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September 27, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1717-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

[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: 329337. 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

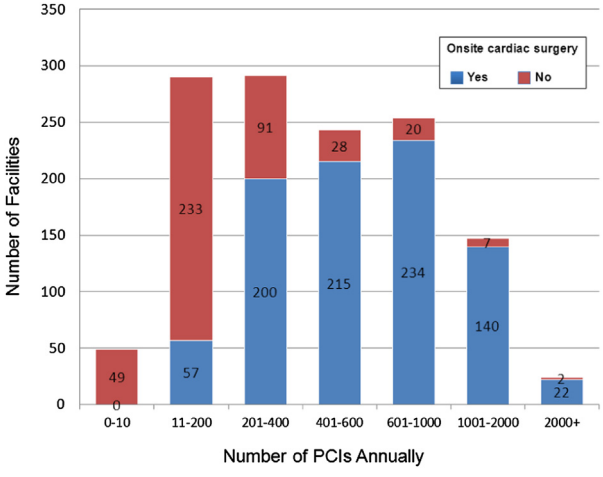

Figure 1. PCI Volume at Facilities With and Without Cardiac Surgery

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

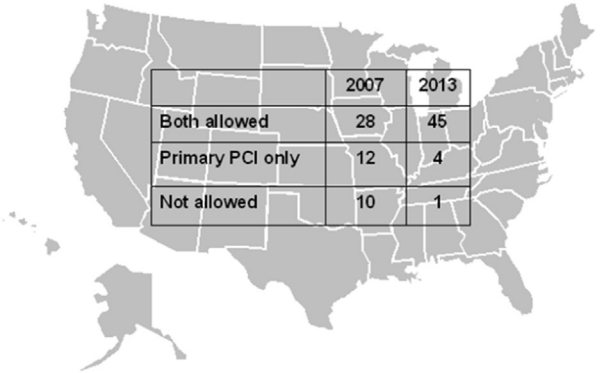

Figure 2. Change in the Availability of PCI Without On-Site Surgery From 2007 to 2013

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

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June 17, 2014:2624–41

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.* *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.

REFERENCES

1. Dehmer GJ, Blankenship J, Wharton TP 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. Catheter Cardiovasc Interv 2007;69:471–8.
2. Levine GN, Bates ER, Blankenship JC, 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. J Am Coll Cardiol 2011;58:e44–122.
3. Bashore TM, Balter S, Barac A, et al. 2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update. J Am Coll Cardiol 2012;59:2221–305.
4. Harold JG, Bass TA, Bashore TM, et al. ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures: A report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training (Writing Committee to Update the 2007 Clinical Competence Statement on Cardiac Interventional Procedures). J Am Coll Cardiol 2013;62:357–96.
5. Laslett LJ, Alagona P, Clark BA, et al. The worldwide environment of cardiovascular disease: Prevalence, diagnosis, therapy, and policy issues. J Am Coll Cardiol 2012;60:S1–49.
6. Yeh RW, Sidney S, Chandra M, et al. Population trends in the incidence and outcomes of acute myocardial infarction. N Engl J Med 2010;362:2155–65.
7. Maroney J, Khan S, Powell W, Klein LW. Current operator volumes of invasive coronary procedures in medicare patients: Implications for future manpower needs in the catheterization laboratory. Catheter Cardiovasc Interv 2013;81:34–9.
8. Dehmer GJ, Weaver D, Roe MT, et al. A contemporary view of diagnostic cardiac catheterization and percutaneous coronary intervention in the United States: A report from the CathPCI Registry of the National Cardiovascular Data Registry, 2010 through June 2011. J Am Coll Cardiol 2012;60:2017–31.

