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Clinical Decision Making

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

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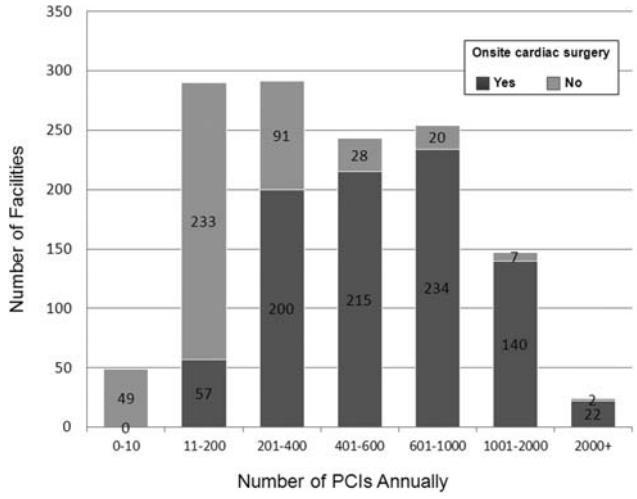

Fig. 1. PCI volume at facilities with and without cardiac surgery. (Reproduced from Ref [8] with permission. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

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 reevaluate 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;
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 $\leq$400 PCIs and 26% performed $\leq$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 $\leq$200 PCI procedures. F1

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 revaluated 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]. F2

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

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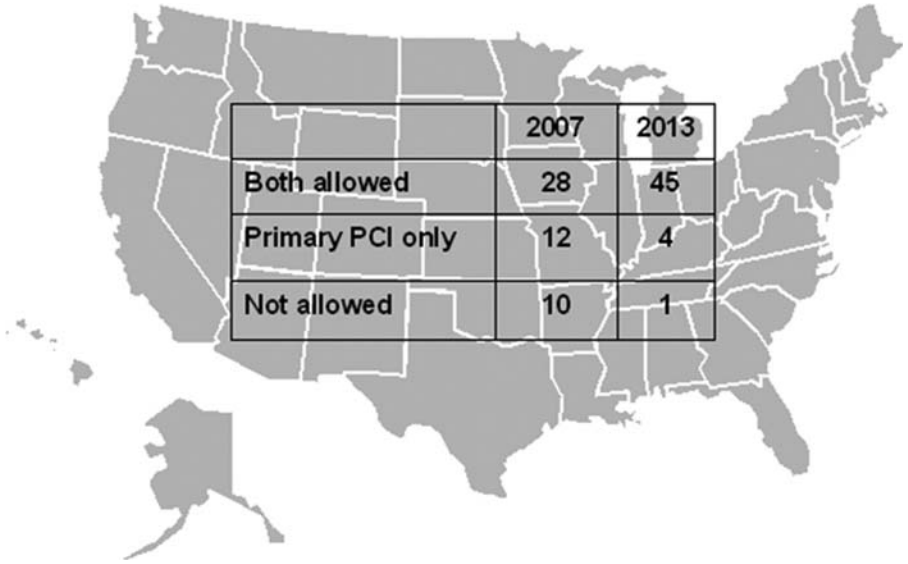

Fig. 2. Change in the availability of PCI without on-site surgery from 2007 to 2013. The numbers shown indicate the number of states where primary and nonprimary PCI without on-site surgery are allowed.

difference for in-hospital or 30-day mortality between sites with and without on-site surgery (Table I). 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 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 II). 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%, respectively, at 12 months (relative risk, 0.98; 95% one-sided upper confidence limit, 1.13; $P < 0.001$ for noninferiority). 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

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TABLE I. 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	1214	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	1470	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 Mayo Clinic experience	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.
		Yes	667	3.1		0.6		
Meta-analyses								
Zia [2011] [19]		No	8703	6.1	0.93 (0.83–1.05)	3.0	0.87 (0.68–1.11)	9 studies included in the analysis
		Yes	97386	7.6		3.4		
Singh M [2011] [20]		No	16489	4.6	0.96 (0.88–1.05)	0.22	0.53 (0.35–0.79)	11 studies included in the analysis
		Yes	107585	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.

