Recommendations	Source
Requisite support equipment must be available and in good working order to respond to emergency situations.	PCI-GL PCI-CS ML
Should demonstrate appropriate planning for program development and should complete both a primary PCI development program and an elective PCI development program. Program developments to include routine care process and case selection review.	AHA D2B
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services such as intensive care, advanced imaging (CT, MR and other vascular imaging), respiratory care, blood bank and nephrology consultation with access to dialysis.	PCI-GL, PCI-CS ECD
The institution should have systems for credentialing and governing the PCI program. On-site data collection, quality assessment, quality improvement and error management are essential. Each institution must establish an ongoing mechanism for valid and continuous peer review of its quality and outcomes. A quality improvement program should routinely 1) review quality and outcomes of the entire program; 2) review results of individual operators; 3) include risk adjustment; 4) provide peer review of difficult or complicated cases; and 5) perform random case reviews. The review process should assess the appropriateness of the interventional procedures. Evaluation should include the clinical indications for the procedure, technical performance and the quality and interpretation of the coronary angiograms.	PCI-CS, AHA, PCI-GL ECD
Written agreements for emergency transfer of patients to a facility with cardiac surgery must exist. Transport protocols should be tested a minimum of 2 times per year involving both the referring and receiving facility. Develop agreements with a ground or air ambulance service capable of advanced life support and IABP transfer that guarantees a transport vehicle will be on-site to begin transport in ≤30 min *and arrival at the surgical hospital within 60 min of the decision to declare the need for emergency surgery.* Tertiary facility must agree to accept emergent and nonemergent transfers for additional medical care, cardiac surgery or intervention. *Tertiary centers should be able to establish cardiopulmonary bypass on emergency transfer patients within <120 min of an urgent referral.*	PCI-GL, AHA PCI-CS ECD *New*
Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability. The capability for real-time transfer of images and hemodynamic data (via T-1 transmission line) as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is highly recommended.	PCI-GL PCI-CS ML
Appropriate inventory of interventional equipment, including guide catheters, balloons and stents in multiple sizes; thrombectomy and distal protection devices; covered stents; temporary pacemakers; and pericardiocentesis trays. *Access to other diagnostic modalities such as intravascular ultrasound and fractional flow reserve is required.* Rotational or other atherectomy devices and the treatment of CTOs should not be performed in facilities without on-site surgery.	PCI-GL, PCI-CS *New*
Meticulous clinical and angiographic selection criteria for PCI (Table 5).	PCI-GL, AHA
Participation in a national data registry, such as the ACC NCDR in the United States is required. This allows benchmarking, risk adjustment and facilitates outcomes analysis of local data.	PCI-GL ECD AHA
A program should be in place to track and ensure treatments with ACC/AHA guideline-based Class I therapies, both acutely and at discharge.	PCI-CS, ML
Full service laboratories (both primary and elective PCI, with and without on-site cardiac surgery) performing <200 cases annually must have stringent systems and process protocols with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger volume facilities. Both physicians and staff should have the opportunity to work at a high volume center to enhance their skills. The continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations should be questioned and any laboratory that cannot maintain satisfactory outcomes should be closed.	PCI-CS
Geographic isolation exists if the emergency transport time to another facility is >30 min.	*New*
Satisfactory outcomes should be defined by each local facility as part of their quality review process and should be based on national or regional benchmarks. Programs that fail to meet their established criteria for satisfactory performance for 2 consecutive quarters must undertake efforts to improve engaging outside experts if necessary. Failure to improve quality metrics should also be grounds for program closure regardless of the location.	ML PCI-CS D2B
As part of the local continuous quality improvement program, there should be a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of improvement opportunities.	PCI-GL

Continued on the next page

This can be an additional financial motivator for developing PCI facilities (52). How the further bundling of payments and reimbursements on a global or capitated basis by accountable care organizations (ACO) will affect PCI programs is unclear at this time, but given the concerns about the cost of healthcare, increases in payments are unlikely (53,54). However, even in an ACO environment, hospitals might benefit from keeping cardiovascular procedures in-house where they have the ability to control costs rather than transferring patients to tertiary hospitals.

The Volume-Outcome Relationship for PCI and the Certificate of Need

There are 26 states with Certificate of Need (CON) regulations for the development of cardiac catheterization laboratories, but the effect of such regulations is uncertain. Ho et al. found that the removal of state cardiac CON regulations was associated with an increase in the number of hospitals performing CABG and PCI, but the statewide number of procedures was unchanged. The average procedure volume per hospital for both CABG and PCI therefore declined (55). Despite this, they found no

Table 3. Continued

STEMI Treatment Recommendations	
Each community should develop a STEMI system of care that follows standards at least as strong as those developed for Mission Lifeline, including: • Performance of primary PCI as the first-choice treatment for STEMI to ensure streamlined care paths and increased case volumes. • A process for prehospital identification and activation. • Protocols for triage, diagnosis and cardiac catheterization laboratory activation should be established within the primary PCI hospital/STEMI-Receiving Center. • A single activation phone call should alert the STEMI team. Criteria for EMS activation of the cardiac catheterization laboratory should be established in conjunction with EMS providers. • Transfer protocols for patients who arrive at STEMI referral centers who are in cardiogenic shock and/or are primary PCI candidates ineligible for fibrinolytic drugs.	2009 PCI-GL 2011 PCI-GL ML D2B
STEMI receiving centers should be available and on-call 24 hours/7 days a week (no diversion) to perform primary PCI. Primary PCI should not be performed at facilities unless it is provided on a 24/7 schedule.[a] The cardiac catheterization laboratory staff and interventional cardiologist should arrive within 30 min of a STEMI activation call. Facilities should have a plan for triage and treatment of simultaneous presentation of STEMI patients.	PCI-GL, AHA ML
STEMI receiving centers should perform a minimum of 36 primary PCI procedures annually, and these procedures should ideally be performed at facilities that perform a minimum of 200 total PCI procedures annually.	PCI-GL PCI-CS ML
Facilities performing only primary PCI should perform a minimum of 36 primary PCIs annually and work in collaboration with a high volume PCI facility to ensure good outcomes	PCI-GL PCI-CS
There should be a recognized STEMI-Receiving Center liaison/system coordinator to the system and a recognized physician champion.	ML
The STEMI-Receiving Centers should participate in the Mission Lifeline-approved data collection tool, ACTION Registry-Get with the Guidelines™.	ML D2B
They should also participate in the regional Mission Lifeline Stakeholder group (if available) to contribute to the development of a regional STEMI System of Care Plan	ML
Monthly multidisciplinary team meetings to evaluate outcomes and quality improvement data. Operational issues should be reviewed, problems identified, and solutions implemented. The following measurements should be evaluated on an ongoing basis: a. Door-to-first device time, nontransfer patients b. STEMI Referral Hospital ED door-to-balloon (first device used) time c. First medical contact to balloon inflation (first device used) time, nontransfer patients d. First medical contact to balloon inflation (first device used) time, transfer patients e. Proportion of eligible patients receiving reperfusion therapy f. Proportion of eligible patients administered guideline-based class I therapies g. Proportion of patients with field diagnosis of STEMI and activation of the Cardiac Catheterization Laboratory for intended primary PCI who i. do not undergo acute catheterization because of misdiagnosis ii. undergo acute catheterization and found to have no elevation in cardiac biomarkers and no revascularization in the first 24 h h. In-hospital mortality	ML

Italics font: New or modified recommendation in the document.

[a]Required for U.S. facilities but might not be possible for all facilities worldwide.

ACC, American College of Cardiology; AHA, American Heart Association policy statement; CT, computed tomography; CTO, chronic total occlusion; D2B, Door-to-Balloon Alliance; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; EMS, emergency medical systems; GL, Guidelines; IABP, intra-aortic balloon pump; IVUS, intravascular ultrasound; ML, Mission Lifeline; MR, magnetic resonance; New, New recommendation in this document; NCDR, National Cardiovascular Data Registry; PCI-CS, 2013 PCI Competency Statement; PCI-GL, 2011 ACCF/AHA/SCAI PCI guidelines; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; and STEMI, ST-segment elevation myocardial infarction.

evidence that CON regulations lowered procedural mortality rates for CABG or PCI. In other studies, CON regulation of cardiac catheterization was associated with care that was judged more appropriate, whereas the removal of CON regulation of cardiac surgery has been associated with an increase in low-volume cardiac surgical centers and increased mortality (56,57). Concerns have been raised that the proliferation of small centers performing complex procedures that have a small but definite risk of important complications might dilute the ability to provide efficient high quality service (52,58). Reduced mortality has been associated with an increased volume of primary PCI procedures in centers, higher volume operators, total volume of PCIs in centers, and the commitment of a center to provide PCI rather than fibrinolytic therapy (59–63). Lieu et al. reported that redundant or low-volume primary PCI programs were cost ineffective (64). Elective PCI at centers without on-site surgery was more expensive than PCI at centers with on-site surgery in one case-matched study (65). In addition, the high fixed costs of a cardiac surgery program in the face of decreasing surgical volumes is leading to the consolidation of numerous smaller surgery programs, depriving some PCI programs of surgical backup.

The issue of a PCI volume-outcome relationship was extensively reviewed in the 2013 PCI Competency document for centers with and without on-site surgery and for primary and elective PCI (4). The document concluded that in the current era, volume-outcome relationships are not as robust as in the past when balloon angioplasty was the only treatment modality. However, an institutional volume threshold of <200 PCIs annually appeared to be

consistently associated with worse outcomes. Primary PCI volume ≤ the guideline-recommended minimum of 36 annually was associated with worse in-hospital mortality in a recent series of over 86,000 patients in the NCDR (66). The cutoff points of <200 total PCIs annually and ≤36 primary PCIs annually has important implications because 26% of the PCI facilities submitting data to the NCDR performed ≤200 total PCIs annually and 38% performed ≤36 primary PCIs annually (8,66). Recent data suggested a modest volume-outcome relationship for variables other than mortality, but these data have limitations and are not consistent across all studies (4). Although there was an association between annual PCI volumes <200 and worse outcomes, there was no association between higher annual hospital volumes and improved outcomes at higher volume PCI centers. There was less evidence to support a threshold for individual operator volume for both elective and primary PCI.

Recommendations

We have provided recommendations for PCI without on-site surgery that are a composite of recommendations from the 2007 SCAI Expert Consensus Statement, the 2011 PCI guidelines, the 2012 Expert Consensus Document on Cardiac Catheterization Laboratory Standards, the 2013 PCI Competency statement and recommendations from the policy statement of the American Heart Association and requirements for the Mission Lifeline program and D2B Alliance (1–4,40,43,44). Redundant recommendations from these documents were consolidated, and the writing committee included several new recommendations consistent with evolving practice standards.

Facility Requirements for PCI Programs Without On-Site Surgery

Facility requirements are similar to those presented in past documents but now include a greater emphasis on the presence of quality review programs for facilities and operators, as described in the 2013 PCI competency document (4) (Table 3). Diagnostic modalities such as IVUS and especially fractional flow reserve previously considered desirable for facilities without on-site surgery have now increased in importance and are necessary for all PCI centers.

The 2013 PCI Competency Document identified a signal suggesting that an institutional volume threshold of <200 PCIs/year was associated with worse outcomes. Therefore, the 2013 Competency Document recommended that the continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations be questioned and that any laboratory that cannot maintain satisfactory outcomes should be closed. Past documents have not specified any criteria for geographic isolation. The writing committee suggests it be defined not by distance but by the time required for emergency transport of a STEMI patient to another facility. Hospitals justify the creation of new PCI centers without on-site surgery by stating that they improve access for geographically under-served populations and allow patients to be cared for in close geographic proximity to their own families and physicians. However, multiple low-volume and partial-service PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health system and have not been shown to improve access (46–49). If the transfer time is ≤30 min, it is reasonable

Table 4. Personnel Requirements for PCI Programs Without On-Site Surgery

Personnel Recommendations	Source
Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.	PCI GL PCI-CS
Coronary care unit nursing staff must be experienced and comfortable with invasive hemodynamic monitoring, operation of temporary pacemaker, management of IABP, *management of in-dwelling arterial/venous sheaths and identifying potential complications such as abrupt closure, recurrent ischemia and access site complications.*	PCI-GL PCI-CS *New*
Personnel should be capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.	PCI-GL
Operators should have ABIM board certification in interventional cardiology and maintain certification, with the exception of operators who have gone through equivalent training outside the United States and are ineligible for ABIM certification and recertification exams.	PCI CS
Interventional cardiologists should perform a minimum of 50 coronary interventional procedures per year (averaged over a 2-year period) to maintain competency.	PCI-CS
Primary PCI should be performed by experienced operators who perform a minimum of 50 elective PCI procedures per year and, ideally, at least 11 primary PCI procedures per year. Ideally, these procedures should be performed in institutions that perform more than 200 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.	PCI-CS ML
Facilities should develop internal review processes to assess operators performing <50 PCIs annually. Individual operator level volume is one of several factors that should be considered in assessing operator competence, which include lifetime experience, institutional volume, individual operator's other cardiovascular interventions and quality assessment of the operator's ongoing performance.	PCI-CS
It is unwise for a newly trained interventional cardiologist to start a new PCI program. Newly trained interventional cardiologists joining an established PCI program should be mentored by existing physicians until it is determined their skills, judgment and outcomes are acceptable.	*New*

Italics font: New or modified recommendation in the document.
ABIM, American Board of Internal Medicine; ML, Mission Lifeline; PCI-CS, 2013 PCI Competency Statement; PCI-GL, 2011 ACCF/AHA/SCAI PCI guidelines; IABP, intra-aortic balloon pump; New, new recommendation in this document; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.

to assume that transfer to the nearest PCI center will provide reperfusion as rapidly as if it were available at the first hospital. For transport times longer than 30 min, performing PCI on-site is likely to be quicker than a transfer. The development of PCI facilities within a 30-min emergency transfer time to an established facility is therefore strongly discouraged.

What constitutes a reasonable transport time for a patient requiring emergency surgery has not been consistently addressed in prior documents. Both CPORT-E and MASS-COMM studies provide guidance contained in their on-line supplementary materials (9,11). Both require a transport vehicle to be available to begin transport within 30 min and arrival at the surgical hospital within 60 min of the decision to declare the need for emergency surgery. MASS-COMM further recommends that surgical intervention begin within 120 min. Given the existing data on the distribution of PCI facilities in the US, the performance of elective PCI at facilities that cannot meet these transfer times is discouraged (46,47).

The 2013 PCI competency document also states that any laboratory that cannot maintain satisfactory outcomes should be closed; however, there is currently no national definition for "satisfactory outcomes". The writing committee recommends that these be defined by each PCI center, including those with on-site surgery, as part of their quality review process, using national benchmark

Table 5. Recommendations for Off-Site Surgical Backup and Case Selection

Recommendations—Cardiologist–Cardiac Surgeon Interactions	Source
Interventional cardiologists must establish a working relationship with cardiac surgeons at the receiving facility.	PCI-GL ECD
Cardiac surgeons should have privileges at the referring facility to allow review of treatment options as time allows.	PCI-GL ECD
Ideally, face-to-face meetings between cardiothoracic surgeons and cardiologists involved should occur on a regular basis *(Heart Team approach) especially for the discussion of management of patients undergoing nonprimary PCI who have left main, three-vessel CAD or two-vessel CAD with involvement of the LAD or comorbidities such as diabetes, depressed LV function or complex anatomy.*	PCI-GL ECD *New*
Cardiac surgeon and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours.	PCI-GL ECD
Surgeon and receiving facility ensure that patients will be accepted based on medical condition, capacity of surgeon to provide services at the time of request and availability of resources. If this cannot be ensured before the start of an elective procedure, the case should not be done at that time.	PCI-GL ECD
Interventional cardiologists must review with surgeons the immediate needs and status of any patient transferred for urgent surgery.	PCI-GL ECD
Interventional cardiologist should be familiar with and have immediate access to appropriate life support devices, such an intraaortic balloon pumps, and should be qualified for handling emergencies such as pericardial tamponade and embolization.	PCI-GL ECD
Hospital administrations from both facilities endorse the transfer agreement.	PCI-GL ECD
Transferring physicians obtain consent for surgery from patients or appropriate surrogates.	PCI-GL ECD
Initial informed consent for PCI discloses that the procedure is being performed without on-site surgical backup and acknowledges the possibility of risks related to transfer. The consent process should include the risk of urgent surgery and state that a written plan for transfer exists. *Consent for PCI should be obtained before the procedure and before any sedatives are given. Consent for PCI obtained while the patient is on the table is not informed consent and is unacceptable in non-emergency situations.*	PCI-GL ECD *New*
Recommendations—Case Selection and Management	
Avoid intervention in patients with: • >50% diameter stenosis of left main artery proximal to infarct-related lesion, especially if the area in jeopardy is relatively small and overall LV function is not severely impaired. • Long, calcified, or severely angulated target lesions at high risk for PCI failure with TIMI flow grade 3 present during initial diagnostic angiography. • Lesions in areas other than the infarct artery (unless they appeared to be flow limiting in patients with hemodynamic instability or ongoing symptoms). • Lesions with TIMI flow grade 3 in patients with left main or three-vessel disease where bypass surgery is likely a superior revascularization strategy compared with PCI. • Culprit lesions in more distal branches that jeopardize only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention. • *Chronic total occlusion.*	PCI-GL ECD *New*
The management of patients with STEMI resuscitated from sudden cardiac death is complex, and decisions about the need for immediate PCI with or without therapeutic hypothermia or possible transfer to a tertiary facility for treatment should be individualized.	
Emergency transfer for coronary bypass surgery patients with • High-grade left main or three-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with IABP support. • Failed or unstable PCI result and ongoing ischemia, with IABP support during transfer.	PCI-GL ECD

Italics font: New or modified recommendation in the document.

CTO, chronic total occlusion; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; PCI-GL, 2011 ACCF/AHA/SCAI PCI Guidelines; IABP, intraaortic balloon pump; LV, left ventricle; New, new recommendation in this document; PCI, percutaneous coronary intervention; TIMI, thrombolysis in myocardial infarction.

Table 6. Patient and Lesion Characteristics That Could Be Unsuitable for Nonemergency Procedures at Facilities Without On-Site Cardiac Surgery

High-risk patients	Source
• Decompensated congestive heart failure (Killip Class ≥3) without evidence for active ischemia.	PCI-GL
• Recent (<8 weeks) cerebrovascular accident.	AHA
• Advanced malignancy.	ECD
• Known clotting disorders.	
• LVEF ≤30%.	
• Chronic kidney disease (creatinine >2.0 mg/dL or creatinine clearance <60 mL/min).	
• Serious ongoing ventricular arrhythmias.	
• Patients with left main stenosis (>50% diameter) or three-vessel disease unprotected by prior bypass surgery (>70% stenoses in the proximal or mid segments of all major epicardial coronary arteries), treatment of any or all stenoses. Scoring systems, such as SYNTAX, may be useful in defining the extent of disease and type of revascularization procedure.	
• Patients with a single-target lesion that jeopardizes an extensive amount of myocardium.	
• Patients undergoing intervention on the last remaining conduit to the heart.	
High-risk lesions	
• Unprotected left main stenosis.	PCI-GL
• Diffuse disease (>20 mm in length).	
• Extremely angulated segment (>90%) or excessive proximal or in-lesion tortuosity.	ECD
• More than moderate calcification of a stenosis or proximal segment	*New*
• Inability to protect major side branches.	
• Degenerated older vein grafts with friable lesions.	
• Substantial thrombus in the vessel or at the lesion site.	
• Any other feature that could, in the operator's judgment, impede successful stent deployment.	
• Anticipated need for rotational or other atherectomy device, cutting balloon or laser.	
The characteristics listed above identify high-risk patient and lesion features but are not absolute contraindications to performing PCI at a facility without on-site surgery. For example, an elevated creatinine level increases the procedure risk for the patient, but this is not unique to facilities without on-site surgery and treatments to mitigate this complication can be used at all facilities. Ultimately, the operator should consider all factors and make a decision about the suitability of the patient for PCI at the facility.	*New*
Strategy for surgical backup based on lesion and patient risk	
• High-risk patients with high-risk lesions should not undergo nonemergency PCI at a facility without on-site surgery.	PCI-GL
• High-risk patients with nonhigh-risk lesions: Nonemergency patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room are immediately available is necessary.	
• Non-high-risk patients with high-risk lesions require no additional precautions.	
• Non-high-risk patients with nonhigh-risk lesions require no additional precautions. Best scenario for PCI without on-site surgery.	