9. Aversano T, Lemmon CC, Liu L, Atlantic CPORT Investigators. Outcomes of PCI at hospitals with or without on-site cardiac surgery. N Engl J Med 2012;366:1792–802.
10. Personal communication. John Rumsfeld, MD PhD. National Director of Cardiology, U.S. Veterans Health Administration.
11. Jacobs AK, Normand SL, Massaro JM, et al., the MASS COMM Investigators. Nonemergency PCI at hospitals with or without on-site cardiac surgery. N Engl J Med 2013;368:1498–508.
12. Carlsson J, James SN, Ståhle E, Höfer S, Lagerqvist B. Outcome of percutaneous coronary intervention in hospitals with and without on-site cardiac surgery standby. Heart 2007;93:335–8.
13. Peels HO, de Swart H, Ploeg TV, et al. Percutaneous coronary intervention with off-site cardiac surgery backup for acute myocardial infarction as a strategy to reduce door-to-balloon time. Am J Cardiol 2007;100:1353–8.
14. Pereira H, da Silva PC, Gonçalves L, José B, Investigadores do Registo Nacional de Cardiologia de Intervenção. Elective and primary angioplasty at hospitals without on-site surgery versus with on-site surgery: results from a national registry. Rev Port Cardiol 2008;27:769–82.
15. Kutcher MA, Klein LW, Ou FS, et al., National Cardiovascular Data Registry. Percutaneous coronary interventions in facilities without cardiac surgery on site: A report from the National Cardiovascular Data Registry (NCDR). J Am Coll Cardiol 2009;54:16–24.
16. Pride YB, Canto JG, Frederick PD, Gibson CM, NRMI Investigators. Outcomes among patients with ST-segment-elevation myocardial infarction presenting to interventional hospitals with and without on-site cardiac surgery. Circ Cardiovasc Qual Outcomes 2009;2:574–82.
17. Hannan EL, Zhong Y, Racz M, et al. Outcomes for patients with ST-elevation myocardial infarction in hospitals with and without onsite coronary artery bypass graft surgery: the New York State experience. Circ Cardiovasc Interv 2009;2:519–27.
18. Singh M, Gersh BJ, Lennon RJ, et al. Outcomes of a system-wide protocol for elective and nonelective coronary angioplasty at sites without on-site surgery: The Mayo Clinic experience. Mayo Clin Proc 2009;84:501–8.
19. Zia MI, Wijeysundera HC, Tu JV, Lee DS, Ko DT. Percutaneous coronary intervention with vs without on-site cardiac surgery backup: A systematic review. Can J Cardiol 2011;27:664.e9–16.
20. Singh M, Holmes DR Jr., Dehmer GJ, et al. Percutaneous coronary intervention at centers with and without on-site surgery: A meta-analysis. JAMA 2011;306:2487–94.
21. Frutkin AD, Mehta SK, Patel T, et al. Outcomes of 1,090 consecutive, elective, nonselected percutaneous coronary interventions at a community hospital without onsite cardiac surgery. Am J Cardiol 2008;101:53–7.
22. Pride YB, Canto JG, Frederick PD, Gibson CM, NRMI Investigators. Outcomes among patients with non-ST-segment elevation myocardial infarction presenting to interventional hospitals with and without on-site cardiac surgery. J Am Coll Cardiol Intv 2009;2:944–52.
23. Singh PP, Singh M, Bedi US, et al. Outcomes of nonemergent percutaneous coronary intervention with and without on-site surgical backup: A meta-analysis. Am J Ther 2011;18:e22–8.
24. Kushner FG, Hand M, Smith SC Jr., et al. 2009 focused updates: ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction (updating the 2004 guideline and 2007 focused update) and ACC/AHA/SCAI guidelines on percutaneous coronary intervention (updating the 2005 guideline and 2007 focused update): A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2009;54:2205–41.
25. O'Gara PT, Kushner FG, Ascheim DD, et al. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2013;61:e78–140.
26. Hillis L, Smith PK, Anderson JL, et al. 2011 ACCF/AHA guideline for coronary artery bypass graft surgery: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines Developed in Collaboration With the American Association for Thoracic Surgery, Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons. J Am Coll Cardiol 2011;58:e123–210.
27. Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS); European Association for Percutaneous Cardiovascular Interventions (EAPCI), Wijns W, Kolh P, Danchin N, et al. Guidelines on myocardial revascularization. Eur Heart J 2010;31:2501–55.
28. Steg PG, James SK, Atar D, et al. ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation. Eur Heart J 2012;33:2569–619.
29. Widimsky P, Wijns W, Fajadet J, et al. Reperfusion therapy for ST elevation acute myocardial infarction in Europe: Description of the current situation in 30 countries. Eur Heart J 2010;31:943–57.
30. Gershlick AH, Banning AP, Myat A, Verheugt FWA, Gersh BJ. Reperfusion therapy for STEMI: Is there still a role for thrombolysis in the era of primary percutaneous coronary intervention? Lancet 2013;382:624–32.
31. Dawkins KD, Gershlick T, de Belder M, et al., Joint Working Group on Percutaneous Coronary Intervention of the British Cardiovascular Intervention Society and the British Cardiac Society. Coronary angioplasty: Guidelines for good practice and training. Heart 2005;91 Suppl VI:vi1–27.
32. Guidelines on Support Facilities for Coronary Angiography and Percutaneous Coronary Intervention (PCI) including Guidelines on the Performance of Procedures in Rural Sites. The Cardiac Society of Australia and New Zealand (2011). Available at: http://www.csanz.edu.au/LinkClick.aspx?fileticket=XwJu1B7jn9k%3d&tabid=170. Accessed August 19, 2013.
33. Oliveras EE, Hernández Antolín RA, Bescós LL, Burgos JM, Moya-Prats JLP. Requirements to perform coronary interventions at hospitals without coronary surgery. Guidelines of the Spanish Society of Cardiology. Rev Esp Cardiol 1999;52:5–12.
34. Fernández-Avilés F, Alonso Martín J, María Augé Sanpera J, et al. Continuous practice and advanced training in interventional cardiology. Recommendations for the assessment and maintenance of proficiency in interventional cardiology. A statement for physicians and advanced training units from the Section of Hemodynamics and Interventional Cardiology of the Spanish Society of Cardiology. Rev Esp Cardiol 2000;53:1613–25.
35. Morís De La Tassa C, Cequier Fillat AR, et al. Sociedad Española de Cardiología. Guidelines of the Spanish Society of Cardiology on requirements and equipment in hemodynamic and interventional cardiology. Rev Esp Cardiol 2001;54:741–50.
36. Moura AV, Gottschall CA, Costa EA, Falcao FC, Prudente ML, Furtado RJC. Sociedade Brasileira de Cardiologia. Guidelines for the indications and use of percutaneous interventions and intracoronary stent in clinical practice. Arq Bras Cardiol 2003;80:1–14.
37. Deutsche Gessellschaft fur Herz- und Kreislaufforschung. Kommission fur Klinische Kardiologie (unter Mitwirking der Arbeitsgruppe Transluminale Angioplastie): Empfehlungen fur die Durchfuhrung der Perkutanen Transluminalen Koronarangioplastie (PTCA). Z Kardiol 1987;76:382–5.
38. Tebbe U, Hochadel M, Bramlage P, et al. In-hospital outcomes after elective and non-elective percutaneous coronary interventions in hospitals with and without on-site cardiac surgery backup. Clin Res Cardiol 2009;98:701–7.
39. Legrand V, Wijns W, Vandenbranden F, et al. Belgian Working Group on Invasive Cardiology. Guidelines for percutaneous coronary intervention by the Belgian Working Group on Invasive Cardiology. Acta Cardiol 2003;58:341–8.
40. Percutaneous Coronary Intervention (PCI) without Surgical Back-up Policy Guidance March 7, 2012. Available at: www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_437472.pdf. Accessed June 19, 2013.
41. Jacobs AK, Antman EM, Faxon DP, Gregory T, Solis P. Development of systems of care for ST-elevation myocardial infarction patients: Executive summary. Circulation 2007;116:217–30.
42. Jacobs AK, Antman EM, Ellrodt G, et al. Recommendation to develop strategies to increase the number of ST-segment-elevation myocardial infarction patients with timely access to primary percutaneous coronary intervention. Circulation 2006;113:2152–63.
43. Mission Lifeline Program. http://www.heart.org/HEARTORG/HealthcareResearch/MissionLifelineHomePage/Mission-Lifeline-Home-Page_UCM_305495_SubHomePage.jsp. Accessed March 31, 2013.