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TABLE II. 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	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)
	Registry	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	No	4831	0.5	1.43 (0.85–2.41)	0.7	3.14 (2.13–4.63)	
	Registry	Yes	5584	0.7		2.1		
Kutcher (2009) [15]	Multicenter NCDR	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
	Registry	Yes	268,312	0.8		0.3		
Pride (2009) [22]	Multicenter NRMI	No	1,282	1.0	0.76 (0.37–1.58)			Only patients with NSTEMI included in study cohort
	Registry	Yes	1,282	1.3				
Singh (2009) [18]	3 sites Mayo clinic	No	1,842	0.2	0.57 (0.17–1.95)	0	1.00 (0.02–50.4)	Propensity matched patient cohort
	Experience	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	2774	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	28552	1.6	1.03 (0.64–1.66)	1.0	1.38 (0.65–2.95)	6 studies included in the analysis
		Yes	881261	2.1		0.9		
Singh M (2011) [20]		No	30423	0.9	1.15 (0.93–1.41)	0.17	1.21 (0.52–2.85)	9 studies included in the analysis
		Yes	883865	0.8		0.29		
Singh PP (2011) [23]		No	1812	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	4039	0.72		0.02		

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

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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 Guidelines 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

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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

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(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^{TM}] 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

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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. 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 transfering 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 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 $\leq$ 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.

TABLE III. 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 $\leq$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 V).	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 for a STEMI patient 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

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TABLE III. *Continued*

General Recommendations	Source
STEMI Treatment Recommendations	
Each community should develop a STEMI system of care that follows standards at least as strong as those developed for Mission Lifeline, including:	2009 PCI-GL
• Performance of primary PCI as the first-choice treatment for STEMI to ensure streamlined care paths and increased case volumes.	2011 PCI-GL
• A process for prehospital identification and activation.	
• Protocols for triage, diagnosis and cardiac catheterization laboratory activation should be established within the primary PCI hospital/STEMI-Receiving Center.	ML D2B
• A single activation phone call should alert the STEMI team. Criteria for EMS activation of the cardiac catheterization laboratory should be established in conjunction with EMS providers.	
• Transfer protocols for patients who arrive at STEMI referral centers who are in cardiogenic shock and/or are primary PCI candidates ineligible for fibrinolytic drugs.	
STEMI receiving centers should be available and on-call 24 hours/7 days a week (no diversion) to perform primary PCI. Primary PCI should not be performed at facilities unless it is provided on a 24/7 schedule.[a] The cardiac catheterization laboratory staff and interventional cardiologist should arrive within 30 min of a STEMI activation call. Facilities should have a plan for triage and treatment of simultaneous presentation of STEMI patients.	PCI-GL, AHA ML
STEMI receiving centers should perform a minimum of 36 primary PCI procedures annually, and these procedures should ideally be performed at facilities that perform a minimum of 200 total PCI procedures annually.	PCI-GL PCI-CS ML
Facilities performing only primary PCI should perform a minimum of 36 primary PCIs annually and work in collaboration with a high volume PCI facility to ensure good outcomes	PCI-GL PCI-CS
There should be a recognized STEMI-Receiving Center liaison/system coordinator to the system and a recognized physician champion.	ML
The STEMI-Receiving Centers should participate in the Mission Lifeline-approved data collection tool, ACTION Registry-Get with the Guidelines™.	ML D2B
They should also participate in the regional Mission Lifeline Stakeholder group (if available) to contribute to the development of a regional STEMI System of Care Plan	ML
Monthly multidisciplinary team meetings to evaluate outcomes and quality improvement data. Operational issues should be reviewed, problems identified, and solutions implemented. The following measurements should be evaluated on an ongoing basis:	ML
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	

[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.

Italics font: New or modified recommendation in the document.

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.

TABLE IV. 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*

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.

Italics font: New or modified recommendation in the document.

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 III). 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 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].

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TABLE V. Recommendations for Off-Site Surgical Backup and Case Selection

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

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.
Italics font: New or modified recommendation in the document

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 data. Programs failing to meet established criteria for satisfactory performance for two consecutive quarters must undertake efforts to improve their

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TABLE VI. 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 <60mL/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].	ECD
• Extremely angulated segment [>90%] or excessive proximal or in-lesion tortuosity.	*New*
• More than moderate calcification of a stenosis or proximal segment	
• 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 levels 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.	

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.
Italics font: New or modified recommendation in the document.

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 statistically 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
T4 >36 primary PCI procedures annually (Table IV). 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 cardi-
T5 ologists and cardiac surgeons are listed in Table V. 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 V, and criteria for identifying high-risk lesions
T6 and patients are contained in Table VI. 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, Seth A, Morrison DA, DiMario C, Muller D, Kellett M, Uretsky BF. 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;69:471–478.
2. Levine GN, Bates ER, Blankenship JC, Bailey SR, Bittl JA, Cercek B, Chambers CE, Ellis SG, Guyton RA, Hollenberg SM, Khot UN, Lange RA, Mauri L, Mehran R, Moussa ID, Mukherjee D, Nallamothu BK, Ting HH. 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–e122.