Italics font: New or modified recommendation in the document.
CTO, chronic total occlusion; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; PCI-GL, 2011 ACCF/AHA/SCAI PCI Guidelines; LVEF, left ventricular ejection fraction; New, new recommendation; PCI, percutaneous coronary intervention; SYNTAX, Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery.

data. Programs failing to meet established criteria for satisfactory performance for two consecutive quarters must undertake efforts to improve their performance, engaging outside experts if necessary. Failure to improve quality metrics should lead to program closure regardless of the location. To ensure proper assessment and monitoring, laboratories are required to submit data to a national data registry, have regular meetings to discuss key performance metrics and develop plans for the correction of any deficiencies. Especially with facility PCI volumes decreasing, it becomes increasingly difficult to determine whether there are significant differences in the data reports from year to year. For example, to detect (with statistical certainty) a doubling of in-hospital mortality from 1% to 2% at a hospital with an annual case volume of 200 PCIs, nearly 4 years of continuous data collection would be required. This does not negate the importance of data submission to a national registry that can help identify trends, but it emphasizes why these same data must be carefully evaluated and adjudicated at the local facility. The importance of unbiased local or external peer review cannot be overemphasized (67,68). Implementation of the SCAI Quality Toolkit and certification by Accreditation for Cardiovascular Excellence (ACE) are recommended as resources for improving quality (69,70).

Personnel Requirements for PCI Programs Without On-Site Surgery

Recognizing the potential for isolation and the advantage of clinical experience, the 2007 SCAI Expert Consensus Document included a recommendation that operators at PCI programs without on-site surgery perform at least 100 total and 18 primary PCIs annually, a recommendation that might not be achievable in the current environment. The 2013 PCI Competency Document moves away from strict volume requirements to focus more on achieving quality metrics for facilities and individual operators. As noted earlier, the 2013 Competency document recommended that operators perform a minimum of 50 PCIs annually (averaged over 2 years), including no less than 11 primary PCIs annually. Ideally, these procedures should be performed in institutions performing >200

total and >36 primary PCI procedures annually (Table 4). Again acknowledging the importance of experience, the 2007 SCAI Expert Consensus Document suggested that initial operators at a new program without on-site surgery should have a lifetime experience of >500 PCIs as primary operator after completing a fellowship. In the current environment of decreasing PCI volumes and in view of the recommendations of the 2013 PCI competence document, this number would be difficult to achieve. Nevertheless, it is unwise for a newly trained interventional cardiologist to start a new PCI program. Newly trained interventional cardiologists joining an established PCI program should be mentored by more experienced physicians until it is determined that the skills, judgment and outcomes of these new cardiologists are acceptable.

Requirements for Off-Site Surgical Backup

Recommendations for the interactions between cardiologists and cardiac surgeons are listed in Table 5. A limitation of programs performing PCI without on-site surgery is the lack of on-site access to a cardiac surgeon for consultation about revascularization options. This makes the concept of a Heart Team consultation more difficult to achieve and could necessitate performing only diagnostic catheterization until a case review with a cardiac surgeon can be performed. The application of telemedicine consultations with a heart surgeon could facilitate these interactions. In reality, many of the nonemergency patients who merit discussion by a Heart Team are not optimal candidates for PCI at facilities without on-site cardiac surgery. It is important to emphasize that the role of the cardiac surgeon is not confined to the treatment of PCI complications but includes the participation in decisions about revascularization options. Recommendations for case selection at facilities without on-site surgery are shown in Table 5, and criteria for identifying high-risk lesions and patients are contained in Table 6. There are statistical models for identifying PCI patients at higher risk for mortality or emergency CABG that could be helpful for identifying patients who should not undergo PCI at facilities without on-site surgery (18,71). However, these models have not been tested or applied on a large scale to determine the advisability of performing a PCI at facilities without on-site surgery.

The Delivery of PCI Services in the Future

As a result of the additional randomized studies on PCI without on-site surgery and the recent change in guideline recommendations, the performance of PCI without on-site surgery in the US has gained greater acceptance, and questions about its safety in the presence of a proven, well defined, and protocol driven approach have diminished. PCI programs should be evaluated based on their ability to: (a) sustain adequate quality metrics, (b) provide access to elective and emergency PCI procedures that would otherwise be unavailable in their service area, and (c) maintain the operator and institutional volumes recommended in the 2013 PCI Competency Document. For the future, the focus must now shift to developing a rational plan for the distribution of PCI services. Small PCI programs with large fixed costs are inefficient and unnecessary if they do not improve access in areas of need. However, it is unlikely that issues of system-wide efficiency will be addressed without central planning on the state or federal level. This writing group reaffirms the statement from the 2011 ACCF/AHA/SCAI PCI Guidelines that "desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery" and suggests that new programs offering PCI without on-site surgery are inappropriate unless they clearly serve geographically isolated populations. The writing group recognizes the need for ongoing study and surveillance of all PCI programs through participation in national databases encourages public reporting of their results and acknowledges that further declines in PCI volumes might necessitate the closure of PCI programs in the future.

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Key Words: ACC Clinical Expert Consensus Document ■ angioplasty ■ consensus ■ coronary artery bypass surgery.

Appendix 1. Author Relationships With Industry and Other Entities (Relevant)—SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
James C. Blankenship	Geisinger Medical Center—Director, Cardiac Catheterization Laboratory	None	None	None	• Abiomed* • AstraZeneca* • Boston Scientific* • Kai Pharmaceutical* • Novartis* • Schering Plough • The Medicines Company* • Volcano*	• SCAI—Vice President*	None
Mehmet Cilingiroglu	Arkansas Heart Hospital	None	None	None	None	None	None
Greg J. Dehmer (Chair)	Texas A&M College of Medicine, Scott & White Clinic Cardiology Division—Professor of Medicine; Director of Cardiology	None	None	None	None	None	None
James G. Dwyer	Heart and Vascular Center of Northern Arizona	None	None	None	None	None	None
Dmitriy N. Feldman	New York Presbyterian Hospital/Cornell	• Gilead • Maquet	• Abbott Vascular • Bristol-Myers Squibb* • Daiichi-Sankyo • Eli Lilly • Pfizer • The Medicines Company*	None	None	None	None
Timothy J. Gardner	Christiana Care Health System—Medical Director	None	None	None	None	None	None
Cindy L. Grines	Harper University Hospital—Vice President	• Abbott Vascular • Bristol-Myers Squibb • Lilly USA • Merck • The Medicines Company • Volcano*	None	None	None	• *Journal of Interventional Cardiology*†	None
Mandeep Singh	Mayo Clinic	None	None	None	None	None	None

This table represents all healthcare relationships of committee members with industry and other entities that were reported by authors, including those not deemed to be relevant to this document, at the time this document was under development. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$10,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Please refer to http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx for definitions of disclosure categories or additional information about the ACCF Disclosure Policy for Writing Committees.

*No financial benefit.

†Significant relationship.

ACC indicates American College of Cardiology; AMA, American Medical Association; FDA, U.S. Food and Drug Administration; NHLBI, National Heart, Lung, and Blood Institute; SCAI, Society for Cardiovascular Angiography and Interventions.

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Appendix 2. Peer Reviewer Relationships With Industry and Other Entities (Relevant)—SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

Peer Reviewer	Representation	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Eric R. Bates	Content Reviewer—AHA and Content Reviewer—ACCF/AHA/SCAI PCI Guideline	University of Michigan Hospitals and Health Centers—Professor of Medicine	• AstraZeneca • BMS • Daiichi-Sankyo • Eli Lilly • Merck/ Schering-Plough • Sanofi-aventis	None	None	None	None	None
Ashequl M. Islam	Official Reviewer—SCAI	Baystate Medical Center—Program Director, Interventional Cardiology Fellowship	• Edwards Lifesciences	• Daiichi-Sankyo • Eli Lilly	None	None	None	None
Hani Jneid	Official Reviewer—ACCF Task Force on Clinical Expert Consensus Documents	Baylor College of Medicine - MEDVAMC—Associate Professor of Medicine	None	None	None	None	None	None
Steven P. Marso	Official Reviewer—SCAI	Saint Luke's Mid America Heart Institute; University of Missouri-Kansas City—Professor of Medicine	None	None	None	None	• Amylin* • St. Jude Medical* • Terumo Medical* • The Medicines Company* • Volcano Corporation*	None
Laura Mauri	Official Reviewer—AHA	Harvard Medical School—Associate Professor of Medicine; Brigham & Women's Hospital	• Medtronic • St. Jude Medical	None	None	• Abbott Vascular* • Boston Scientific* • Bristol-Myers Squibb* • Cordis Corporation* • Daiichi-Sankyo* • Eli Lilly* • Medtronic* • Sanofi-aventis*	None	None
Srinivas Murali	Official Reviewer—ACC Board of Governors	Allegheny General Hospital—Director, Division of Cardiovascular Medicine	• Advisory Board • Actelion • Gilead Pharma	• Actelion	None	• Gilead Pharma • St. Jude Medical	None	None
Barry Uretsky	Official Reviewer—SCAI	University of Arkansas for Medical Sciences—Clinical Professor of Medicine	None	None	None	• St. Jude Medical*	None	None
Howard Walpole	Official Reviewer—ACCF Board of Trustees	Okyanos Heart Institute—Chief Medical Officer	None	None	None	None	None	None
Thomas M. Bashore	Content Reviewer—ACCF/AHA/SCAI Clinical Competence Statement on CIP	Duke University Medical Center—Professor of Medicine; Clinical Chief, Division of Cardiology	None	None	None	None	None	None

Continued on the next page

Appendix 2. Continued

Peer Reviewer	Representation	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
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Glenn N. Levine	Content Reviewer—ACCF/AHA/SCAI PCI Guideline and ACCF/AHA/SCAI Clinical Competence Statement on CIP	Baylor College of Medicine—Professor of Medicine	None	None	None	None	None	None
Pasala S. Ravichandran	Content Reviewer—ACCF Surgeons Section Leadership Council	Oregon Health & Science University—Associate Professor	None	None	None	None	None	None
Sidney C. Smith, Jr.	Content Reviewer—ACCF Individual	Center for Cardiovascular Science and Medicine—Professor of Medicine; Director	None	None	None	None	None	None

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ACCF indicates American College of Cardiology; AHA, American Heart Association; CABG, Coronary Artery Bypass Graft Surgery; CIP, Coronary Interventional Procedures; PCI, Percutaneous Coronary Intervention; SCAI, Society of Cardiovascular Angiography & Interventions.

EXHIBIT E

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CORE CURRICULUM

WILEY

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 (i.e., 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 (e.g., 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 (e.g., 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 (e.g., 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 (e.g., 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

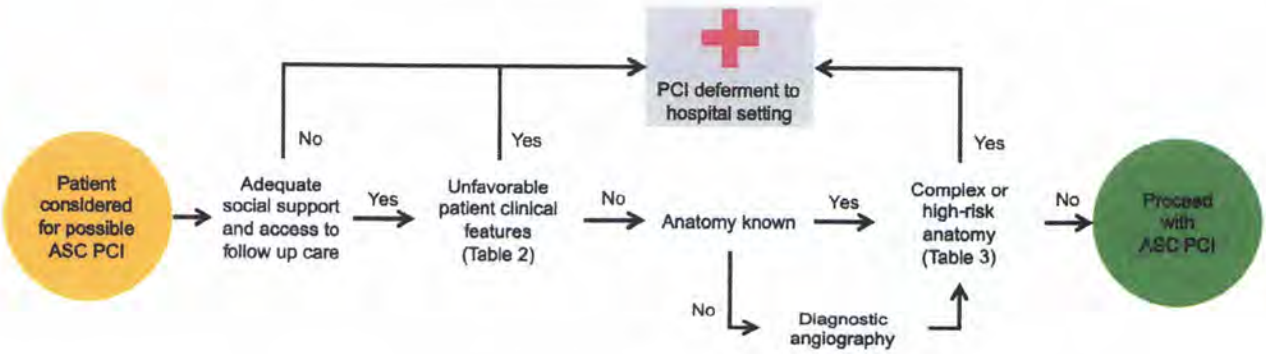
PCI in the ASC site of service should be performed with the same expectations for quality as in the hospital. A quality program must be in place to evaluate procedure appropriateness, technical performance, and assurance of quality of care. The SCAI/ACC/AHA Expert Consensus Document on PCI Without On-Site 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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EXHIBIT F

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EXPERT CONSENSUS DECISION PATHWAY

2021 ACC Expert Consensus Decision Pathway on Same-Day Discharge After Percutaneous Coronary Intervention

A Report of the American College of Cardiology Solution Set Oversight Committee

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PREFACE

The American College of Cardiology (ACC) has a long history of developing documents (e.g., decision pathways, health policy statements, appropriate use criteria) to provide members with guidance on both clinical and nonclinical topics relevant to cardiovascular care. In most circumstances, these documents have been created to complement clinical practice guidelines and to inform clinicians about areas where evidence may be new and evolving or where sufficient data may be more limited. Despite this, numerous care gaps continue to exist, highlighting the need for more streamlined and efficient processes to implement best practices in service to improved patient care.

Central to the ACC's strategic plan is the generation of "actionable knowledge"—a concept that places emphasis on making clinical information easier to consume, share, integrate, and update. To this end, the ACC has evolved from developing isolated documents to developing integrated "solution sets." Solution sets are groups of closely related activities, policy, mobile applications, decision support, and other tools necessary to transform care and/or improve heart health. Solution sets address key questions facing care teams and attempt to provide practical guidance to be applied at the point of care. They use both established and emerging methods to disseminate information for cardiovascular conditions and their related management. The success of the solution sets rests firmly on their ability to have a measurable impact on the delivery of care. Because solution sets reflect current evidence and ongoing gaps in care, the associated tools will be refined over time to best match changing evidence and member needs.

Expert consensus decision pathways (ECDPs) represent a key component of solution sets. The methodology for ECDPs is grounded in assembling a group of clinical experts to develop content that addresses key questions facing our members across a range of high-value clinical topics (1). This content is used to inform the development of various tools that accelerate real-time use of clinical policy at the point of care. They are not intended to provide a single correct answer; rather, they encourage clinicians to ask questions and consider important factors as they define treatment plans for their patients. Whenever appropriate, ECDPs seek to provide unified articulation of clinical practice guidelines, appropriate use criteria, and other related ACC clinical policy. In some cases, covered topics will be addressed in subsequent clinical practice guidelines as the evidence base evolves. In other cases, these will serve as stand-alone policy.

Ty J. Gluckman, MD, FACC
Chair, ACC Solution Set Oversight Committee

1. INTRODUCTION

The evolution of percutaneous coronary intervention (PCI) has led to improved safety and efficacy, with data showing that in the context of a same-day discharge (SDD) clinical pathway, overnight monitoring can be avoided, allowing for SDD in selected patients with no increased rate of death, rehospitalization, or other complications, and with the potential to increase safety (2). However, these data are largely observational, with only small randomized trials supporting SDD, and thus, uncertainty around SDD for PCI remains (3). This ECDP aims to address this uncertainty and provide guidance about the key patient, clinical, and systems factors, such as operational resources, that must be in place to ensure the safety of SDD after PCI.

1.1. Benefits of SDD

Same-day discharge after PCI benefits both patients and facilities. A common misconception is that patients may

experience apprehension of SDD stemming from stress or anxiety about not being monitored after a cardiac procedure. Evidence supports the notion that the majority of patients prefer SDD and the ability to return to the comfort of their home following their PCI. A prospective study of patients undergoing elective PCI randomized to same- or next-day discharge at 2 major U.S. medical centers found that nearly 80% of patients in both cohorts reported high levels of coping, as assessed by the Readiness for Hospital Discharge scale (4). Additionally, a 30-day post-PCI follow-up found that 79% of same-day versus 49% of next-day discharge patients were satisfied with the timing of their discharge. The majority of these patients, including 80% of the SDD group and 68% of the next-day cohort, reported a preference for SDD for future PCI procedures. This preference for SDD after PCI has been confirmed in subsequent studies (5).

The impetus for SDD for PCI reflects not only patient preference and satisfaction, but also safety. In terms of major adverse cardiovascular events, meta-analyses have found no difference between same- and next-day discharge following PCI (6,7). However, data suggest that approximately 8% of hospitalizations are associated with highly undesirable events such as hospital-acquired infections or falls leading to injury (8,9). Furthermore, the inpatient setting is well known to provide an undesirable atmosphere for recovery due to a lack of privacy, frequent interruptions/awakening for examination and/or blood draws, and a plethora of unrelenting noises, leaving patients susceptible to posthospitalization syndromes (10).

From a facilities operations standpoint, SDD for PCI offers several key benefits. Currently, many facilities are unable to meet the admission demands of their emergency departments. These shortcomings are often the result of failure to optimize patient flow on a facilities-wide level. One such example involves the routine use of inpatient beds for post-PCI patients. During times of need for enhanced bed utilization in the cardiovascular services line, this healthcare practice results in a delay of specialized care, illustrating how, within a healthcare system, the failure of an individual component to operate at maximum efficiency can contribute to suboptimal performance of the overall system (11). Opportunities to increase efficiency are important to keep in mind because cardiovascular disease is a leading cause of admission to U.S. hospitals (12). Implementation of SDD for PCI is one way to increase inpatient bed availability.

Lastly, SDD for PCI may offer facilities and/or hospitals an economic advantage. Studies have found SDD for PCI to be associated with a relative reduction of as much as 50% in health system costs (13). These savings stem from the fact that procedures are elective for the majority of patients considered for SDD. Same-day discharge for PCI also leads to a reduction in supplies and room and board costs, 2 significant areas that drive savings; indeed, SDD for PCI results in savings of a minimum of $5,000 per case (14). This number was found to increase up to $7,000 when SDD for PCI occurs in the setting of radial access, in which cost savings accrue through decreases in either vascular complications or the need for the closure devices required with a femoral access approach (15). In sum, it is estimated that the use of SDD in 50% of elective PCIs would result in savings of $200 million to $500 million per year for U.S. healthcare systems (3,16). It is important to note that the implementation of an SDD program may require investment from facilities in terms of increased staffing models to accommodate discharges that may occur in the late afternoon or evening.

2. METHODS

This ECDP emerged out of a proposal to the ACC's Task Force on Expert Consensus Decision Pathways (whose tasks are now under the umbrella of the Solution Set Oversight Committee [SSOC]; see the Preface for the definition of this committee). The primary contacts for the proposal, Drs. Sunil V. Rao and Mladen I. Vidovich, became the Chair and Vice Chair of the ECDP, respectively. The Chair and Vice Chair identified an additional 7 members to form a working group (WG). WG members were vetted for relationships with industry (RWI) to ensure that a majority did not have RWI; throughout the writing process, WG members were reminded to report any new relationships that arose.