44. D2B Alliance. Available at: http://www.d2balliance.org. Accessed August 16, 2013.
45. Bradley EH, Nallamothu BK, Herrin J, et al. National efforts to improve door-to-balloon time results from the Door-to-Balloon Alliance. J Am Coll Cardiol 2009;54:2423–9.
46. Nallamothu BK, Bates ER, Wang Y, Bradley EH, Krumholz HM. Driving times and distances to hospitals with percutaneous coronary intervention in the United States: Implications for prehospital triage of patients with ST-elevation myocardial infarction. Circulation 2006;113:1189–95.
47. Concannon TW, Nelson J, Goetz J, Griffith JL. A percutaneous coronary intervention lab in every hospital? Circ Cardiovasc Qual Outcomes 2012;5:14–20.
48. Buckley JW, Bates ER, Nallamothu BK. Primary percutaneous coronary intervention expansion to hospitals without on-site cardiac surgery in Michigan: A geographic information systems analysis. Am Heart J 2008;155:668–72.
49. Horwitz JR, Nichols A, Nallamothu BK, Sasson C, Iwashyna TJ. Expansion of invasive cardiac services in the United States. Circulation 2013;128:803–10.
50. Kinlay S. The trials and tribulations of percutaneous coronary intervention in hospitals without on-site CABG surgery. JAMA 2011; 306:2507–9.
51. Album D, Westin S. Do diseases have a prestige hierarchy? A survey among physicians and medical students. Soc Sci Med 2008;66:182–8.
52. O'Neill WW. A case against low volume percutaneous coronary intervention centers. Circulation 2009;120:546–8.
53. Rittenhouse DR. Primary care and accountable care- two essential elements of delivery-system reform. N Engl J Med 2009;361:2301–3.
54. Greaney TL. Accountable care organizations—The fork in the road. N Engl J Med 2011;364:e11.
55. Ho V, Meei-Hsiang K-G, Jollis JG. Certificate of need (CON) for cardiac care: Controversy over the contributions of CON. Health Serv Res 2009;44:483–500.
56. Ross JS, Ho V, Wang Y, et al. Certificate of need regulation and cardiac catheterization appropriateness after acute myocardial infarction. Circulation 2007;115:1012–9.
57. Vaughan-Sarrazin MS, Hannan EL, Gornley CJ. Mortality in Medicare beneficiaries following coronary artery bypass graft surgery in states with and without certificate of need regulations. JAMA 2002;288:1859–66.
58. Topol EJ, Kereiakes DJ. Regionalization of care for acute ischemic heart disease. Circulation 2003;107:1463–6.
59. Canto JG, Every NR, Magid DJ, et al. The volume of primary angioplasty procedures and survival after acute myocardial infarction. N Engl J Med 2000;342:1573–80.
60. Srinivas VS, Hailpern SM, Koss E, Monrad ES, Alderman MH. Effect of physician volume on the relationship between hospital volume and mortality during primary angioplasty. J Am Coll Cardiol 2009;53:574–9.
61. Ho V. Evolution of the volume-outcome relation for hospitals performing coronary angioplasty. Circulation 2000;101:1806–11.
62. Nallamothu BK, Wang Y, Magid DJ, McNamara CV, Krumholz HM. Relation between hospital specialization with primary percutaneous coronary intervention and clinical outcomes in ST-segment elevation myocardial infarction. Circulation 2006;113:222–9.
63. Hannan EL, Wu C, Walford G, et al. Volume-outcome relationships for percutaneous coronary interventions in the stent era. Circulation 2005;112:1171–9.
64. Lieu TA, Gurley RJ, Lundstrom RJ, et al. Projected cost-effectiveness of primary angioplasty for acute myocardial infarction. J Am Coll Cardiol 1997;30:1741–50.
65. Long KH, McMurtry EK, Lennon RJ, et al. Elective percutaneous coronary intervention without on-site cardiac surgery: clinical and economic implications. Med Care 2006;44:406–13.
66. Kontos MC, Wang Y, Chaudhry SI, Vetrovec GW, Curtis J, Messenger J, on behalf of the NCDR. Lower hospital volume is associated with higher in-hospital mortality in patients undergoing primary percutaneous coronary intervention for ST-segment-elevation myocardial infarction: A report from the NCDR. Circ Cardiovasc Qual Outcomes 2013;6:659–67.
67. Klein LW, Uretsky BF, Chambers C, et al., Society of Cardiovascular Angiography and Interventions. Quality assessment and improvement in interventional cardiology: A position statement of the Society of Cardiovascular Angiography and Interventions, part 1: Standards for quality assessment and improvement in interventional cardiology. Catheter Cardiovasc Interv 2011;77:927–35.
68. Klein LW, Ho KK, Singh M, et al., Society of Cardiovascular Angiography and Interventions. Quality assessment and improvement in interventional cardiology: A Position Statement of the Society of Cardiovascular Angiography and Interventions, Part II: public reporting and risk adjustment. Catheter Cardiovasc Interv 2011;78:493–502.
69. SCAI Quality Improvement Toolkit (SCAI-QIT). Available at: http://www.scai.org/QIT/Default.aspx. Accessed June 3, 2013.
70. Accreditation for Cardiovascular Excellence. Available at: http://www.cvexcel.org/default.aspx. Accessed June 4, 2013.
71. Brennan JM, Curtis JP, Dai D, et al., National Cardiovascular Data Registry. Enhanced Mortality Risk Prediction With a Focus on High-Risk Percutaneous Coronary Intervention: Results From 1,208, 137 Procedures in the NCDR (National Cardiovascular Data Registry). J Am Coll Cardiol Intv 2013;6:790–9.

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

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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.