3. Bashore TM, Balter S, Barac A, Byrne JG, Cavendish JJ, Chambers CE, Hermiller JB Jr, Kinlay S, Landzberg JS, Laskey WK, McKay CR, Miller JM, Moliterno DJ, Moore JWM, Oliver-McNeil SM, Popma JJ, Tommaso CL. 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;59:2221–2305.
4. Harold JG, Bass TA, Bashore TM, Brindis RG, Brush JE, Burke JA, Dehmer GJ, Deychak YA, Jneid H, Jollis JG, Landzberg JS, Levine GN, McClurken JB, Messenger JC, Moussa ID, Muhlestein JB, Pomerantz RM, Sanborn TA, Sivaram CA, White, CJ, Williams ES. 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 Assocation/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;62:357–396.
5. Laslett LJ, Alagona P, Clark BA, Drozda JP, Saldivar F, Wilson SR, Poe C, Hart M. The worldwide environment of cardiovascular disease: Prevalence, diagnosis, therapy, and policy issues. J Am Coll Cardiol 2012;60:S1–S49.
6. Yeh RW, Sidney S, Chandra M, Sorel M, Selby JV, Go AS. Population trends in the incidence and outcomes of acute myocardial infarction. N Engl J Med 2010;362:2155–2165.
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;81:34–39.
8. Dehmer GJ, Weaver D, Roe MT, Milford-Beland S, Fitzgerald S, Hermann A, Messenger J, Moussa I, Garratt K, Rumsfeld J, Brindis RG. 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;60:2017–2031.
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;366:1792–1802.
10. Personal communication. John Rumsfeld, MD PhD. National Director of Cardiology, U.S. Veterans Health Administration.
11. Jacobs AK, Normand SL, Massaro JM, Cutlip DE, Carrozza JP Jr, Marks AD, Murphy N, Romm IK, Biondolillo M, Mauri L; the MASS COMM Investigators. Nonemergency PCI at hospitals with or without on-site cardiac surgery. New Eng J Med 2013;368:1498–1508.
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;93:335–338.
13. Peels HO, de Swart H, Ploeg TV, Hautvast RW, Cornel JH, Arnold AE, Wharton TP, Umans VA. 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;100:1353–1358.
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;27:769–782.
15. Kutcher MA, Klein LW, Ou FS, Wharton TP Jr, Dehmer GJ, Singh M, Anderson HV, Rumsfeld JS, Weintraub WS, Shaw RE, Sacrinty MT, Woodward A, Peterson ED, Brindis RG;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;2:574–582.
17. Hannan EL, Zhong Y, Racz M, Jacobs AK, Walford G, Cozzens K, Holmes DR, Jones RH, Hibberd M, Doran D, Whalen D, King SB III. 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;2:519–527.
18. Singh M, Gersh BJ, Lennon RJ, Ting HH, Holmes DR Jr, Doyle BJ, Rihal CS. 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;84:501–508.
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, Lennon RJ, Wharton TP, Kutcher MA, Aversano T, Rihal CS. Percutaneous coronary intervention at centers with and without on-site surgery: A meta-analysis. JAMA 2011;306:2487–2494.
21. Frutkin AD, Mehta SK, Patel T, Menon P, Safley DM, House J, Barth CW III, Grantham JA, Marso SP. Outcomes of 1,090 consecutive, elective, nonselected percutaneous coronary interventions at a community hospital without onsite cardiac surgery. Am J Cardiol 2008;101:53–57.
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. JACC Cardiovasc Interv 2009;2:944–952.
23. Singh PP, Singh M, Bedi US, Adigopula S, Singh S, Kodumuri V, Molnar J, Ahmed A, Arora R, Khosla S. Outcomes of nonemergent percutaneous coronary intervention with and without on-site surgical backup: A meta-analysis. Am J Ther 2011;18:e22–e28.
24. Kushner FG, Hand M, Smith SC Jr, King SB 3rd, Anderson JL, Antman EM, Bailey SR, Bates ER, Blankenship JC, Casey DE Jr, Green LA, Hochman JS, Jacobs AK, Krumholz HM, Morrison DA, Ornato JP, Pearle DL, Peterson ED, Sloan MA, Whitlow PL, Williams DO. 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;54:2205–2241.
25. O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, Ettinger SM, Fang JC, Fesmire FM, Franklin BA, Granger CB, Krumholz HM, Linderbaum JA, Morrow DA, Newby LK, Ornato JP, Ou N, Radford MJ, Tamis-Holland JE, Tommaso CL, Tracy CM, Woo YJ, Zhao DX, Anderson JL, Jacobs AK, Halperin JL, Albert NM, Brindis RG,

Creager MA, DeMets D, Guyton RA, Hochman JS, Kovacs RJ, Kushner FG, Ohman EM, Stevenson WG, Yancy CW. 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–e140.