A kickoff call was held among the WG in October 2018 to explain the goal and process of the ECDP, followed by biweekly calls with the group. During the biweekly calls, the WG reviewed a questionnaire developed by ACC's Implementation Tools team to help ECDP authors determine the optimal scope, format, and clinical content of ACC tools. The WG discussed these questions over several calls and determined the factors that should be considered when deciding if a PCI patient should be recommended for SDD or overnight stay. The WG, in consultation with the ACC's Implementation Tools team, determined that a checklist best fit the needs of this ECDP. The biweekly calls were then used as a format in which to discuss and come to a consensus about the patient- and systems-specific factors that should be considered when determining if SDD is appropriate. These factors were incorporated into the checklist decision tool. The completed checklist was then tested for usability among a group of experts.

Once the checklist was complete, the WG wrote the ECDP on SDD, which presents the rationale and evidence underlying SDD after PCI.

The ACC and the SSOC recognize the importance of avoiding real or perceived RWI or other entities that may affect clinical policy. The ACC maintains a database that tracks all relevant relationships for ACC members and persons who participate in ACC activities, including those involved in the development of ECDPs. ECDPs follow ACC RWI Policy in determining what constitutes a relevant relationship, with additional vetting by the SSOC.

ECDP writing groups must be chaired or co-chaired by an individual with no relevant RWI. Although vice chairs and writing group members may have relevant RWI, they must constitute less than 50% of the writing group. Relevant disclosures for the writing group and external reviewers can be found in Appendixes 1 and 2. To ensure complete transparency, a full list of disclosure information, including relationships not pertinent to this document, is available in a Supplemental Appendix 1. Participants are discouraged from acquiring relevant RWI throughout the writing process.

3. ASSUMPTIONS AND DEFINITIONS

3.1. Assumptions

1. This ECDP on SDD after PCI is applicable to anyone presenting for an elective PCI but is not applicable to patients presenting with ST-elevation myocardial infarction (STEMI) or non-ST-elevation myocardial infarction (NSTEMI). Patients with presentations of STEMI or NSTEMI should be hospitalized ≥1 night in the inpatient setting for postprocedural monitoring based on presentation and clinical features, as well as procedure-related considerations. (It should be noted that this tool is applicable to staged procedures performed after the index PCI procedure for patients who initially presented with NSTEMI or STEMI. This includes patients who undergo a staged PCI during the index hospitalization for NSTEMI or STEMI, or patients who are discharged home and return for a planned staged PCI).
2. The focus of this ECDP is the role of SDD in an adult population undergoing elective PCI. The pathway does not address the role of SDD in a pediatric population.
3. This ECDP defines postprocedural processes that should be implemented for successful SDD, including confirmation of the patient's receipt of a $P2Y_{12}$ inhibitor ($P2Y_{12}i$) prescription, instructions on how to monitor the access site, and confirmation that the patient has appropriate outpatient follow-up scheduled. It is assumed that these discharge instructions will be adapted to conform with the protocols of individual institutions. The format of this ECDP, currently a checklist, may be adapted to fit the needs and processes of individual institutions.
4. This document encourages shared decision-making with the patient about whether to pursue SDD after PCI.
5. This pathway endorses the 2015 ACC/AHA/SCAI Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction: An Update of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention and the 2013 ACCF/AHA Guideline for the Management of ST-elevation Myocardial Infarction (17,18).
6. The recommendations outlined in this document may be superseded by new evidence.

3.2. Definitions

Additional terms within the checklist are further defined in Supplemental Table 1, "Defining Concepts."

Elective Procedure: We define elective PCI as described in the National Cardiovascular Data Registry CathPCI Registry, which states: "The (PCI) procedure performed on an outpatient basis without significant risk of infarction or death" (19).

Urgent Procedure: When there is concern for ongoing ischemia or infarction, an urgent coronary angiogram +/- PCI would be warranted. "Urgent" procedures are generally defined as those performed in hospitalized patients prior to discharge.

Emergent Procedure: When there is concern for death or hemodynamic compromise, an emergent coronary angiogram +/- PCI would be warranted. Emergent procedures should be performed on patients with inpatient status or in patients for whom postprocedure hospital admission is planned.

Overnight Stay: A patient may present for a same-day procedure but then be placed on monitoring overnight within the facility and/or hospital. Observation stays are defined as stays that do not extend >24 hours from the time of presentation (20,21).

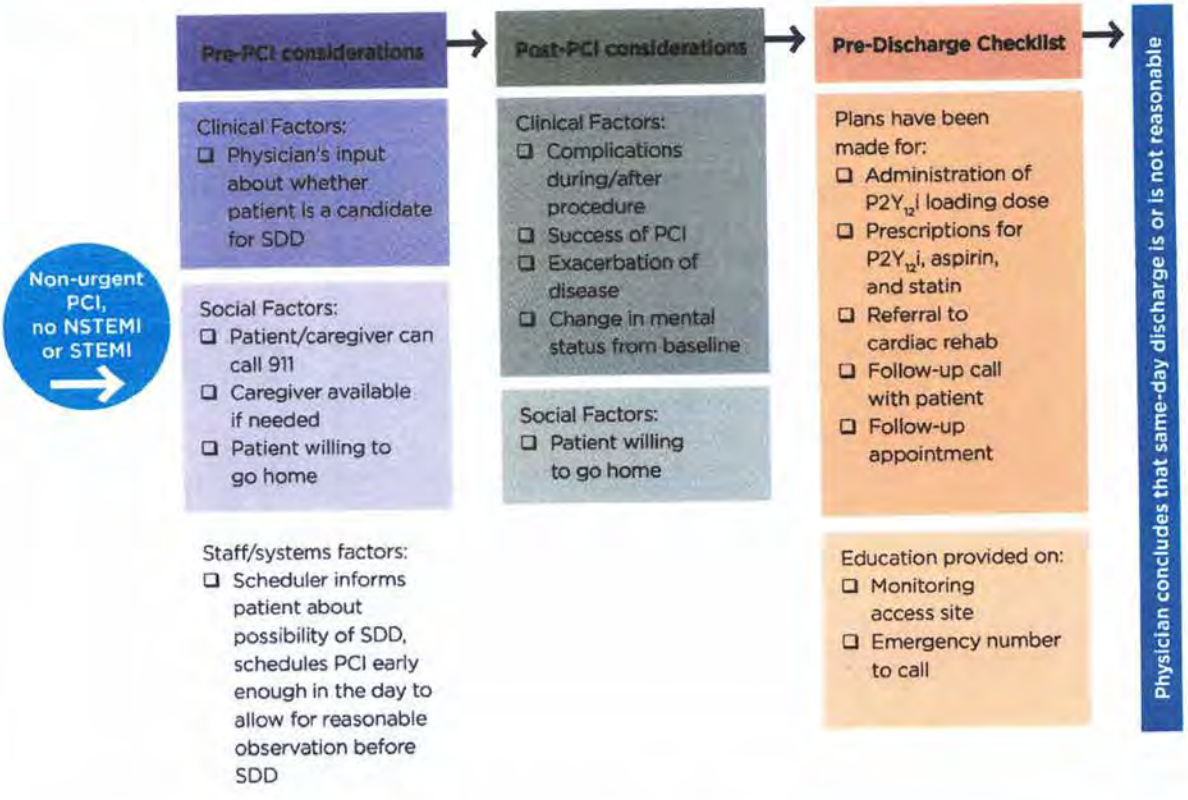
Same-Day Discharge (SDD): Same-day discharge after PCI is defined as a stay after a PCI procedure that does not include supervised overnight monitoring in the facility and/or hospital. The patient will stay for routine monitoring of variable duration after the procedure, based on factors such as access site and procedural characteristics, but will typically be discharged within 12 hours after arrival at the facility or catheterization laboratory (some monitoring periods may be shorter or longer).

PCI Success: We define PCI success using the National Cardiovascular Data Registry definition: <50% post-stenosis, TIMI 3 flow, and 20% or greater reduction from pre- to post-stenosis (17).

Adequate Caregiver Support: Support from a person who has the ability and willingness to: 1) accompany the patient home or to the caregiver's home; 2) stay with the patient overnight after discharge; 3) access emergency services; and 4) help with the activities of daily living.

4. PATHWAY SUMMARY GRAPHIC

FIGURE 1 Summary Graphic: Clinical, Patient, and Systems/Staff Factors to Consider Before and After PCI When Deciding on Same-Day Discharge



Graphic depiction showing the factors that affect the decision for same-day discharge for PCI. Preprocedural and postprocedural considerations, including patient social factors, patient clinical factors, staff/system factors, and completion of discharge checklist, all influence the decision on SDD.

NSTEMI = non-ST-elevation myocardial infarction; $P2Y_{12}i$ = $P2Y_{12}$ inhibitors; PCI = percutaneous coronary intervention; SDD = same-day discharge; STEMI = ST-elevation myocardial infarction.

5. DESCRIPTION, RATIONALE, AND IMPLICATION OF PATHWAY

5.1. Overview of the Goal and Uses of the Checklist

The WG determined that a checklist (**Table 1**) would be the best format for evaluating the factors that inform whether SDD is appropriate after planned or ad hoc PCI. A digital version of the checklist can also be found on ACC.org. The checklist is intended to document both initial patient eligibility before the procedure as well as the absence of subsequent exclusionary criteria during the peri- and post-PCI periods. Ideally, patients suitable for SDD should be identified prior to the procedure and be informed as early as possible of the goal for SDD. This advance notice may help identify unforeseen barriers to SDD and provide an opportunity to address patients' and caregivers' expectations and concerns. This timeline for patient notification, however, might not be applicable in every institution, and therefore, institutions are expected to adapt the checklist to meet their individual workflow needs.

The following general principles apply to the checklist:

1. It should be underscored that this checklist should not be considered prescriptive but rather a guide to help with decision-making.
2. The checklist offers considerable scope for adaptation to suit individual practice patterns. The workflow of

TABLE 1 Checklist for Consideration of Same-Day Discharge After PCI

Members of the care team complete this checklist to decide whether the patient undergoing PCI is a reasonable candidate for same-day discharge or should be monitored overnight.

The questions below do not need to be answered in order; however, it is recommended that a decision to discharge a patient on the same day as the PCI should be made only after all questions have been answered.

	Pre-Procedure Evaluation			
Patient Factors: Clinical	1. Is the patient experiencing an STEMI or NSTEMI?	❑ No ↓	❑ Yes ------→	Monitor patient overnight
Patient Factors: Clinical	2. Does any member of the care team feel for any other reason that the patient is not a candidate for same-day discharge?	❑ No ↓	❑ Yes ------→	
Patient Factors: Social	3. Does the patient have adequate caregiver support?*	❑ Yes ↓	❑ No ------→	
Patient Factors: Social	4. Can the patient or caregiver reach 911, if necessary?	❑ Yes ↓	❑ No ------→	
Patient Factors: Social	5. Is the patient willing to be discharged the same day (shared decision-making)?	❑ Yes ↓	❑ No ------→	
Staff/System Factors	6. Is the patient scheduled early enough in the day so that they can be observed for a sufficient amount of time (4-6 hours post-procedure) and discharged at a reasonable time?	❑ Yes ↓	❑ No ------→	
	Care Team Action ← Once the procedure is finished, complete the Post-Procedure Evaluation on the next page to confirm same-day discharge.			

Notes (does the clinician want to note anything not captured on the checklist?):

*Caregiver support is defined as support from a person who has the ability and willingness to: 1) accompany the patient home or to the caregiver's home; 2) stay with the patient overnight after discharge; 3) access emergency services; and 4) help with the activities of daily living.

Continued on the next page

individual facility systems will determine when and by whom the checklist will be completed.

3. Although SDD applies to both transradial and transfemoral access, the use of large-bore femoral sheaths (e.g., ≥7-F) might prompt consideration for overnight monitoring, given some concern for the elevated risk of late bleeding compared with the use of smaller-caliber sheaths.
4. Although the checklist may be initiated before the PCI, a final decision about SDD should only be made after all checklist items have been answered; it is possible that the checklist may not be completed in its entirety until after the procedure.

TABLE 1 **Continued**

Post-Procedure Evaluation			
7. Did complications occur during the procedure?†	❑ No ↓	❑ Yes -----→	Monitor patient overnight
8. Was PCI successful?‡	❑ Yes ↓	❑ No -----→	
9. Is the patient experiencing any of the following post-procedure? Stroke, bleed, vascular complications, allergic reaction, unresolved and/or severe chest pain, acute heart failure, persistent ischemic ECG changes, dysrhythmia, or any other unforeseen complications.	❑ No ↓	❑ Yes -----→	
10. Is there an exacerbation of an underlying disease (e.g., heart failure, high blood pressure, diabetes, COPD flare)?	❑ No ↓	❑ Yes -----→	
11. Is the patient's mental status the same as baseline presentation?	❑ Yes ↓	❑ No -----→	
12. Is the patient willing to be discharged the same day (shared decision-making)?	❑ Yes ↓	❑ No -----→	
Proceed to the Pre-Discharge Checklist			

Pre-Discharge Checklist
__ 1. Confirm that loading dose of $P2Y_{12}i$ has been administered.
__ 2. Confirm patient has received prescriptions for at least 30 days of $P2Y_{12}i$.
__ 3. Confirm prescription for aspirin and statin.
__ 4. Confirm referral to cardiac rehab.
__ 5. _____ (Name of person responsible for following up with patient) plans on calling patient the day after discharge.
__ 6. The cath lab/postprocedural staff has provided education to patient on how to monitor access site (in-person training, handouts, videos, etc.) and the importance of taking DAPT as prescribed and the specific risks of premature discontinuation.
__ 7. The cath lab/postprocedural staff has provided the patient with an emergency number to call.
__ 8. The cath lab/postprocedural staff has scheduled a follow-up appointment.
↓
Physician concludes that same-day discharge is reasonable
Notes (does the clinician want to note anything not captured on the checklist?):

†Examples include persistent slow flow or no flow, compromise of large side branch resulting in chest pain, untreated dissection, perforation, allergic reaction to contrast medium (anaphylaxis).

‡Success defined using the NCDR definition: <50% post-stenosis, TIMI 3 flow, and 20% or greater reduction from pre- to post-stenosis.

COPD = chronic obstructive pulmonary disease; DAPT = dual antiplatelet therapy; ECG = electrocardiogram; NCDR = The National Cardiovascular Data Registry; NSTEMI = non-ST-elevation myocardial infarction; $P2Y_{12}i$ = $P2Y_{12}$ inhibitors; PCI = percutaneous coronary intervention; TIMI = thrombolysis in myocardial infarction.

The checklist (**Table 1**) delineates 3 time periods in which to evaluate whether patients meet eligibility criteria.

5.2. Preprocedure

The preprocedure checklist is divided into 2 main categories: patient clinical factors and patient social factors.

5.2.1. Clinical Factors

The pre-procedure checklist items are intended to guide the clinician to a decision regarding SDD. The first patient factor to consider is whether the patient is experiencing a myocardial infarction. As stated in a previous section, patients with presentations of STEMI or NSTEMI are hospitalized ≥1 night in the inpatient setting for postprocedural monitoring based on presentation and clinical features, as well as procedure-related considerations. However, the WG recognizes that clinicians may sometimes make decisions based on a more subjective, overall clinical impression. Therefore, the WG included the question, "Does any member of the care team feel for any other reason that the patient is not a candidate for same-day discharge?" to reinforce the option of recommending overnight monitoring after PCI, even when the checklist suggests the patient is eligible for SDD. Coronary anatomic considerations that preclude SDD are also at the discretion of the procedural team due to the absence of published data on specific lesion types or procedures that do or do not lend themselves to SDD.

The pre-procedure checklist also provides an open notes section that allows clinicians to expand upon their reasoning for SDD or overnight stay. In addition, the open notes section gives clinicians the option of using the checklist to supplement electronic health record (EHR) notes.

5.2.2. Social Factors

During discussion among the WG, consensus emerged that social factors are key in deciding whether SDD after PCI is appropriate; a patient may be deemed clinically fit to go home, but may not have adequate social support (e.g., no caregiver to monitor them for the next 24 hours, or in the case of people without stable residence, no home to which to return).

Both the preprocedure and postprocedure evaluation sections include the question: "Is the patient willing to be discharged the same day?" This question is designed to reinforce patient-centered practices and to ensure that the patient fully understands the possibility of SDD and agrees to leave the hospital and/or the facility the day of the PCI.

Ideally, the patient and caregiver(s) are told about the possibility of SDD at the time the procedure is scheduled; it is recognized that this timing may not always be possible, depending on the workflow of individual institutions.

5.2.3. Staff/System Factors

Importantly, it may be preferable to schedule the procedure for earlier in the day in order to allow a sufficient period of postprocedural monitoring, resumption of baseline preprocedure ambulatory status, and SDD at a reasonable time. A 4- to 6-hour postprocedural period is commonly used at most institutions (22,23).

All terms in the preprocedure section are explained further in Supplemental Table 1, "Defining Concepts."

5.3. Postprocedure

The postprocedure checklist focuses on the absence or presence of factors that indicate the patient's clinical stability, and thus, their eligibility to be considered for SDD. It should be noted that procedural success is only 1 of the factors to be considered here—hospitalization may coincide with other events that warrant an overnight stay, such as exacerbation of underlying disease or change in baseline mental state.

5.4. Predischarge

The care team confirms the absence of postprocedural exclusions, reconfirms completion of all portions of the checklist, and ensures that discharge instructions are communicated to the patient.

The pre-discharge section of the checklist should be completed after it has been determined that the patient meets all of the preprocedure and postprocedure criteria for SDD. The items on the checklist ensure that the patient is leaving the facility with the appropriate instructions for medication and for monitoring the access site. Providing at least 7 days of dual antiplatelet therapy (DAPT) prior to discharge is preferred, when possible, in order to minimize gaps in antiplatelet coverage. A specific person should be designated to contact the patient the day after discharge. The exact content of the discharge educational materials is left to the discretion of individual institutions. Level of activity after SDD, including driving, should follow local protocols.

Figure 2 presents 6 clinical scenarios showing how the checklist may be used to determine whether a patient who had a PCI should be considered for SDD or for overnight monitoring (4 additional scenarios can be found in Supplemental Figure 1).

FIGURE 2 Six Clinical Scenarios Showing the Rationale for SDD or Overnight Monitoring

Complex Patient, Eligible for SDD

Patient: 86-year-old man, accompanied by his wife.

Medical History: S/p CABG 22 years prior with SVG to OM and IMA to LAD now has angina that prevents him from farming. Patient also has AF treated with aspirin, nitrates, diltiazem, ranolazine, and warfarin.

Investigation: Stress test showed severe lateral-wall ischemia. Dx cath showed graft-dependent LCx and LAD with a degenerated SVG to OM graft that had a bulky, calcified lesion just distal to the ostium.

Management: Using the right radial artery, a 6-F, 0.75 AL was used to engage the SVG. An embolic protection device could not be used due to anatomic considerations. The lesion was treated with a cutting balloon and a 3.5-mm DES with excellent results and persistent TIMI-3 flow. Procedure time was 1 h. Four h later, the patient was ambulating and free of angina.

DECISION: Cath lab staff and/or physician completed the Same-Day Discharge Checklist and physician confirmed that SDD is reasonable.

Post-Procedure Exclusion

Patient: 85-year-old woman, accompanied by husband who has mild dementia.

Medical History: Coronary angiography 8 years prior demonstrated a 90% lesion of the proximal RCA s/p PCI with BMS.

Investigation: Stress test showed severe inferior wall ischemia. Dx cath showed significant ISR of the prior RCA stent.

Management: Using the left radial artery, a 6-F, JR4 guide caused significant radial artery spasm. RFA access was obtained. An excellent angiographic result was obtained with a 3.0 × 15 mm DES. Procedure time was 1.5 h. Post-cath, the patient developed a significant hematoma at the femoral access site and reported pain. The hematoma resolved with additional manual compression.

DECISION: Given issues with social support and access site complications, the cath lab staff and/or physician deemed the patient not a candidate for SDD, according to the Same-Day Discharge Checklist.

Post-Procedure Exclusion

Patient: 75-year-old woman, accompanied by her husband.

Medical History: PAD, hypertension, hyperlipidemia, diabetes mellitus, and ESRD with dialysis 3 times per week. Patient having chest pain with dialysis.

Investigation: Nuclear stress test concerning for anterior wall ischemia. Right radial approach aborted due to tortuosity (fistula in left arm). RFA used as back-up approach. Dx cath showed 90% calcified mid-LAD lesion.

Management: A 6-F left coronary guide catheter was placed into the LM coronary artery. Lesion treated with 4 runs of atherectomy with 1 episode of slow flow. Despite atherectomy, stent delivery was difficult. Patient reported chest pain during procedure. Ultimately, a 3.25 × 28 mm DES was delivered. D2 was lost and could not be rescued. Control of femoral access with sheath pull was difficult and a small hematoma was present.

DECISION: The postprocedure section of the Same-Day Discharge Checklist highlighted procedural complications and postprocedure vascular complications. The patient is deemed not a candidate for SDD.

Post-Procedure Exclusion

Patient: 45-year-old man.

Medical History: Familial hypercholesterolemia and lupus, presents urgently (<24 h) for an angiogram due to unstable angina symptoms as an outpatient.

Management: Radial access and successful stent placement to the mid LAD. However, there was a guide dissection of the LM artery, resulting in chest discomfort, requiring additional stenting of the LM artery into the LAD. The patient was initiated on ticagrelor and 2 h later in the postprocedure room reported dyspnea.

DECISION: The postprocedure section of the Same-Day Discharge Checklist highlighted procedural complications and postprocedure dyspnea. The patient is deemed not a candidate for SDD.

FIGURE 2 Continued

Patient Eligible for SDD

Patient: 70-year-old woman with polio using arm crutches.

Medical History: Type 2 diabetes, CCS 3 angina on 3 antianginal agents.

Management: Femoral access PCI with successful DES to the LAD. Successful closure of femoral arteriotomy. DAPT had been initiated 2 weeks prior to the procedure, and there are no medicine changes. Her daughter will drive and stay with her through the night. No symptoms in recovery.

DECISION: Cath lab staff and/or physician completed the Same-Day Discharge Checklist and physician confirmed that SDD is reasonable

Pre-Procedure Exclusion

Patient: 80-year-old widower accompanied by his daughter, who flew in for the day. He wants to stay overnight like his neighbor did.

Medical History: Hypertension well-controlled, physically active. Recently developed chest pain on effort that limited his ADLs.

Investigation: Stress echocardiogram showed extensive anterior wall motion abnormality at a low exercise load. Right radial approach was used but there was significant radial artery spasm with manipulation of diagnostic catheters. A proximal, type-A stenosis of 95% was found in the LAD.

Management: A 6.5-F sheathless guide was passed up the radial artery without further spasm. The lesion was treated with a 2.5-mm balloon, then underwent IVUS to size the vessel to the stent. A 4.0 × 18 mm DES was delivered and post-dilated at 18 ATMS. Repeat IVUS showed full expansion and no overlap into the LM. Procedure was terminated and patient returned to the recovery unit. The radial sheath was removed without incident. The nurse called the man's daughter to let her know that the procedure went well, and she left a message on the daughter's cell phone. The patient was hesitant to be home alone.

DECISION: Overnight stay due to patient preference

ADLs = activities of daily living; AF = atrial fibrillation; AL = Amplatz left; BMS = bare metal stent; CABG = coronary artery bypass grafting; CCS = Canadian Cardiovascular Score; D2 = second diagonal branch; DAPT = dual antiplatelet therapy; DES = drug-eluting stent; Dx cath = case diagnostic cardiac catheterization; EBU = extra backup; ESRD = end-stage renal disease; h = hour; IMA = internal mammary artery; ISR = in-stent restenosis; IVUS = intravascular ultrasound; LAD = left anterior descending artery; LCX = left circumflex artery; LM = left main; OM = obtuse marginal artery; PAD = peripheral artery disease; PCI = percutaneous coronary intervention; RCA = right coronary artery; RFA = right femoral artery; SDD = same-day discharge; s/p = status post; SVG = saphenous vein graft; TIMI = thrombolysis in myocardial infarction.

6. SYSTEMS/WORKFLOW ISSUES RELATING TO A CHECKLIST FOR SDD AFTER PCI

6.1. Implementing an SDD Protocol Among Members of the Cardiovascular Team

Implementation of safe, effective SDD will be dependent on the identification of specific team members responsible for its delivery. In addition to the outpatient cardiology clinical staff and cardiac catheterization laboratory operational staff, other members of the cardiovascular team, including pharmacists, staff in the preprocedural or postprocedural areas, and those who work in registration, may play the greatest role in implementing the SDD checklist. The SDD checklist should be presented as a tool that addresses multiple facets of the patient care pathway, ensuring safe patient recovery, education, and follow-up. Ideally, the process of completing the checklist enhances communication between staff and physicians on patient-specific concerns.

6.2. The Importance of Obtaining Buy-In Among Hospital and/or Facility Administration

We encourage physician-champions of SDD to meet with staff administrators to: 1) present the data on PCI safety and utility; and 2) communicate the expectation that staff will complete the checklist and ensure that appropriate patients can undergo a safe SDD. It is recommended that each facility devise a protocol for the SDD that includes all elements from the checklist (24). In addition, meetings with different groups of the team (advanced practice providers/nursing/pharmacy/registration) to discuss their specific roles can help to reduce barriers to

implementation and provide a forum in which experienced staff can offer input into tailoring the checklist around the specific needs of their patient population and institution. For example, SDD candidates who are identified preprocedurally could benefit from earlier procedure times, an effort that requires coordination between the scheduling and administrative team members to ensure adequate time for completion of the procedure and SDD checklist.

6.3. Importance of Emphasizing Post-PCI DAPT

The importance of adequate DAPT involving $P2Y_{12}$i must be at the forefront of the checklist from a preprocedural and postprocedural vantage. Practice patterns regarding $P2Y_{12}$i loading and maintenance vary among physicians, with providers initiating $P2Y_{12}$i either days before the procedure, while in the pre-procedural area, or while in the cardiac catheterization laboratory after defining the coronary anatomy (17). Regardless of the variations in timing, all instances of PCI guideline-directed loading and maintenance of DAPT provide optimum results and decrease the incidence of stent thrombosis. Orders for outpatient loading and maintenance or preprocedural DAPT loading should be confirmed in the EHR and communicated between preprocedural and procedural nursing and then verbally to the patient. Once ordered, the procedural loading should be communicated to postprocedural staff and then administered to the patient. If the $P2Y_{12}$i is a new medication initiated in the SDD setting, a prescription to the facility's outpatient pharmacy should be expedited so that the medications are in the hands of the patient/responsible caregiver prior to leaving the facility. Additionally, a prescription should also be sent to the patient's preferred outpatient pharmacy.

In addition to the DAPT loading dose, the EHR should also confirm prescriptions for aspirin and statin therapy as well as a referral to cardiac rehabilitation.

6.4. Integration of Checklist Data Into the EHR

With the aid of hospital or facilities informational technology staff, the SDD checklist can be integrated into the patient EHR. For example, certain elements of the checklist, including instructions about medications and follow-up care, would ideally be included within discharge summaries given to patients. Other elements of the checklist may also be added to the clinical discharge summary, for example, from the free notes section. Patient-specific details from these summaries could be used by cardiologists and/or other clinicians during subsequent visits to address patients' ongoing health care needs.

In addition, the SDD checklist provides a means by which facilities may more quickly and accurately account for safety and efficiency. For example, the checklist can provide information (in the EHR or other database) detailing whether important known safety metrics (e.g., administration of DAPT and discharge instructions) have been met. The checklist can also provide documentation on perhaps more personal aspects of patient care, such as the presence of a reliable individual who can provide transit home and reasonably monitor the access site and overall condition of the patient. The checklist may also provide an opportunity to assess patient satisfaction, an observable metric recorded by many facilities and hospital systems, as well as part of the Hospital Consumer Assessment of Healthcare Providers and Systems survey from the Centers for Medicare and Medicaid Services (25).

7. DISCUSSION AND IMPLICATION OF PATHWAY

PCI has evolved in safety and efficacy such that many patients can leave facilities the same day as the procedure, with retrospective data showing no increase in death or rehospitalization compared with patients who stay for overnight monitoring (2). In addition, SDD is preferred by patients and can increase savings and bed capacity (6,26). However, uncertainty around SDD for PCI remains. This ECDP has aimed to address this uncertainty, providing clinicians with a checklist of clinical, social, and facility/systems factors that indicate whether a patient can be safely considered for SDD. The ideal time to begin the checklist is before the procedure, but depending on the workflow and resources of individual institutions, the checklist may also be started and completed after the procedure. On this note, the WG was careful to create a checklist that can be adapted to meet the needs of individual institutions.

The need for administrative buy-in for SDD and an SDD checklist should not be underemphasized; implementing a protocol around SDD will necessarily require changes in workflow and a clear identification of the cardiovascular team members who will complete the checklist, communicate the possibility of SDD to the patient, and ensure that the patient has the appropriate and relevant discharge information as well as a $P2Y_{12}$i dose administered along with a prescription. Physician-champions of the checklist and SDD can also communicate the potential of the checklist to enrich EHR data through the open notes section of the tool.

It is the belief of the WG that implementing this checklist, and thus likely widening the pool of patients who can be identified as candidates for safe SDD, will lead to greater patient satisfaction and awareness as well as increased savings within facilities. Implementation of this checklist also provides institutions with an opportunity to carry out quality evaluations as data from the checklist

can be used to inform the evolution of future checklists and protocols in SDD for PCI.

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KEY WORDS ACC Expert Consensus Decision Pathway, percutaneous coronary intervention, same-day discharge

APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2021 ACC EXPERT CONSENSUS DECISION PATHWAY ON SAME-DAY DISCHARGE AFTER PCI

To avoid actual, potential, or perceived conflicts of interest that may arise as a result of industry relationships or personal interests among the writing committee, all members of the writing committee, as well as peer reviewers of the document, are asked to disclose all current healthcare-related relationships, including those existing 12 months before initiation of the writing effort. The ACC Task Force on Expert Consensus Decision Pathways reviews these disclosures to determine what companies make products (on market or in development) that pertain to the document under development. Based on this information, a writing committee is formed to include a majority of members with no *relevant* relationships with industry (RWI), led by a chair with no *relevant* RWI. RWI is reviewed on all conference calls and updated as changes occur. Author RWI pertinent to this document is disclosed in the table below and peer reviewer RWI is disclosed in Appendix 2. Additionally, to ensure complete transparency, authors' *comprehensive disclosure information*—including RWI not pertinent to this document—is available in a Supplemental Appendix 1. Disclosure information for the ACC Solution Set Oversight Committee is also available online at http://www.acc.org/guidelines/about-guidelines-and-clinical-documents/guidelines-and-documents-task-forces, as well as the ACC disclosure policy for document development at http://www.acc.org/guidelines/about-guidelines-and-clinical-documents/relationships-with-industry-policy.

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ACC = American College of Cardiology.

APPENDIX 2. PEER REVIEWER INFORMATION—2021 ACC EXPERT CONSENSUS DECISION PATHWAY ON SAME-DAY DISCHARGE AFTER PCI

This table represents the individuals, organizations, and groups that peer reviewed this document. A list of corresponding comprehensive healthcare-related disclosures for each reviewer is available in a Supplemental Appendix 2.

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ACC = American College of Cardiology; LSU = Louisiana State University; UCLA = University of California, Los Angeles; VAMC = Veterans Administration Medical Center.

APPENDIX 3. ABBREVIATIONS

ACC = American College of Cardiology
DAPT = dual antiplatelet therapy
ECDP = Expert Consensus Decision Pathways
EHR = electronic health record
NSTEMI = non-ST-elevation myocardial infarction
$P2Y_{12}i$ = $P2Y_{12}$ inhibitors
PCI = percutaneous coronary intervention
RWI = relationships with industry
SDD = same-day discharge
STEMI = ST-elevation myocardial infarction
WG = working group

EXHIBIT G

Ambulatory Surgery Centers Are a Safe and Cost-Effective Setting for Diagnostic and Therapeutic Cardiac Catheterization Procedures

Introduction

This paper explains why Alabama's State Health Planning and Development Agency (hereafter the Agency) and Certificate of Need Review Board (hereafter the Board) should approve cardiac catheterization labs (cath labs) in ambulatory surgery centers (ASCs) with reasonable conditions to assure patient safety. Attachment 1 to this paper includes the tables and analysis referenced in the text. Attachment 2 is a bibliography of the documents reviewed and cited. This paper was written by Ronald T. Luke, JD, PhD, James E. Stidham, MBA, CASC, Ralph B. Redd, MD, and Thomas J. Wool, MD, FACC. Attachment 3 includes curricula vitae for the authors.

The statistical data and the 2019 and 2020 position statements by governing cardiology professional societies (American College of Cardiology [ACC] and Society for Cardiovascular Angiography and Intervention [SCAI]) support that the cardiac procedures of interest can be performed in ASCs with the same degree of safety as in hospital settings. Economic data and the 2019 payment decisions by the Centers for Medicare and Medicaid Services (CMS) prove that there is significant cost savings to both patients and insurance payers when the procedures of interest are performed in ASCs. Patients treated in ASCs have fewer surgical site infections.[1, 2] Patients undergoing the cardiac procedures of interest in an ASC setting are thus protected from exposure to nosocomial (hospital-acquired) infections. These hospital-acquired infections can lead to significant morbidity and mortality in patients undergoing the cardiac procedures of interest. By treating these patients in ASCs and reducing the risk of infection, their care would be

[1] Ambulatory Surgery Center Association, Outcomes Monitoring Project, 3rd Quarter 2011, https://www.ascassociation.org/advancingsurgicalcare/aboutascs/industryoverview/apositivetrendinhealthcare.
[2] Thomas D. Wilson, "Benchmarking Study of 1,000,000 Surgeries in ASCs Demonstrates Minimal Surgical Site Infections, Emergency Department Visits, and Readmission Rates," ASC Communications, August, 24, 2017, https://montereysurgerycenter.com/wp-content/uploads/2017/09/Beckers-Article-Benchmarking-Aug-24-2017.pdf.

less likely to be delayed due to patients' fear of infectious exposure. Procedures performed in ASCs are also less likely to be delayed, as ASCs only perform scheduled elective procedures.

The state of Alabama should allow ASC-based cath labs to perform diagnostic cardiac catherization (DCC), percutaneous coronary intervention (PCI), placement of cardiac pacemakers and defibrillators, and the other endovascular and cardiac procedures in Table 1 of Attachment 1, collectively called the "Cardiac Procedures of Interest" (see page 26). The Alabama CON program regulates development of new ASCs and cath labs. The Board can only approve applications consistent with the State Health Plan (SHP), which says: "fixed-based cardiac catheterization services are the only acceptable method for providing cardiac catheterization services to the people in Alabama."[3] Therefore, the Board may not approve applications for mobile cath labs. A cath lab in either a hospital or an ASC is a fixed-base cath lab. Nothing in the SHP requires a fixed-base cath lab to be in a hospital.

Cardiac catheterization procedures are performed in ASCs throughout the United States. This paper presents specific data from all-payor databases from Texas and Florida on experience in ASCs with the cardiac procedures of interest. The Texas and Florida claims data show clinical outcomes and utilization trends. These two states were chosen for two reasons: they allow the cardiac procedures of interest in ASCs, and they make all-payor data for ASCs publicly available.

This paper summarizes guidance on safety, efficacy, and patient selection for cath labs in ASCs from medical professional societies and CMS. The cardiac professional societies have reached a consensus on these issues. CMS has determined which procedures may be safely performed in an ASC on appropriate Medicare patients.

Background on Cardiac Procedures of Interest

The cardiac procedures of interest in Table 1 (page 26) fall into four categories: (1) endovascular revascularization procedures, (2) pacemaker and defibrillator procedures, (3)

[3] State Health Planning and Development Agency, Alabama State Health Plan, 2014-2017, Section 410-2-3-.03(3).

diagnostic cardiac catheterizations, and (4) coronary therapeutic services and procedures. These procedures have been performed for many years on outpatients in hospital cath labs.

CMS decides annually which procedures can be safely performed in an ASC for Medicare patients. Over time, CMS has expanded the list of procedures. Before approving payment for a procedure performed in an ASC, CMS solicits comments and research from interested parties. Professional societies, individual physicians, and medical associations submit comments for or against adding procedures to the list. CMS reviews and responds to the comments and the available data on safety and clinical appropriateness.

Table 2 of Attachment 1 (page 29) shows the year Medicare began paying for each cardiac procedure of interest in ASCs. Medicare began paying ASCs for insertion of pacemakers and defibrillators before 2010, for endovascular revascularization procedures through the iliac artery in 2011,[4] and for endovascular revascularization using femoral and tibial approaches in 2012.[5] In 2020, CMS pays ASCs for all the cardiac procedures of interest. In several states these procedures have been performed in ASCs for many years.

PCI is used to treat unstable angina, acute myocardial infarctions, and multivessel coronary artery disease. It is now one of the most commonly performed cardiac procedures.[6] The first PCI, also known as coronary angioplasty, was performed in 1977. In October 1994, the *International Classification of Diseases, Ninth Revision*, created a new code to distinguish between angioplasty via balloon and angioplasty with a stent, reflecting a shift in PCI techniques.[7] As PCI procedures became more common, new techniques and devices improved outcomes and shortened recovery times. Hospitals began subsequently delivering cardiac care on an outpatient basis.

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[4] The American Medical Association categorizes medical services under Current Procedural Terminal (CPT) codes. Here, the relevant CPT codes are 37220, 37221, 37222, 37223.
[5] CPT codes 37224, 37228, 37225, 37229, 37226, 37230 37227, 37231.
[6] George Stouffer III, "Percutaneous Coronary Intervention (PCI)," *Medscape*, updated November 27, 2019, https://emedicine.medscape.com/article/161446-overview.
[7] Chuck Shih and Elise Berliner, "Diffusion of New Technology and Payment Policies: Coronary Stents," *Health Affairs* 27, no. 6 (Nov./Dec. 2008): 1566–1576, https://doi.org/10.1377/hlthaff.27.6.1566.

In 2018, CMS paid for peripheral revascularization, pacemaker, and implantable defibrillator surgeries in Alaska, Arizona, California, Colorado, Florida, Illinois, Indiana, Kansas, Kentucky, Louisiana, Missouri, Nebraska, New Jersey, Nevada, New York, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Washington, and Wisconsin. The most commonly performed peripheral revascularization, pacemaker, and defibrillator procedures at ASCs were:

- 33208: Insertion of new or replacement permanent pacemaker with transvenous electrodes, atrial and ventricular (CMS paid for 709 procedures at ASCs);
- 33228: Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator, dual lead system (CMS paid for 682 procedures at ASCs);
- 33249: Insertion or replacement of permanent implantable defibrillator system, with transvenous leads, single or dual chamber (CMS paid for 412 procedures at ASCs).