26. Hillis L, Smith PK, Anderson JL, Bittl JA, Bridges CR, Byrne JG, Cigarroa JE, DiSesa VJ, Hiratzka LF, Hutter AM Jr, Jessen ME, Keeley EC, Lahey SJ, Lange RA, London MJ, Mack MJ, Patel MR, Puskas JD, Sabik JF, Selnes O, Shahian DM, Trost JC, Winniford MD, Jacobs AK, Anderson JL, Albert N, Creager MA, Ettinger SM, Guyton RA, Halperin JL, Hochman JS, Kushner FG, Ohman EM, Stevenson W, Yancy CW. 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–e210.
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, Di Mario C, Falk V, Folliguet T, Garg S, Huber K, James S, Knuuti J, Lopez-Sendon J, Marco J, Menicanti L, Ostojic M, Piepoli MF, Pirlet C, Pomar JL, Reifart N, Ribichini FL, Schalij MJ, Sergeant P, Serruys PW, Silber S, Sousa Uva M, Taggart D. Guidelines on myocardial revascularization. Eur Heart J 2010;31:2501–2555.
28. Steg PG, James SK, Atar D, Badano LP, Blömstrom-Lundqvist C, Borger MA, Di Mario C, Dickstein K, Ducrocq G, Fernandez-Aviles F, Gershlick AH, Giannuzzi P, Halvorsen S, Huber K, Juni P, Kastrati A, Knuuti J, Lenzen MJ, Mahaffey KW, Valgimigli M, van 't Hof A, Widimsky P, Zahger D. ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation. Eur Heart J 2012;33:2569–2619.
29. Widimsky P, Wijns W, Fajadet J, de Belder M, Knot J, Aaberge L, Andrikopoulos G, Baz JA, Betriu A, Claeys M, Danchin N, Djambazov S, Erne P, Hartikainen J, Huber K, Kala P, Klinceva M, Kristensen SD, Ludman P, Ferre JM, Merkely B, Milicic D, Morais J, Noc M, Opolski G, Ostojic M, Radovanovic D, De Servi S, Stenestrand U, Studencan M, Tubaro M, Vasiljevic Z, Weidinger F, Witkowski A, Zeymer U. Reperfusion therapy for ST elevation acute myocardial infarction in Europe: Description of the current situation in 30 countries. Eur Heart J 2010;31:943–957.
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;382:624–632.
31. Dawkins KD, Gershlick T, de Belder M, Chauhan A, Venn G, Schofield P, Smith D, Watkins J, Gray HH,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–vi27.
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, García Fernández E, Macaya de Miguel C, Melgares Moreno R, Valdés Chavarri M. 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;53:1613–1625.
35. Morís De La Tassa C, Cequier Fillat AR, Moreu Burgos J, Pérez Hernández H, Aguirre Salcedo JM;Sociedad Española de Cardiología. Guidelines of the Spanish Society of Cardiology on requirements and equipment in hemodynamic and interventional cardiology. Rev Esp Cardiol 2001;54:741–750.
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 Arbeits- gruppe Transluminale Angioplastie): Empfehlungen fur die Durchfuhrung der Perkutanen Transluminalen Koronarangioplas- tie (PTCA). Z Kardiol 1987;76:382–385.
38. Tebbe U, Hochadel M, Bramlage P, Kerber S, Hambrecht R, Grube E, Hauptmann KE, Gottwik M, Elsässer A, Glunz HG, Bonzel T, Carlsson J, Zeymer U, Zahn R, Senges J. 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;98:701–707.
39. Legrand V, Wijns W, Vandenbranden F, Benit E, Boland J, Claeys M, De Scheerder I, Eemans T, Hanet C, Heyndrickx G, Lafontaine P, Materne P, Taeymans Y, Vrints C, Vrolix M. Belgian Working Group on Invasive Cardiology. Guidelines for percutaneous coronary intervention by the Belgian Working Group on Invasive Cardiology. Acta Cardiol 2003;58:341–348.
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;116:217–230.
42. Jacobs AK, Antman EM, Ellrodt G, Faxon DP, Gregory T, Mensah GA, Moyer P, Ornato J, Peterson ED, Sadwin L, Smith SC. 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;113:2152–2163.
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, Ting HH, Stern AF, Nembhard IM, Yuan CT, Green JC, Kline-Rogers E, Wang Y, Curtis JP, Webster TR, Masoudi FA, Fonarow GC, Brush JE Jr, Krumholz HM. National efforts to improve door-to-balloon time