CMS began paying ASCs for right and left heart catheterization procedures in 2019, and for PCI procedures in 2020. ASCs in states without CON regulation have been performing cardiac procedures of interest for several years, as facility payment became available.

The CMS Physician and Other Supplier Public Use Data File shows Medicare beneficiaries had over 29,000 cardiac procedures of interest in Alabama in 2017. Almost 97% of these procedures were performed in hospitals; the remainder were performed in physician offices. To date, no ASCs in Alabama have been approved to provide cath lab services. The SHP permits the Board to approve a cath lab in an ASC. An application for a cath lab in an ASC or hospital must show it meets the other CON statutory and rule criteria.

Cost Savings for Cardiac Procedures of Interest in ASCs

ASCs charge less for cardiac procedures of interest than hospitals. Table 3 in Attachment 1 (beginning on page 30) compares the average facility charge to outpatients for CPT codes 33208, 33228, and 33249 at ASCs and at hospitals by state for Medicare patients.

- For code 33208, average ASC charges varied from 22.3% to 52.0% of outpatient charges.
- For code 33228, average ASC charges varied from 21.1% to 55.5% of outpatient charges.
- For code 33249, average ASC charges varied from 45.4% to 114.3% of outpatient charges. The only instance where average ASC charges were higher than outpatient charges was for code 33249 in Kansas.

CMS calculates payment for outpatient cardiac procedures of interest differently for ASCs and hospitals. This means cost savings for Medicare and Medicare beneficiaries as well as for health plans and their members that base allowed amounts on Medicare fee schedules. CMS estimated that moving 5% of coronary interventions nationwide from a hospital outpatient setting to ASCs would reduce Medicare payments by about $20 million and beneficiary copays by about $5 million in 2020.[8]

The Medicare allowed amount for a procedure in an ASC is lower than for the same procedure at a hospital. Medicare employs the same methodology for determining ASC and outpatient hospital payment, but applies a lower conversion factor in determining allowed amounts for ASCs. For 2020, the conversion factor for ASC payment ($47.747) is 59% of the hospital outpatient factor ($80.784). Allowed amounts for ASCs are further reduced by multiplying the base ambulatory payment classification (APC) weight by a weight scalar. In 2020, that weight is 0.885.[9] The table below summarizes the difference between 2020 Medicare payments to hospitals versus ASCs for outpatient procedures.

[8] Todd Neale, "CMS Finalizes Rule Allowing Reimbursement of PCI in Ambulatory Centers," *tctMD/the heart beat*, November 4, 2019, https://www.tctmd.com/news/cms-finalizes-rule-allowing-reimbursement-pci-ambulatory-centers.
[9] 82 Fed. Reg. 59418 (Dec. 14, 2017).

Medicare Reimbursement for Outpatient Procedures at Hospitals and ASCs

	Outpatient Hospital	ASC
2020 Conversion Factor[10]	$80.784	$47.747
Step 1	Assign services to ambulatory payment classification (APC) group based on resource requirements of services	
Step 2	APC Relative Weight	**88.5%** of APC Relative Weight
Step 3	**60%** of APC = Labor Portion	**50%** of APC = Labor Portion
Step 4	Determine Wage Index based on Geographic Location	
Step 5	Labor Portion x Wage Index	
Step 6	**40%** x APC = Non-Labor Portion	**50%** of APC = Non-Labor Portion
Step 7	Payment Rate = ((Labor Portion x Wage Index) + Non-Labor Portion) x Conversion Factor	

CMS has a different payment method for "device-intensive procedures" for which the device accounts for more than 30% of the total payment. For these procedures, the ASC payment is divided into a device portion and a non-device portion. The ASC receives the same amount as a hospital for the device portion.[11] The non-device portion is paid at the standard ASC rate, using the methodology described above.

Table 4 in Attachment 1 (page 33) shows the Medicare allowed amounts for a hypothetical ASC in Montgomery County, Alabama, compared to Medicare allowed amounts for outpatient procedures at Baptist East and Baptist South hospitals in Montgomery County. For those procedures, Medicare's allowable amounts for the ASC are about half the allowable amounts for a hospital. We were unable to compute a payment comparison for the device-dependent procedures, as doing so requires information on the exact device being used, which was not available.

[10] 82 Fed. Reg. 59258 and 59421 (Dec. 14, 2017).
[11] MedPAC, Ambulatory Surgical Center Services Payment System, October 2020, available at: http://medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_20_asc_final_sec.pdf?sfvrsn=0

Data on Cardiac Procedures of Interest from Texas and Florida

Texas and Florida have allowed ASCs to perform cardiac procedures of interest for several years. They publish all-payor claim-level data for hospitals and ASCs showing procedures performed and patient discharge status. Florida also has public claim-level data for cardiac procedures of interest performed in separately licensed cath labs not located in a hospital or ASC.

Cardiac Procedures of Interest at Texas ASCs

Hospitals and ASCs in Texas must report claim-level data for invasive surgical or radiological procedures and for any emergency department visits to the Texas Department of State Health Services, Health Care Information Collection (THCIC).[12] Hospitals and ASCs must report all the procedures in Table 1 to THCIC.[13] Table 5 in Attachment 1 (page 35) shows the number of procedures by CPT code performed at ASCs in Texas in 2018 and 2019. In 2018, 1,479 cardiac procedures of interest were performed at Texas ASCs. In 2019, 4,375 cardiac procedures of interest were performed at Texas ASCs, a 296% year-over-year increase.

In 2019, 23 ASCs in Texas performed the cardiac procedures of interest. Of these ASCs, 13 specialized in cardiac and vascular procedures and accounted for over 95% of the cardiac procedures of interest in Texas ASCs. The other 10 ASCs appear to be multi-specialty ASCs. Table 6 in Attachment 1 (page 36) lists the ASCs in Texas that reported cardiac procedures of interest. Shaded cells indicate ASCs specializing in cardiac and vascular procedures. Table 7 in Attachment 1 (page 37) shows the discharge status of the patients in 2019. A blank discharge status is assumed to indicate the patient was discharged home. No patients died from cardiac procedures of interest at ASCs in 2018 or 2019. In 2019, over 97% of patients were discharged home, with fewer than 2.5% of patients being admitted or readmitted to hospitals following the

[12] See Texas Health and Human Services, Texas Health Care Information Collection, Texas Outpatient Public Use Data File (PUDF) documentation and information available at:
https://www.dshs.state.tx.us/thcic/OutpatientFacilities/OutpatientPUDF.shtm
[13] See THCIC HCPCS-Code-worksheet-for-2020.xlsx, available at:
https://www.dshs.state.tx.us/thcic/OutpatientFacilities/HCPCS-Code-worksheet-for-2020.xls

procedure. One of the 23 ASCs was an outlier, with a high readmission rate. When that facility is removed, the readmission rate for patients treated at the remaining 22 ASCs was 0.7%.

Cardiac Procedures of Interest in Florida

Florida has a separate licensure category for cath labs not in hospitals or ASCs: "'Cardiac catheterization laboratory' means a freestanding facility that employs or contracts with licensed health care professionals to provide diagnostic or therapeutic services for cardiac conditions such as cardiac catheterization or balloon angioplasty."[14] Florida's Agency for Health Care Administration (AHCA) maintains an ambulatory surgery public data set which has data from outpatient hospitals, ASCs, and freestanding cath labs.[15] Table 8 in Attachment 1 (page 38) shows the number of procedures by CPT code performed at ASCs and cath labs in Florida in 2018 and 2019.[16] In 2018, 6,625 cardiac procedures of interest were performed at ASCs and cath labs in Florida. In 2019, this number grew to 7,161. As with Texas's numbers, these amounts should continue to increase in 2020, reflecting increased coverage of procedures by Medicare.

In 2019, 30 ASCs and cath labs in Florida performed cardiac procedures of interest. Of these facilities, 9 specialized in cardiac and vascular procedures and accounted for 94.9% of the cardiac procedures of interest outside of hospitals. Table 9 in Attachment 1 (page 39) lists the non-hospital facilities in Florida that performed these procedures. Shaded cells indicate facilities specializing in cardiac and vascular procedures. In 2019, 99.8% of patients were discharged home. No patients died, and only 0.02% of patients having cardiac procedures of interest at these facilities were admitted or readmitted to hospitals. Cardiac procedures of interest in Texas and Florida are overwhelmingly safe when performed at facilities other than hospitals.

[14] Florida Statutes §408.07(9).
[15] More information on Florida's ambulatory data, please see information from The Office of Data Dissemination and Transparency at: https://www.floridahealthfinder.gov/Researchers/OrderData/order-data.aspx.
[16] All four quarters of 2019 data were available and have been used.

Professional Cardiac Organizations Support Performing Cardiac Procedures of Interest in ASCs

Diagnostic Cardiac Catheterization Procedures in an ASC

2012 ACCF/SCAI Expert Consensus Document

In 2012, the ACCF (American College of Cardiology Foundation) and SCAI published an update to their 2001 expert consensus document on cath lab standards.[17] The update provided the ACCF and documented cosponsors' opinions on cath lab standards, since the clinical practice and technology of cardiac catherization had evolved over the past decade.

The 2012 ACCF/SCAI document acknowledged that, as safety risks in both diagnostic and interventional procedures decrease, more patients are expanding into outpatient settings. Given this transition, the document focused on providing quality assurance standards, including the use of national databases to provide benchmarks. The authors also reviewed several suggested standards, including laboratory environments for cardiac catheterization at a facility without cardiovascular surgery, quality assurance issues, procedural issues, post-procedural issues, personnel issues, hybrid laboratories, ethical concerns, x-ray imaging and radiation safety, and concerns regarding pediatric catheterization patients.

With information showing "remarkably low risk now associated with diagnostic cardiac catheterizations," the 2012 document states:

[17] T.M. Bashore, S. Balter, A. Barac, et al., "2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update: A Report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents," *Journal of the American College of Cardiology* 59, no. 24 (June 2012): 2221–2305, https://doi.org/10.1016/j.jacc.2012.02.010.

> *The 2001 ACCF/SCAI consensus document suggests limiting diagnostic procedures in laboratories without cardiovascular surgical backup to the very lowest-risk patients; the current document lifts almost all these restrictions.* ***Limitations related to age, congestive heart failure (CHF) status, the severity in stress test abnormalities, left ventricular (LV) function, and the presence of valve disease have all been removed.***[18]

The consensus document did not change its recommendation that patients with pulmonary edema due to ischemia, patients with complex congenital heart disease, and pediatric patients be treated only in full-service facilities with cardiovascular surgery.[19] Nor did it suggest therapeutic procedures be performed in facilities without cardiovascular surgical backup.

Due to the growing complexity and sophistication of modern cath labs, the committee stressed the importance of an active quality assurance system and strongly encouraged participation in national registries, such as ACC's National Cardiovascular Data Registry (NCDR). Cath labs should track and collect patient outcomes, along with other outcome-related indicators, including structural, patient care, system-specific, guideline-driven, and cost-related items. These elements must have a foundation in "serious commitment from the facility administration to ensure that a robust QA/QI program is in place and the program committee is active and aggressive regarding its responsibilities."[20]

CMS's 2019 Authorization for Cardiac Catheterization Codes to be Paid in an ASC

Beginning January 1, 2019, CMS expanded the ASC payment system's definition of "surgery" to include "surgery-like" cardiac catheterization procedures with CPT codes outside of the surgical range.[21] This decision was made in response to comments submitted by

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[18] Bashore et al., "2012 Consensus Update," 2225. Emphasis added.
[19] The consensus document defined "full-service" as hospitals with cardiovascular surgery, cardiovascular anesthesia, and consulting services in vascular, nephrology, neurology, and hematology. (Bashore et al., "2012 Consensus Update," 2224).
[20] Bashore et al., "2012 Consensus Update," 2226.
[21] Since implementation of the ASC prospective payment system, CMS has defined a "surgical" procedure as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as "surgery" (CPT codes 10000–69999) (72 Fed. Reg. 42478). Also included are "surgical" procedures described by Level II HCPCS codes or Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that do not pose a significant safety risk, would not expect to require an overnight stay when performed in an ASC, and are separately paid under the OPPS (72 Fed. Reg. 42478).

stakeholders in the 2018 Medicare hospital outpatient prospective payment system (OPPS)/ASC final rule comment period. Stakeholders noted that certain cardiovascular procedures outside of CPT surgical range are similar to procedures within it. CMS also acknowledged the American Medical Association's (AMA) explicit statement that listing a procedure in a specific section of its CPT code manual should not be interpreted as a strict classification.[22] Acknowledging that the CPT surgical range is more appropriately used as a guide, rather than a strict determinant, allowed CMS more flexibility to include more "surgery-like" procedures in the ASC Covered Procedures List (CPL).

For 2019, CMS proposed adding twelve cardiac catheterization procedures to the ASC CPL. The procedures were described by CMS as:

> *Category I CPT codes that are not in the surgical range but directly crosswalk or are clinically similar to procedures in the Category I CPT code surgical range that we have determined do not pose a significant safety risk, would not be expected to require an overnight stay when performed in an ASC, and are separately paid under the OPPS.*[23]

CMS developed this proposal after reviewing HCPCS codes not currently on the ASC CPL but which would be appropriate for an ASC setting due to changes in technology or medical practice. CMS reviewed clinical characteristics of these procedures and consulted with stakeholders and clinical advisors to ensure procedures could be conducted safely in an ASC. CMS determined:

> *After reviewing the clinical characteristics of these procedures and consulting with stakeholders and our clinical advisors, we determined that these 12 procedures are separately paid under the OPPS, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure.*[24]

CMS requested stakeholders submit any specific safety concerns and comment on the safety of the twelve proposed cardiac catheterization procedures. Most commenters agreed that

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[22] 83 Fed. Reg. 59029 (Nov. 21, 2018).
[23] 83 Fed. Reg. 59044–59045 (Nov. 21, 2018).
[24] 83 Fed. Reg. 59045 (Nov. 21, 2018).

beneficiary safety was not at risk, and addition of the twelve cardiac catheterization procedures would achieve savings by moving procedures out of the more expensive hospital outpatient setting. The ACC agreed with CMS's clinical assessment of safety in an ASC.[25] A few commentors thought some of the procedures could not be performed safely in an ASC. One commentor suggested CMS require an ASC to meet facility standards that mirror rigorous, hospital-based cardiac catheterization standards before allowing the twelve procedures to be covered. Other commentors expressed concerns that the additional procedures would cause "cherry picking," which would mean hospital outpatient departments had sicker and higher-cost patients. CMS disagreed with the comments on increased risk to beneficiary safety, stating:

> *[M]any of these procedures are already performed safely in the physician's office setting. The procedures have been reviewed by CMS medical officers and we have assessed each against the regulatory safety criteria and believe that they meet all of those criteria. Further, we believe these procedures are clinically similar to peripheral endovascular procedures which are already currently included on the ASC CPL.*[26]

After reviewing the clinical characteristics of the procedures, CMS determined they were similar to other procedures on the ASC CPL, and could therefore be safely performed in an ASC. CMS also noted that existing conditions of coverage for ASCs (e.g., regulation 42 C.F.R. §416.166(c)) protect patients by prohibiting ASC payment for procedures that generally result in substantial blood loss or major or prolonged invasion of body cavities, or directly involve major blood vessels.[27] Regarding "cherry picking," CMS acknowledged it would be possible but did not believe procedures should be prohibited on that basis.

During the public comment period, commentors proposed adding cardiovascular procedures in the ASC CPL. CMS agreed to include five additional cardiac catheterization procedures, and stated:

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[25] C. Michael Valentine to Seema Verma, 24 September 2018, p. 9, https://www.acc.org/-/media/Non-Clinical/Files-PDFs-Excel-MS-Word-etc/Latest-in-Cardiology/Advocacy-and-Policy/ACC_OPPS_Comments_Letterhead-9_24_18.pdf?la=en&hash=EAC2E950D960B5618C2166B325240EF5FF9D26F7.
[26] 83 Fed. Reg. 59045 (Nov. 21, 2018).
[27] 83 Fed. Reg. 59045 (Nov. 21, 2018).

> *We believe these procedures would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure, and are separately paid under the OPPS.*[28]

In 2019, CMS added seventeen cardiac catheterization procedures to the ASC CPL. Eleven are in the set of cardiac procedures of interest discussed in this paper. Table 2 in Attachment 1 shows the cardiac procedures of interest CMS added in 2019.

Therapeutic Cardiac Catheterization Procedures in an ASC

Therapeutic cardiac catherization procedures are often referred to as percutaneous coronary interventions (PCI). PCI, also known as coronary angioplasty, was first performed in 1977. Between 1977 and 2020, when CMS began paying for PCI in an ASC setting, the expert consensus on where and how PCI procedures could be safely performed evolved. The technology involved in the procedures has also improved significantly. This section of the paper discusses the expert consensus documents on PCI published in the last 13 years, leading to CMS's inclusion of these procedures for payment in an ASC.

2007 SCAI Expert Consensus Document

In 2007, SCAI published an expert opinion document on the status and future of PCI in facilities without on-site surgical backup. The document summarized the available data on the performance of PCI without on-site cardiac surgery in the United States, reviewed the existing literature, and examined recommendations for the performance of PCI in this setting from programs in the United States and abroad. From this, SCAI defined the best practices for facilities performing PCI without on-site cardiac surgery and made recommendations. Their recommendations focused on patient safety to ensure acceptable risks and outcomes when performing PCI without on-site cardiac surgery. The authors specifically state:

[28] 83 Fed. Reg. 59046 (Nov. 21, 2018).

> *This is not an open endorsement of PCI without on-site surgery and we do not support wide-spread use of PCI without on-site surgery especially in the United States, but acknowledge that this practice may be appropriate in some circumstances.*[29]

The 2007 consensus document also recommended that any decision to provide PCI in a setting without on-site cardiac surgery should be based on health needs of the local area and not financial factors. The document highlighted the importance of using a country's benchmarks for program performance to evaluate the outcomes of its PCI programs. It recommended PCI providers without on-site surgery perform at least 100 procedures a year, while initial operators should not perform PCI in such a facility until they have performed at least 500 PCI procedures in their lifetime.[30] Quality assurance programs were recommended either through an independent facility or external agency. Finally, the authors stressed the importance of further data collection and analysis for future care.

2011 ACCF/AHA/SCAI Guideline for PCI

The ACCF and the American Heart Association (AHA) created a Task Force on Practice Guidelines to develop, update, and revise practice guidelines for cardiovascular disease and procedures. To develop balanced, patient-centric recommendations for clinical practice, the committee reviews and evaluates previous guidelines to keep pace with advances and innovations in interventional cardiology. In 2011, the committee updated its PCI recommendations. Recognizing that primary and elective PCI can be performed with high success, a low mortality rate, and a low rate for emergency surgery at hospitals without on-site cardiac surgical backup, they recommended considering elective PCI in these settings. Primary PCI would be "reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished."[31] They stressed the importance of accurately assessing

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[29] G.J. Dehmer, J.C. Blankenship, T.P. Wharton Jr., et al., "The Current Status and Future Direction of Percutaneous Coronary Intervention without On-site Surgical Backup: An Expert Consensus Document from the Society for Cardiovascular Angiography and Interventions," *Catheterization and Cardiovascular Interventions* 69, no. 4 (Mar. 2007): 476, https://doi.org/10.1002/ccd.21097.

[30] Dehmer et al., "Current Status," 477.

[31] G.N. Levine, E.R. Bates, J.C. Blankenship, et al., "2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions," *Journal of the American College of Cardiology* 58, no. 24 (Dec. 2011): e65, https://doi.org/10.1016/j.jacc.2011.08.007.

complication rates and patient outcomes in all PCI programs, and urged that a PCI program without on-site cardiac surgery should be considered only "if this program will clearly fill a void in the healthcare needs of the community," not for financial or market gain.[32]

2012 ACCF/SCAI Expert Consensus Document

The portions of the 2012 ACCF/SCAI expert consensus document pertaining primarily to diagnostic and interventional cardiac catheterization procedures other than PCI are discussed earlier in this paper. This section focuses on ACCF/SCAI recommendations and analysis pertaining to PCI. Regarding PCI, the committee opined elective and primary PCI are permissible in a facility without cardiovascular surgery if the facility strictly adheres to national guidelines. The committee highlighted the importance of a working relationship with a larger cardiovascular surgical services facility and an emergency transportation system. In addition to adhering to national volume guidelines, a facility offering therapeutic cardiac catheterization (such as PCI) should maintain a strong, active quality assurance/quality improvement (QA/QI) program, and remain operational 24 hours a day, 7 days a week, if an ST-elevation myocardial infarction (STEMI) program is in place. Ensuring minimum caseload volumes and training for interventional procedures are also important. Evolving guidelines for elective and primary PCI in a facility without cardiovascular surgical backup suggest these procedures can be done safely.

The 2012 ACCF/SCAI consensus document stressed the importance of comprehensive systems for urgent transfer of patients to a facility with cardiovascular surgical support, documentation that all medication and indication guidelines are being observed, and 24/7 accessibility.[33] It also discussed the importance of standards in patient preparation, procedural issues, technical hemodynamic issues, vascular hemostasis, and medication use. Physicians should receive consent to the place of service from patients, and clearly present all risks, benefits, alternatives, and the potential need for ad hoc procedures. Specific to PCI, the document discussed how consent forms should call attention to potential for emergency surgery. It also

[32] Levine et al., "ACCF/AHA/SCAI Guideline," e44–e122.
[33] Bashore et al., "2012 Consensus Update," 2227.

discussed standards for vascular hemostasis in post-procedural issues, including use of NCDR database bleeding risk score for PCI, which can help identify high-risk patients.

2014 SCAI/ACC/AHA Expert Consensus Document

In response to the growing body of research comparing PCI outcomes at facilities with and without on-site cardiac surgery, SCAI, ACC, and the AHA writing committee prepared an update to SCAI's 2007 expert consensus document. With fewer safety concerns regarding PCI without on-site surgery, they explored the delivery of PCI in this setting. The goals of this document were to:[34]

- Determine current trends in the prevalence of PCI without on-site surgery in the US;
- Summarize new literature related to the performance of PCI without on-site surgery;
- Review existing guidelines, expert consensus documents, competency statements, and other documents related to PCI without on-site surgery, and summarize all relevant information into one resource document;
- Outline the current best practice methods and requirements for facilities engaged in performing PCI without on-site surgery; and
- Evaluate the role of PCI without on-site surgery within the US health care system.

Trends in PCI at the time of the article showed an overall reduction in the number of procedures from 2006 to 2014. PCI at facilities without on-site surgery increased since 2007, however. The writing committee analyzed literature on primary PCI and found no difference for in-hospital or 30-day mortality between sites with and without on-site cardiac surgery.[35] For conditions other than STEMI, authors found that recent studies of PCI without on-site surgery showed "no indication of increased mortality or a greater need for emergency CABG for either primary or nonprimary PCI at sites without on-site cardiac surgery."[36]

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[34] G.J. Dehmer, J.C. Blankenship, M. Cilingiroglu, et al., "SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention without On-site Surgical Backup," *Journal of the American College of Cardiology* 63, no. 23 (June 2014): 2624–2641, https://doi.org/10.1016/j.jacc.2014.03.002.
[35] Dehmer et al., "2014 Update," 2625.
[36] Dehmer et al., "2014 Update," 2627.

The 2014 expert consensus document combined various recommendations from earlier publications to develop a unified recommendation that included requirements for facilities, personnel, and off-site surgical backup. The writing committee recommended facility requirements similar to those presented in other documents, with an increased emphasis on quality review programs. They adopted and expanded on the 2013 PCI Competency Document, to ensure the quality of facilities. They also recommended improving transportation, and defining what "satisfactory outcomes" a laboratory must maintain to avoid closure, since no national definition for "satisfactory outcome" existed.[37] The writing committee supported implementation of the SCAI Quality Toolkit and Accreditation for Cardiovascular Excellence (ACE) certification to improve quality.

Regarding personnel, the writing committee adopted guidelines based on quality metrics for facilities and operators. They made recommendations for training staff, and described training hour and experience requirements for PCI programs without on-site surgery. The committee also created a new recommendation, that existing physicians should train new interventional cardiologists joining established PCI programs until they are determined to have acceptable skills, judgment, and outcomes.

In making their recommendations, the committee recognized that performing PCI without on-site surgery limits interaction between cardiologists and cardiac surgeons and makes heart team consultation more difficult. They acknowledged, however, that alternatives such as telemedicine can adequately replace in-person interactions. In outlining recommendations from previous publications, they also discussed the importance of identifying PCI patients at higher risk for mortality or emergency CABG.

The writing committee concluded the growth in PCI procedures without on-site cardiac surgery warrants evaluation of programs based on their ability to: (a) sustain adequate quality metrics, (b) provide access to elective and emergency PCI procedures that would otherwise be

[37] Dehmer et al., "2014 Update," 2634.

unavailable in their service area, and (c) maintain the operator and institutional volumes recommended in the 2013 PCI Competency Document.[38] The document concludes:

> *This writing group reaffirms the statement from the 2011 ACCF/AHA/SCAI PCI Guidelines that "desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery," and suggests that new programs offering PCI without on-site surgery are inappropriate unless they clearly serve geographically isolated populations.*[39]

CMS's 2020 Addition of PCI Procedures to the Approved List for ASCs

In 2019, CMS determined that certain PCI procedures, specifically the coronary CPT codes 92920 and 92928, "can be safely performed in the ASC setting, for certain Medicare patients," and that "expert consensus, clinical guidelines, and clinical studies establish that percutaneous coronary interventions can be safely performed in an ASC setting."[40] When CMS proposed paying for PCI in ASCs for appropriate patients, the ACC and SCAI wrote letters supporting the addition of PCI procedures. The ACC stated its agreement with "CMS's clinical assessment that these procedures can safely be performed in the ASC setting" and recommended ASCs follow guidance in the 2014 SCAI/ACC/AHA Expert Consensus Document to ensure quality of care. The ACC stated that "allowing these PCI procedures to be performed in an ASC is in line with CMS's goals to expand access to services and encourage the delivery of care in the lowest cost setting."[41] Similarly, SCAI states that

> *elective, non-emergent percutaneous coronary angioplasty and coronary stenting procedures have relatively low complication rates and are not expected to pose a significant risk to Medicare beneficiary safety and do not typically require inpatient level care following the procedure.*[42]

SCAI noted the importance of ensuring that PCI patients in ASC settings receive the same quality of care as their counterparts in a hospital outpatient setting. Its detailed

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[38] Dehmer et al. "2014 Update," 2636.
[39] Dehmer et al., "2014 Update," 2636.
[40] 84 Fed. Reg. 61387.
[41] Richard Kovacs to Seema Verma, 27 September 2019 (RE: CMS-1717-P).
[42] Ehtisham Mahmud to Seema Verma, 27 August 2019 (RE: CMS-1717-P).

recommendations for ensuring quality of care are discussed in the 2020 SCAI Position Statement. Medicare began paying for PCI procedures in an ASC setting on January 1, 2020.

2020 SCAI Position Statement

SCAI published a position statement on performing PCI in ambulatory surgical centers in May 2020. Written by a working group of SCAI members with "significant prior experience with PCI in an ASC," the paper was "intended to provide guidance for the development of an ASC-based PCI program."[43] The authors "reviewed relevant clinical guidelines and consensus papers" on PCI in an outpatient setting, and outcomes data from randomized trials supporting same-day discharge after PCI. They concluded:

> *In appropriately selected patients for outpatient PCI, clinical outcomes for same-day discharge or routine overnight observation are comparable without any difference in short-term or long-term adverse events.*[44]

The SCAI statement discussed standards, equipment, transfer protocols, patient selection characteristics, performance checklists, and ethical considerations to bolster both efficacy and safety. Intended as a "foundation of principles to promote safe performance of elective PCI in ambulatory surgery centers,"[45] the document and its guidelines focused on PCI procedures in ASCs. To provide the highest quality of care in the safest environment, ASC-based cath labs should adopt the guidelines, policies, and best practices in the position statement.

Patient Selection

Patient selection is a key element to ensure patient safety and good outcomes. SCAI's conceptual flow chart, reproduced on the next page, provides a model for patient selection in an ASC.

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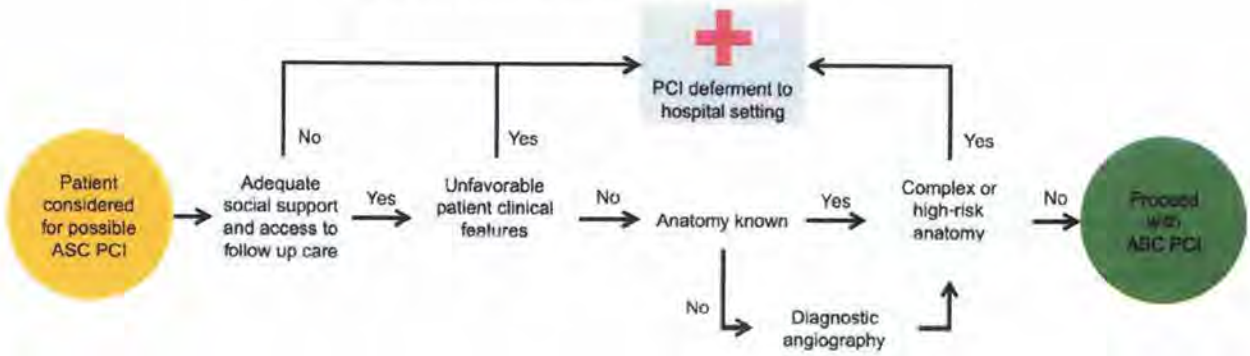
[43] L.C. Box, J.C. Blankenship, T.D. Henry, et al., "SCAI Position Statement on the Performance of Percutaneous Coronary Intervention in Ambulatory Surgical Centers," *Catheterization and Cardiovascular Interventions* 96, no. 4 (May 2020), https://doi.org/10.1002/ccd.28991.
[44] Box et al., "SCAI Position Statement," 2.
[45] Box et al., "SCAI Position Statement," 8.

SCAI Patient Selection Flow Chart



Source: Box et al., "SCAI Position Statement," 6.

SCAI states that "patients with high-risk clinical features" and those with "complex or high-risk lesions characteristics" should be treated in a hospital. SCAI suggests physicians follow the patient lesion characteristic guidelines in the table below when selecting patients for treatment at an ASC. Patients with unfavorable lesion characteristics should be treated in a hospital.

Clinical staff should make a detailed assessment of each patient before he or she is scheduled for a procedure. The prescheduling assessment should confirm the patient has appropriate clinical characteristics, adequate support at home, and transportation after the procedure. The patient assessment process includes a morning-of procedure assessment and a post-procedure assessment. The morning-of assessment should confirm transportation and social support, obtain informed consent, and confirm that the patient's clinical characteristics are still appropriate for PCI in the ASC. After the procedure, clinical staff should assess whether the PCI procedure was successful and assess site hemostasis. Any patient who needs treatment at a hospital, under SCAI's guidelines, should be referred or transported to a hospital.

SCAI Patient Conditions and Lesion Characteristics Warranting PCI Deferment to a Hospital

Unfavorable Patient Conditions
• Decompensated CHF (NYHA class 3–4) • Recent TIA/stroke (<8 weeks) • Left ventricular ejection fraction < 30% • Chronic kidney disease with an estimated glomerular filtration rate < 45 ml/min/1.73 m2 • Anemia (Hgb < 9 g/dl) or coagulopathy (e.g., INR >1.5 or platelet count < 100 K) • Acute coronary syndrome • Severe pulmonary hypertension or disease (advanced COPD or patients on supplemental oxygen) • Unprotected left main stenosis or three-vessel CAD • Any cardiac or noncardiac signs of clinical instability • Significant PAD limiting femoral and radial access • Severe aortic stenosis • Severe contrast allergy • Operator judgment on other condition(s)
Complex or High-Risk Lesion Characteristics
• Bifurcation lesions with significant side branch involvement • Severe lesion calcification • Extremely angulated segment or excessive proximal tortuosity • Bypass graft lesions • Chronic total occlusions • Other vessel characteristics that the operator judges would impede stent deployment • Thrombus in target vessel or lesion • Unprotected left main lesions • Last remaining conduit • Possible need for upfront mechanical circulatory support

Source: Box et al., "SCAI Position Statement," 6.

Standards and Quality Assurance

The SCAI position statement recommends adoption of the standards outlined in the 2012 ACC/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards. The ACC CCL v2 accreditation, discussed in the Accreditation section below, incorporates the

Consensus Document standards.[46] An ASC that attains CCL v2 accreditation meets the standards outlined in the 2012 Consensus Document.

The 2020 SCAI position statement calls for a distinct post-procedure recovery room with adequate equipment, including telemetry, blood pressure cuffs and pulse oximetry, and additional emergency equipment,[47] in a separate post-procedure room. SCAI recommends all direct patient care staff be ACLS certified and all nursing services be directed by a Registered Nurse, BSN. The table below, reproduced from the SCAI position statement, summarizes key features of a high-quality ASC-based PCI program.

Key Features of a High-Quality ASC PCI Program

Pre-procedural	Procedural	Post-procedural
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

Source: Box et al., "SCAI Position Statement," 7.

[46] American College of Cardiology, Cardiac Cath Lab Accreditation, available at https://cvquality.acc.org/accreditation/services/CCL.

[47] Box et al., "SCAI Position Statement," 4. Equipment includes pericardiocentesis tray, echocardiography/ultrasound, temporary transvenous pacemaker, covered stents, mechanical circulatory support, ACLS supplies, and an on-site provider with expertise in endotracheal intubation and airway management.

Accreditation

The SCAI position paper recommends that cath labs in ASCs meet the standards in the 2012 ACC/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards.[48] The ACC offers Cardiac Catheterization Laboratory v2 accreditation (CCL v2) incorporating the ACC and SCAI standards and other evidence-based quality initiatives.[49] Leading interventional cardiologists and cath lab administrators created CCL v2 accreditation[50] to improve care in cath labs in hospitals and ASCs. Attaining ACC CCLv2 accreditation ensures a cath lab meets the high standards of the ACC and SCAI.

Participation in the NCDR CathPCI Registry is a requirement for CCL v2 accreditation. The CathPCI Registry captures data on characteristics, treatments, and outcomes of patients who receive diagnostic cardiac catheterizations and PCI. The CathPCI Registry captures data that measure adherence to the ACC and AHA clinical practice guidelines, performance standards, and appropriate use criteria.[51] The CathPCI Registry analyzes reported data and gives providers the necessary metrics. The data collected is not static. For example, CathPCI developed a new COVID-19 data set "to provide key insights on the quality of care and outcomes of heart disease in the COVID-19 era."[52]

ACC accreditation has 6 essential components, each with mandatory requirements:

1. Governance
    - Designated Medical Director, with position description
    - Process to monitor and track physician credentials
    - Written charter
    - Annual staff education

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[48] Bashore et al., "2012 Consensus Update," 2305.
[49] American College of Cardiology, "Features and Benefits of Cardiac Cath Lab Accreditation," https://cvquality.acc.org/accreditation/services/CCL/CCLBenefits#:~:text=Features%20and%20Benefits%20of%20Cardiac,based%20science%20with%20quality%20initiatives.
[50] American College of Cardiology, "Features and Benefits."
[51] American College of Cardiology, National Cardiovascular Data Registry, "Hospital Registries," https://cvquality.acc.org/NCDR-Home/Registries/Hospital-Registries.
[52] American College of Cardiology, National Cardiovascular Data Registry, Hospital Registries, CathPCI Registry, https://cvquality.acc.org/NCDR-Home/registries/hospital-registries/cathpci-registry.

- Competencies for low-volume, high-risk procedures
- Formation of multi-disciplinary team and quarterly meetings
- Preliminary and final report requirements
- Requirements for sites without on-site cardiothoracic surgery

2. Quality
   - Quality Assurance and Process Improvement Plan (QAPI)
   - Requirements for new staff orientation
   - Process for inventory management and new products
   - Monitoring and tracking CathPCI Registry metrics
   - Infection control guidelines to reduce patient risk
   - Formal process to monitor and track radiation exposure for patients, staff, and physicians
   - Same-day discharge inclusion and exclusion criteria
   - Process to track annual volumes
3. Pre-Procedure
   - Pre-procedural requirements and checklist
   - Defined screening to identify patients at risk for bleeding
   - ID and address patients at risk for contrast-induced nephropathy or contrast reactions
   - Access site evaluation
   - Requirements for cardiovascular implantable electronic devices
4. Peri-Procedure
   - Procedural hemodynamic monitoring
   - Universal Time Out requirements
   - Guideline-driven medical therapy in the cardiac CCL
   - Protocol for peri-procedural complications and treatment modalities available
   - Process to ensure safe working equipment, availability of ventricular assist devices, and competencies

- Coagulation monitoring

5. Post-Procedure
   - Communication process with patient's family
   - Process outlining post-procedure report requirements
   - Protocol for sheath management and medication administration
   - Process that identifies appropriate recovery for the CLL patient
   - Process to ensure discharge instructions provided, with all patients receiving follow-up phone call within 24 hours
6. Clinical Quality
   - QAPI initiative that results in improvement in care and safety in at least 2 NCDR CathPCI Registry Measures

An accredited ASC will have quality of care that equals or exceeds that of a hospital cath lab. Only three hospitals in Alabama have ACC cath lab accreditation: Cullman Regional Medical Center, Riverview Regional Medical Center in Gadsden, and Grandview Medical Center in Birmingham.

Summary

CMS determined all the cardiac procedures of interest are safe and effective at an ASC. Performing cardiac procedures of interest at ASCs rather than hospitals reduces costs, risk of infection, and delays in treatment, and increases patient satisfaction. These procedures have been safely performed at ASCs in Florida, Texas, and many other states for several years. The Alabama CON Agency and the Board should approve applications for cath labs in ASCs with appropriate conditions on accreditation and patient selection.