results from the Door-to-Balloon Alliance. J Am Coll Cardiol 2009;54:2423–2429.
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;113:1189–1195.
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;155:668–672.
49. Horwitz JR, Nichols A, Nallamothu BK, Sasson C, Iwashyna TJ. Expansion of invasive cardiac services in the United States. Circulation 2013;128:803–810.
50. Kinlay S. The trials and tribulations of percutaneous coronary intervention in hospitals without on-site CABG surgery. JAMA 2011;306:2507–2509.
51. Album D, Westin S. Do diseases have a prestige hierarchy? A survey among physicians and medical students. Soc Sci Med 2008;66:182–188.
52. O'Neill WW. A case against low volume percutaneous coronary intervention centers. Circulation 2009;120:546–548.
53. Rittenhouse DR. Primary care and accountable care- two essential elements of delivery-system reform. N Engl J Med 2009; 361:2301–2303.
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: Controversey over the contributions of CON. Health Serv Res 2009;44:483–500.
56. Ross JS, Ho V, Wang Y, Cha SS, Epstein AJ, Masoudi FA, Nallamothu BK, Krumholz HM. Certificate of need regulation and cardiac catheterization appropriateness after acute myocardial infarction. Circulation 2007;115:1012–1019.
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;288:1859–1866.
58. Topol EJ, Kereiakes DJ. Regionalization of care for acute ischemic heart disease. Circulation 2003;107:1463–1466.
59. Canto JG, Every NR, Magid DJ, Rogers WJ, Malmgren JA, Frederick PD, French WJ, Tiefenbrunn AJ, Misra VK, Kiefe CI, Barron HV. The volume of primary angioplasty procedures and survival after acute myocardial infarction. N Engl J Med 2000; 342:1573–1580.
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;53:574–579.
61. Ho V. Evolution of the volume-outcome relation for hospitals performing coronary angioplasty. Circulation 2000;101:1806–1811.
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: 222–229.
63. Hannan EL, Wu C, Walford G, King SB 3rd, Holmes DR Jr, Ambrose JA, Sharma S, Katz S, Clark LT, Jones RH. Volume-outcome relationships for percutaneous coronary interventions in the stent era. Circulation 2005;112:1171–1179.
64. Lieu TA, Gurley RJ, Lundstrom RJ, Ray GT, Fireman BH, Weinstein MC, Parmley WW. Projected cost-effectiveness of primary angioplasty for acute myocardial infarction. J Am Coll Cardiol 1997;30:1741–1750.
65. Long KH, McMurtry EK, Lennon RJ, Chapman AC, Singh M, Rihal CS, Wood DL, Holmes DR Jr, Ting HH. Elective percutaneous coronary intervention without on-site cardiac surgery: clinical and economic implications. Med Care 2006;44:406–413.
66. Kontos MC, Wang Y, Chaudhry SI, Vetrovec GW, Curtis J, Messenger J; on behalf ofthe 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;6:659–667.
67. Klein LW, Uretsky BF, Chambers C, Anderson HV, Hillegass WB, Singh M, Ho KK, Rao SV, Reilly J, Weiner BH, Kern M, Bailey S;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;77:927–935.
68. Klein LW, Ho KK, Singh M, Anderson HV, Hillegass WB, Uretsky BF, Chambers C, Rao SV, Reilly J, Weiner BH, Kern M, Bailey S;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, Fitzgerald S, Khandelwal AK, Spertus JA, Rao SV, Singh M, Shaw RE, Ho KK, Krone RJ, Weintraub WS, Weaver WD, Peterson ED;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). JACC Cardiovasc Interv 2013;6:790–799.

APPENDIX 1. SCAI/ACCF/AHA Expert Consensus Document Update on Percutaneous Coronary Intervention without On-Site Surgical Backup—Author Relationships with Industry and Other Entities (Relevant)

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* • Astra-Zeneca* • 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 Meyers 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, Food and Drug Administration; NHLBI, National Heart Lung and Blood Institute; SCAI, Society for Cardiovascular Angiography and Intervention.