Attachment 1

Table 1
Cardiac Procedures of Interest

Code	Description
33206	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial
33207	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular
33208	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular
33227	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; single lead system
33228	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; dual lead system
33231	Insertion of implantable defibrillator pulse generator only; with existing multiple leads
33241	Removal of implantable defibrillator pulse generator only
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system
33263	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system
33264	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; multiple lead system
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)
33235	Removal of transvenous pacemaker electrode(s); dual lead system
93451	Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed
93452	Left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed
93453	Combined right and left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed
93454	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation;
93455	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography
93456	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right heart catheterization

Table 1
Cardiac Procedures of Interest

Code	Description
93457	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography and right heart catheterization
93458	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography,
93459	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography
93460	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed
93461	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
37220	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal angioplasty
37222	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal angioplasty (list separately in addition to code for primary procedure)
37224	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty
37228	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty
37225	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed
37229	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed
37221	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed

Table 1
Cardiac Procedures of Interest

Code	Description
37223	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (list separately in addition to code for primary procedure)
37226	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37230	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37227	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed
37231	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed

Source: CPT Descriptions are from encoderpro.com, and are copyrighted by the AMA.

Table 2
Cardiac Codes CMS Pays at ASCs

Code	Code Type	Medicare Payable At ASCs Since
33206	Pacemaker or Pacing Cardioverter-Defibrillator	Before 2010
33207	Pacemaker or Pacing Cardioverter-Defibrillator	Before 2010
33208	Pacemaker or Pacing Cardioverter-Defibrillator	Before 2010
33227	Pacemaker or Pacing Cardioverter-Defibrillator	Before 2010
33228	Pacemaker or Pacing Cardioverter-Defibrillator	Before 2010
33231	Pacemaker or Pacing Cardioverter-Defibrillator	Before 2010
33241	Pacemaker or Pacing Cardioverter-Defibrillator	Before 2010
33249	Pacemaker or Pacing Cardioverter-Defibrillator	Before 2010
33270	Pacemaker or Pacing Cardioverter-Defibrillator	Before 2010
33262	Pacemaker or Pacing Cardioverter-Defibrillator	Before 2010
33263	Pacemaker or Pacing Cardioverter-Defibrillator	Before 2010
33264	Pacemaker or Pacing Cardioverter-Defibrillator	Before 2010
33224	Pacemaker or Pacing Cardioverter-Defibrillator	Before 2010
33235	Pacemaker or Pacing Cardioverter-Defibrillator	Before 2010
93451	Cardiac Catheterization	January 1, 2019
93452	Cardiac Catheterization	January 1, 2019
93453	Cardiac Catheterization	January 1, 2019
93454	Cardiac Catheterization	January 1, 2019
93455	Cardiac Catheterization	January 1, 2019
93456	Cardiac Catheterization	January 1, 2019
93457	Cardiac Catheterization	January 1, 2019
93458	Cardiac Catheterization	January 1, 2019
93459	Cardiac Catheterization	January 1, 2019
93460	Cardiac Catheterization	January 1, 2019
93461	Cardiac Catheterization	January 1, 2019
92920	Coronary Therapeutic Services and Procedures	January 1, 2020
92928	Coronary Therapeutic Services and Procedures	January 1, 2020
37220	Endovascular Revascularization Procedures	January 1, 2011
37222	Endovascular Revascularization Procedures	January 1, 2011
37224	Endovascular Revascularization Procedures	January 1, 2012
37228	Endovascular Revascularization Procedures	January 1, 2012
37225	Endovascular Revascularization Procedures	January 1, 2012
37229	Endovascular Revascularization Procedures	January 1, 2012
37221	Endovascular Revascularization Procedures	January 1, 2011
37223	Endovascular Revascularization Procedures	January 1, 2011
37226	Endovascular Revascularization Procedures	January 1, 2012
37230	Endovascular Revascularization Procedures	January 1, 2012
37227	Endovascular Revascularization Procedures	January 1, 2012
37231	Endovascular Revascularization Procedures	January 1, 2012

Source: 2010_ASC_Approved HCPCS Codes and Payment Rates, January 2019 Addenda and October 2018 Addenda, and October 2019 Addenda and CY 2020 Apr ASC BB, all available from ww.cms.gov.

Table 3a
Average Charges at ASCs and Outpatient Hospitals in the Same State for Most Common Codes

Code 33208: Insertion of new or replacement permanent pacemaker with transvenous electrodes, atrial and ventricular (CMS paid for 709 procedures at ASCs)

State	ASC Average Charge	Outpatient Hospital Average Charge	Ratio of ASC to OP Charge
AK	$9,339.40	$20,165.71	46.31%
AZ	$7,801.82	$24,566.92	31.76%
CA	$9,713.90	$26,597.14	36.52%
FL	$7,245.66	$26,625.51	27.21%
KS	$7,249.23	$18,418.35	39.36%
LA	$6,947.00	$20,485.58	33.91%
MO	$7,481.29	$16,734.61	44.71%
NV	$8,603.84	$37,869.13	22.72%
OH	$7,633.60	$15,832.11	48.22%
OK	$7,430.67	$21,091.32	35.23%
OR	$7,978.00	$18,250.16	43.71%
TN	$7,256.20	$23,567.40	30.79%
TX	$7,311.03	$21,324.06	34.29%
WI	$7,636.33	$15,555.56	49.09%

Source: 2018 CMS ASC LDS File, 2018 CMS Outpatient SAF file.

Table 3b
Average Charges at ASCs and Outpatient Hospitals in the Same State for Most Common Codes

Code 33228: Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator, dual lead system (CMS paid for 682 procedures at ASCs)

State	ASC Average Charge	Outpatient Hospital Average Charge	Ratio of ASC to OP Charge
AK	$9,177.72	$27,766.99	33.05%
AZ	$7,780.23	$19,226.68	40.47%
CA	$9,560.64	$25,521.54	37.46%
CO	$7,740.00	$22,800.26	33.95%
FL	$7,212.88	$24,045.88	30.00%
IL	$7,378.75	$20,674.28	35.69%
KS	$7,080.55	$14,646.34	48.34%
LA	$6,939.55	$22,586.18	30.72%
MO	$7,378.69	$15,422.62	47.84%
NE	$7,070.33	$13,342.44	52.99%
NJ	$8,798.39	$19,552.24	45.00%
NV	$8,460.78	$40,120.98	21.09%
NY	$8,798.50	$15,847.37	55.52%
OH	$7,270.15	$14,231.88	51.08%
OK	$6,505.67	$18,577.08	35.02%
OR	$7,941.25	$16,074.13	49.40%
PA	$7,309.00	$23,342.79	31.31%
SC	$7,087.50	$19,027.47	37.25%
TN	$6,697.67	$25,574.86	26.19%
TX	$7,116.73	$20,750.72	34.30%
WA	$8,344.00	$16,969.21	49.17%
WI	$7,574.80	$14,882.67	50.90%

Source: 2018 CMS ASC LDS File, 2018 CMS Outpatient SAF file.

Table 3c
Average Charges at ASCs and Outpatient Hospitals in the Same State for Most Common Codes

Code 33249: Insertion or replacement of permanent implantable defibrillator system, with transvenous leads, single or dual chamber (CMS paid for 412 procedures at ASCs).

State	ASC Average Charge	Outpatient Hospital Average Charge	Ratio of ASC to OP Charge
AK	$31,025.67	$64,042.82	48.45%
AZ	$27,062.95	$37,558.92	72.05%
CA	$35,670.66	$52,727.97	67.65%
FL	$24,059.21	$53,045.59	45.36%
KS	$24,629.09	$21,547.94	114.30%
LA	$24,161.16	$47,247.48	51.14%
MO	$25,666.08	$34,030.93	75.42%
NV	$29,430.16	$59,438.44	49.51%
OH	$26,228.50	$34,651.20	75.69%
OR	$27,622.67	$34,638.10	79.75%
TN	$23,297.50	$50,187.18	46.42%
TX	$24,816.88	$47,399.40	52.36%
WI	$26,348.55	$34,217.11	77.00%

Source: 2018 CMS ASC LDS File, 2018 CMS Outpatient SAF file.

Table 4

Medicare Payment for Select CPT Codes at Outpatient Hospitals and Hypothetical ASC in Montgomery County, AL

		ASC Payment			Baptist South Payment			Baptist East Payment		
CPT Code	Ambulatory Payment Classificaton	Coinsurance	Medicare Payment	Total Payment	Coinsurance	Medicare Payment	Total Payment	Coinsurance	Medicare Payment	Total Payment
93452	5191	$ 241.43	$ 965.74	$1,207.17	$ 761.30	$1,748.02	$2,509.32	$ 761.30	$1,748.02	$2,509.32
93453	5191	$ 241.43	$ 965.74	$1,207.17	$ 761.30	$1,748.02	$2,509.32	$ 761.30	$1,748.02	$2,509.32
93454	5191	$ 241.43	$ 965.74	$1,207.17	$ 761.30	$1,748.02	$2,509.32	$ 761.30	$1,748.02	$2,509.32
93455	5191	$ 241.43	$ 965.74	$1,207.17	$ 761.30	$1,748.02	$2,509.32	$ 761.30	$1,748.02	$2,509.32
93457	5191	$ 241.43	$ 965.74	$1,207.17	$ 761.30	$1,748.02	$2,509.32	$ 761.30	$1,748.02	$2,509.32
93458	5191	$ 241.43	$ 965.74	$1,207.17	$ 761.30	$1,748.02	$2,509.32	$ 761.30	$1,748.02	$2,509.32
93459	5191	$ 241.43	$ 965.74	$1,207.17	$ 761.30	$1,748.02	$2,509.32	$ 761.30	$1,748.02	$2,509.32
93460	5191	$ 241.43	$ 965.74	$1,207.17	$ 761.30	$1,748.02	$2,509.32	$ 761.30	$1,748.02	$2,509.32
93461	5191	$ 241.43	$ 965.74	$1,207.17	$ 761.30	$1,748.02	$2,509.32	$ 761.30	$1,748.02	$2,509.32
93451	5191	$ 241.43	$ 965.74	$1,207.17	$ 761.30	$1,748.02	$2,509.32	$ 761.30	$1,748.02	$2,509.32
93456	5191	$ 241.43	$ 965.74	$1,207.17	$ 761.30	$1,748.02	$2,509.32	$ 761.30	$1,748.02	$2,509.32
33241	5221	$ 264.87	$1,059.49	$1,324.36	$ 525.48	$2,101.88	$2,627.36	$ 525.48	$2,101.88	$2,627.36
37220	5192	$ 376.24	$1,504.96	$1,881.20	$ 872.37	$3,489.45	$4,361.82	$ 872.37	$3,489.45	$4,361.82

Table 4

Medicare Payment for Select CPT Codes at Outpatient Hospitals and Hypothetical ASC in Montgomery County, AL

		ASC Payment			Baptist South Payment			Baptist East Payment		
CPT Code	Ambulatory Payment Classificaton	Coinsurance	Medicare Payment	Total Payment	Coinsurance	Medicare Payment	Total Payment	Coinsurance	Medicare Payment	Total Payment
33207	Device Dependent Procedure									
33208	Device Dependent Procedure									
33235	Device Dependent Procedure									
33224	Device Dependent Procedure									
33206	Device Dependent Procedure									
33227	Device Dependent Procedure									
33228	Device Dependent Procedure									
33262	Device Dependent Procedure									
33263	Device Dependent Procedure									
33264	Device Dependent Procedure									
92920	Device Dependent Procedure									
92928	Device Dependent Procedure									
33231	Device Dependent Procedure									
33249	Device Dependent Procedure									
33270	Device Dependent Procedure									
37222	Packaged Service/Not Separately Payable									
37224	Device Dependent Procedure									
37228	Device Dependent Procedure									
37225	Device Dependent Procedure									
37229	Device Dependent Procedure									
37221	Device Dependent Procedure									
37223	Packaged Service/Not Separately Payable									
37226	Device Dependent Procedure									
37230	Device Dependent Procedure									
37227	Device Dependent Procedure									
37231	Device Dependent Procedure									

Source: EncoderPlus software by MicroDyn.

Table 5
Cardiac Procedures in ASCs in Texas by CPT Code

CPT Code	2018	2019
33206	5	5
33207	21	55
33208	265	586
33224		4
33227	23	32
33228	141	250
33235	6	11
33241	13	23
33249	208	376
33262	17	29
33263	57	76
33264	67	96
37220	6	21
37221	24	54
37222	2	2
37223	5	6
37224	13	35
37225	49	86
37226	12	29
37227	17	34
37228	32	39
37229	23	47
37230	6	8
37231		3
92920	4	7
92928	21	6
93451	13	37
93452	26	4
93453	2	1
93454	17	72
93455		14
93456	1	18
93457		2
93458	255	1621
93459	39	241
93460	82	382
93461	7	63
Total	**1,479**	**4,375**

Source: THCIC Outpatient PUDF, 2018 and 2019.

Table 6
ASCs in Texas with Cardiac Procedures of Interest

Ambulatory Surgical Center	Total Procedures of Interest Performed, 2019
Advanced Cardiovascular Surgery Center at Methodist West Housto	351
Amarillo Endoscopy Center	4
Baytown Heart & Vascular Surgery Center	128
Beaumont Heart & Vascular Surgery Center	575
Cardiology Center of Amarillo ASC	619
College Park Heart & Vascular Surgery Center	96
Day Surgery Center at Denton Regional Medical Center	15
Heart of Texas Surgery Center	80
J Graff Surgery Center	15
Medfinity Health Surgery Center - HEB	118
Medfinity Health Surgery Center Plano	375
Methodist Ambulatory Surgery Center Medical Center	14
Nacogdoches Surgery Center	16
North Houston Cardiovascular Surgery Center	101
North Park Heart & Vascular Surgery Center	72
Saint Raphaels Surgery Center	49
The Heart & Vascular Surgery Center	403
Total Vascular Care	3
Tyler Cardiac and Endovascular Surgery Center	482
Valley Ambulatory Surgical Center	2
Waco Cardiology Cath Lab & Surgery Center	847
Willow Creek Surgery Center	9
Memorial Hermann Surgery Center Conroe	1
Total	**4,375**

Source: THCIC Outpatient PUDF, 2019.

Table 7
Discharge Status of Patients Undergoing Cardiac Procedures of Interest at Texas ASCs

Discharge Status	Number of Discharges	% of Total Discharges
Discharge Home	4,256	97.28%
Discharged/Transferred to Inpatient Hospital	109	2.49%
Deceased	0	0.00%
Other	10	0.23%
Total	**4,375**	**100.00%**

Source: THCIC Outpatient PUDF, 2019.

Table 8
Cardiac Procedures in ASCs in Florida by CPT Code

CPT Code	2018	2019
33206		5
33207		28
33208	149	166
33227	23	28
33228	136	137
33235	1	2
33241	5	3
33249	43	35
33262	9	6
37220	83	105
37221	290	316
37222	18	18
37223	39	33
37224	213	236
37225	675	781
37226	253	292
37227	368	358
37228	254	288
37229	344	379
37230	35	69
37231	19	44
92920	9	23
92928	595	687
93451	45	65
93452	140	137
93453	41	63
93454	277	197
93455	18	11
93456	14	14
93457	1	1
93458	1,704	1,873
93459	208	213
93460	504	458
93461	112	90
Total	**6,625**	**7,161**

Source: AHCA Ambulatory and Emergency Department Patient Data Limited Data Set, 2018 and 2019.

Table 9
ASCs and Catheterization Laboratories in Florida with Cardiac Procedures of Interest

Facility	Total Procedures of Interest Performed, 2019
New Port Richey Surgery Center at Trinity	11
Gulf Coast Surgery Center	17
Emerald Coast Surgery Center	9
Surgery Center of Ocala	81
Total Surgery Center	75
St Lucie Surgery Center	7
Atlantic Cardiolink	422
Florida Cath Lab L.L.C.	900
First Coast Cardiovascular Institute PA	1,062
Cardiovascular Institute of Central Florida	843
Lake Cardiovascular Diagnostic Center	677
Clearwater Cardiovascular And Interventional Consultants	2,200
First Coast Cardiovascular Institute PA-2	105
First Coast Heart & Vascular-1	545
Bayview Surgery Center	29
Jupiter Outpatient Surgery Center, LLC	4
Gladiolus Surgery Center	5
Clermont Ambulatory Surgical Center LLP	2
Panama City Surgery Center	1
Bayonet Point Surgery & Endoscopy Center	1
Day Surgery Center	9
Sand Lake Surgery Center	1
Surgery Center Of Key West, LLC	6
Broward Specialty Surgical Center	2
Maitland Surgery Center	19
Endo-Surgical Center Of Florida, LLC	2
Titusville Center For Surgical Excellence	3
Marion Surgery Center	17
Surgery Center of Naples	64
Ft Lauderdale Heart & Rhythm Surgery Center	42
Total	**7,161**

Source: AHCA Ambulatory and Emergency Department Patient Data Limited Data Set, 2018 and 2019.

Attachment 2

Works Cited

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Dehmer, G.J., J.C. Blankenship, M. Cilingiroglu, J.G. Dwyer, D.N. Feldman, T.J. Gardner, C.L. Grines, and M. Singh. "SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention without On-site Surgical Backup." *Journal of the American College of Cardiology* 63, no. 23 (June 2014): 2624–2641. https://doi.org/10.1016/j.jacc.2014.03.002.

Dehmer, G.J., J.C. Blankenship, T.P. Wharton Jr., A. Seth, D.A. Morrison, C. DiMario, D. Muller, M. Kellett, and B.F. Uretsky. "The Current Status and Future Direction of Percutaneous Coronary Intervention without On-site Surgical Backup: An Expert Consensus Document from the Society for Cardiovascular Angiography and

Interventions." *Catheterization and Cardiovascular Interventions* 69, no. 4 (Mar. 2007): 471–478. https://doi.org/10.1002/ccd.21097.

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Valentine, C. Michael. Letter to Seema Verma. 24 September 2018. https://www.acc.org/-/media/Non-Clinical/Files-PDFs-Excel-MS-Word-etc/Latest-in-Cardiology/Advocacy-and-Policy/ACC_OPPS_Comments_Letterhead-9_24_18.pdf?la=en&hash=EAC2E950D960B5618C2166B325240EF5FF9D26F7.

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Attachment 3

Ronald T. Luke, J.D., Ph.D.

EDUCATION

Harvard University, Kennedy School of Government
Doctor of Philosophy in Public Policy, 1975

The University of Texas at Austin, School of Law
Doctor of Jurisprudence, 1974

Harvard University, Kennedy School of Government
Master of Public Policy, 1972
National Science Foundation Fellow in Economics
1970 - 1972

Harvard University
Bachelor of Arts in Social Studies, Magna cum Laude, 1970
Phi Beta Kappa, 1970

PROFESSIONAL EXPERIENCE

RESEARCH & PLANNING CONSULTANTS, L.P. (RPC), Austin, Texas
President (1979 - Present); Vice President of Operations (1976 - 1979)

Dr. Luke has developed RPC as an inter-disciplinary firm providing economic, financial, and public policy studies. As President and owner, he supervises RPC's professional staff and maintains high standards for the firm's work products.

He has been accepted as an expert in economics, socioeconomic impact analysis, and policy analysis by state and federal courts, and state administrative agencies. The types of cases in which he has provided expert testimony include personal injury, contractual disputes, health care payment disputes, construction defects, utility construction permitting, and certificate of need. He has testified on health care matters including market structure, billing fraud and abuse, reasonableness of charges, medical staff credentialing, workers' compensation fee guidelines, utilization review, physician contracts, and managed care contracts.

He was an original member, and later chairman, of the Texas Department of Insurance's Utilization Review Advisory Committee. Governor George W. Bush appointed him as an original member of the Texas Health Care Information Council, where he had a major role in the development of the Texas hospital discharge data system. Governor Rick Perry appointed him to the Texas Health and Human Services Council, which oversees the Medicaid and CHIP programs. He has served as an advisor to committees of the Texas Legislature on health insurance mandates and major revisions to the Workers' Compensation Act. Governor Perry appointed him to the Board of the Texas Institute for Health Care Quality and Efficiency. He is also a Director of the Texas Association of Business where he chairs TAB's Health Policy Committee.

FORTE, INC., Austin, Texas President
(1986 - 2005)

Dr. Luke has almost two decades of experience in medical bill review and utilization review. In 1986, he established Forté to provide health cost management services, with special attention to workers' compensation medical care. In June 2005, Forté was sold to a national insurance broker. Forté provides medical bill review and utilization review services nationwide and case management services in Texas. Forté's clients are insurers and self-insured employers.

GULF COAST REGIONAL MENTAL HEALTH MENTAL RETARDATION CENTER,
Galveston, Texas
Director of Administrative Services (1974 - 1976)

While preparing his dissertation, Dr. Luke was a consultant to the Gulf Coast Regional Mental Health and Mental Retardation Center on the development of alternatives to state institutions. After completing his degrees, he became Director of Administrative Services for the Center with responsibility for planning, financial management, and management information systems.

PAST AND CURRENT AFFILIATIONS

- Texas Institute for Health Care Quality and Efficiency, Board of Directors,
- State Bar of Texas
- American Bar Association
- National Health Lawyers Association
- National Association of Forensic Economists
- Medical Group Management Association
- Texas Health Care Information Council, Member and Committee Chair
- Austin-Travis County Mental Health Mental Retardation Center, Board of Directors
- Samaritan Counseling Center, Board of Directors
- Easter Seals Central Texas, Officer and Director
- Texas Department of Insurance, Utilization Review Advisory Committee, Member and Chair
- Texas Business Group on Health, Board of Directors
- Texas Association of Business, Board of Directors, Chair Health Policy Committee
- Texas Health and Human Services Council, Member
- Texas Health and Human Services Commission, Integrated Care Management Advisory Committee, Vice Chair
- Texas Health Care Services Integrity Partnership, Chair
- American Bar Foundation, Life Fellow
- The College of the State Bar of Texas, Member
- Capitol Area Council, BSA, Board of Directors
- Harvard Club of Austin, Officer and Director

TEACHING IN HIGHER EDUCATION

Dr. Luke taught courses on public finance and policy analysis utilizing health care case studies at University of Texas at Austin Business School (1978) and University of Houston at Clear Lake City (1975).

James E. Stidham, MBA, CASC

EDUCATION

Lamar University/Andersen University, Beaumont, Texas
Master of Business Administration, 1982

Lamar University, Beaumont, Texas
Bachelor of Business Administration, 1975

CERTIFICATIONS

Certified Administrator Surgery Center (CASC), 2002

PROFESSIONAL EXPERIENCE

HEALTHCARE MANAGEMENT ASSOCIATES, INC. April 1996 – present
President and consultant providing management guidance, strategic planning and direction to de novo and existing ambulatory surgery centers, and diagnostic imaging centers. Certificate of Need testimony and support.

OUTPATIENT SERVICES EAST 1984 – 2008
President and Chief Executive Officer – Responsible for all daily operations, budgets and interaction with Medical Staff and Board of Directors. Center began as a 2,000-case center and grew to 15,000 annual cases.

JEFFERSON COUNTY MEDICAL SOCIETY 1982 – 1984
Director of Foundation Trust – Established the first group purchasing program for physicians in the country. Developed, managed, and directed growth to membership in excess of 1,000 physicians. Assisted in excess of 150 physicians in the formation of their practices.

PROFESSIONAL MEMBERSHIPS

Statewide Healthcare Coordinating Council, Appointed by Governor Bob Riley February 2007
Reappointed February 2009 (3-year term)

Alabama Association of Ambulatory Surgery Centers, President two terms, 1986-1988, 1989-1991, Treasurer, 1991 to 2008
State Medicaid Advisory Board 1995-2000
Medical Group Management Association - State of Alabama
Recipient of "Top 40 under 40" award – 1993
Top Healthcare Executive---Jefferson County, Alabama—1998

PRESENTATIONS

Second Annual Emerging Surgical Techniques, Atlanta, Georgia. *Ancillary Income models. Role of Ambulatory Surgery Centers in Orthopedic practices.* April 16, 2005.

International Conference Health and Wellbeing in a Diverse Society, Perth, Australia. *The American Ambulatory Surgery Center, Past, Present and Future. The Expansion of Services to include Recovery Care - Financial and Operational Impact.* December 11, 1995

Second European Congress on Ambulatory Surgery, Brussels, Belgium. *Recovery Care Centers, The Impact of Extended Hours in an Ambulatory Surgery Setting.* March 18, 1993.

National convention of Federated Ambulatory Surgery Association Meeting, Washington, DC. *Diagnostic Centers and Ambulatory Surgery Centers, The Formation of State Ambulatory Surgery Associations, and Joint Ventures and Physicians.* May 2, 1988,

CURRICULUM VITAE

Ralph B. Redd, MD, FACS
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PRACTICE EXPERIENCE

Montgomery Vascular Surgery, P.C.	2003- Present

LICENSURE AND BOARD CERTIFICATION

Alabama
American Board of Surgery, General Surgery, 2003
American Board of Surgery, Vascular Surgery, 2005

EDUCATION

Undergraduate	Georgia Institute of Technology Atlanta, Georgia	1993
Medical	Emory University School of Medicine Atlanta, Georgia	1997
General Surgical Residency	Carolinas Medical Center Charlotte, North Carolina	1997-2002
Vascular Surgery Fellowship	St. Louis University St. Louis, Missouri	2002-2003

HONORS

Georgia Tech Dean's List
National Society of Black Engineers Academic Achievement Award
Omega Chi Epsilon Honor Society
Florida Power and Light Scholarship
Irene Woodruff Scholarship
Joseph B. Whitehead Surgical Scholarship
Hamilton Holmes Scholarship

HOSPITAL PRIVILEGES

Baptist South, Montgomery, Alabama	2003-Present
Baptist East, Montgomery, Alabama	2003-Present

FACULTY

Assistant Professor, UAB College of Medicine, Montgomery campus, May 2018-current

ACADEMIC APPOINTMENTS

Research Assistant High frequency modules Dept. of Chemical Engineering Georgia Institute of Technology	1992-1993
Research Assistant Dept. of Neurology Emory University School of Medicine	1994-1995

EXTRACURRICULAR ACTIVITIES

American Red Cross (Volunteer)
March of Dimes Association (Volunteer)
Big Brother Program of Renfroe
Elementary (Decatur, Georgia)

COMMITTEES

Morbidity & Mortality Committee	2010-2011
Medical Executive Committee	2010-2011 and 2014-2015
Vice Chair of Surgery	2010-2011
OR Advisory Committee	2009-Present
Quality Assurance/Quality Improvement	2010-2011
Infection Control Committee	2008-2011
Blood Utilization Committee	2006-2008
Carotid Stent Ad Hoc Committee	2006-present

HOSPITAL EXPERIENCE

Summer Intern, Dept. of Anesthesiology Emory University School of Medicine	1994
Summer Intern, Dept. of Neurology Emory University School of Medicine	1994-1995

OCCUPATIONAL EXPERIENCE

Co-op Chemical Engineer
Amoco Chemical Company
Mt. Pleasant, SC
Intern Chemical Engineer
Air Products Corporation
Allentown, PA
Intern Chemical Engineer
Kimberly Clark Corporation
Atlanta, GA

PROFESSIONAL ASSOCIATIONS

Fellowship American College of Surgeons (FACS)
American College of Surgeons Candidate Group
American Medical Association
National Medical Association
National Society of Black Engineers

MILITARY EXPERIENCE

Captain, US Army Reserve
NAAD Detachment

RESEARCH AND PUBLICATIONS

1. Redd R, Greene F. Isolated Limb Perfusion: Is it a Useful Technique or a Futile Last Gasp? Current Surgery 2000; 57/3:209-214.

2. Redd R, Auchus A. Effects of Hypertension on Alzheimer's Disease in African Americans. Abstract and poster presentation given at the 1995 American Academy of Neurology Annual Convention, Seattle, WA.

INVITED LECTURES

1. Peripheral Artery Aneurysms. Vascular Grand Rounds, Carolinas Medical Center, April 2002.

2. Current Management of Acute Diverticulitis. Gastrointestinal Grand Rounds, Carolinas Medical Center, December 2001.

3. Bile and Gallstone Formation. Carolinas Medical Center, March 2000.

4. Management of Enterocutaneous Fistulas. Gastrointestinal Grand Rounds, Carolinas Medical Center, January 2000.

5. Diagnosis and Management of MEN Syndromes. Endocrine Grand Rounds, Carolinas Medical Center, November 1999.

6. Enteral and Parenteral Nutrition. Carolinas Medical Center, August 1999.

7. Thyroid Physiology. Carolinas Medical Center, October 1999.

CURRICULUM VITAE

PERSONAL DATA

Name:	Thomas J. Wool, M.D., F.A.C.C
Date of Birth:	March 3, 1950
Place of Birth:	Temple, Texas

BUSINESS ADDRESS

Southeastern Cardiology Consultants P.C.
2055 East South Blvd.
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Montgomery, AL 36116
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EDUCATION

High School:

The Montgomery Academy, 1968
Montgomery, Alabama

College:

Dartmouth College, 1968–1972
Hanover, New Hampshire
Honors in History

Medical School:

University of South Alabama, College of Medicine, 7/1972–6/1976
Mobile, Alabama

- M.D., Dean's Award
- Alpha Omega Alpha, Medical Honor Society
- Graduated first in class

Internship:	The University of Texas, Southwestern Medical School Dallas Texas Internship in Internal Medicine, 7/1976–6/1977
Residency:	The University of Texas, Southwestern Medical School Dallas, Texas Residency in Internal Medicine, 7/1977–6/1979
Fellowship:	University of Alabama at Birmingham Birmingham, Alabama Fellowship in Cardiovascular Disease, 7/1979–6/1981

CERTIFICATIONS

- National Board of Medical Examiners, 1977
- American Board of Internal Medicine, 1979
- American Board of Internal Medicine, Subspecialty of Cardiovascular Disease, 1981
- Fellow of the American College of Cardiology, March 1984
- North American Society of Pacing and Electro Physiology, Certification in Cardiac Pacing, 1986
- Institute for Clinical Examinations: Proficiency in the Interpretation of Electrocardiogram, 1999-2009
- Diplomat in Interventional Cardiology, American Board of Internal Medicine, 1999
- Recertification in Interventional Cardiology, 1/14/2010–12/31/2020

LICENSURES

Alabama: 7842, issued 6/30/1977 (current)

Texas: F0834, issued 1978

COMMITTEES

Baptist Medical Center South, Montgomery, Alabama

- Vice Chairman, 2000, Cardiology Subsection, Department of Medicine
- Quality Improvement Committee
- Chief, Internal Medicine
- Chairman, Cardiology Department, 2016–2019
- Medical Executive Committee
- Cardiac Council

Jackson Hospital, Montgomery, Alabama

- Chief of Staff, 7/1995–6/1996
- Board of Trustees, 1988, 1989, 1990, 1991, 1992
- Chairman, Department of Medicine, 1988, 1989, 1990
- Chairman of Cardiology, 1992–1993

Montgomery Regional Medical Center, Montgomery, Alabama

- Chairman, Patient Care Committee, 1985, 1986, 1987, 1988, 1989
- Medical Executive Committee, 1986, 1987, 1988, 1989, 1990, 1991, 1992
- Chairman, Intensive and Critical Care Committee, 1985, 1986, 1987, 1988, 1989
- Chairman, Special Care Units Committee, 1990, 1991, 1992, 1993
- Chairman of Cardiology Section, Medicine Department, 1987–1988, 1989–1990, 1991–1992, 1993, 2016–2019
- Emergency Department Committee, 1991, 1992, 1993

RESEARCH

Sub-investigator for "Pravastatin of Atorvastatin Evaluation and Infection Therapy (PROVE IT-TIMI 22)."

Sub-investigator for the study "A Double-Blind, Randomized, Placebo-Controlled Trial Evaluating the Safety and Efficacy of Eplerenone in Patients with Heart Failure Following Acute Myocardial Infarction (EPHESUS)."

Sub-investigator for the study "The Effect of LDL-Cholesterol Lowering Beyond Currently Recommended Targets in Patients with Pre-Existing CHD (TNT)."

Sub-investigator for the study "Prevention of Events with Angiotensin Converting Enzyme Inhibition (PEACE)."

Sub-investigator for the study "A Phase III International Randomized, Double-Blind, Placebo-Controlled Trial Evaluation the Safety and Efficacy of Orbofiban in Patients with Unstable Coronary Syndromes (OPUS-TIMI 16)."

Sub-investigator for multiple Medtronic lead studies

Sapphire Trial

SEATTLE II Trial

ORBIT II Trial

QUAD PAS

AdaptResponse

EXHIBIT H

EXHIBIT H

Proposed Language of

Requested State Health Plan Amendment[1]

410-2-3-.03. Cardiac Services

(1) Hospital and Ambulatory Surgery Center Fixed-Based Cardiac Catheterization Laboratories

(a) Discussion

1. During the past four decades, an evolution in cardiac catheterization has taken place. The role of the cardiac catheterization laboratory has progressed from study of cardiac function and anatomy for purposes of diagnosis to evaluation of candidates for surgery and finally, to providing catheter-based, nonsurgical interventional treatment. This progress has stimulated an increase in demand for cardiac catheterization services.

2. From about 1982 to the present, there has been an unprecedented proliferation of cardiac catheterization services, which have now been expanded to a wider group of patients and diseases. The increase in patients and laboratories has been stimulated by the development of nonsurgical catheterization laboratory-based therapeutic procedures for palliation of both stable and unstable ischemic heart disease as well as selected valvular and congenital heart diseases, arrhythmias, and other problems. Many noncardiac diagnostic and therapeutic vascular procedures are now being performed in cardiac catheterization laboratory settings, but this area is still evolving. As newer cardiac diagnostic and treatment modalities are developed, it is highly likely that the role of cardiac catheterization will continue to evolve. Certain cardiac catheterization procedures are now offered in physicians' offices outside of the usual hospital environment. Groups such as the American College of Cardiology Foundation and the Society for Cardiovascular Angiography and Interventions have now found it acceptable for cardiac catheterization procedures, including Percutaneous Coronary Interventions (PCI), to be performed on a same-day discharge basis within an Ambulatory Surgery Center (ASC) setting.

3. Fixed-based cardiac catheterization services located in Medicare certified hospitals and ambulatory surgery centers are the only acceptable method for providing cardiac catheterization services to the people in Alabama.

4. For purposes of this section, a cardiac catheterization "procedure equivalent" is defined as a unit of measure which reflects the relative average length of time one patient spends in one session in a cardiac catheterization laboratory. One procedure equivalent equals 1.5 hours utilization time.

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[1] The proposed amendment addresses only Section 410-2-3-.03(1). As a result, any language from Section 410-2-3-.03(2) is not included herein, but should be carried forward as previously adopted.

(b) Planning Policies

1. Planning Policy.

Diagnostic catheterizations shall be weighed as 1.0 equivalents, while therapeutic/interventional catheterizations (Percutaneous Transluminal Coronary Angioplasty (PTCA), directional coronary atherectomy, rotational coronary atherectomy, intracoronary stent deployment, and intracoronary fibrinolysis, cardiac valvuloplasty, and similarly complex therapeutic procedures) and pediatric catheterizations shall be weighed as 2.0 equivalents. Electrophysiology shall be weighed as 3.0 equivalents for diagnostic and 4.0 equivalents for therapeutic procedures. For multi-purpose rooms, each special procedure performed in such rooms which is not a cardiac catheterization procedure shall be weighed as one equivalent.

2. Planning Policy - New Institutional Service.

New "fixed-based" cardiac catheterization services shall be approved only if the following conditions are met:

(a) Each facility in the county has performed at least 1,000 equivalent procedures per unit for the most recent year;

(b) An applicant for diagnostic/therapeutic cardiac catheterization must project that the proposed service shall perform a minimum of 875 equivalent procedures (60% of capacity) annually within three years of initiation of services;

(c) An applicant for diagnostic catheterization only must project that the proposed service shall perform a minimum of 750 procedures per room per year within three years of initiation of services; and

(d) At least two physicians, licensed in Alabama, with training and experience in cardiac catheterization shall provide coverage at the proposed facility.

3. Planning Policy - Expansion of Existing Service.

Expansion of an existing cardiac catheterization service shall only be approved if:

(a) If an applicant has performed 1,000 equivalent procedures per unit (80% of capacity) for each of the past two years, the facility may apply for expansion of catheterization services regardless of the utilization of other facilities in the county;

(b) Adult and pediatric procedures may be separated for those institutions with a dedicated pediatric catheterization lab in operation.

4. Planning Policy.

Pediatric cardiac catheterization laboratories shall only be located in institutions with comprehensive pediatric services, pediatric cardiac surgery services, and a tertiary pediatric intensive care unit.

5. Planning Policy.

All hospitals and ambulatory surgery centers providing cardiac catheterization services without open-heart surgical capability ("OSS") shall have written transfer agreements with an existing open-heart program located within 45 minutes by air or ground ambulance service door to door from the referring facility. Acute care hospitals providing diagnostic cardiac catheterization services may provide emergency interventional/therapeutic cardiac catheterization procedures. Notwithstanding anything in the State Health Plan to the contrary, an acute care hospital or ambulatory surgery center without on-site open-heart surgery capability may provide elective percutaneous coronary intervention (PCI) if the following criteria are met:

(a) The hospital shall maintain twenty-four (24) hour, seven (7) day a week continuous coverage by at least one interventional cardiologist and catheterization laboratory team for primary PCI treatment of ST elevation myocardial infarction; the ambulatory surgery center shall have such coverage at any time a patient is on the premises;

(b) The hospital or ambulatory surgery center shall participate in a recognized national registry for cardiac catheterizations and PCI procedures, such as the National Cardiovascular Data Registry (NCDR);

(c) The hospital or ambulatory surgery center shall obtain informed patient consent for all elective PCI procedures, including an informed consent process in which it is clearly stated that the ~~hospital~~ facility does not offer OSS, and which clearly states that the patient may request at any time to be transferred to a hospital with OSS to undergo the PCI procedure;

(d) The hospital or ambulatory surgery center shall conduct quarterly quality review of the elective PCI services under supervision of its serving interventional cardiologists;

(e) The hospital or ambulatory surgery center shall demonstrate that applicable requirements in Planning Policy 2 (b) of this subsection (Ala. Admin. Code 410-2-3-.03(1)(b)(2)) will be met; and

(f) Hospitals and ambulatory surgery centers shall use their best efforts to perform a minimum of 200 PCI cases per year. Any hospital or ambulatory surgery center performing less than 150 cases per year after the second full year of PCI operations must agree to an independent quality review of its program by an outside interventional cardiologist who is a member of the American College of Cardiology and to report a summary of such quality review confidentially to the Executive Director of SHPDA.

The CON Review Board shall consider the most recent recommendations/guidelines for cardiac catheterizations adopted by the American College of Cardiology Foundation, the American Heart Association Task Force on Practice Guidelines, and the Society for

Cardiovascular Angiography and Interventions as an informational resource in considering any CON application for elective PCI services.

6. Planning Policy.

Applicants for new or expanded cardiac catheterization services must demonstrate that sufficient numbers of qualified medical, nursing, and technical personnel will be available to ensure that quality health care will be maintained without detrimentally affecting staffing patterns at existing programs within the same service area.